Reoperation rates after breast conserving surgery for breast cancer among women in England: retrospective study of hospital episode statistics

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Abstract

Objectives To examine whether rate of reoperation after breast conserving surgery is associated with patients’ characteristics and investigate whether reoperation rates vary among English NHS trusts.

Design Cohort study using patient level data from hospital episode statistics.

Setting English NHS trusts.

Participants Adult women who had breast conserving surgery between 1 April 2005 and 31 March 2008.

Main outcome measure Reoperation rates after primary breast conserving surgery within 3 months, adjusted using logistic regression for tumour type, age, comorbidity, and socioeconomic deprivation. Tumours were grouped by whether a carcinoma in situ component was coded at the time of the primary breast conserving surgery.

Results 55 297 women had primary breast conserving surgery in 156 NHS trusts during the three year period. 11 032 (20.0%, 95% confidence interval 19.6% to 20.3%) women had at least one reoperation. 10 212 (18.5%, 18.2% to 18.8%) had one reoperation only; of these, 5943 (10.7%, 10.5% to 11.0%) had another breast conserving procedure and 4269 (7.7%, 7.5% to 7.9%) had a mastectomy. Of the 45 793 women with isolated invasive disease, 8229 (18.0%) had at least one reoperation. In comparison, 2803 (29.5%) of the 9504 women with carcinoma in situ had at least one reoperation (adjusted odds ratio 1.9, 95% confidence interval 1.8 to 2.0). Substantial differences were found in the adjusted reoperation rates among the NHS trusts (10th and 90th centiles 12.2% and 30.2%).

Conclusion: One in five women who had breast conserving surgery in England had a reoperation. Reoperation was nearly twice as likely when the tumour had a carcinoma in situ component coded. Women should be informed of this reoperation risk when deciding on the type of surgical treatment of their breast cancer.

Introduction

Each year, 430 000 new cases of breast cancer are diagnosed in Europe and 250 000 in the United States. 1 2 In England, around 45 000 women are diagnosed as having breast cancer annually, 3 and in 2008 58% had breast conserving surgery. 4 Breast conserving surgery involves removing only part of the affected breast and, when combined with postoperative radiotherapy, produces survival rates similar to those achieved with mastectomy alone for women with invasive disease. 5 The choice of breast conserving surgery or mastectomy depends on the extent of the cancer, the size of the tumour relative to the size of the breast, its location, and the patient’s preference. Preoperative chemotherapy may reduce the size of a tumour to allow breast conserving surgery, but a slightly higher risk of local recurrence exists compared with mastectomy. 6

The adoption of breast conserving surgery has been aided by advances in imaging techniques and the use of radiologically placed guide wires. 7 8 Both have improved surgeons’ ability to localise tumours. However, certain circumstances can complicate breast conserving surgery. Firstly, surgery becomes more complex for multifocal disease, which is found in up to 35% of...
Women with breast cancer.6 Secondly, women may have invasive disease, carcinoma in situ (non-invasive disease) only, or a combination of both. Identifying the presence and extent of a carcinoma in situ component is more difficult using standard clinical or radiological techniques than is isolated invasive disease.10 Primary breast conserving surgery may therefore result in incomplete excision of cancer or inadequate clearance margins, which both typically require women to have reoperation to the breast.11 This is usually done as soon as possible to minimise the delay to adjuvant treatments, which could increase the risk of recurrence. A breast reoperation may involve a further breast conserving procedure or mastectomy. Reoperation after breast conserving surgery has various undesirable consequences. It may delay adjuvant treatments, and some evidence suggests that it is associated with increased rates of local and distant recurrence.12 13 It is likely to cause a significantly poorer cosmetic outcome, regardless of whether the reoperation is a second breast conserving procedure or a mastectomy.14 Reoperation also puts women through the emotional distress of being told that their cancer has not been completely excised and leads to delays in their recovery. This extended recovery period can hinder the ability of women to resume work and other activities, so it has an adverse socioeconomic effect. The additional procedures also represent a burden to the healthcare system in terms of potentially avoidable financial costs and lower levels of productivity. Few studies have examined reoperation rates after breast conserving surgery, and uncertainty exists about how likely women are to need reoperation. Estimated rates from international hospital based studies have ranged from 17% to 68%.10 11 15-18 In this study, we estimated rates of breast reoperation after primary breast conserving surgery among women treated in English NHS trusts. We examined whether rate of reoperation after breast conserving surgery was associated with patients’ characteristics and whether reoperation rates varied among English NHS trusts. The NHS does close to 90% of breast cancer surgery in England.19

Methods

Patient selection and definitions

The study used data extracted from the hospital episode statistics. This database contains records describing the type, timing, and location of all surgery for breast cancer among patients admitted to NHS acute trusts in England.20 Patients’ diagnoses, comorbidities, and complications are coded using ICD-10 (international classification of diseases, 10th revision),13 and procedures are coded using the classification of surgical operations from the UK Office of Population Censuses and Surveys (OPCS), version 4.21

This study included all women aged over 16 years with a diagnosis of invasive carcinoma (ICD-10 code: C50) or carcinoma in situ (D05) of the breast who had unilateral breast conserving surgery between 1 April 2005 and 31 March 2008. The three digit code for carcinoma in situ covers both ductal (D05.1) and lobular (D05.0) carcinoma in situ, but the subtype may be left unspecified (D05.9). Although most women with a D05 code had ductal carcinoma in situ, the proportion of women with an unspecified subtype varied between NHS trusts. We therefore used the three digit ICD-10 code to avoid artificially introducing variation.

We used diagnostic information in the record of the primary surgery to identify tumour type. We grouped women according to whether or not a carcinoma in situ component was recorded instead of the presence or absence of invasive disease, the more common approach. This was because tumours with a carcinoma in situ component are considered to be more difficult to localise preoperatively, making them harder to excise completely.10 21

In English NHS trusts, coders first record information on diagnosis (C50, D05, or both) based on preoperative biopsy findings. They then amend these diagnoses, if required, after receipt of the definitive postoperative histology results.

We identified primary breast conserving surgery (OPCS codes B28.1, B28.2, B28.3, B28.5, B28.8, and B28.9) and mastectomy (B27) procedures. As hospital episode statistics do not contain the date of diagnosis of cancer, we reviewed each woman’s hospital admissions in the preceding year to ensure that the breast conserving surgery operation identified between April 2005 and March 2008 was their first procedure for breast cancer.

We identified subsequent breast conserving procedures done on the same breast (that is, coded with the same laterality) by using a range of breast operation codes (B28.1, B28.2, B28.3, B28.4, B28.5, B28.8, and B28.9) (see appendix for description of codes). This was because the specific code for re-excision of breast margins (B28.4) was not used consistently across NHS trusts. We also identified subsequent mastectomies (B27) done on the same breast after the initial primary breast conserving surgery. We excluded 27 subsequent operations done within one week of the primary breast conserving surgery, assuming that they were for postoperative complications. We limited the definition of reoperation to procedures done within three months to avoid including operations to treat early local recurrence.

We recorded age at admission, comorbidity, and socioeconomic deprivation. We used the Royal College of Surgeons of England’s modified Charlson score to calculate comorbidity.22 This sums the number of chronic comorbid conditions (excluding cancer) recorded in the index admission and the number of acute or chronic comorbid conditions recorded in any hospital admissions over the previous year. We used the area based index of multiple deprivation for 2007 to measure socioeconomic deprivation.23 The index combines indicators of income, employment, education, and health deprivation for small geographical areas of about 1500 people. We assigned the deprivation score by using the patient’s area of residence and then grouped patients into five categories ranging from 1 (least deprived) to 5 (most deprived) divided by the quintiles of the scores.

Statistical analysis

We calculated reoperation rates for England overall, for various groups of patients, and for each NHS trust. We used the χ² test to assess differences between unadjusted rates. All P values were two sided, and we considered those lower than 0.05 to be statistically significant.

We used multivariable logistic regression to examine the relation between the risk of reoperation and patients’ characteristics (age at admission, tumour group, comorbidity, and socioeconomic deprivation). We then used this model to derive risk adjusted reoperation rates for each NHS trust. We summed the probabilities of reoperation for women treated at the same NHS trust to give its predicted rate of reoperation. We produced risk adjusted reoperation rates for each NHS trust by dividing its unadjusted reoperation rate by its predicted rate and multiplying this ratio by the national reoperation rate.

We used a funnel plot to examine the variation in adjusted reoperation rates among the NHS trusts that did more than 30 primary breast conserving surgery procedures over the three year period.24 This plot tests whether the reoperation rate of a
trust differs significantly from the national rate for England. Two funnel limits indicate the ranges within which 95% or 99.8% of NHS trusts would be expected to fall if variation from the national rate was due only to random fluctuations. We used Stata version 10 for all calculations.

Results

Between 1 April 2005 and 31 March 2008, we identified 104 917 women with breast cancer who had primary breast cancer surgery at 163 English NHS trusts. We excluded 4293 (4.1%) women who had simultaneous operations on both breasts and 4742 (4.5%) with primary procedures that did not have the laterality coded. This left 95 882 women in the analysis cohort. Of these women, 55 297 (57.7%) had breast conserving surgery and 40 585 (42.3%) had mastectomy as their primary therapeutic procedure (fig 1). Among the 55 297 women who had primary breast conserving surgery, 45 793 (82.8%) had isolated invasive disease, 6622 (12.0%) had isolated in situ disease, and 2882 (5.2%) had both invasive and in situ disease coded in their primary breast conserving surgery record. Thus, a total of 9504 (17.2%) women had a carcinoma in situ component recorded at the time of the primary breast conserving surgery.

Reoperation rates at individual NHS trusts

One hundred and forty-eight English NHS trusts did more than 30 primary breast conserving surgery procedures over the three year period (the “minimum volume” criterion excluded 58 women). We excluded a further 306 women for whom information about their age and deprivation category was missing (table 2). The reoperation rate among women who had breast conserving surgery varied significantly across the 148 trusts (fig 2); the 10th and 90th centiles of the rates were 12.4% and 29.5%. The effect of adjusting the reoperation rates for patients’ characteristics (age at admission, tumour group, comorbidity, and socioeconomic deprivation) differed across the trusts; 11 values changed by an absolute value of at least 2%. However, this did not reduce the between trust variation overall (fig 3). The 10th and 90th centiles of the adjusted reoperation rates were 12.2% and 30.2%. We found no evidence that reoperation rates were related to the level of activity at an NHS trust.

Discussion

Reoperation after breast conserving surgery for breast cancer can result in a poorer cosmetic outcome compared with mastectomy, and evidence shows that reoperation is associated with increased rates of local and distant recurrence.1 2 7 8 9. One in five women who had primary breast conserving surgery in the English NHS between April 2005 and March 2008 needed a breast reoperation within three months. Moreover, among women who had breast conserving surgery as a reoperation, one in seven needed further surgery. Reoperation was more common among women with a carcinoma in situ component recorded at the time of the primary breast conserving surgery than in those without (29.5% v 18.0%). It was also more common among younger women.

A fourfold variation existed in the reoperation rate between the English NHS trusts. This raises questions about the uniformity of the selection criteria for both primary breast conserving surgery and reoperation, and it highlights the need for cancer networks and professional organisations to develop initiatives aimed at reducing the risk of reoperation. The current situation is unsatisfactory as it results in women having experiences of care that depend on where they are treated. This is of concern because around 40% of women who had a reoperation after breast conserving surgery ended up having a mastectomy. The reasons for the lower rates of reoperation at particular NHS trusts should be explored so that lessons can be learnt and disseminated.

Strengths and limitations of study

Our study has several strengths. It used a comprehensive national database, which reduces the risk of selection bias. We focused on breast reoperation rates and did not include subsequent operations to the axilla, and we required primary and subsequent procedures to have the same laterality to avoid including contralateral procedures as reoperations. We chose to estimate reoperation rates by provider and not by surgical team, because NHS trust is reliably coded in hospital episode statistics, whereas the coding of surgical team has not been validated, and because the volume of activity at the level of the surgeon would give limited statistical precision. Finally, the timeframe for classifying subsequent procedures as reoperation avoided inclusion of operations for complications or for early local recurrence. As a sensitivity analysis, follow-up was extended to six months (used by some studies), and we found that this had little effect: the overall reoperation rate increased from 20.0% to 20.6%.

The hospital episode statistics database does not include records of treatment in private hospitals, and a small number of women who have their primary breast conserving surgery in an NHS hospital would have had a therapeutic reoperation in a private hospital. This migration will have lowered our estimates of overall reoperation rates, although the degree of underestimation is likely to be minimal. The effect on the rates of NHS trusts is also likely to be small compared with the variation observed.
Another limitation is the potential for inaccuracies in the coding of diagnoses and procedures within hospital episode statistics.\textsuperscript{19} Reoperation rates would be affected by the omission or miscoding of the procedure and laterality of the operation. However, validation work done for breast cancer surgery suggests that procedure codes in hospital episode statistics are accurate, with 90-93\% agreement with data provided by surgeons across English regions.\textsuperscript{30} We used a wide range of codes to identify reoperations to minimise the effect of coding errors on the observed reoperation rate. As a result, we expect the overall effect of coding errors to be small.

Our results would be influenced by the accuracy of the coding of a carcinoma in situ component. Clinical coding teams record information on diagnosis (C50, D05, or both) based on preoperative biopsy findings initially and then amend these diagnoses, if necessary, after receipt of the definitive postoperative histology results. In other words, we categorised women on the basis of their postoperative diagnosis, whereas decisions about whether to do breast conserving surgery were based on the histological diagnosis available before surgery. Overall, 17\% of women in the hospital episode statistics were coded as having carcinoma in situ. This is similar to another large retrospective study,\textsuperscript{24} although other studies have reported higher prevalence rates.\textsuperscript{25} Such misclassification would result in an overestimate of the reoperation rate among women with only invasive disease, and the relative risk between the risk of reoperation and the presence of carcinoma in situ would be underestimated owing to “regression dilution.”\textsuperscript{35}

Finally, the hospital episode statistics database does not contain information on some potential confounders such as lobular histology, location and size of tumour, mammographic density, and lymphovascular invasion.\textsuperscript{7, 27, 34} Omission of these factors from the risk adjustment model could reduce its discriminatory performance. However, differences in the prevalence of these characteristics among NHS trusts are unlikely to account for the large variation observed between organisations.

**Comparison with other studies**

Reported reoperation rates after primary breast conserving surgery vary considerably. Some single centre series found rates varying from 17\% to 68\%.\textsuperscript{18, 31, 34} The UK NHS Breast Screening Programme reported a 22\% therapeutic reoperation rate for invasive disease and a 26\% rate for isolated non-invasive disease among a sample of UK surgeons in 2007-08.\textsuperscript{14} The UK All Breast Cancer report reported that 20\% of patients with invasive disease and 29\% of women with non-invasive disease had repeat operations.\textsuperscript{29} Overseas, a study from the Netherlands which combined data from 16 hospitals on 961 patients reported a reoperation rate of 28.9\%; around 50\% of these reoperations were mastectomies.\textsuperscript{15} Using data on 2206 women who had invasive disease from four specialist centres in the United States, another study reported that 23\% of women had one reoperation, 9\% had two reoperations, and 1\% had three reoperations.\textsuperscript{17} A study from Germany of 565 women reported an overall reoperation rate of 21.4\% and rates of 10\% and 29\% for women with and without an in situ component.\textsuperscript{28}

Comparing the results of studies on reoperation rates after breast conserving surgery is hampered by differences in the enrolled populations and variable definitions, particularly across studies from different countries.\textsuperscript{19} Our results are broadly similar to those of other UK and international studies, but caution is needed owing to methodological differences. The NHS Breast Screening Programme was based on women with cancers detected by screening, who are likely to have relatively small tumours with a lower grade and stage. The All Breast Cancer report (which combined cancer registry and hospital episode statistics data) included all primary operations (breast conserving surgery and mastectomy) for men and women diagnosed as having breast cancer, and the derivation of repeat operation included axillary surgery as well as re-excision of breast tissue.

**Implications of our findings for clinical practice**

Breast conserving surgery followed by radiotherapy has been shown to give the same survival benefit as mastectomy for women with localised tumours.\textsuperscript{1} The choice between breast conserving surgery and mastectomy therefore depends on balancing the need to achieve complete excision of the tumour with patients’ preferences about cosmetic appearance. Clinical factors that influence this choice include the type, location, and spread of the tumour, multifocal disease, the ratio of tumour size to breast size, and the use of neoadjuvant systemic treatment.\textsuperscript{14} Our results highlight the importance of women also being made aware of the local rates of reoperation after primary breast conserving surgery when choosing their primary treatment, along with the likelihood of proceeding to mastectomy. In addition, our results emphasise the importance of offering mastectomy with immediate breast reconstruction as an alternative primary treatment option to women unless significant comorbidity or planned adjuvant treatment precludes this option.\textsuperscript{6} This option preserves the breast mound while making further therapeutic reoperation extremely unlikely.

An important finding of our study is that reoperation rates after breast conserving surgery were higher in women with a carcinoma in situ component recorded at the time of their primary surgery. Although postoperatively identified carcinoma in situ at the invasive tumour margin is generally accepted to be a cause of inadequate surgical margins,\textsuperscript{3} women in this study without an invasive component must have had their in situ disease identified preoperatively. This suggests that the problem partly relates to difficulties in identifying the extent rather than just the presence of carcinoma in situ, because many such tumours are multifocal.\textsuperscript{17, 33} Greater use of imaging techniques, such as whole breast ultrasonography,\textsuperscript{3} may help to reduce this problem.

**Interpreting variation in reoperation rates between English NHS trusts**

Our study showed that some English NHS trusts had adjusted reoperation rates below 10\%, whereas for others it was above 30\%. The variation was evident across NHS trusts that had low, medium, and high levels of activity, and we found no evidence of a volume-outcome relation. Surgery for early breast cancer is regarded as “preference sensitive” care, in which between provider variation may be legitimate because it reflects patients’ preferences for alternative treatment options.\textsuperscript{30} For this reason, expecting all NHS trusts to have the same underlying reoperation rate would be unreasonable. However, the variation is sufficiently large to suggest that it reflects differences in clinical practice at various points during the therapeutic pathway, as well as patients’ preferences. Practice related causes of variation could include differences in selection protocols for breast conserving surgery, poor surgical technique, and differences in how resection margins are assessed (although the effect of this last could be small given the national pathology reporting guidelines\textsuperscript{28}). Nonetheless, the worse outcomes associated with reoperation mean that efforts are needed to reduce the risk of it occurring. As discussed above, this may come from improved imaging. The systematic practice of cavity margin resection has
also been advocated as a means to reduce the likelihood of surgical re-excision. 33

An important cause of variation among these clinical factors is probably the lack of consensus on what constitutes an adequate excision margin, particularly when adjuvant radiotherapy is planned. The US National Cancer Institute has questioned the need for completely clear microscopic margins in breast conserving surgery, 34 whereas the National Institute for Health and Clinical Excellence in England has recommended a minimum 2 mm radial excision margin for ductal carcinoma in situ but has not recommended margins for invasive disease. 35 In Canada, national guidelines apply only to invasive disease and recommend that margins are macroscopically clear and that any involved margins should be re-excised. 36 This lack of consensus also affects research in this area, as studies adopt varying definitions of positive margin status. 37 The uncertainty about adequate excision margins has led the Association of Breast Surgery to recommend that UK hospitals should develop their own local protocols for reoperation. 38 Research is urgently needed on how different approaches of dealing with incomplete margins influence the likelihood of local recurrence.

For these reasons, interpreting these reoperation rates derived from hospital episode statistics as indicators of the quality of care at individual trusts cannot be justified. Information on local protocols is lacking, and data on potential confounders is too limited in hospital episode statistics. 39 In addition, data on rates of local recurrence are unavailable, and NHS trusts with low reoperation rates as well as those with high rates could have higher rates of recurrence. We suggest that the rate of reoperation would be a reliable measure of hospital performance only if it is derived in the context of a national clinical audit that has the requisite data items.

Conclusion

Just over half of women diagnosed as having breast cancer in England now select breast conserving surgery as their primary treatment. Cosmetic outcomes after surgery for breast cancer are an important consideration, and women should be made aware of the local rates of reoperation after primary breast conserving surgery, along with the likelihood of proceeding to mastectomy. In addition, breast cancer teams should do a local review of surgical technique, the definition of an adequate excision margin, imaging methods, and criteria for selecting patients. This may lead to an overall reduction in the reoperation rate after breast conserving surgery.

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Contributors: RJ, DAC, GL, and OK conceived the study. RJ, DAC, GL, OK, JHPvdM, JP, CS, and CMC designed the study. MT and DAC did the statistical analyses. RJ, DAC, and JHPvdM wrote the manuscript. MT, GL, OK, JP, CS, and CMC commented on and revised drafts. DAC is the guarantor.

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Competing interests: All authors have completed the Unified Competing Interest form at http://www.icmje.org/col1_disclosure.pdf (available on request from the corresponding author) and declare: no support from any organisation for the submitted work; no financial relationships with any organisations that might have an interest in the submitted work in the previous three years; no other relationships or activities that could appear to have influenced the submitted work.

Ethical approval: The study is exempt from UK National Research Ethics Committee approval as it involved analysis of an existing dataset of anonymised data for service evaluation. Approvals for the use of hospital episode statistics data were obtained as part of the standard hospitals episode statistics approval process.

Data sharing: No additional data available.

What is already known on this topic

More than half of the 45,000 women diagnosed as having breast cancer in England have breast conserving surgery (BCS).

BCS may result in incomplete excision of the tumour, which typically requires women to have either another breast conserving procedure or a mastectomy.

Studies on the rate of reoperation after BCS have been uncommon, and estimated rates vary from 17% to 68%.

What this study adds

One in five women who had primary BCS in the English NHS between April 2005 and March 2008 needed at least one breast reoperation within three months; about 40% of these had a mastectomy.

Reoperation was more common among women with a carcinoma in situ component recorded at the time of the primary BCS than in those with isolated invasive carcinoma (29.5% v 18.0%).

Reoperation rates varied substantially between NHS trusts, raising questions about the uniformity of the selection criteria for both primary BCS and reoperation.

References:


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Table 1| Patterns of breast reoperation within three months of primary breast conserving surgery, categorised by type of tumour

<table>
<thead>
<tr>
<th>Patient group</th>
<th>Women without carcinoma in situ disease</th>
<th>Women with carcinoma in situ disease</th>
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<tbody>
<tr>
<td></td>
<td>No</td>
<td>% (95% CI)</td>
</tr>
<tr>
<td>Women who had breast conserving surgery</td>
<td>45 793</td>
<td>82.0 (81.7 to 82.4)</td>
</tr>
<tr>
<td>Women who had no reoperation</td>
<td>37 564</td>
<td>9.7 (9.4 to 10.0)</td>
</tr>
<tr>
<td>Women who had one reoperation:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Additional breast conserving operation</td>
<td>4441</td>
<td>7.0 (6.8 to 7.2)</td>
</tr>
<tr>
<td>Mastectomy</td>
<td>3201</td>
<td></td>
</tr>
<tr>
<td>Women who had two or more reoperations</td>
<td>587</td>
<td>1.3 (1.2 to 1.4)</td>
</tr>
<tr>
<td>Characteristic</td>
<td>All women</td>
<td>No (%) women with breast reoperation</td>
</tr>
<tr>
<td>--------------------------------------</td>
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<td>--------------------------------------</td>
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<tr>
<td><strong>Type of tumour:</strong></td>
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</tr>
<tr>
<td>Without in situ disease coded</td>
<td>45 793</td>
<td>8229 (18.0)</td>
</tr>
<tr>
<td>With in situ disease component coded</td>
<td>9504</td>
<td>2803 (29.5)</td>
</tr>
<tr>
<td><strong>Age (years):</strong></td>
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<tr>
<td>&lt;40</td>
<td>2348</td>
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<td>40-49</td>
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<td>12 802</td>
<td>2661 (20.7)</td>
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<tr>
<td>2</td>
<td>12 645</td>
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<tr>
<td>3</td>
<td>11 673</td>
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<tr>
<td>4</td>
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<td>48 697</td>
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<td>5991</td>
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<td>≥2</td>
<td>609</td>
<td>82 (13.5)</td>
</tr>
</tbody>
</table>

*Based on complete case analysis, which excluded 306 (0.6%) women without index of multiple deprivation score; age was also unknown for six of these women.
Figures

Fig 1 Inclusion of patients in study

Fig 2 Unadjusted breast reoperation rates in English NHS acute hospital organisations for women who had breast conserving surgery for breast cancer between 2005 and 2008. BCS=breast conserving surgery

Fig 3 Risk adjusted breast reoperation rates in English NHS acute hospital organisations for women who had breast conserving surgery for breast cancer between 2005 and 2008. BCS=breast conserving surgery