Abdominal sacral colpopexy or vaginal sacrospinous colpopexy for vaginal vault prolapse: a prospective randomized study

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Record Status
This is a critical abstract of an economic evaluation that meets the criteria for inclusion on NHS EED. Each abstract contains a brief summary of the methods, the results and conclusions followed by a detailed critical assessment on the reliability of the study and the conclusions drawn.

Health technology
The use of abdominal sacral colpopexy and vaginal sacrospinous colpopexy in the treatment of vaginal vault prolapse.

Type of intervention
Treatment.

Economic study type
Cost-effectiveness analysis.

Study population
The study sample comprised women who required surgical treatment for vaginal vault prolapse. Women with symptomatic posthysterectomy vaginal vault prolapse that extended to or beyond the introitus were included in the study. Women who had already undergone a sacral colpopexy, or who had a significantly foreshortened vagina, were excluded.

Setting
The setting was secondary care. The economic study was carried out in Australia.

Dates to which data relate
The effectiveness and resource use data were gathered from September 1997 to December 2000. The price year was not reported.

Source of effectiveness data
The effectiveness evidence was derived from a single study.

Link between effectiveness and cost data
It was unclear whether the costing was carried out prospectively on the same sample of patients as that used in the effectiveness study, or carried out prospectively on a sub-group of patients.

Study sample
Power calculations were performed in the preliminary phase of the study. These were based on a 58% success rate for the abdominal group, a 29% success rate for the vaginal group, a significance level of 5% and a statistical power of 80%. This led to a sample size of 40 women in each group, which was increased to 95 to minimise the impact of loss to follow-up (expected to be around 15%). Eligible women were identified at the study hospitals and 95 agreed to participate in the study. It was not stated whether some women were invited but refused to participate, or whether some
patients were excluded from the initial study sample for any reason. Forty-seven women were randomly assigned to the abdominal group and 48 to the vaginal group. The mean age of the women was 63.4 (+/- 10.3) years (age range: 39 - 84) in the abdominal group and 62.9 (+/- 10.3) years (age range: 35 - 88) in the vaginal group.

Study design
This was a prospective, open, randomised controlled trial that was carried out at the Urogynaecology Units at the Mercy and Royal Women's Hospitals (Melbourne) and the Royal Women's and Mater Hospitals (Brisbane), Australia. Women with stress urinary incontinence were stratified to ensure equal representation in each group. The women were allocated to the study groups via computer-generated randomisation lists. Postoperative evaluations were performed at 6 weeks, 6 months and annually thereafter. The mean follow-up was 24 months (range: 6 - 60) in the abdominal group and 22 months (range: 6 - 58) in the vaginal group. Six women were lost to follow-up, one in the abdominal group (lost contact) and five in the vaginal group (1 died of pneumonia, 2 had dementia and 2 lost contact).

Analysis of effectiveness
The analysis of effectiveness was based on intention to treat for preoperative outcomes and on treatment completers only for postoperative outcomes. The outcome measures used were:

- perioperative outcomes including operating time, blood loss, inpatient days, catheter days, and return to activities of daily living;
- subjective success (women with no symptom of prolapse);
- objective success (women who, on examination, had no vaginal prolapse beyond the halfway point of the vagina during a Valsalva manoeuvre; no prolapse greater or equal to grade 2 at any vaginal site);
- patient satisfaction, scored on a visual analogue scale from 0 to 100;
- quality of life, measured using the Short Urinary Distress Inventory, the Short Incontinence Impact Questionnaire, modified sexual function questionnaires, and the SF-36 scale; and
- complications.

An analysis of variance and multivariate regression analysis were carried out to determine whether the differences between the groups were statistically significant after adjusting for baseline preoperative values. The two groups were comparable at baseline in terms of their demographics, disease characteristics, relevant prior surgery, and concomitant surgical procedures.

Effectiveness results
The operative time was 106 (+/- 37) minutes (range: 45 - 100) in the abdominal group and 76 (+/- 42) minutes (range: 26 - 300) in the vaginal group, (p<0.01).

Return to normal activities of daily living required 34 (+/- 12.1) days (range: 4 - 64) in the abdominal group and 25.7 (+/- 9.7) days (range: 6 - 42) in the vaginal group, (p<0.01).

There was no statistically significant difference in terms of blood loss, inpatient days and catheter days.

The subjective success rate was 94% (43 of 46 women) in the abdominal group versus 91% (39 of 43 women) in the vaginal group, (p=0.19).

The objective success rate was 76% (35 out of 46) in the abdominal group versus 69% (29 out of 42) in the vaginal group, (p=0.46).

Mean patient satisfaction with surgery was 85% (39 out of 46) in the abdominal group versus 81% (35 out of 43) in the
vaginal group, (p=0.78).

Other minor clinical (peri- and postoperative) outcomes were used but generally none were statistically significant. The exception was the rate of cumulative anterior vaginal wall and vault prolapse, which was seen in 13% (6 of 46 women) of the abdominal group and in 45% (19 of 42 women) of the vaginal group, (p=0.01).

The complications observed were comparable between the groups.

All quality of life measures improved in both groups but to a similar extent.

There was a significant and similar reduction in both the Short Urinary Distress Inventory and Short Incontinence Impact Questionnaire scores after the procedure in both groups.

There was a significant improvement in the physical role parameter of the SF-36 Health Survey in the abdominal group, and in the physical function and bodily pain parameter in the vaginal group.

There was no significant change in pre- or postoperative sexual activity in either group, (p=0.44 and p=0.69, respectively).

The regression analysis showed that none of the baseline factors had a significant impact on the results of the analysis.

**Clinical conclusions**
The effectiveness study showed that the two surgical procedures were equally effective in terms of the primary clinical outcomes and quality of life in the treatment of vaginal vault prolapse.

**Measure of benefits used in the economic analysis**
No summary benefit measure was used in the economic analysis because the two surgical procedures were considered to be equally effective. Therefore, a cost-minimisation analysis was performed.

**Direct costs**
Discounting was not relevant since the costs were incurred during a short time. The health services included in the economic evaluation were bed days and surgical procedures (costs of operating theatre). The unit costs and the quantities of resources used were reported separately. The cost/resource boundary of the study was unclear, but it was likely to have been that of the hospital. It is likely that resource use was estimated using actual data derived from the sample of women involved in the effectiveness study. The source of the cost data was not reported. The price year was not given.

**Statistical analysis of costs**
Statistical tests were conducted to test the statistical significance of differences in the estimated costs. The type of test used was not reported.

**Indirect Costs**
The indirect costs were not considered in the economic analysis.

**Currency**
Australian dollars (Aus$).

**Sensitivity analysis**
Sensitivity analyses were not performed.
Estimated benefits used in the economic analysis
See the 'Effectiveness Results' section.

Cost results
The average cost per patient was Aus$6,450 in the abdominal group and Aus$4,575 in the vaginal group, (p<0.01).

Synthesis of costs and benefits
Not relevant as a cost-minimisation analysis was performed.

Authors’ conclusions
Sacral colpopexy and vaginal sacrospinous colpopexy were equally effective for the treatment of vaginal vault prolapse. However, sacral colpopexy was associated with a longer operative time, a slower return to activities of daily living, and greater costs than sacrospinous colpopexy.

CRD COMMENTARY - Selection of comparators
The authors stated that abdominal sacral colpopexy and vaginal sacrospinous colpopexy were two widely used approaches for the treatment of vaginal vault prolapse. You should decide whether they are valid comparators in your own setting.

Validity of estimate of measure of effectiveness
The basis of the analysis of effectiveness was a randomised trial, which was appropriate for the study question. The two groups of patients were comparable at baseline and the data were derived from several centres. The outcome assessment was not blinded, therefore some biases could have affected the results of the analysis. The method used to select the sample was not described clearly and it was not stated whether some patients were excluded from the initial study sample. Therefore, it is difficult to assess whether the study sample was representative of the study population. Power calculations were carried out in the preliminary phase of the study on the basis of success rates. However, the authors noted that a larger sample size (at least 250 patients) would have been required to detect real differences between the groups. Further limitations were the loss to follow-up and the fact that the analysis of the clinical study was partly based on treatment completers only. These issues tend to limit the internal validity of the analysis.

Validity of estimate of measure of benefit
No summary benefit measure was used in the analysis because a cost-minimisation analysis was conducted.

Validity of estimate of costs
The authors did not report the perspective adopted in the study. Overall, the analysis of the costs was a secondary objective of the study. The economic evaluation was limited to those resources strictly related to the surgical procedure. The unit costs were provided but the price year was not, thus making reflation exercises in other settings difficult. The source of the cost data was not reported. Statistical tests were carried out when the cost estimates were compared. However, it appears that the estimates were specific to the study setting and sensitivity analyses on resource quantities and unit costs were not performed.

Other issues
The study referred to women with vaginal vault prolapse and this was reflected in the conclusions of the analysis. The results were not presented selectively and the conclusions accurately reflected the scope of the study. The authors compared their effectiveness results with those from published studies. They provided an explanation for the differences observed, which were mainly due to differences in the patients’ characteristics and surgical techniques used.
However, the authors did not compare their cost results with those from other studies. The issue of the generalisability of the study results to other settings was not addressed and sensitivity analyses were not carried out. Therefore, the external validity of the analysis was low. The authors noted some limitations to the validity of the study, which have been reported already.

**Implications of the study**
The authors suggested that the abdominal approach could be preferable in women with predominately anterior and vault prolapse. The vaginal approach should be limited to those women with predominately posterior and vault prolapse.

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