Laparoscopic retropubic urethropexy

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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
Laparoscopic retropubic urethropexy using balloon distention and staple fixation of the prosthetic mesh suspension.

Type of intervention
Treatment.

Economic study type
Cost-effectiveness analysis.

Study population
A cohort of 100 patients with genuine stress urinary incontinence (as detected by history, in-office urethropexy including urethral pressurecystometrics, "obvious lossof urine with stress", and positive Q-Tip test) undergoing endoscopic bladder neck suspension.

Setting
Hospital. The economic study was carried out in Englewood, CO, USA.

Dates to which data relate
The effectiveness data, and some resource use data, were collected during 1993-95. The price year was not reported.

Source of effectiveness data
Effectiveness data were derived from a single study and review of previously completed studies.

Link between effectiveness and cost data
The relationship between the effectiveness study and the costing was not clearly reported.

Study sample
A cohort of 100 patients with genuine stress urinary incontinence underwent endoscopic bladder neck suspension. The average age was 56 years (range: 32 - 81) (92% post-menopausal). Fifty-four percent of the patients had experienced symptoms of stress urinary incontinence for 2 to 4 years, whilst 32% had done so for 8 months to 1 year. Nine women had been incontinent for 5 to 9 years and another 5 women had symptoms for 10 years or more. Power calculations to determine the sample size were not given.

Study design
Case series study. The duration of the follow-up period was at least 2 years for 29% of the patients, and between 1 and
2 years for 71% of the patients. The loss to follow up was not stated.

Analysis of effectiveness
It is not clear whether the analysis of the clinical study was based on intention to treat or on treatment completers only. The primary health outcomes used in the analysis were the success rate, operating time, anaesthesia, morbidity, voiding time, length of hospital stay and patient satisfaction.

Effectiveness results
Operating time was estimated to be less than 30 minutes in 89% of cases, up to 1 hour in 6 cases and between 60 and 90 minutes in 5 cases. Transabdominal laparoscopic repair was performed under general anaesthesia in 54% of women and with epidural anaesthesia for the remainder. Curative results were estimated to be achieved in 91% of women. An additional 6% was estimated to report satisfaction with the degree of improvement in continence. Three patients were estimated to have surgeries which failed to correct incontinence. All were estimated to have short urethras on urodynamic studies, and a 50% chance of a positive result had been anticipated. Thirteen women experienced a prolonged voiding time between 18 and 20 hours with eight having a concomitant associated procedure. Six patients were estimated to have urinary tract infection after hospital discharge, and 2 to have respiratory illnesses associated with upper respiratory infection or asthma. Other morbidities were estimated to include nausea and vomiting (2 cases), shoulder pain (2), headache (1) and severe back pain (1). Postoperative pain was estimated to be minimal in over 90% of the patients and moderate in 8: one woman complained of severe back pain. The hospital stay (for laparoscopic Burch repair, n=65) was estimated to be less than 24 hours for all but 2 patients.

Clinical conclusions
Extraperitoneal, retropubic, bladder mesh suspension results in a durable repair and it is associated with minimal operating time and morbidity and maximum patient satisfaction and clinical benefit.

Outcomes assessed in the review
Cure rates at follow-up periods of 1 to 2 years were derived from a review.

Study designs and other criteria for inclusion in the review
At least one randomised controlled study was included. No additional details were provided.

Sources searched to identify primary studies
Not stated.

Criteria used to ensure the validity of primary studies
Not stated.

Methods used to judge relevance and validity, and for extracting data
Not stated.

Number of primary studies included
At least two studies were included, and one further study appears to be an additional report of one of these studies, based on a longer follow-up.

Methods of combining primary studies
Not stated.

Investigation of differences between primary studies
Not stated.

Results of the review
The cure rates for open Burch procedures vary between 85% and 91%.

Measure of benefits used in the economic analysis
The measure of benefits was additional successfully treated cases.

Direct costs
The operating costs of treatment, hospital stay and anaesthesia were included in the analysis. Some quantities of resource use were analysed separately from costs. It appears that follow-up costs were not included in the analysis and, consequently, no discounting was stated. The quantity/cost boundary adopted was the hospital. The source of the unit cost data was not clearly stated. The price date was not stated.

Currency
US dollars ($).

Sensitivity analysis
No sensitivity analysis was performed.

Estimated benefits used in the economic analysis
Curative results were estimated to be achieved in 91% of women. An additional 6% were estimated to report satisfaction with the degree of improvement in continence. Three patients were estimated to have surgeries which failed to correct incontinence. The cure rates for open Burch procedures vary between 85% and 91% in various previously completed studies.

Cost results
The total cost of the inpatient open Burch procedure was estimated to average $6,370. The total outpatient charge to the patient was estimated to average $3,220 (According to the authors, the higher cost was attributable to longer operative and anaesthesia time as well as to the average 3 day hospital stay for the former strategy).

Synthesis of costs and benefits
A synthesis of the estimated benefits and costs was not provided since the intervention turned out to be the dominant strategy.

Authors' conclusions
The laparoscopic retroperitoneal urethropexy treatment is believed to be a cost-effective strategy and to have a potential for widespread application as a simple, reliable form of endoscopic bladder neck suspension. The fact that nearly half of the patients received epidural anaesthesia with the intervention, combined with the short operating time, contributed to early hospital discharge and high patient satisfaction. The limited morbidity observed was significant as it heightens the degree of patient and surgeon acceptance. Patients under the intervention usually return to normal activity (except for heavy lifting) in 2 to 3 days. Those undergoing the open Burch procedure do not return to normal
activity for 2 to 3 weeks.

CRD COMMENTARY - Selection of comparators
The reason for the choice of the comparator is clear as the open Burch procedure has been one of the traditional standards of choice in the setting in question.

Validity of estimate of measure of benefit
The estimate of measure of benefit used in the economic analysis may be open to question due to the lack of a detailed description of the methodology used in the review/synthesis of the literature, which was used as a source of crucial data for the effectiveness study.

Validity of estimate of costs
Some resource quantities were reported separately from the costs. Adequate details of methods of quantity/cost estimation were not given (e.g. price date, source of resource use data for the comparator and unit cost data). Important cost items may have been omitted (e.g. costs of complications after hospital discharge).

Other issues
The authors' conclusions may not be justified, given the uncertainties in the data. The issue of generalisability to other settings was not fully addressed.

Implications of the study
Further prospective, controlled studies are needed in order to address the issue of the cost-effectiveness of the laparoscopic retropubic urethropexy for women with stress urinary incontinence. Economic data collection alongside the trial(s) would add valuable evidence to such discussion.

Source of funding
None stated.

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