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Tania Lourenco, Robert Pickard, Luke Vale, Adrian Grant, Cynthia Fraser, Graeme MacLennan, James N'Dow and and the Benign Prostatic Enlargement team

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Alternative approaches to endoscopic ablation for benign enlargement of the prostate: systematic review of randomised controlled trials

Tania Lourenço, research fellow,1 Robert Pickard, senior clinical lecturer,2 Luke Vale, professor of health technology assessment,1,3 Adrian Grant, professor of health services research,1 Cynthia Fraser, information officer,1 Graeme MacLennan, statistician,1 James N’Dow, professor of urology,4 and the Benign Prostatic Enlargement team

ABSTRACT
Objective To compare the effectiveness and risk profile of newer methods for endoscopic ablation of the prostate against the current standard of transurethral resection.

Design Systematic review and meta-analysis.

Data sources Electronic and paper records in subject area up to March 2006.

Review methods We searched for randomised controlled trials of endoscopic ablative interventions that included transurethral resection of prostate as one of the treatment arms. Two reviewers independently extracted data and assessed quality. Meta-analyses of prespecified outcomes were done using fixed and random effects models and reported using relative risk or weighted mean difference.

Results We identified 45 randomised controlled trials meeting the inclusion criteria and reporting on 3970 participants. The reports were of moderate to poor quality, with small sample sizes. None of the newer technologies resulted in significantly greater improvement in symptoms than transurethral resection at 12 months, although a small sample size suggested a better outcome with holmium laser enucleation (random effects weighted mean difference -0.82, 95% confidence interval 1.76 to 0.12) and worse outcome with laser vaporisation (1.49, 95% confidence interval 0.40 to 3.39). Improvements in secondary measures, such as peak urinary flow rate, were consistent with change in symptoms. Blood transfusion rates were higher for transurethral resection than for the newer methods (4.8% vs 0.7%) and men undergoing laser ablation were much more likely to experience urinary retention (6.7% vs 2.3% and 3.6% vs 1.1%). Hospital stay was up to one day shorter for the newer technologies.

Conclusions Although men undergoing more modern methods of removing benign prostatic enlargement have similar outcomes to standard transurethral resection of prostate along with fewer requirements for blood transfusion and shorter hospital stay, the quality of current evidence is poor. The lack of any clearly more effective procedure suggests that transurethral resection should remain the standard approach.

METHODS
To identify published and unpublished reports of relevant randomised controlled trials we carried out highly sensitive electronic searches of Medline (1966-September, week 3, 2006), Embase (1980-2006, week 2.3% and 3.6% vs 1.1%). Hospital stay was up to one day shorter.
Table 1 | Summary of baseline characteristics of included studies on alternative approaches to endoscopic ablation for benign enlargement of prostate. Values are means unless stated otherwise

<table>
<thead>
<tr>
<th>Study</th>
<th>Comparator with transurethral resection of prostate</th>
<th>No of participants</th>
<th>Age (years)</th>
<th>Symptom score*</th>
<th>Urine flow (Qmax ml/s)</th>
<th>Residual volume (ml)</th>
<th>Prostate size (ml)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gupta 2006w1</td>
<td>Holmium laser enucleation</td>
<td>50, 50</td>
<td>66, 66</td>
<td>23.4, 23.3</td>
<td>5.1, 4.5</td>
<td>112, 84</td>
<td>58, 60</td>
</tr>
<tr>
<td>Kuntz 2004w2</td>
<td>Holmium laser enucleation</td>
<td>100, 100</td>
<td>68, 69</td>
<td>22.1, 21.4</td>
<td>4.9, 5.9</td>
<td>238, 216</td>
<td>53, 50</td>
</tr>
<tr>
<td>Montorsi 2004w3</td>
<td>Holmium laser enucleation</td>
<td>52, 48</td>
<td>65, 64</td>
<td>21.6, 21.9</td>
<td>8.2, 7.8</td>
<td>4, 4</td>
<td>70, 56</td>
</tr>
<tr>
<td>Westenberg 2004w4</td>
<td>Holmium laser enucleation</td>
<td>61, 59</td>
<td>67, 67</td>
<td>21.9, 23.0</td>
<td>8.9, 9.1</td>
<td>88, 85</td>
<td>44, 45</td>
</tr>
<tr>
<td>Wilson 2006w5</td>
<td>Holmium laser enucleation</td>
<td>30, 30</td>
<td>71, 70</td>
<td>26.0, 23.7</td>
<td>8.4, 8.3</td>
<td>113, 126</td>
<td>78, 70</td>
</tr>
<tr>
<td>Bouchler-Hayes 2006w6</td>
<td>Laser vaporisation</td>
<td>38, 38</td>
<td>65, 66</td>
<td>NR, NR</td>
<td>NR, NR</td>
<td>NR, NR</td>
<td>42, 33</td>
</tr>
<tr>
<td>Carter 1999w7</td>
<td>Laser vaporisation</td>
<td>95, 96</td>
<td>68, 67</td>
<td>20.3, 19.8</td>
<td>9.0, 9.5</td>
<td>109, 135</td>
<td>42, 42</td>
</tr>
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</tr>
</tbody>
</table>

NR = not reported. Total number of trials is 45 with 47 relevant comparisons.

*International prostate symptom score or American Urological Association symptom index.
†Median.
‡Danish prostatic symptom score (Dan-PSSI-1).
38), Medline In-Process (27 September 2006), Biosis (1985-22 September 2006), Science Citation Index (1981-23 September 2006), ISI Proceedings (1990-18 March 2006), Cochrane Controlled Trials Register and Cochrane Database of Systematic Reviews (Cochrane Library, Issue 1, 2006), Database of Abstracts of Reviews of Effectiveness (March 2006), National Research Register (Issue 1, 2006), Clinical Trials (March 2006), and Current Controlled Trials (March 2006). We also searched the proceedings of recent conferences of the European Association of Urology, American Urological Association, and British Association of Urological Surgeons. We defined ablative endoscopic treatments as those that resulted in immediate removal of tissue, usually by resection or vaporisation, and did not include procedures that caused delayed tissue necrosis, such as microwave and radiofrequency therapy. Searches were not restricted by publication year or language and included conference proceedings and abstracts. We scanned the reference lists of all included studies to identify additional potentially relevant studies. (Full details of the search strategies are available from the authors.) Two reviewers (TL, Angela Coutts, or Susan Wong) independently screened the titles and abstracts of identified papers and obtained full text copies of all potentially relevant studies.

### Study selection and study characteristics

We included randomised controlled trials if they assessed endoscopic ablative interventions and included transurethral resection as one of the treatment arms. We excluded trials that reported on men without a clinical diagnosis of benign prostatic enlargement; comparisons with conservative management; and trials of interventions not involving tissue removal, such as transurethral incision. Table 1 lists the interventions considered (also see supplementary table 1 on bmj.com).

The primary outcome measure was change in symptom score at 12 months after surgery, measured by the international prostate symptom score or the American Urological Association symptom index—these were considered equivalent and therefore we combined the results from trials using these instruments. The international prostate symptom score or American Urological Association symptom questionnaire asks men to rate four voiding symptoms (poor stream, intermittent flow, straining, incomplete emptying) and three storage symptoms (frequency, nocturia, urgency) on a scale from 0 (not present) to 5 (severe) to give a total score ranging from 0 to 35, with severity of symptoms defined as mild (0-7), moderate (8-19), or severe (20-35).

Secondary outcomes were blood transfusion, urinary incontinence, urinary retention, urinary tract infection, loss of ejaculation, erectile dysfunction, quality of life, peak urine flow rate, duration of operation, length of hospital stay, and reoperation. We considered all reports of prespecified complications regardless of their timing. As separate reporting of bladder neck stenosis and urethral stricture was inconsistent we combined these complications.

### Validity assessment and data abstraction

Two reviewers (TL, AC, or SW) independently assessed the methodological quality of the full text studies using an assessment tool drawing on the schema suggested by the National Health Service Centre for Reviews and Dissemination, Verhagen et al., Downs and Black, and the generic appraisal tool for epidemiology. Judgments on quality were based on the qualitative assessment of the number and type of criteria met by individual studies.
Transurethral vaporisation:

- Loss of ejaculation: 2 trials, Relative risk (95% CI): 1.14 (0.95 to 1.36), P = 0.15
- Erectile dysfunction: 1 trial, Relative risk (95% CI): NE, P = NE

Laser vapourisation:

- Loss of ejaculation: 5 trials, Relative risk (95% CI): 0.22 (0.13 to 0.39), P < 0.001
- Erectile dysfunction: 2 trials, Relative risk (95% CI): 8.89 (1.29 to 61.37), P = 0.03

Transurethral enucleation:

- Loss of ejaculation: 1 trial, Relative risk (95% CI): NE, P = NE
- Erectile dysfunction: 1 trial, Relative risk (95% CI): NE, P = NE

Bipolar transurethral resection:

- Loss of ejaculation: 6 trials, Relative risk (95% CI): 0.78 (0.64 to 0.95), P = 0.01
- Erectile dysfunction: 8 trials, Relative risk (95% CI): 1.02 (0.70 to 1.47), P = 0.93

NE = not estimable.

The two reviewers recorded details of methodology, interventions, participants’ characteristics, and outcomes on a data extraction form. Any differences that could not be resolved through discussion were decided by an arbiter. For trials with multiple publications we included only the most complete report for each outcome.

Quantitative data synthesis

For meta-analysis we combined data on dichotomous outcomes using the Mantel-Haenszel relative risk method. For continuous outcomes we used the inverse variance weighted mean difference method and 95% confidence intervals. We intended to report results using a fixed effects model throughout, but we had to use a random effects model for symptom score and peak urine flow rate because of statistical heterogeneity, explored by χ² tests and I² statistics. We used the standard Cochrane software RevMan 4.2.8 for meta-analyses.

RESULTS

The initial search generated 3794 reports, of which 621 were selected for full assessment (see supplementary fig 1 on bmj.com). Eighty reports describing 45 trials met the eligibility criteria (table 1).

The 45 randomised controlled trials were assessed as being of moderate or poor quality (see supplementary table 2 on bmj.com). Only six studies (13%) explicitly stated that an intention to treat analysis was done and in three of these the analysis was compromised by failure to include all the participants in each arm at follow-up assessments. The eligible randomised controlled trials included 47 relevant comparisons involving 3970 participants. Study setting and baseline characteristics of the patients, such as severity of the disease, varied across the included trials. Differences in outcome for bipolar transurethral vapourisation and bipolar transurethral vaporesection could not be assessed owing to lack of data.

Quantitative data synthesis

Symptom scores—The results from studies reporting changes in symptom score from baseline to 12 months showed significant heterogeneity, and hence random effect meta-analyses were done (fig 1). Larger mean changes were reported after holmium laser enucleation in all five trials with suitable data (weighted mean difference = −0.82, 95% confidence interval −1.76 to 0.12; P = 0.09). In contrast, of four trials on laser vapourisation (weight mean difference = −0.07 to 0.95; P = 0.42; P = 0.18; 0.07 to 0.46; P < 0.001) compared with transurethral resection, whereas no significant difference was found for transurethral vaporesection and bipolar transurethral resection, or transurethral vapourisation. The seven trials with data that could not be included in the meta-analysis were consistent with these findings (see supplementary table 3 on bmj.com).

Peak urine flow rate—The results for peak urine flow rate at 12 months were generally consistent with those for symptom scores. Compared with transurethral resection of the prostate higher rates were reported for holmium laser enucleation (weighted mean difference = 1.48 ml/s, 95% confidence interval 0.58 to 2.40; P < 0.001) and lower rates for laser vapourisation (−2.02 ml/s, −4.75 to 0.81; P = 0.15); overall, no differences were found after the other procedures, but heterogeneity was present between the individual trials (fig 2).

Quality of life—The quality of life of patients at 12 months after surgery was sparsely reported across the different interventions (see supplementary table 3 on bmj.com). When reported, quality of life was mainly rated using the international prostate symptom quality of life question score from 0 (good) to 6 (poor). No differences in improvements in quality of life scores were detected, but confidence intervals were wide.

Blood transfusion—Meta-analyses showed evidence of a lower rate of blood transfusion after holmium laser enucleation (relative risk 0.27, 95% confidence interval 0.40 to 0.39; P = 0.001) compared with transurethral resection, whereas no significant difference was found for transurethral vaporesection and bipolar transurethral resection (fig 3). Combining data for all newer interventions showed an absolute risk reduction from 4.8% to 0.7%.

Urinary retention—The risk of postoperative urinary retention requiring recatheterisation was higher after laser vapourisation and transurethral vapourisation than after transurethral resection (11.3%, relative risk 2.89, 95% confidence interval 1.53 to 5.29; 8.9% to 2.5%, respectively), whereas no differences were seen with holmium laser enucleation and bipolar transurethral resection (fig 3). Data on transurethral vaporesection were insufficient for meta-analysis.

Strictures—The rate of strictures during follow-up after holmium laser enucleation, transurethral resection, or transurethral vapourisation could not be assessed owing to lack of data.
vaporesection, bipolar transurethral resection, and transurethral vapouresection was similar to that after transurethral resection. Strictures were less common after laser vapouresection (relative risk 0.54, 95% confidence interval 0.32 to 0.90; P=0.02) than after transurethral resection, with a consistent effect seen in six\textsuperscript{w6-w13 w14} of nine studies reporting this outcome (see supplementary figure 2 on bmj.com). In this comparison, eight of the 13 (62%) strictures reported in the laser vapouresection group and 11 of the 27 (41%) strictures reported in the transurethral resection group were bladder neck contractures (see supplementary fig 2 on bmj.com).

Incontinence—Men undergoing laser vapouresection had a higher risk of urinary incontinence (relative risk 2.24, 1.03 to 4.88; P=0.04) but the difference was seen in only one trial,\textsuperscript{w15} with high rates in both groups, and the type of incontinence was not fully described. For all the other interventions the occurrence of incontinence did not differ compared with transurethral resection (see supplementary fig 2 on bmj.com).

Urinary tract infection—No evidence was found of differences in the occurrence of postoperative urinary tract infection (see supplementary fig 2 on bmj.com).

Sexual dysfunction—Loss of ejaculation was less often experienced by sexually active men undergoing laser vapouresection (relative risk 0.22, 0.13 to 0.39; P<0.001) or transurethral vapouresection (0.78, 0.64 to 0.95; P<0.01) than transurethral resection. The risk of erectile dysfunction was higher for sexually active men undergoing laser vapouresection (8.89, 1.29 to 61.37), whereas the other interventions showed similar rates to transurethral resection (table 2). This result should be treated with caution as the confidence interval was large and therefore clinically important differences may have occurred between the two groups.

Descriptors of care—Of the assessed interventions only holmium laser enucleation showed a difference in duration of surgery compared with transurethral resection, taking on average 17 minutes longer (95% confidence interval 13.43 to 20.47, P<0.001). Hospital stay was shorter for all the interventions compared with transurethral resection, generally by one day or less (table 3). The need for a second procedure during follow-up was more common after laser vapouresection than after transurethral resection (9.3% v 5.4%; relative risk 1.68, 95% confidence interval 0.97 to 2.63; P=0.04). No evidence was found of differences in reoperation rate between transurethral resection and the other ablative procedures, but confidence intervals were wide (table 3). Studies did not differentiate between further procedures to correct complications and those done for lack of efficacy.

**DISCUSSION**

In this systematic review we considered data from 3970 participants across 45 randomised controlled trials of moderate to poor quality. We found no evidence of a difference in outcomes for symptoms using any of the newer technologies for endoscopic ablation of benign enlargement of the prostate over transurethral resection at 12 months, although there was a trend favouring holmium laser enucleation and against laser vapouresection. Patterns of improvement in peak urine flow rate were consistent with change in symptoms. Blood transfusion rates were higher for transurethral resection than for the newer methods, with the exception of bipolar transurethral resection. Men undergoing laser or diathermy vapouresection were more likely to experience urinary retention. Hospital stay was up to one day shorter for the newer technologies.

The randomised controlled trials identified by this review were not powered to detect differences in the low rates of mortality and major morbidity associated with transurethral resection of the prostate and...
Table 3 | Descriptors of care after alternative approaches to endoscopic ablation for benign enlargement of prostate

<table>
<thead>
<tr>
<th>Outcome</th>
<th>No of trials in meta-analysis (total reporting outcome)</th>
<th>Effect size (95% CI)</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Holmium laser enucleation</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Duration of operation</td>
<td>5 (5)</td>
<td>16.96* (13.45 to 20.47)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Length of hospital stay</td>
<td>4 (4)</td>
<td>-1.05* (-1.20 to -0.89)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Reoperation</td>
<td>4 (4)</td>
<td>0.63† (0.32 to 1.44)</td>
<td>0.31</td>
</tr>
<tr>
<td>Laser vapourisation</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Duration of operation</td>
<td>4 (9)</td>
<td>0.29* (-2.19 to 2.78)</td>
<td>0.82</td>
</tr>
<tr>
<td>Length of hospital stay</td>
<td>2 (9)</td>
<td>-1.39* (-1.69 to -1.10)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Reoperation</td>
<td>9 (9)</td>
<td>1.63† (1.03 to 2.74)</td>
<td>0.004</td>
</tr>
<tr>
<td>Transurethral vaporisation</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Duration of operation</td>
<td>2 (2)</td>
<td>1.06* (1.70 to 10.83)</td>
<td>0.83</td>
</tr>
<tr>
<td>Length of hospital stay</td>
<td>1 (1)</td>
<td>-0.41* (-0.54 to -0.28)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Reoperation</td>
<td>2 (2)</td>
<td>1.90† (0.80 to 4.52)</td>
<td>0.15</td>
</tr>
<tr>
<td>Bipolar transurethral resection</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Duration of operation</td>
<td>4 (5)</td>
<td>-4.56* (-15.36 to 6.23)</td>
<td>0.41</td>
</tr>
<tr>
<td>Length of hospital stay</td>
<td>1 (2)</td>
<td>-0.70* (-1.37 to -0.03)</td>
<td>0.04</td>
</tr>
<tr>
<td>Reoperation</td>
<td>3 (3)</td>
<td>1.46† (0.25 to 8.57)</td>
<td>0.67</td>
</tr>
<tr>
<td>Transurethral resection</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Duration of operation</td>
<td>8 (14)</td>
<td>-1.62* (-12.23 to 8.99)</td>
<td>0.76</td>
</tr>
<tr>
<td>Length of hospital stay</td>
<td>8 (11)</td>
<td>-1.00* (-1.25 to -0.75)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Reoperation</td>
<td>7 (7)</td>
<td>1.04† (0.53 to 2.07)</td>
<td>0.90</td>
</tr>
</tbody>
</table>

*Weighted mean difference.†Relative risk.

Another driver for change in countries with highly developed healthcare services is reduction in hospital stay. This is one area of achievement for the newer endoscopic treatments for clinical benign enlargement of the prostate, with an average saving of one bed day. This is likely to be positively received by patients and healthcare managers given the risks and costs of stays in hospital. It could be argued, however, that managed care pathways are shortening hospital stay for all procedures, including transurethral resection of prostate, and in consequence the cost saving for patients and healthcare providers may be small.6

Strengths and limitations of the review

We have used the best available methods to identify, review, and meta-analyse data available to us. Several limitations must be noted, however, when interpreting the results of this review. Heterogeneity in results for the primary outcome measure of reduction in symptoms score presented problems in deriving a valid meta-analysis, which we overcame by using a random effects model. Clinical reasons for this heterogeneity include differences in baseline score for symptoms between studies and failure to control for other variables that may result in greater improvement in symptoms, such as initial prostate volume and the presence of urodynamic obstruction.

As with all secondary research it is possible to miss data owing to non-publication or non-appearance on the search strategy. A particular problem with the present review was that over half of the reports that met the initial inclusion criteria were only in abstract form. This made it impossible for us to assess all relevant data, and the exclusion of these studies prevented estimation of publication bias. The reasons why so many trials were reported only as abstracts were unclear and ideally should be investigated because publication bias in another setting accounted for up to 45% of an observed association, which may change the direction of effect.7

The moderate to poor methodological quality of the studies, together with the high number of comparisons, diluted the opportunities for meta-analysis. The confidence intervals around estimates of differences were often wide and this may have resulted in a failure to detect clinically important differences.89 The comparisons were against the standard of transurethral resection of prostate and therefore this limited our ability to assess how newer ablative treatments performed against each other. Study inclusion criteria such as prostate size also varied considerably between the trials, which questions the generalisability of the findings to everyday practice. This was exacerbated by variation and evolution in operative technique and treatment protocols between studies investigating the same basic technology. These variations were of particular concern for studies involving laser technology where there was variation in wavelength and power settings, together with site and duration of laser application.
Fig 3 | Blood transfusion and urinary retention after endoscopic techniques for ablation of benign enlargement of prostate. TURP=transurethral resection of prostate
WHAT IS ALREADY KNOWN ON THIS TOPIC

Transurethral resection of the prostate is the standard surgical procedure for benign prostatic enlargement

Transurethral resection provides a consistent, high likelihood of improvement, but is associated with relatively high risk of adverse events

A range of newer alternative ablative procedures has been tried in clinical practice

WHAT THIS STUDY ADDS

Newer ablative procedures for benign prostatic enlargement tested show similar improvement of symptoms as transurethral resection, with some evidence of fewer adverse effects

Holmium laser enucleation is a more promising alternative to transurethral resection but needs further evaluation

In the United Kingdom about 50% of endoscopic prostatectomies are carried out for indications other than lower urinary tract symptoms, predominantly urinary retention. Exclusion of such patients from randomised controlled trials considered in this review makes it difficult to extrapolate the findings to these circumstances, although the rationale for ablation surgery of prostate is similar. It could be speculated that the higher rate of voiding difficulties after vapourisation procedures would tend to favour transurethral resection, whereas the greater risk of bleeding complications in men catheterised preoperatively would favour the newer technologies. Ideally, men undergoing surgery for retention should be included in future trials.

Most of the included randomised controlled trials were poorly reported, which may be associated with low levels of methodological quality. Without adequate reporting, the assessment of quality becomes impossible, and the drive to ensure adherence to standardised conduct and reporting guidelines for randomised controlled trials has much to commend it from the systematic reviewer’s point of view. Reporting of allocation concealment was unclear in 74% of the included studies and 14% used an inadequate approach for concealment of randomisation. This increases the risk of selection bias by disrupting the assignment sequence and may result in loss of the advantages of randomisation, generating biased estimates of treatment effects.

Many studies failed to report point estimates and measures of variability, which hinders calculation of the precision of the overall pooled estimate and calculation of weighted mean difference when a standard deviation is required. It is possible that if means and standard deviations were reported more consistently, effect sizes would be different. This is another reason why adherence to consolidated standards of reporting trials guidelines for reporting of randomised controlled trials greatly aids the conduct of robust meta-analyses.

The usefulness of individual trial data together with systematic review is to some extent determined by the current context of patient care, which often changes before findings can be published. In the present case some procedures such as transurethral vapourisation of the prostate have been abandoned despite a reasonable evidence base for their efficacy. In contrast, techniques using more recent technology such as bipolar transurethral resection and potassium-titanyl-phosphate laser vapourisation have now entered routine use without adequate published evidence of safety and cost effectiveness. In addition, the standard of transurethral resection of prostate has not stood still, with the improvements making the operation more uniform in outcome and less morbid in terms of adverse effects.

Conclusions

On the basis of current evidence it is not possible to reliably identify the most promising tissue ablative intervention for benign enlargement of the prostate. Transurethral resection of the prostate continues to be effective although it is associated with potentially significant morbidity. Of all the newer technologies assessed in this study, holmium laser enucleation seems to have the most promise. Nevertheless, the quality of the available evidence is poor and therefore research efforts in the management of benign prostatic enlargement should be concentrated on more efficient performance of higher quality, more rigorous, randomised controlled trials where outcomes and interventions are clearly defined and the timing of outcome measurement is registered. It is also essential that the reasons for reoperation are clearly stated, including when this decision is largely driven by patient choice.


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