Cost-effectiveness of urodynamic testing before surgery for women with pelvic organ prolapse and stress urinary incontinence

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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
Urodynamic testing before surgery for women with pelvic organ prolapse and stress urinary incontinence (SUI).

Type of intervention
Diagnosis.

Economic study type
Cost-effectiveness analysis.

Study population
The study population was hypothetical adult women with symptomatic pelvic organ prolapse and symptoms of SUI, with or without urgency, frequency, or nocturia. Other inclusion criteria were: no previous surgical treatment for urinary incontinence or prolapse; no history of neurologic conditions; no causes of acute or reversible urinary incontinence (e.g. urinary tract infection or drug side effects); and no history of pelvic radiation or surgery for pelvic cancer.

Setting
The study setting was primary care. The economic study was carried out in Ohio, USA.

Dates to which data relate
Effectiveness evidence was drawn from studies published between 1980 and 1999. Evidence on the surgical procedures employed and hence, the resources used, was taken from studies published between 1989 and 1998. Costs for all tests and procedures were obtained from 1998 sources. Although not specifically stated it is likely that the price year was also 1998.

Source of effectiveness data
Effectiveness data were derived from a review/synthesis of completed studies, supplemented by the authors' estimates.

Modelling
A decision-tree model was used to estimate costs and outcomes for the study. A simple and full version of the model was developed. The full version allowed for a range of complications following surgery.

Outcomes assessed in the review
Outcomes assessed in the literature review were:
the prevalence of diagnoses of urodynamically confirmed genuine stress urinary incontinence (GSUI), intrinsic sphincteric deficiency (ISD), mixed urinary incontinence (MUI) and detrusor instability (DI);

urodynamic sensitivity and specificity measures;

the cure rates of procedures for urinary incontinence;

rates for urinary retention or incontinence following procedures;

probabilities of ISD or DI being the cause of recurrent urinary incontinence following initial procedures.

**Study designs and other criteria for inclusion in the review**
The authors did not state what study designs they included in their review or the inclusion criteria for studies (other than the studies included were English language papers only).

**Sources searched to identify primary studies**
MEDLINE from 1966 to 1999 was searched, supplemented by references in recovered articles.

**Criteria used to ensure the validity of primary studies**
No criteria were reported.

**Methods used to judge relevance and validity, and for extracting data**
The methods used were not reported.

**Number of primary studies included**
45 primary studies were included in the review.

**Methods of combining primary studies**
Where data were available from more than one source, the baseline parameter was the average of reported values. The highest and lowest reported values formed the ranges for the sensitivity analyses.

**Investigation of differences between primary studies**
The authors stated that length of follow-up of patients varied between studies, so, for the purpose of the model, they assumed that the cure rate following surgery was stable over at least one year.

**Results of the review**
The results of the review were as follows:

The prevalences of diagnoses from urodynamic testing were 67% (range: 36% - 87%) for GSUI, 13% (range: 11% - 41%) for ISD, 18% (range: 9% - 37%) for MUI, and 2% (range: 0% - 5%) for DI.

The sensitivity of the urodynamic tests to GSUI was 86% (range: 78% - 94%). The probability of a type-I error in testing for DI was 14% (range: 7% - 18%). The probability of a type-II error in testing for DI was 25% (range: 22% - 28%).

Average cure rates for surgical procedures for the various diagnoses (except DI) ranged between 71% (range: 64% - 78%) for cure rate after urethrolysis for urinary retention to 89% (range: 62% - 97%) after sling procedure for ISD. The cure rate for sling procedures for DI was 31% (range: 25% - 35%), and the cure rate for medical treatment of DI
was 68% (range: 59% - 80%).

Complications rates (urinary retention/incontinence) following surgical procedures ranged from 1.7% (range: 0% - 5%) for permanent urinary retention after sling procedure to 18% (range: 12% - 23%) for persistent urinary retention after urethrolysis.

**Methods used to derive estimates of effectiveness**
The authors’ consensus was used to derive estimates of effectiveness.

**Estimates of effectiveness and key assumptions**
The authors estimated sensitivity and specificity values for remaining urodynamic tests, and the probability that complications following surgery were attributable to ISD, DI or recurrent hypermobility. The estimated values were as follows:

- **urodynamic result positive for mixed urinary incontinence when mixed urinary incontinence is true condition (true-positive rate for mixed urinary incontinence), 75% (range: 67% - 83%);**
- **urodynamic result positive for detrusor instability when detrusor instability is true condition (true-positive rate for detrusor instability), 86% (range: 76% - 92%);**
- **urodynamic result positive for genuine stress urinary incontinence when detrusor instability is true condition (false-positive for genuine stress urinary incontinence), 0.05% (range: 0.04% - 0.06%);**
- **intrinsic sphincteric deficiency as cause of recurrent urinary incontinence after initial sling procedure for detrusor instability or mixed urinary incontinence, 20% (range: 10% - 30%);**
- **detrusor instability as cause of recurrent urinary incontinence after initial sling procedure for detrusor instability or mixed urinary incontinence, 50% (range: 40% - 60%); and**
- **recurrent hypermobility as cause of recurrent urinary incontinence after initial sling procedure for detrusor instability or mixed urinary incontinence, 30% (range: 20% - 40%).**

**Measure of benefits used in the economic analysis**
The measure of benefits used was cures of urinary incontinence.

**Direct costs**
The resource unit costs were reported. These were applicable to a hospital only. Direct costs included urodynamic testing, initial and repeat sling procedures, urethrolysis, collagen injection, medical treatment for DI, care related to urinary incontinence for 1 year, and care related to urinary retention for one year.

The authors acknowledge that the costs of 'basic office evaluation' and prolapse surgery were excluded as these costs were common to both arms of the study. Hospital service costs accounted for labour, non-labour and capital costs. Clinician services were standard costs, and costs for outpatient tests and procedures included facility and staff costs. The cost of one year of care was based on the cost of a 1-year course of oxybutynin.

Cost data were based on DRG group weightings from the 1998 Federal Register.

As all costs were incurred over a single year, discounting was not relevant. The study reported marginal costs. The price year was not explicitly stated.

**Indirect Costs**
No indirect costs were included.

**Currency**

US dollars ($).

**Sensitivity analysis**

A one-way sensitivity analysis and threshold analyses were conducted on all parameters (costs and proportions) in the model. Parameter estimates based on the authors' judgement were varied by +/- 10% from base.

**Estimated benefits used in the economic analysis**

In the simple model, the cure rate of urinary incontinence was 84.5% for urodynamic testing, and 83.9% for 'basic office evaluation'.

In the full model, the cure rate of urinary incontinence was 96.2% (urodynamic testing) and 96.1% ('basic office evaluation').

**Cost results**

In the simple model, the 'average cost of treatment' for the urodynamic testing strategy was $5,271, compared with $4,918 for 'basic office evaluation'.

In the full model, the 'average cost of treatment' for the urodynamic testing strategy was $5,302, compared with $4,959 for 'basic office evaluation'.

**Synthesis of costs and benefits**

The authors combined cost and effectiveness as the incremental cost per additional cure of urinary incontinence.

The incremental cost per additional cure of urinary incontinence was $55,495 (simple model), and $328,601 (full model).

The authors stated that the cost-effectiveness was not influenced by changes in parameter estimates within the defined ranges. In the simple model, only when the prevalence of DI was greater than 7% (greater than 8% in the full model) or the cost of urodynamic testing was less than $129 (less than $103 in the full model) was urodynamic testing "more cost-effective than basic office evaluation". (Although the authors did not define a maximum willingness-to-pay for an additional cure of incontinence. Please see commentary below).

**Authors' conclusions**

The routine use of urodynamic testing before surgery in women with pelvic organ prolapse and urinary incontinence does not improve cure rates and is not cost-effective relative to 'basic office evaluation'.

**CRD COMMENTARY - Selection of comparators**

Although no explicit justification was given for the comparator used, it would appear to have represented current practice in the authors' setting. You, as a user of the database, should decide if the comparator represents current practice in your own setting.

**Validity of estimate of measure of effectiveness**

The authors stated that a review of the literature had been undertaken, but this was not conducted in a systematic way. The authors commented that the aim of the review was to identify the range of reported outcomes, rather than include
all published reports. The criteria for study inclusion in the review were not stated, thus, it is not possible to assess whether all relevant research of sufficient quality was incorporated in the review. Effectiveness estimates were combined using credible narrative methods.

For those estimates where no published data were available, the authors provided their best estimate by consensus amongst themselves. The authors did not justify their choice of assumptions. Estimates were investigated by sensitivity analysis. The ranges used appear to be appropriate.

Validity of estimate of measure of benefit
The estimation of benefits was modelled. The instrument used to derive a measure of health benefit, a decision-tree model, was appropriate for this purpose.

Validity of estimate of costs
Although the authors reported that costs were estimated from the societal perspective, indirect costs and out-of-pocket costs to patients were not included. Costs included were relevant to a hospital only. The estimates of cost of care related to urinary incontinence or retention for one year were based on drug treatment alone. This is an over-simplification, and ignores the possibility of hospital or GP visits by the patient.

Some costs were omitted because they were common to both arms of the study (for example, the cost of initial ‘basic office evaluation’ and prolapse surgery), and thus would not affect the results.

Unit costs were reported, however quantities were not. A sensitivity analysis was performed around all cost estimates at 20% below and 20% above the base case.

Other issues
The authors made appropriate comparisons of their findings with those from other studies but did not address the issue of generalisability to other settings. The authors do not appear to have presented their results selectively. It would have aided transparency had the authors presented a table of the raw results from running a hypothetical cohort of patients through the model. The study population was well defined and consisted of women with pelvic organ prolapse and urinary incontinence. This was reflected in the authors’ conclusions.

The authors acknowledged that they had excluded indirect costs from the study. This contradicts their assertion that this study was from the societal perspective. They also stated that they chose an intermediate rather than final outcome (incontinence cures rather than quality adjusted life-years). This prevents comparison of the results of this study with other diverse interventions, such as for heart disease or diabetes.

It is unclear why the authors created both a simple and full version of their model. As the full version includes clinically relevant and cost-imposing events (repeat surgery), the simple model would appear insufficient.

The sensitivity analysis seems confused. There were insufficient data to permit independent assessment of the appropriateness of the authors’ conclusions: the authors could have defined a maximum willingness-to-pay for an extra incontinence cure, and based the threshold analysis on this. In the sense the authors have used, saying that one arm is more cost-effective than another is not helpful regarding the optimal choice.

The transparency of the study would have been aided by explicitly stating in the method that the only difference between the two arms is the treatment for DI. An appropriate hypothesis would therefore be that the urodynamics test will identify the form of incontinence more accurately, so patients with true DI will get a more effective treatment, hence improving overall effectiveness of the treatment arm, without substantially increasing cost (i.e. the strategy will be partially dominant).

Implications of the study
The authors state that, as the results of this cost-effectiveness analysis are ‘unequivocal’, it is unnecessary to carry out a
clinical trial of this technology (urodynamic testing) to confirm the results with appropriate patient populations. This is justified on the grounds that only two parameter estimates influence the results, and then only when the parameters were increased well beyond a 'clinically reasonable' range.

This implication should be treated with caution as the authors did not define what they meant by 'unequivocal', and the confusion over the sensitivity analysis referred to in the commentary above.

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