Laparoscopic Burch colposuspension: comparison of effectiveness of extraperitoneal and transperitoneal techniques

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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 study assessed two laparoscopic colposuspension procedures for the treatment of genuine stress incontinence (GSI). The two approaches were extraperitoneal colposuspension using mesh fixed with tacks and transperitoneal laparoscopic colposuspension using sutures.

Type of intervention
Treatment.

Economic study type
Cost-effectiveness analysis.

Study population
The study population comprised women with a diagnosis of genuine urinary stress incontinence with urethral hypermobility, who underwent laparoscopic Burch colposuspension. Women were excluded if they underwent additional surgical procedures at the time of colposuspension, or had undergone surgery before for urinary incontinence. Women were also excluded if they had a urodynamic diagnosis of detrusor instability, or stress incontinence due to low urethral closure pressure.

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

Dates to which data relate
The effectiveness and resource use evidence related to January 1995 and January 2001. The price year was not reported.

Source of effectiveness data
The effectiveness data were derived from a single study.

Link between effectiveness and cost data
The costing was carried out retrospectively using the same sample of patients that provided the effectiveness and cost data.

Study sample
Power calculations were not reported. A total of 64 patients who underwent laparoscopic Burch colposuspension were included in the analysis. These patients were divided in two groups. Group A included 36 women who had undergone
laparoscopic transperitoneal colposuspension, while group B included 28 women who had undergone laparoscopic extraperitoneal colposuspension. The mean age of the patients was 44.4 (+/- 7.1) years in group A and 45.7 (+/- 8.2) years in group B.

**Study design**
This was a retrospective cohort study. The mean follow-up was 25.7 months in group A and 27.3 months in group B, (p=0.082). No blinding of the outcome assessment was reported. One surgeon performed all the laparoscopic colposuspension procedures. No loss to follow-up was reported.

**Analysis of effectiveness**
The primary health outcome assessed in the effectiveness analysis was the rate of cure (i.e. postoperative continence). Continence was evaluated in all patients by simple cystometry, with a cough stress test in the standing position, at the follow-up visit. The secondary health outcomes were:

- the duration of the surgical procedure,
- blood loss,
- the catheterisation time,
- the rate of patients resuming spontaneous voiding at 24 hours,
- intraoperative and postoperative complications, and
- hospital stay.

All patients were assessed first at 6 weeks postoperatively, and then at 6 months and every 6 months thereafter. Patients who did not return for follow-up visits were contacted by telephone or mail and asked to attend the urogynaecology clinic for a follow-up examination.

There were no significant differences between the groups in any of the baseline demographic and clinical characteristics.

**Effectiveness results**
At the last follow-up, 33 (91.7%) of the 36 patients in the group A and 23 (82.1%) of the 28 patients in the group B were continent. Although the cure rate was higher with the transperitoneal approach than the extraperitoneal approach, the difference was not statistically significant, (p=0.22).

The average hospital stay was 2.05 (+/- 1.01) days (range: 1 - 6) for patients in group A and 1.57 (+/- 0.79) days (range: 1 - 4) for those in group B, (p=0.022).

The average operating time was 58.1 (+/- 8.7) minutes in group A and 46.8 (+/- 7.6 minutes) in group B, (p=0.001).

The rate of patients resuming spontaneous voiding at 24 hours was significantly different between the two groups, 63.9% in group A versus 85.7% in group B, (p=0.045).

There was no significant difference in the mean blood loss between the two groups, 67.1 (+/- 27.9) mL (range: 30 - 150) in group A versus 76.8 (+/- 38.4) mL (range: 40 - 200) in group B, (p=0.51).

There was no significant difference in the intraoperative complication rate between the two groups, (p=0.62), or the overall complications, (p=0.25). One patient in group A and 4 patients in group B developed denovo detrusor instability. One patient in group B developed wound infection, and one patient in group A developed urinary retention.
Clinical conclusions
The authors' conclusion focused on the primary health outcome. They concluded that although the cure rate was higher for patients undergoing the transperitoneal procedure using sutures than for those undergoing the extraperitoneal procedure using mesh fixed with tacks, this difference was not statistically significant between the two procedures.

Measure of benefits used in the economic analysis
No summary measure of benefit was used. The cost and effects were left disaggregated and the study was therefore classified as a cost-consequences analysis.

Direct costs
No details on the categories of costs included in the analysis were provided. Professional fees charged by the surgeon or anaesthesiologist were excluded because of variable reimbursements by third-party payers. Discounting was not carried out. The quantities and the costs were not analysed separately. Hospital charges were assessed instead of costs and were determined by a review of billing records. The unit costs of the mesh, balloon dissector, track and absorbable suture were reported. The price year was not reported.

Statistical analysis of costs
The costs were expressed as the mean +/- the standard deviation. They were analysed using the non-parametric Mann-Whitney U-test.

Indirect Costs
The indirect costs were not included.

Currency
US dollars ($).

Sensitivity analysis
No sensitivity analysis was reported.

Estimated benefits used in the economic analysis
See the 'Effectiveness Results' section.

Cost results
The total hospital charges for group B ($2,234 +/- 262) were significantly higher than those for group A ($1,348 +/- 285), (p=0.001).

The use of sutures was much less costly than mesh fixed with tacks.

It was not stated whether or not the costs associated with complications were included in the analysis.

Synthesis of costs and benefits
Not relevant, as no summary measure of benefit was derived.

Authors' conclusions
The transperitoneal approach using sutures had a lower cost in comparison with the extraperitoneal procedure using
mesh fixed with tacks. There was no statistically significant difference between the two procedures in the cure rate. The authors concluded "lower cost is the superiority of the transperitoneal suture technique".

CRD COMMENTARY - Selection of comparators
A justification was given for the comparators used. They reflected laparoscopic Burch procedures described in the literature and were the two approaches conducted in the authors’ setting. You should judge whether these procedures are relevant in your setting, or whether other comparators from other techniques could have been relevant as well.

Validity of estimate of measure of effectiveness
The analysis was based on a convenience retrospective sample over 6-year period. The possibility of biases and confounding is likely to be high and may limit the validity of the comparison between groups. Since no significant clinical differences were detected in cure rate (which was the primary outcome of the study), concerns about sample size and power are important. The authors did not report that power calculations had been undertaken. Moreover, the authors did not provide evidence that the study sample was representative of the study population, which may limit the external validity of the study. The study represents a single surgeon experience with laparoscopic colposuspension procedures, and this also limits the extrapolation of the results to other settings. Appropriate statistical analyses were undertaken to ensure the comparability of the patient groups.

Validity of estimate of measure of benefit
The authors did not derive a measure of health benefit. The reader is referred to the 'Validity of estimate of measure of effectiveness' field (above).

Validity of estimate of costs
The perspective adopted was unclear, but it appears to have been consistent with that of a health care provider. Also, adequate details of the method used for the cost estimation were not given. The authors failed to report the cost categories or cost items, so it was not possible to assess whether all the relevant categories of costs were included in the analysis. It was reported that professional fees charged by the surgeon or anaesthesiologist were excluded from the analysis. This exclusion could affect the magnitude of the study conclusions, as professional fees would make the transperitoneal approach using sutures more expensive (higher operative time than the extraperitoneal procedure). In addition, it was unclear whether or not the costs associated with complications were included in the analysis.

The costs and the quantities were not reported separately, thus limiting the extrapolation of the results to other settings. However, the quantities associated with the length of hospital stay and procedures were reported in full. Charges were used to proxy prices, thus presenting a breakdown to the unit costs for the resource quantities. The date to which the prices related was not reported, which will prevent any possible inflation exercises. Discounting was not carried out, which was inappropriate since the costs were assessed over more than 2 years.

Other issues
The authors made appropriate comparisons of their effectiveness results with those from other studies, and found similar results. The issue of the generalisability to other settings was not addressed. The results of the analysis were adequately reported and the authors' conclusions reflected the scope of the analysis. The authors did not report any future limitations of their study.

Implications of the study
The authors suggested that long-term studies on a larger sample are necessary because of a time-dependent decrease in cure rate after anti-incontinence surgeries. The authors did not make any specific recommendations for practice or policy.
Source of funding
None stated.

Bibliographic details

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