THE IMPACT OF COMORBIDITY ON THE OUTCOME OF TOTAL HIP REPLACEMENT IN JAPAN AND THE UNITED KINGDOM

by

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ABSTRACT

The impact of comorbidity on patient outcomes following an intervention has been largely ignored. No studies have been reported in the UK or Japan. The aim of this thesis was to assess the impact of comorbidity on the outcome of a common major surgical operation - total hip replacement.

Comorbidity was measured using the Index of Co-Existent Disease developed in the USA, which reliability was assessed. Two retrospective cohorts, one in Japan and one in the UK were studied. Data were collected from patients' case notes extraction and by postal questionnaire to patients one year after surgery.

After THR, patient's health status was improved in both countries and satisfaction for care was high. Significant differences in in-hospital complications were observed between Japan and the UK in terms of complication rate, type and severity, and their association with independent variables. Comorbidity was significantly associated with serious complications and with change in health status in the UK and with minor complications in Japan.

A logistic regression model using the ICED and independent confounding factors suggested a significant relationship between comorbidity and complications. However, the model did not fit the data well. A multiple regression model for change in health status showed that much of the variance was explained by the preoperative health status but not by comorbidity. The low number of serious complications in Japan and the high complication rate in patients in the lowest comorbidity severity level in the UK made the predictive power weak.

Finally, through the experience of this study, some recommendations for clinical practice and further research are discussed.

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CHAPTER 1

INTRODUCTION AND LITERATURE REVIEW

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1 Introduction

Total hip replacement (THR) surgery is one of the most successful orthopaedic advances this century. It was preceded by two arthroplastic measures, namely cup arthroplasty used to resurface the degenerated femoral head and femoral endoprosthesis used in the case of fracture of the neck of the femur. In the UK, Charnley's original THR consisted of acetabular and femoral components cemented to the bones. Continuous refinements in materials and design have established THR as the major solution for hip arthritis.

The pathology of hip arthritis includes both primary degenerative osteoarthritis and secondary arthritis following rheumatoid arthritis and other connective tissue disorders, trauma, and avascular necrosis. The majority of patients undergoing THR today suffer from primary osteoarthritis which develops over decades and usually becomes evident after 60 years of age.

Extended longevity has also led to increasing demand on functional status, in order to maintain an active life style and to sustain physical independence. Fitness of hip joints play an important part in determining a person's functional status. Joint degeneration is irreversible and patients may become confined to a wheelchair or be bedbound. Their quality of life can be reduced and their need for social resources such as health care and community welfare services increased.

As the population ages, the prevalence of co-existent diseases increases. The extent of co-existent diseases in patients with hip arthritis could have a significant impact on the outcome of any treatment, including THR. In many studies of therapeutic efficacy, however, restrictive eligibility criteria have been employed to eliminate patients who have serious comorbid disease. As a result, studies that address whether treatments are effective among patients without comorbid conditions have limited generalisability. An alternative is to classify comorbidity and take it into account in assessing outcome.

Initially, comorbidity was measured using a dichotomous classification -the presence or absence of co-existent diseases- with no consideration of its severity. Then new indices were designed in the USA which considered the number and the severity of co-existent diseases. However, such measures have rarely been validated in other countries.

Recently in the USA Greenfield and colleagues (1) demonstrated the presence and amount of co-existent disease to be a significant predictor of postoperative complications. Functional outcomes, such as disability, were also strongly related to pre-operative co-existent disease. Moreover, a measure of co-existent disease was crucial in explaining differences between hospitals in recovery from THR. They suggested that information routinely available in almost every patient's medical record could be used to adjust for important differences between hospitals in the amount of co-existent disease suffered by their patients. If its not accounted for, comparison of outcome between hospitals may be misleading.

Previous studies on the appropriateness of total hip replacement have described wide variations among surgeons in their views of the importance of the presence or absence of different levels of comorbidity (2). Therefore the impact of comorbidity needs to be clarified to enable better agreement on appropriate clinical indications for THR to be achieved.

This chapter first reviews the development of methods for measuring comorbidity, then the literature on the indications for and the outcome of THR, before describing the aims and objectives of this thesis.

2. Comorbidity

2-1. The need for outcome assessment

As the population ages, demand grows for a wider range of health services to meet elderly specific patho-physiology (3). Advancing science and technology have brought about more possibilities to cure diseases, though doubts are being raised about the efficacy of some expensive medical procedures (4). Consequently, payers, purchasers, providers, and more recently patients have been seeking ways to deliver maximally effective care as cheaply as possible (5).

2-1a. A brief history of outcome research

One of the first advocates of studies that measure patient outcomes was Codman (6). What he called the "end result" of care in the evaluation of clinical practice was not only a professional activity, but also an organisational, administrative, and economic enterprise. His work was followed by researchers such as Shapiro at the Health Insurance Plan of Greater New York, in the study of prematurity and perinatal mortality (7). In the UK, Lipworth compared case fatality in teaching and non-teaching hospitals (8).

Quality is often discussed in terms of the structure, process and outcome of care (9). In the history of research on quality of care, most emphasis has been on the measurement of the process of care and within that on of the technical quality of care (10-12). Donabedian cites the work of Lee and Jones (13) as the landmark study on the process of care as it offered a concept of quality, a declaration of socially responsible professional norms as the standards of assessment, and an explicit enunciation of such standards (14).

There have also been explorations of the relationship between process and structure, such as studies of implicit / explicit criteria and auditing (15-17). The degree of agreement on criteria has been studied among members of groups of physicians, as well as among groups of physicians differentiated by specialty or other attributes (18). Another refinement in establishing criteria of process has involved linking criteria formulation more directly to decision analysis (15,19).

Recently the emphasis has returned to patient outcomes. For instance, the Joint Commission on Accreditation of Healthcare Organizations has embarked on a shift toward outcome measurement. Also, the Health Care Financing Administration has released Medicare mortality data in an attempt to monitor the effectiveness of health care providers. In addition, a concern with patient outcomes strongly drives the current directions of research on equity in health services such as geographic variations in the use of services (20).

The reason for this shift of research interest from process of care to outcome is partly because process criteria have often been difficult to relate to patient outcome (11, 12, 21-23). In addition, Lohr attributes the change of emphasis partly to "health accounting" (24) concepts, which arose from the growing concern about the impact of cost (or expenditure) containment on patient well-being.

2-1b. Methods for evaluating effectiveness

Broadly speaking, there are two methods for evaluating the effectiveness of health care - experimental and observational.

Well-conducted randomised controlled trials (RCTs) remain the ideal method for assessing effectiveness. However, an exclusive reliance on RCTs to provide definite information about effectiveness is not the answer (5). RCTs are out of the question when there is little uncertainty among clinicians. In addition, they may require too many resources, take too long to conduct, exclude some subgroups of patients who are too ill or too difficult to enroll for randomisation, and meet with ethical objections.

In addition to randomised studies, evaluation of effectiveness requires the complementary and intelligent use of administrative and scientific data sets, a variety of which have been established and have become increasingly important resources for research. In health services research, the following data sources exist (25,26): i) administrative data; ii) medical record information; iii) patient-derived data. Studies have focused primarily on the first two.

Claims-based databases maintained by medical insurance plans have been used (27,28). Roos describes the potential benefits of such data as "the availability of population-based information in many jurisdictions; large numbers of cases; long-term follow-up; relatively low cost compared with primary data collection; and the possibility of record linkage to further increase the information available"(28). Although it appeals in such practical implications as the costliness and feasibility of using the system, there are serious limitations regarding information on severity and comorbidity. In addition, the way a system is developed may have implications for its generalisability to other data bases or health care settings. Therefore, it is suggested that it should be used with great caution because data elements contain only limited clinical information and the accuracy of some elements is uncertain (29,30). Moreover, bias in reporting may occur. For example, chronic disorders are often underreported for patients with life-threatening disorders (31,32). Mendenhall attributes the difficulty of relating billing data to quality assurance as follows: perceived lack of clinical content; the organisation of data with no logical taxonomic structure; the lack of uniformity in billing definition; and the lack of data comparability between hospitals (33).

An alternative is to use medical records. There has been a fair amount of attention paid to the completeness and accuracy of the record, and to the implications of this to quality assessment as well as clinical management (34-36). Iezzoni has described difficulties in the use of medical records for health services research. These include: the quality of clinical information in terms of completeness, accuracy, and validity; concerns about the confidentiality of patient data influencing the information kept in the records; and the high cost of research based on medical record extraction (26). Particularly for the quality of clinical information, Iezzoni summarised possible biases as: those existing in the nature of the data elements (e.g. technology dependence); those in the data collection approach (e.g. differences in case note documentation); and those in the severity findings by manipulation of clinical data (e.g. by increasing testing). Moreover, to collect such data, "a good reviewer must remain vigilant, to spot the unexpected but significant findings amid all the normal material" and it requires a well-ordered, well-dated, legible, and complete medical record which is an unattainable ideal in current system (37).

2-1c. Measures of outcome

As the end results of medical care, the concept of outcome usually directs attention to the classic five Ds which measure negative rather than positive outcomes: death, disease, disability, discomfort, and dissatisfaction (10).

(c-1) Mortality

Using routine official information, death is frequently related to several standard time period; in hospital- (38,39), 30 days- (31,40,41), 60 days- (42), 1 year- (43-45), or longer (46,47). Mortality has often been compared among hospitals as a surrogate index of their quality of care (20,48-51). For example, significantly higher death rates have been detected for patients operated in small hospitals (20). On the other hand, risk-adjusted mortality indices suggest such differences depend on the time period chosen (48).

(c-2) Complications and adverse outcomes

Death is a relatively unusual consequence for most medical and surgical care, so other outcome measures have been used. For example, wound infection rates have been compared by surgeons as an indicator of the care delivered by their colleagues (52), and adverse events or complications have been used to compare health care providers (45,53-55). Brennan et al suggest that adverse events and negligence are not randomly distributed and that certain types of hospitals have significantly higher rates of injuries due to substandard care (53).

One methodological problem in this area is the semantic distinction between acute comorbidities, complications, iatrogenic illnesses, adverse events, and other similar terms. Whether it is important to distinguish acute comorbidities related to a natural progression of an underlying disease versus those caused by iatrogenic events depends on the research goals.

(c-3) Symptoms, health status, and quality of life

Other frequently employed measurements are patients' self-evaluation of any change in symptoms, in daily functioning, or in their sense of well-being and the health-related quality of life (5). Indeed, the positive aspects of health have recently become preferred, including states of physiologic, physical, and emotional health, and satisfaction (10). For example, in studies of chronic diseases in which mortality is rare and the goal of medical care is to control the course of the disease and improve quality of life, the use of patient reported measures of health status is especially important. Even trials for treatment of life threatening disease such as cancer have come to require more regular inclusion of quality of life and outcome measure (56-58). Overall, Nelson has concluded that "the measurement of health and function is reaching its maturity as a technical science" and "to move their use outside the laboratory will now require investment in assessing not their validity but their clinical utility." (59)

2-1d. The need for risk adjustment

Since the need for risk adjustment was understood in outcome research, the use of crude data has been criticised as of little value and potentially misleading. For example, a study of 361 hospitals with outlier mortality rates revealed that only 6% were of substandard quality as judged by a peer review organisation (60). On the other hand, another report found that some hospitals with known quality shortfalls were not predicted by mortality statistics (61).

2-2. Risk adjustment

Study of risk has been in progress on many aspects of life especially about physical hazards, because of the immediate and obvious relationship between cause and effect. In the UK, the Royal Society defined 'risk' as the probability of an adverse event. (62)

In health care research, in order to adjust for risks a method "should control for multiple dimensions of risk, including the risk associated with given clinical conditions, the risk associated with different diagnostic or operative approaches to care, and the risk associated with different levels of patient severity of illness"(48). A good categorisation system for risk measurement, Horn suggests, should have medical meaningfulness of the groups, homogeneity within the groups, and depend on intrinsic patient characteristics (63). Consequently the best choice of variables depends on the ultimate use of the system.

Efforts to adjust risks for severity of illness have led to the emergence of a variety of scales. Some are developed with the aim of adjusting for resource utilisation, while others for outcome assessment. Some scales are diagnosis- or disease-specific, while others are generic. For the source of information, many measures use computerised databases such as insurance claims data or discharge abstracts, but some require complete medical record review or prospective data collection. Methods included in this review are limited to methods applied to hospitalised patients. For primary care or ambulatory patients, several methods have also been developed (64-70).

2-2a. Adjustment for resource use

(a-1) DRGs (Diagnosis-Related Groups)

In the enactment and implementation of the prospective payment system for hospitals in the USA, Health Care Financing Administration instituted the DRG classification and reimbursement system for payment of inpatient hospital care for Medicare beneficiaries (71). The system is essentially a case-mix system to reimburse hospitals for treating patients based on the average amount of hospital resources used in treating a patient within a particular diagnostic category. The major improvement in the revised version which classifies patients into 470 categories, were adjustments for surgical procedures, comorbidities, complications, and in some cases, age and sex (72,73).

Iezzoni has criticised medical DRGs because of the possibility of clinical overlap (74). Although supposedly a diagnosis-specific scale, some DRGs are symptom-related, pathology-related, or severity-related. Clinically, many medical DRGs are not mutually exclusive because they are based on the ICD-9-CM coding system which groups diseases by anatomical site. Gonnella has also questioned the homogeneity of the diseases, the arbitrary classification by age and complication/comorbidity, the partitioning of cases into medical and surgical treatment, and the fact that it is based upon actual utilisation patterns (75).

(a-2) PMCs (Patient Management Categories)

Developed by Young (76), this system seeks to develop physician-identified patient categories that are based on information obtained from both patient admission and discharge records. Data for analysis are obtained from computerised discharge abstracts which review the entire hospitalisation. Patients are categorised by considering both the reason for admission and the discharge diagnosis together. Anticipated components of care are identified for each PMC and together with estimates of relative costs for each component, an estimate of total expected resource use is developed. Therefore the emphasis is placed on identification of necessary and effective treatment modalities rather than focusing on actual resource use. The derivation and validation of this scale has been reported recently by the developers (77).

(a-3) RUGs (Resource Utilisation Groups)

Originally developed by Fries and Cooney (78), this classification system clusters patients with similar relative needs for resources, in particular, nursing time. RUG-II used in New York, is a new version that has replaced an average cost Medicaid payment system with a prospective case-mix adjusted per diem payment. RUG-II classifies patients into one of five groups (special care, rehabilitation, clinically complex, severe behavioral problems, reduced physical functioning), then divides them into sub-groups based on an activity of daily living score. The introduction of RUG-II has brought a significant change in the mix of patient admitted to nursing homes, particularly to those financially constrained (79,80).

2-2b. Adjustment for outcome assessment

(b-1) DS (Disease Staging)

Developed by Gonnella et al (81,82), this is a method for measuring the severity of specific, well-defined diseases. Severity is defined as the likelihood of death or residual impairment as a result of the disease. A diagnosis is classified according to: the characteristic pathophysiological change in the organ or organ system involved; the etiologic factor or set of factors causing the pathophysiological changes; and the severity of the problem. In staging, diseases are generally divided into four categories of severity: from stage 1, conditions with no complications or problems of minimal severity, to stage 4, death. Medical staging criteria have been developed for 420 diagnoses and a computer software system has been developed to employ staging on large-scale data bases (83). However, Brewster criticises it in that it is still based on discharge diagnosis and requires information on the entire stay (84). Moreover, because it allocates patients over four levels, it limits cases to two or three categories.

(b-2) COMPLEX (Disease Complexity)

Developed by the Mayo Clinic study group in 1992, this is an adaptation of the computerised version of Disease Staging to provide a general measure of disease complexity on discharge (42). It counts significantly affected body systems (unrelated conditions) - those that have at least one diagnostic category with a severity rank of 2 or more - for each patient. The severity ranking system used is adapted from the Disease Staging system, ranging from stage 1 to 4. By taking advantage of the classification of each disease category into 1 of 16 body systems, COMPLEX provides a measure that decreases the effect of possible redundancy and relatively minor conditions. When examined in a population aged 65 years or older, a significant association was observed between the COMPLEX score and hospital readmission after adjustment for age, sex, diagnosis, and severity. As COMPLEX is based on hospital discharge abstracts and the ICD-9 coding system, it suffers from a lack of precision.

(b-3) MEDISGRPS (The Medical Illness Severity Grouping System)

MEDISGRPS is a prominent, proprietary severity-measurement system (84). It produces admission scores from 0 through 4, indicating increasing risk of short term organ failure. Independent of diagnosis, however, many key clinical findings are disease specific. The first review (the admission review) is derived from testing within two days of admission. Review 2 (the midstay review) aims to identify morbidity arising during the hospitalization and to assess whether the patient has responded to treatment. Given that many key clinical findings are condition-specific, it closely resembles the clinical components of nongeneric severity algorithms, such as the medical criteria version of

Disease Staging or the Computerized Severity Index. In reviewing MEDISGRPS, Iezzoni has criticised the relatively heavy weight given to findings from specialised diagnostic technologies which could affect comparisons across hospitals of different teaching status and practices for their diagnostic workups; its generic nature the simplicity of which exacts a certain cost , and the equal weight on failures across organ systems; and its untested utility for widespread quality measurement. However, when MEDISGRPS was applied to general medical patients in an English teaching hospital, a highly significant association was observed between increasing severity and both length of stay and mortality (85).

(b-4) ASA-PS (The Physical Status Classification by the American Society of Anesthesiologists)

This is the most widely used risk adjustment method in clinical settings to standardise physical status (86,87). When Dripps and his colleagues examined 33,224 patients given anaesthesia, the classification clearly showed that death was related to the physical condition of the patient (86). The scale assigns patient's physical status into five classes; from class 1, a normally healthy patient, to class 5, a moribund patient who is not expected to survive for 24 hours with or without operation. The consistency of the ASA-PS was tested by a questionnaire sent to 304 anesthesiologists (87). When ten hypothetical patients were scored, the mean number of patients rated consistently was 5.9. The anesthesiologists differed in their judgement of patients who were elderly, obese, had a previous myocardial infarction, and or anemic.

(b-5) APACHE (Acute Physiology and Chronic Health Evaluation)

First developed in 1981 (88), this is frequently used in critical care medicine. Revised twice later (89,90), the APACHE scoring system has been widely studied in intensive care (38). Originally developed for estimation of the pretreatment risk of death in severely ill patients, a review of 5,020 patients in intensive care demonstrated it was a useful tool to predict hospital mortality. APACHE II had subsequently been applied in the UK (91), New Zealand and Japan (92,93).

(b-6) SOII (Severity of Illness Index) and CSI (Computerised Severity Index)

The Severity of Illness (SOII) Index, one of the more comprehensive indicators, has been extensively studied (94-97). It evolved from the AS-SCORE instrument which included data on a patient's age, single- or multiple-organ system involvement, stage of disease, complications, and response to therapy (98). Developed primarily as a statistical tool, the index is designed to reflect the relative severity of illness across patients, not diagnoses or diseases. The index is based on seven criteria: stage of the principal diagnosis: other interacting conditions that the patient has and that affect the hospital stay: rate of response to therapy or rate of recovery: residual impairment remaining after therapy for the acute aspect of the hospitalisation: complications of the principal diagnosis: dependency on hospital (primarily nursing) staff: and extent of non-operating-room procedures. Each of these variables is scored into one of four levels of increasing severity.

For the CSI, data are gathered at several points during the hospital stay to monitor the quality of care (95). Reliability and validity has been demonstrated by the developers (99,100), though it has not been replicated by other researchers (101).

2-2c. Limitations of risk adjustment methods

There is much confusion about the role of risk adjustment systems in clinical research, quality assurance, and clinical decision making, partly because of a lack of clarity about the relationship between the methodological requirements of a scoring system and the purpose for which it is developed and used (102). Four principal aspects need to be considered when developing or assessing a method.

(c-1) Balance between data simplicity and predictive power

The desire to treat all cases identically introduces simplicity that is appealing, especially in the midst of the vagaries of diagnostic terminology. Particularly for generic scales, it is a dilemma to improve predictive power in a simplified measurement. As a result systems are sometimes criticised because of the limited number of risk factors incorporated. For example, comparing surgical infection rates has been questioned because data were "not controlled for the patient's underlying illness before surgery, the duration of preoperative hospitalisation, the duration of the operation, and several other factors known to alter the risk of postoperative infection"(103). Also in attempting to evaluate the usefulness of ASA PS, Cohen found it "appears to predict intraoperative and major postoperative complications independently, but alone it is insufficient to predict anesthetic morbidity in the immediate postoperative period"(104,105). Similar difficulty was also reported in another study (27,28).

At the other extreme, problems arise from the detailed measurement required by some methods, such as the CSI. Measures include the response to therapy, procedures performed, impairment remaining, as well as laboratory data. "One of its significant drawbacks", Gross remarks, "is that it takes 5 to 30 minutes to score a patient"(106). Some are so complex that they require an expensive computerised program for analysis.

(c-2) Reliability of the method

Risk adjustment methods must be able to be reapplied consistently by the same observer or rater (intrarater reliability) or by different raters (interrater reliability). Agreement among different raters is a more rigorous test of reliability and is the usual focus of reliability analyses. There are two possible reasons for poor inter-rater reliability: the method is flawed or implementation is poor. Many scores specifically eliminate groups of patients to improve their predictive power but as a result are subject to selection bias, which preclude their universal use.

In testing several methods, Schumacher found both the SOII and the Adverse Patient Occurrence Index (APOI) had low interrater-agreement (107). After failing to achieve satisfactory agreement, the lack of rater's training was claimed by the designer (108). Acknowledging the importance of full training, however, the study group suggested the reasons for poor performance were: an environment where case notes were unfamiliar to raters, with time pressures and no help from colleagues: the lack of a reference group: the unequal probability of cases occurring in a given level: and better reliability at the extremes of severity. The risk of the use of a single method to summarise data has been previously described (109). Schumacher has suggested a disease-specific analysis and payment-appeal process as more appropriate than system-wide adjustments with single unreliable instruments (107).

(c-3) Validity of the method

Validity is a multidimensional concept. According to Donabedian. "the question of validity covers two large domains. The first has to do with the accuracy of the data and the precision of the measures that are constructed with these data. The second has to do with the justifiability of the inferences that are drawn from the data and the measurements"(110). Given different notions of risk and outcome, assessing the validity of a risk adjustment method requires careful attention to the fundamental conceptualisation of risk, illness, outcome, and the goals of the analysis.

Among numerous different dimensions of validity, Iezzoni recommended the following as the most important: face validity, content validity, criterion or construct validity, predictive validity, and attributional validity (26).

Methods may be invalid for several reasons. Vincent suggested the subjectivity of the score, advances in therapy, and the influence of a given therapy (111). Scoring systems may also not be superior to assessment by doctors and nurses, and more sophistication is required (112). Due to their low sensitivity and specificity, methods will probably not apply to individual decisions.

International application of measures also requires special attention. For example, APACHE II (91) and MEDISGRPS (85), both developed in the USA, were shown not to be valid in the UK and Ireland. In review of 8,796 admissions to intensive care units, the APACHE II equation was found not to fit the British and Irish data uniformly and straight use of American equation was warned (91). Similarly when MEDISGRPS was applied to English patients, diagnostic group alone accounted for about twice the amount of variation explained by severity (85).

(c-4) Lack of comorbidity data

Another criticism has focused on the failure of risk adjustment methods to include information on comorbidity (20,113). Most of these systems fundamentally ignore the concept of complexity of illness, which encompasses comorbidities, their interactions, and the resultant effect on a patient's health. Although the Q-scale in the Disease Staging system (83) combines information from coexisting diseases, it weights the categories by expected utilisation of resources and thereby potentially limits its usefulness for adjusting for outcome. Specific comorbidities have been demonstrated as having an association with particular outcomes such that they should be included as separate covariates in a risk adjustment method (42). Questions have also been raised as to whether large intermodality differences in outcome may have resulted from comorbidity differences (43,114).

Even if comorbidity is considered in case-mix adjustment, special attention needs to be paid to how it is measured. Only those diseases and health problems that a patient has before an intervention should be classified as comorbidities. Any new problems arising after the intervention should be classified as complications and included as outcomes. Shapiro classified comorbidity into "limited other diagnoses" (secondary diagnoses that were very unlikely to result from care received) and "full other diagnoses" (all secondary diagnoses irrespective of whether they might have been due to care received) (115). Estimates of mortality differences were substantially affected by which secondary diagnoses were used in the case-mix adjustment. The study concluded that "judgments of quality should not be based on administrative data unless models can be developed that validly capture level of sickness at admission."

2-3. Measurement of comorbidity

Although co-existent conditions may effect outcome (5,25), few studies have addressed the impact of the extent and intensity of co-existent disease. Outcomes obtained may be due more to the differences in prognostic factors than to the medical care received (43,114). In studies of the effectiveness of care, the need to measure and adjust for comorbidity to predict prognoses such as postoperative hospital complications, long-term recovery from surgery or health status has been recognised (31,40). For examples, illustrate this. First, in a population-based study of osteoporotic hip fracture, Fisher found that at younger ages the presence of comorbidity or residence in a nursing home was more strongly related to survival than at older ages (44). Second, in a study of patients with end-stage renal disease it was shown that lower mortality rates for transplant recipients relative to dialysis patients are due, in part, to a healthier case mix among patients receiving transplants (116). Third, Hall suggested measures of the severity of illness and the extent of comorbidity were more important in determining the risk of a poor outcome than was the identity of the diseased organ (117). And finally, Greenfield and colleagues found that comorbidity was a critical factor when assessing the quality of patient care and when comparing patient outcomes in different hospitals (113).

2-3a. Early days

In reviewing the days before comorbidity was studied, Feinstein described how "the inter-relationships and effects of multiple diseases have not received suitable taxonomic attention in clinical science. In the statistics assembled for both the occurrence and management of human ailments, sick people usually receive strictly one-disease classifications that ignore the co-morbidity of other diseases occurring in addition to the index disease under consideration"(118). Such problems were not particularly important when much epidemiological and clinical science was concerned with the relatively uniform events that occurred during epidemics of acute infectious disease. However, it became a major barrier in the modern era of chronic diseases.

The most primitive step in adjustment is to classify patients by the presence or absence of any comorbidity. However, Jencks found that when any comorbid condition was included (whether it was an acute, active problem or a chronic and inactive problem), it did not always correlate with patient outcome, in particular, with inpatient mortality (31). In contrast, Munoz correlated the total number of additional ICD-9-CM codes beyond the principal diagnosis with mortality and showed a direct correlation (119).

2-3b. Classification by Kaplan & Feinstein

One of the earliest attempts to classify comorbid conditions was developed by Kaplan and Feinstein. They classified each comorbid diagnosis from grade 0 to 3 depending on the severity of the disease (118,120).

First, they measured comorbidity at three times; initial, post-zero interval (the time of entry to the study), and subsequent co-morbidity (including complication). The initial comorbidity was further classified into diagnostic, prognostic, and pathogenic. In their classification of diabetes mellitus, pathogenic type was further recorded as either vascular or nonvascular. Also prognostic severity was classified as either cogent or non-cogent depending on whether it might be expected to impair a patient's long-term survival.

Hence, the term non-cogent was applied to chronic conditions that could be well controlled with or without medication and that had no direct effects on vital organs. Similarly, episodic events that had occurred once in the past without involvement of the heart or brain, and without permanent effects were termed non-cogent. The severity of cogent comorbidity was classified as Grades 1, 2, and 3 (The Grade 0 was for those with non-cogent or no comorbidity) (120). Pompei et al applied this classification to examine one year mortality prediction, and found that increasing severity of comorbidity correlated with one year survival (43). In their following study, the predictive ability was shown to be limited to one year mortality (45).

Applying the Kaplan-Feinstein index, Pompei et al showed that the number of comorbid conditions was an independent predictor of survival during hospitalisation (43,45). They found only severe comorbidity was associated with a decreased survival after taking into account functional ability and illness severity, and suggested the use of such predictors of prognosis to complement any disease specific staging system which might be available (43).

2-3c. Charlson index and the issue of weighting

Kaplan and Feinstein's approach was further developed and modified by Charlson who produced a predictor of in-hospital mortality (121). This index was developed to predict risk of death attributable to comorbid diseases, not to primary diseases. Conditions that had completely resolved or a history of operation for currently inactive conditions were not counted as comorbid diseases. The comorbid conditions were classified according to the taxonomy devised by Kaplan and Feinstein (120). Then a weighted index was developed based on the in-hospital and one year mortality data according to the relative risk, to assign each comorbidity a weight ranging from 1 to 3.

In effect, this approach does not take into account the severity of a comorbid disease but its diagnosis. It adjusts risk by assigning different weights. For example, for metastatic solid tumor of the acquired immune deficiency syndrome, the assigned weight was 6 while most other comorbidities were assigned either 1 or 2. These weighted comorbidities were added together to produce a total burden of comorbidity. The index was tested on primary breast cancer patients and proved its reliability and validity.

The differences between the Kaplan-Feinstein comorbidity grade and Charlson index are that the former counts the severity of each comorbidity while the latter does not, and the former takes the peak intensity of comorbidities whereas the latter sums up each weight to derive a total score. Despite such differences, a high correlation was observed between these two indices when comorbidity was incorporated in a comparison of mortality following transurethral resection of the prostate and open prostatectomy (47).

The Charlson index has also been used successfully when dichotomised into those with and those without comorbidity. Fisher showed case fatality following hip fracture was higher for those who had documented comorbidity (44). In attempting to improve risk adjustment in claims-based research Roos showed that the dichotomised Charlson index was satisfactory for the studied population. However for other populations, they suggested it might provide valuable additional information if not dichotomised (27). When it was applied to the analysis of mortality and reoperation after prostatectomy, no change was found in the relative risk before and after including comorbidities in the risk adjustment (46,122).

Originally the Charlson index was designed for use with medical records. However, Deyo examined this index on administrative databases applying the International Classification of Diseases (ICD-9-CM) diagnosis and found an association with postoperative complications, mortality, blood transfusion, discharge to nursing home, length of hospital stay, and hospital charges (123,124).

In contrast, Romano argued that the Charlson index should be applied with great caution to administrative data because different investigators working independently assigned different sets of ICD-9-CM codes to the same Charlson-defined comorbidities (125). Also, he suggested that comorbid conditions have different clinical significance depending on the primary diagnosis or surgical procedure. In addition, summation of comorbidities has been disputed. Finally, the Charlson index has been criticised as having too few observations to exclude significant interactions among patients with multiple comorbidities. Romano recommended investigators should use their own data to re-estimate the weights, especially if a dependent variable other than 1-year mortality is under consideration (125-127).

2-3d. Composite index

To avoid relying on a single index which assessed only diagnoses, Greenfield and colleagues included two other additional aspects into their original Comorbidity Index:
(i) the baseline severity of the comorbid condition when first diagnosed;
(ii) any acute exacerbation at the time of the hospital admission; and
(iii) the functional status or the effect of all diseases on a patient at that point in time.
Using this index, wide variation in case-mix was demonstrated among elderly cancer patients (113) which accounted for some of the observed differences in hospital mortality. Similarly, the relationship between patient age and the patterns of care in prostatectomy and breast cancer patients was demonstrated (54,128). Ellwood found this index of particular appeal for widespread use in outcomes management because of its reliability, feasibility, and comprehensiveness (4).

This index was later modified to the Index of Co-Existent Disease (ICED) (1,129), eliminating acute exacerbation from the original. Using the ICED in the USA, Greenfield et al (1) have determined the extent to which co-existent disease predicted the occurrence of in-hospital complications and one-year self-reported health status for patients undergoing a total hip replacement. Complication rates ranged from 3% to 41% between the lowest and the highest levels of the ICED. Moreover, health status a year after surgery was also strongly related to ICED scores after controlling for gender, age, education, and marital status. Furthermore, inclusion of the ICED for adjustment of patient characteristics diminished differences among hospitals.

Cleary et al used the ICED for adjustment of length of stay for six medical and surgical conditions (129). Statistical adjustment for case-mix differences using the ICED accounted for most of the interhospital differences in length of stay for total hip replacement, but little for other conditions such as acute myocardial infarction and cholecystectomy.

Subsequently, in an application of their ICED in a retrospective cohort study in Italy, Nicolucci and colleagues found that comorbidity was a powerful independent prognostic factor in determining mortality of end-stage renal disease patients (130). Another study on 69 peritoneal dialysis patients by Athienites et al also supported this finding, and suggested the ICED was more informative than simple enumeration of comorbid conditions (131).

ICED has also been used to explore the relationship between case-mix and hospital readmission (132). In an attempt to identify patients at increased risk for hospital readmission, Waite et al used the Charlson Index, Kaplan-Feinstein Index, and the ICED. The result suggested none of these three indices discriminated among patients who did and those who did not have 6-month hospital readmissions, and factors other than summary scores derived from these indices should be used to identify patients at high risk for admission.

There are no published studies of the use of any of these three indices in the UK. Their validity and reliability in the UK therefore remains untested and unknown.

3. Total hip replacement (THR)

3-1. Introduction

Present artificial hip-joint surgery has developed from implants for patients with femoral neck fractures. Because of poor bony union after subcapital femoral neck fracture, endoprosthesis surgery was designed to replace bone with metallic implants consisting of a large femoral head and long stem (133-135). For degenerated hip arthrosis, however, a solution was also required for the damaged acetabulum. Early attempts failed in long term use (136-138). The success of today's THR owes much to the pioneering work by John Charnley. After his series of experiments (139), Charnley developed a low-friction arthroplasty with a polyethylene acetabular component and a femoral prosthesis with a small head. He also used polymethylmethacrylate as cement to fix these implants to bones (138). Those investigations served as landmark studies in the comprehension of joint function (140). However, the problems of wear, granuloma formation, and bone lysis nearly ended Charnley's project. The failure rate was as high as 95%. Moreover, he had encountered a sepsis rate of nearly 10% accompanied by clinical disasters and massive human morbidity. To combat these disappointments, Charnley developed unique operating facilities to eliminate operative infection and found new plastic material for the acetabular component (141).

Charnley's THR was certainly far more stable than earlier versions. In later years however increasing numbers of mechanical failures led to a reconsideration of the use of cement. So many new designs and techniques were developed in the 1980s, together with the development of the cementless THR such as press-fit, porous-coated, and threaded implants. Greater survival of prostheses was expected for cementless THR (142). The use of cement has also been questioned because of possible cardiac toxicity due to the monomers it contains and the longer duration of surgery (143). However, cementless THR has been criticised because its surface area may be too small to assure rigid bonding (144).

Recently hybrid THRs, in which a cementless acetabular component is combined with a cemented femoral component, have been tried as a solution. Preliminary results reported excellent pain relief and radiographic stability (145,146). Moreover, it requires shorter operating time, less blood loss, and does not require a trochanter osteotomy. An increased range of motion was also reported (147), although the rate of hypertrophic ossification varies (145,148). As these reports are of short follow-up studies, further investigation should be awaited. This is the introduction of a new concept that each case should be dealt individually, cemented or cementless. However, in assessment of these new implants, it was warned that "only by evaluating long-term clinical performance can the potential success or failure of an operative procedure or device be determined"(142).

Use of THR has also been extended to patients with a femoral neck fracture because osteoarthritic change can frequently be identified in this age group and eventually they'll need a THR (149,150). Close observation is necessary because they are more likely to have significant comorbidity and subsequent perioperative complications (149).

As regards the rating of disease severity, many classification methods have been published since the development of Merle d'Aubigne's rating scale for scoring hip function (151-156). The proliferation of these scales was criticised for using different criteria for roentgenographic loosening (142) which made it impossible to compare the results without common descriptors or standard nomenclature (157). There were also problems with interobserver variability of interpreting hip X-rays (158,159), discrepancy "between roentgenographic loosening parameters and clinical findings (142), and between findings at surgery and preoperative roentgenographic data (160), such as benign subsidence (155,161,162). Finally in 1990 in the USA, authorized parameters were published for the clinical and radiographic evaluation of THR, so that standard terminology could be adopted by representative authorities (157,163).

In this chapter, evaluation of several different outcome of THR are considered: mortality; complications; symptomatic and health status change; and satisfaction. Each will be considered in turn and the finding summarised in Table 1-1.

3-2. Mortality

Recent developments in the control of infection have significantly reduced surgical mortality. For example, in a study of 10,545 THRs performed in the UK in 1976-85, 90 day mortality was 0.9% and one year mortality was 1.9% (164). In a study of 149 Charnley THRs performed at UCLA Medical Center in 1986, it was demonstrated that 5 (3.4%) patients died during the first 2 years after surgery, and 3 more patients in the next 2 year interval (165). Mortality in elderly patients, such as octogenarians, is generally higher. The mortality of 100 patients whose mean age was 80 years was 4% during an average hospital stay of 42 days (166). In another study of patients aged 80 years or more, one in 42 patients died during the first 30 days. Moreover, at follow-up 5 years after surgery, 19 patients (45%) were known to have died (167). What is noteworthy in most long-term studies of THR is that the majority of the patients die before the assessment time. For example, in Charnley's follow-up study only 33 of 396 patients were alive for a follow-up examination 15 years later (168).

3-3. Complications

3-3a. Immediate complications

(a-1) Deep Vein Thrombosis (DVT) / Pulmonary Embolism (PE)

Venous thromboembolic disease remains the most common and potentially fatal complication after total hip arthroplasty (169). In a study of 253 patients undergoing total hip arthroplasty, calf vein thrombosis was documented in 29 (11.5%) patients by venography (170). Another study demonstrated 16 (24%) patients out of 66 had DVT

(171). Use of heparin has been the subject of many studies (171-174). DVT has been a rare event in Japan (175), though the adaptation of a Western life style and awareness of DVT have led to greater use of diagnostic techniques and brought increasing numbers of case reports (176).

(a-2) Urinary Tract Infection (UTI)

Urinary tract infection induced by an indwelling catheter is the most common nosocomial infection following THR, although it has received little attention in orthopaedic surgery. Patients with bacteruria after THR have a higher incidence of deep sepsis than those without UTI (3.4% vs 1.5%) (177). In one randomised controlled trial, a reduction in mortality was associated with reduction in nosocomial UTI (178). Short-term use of catheter is recommended for THR patients to prevent urinary retention and following infection (179,180), although the results are questioned (181).

(a-3) Joint infection

Foreign material implanted within the human body carries a high risk of infection. Moreover, the diagnosis of sepsis in THR tends to be obscured because of the use of cement (182). A 'glycocalyx' coating on implants has been suggested as being responsible (183). Due to a lack of established diagnostic criteria, varying rates of infection have been reported. In addition, the use of antibiotics masks microbiological examination and in the early years, anaerobes and tissue biopsies were not cultured routinely (184).

Dental surgery may pose a risk through the threat of hematogenous spread of infection. The use of prophylactic antibiotics remains controversial and no universally accepted protocol exists (185-188).

(a-4) Dislocation

The reported rate of postoperative dislocation varies from 1.1% (189) to 3.7% (190). Previous hip surgery has been identified as the most important risk factor (191). Laxation was classified to aid decisions about its treatment (192) and if not accompanied by detachment of the greater trochanter, proper positioning of the acetabular component and muscle strengthening exercises are suggested as important measures to prevent this complication (189,193).

(a-5) Intraoperative femoral fracture

Intraoperative fracture of the femur following THR has been reported to occur in 3% (194,195) to 4.1% (196) of primary THRs, and 2.2% (197) to 6.3% (198) of revision operations. Most of the fractures (70%) occurred at the distal end of the femoral stem (199) and were internally fixed with or without postoperative casting. One study, however, reported that only half of intraoperative fractures were identified during surgery (194). Possible risk factors include osteoporosis and aggressive canal filling (196). Studies of mechanical design of the femoral component have also shown that fractures occur more frequently with implants with straight, smaller femoral stem than with the anatomically designed larger prostheses (195,196).

3-3b. Late complications

(b-1) Loosening and revision surgery

The most frequent long-term complication is the loosening of implants and the need for revision surgery. Differences in the length of the observation period (165,200), the proportion of patients reviewed, the definition of failure, and the type of prosthesis make it difficult to compare the results. Also survival analysis has not always been used and the distinction between acetabular component or femoral component failure has been incompletely reported. In summary, the failure rate of cemented THR has been reported as 1% per year in patients older than 50 years, and 2% or higher in younger patients (201). Similar rates were observed for cementless THR. While improved cementing and hybrid THR have been tried in an attempt to solve implant loosening, the presence of particulate debris has become the primary problem for THR by causing osteolysis and socket loosening (140,202,203). Improved surface coating by new materials may reduce the incidence of osteolysis by debris.

The results of cemented revision THR have not been as encouraging as those for primary arthroplasty. 29% loosening has been found in revision cemented THR after only 2.1 years (204) and in another study 20% of acetabular components and 44% of femoral components were loose after 4.5 years (205). Moreover, the results of rerevision cemented THR are even more discouraging (206).

(b-2) Ossification

The incidence of ossification ranges from 2-20% (139,148,207-210). Ossification is sometimes associated with severe limitation of movement and pain. The incidence is significantly greater in patients who developed post-operative hematomas, prolonged wound drainage, or superficial infection, as well as those whose surgical exposure was difficult. Various suggestions have been made to avoid this complication, such as postoperative radiation, excision of bone (211,212) and preventive treatment with indomethacin (213), though use of non-steroidal antiinflammatory drugs is still controversial.

(b-3) Postoperative femoral fracture

The incidence of postoperative fracture varies from 1.6% within a mean time of 3.7 years (214) to 5% within 10-years (215). In addition to the risk factors suggested for intraoperative fracture, an association has been observed with patient's age, body height and weight, osteoporosis and operative procedure, such as perforation of the femoral cortex and duration of surgery (214-216).

(b-4) Trochanter problems

Osteotomy of the greater trochanter by the lateral approach and its reattachment with wire is an important part of Charnley's THR, because of its excellent exposure allowing accurate placement and fixation of implants as well as changing the stress moment by its reattachment to a new position. However, trochanter-related problems such as trochanteric bursitis, delayed and non-union of the greater trochanter, fracture of the wires with separation of the trochanter producing pain, a Trendelenburg gait and hip instability, are also well recognised particularly after revision arthroplasty (217-219).

Table 1-1: Summary of previously reported outcomes of THR

Outcome	Incidence	Note		Reference No.
MORTALITY				
30 days	2.4%	elderly patients (≥80 years)		167
90 days	1.0%			164
1 Yrs	2.1%			164
2 Yrs	3.4%			165
4 Yrs	5.4%			165
5 Yrs	45 %	elderly patients (≥80 years)		166
15 Yrs	91.7%			167
COMPLICATIONS				
Immediate:				
DVT/PE	10 - 34.3%	DVT		170-173
	1.2 - 3.6%	PE		173
UTI	0-43%	depends on the use of catheter		165,179, 220,221
Joint infection	<1%	Primary THR		210
	<3%	Revision THR		210
Dislocation	1.1 - 3.7%			189,190 193,201
Intraoperative fracture				
	3 - 4.1%	Primary THR		194-196
	2.2 - 6.3%	Revision THR		197,198
Late:				
Loosening identified-		Loosened component	Observation period	
by X-ray	4%	Overall	2 Yrs	140
	10 - 15%	Acetabular	10 Yrs	210
	30 - 50%	Femoral	10 Yrs	210
	3%	Femoral (new cementing)	11 Yrs	210
by revision	10 - 30%	Overall	10 Yrs	210
Ossification	2 - 20%			155,209 210
Postoperative fracture	1.6 - 5%	≤10 year		214,215
Trochanter-related	12.4%	Primary THR		217
	4.2%	Revision THR		222

3-4. Symptomatic and health status change

3-4a. Symptoms

Immediate relief from hip pain is the most striking benefit of THR, as well as an improved range of motion. In Charnley's initial study of 97 hips, most patients had no pain at three weeks after surgery and could undertake leg raising exercises (138). As THR was practiced more, longer term outcome has been considered because bony remodelling takes a long time. At a minimum of 15-years follow-up of cemented THR, 80 - 90% of patients were functioning with little or no pain (142). Such long term follow-up is difficult as it is not always possible to bring in patients for follow-up examination several years after surgery, especially those who are doing well (165). In the case of cementless THR, the reported prevalence of significant limp (0 - 21%) and thigh pain (12 - 26%) has varied widely (142). Improvement in the average range of movement has not been found to be related to the use of cement (165,223).

3-4b. Functional ability

In study of 149 cemented THR patients, their mean functional status had improved from 3.5 to 7.1 (on an 8 point scale) 4 years after surgery and this improvement was then maintained over a ten-year period (165). Substantial improvements in functional status have been observed during the first three months after operation (224).

3-4c. Quality of life

In general due to over-emphasis on physician-defined pain relief and measures of technical success, improvements in patients' quality of life and satisfaction are often neglected or only marginally considered.

In one study of 38 patients who underwent hip or knee arthroplasty, a large improvement in their quality of life was detected three months after using five instruments including Index of Well Being and Sickness Impact Profile (224). The study of 54 THR patients using three different scales (Sickness Impact Profile, rating on a visual analogue scale, and a utility measure) all showed increases in their quality of life after surgery (225). In O'Boyle's schedule for the evaluation of patient-generated quality of life (SEIQoL), the quality of life of THR patients increased postoperatively to a significantly higher level than that of controls (226).

In general, surgery has not been shown to change work status because the mean age of patients has been over 65 years (227). In Hertzman's study, 42 of 92 nonretired patients in their 50s were on sick leave for more than 6 months before surgery. Patients with blue-collar work preoperatively had a higher risk than white-collar workers of early retirement after THR (228).

3-5. Satisfaction

Although the methods of measurement were different, most studies have reported high level of satisfaction in THR patients. 100% of the 59 patients who responded were satisfied with the procedure (229,230). When patient satisfaction was measured by a 5 point-scale (1 indicated the highest satisfaction) in a study of 356 THR patients, the average level was 1.4 with little interhospital difference (181). Patient satisfaction has also been used to compare the outcome of different type of implant, This suggested greater satisfaction with a cemented femoral stem than with a cementless stem (231).

While most studies in Western countries report high levels of patient satisfaction, the same is not true for Japanese patients. As the Japanese life style requires more hip flexion than the European (232), dissatisfaction with continuing pain and inability to sit on their legs has been found (233).

3-6. Determinants of outcome

3-6a. Patient factors

(a-1) Age

Analysis of patients younger than fifty-five years old shows 10-year survivals of the implant to be 87.6%, suggesting that a primary cemented THR can be expected to function durably in an active middle-aged patient (234). However, the use of cemented THR has been questioned in patients younger than thirty years old (235), forty-five years old (236) and forty years old (237). In general, for young patients in Japan, a variety of arthroplasties other than THR are performed, following Charnley's advice to delay operation in the young patient with osteoarthrosis of the hip (232, 238-240). On the other hand as many as 72% of THRs in octogenarians had complications (excessive bleeding, postoperative confusion, urinary tract infection, and dislocation), although different ones from those experienced by younger patients who mostly suffered mechanical problems such as loosening (167). However, another study suggested that age should not be a contraindication to hip replacement, with patient selection made on the basis of symptomatology and overall health (241).

(a-2) Anatomy

There is a special concern about the hip anatomy of Japanese patients. In general, finding a prosthesis to fit Japanese patients is difficult because of their much smaller and shallower acetabula, slender femoral stems (240,241) and straight femoral neck (242). Acetabular deficiency is a particular problem for the Japanese. One survey revealed 88.3% of THR patients had congenital dislocation and acetabular dysplasia (232). This factor is reflected in the even greater preponderance of females needing THR than in the West (240,243). Due to a nationwide campaign in Japan (244,245), infant hip screening is now performed thoroughly and morbidity has been decreasing for the last two decades (246). However, the reduction rate by Pavlic splint has also been decreasing (from 87.1% to 80.3%), implying a relative increase of more difficult cases.

A marked deficiency of the bone stock necessary for acetabular reconstruction in THR, means that the operation may become a technical hazard and may not be feasible (247). A new operative technique, using the excised femoral head to fix to the acetabulum, takes advantage of an autograft being contoured to the ilium, and also enough volume and strength to fix (247). Moreover, its use may eliminate the necessity of taking an autogenous bone graft from another site. As a result, two studies have reported that only one case out of 300 hips undergoing Charnley THR had to be revised because of mechanical loosening (232,248).

(a-3) Diagnosis

Early mechanical loosenings of acrylic-fixed implants were predicted in osteoarthritis patients and patients under 30 years of age (237). Other reports were also discouraging about the use of THR in rheumatoid arthritis patients (240,249-251). For uncemented THR, however, despite the use of corticosteroid and antiinflammatory medications which were suspected to retard bone growth, no failure was found (223). In addition, decreased activity levels by these patients might benefit stability. In Japan the proportion of rheumatoid arthritis patients receiving THR is smaller than in the West (240,248). However, as most studies have been done on secondary osteoarthritis patients in Japan, not enough information is available. For aseptic necrosis of the femoral head, reports suggest better survival than for osteoarthritis patients, and better in older patients than in younger (240,252).

(a-4) Other factors (weight, number of affected hips, operation)

Among other risk factors for loosening, body weight has been demonstrated as the most important (165,200,250) and is a consistently better predictor than sex (253). Significantly better results in bilateral THR cases were observed than unilateral cases, which suggested that increased daily activity of unilateral patients might be the reason

(240,254). In general, revision surgery demonstrated poorer results in comparison with primary surgery (142) and even worse in rerevision surgery.

3-6b. Health care factors

(b-1) Laboratory investigations

In retrospective analyses, many of the preoperative laboratory tests have been shown to have no value in predicting the postoperative course (255). The only tests found to be useful were urinalysis, serum glutamate oxaloacetate transaminase, and lactic dehydrogenase. Despite the enormous cost of laboratory testing and radiographic examinations in the U.S., physicians are mostly unaware of these findings and sometimes order tests to protect themselves against potential malpractice suits (255).

(b-2) Use of cement

Cemented THR can get excellent immediate interlock. However, the long-term durability has been questioned in younger and more active patients. Poor results have led surgeons to reconsider their cementing technique and to improvements in component design (253,256-261). As a result, a marked reduction has been observed in the rate of loosening of the femoral component, but not in the incidence of acetabular loosening (256,262).

(b-3) Transfusion

Transfusion of prebanked autologous blood has become popular during the past decade. Autologous transfusion has often been reported to reduce the amount of homologous transfusion, and increase postoperative hemoglobin level (263). One difficulty is that the majority of patients undergoing THR are elderly and often anaemic, and are unable to donate sufficient quantities of blood to satisfy their operative requirement (264). The use of recombinant erythropoietin has been suggested for rheumatoid arthritis patients who are often anaemic (265). One proposed solution in revision THR has been to reduce blood loss, undertake preoperative blood donation and attempt intraoperative blood salvage (266). While autologous preoperative donation has increased dramatically (267), intraoperative autologous transfusion has been reported as not cost-effective in primary THR and its use should be restricted to revision surgery (268,269). In addition, some patients have been found to prefer to run the risk of homologous transfusion (268).

(b-4) Postoperative mobilisation

For cemented THRs, patients are allowed to take full weight as soon as possible after the operation, 9.5 postoperative days on average (138,270). However this is controversial for patients with a bone graft (242,247). For a cementless prosthesis, previous suggestions that it should not be subjected to any load for three months (271) is viewed as impractical (144). In general the length of hospital stay in Japan is much longer. A long non-weight bearing period is often recommended, especially for cementless THR (272).

(b-5) Other factors (physiotherapy, analgesics, wound drainage)

A comparative study of seven- and five-day physiotherapy coverage suggested the consecutive therapy without increasing the number of treatments would not reduce length of stay (273). Also in the study of groups with or without physiotherapy service, no major differences were found in length of stay between the groups (274). On the other hand, the use of a community physiotherapist (275,276) has led to estimated savings of £21,500 a year for a practice of 12,000 patients, which suggested that early access to physiotherapy is likely to reduce the costs of drug prescribing (277). Patient controlled analgesia has been recommended as potentially superior to control postoperative pain (278,279) and no benefit has been found in the use of wound drains (280).

Table 1-2: Summary of previously reported determinants of outcomes

Determinant	Factors associated with poor outcomes
PATIENT	
Age	Younger age (and/or more activity) Very elderly
Anatomy	Shallow acetabulum Straight femoral neck Slender femoral stem
Diagnosis	Rheumatoid arthritis (controversial)
Others	Obesity Unilateral operation Revision surgery
HEALTH CARE	
Use of cement	Cemented acetabulum Cementless femur
Transfusion	Homologous transfusion
Mobilisation	Late mobilisation
Others	Lack of physiotherapy Conventional analgesia Wound drainage

4. Aims and objectives

4-1. Aims

The aim of this thesis was to assess the impact that comorbidity has on the outcome of health care interventions in Japan and the UK. To do this a USA-derived comorbidity index (ICED) was investigated in patients undergoing total hip replacement (THR).

4-2. Objectives

There were seven objectives:

1) to compare the preoperative health and clinical management of patients in Japan and in the UK, and between hospitals within the UK;
2) to describe the outcome of total hip replacement one year after surgery;
3) to compare the outcome of THR in the UK and Japan;
4) to assess the feasibility and reliability of a comorbidity measure (ICED) developed in the USA;
5) to determine the effect of comorbidity on postoperative complications and health status one year after surgery both in Japan and in the UK;
6) to identify factors confounding the relationship between comorbidity and outcome;
7) to improve the power of comorbidity to predict serious complications.

4-3. Outline

This thesis consists of eight chapters. Chapters 2 and 3 describe the methods and the practicalities of conducting the study and the recruitment and response rates. The validity and reliability both of the ICED and health status measurement are reported in Chapter 4. Then in Chapters 5 and 6 the descriptive results are presented - the preoperative health status of patients, their clinical management and their outcome. Based on these findings, predictive analyses were carried out and these are presented in Chapter 7. Finally the implication of the results for clinical practice and further research are discussed in Chapter 8.

CHAPTER 2

MATERIALS AND METHODS

- INDEX -

Chapter 2: Materials and methods

This chapter describes the materials and methods employed in the study. First, the study design and criteria for inclusion of hospitals and patients are explained. Second the development of the questionnaires for a one-year follow up of patients is described, followed by the method of abstracting data from the patients' case-notes. Finally the methods of statistical analysis are documented.

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1. Design and sampling population

1-1. Study design

The study design was two retrospective cohorts of patients who underwent THR one in Japan and one in the UK. Postal questionnaires were used for a one-year follow-up and data were abstracted from patients' case notes. Data collection in Japan took place from June to December 1993, and in the UK from January to September 1994.

The study had two data sources; clinical data on the index admission extracted from patients' case notes; and patients' self-administered questionnaires about one year after surgery. After obtaining ethics committees' approval (in the UK), the names and addresses of eligible patients were identified retrospectively by participating surgeons, and the questionnaires were sent with a letter explaining the study (Appendix 1-4). Patients were invited to participate, and their consent was obtained for data to be abstracted from their case notes. Non-responders were sent two reminder letters at three week intervals after the initial questionnaire. Finally, persistent non-responders were reminded by telephone call. In receipt of their consent, their case notes were examined and the data were collected.

1-2. Participating hospitals

The sampling frame was originally designed to provide a variety of hospitals in terms of teaching status and location. In Japan, hospitals were first selected by their activities in hip surgery known through academic exchange. However, due to the generally small volume of surgical practice in Japanese hospitals, hospitals were contacted throughout the country and all interested hospitals were included irrespective of their patients volume or teaching status. The lack of ethics committees in Japanese hospitals means that, permission was given by the professors of the orthopaedic department in the teaching hospitals and by the chief surgeon in non-teaching hospitals. Particular difficulty was experienced with teaching hospitals which were not used to collaborating with unfamiliar researchers and had a strong fear of confidentiality of patient information (Table 2-1).

Table 2-1: Participating Japanese hospitals
(from Apr - Dec 92' unless otherwise specified)

Hospitals	Period of recruitment	No. of patients identified (Total=300)
Teaching:		
Teikyo Univ Hospital, Kawasaki, Kanagawa	-	5
Tohoku Univ Hospital, Sendai, Miyagi	Jun - Dec 92'	7
Kyoto Pref Univ Hospital, Kyoto	-	8
Osaka City Univ Hospital, Osaka	May - Dec 92'	12
Kobe Univ Hospital, Kobe, Hyogo	-	13
Tokyo Med Dent Univ Hospital, Tokyo	-	15
Juntendo Univ Hospital, Tokyo	-	16
Nagasaki Univ Hospital, Nagasaki	-	18
Kinki Univ Hospital, Osaka Sayama, Osaka	-	22
Shinshu Univ Hospital, Matsuyama, Nagano	-	23
Kyushu Univ Hospital, Fukuoka	-	47
Showa Univ Hospital, Yokohama, Kanagawa	-	59
Non-teaching:		
Kameda General Hospital, Kamogawa, Chiba	-	9
Kagoshima Municipal Hospital, Kagoshima	May - Dec 92'	10
Kumamoto Kinoh Hospital, Kumamoto	-	36

In the UK, hospitals were selected from North Thames health region, within about an hour's journey for the author. Hospitals were chosen on the basis of at least one of the surgeons having expressed an interest in outcome research (Table 2-2).

Table 2-2: Participating UK hospitals

Hospitals	Period of recruitment	No. of patients identified (Total=373)
Teaching:		
St. Mary's Hospital, London	Jan 93' - Aug 93'	44
Royal Free Hospital, London	Dec 92' - Aug 93'	49
Royal National Orthopaedic Hospital, Stanmore	Feb 93' - Oct 93'	114
Non-teaching:		
Bedford General Hospital, Bedford	Apr 93' - Aug 93'	23
West Middlesex Univ Hospital, Middlesex	Sept 92' - Aug 93'	67
Whipps Cross Hospital, London	Nov 92' - Aug 93'	76

1-3. Patient eligibility for the study

In both Japan and the UK, all consecutive patients who underwent THR one year (between nine and fifteen months) before the study were eligible for inclusion unless:

1. the operation was a revision of a previous procedure on the same hip
2. the operation was bilateral during one theatre episode
3. a diagnosis of Paget's Disease or femoral fracture
4. younger than 18 years of age
5. they had metastatic cancer
6. they were undergoing chemotherapy

7. they had a diagnoses of acquired immune deficiency syndrome (AIDS), or were transplant patients.

2. Health status questionnaire development

The health status questionnaire was a self-administered questionnaire sent to patients about 12 months after surgery which enquired about their sociodemographic characteristics, health-related quality of life before and after total hip replacement, perceived improvement in health status, health care utilisation and satisfaction with care (281,282). Full versions of those used in Japan and the UK appear in Appendix 3 and 4. It was designed to assess disability and to detect clinically meaningful changes in health status. In order to be able to compare the results with those previously published in the USA, the questionnaires used in Japan and the UK retained as many similarities as possible to the USA version (1).

The reliability and validity of the US questionnaire have been reported in terms of construct validity and internal consistency (283). Its sensitivity to change has been reported in patients who underwent one of four surgical procedures, including total hip replacement (283).

However, because of the difference in health care system, questions about the number of doctor's consultations were changed in the UK so that patients could choose among several types of health professionals including nurses and physiotherapists (Questions 5 and 6 of the UK form). Moreover in the UK, a question was added to ask if patients had received help from lay carers (Q.7 of the UK form). For Japan, the USA versions of these questions were retained due to the similarity of their health care systems.

Questions about a patient's education level (Q.73 in the UK and Q.61 in Japan) and employment status (Qs.77 and 78 in the UK, and Qs.65 and 66 in Japan) were also changed due to international differences in the education systems and labor patterns.
For the UK, some wording was changed to increase its comprehensibility for a British audience. For example, 'hospitalization' was changed to 'admission' or 'hip operation' throughout the questionnaire. Questions such as 'Have you felt downhearted and blue?' was changed to '... and sad?' and also 'homemaker' to 'housework' (Qs.77,78).

In Japan, as a result of the reluctance of participating surgeons, most of the questions asking about a patient's mental health, feeling of fatigue, and cognitive problems were excluded. As a result, the number of questions asked of Japanese patients was 66, and to of British patients, 78.

A patient's health status was based on the mean score of responses to 12 questions about how much difficulty the respondent had doing different activities. There were three questions on the basic activities of daily living (eating, dressing and bathing), six questions on instrumental activity of daily living (such as doing light work around the house, walking several blocks, and doing vigorous activities) and three questions on social activity (visiting friends, participating in community activities, and taking care of family members). These three scales made up the core of health status. In addition, mental health status was based on five questions such as 'Have you been a very nervous person? and 'Were you a happy person?.

The questionnaire sought information on the patient's perception of their health status in the month prior to surgery and in the most recent month. Scores for each scale were averaged and transformed to the range from 0 to 100, with a score of 100 indicating maximum health status. Also, five single item questions asked about other aspects of their health such as the number of days patients had reduced their normal activity because of their health and how satisfied they were with their sexual relationships.

In preparing the questionnaire for Japanese patients, the UK questionnaire was first translated into Japanese by the author. Then, in order to secure the accuracy of translation, it was back-translated to English by a bi-lingual translator and the result was compared with the initial UK version.

Postal surveys have rarely been carried out in Japan so the questionnaires were sent to a small number of patients to find out the feasibility of such a strategy. Also this preliminary survey was requested by many of participating surgeons who were concerned about the length and content of the questionnaires. Hence the aims of the pilot study were to see (1) if Japanese patients would respond to a postal questionnaire, (2) the response rate to the questionnaire, and (3) if the length of the questionnaire might affect the response rate.

The original length questionnaire (long) and a shortened version were sent to 10 patients each, followed by one postal reminder. All 12 questions necessary to calculate health status before and after THR were included in the short version of questionnaire. Of those who received the long questionnaires, 66% of them responded within 2 weeks, and after a reminder all of them returned the questionnaires. 99.5% of the original 66 questions were answered, except for one patient who didn't answer any of the health status questions. For the short form, the final response was 89% with all the questions answered. As no significant difference was found in the response patterns, the long questionnaire was chosen for use in the main study.

3. Case note review

Case notes were reviewed to abstract information about the primary disease; co-existent diseases; in-hospital complications; length of stay; past history of joint surgery (on the either hip or knee); and the surgical procedures employed. The proforma used appear in Appendix 5 and 6.

The definition of comorbidity used in this study was the overall severity of illness due to diseases other than hip disease that could effect recovery from surgery during the period of observation. To measure the amount of preoperative comorbidity, the ICED (Index of Co-Existent Disease) was used.

3-1. ICED (Index of Co-existent Disease)

Two dimensions were identified as contributing to a single composite index of co-existent disease: the severity of specific diseases and a measure of general functional status. A full description of the ICED scoring system appears in Appendix 7.

3-1a. Index of disease severity (IDS)

To assess the severity of comorbid conditions, information was collected from all parts of the medical notes including the anesthesia notes, medical consultations, laboratory reports, and operation reports.

Thirteen categories of co-existent medical conditions were included: organic heart disease, ischemic heart disease, primary arrhythmias & conduction problems, congestive heart failure, hypertension, cerebral vascular accident, peripheral vascular disease, diabetes mellitus, respiratory problems, malignancies, hepatobiliary disease, renal disease, and gastro-intestinal disease. For each condition, each patient was placed into one of four mutually exclusive levels using an explicit list of symptoms, signs, and laboratory tests indicating the presence and severity of the condition, based on an approach derived from the Disease Staging system. An example of this for one disease - diabetes mellitus - is shown in Table 2-3.

Table 2-3: Example of classification by index of disease severity (IDS): Diabetes mellitus

IDS 0:	Absence of coexistent disease
IDS 1:	Chemical diabetes only, not on medication
IDS 2:	Controlled (BS<300) on medications, insulin, or diet
IDS 3:	Diabetes not controlled (BS>300) or with any of neuropathy, nephropathy, (creatinine 3.0-6.0), retinopathy, gangrene, etc.

After assessment in the 13 categories of co-existent diseases, the peak score among them was chosen to represent the subindex of disease severity, irrespective of which disease category it applied to.

3-1b. Functional severity (FS)

The second dimension, functional severity, was intended to measure the global impact of all conditions, diagnosed or not, on the patient's preoperative health. Ten areas were identified: circulation, respiration, neurological, mental, urinary, fecal, feeding, vision, hearing and speech. The same sources of information as for disease severity were used, plus the nursing notes. Following explicit scoring rules, each of the ten areas was classified into one of three functional severity levels. The classification of neurological function is shown as an example in Table 2-4.

Table 2-4: Example of classification by functional severity index: Neurological severity

FS 0:	No problems; a neurological disease with no symptoms
FS 1:	Dizziness, numbness, seizures by history (controlled), syncope by history
FS 2:	Ataxia, partial paralysis, seizures (uncontrolled), bedridden

After assessment of all 10 categories of function, the peak score among them was chosen to represent the subindex of functional severity, irrespective of which functional category it was rated for.

3-1c. Formation of ICED

The scores for the two dimensions were condensed into a single global measure of co-existent diseases called the ICED. It was an ordinal variable in which the scores for the two dimensions were combined to form four levels that were mutually exclusive and clinically meaningful (Table 2-5).

Table 2-5: Grouping system of two subindices into the composite index (ICED)

Peak Intensity of Disease Severity (0,1,2,3)	Peak Intensity of Functional Severity (0,1,2)	ICED Levels (1,2,3,4)
0	0	1
0	1	1
1	0	2
2	0	2
1	1	3
2	1	3
3	any (0,1 or 2)	4
any (0 - 3)	2	4

3-2. In-hospital complications

A list of postoperative complications was selected of both a serious and minor nature. Serious complications included hypotension, coma, neuropathy, pulmonary embolism, septicemia, shock, myocardial infarction, congestive heart failure, cerebro-vascular accident (stroke), and renal failure.

Minor complications were defined as any new postsurgical events that potentially could create discomfort or prolong the stay in the hospital, such as mild pneumonia, fever, urinary infection, gastrointestinal problems, and wound infection.

4. Analysis

4-1. In-hospital complications

For the dichotomous dependent variables, such as whether or not the patient experienced a complication, estimates of association were expressed in terms of Odds Ratios (OR). The Chi square test for trend was used for associations of complications with severity of illness.

After conducting bivariate analyses, multivariate analysis to identify the effect of each of the potential confounders was undertaken. A logistic model was fitted using maximum likelihood estimation techniques. The predictive value of co-existent disease was determined.

4-2. Change in health status following THR

Because of the distribution of change in health status was not normally distributed, non-parametric analyses were used. However, mean value and standard deviation/error were shown together the results from non-parametric analyses, in consideration of their common use for comparison.

Mann-Whitney U test or Kruskal-Wallis test was used for continuous dependent variables in comparing the mean rank of groups. In comparison of health status before and after THR, significance was examined by Wilcoxon matched-pair test. In order to estimate the relationship between the measure of comorbidity (ICED) and the dependent variables, least squares multiple linear regression was used while controlling for the effects of the other covariates. Covariates were identified by means of bivariate analysis and then selected in stepwise, multivariate procedures. A final model was then fitted to describe the association between the measure of co-existent disease and the outcomes, taking into account the effect of the covariates.

5. Summary

Design and sampling population: Two retrospective cohorts of patients who underwent primary THR one year before the study. 300 patients treated in 15 Japanese hospitals during 1992 and 373 patients treated in 6 UK hospitals (3 teaching and 3 non-teaching status) between September 1992 and October 1993.

Health status questionnaire development: A self-administered postal questionnaire was sent about 12 months after THR to enquire about sociodemographic characteristics, health status and health related quality of life before and after THR, health care utilisation and satisfaction with care. The questionnaires were modifications of one

previously used in the USA. A pilot study in Japan found the response rate was unaffected by the length of the questionnaire.

Case note review: Case notes were reviewed to abstract information about the primary disease, comorbidity, in-hospital complications and clinical management. Comorbidity was measured using the Index of Co-Existent Disease (ICED).

Analysis: The incidence of in-hospital complications was first examined in bivariate analyses. The relationship between comorbidity and complications was then explored using multivariate analysis and a logistic model was fitted. For change in health status, non-parametric analyses were used. Covariates were identified by bivariate analyses and a multivariate model was fitted to described the association between the ICED and the change in health status.

CHAPTER 3

RECRUITMENT AND RESPONSE

- INDEX -

Chapter 3: Recruitment and response

This chapter describes the recruitment of patients and response rates. First the number of eligible cases are considered. Then the response rate to the mailed questionnaire to the patients is considered along with an exploration of possible response bias. Finally case note abstraction is described and the difference in available recorded information between Japan and the UK is discussed.

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1. Eligibility

In both countries, some of the patients initially identified for inclusion in the study (10 in Japan; 24 in the UK) had to be excluded as they failed to meet the inclusion criteria. In the UK this arose, because the patients' list was prepared by participating surgeons in only two out of the six hospitals. In the four other hospitals, operated cases were first identified by the author from theatre registers. The hospital computer was then used to obtain the patient's address for mailing. Mis-classification arose because either the operative procedure or the underlying diagnosis had not been precisely enough classified in the theatre register as regards whether the case was a primary or secondary (revision) operation, unilateral or bilateral, and THR for hip arthritis or hemiarthroplasty (artificial femoral head) for femoral neck fracture. The increasing application of hemiarthroplasty for arthritis of the hip in which the acetabulum is conserved, plus the recent trend of using THR in patients with a femoral neck fracture, both contributed to difficulties in the correct identification of eligible cases. In the latter case, patients' ineligibility became evident only after their notes were studied. This was also the case when a patient was undergoing chemotherapy or suffering from metastatic cancer.

2. Response rate to postal questionnaire

Table 3-2 shows the result of data collection in Japan and the UK for eligible patients. There were four categories of non-responders to the postal questionnaire: some were currently inpatients; a few had died; some refused to participate; and some could not be traced despite approaches to their GPs. As a result, their vital status a year after surgery remained unknown. Overall the recruitment rates were high (Japan 85.3%; UK 80.7%).

Table 3-2: Number and percent of eligible patients recruited and case notes found in Japan and the UK

	JAPAN		UK	
	N	(%)	N	(%)
Eligible patients	300		373	
One year follow-up				
Current inpatient	3	(1.0)	3	(0.8)
Dead	2	(0.7)	6	(1.6)
Refused (alive)	27	(9.0)	58	(15.5)
Not traced (vital status unknown)	12	(4.0)	5	(1.3)
Recruited patients	256	(85.3)	301	(80.7)
Case notes found	249	(83.0)	274	(73.5)
Medical information complete	249	(83.0)	268	(71.8)

During the year after discharge, 2 patients in Japan and 6 in the UK died. It was difficult to judge if these deaths were related to the original diagnosis or operation. In addition, 3 cases in each country were unable to answer the questionnaire because they were currently in-patients. The causes of their admission included revision of THR and surgery on their other hip or knee replacement.

A commoner problem was inaccuracies in patients' addresses. More patients in Japan were out of reach because the hospital's information on their address or telephone number was incorrect. Although Japanese patients tended to attend the hospital for a variety of conditions more frequently than British patients, their vital status was unknown after they changed their doctors. As British patients were usually looked after by their general practitioner, who kept updated information, it was possible to check their vital status even if they changed their address.

In both countries completed questionnaires were returned in almost the same period after mailing. Nearly half the patients answered within two weeks of mailing.

3. Questionnaire completeness

In terms of questionnaire completion, a few patients failed to answer all the questions. From their notes written in the blank space, it appeared that they could not answer either because there were too many questions, or because deterioration of their other joint made it difficult for them to identify the source of their problems. Some patients also seemed to have difficulty answering the 12 questions about their health status before and after the operation because of the similar tabulated appearance of the questions which only differed by the heading described the period in question. As a result some patients answered only half of the questionnaire, either the preoperative or postoperative questions. For the 12 questions about their health status, 10 (3.9%) patients in Japan did not answer questions for their preoperative status, and 9 (3.5%) for postoperative. In the UK, 4 (1.3%) patients failed to complete the answer for preoperative status and 9 (3.0%) for postoperative.

Another problem arose with the questions asking about their mental health. These looked difficult to answer and some patients did not see what relevance they had to their hip problems and refused to answer. Although Japanese patients had fewer mental health questions to answer than British patients (3 for Japan, 5 for the UK), the completion rates were almost the same. For preoperative mental health questions, 8 Japanese and 14 British patients did not answer, and for postoperative questions, 12 Japanese and 9 British did not do so. Some patients in the UK (3 patients for preoperative questions and

6 for postoperative) always ticked the same column regardless of the question asked, despite the questions varying between positive and negative forms ("Were you a happy person?" and "Have you been a very nervous person?"). Their answers were eliminated from the analysis.

Table 3-3a shows the number and percentage of patients who did not answer particular questions. The levels of missing data in the earlier USA study are also included for comparison.

Table 3-3a: Number and percent of missing data for single questions

Item	JAPAN N	JAPAN (%)	UK N	UK (%)	USA N	USA (%)
Perceived health	10	(3.9)	6	(2.0)	3	(1.1)
Comparative health	9	(3.5)	5	(1.7)	3	(1.1)
Sexual satisfaction	32	(12.5)	50	(16.6)	30	(10.6)
Former employment	19	(7.4)	14	(4.6)	49	(17.3)
Current employment	22	(8.6)	12	(4.0)	16	(5.7)
Education level	8	(3.1)	12	(4.0)	10	(3.5)
Marital status	12	(4.7)	5	(1.7)	3	(1.1)
Living alone	11	(4.3)	8	(2.7)	NA	
Home ownership	10	(3.9)	5	(1.7)	NA	

In general, the level of missing data among Japanese patients was higher than for British or American patients, with the exception of education level. Among the missing items, questions about sexual satisfaction and employment status yielded the highest nonresponse rate in all three countries. Instead of selecting available answers, respondents frequently commented that their old age meant they had retired from the particular activity in question.

Table 3-3b shows the percentage of patients with items missing in the indices of health status. The percentage of patients with all index items missing is shown by %all. For those with missing data, the modal number of items missing is also shown.

Table 3-3b: Percent and the modal number of missing data
for indices consisting of multiple questions

Indices (N of questions)	JAPAN %any	JAPAN %all	JAPAN mode	UK %any	UK %all	UK mode	USA %any	USA %all	USA mode
Basic ADL (3)									
Preoperative	5.1	3.9	3	4.0	1.3	1	6.0	2.8	3
Postoperative	6.3	3.9	3	5.6	3.3	3	4.6	1.1	1
Pre or postoperative	-	1.9	-	-	1.3	-			
Instrumental ADL (6)									
Preoperative	11.7	3.9	1	11.0	2.0	1	10.6	2.8	1
Postoperative	13.3	3.5	1	17.6	5.3	1	16.3	1.1	1
Pre or postoperative	-	1.9	-	-	1.3	-			
Social activity (3)									
Preoperative	11.7	4.7	1	10.3	4.3	3	9.5	4.2	3
Postoperative	12.1	4.3	1	15.3	5.0	1	11.3	3.9	1
Pre or postoperative	-	7.0	-	-	6.6	-			
Mental health (5)*									
Preoperative	4.7	3.1	1-2	4.7	2.3	1	8.5	3.5	5
Postoperative	5.1	4.7	1	9.3	4.3	5	7.1	1.4	1
Pre or postoperative	-	1.6	-	-	1.3	-			
Care satisfaction (3)	2.7	1.6	3	3.0	0.6	1	4.6	2.8	3

*The number of mental health questions in the Japanese study was three.

Despite considerable international differences in culture and health care system, a striking similarity was observed in the pattern of missing data across the five indices studied. In general, questions about basic ADL, mental health, and care satisfaction were more often answered than those on instrumental ADL and social activity. However, the modal number of missing data was less for the latter, suggesting that patients tried to answer as much as possible without ignoring the whole index.

In the USA study, Guadagnoli and Cleary investigated whether missing data was related to a patient's age or their health status (284). They found the total number of missing data did not vary with age but that the better the health status of patients the less the amount of missing data. Table 3-3c shows similar analyses for British and Japanese patients. Health status was measured by the average of basic ADL, instrumental ADL, and social activity.

Table 3-3c: Statistical significance of the association between patient age or functional status and missing answers to single questions (examined by Mann-Whitney U test; NS= not significant at 5% level)

	JAPAN			UK		
	Age	Health Status		Age	Health Status	
Item/Scale		Pre-op	Post-op		Pre-op	Post-op
Perceived health	NS	NS	NS	NS	NS	NS
Comparative health	NS	NS	NS	NS	NS	NS
Sexual satisfaction	NS	NS	NS	0.018	NS	NS
Former employment	NS	NS	NS	0.005	NS	NS
Current employment	NS	NS	NS	0.022	NS	<0.001
Education level	NS	0.025	NS	NS	NS	NS
Marital status	NS	NS	NS	NS	NS	NS
Living alone	NS	NS	NS	NS	NS	NS
Home ownership	NS	0.013	NS	NS	NS	NS

Missing data in Japan did not correlate with patient age. In contrast, in the UK older patients were less likely to answer the questions asking about their sexual relationships and employment status. The influence of health status on missing data showed a different pattern between Japan and the UK. Patients in Japan with poorer health status before surgery were less likely to answer questions regarding their education and house ownership. No such association existed in the UK. British patients were less likely to answer questions asking about their current employment status if they had poorer health status following surgery.

Analysis of any association between missing data in each of the five indices with patient age is shown in Table 3-3d. On the whole, in Japan patient age did not correlate with missing data on any index except for postoperative mental health. In contrast in the UK, significant associations were observed between older patients and missing data for all indices except preoperative basic ADL. In both countries, however, patient's age was strongly associated with a patient missing some questions from either the preoperative or the postoperative index.

Table 3-3d: Statistical significance of the association between patient age and missing answers for indices consisting of multiple questions (examined by Mann-Whitney U test; NS= not significant at 5% level)

Indices	JAPAN	UK
Basic ADL		
Preoperative	NS	NS
Postoperative	NS	<0.05
Pre- or postoperative	<0.05	<0.05
Instrumental ADL		
Preoperative	NS	<0.0001
Postoperative	NS	<0.0001
Pre- or postoperative	<0.01	<0.0001
Social activity		
Preoperative	NS	<0.01
Postoperative	NS	<0.005
Pre- or postoperative	NS	<0.001
Mental health		
Preoperative	NS	<0.005
Postoperative	<0.05	<0.05
Pre- or postoperative	<0.05	<0.005
Care satisfaction	NS	NS

4. Case note review

The rate of case note retrieval for the patients recruited was high in both countries -97.3% of recruited patients in Japan and 91.0% in the UK- as was the level of complete medical information available. Collection of data from the case notes was markedly different between the two countries. All the Japanese case notes were collected in one visit at each hospital, while in the UK several visits were necessary.

Remarkable differences in case note management was also observed between Japanese and British hospitals. In Japan, each admission note was edited and bound in a single folder for the same patient. Consequently there was no mix-up of data from different admissions. Outpatient notes were edited in continuous chronological order and kept separate from the admission folder. The notes were bound firmly, with all forms and laboratory reports pasted in in an orderly way. Because most of the participating Japanese hospitals were teaching affiliated, they often had their own methods such as a routine data entry form for physical examination and computerised maintenance system, although these were often not compatible between different hospitals. A disadvantage of the Japanese system was that not all hospitals had introduced a common filing system across all the departments so sometimes information was not available from other specialties. Moreover, free access for patients to any hospital plus the lack of a GP providing continuity of care made it impossible to find out the vital status of patients who did not respond to the questionnaire.

In the UK, all patient information was bound chronologically including outpatient and admission data. Therefore, in theory, the whole history of a patient's use of health services should have been available. This rule was not always practiced and data were often missing. Not all the forms and reports were dated and it was sometimes difficult to know which admission a particular document referred to. In most cases outpatient consultations were typed, which significantly facilitated correct data identification. However, it also seemed to be part of the reason why many notes were not returned to the medical records department even months after a consultation. A variety of administrative forms were often found which had not been completed or carried only minimum or repetitive information. Basic patient information such as date of birth and discharge status were available from the hospital computer database, though it was not always possible to ascertain whether the patient was still alive or not. In theory, such computer systems should be able to identify eligible patients for a study such as this one. In practice, such a function was impossible without a competent technician whose help was not always available.

Table 3-4 shows some examples of the proportions of data recorded on admission in Japanese and British hospitals. While administrative data were recorded for all cases in both countries, clinical data were more often recorded in Japanese hospitals than British. For anaesthetic information such as body height, body weight, and ASA PS, few British hospitals recorded these on a routine basis. Also the amount of blood lost in the theatre was not always counted. The one exception to this general pattern was information on the surgical approach adopted.

Table 3-4: Completeness of data for common variables in the case notes in Japan and the UK

Data	JAPAN (%)	UK (%)
Administrative:		
Date of birth, operation, sex	100	100
Date of admission/discharge	100	100
Medical history:		
Drinking	90	72
Smoking	90	87
Social status:		
Living alone or not	100	78
Physical examination :		
Body height	100	14
Body weight	100	58
Clinical information:		
Surgical approach	68	93
ASA PS	100	41
Blood lost in the theatre	100	63
Blood lost in the ward	97	75
Preoperative Hemoglobin	100	93

It was difficult to know if in the UK the information was not collected, was collected but not recorded, or merely lost. Differences in data recording were also observed between hospitals within countries. For example in all Japanese hospitals, the amount of blood lost in the theatre was routinely recorded while that lost in the ward was often not recorded or measurement was less precisely carried. Another problem when comparing the two countries was the definition of some factors. For example, duration of surgery and of anaesthesia were separately measured and recorded in Japan, but not in the UK. Thus duration of surgery may not have been comparable.

One possible explanation for better data collection in Japanese hospitals could be that the anaesthesiologists were more demanding. Usually, for patients undergoing general anaesthesia, not only body height / weight but a full laboratory examination is requested. A respiratory function test is almost mandatory, irrespective of the patient's general health status or past history. A general preference for laboratory tests rather than history taking or physical examination could be another reason. Finally, financial incentives for insurance payment and more defensive medicine could play a part. As a result, Japanese anaesthesia records keep more detailed data, such as ASA PS scoring and operation time.

In most orthopaedic departments in Japanese hospitals, the severity of primary hip arthritis was scored according to guidelines issued by the Japanese Orthopaedic Association. Consequently the degree of pain, range of motion, and activities of daily living were uniformly recorded. Especially in teaching hospitals, more detailed surgical information was recorded such as the angle and size of nailing and tightness of joint. This was not always true, even in the UK teaching hospitals. The exception was data on the surgical approach which was largely ignored in Japanese hospitals, perhaps because surgeons tend to always follow the same technique making the routine recording of such information unnecessary.

On the whole in the UK except for one teaching hospital, no marked differences were found between teaching and non-teaching hospitals in terms of the completeness of data recorded. In both countries attempts were made to get quantitative data about the severity of the affected joint, such as the range of motion or leg length difference. However, too often the measurement differed considerably among observers and was not thought to be reliable.

5. Summary

Eligibility: 10 patients in Japan and 24 in the UK were excluded as they had been mis-classified in the sampling frame (the theatre registers) in terms of the procedure carried out or the primary diagnosis.

Recruitment rate: High recruitment rates were obtained both in Japan (85.3%) and the UK (80.7%). Some of the non-recruited patients were currently inpatients, could not be traced or had died.

Questionnaire completeness: Apart from questions on sexual satisfaction, most questions were answered by over 95% of respondents. Generally, Japanese patients were more likely than British or American patients not to answer a question. However for multiple questions making up the health status indices, the pattern of missing data was remarkably similar among the three countries. In the UK, older patients were significantly less likely than younger patients to answer questions on health status.

Case note review: The rate of case note retrieval was over 90% in both countries, although it was much easier to find case notes in Japan than in the UK. Differences were also observed in the organisation and presentation of case notes between the two countries. More clinical data were recorded in Japanese hospitals than British.

CHAPTER 4

ACCURACY OF MEASUREMENTS

- INDEX -

Chapter 4: Accuracy of measurements

This chapter reports on the accuracy of the measurement tools used in this study. The reliability, validity, and responsiveness of the self-administered questionnaire which measured health status is discussed. Second, the reliability of measuring the severity of comorbidity using the ICED is reported in terms of inter-observer and intra-observer differences. Reasons for any observed differences are then discussed.

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1. Health status measurement by questionnaire

1-1. Internal consistency

In order to measure the reliability of the postal questionnaire to patients, the internal consistency of the health status scores before and after THR were examined (Table 4-1a). Cronbach's alpha, based on the average correlation of items within a test, was calculated for each dimension of health status. The number of items for each dimension was 3 for basic ADL, 6 for instrumental ADL, and 3 for social activity. For mental health it was 5 in the UK and the USA, but 3 in Japan. For fatigue and cognitive problems, there were 2 items for each test.

The basic-ADL, instrumental-ADL, and social activity indices all had good internal consistency, generally close to or greater than 0.70. In general, internal consistency in the UK was almost the same or less than in Japan and the USA, which was reversed postoperatively.

Mental health index had the least reliability in Japan before and after surgery among the four indices examined, but not in the UK and in the USA. Although the data for mental health scores were not exactly comparable due to the different number of questions asked, the shorter index in Japan yielded a lower reliability than in the UK and in the USA. Likewise, the indices assessing cognitive problems and fatigue, both consisting of only two questions, had relatively lower reliability. When compared before and after surgery, these shorter indices were less consistent but other indices were stable.

Table 4-1a: Internal consistency (Cronbach's alpha) of health status indices before and after THR

Indices	JAPAN	UK	USA
Basic ADL			
Preoperative	0.85	0.77	0.82
Postoperative	0.83	0.85	0.75
Instrumental ADL			
Preoperative	0.88	0.81	0.88
Postoperative	0.84	0.84	0.85
Social activity			
Preoperative	0.80	0.71	0.88
Postoperative	0.72	0.71	0.88
Mental health			
Preoperative	0.69	0.74	0.80
Postoperative	0.49	0.74	0.74
Cognitive problems			
Preoperative	-	0.38	0.59
Postoperative	-	0.61	0.42
Fatigue			
Preoperative	-	0.71	0.81
Postoperative	-	0.72	0.66

1-2. Construct validity

Construct validity was examined by means of the correlation coefficient between several single item measures and indices assessing each postoperative dimension of health (basic ADL, instrumental ADL, social activity, and mental health) (Table 4-1b).

The correlations were moderately high in both countries, statistically all significant ($p<0.01$) and bigger in the UK than in Japan. The correlation among the four indices of health status with these single item measures was similar, suggesting that partly because there was a substantial overlap among the four indices.

Perceived improvement in health and change in the way patients felt had the least correlation with all dimensions of health status both in Japan and in the UK, suggesting the relatively weak representation of postoperative health status by such a question asking on time series.

Table 4-1b: Construct validity (correlation coefficients) of health status indices examined in Japan and the UK (All significant at p<0.01)

JAPAN	Basic ADL	Instrumental ADL	Social Activity	Mental Health
Postoperative status:				
General assessment of health	0.36	0.40	0.32	0.32
Expected health	0.27	0.36	0.28	0.28
Expected activity	0.25	0.29	0.26	0.21
Change in status:				
Perceived improvement in health	0.26	0.40	0.28	0.35
Perception of change in feeling	0.23	0.35	0.23	0.32
Happiness about THR	0.27	0.43	0.28	0.40

UK	Basic ADL	Instrumental ADL	Social Activity	Mental Health
Postoperative status:				
General assessment of health	0.45	0.51	0.45	0.48
Expected health	0.40	0.45	0.34	0.38
Expected activity	0.47	0.53	0.47	0.30
Change in status:				
Perceived improvement in health	0.39	0.40	0.37	0.27
Perception of change in feeling	0.44	0.42	0.35	0.31
Happiness about THR	0.50	0.46	0.43	0.32

1-3. Responsiveness

Although the scores in functions were not normally distributed in Japan and the UK, the responsiveness of the scales were compared with previously reported result from the USA using the *t* scores representing the difference between preoperative and postoperative function, divided by the standard error of the difference (Table 4-1c). The scores for all indices suggest statistically significant improvements ($p<0.0001$) after THR. There were some differences both among countries and indices.

Table 4-1c: Impact of THR on outcomes represented by t-score of difference in functions

Functioning	JAPAN	UK	USA
Limping	16.0	19.5	19.9
Need for walking support	10.0	7.4	8.0
Basic-ADL	13.3	18.8	17.5
Instrumental-ADL	12.3	17.8	18.1
Social activity	10.0	12.9	13.4
Mental health	13.2	5.5	9.4

2. Measurement of comorbidity by the ICED

2-1. Inter-rater reliability

Inter-rater reliability was examined twice in the UK. It was not possible to carry out such analyses in Japan for practical reasons.

2-1a. First study with two raters

Two raters each examined 39 case notes to rate patients' comorbidity. Both raters were qualified doctors; the author, a Japanese orthopaedic specialist (rater A: in the following tables), and a UK general practitioner (rater B). After one full-day training session, the 39 case notes were examined and comorbidity was rated independently. Table 4-2a shows the percentage of agreement between the two raters.

The level of agreement at subindex level was analysed using kappa statistics. After correcting for chance agreement, the value of kappa for the IDS subindex was smaller than that for the FS subindex. When the extent of marginally permitted agreement was included by way of the ratio of kappa (K) to kappa maximum (Kmax), agreement for the FS index was still higher than for the IDS index.

Table 4-2a: Interrater reliability test in the 1st study with two raters (N=39)

	IDS	FS	ICED
	N (%)	N (%)	N [%]
%Agreement			
Both agreed	25 (64)	36 (92)	27 (69)
Disagreed	14 (36)	3 (8)	12 (31)
Kappa statistics	IDS	FS	ICED
Kappa	0.49	0.85	0.57
Kappa Maximum (Kmax)	0.64	0.85	0.75
K/Kmax	0.77	1.00	0.76

The other analysis to estimate reliability is derived from a random effects analysis of variance model. The intraclass correlation coefficient was calculated as the ratio of case variance to total variance. In this study, it was computed from a single-factor, repeated measures design analysis of variance. The result, like the kappa statistics, showed greater agreement for the FS index (0.7540) than for the IDS index (0.7132) and the ICED (0.7067).

2-1b. Second study with three raters

Analysis of the cases in which disagreement occurred led to a greater understanding of the reasons for inter-rater differences. Having undertaken this analysis it was felt that it would be interesting to test two hypotheses: that the interrater reliability could be improved by more training of the raters as had occurred in discussing their differences; and that higher reliability would be achieved between doctors from the same specialty. A second trial was therefore undertaken.

Three raters each examined 49 case notes. The third rater (rater C), an UK orthopaedic registrar joined the two existing raters A and B. Rater C received the same training as given to rater B. The case notes were then examined by all three independently.

All three raters agreed on the ICED category for 53% of the cases (26 out of 49 cases) (Table 4-2b-1). In a further 41% of cases, two of the three raters agreed. However for 6% of the cases, all three raters disagreed. At the subindex level, more agreement was obtained for functional severity (FS) scores than for the index of disease severity (IDS).

Table 4-2b-1: % Agreement among three raters (2nd study: N=49)

	IDS		FS		ICED	
%Agreement	N	(%)	N	(%)	N	(%)
All agreed	24	(49)	43	(88)	26	(53)
Two agreed	18	(37)	6	(12)	20	(41)
All disagreed	7	(14)	0	(0)	3	(6)
At least two agreed	42	(86)	49	(100)	46	(94)

The level of agreement at subindex level was analysed using kappa statistics (Table 4-2b-2). Similar to the first study, the values of kappa for the IDS subindex were always smaller than those for FS subindex when any two raters were compared. In terms of the ratio of kappa (K) to kappa maximum (Kmax), the agreement in the FS index was still higher than in the IDS index.

Table 4-2b-2: Kappa statistics among three raters (2nd study)

	Raters combination		
Kappa	A/B	A/C	B/C
IDS subindex	0.51	0.39	0.45
FS subindex	0.97	0.73	0.64
ICED	0.56	0.35	0.51
K/Kmax	A/B	A/C	B/C
IDS subindex	0.66	0.55	0.61
FS subindex	1.00	0.85	0.78
ICED	0.61	0.50	0.69

The result of intraclass correlation coefficient analyses is shown in Table 4-2b-3. Again like the kappa statistics, it showed the best agreement in the FS index.

Table 4-2b-3: Intraclass correlation coefficient among three raters (2nd study)

Indices	Intraclass correlation coefficient
IDS subindex	0.604
FS subindex	0.768
ICED	0.569

Among the three raters, raters A and B were more often likely to agree than the other two possible combinations (A/C and B/C). The worst level of agreement for the IDS and ICED was A/C and for the FS was B/C. As regards the IDS, differences between A and B and between B and C usually arose because B scored patients as having less severe comorbidity (Table 4-2b-4). There was no consistent pattern in the differences between A and C. In 11 cases rater A scored more severely than rater C at the IDS subindex level, while in 10 other cases their scores were reversed.

Table 4-2b-4: Number of cases in which raters disagreed (N=49) (2nd study)

	Rater's score comparison*		
Score	A>B	A>C	B>C
IDS subindex	13	11	4
FS subindex	1	0	1
ICED	9	9	4

Score	A<B	A<C	B<C
IDS subindex	4	10	15
FS subindex	1	4	5
ICED	5	11	11

*Raters with larger scores judged the comorbidity more severe.

From these results, the first hypothesis that the interrater reliability could be improved by more training of the raters seemed unlikely to be true because apparently increased kappa for IDS and FS might have come from the different sample distribution in two trials. The result that the ratio of kappa to kappa maximum was not improved in the second trial also suggested to reject the first hypothesis. The second hypothesis that higher reliability would be achieved between doctors from the same specialty was similarly to be rejected from the results shown between raters A and C.

What relevance might such inter-rater differences have had in predicting outcomes? Eighteen out of the 49 cases were identified later as having had a serious in-hospital complication. Their distribution was compared with the classification of 49 patients by three raters (Table 4-2b-5). Because of the small sample size, it was difficult to evaluate their association with each rater's classification. In short, rater A stratified cases into four subgroups in which the complication rates ranged from 28% to 50% with a consistent gradient from level 1 to level 4. In the two other raters' classification, the complication rates were not so consistent.

Table 4-2b-5: Relationship of each rater's classification with occurrence of serious complications (2nd study)

	A		B		C	
	complication	N (%)	complication	N (%)	complication	N (%)
ICED level 1	5	18 (28)	4	20 (20)	4	13 (31)
ICED level 2	1	3 (33)	2	4 (50)	1	4 (24)
ICED level 3	9	22 (41)	9	21 (43)	11	29 (38)
ICED level 4	3	6 (50)	3	4 (75)	2	3 (67)

2-2. Intra-rater reliability

One reviewer (the author) rated 45 case notes twice at a mean interval of 82.5 (SD=0.5) days. As shown in Table 4-2c, ratings were very stable over time. Kappa statistics suggested almost perfect agreement both at subindex (ICD, FS) and at composite index (ICED) level, and so did the intraclass correlation coefficient.

Not surprisingly, a result of this minimum change in stratification, both the distribution of comorbidity and the proportion of in-hospital complication were not affected (data not shown).

Table 4-2c: Summary statistics of intrarater reliability

% Agreement between 1st and 2nd rating

IDS	98%	(44/45 agreed)
FS	96%	(43/45 agreed)
ICED	93%	(42/45 agreed)

Kappa statistics

Kappa (K)		Kappa Maximum (Kmax)		(K/Kmax)
IDS	0.969	IDS	0.969	(1.00)
FS	0.910	FS	0.910	(1.00)
ICED	0.905	ICED	0.969	(0.93)

Intraclass correlation coefficient

IDS	0.9908
FS	0.8119
ICED	0.9452

2-3. Sources of disagreement

The sources of disagreement between raters in assigning comorbidity were felt to arise for three reasons: the case notes; the raters; and the ICED protocol

2-3a. Case notes

Case notes in the UK are intended to be stored in chronological order, including both inpatient and outpatient records. Although this was not practiced well in most of the six British hospitals included in the study, all 49 notes studied in the reliability test with three raters were from a teaching hospital, and they were well organised and maintained. Fewer handwritten data were observed than in the other hospitals. Patients had been seen on several occasions before surgery including pre-admission clerking by a house officer and presentation of the case to senior clinical staff. This sometimes led to conflicting information regarding the patient's comorbidity, because surgeons did not always agree with their colleagues in their assessment of a patient's risk for operation/anaesthesia.

Also it could be the case that the patients present only their major co-existing diseases/disabilities to doctors, and whatever they think is trivial, they mention only to the nursing staff. This self-selection of information by patients could lead to doctor's and nurse's records differing. For example, when patients had shortness of breath on exercise it could be written in either or both sections of the notes in a different wording.

2-3b. Raters

In this study, raters differed from each other in terms of their speciality, nationality, and country of training. In comparison with orthopaedic surgeons, general practitioners (GPs) see cardiorespiratory disorders more frequently. On the other hand surgeons are more likely to experience acute deterioration in patients perioperatively. These work habits might lead to different views of clinical severity. Seeing patients doing well in their daily life in the community despite their illness may encourage lower scores in physiological impairment categories (as used in the IDS), while witnessing serious in-hospital problems may make surgeons cautious about every abnormal measurement found.

As for differences in health care systems, Japan permits patient's direct referral to hospital care while in the UK this is limited via GP referral. British GPs select the patients to be seen by surgeons, who could be looked after by surgeons in Japan to some extent. From this difference in the range of patients, Japanese doctors might have intermediate view between British surgeon and GPs.

The cultural upbringing of the raters might have led to their different concepts of acceptable health. Japanese care much about cleanliness, and even a minor disorder is viewed as a sickness whether it threatens one's ultimate survival or not. Nationwide health insurance coverage, effective health promotion, and the introduction of regular health check-ups have encouraged the Japanese to look for any change in their physiological status and then to seek treatment. In contrast in the UK, people prefer to maintain their independence. Assisted by the development of social welfare and community health services, the elderly and disabled can live on their own despite their health difficulties. The range of what 'health' means in the UK is wider than in Japan. This general difference may effect the rater's view of sickness.

2-3c. ICED protocol

The USA manual for using the ICED provided general guidance in the classification of specific problems and guidelines for individual diseases. In 20 pages, it covered 13 physiological conditions and 10 physical conditions. Despite this several problems were encountered.

c-1) Index of disease severity (IDS):

Among the 13 diseases, cardiac disorders received most attention (4 out of the 13: organic heart disease, ischemic heart disease, primary arrhythmias & conduction problems, congestive heart failure). The next most referred system/organ were vascular diseases (hypertension, cerebral vascular accident, peripheral vascular disease). Other conditions were not classified in as much detail. The ICED was therefore heavily weighted to circulatory risk. Among the four cardiac diagnoses, the instructions state that none of them overlap each other. For example, if an electrocardiogram showed ischemic change, it was suggested that 'primary arrhythmias & conduction problems' but not 'ischemic heart disease' should be affirmed.

In practice, raters found the definition of each category of disorder was not extensive enough to cover the wide range of patients' conditions. For example, in respiratory problems which includes asthma, there was no indication as to which level to assign patients who used daily inhalation therapy for years without suffering an attack.

Pre-symptomatic disease may be first detected on admission, such as a patient found to be hypertensive at hospital. The shorter the length of preoperative hospital stay, during which patient's blood pressure may be checked a few times by different hospital staff, the more difficult it would be to see if a patient had pathological hypertension or was merely agitated (white-coat hypertension). Usually a preoperative check list of the pharmaceuticals that patients were taking before admission was helpful in figuring out the severity of any hypertension, but raters had to rely on case notes which were not always complete in keeping every form.

The length of the past history of a condition was also a potential problem of interpretation. In the malignancy category, a history of cancer was classified according to the number of years since the last treatment (more than 5 years' history was level 1, less than 5 but more than 1 year was level 2). In practice, medical records often failed to specify the period.

Also, some periods which were left open-ended caused difficulty. In hepatobiliary disease, a history of hepatitis of more than 1 year ago was classified as level 1. When a patient was recorded as having had childhood jaundice, raters disagreed as to how to classify the severity.

There was also some concern about the relative severity of conditions in different physiological categories. For example, a history of one transient ischemic attack with no residual effects was classified as level 1 in the cerebro-vascular accident category and a history of cerebro-vascular accident was given level 2 or more. However, raters felt this was not consistent with the levels for diabetes mellitus. For example, diabetes is classified regardless of the means of treatment ('Level 2=controlled diabetes on medications, insulin, or diet').

c-2) Functional severity (FS):

The ICED considers functional severity as 'not diagnosed but relevant diseases' which 'may have an impact on the function of the patient'. Severity was classified according to its absence or presence and its extent (level 1 was for mild/moderate and level 2 for serious/severe impairment).

Raters found this subindex sometimes overlapped with the physiological impairment subindex. In assessing the severity of cardiorespiratory disorders, both subindices have matching categories. For example, when a patient with congestive heart failure and well controlled asthma had ankle edema and shortness of breath, the severity would be level 2 in the congestive heart failure category in the disease severity subindex. But raters disagreed if they should or should not assign to level 1 in functional severity for his/her shortness of breath, because its cause had already been diagnosed. Also it was unclear whether it had to be in the circulation or respiration category of the IDS.

It was felt that the subindex should refer to more conditions, including those that are relatively rare. In the neurological category, raters found no categories mentioned Parkinson's disease which was thought to give some degrees of functional severity.

Sometimes selection of the appropriate severity level proved difficult. For example, in the urinary category, incontinence was assigned level 2. When raters came to score the severity of stress incontinence, it was unclear whether it was level 2 or 1. Similar uncertainty occurred with 'occasional incontinence'.

Consistency in classification of severity was also questioned. As most of the patients in this study was elderly people, they often wore glasses and/or a hearing aid. In the vision category, level 0 was for those with no problems and level 2 was for severe blurring or blindness. Raters therefore assigned level 1 to those wearing glasses. In most instances no information was available as to how much patients needed glasses. On the other hand, a patient was classified as level 0 in the hearing category even with hearing aid.

3. Summary

Health status measurement by questionnaire: Internal consistency of health status measures was high in all countries, though lower for the indices made up of only 2 or 3 questions than for those with 5 or 6 questions. Construct validity was moderately high in both countries. Responsiveness of the questionnaire to differences in function was also good.

Measurement of comorbidity by the ICED: Intrarater reliability was high for both subindices and the ICED. Interrater reliability was examined twice, with similar results. Lower agreement was observed with the subindex of co-existent disease (kappa 0.5) than with the functional severity subindex (kappa 0.64-0.97). Disagreements are thought to have arisen as a result of the poor quality of case notes, differences in the cultural and professional backgrounds of the raters, and difficulties in interpreting the rules for using the ICED.

CHAPTER 5

Preoperative health status of patients and their clinical management

- INDEX -

Chapter 5: Preoperative health status of patients and their clinical management

In this chapter, patients are described in terms of their sociodemographics, disease severity, and comorbidity. Patients from Japan and from the UK are compared, as well as some comparisons with previously published data on USA patients. The clinical management of both Japanese and British patients is also described. Finally, some inter-hospital comparisons in the UK are presented. Due to the small sample size in each hospital, similar analyses were not possible for Japanese data.

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1. Sociodemographic characteristics

The characteristics of the patients who participated in the study are presented in Table 5-1.

1-1. Age

The age distribution was significantly different among the three countries. Japanese patients were the youngest and British patients the oldest. This contrasts with the difference in the average life spans in the three countries: Japanese expectation of life is about four years longer than that of the UK and the USA for both sexes. One possible explanation is cultural differences in illness behavior. In general, the Japanese are very concerned about any risk associated with an intervention and so tend to decline treatment if any possible complication is suggested. This attitude is observed not only in patients themselves but in their family and in their doctors. Thus, the observed age difference in this study may represent a preference among older (and therefore sicker) patients in Japan to forego surgery because of the greater risk they face compared with younger patients.
Also younger people may have more access to health services in Japan which could facilitate more consultations with doctors at the very early stage of diseases, plus

extensive nationwide health promotion which might lead to increased attention to any change in their health status.

1-2. Sex

The gender distribution demonstrated another clear difference. The majority of Japanese patients were female, perhaps reflecting the different etiology of hip arthritis in Japan where congenital hip dislocation has been commoner, particularly among females. The proportion of female patients in the UK was similar to that in the USA.

1-3. Married

The proportion of married patients was higher in Japan than in the UK and the USA, reflecting the significant difference in their age distribution in which the older British patients are more likely to be widowed (25.3%) than the younger Japanese (15.6%). Also more British patients were found to be separated or divorced (6.8%) than the Japanese (2.9%).

1-4. Living alone

Fewer Japanese patients were living alone than was true for British patients. This is consistent with the national preference of Japanese people who are more likely to stay together in an extended family. A Japanese national survey in 1989 showed 35.7% of households with an elderly person was an extended family including three generations (285). Although the number of cohabitants per household has been steadily decreasing in Japan, national statistics for 1992 showed that the proportion of the elderly (65 years or older) living alone was 11.2% (285). In the UK, 29% of those aged 65-74, and 48% of those aged 75 years or older were living alone in 1992 (286). These figures are similar to those found in this study.

1-5. Home ownership

Because of the advanced age of the patients in this study, most of them were owner-occupiers in both countries. National statistics for home ownership was not available in Japan, however, a British survey in 1992 suggested 66% of the households were owner occupied (286). In this study a similar figure was obtained for THR patients.

1-6. Education

Because of the difference in school education systems, patients' educational level was measured in different ways in each country. In Japan, patients were asked whether they finished primary education (usually 15 years of age) or received higher education, while in the UK patients were asked about the age at which they completed their full-time education. The questionnaire for the Japanese patients had a selection of five answers; primary education (15 years), high school (18 years), polytechnic (20 years), college (22 years), postgraduate school (26 years). In the UK, answers were selected from; age 15 years or under, 16-18 years, 19 years or over.

When the patients were compared by the age at which they completed their education, a significant difference was observed. Japanese patients were more likely to have continued past 15 years of age. Similar proportion had gone on to higher education.

1-7. Work status

In general, most of the patients in both countries were not in employment, reflecting their advanced age. There was no statistically significant difference between the proportion of Japanese and British patients working.

1-8. Habit in drinking/smoking

Information on drinking and smoking were obtained from the case notes and missing data were eliminated from analysis. The accuracy of the data were limited by patients' accuracy in reporting and whether or not a record was made in the case notes. As drinking and smoking were simply categorised as 'Yes' or 'No', it is not clear how someone who recently stopped was recorded. Overall, more British patients were current smokers than Japanese. In contrast there was no significant difference in drinking habits (answered in terms of the usual amount consumed).

Table 5-1: Comparison of patients' sociodemographic characteristics between Japan (N=256), UK (N=301) and USA (N=356)

	Number (%) of patients			
Patient characteristics	Japan	UK	Probability* Japan vs UK	USA
Mean age, years +/-SD	60+/-10	68+/-12	<0.0001[a]	64+/-13
Female	217 (84.8)	193 (64.1)	<0.0001[b]	203 (57)
Married	188 (77.0)	173 (58.4)	<0.0001[b]	228 (64)
Living alone	28 (11.4)	102 (34.8)	<0.0001[b]	
House ownership	208 (84.6)	191 (64.5)	<0.0001[b]	
Education				
age of completion, years				
15≥	53 (21.4)	179 (61.9)	<0.0001[c]	
16 - 18	163 (65.7)	68 (23.5)		
19≤	32 (12.9)	42 (14.5)		
Work status				
Working full/part time	66 (27.8)	59 (20.6)	0.0513[b]	
Habit				
Current drinker	56 (25.0)	38 (19.9)	0.2174[b]	
Current smoker	27 (12.1)	83 (35.5)	<0.0001[b]	

*: Probability was examined between Japan and the UK. a, based on t test; b, Chi square test; c, Mann-Whitney U test.

2. Severity of hip disease

2-1. Diagnosis

The primary diagnoses of hip arthritis were similar in the two countries (Table 5-2a). The majority of patients had osteoarthritis, including both primary and secondary causes. The proportions of the patients suffered from rheumatoid arthritis and avascular necrosis were relatively smaller than previous studies have reported. Other diagnoses included systemic connective tissue diseases such as osteogenesis imperfecta and ankylosing spondylitis.

2-2. Past history of hip/knee surgery

The proportion of patients who had previously undergone surgery on either of their hips was significantly higher in the UK than in Japan. In both countries, about 6% of the patients had had surgery previously on the same hip as the index operation for this study. However, British patients were more likely to have had surgery on the other hip than in Japan. Most operations on the contralateral hip had been THR, either primary or revision. The result may reflect international difference in the practice of THR, which has been commoner in the UK than in Japan. For past history of knee surgery, significantly more British patients had undergone surgery than the Japanese.

Table 5-2a: Comparison of clinical profile of hip disease between Japan, UK and USA

	Number (%) of patients			
	Japan N=249	UK N=268	Probability* Japan vs UK	USA N=356
Primary diagnosis				
Osteoarthritis	219 (88.0)	244 (91.0)	0.1251	-
Rheumatoid arthritis	12 (4.8)	15 (5.6)		-
Avascular necrosis**	16 (6.4)	6 (2.2)		-
Others	2 (0.8)	3 (1.1)		-
Prior hip surgery (either side)	51 (20.5)	76 (28.4)	**0.0376**	(28)
on the same hip	15 (6.0)	16 (6.0)	0.9794	-
on the other hip	43 (17.3)	68 (25.4)	**0.0249**	-
THR in the other hip	31 (12.4)	60 (22.4)	**0.0030**	-
Prior knee surgery	4 (1.6)	15 (5.6)	**0.0160**	(3)

* Statistical significance was compared between Japan and the UK, based on Chi square test.

** Avascular necrosis included both idiopathic and secondary causes.

2-3. Patient self-evaluation of hip disability

Preoperative hip disability was measured in terms of the severity of any limp and the need for walking supports (Table 5-2b). Patients were asked how much of a limp they had before the index operation. Limp was evaluated on a scale from 1 to 5, where 1 indicated no limp and 5 indicated patients could not walk. There was a striking difference between the two countries. British patients perceived that they were significantly more disabled with 59% severely affected or unable to walk compared with 28% of Japanese patients.

Also, patients were asked the type of walking support they used before the operation. Most of the patients did not need any support or only used a single cane/crutch. Although the UK patients made more use of supports than Japanese patients, the difference was not as great as the difference in perceptions of the severity of their limp.

Table 5-2b: Patient perception of limp and the need for walking support before THR

	Number of patient (%) JAPAN N=256	UK N=301	Probability (Mann-Whitney)
Severity of limp			
1. None	5 (2.0)	9 (3.1)	**<0.0001**
2. Slight	64 (25.3)	28 (9.5)	
3. Moderate	114 (45.1)	85 (28.8)	
4. Severe	48 (19.0)	151 (51.2)	
5. Unable to walk	22 (8.7)	22 (7.5)	
- Missing	3	6	
Walking support			
None (or rarely)	91 (36.5)	75 (25.3)	**<0.0001**
Single care or crutch	123 (49.4)	136 (45.8)	
Two canes or crutches	20 (8.0)	54 (18.2)	
Walker	6 (2.4)	9 (3.0)	
Wheelchair	9 (3.6)	23 (7.7)	
Missing	7	4	

2-4. Obesity

Because data on height and weight were missing from 228 (85.1%) case notes of British patients, analysis was done on Japanese patients only. Data from the Japanese cohort were compared with those from a national survey (287), adjusted for age and sex. Among the 248 patients whose height and weight were known, nearly half of them were in the normal range (25 - 75 percentile) (Table 5-2c). About 10% of the patients were categorised into either 'fat' or 'thin'. In general, the Japanese patients were similar in distribution to the general population.

Table 5-2c: Distribution of patient obesity in Japan (N=249)

Category of obesity	Percentile in Japanese population	Number of patient	% Total
Fat	<10	25	10.1
Moderately fat	10-25	47	19.0
Normal	25-75	121	48.8
Moderately thin	75-90	30	12.1
Thin	90<	25	10.1
Missing		1	-

3. Comorbidity

3-1. Distribution of patients classified by ICED

In all three countries, the distribution of patients classified by the co-existent disease severity subindex was bi-phasic: there were fewer patients at level one than at level zero or two (Table 5-3a). This trend was partially changed when composing the ICED by adding in the other subindex, functional severity, which shifted some of the level two patients to lower levels. This was because of the predominance of level zero classifications in the functional severity sub-index. As a result, the ICED scores were closer to a normal distribution in the UK and the USA, however, the majority of Japanese patients were still dichotomised to either no or mild co-existent disease. A striking difference was observed in the proportion of patients with moderate to severe levels of comorbidity. In Japan, 14.8% of patients were classified in level 3 and 4, while it was 43.3% in the UK and 34.1% in the USA.

Table 5-3a: Number and percent of patients classified by the two subindices (co-existent disease severity and functional severity), and the ICED

Index	Levels of index	N at each level (% total) JAPAN N=249		UK N=268		USA N=356	
Co-existent disease severity subindex	0	105	(42.2)	73	(27.2)	105	(29.5)
	1	65	(26.1)	36	(13.4)	68	(19.1)
	2	74	(29.7)	116	(43.3)	172	(48.3)
	3	5	(2.0)	43	(16.0)	11	(3.1)
Functional severity subindex	0	204	(81.9)	162	(60.4)	213	(60.0)
	1	42	(16.9)	93	(34.7)	132	(37.2)
	2	3	(1.2)	13	(4.9)	10	(2.8)
	Unknown					1	
Index of co-existent disease (ICED)	1	105	(42.2)	70	(26.1)	103	(29.0)
	2	107	(43.0)	82	(30.6)	131	(36.9)
	3	30	(12.0)	63	(23.5)	104	(29.3)
	4	7	(2.8)	53	(19.8)	17	(4.8)
	Unknown					1	

3-2. Prevalence of co-existent diseases

The variety of co-existent diseases in British patients was greater than in Japan (Table 5-3b). In both countries, hypertension (about a third of patients) and arrhythmia (about a quarter of patients) were the most frequently observed. Significant differences were observed between the two countries in the prevalence of cardiovascular (organic heart disease, ischemic heart disease, congestive heart failure, hypertension, peripheral vascular disease), diabetes mellitus, renal disease, and gastrointestinal diseases. 95% confidence interval of the proportion is shown in Table 5-3c for the diseases with significant differences observed between Japan and the UK.

Due to the lack of use of a universal disease classification system, national health statistics are not comparable. However, the study results suggested similar findings to what was expected. For example, the results for cardiovascular and blood pressure disorders were in agreement with previous reports (288-292) which have suggested a lower risk in the Japanese population. In contrast, similar levels of morbidity were expected for diabetes (1.6 in Japan, 1.8 in the UK) (288,289) but this was not so with these study groups.

Table 5-3b: Comparison of prevalence of co-existent diseases between Japan and the UK

Co-existent disease	Number of patients (%) JAPAN (N=249)	UK (N=268)	Probability (Chi square)
Organic Heart Disease	3 (1.2)	15 (5.6)	**0.0131**
Ischemic Heart Disease	16 (6.4)	34 (12.7)	**0.0161**
Arrhythmia	67 (26.9)	67 (25.0)	0.6209
Congestive Heart Failure	2 (0.8)	38 (14.2)	**<0.0001**
Hypertension	67 (26.9)	101 (37.7)	**0.0089**
Cerebral Vascular Accident	5 (2.0)	7 (2.6)	0.8702
Peripheral Vascular Disease	1 (0.4)	33 (12.3)	**<0.0001**
Diabetes Mellitus	18 (7.2)	9 (3.4)	**0.0481**
Respiratory Disease	10 (4.0)	18 (6.7)	0.1753
Malignancy	8 (3.2)	6 (2.2)	0.4954
Hepatobiliary Disease	3 (1.2)	7 (2.6)	0.4002
Renal Disease	10 (4.0)	23 (8.6)	**0.0338**
Gastrointestinal Disease	6 (2.4)	34 (12.7)	**<0.0001**

Table 5-3c: Mean proportions (95% confidence intervals) of diseases showing significant differences between Japan and the UK

Co-existent disease	Mean proportion (95% confidence intervals) JAPAN	UK
Organic Heart Disease	1.2 (0.3 - 3.8)	5.6 (3.3 - 9.3)
Ischemic Heart Disease	6.4 (3.8 - 10.4)	12.7 (9.1 - 17.4)
Congestive Heart Failure	0.8 (0.1 - 3.2)	14.2 (10.4 - 19.1)
Hypertension	26.9 (21.6 - 33.0)	37.7 (31.9 - 43.8)
Peripheral Vascular Disease	0.4 (0.0 - 2.6)	12.3 (8.7 - 17.0)
Diabetes Mellitus	7.2 (4.5 - 11.4)	3.4 (1.7 - 6.5)
Renal Disease	4.0 (2.1 - 7.5)	8.6 (5.6 - 12.8)
Gastrointestinal Disease	2.4 (1.0 - 5.4)	12.7 (9.1 - 17.4)

3-3. Prevalence of functional severity

As can been seen from the functional severity subindex results in Table 5-3a, more British patients suffered from condition that effected their functioning than Japanese patients. Particularly significant differences involved respiratory, neurological, urinary and fecal function (Table 5-3d). 95% confidence interval of the proportions is shown in Table 5-3e. Among those who had respiratory disability, asthma was the most frequent cause in the UK.

Table 5-3d: Comparison of prevalence of functional severity between Japan and the UK

Function	Number of patients (%) JAPAN	Number of patients (%) UK	Probability (Chi square)
Circulatory	0 (0)	1 (0.4)	0.9706
Respiratory	2 (0.8)	29 (10.8)	**<0.0001**
Neurological	0 (0)	12 (4.5)	**0.0021**
Mental Status	3 (1.2)	11 (4.1)	0.0787
Urinary	6 (2.4)	36 (13.4)	**<0.0001**
Fecal	4 (1.6)	36 (13.4)	**<0.0001**
Feeding	2 (0.8)	0 (0)	0.4466
Vision	1 (0.4)	0 (0)	0.9706
Hearing	28 (11.2)	22 (8.2)	0.2432
Speech	0 (0)	0 (0)	-

Table 5-3e: Mean proportions (95% confidence intervals) of functions showing significant differences between Japan and the UK

Function	Mean proportion (95% confidence intervals) JAPAN	Mean proportion (95% confidence intervals) UK
Respiratory	0.8 (0.1 - 3.2)	10.8 (7.5 - 15.3)
Neurological	0.0 (0.0 - 1.9)	4.5 (2.4 - 7.9)
Urinary	2.4 (1.0 - 5.4)	13.4 (9.7 - 18.2)
Fecal	1.6 (0.5 - 4.3)	13.4 (9.7 - 18.2)

4. Health status

4-1. ASA-PS

Unfortunately ASA-PS data were missing in 159 (59.3%) of British patients so no analysis were possible.

In Japan and the USA, the distribution of patients classified by ASA-PS (Physical Status classification by American Society of Anesthetists) resembled that for the ICED (Table 5-4a). Few Japanese patients were in the moderate or severe levels, while in the USA almost the same number of patients were classified in level zero or level two.

Table 5-4a: Number and percent of patients classified by ASA PS (Japan/USA)

Index	Levels of index	Number at each level (% total) JAPAN N=249	USA N=356
ASA-PS	1	107 (43.1)	55 (15.9)
	2	134 (53.6)	230 (66.5)
	3	8 (3.2)	55 (15.9)
	4	0 (0.0)	6 (1.7)
	Unknown		10

4-2. General health status

Table 5-4b shows the mean health status scores of patients in the three countries measured using the basic ADL, instrumental ADL, social activity and a mental health scales. As the distribution of health status scores were not normal in Japan and the UK, statistical significance was examined using the Mann-Whitney test.

Comparison between Japan and the UK revealed significant difference for instrumental ADL and mental health, in which preoperative health status was better in Japan for instrumental ADL and in the UK for mental health (Table 5-4c). Mental health in the UK was significantly better than in Japan, irrespective to the number of questions asked. Basic ADL and social activity were also different but not statistically significant.

Table 5-4b: Mean health status scores before THR (Japan/UK/USA)

Preoperative Health Status	Mean Scores (SD) Japan N=256	UK N=301	USA N=283
Basic ADL	60.5 (25.7)	56.2 (20.8)	65 (24)
Instrumental ADL	38.5 (24.9)	33.4 (22.7)	42 (21)
Social Activity	39.5 (33.0)	44.3 (31.0)	60 (31)
Mental health	33.0 (20.1)	57.4 (16.6)	-

Table 5-4c: Preoperative health status scores before THR (Japan/UK)

Preoperative Health Status	Mean	SE	95% Confidence Interval	Probability Japan vs UK (Mann-Whitney)
Basic ADL				
JAPAN	60.5	1.6	57.3 - 63.7	0.0551
UK	56.2	1.2	53.9 - 58.6	
Instrumental ADL				
JAPAN	38.5	1.6	35.4 - 41.7	**0.0395**
UK	33.4	1.3	30.8 - 36.0	
Social Activity				
JAPAN	39.5	2.2	35.2 - 43.9	0.0583
UK	44.3	1.9	40.6 - 48.0	
Mental health*				
JAPAN	33.0	1.3	30.4 - 35.5	**<0.0001**
UK (5 questions)	57.4	1.0	55.5 - 59.4	
UK (3 questions)	71.5	1.2	69.0 - 73.9	**(<0.0001)**

* Mental health status in Japan was compared with the UK, using the British answers to the original five questions, and to the same three questions as asked to Japanese patients.

4-3. Relationship with patient characteristics

Each of the three dimensions of health status (basic ADL, instrumental ADL, social activity) was analysed for any association with patient characteristics. Mental health is not included in the analyses because of the difference in the number of questions asked in Japan from that in the UK, and of lack of data from USA to compare with. Patient's age was quarterlised using all cases combined before grouping lower two quartiles. A summary of the bivariate analyses is shown in Table 5-4d. Patient's age was significantly related with social activity in both countries and with instrumental ADL in Japan. Significant associations were observed with patients' sex in the UK for two dimensions of activity, in that female patients had worse health than males. Education level was also significantly associated with basic ADL in both countries, and with social activity in the UK.

Table 5-4d: Relationship between preoperative health status and patient sociodemographics

	JAPAN			UK		
Variable#	B-ADL	I-ADL	SA	B-ADL	I-ADL	SA
Age*	0.1474	**0.0492**	**0.0222**	0.3781	0.4733	**0.0378**
Sex	0.6557	0.6898	0.1266	0.0646	**0.0141**	**0.0299**
Marital status	0.7063	0.6926	0.0654	0.8539	0.2487	0.2237
Living status	0.5977	0.1551	0.6495	0.2273	0.8036	**0.0215**
Home ownership	0.3551	0.9102	0.4523	0.2346	0.4648	**0.0148**
Education level	**0.0481**	0.1966	0.3379	**0.0056**	0.1379	**0.0040**

B-ADL indicates basic ADL; I-ADL, instrumental ADL; SA, social activity.

* Age was classified into three groups: <66 years, 66 - 73 years, and ≥73 years using 50 and 75 percentiles.

#: The number of patients was 249 in Japan and 268 in the UK for age; for other variables, 256 in Japan and 301 in the UK. Significance was examined by Kruskal-Wallis test (age and education level) and Mann-Whitney test (sex, marital, living, house).

In both countries, the severity of hip disease was significantly associated with preoperative health status (Table 5-4e). A past history of hip surgery was a significant variable in Japan for all three measures of health status but only for basic ADL in the UK. In both countries, all dimensions of health status was significantly associated with preoperative limp and need for walking support.

Table 5-4e : Relationship between preoperative health status and severity of hip disease

Variable	JAPAN B-ADL	JAPAN I-ADL	JAPAN SA	UK B-ADL	UK I-ADL	UK SA
Previous hip surgery	**0.0131**	**0.0012**	**0.0022**	**0.0493**	0.2937	0.3216
Limp	**<0.0001**	**<0.0001**	**<0.0001**	**<0.0001**	**<0.0001**	**<0.0001**
Walking support	**<0.0001**	**<0.0001**	**<0.0001**	**<0.0001**	**<0.0001**	**<0.0001**

B-ADL indicates basic ADL; I-ADL, instrumental ADL; SA, social activity.
#: The number of patients was 249 in Japan and 268 in the UK for previous hip surgery; for limp and walking support, 256 in Japan and 301 in the UK. Significance was examined by Mann-Whitney U test (previous hip surgery) and Kruskal-Wallis test (limp, walking support).

The following Tables 5-4f and 5-4g show the analyses of variables significantly associated with preoperative health status (shown in bold letters in Tables 5-4d and 5-4e).

Table 5-4f: Significant associations of variables with preoperative health status in Japan

Variable	Number of patients	Change in health status Mean	SE	Mean rank
Basic ADL				
Education completed at				
≤15 years	52	53.5	3.7	101.8
16 - 18 years	159	62.4	2.0	126.0
≥19 years	32	65.6	3.8	135.1
With previous hip surgery	47	52.5	3.6	97.4
Without prev. hip surgery	191	62.7	1.9	124.9
No limp	4	100.0	0.0	226.5
Slight limp	60	72.4	3.1	154.7
Moderate limp	111	62.1	2.3	126.0
Severe limp	46	50.0	2.9	92.5
Unable to walk	22	35.8	4.8	55.3
No walking support	88	75.1	2.4	159.3
Single cane/crutch	118	55.3	2.2	104.8
Two canes/crutches	19	50.6	4.9	91.5
Walker	6	38.9	7.5	63.1
Wheelchair	9	30.9	9.9	46.5

Variable	Number of patients	Change in health status Mean	SE	Mean rank
Instrumental ADL				
<66 years	157	41.1	2.0	125.6
66 - 73 years	55	33.1	2.9	104.4
≥73 years	23	32.5	5.5	98.9
With previous hip surgery	48	28.9	3.3	89.8
Without prev. hip surgery	187	40.8	1.8	125.3
No limp	4	77.8	4.5	216.5
Slight limp	59	48.6	3.3	147.8
Moderate limp	111	39.9	2.2	125.9
Severe limp	45	29.2	2.7	96.0
Unable to walk	21	16.8	4.7	49.2
No walking support	88	51.0	2.5	154.6
Single cane/crutch	115	34.4	2.1	106.4
Two canes/crutches	19	24.5	4.5	75.7
Walker	6	27.6	3.2	90.7
Wheelchair	9	15.4	10.9	41.6
Social activity				
<66 years	148	41.9	2.9	113.4
66 - 73 years	46	39.5	4.9	108.9
≥73 years	22	23.0	6.5	74.4
With previous hip surgery	42	25.8	4.3	82.2
Without prev. hip surgery	174	42.7	2.5	114.9
No limp	4	83.3	7.2	190.5
Slight limp	54	55.6	4.3	141.8
Moderate limp	104	38.0	3.2	109.1
Severe limp	39	28.6	4.4	91.0
Unable to walk	20	15.0	5.2	61.0
No walking support	82	58.7	3.2	145.1
Single cane/crutch	106	31.2	2.9	92.8
Two canes/crutches	15	25.6	7.7	80.3
Walker	5	12.2	5.1	56.3
Wheelchair	9	13.0	11.0	48.3

Table 5-4g: Significant associations of variables with preoperative health status in the UK

Variable	Number of patients	Change in health status Mean	SE	Mean rank
Basic ADL				
Education completed at				
≤15 years	177	53.3	1.5	130.6
16 - 18 years	66	61.4	2.7	160.9
≥19 years	41	62.1	3.4	164.3
With previous hip surgery	75	60.7	2.6	146.3
Without prev. hip surgery	188	54.8	1.5	126.3
No limp	9	67.9	7.5	191.5
Slight limp	27	74.1	3.3	215.0
Moderate limp	84	65.2	1.8	182.4
Severe limp	149	51.2	1.5	123.1
Unable to walk	21	29.6	3.3	47.6
No walking support	74	69.1	2.2	197.0
Single cane/crutch	135	55.5	1.7	145.7
Two canes/crutches	53	46.4	2.2	104.5
Walker	8	50.0	8.4	113.9
Wheelchair	23	44.4	4.4	102.9
Instrumental ADL				
Female	187	31.0	2.3	136.6
Male	103	37.8	2.3	161.8
No limp	9	33.2	8.4	141.2
Slight limp	25	58.9	4.2	229.2
Moderate limp	83	45.0	2.2	188.1
Severe limp	147	25.9	1.5	116.6
Unable to walk	21	8.7	2.3	47.7
No walking support	75	46.0	2.5	189.7
Single cane/crutch	133	36.1	1.8	157.2
Two canes/crutches	50	16.8	2.2	82.0
Walker	8	26.1	11.3	101.3
Wheelchair	22	14.5	2.9	71.9
Social activity				
<66 years	90	49.6	3.3	133.2
66 - 73 years	75	42.9	3.7	118.2
≥73 years	74	37.0	3.5	105.8
Female	168	41.0	2.3	126.2
Male	99	49.9	3.2	147.2
Living alone	85	38.3	3.5	117.0
Living with	179	47.3	2.3	139.9
Home owned	173	47.8	2.4	140.7
Home not owned	91	37.8	3.1	116.9

Variable	Number of patients	Change in health status Mean	SE	Mean rank
Education completed at				
≤15 years	156	39.1	2.5	118.0
16 - 18 years	64	54.2	3.8	153.2
≥19 years	39	48.3	4.8	139.7
No limp	8	41.7	13.6	124.0
Slight limp	22	80.6	4.6	214.3
Moderate limp	78	52.8	3.5	153.8
Severe limp	137	37.7	2.3	117.8
Unable to walk	18	10.5	3.3	48.4
No walking support	71	62.8	3.4	178.1
Single cane/crutch	122	46.4	2.6	140.1
Two canes/crutches	44	10.2	2.9	70.9
Walker	6	32.4	15.3	101.7
Wheelchair	23	26.3	5.6	89.0

4-4. Relationship with the ICED

Preoperative health status was examined in relation to severity of comorbidity (Tables 5-4h and 5-4i). Basic ADL and social activity were weakly associated with the ICED in Japan, but it was not statistically significant. In the UK, all three dimensions of health status was associated with co-existent disease subindex but not with the ICED.

Table 5-4h: Preoperative health status and severity of comorbidity in Japan

Health status scales by comorbidity index	Levels of index	Mean (SE) change in health status	Probability (Kruskal-Wallis)
Basic ADL			
Co-existent disease severity subindex	0	63.8 (2.3)	0.2514
	1	60.0 (3.7)	
	2	58.4 (3.0)	
	3	40.0 (11.4)	
Functional severity subindex	0	61.5 (1.8)	0.1633
	1	58.8 (4.3)	
	2	29.6 (16.1)	
Index of co-existent disease (ICED)	1	63.8 (2.3)	0.0568
	2	60.6 (2.6)	
	3	56.7 (5.2)	
	4	33.3 (9.7)	
Instrumental ADL			
Co-existent disease severity subindex	0	40.7 (2.5)	0.4148
	1	36.8 (3.2)	
	2	37.3 (2.9)	
	3	25.8 (12.2)	
Functional severity subindex	0	38.6 (1.8)	0.8510
	1	37.4 (4.0)	
	2	33.3 (33.3)	
Index of co-existent disease (ICED)	1	40.7 (2.5)	0.1864
	2	38.1 (2.4)	
	3	34.6 (4.6)	
	4	21.5 (10.8)	
Social activity			
Co-existent disease severity subindex	0	44.9 (3.4)	0.1664
	1	35.1 (4.4)	
	2	36.2 (4.1)	
	3	34.7 (12.5)	
Functional severity subindex	0	40.7 (2.4)	0.3677
	1	33.8 (5.6)	
	2	27.8 (27.8)	
Index of co-existent disease (ICED)	1	44.9 (3.4)	0.0701
	2	37.8 (3.4)	
	3	29.4 (6.5)	
	4	27.8 (11.9)	

Table 5-4i: Preoperative health status and severity of comorbidity in the UK

Health status scales by comorbidity index	Levels of index	Mean (SE) change in health status	Probability (Kruskal-Wallis)
Basic ADL			
Co-existent disease severity subindex	0	56.0 (2.7)	**0.0187**
	1	62.8 (3.5)	
	2	52.4 (1.8)	
	3	56.4 (3.6)	
Functional severity subindex	0	57.0 (1.7)	0.8125
	1	56.0 (2.1)	
	2	53.0 (6.3)	
Index of co-existent disease (ICED)	1	59.5 (2.7)	0.4623
	2	54.4 (2.2)	
	3	56.3 (2.5)	
	4	56.0 (3.2)	
Instrumental ADL			
Co-existent disease severity subindex	0	35.7 (2.7)	**0.0077**
	1	43.3 (3.5)	
	2	29.4 (2.1)	
	3	33.3 (3.7)	
Functional severity subindex	0	35.1 (1.9)	0.2630
	1	32.4 (2.4)	
	2	23.5 (5.9)	
Index of co-existent disease (ICED)	1	35.4 (2.8)	0.8591
	2	33.1 (2.6)	
	3	33.8 (2.9)	
	4	31.6 (3.3)	
Social activity			
Co-existent disease severity subindex	0	50.3 (3.6)	**0.0051**
	1	55.6 (5.7)	
	2	37.3 (2.9)	
	3	34.1 (5.9)	
Functional severity subindex	0	46.1 (2.5)	0.2558
	1	39.6 (3.6)	
	2	38.9 (11.0)	
Index of co-existent disease (ICED)	1	50.0 (3.7)	0.1655
	2	43.4 (3.5)	
	3	41.1 (4.3)	
	4	37.7 (5.2)	

5. Clinical management

5-1. Anaesthesia

Nearly all British patients underwent general anaesthesia (Table 5-5a). Japanese patients were more likely to have lumbar or epidural anaesthesia, partly reflecting the shortage of anaesthesiologists. The other reason could be that more Japanese anaesthesiologists judged regional anaesthesia to be less risky for elderly patients.

5-2. Duration of surgery

The average duration of surgery was longest in the USA and shortest in the UK. This difference may even have been underestimated because the British data may not be exactly comparable due to a lack of precise information in the case notes. The duration of anaesthesia but not of surgery was often recorded so that the actual time required for surgery in the UK was believed to be shorter than shown (personal communication - Mr Middleton). In Japan a considerable proportion of patients (34.5%) underwent a bone graft from the femoral head, because of the lack of bone stock in the acetabulum in many Japanese patients. As bone grafting was rarely practiced in the UK, this extra procedure in Japan may have contributed to the longer operating time.

5-3. Surgical approach

Anterior or anterolateral approach was significantly commoner in Japan than in the UK, however, due to considerable proportion of missing data in Japanese case notes (32.7% was missing in Japan, while 7.5% in the UK) further analysis was difficult.

5-4. Transfusion

Blood transfusion was more often used in Japan than in the UK and the USA, two countries where the risk of blood transmitted diseases such as hepatitis and HIV is perceived to be greater.

5-5. Cementing

Use of bone cement showed a marked difference between Japan and the UK. Cement was used in 89% of patients in the UK, while in Japan it was used in only 41%. Cementless THR was the major procedure in Japan, though the use of hybrid THR has increased (Table 5-5b). In the USA, procedures were classified as with or without cement, with hybrid THR included in the cemented category in the USA. The majority of 'cemented' THRs in the USA today are of the hybrid type (personal communication - Dr Poss). In the history of THR, cement was first employed in the UK. On the other hand it was in the USA that cementless and hybrid THR were developed. Therefore the use of cement in the three countries appears to reflect historical antecedents.

Cement use was significantly associated with patient age in both countries. In Japan, the mean age of patients was closer for the three type of cement use, however in the UK the mean age of patients with a cemented THR was much higher than for either hybrid or cementless THRs. Current opinion of cementless (and recently hybrid) THR as the first choice for younger patients in consideration of the possible future need for revision, and the shorter life expectancy in the UK may be the reasons why the mean ages for use of cementless and hybrid THR differ.

Table 5-5a: International comparison of clinical management

	Number (%) of patients			
	Japan	UK	Probability* Japan vs UK	USA
General anaesthesia	200 (80.3)	260 (97.0)	**<0.0001**	(86)
Mean duration of surgery (mins+/-SD)	143+/-52	105+/-29	-	190+/-60
Surgical approach (anterior/anterolateral)	86 (50.4)	60 (24.2)	**<0.0001**	-
Transfusion	238 (96.0)	208 (77.6)	**<0.0001**	(73)
Cemented prosthesis	101 (40.6)	232 (88.5)	**<0.0001**	(54)

Duration of surgery was not examined statistically due to different definitions of duration.
*: based on Chi square test.

Table 5-5b: International comparison of cement use

	Japan	UK	Probability Japan vs UK	USA
Cementing profile	Number (%) of patients			
both cemented	61 (24.5)	209 (79.8)	**<0.0001**[a]	(54)
hybrid	40 (16.1)	23 (8.8)		
cementless	148 (59.4)	30 (11.5)		(46)
missing	0	6		
Age by cement use (years)	Mean age, years (SE)			
both cemented	66.2 (0.9)	72.5 (0.6)	**<0.0001**[b]	-
hybrid	62.9 (1.4)	55.0 (2.1)		-
cementless	57.4 (0.8)	48.0 (2.2)		-
Probability (within country)	**<0.0001**[c]	**<0.0001**[c]		

a: based on Chi square test, b: based on F-test from two-way analysis of variance, c: based on F-test from one-way analysis of variance.

6. Length of stay in the UK

Differences in the health care systems account for much of the difference in the length of stay between Japan and the UK. In Japan there is a strong financial incentive leading to Japanese patients staying much longer (average 69.0 days). Length of hospital stay was therefore only studied in the UK hospitals.

6-1. Preoperative and total length of stay

The mean total length of stay was 14.2 days, the median total length of stay was 14.0 days, and the median preoperative stay was 1.0 day. When total length of stay was classified by preoperative stay, statistically significant relationship was observed (Table 5-6a). The majority of patients were operated on the day after admission. Patient's postoperative length of stay tended to be significantly associated with their preoperative length of stay.

Table 5-6a: Relationship between preoperative and total length of stay (UK)

Preoperative length of stay, days	Number of patients	Mean length of stay, days (SE)	
		Postoperative	Total
≤1	136	14.4 (0.8)	15.4 (0.8)
2	91	12.8 (0.6)	14.8 (0.6)
3	20	16.6 (1.3)	19.6 (1.3)
4≤	18	17.1 (3.3)	24.9 (3.3)
Total	265	14.2 (0.5)	16.1 (0.5)
Missing	3		
Probability (Kruskal-Wallis)		**0.0027**	**<0.0001**

6-2. Relationship with patient characteristics

The relationship of length of stay and the sociodemographic characteristics of patients (age, sex, marital status, living alone, home ownership and education level) was examined. Only patient age was significantly associated (Table 5-6b). Older patients (in the top quartile, 76 years or older) tended to stay longer than younger ones, although there was no significant difference in their preoperative length of stay.

Table 5-6b: Length of stay and patient age dichotomised at 76 years (UK)

	Mean length of stay, days (SE)			
	Younger (N=188)	Older (N=77)	Total (N=265)	Probability (Mann-Whitney)
Preoperative	1.8 (0.1)	2.3 (0.4)	1.9 (0.1)	0.1183
Postoperative	13.2 (0.5)	16.6 (1.3)	14.2 (0.5)	**<0.0001**
Total	15.0 (0.5)	18.9 (1.3)	16.1 (0.5)	**0.0001**

6-3. Relationship with clinical management

A significant difference was observed in relation to the use of cement (Table 5-6c). Patients who received a hybrid THR were discharged earlier. As has already been shown in Table 5-5b, the average age of patients for hybrid THRs was younger than the cemented, but older than the cementless. Thus age may not be the only cause of a shorter length of stay for hybrid THR patients.

Other treatment profiles examined were duration of anaesthesia, general anaesthesia, amount of transfusion, and surgical approach. None of them were significantly associated with length of stay.

Table 5-6c: Relationship between cement use and total length of stay (UK)

Cement use	Number of patients	Mean length of stay days (SE)	Probability (Kruskal-Wallis)
Cemented	206	16.7 (0.6)	**0.0012**
Hybrid	23	12.4 (0.6)	
Cementless	30	15.1 (1.1)	
Total	259	16.2 (0.5)	
Missing	9		

6-4. Relationship with comorbidity

When total length of stay was classified by severity of comorbidity, a statistically significant association was observed for the co-existent disease subindex and the ICED (Table 5-6d). Both indices stratified patients into four subgroups in which the total length of stay was longer with increasing severity of comorbidity. Such an association with comorbidity was not found for preoperative length of stay but was confined to the postoperative period ($p<0.005$ for co-existent disease subindex, and the ICED; data not shown).

Table 5-6d: Total length of stay classified by severity of comorbidity (UK)

Index	Levels of index	Number of patients	Mean (SE) length of stay days	Probability (Kruskal-Wallis)
Co-existent disease subindex	0	73	14.4 (0.7)	**0.0001**
	1	36	13.9 (0.5)	
	2	114	17.2 (1.0)	
	3	42	18.1 (1.2)	
	Missing	3		
Functional severity subindex	0	159	16.2 (0.8)	0.1935
	1	93	16.1 (0.6)	
	2	13	15.5 (1.3)	
	Missing	3		
Index of co-existent disease (ICED)	1	70	14.4 (0.8)	**0.0002**
	2	80	16.7 (1.4)	
	3	63	16.1 (0.7)	
	4	52	17.7 (1.0)	
	Missing	3		

6-5. Relationship with in-hospital complication

The postoperative length of stay was significantly associated with serious and minor complications (Table 5-6e). However, preoperative length of stay did not correlate with any complication.

Table 5-6e: Relationship between length of stay and in-hospital complications (UK)

In-hospital complication		Number of patients	Mean (SE) length of stay, days Postoperative	Total
Serious				
	With	52	15.9 (1.1)	17.4 (1.1)
	Without	213	13.8 (0.6)	15.8 (0.6)
	Probability (Mann-Whitney)		**0.0362**	0.0850
Minor				
	With	55	18.5 (2.0)	20.8 (2.0)
	Without	210	13.1 (0.3)	14.9 (0.4)
	Probability (Mann-Whitney)		**0.0006**	**0.0002**
Overall				
	With	94	16.6 (1.2)	18.6 (1.3)
	Without	171	12.9 (0.4)	14.8 (0.4)
	Probability (Mann-Whitney)		**0.0023**	**0.0019**

6-6. Relationship with change in health status

Change in health status had a significant association with length of stay. In Table 5-6f, patient health status was examined by dichotomised length of stay groups, using the top quartile of the length of stay distribution (17 days) as the cut-off. Improvement in both instrumental ADL and social activity were significantly greater in the shorter than in the longer stay group. It suggests the former had more physiological resources to recover from surgery and achieve improvement in their health status during their convalescent period.

Table 5-6f: Change in health status and length of stay dichotomised at 17 days (UK)

Health status indices	Length of stay	Number of patients	Mean (SE) change in health status	Probability (Mann-Whitney)
Basic ADL	Shorter	189	29.1 (1.6)	0.1343
	Longer	70	24.2 (3.6)	
	Missing	9		
Instrumental ADL	Shorter	188	34.8 (2.0)	**0.0108**
	Longer	68	23.6 (4.2)	
	Missing	12		
Social activity	Shorter	179	34.3 (2.5)	**0.0264**
	Longer	65	24.4 (5.6)	
	Missing	24		

7. Interhospital differences in the UK

7-1. Sociodemographic characteristics

Table 5-7a shows interhospital differences in the sociodemographic characteristics of patients in the UK. The differences were statistically significant among the six hospitals as regards age, home ownership and education level, but not for sex, marital status, and living alone.

Table 5-7a: Interhospital difference in patient sociodemographic characteristics (UK)

Age

Hospital	Mean (SE) years	Probability	Significance test
A	70.4 (1.4)	**0.0336**	Kruskal-Wallis
B	70.6 (1.8)		
C	69.4 (2.5)		
D	70.1 (2.1)		
E	64.6 (1.4)		
F	68.6 (2.5)		
Total	68.3 (0.8)		

Male

Hospital	Number (%) of male	Probability	Significance test
A	23 (35.4)	0.6593	Chi square
B	19 (39.6)		
C	14 (40.0)		
D	14 (38.9)		
E	28 (29.5)		
F	10 (45.5)		
Total	108 (35.9)		

Married

Hospital	Number (%) of married	Probability	Significance test
A	34 (52.3)	0.0533	Chi square
B	26 (55.3)		
C	16 (47.1)		
D	19 (52.8)		
E	61 (64.9)		
F	17 (85.0)		
Total	173 (58.4)		

Living alone

Hospital	Number (%) of living alone	Probability	Significance test
A	25 (39.7)	0.0922	Chi square
B	19 (40.4)		
C	15 (45.5)		
D	13 (36.1)		
E	28 (29.8)		
F	2 (10.0)		
Total	102 (34.8)		

Home ownership

Hospital	Number (%) of owners	Probability	Significance test
A	36 (55.4)	**0.0002**	Chi square
B	30 (63.8)		
C	20 (58.8)		
D	14 (38.9)		
E	75 (79.8)		
F	16 (80.0)		
Total	191 (64.5)		

Education	Number of patients (%)			
	Age completed			
Hospital	≤15	16 - 18	19≤	Probability
A	50 (76.9)	13 (20.0)	2 (3.0)	**<0.0001**
B	27 (57.4)	11 (23.4)	9 (19.1)	Chi square
C	11 (33.3)	9 (27.3)	13 (39.4)	
D	19 (54.3)	12 (34.3)	4 (11.4)	
E	55 (61.1)	22 (24.4)	13 (14.4)	
F	17 (89.5)	1 (5.3)	1 (5.3)	
Total	179 (61.9)	68 (23.5)	42 (14.5)	

When the data were classified according to the teaching status of the hospital, patients at teaching hospitals were significantly more likely to have continued in full-time education longer (Table 5-7b). There was no significant difference in their age, sex, marital and living status.

Table 5-7b: Difference in patient characteristics by teaching status (UK)

Patient characteristics	Hospital: Teaching	Hospital: Non-teaching	Probability (test)
Age	Mean age, years (SE)		
	66.7 (1.1)	70.2 (1.0)	0.0568 (Mann-Whitney)
	Number of patients (%)		
Male	56 (33.7)	52 (38.5)	0.3895 (Chi square)
Married	96 (58.5)	77 (58.3)	0.9719 (Chi square)
Living alone	56 (34.4)	46 (35.4)	0.8543 (Chi square)
Education, age completed			
15≥	85 (53.8)	94 (71.8)	**0.0053** (Chi square)
16 - 18	43 (27.2)	25 (19.1)	
19≤	30 (19.0)	12 (9.2)	

7-2. Severity of hip disease

Hip disease was compared among the six hospitals in terms of primary diagnosis, past history of hip surgery, and patient need for walking support and limp (Table 5-7c). Significant differences were observed for the proportions of primary diagnoses and past history of hip surgery, but not for those of need for walking support and limp.

Table 5-7c: Interhospital difference in severity of hip disease (UK)

Primary diagnosis

	Number of patients (%)				
Hospital	Osteo-arthritis	Rheumatoid arthritis	Avascular necrosis	Others	Probability
A	62 (96.9)	1 (1.6)	1 (1.6)	0 (-)	**0.0264**
B	36 (97.3)	1 (2.7)	0 (-)	0 (-)	(Chi square)
C	31 (86.1)	2 (5.6)	3 (8.3)	0 (-)	
D	20 (76.9)	5 (19.2)	0 (-)	1 (3.8)	
E	79 (91.9)	4 (4.7)	2 (2.3)	1 (1.2)	
F	16 (84.2)	2 (10.5)	0 (-)	1 (5.3)	
Total	244 (91.0)	15 (5.6)	6 (2.2)	3 (1.1)	

Previous hip surgery

	Number (%) of patients			
Hospital	Either hip	Same hip	Other hip	Total
A	14 (21.9)	0 (-)	14 (21.9)	64
B	9 (24.3)	1 (2.7)	8 (21.6)	37
C	15 (41.7)	2 (5.6)	15 (41.7)	36
D	5 (19.2)	0 (-)	5 (19.2)	26
E	32 (37.2)	13 (15.1)	25 (29.1)	86
F	1 (5.3)	0 (-)	1 (5.3)	19
Total	76 (28.4)	16 (6.0)	68 (25.4)	268
Probability (Chi square)	**0.0148**	**0.0010**	0.0523	

Walking support

Hospital	None	Slight	Moderate	Severe	Unable to walk	Probability (Kruskal - Wallis)
	Number (%) of patients at each hospital					
A	10 (15.4)	36 (55.4)	9 (13.9)	3 (4.6)	7 (10.8)	0.7555
B	14 (29.8)	20 (42.6)	9 (19.2)	2 (4.3)	2 (4.3)	
C	11 (31.4)	14 (40.0)	6 (17.1)	2 (5.7)	2 (5.7)	
D	10 (28.6)	16 (45.7)	7 (20.0)	0 (0.0)	2 (5.7)	
E	26 (27.7)	38 (40.4)	19 (20.2)	2 (2.1)	9 (9.6)	
F	4 (19.1)	12 (57.1)	4 (19.1)	0 (0.0)	1 (4.8)	
Total	75 (25.3)	136 (45.8)	54 (18.2)	9 (3.0)	23 (7.7)	

Limp

Hospital	None	Slight	Moderate	Severe	Unable to walk	Probability (Kruskal - Wallis)
	Number (%) of patients at each hospital					
A	0 (-)	5 (7.8)	20 (31.3)	35 (54.7)	4 (6.3)	0.1117
B	5 (10.4)	7 (14.6)	14 (29.2)	20 (41.7)	2 (4.2)	
C	2 (5.7)	3 (8.6)	11 (31.4)	15 (42.9)	4 (11.4)	
D	0 (-)	4 (11.4)	13 (37.1)	16 (45.7)	2 (5.7)	
E	1 (1.1)	8 (8.7)	22 (23.9)	53 (57.6)	8 (8.7)	
F	1 (4.8)	1 (4.8)	5 (23.8)	12 (57.1)	2 (9.5)	
Total	9 (3.1)	28 (9.5)	85 (28.8)	151 (51.2)	22 (7.5)	

Table 5-7d shows the diagnosis of primary hip disease classified by the teaching status of the hospitals. Although there was no statistically significant difference in the distribution of primary diagnoses between teaching and non-teaching hospitals, more rheumatoid arthritis and avascular necrosis patients were treated at teaching hospitals, suggesting the patients may have required specialty care.

Regarding a past history of hip surgery, significant differences were observed in the proportion of patients between teaching and non-teaching hospitals. Patients treated at the teaching hospitals were more likely to have had previous surgery on both hips, suggesting a more complicated, long term disease burden and greater clinical challenge.

Need for walking support and patient perceived limp were not significantly different between teaching and non-teaching hospitals.

Table 5-7d: Clinical profiles of primary hip disease by teaching status of the hospital (UK)

	Number of patients (%)		
	Teaching	Non-teaching	Probability
Primary diagnosis			
Osteoarthritis	130 (87.8)	114 (95.0)	0.2178
Rheumatoid arthritis	11 (7.4)	4 (3.3)	(Chi square)
Avascular necrosis	5 (3.4)	1 (0.8)	
Others	2 (1.4)	1 (0.8)	
Past history			
Prior hip surgery (either side)	52 (35.1)	24 (20.0)	**0.0063**
on the same hip	15 (10.1)	1 (0.8)	**0.0014**
on the other hip	45 (30.4)	23 (19.2)	**0.0355**
			(Chi square)
Walking support			
None	47 (28.7)	28 (21.1)	0.5037
Slight	68 (41.5)	68 (51.1)	(Mann-Whitney)
Moderate	32 (19.5)	22 (16.5)	
Severe	4 (2.4)	5 (3.8)	
Unable to walk	13 (7.9)	10 (7.5)	
Limp			
None	3 (1.9)	6 (4.5)	0.3044
Slight	15 (9.3)	13 (9.8)	(Mann-Whitney)
Moderate	46 (28.4)	39 (29.3)	
Severe	84 (51.9)	67 (50.4)	
Unable to walk	14 (8.6)	7 (6.0)	

7-3. Comorbidity

Interhospital differences in severity of comorbidity were statistically significant (Table 5-7e). However, the differences were not significantly related to their teaching status (p=0.1835, based on Mann-Whitney U test).

Table 5-7e: Interhospital differences in severity of comorbidity (UK)

Hospital	Number (%) of patients ICED Level 1	Level 2	Level 3	Level 4	Probability (Kruskal - Wallis)
A	8 (12.5)	19 (29.7)	19 (29.7)	18 (28.1)	**0.0152**
B	14 (37.8)	12 (32.4)	8 (21.6)	3 (8.1)	
C	8 (22.2)	12 (33.3)	7 (19.4)	9 (25.0)	
D	7 (26.9)	10 (38.5)	4 (15.4)	5 (19.2)	
E	27 (31.4)	25 (29.1)	22 (25.6)	12 (14.0)	
F	6 (31.6)	4 (21.1)	3 (15.8)	6 (31.6)	
Total	70 (26.1)	82 (30.6)	63 (23.5)	53 (19.8)	

7-4. Clinical management

Most of the hospitals used general anaesthesia, though in hospital F over a quarter of patients underwent regional anaesthesia (epidural or spinal) (Table 5-7f). As shown in Table 5-7e, almost a third of patients in this hospital were of ICED level 4, which suggested general anaesthesia was less appropriate.

Striking difference was observed in surgical approach. More than a third of the patients in hospitals A and E were operated through anterior or anterolateral approach whereas not any patients in hospitals B and F. However, the proportion of surgical approach was not associated with the teaching status of hospitals.

Transfusion practice also showed remarkable differences among hospitals. The proportion of patients transfused ranged from 63% to 90%. Likewise, the number of units transfused varied.

Use of cement was analysed in terms of the proportion of cemented, hybrid, and cementless THRs. There was a consistent percentage of cemented THR of around 80% . In contrast, the ratio varied among hospitals in the use of hybrid and cementless implant. When clinical management was compared in association with the teaching status of hospitals, no significant differences were observed.

Table 5-7f: Interhospital differences in clinical management among the UK hospitals

General anaesthesia

Hospital	Number (%) of patients	Probability	Significance test
A	64 (100.0)	**<0.0001**	Chi square
B	37 (100.0)		
C	36 (100.0)		
D	26 (100.0)		
E	83 (96.5)		
F	14 (73.7)		
Total	260 (97.0)		

Anterior/Anterolateral approach

Hospital	Number (%) of patients	Probability	Significance test
A	25 (44.6)	**<0.0001**	Chi square
B	0 (0.0)		
C	4 (11.1)		
D	1 (4.3)		
E	30 (36.6)		
F	0 (0.0)		
Total	60 (24.2)		

Transfusion

Hospital	Number (%) of Transfused patients	Mean (SE) number of Transfused units
A	53 (82.8)	2.5 (0.2)
B	25 (67.6)	1.8 (0.3)
C	24 (66.7)	1.8 (0.3)
D	17 (65.4)	1.4 (0.2)
E	77 (89.5)	2.8 (0.2)
F	12 (63.2)	1.8 (0.4)
Total	208 (77.6)	2.2 (0.1)
Probability (Chi square)	**0.0042**	**0.0007**

Cement use

Hospital	Number (%) of patients				Probability
	Cemented	Hybrid	Cementless	Total	(Chi square)
A	55 (88.7)	6 (9.7)	1 (1.6)	62	**0.0048**
B	28 (77.8)	1 (2.8)	7 (19.4)	36	
C	28 (80.0)	0 (-)	7 (20.0)	35	
D	20 (80.0)	5 (20.0)	0 (-)	25	
E	62 (72.1)	10 (11.6)	14 (16.3)	86	
F	16 (88.9)	1 (5.6)	1 (5.6)	18	
Total	209 (79.8)	23 (8.8)	30 (11.5)	262	

7-5. Length of stay

There was a statistically significant interhospital difference in the unadjusted length of stay in the UK, at preoperative, postoperative and total period (Table 5-7g). When classified by their teaching status, the total and postoperative length of stay were significantly longer in non-teaching hospital but not the preoperative stay.

Table 5-7g: Interhospital differences in length of stay (UK)

	Number of patients	Mean length of stay, days (SE)		
		Preoperative	Postoperative	Total
Hospitals				
A	64	1.8 (0.1)	14.6 (0.8)	16.5 (0.8)
B	37	2.5 (0.5)	16.9 (2.4)	19.5 (2.4)
C	36	1.7 (0.3)	15.0 (0.9)	16.7 (1.0)
D	25	1.5 (0.3)	14.8 (2.4)	16.3 (2.6)
E	85	2.2 (0.3)	11.9 (0.5)	14.1 (0.6)
F	18	0.9 (0.1)	15.4 (1.6)	16.3 (1.6)
Total	265	1.9 (0.1)	14.2 (0.5)	16.1 (0.5)
Missing	3			
Probability (Kruskal-Wallis)		**<0.0001**	**<0.0001**	**<0.0001**
Teaching status				
Teaching	146	2.0 (2.5)	13.2 (6.8)	15.1 (7.5)
Non-teaching	119	1.9 (1.8)	15.5 (9.7)	17.4 (9.7)
Total	265	1.9 (2.2)	14.2 (8.3)	16.1 (8.6)
Missing	3			
Probability (Mann-Whitney)		0.2189	**0.0004**	**0.0002**

8. Summary

Patient sociodemographics: Japanese patients were younger and more likely to be female, married, living with others, finished education at an older age and not smoke, than British patients.

Hip disease: More severe in British patients in terms of a history of previous hip surgery and perception of limp. The need for a walking support was only slightly greater in British patients. The mix of underlying diagnoses were similar.

Comorbidity: Japanese patients were more likely to be classified to lower severity levels than British patients. Arrhythmia and hypertension were common in both countries; organic and ischaemic heart disease, congestive heart failure, peripheral vascular disease, renal disease, and gastrointestinal disease were commoner in the UK, and diabetes mellitus was commoner in Japan.

Health status: Japanese patients had better health status as regards instrumental ADL and worse as regards mental health. There was no significant difference in terms of basic ADL and social activity. Health status was associated with patient's age and severity of hip disease in Japan and with patient's sex, living alone and home ownership in the UK. No association was observed between health status and comorbidity (the ICED).

Clinical management: General anaesthesia was commoner, the duration of surgery was less, and the anterior/anterolateral approach and blood transfusion were less frequently used in the UK than in Japan. Cement was used more often in the UK and in older patients.

Length of stay in the UK: Preoperative stay was associated with the total length of stay. Longer postoperative stay was observed in patients who were older, had a non-hybrid THR, had severe comorbidity, had an in-hospital complication and subsequently reported a poorer improvement in their health status.

Interhospital differences: Significant differences were found as regards patient's age, educational level, home ownership, primary diagnosis, past history of hip surgery, and comorbidity. There was no statistically significant difference in severity of hip disease (limp and use of walking support). Patients in teaching hospitals only differed significantly from non-teaching in that they were more likely to have received higher education and undergone previous hip surgery, both on the same and the contralateral hip. Use of general anaesthesia, surgical approach, transfusion and cement differed among the six hospitals, but not between teaching and non-teaching hospitals. Mean length of stay differed between the six UK hospitals, and was shorter in teaching hospitals.

CHAPTER 6

OUTCOME OF THR

- INDEX -

Chapter 6: Outcome of THR

This chapter describes the outcomes of patients in terms of in-hospital complications, change in health status and mobility, readmissions and patient satisfaction. Where applicable, data are compared before and after surgery. Having presented univariate analyses of these outcomes, the association between comorbidity and the two outcomes of major interest (in-hospital complications and health status) are examined. Finally, the relationships between these outcomes and other independent variables are described.

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1. Outcomes

1-1. Mortality

During the follow-up period, 2 patients in Japan and 6 patients in the UK died. Among them, 1 patient in Japan and 4 patients in the UK were known to have died within one year of the index operation. The other 3 deaths occurred just over 12 months after the operation. Thus one-year mortality was 0.3% in Japan and 1.1% in the UK. Due to the difficulty of getting further mortality information, their cause of death and the relevance to the index admission were not available. The small number of deaths also limited further analyses. In addition, failure to trace 12 eligible patients in Japan and 5 in the UK (Table 3-2) make any assessment of post-operative mortality uncertain.

1-2. Serious complications

The total number of the patients with serious in-hospital complications was 11 (4.4%; 95% confidence interval=2.3% - 8.0%) in Japan, 52 (19.4%; 95% confidence interval

=15.0% - 24.8%) in the UK, and 38 (10.7%; 95% confidence interval=7.8% - 14.5%) in the USA. Table 6-1a shows the types and numbers of serious in-hospital complications. Serious complications found in Japanese patients were limited mostly to neuropathy. Relatively more cardiac disorders were observed in the USA, while postoperative hypotension was more common in the UK. Possible reasons for this will be discussed later in this chapter. 95% confidence interval of the hypotension rate was 0.1% - 3.2% in Japan and 8.7% - 17.0% in the UK.

Table 6-1a: Number and percent of serious in-hospital complications

Serious Complications	Number (%) of patients Japan N=249	UK N=268	Probability* Japan vs UK	USA N=356
General				
Shock	0 (-)	0 (-)	-	1 (0.3)
Septicemia	0 (-)	1 (0.4)	0.9706	0 (-)
Cardiovascular				
Cardiac arrest	0 (-)	1 (0.4)	0.9706	0 (-)
Myocardial infarction	0 (-)	1 (0.4)	0.9706	5 (1.4)
Congestive heart failure	0 (-)	0 (-)	-	5 (1.4)
Hypotension	2 (0.8)	33 (12.3)	**<0.0001**	12 (3.4)
Peripheral vascular				
Pulmonary embolism	0 (-)	0 (-)	-	2 (0.6)
Deep vein thrombosis	0 (-)	2 (0.7)	0.5113	0 (-)
Respiratory failure	0 (-)	1 (0.4)	0.9706	0 (-)
Neurological				
Coma	0 (-)	0 (-)	-	1 (0.3)
Neuropathy	7 (2.8)	6 (2.2)	0.8932	11 (3.1)
Renal failure	2 (0.8)	1 (0.4)	0.9491	2 (0.6)
Gastrointestinal				
Acute abdomen	0 (-)	1 (0.4)	0.9706	0 (-)
Gastrointestinal bleeding	0 (-)	2 (0.7)	0.5113	0 (-)
Others	0 (-)	7 (2.6)	**0.0288**	0 (-)

*: Probability based on Chi square test with continuity correction.

1-3. Minor complications

The proportion of patients with minor in-hospital complications was similar in all three countries; 52 (20.9%; 95% confidence interval=16.1% - 26.6%) in Japan, 56 (20.9%; 95% confidence interval=16.3% - 26.4%) in the UK, and 87 (24.4%; 95% confidence interval =20.1% - 29.3%) in the USA.

The frequency of specific minor in-hospital complications is shown in Table 6-1b and 95% confidence interval of complication rates with significant differences in Table 6-1c. The only data available for the USA was for fever (reported in 160 cases) and pneumonia (85 cases), neither of which were often reported in Japan and the UK. Wound related problems such as infection and delayed healing were commonly reported both in Japan and the UK. Dislocation, and gastrointestinal symptoms were more frequently observed in Japan, whereas in the UK bed sores and suspected deep vein thrombosis were significantly more frequent.

Special caution should be taken in comparing these data. For example, postoperative fever was in fact very commonly found both in Japanese and in UK hospitals. However, because of the definition of fever (>101°F) most of the episodes were not counted in this study as they did not reach this temperature. Also reporting bias is likely to be a problem with minor complications as they may be ignored by health care workers and even if noticed, the description in the case notes may not provide as much detail as for serious complications.

Table 6-1b: Number and percent of minor in-hospital complications

Minor Complications	Number (%) of patients Japan N=249	UK N=268	Probability Japan vs UK (Chi square*)
General			
Fever	9 (3.6)	9 (3.4)	0.8738
Cardiovascular			
Angina / Arrhythmia	1 (0.4)	6 (2.2)	0.1541
Peripheral vascular			
Suspected deep vein thrombosis	0 (-)	10 (3.7)	**0.0058**
Respiratory			
Pneumonia	1 (0.4)	4 (1.5)	0.4141
Mental			
Confusion	2 (0.8)	3 (1.1)	0.9341
Renal			
Urinary tract infection	8 (3.2)	3 (1.1)	0.1792
Gastrointestinal symptoms	10 (4.0)	0 (-)	**0.0028**
Local			
Wound infection / oozing	15 (6.0)	13 (4.9)	0.5559
Bed sores	1 (0.4)	13 (4.9)	**0.0045**
Dislocation	11 (4.4)	3 (1.1)	**0.0416**
Others	1 (0.4)	0 (-)	0.9706

*: Probability based on Chi square test with continuity correction.

Table 6-1c: 95% confidence interval of the proportions of minor complications of significant differences between Japan and the UK

Minor complication	Mean proportion (95% confidence interval) JAPAN	UK
Suspected deep vein thrombosis	0.0 (0.0 - 1.9)	3.7 (1.9 - 7.0)
Gastrointestinal symptoms	4.0 (2.1 - 7.5)	0.0 (0.0 - 1.8)
Bed sores	0.4 (0.0 - 2.6)	4.9 (2.7 - 8.4)
Dislocation	4.4 (2.3 - 8.0)	1.1 (0.3 - 3.5)

1-4. Overall complications

Serious and minor in-hospital complications combined were reported in 61 (24.5%; 95% confidence interval=19.4% - 30.4%) patients in Japan and 108 (40.3%; 95% confidence interval=34.4% - 46.5%) in the UK. Among Japanese patients, two cases were reported to have had both serious and minor complications whereas in the UK, there were no such cases.

1-5. Health status

Table 6-1d shows the mean health status scores before and one year after THR in the three countries. The postoperative scores were higher (indicating an improvement) in all dimensions examined, in all countries. Both preoperative and postoperative scores were consistently higher in the USA than in Japan and the UK.

Table 6-1d: Mean health status score before and after THR (Japan/UK/USA)

Health status by country	Preoperative N	Preoperative Mean	(SD)	Postoperative N	Postoperative Mean	(SD)
Basic ADL						
JAPAN	245	60.5	(25.7)	245	87.7	(19.8)
UK	295	56.2	(20.8)	290	84.0	(18.7)
USA		65	(24)		90	(15)
Instrumental ADL						
JAPAN	242	38.5	(24.9)	245	65.9	(26.0)
UK	290	33.4	(22.7)	285	65.2	(28.3)
USA		42	(21)		74	(25)
Social activity						
JAPAN	222	39.5	(33.0)	226	64.3	(35.9)
UK	267	44.3	(31.0)	259	74.7	(31.9)
USA		60	(31)		87	(25)
Mental health						
JAPAN	240	33.0	(20.1)	241	55.6	(16.8)
UK	289	57.4	(16.6)	282	62.4	(14.7)
USA		-			-	

As the health status scores were not normally distributed, the significance of changes in scores following surgery were tested using the Wilcoxon matched-pairs test (Table 6-1e). In the four dimensions examined, the health status of both Japanese and British patients were significantly improved following surgery. The extent of this change in health status was also compared between Japan and the UK, using the Mann-Whitney U test. Although there was no significant difference observed in the changes in basic ADL, social activity, and instrumental ADL, mental health improved more in Japanese than in British patients. Particular difference was observed in the change in mental health, in which preoperative score was significantly lower in Japan (Tables 5-4b and 5-4c). Improvement in mental health in the UK (mean change=5.6, SE=1.1) was similar when the same three questions were analysed as in Japan.

Table 6-1e: Change in health status in Japan and the UK

Health status scales	JAPAN	UK	Probability (Mann-Whitney) Japan vs UK
Basic ADL			
Mean change (SE)	27.6 (1.7)	28.0 (1.4)	-
Probability (Wilcoxon)	**<0.0001**	**<0.0001**	0.5963
Instrumental ADL			
Mean change (SE)	27.6 (2.0)	32.1 (1.7)	-
Probability (Wilcoxon)	**<0.0001**	**<0.0001**	0.0523
Social activity			
Mean change (SE)	26.9 (2.7)	31.5 (2.1)	-
Probability (Wilcoxon)	**<0.0001**	**<0.0001**	0.2682
Mental health			
Mean change (SE)	27.6 (1.8)	4.8 (0.9)	-
Probability (Wilcoxon)	**<0.0001**	**<0.0001**	**<0.0001**

1-6. Mobility

Patients were asked about the average amount of pain they experienced when performing particular activities one year after the operation (Table 6-1f). Pain was scored from 0 to 7, where 0 indicated no pain and 7 indicated severe pain. For most activities, Japanese patients had a higher mean pain score than the British patients. However, the difference was statistically significant only for climbing stairs.

Table 6-1f: Mean level of pain reported for different activities one year after surgery by Japanese (N=256) and British (N=301) patients

Activity	Mean level of pain (SE) JAPAN	UK	Probability (Mann-Whitney)
Getting in/out of bed	1.5 (0.1)	1.3 (0.1)	0.0661
Rising from a sitting position	1.6 (0.1)	1.7 (0.1)	0.7772
Walking inside the house	1.3 (0.1)	1.1 (0.1)	0.0510
Walking outside the house	1.8 (0.1)	1.8 (0.1)	0.6230
Climbing stairs	2.3 (0.1)	1.8 (0.1)	**0.0031**
Doing yard work/shopping	2.2 (0.1)	2.0 (0.1)	0.1244
Putting on stockings/pants	2.0 (0.1)	1.8 (0.1)	0.0635

Changes in limp and the need for a walking support were examined using the Wilcoxon matched-pairs test. Significant improvements were detected in both countries (Table 6-1g). Preoperatively, there had been a significant difference between Japan and the UK in both limping and the need for a walking support (Chapter 5). Although postoperative limping remained significantly more severe in the UK than in Japan, the difference disappeared for walking support.

Table 6-1g: Change in limp and walking supports following THR

	Number of patients (%)				Probability
	Japan		UK		Japan vs UK
	Pre-op	Post-op	Pre-op	Post-op	Post-op
Limp					
None	5 (2.0)	69 (27.5)	9 (3.1)	67 (22.8)	**0.0006***
Slight	64 (25.3)	151 (60.2)	28 (9.5)	145 (49.3)	
Moderate	114 (45.1)	24 (9.6)	85 (28.8)	60 (20.4)	
Severe	48 (19.0)	3 (1.2)	151 (51.2)	18 (6.1)	
Unable to walk	22 (8.7)	4 (1.6)	22 (7.5)	4 (1.4)	
Missing	3	5	6	7	
Probability (Wilcoxon)	**<0.0001**		**<0.0001**		
Walking support					
None (or rarely)	91 (36.5)	95 (38.2)	75 (25.3)	131 (44.7)	0.6965*
Single cane/crutch	123 (49.4)	136 (54.6)	136 (45.8)	121 (41.3)	
Two canes/crutches	20 (8.0)	13 (5.2)	54 (18.2)	23 (7.8)	
Walker	6 (2.4)	1 (0.4)	9 (3.0)	7 (2.4)	
Wheelchair	9 (3.6)	4 (1.6)	23 (7.7)	11 (3.8)	
Missing	7	7	4	8	
Probability (Wilcoxon)	**0.0338**		**<0.0001**		

* : Postoperative limp and walking support compared between Japan and the UK, using Mann-Whitney U test.

1-7. Global measures

The proportion of patients who were employed declined in both countries (Table 6-1h). Although similar proportion of patients were employed postoperatively, this change was significantly more evident in Japan than in the UK due to their relatively higher ratio of preoperative employment.

Table 6-1h : Number and percent of patients employed before and after THR in Japan and the UK

Work status	Number (%) of patients Japan	UK	Probability (Chi square)
Preoperative	66 (27.8)	59 (20.6)	0.0513
Postoperative	42 (17.9)	52 (18.0)	0.9895
Probability (Chi square)	**0.0193**	0.4353	

Patients were asked for their views on the overall change in their health by means of some global questions (Table 6-1i). In both countries, the majority of patients perceived their health improved and improved beyond their expectation. Also most patients felt somewhat or much better and were happy about having had the operation.

Comparing the two countries, Japanese patients were more likely to describe their health as better and thought it better than they had expected. This suggests Japanese patients may have had lower expectations as to the effect of the operation. On the other hand, British patients were more likely to feel the operation had made them feel better and to state that they were very happy about having had the operation.

Table 6-1i : Patient perception of global change in health: significance examined by Mann-Whitney U test

Questions about change in health	Number of patients (%) JAPAN	UK	Probability
My health now is:			
1. Better	187 (75.7)	194 (65.5)	**0.0348**
2. Same	46 (18.6)	80 (27.0)	
3. Worse	14 (5.7)	22 (7.4)	
Missing	9	5	
My health is:			
1. Much better than I expected	125 (50.6)	114 (38.5)	**<0.0001**
2. Somewhat better than I expected	79 (32.0)	71 (24.0)	
3. What I expected	23 (9.3)	61 (20.6)	
4. Somewhat worse than I expected	16 (6.5)	40 (13.5)	
5. Much worse than I expected	4 (1.6)	10 (3.4)	
Missing	9	5	
Operation changed the way I feel:			
1. Much better	98 (39.4)	185 (62.1)	**<0.0001**
2. Somewhat better	108 (43.4)	57 (19.1)	
3. A little better	37 (14.9)	20 (6.7)	
4. About the same	1 (0.4)	16 (5.4)	
5. A little worse	3 (1.2)	4 (1.3)	
6. Somewhat worse	1 (0.4)	9 (3.0)	
7. Much worse	1 (0.4)	7 (2.3)	
Missing	7	3	
About having had the operation:			
1. I'm very happy	121 (48.6)	201 (67.7)	**<0.0001**
2. I'm happy	118 (47.4)	81 (27.3)	
3. I'm not so happy	8 (3.2)	9 (3.0)	
4. I'm not happy at all	2 (0.8)	6 (2.0)	
Missing	7	4	

These types of global outcomes can be effected by the outcomes of postoperative complications. To explore the impact of such factors, the outcomes of patients who experienced a dislocation of the joint were compared with those who did not. Once dislocated, a manual or open reduction under general anaesthesia is required and patients experience extreme pain and immobility. Moreover, after successful reduction patients have to fix the hip for some time with appliances until the joint stabilises. Thus it's highly likely to leave patients dissatisfied. This was the case in the UK (Table 6-1j).

Table 6-1j : Postoperative dislocation and patient perception of health: significance level examined by Mann-Whitney U test

Question about health	Range* of score	Mean score (SE) Dislocated	Not dislocated	Probability
JAPAN				
My health is better than before	1 - 3	1.6 (0.2)	1.3 (0.0)	**0.0112**
Operation changed the way I feel	1 - 7	2.1 (0.3)	1.8 (0.1)	0.6013
I'm happy to have had operation	1 - 4	1.7 (0.2)	1.6 (0.0)	0.4687
UK				
My health is better than before	1 - 3	1.8 (0.2)	1.4 (0.0)	**0.0168**
Operation changed the way I feel	1 - 7	3.1 (0.6)	1.7 (0.1)	**0.0177**
I'm happy to have had operation	1 - 4	2.0 (0.3)	1.4 (0.0)	**0.0027**

* Score of health is as shown in Table 6-1i.

1-8. Readmission rate

Patients were asked if they had been admitted to any hospital in the period between the index admission and the follow-up questionnaire one year later. All readmissions were included due to the difficulties in identifying their relevance to the index operation.

The number of patients who were readmitted to hospital was 33 (12.9%) in Japan and 65 (21.6%) in the UK. If limited to readmissions within 3 months of their operation, the readmission rates were similar: 14 (5.5%) patients in Japan and 18 (6.0%) in the UK. Comparison are difficult however due to the long lengths of postoperative stay in Japan and because patients in Japan may be transferred to another hospital for convalescence and this would be counted as a readmission.

Table 6-1k shows the reasons for readmission. In both Japan and the UK, there were a substantial number of patients readmitted because of problems related to the other hip or the knees. Dislocation was frequent during the first 3 months in the UK (4 patients out of 7), suggesting their hips were unstable during the early stage of convalescence. Similar to the differences observed in the data on preoperative comorbidity (Chapter 5), cardio-pulmonary disorders were commoner in the UK, while in Japan gastrointestinal disease was more of a problem. Included in 'others' in Japan were those who were transferred to other hospitals for convalescence (9 patients).

Table 6-1k : Reasons for readmission in Japan and the UK

Reason	Number of readmission (%) JAPAN	UK
Joint		
Dislocation	1 (3.0)	7 (10.8)
Other hip/knee related	9 (27.3)	20 (30.8)
Cardiac disorders	1 (3.0)	5 (7.7)
Vascular system		
Cerebrovascular	1 (3.0)	0 (-)
Peripheral vascular	0 (-)	7 (10.8)
Respiratory	0 (-)	3 (4.6)
Renal disease	1 (3.0)	7 (10.8)
Malignancy	0 (-)	1 (1.5)
Hepatobiliary	0 (-)	1 (1.5)
Gastrointestinal	5 (15.2)	3 (4.6)
Mental disorder	0 (-)	1 (1.5)
Vision	3 (9.1)	3 (4.6)
Others	12 (36.4)	7 (10.8)
Total	33	65

When patient characteristics were examined in relation to the readmission rate, no sociodemographic variables showed significant association in either country. In the UK, patients were more likely to be readmitted if they had had no previous hip surgery, did not undergo a hybrid THR, and had their surgery under regional anaesthesia (Table 6-11). Decreased daily activity by the patients who had had a previous hip surgery could be part of the reason why they had a lower readmission rate, as well as being relatively more conscious about their health. Regional anaesthesia is more likely to be used in older, sicker patients at higher operative risk.

Table 6-11 : Patient characteristics and readmission in the UK

Patient characteristics	Number of patients	Number of readmissions	Readmission rate, % (95% Conf.Int)	Probability (Chi square)
Previous hip surgery				
Same hip (not THR)	16	1	6.3 (0.3-32.3)	0.1595
Other hip (not THR)	8	0	0.0 (0.0-40.2)	0.1530
Other hip (THR)	60	8	13.3 (6.3-25.1)	0.1506
No surgery	191	45	23.6 (17.9-30.3)	**0.0160**
Cement use				
Cemented	208	46	22.1 (16.8-28.5)	**0.0365**
Hybrid	23	0	0 (0.0-17.8)	
Cementless	30	5	16.7 (6.3-35.5)	
General anaesthesia				
Yes	259	48	18.5 (14.1-23.9)	**0.0021**
No	8	5	62.5 (25.9-89.8)	

Among the six UK hospitals, the readmission rate ranged from 17 to 38%, though this was not statistically significant (Table 6-1m). The range in the UK (21%) was larger than that reported in the USA (14%). There was no significant difference in readmission rate between teaching and non-teaching hospitals.

Table 6-1m: Interhospital difference in readmission rate (UK)

Hospital	Number of patients	Number of readmission	Readmission rate, % (95% Conf.Int)	Probability (Chi square)
A	65	11	16.9 (9.2-28.7)	0.1644
B	48	10	20.8 (11.0-35.4)	
C	35	7	20.0 (9.6-37.5)	
D	36	12	33.3 (19.1-51.1)	
E	94	17	18.1 (11.2-27.7)	
F	21	8	38.1 (19.0-61.3)	
Total	299	65	21.7 (17.3-26.9)	
Missing	2			
Teaching status				
Teaching	165	36	21.8 (15.9-29.1)	0.9707
Non-teaching	134	29	21.6 (15.2-29.8)	
Missing	2			

1-9. Satisfaction

Questions were asked about patients' satisfaction with the information they received in the hospital, the management of their pain, and their overall satisfaction with care. Answers were on a five-point scale (1 indicated very satisfied; 5, very dissatisfied). As the distribution of the three scores were similar in both countries, they were averaged and compared to each other.

There was a high degree of satisfaction in all three countries (mean score in Japan was 1.7; in the UK, 1.5; in the USA, 1.3-1.5). Ratings were typically around 1.5, suggesting an average rating between "very satisfied" and "somewhat satisfied." The difference in satisfaction with care between the UK and Japan was statistically significant ($p<0.0001$, based on Mann-Whitney U test) with the UK patients more satisfied than the Japanese. In the UK, patients who had regional anaesthesia were less satisfied (mean satisfaction score 2.0; SE=0.4) than those with general anaesthesia (1.5; SE=0.1) ($p=0.0466$ based on Mann-Whitney U test). There was no significant association found in Japanese patients.

Satisfaction with care differed significantly between the six UK hospitals (Table 6-1n). When classified by their teaching status, satisfaction was significantly higher in teaching hospitals than in non-teaching hospitals.

Table 6-1n : Interhospital difference in care satisfaction (UK)

Hospital	Number of patients	Mean (SE) score of satisfaction	Probability
A	64	1.6 (0.1)	**0.0293**
B	48	1.6 (0.1)	(Kruskal-Wallis)
C	35	1.2 (0.1)	
D	33	1.6 (0.1)	
E	95	1.4 (0.1)	
F	22	1.7 (0.2)	
Total	296	1.5 (0.0)	
Teaching status:			
Teaching	162	1.4 (0.1)	**0.0081**
Non-teaching	134	1.6 (0.1)	(Mann-Whitney)

2. Relationship between outcomes and comorbidity

Only some outcomes were considered further for the following reasons:

(1) there were too few deaths to analyse the relationship between mortality and comorbidity;

(2) the ICED was designed primarily to predict postoperative complications; and

(3) one of the aims of this study is to test the predictive power of the ICED for change in health status, which is the principal objective of THR.

Therefore, the following analyses and discussions focus on two outcomes: in-hospital complications and change in health status.

2-1. Serious complications

The rate of serious in-hospital complications by the level of comorbidity is shown in Table 6-2a. When classified by the co-existent disease severity subindex, serious in-hospital complications were most frequently observed in level 3 in all three countries. In Japan there was no clear trend. Complications were rare in levels 0, 1 and 2 and common in level 3. In the UK, there was significant evidence of increasing complications with increasing severity (Chi square for trend=5.8; $p<0.05$). In the USA there was a statistically significant increasing risk of serious complications with increasing severity (Chi square for trend=10.3; $p<0.005$).

There was no clear association between complications and functional severity in Japan or the UK. In Japan, all the patients with serious complications were classified at level 0 while in the UK complications were more likely to occur in patients with the middle level of functional severity. In contrast, in the USA the rise in prevalence was in good accord with the increment in functional severity (Chi square for trend=15.9; $p<0.001$).

The composite index, the ICED, encompassed these observed differences in the distributions of complications by levels of severity of co-existent disease and function. The relative risk of a serious complication occurring in a patient with ICED level 4 compared with the ICED level 1 varied between the three countries. In Japan the risk was about four times greater, in the UK twice as great and in the USA over 14 times as great. For Japanese patients, a similar pattern to that seen with the co-existent disease severity subindex was seen in which there was no clear trend. In the UK, a significant trend emerged in a dichotomised pattern in which complication rates in levels 1 and 2 were similar and those in levels 3 and 4 were similar (Chi square for trend=4.2; $p<0.05$). In the USA, the complication rates ranged from 3 to 41% with a consistent and statistically significant exponential increase from level 1 to level 4 (Chi square for trend=22.6; $p<0.001$).

A similar pattern was observed with the ASA PS in Japanese and American patients. As with the ICED, the complication rate in Japan was low in grades 1 and 2 and high in grade 3. In the USA the prevalence of complications increased exponentially from lower to higher levels of ASA PS severity ($p=0.06$).

Table 6-2a: Number and percent of patients with serious in-hospital complications for the two subindices (co-existent disease severity and functional severity), for the ICED (combining disease severity and functional severity), and for ASA PS in Japan, the UK and the USA

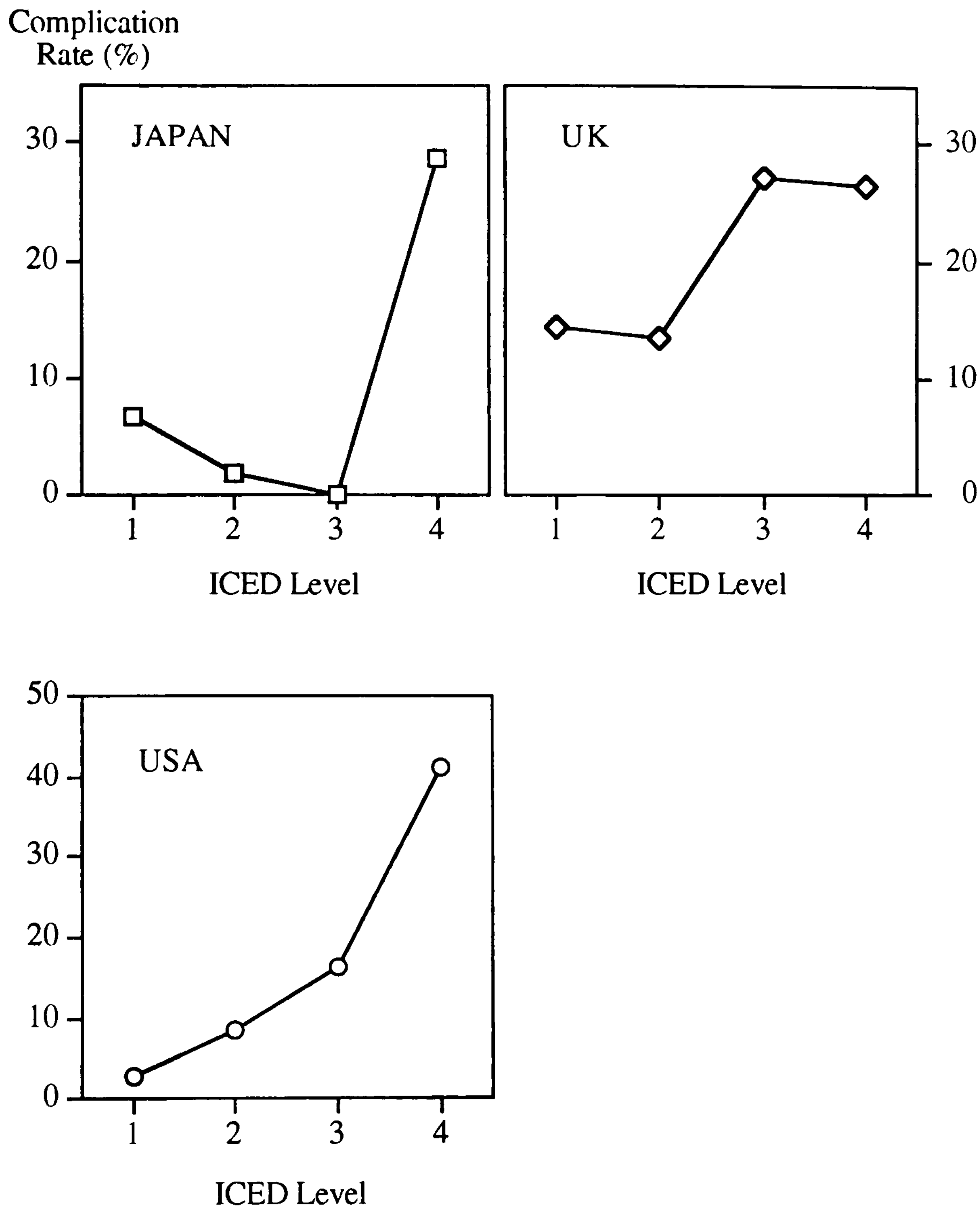
Index	Levels of index	Number (%) of patients with complication* JAPAN N=249	UK N=268	USA N=356
Co-existent disease severity subindex	0	7 (6.7)	10 (13.7)[a]	4 (3.8)[b]
	1	0 (0.0)	7 (19.4)	7 (10.2)
	2	2 (2.7)	21 (18.1)	23 (13.4)
	3	2 (40.0)	14 (32.6)	4 (36.4)
Functional severity subindex	0	11 (5.4)	26 (16.0)	14 (6.6)[c]
	1	0 (0.0)	24 (25.8)	19 (14.4)
	2	0 (0.0)	2 (15.4)	5 (50.8)
Index of co-existent disease (ICED)	1	7 (6.7)	10 (14.3)[a]	3 (2.9)[c]
	2	2 (1.9)	11 (13.4)	11 (8.4)
	3	0 (0.0)	17 (27.0)	17 (16.3)
	4	2 (28.6)	14 (26.4)	7 (41.2)
ASA PS	1	6 (8.4)	-	3 (5.0)
	2	3 (2.2)	-	22 (10.0)
	3	2 (40.0)	-	11 (20.0)

*: Percent of patients with in-hospital complications in total number of patients classified at each level of severity.

a; p<0.05, b; p<0.005, c; p<0.001 based on Chi square for trend (df=1).

The relationship between serious in-hospital complications and the ICED was clearly different between the three countries (Fig6-2a). In Japan, the curve showed a sharp rise at the highest ICED level suggesting a threshold effect. In the UK, the figure was almost dichotomised between levels 1 and 2 and levels 3 and 4. In the USA, an exponential relationship was apparent.

Figure 6-2a: Serious in-hospital complication rate in Japan, UK, and USA



2-2. Minor complications

The distribution of minor complications by level of comorbidity is shown in Table 6-2b. Compared with the distribution of serious complications, significant trends were observed in Japan with classification by the co-existent disease severity subindex (Chi square for trend=6.357; $p<0.05$), the ICED (Chi square for trend=12.096; $p<0.005$) and the ASA PS (Chi square for trend=7.911; $p<0.005$). In the UK, the pattern was similar to that for serious complications - the rates among the two lower levels were similar as were the rates among the two higher levels.

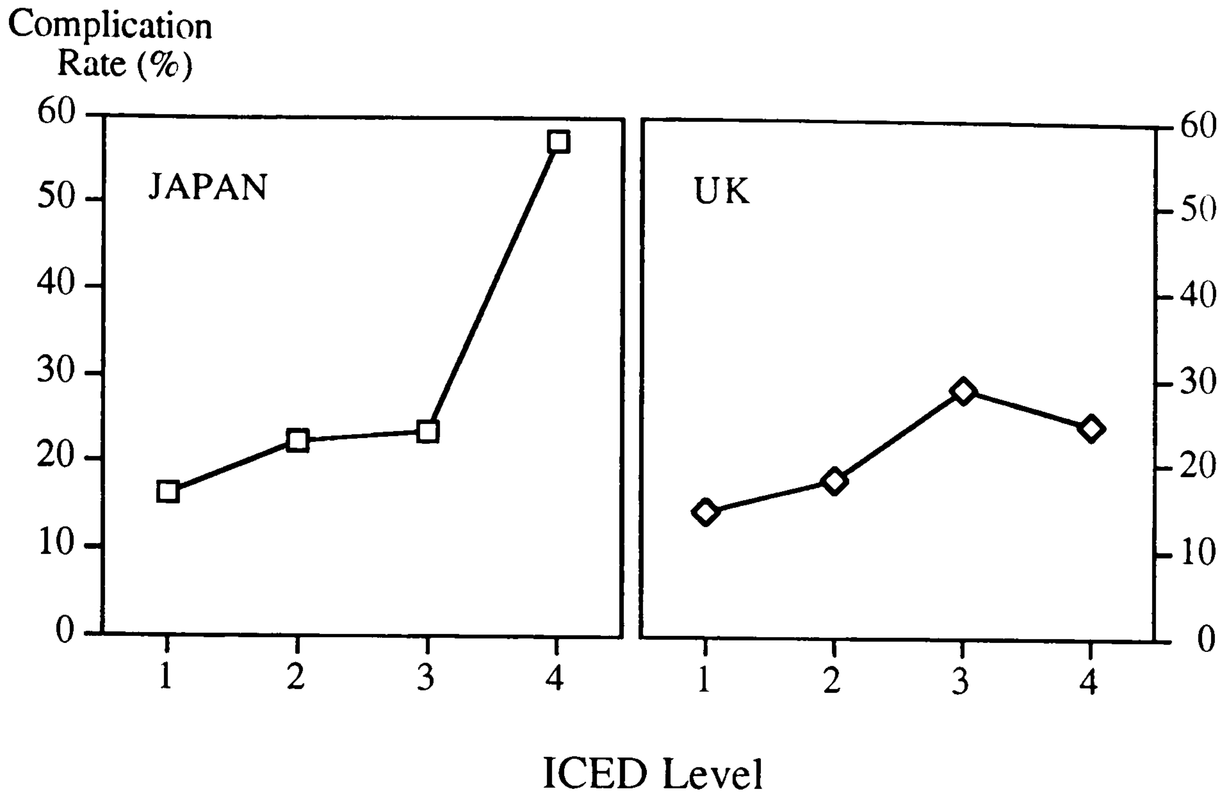
Table 6-2b: Number and percent of patients with minor in-hospital complications for the two subindices (co-existent disease severity and functional severity), for the ICED (combining disease severity and functional severity), and for ASA PS in Japan and the UK

Index	Levels of index	Number (%) of patients with complication* JAPAN N=249	UK N=268
Co-existent disease severity subindex	0	17 (16.2)[a]	10 (13.7)
	1	12 (18.5)	7 (19.4)
	2	21 (28.4)	29 (25.0)
	3	2 (40.0)	10 (23.3)
Functional severity subindex	0	40 (19.6)	31 (19.1)
	1	10 (23.8)	21 (22.6)
	2	2 (66.7)	4 (30.8)
Index of co-existent disease (ICED)	1	17 (16.2)[b]	10 (14.3)
	2	24 (22.4)	15 (18.3)
	3	7 (23.3)	18 (28.6)
	4	4 (57.1)	13 (24.5)
ASA PS	1	15 (14.0)[b]	-
	2	33 (24.7)	-
	3	4 (50.0)	-

*: Percent of patients with in-hospital complications in total number of patients classified at each level of severity.
a; p<0.05, b; p<0.005, based on Chi square for trend (df=1).

The following figure shows the relationship between the minor in-hospital complication rate and the ICED, again demonstrating the threshold effect in Japan (Fig 6-2b). There was no clear pattern observed in the UK data.

Figure 6-2b: Minor in-hospital complication rate in Japan and the UK



2-3. Overall complications

Table 6-2c shows the distribution of the overall complication rates by level of severity of comorbidity. Both in Japan and the UK, the association of overall complications with severity of comorbidity was significant when classified by the co-existent disease subindex (Japan: Chi square for trend=4.52; p<0.05 and UK: Chi square for trend=9.139; p<0.005), the ICED (Japan: Chi square for trend=5.46; p<0.05 and UK: Chi square for trend=8.226; p<0.005). In addition, in Japan there was a significant association with the ASA PS (Chi square for trend=8.59;p<0.005). Figure 6-2c shows the relationship between overall in-hospital complication rate and the ICED.

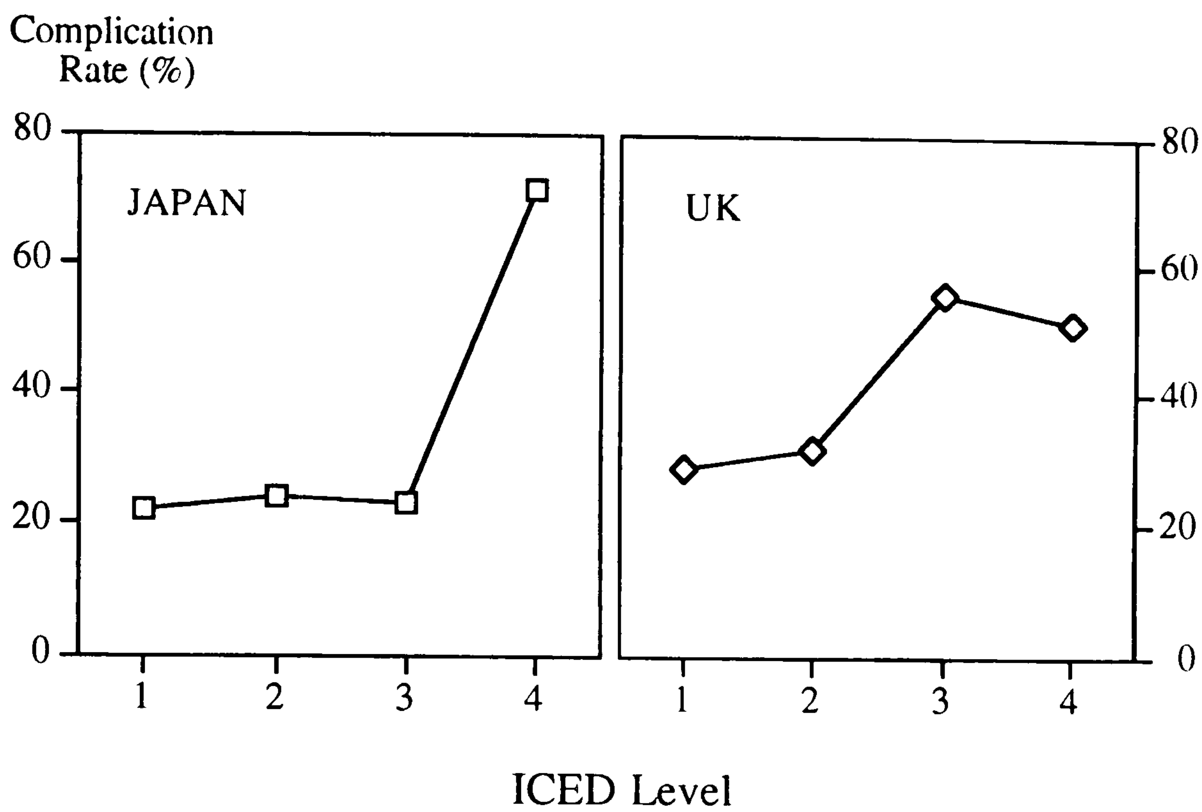
Table 6-2c: Number and percent of patients with overall in-hospital complications for the two subindices (co-existent disease severity and functional severity), for the ICED (combining disease severity and functional severity), and for ASA PS in Japan and the UK

Index	Levels of index	Number (%) of patients with complication* JAPAN N=249	UK N=268
Co-existent disease severity subindex	0	23 (21.9)[a]	20 (27.4)[b]
	1	12 (18.5)	14 (38.9)
	2	23 (31.1)	50 (43.1)
	3	3 (60.0)	24 (55.8)
Functional severity subindex	0	49 (24.0)	57 (35.2)
	1	10 (23.8)	45 (48.4)
	2	2 (66.7)	6 (46.2)
Index of co-existent disease (ICED)	1	23 (21.9)[a]	20 (28.6)[b]
	2	26 (24.3)	26 (31.7)
	3	7 (23.3)	35 (55.6)
	4	5 (71.4)	27 (50.9)
ASA PS	1	20 (18.7)[b]	-
	2	36 (26.9)	-
	3	5 (62.5)	-

*: Percent of patients with in-hospital complications in total number of patients classified at each level of severity.

a; p<0.05, b; p<0.005, based on Chi square for trend (df=1).

Figure 6-2c: Overall in-hospital complication rate in Japan and the UK



2-4. Change in health status

Among the four dimensions in health status described in Chapter 6-1-5, basic ADL, instrumental ADL and social activity was compared before and after THR. Mental health was not included because of the difference in the number of questions asked in Japan from the UK.

Change in health status following THR was examined in relation to the severity of comorbidity measured by the ICED. For each of the three dimensions of health status, there was no significant association with the ICED in Japan (Table 6-2d). In contrast a significant association was found in the UK with both the functional severity subindex and the ICED (Table 6-2e). For all three dimensions of health status, patients with less comorbidity reported greater improvement in their health status.

Table 6-2d: Change in health status and severity of comorbidity in Japan

Health status scales by comorbidity index	Levels of index	Mean (SE) change in health status	Probability (Kruskal-Wallis)
Basic ADL			
Co-existent disease severity subindex	0	24.4 (2.4)	0.1689
	1	27.7 (4.2)	
	2	29.4 (3.2)	
	3	53.3 (12.4)	
Functional severity subindex	0	26.7 (2.0)	0.6870
	1	29.3 (4.1)	
	2	44.4 (25.7)	
Index of co-existent disease (ICED)	1	24.4 (2.4)	0.1645
	2	27.4 (3.0)	
	3	31.7 (5.0)	
	4	50.8 (13.0)	
Instrumental ADL			
Co-existent disease severity subindex	0	28.1 (3.0)	0.4801
	1	24.7 (4.7)	
	2	28.0 (3.0)	
	3	49.8 (12.6)	
Functional severity subindex	0	27.1 (2.2)	0.5939
	1	30.0 (4.8)	
	2	41.7 (13.9)	
Index of co-existent disease (ICED)	1	28.1 (3.0)	0.2127
	2	24.9 (3.1)	
	3	31.3 (5.3)	
	4	50.7 (10.4)	
Social activity			
Co-existent disease severity subindex	0	24.7 (4.0)	0.5496
	1	22.3 (6.2)	
	2	31.4 (4.3)	
	3	44.4 (20.4)	
Functional severity subindex	0	24.4 (3.0)	0.1049
	1	38.4 (6.0)	
	2	5.6 (5.6)	
Index of co-existent disease (ICED)	1	24.7 (4.0)	0.1702
	2	23.4 (4.3)	
	3	42.0 (6.6)	
	4	35.6 (18.1)	

Table 6-2e: Change in health status and severity of comorbidity in the UK

Health status scales by comorbidity index	Levels of index	Mean (SE) change in health status	Probability (Kruskal-Wallis)
Basic ADL			
Co-existent disease severity subindex	0	24.8 (3.1)	0.1617
	1	25.5 (3.8)	
	2	31.0 (2.2)	
	3	25.8 (3.2)	
Functional severity subindex	0	30.6 (1.9)	0.0572
	1	24.7 (2.4)	
	2	15.4 (8.3)	
Index of co-existent disease (ICED)	1	27.1 (2.9)	**0.0350**
	2	33.5 (2.6)	
	3	24.6 (3.1)	
	4	23.2 (3.4)	
Instrumental ADL			
Co-existent disease severity subindex	0	33.1 (3.7)	0.6646
	1	34.8 (4.0)	
	2	31.0 (2.9)	
	3	29.5 (3.4)	
Functional severity subindex	0	35.7 (2.3)	**0.0166**
	1	27.6 (2.7)	
	2	14.3 (11.3)	
Index of co-existent disease (ICED)	1	35.6 (3.5)	**0.0376**
	2	36.6 (3.5)	
	3	25.6 (3.4)	
	4	26.8 (3.9)	
Social activity			
Co-existent disease severity subindex	0	29.3 (4.2)	0.5777
	1	32.6 (6.0)	
	2	34.5 (3.7)	
	3	27.6 (5.7)	
Functional severity subindex	0	34.9 (2.8)	**0.0141**
	1	29.7 (4.2)	
	2	4.4 (7.3)	
Index of co-existent disease (ICED)	1	31.6 (4.2)	0.0549
	2	39.1 (4.0)	
	3	29.4 (5.2)	
	4	22.6 (5.0)	

Figures 6-2d, 6-2e and 6-2f show the relationship between change in each dimension of health status and the ICED (mean change with standard error plotted). The interpretation was difficult in Japan because of the large standard error at the highest level of the ICED, in which only 7 patients were classified. However, reflecting the weak association with preoperative basic ADL and social activity, the mean change in these two dimensions was increasing with the severity of the ICED except for the highest level. A weak dichotomous pattern was observed again in the UK, particularly for instrumental ADL, in which lower ICED levels had greater change in health status.

Figure 6-2d: Change in mean (+/-SEM) basic ADL in Japan and the UK

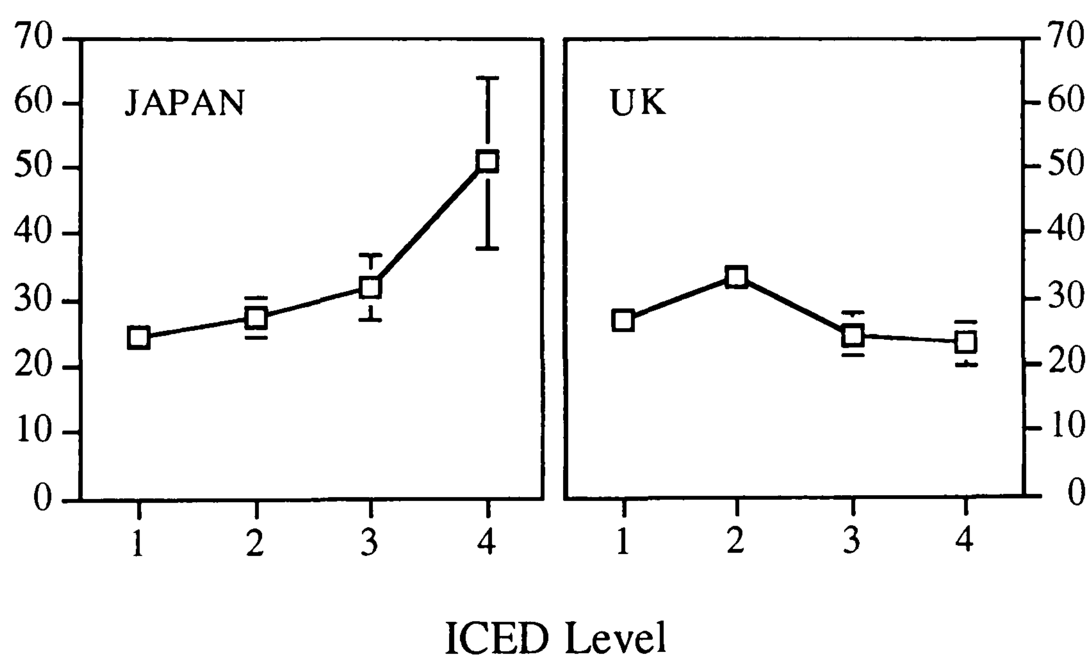


Figure 6-2e: Change in mean (+/- SEM) instrumental ADL in Japan and the UK

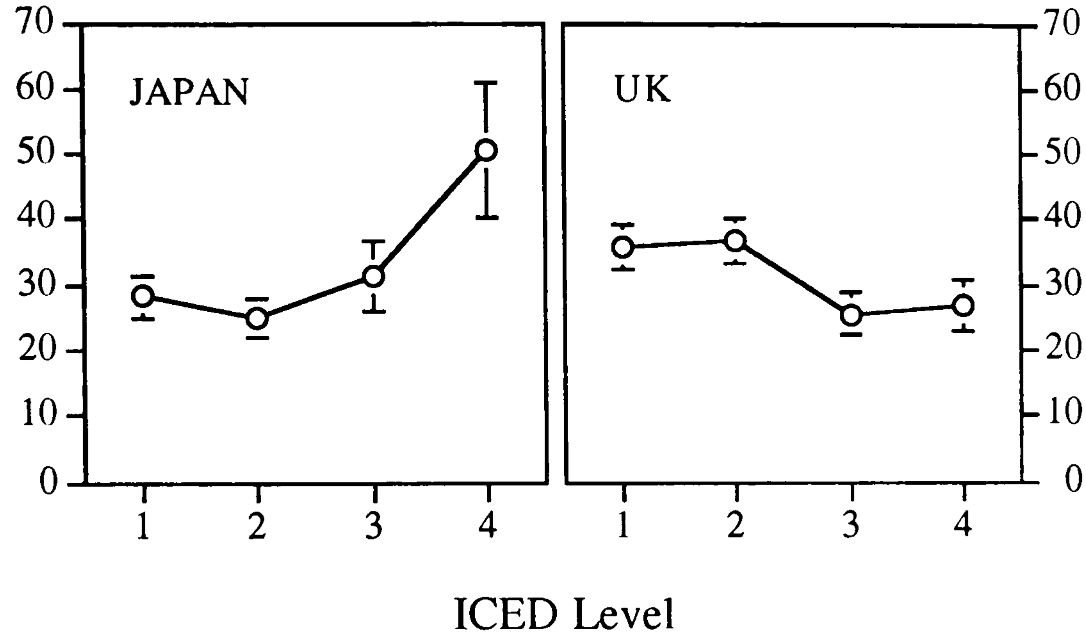
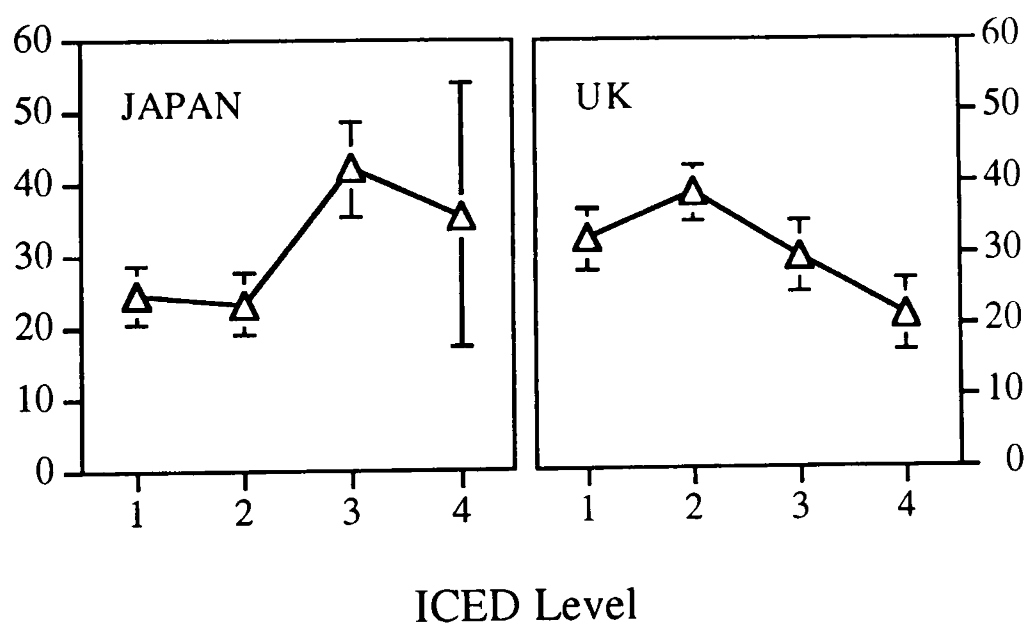


Figure 6-2f: Change in mean (+/- SEM) social activity in Japan and the UK



3. Relationship between outcomes and other independent variables

From previously published studies, several factors were considered as potentially confounding the relationship between comorbidity and outcome (Table 6-3a). The relationship between such factors and outcomes were examined. Some additional factors were analysed for some specific outcomes.

Table 6-3a: Independent variables considered as possible confounding factors

Sociodemographic:	age, sex, living alone, marital status, education level, home ownership
Severity of hip disease:	past history of hip surgery, limp, need for walking support
Clinical management:	anaesthesia, duration of surgery, amount of transfusion, cement use, surgical approach, hospital (in the UK only)

3-1. Serious complications

Among the variables examined in relation to the occurrence of serious in-hospital complications in the UK, only two were found to be significantly associated: the surgical approach and the hospital (Table 6-3b). Significant interaction was observed between surgical approach and hospital ($p<0.0001$, based on Chi square test) suggesting that the difference in complication rates between hospitals may have arisen from the surgical approach adepted. There was no association between surgical approach and the duration of anaesthesia. In Japan, no factors were found to be significantly associated with serious complications.

Table 6-3b: Factors significantly related to serious in-hospital complications in the UK

Variables	Number of patients	Number of complications	Complication rate, % (95% Conf.Int)	Probability (Chi square)
Surgical approach				
Anterior/Anterolateral	60	18	30.0 (19.2-43.4)	**0.0221**
Lateral/Posterior/ Posterolateral	188	31	16.5 (11.6-22.8)	
Hospital				
A	64	7	10.9 (4.9-21.8)	**0.0128**
B	37	4	10.8 (3.5-26.4)	
C	36	5	13.9 (5.2-30.3)	
D	26	4	15.4 (5.5-35.7)	
E	86	25	29.1 (20.0-40.0)	
F	19	7	36.8 (17.2-61.4)	

The two most frequent serious complications, hypotension and neuropathy, were investigated further as follows.

3-1a. Hypotension

Criteria of postoperative hypotension in this study was a drop in blood pressure to below 90/60 mmHg, observed any time during the admission, whether or not it immediately recovered. The frequencies of postoperative hypotension varied considerably between countries; 0.8% in Japan, 12.3% in the UK, and 3.4% in the USA. Due to the small number of cases in Japan, further analyses were confined to the UK cases. When the 33 UK patients were compared with those without hypotension, there was no difference as regards their age, sex, length of stay (preoperative and total), use of cement, duration of anaesthesia (surgery), and occurrence of postoperative dislocation (Table 6-3c).

Table 6-3c: Relationship between postoperative hypotension and patient characteristics (UK)

Variables			Probability
Age			
	Number of patient	Mean age (95% Conf.Int)	(Mann-Whitney)
With hypotension	33	69.9 (66.5 - 73.3)	0.6868
Without hypotension	235	68.1 (66.4 - 69.7)	
Sex			
	With hypotension (N=33)	Without hypotension (N=232)	(Chi square)
Male	9	88	0.2548
Female	24	147	
Length of stay			
	Mean stay, days (95% Conf.Int)		
Period of stay	With hypotension (N=33)	Without hypotension (N=232)	(Mann-Whitney)
Preoperative	1.6 (1.2 - 2.0)	2.0 (1.7 - 2.3)	0.2543
Postoperative	15.4 (13.0 - 17.9)	14.0 (12.9 - 15.1)	0.1534
Total	17.0 (14.6 - 19.4)	16.0 (14.9 - 17.2)	0.2781
Cement			
	With hypotension (N=30)	Without hypotension (N=232)	(Chi square)
Both cemented	28	181	0.1441
Hybrid	1	22	
Cementless	1	29	
Duration of anaesthesia/surgery			
	Number of patient	Mean duration, min (95% Conf.Int)	(Mann-Whitney)
With hypotension	29	106.7 (97.8 - 115.6)	0.3273
Without hypotension	220	104.5 (100.5 - 108.4)	
Dislocation			
	With hypotension (N=33)	Without hypotension (N=235)	(Chi square)
Dislocated	0	3	1.0000
Not dislocated	33	232	

The difference in incidence among the six hospitals was statistically significant (Table 6-3d). In hospital F, postoperative hypotension was observed more frequently than in the other hospitals. There was no significant difference in the incidence between teaching and non-teaching hospitals.

Table 6-3d: Interhospital difference in postoperative hypotension rate in the UK

Hospital	Number of patients	Number of hypotension	Hypotension rate, % (95% Conf.Int)	Probability (Chi square)
A	64	4	6.3 (2.0-16.0)	**0.0041**
B	37	1	2.7 (0.1-15.8)	
C	36	4	11.1 (3.6-27.0)	
D	26	3	11.5 (3.0-31.3)	
E	86	14	16.3 (9.5-26.2)	
F	19	7	36.8 (17.2-61.4)	
Total	268	33	12.3 (8.7-17.0)	
Teaching status				
Teaching	148	21	14.2 (9.2-21.1)	0.2993
Non-teaching	120	12	10.0 (5.5-17.2)	

Possible causes of the international and inter-hospital differences were: 1) the detection of hypotension, 2) patient characteristics, 3) reporting bias, and 4) the quality of postoperative care.

(a-1) The detection of hypotension

It is unlikely that an episode of hypotension would have been mistakenly detected. Most hypotension was reported on the day or the day after surgery, though some patients were hypotensive when receiving physiotherapy or at a later time on the ward. Because it brings immediate staff attention once it happens and blood pressure would be measured frequently until it stabilised, errors in detection are considered unlikely to be the cause of observed differences.

(a-2) Patient characteristics

Compared with Japanese patients, the UK patients were 8 years older on average (Table 5-1), with more comorbidity, particularly insufficient cardiac function (Table 5-3b). Considering Japanese live about four years longer than Britons, the difference in mean patient age could be even more significant as regards physiological age leading to more cardiac dysfunction for the UK patients. Although the USA figure is not available regarding their cardiac comorbidity, the number of complications (Table 6-1a) suggests the presence of a substantial number of patients at risk of heart failure.

(a-3) Reporting bias

Health professionals in all countries should be equally motivated to report medical findings in the case notes. On the other hand they might underreport complications if there is a financial disincentive. This is unlikely in Japan because the insurance system is based on a fee-for-service method, in which the more procedures performed, including blood pressure monitoring, the larger the profit. Recording of every procedure is mandatory for charging purposes. In contrast, in the UK there are neither financial incentives nor disincentives to report blood pressure measurements. In the USA, where the majority of patients undergoing THR are eligible for Medicare, the payment is fixed, adjusted for complications. This is likely to provide staff with an incentive to report in-hospital complications. Thus, financial incentives cannot be accountable for the differences in rates of hypotension reported.

Another possibility is the teaching status of the hospitals. In general, teaching hospital staff kept more information in the case notes, perhaps for research purposes, while in community or district general hospitals the amount of data was relatively less. However, the majority of Japanese hospitals were teaching hospitals whereas only half the UK hospitals were. So this too is unlikely to account for the international differences in the rates observed.

(a-4) Quality of postoperative care

The biggest difference in postoperative care between Japan and the UK was in the long length of hospital stay in Japan. For THR patients in Japan, it is usually recommended to stay in bed during the first week after surgery and then gradually start mobilisation. Walking exercises only start two weeks after the surgery, when British and American patients are already being discharged from hospital. Also during their hospital stay, Japanese patients usually receive three to four days' (sometimes a week or more) intravenous infusion to supplement their oral intake of water. This double effect of bed rest and fluid replacement may have contributed, to some extent, to maintaining their blood pressure. Because of differences in the recording of fluid balance between Japanese and British hospitals, it was difficult to know how far fluid replacement prevented hypotension.

The other possibility is the method of anaesthesia. In the UK, a significantly higher proportion of patients underwent general anaesthesia than in Japan and the USA. Moreover, in the UK general anaesthesia was often applied in combination with regional anaesthesia. This was to control the level of analgesia and sedation so that the anaesthesia would not be too deep. Although no data were available regarding the depth of anaesthesia, frequent postoperative hypotension may also suggest the poor recovery of British patients after such anaesthesia. However, none of these factors would explain why the UK hospitals had more cases of hypotension than the USA where postoperative care is similar and the length of hospital stay is even shorter than in the UK.

In conclusion, it would appear that differences in patient characteristics plus, perhaps, differences in clinical management accounted for the observed differences in the rates of hypotension.

3-1b. Neuropathy

The incidence of neuropathy was similar among the three countries; 2.8% in Japan, 2.2% in the UK, 3.4% in the USA. The anatomical position of the sciatic nerve suggests a posterior approach to the hip joint is more likely to cause neuropathy than anterolateral. The proportion of lateral/posterior/posterolateral approaches was 49.4% in Japan, about two thirds of that in the UK (75.8%). Despite this the rates of neuropathy were similar.

Other possible factors associated with neuropathy include: a previous surgery on the same hip which may lead to scar formation in the surrounding tissue which could reduce flexibility and require extra effort to develop the surgical area for better exposure; use of cement which takes extra time during the surgery which may be associated with developing neuropathy; and postoperative dislocation, which usually occurs in a posterior direction and may damage the sciatic nerve temporarily.

Therefore past history, cement use, duration of surgery, total blood loss, and dislocation were examined for any association with neuropathy. However, none of these factors were associated with postoperative neuropathy in Japan or in the UK (Tables 6-3e and 6-3f).

Table 6-3e: Relationship between neuropathy and patient characteristics in Japan

Variables			Probability
Previous hip surgery			
	With neuropathy (N=7)	Without neuropathy (N=242)	(Chi square)
Operated	3	48	0.3111
Never operated	4	194	
Cement			
	With neuropathy (N=7)	Without neuropathy (N=242)	(Chi square)
Both cemented	4	57	0.0910
Hybrid	0	40	
Cementless	3	145	
Duration of anaesthesia/surgery			
	Number of patient	Mean duration, min (95% Conf.Int)	(Mann-Whitney)
With neuropathy	7	164.1 (120.3 - 208.0)	0.2360
Without neuropathy	242	142.5 (135.9 - 149.1)	
Total blood loss			
	Number of patient	Mean blood loss (95% Conf.Int)	(Mann-Whitney)
With neuropathy	6	1257.8 (857.3 - 1658.4)	0.8582
Without neuropathy	234	1327.3 (1259.3 - 1395.2)	
Dislocation			
	With neuropathy (N=7)	Without neuropathy (N=242)	(Chi square)
Dislocated	0	11	1.0000
Not dislocated	7	231	

Table 6-3f: Relationship between neuropathy and patient characteristics in the UK

Variables			Probability
Previous hip surgery			
	With neuropathy (N=6)	Without neuropathy (N=262)	(Chi square)
Operated	1	75	0.8536
Never operated	5	187	
Cement			
	With neuropathy (N=5)	Without neuropathy (N=257)	(Chi square)
Both cemented	3	206	0.5204
Hybrid	1	22	
Cementless	1	29	
Duration of anaesthesia/surgery			
	Number of patient	Mean duration, min (95% Conf.Int)	(Mann-Whitney)
With neuropathy	5	111.0 (57.3 - 164.7)	0.9421
Without neuropathy	244	104.6 (100.9 - 108.2)	
Total blood loss			
	Number of patient	Mean blood loss (95% Conf.Int)	(Mann-Whitney)
With neuropathy	5	844.4 (26.3 - 1662.5)	0.4850
Without neuropathy	220	1034.2 (941.3 - 1127.1)	
Dislocation			
	With neuropathy (N=6)	Without neuropathy (N=262)	(Chi square)
Dislocated	0	3	1.0000
Not dislocated	6	259	

3-2. Minor complications

Of all the variables examined in relation to episodes of minor in-hospital complications in the UK, only the patient's education level was found to be significantly associated ($p<0.005$, based on Chi square test). In Japan, no variables were found to be significant.

One of the commonest complications was dislocation. Several factors were examined for an association with dislocation: previous surgery on the same hip, surgical approach, use of cement, duration of surgery, total blood loss as an indicator of surgical difficulty and length of stay. In Japan where shallow acetabula were common and a bone graft was often necessary (34.5% of cases) it was more difficult to reconstruct the joint. However, none of these variables was significantly related to dislocation.

3-3. Overall complication rate

Previous hip surgery was the only factor found to be significantly associated with the overall complication rate in Japan (Table 6-3g). In the UK, the only factor found to be significantly associated with the overall complication rate was the hospital.

Table 6-3g: Relationship between patient characteristics and overall complication rate

JAPAN

Previous hip surgery	Number of patients	Number of complication	Complication rate, % (95% Conf.Int)	Probability (Chi square)
Yes	51	18	35.3 (22.8-50.0)	**0.0444**
No	198	43	21.7 (16.3-28.2)	
Total	249	61	24.5 (19.4-30.4)	

UK

Hospital	Number of patients	Number of complication	Complication rate, % (95% Conf.Int)	Probability (Chi square)
A	64	18	28.1 (17.9-41.0)	**0.0097**
B	37	11	29.7 (16.4-47.2)	
C	36	6	16.7 (7.0-33.5)	
D	26	11	42.3 (24.0-62.8)	
E	86	38	44.2 (33.6-55.3)	
F	19	11	57.9 (34.0-78.9)	

3-4. Change in health status

In Japan, the factors significantly associated with a change in health status were age, sex, whether the patient lived alone and education level (Table 6-3h). In the UK, marital status and whether living alone were found to be significantly associated with instrumental ADL. Among the three dimensions of health status, sociodemographic factors were significantly associated with a change in instrumental ADL rather than basic ADL or social activity.

Table 6-3h: Relationship between change in health status and patient sociodemographic characteristics

Variable	JAPAN B-ADL	JAPAN I-ADL	JAPAN SA	UK B-ADL	UK I-ADL	UK SA
Age*	0.3094	**0.0179**	0.1832	0.2399	0.3532	0.2462
Sex	0.0655	**0.0024**	0.0940	0.1568	0.8454	0.5015
Marital status	0.3796	0.3013	0.2762	0.7078	**0.0105**	0.6655
Living alone	0.1153	**0.0053**	**0.0177**	0.6015	**0.0276**	0.7891
Home ownership	0.4042	0.7443	0.9433	0.4870	0.2376	0.4380
Education level	0.4749	**0.0083**	**0.0355**	0.3816	0.8885	0.2067

B-ADL indicates basic ADL; I-ADL, instrumental ADL; SA, social activity.
Significance test examined by Mann-Whitney U test (sex, marital, living, home, previous hip) and Kruskal-Wallis test (age, education).
* Age was dichotomised 57-66 years or others, using 25 and 50 percentiles as cut-off.

In both countries, the severity of preoperative limp was significantly associated with change in health status (Table 6-3i). Previous hip surgery was not associated with any dimension of health status. A significant association was also found between the need of walking support and basic ADL. Compared to relationship with preoperative health status, previous hip surgery became not significant with any dimensions but preoperative limp remained significant.

Table 6-3i : Relationship between change in health status and severity of hip disease

Variable	JAPAN			UK		
	B-ADL	I-ADL	SA	B-ADL	I-ADL	SA
Previous hip surgery	0.6746	0.6172	0.1851	0.1272	0.9315	0.4489
Limp	**<0.0001**	**0.0001**	**0.0001**	**<0.0001**	**<0.0001**	**0.0004**
Walking support	**0.0006**	0.3288	0.1019	**0.0048**	0.2403	0.1541

B-ADL indicates basic ADL; I-ADL, instrumental ADL; SA, social activity.
Significance test examined by Mann-Whitney U test (previous hip surgery) and Kruskal-Wallis test (limp, walking support).

The following Tables 6-3j and 6-3k show the analyses of variables significantly associated with change in health status (shown in bold letters in Tables 6-3h and 6-3i).

Table 6-3j : Significant association of variables with change in health status in Japan

Variable	Number of patients	Change in health status Mean	SE	Mean rank
Basic ADL				
No limp	4	-5.6	5.6	30.9
Slight limp	59	17.3	3.4	93.2
Moderate limp	110	25.1	2.3	113.8
Severe limp	43	40.3	3.8	153.0
Unable to walk	21	48.1	6.6	166.2
No walking support	87	19.7	2.6	97.3
Single cane/crutch	116	29.6	2.6	124.7
Two canes/crutches	18	34.9	5.6	138.0
Walker	6	35.2	8.3	138.6
Wheelchair	8	59.7	10.9	186.4
Instrumental ADL				
≤55 years	85	31.6	3.6	125.4
57 - 66 years	69	21.7	3.5	99.2
66 - 73 years	53	28.1	3.8	116.5
≥73 years	22	30.4	4.3	120.6
Female	198	25.1	2.2	112.6
Male	38	40.5	4.1	149.2
Living alone	27	14.4	5.0	82.7
Living with	205	29.1	2.1	121.0
Education completed at				
≤15 years	49	22.8	3.7	105.1
16 - 18 years	152	25.9	2.5	114.6
≥19 years	32	41.0	4.9	150.5
No limp	4	-5.6	13.8	45.8
Slight limp	58	15.6	4.3	92.8
Moderate limp	109	27.2	2.7	117.1
Severe limp	43	38.1	3.5	143.9
Unable to walk	20	46.0	8.0	149.1
Social activity				
Living alone	20	8.3	7.8	75.0
Living with	190	28.8	2.9	108.7
Education completed at				
≤15 years	43	20.9	4.8	95.4
16 - 18 years	137	25.0	3.6	104.3
≥19 years	32	42.0	6.4	130.8
No limp	4	-13.9	21.0	48.6
Slight limp	51	7.3	5.0	76.4
Moderate limp	100	31.2	3.9	114.1
Severe limp	38	37.0	5.5	120.3
Unable to walk	19	45.3	9.0	132.1

Table 6-3k : Significant association of variables with change in health status in the UK

Variable	Number of patients	Change in health status Mean	SE	Mean rank
Basic ADL				
No limp	9	9.9	5.9	75.2
Slight limp	27	10.3	5.2	87.5
Moderate limp	80	19.3	2.5	111.4
Severe limp	148	33.4	1.8	163.0
Unable to walk	21	50.8	4.8	223.1
No walking support	72	19.9	3.3	116.6
Single cane/crutch	133	28.5	1.9	145.2
Two canes/crutches	52	34.9	3.5	170.1
Walker	8	33.3	7.9	161.9
Wheelchair	23	32.4	6.2	163.9
Instrumental ADL				
Not married	113	26.6	2.9	125.0
Married	166	35.7	2.3	150.2
Living alone	93	25.9	3.3	124.1
Living with	184	34.9	2.1	146.5
No limp	9	14.8	3.6	77.5
Slight limp	25	17.2	5.9	97.9
Moderate limp	81	23.2	3.3	116.4
Severe limp	144	38.0	2.3	157.0
Unable to walk	19	50.8	8.3	189.7
Social activity				
No limp	7	15.9	13.0	90.6
Slight limp	19	1.8	8.0	72.1
Moderate limp	74	26.3	3.6	114.8
Severe limp	135	37.3	3.2	139.5
Unable to walk	17	44.4	10.8	149.9

4. Summary

Mortality: Known one year mortality was 0.3% in Japan and 1.1% in the UK, but both may be underestimated as some eligible patients were never traced.

Serious complications: Commoner in the UK (19.4%) than in Japan (4.4%) or the USA (10.7%). Most likely to be hypotension (12.3%) in the UK and neuropathy (2.8%) in Japan. The ICED was not significantly associated with the rate of serious complications in Japan but was in the UK. The pattern of association suggested a threshold effect in Japan whereas it was dichotomous in the UK. The serious complication rate was also associated with the surgical approach and the hospital of treatment in the UK. No variables were found to be significantly related to serious complications in Japan.

Minor complications: The incidence was similar in all three countries. Dislocation and gastrointestinal symptoms were commoner in Japan whereas suspected deep vein thrombosis and bed sores were commoner in the UK. The ICED was significantly associated with the minor complication rate in Japan but not in the UK. The pattern of association in Japan again suggested a threshold effect but there was no clear pattern in the UK.

Overall complications: The ICED was significantly associated with the overall complication rate in both countries. Similar patterns of association were observed to those for serious complications. Overall complications were also associated with previous hip surgery in Japan and the hospital of treatment in the UK.

Change in health status: Health status improved in all countries following surgery. The only international difference was that mental health improved more in Japan than in the UK. The ICED was not significantly associated with change in health status in Japan

but in the UK there was a significant dichotomous pattern in which patients with less comorbidity reported greater improvement in basic and instrumental ADL scores. Patient's age, sex, living alone and education were associated with change in health status in Japan whereas marital status and living alone were associated in the UK. In both countries, preoperative severity of hip disease was strongly associated with change in health status.

Mobility/Symptoms: Significant improvements in mobility were reported both in Japan and the UK. British patients, who were more severely affected before surgery, reported significantly more persistent disability one year after. Surgery had little impact on patient's use of walking supports in Japan. In contrast, significantly fewer British patients required such aids after surgery.

Global measures: Japanese patients were more likely than British patients to describe their health as better and thought it better than they had expected. This suggests Japanese patients may have had lower expectations as to the effect of the operation. On the other hand, British patients were more likely to feel the operation had made them feel better and to state that they were very happy about having had the operation.

Readmission: Significantly lower readmission rates were found in patients with previous hip surgery, hybrid THR and general anaesthesia in the UK. No significant association was found in Japan.

Satisfaction: A high degree of satisfaction was found in all three countries. British patients were more likely to be satisfied if they underwent general anaesthesia and were treated in a teaching hospital. No significant associations were found in Japan.

CHAPTER 7

PREDICTIVE POWER OF THE ICED

- INDEX -

Chapter 7: Predictive power of the ICED

This chapter describes the use of regression models to explore the relationship between comorbidity and outcomes. Dependent variables chosen as outcomes were in-hospital complications and change in health status. Independent variables for the regression model were identified from the literature and bivariate analyses reported in Chapter 6. Finally, attempts were made to improve the power of the ICED to predict serious complications.

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In the search for the influence of comorbidity on the outcome of THR, analyses were undertaken to define the extent to which other factors confounded the association. Variables included in the regression model were chosen on the basis of the literature review reported in Chapter 1, and from those found to be significant on bivariate analyses reported in Chapter 6. Tables 7-1a and 7-1b show the correlation matrix of variables in Japan and in the UK. Significantly correlated coefficients ($p<0.05$) are shown in bold.

The ICED was more often found significantly correlated with patient sociodemographics, preoperative severity of hip disease and health status in Japan than in the UK. However, the pattern of significant relationships was generally similar between the two countries. For example, there were few significant correlations between in-hospital complications and patient variables in either country. In contrast, change in health status was correlated with preoperative status as well as with preoperative severity of hip disease (limp and need for walking support) in both countries. Among patient's sociodemographic characteristics, patient's age and education level were often found significantly correlated with other variables.

ASA PS (available only in Japan) was strongly correlated with the ICED, minor and overall complications, age, education level, preoperative basic ADL, and use of cement.

			Complication			Change in:			Transformed		Sociodemographic				
		ICED	serious	minor	overall	B-ADL	I-ADL	SA	B-ADL	SA	age	female	married	alone	educatio
Comorbidity	ICED	1.000													
Complication	serious	-0.008	1.000												
	minor	**0.138**	-0.014	1.000											
	overall	0.108	**0.377**	**0.902**	1.000										
Change in:	B-ADL	**0.153**	0.056	-0.090	-0.061	1.000									
	I-ADL	0.064	0.036	-0.105	-0.086	**0.712**	1.000								
	SA	0.103	0.046	-0.078	-0.048	**0.670**	**0.818**	1.000							
Transformed change in:	B-ADL	**0.153**	0.055	-0.090	-0.061	+	**0.711**	**0.670**	1.000						
	SA	0.100	0.014	-0.080	-0.070	**0.637**	**0.760**	+	**0.637**	1.000					
Socio-demographic	age	**0.287**	-0.089	0.117	0.068	0.076	-0.072	-0.023	0.075	-0.051	1.000				
	female	**-0.151**	-0.015	0.004	-0.012	-0.124	**-0.191**	-0.100	-0.126	-0.106	-0.001	1.000			
	married	-0.060	0.015	0.057	0.056	0.054	0.075	0.075	0.055	0.097	**-0.157**	**-0.189**	1.000		
	alone	0.056	0.044	0.064	0.088	-0.088	**-0.163**	**-0.160**	-0.088	**-0.202**	0.002	0.091	**-0.518**	1.000	
	education	**-0.164**	-0.003	-0.102	-0.083	-0.007	**0.134**	0.121	-0.007	0.126	**-0.381**	-0.024	0.032	0.073	1.000
Hip severity	prev hip op	-0.032	0.085	0.107	**0.127**	0.030	0.045	0.104	0.029	0.045	-0.070	**0.137**	-0.029	0.044	-0.072
	walk support	**0.164**	0.050	0.036	0.045	**0.287**	0.104	0.136	**0.286**	0.111	**0.162**	0.123	-0.038	-0.030	**-0.149**
	limp	0.038	0.067	-0.072	-0.055	**0.385**	**0.324**	**0.320**	**0.364**	**0.308**	-0.082	-0.075	0.052	-0.043	0.027
Preoperative	B-ADL	**-0.171**	-0.044	-0.046	-0.049	**-0.758**	**-0.420**	**-0.429**	**-0.758**	**-0.409**	**-0.138**	-0.018	0.021	-0.037	**0.155**
	I-ADL	-0.122	-0.023	-0.029	-0.022	**-0.621**	**-0.597**	**-0.549**	**-0.621**	**-0.518**	-0.112	-0.018	-0.007	0.113	0.108
	SA	**-0.164**	0.023	-0.037	-0.028	**-0.593**	**-0.454**	**-0.592**	**-0.593**	**-0.555**	**-0.155**	-0.107	0.097	0.054	0.076
	ASA PS	**0.593**	0.013	**0.173**	**0.157**	0.082	-0.036	0.004	0.082	-0.001	**0.208**	-0.090	-0.099	0.117	**-0.142**
Clinical management	cement type	**-0.158**	**-0.135**	-0.002	-0.048	-0.079	-0.007	0.084	-0.081	0.105	**-0.377**	0.047	0.112	-0.115	**0.199**
	anaesthesia	0.026	0.057	-0.069	-0.047	-0.032	-0.010	0.022	-0.031	0.007	-0.053	0.120	-0.002	-0.044	-0.001

Table 7-1a: Correlation matrix of the variables in Japan (continued overleaf)

		Hip severity			Preoperative				Clinical manage	
		hip op	support	limp	B-ADL	I-ADL	SA	ASA PS	cement	anaest
Comorbidity	ICED									
Complication	serious									
	minor									
	overall									
Change in:	B-ADL									
	I-ADL									
	SA									
Transformed change in:	B-ADL									
	SA									
Socio-demographic	age									
	female									
	married									
	alone									
	education									
Hip severity	prev hip op	1.000								
	walk support	**0.167**	1.000							
	limp	-0.018	**0.297**	1.000						
Preoperative	B-ADL	**-0.158**	**-0.433**	**-0.449**	1.000					
	I-ADL	**-0.195**	**-0.379**	**-0.405**	**0.779**	1.000				
	SA	**-0.205**	**-0.406**	**-0.387**	**0.723**	**0.840**	1.000			
	ASA PS	-0.031	0.178	0.090	**-0.152**	-0.100	-0.111	1.000		
Clinical management	cement type	-0.010	-0.140	-0.018	**0.202**	0.160	0.086	**-0.184**	1.000	
	anaesthesia	0.001	0.036	-0.005	0.026	0.001	-0.020	0.101	-0.034	1.000

Table 7-1a: Correlation matrix of the variables in Japan (continued)

			Complication			Change in:			Transformed		Sociodemographic				
		ICED	serious	minor	overall	B-ADL	I-ADL	SA	B-ADL	SA	age	female	married	alone	educatio
Comorbidity	ICED	1.000													
Complication	serious	**0.139**	1.000												
	minor	0.114	0.0495	1.000											
	overall	**0.167**	**0.662**	**0.694**	1.000										
Change in:	B-ADL	-0.092	0.008	-0.057	-0.037	1.000									
	I-ADL	**-0.145**	-0.075	-0.037	-0.065	**0.729**	1.000								
	SA	-0.104	-0.048	-0.090	-0.102	**0.642**	**0.685**	1.000							
Transformed change in:	B-ADL	-0.089	0.007	-0.059	-0.039	+	**0.729**	**0.641**	1.000						
	SA	-0.104	-0.061	-0.115	-0.124	**0.613**	**0.663**	+	**0.612**	1.000					
Socio-demographic	age	**0.355**	0.013	0.097	0.073	0.014	-0.114	0.051	0.016	0.040	1.000				
	female	0.013	-0.023	0.024	-0.010	0.069	-0.020	0.045	0.069	0.059	0.049	1.000			
	married	-0.074	0.013	0.021	0.006	0.041	**0.170**	0.019	0.038	0.030	**-0.218**	**-0.288**	1.000		
	alone	0.110	0.016	-0.019	0.005	0.010	**-0.155**	0.019	0.014	0.001	**0.334**	**0.281**	**-0.847**	1.000	
	education	-0.112	-0.009	**-0.172**	**-0.131**	-0.080	-0.045	-0.083	-0.080	-0.048	**-0.295**	-0.023	0.048	-0.089	1.000
Hip severity	prev hip op	-0.116	-0.058	0.002	-0.051	-0.080	-0.024	-0.044	-0.082	-0.058	**0.143**	-0.060	-0.045	0.056	**0.160**
	walk support	0.107	-0.078	0.045	-0.025	**0.185**	0.057	0.050	**0.184**	-0.009	0.116	0.100	-0.041	0.090	-0.065
	limp	-0.082	-0.004	-0.025	-0.004	**0.453**	**0.330**	**0.271**	**0.453**	**0.228**	-0.074	0.098	0.048	-0.038	0.011
Preoperative	B-ADL	-0.046	0.033	-0.113	-0.031	**-0.646**	**-0.299**	**-0.327**	**-0.644**	**-0.289**	-0.111	-0.100	-0.013	-0.080	**0.179**
	I-ADL	-0.049	0.077	-0.103	-0.003	**-0.437**	**-0.403**	**-0.294**	**-0.436**	**-0.249**	-0.063	**-0.133**	-0.070	0.015	0.106
	SA	**-0.132**	0.056	-0.085	0.027	**-0.377**	**-0.230**	**-0.516**	**-0.376**	**-0.433**	**-0.202**	**-0.146**	0.108	**-0.171**	**0.129**
Clinical management	cement type	**-0.274**	-0.110	-0.094	**-0.134**	-0.034	0.045	-0.038	-0.037	-0.025	**-0.694**	-0.046	0.115	**-0.176**	**0.283**
	ant approach	0.040	**0.145**	-0.083	0.034	-0.003	0.025	0.047	-0.004	0.067	0.057	0.080	-0.066	0.054	-0.086
	anaesthesia	0.020	-0.080	-0.072	-0.053	0.094	0.077	0.080	0.094	0.122	0.145	0.005	-0.103	0.129	-0.081

Table 7-1b: Correlation matrix of the variables in the UK (continued overleaf)

		Hip severity			Preoperative			Clinical management		
		hip op	support	limp	B-ADL	I-ADL	SA	cement	ant apprc	anaest
Comorbidity	ICED									
Complication	serious									
	minor									
	overall									
Change in:	B-ADL									
	I-ADL									
	SA									
Transformed change in:	B-ADL									
	SA									
Socio-demographic	age									
	female									
	married									
	alone									
	education									
Hip severity	prev hip op	1.000								
	walk support	0.038	1.000							
	limp	-0.035	**0.317**	1.000						
Preoperative	B-ADL	**0.125**	**-0.364**	**-0.510**	1.000					
	I-ADL	0.109	**-0.450**	**-0.489**	**0.742**	1.000				
	SA	0.071	**-0.405**	**-0.397**	**0.675**	**0.739**	1.000			
Clinical management	cement type	**0.142**	-0.092	0.058	0.088	0.061	**0.163**	1.000		
	ant approach	0.085	0.005	-0.014	0.058	0.027	0.062	**-0.150**	1.000	
	anaesthesia	0.013	-0.020	**-0.153**	0.031	-0.003	-0.013	-0.016	0.103	1.000

Table 7-1b: Correlation matrix of the variables in the UK (continued)

1. In-hospital complications

1-1. Regression models for Japan and for the UK

In order to see which patient variables were confounding the possible effect of comorbidity (measured by the ICED) on the in-hospital complication rate, a logistic regression model was developed. Each level of the ICED was treated as a dummy variable, using level 1 as a reference category. Potential predictor variables identified by bivariate analyses were further examined by forward stepwise selection with the likelihood-ratio criterion of $p<0.05$.

In the UK, the only variable with a significant association with serious complications was surgical approach and the only one associated with minor complications was the patient's education level. In Japan, only a past history of hip surgery was significantly related to overall complications. The possible impact of confounding between the ICED and outcome was explored for the following dependent variables: serious complications and minor complications in the UK and overall complications in Japan.

Table 7-1c shows the estimates of the logistic model. In the UK, higher levels of the ICED were significant predictors of serious complications but not of minor complications. Odds ratios of ICED levels 3 and 4 for serious complications were similar, reflecting the dichotomous nature of the ICED in the UK. Surgical approach was a significant variable in the equation for serious complications, with similar predictive power to the higher levels of the ICED. Education level was a significant predictor for minor complications. Patients who completed their education at an age of 16 years or older were less likely to have a complication than those completing their education at a younger age.

. In Japan, only the highest level of the ICED was a significant independent predictor of overall complications. The odds ratio of ICED level 4 was significantly high, suggesting a threshold effect at this highest level. Patients who had previous hip operations were twice as more likely as those who had not.

Table 7-1c: Prediction of in-hospital complications from ICED

Variable* (Number of cases analysed)	Unstandardised Regression Estimates	Standard Error of Estimate	Odds Ratio (95% Confidence Interval)
UK			
Serious complication (248)			
Constant	-2.11	0.39	-
ICED level 2	-0.04	0.51	0.97 (0.35-2.61)
ICED level 3	0.94	0.48	2.56 (1.00-6.56)[a]
ICED level 4	1.03	0.50	2.79 (1.05-7.46)[a]
Anterior approach	0.77	0.35	2.16 (1.09-4.29)[a]
Minor complication (258)			
Constant	-1.42	0.36	-
ICED level 2	0.30	0.45	1.34 (0.55-3.27)
ICED level 3	0.73	0.45	2.07 (0.85-5.03)
ICED level 4	0.56	0.48	1.75 (0.68-4.52)
Education (≥16 yrs)	-1.06	0.38	0.35 (0.17-0.73)[b]
JAPAN			
Overall complication (249)			
Constant	-1.46	0.26	-
ICED level 2	0.16	0.33	1.17 (0.61-2.24)
ICED level 3	0.10	0.50	1.10 (0.41-2.94)
ICED level 4	2.28	0.88	9.81 (1.74-54.86)[b]
Previous hip surgery	0.73	0.35	2.08 (1.05-4.12)[a]

*: Each level of ICED was treated as a dummy variable, using level 1 as the reference; education level by the age of completion dichotomised <16 or ≥16 years.

a: $p<0.05$, b: $p<0.01$.

The association between the ICED and serious complications in the UK was more significant when it was dichotomised level 1+2 or 3+4 (Table 7-1d). This was not so for minor complications in the UK, or for overall complications in Japan.

Table 7-1d: Prediction of serious complication from dichotomised ICED adjusting for surgical approach (UK)

Variable* (N=248)	Unstandardised Regression Estimates	Standard Error of Estimate	Odds Ratio (95% Confidence Interval)
Constant	-2.13	0.28	-
ICED level 3+4	1.00	0.33	2.71 (1.42-5.19)[a]
Anterior approach	0.77	0.35	2.15 (1.09-4.29)[b]

*: ICED levels were dichotomised level 1+2 or level 3+4. Level 1+2 was used as the reference.
a: $p<0.005$, b: $p<0.05$.

The adequacies of the resulting models shown in Tables 7-1c and 7-1d were examined using residual analysis as a diagnostic statistic. When the normal probability of the deviances was examined, the distribution was not normal in all the regression models, suggesting the models did not fit the data well. Figure 7-1a (Appendix 8) shows the plots of deviances from the regression model for serious complications in the UK, in which each of the four levels of the ICED was treated as a dummy variable using level 1 as the reference as shown in Table 7-1c. The distribution of deviances was interrupted in the middle and looked almost like two parallel lines (Fig 7-1a). When the ICED was dichotomised as shown in Table 7-1d, the result was similar (Fig 7-1b). Other models also showed non-normal distributions of deviances.

1-2. UK/Japan combined model

In order to examine the influence of nationality (differences between the Japanese and British experiences), data from the two countries were combined to form a single database. ICED was entered using level 1 as the reference category. Nationality was included as a proxy of the known and unknown differences in patient's characteristics and clinical management between the two countries. Each nationality was treated as a dummy variable, using Japan as the reference. Stepwise selection of other possible explanatory variables suggested that nationality could be a significant predictor only of minor complications (Table 7-1e). Other variables such as patient characteristics (age, sex, marital status, living alone) and severity of hip disease (previous hip surgery, preoperative limp/walking support) were not significant predictors, but education level was. Patients who completed their education earlier were more likely to experience minor complications whereas those who went on to higher education were less likely to have a complication (serious or minor).

Table 7-1e: Logistic regression for in-hospital complication (all cases)

Variable*	Unstandardised Regression Estimates	Standard Error of Estimate	Odds Ratio (95% Confidence Interval)
Serious complication (N=517)			
Constant	-1.57	0.23	-
ICED level 2	0.23	0.28	1.26 (0.73-2.18)
ICED level 3	0.75	0.32	2.11 (1.13-3.96)[a]
ICED level 4	1.03	0.37	2.80 (1.36-5.78)[a]
Nation-UK	-0.35	0.24	0.70 (0.44-1.13)
Minor complication (N=499)			
Constant	-1.07	0.30	-
ICED level 2	0.28	0.28	1.32 (0.76-2.28)
ICED level 3	0.64	0.33	1.90 (1.00-3.60)
ICED level 4	0.79	0.38	2.21 (1.05-4.63)
Nation-UK	-0.47	0.26	0.62 (0.38-1.03)[a]
Education (≥16 yrs)	-0.69	0.25	0.50 (0.31-0.81)[b]
Overall complication (N=499)			
Constant	-1.19	0.21	-
ICED level 2	0.13	0.25	1.14 (0.69-1.81)
ICED level 3	0.56	0.29	1.74 (1.08-3.29)
ICED level 4	0.80	0.36	2.24 (1.25-4.55)[a]
Nation-UK	0.33	0.21	1.39 (0.77-1.87)
Education (≥19 yrs)	-0.66	0.33	0.52 (0.48-1.11)[a]

*: Each education level was treated as a dummy variable, by completion of age (≤15 years, 16 - 18 years, ≥19 years). Each nation was treated as a dummy variable, using the Japanese as the reference category.

a: $p<0.05$, b: $p<0.01$

1-3. Summary of regression models for in-hospital complications

Higher levels of the ICED were significant independent predictors of serious complications in the UK. A dichotomous pattern was identified which was also apparent when the four levels of the ICED were grouped into lower and higher levels. In contrast, in a logistic regression model for overall complications in Japan, the highest level of the ICED was the only level of comorbidity with a significantly high odds ratio. In the UK, surgical approach was a significant independent predictor for serious complications, and education level was for minor complications. In Japan, a past history of hip surgery was a significant variable for overall complications. Residual analyses, however, suggested the model did not fit the data well.

In a combined model including all cases in Japan and the UK, higher levels of the ICED were significant predictors for serious complications and the highest level was significant for overall complications. Nationality was a significant predictor for minor complications - British patients were less likely to suffer a minor complications. Irrespective to their nationality, patient's education level was a significant predictor of minor and overall complications.

2. Change in health status

2-1. Model building based on bivariate findings

Change in health status was almost normally distributed for instrumental ADL but not for basic ADL and social activity (Figures 7-2a to 7-2f in Appendix 8). As basic ADL scores were almost multiples of 11, the data were transformed by dividing by 11 and rounding to integer values. After this transformation, basic ADL became near-normally distributed

(Figures 7-2g and 7-2h in Appendix 8). Change in social activity was grouped into four categories: much improved; somewhat improved; little or no change; worse. As all three dimensions of preoperative health status were also not normally distributed (data not shown), basic ADL and social activity were both grouped into four categories and instrumental ADL into six categories. Possible confounding variables were chosen from those already known to be significantly associated with change in health status as reported in Chapter 6, and further selected by log linear test (significance level: $p<0.05$). Preoperative limp and need for walking support were treated as a dummy variable, using the least severe level (no need for walking support / no limp) as the reference. Table 7-2a shows the model that best explained the variance in change in health status in Japan and in the UK.

In general, less than a half of the total variance in change in health status was explained by these variables. Change in health status was explained more in the Japanese model than in the British model in all three dimensions, particularly in instrumental ADL and social activity. Basic ADL was best explained in both countries. In each equation, preoperative health status had the greatest explanatory power with little contribution observed from comorbidity (measured by the ICED), sociodemographic factors (sex and education level), and preoperative severity of hip disease (need for walking support and limp).

Table 7-2a: Percentage of total variance explained in the regression model for change in health status in Japan and the UK: explanatory variables chosen from bivariate analyses

Health status	JAPAN	UK	
Variables*	% Variance explained	Variables*	% Variance explained
Basic ADL			
ICED	1.8	ICED	1.8
Preoperative B-ADL	46.1	Preoperative B-ADL	35.3
Walking support	2.0	Limp	1.9
Total	49.9	Total	39.0
Instrumental ADL			
ICED	0.8	ICED	1.9
Preoperative I-ADL	23.7	Preoperative I-ADL	6.5
Female/Education	5.8	Limp	4.3
Total	30.3	Total	12.7
Social activity			
ICED	1.3	ICED	1.4
Preoperative SA	19.9	Preoperative SA	8.9
Total	21.2	Total	10.3

*: Each level of ICED was treated as a dummy variable, using level 1 as the reference. B-ADL indicates basic ADL; I-ADL, instrumental ADL; SA, social activity. Limp indicates the patient's perception of preoperative limp.

Tables 7-2b and 7-2c show the explanatory power and the significance of independent variables used in the equations shown in Table 7-2a. In all dimensions, preoperative health status was a significant predictor. Also, patient's need for walking support, sex, and education level in Japan and preoperative limp in the UK were significant variables for some dimensions of health status. The ICED was not a significant predictor for any dimensions, and change in all three dimensions of health status were more strongly dependent on the preoperative level of health status.

Table 7-2b: Regression analysis of change in health status in Japan: explanatory variables chosen from bivariate analyses

Explanatory variables*	Regression unstandardised estimates	Standard error of estimate	Beta	t	Probability
Basic ADL					
Constant	8.64	0.55	-	-	
ICED level 2	0.10	0.25	0.02	0.40	0.6928
level 3	0.41	0.38	0.05	1.05	0.2932
level 4	-0.16	0.71	-0.01	-0.23	0.8202
Preoperative B-ADL	-2.10	0.15	-0.73	-13.77	**<0.0001**
Walking support					
-Single cane	-0.58	0.27	-0.12	-2.13	**0.0342**
-Two canes	-0.21	0.47	-0.02	-0.43	0.6646
-Walker	-1.49	0.77	-0.10	-1.93	0.0552
-Wheelchair	0.95	0.68	0.07	1.39	0.1649
Instrumental ADL					
Constant	72.46	7.14	-	-	
ICED level 2	-3.23	3.64	-0.05	-0.89	0.3755
level 3	-4.47	5.60	-0.05	-0.80	0.4253
level 4	10.56	10.61	0.06	1.00	0.3203
Preoperative I-ADL	-9.97	1.08	-0.53	-9.21	**<0.0001**
Female	-18.14	4.49	-0.23	-4.04	**0.0001**
Education (≥16 yrs)	9.61	4.21	0.13	2.28	**0.0236**
Social activity					
Constant	3.74	0.16	-	-	
ICED level 2	-0.08	0.12	-0.05	-0.69	0.4918
level 3	0.20	0.19	0.07	1.06	0.2896
level 4	-0.10	0.38	-0.02	-0.25	0.8020
Preoperative SA	-0.46	0.06	-0.45	-7.28	**<0.0001**

*: Each level of ICED was treated as a dummy variable, using level 1 as the reference. Education level was dichotomised <16 years or ≥16 years, by completion of age . B-ADL indicates basic ADL; I-ADL, instrumental ADL; SA, social activity.

Table 7-2c: Regression analysis of change in health status in the UK: explanatory variables chosen from bivariate analyses

Explanatory variables*	Regression unstandardised estimates	Standard error of estimate	Beta	t	Probability
Basic ADL					
Constant	5.79	0.90	-	-	
ICED level 2	0.36	0.28	0.08	1.26	0.2075
level 3	-0.31	0.30	-0.06	-1.01	0.3106
level 4	-0.43	0.32	-0.08	-1.34	0.1827
Preoperative B-ADL	-1.55	0.18	-0.49	-8.47	**<0.0001**
Limp -Slight	0.01	0.68	0.00	0.01	0.9887
-Moderate	0.58	0.63	0.12	0.92	0.3600
-Severe	1.16	0.63	0.27	1.84	0.0672
-Unable to walk	1.60	0.77	0.19	2.09	**0.0375**
Instrumental ADL					
Constant	26.66	11.02	-	-	
ICED level 2	0.99	4.59	0.02	0.22	0.8297
level 3	-8.88	4.90	-0.14	-1.81	0.0713
level 4	-7.88	5.22	-0.11	-1.51	0.1328
Preoperative I-ADL	-2.91	1.28	-0.16	-2.27	**0.0241**
Limp -Slight	5.14	11.15	0.05	0.46	0.6450
-Moderate	12.00	9.99	0.19	1.20	0.2309
-Severe	22.94	9.81	0.40	2.34	**0.0202**
-Unable to walk	27.19	11.88	0.24	2.29	**0.0230**
Social activity					
Constant	3.48	0.16	-	-	
ICED level 2	0.12	0.14	0.07	0.84	0.4026
level 3	-0.10	0.15	-0.05	-0.64	0.5253
level 4	-0.32	0.17	-0.15	-1.95	0.0531
Preoperative SA	-0.27	0.06	-0.30	-4.66	**<0.0001**

*: B-ADL indicates basic ADL; I-ADL, instrumental ADL; SA, social activity. Limp indicates the patient's perception of preoperative limp. Each level of ICED was treated as a dummy variable, using level 1 as the reference.

The regression models based on the findings from bivariate analyses (shown in Table 7-2a) were examined by residual analyses to check for violations of assumptions.
Figures 7-2i and 7-2j (Appendix 8) show the plot of studentised residuals against the predicted values for the change in instrumental ADL and social activity in Japan. The residuals were almost randomly distributed in instrumental ADL. but they were aggregated in social activity. In the UK, the distribution of residuals were similar to Japan in all three dimensions of health status and Figures 7-2k and 7-2l (Appendix 8) show the plots for instrumental ADL and social activity. The plot for the change in basic ADL was similar to that for social activity in both countries (data not shown).

As the assumption of homogeneity of variance was thought not to be met for change in social activity, the observed distribution of residuals was compared to that expected under the assumption of normality. When the two cumulative distributions were plotted against each other for a series of points, the plot for instrumental ADL was almost linear (Fig 7-2m in Appendix 8) whereas for social activity in Japan was non linear (Fig 7-2n in Appendix 8). The results were similar for the UK data (Figures 7-2o and 7-2p in Appendix 8).

2-2. Equation based on fixed combination of variables

Relevant variables were selected from the literature review to form a fixed combination of explanatory variables to see how much of the total variance in Japan and the UK were explained (Table 7-2d). In addition to comorbidity (measured by the ICED) and preoperative health status, variables used in the equation were patient's sociodemographics (age, sex, marital status, living alone, education level) and preoperative severity of hip disease (previous hip surgery, limp and need for walking support). Change in basic ADL and social activity and preoperative health status in all three dimensions were transformed as described in the preceding section.

Similar to the results derived from models based on bivariate analyses based-models shown in Table 7-2a, change in health status was explained better in Japan than it was in the UK in all three dimensions. In both countries change in basic ADL was best explained. Inclusion of preoperative health status explained most of the variance in all dimensions. The increase in explanatory power for instrumental ADL and social activity was almost doubled in Japan compared with the UK. Comorbidity, sociodemographics and severity of hip disease contributed little to explaining the variance in change in health status.

On the whole, the explanatory power of the models based on a fixed combination of variables was similar to or only slightly better than the regression models based on bivariate analyses, despite using a greater variety of possible explanatory variables.

Table 7-2d: Variance in change in health status explained by fixed equation

JAPAN	Variance explained, %		
Variable*	Basic ADL	Instrumental ADL	Social activity
Comorbidity by ICED	1.8	0.8	1.3
Preoperative health status	46.1	23.7	19.9
Sociodemographic	4.1	9.3	6.9
Severity of hip disease	1.1	0.7	1.1
Total	53.1	34.5	29.2

UK	Variance explained, %		
Variable*	Basic ADL	Instrumental ADL	Social activity
Comorbidity by ICED	1.8	1.9	1.4
Preoperative health status	35.3	6.5	8.9
Sociodemographic	0.7	1.7	2.0
Severity of hip disease	2.7	4.5	2.7
Total	40.5	14.6	15.0

*: Patient sociodemographic characteristics were; age (dichotomised to below 67 years and 67 and above), sex, marital status, living alone, education. Severity of hip disease was measured by previous hip surgery, preoperative limp and need for walking support. Each level of ICED was treated as a dummy variable, using level 1 as the reference.

2-3. Exchanging models between Japan and the UK

In order to see which complication was most influenced by differences between the Japanese and British experiences, data from the two countries were combined to form a single database. Nationality was included as a proxy of the known and unknown differences in patient's characteristics and clinical management between the two countries, using the Japanese as the reference. Significant predictive variables were selected by stepwise selection to enter into a regression model based on the primary equation containing the ICED and preoperative health status.

Similar to the national models shown in Table 7-2a, preoperative health status was significant in all three dimensions of health status (Table 7-2e). Also sociodemographics and severity of hip disease were significantly associated with change in all three dimensions of health status. The ICED was not a significant predictor in any dimensions. Nationality was found to be weakly associated with basic ADL but not significant. The amount of total variance explained was 44.6% for basic ADL, 20.1% for instrumental ADL, and 20.1% for social activity.

Table 7-2e: Regression model for change in health status in all cases

Variables*	Regression unstandardised estimates	Standard error of estimate	Beta	t	Probability
Basic ADL					
Constant	6.68	0.67	-	-	
ICED level 2	0.21	0.19	0.04	1.11	0.2652
level 3	-0.21	0.23	-0.03	-0.90	0.3715
level 4	-0.36	0.28	-0.05	-1.29	0.1972
Preoperative B-ADL	-1.77	0.11	-0.59	-15.43	**<0.0001**
Nationality-UK	-0.34	0.17	-0.07	-1.92	0.0553
Slight limp	0.36	0.53	0.06	0.67	0.5037
Moderate limp	1.19	0.52	0.25	2.28	**0.0232**
Severe limp	0.65	0.52	0.14	1.25	0.2117
Unable to walk	1.37	0.59	0.16	2.31	**0.0211**

Variables*	Regression unstandardised estimates	Standard error of estimate	Beta	t	Probability
Instrumental ADL					
Constant	47.84	9.72	-	-	
ICED level 2	-1.05	2.89	-0.02	-0.36	0.7159
level 3	-6.60	3.64	-0.09	-1.81	0.0705
level 4	-5.24	4.45	-0.06	-1.18	0.2392
Preoperative I-ADL	-6.89	0.95	-0.37	-7.26	**<0.0001**
Nationality-UK	-0.76	2.79	-0.01	-0.27	0.7861
Female	-8.98	2.83	-0.14	-3.17	**0.0016**
Single cane/crutch	-4.63	2.99	-0.08	-1.55	0.1216
Two canes/crutches	-4.66	4.57	-0.05	-1.02	0.3090
Walker	-14.49	7.79	-0.08	-1.86	0.0636
Wheelchair	-15.45	6.18	-0.13	-2.50	**0.0127**
Slight limp	10.07	8.23	0.13	1.22	0.2220
Moderate limp	16.25	7.93	0.27	2.05	**0.0410**
Severe limp	23.74	8.00	0.39	2.97	**0.0032**
Unable to walk	29.84	9.28	0.27	3.22	**0.0014**
Social activity					
Constant	3.00	0.29	-	-	
ICED level 2	0.01	0.09	0.01	0.13	0.8957
level 3	-0.03	0.12	-0.01	-0.22	0.8282
level 4	-0.27	0.14	-0.09	-1.87	0.0622
Preoperative SA	-0.34	0.04	-0.37	-7.65	**<0.0001**
Nationality-UK	0.05	0.09	0.03	-0.51	0.6135
Single cane/crutch	-0.01	0.10	-0.01	-0.10	0.9174
Two canes/crutches	-0.10	0.14	-0.04	-0.69	0.4883
Walker	-0.16	0.28	-0.03	-0.58	0.5597
Wheelchair	-0.49	0.19	-0.14	-2.63	**0.0087**
Slight limp	0.28	0.27	0.11	1.02	0.3087
Moderate limp	0.64	0.26	0.35	2.44	**0.0153**
Severe limp	0.74	0.27	0.40	2.78	**0.0057**
Unable to walk	0.82	9.30	0.24	2.68	**0.0076**

* B-ADL indicates basic ADL; I-ADL, instrumental ADL; SA, social activity.

Patient's nationality was treated as a dummy variable, using the Japanese as the reference category. Each level of ICED was treated as a dummy, using level 1 as the reference.

2-4. Summary of regression models for change in health status

Variance in change in health status was mostly explained by preoperative health status, and little by the ICED and other patient variables. Among three dimensions of health status, basic ADL was best explained in both countries. Although the proportion of total variance explained was greater in Japan than in the UK, the ICED was not a significant predictor of any dimensions of health status in both countries. The degree of variance explained with selected variables was similar to that when all possible patient variables were included in the regression model.

The regression model for combined British and Japanese cases also confirmed the findings from each national model, in that preoperative health status was the most significant predictor of change in health status. Difference in nationality was not significant in prediction of change in any dimensions of health status.

3. Attempts to improve prediction for serious in-hospital complications

3-1. Change in criteria of complications

In previous chapters the inclusion criteria for serious in-hospital complications have been challenged. In particular the inclusion of dislocation as a minor complication and neuropathy as a serious complication are questionable. Therefore, an attempt was made to change the definition of serious complications by excluding neuropathy and including dislocation. Table 7-3a shows the relationship between the ICED and the newly defined serious complications.

Table 7-3a: Number and percent of patients with a serious in-hospital complication classified by the ICED in Japan and the UK: comparison of original and new criteria (NS: not significant at p<0.05)

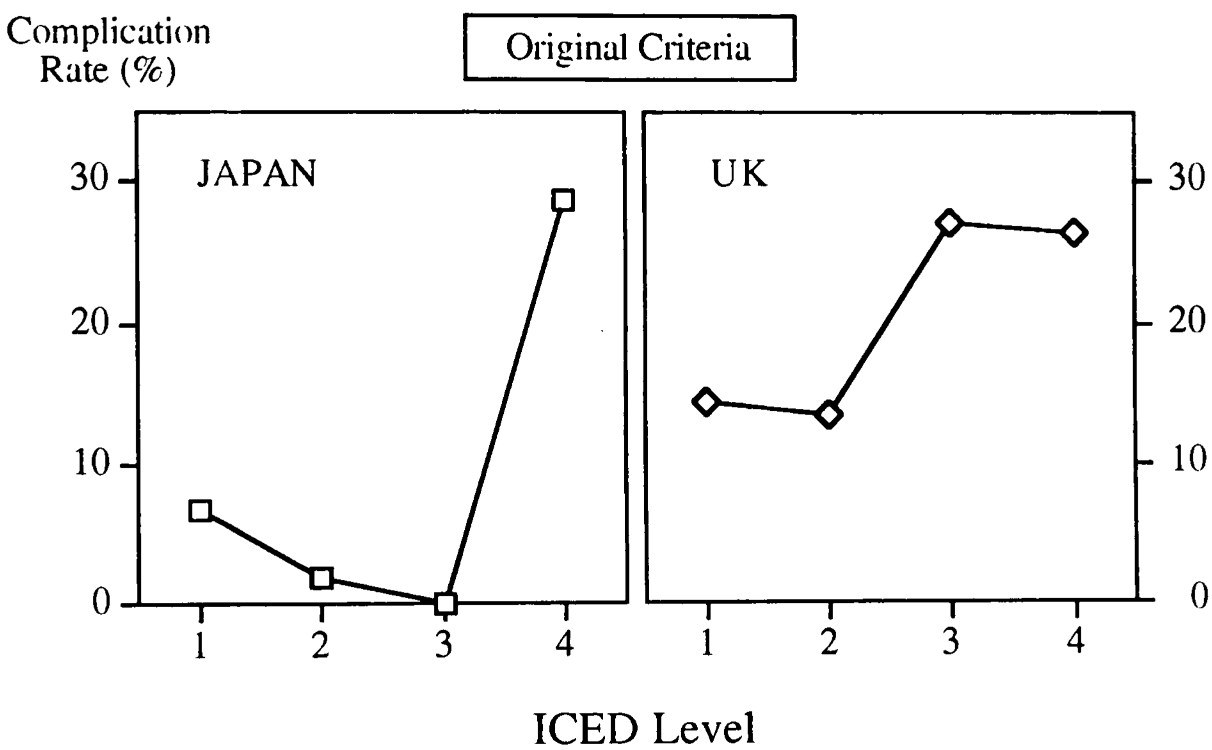
Criteria of serious complication*	Levels of the ICED	Number (%) of patients with complication JAPAN N=249	UK N=268
Original	1	7 (6.7)	10 (14.3)
	2	2 (1.9)	11 (13.4)
	3	0 (0.0)	17 (27.0)
	4	2 (28.6)	14 (26.4)
Chi square for trend (df=1)		0.941	4.185
Probability		NS	**<0.05**
New	1	1 (1.0)	7 (10.0)
	2	2 (1.9)	11 (13.4)
	3	0 (0.0)	16 (25.4)
	4	2 (28.6)	14 (26.4)
Chi square for trend (df=1)		13.467	6.601
Probability		**<0.001**	**<0.05**

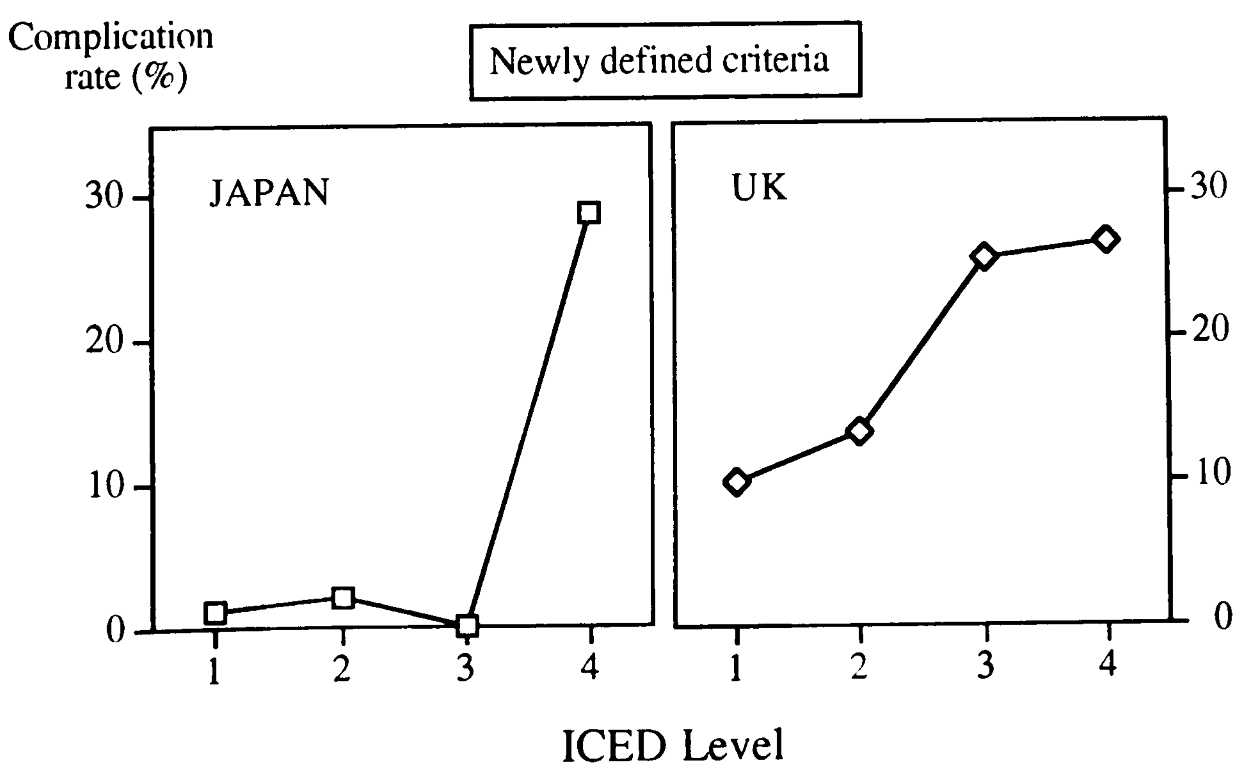
* New criteria of serious complication excludes neuropathy and includes dislocation.

The change in criteria reduced the number of patients with a serious complication from 11 to 5 in Japan, and from 52 to 48 in the UK. As a result, the complication rate became significantly associated with the ICED in Japan, and the level of significance in the UK slightly increased. No other variables were found to be significantly associated with this newly defined outcome. These included sociodemographic (age, sex, marital status, living alone, education), severity of hip disease (previous hip surgery, preoperative limp and need for walking support), and clinical management variables (surgical approach, hybrid THR, hospital, teaching status).

Figure 7-3a illustrates the relationship of the original and newly defined serious complication rate with the ICED. The previously observed threshold effect in Japan was enhanced by the reduction in complication rate in ICED level 1. In the UK, the dichotomous pattern was modified into more of an S-shaped curve.

Figure 7-3a: Serious in-hospital complication rate in Japan and the UK: defined by original / new criteria





In order to see how such change in criteria of outcome might effect the predictive power of the ICED, a logistic model was developed. Although surgical approach had been found to be a significant independent predictor with the ICED (Chapter 7), no variables were found to be significantly associated with the newly defined outcome.

Table 7-3b shows the results both for the original and the new criteria of serious complications. Higher levels of ICED were significant independent variables with increasing odds ratios, however, surgical approach became insignificant. This change in significance of surgical approach was also observed in the regression model for the new criteria of serious complications, in which the ICED was dichotomised to levels 1/2 or 3/4.

Table 7-3b: Prediction of serious complications of different criteria examined in logistic model with the four levels or dichotomised ICED (UK)

Criteria of serious complication* (N=248)	Unstandardised Regression Estimates	Standard Error of Estimate	Odds Ratio (95% Confidence Interval)
Original			
Constant	-2.11	0.39	-
ICED level 2	-0.04	0.51	0.97 (0.35-2.61)
ICED level 3	0.94	0.48	2.56 (1.00-6.56)[a]
ICED level 4	1.03	0.50	2.79 (1.05-7.46)[a]
Anterior approach	0.77	0.35	2.16 (1.09-4.29)[a]
New			
Constant	-2.36	0.44	-
ICED level 2	0.31	0.55	1.37 (0.47-4.01)
ICED level 3	1.20	0.52	3.31 (1.19-9.21)[a]
ICED level 4	1.35	0.54	3.87 (1.35-11.00)[a]
Anterior approach	0.50	0.37	1.65 (0.80-3.38)

Criteria of serious complication* (N=248)	Unstandardised Regression Estimates	Standard Error of Estimate	Odds Ratio (95% Confidence Interval)
Original			
Constant	-2.13	0.28	-
ICED level 3+4	1.00	0.33	2.71 (1.42-5.19)[b]
Anterior approach	0.77	0.35	2.15 (1.09-4.29)[a]
New			
Constant	-2.18	0.28	-
ICED level 3+4	1.08	0.34	2.96 (1.51-5.79)[b]
Anterior approach	0.50	0.37	2.65 (0.81-3.39)

*: New criteria of serious complication excludes neuropathy and includes dislocation. ICED levels were dichotomised level 1+2 or level 3+4. Level 1+2 was used as the reference.

a: $p<0.05$, b: $p<0.005$.

3-2. Change in the structure of the ICED

In Chapter 6 the lack of an association between the functional severity index of the ICED and in-hospital complications, both serious and minor, was demonstrated. Thus attempts to alter the ICED to improve its predictive power focused on the other subindex, that of co-existent disease (IDS).

Although the ICED takes the severity of each co-existent disease into account, the final severity score is the peak intensity of two or more diseases that a patient might have. Thus analyses of trend between complication rate and the severity level for each co-existent disease would not directly relate to the association of the final ICED score and complication rate. Also as co-existent disease scores were derived from the patients' case notes at the time of abstracting data, it was impossible to reclassify the level of severity of co-existent disease. Attempts were therefore made to identify which co-existent diseases were most predictive of serious complications, irrespective of their severity. These co-existent diseases could then be used to form a new index, taking the peak intensity score among them. This new index was examined in relation to the serious complication rate, using both the original and the new criteria described above.

The prevalence of co-existent diseases was shown previously (Table 5-3b). Tables 7-3c and 7-3d show the relationship between serious complications and each of the 13 co-existent diseases.

Table 7-3c: Prevalence of co-existent disease in patients suffering a serious complication (original criteria) in Japan

	Number (%) of patients		
Co-existent Disease	with complication N=11	without complication N=238	Probability (Chi square)
Organic heart disease	1 (9.1)	2 (0.8)	0.2989
Ischemic heart disease	0 (-)	16 (6.7)	0.7948
Arrhythmia	3 (27.3)	64 (26.9)	0.7491
Congestive heart disease	0 (-)	2 (0.8)	0.1550
Hypertension	1 (9.1)	66 (27.7)	0.3100
Cerebrovascular disease	0 (-)	5 (2.1)	0.5394
Peripheral vascular disease	0 (-)	1 (0.4)	**0.0262***
Diabetes mellitus	0 (-)	18 (7.6)	0.7252
Respiratory disease	0 (-)	10 (4.2)	0.9271
Malignancy	1 (9.1)	7 (2.9)	0.7977
Hepatobiliary disease	0 (-)	3 (1.3)	0.2989
Renal disease	2 (18.2)	8 (3.4)	0.0965
Gastrointestinal disease	1 (9.1)	5 (2.1)	0.6366

* 95% confidence interval was 0.0%-32.2% with complication and 0.0%-2.7% without complication.

Table 7-3d: Prevalence of co-existent disease in patients suffering a serious complication (original criteria) in the UK

Co-existent Disease	Number (%) of patients with complication N=52	Number (%) of patients without complication N=216	Probability (Chi square)
Organic heart disease	5 (9.6)	10 (4.6)	0.1603
Ischemic heart disease	5 (9.6)	29 (13.4)	0.4586
Arrhythmia	19 (36.5)	48 (22.2)	**0.0323**
Congestive heart disease	13 (25.0)	25 (11.6)	**0.0127**
Hypertension	19 (36.5)	82 (38.0)	0.8491
Cerebrovascular disease	1 (1.9)	6 (2.8)	0.8908
Peripheral vascular disease	7 (13.5)	26 (12.0)	0.7790
Diabetes mellitus	2 (3.8)	7 (3.2)	0.8328
Respiratory disease	1 (1.9)	17 (7.9)	0.2188
Malignancy	0 (-)	6 (2.8)	0.4880
Hepatobiliary disease	4 (7.7)	3 (1.4)	**0.0380**
Renal disease	6 (11.5)	17 (7.9)	0.3966
Gastrointestinal disease	8 (15.4)	26 (12.0)	0.5150

	95% confidence interval of proportion with complication	95% confidence interval of proportion without complication
Arrhythmia	36.5 (24.0 - 51.0)	22.2 (17.0 - 28.5)
Congestive heart disease	25.0 (14.5 - 39.2)	11.6 (7.8 - 16.8)
Hepatobiliary disease	7.7 (2.5 - 19.4)	1.4 (0.4 - 4.3)

Statistically significant associations were observed with peripheral vascular disease in Japan (based on only one case), and arrhythmia, congestive heart failure, and hepatobiliary disease in the UK. Because only one patient suffered from peripheral vascular disease in Japan, further analyses were limited to the UK data.

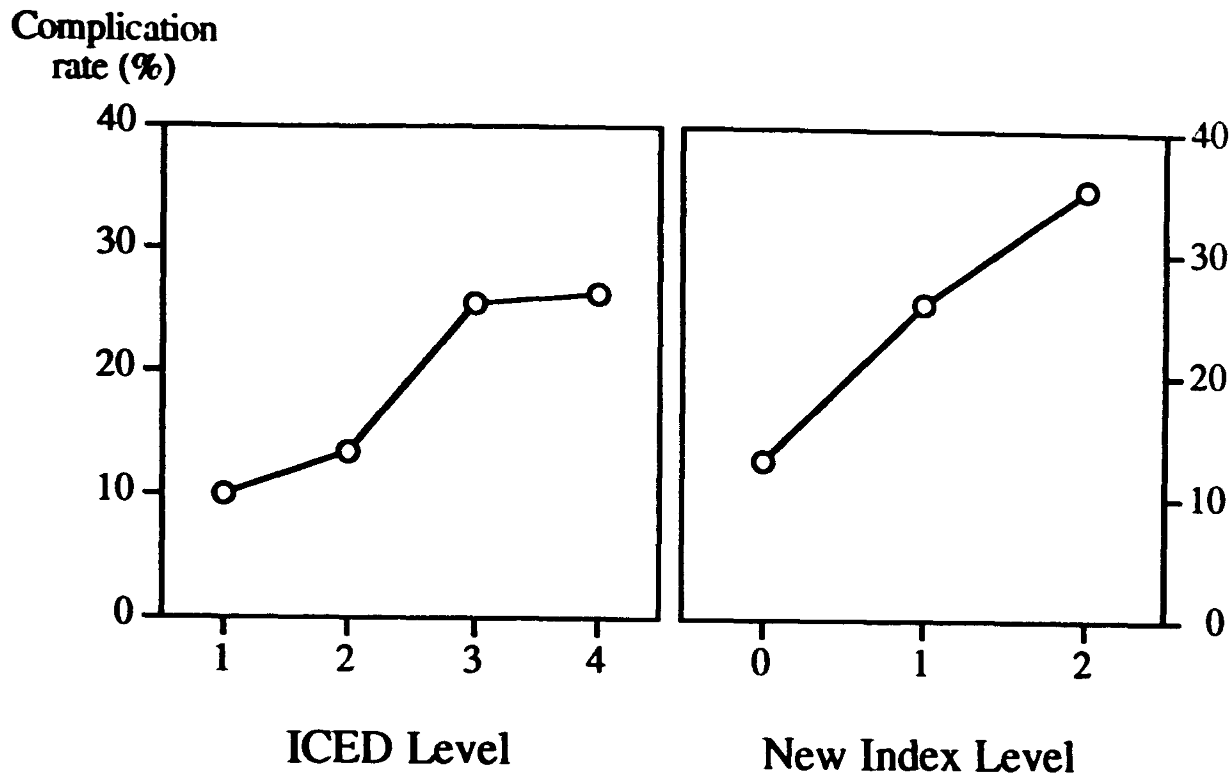
Using three significantly associated diseases, a final severity score was derived from the peak intensity among them, as described in the original method to define the ICED level (Chapter 2). As only one patient was classified at the new index level 3, it was combined with the data at level 2 so that the new index had three levels (0 to 2).

The relationships between serious complications in the UK (original criteria) and on the one hand the ICED, and the other hand the new index of co-existent disease are shown in Table 7-3e and Fig 7-3b. This new index was found to be more significantly associated with serious complications. Introduction of the new index also changed the dichotomous pattern previously observed with the ICED into an almost linear relationship. A similar association was observed when the new index was applied to serious complications defined using the new criteria described above (data not shown).

Table 7-3e: Number and percent of patients with serious in-hospital complications for the ICED and new index (UK)

Index	Levels of index	Number of patient	Number (%) of patient with complication	Chi square for trend	Probability
ICED	1	70	10 (14.3)	4.2	**<0.05**
	2	82	11 (13.4)		
	3	63	17 (27.0)		
	4	53	14 (26.4)		
New index	0	171	22 (12.9)	12.8	**<0.001**
	1	43	11 (25.6)		
	2	54	19 (35.2)		

Fig 7-3b: Relationship of serious coplication and comorbidity index (UK)



3-3 Predictive power of the new models

Finally, the prediction of serious complications was examined using the new index of comorbidity , taking level 0 as the reference (Table 7-3f). The highest level of the new index was a significant independent predictor of serious complications using the original criteria. Surgical approach became insignificant using the new index to predict serious complications using the new criteria. Using the new criteria of serious complications, both levels of the new index were significant predictors. As regards outcome prediction, however, only 5 complications out of the 49 that occurred were predicted using the original criteria, and none using the new criteria.

As a result, the prediction of serious complications seemed best when they were defined using the original criteria and the new co-existent disease index was employed. However, the improved prediction demonstrated in this study is of uncertain validity unless it can be reproduced in other independently collected data.

Table 7-3f: Prediction of serious complications of different criteria examined in logistic model with the new index (UK)

Criteria of serious complication* (N=248)	Unstandardised Regression Estimates	Standard Error of Estimate	Odds Ratio (95% Confidence Interval)
Original			
Constant	-2.21	0.28	-
New index level 1	0.83	0.45	2.29 (0.95-5.49)
New index level 2	1.49	0.39	4.43 (2.08-9.43)[a]
Anterior approach	0.90	0.36	2.47 (1.21-5.04)[b]
New			
Constant	-2.29	0.29	-
New index level 1	1.17	0.44	3.21 (1.34-7.67)[c]
New index level 2	1.54	0.39	4.67 (2.16-10.10)[a]
Anterior approach	0.61	0.38	1.83 (0.87-3.85)

*: New criteria of serious complication excludes neuropathy and includes dislocation.

a: $p<0.0005$, b: $p<0.05$, c: $p<0.01$.

3-4. Discussion of the predictive power of the regression models

3-4a. Prediction of serious complications in Japan

On the whole, the number of serious in-hospital complications (11) was too small to correlate with comorbidity. Apart from the complications observed in patients in ICED level 4, complications were as likely to arise by chance or at least without significant relevance to the level of comorbidity. Indeed, the majority of the complications were neuropathy and not related to a patient's physiological conditions. As a consequence, almost all complications defined using the new criteria were limited to patients with the highest ICED level, which therefore enhanced the threshold effect of the ICED.

3-4b. Prediction of serious complications in the UK

Prediction of serious complications was limited in all attempts in the UK because of the high complication rate observed in the lowest level of the ICED. In this study the significance of the relationship between the ICED and complications was examined in two ways; Chi square for trend and logistic regression analysis. Both analyses were based on the relative risk of complications at each level of comorbidity in comparison to the baseline level, ICED level 1. Although the statistical analyses suggested a significant association, the increase was marginal and not large enough for successful prediction. Similar difficulty was also observed in the relationship with change in health status. Although a significant trend was observed in the UK in which the higher levels of the ICED were associated with less improvement in health status, the change in health status measured at the ICED level 1 was often less than that at the level 2, suggesting poor classification of comorbidity at lower levels.

Such a lack of relationship between the ICED and outcomes in the UK may have arisen for two reasons: (1) inability of the ICED to reflect accurately a patient's comorbidity level, and (2) inadequacies in the preoperative observation of a patient's condition. Inability of the ICED can be seen in the large regression estimate by the constant in the regression model. For example, mean patients' age in the UK was older than in Japan and the USA, suggesting British patients had fewer physiological resources to assist recovery from the operation. Although patient's chronological age was not statistically significantly associated with the serious complication rate, there may be unknown variables that would explain the difference among patients classified in the same severity level.

As regards the second possibility, there are considerable differences the way clinicians practice between the three countries. In the UK, a patient's preoperative length of stay is much shorter than in Japan and the number of laboratory examination performed is much less than in the USA. As regards continuity of care, in theory it should be assured by good communication with the patient's GP through exchange of information. However, when compared with Japanese patients who are looked after by the same doctor throughout the episode of care and have plenty of opportunities to discuss the results of the preoperative examination, it might be difficult to reach a better understanding of a patient's preoperative status in the British system. Consequently some of the patient's information could be lost and, as a result, patients may be more likely to be classified to a lower level of the ICED.

4. Summary

In-hospital complications: Higher levels of the ICED were significant predictors for serious complications in the UK and overall complications in Japan. For all cases in Japan and the UK, comorbidity was a significant explanatory variable for serious and overall complications.

Change in health status: The ICED was not a significant predictor in Japan and the UK. For all cases in both countries, the ICED was not a significant predictor for change in health status. Nationality was not a significant predictor for change in any dimensions of health status.

Attempts to improve prediction: Prediction of serious in-hospital complications was improved by changes in the complication criteria, and by a new comorbidity index based on fewer number of more predictable co-existent diseases. A high complication rate at the lowest level of the ICED limited further improvement.

CHAPTER 8

CONCLUSIONS

- INDEX -

Chapter 8: Conclusions

To conclude this study, the seven original objectives are reviewed. For each objective, the methodological limitations are described and their possible impact discussed. Finally the implications of the results both for clinical practice and future research are considered.

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1. To compare preoperative health and clinical management of patients in Japan and in the UK, and between hospitals within the UK

1-1. Findings from this study

As regards patients' sociodemographics, Japanese patients were younger and more likely to be female, married, living with others, finished education at an older age and not smoke, than British patients. Hip disease was more severe in British patients in terms of a history of previous hip surgery and perception of limp, but not as striking a difference in terms of the need for a walking support. The mix of diagnoses of hip disease were similar.

Japanese patients were more likely to be classified to lower levels of severity of comorbidity than British patients. Arrhythmia and hypertension were common in both countries; organic and ischemic heart disease, congestive heart failure, peripheral vascular disease, renal disease, and gastrointestinal disease were commoner in the UK; and diabetes mellitus was commoner in Japan.

Japanese patients had significantly better health status as regards instrumental ADL but worse for mental health status. Health status was associated with patient's age and severity of hip disease in Japan, and with patient's sex, living alone and home ownership in the UK. No association was observed between health status and comorbidity (the ICED).

In terms of clinical management, general anaesthesia was commoner, the duration of surgery was less, and the anterior/anterolateral approach and blood transfusion were less frequently used in the UK than in Japan. Cement was used more often in the UK and in older patients.

Significant differences were found between the six British hospitals as regards patient's age, educational level, home ownership, primary diagnosis, past history of hip surgery, and comorbidity. There was no statistically significant difference in severity of hip disease. Patients in teaching hospitals only differed significantly from non-teaching in that they were more likely to have received higher education and undergone previous hip surgery. Use of general anaesthesia, surgical approach, transfusion and cement differed among the six hospitals, but not between teaching and non-teaching hospitals. The mean length of stay differed between the six UK hospitals, and was shorter in teaching hospitals.

1-2. Methodological limitations

Difference in routine data collection in hospitals between Japan and the UK meant that some patient's characteristics were not available for comparison such as body height and weight, ASA PS, and surgical approach. Even if data were available, its accuracy was sometimes uncertain such as drinking and smoking habits and preoperative clinical assessment of disease severity. In Japan, interhospital comparisons were impossible due to the small surgical volume in most hospitals.

The patient questionnaires used in the two countries were identical except for the questions on mental health (the Japanese version asked fewer questions). Due to differences in the financing of the health care systems, it was meaningless to compare lengths of stay and readmission rate between the two countries.

1-3. Discussion

Japanese patients were clearly healthier than British patients not only as regards the severity of their primary condition (hip disease) but also they suffered fewer co-existent diseases. This may partly reflect their being younger. This difference may be exaggerated by the longer life expectancy in Japan which might result in their age-specific health status being better (i.e., a 60 year old Japanese person being healthier than a Briton of the same age).

A second noteworthy difference between the two countries was the greater propensity for Japanese patients to use walking supports. For a given level of immobility (measured by the patient's own perception of limping) Japanese patients were more likely to use aids. Why might this be so given that Japanese patients were generally healthier than British patients? It could be because Japanese patients need to carry on everyday matters for themselves and have less access to motorised transport. However, these are inconsistent with the finding that Japanese patients are more likely to be living with others. An alternative explanation is that Japanese patients are more cautious about their health and welfare and more risk averse.

Another striking difference between the two countries was the tendency for Japanese patients to report worse mental health than the British. This may reflect the greater impact immobility has on their life-style leading to a higher likelihood of becoming depressed. Japanese patients may be less able and willing to complain of their disabilities and may delay seeking medical help. The likelihood that the etiology of their hip arthritis was congenital dislocation means they may have been suffering since childhood which might have harmed their mental health more than British patients who develop arthritis in middle and old age. Alternatively, the British patients response to their condition may reflect a general stoicism to ill-health and lower expectations.

Turning to clinical management, there is evidence of a more cautious approach in Japan which may again reflect a cultural difference in which the Japanese are more risk averse than British patients and surgeons.

Finally the significant differences between British hospitals in their case-mix has implications for inter-hospital comparative audit and for commissioning. Unless such differences are taken into account, both activities may be based on doubtful comparisons.

2. To describe the outcome of THR one year after surgery

2-1. Findings from this study

The known one year mortality was 0.3% in Japan and 1.1% in the UK, but both may be underestimated as some eligible patients were never traced. In total, about 25% of Japanese patients and 40% of British patients had some complication during their stay in hospital. In both countries serious in-hospital complications were less frequently observed than minor ones. Hypotension and neuropathy were the commonest serious complications, and wound infection was the most frequent among the minor complications.

In both countries there was a significant improvement in patient's health status after surgery. Such changes were observed not only in physical health but also in mental health. The severity of hip disease was significantly relieved in terms of patient's postoperative mobility. The severity of limping perceived by patients and their need for walking support were both significantly decreased. Patients reported their health had improved beyond their expectation and were happy to have had the operation. They were highly satisfied with the care they received during their stay in hospital though patients who suffered a postoperative dislocation were less satisfied.

2-2. Methodological limitations

Data collection on post-discharge mortality was not always possible in Japan because of the lack of continuity in data collection. Even in the UK where patient's data were organised continuously, the amount of information available from hospital computers and GPs was limited. Despite strenuous efforts, it was not possible to trace some cases. The small size of the two cohorts makes accurate assessment of postoperative mortality unreliable.

Although, in theory, clinical data were measured and recorded in a similar way in both countries, there was variation in the way the diagnosis of in-hospital complications were confirmed. Also, interhospital differences were observed in both countries in the way medical information was routinely recorded and categorised in the case notes.

The measurement of complication rates was obviously dependent on the definitions of serious and minor events. The inclusion of neuropathy as well as the exclusion of dislocation from serious complications could be challenged clinically.

Recruitment for the questionnaire study was successful in both countries with a high response rate and high degree of data completion. As has been noted, difficulty in implementing the same questions on mental health status impeded comparisons between Japan and the UK.

2-3. Discussion

Overall, THR is a highly successful operation for most patients. Improvements in disability were reflected in improvements in their quality of life and their level of satisfaction. This is partly because this study limited eligibility to primary THR patients, and excluded revision surgery and patients presenting with a femoral neck fracture who are more likely to experience an in-hospital complication or have a poorer postoperative recovery. Also the short follow-up period of one year provides only a limited account of the outcome of THR. A longer observation period might show some differences not found in this study.

A doctor's choice of diagnostic methods might add another complexity to the measurement of outcomes as well as comorbidity. The lack of universally agreed definitions of complications (particularly minor ones) makes the measurement of rates difficult and makes comparisons difficult to interpret. More precise instruction on the identification of complications is necessary when using the ICED to adjust for such outcomes.

3. To compare the outcome of THR in Japan and the UK

3-1. Findings from this study

As regards in-hospital complications, statistically significant differences were observed in their incidence between the two countries. The serious complication rate was higher in the UK than in Japan, whereas it was similar for minor complications. A variety of serious complications were observed in the UK, with a particularly high incidence of hypotension. In Japan, neuropathy was the most common serious complication. In contrast, similar types of minor complications were observed in both countries.

Dislocation and gastrointestinal symptoms were commoner in Japan whereas in the UK they were most often suspected deep vein thrombosis and bed sores.

As regards change in mobility/symptoms, British patients, who were more severely affected before surgery, reported significantly more persistent disability one year after. While surgery had little impact on patient's use of walking supports in Japan, significantly fewer British patients required such aids after surgery.

Change in health status showed a striking similarity between Japan and the UK. Particularly for mental health status Japanese patients reported more change than British.

The readmission rate was higher in the UK than in Japan. Significantly lower readmission rates were found in patients with previous hip surgery, hybrid THR and general anaesthesia in the UK.

In terms of global measures, Japanese patients were more likely to describe their health as better and better than they had expected. On the other hand, British patients were more likely to report the operation had made them feel better and to state that they were very happy about having had the operation. British patients were more likely to be satisfied with their care if they underwent general anaesthesia and were treated in a teaching hospital. No significant associations were found in Japan.

3-2. Methodological limitations

There were some difficulties experienced in collecting comparable data because of differences in definitions and measurement. For example, current case notes in both countries were useful sources of data on such aspects as preoperative examination, clinical management and in-hospital complications. However, some differences were observed in routine data recording between Japan and the UK. For example, recording of data on ASA PS, amount of blood lost, and information on the surgical approach differed between the two countries.

As regards comparison of outcomes in general, considerable differences in the length of the observation period (length of stay) was a major methodological limitation for making meaningful international comparisons. Length of stay in Japanese hospitals was almost four times as long as in British hospitals.

3-3. Discussion

Some of the observed differences in practice might have arisen from differences in the financial system of health services between the two countries. In Japan there are financial incentives to intervene whereas in the UK there were disincentives. Several differences would not, however, be effected by such differences in health service organisation.

First, the higher frequency of neuropathy in Japan and of hypotension in the UK. As was shown in a previous Chapter, none of the patient variables collected in this study were significantly associated with these serious complications. One possible explanation of neuropathy might be a difference in surgical skill. The significant difference in interhospital hypotension rates in the UK suggested the effect of postoperative clinical management was likely to be the cause. Although it was not possible to identify which aspect of patient care were responsible for such interhospital differences in outcome, a striking difference in hypotension rate between Japan and the UK suggested quality of postoperative care might be a possible reason.

Secondly, British patients were more likely to be readmitted if they had had no previous hip surgery, did not undergo a hybrid THR, and had their surgery under regional anaesthesia. The reason for the association with a lack of previous hip surgery is unclear. It may be that other patients who had previously experienced hip surgery were more careful during the convalescent period or had lower expectations and made less demand to be readmitted. The use of hybrid THR appeared to reflect clinical judgment rather than any objective patient characteristic. As such, it is possible that these clinicians who favoured hybrid THR were also less likely to readmit patients. Patients selected for regional anaesthesia were those at higher risk who are also more likely to suffer a complication. The finding suggests however the patient's severity of disease outweighed such differential anaesthetic effort to control their physiological status and to prevent higher readmission rate.

The third issue concerns the persistent postoperative disability observed in British patients in terms of their perception of limp. As an actual difference in leg length and decreased muscle strength due to long term hip arthritis are the major reasons of limp, less improvement in British patients than in the Japanese suggests their hip arthritis had been more severe and suffered over a longer period.

Fourth, surgery had less impact on the need for walking support in Japan than in the UK. This may reflect greater caution on the part of Japanese patients. Their housing could also be a reason, as the use of walkers and wheelchairs in Japan is not easy, even though their use may have been recommended by their surgeons.

The fifth issue centered on the greater improvement in mental health status in Japan than in the UK, though their postoperative score was still significantly worse than that of the British. Even when the analyses of British answers were limited to the same three questions as those asked to the Japanese, the change in mental health was less in British patients. This partly reflects the very poor mental health before surgery of Japanese patients which allowed for the possibility of greater improvement following surgery.

Finally, the Japanese had a lower expectation of surgery reflecting a lower expectation of invasive treatment generally. Their first preference is usually for non-surgical therapy. The national negligence of surgery is reflected in their lack of national statistics on the use of surgery. Surgical rates are generally believed to be substantially lower than in the

West, and the small number of patients collected from each Japanese hospital in this study supports such a belief. Thus, patients in this study might have been delighted by the improvement in their health which went beyond their expectations.

4. To assess the feasibility and reliability of a comorbidity measure developed in the USA (ICED)

4-1. Findings from this study

Measurement of comorbidity by the ICED was examined in terms of interrater and intrarater reliability. Interrater reliability was examined twice, with similar results. Lower agreement was observed with the subindex of co-existent disease (kappa 0.5) than with the functional severity subindex (kappa 0.64-0.97). Intrarater reliability was high for both subindices and the ICED.

4-2. Methodological limitations

Almost all disease and functional categories of the two subindices (co-existent disease severity and functional severity) required for the ICED had been recorded in the patients' case notes in both countries. However, the severity of comorbidity was not always described in the same way as it was defined in the ICED coding manual. The instructions did not cope adequately with the diversity in clinical observation and recording found.

Disagreement between raters arose from shortcomings in the organisation of case notes, differences in judgment by the raters, and limitations in the ICED protocol. Case notes in the UK were not maintained well and sometimes data were missing. Reporting bias by patients and health carers was a possible source of disagreement, as well as the way raters judged it. Finally the current instruction manual of the ICED coding was found not to be explicit enough in its clinical descriptions. Classification of the relative severity of conditions was not consistent throughout the 13 co-existent disease categories. For the functional severity subindex, some overlap with co-existent disease subindex was found. In addition, it was felt that more than 10 categories of function would have been beneficial. More detailed information was needed to meet the diversity in clinical observation and practice found in the case notes.

4-3. Discussion

Feasibility was limited by the availability of case notes, non-standardised recording of data, and missing data. In particular, how to deal with missing data should have been clearer. In current practice, if the respective data were missing, it was judged as no comorbidity. Thus, the less complete the recording of data, the lower the level of comorbidity will be, regardless of the actual level.

The reliability of use of the ICED was limited by the data limitations described above, interpretation by the raters, and the ICED instrument. All three raters who participated in this study were highly qualified and clinically trained. The results suggested that the training had little impact on the level of agreement between the raters. However, their supposedly advantageous clinical experience might have worked the other way by bringing in their own image of patients described in the case notes. In most studies of risk adjustment, data are collected by trained medical personnel but not usually by doctors, in which case the ICED might be more likely to be determined by instruction rather than the rater's interpretation.

5. To determine the effect of comorbidity on postoperative complications and health status one year after surgery both in Japan and the UK

5-1. Findings from this study

The ICED was not significantly associated with the rate of serious complications in Japan but was in the UK. The pattern of association suggested a threshold effect in Japan whereas it was dichotomous in the UK. In relation to minor complications, the ICED was significantly associated in Japan but not in the UK. The pattern of association with minor complications in Japan again suggested a threshold effect but there was no clear pattern in the UK. As regards association with the overall complication rate, the ICED was significantly associated in both countries. Similar patterns of association were observed to those for serious complications.

Change in health status was not significantly associated with the ICED in Japan, but in the UK there was a significant dichotomous pattern in which patients with less preoperative comorbidity reported slightly greater improvement in basic and instrumental ADL scores.

5-2. Methodological limitations

Major limitations in the analyses of serious in-hospital complications in Japan was the small number of episodes as outcome. The relatively high complication rate in the lowest level of the ICED in the UK was another limitation of this study, in which only marginal increase in complication rate had to be assessed in relation to comorbidity.

5-3. Discussion

The significant association with complications was in contrast with the less marked association with change in health status, suggesting the closer link between comorbidity and complications. This might be of particular importance when the primary disease is not life-threatening such as hip arthritis. In contrast, change in health status was mostly effected by the preoperative health status rather than the level of comorbidity.

The pattern of the association between comorbidity and complication rate was different between the countries: a threshold effect was observed in Japan, a dichotomous pattern in the UK. The ICED did not perform uniformly in Japan and the UK, as it had in the USA. In Japan, the small number of patients classified at the highest level of the ICED made analyses difficult. In the UK, the high complication rate observed in patients with low levels of comorbidity limited the relationship with the ICED. Redefining the criteria for serious complications successfully reduced the complication rate at the lowest level of the ICED and increased the odds ratios at the higher levels.

6. To identify factors confounding the relationship between comorbidity and outcome

6-1. Findings from this study

Higher levels of the ICED were significant predictors of serious complications in the UK and of overall complications in Japan. In the UK the serious complication rate was also associated with the surgical approach and minor complications were associated with educational level. In Japan, overall complications were associated with previous hip surgery. In fitting logistic regression models, these variables (surgical approach, educational level, and previous hip surgery) were found to be significant independent predictors of outcome.

The ICED was not a significant predictor of change in health status either in Japan or the UK. Patient's sex, educational level and preoperative need for walking support were significantly associated with change in health status in Japan whereas preoperative severity of limp was associated in the UK. When all patients from both countries were combined, the ICED was not a significant predictor of change in any dimensions of health status. Nationality was not a significant predictor either.

6-2. Methodological limitations

In building regression models for change in health status, the non-normal distribution of change in basic ADL and social activity as well as preoperative health status in all three dimensions had to be transformed to the near-normal, or grouped into categorical variables. The distribution of social activity proved difficult to normalise.

6-3. Discussion

In selecting significant independent predictors for the serious complication rate in the UK, surgical approach was chosen as a significant variable but hospital was not. However, there was a significant association between surgical approach and hospital, suggesting surgeons had a preference for a particular approach. Thus, interhospital differences in serious complication rates might have been due to differences in surgical approach rather than the overall quality of care provided by the hospital .

Education level was a significant predictor of minor complications in the combined model, as well as in the UK model. The higher a patient's level of education, the lower the risk of a minor complication. Reasons for this association are unclear, but may reflect better compliance with medical instructions during the postoperative period by more highly educated patients. In addition, their higher socio-economic status would mean that their living conditions were better and they probably enjoyed more help and assistance from others.

Change in health status was mostly explained by preoperative health status and to a lesser extent by the severity of hip disease but not by the ICED. Nationality was not a significant predictor in any dimensions of health status.

7. To improve the power of comorbidity to predict serious complications

7-1. Findings from this study

Prediction of serious in-hospital complications in the UK was improved by changes to the complication criteria. The threshold nature of the association between complications and the ICED in Japan was enhanced whereas in the UK the dichotomous pattern became less marked.

The structure of the ICED was changed to create a new index with fewer more predictable co-existent diseases. Analysis was limited to the UK model, in which a linear association between complications and the new index was observed. A logistic regression model suggested that changes both to the ICED structure and the complication criteria enhanced the predictive power of the ICED.

7-2. Methodological limitations

The rare incidence of serious complications in Japan made analyses impossible.

Assigning the peak severity of any single disease as a final severity score also made it difficult to interpret the results from individual analyses of the relationship between the severity of each co-existent disease and the complication rate.

Although the association between serious complications and the ICED was improved, the predictive power was limited. The relatively high complication rate observed at the lowest level of the ICED in the UK was a possible reason for difficulty in prediction.

7-3. Discussion

In discussion of risk adjustment methods, most emphasis has been generally put on the classification and weighting of independent variables but relatively less attention has been paid to the definition of the outcome. In this study, change in the criteria of serious complications brought about a stronger association between the ICED and outcome and modified the pattern in both countries, suggesting the importance of the outcome criteria used. Change in outcome criteria also made surgical approach insignificant as a predictor of serious complications in the UK. When the relationship between the new outcome criteria and hospitals was examined, six neuropathy cases were excluded, half of whom were from hospital E, where the anterior approach was frequently used. Although there was no significant association between surgical approach and neuropathy, the result may suggest an indirect relationship through differences in the quality of care.

Another attempt presented was to change the structure of the ICED by minimising the number of comorbidities to the most predictable for outcome. The results showed a linear association between severity of comorbidity and serious complication rate. However, without testing in other population than that used in this study, the validity of such a new development is unknown.

8. Recommendations for clinical practice

What implication do the findings of this study have for the clinical management of THR patients? There are several ways in which the measurement of comorbidity might possibly effect clinical practice: in assisting the clinical management of THR patients; to make commissioning more sensitive; and to enhance audit, in particular interhospital comparisons. In addition, the potential benefit of using the ICED rather than the simpler ASA PS needs to be considered.

8-1. Clinical management of THR patients

In this study, comorbidity data were shown to be able to provide an indication of the likelihood of postoperative complications. However, currently no standard method is used to identify and record comorbidity in clinical practice. If comorbidity information was routinely classified and recorded in case notes in the structured way used in the ICED, it would help organise clinical data. Such data could assist surgeons to identify patients at greater risk and to make decisions to employ preventive measures to avoid or reduce risks of complications.

8-2. Purchasing health care

This study has shown that the ICED can be helpful in identifying the cases most likely to experience postoperative complications. If such predictive information were available, commissioning hospital care could be improved by adjusting risks for outcomes and using differential costing that recognised such differences in risk. This would help to reduce cross-subsidisation of cases with higher levels of comorbidity by those with lower levels.

8-3. Audit of THR practice

After a long history of development, postoperative mortality of THR is now negligibly low despite the majority of patients being elderly. However, for comparison of outcomes other than mortality such as in-hospital complications, comparative analyses of postoperative results among hospitals require good risk adjustment not only for the primary disease but for comorbidity. For comparative audit of outcomes among hospitals with different case mixes such as were seen in this study, good quality data on comorbidity derived from similar, standardised recording is needed. The ICED could be used as a standard method of measuring comorbidity.

8-4. Comparison with ASA PS

In view of the considerable work involved in collecting data for the ICED, the decision as to whether or not to use it rather than alternative simpler methods of risk adjustment must be considered.

In Japan, where recording of the ASA PS is already routinely practiced, the additional effect of using the ICED has been shown to be limited. In this study, ASA PS was significantly associated with the ICED (Spearman rank correlation coefficient =0.6421; $p<0.0001$). Moreover, the highest level of ASA PS was found to be a statistically significant predictor both for minor and overall complications (data not shown), suggesting the limited value of collecting the additional clinical data needed for the ICED.

The same may be true in the UK but couldn't be assessed as the ASA PS is not usually recorded. However, the presence of relatively older and sicker patients may justify the extra effort required of collecting data for the ICED particularly if its predictive power could be improved.

9. Recommendations for further research

Finally, several different issues for further research in this field are suggested.

9-1. Use for different outcomes

Due to preventive measures, mortality following THR is negligible and postoperative death was not used as an outcome, just as it hadn't been in the original study in the USA. However, death is the most severe type of complication that can occur so it's exclusion could be questioned. Moreover, because of the low risk of dying of arthritis, the adjustment by comorbidity will make even more sense than in other diseases/interventions such as coronary artery by-pass graft surgery for ischemic heart disease in which the primary disease could be severe enough as a major cause of mortality. Thus, even though death would be difficult to predict given its low incidence, postoperative death could be included in the category of serious complications to be assessed as an important outcome. Analysis of the predictive power of the ICED for serious complication including deaths should be carried out.

9-2. Prospective use of the ICED

Previous chapters discussed the difficulties of using the ICED when data definitions are diverse across the hospitals due to a lack of homogeneous criteria on comorbidities and outcomes. Therefore, the second recommendation is to establish the definition of all the key data elements, seek a consensus about their use among health professionals, and run a prospective study. Guidelines to identify comorbidities and outcomes should be explicitly written and meet the diversity of clinical practice. In these ways, better quality data could be obtained.

9-3. Use in high risk cases - emergencies and elderly

For most elective operations, patients are selected according to their physiological condition and any serious comorbidity is treated before surgery. Therefore patients are relatively stable with risks reduced.

It is possible, however, that comorbidity is a more important determinant of outcome in emergency patients in whom stabilisation of their co-existent diseases may not be feasible before surgery. Also, it may be of greater practical use in very elderly patients who are more likely to suffer from multiple pathology. In such cases, the ICED could be advantageous for routine use as it doesn't require any additional examination than that in current practice. Thus, studies of the ICED in emergency and in very elderly patients would be worth performing.

9-4. Creation of new Japanese and new British models

As described in the preceding chapter, an attempt to change the structure of the ICED was very limited because the severity of comorbidity was collected according to the existing ICED severity grades and not as raw data which could be reclassified. New index could be developed if data were collected prospectively in each country. Raw clinical data should be collected and co-existent disease severity and functional severity could be composed in different way from that used in the ICED. Although this would require considerable research effort, the predictive power and validity of the new indices made for each country would be greater as it would more accurately reflect current practice.

9-5. Test in other conditions and procedures

The ICED could be tested in procedures other than THR. In the USA, for example, it was tested in acute myocardial infarction, coronary artery bypass graft surgery, and cholecystectomy. The ICED was also used to assess mortality in patients with end stage renal disease in Italy and the USA. Application in such different conditions and procedures would demonstrate the utility of the index.

9-6. Creation of disease-specific models

Although a generic comorbidity index is preferable, disease-specific indices are likely to have greater predictive power. Using retrospectively collected data, an extensive review of current practice would help to identify the most predictable factors. Clarifying outcome definitions, as well as an improved classification of comorbidity severity levels might improve explanatory power of the regression model. Such evidence based risk adjustment would enable a more specific index for the intervention and outcome of interest. As it requires considerable research investment in developing and testing a new index, the benefit of developing a specific model should be carefully considered first.

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APPENDICES

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Appendix-1

Information for Japanese Patients

London School of Hygiene and Tropical Medicine
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Department of Public Health and Policy
Health Services Research Unit

「人工股関節全置換術に関する国際調査」についてのお願い

本調査は、現在先進国で多く実施されている人工股関節全置換術に対する術後評価として、日本、アメリカ、イギリスの３ケ国の大学の研究者による共同研究として企画されたものです。

研究に合意した各病院整形外科担当医から提供された患者さんのお名前と住所のリストから、あなたを今回の調査の回答者の一人として選ばさせていただきました。その他のカルテ情報はいっさい公開されておりません。

この調査は第一段階として、股関節手術後約１年を経過した患者さんに対して、手術の前と後での日常生活にどのような変化があったかを中心に、手術に対する患者さんのご意見をお伺いします。アンケートへの記入は20分くらいで終わると思いますが、もしわからないところがありましたら下記担当者あてまでご連絡をいただければ、いつでも喜んでご説明させていただくことにしております。
また調査の第二段階として、カルテに記載されている臨床情報のうち、入院中のできごと（手術も含めて）に関するデータが必要となります。内容としては、手術時間、人工股関節のタイプ、出血や輸血、入院中の合併症といった医学的情報を収集させていただきたいと思います。

これらのアンケートとカルテ情報は、治療を受けられた患者さんの術後評価に極めて重要なもので、今後の人工股関節全置換術の検討にも大きな意義を持ちます。もちろんすべての情報は、患者さんのプライバシーを守るために今回の調査に限って収集し、極秘扱いといたします。またこの調査への参加または不参加は、患者さんの自由意志によるもので、今後の治療にとって何ら支障をきたすものではありませんし、いつでも自由に辞めることができます。

これは皆さんが人工股関節手術で平成　　年　　月に入院された頃のことについての質問がほとんどですので、どうぞこのことをあらかじめご了承下さい。

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Appendix-2

Information for British Patients

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NORTH THAMES HIP SURGERY STUDY

Information for Patients

Although we know much about the long term benefits of surgery for hip arthritis we need to increase our knowledge of the effect of coexistent disease on the postoperative recovery from their operation. To do this we are asking approximately 400 patients, who underwent surgery about a year ago, to take part in this study. We hope our results will lead to a better understanding about hip surgery and the results of surgical treatment.

This questionnaire asks you about your health status and quality of life, for example, the way you have been feeling recently, your physical and social activities.

All the information you give us will be treated as confidential. Your name, address and personal details will not be revealed to anyone. Also the views you express will not be provided to the surgeon who did the operation in any way that would allow him to identity you.

We hope you are willing to help us with this study. Agreeing to take part will not affect the way you are treated in the future. If you are willing to take part please complete the consent form on the front of the questionnaire and return it with the completed questionnaire in the envelope provided.

If you have any questions about the study please do not hesitate to contact me by telephone on **071 927 2105**.

Kyoko Imamura
Research Surgeon

Appendix-3

Questionnaire for Japanese Patients

人工股関節全置換術を受けた皆さんへ

この調査にご協力いただきまして、まことにありがとうございます。
この質問は皆さんの健康についての大事な情報を私どもに伝えてくれるものです。

皆さんがこの調査の対象となっていることについては厳重な親展扱いとし、他には何もご協力をお願いすることはございません。

この小冊子の各質問を注意してご覧下さい。一番皆さんの状況に合うと思われるものを○で囲むか、または適当なお答えを記入して下さい。

あてはまると思われる質問すべてにお答え下さい。もし回答のなかにぴったりあてはまるものがなかったら、なるべく近いと思われるものを選んで下さい。

この質問は、手術を受けられたご本人が記入して下さい。
もし誰かに手伝ってもらう場合には、それが下記のどなたかをお知らせ下さい（番号を○で囲んで下さい）。

= 配偶者（妻または夫）	1
= 親しい友人	2
= 近所の人	3
= その他の家族（親、兄弟、姉妹、息子、娘）	4
= 看護婦または付添婦	5
= その他	6

以上の点についてご理解をいただけましたら、どうか下記の同意書に署名をお願いします。
皆様のご協力に心から感謝申し上げます。

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カルテの使用に関する同意書（インフォームドコンセント）

私は人工股関節全置換術の術後評価を目的として企画された調査への参加に同意します。
ここに提供した情報に加えて、当該研究機関の研究者に私のカルテの閲覧を許可することを承諾します。

＿＿＿＿＿＿＿＿＿＿＿＿　　平成　年　月　日
（署　名）　　（日　付）

まずはじめに、最近の調子についてお聞かせ下さい。
一番皆さんの状況に合うと思われる番号を○で囲んで下さい。

1．全体としての健康状態はいかがですか？

大変良い………………… 1
まあ良い………………… 2
普通 ……………………… 3
悪い ……………………… 4

2．手術を受ける前とくらべて、体調は今の方がいいですか、悪いですか、それともだいたい同じくらいですか？

今の方がいい ………… 1
今の方が悪い………… 2
同じくらい …………… 3

3．このひと月に病気やけがのために一日中、またはその大半を寝て過ごさなければならなかったことが何日ありましたか？

過去一ヶ月のうち床についた日数 ＿＿＿＿＿＿日
（日　数）

4．このひと月に病気やけがのために、いつもは半日以上やっていることができなかった日は何日ありましたか？（寝こんだ日数は数えないで下さい）

過去一ヶ月に半日以上の日常活動がだめになった日数 ＿＿＿＿＿＿日
（日　数）

5．股関節手術を受けてから、手術した股関節について医者の診察を何回受けましたか？
（入院中の診察は数えないで下さい）

＿＿＿＿＿＿回
（回　数）

6．股関節手術を受けてから、手術以外のことで医者の診察を何回受けましたか？
（入院中の診察は数えないで下さい）

＿＿＿＿＿＿回
（回　数）

もし股関節手術のあとに入院したことがありましたら、どういうことで入院されたのかお聞かせ下さい。手術の後での入院であれば何でも結構ですから、下の質問にお答え下さい。

7．股関節手術の後での最初の入院

1. 入院日：平成　　年　　月　　日

2. 病院の名称　：＿＿＿＿＿＿＿＿＿＿＿＿＿＿＿＿＿＿＿＿

病院の住所　：＿＿＿＿＿市

3. 入院の理由　：＿＿＿＿＿＿＿＿＿＿＿＿＿＿＿＿＿＿＿＿

4. 入院はあらかじめ予定していましたか、それとも緊急入院でしたか？

予定入院＿＿＿＿＿＿　　緊急入院＿＿＿＿＿＿

5. 入院した日数：＿＿＿＿＿日

6. その入院中に手術を受けたことがありましたか？

はい＿＿＿＿＿＿　　いいえ＿＿＿＿＿＿

もしあれば、どういう手術でしたか？：＿＿＿＿＿＿＿＿＿＿＿＿＿＿

8．股関節手術の後での二度目の入院

1. 入院日：平成　　年　　月　　日

2. 病院の名称　：＿＿＿＿＿＿＿＿＿＿＿＿＿＿＿＿＿＿＿＿

病院の住所　：＿＿＿＿＿市

3. 入院の理由　：＿＿＿＿＿＿＿＿＿＿＿＿＿＿＿＿＿＿＿＿

4. 入院はあらかじめ予定していましたか、それとも緊急入院でしたか？

予定入院＿＿＿＿＿＿　　緊急入院＿＿＿＿＿＿

5. 入院した日数：＿＿＿＿＿日

6. その入院中に手術を受けたことがありましたか？

はい＿＿＿＿＿＿　　いいえ＿＿＿＿＿＿

もしあれば、どういう手術でしたか？：＿＿＿＿＿＿＿＿＿＿＿＿＿＿

9. 上記のほかに、股関節手術を受けてから入院したことがあれば、その場所とだいたいの期日を下に記入して下さい。

入院の場所	入院期日
____________________	平成　　年　　月　　日
____________________	平成　　年　　月　　日

皆さんが股関節手術を受けてからおよそ1年になります。
このひと月にどうだったかを考えながら下記の質問に答えて下さい。

10. このひと月に経験した痛みを平均してみて、一番近いと思われる番号を○で囲んで下さい。
それぞれの活動について0から7までに分け、0を全然痛くない、7を非常に痛いとします。

	全然痛くない							非常に痛い
寝起きの際の動作	0	1	2	3	4	5	6	7
腰掛けの姿勢から立ち上がること	0	1	2	3	4	5	6	7
家の中を歩くこと	0	1	2	3	4	5	6	7
戸外を歩くこと	0	1	2	3	4	5	6	7
階段を昇ること	0	1	2	3	4	5	6	7
庭仕事または買物	0	1	2	3	4	5	6	7
靴下やズボンをはくこと	0	1	2	3	4	5	6	7

11. 全体としてこのひと月にあった痛みは、股関節手術を受ける前にあったものより軽いですか、それともひどいですか？
1　ずっと良い　　2　まあ良い　　3　ほぼ同じ
4　やや悪い　　5　ずっと悪い

12. 手術を受ける一ヶ月前に、歩くのにはどんなものを使っていましたか？
1　何もいらなかった（または、めったにいらなかった）　　2　松葉杖かステッキを一本
3　松葉杖かステッキを二本　　4　歩行器　　5　車椅子

13. 今は、歩くのにどんなものを使いますか？
1　何もいらない（または、めったにいらない）　　2　松葉杖かステッキを一本
3　松葉杖かステッキを二本　　4　歩行器　　5　車椅子

14. 手術を受けてから股関節がはずれた（脱臼した）ことがありますか？

はい .... 1　　いいえ 2

もしあれば、何回ありましたか？ ＿＿＿＿＿回

15. 手術を受ける前にはどのくらいびっこをひいていましたか？

1　全くなし	2　少しだけ	3　かなり
4　非常にひどく	5　歩けない	

16. 今はどのくらいびっこをひいていますか？

1　全くなし	2　少しだけ	3　かなり
4　非常にひどく	5　歩けない	

17. このひと月に痛みのために、または眠れるように何か薬をのんだことがありますか？

はい .... 1　　いいえ 2

もしあれば、何回のみましたか？ 週に＿＿＿＿＿回

どんな薬でしたか？ ＿＿＿＿＿＿＿＿＿＿＿＿＿＿＿＿

今度は社会的な活動についていくつかお伺いします。

18. 親しい友人は何人ぐらいいますか？；一緒にいてくつろぐことができ、思っていることを話しあえる人のことです（身内も含めて）。

人数を記入して下さい：＿＿＿＿＿＿人の親友や身内がいる

19. このひと月にだいたい何回ぐらい友人や身内と一緒に外出したり、お互いの家に遊びに行ったり、または電話で話したりしましたか？

1　毎日	2　週に何回か	3　だいたい週に一度
4　月に2、3回	5　だいたい月に一度	6　全然なし

20. このひと月に性的な関係で満足しましたか？

1　大変満足している	2　満足している	3　よくわからない
4　不満である	5　大変不満である	6　全く性的関係がなかった

この質問表は身体的また社会的活動について述べています。このひと月に平均してこれらの活動がどのくらい大変だったかをお伺いします。大変かどうかとは、からだの調子でどのくらいがんばらなければならなかったかをさします。一番近いと思われる番号を○で囲んで下さい。

このひと月にどのくらい行動に支障をきたしましたか？	たいていは難なくこなせた	たいていはちょっと難あり	たいていはかなり苦労した	たいていはからだの具合でやらなかった	たいていはその他の理由でやらなかった
21 自分の身の回りのこと、例えば食事、着衣、入浴は？	4	3	2	1	0
22 ベッドや椅子からの動作は？	4	3	2	1	0
23 数百メートル歩くには？	4	3	2	1	0
24 百メートル歩いたり、または階段を踊り場まで昇るのは？	4	3	2	1	0
25 家のまわりとか室内を歩くのは？	4	3	2	1	0
26 掃除、軽い庭仕事、管理などの家のまわりの仕事は？	4	3	2	1	0
27 食料品の買物などの用足しは？	4	3	2	1	0
28 車の運転や公共交通機関の利用は？	4	3	2	1	0
29 身内や友人を訪ねるのは？	4	3	2	1	0
30 宗教行事や近所とのつきあいまたはボランテイアなどの地域活動に参加するのは？	4	3	2	1	0
31 家族など自分以外の人の世話をするのは？	4	3	2	1	0
32 走ったり、重いものを持ち上げたりの激しい運動は？	4	3	2	1	0

次の質問はこのひと月にどういう感じで、またどう過ごしたかについてお伺いします。これまでの感じから一番近いと思われる番号を○で囲んで下さい。

このひと月で下記のようなことがどのくらいのあいだありましたか？	いつもあった	ほとんどいつもあった	しばしばあった	ときどきあった	まれにはあった	全然なかった
33 かなり神経質だったか？	1	2	3	4	5	6
34 落ち込んだり、悲しかったりしたか？	1	2	3	4	5	6
35 愉快に過ごしたか？	1	2	3	4	5	6
36 日中、横になって休まなければならないことがあったか？	1	2	3	4	5	6

次は医療についての記述です。股関節手術で入院した時に受けた治療のことを思い出しながら、それぞれを注意して読んで下さい。各記述例の横にある番号のうち、一番自分の考えに近いと思われるものを○で囲んで下さい。記述によっては似かよったふうにみえますが、それぞれは別のものです。各記述を個別のものとして考えて下さい。どれが正しいとか間違っているということではありません。皆さんの意見や一番強い印象としてお伺いしたいと思います。

どのくらい満足ですか？	非常に満足している	まあ満足している	満足でも不満でもない	やや不満である	非常に不満である
37　手術に関して受けた説明について？	1	2	3	4	5
38　痛みに対しての処置について？	1	2	3	4	5
39　入院全体に関して？	1	2	3	4	5

40. 入院期間についてどう思われますか？
1　非常に長すぎる　　2　やや長すぎる　　3　ちょうど良い
4　やや短すぎる　　5　非常に短すぎる

41. 手術を受けてみて、現在では股関節の感じとしてはどう変わりましたか？
1　非常に良くなった　　2　かなり良くなった　　3　やや良くなった
4　あまり変わらないようだ
5　やや悪くなった　　6　かなり悪くなった　　7　非常に悪くなった

42. 手術を受けたことについて、現在、どんな風に感じていますか？
1　非常に喜んでいる　　2　喜んでいる
3　あまりうれしくない　　4　全然うれしくない

43. 全体として、予想していたのとくらべて今の方が具合がいいですか、それとも悪いですか？
1　非常に良い　　2　やや良い　　3　予想したとおり
4　やや悪い　　5　非常に悪い

44. 手術がすんだらやろうと思っていたこととくらべて、現在の活動はどうですか？
1　思ったよりずっと落ちた　　2　思ったよりやや落ちた　　3　だいたいこんなもの
4　思ったよりややいい　　5　思ったよりずっといい

この質問表は身体的また社会的活動について述べています。股関節手術を受ける前の月には平均してこれらの活動がどのくらい大変だったかをお伺いします。大変かどうかとはからだの調子でどのくらいがんばらなければならなかったかをさします。一番近いと思われる番号を○で囲んで下さい。

股関節手術を受ける前の月にはどのくらい行動に支障をきたしていましたか？	たいていは難なくこなせた	たいていはちょっと難あり	たいていはかなり苦労した	たいていはからだの具合でやらなかった	たいていはその他の理由でやらなかった
45 自分の身の回りのこと、例えば食事、着衣、入浴は？	4	3	2	1	0
46 ベッドや椅子からの動作は？	4	3	2	1	0
47 数百メートル歩くには？	4	3	2	1	0
48 百メートル歩いたり、または階段を踊り場まで昇るのは？	4	3	2	1	0
49 家のまわりとか室内を歩くのは？	4	3	2	1	0
50 掃除、軽い庭仕事、管理などの家のまわりの仕事は？	4	3	2	1	0
51 食料品の買物などの用足しは？	4	3	2	1	0
52 車の運転や公共交通機関の利用は？	4	3	2	1	0
53 身内や友人を訪ねるのは？	4	3	2	1	0
54 宗教行事や近所とのつきあいまたはボランテイアなどの地域活動に参加するのは？	4	3	2	1	0
55 家族など自分以外の人の世話をするのは？	4	3	2	1	0
56 走ったり、重いものを持ち上げたりの激しい運動は？	4	3	2	1	0

次の質問は股関節手術を受ける前の月にはどういう感じで、またどう過ごしたかについてお伺いします。これまでの感じから一番近いと思われる番号を○で囲んで下さい。

股関節手術を受ける前の月に下記のようなことがどのくらいのあいだありましたか？	いつもあった	ほとんどいつもあった	しばしばあった	ときどきあった	まれにはあった	全然なかった
57 かなり神経質だったか？	1	2	3	4	5	6
58 落ち込んだり、悲しかったりしたか？	1	2	3	4	5	6
59 愉快に過ごしたか？	1	2	3	4	5	6
60 日中、横になって休まなければならないことがあったか？	1	2	3	4	5	6

他の回答者の方々の体験と比較するために、あなた御自身のことについていくつかお尋ねします。

61. 最終学歴としてはつぎのどれがあてはまりますか？
 1 中学又は高校卒業　2 短大又は高等専門学校卒業
 3 四年制大学卒業　4 大学院修了　5 その他（　　　　）

62. 結婚していらっしゃいますか？
 1 既婚　2 死別
 3 別居または離婚　4 未婚

63. 生活状況は下のどちらがあてはまりますか？
 1 独居　2 配偶者／家族または友人と同居

64. あなたと家族の住まいとしては下記のどれが一番あてはまりますか？
 1 公共住宅　2 賃貸住宅
 3 所有している　4 その他（　　　　）

65. このひと月の就業状況としては、下記のうちどれが一番近いですか？
 1 常勤　2 パートタイム　3 からだの具合で働いていない
 4 求職中で、働いていない　5 股関節の具合で退職した　6 その他の理由で退職した
 7 主婦専業

66. 股関節手術を受ける前の月の仕事としては、下記のうちどれが一番近いですか？
 1 常勤　2 パートタイム　3 からだの具合で働いていない
 4 求職中で、働いていない　5 股関節の具合で退職した　6 その他の理由で退職した
 7 主婦専業

股関節手術を受ける前の月に仕事をしていた方は、職業名と、どんな仕事かを簡単に下にご記入下さい。

____

____

コメント

皆さんの股関節手術についてどんな意見でも結構ですからお聞かせ下さい。

以上、質問にお答えいただき、まことにありがとうございました。
どうぞ同封の封筒をご利用のうえ、熊本機能病院　今村恭子までお送り下さいますようお願いします。

Appendix-4

Questionnaire for British Patients

NORTH THAMES HIP SURGERY STUDY

Thank you very much for helping us with this survey.

This questionnaire will provide us with important information about your health.

Any information that would permit you to be identified as a member of the study will be regarded as strictly confidential and will be used only for this study.

Please make sure you answer every question. Circle the number of the answer that most closely fits you. If none of the answers provided seems exactly right, choose the one that comes nearest to being right for you.

Please remember most of these questions are about you when you were in the hospital for your hip replacement surgery in

______/______
(Month/ Year)

We would like you to fill out this questionnaire. If someone else is helping you, please let us know who:

		(Circle one)
a.	Spouse (wife or husband)	1
b.	Boyfriend or girlfriend	2
c.	Neighbour	3
d.	Other relative (parent, sister, brother, son, daughter)	4
e.	Nurse or health attendant	5
f.	Other	6

- -

CONSENT FORM

I have read and understood the information about the North Thames Hip Surgery Study and I am willing to take part.

Please sign here ________________________________

Before you start, please fill in today's date ____/____/____
Day Mo Yr

To start, we would like to know how you have been feeling recently. Please circle the number of the answer that most closely fits you.

1. In general, would you say your health is. . .

Excellent	1
Good	2
Fair	3
Poor	4

2. Compared with the period prior to your hip operation, would you say your health now is better, worse, or about the same?

Better	1
Worse	2
Same	3

3. During the past month, on how many days did illness or injury keep you in bed all or most of the day?

DAYS IN BED DURING THE PAST MONTH ________
No. of days

4. During the past month, how many days did you cut down on the things you usually do for one-half day or more because of an illness or injury? (DO NOT COUNT DAYS SPENT IN BED.)

DAYS CUT DOWN ON THINGS USUALLY DO FOR 1/2 DAY OR MORE DURING THE PAST MONTH ________
No. of days

5. Since your hip operation, have you used any of the following services <u>for problems</u> with the hip that was operated on?
Please tick for each one.

General Practitioner	1 ☐ Yes	2 ☐ No
Practice nurse	1 ☐ Yes	2 ☐ No
Hospital outpatients	1 ☐ Yes	2 ☐ No
District nurse	1 ☐ Yes	2 ☐ No
Physiotherapist	1 ☐ Yes	2 ☐ No
Other (please specify)	1 ☐ Yes	2 ☐ No

6. Since your hip operation, how much rehabilitation or help with regaining your mobility did you receive from health service staff?
Please tick one.

1 ☐ None　　2 ☐ A little　　3 ☐ Quite a lot　　4 ☐ A great deal

7. How much <u>extra help</u> from friends, family or neighbors have you had since your hip operation?
Please tick one.

1 ☐ None　　2 ☐ A little　　3 ☐ Quite a lot　　4 ☐ A great deal

We would like to know if you have been admitted to hospital since your hip replacement and what the reasons for those admissions were. Please answer the following questions for any admission since your hip operation.

8. First admission since your hip operation:

a. Date: ____/____/____
Mo. Day Yr.

b. Name of hospital ______________________

City ______________________

c. Reason for admission ______________________

d. Did you plan to come back or was it an emergency admission?

Planned ______________　　Emergency ______________

e. Number of days in hospital ______________

f. Did you have any surgery during this admission?

YES ______________　　NO ______________

If yes, indicate type: ______________________

9. **Second admission since your hip operation:**

a. Date: ____/____/____
Day Mo Yr

b. Name of hospital ______________________________

City ______________________________

c. Reason for admission ______________________________

d. Did you plan to come back or was it an emergency admission?

Planned ____________ Emergency ____________

e. Number of days in hospital ____________

f. Did you have any surgery during this admission?

YES ____________ NO ____________

If yes, indicate type: ______________________________

10. **Third admission since your hip operation:**

a. Date: ____/____/____
Day Mo Yr

b. Name of hospital ______________________________

City ______________________________

c. Reason for admission ______________________________

d. Did you plan to come back or was it an emergency admission?

Planned ____________ Emergency ____________

e. Number of days in hospital ____________

f. Did you have any surgery during this admission?

YES ____________ NO ____________

If yes, indicate type: ______________________________

11. Please list below the location and approximate dates of any other admissions to hospital since your hip operation.

PLACE	DATE
______________________________	____________
______________________________	____________
______________________________	____________

It has now been about one year since your total hip replacement. Please think about how you have been feeling during the past month as you answer these questions.

12. For each activity you perform, on the scale from 0 to 7, where 0= NO PAIN and 7=SEVERE PAIN, circle the number that best represents the average amount of PAIN you have experienced when performing the activity, during the past month.

	NO PAIN							SEVERE PAIN
Getting in/out of bed	0	1	2	3	4	5	6	7
Rising from a sitting position	0	1	2	3	4	5	6	7
Walking inside the house	0	1	2	3	4	5	6	7
Walking outside the house	0	1	2	3	4	5	6	7
Climbing stairs	0	1	2	3	4	5	6	7
Doing yardwork/shopping	0	1	2	3	4	5	6	7
Putting on stockings/pants	0	1	2	3	4	5	6	7

13. In general would you say your pain in the past month is better or worse than the pain you had prior to your hip surgery?

Much Better	Somewhat Better	About the Same	Somewhat Worse	Much Worse
1	2	3	4	5

14. In the month before your surgery, what type of walking supports did you use?

None (or rarely).. 1
Single cane or crutch 2
Two canes or crutches 3
Walker 4
Wheelchair 5

15. What type of walking supports do you use now?

None (or rarely).. 1
Single cane or crutch 2
Two canes or crutches 3
Walker 4
Wheelchair 5

16. Have you had a displaced hip since your operation?

YES .... 1 NO 2

If yes, how many times has this happened? ________________

17. Before your surgery, how much of a limp did you have?

None	Slight	Moderate	Severe	Could not Walk
1	2	3	4	5

18. How much of a limp do you have now?

None	Slight	Moderate	Severe	Cannot Walk
1	2	3	4	5

19. In the past month have you taken any medication for pain or to help you sleep?

YES .... 1 NO 2

If yes, how often do you take these medications? ________ times per week

What is the medication for? ________________________________

We would now like to ask you some questions about your social activities.

20. About how many close friends do you have; people you feel at ease with and can talk with about what is on your mind? (You may include relatives.)

Enter number on line: ____________________Close friends and relatives

21. During the past month, about how often did you get together with friends or relatives, like going out together, visiting in each other's homes, or talking on the telephone?

(Circle One)

Every day 6

Several times a week 5

About once a week 4

2 or 3 times during the month 3

About once a month 2

Not at all 1

22. During the past month, how satisfied were you with your sexual relationships?

(Circle One)

Very satisfied 5

Satisfied 4

Not sure 3

Dissatisfied 2

Very dissatisfied 1

Did not have any sexual relationships 0

This group of questions refers to many types of physical and social activities. We would like to know how difficult it was for you to do each of these activities, on average, during the past month. By difficult, we mean how hard was it or how much physical effort it took to do the activity because of your health. Please circle the number of the answer that most closely fits you for each question.

DURING THE PAST MONTH, HOW MUCH PHYSICAL DIFFICULTY DID YOU HAVE...	USUALLY DID WITH NO DIFFICULTY	USUALLY DID WITH SOME DIFFICULTY	USUALLY DID WITH MUCH DIFFICULTY	USUALLY DID NOT DO BECAUSE OF HEALTH	USUALLY DID NOT DO FOR OTHER REASONS
23. Taking care of yourself, that is, eating dressing, or bathing?	4	3	2	1	0
24. Moving in and out of a bed or chair?	4	3	2	1	0
25. Walking several blocks?	4	3	2	1	0
26. Walking one block or climbing one flight of stairs?	4	3	2	1	0
27. Walking indoors, such as around your home?	4	3	2	1	0
28. Doing work around the house such as cleaning, light gardening, home maintenance?	4	3	2	1	0
29. Doing errands, such as grocery shopping?	4	3	2	1	0
30. Driving a car or using public transportation?	4	3	2	1	0
31. Visiting with relatives or friends?	4	3	2	1	0
32. Participating in community activities such as religious services, social activities, or volunteer work?	4	3	2	1	0
33. Taking care of other people such as family members?	4	3	2	1	0
34. Doing vigorous activities such as running or lifting heavy objects?	4	3	2	1	0

These next questions ask about how you feel and how things have been with you **during the past month**. For each question, please circle the number for the answer that comes closest to the way you have been feeling.

DURING THE PAST MONTH, HOW MUCH OF THE TIME:	ALL OF THE TIME	MOST OF THE TIME	A GOOD BIT OF THE TIME	SOME OF THE TIME	A LITTLE OF THE TIME	NONE OF THE TIME
35. Have you been a very nervous person?	1	2	3	4	5	6
36. Have you felt calm and peaceful?	1	2	3	4	5	6
37. Have you felt downhearted and sad?	1	2	3	4	5	6
38. Were you a happy person?	1	2	3	4	5	6
39. Did you feel so down in the dumps that nothing could cheer you up?	1	2	3	4	5	6
40. Did you feel fatigued or tired?	1	2	3	4	5	6
41. Did you have to lie down during the day in order to rest?	1	2	3	4	5	6
42. Did you feel confused or disoriented; i.e., didn't know who you were or who was around?	1	2	3	4	5	6
43. Did you have difficulty doing activities involving concentration and thinking?	1	2	3	4	5	6

Next are some statements about medical care. Please read each one carefully, keeping in mind the care you received during and after your hip operation. On the line next to each statement, circle the number for the opinion that is closest to your own view. Some statements look similar to others, but each statement is different. You should consider each statement by itself. There are no right or wrong answers. We are only interested in your opinions or best impression.

HOW SATISFIED WERE YOU WITH:	VERY SATISFIED	SOMEWHAT SATISFIED	NEITHER SATISFIED NOR DISSATISFIED	SOMEWHAT DISSATISFIED	VERY DISSATISFIED
44. The information you were given about your surgery?	1	2	3	4	5
45. The way your pain was treated?	1	2	3	4	5
46. Your hospital stay in general?	1	2	3	4	5

47. Do you feel the length of time you spent in the hospital was:

Much too Long	Somewhat too Long	Just Right	Somewhat too Short	Much too Short
1	2	3	4	5

48. How has the operation changed the way you feel?

I feel much better 1
I feel somewhat better 2
I feel a little better 3
I feel about the same 4
I feel a little worse 5
I feel somewhat worse 6
I feel much worse 7

49. How do you now feel about having had the operation?

I am very happy I had the operation 1
I am happy that I had the operation 2
I am not so happy that I had the operation 3
I am not happy at all that I had the operation 4

50. Overall, is your health better or worse than you expected it to be at this point?

Much Better	Somewhat Better	What I Expected	Somewhat Worse	Much Worse
1	2	3	4	5

51. How do your activities compare to what you had planned to do after your operation?

Doing much less than I expected	Doing somewhat less than I expected	Doing about what I expected	Somewhat more	Much more
1	2	3	4	5

This group of questions refers to many types of physical and social activities. We would like to know how difficult it was for you to do each of these activities, on average, **during the month before your hip operation.** By difficult, we mean how hard it was or how much physical effort it took to do the activity **because of your health. Please circle the number of the answer that most closely fits you for each question.**

DURING THE MONTH BEFORE YOUR HIP OPERATION, HOW MUCH PHYSICAL DIFFICULTY DID YOU HAVE:	USUALLY DID WITH NO DIFFICULTY	USUALLY DID WITH SOME DIFFICULTY	USUALLY DID WITH MUCH DIFFICULTY	USUALLY DID NOT DO BECAUSE OF HEALTH	USUALLY DID NOT DO FOR OTHER REASONS
52. Taking care of yourself, that is, eating dressing, or bathing?	4	3	2	1	0
53. Moving in and out of a bed or chair?	4	3	2	1	0
54. Walking several blocks?	4	3	2	1	0
55. Walking one block or climbing one flight of stairs?	4	3	2	1	0
56. Walking indoors, such as around your home?	4	3	2	1	0
57. Doing work around the house such as cleaning, light gardening, home maintenance?	4	3	2	1	0
58. Doing errands, such as grocery shopping?	4	3	2	1	0
59. Driving a car or using public transportation?	4	3	2	1	0
60. Visiting with relatives or friends?	4	3	2	1	0
61. Participating in community activities such as religious services, social activities, or volunteer work?	4	3	2	1	0
62. Taking care of other people such as family members?	4	3	2	1	0
63. Doing vigorous activities such as running, lifting heavy objects, or participating in strenuous sports?	4	3	2	1	0

These next questions ask about how you felt and how things were **during the month before your hip operation**. For each question, please circle the number for the answer that comes closest to the way you have been feeling.

DURING THE MONTH BEFORE YOUR HIP OPERATION, HOW MUCH OF THE TIME:	ALL OF THE TIME	MOST OF THE TIME	A GOOD BIT OF THE TIME	SOME OF THE TIME	A LITTLE OF THE TIME	NONE OF THE TIME
64. Have you been a very nervous person?	1	2	3	4	5	6
65. Have you felt calm and peaceful?	1	2	3	4	5	6
66. Have you felt downhearted and sad?	1	2	3	4	5	6
67. Were you a happy person?	1	2	3	4	5	6
68. Did you feel so down in the dumps that nothing could cheer you up?	1	2	3	4	5	6
69. Did you feel fatigued or tired?	1	2	3	4	5	6
70. Did you have to lie down during the day in order to rest?	1	2	3	4	5	6
71. Did you feel confused or disoriented; i.e., didn't know who you were or who was around?	1	2	3	4	5	6
72. Did you have difficulty doing activities involving concentration and thinking?	1	2	3	4	5	6

In order to compare your experiences with other patients, we would like to know a little more about you as a person.

73. At what age did you finish full-time education? (Circle one)

15 or under	16-18 years	19 or over
1	2	3

74. Are you : (Circle one)

Married or Living as married 1
Widowed 2
Separated or divorced 3
Never married 4

75. Which of the following best describes your living arrangement? (Circle one)

Live alone 1
Live with spouse/family or friends 2

76. Which type of accommodation do you live in?

Council flat / home 1
Privately rented or housing association 2
Owner occupier 3
Other 4

77. Which of the following statements best describes your work situation during the past month? (Circle one)

Working full-time 1
Working part-time 2
Unemployed because of my health 3
Unemployed, looking for work 4
Retired because of my hip condition 5
Retired for other reasons 6
Housework, full-time 7

78. Which of the following statements best describes your work situation for **the month before your hip operation?** (Circle one)

Working full-time 1
Working part-time 2
Unemployed because of my health 3
Unemployed, looking for work 4
Retired because of my hip condition 5
Retired for other reasons 6
Housework, full-time 7

If you were working **the month before your hip operation**, please give the names of the job and brief details of what you actually did.

____

____

COMMENTS

We are interested in any other comments you have about your hip operation.

Thank you for completing this questionnaire.
Please return it to Dr Kyoko Imamura (Health Services Research Unit, London School of Hygiene and Tropical Medicine, Keppel Street, London WC1E 7HT), in the stamped addressed envelope provided.

Appendix-5

Case Notes Extraction Sheet for Japan

患者氏名：
ふりがな：
住　所　：〒
電話番号：自宅　(　　　)
　　　　　勤務先 (　　　)

外来番号
入院番号

生年月日：明大昭　　年　　月　　日
年令：　　　才
性別：男／女
職業：無／退／その他 (　　　　　　　　　　)
勤務先名称：
生活：独居／同居
住居：自宅／病院／ホーム／他 (　　　　　　)
婚姻：未／既／死別／別居／離婚
保険：国／社／生／老／その他 (　　　　　)
診断 1：変股／骨頭壊死／骨折
　　　その他 (　　　　　　　　　　　)
診断 2：(　　　　　　　　　　　　　)
病側　：右／左
対側股：症状有／無
既往歴：先股脱／臼蓋形成不全／他 (　　　)
手術歴：右股／左股／膝／脊椎／他 (　　　)
入院日：平　　年　　月　　日
退院日：平　　年　　月　　日
手術日：平　　年　　月　　日
主治医：
術　者：
入院別：予定／救急／転院／転棟
転帰：自宅／病院／ホーム／死亡／他
飲　酒：はい／いいえ
タバコ：はい／いいえ

疼痛の程度
1：夜間痛、寝たきりか杖で２～３ｍ
2：歩行開始時痛で杖で歩く
3：我慢できるが距離制限、ステッキ１本必要
4：安静ですぐ治る運動時痛、ステッキ１本で長距離歩く
5：跛行あるも軽い痛みか稀で制限なし、ステッキ不要

肥満度
身長：　　m　　cm
体重：　　kg

その他の障害
膝　：同側／対側
脊椎

生理的障害

循環器系

器質的心疾患	(0	1	2	3	4)
虚血性心疾患	(0	1	2	3	4)
一次性不整脈	(0	1	2	3	4)
鬱血性心疾患	(0	1	2	3	4)
高血圧	(0	1	2	3	4)

非循環器系

脳血管障害	(0	1	2	3	4)
末梢血管障害	(0	1	2	3	4)

その他

糖尿病	(0	1	2	3	4)
呼吸器疾患	(0	1	2	3	4)
悪性腫瘍	(0	1	2	3	4)
肝胆道系疾患	(0	1	2	3	4)
腎疾患	(0	1	2	3	4)
関節炎	(0	1	2	3	4)
消化器系疾患	(0	1	2	3	4)

肉体的障害

循環	(0	1	2)
呼吸	(0	1	2)
神経	(0	1	2)
精神	(0	1	2)
尿路	(0	1	2)
排便	(0	1	2)
摂食	(0	1	2)
視力	(0	1	2)
聴力	(0	1	2)
会話	(0	1	2)

手術状況
麻酔：全身／腰麻／硬膜外
ASA：１／２／３
麻酔時間：
手術時間：
出血量：術中 (　　　　) 病棟 (　　　　)
輸血量：保存血／自己血／混合／他 (　　)
型式：
セメント：臼蓋／大腿骨／ハイブリッド
侵入路：後外側／前方／後方／側方
抗生物質：(　　) 日、名 (　　　　　　)
予備投与：はい／いいえ
血栓予防：種類 (　　　　　　　　　　)
合併症：
骨移植：骨盤／骨頭／他 (　　　　　)
術前Ht：(　　　) %

合併症

軽度
肺炎 (X-p、抗生剤)
発熱 (38.3<，２回／日)
尿路感染症 (培養、抗生剤)
消化器症状
術創感染 (２日以上発赤硬化)

重症
低血圧 (<90/60)
昏睡
肺塞栓
脱臼
敗血症
ショック
心筋梗塞、鬱血性心不全
脳血管障害
腎不全 (BUN,Creat)
神経麻痺
術中骨折
転倒骨折

検査

Appendix-6

Case Notes Extraction Sheet for the UK

DEMOGRAPHIC INFORMATION

Subject #: ____________________

Name: ____________________

Chart Review : __/__/__ (DD/MM/YY)

Admn Date: __/__/__ (DD/MM/YY)

Disch Date: __/__/__ (DD/MM/YY)

Date of Birth: __/__/__ (DD/MM/YY)

Primary Admission Diag: ____________________

Sex: 1 [ ] Female
2 [ ] Male

Live Alone: 1 [ ] Yes
2 [ ] No
3 [ ] Unknown

Marital Status: 1 [ ] Never married
2 [ ] Married
3 [ ] Separated/Divorced
4 [ ] Widowed
5 [ ] Unknown

Admit Type 1 [ ] Emergent
2 [ ] Transfer
3 [ ] Scheduled/Elective
4 [ ] In-house transfer
5 [ ] Other
6 [ ] Unknown

DISEASE SEVERITY

Same Joint Previous:

	YES	NO
Osteotomy	1 [ ]	2 [ ]
Hip pinning	1 [ ]	2 [ ]

Other (specify) ____________________

Other Joint Previous:

	YES	NO
Osteotomy	1 [ ]	2 [ ]
Hip pinning	1 [ ]	2 [ ]
Total Hip Replacement	1 [ ]	2 [ ]

Other (specify) ____________________

Knees Previous:

	YES	NO
Replacement of one knee	1 [ ]	2 [ ]
Replacement of both knees	1 [ ]	2 [ ]
Osteotomy of one knee	1 [ ]	2 [ ]
Osteotomy of both knees	1 [ ]	2 [ ]

Other (specify) ____________________

	YES	NO
Spinal Problem:	1 [ ]	2 [ ]

RISK FACTORS

	YES	NO
Alcohol	1 [ ]	2 [ ]
Smoking	1 [ ]	2 [ ]
Obesity	1 [ ]	2 [ ]

Height: ____________ (inches)

Weight: ____________ (lbs.)

DISEASE SPECIFIC SURGICAL DATA

Surgical Approach:
1 [ ] Anterior
2 [ ] Posterior
3 [ ] Lateral
4 [ ] Other (specify) ____________

Bone Graft: 1 [ ] Femur
2 [ ] Acetabular
3 [ ] None

Prosthesis Type?
1 [ ] Cement
2 [ ] Cementless
3 [ ] Not documented
4 [ ] Other (specify) ____________

SURGICAL DATA

Surgery Date: __/__/__ (DD/MM/YY)

Anesthesia type: 1 [ ] General 3 [ ] Local
2 [ ] Regional 4 [ ] Unknown

Time started: ____:____

Time ended: ____:____

Blood loss in O.T.: ____________

Blood loss in Ward.: ____________

Transfusion.: ____________

Initial Hematocrit? ____________

Final Hematocrit? ____________

ASA classification ____________

DVT Prevention: 1 [ ] YES 2 [ ] NO

Venogram? 1 [ ] YES 2 [ ] NO

If yes, results? ____________

Blood Clot Prevention:
1 [ ] Coumadin
2 [ ] Heparin
3 [ ] Pneumatic Compression
4 [ ] Other (specify) ____________

DISEASE SPECIFIC POST-OP COMPLICATIONS

Dislocation?	1 [ ]	2 [ ]
Thrombophlebitis?	1 [ ]	2 [ ]
Hematoma?	1 [ ]	2 [ ]

Post Surgical Complications? 1 [ ] YES 2 [ ] NO

Pneumonia/Pulmonary Complications?

	YES	NO
Documented	1 [ ]	2 [ ]
Interpreted mentioning a. cough and fever>101F or b. sputum and fever>101F	1 [ ]	2 [ ]
Interpreted from culture resultts	1 [ ]	2 [ ]
Interpreted from chest X-ray	1 [ ]	2 [ ]
Antibiotic start or change	1 [ ]	2 [ ]

	YES	NO
Significant Cardiac Changes:	1 [ ]	2 [ ]
MI?	1 [ ]	2 [ ]
CHF?	1 [ ]	2 [ ]
Stroke?	1 [ ]	2 [ ]
UTI?	1 [ ]	2 [ ]
Wound drainage?	1 [ ]	2 [ ]
Wound infection?	1 [ ]	2 [ ]
Systemic infection?	1 [ ]	2 [ ]
Renal Failure?	1 [ ]	2 [ ]

Pulmonary Embolism?
1 [ ] Documented
2 [ ] Not documented

Blood Pressure Drop?
1 [ ] Documented
2 [ ] BP<90/60 mmHg at any point during hospitalisation?

Coma? 1 [ ] Documented
2 [ ] Not documented

Fever? 1 [ ] Documented as >101F38.3C twice in 24 hours
2 [ ] Not documented

Gastro-intestinal Complications?

Documented :	1 [ ]	2 [ ]
Postitive X-Ray findings :	1 [ ]	2 [ ]
Insertion of a decompression tube :	1 [ ]	2 [ ]

Neuropathy? 1 [ ] Documented
2 [ ] Not documented

Shock?
1 [ ] Documented
2 [ ] Not documented

Septicemia/Bacteremia?
1 [ ] Documented
2 [ ] Not documented

COMORBIDITY INDEX

ORGANIC HEART DISEASE	0	1	2	3
ISCHEMIC HEART DISEASE	0	1	2	3
ARRHYTHMIAS	0	1	2	3
CONGESTIVE HEART FAILURE	0	1	2	3
HYPERTENSION	0	1	2	3
CEREBRAL VASCULAR ACCIDENT	0	1	2	3
PERIPHERAL VASCULAR DISEASE	0	1	2	3
DIABETES MELLITUS	0	1	2	3
RESPIRATORY PROBLEMS	0	1	2	3
MALIGNANCIES	0	1	2	3
LIVER DISEASE	0	1	2	3
RENAL DISEASE	0	1	2	3
GASTRO-INTESTINAL DISEASES	0	1	2	3

FUNCTIONAL STATUS

CIRCULATION	0	1	2
RESPIRATION	0	1	2
NEUROLOGICAL	0	1	2
MENTAL STATUS	0	1	2
URINARY	0	1	2
FECAL	0	1	2
FEEDING	0	1	2
VISION	0	1	2
HEARING	0	1	2
SPEECH	0	1	2

Appendix-7

The Index of Coexistent Disease (ICED)

1 Scoring system

The two dimensions are scored separately using medical data recorded in admission. To determine patients' overall burden of comorbidity, scores are determined for each component.

(1) The disease severity

The severity of each of a selected list of 13 disease categories is recorded before surgery. Each condition, or set of conditions in a given category, is classified into one of four mutually exclusive ranks. The conditions are rated by using an explicit list of symptoms, signs and lab tests indicating the presence of increasing severity of each identified condition.

(2) The functional severity

This component is intended to act as a snapshot of the impact of all the conditions, diagnosed or not, on the patient's current functional status. Ten body systems are assessed by using explicit criteria, and the severity impairment of each system is classified in one of three levels, with the higher level indicating increasing impairment.

2 Disease severity

2-1 General characteristics

Grade 0 Absence of coexistent disease in that category

Grade 1 A comorbid condition which is asymptomatic or mildly symptomatic where there is little or no comorbidity

Grade 2 A mild to moderate condition that is generally symptomatic and requires medical intervention. This also includes past conditions, presently benign, that still present a moderate risk of morbidity

Grade 3 An uncontrolled condition which causes moderate to severe disease manifestations during medical care. These conditions are usually acute or subactive and require medical intervention.

2-2 Specific classification

2-2-1 Organic heart disease (OHD)

Grade 0 Absence of coexistent disease

Grade 1 Asymptomatic with ECG or echo changes only; no murmur or gallops by physical examination. No rales, increased JVP or edema

Grade 2 Stable with medications, mild/moderate SOB produced by strenuous activities, minimal edema, NYHA Class I-II

Grade 3 Pulmonary congestion/CHF, acute endocarditis, cerebral involvement or emboli, cardiac insufficiency, acute MI (cannot walk 1 block, climb 1 flight of stairs), NYHA Class III-IV

2-2-2 Ischemic heart disease (IHD)

Grade 0 Absence of coexistent disease

Grade 1 Asymptomatic with ischemic ECG, abnormalities, mild angina produced by prolonged exertion (NYHA Class I-II)

Grade 2 History of MI or coronary artery bypass graft surgery (CABG) with no residual effects, minimal CHF, angina or dyspnea produced by activities of daily living (e.g., 1 flight of stairs, 1 block of walk, emotional stress), NYHA Class II

Grade 3 History of acute MI in past 6 months, moderate to severe CHF, angina, SOB at rest, cannot perform most routine activities, NYHA Class III-IV

2-2-3 Primary arrhythmias & conduction problems

Grade 0 Absence of coexistent disease

Grade 1 No medications, asymptomatic with ECG changes only

Grade 2 Controlled with minimal symptoms by medication or pacemaker

Grade 3 Significant symptoms such as recurrent dizziness or syncope due to arrhythmias or conduction blocks

2-2-4 Congestive heart failure (no known IHD or OHD)

Grade 0 Absence of coexistent disease

Grade 1 History of a single episode of CHF easily controlled with no further problems

Grade 2 Mild pedal edema, mild dyspnea on exertion, mild orthopnea, history of multiple episodes of CHF presently under control

Grade 3 Refer to appropriate cardiovascular disease (moderate-severe dyspnea on exertion, moderate-severe pedal edema, cardiomegaly, chronic fatigue)

2-2-5 Hypertension

Grade 0 Absence of coexistent disease

Grade 1 Diagnosed hypertension, not on medications, asymptomatic, physical exam normal or history of treated hypertension but not currently on medications

Grade 2 Under control on anti-hypertensive medications, BP<160/100

Grade 3 On medications, not controlled (BP<160/100), but no central nervous system signs or symptoms of hypertensive crisis

2-2-6 Cerebral Vascular Accident (CVA)

Grade 0 Absence of coexistent disease

Grade 1 History of one transient ischemic attack (TIA) with no residual effects

Grade 2 History of CVAs with no residual effects, history of CVA with mild paraesthesia or ataxia, history >=2 TIAs, aneurysm or partial occlusion with no symptoms

Grade 3 History of CVA resulting in hemiplegia, paraplegia, quadriplegia; acute subarachnoid hemorrhage, frequent TIA

2-2-7 Peripheral Vascular Disease (PVD)

Grade 0	Absence of coexistent disease
Grade 1	History of thrombophlebitis with no residual effects, peripheral vascular bypass graft with no recurrence of symptoms, edema without obstruction
Grade 2	Intermittent claudication from peripheral vascular disease (PVD)
Grade 3	Major edema due to venous obstruction, ischemic ulcer or gangrene, history of pulmonary embolus, rest pain from PVD

2-2-8 Diabetes mellitus

Grade 0	Absence of coexistent disease
Grade 1	Chemical diabetes only, not on medication
Grade 2	Controlled (BS<300) on medications, insulin or diet
Grade 3	Diabetes not controlled (>300) or with any of neuropathy, nephropathy (creatinine 3.0-6.0), retinopathy, gangrene, etc.

2-2-9 Respiratory problems

Grade 0	Absence of coexistent disease
Grade 1	Chronic cough, no medications, physical examination and X-rays normal
Grade 2	Productive morning cough, mild dyspnea performing strenuous activities, pulmonary function test with FEV1 60-80% or predicted
Grade 3	Dyspnea at rest, FEV1<60%, recurrent respiratory infections prior to hospitalisation

2-2-10 Malignancies (excluding Basal cell carcinomas of the skin)

Grade 0	Absence of coexistent disease
Grade 1	History of cancer, but >=5 years since last treatment
Grade 2	History of cancer, between 1 and 5 years since last treatment
Grade 3	Current diagnosis of cancer, or cancer treatment within the last year

2-2-11 Hepatobiliary disease

Grade 0 Absence of coexistent disease

Grade 1 History (1 year or more ago) of hepatitis; mild, asymptomatic cirrhosis

Grade 2 Biliary obstruction, common duct obstruction; recent (< 1Year) history of hepatitis; uncomplicated acute viral hepatitis or toxic/drug induced hepatitis

Grade 3 Chronic persistent hepatitis; chronic, active hepatitis; portal hypertension; hepatic vein thrombosis

2-2-12 Renal disease

Grade 0 Absence of coexistent disease

Grade 1 Acute, uncomplicated UTI; recent history (<3 months) of uncomplicated nephritis, history (<6 months) of nephrolithotomy or ESWL

Grade 2 Acute nephritis, nephrolithiasis, mild renal artery stenosis; chronic UTI

Grade 3 Acute, complicated (BUN>=40 or Creat >=3), obstructive uropathy; renal failure; encephalopathy; moderate/severe renal artery stenosis; working renal transplant

2-2-13 Gastro-intestinal disease

Grade 0 Absence of coexistent disease

Grade 1 History of ulcer <1 year; mildly symptomatic gastritis or diverticulitis; intermittent irritable bowel syndrome

Grade 2 Active ulcer controlled on medication; controlled diverticulitis; hiatal hernia with reflux esophagitis; polyp removal < 1 month; ulcerative colitis with minor manifestations or complications

Grade 3 Any active GI condition resulting in perforation, hemorrhage, obstruction, peritonitis or fistula, including:
Ulcers; Diverticulitis; Appendicitis; Enteritis or ulcerative colitis; Hiatal hernia with anemia, stricture or aspiration pneumonia

3 Functional severity

3-1 General characteristics

Level 0	No significant impairment/normal function
Level 1	Mild or moderate impairment. Selection of level 1 must be based on documentation.
Level 2	Serious/severe impairment. Selection of level 2 must be based on documentation.

3-2 Severity categories

3-2-1 Circulation

Level 0	No problems: walking freely: climb 1 flight of stairs: performance of usual ADL
Level 1	Walking with SOB: chest pain: dizziness (transient): walking with assistance: pacemaker
Level 2	Heart failure with edema: bedridden

3-2-2 Respiration

Level 0	No problems: defined as any chronic lung condition with no symptoms
Level 1	SOB: chronic cough: walking limited to one block
Level 2	COPD documented FEV <60%: tracheotomy: oxygen tank: respirator

3-2-3 Neurological

Level 0	No problems: a neurological disease with no symptoms
Level 1	Dizziness: numbness: seizures by history (controlled): syncope by history
Level 2	Ataxia: partial paralysis: seizures (uncontrolled): bedridden

3-2-4 Mental status

Level 0	No problems
Level 1	Transient condition of mild depression, irrational thinking, hallucinations, suicidal, forgetfulness
Level 2	Chronic/recurring condition of confused, dysoriented, psychotic, long-term depression over many years, intellectual deterioration

3-2-5 Urinary

Level 0	No problems (urinary diagnosis but no symptoms)
Level 1	Hesitancy: dribbling: frequency: occasional incontinence: -ostomy
Level 2	Incontinence: retention

3-2-6 Fecal

Level 0	No problems
Level 1	Chronic diarrhea or constipation: pain with bowel movements: occasional incontinence: -ostomy
Level 2	Incontinence

3-2-7 Feeding

Level 0	No problems
Level 1	Slight motor problems (needs food cut)
Level 2	Paralysis: cannot feed oneself: cannot eat: anorexia: tube feeding

3-2-8 Vision

Level 0	No problems
Level 1	Partial problem (difficulty in reading, driving, etc): slight blurring: slight functional involvement
Level 2	Severe blurring (cannot read, drive, etc): blindness

3-2-9 Hearing

Level 0	No problems: hearing aid
Level 1	Hearing limited to one ear: hard of hearing
Level 2	Deaf

3-2-10 Speech

Level 0	No problems
Level 1	Minor speech problems: slurring: prosthesis, but able to communicate
Level 2	Aphasia (cannot speak or be understood well)

4 Grouping rules

The scoring goal is to have two overall independent subscales reflecting the severity of each of the two dimensions, and, after assigning patients to the two categories, a composite score reflecting the overall amount/severity of comorbidity.

First Step: Assembling an overall physiologic severity score.

In the case in which only one disease has been identified and scored, patients are placed in the level corresponding to that single score. When more than one coexistent disease has been assessed, patients are placed in the level corresponding to the highest single score (peak severity of coexistent diseases), independent of the number of conditions recorded. Eventually a subscale reflecting the maximum of the severity of the coexistent disease roughly corresponds to:

Level 0	No history or evidence of coexistent disease
Level 1	Asymptomatic controlled disease
Level 2	Symptomatic controlled disease
Level 3	Uncontrolled disease

Second Step: Derive an overall estimate of the physical impairment.

The same procedure is adopted to derive the overall physical impairment subscale score. A single number is generated from each system so that patients are classified according to the highest score recorded in these dimensions. This roughly corresponds to:

Level 0	No major identified problem or impairment
Level 1	Mild or moderate impairment
Level 2	Severe/serious impairment

At the end of this process each patient has a comorbidity profile indicating the presence and amount of a given peak disease, the number of identified diseases and the impact of diagnosed or not conditions on physical impairment. A classification system that takes into account two dimensions with 4 and 3 levels respectively generates 12 combinations. The two subscales were condensed into a single composite scale assessing the overall severity of coexistent illness, called Index of Coexistent Disease (ICED) using only 4 categories.

The two dimensions were combined in order to have a 4 point scale where patients were ranked in increasing intensity of physiologic and physical impairment, as shown below.

Peak Intensity of Disease Severity (0,1,2,3)	Peak Intensity of Functional Severity (0,1,2)	ICED Levels (1,2,3,4)
0	0	1
0	1	1
1	0	2
2	0	2
1	1	3
2	1	3
3	any (0,1 or 2)	4
any (0-3)	2	4

Appendix-8

Figures to Chapter 7

Fig 7-1a: Normal plot of deviance from the regression model for serious complication in the UK (using four levels of the ICED)

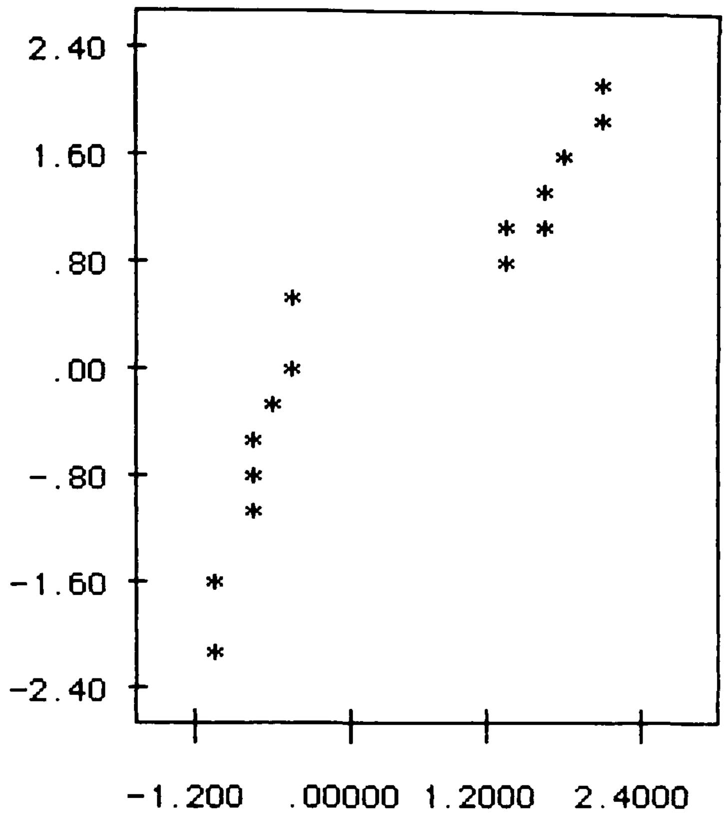

Fig 7-1b: Normal plot of deviance from the regression model for serious complication for the UK (using dichotomised ICED 1/2 or 3/4)

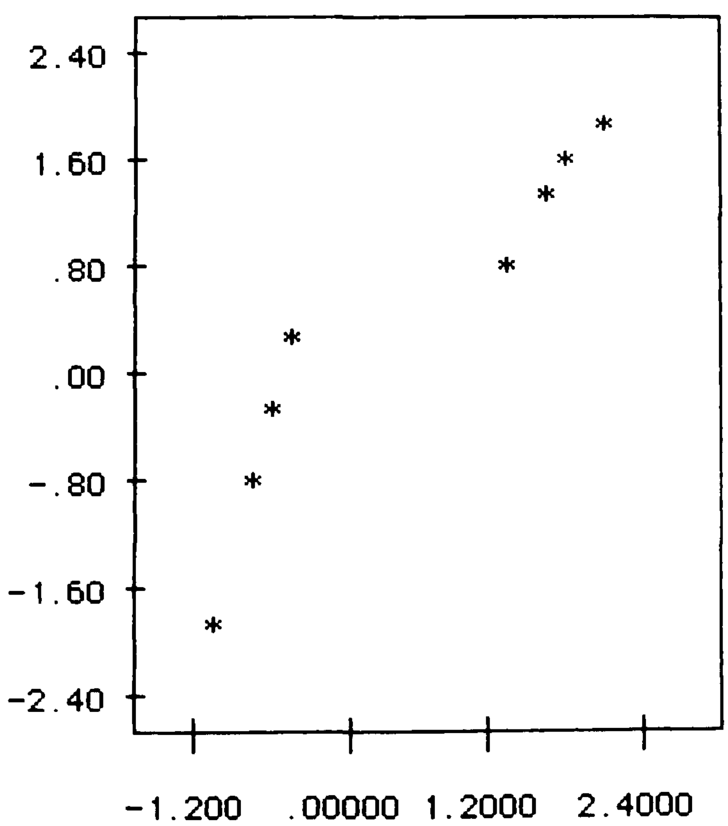

Figure 7-2a: Distribution of change in basic ADL in Japan

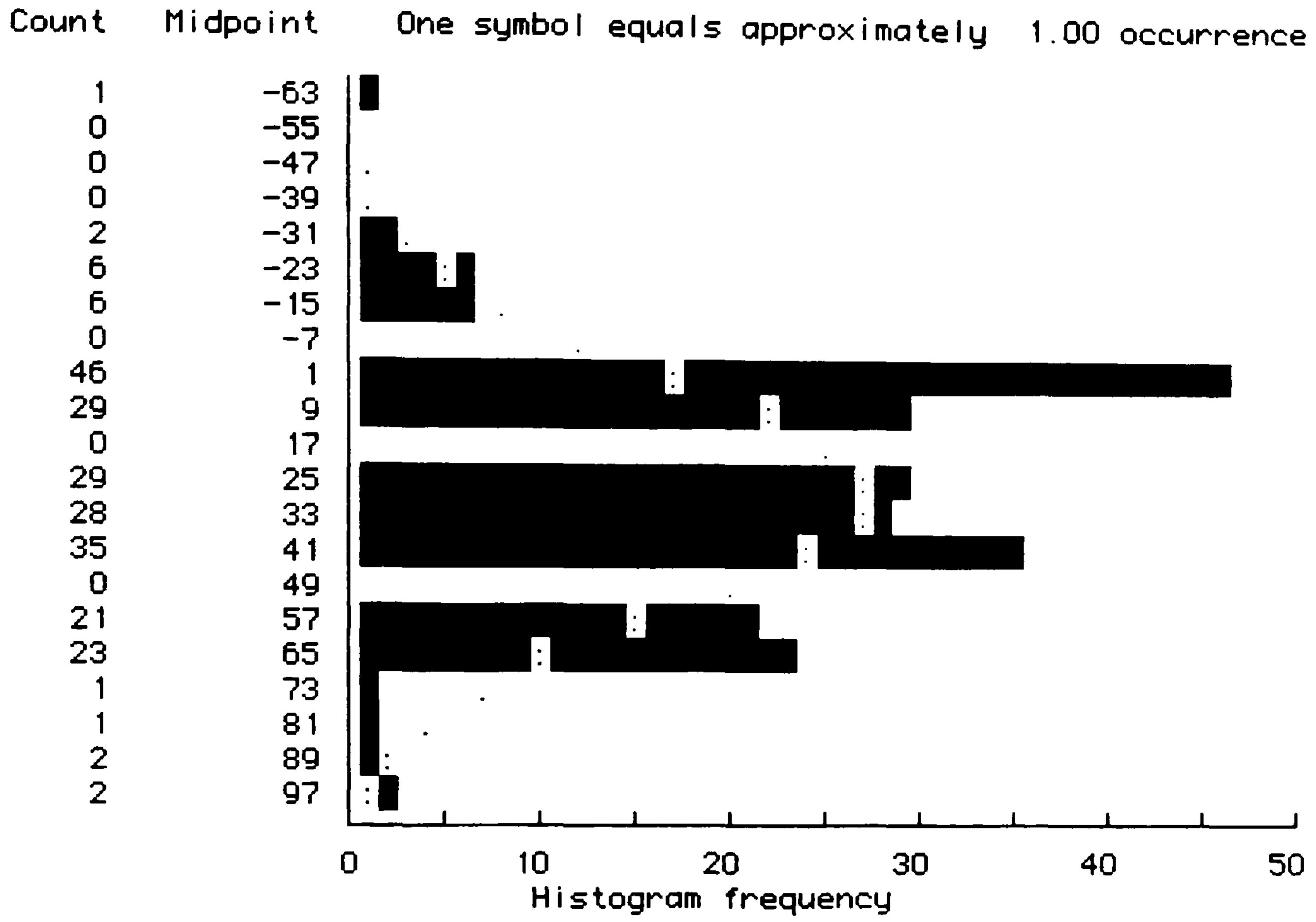

Figure 7-2b: Distribution of change in instrumental ADL in Japan

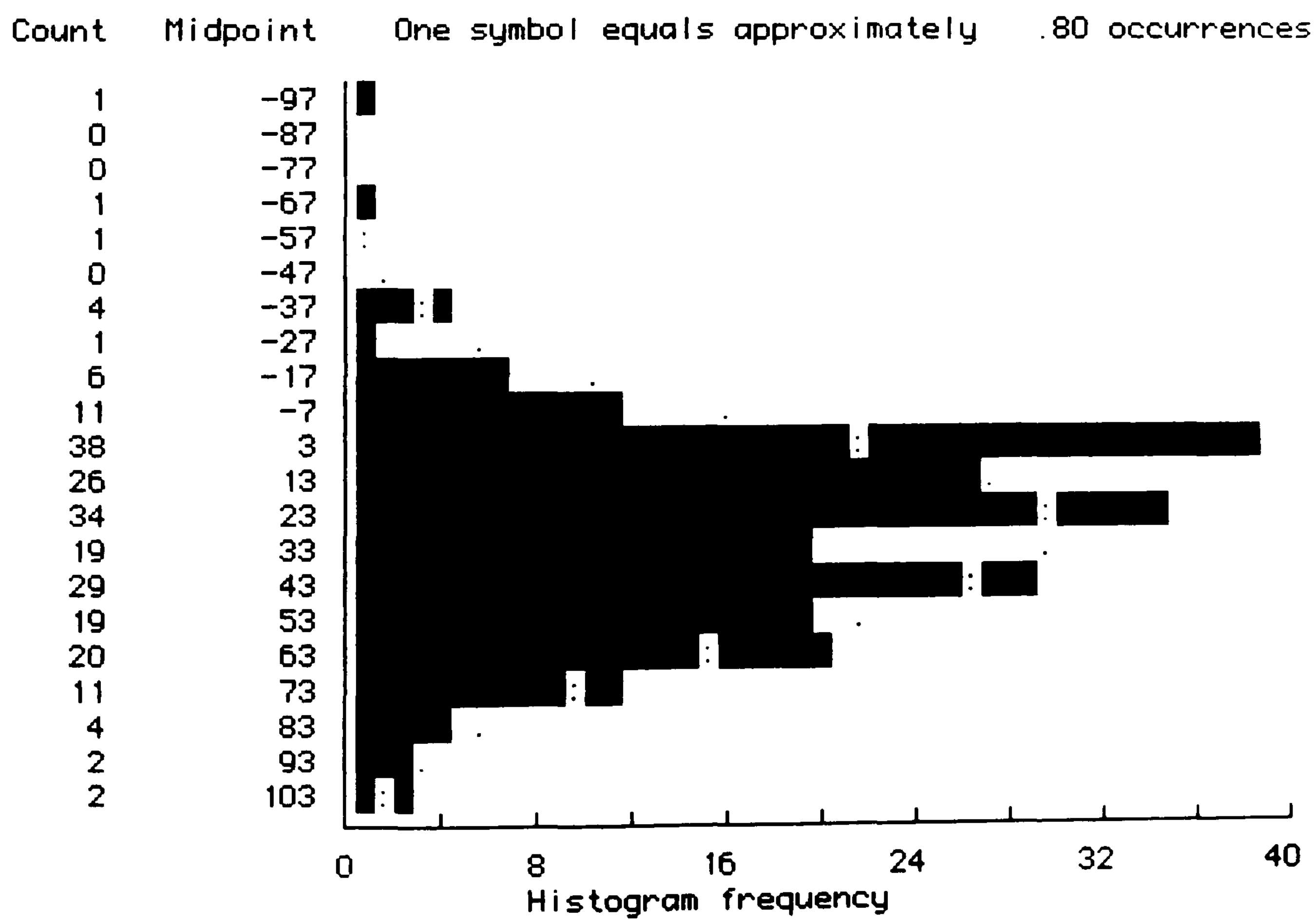

Figure 7-2c: Distribution of change in social activity in Japan

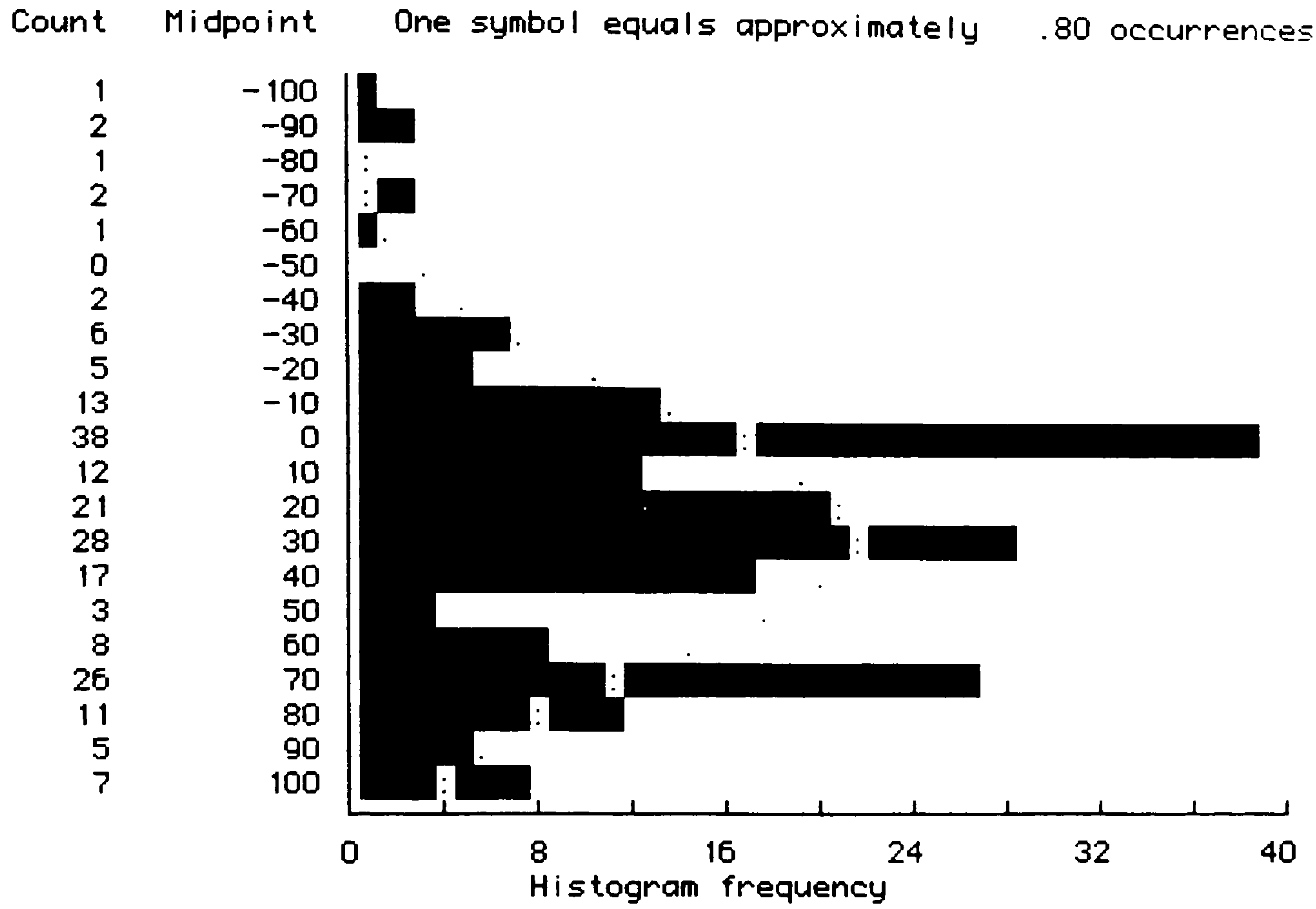

Figure 7-2d: Distribution of change in basic ADL in the UK

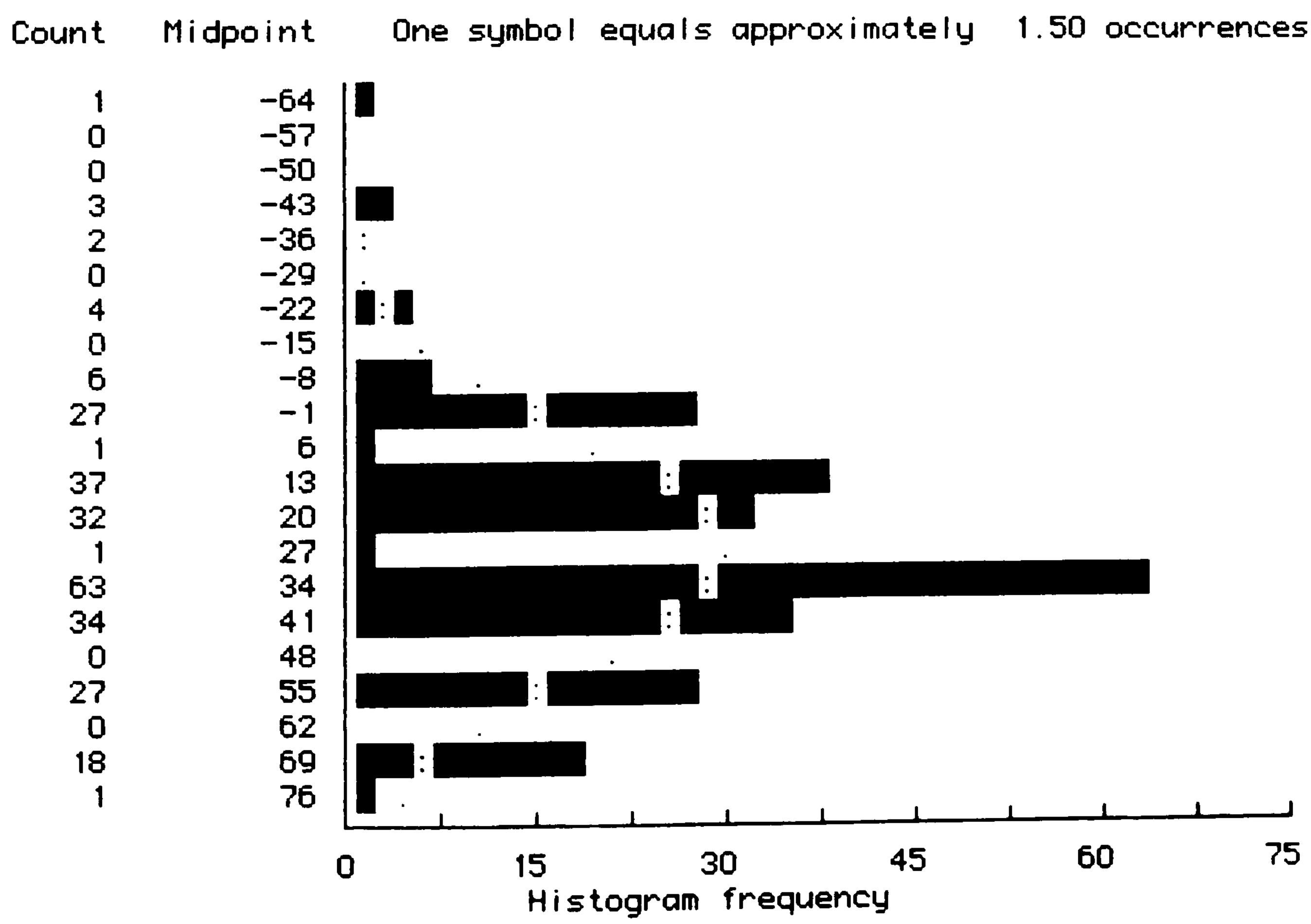

Figure 7-2e: Distribution of change in instrumental ADL in the UK

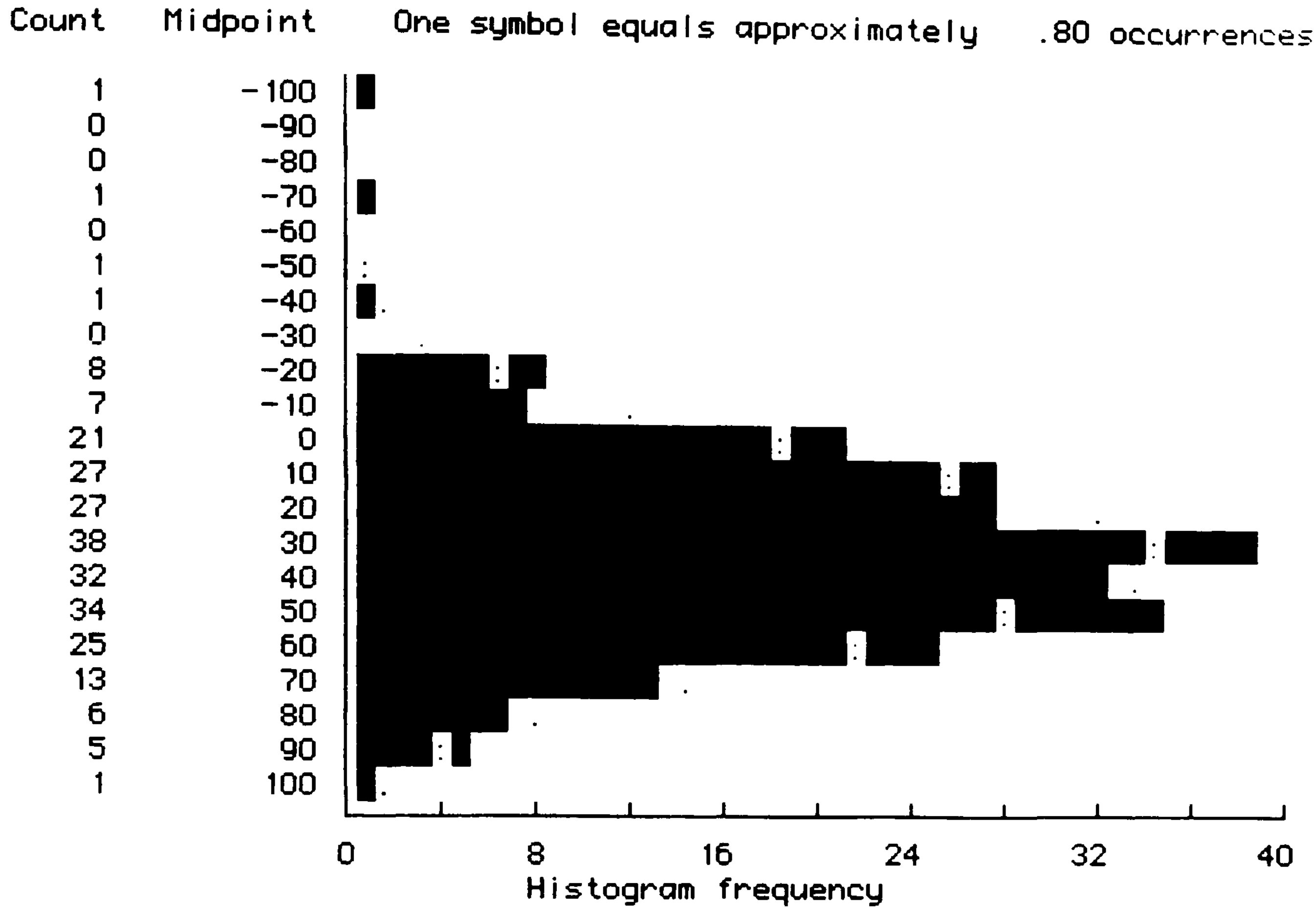

Figure 7-2f: Distribution of change in social activity in the UK

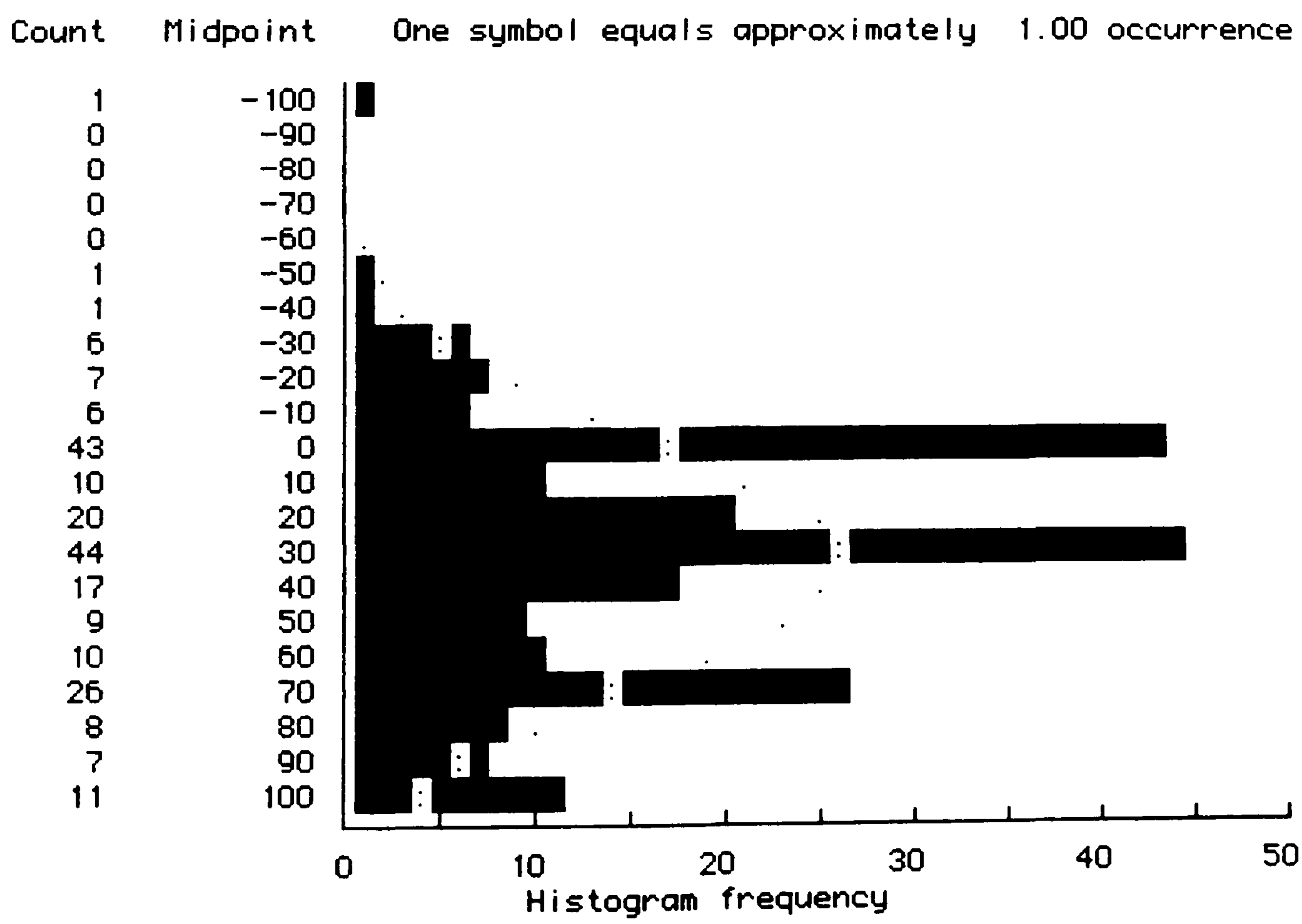

Figure 7-2g: Distribution of change in basic ADL in Japan after transformation

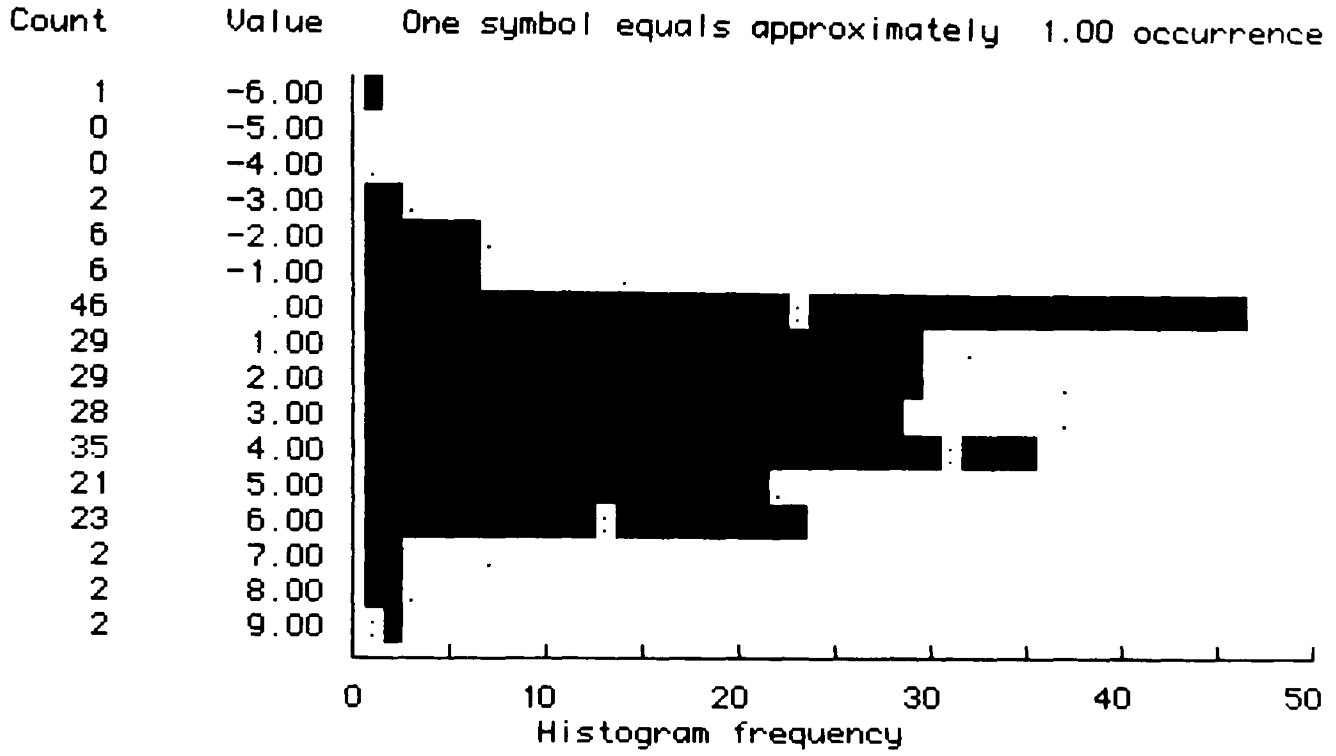

Figure 7-2h: Distribution of change in basic ADL in the UK after transformation

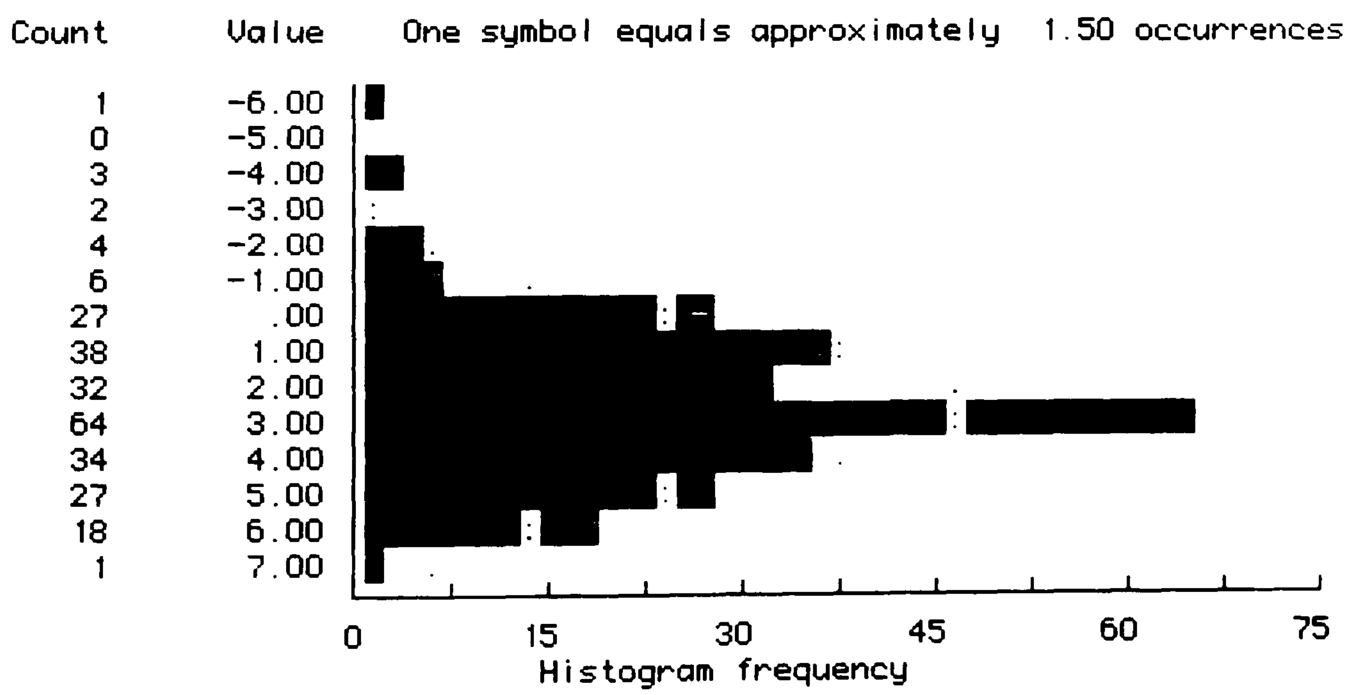

Figure 7-2i: Distribution of residual over predicted value from regression model for change in instrumental ADL in Japan

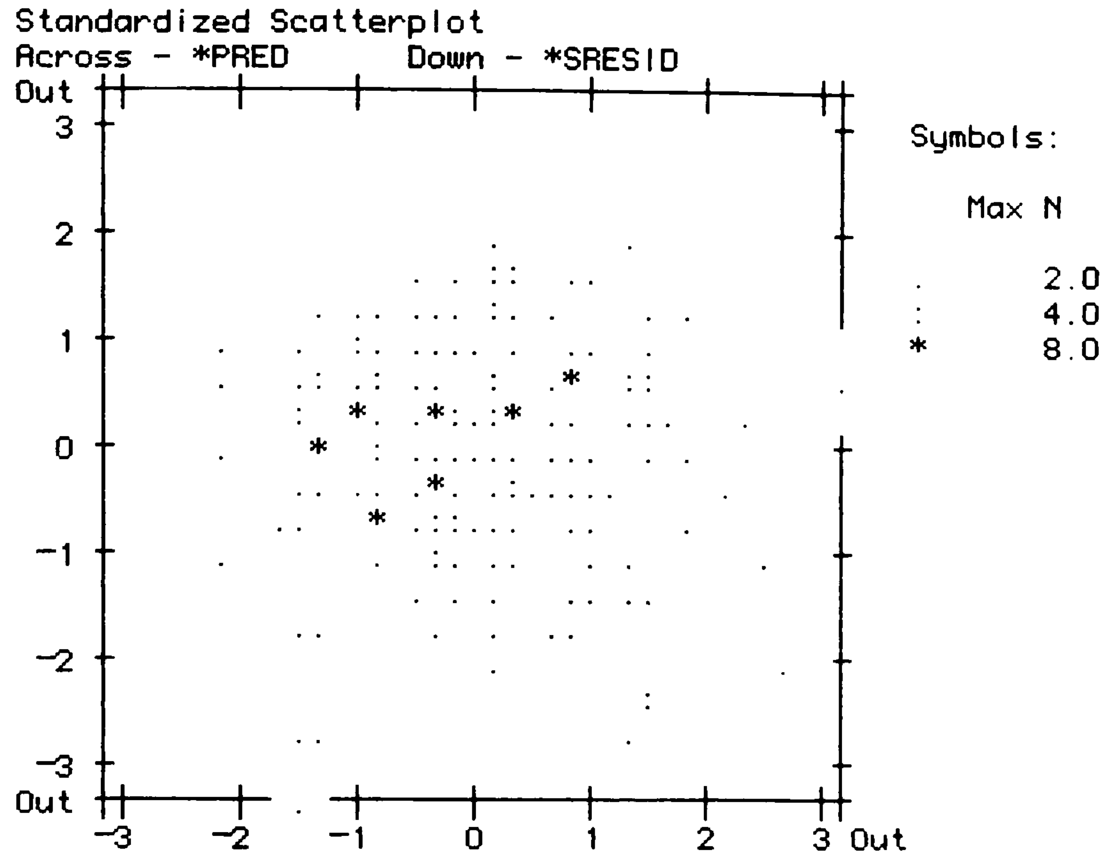

Figure 7-2j: Distribution of residual over predicted value from regression model for change in social activity in Japan

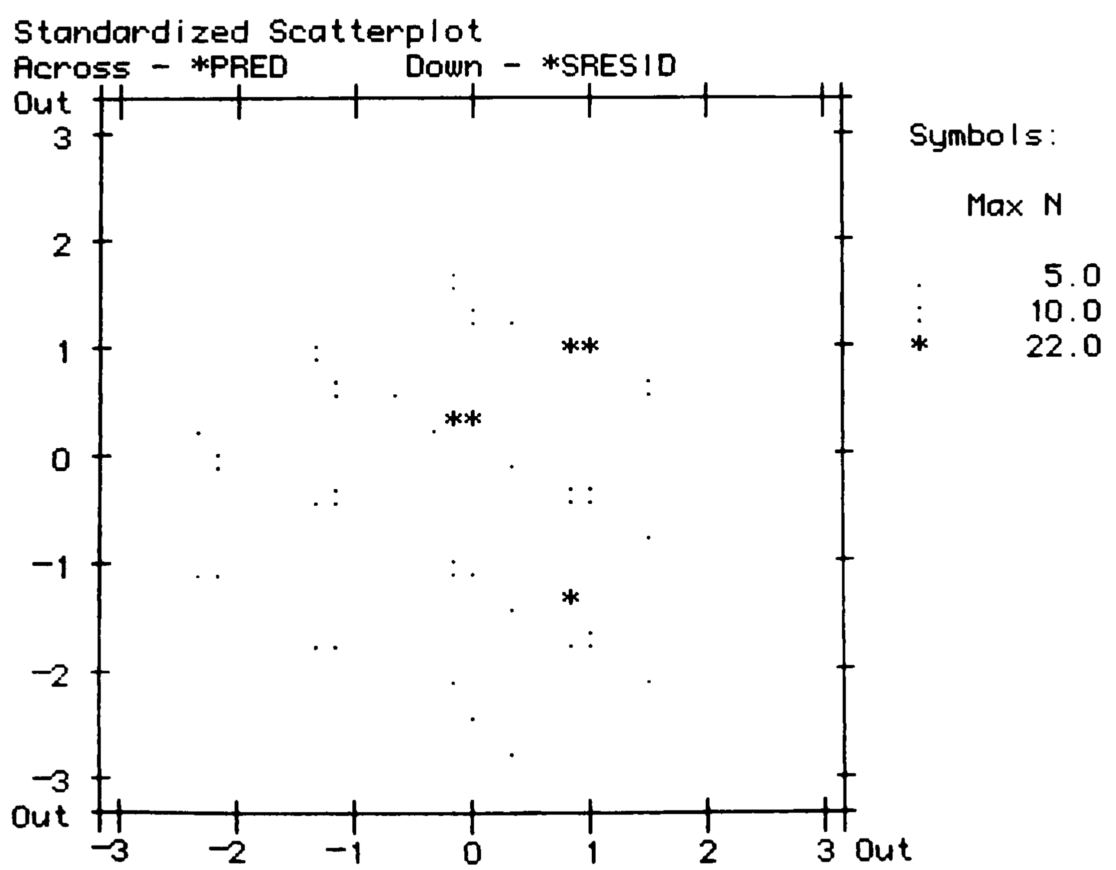

Figure 7-2k: Distribution of residual over predicted value from regression model for change in instrumental ADL in the UK

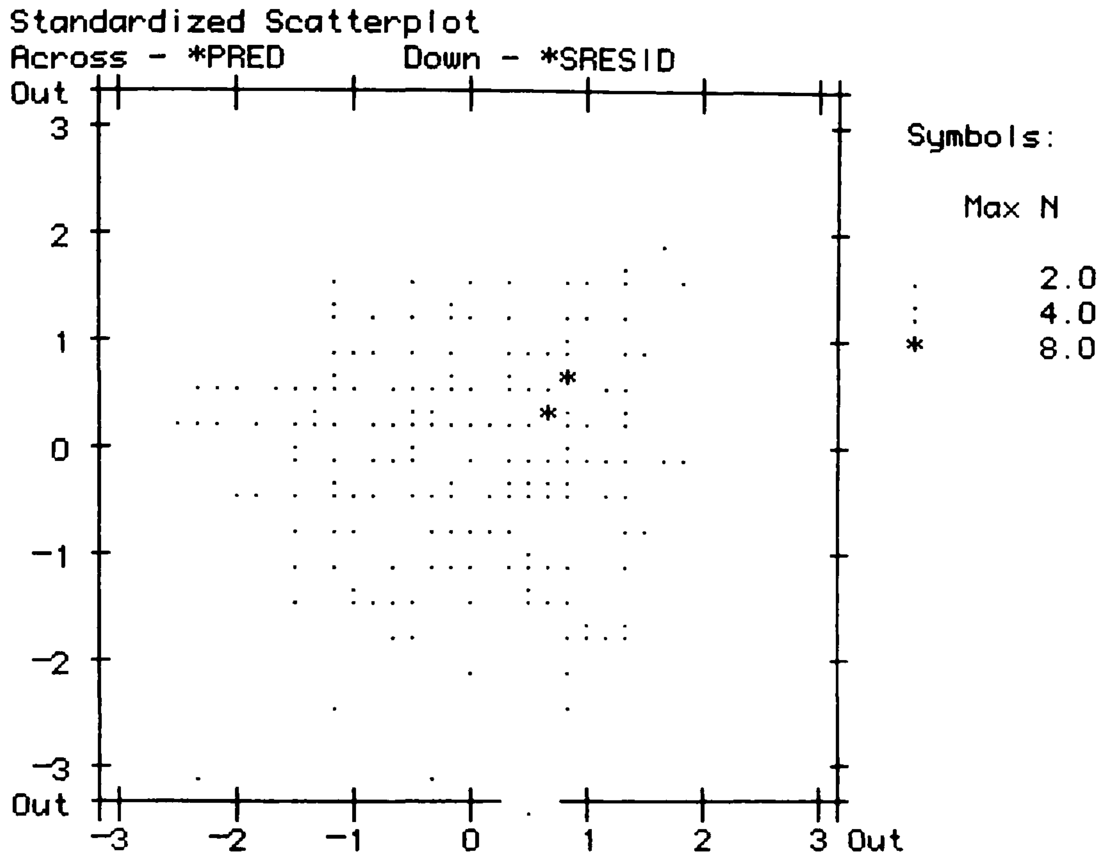

Figure 7-2l: Distribution of residual over predicted value from regression model for change in social activity in the UK

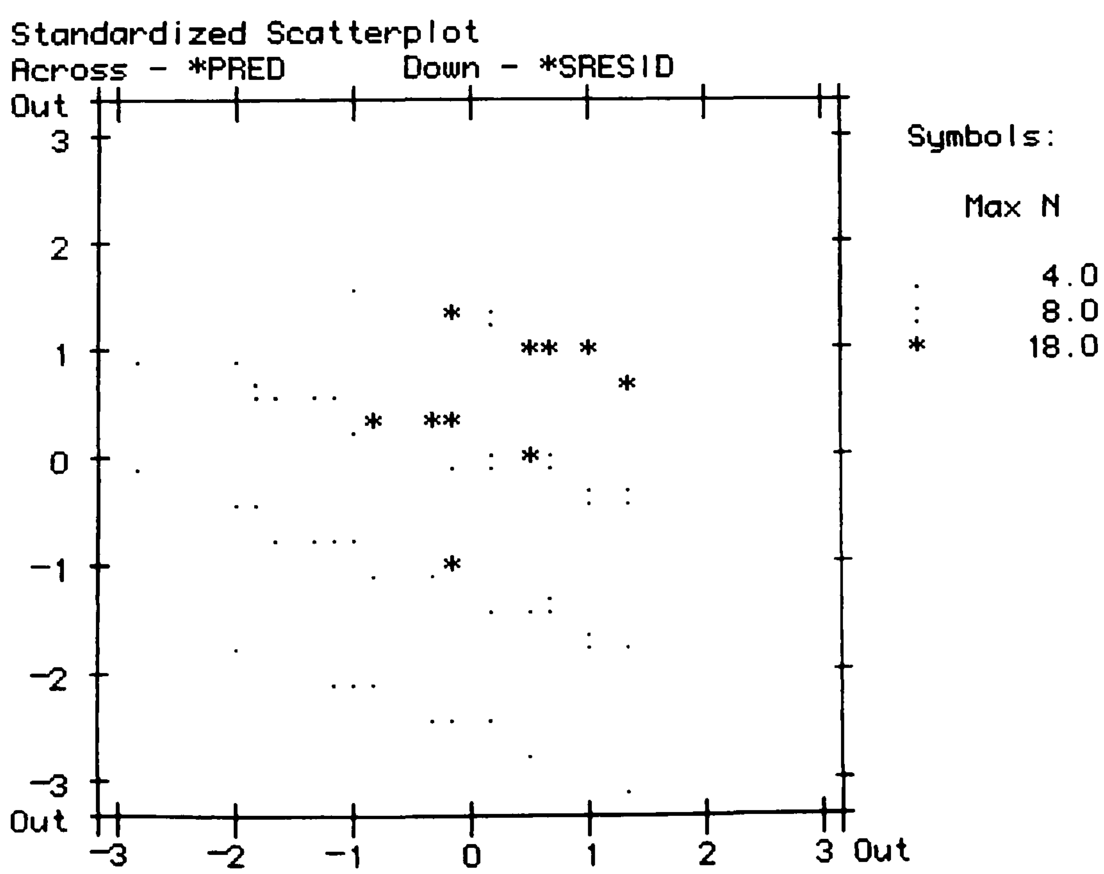

Figure 7-2m: Linearity of observed residual over expected value from regression model for change in instrumental ADL in Japan

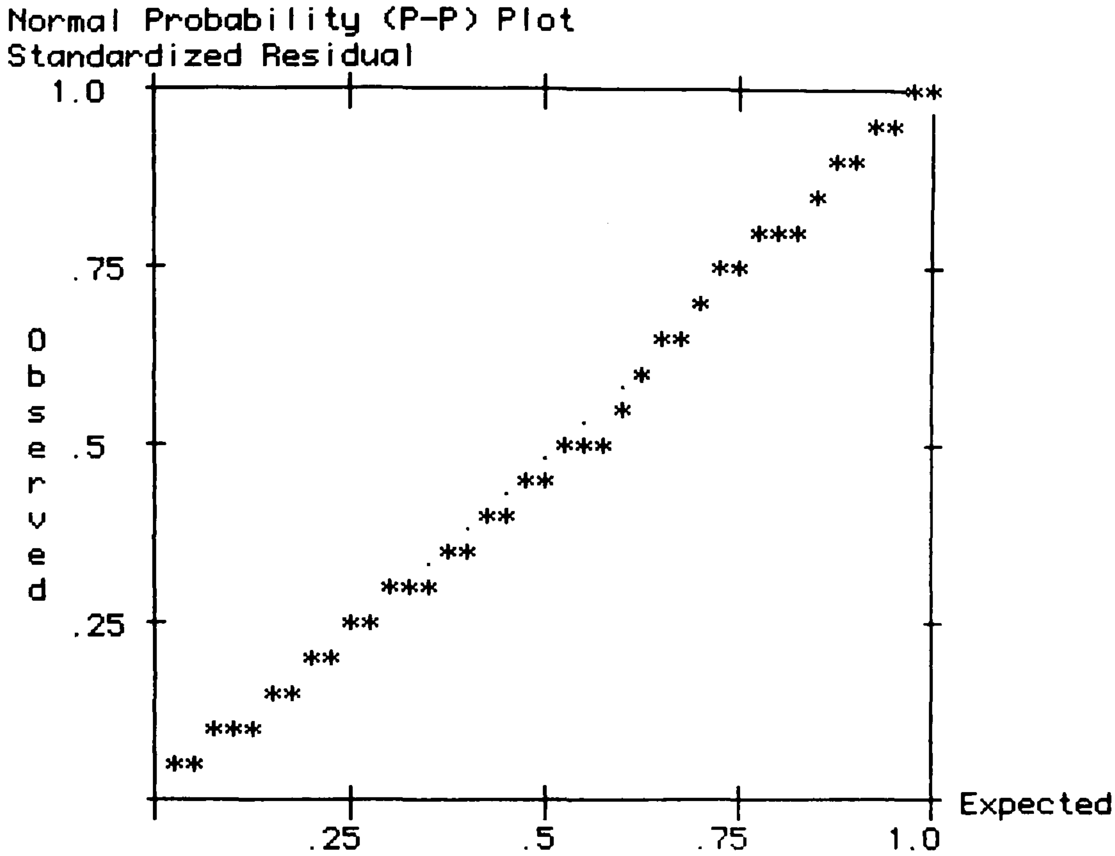

Figure 7-2n: Linearity of observed residual over expected value from regression model for change in social activity in Japan

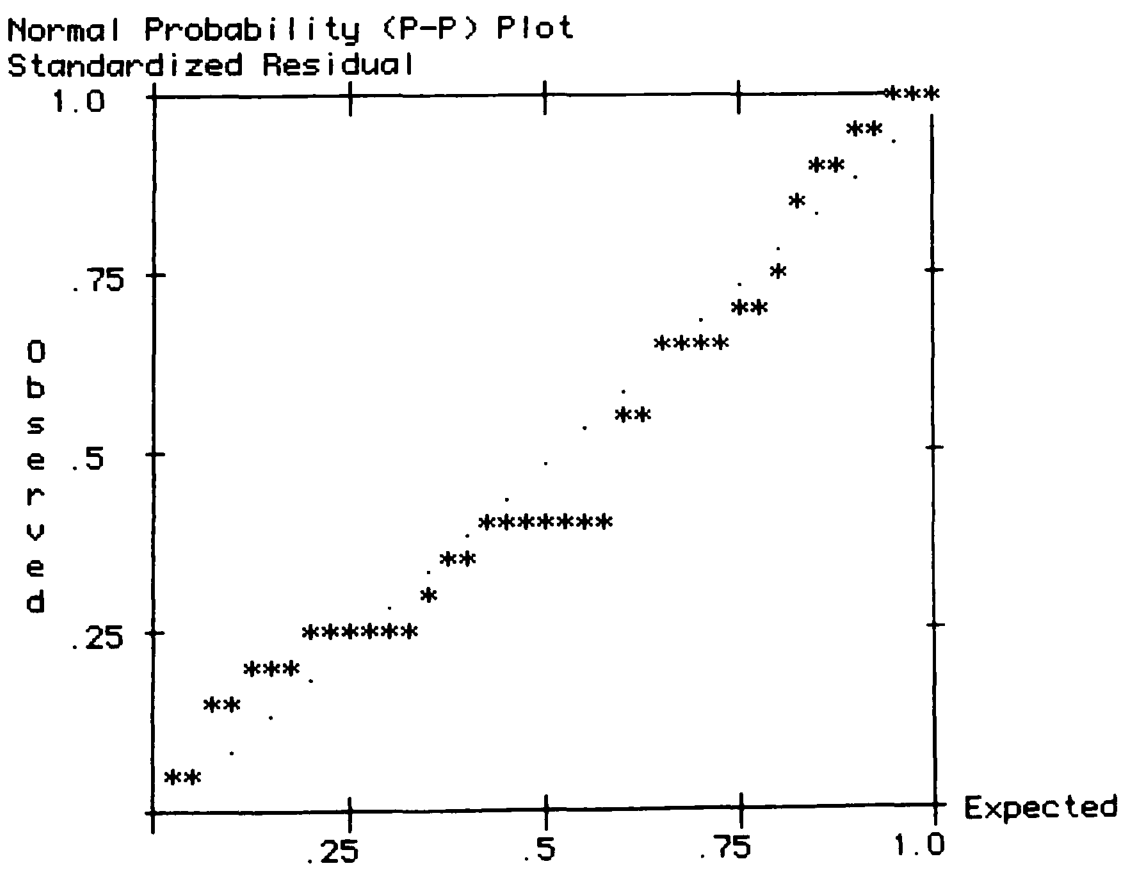

Figure 7-2o: Linearity of observed resicual over expected value from regression model for change in instrumental ADL in the UK

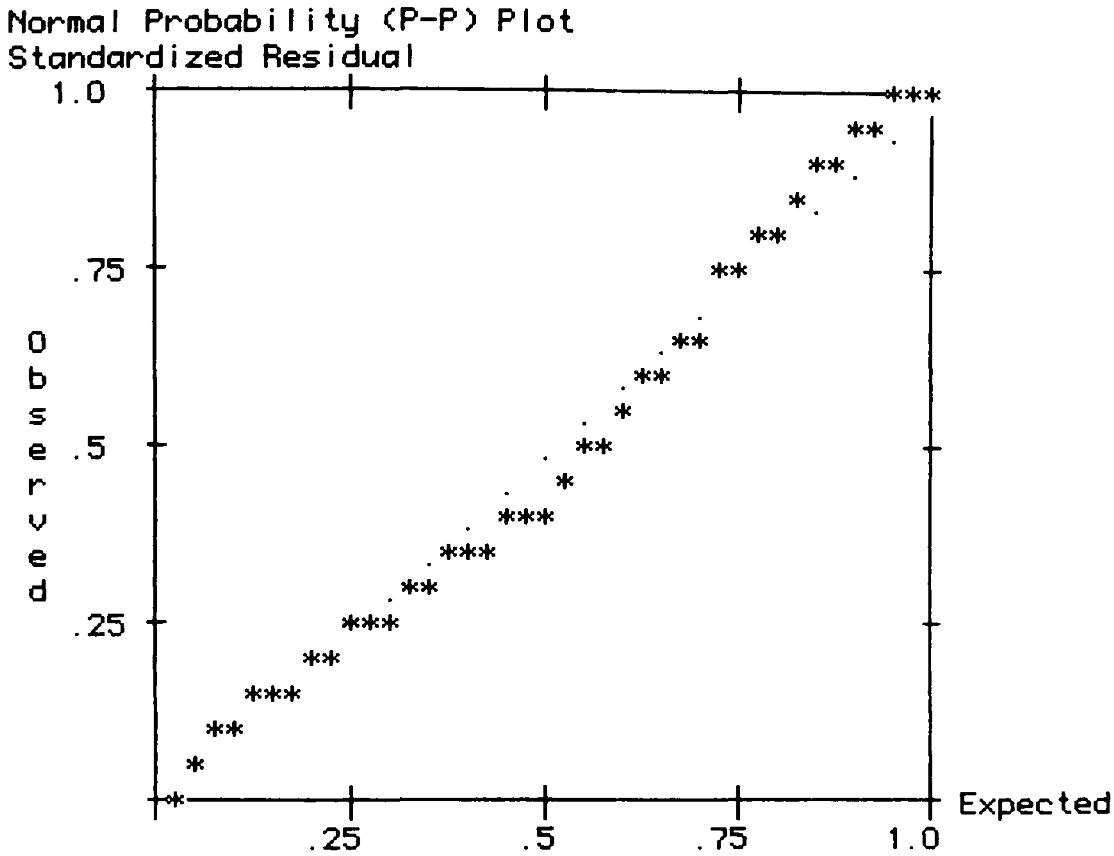

Figure 7-2p: Linearity of observed residual over expected value from regression model for change in social activity in the UK