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Randomised controlled trial of an interactive multimedia decision aid on benign prostatic hypertrophy in primary care

Elizabeth Murray, Hilary Davis, Sharon See Tai, Angela Coulter, Alastair Gray, Andy Haines

Abstract

Objective To determine whether a decision aid on benign prostatic hypertrophy influences decision making, health outcomes, and resource use.

Design Randomised controlled trial.

Setting 33 general practices in the United Kingdom.

Participants 112 men with benign prostatic hypertrophy.

Intervention Patients’ decision aid consisting of an interactive multimedia programme with booklet and printed summary.

Outcome measures Patients’ and general practitioners’ perceptions of who made the decision, decisional conflict scores, treatment choice and prostatectomy rate, American Urological Association symptom scale, costs, anxiety, utility, and general health status.

Results Both patients and general practitioners found the decision aid acceptable. A higher proportion of patients (32% v 4%; mean difference 28%, 95% confidence interval 14% to 41%) and their general practitioners (46% v 25%; 21%, 3% to 40%) perceived that treatment decisions had been made mainly or only by patients in the intervention group compared with the control group. Patients in the intervention group had significantly lower decisional conflict scores than those in the control group at three months (2.3 v 2.6; −0.3, −0.5 to −0.1; P<0.01) and this was maintained at nine months. No differences were found between the groups for anxiety, general health status, prostatic symptoms, utility, or costs (excluding costs associated with the video disc equipment).

Conclusions The decision aid reduced decisional conflict in men with benign prostatic hypertrophy, and the patients played a more active part in decision making. Such programmes could be delivered cheaply by the internet, and there are good arguments for coordinated investment in them, particularly for conditions in which patient utilities are important.

Introduction

The rationale for decision aids is addressed in the accompanying paper. Unlike hormone replacement therapy, prostate surgery is a “Rubicon” procedure—that is, once undertaken it cannot be reversed. In the United States, a pilot study on the impact of a programme to aid in decisions about benign prostatic hyperplasia showed a 40% decrease in surgery rates. This finding was not replicated in a subsequent randomised controlled trial.

We aimed to determine whether an interactive multimedia decision aid in primary care would promote greater patient involvement in decision making and what influence this had on treatment choices and health outcomes. We also aimed to determine the acceptability of such a system to patients and general practitioners and the impact on a general practitioner’s workload and to undertake an economic analysis.

Participants and methods

Patient recruitment

We invited general practitioners in two urban areas (Oxford and London), one suburban area (Harrow), and one semirural area (Thame and the Chilterns) to participate in our study. We asked participating doctors to recruit men with benign prostatic hypertrophy opportunistically. The doctors were asked to retain their normal clinical practice in diagnosing or managing the condition but to refer patients to the study as soon as they were confident about the diagnosis. The men needed a sufficient understanding of English to be able to consult without an interpreter. Men were excluded if there was any clinical suggestion of carcinoma of the prostate or if they had chronic retention of urine, recent urinary tract infection, a history of acute urinary retention or prostate surgery, severe visual or hearing impairment, or severe learning difficulties or mental illness. Ethical approval was obtained from local research ethics committees.

Intervention

The intervention, developed by the Foundation for Informed Medical Decision Making, comprised an interactive multimedia programme with booklet and printed summary. Information was obtained from studies by the Patient Outcome Research Team and other published trials. Treatment options discussed were surgery (prostatectomy or transurethral prostatectomy), balloon dilatation of the prostate, drugs (a blockers and 5a reductase inhibitors), and watchful waiting. Information comprised probabilities of the
Benign Prostatic Hyperplasia: Choosing Surgical or Non Surgical Treatment

Example of printout given to each patient after viewing the programme

Primary care

Possible Benefits of the Treatment Options

1. Surgical Treatment, which includes three approaches:
   - Prostatectomy
   - Transurethral incision of the prostate or TUIP
   - Balloon dilatation of the prostate

2. Non Surgical Treatment, which includes two approaches:
   - Watchful waiting
   - Taking medication

Important Message:
This is a decision to be taken by you and your doctor. How you decide depends on how you feel about your symptoms and how you feel about the possible harms and benefits of the surgical approaches compared to the possible harms and benefits of non-surgical approaches. Not every man is a good candidate for all possible benign prostatic hyperplasia treatments. Your doctor can help explain which treatment would be possible in your situation.

We have summarised the main messages presented in the programme below:

Possible Benefits of the Treatment Options

1. Surgical Options:
   - With prostatectomy and the TUIP there is a good chance for substantial reduction of symptoms. For men with your moderate symptoms by the end of one year, 79% of men have only mild symptoms. Another 15% have moderate symptoms and 6% are putting up with severe symptoms.
   - With balloon dilation 40-70% of men appear to have some symptom improvement soon after, however, the benefits don't last as long as prostatectomy and the TUIP. Only 50% of men followed for two or three years after balloon dilatation are still improved. With balloon dilatation there can be a reduction in symptoms, but seldom for as long as with prostatectomy or TUIP.
   - There is less chance of future prostate problems such as acute retention, urinary tract infection and bladder and kidney damage, after prostatectomy and TUIP.

2. The Non-Surgical Options:
   - With watchful waiting, there is a chance that symptoms may improve on their own. For men with your moderate symptoms, by the end of one year, 28% of men have only mild symptom. Another 47% have moderate symptoms and 16% are putting up with severe symptoms.

Possible Harms of the Treatment Options

1. Surgical Options:
   - For men who choose a prostatectomy:
     - Chance of death: for men in your age group, 4 out of 1000 will die (which means that 996 out of 1000 will survive) within 6 weeks of surgery; however, not all these deaths are due to surgery.
     - Medical complications: about 1% of men will experience medical complications such as a heart attack, stroke, pneumonia or blood clot in the lungs.
     - Readmission: about 8% of men require readmission to the hospital for a prostate related problem within 3 months following surgery.
     - Incontinence: up to 1% of men experience complete loss of control of urine, while 4% of men indicate some partial loss of control.
     - Sexual problems: between 60% and 100% of men experience retrograde ejaculation. About 5% of men consistently have problems getting an erection, while 10-20% have some intermittent problems getting erections after surgery.
     - Reoperation: 4-10% of men will need another operation in the five years following their first prostatectomy.
   - Risks of TUIP compared to prostatectomy:
     - Bleeding and medical complications happen less often than with a prostatectomy.
     - Incontinence may also be less common and retrograde ejaculation happens in only 15 - 40% of men who have a TUIP.
     - Stricture is less common after TUIP. Although reoperation rates aren't well studied for TUIP, some experts worry that the risk of reoperation may be higher because no prostate tissue is removed.
     - For men who chose a balloon dilation:
       - Bleeding and medical complications happen less often than with the other surgical treatments.
       - Incontinence is possible, although cases have been extremely rare, and retrograde ejaculation together with impotence although not well studied also appear to be rare.
       - There is no evidence that this procedure reduces the risks of acute retention, urinary tract infection or bladder and kidney damage when compared to prostatectomy or TUIP.

2. The Non-Surgical Options:
   - For men who choose watchful waiting:
     - There may be an increase in the risks associated with surgery if you decide to have surgery in the future. For men with your symptoms about 5% will decide to have surgery over a one year period.
     - Acute retention will occur in about 7% of men over 5 years, and serious urinary tract infection will occur in less than 2% of men in 5 years.
     - Kidney or bladder damage can occur, but the risk appears to be very low with regular physicians visits to monitor your condition.

For men who choose medication:
- All medications for BPH carry with them some chance of side effects. Dizziness, tiredness, and weakness are the main possible side effects of the alpha blockers. With reductase inhibitors, about 4% of men have problems with sexual function. Any side effects should eventually go away if you stop taking the drug.
- There is very little information available about the side effects of medications for BPH taken for more than a year.
- Alpha blockers must be used cautiously in men with some other medical problems, and by those taking some other medications.
Table 1 Unit costs in pounds sterling (at 1999 prices) and sources of information used in economic evaluation

<table>
<thead>
<tr>
<th>Item</th>
<th>Unit cost</th>
<th>Source</th>
</tr>
</thead>
<tbody>
<tr>
<td>Generic consultation with doctor</td>
<td>14.00</td>
<td>Department of Health</td>
</tr>
<tr>
<td>Doctor’s cost per minute</td>
<td>1.62</td>
<td>Department of Health</td>
</tr>
<tr>
<td>Urology consultation</td>
<td>56.46</td>
<td>English average from trust’s financial return</td>
</tr>
</tbody>
</table>

Tests:
- Urine (microscopy and culture): 6.00 Average from five trusts
- Prostatic specific antigen: 28.17 Average from five trusts
- Ultrasound: 12.00 Average from five trusts
- Cystoscopy: 35.00 Average from five trusts
- Urinary flow: 24.00 Average from five trusts
- Biopsy: 55.00 Average from five trusts
- Transurethral prostatectomy: 1795.00 Average from five trusts

Drugs:
- Tamsulosin 5 mg/day (56 pack of 5 mg): 24.80 British National Formulary
- Prazosin 5 mg/day (56 pack of 500 μg): 2.09 British National Formulary
- Indomethacin 5 mg/day, 20 mg twice daily (60 pack): 12.30 British National Formulary
- Tolerodine 1 mg/day, 2 mg twice daily (36 pack): 32.00 British National Formulary
- Interactive decision aid session: 283.85 See box

We recorded the resources used by each patient over the trial period. These were the equipment and staff time associated with video sessions, the number and duration of consultations with the general practitioners, referrals to urologists, other referrals, drugs related to benign prostatic hypertrophy, tests, and diagnostic and surgical procedures. The unit costs were attached to resource volumes to obtain a total cost per patient. Table 1 shows the unit costs used in the analysis and the sources of information. To aid generalisability of the results we obtained unit costs from national sources where possible.

We measured utility with the Euroqol EQ-5D at baseline and at three and nine months. Valuations of health states were taken from the UK population tariff. We compared point values, summed values over the trial, and changes from baseline to the end of the trial. The box shows the costs of the technology used in the trial; these are not included in the baseline analysis, as an alternative and much less costly delivery system is now available for presenting the same content. We conducted our economic evaluation from the perspective of the healthcare system. All costs are in pounds sterling at 1999 prices.

### Sample size

We postulated that patients with more information would tolerate greater intensity of symptoms without seeking active treatment, as preliminary results from the United States showed a reduced uptake of surgery in the intervention group. Additionally, a concern commonly voiced by general practitioners during the developmental phase of the trial was that the intervention could raise patients’ anxiety. A sample size of 160 patients (80 in each group) would have given us 90% power to detect a difference of 3.7 points (from 15 to 18.7) in the mean scores on the American Urological Association symptom scale for the two groups and 6 points (from the baseline mean score of 32 to 38) on the Spielberger state trait anxiety inventory at the 5% level of significance. Allowing for a 30% dropout rate, we planned to recruit 210 patients; however, both recruitment and dropout rates were less than expected (figure). A retrospective calculation determined that the power to detect the observed difference in decisional conflict score between the two groups at the final assessment was 85% at the 5% significance level.

As recruitment was slower than anticipated, we monitored consultations at one large computerised practice and also identified all patients referred to a local ultrasound department for ultrasonography of the prostate to see whether eligible patients were attending participating general practitioners but not being referred to the study. We were unable to find any missed cases.
Costs of trial technology

Video disc systems were installed in five locations. The video hardware systems were obtained at a cost of £24,300. No insurance or maintenance costs were incurred, but each system had to be kept in a secured room, a locked cupboard, or a combination of these. Arrangements for use of space to store and use the equipment varied between centres, but a total of £3070 was paid over the five centres for storage and room rental.

Software for the disc players was obtained from the Foundation for Informed Decision Making. The cost of software was $1900 (£1118) per video disc, giving a total cost of $9500 (£5590) plus £400 for shipping and insurance.

Because of technological change during the study, the equipment had no residual value by the end of the study. However, the equipment had no residual value by the end of the insurance.

The total cost of $9500 (£5590) plus £400 for shipping and insurance was $9500 (£5590) plus £400 for shipping and insurance.

The total equipment and storage costs were therefore £15,840.

Arrangements for use of space to store and use the equipment varied between centres, but a total of £24,300. No insurance or maintenance costs were incurred, but each system had to be kept in a secured room, a locked cupboard, or a combination of these. Arrangements for use of space to store and use the equipment varied between centres, but a total of £3070 was paid over the five centres for storage and room rental.

A total of 57 patients in the current trial used the equipment across the five centres. The cost per patient involved per viewing session. Based on a research nurse being on F grade, the cost of this time was £5.85 per session.

Statistical analysis

We analysed data for all outcomes for those patients who completed the assessments. We also performed an intention to treat analysis to allow for those patients who did not complete the study and who were therefore unable to provide data at the nine months’ assessment. For that analysis we assumed no change in score on any outcome from the beginning of the study, and we substituted baseline data for the missing data at the final assessment. Where data for resource use were missing for the second follow up only or for individual resource items, we took the mean value for that item in that arm of the study. We present the results for those who completed the nine months’ assessment, as the intention to treat analysis did not alter the results.

We compared the change in scores for the American Urological Association and Spielberger scales from baseline to final assessment between the study groups. We compared the decisional conflict scores between the two groups at three and nine months, as we hypothesised that decisional conflict would be greater closer to the decision making process. We performed Mann-Whitney U tests when data for outcome measures were skewed (as detected by Kolmogorov-
Table 4  Decisional conflict score at three months. Values are means (SDs) unless stated otherwise

<table>
<thead>
<tr>
<th>Intervention group</th>
<th>Control group</th>
<th>Mean difference (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Uncertainty</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Factors contributing to uncertainty</td>
<td>2.3 (0.5)</td>
<td>2.7 (0.6)</td>
</tr>
<tr>
<td>Perceived effective decision making</td>
<td>2.0 (0.4)</td>
<td>2.2 (0.6)</td>
</tr>
<tr>
<td>Total decisional conflict score</td>
<td>2.3 (0.4)</td>
<td>2.6 (0.5)</td>
</tr>
</tbody>
</table>

The decisional conflict scale contains three subscales that elicit uncertainty about choosing between alternatives, awareness of modifiable factors contributing to the uncertainty, and perceived effectiveness of decision making process. Higher scores indicate increased uncertainty in each subscale. Subscales can be combined to give a total decisional conflict score. Subjects with strong intentions to accept or decline a health intervention tend to lower scores and those who remain uncertain tend to higher scores.12  **P<0.01.

Table 5  General practitioners’ and patients’ perceptions of decision making at three months. Values are means (percentages) of patients unless stated otherwise

<table>
<thead>
<tr>
<th>Resource item</th>
<th>Intervention group (n=57)</th>
<th>Control group (n=48)</th>
<th>Mean difference (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>No of consultations: General practitioner</td>
<td>2.27 (1.21)</td>
<td>2.32 (1.62)</td>
<td>-0.05 (-0.61 to 0.51)</td>
</tr>
<tr>
<td>Urologist</td>
<td>0.42 (0.75)</td>
<td>0.55 (0.84)</td>
<td>-0.13 (-0.44 to 0.163)</td>
</tr>
<tr>
<td>Other</td>
<td>0.14 (0.40)</td>
<td>0.22 (0.41)</td>
<td>-0.06 (-0.23 to 0.06)</td>
</tr>
<tr>
<td>No of tests:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Urine</td>
<td>0.26 (0.52)</td>
<td>0.41 (0.57)</td>
<td>-0.14 (-0.38 to 0.07)</td>
</tr>
<tr>
<td>Prostatic specific antigen</td>
<td>0.40 (0.62)</td>
<td>0.28 (0.43)</td>
<td>0.14 (-0.06 to 0.35)</td>
</tr>
<tr>
<td>Ultrasound</td>
<td>0.33 (0.61)</td>
<td>0.27 (0.49)</td>
<td>0.06 (-0.15 to 0.28)</td>
</tr>
<tr>
<td>Cystoscopy</td>
<td>0.04 (0.19)</td>
<td>0.02 (0.14)</td>
<td>0.01 (-0.05 to 0.08)</td>
</tr>
<tr>
<td>Urinary flow</td>
<td>0.25 (0.51)</td>
<td>0.30 (0.58)</td>
<td>-0.06 (-0.27 to 0.16)</td>
</tr>
<tr>
<td>Biopsies</td>
<td>0.05 (0.23)</td>
<td>0.04 (0.20)</td>
<td>0.01 (-0.07 to 0.09)</td>
</tr>
<tr>
<td>No of prostatectomies or referrals for prostatectomies</td>
<td>0.11 (0.31)</td>
<td>0.02 (0.14)</td>
<td>0.08 (-0.01 to 0.18)</td>
</tr>
</tbody>
</table>

*P<0.12, *P<0.01,  **P<0.05,  ***P<0.001.

Impact on decision making

Patients reacted positively to the decision aid (table 3). At three months, patients in the intervention group showed lower decisional conflict on all three subscales and on their total score (table 4); this significant difference was maintained at the final assessment (total score at nine months: mean (SD) scores, intervention group 2.25 (0.38), control group 2.55 (0.50); mean difference −0.33, 95% confidence interval for mean difference −0.51 to −0.14). A higher proportion of both general practitioners and patients perceived that treatment decisions had been made mainly or only by the patients in the intervention group (table 5).

General practitioners were positive about the decision aid; of 50 follow up consultations with patients in the intervention group they said that the decision aid had helped in 46, made no difference in three, and hindered in one.

Anxiety and other health status outcomes

The Spielberger scores were similar at the final assessment in the two groups (Mann-Whitney U test). The American Urological Association scores in both groups improved over the study period. The amount of change was not significantly different in the two groups (median change in score −1 in intervention group, −2 in control group; Mann-Whitney U test, P=0.8). We found no difference between the two groups in the trends over time in the EQ-5D responses nor in the SF-36 scores.

Economic evaluation

Missing data were replaced by conditional means in less than 4% of resource use items. No significant differences were detected in resource volumes used per patient between the groups (table 6).

Table 7  Costs in pounds sterling (at 1999 prices) per patient, by allocation. Values are means (SDs) unless stated otherwise

<table>
<thead>
<tr>
<th>Cost item</th>
<th>Intervention group (n=57)</th>
<th>Control group (n=48)</th>
<th>Mean difference (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Doctor appointments</td>
<td>59.2 (26.9)</td>
<td>56.7 (40.4)</td>
<td>-8.5 (-20.1 to 7.2)</td>
</tr>
<tr>
<td>Urology consultations</td>
<td>23.8 (42.6)</td>
<td>35.9 (47.3)</td>
<td>-12.1 (-24.7 to 10.5)</td>
</tr>
<tr>
<td>Other consultations</td>
<td>2.9 (9.6)</td>
<td>3.6 (5.8)</td>
<td>-0.7 (-3.3 to 1.1)</td>
</tr>
<tr>
<td>Tests and investigative procedures</td>
<td>26.9 (26.9)</td>
<td>23.2 (25.6)</td>
<td>3.6 (-6.8 to 15.8)</td>
</tr>
<tr>
<td>Prostatectomies and referrals for prostatectomy</td>
<td>188.9 (555.8)</td>
<td>37.4 (259.1)</td>
<td>151.6 (-127.2 to 315.8)</td>
</tr>
<tr>
<td>Drugs</td>
<td>18.5 (80.1)</td>
<td>37.6 (86.7)</td>
<td>-19.1 (-53.4 to 19.2)</td>
</tr>
<tr>
<td>Total costs, excluding intervention</td>
<td>310.3 (802.0)</td>
<td>188.8 (309.4)</td>
<td>121.5 (-58.9 to 302.0)</td>
</tr>
<tr>
<td>Total costs, including intervention</td>
<td>594.1 (802.0)</td>
<td>188.8 (309.4)</td>
<td>405.4 (224.8 to 585.8)</td>
</tr>
</tbody>
</table>

***P<0.001.

Smirnov and Shapiro Wilk tests for assessing the normality of data. We present the means and standard deviations for resource use and costs; confidence intervals around mean differences between study groups are based on t tests assuming unequal variances.

Results

Recruitment

Overall, 33 general practices agreed to participate; 12 from Oxford and the Chilterns and 21 from London and Harrow. Between January 1996 and September 1998, 112 men were recruited (figure). Table 2 presents the baseline data on the two groups.
patient in the intervention group increased to £594, compared with £199 in the control group (difference £395, £225 to £586).

Discussion

The decision aid on benign prostatic hypertrophy seemed to increase patients’ participation in decision making. A higher proportion of both patients and general practitioners thought that patients had “mainly or only” made the treatment decisions themselves in the intervention group than in the control group. Patients who viewed the programme had reduced decisional conflict scores (indicating reduced uncertainty about the decision) at three months, and this was maintained at nine months. The intervention was acceptable to both the patients and the doctors. The general practitioners were, however, likely to have had a prior interest in shared decision making. Recently, general practice registrars reported not being trained in the skills required to involve patients in clinical decisions.1

The intervention did not reduce costs; six out of seven completed or planned prostatectomies were in the intervention group. These results make it unlikely that the intervention reduced prostatectomy rates in a UK general practice population, but the study was underpowered to determine whether it caused an increase in the surgical rate.

Methodological considerations

The low recruitment rate prevented us from definitively determining that there was no increase in anxiety in the intervention group; however, the intervention had no noticeable impact on anxiety. The low recruitment rate did not seem to be due to bias in recruiting patients into the trial, as we were unable to detect the non-referral of suitable patients attending the study practices. Moreover, as randomisation occurred after referral it would be unlikely to affect the main conclusion of the study. Although the technology used in these trials is now outdated, this does not affect the main findings, which relate to the interactive multimedia nature of the decision aid. The cost of delivering such programmes by the internet to standard personal computers would be small: equipment costs of £1500 over three years, with a low utilisation rate (two users per weekday) and lower space and staff costs commensurate with a less dedicated technology would bring the cost per session, excluding software, down from £177 to about £5 (€1 equipment, €2.50 staff time, €1.50 space).

Implications for the NHS

Internet sites for people seeking information on health care are proliferating, but many are of low quality. The NHS has the opportunity to provide high quality patient information and decision aids through outlets such as NHS Direct Online, with the potential to enhance patient care through informed patient choice. Accessible evidence based information for patients could play an important part in the drive to promote evidence based health care.

We thank Jo Burns for administrative support, research staff Liz Redfearn, Sue Davis, Jean Catterson, and Marjorie Talbot, and the general practitioners. AH is currently based at the London School of Hygiene and Tropical Medicine, London WC1E 7HT.

What is already known on this topic

Patients want more information about their condition and treatment options, and many want to play an active part in decision making

Decision aids improve patients’ knowledge of their condition and treatment options

What this study adds

The decision aid was highly acceptable to both the patients and their general practitioners

Decisional conflict was reduced in the intervention group

Patients who viewed the programme played a more active part in the decision making process and were less anxious than control patients

Such aids could be introduced throughout the NHS at a relatively low cost by using the internet

Contributors: AC and AH developed the idea for the study, participated in the design of the trial, and helped write the paper. AG initiated the health economic component of the study, determined the health economic data to be collected, participated in the analysis, and helped write the paper. HD coordinated the project, collected the data, participated in the analysis, and helped write the paper. EM, the principal investigator, participated in the research design, coordinated the project, participated in data analysis, and helped write the paper; she will act as guarantor for the paper.

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Competing interests: None declared.


