The cost-effectiveness of preoperative testing (basic office assessment vs urodynamics) for stress urinary incontinence in women


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
Two preoperative testing strategies for women with stress urinary incontinence (SUI) were examined, basic office assessment (BOA) versus urodynamic testing (UT). BOA consisted of a detailed history, physical examination, urine analysis, provocative cough-stress test, and measurement of postvoid residual urine volume. UT comprised dual-channel subtracted cystometrography, uroflowmetry, pressure-flow voiding study, and an assessment of urethral function by urethral pressure profilometry or leak-point pressure measurement.

Type of intervention
Diagnosis.

Economic study type
Cost-effectiveness analysis.

Study population
The study population comprised a hypothetical cohort of healthy women aged 65 years or older, with the predominant symptoms of SUI, with or without urgency, frequency or nocturia. The women had no prior surgical treatment for urinary incontinence, no history of neurological conditions, no causes of acute or reversible incontinence (i.e. urinary tract infection or drug side effects), and no history of pelvic radiation or surgery for pelvic cancer. In addition, the women also had no symptomatic pelvic organ prolapse or prolapse extending beyond the hymen, and had normal screening neurological examination, urethral hypermobility, normal urine analysis, and normal postvoid residual urine volume.

Setting
The setting was a hospital. The economic study was conducted in the USA.

Dates to which data relate
Information on effectiveness and resource use was derived from studies published between 1980 and 1998. The price year was not reported.

Source of effectiveness data
The effectiveness evidence was derived from completed studies and authors' assumptions.

Modelling
A decision tree model was constructed to simulate the management of a hypothetical cohort of women with SUI. After an initial BOA, the patients underwent UT or no further test, then underwent medical and surgical treatments. After primary and secondary treatments, the three possible outcomes were cure of incontinence, urinary retention, or...
persistent incontinence. The primary surgical treatment was retropubic bladder suspension (RBS). The time horizon of
the study was one year, which represented the follow-up period.

Outcomes assessed in the review
The following outcomes were assessed in the review.

The prevalence of urodynamically confirmed genuine stress incontinence (GSI), urodynamically confirmed mixed
incontinence, and urodynamically confirmed detrusor instability (DI), in women with stress symptoms and positive
cough stress tests.

Urodynamic test characteristics, such as UT positive for:
GSI when GSI was true condition (sensitivity or true-positive for GSI),
mixed incontinence when GSI was true condition (false-positive for DI),
GSI when mixed incontinence was true condition (false-negative for DI).

The cure rates after initial RBS for GSI, after repeat RBS for urethral hypermobility and GSI, after initial RBS for DI,
after initial RBS for mixed incontinence, after collagen injection for intrinsic sphincter deficiency (ISD), and after
urethrolysis for retention.

The cure rates for medical treatment for DI and for mixed incontinence.

The rate of permanent retention after initial or repeat RBS.

The rate of recurrent incontinence after urethrolysis.

The rate of persistent retention after urethrolysis.

Recurrent urethral hypermobility as cause of recurrent incontinence after RBS for GSI, DI or mixed incontinence.

ISD as aetiology of recurrent incontinence after RBS for GSI.

DI as aetiology of recurrent incontinence after RBS for GSI.

Study designs and other criteria for inclusion in the review
The studies were classified as properly designed and implemented controlled trials (type A) or properly designed and
implemented clinical series (type B). The designs of the studies included in the review were not described, but there
were more B-type studies than A-type studies.

Sources searched to identify primary studies
MEDLINE was searched from 1966 to 1998 to identify relevant studies published in English-language peer-reviewed
journals. The references in the identified articles were also searched.

Criteria used to ensure the validity of primary studies
The validity of the primary studies was defined by classifying the studies as type A or type B.

Methods used to judge relevance and validity, and for extracting data
Not stated.
Number of primary studies included
Forty-two studies were included in the review.

Methods of combining primary studies
Not stated.

Investigation of differences between primary studies
Not stated.

Results of the review
In women with stress symptoms and positive cough stress tests, the prevalence values were 80% (range: 58 - 89) for urodynamically confirmed GSI, 18% (range: 9 - 37) for urodynamically confirmed mixed incontinence, and 2% (range: 0 - 5) for urodynamically confirmed DI.

Test characteristics for UT:
the rate of UT positive for GSI when GSI was true condition was 86% (range: 78 - 94),
the rate of UT positive for mixed incontinence when GSI was true condition was 14% (range: 7 - 18),
the rate of UT positive for GSI when mixed incontinence was true condition was 25% (range: 22 - 28).

The cure rates were:
86% (range: 78 - 94) after initial RBS for GSI,
86% (range: 82 - 97) after repeat RBS for urethral hypermobility and GSI,
31% (range: 25 - 35) after initial RBS for DI,
78% (range: 30 - 92) after initial RBS for mixed incontinence,
82% (range: 81 - 90) after collagen injection for ISD,
72% (range: 65 - 78) after urethrolysis for retention,
68% (range: 59 - 80) for medical treatment for DI, and
51% (range: 46 - 60) for medical treatment for mixed incontinence.

The rate of permanent retention after initial or repeat RBS was 2.5% (range: 0 - 5).
The rate of recurrent incontinence after urethrolysis was 9% (range: 0 - 15).
The rate of persistent retention after urethrolysis was 19% (range: 12 - 23).
The rate of recurrent urethral hypermobility as cause of recurrent incontinence after RBS for GSI, DI or mixed incontinence was 30% (range: 12 - 67).
The rate of ISD as aetiology of recurrent incontinence after RBS for GSI was 52% (range: 33 - 53).
The rate of DI as aetiology of recurrent incontinence after RBS for GSI was 18% (range: 17 - 33).
Methods used to derive estimates of effectiveness
The authors made some assumptions when the data were not available in the literature.

Estimates of effectiveness and key assumptions
The rate of UT positive for mixed incontinence when mixed was true condition was 75% (range: 67 - 83).

The rate of UT positive for DI when DI was true condition was 86% (range: 76 - 92).

The rate of UT positive for GSI when DI was true condition was 0.05% (range: 0.04 - 0.06).

The rate of UT positive for mixed incontinence when DI was true condition was 13.95 (range: 13.94 - 13.96).

The cure rate for medical treatment for GSI was 0 (range: 0 - 10).

The rate of ISD as aetiology of recurrent incontinence after RBS for DI or mixed incontinence was 20% (range: 10 - 30).

The rate of DI as aetiology of recurrent incontinence after RBS for DI or mixed incontinence was 50% (range: 40 - 60).

Measure of benefits used in the economic analysis
The summary benefit measure used in the economic analysis was the success rate (proportion of women cured of incontinence). This was derived from the decision model.

Direct costs
Discounting was not relevant because the costs were incurred during one year. The unit costs were reported separately from the resources used for the main categories of costs. The cost items were UT, initial or repeat RBS, urethrolysis, collagen injection, medical treatment for DI, care related to incontinence and urinary retention for one year. The cost/resource boundary of the study is likely to have been that of the health service payer. The hospital and procedural costs were obtained from the Medicare Diagnosis-Related Group. The physician costs were calculated using relative value units for specific tests and procedures, multiplied by a standard conversion factor. The costs of the outpatient procedure and tests included facility costs and professional reimbursement. The cost of medication was based on an assumed, twice-daily dose of oxybutynin for one year. Data on resource use were based on probability values derived from the literature and the authors' assumptions. The price year was not reported.

Statistical analysis of costs
Statistical analyses of the costs were not performed.

Indirect Costs
The indirect costs were not included.

Currency
US dollars ($).

Sensitivity analysis
One- and two-way sensitivity analyses were conducted to address the uncertainty in the estimates used in the model. All the inputs were varied using ranges found in the literature. The variables that were estimated from authors’ assumptions and cost data were varied by +/- 10%. Threshold analyses were also conducted to identify the value of the variable that would change the results of the base-case. The ranges were extended beyond their original bounds, if required.
Estimated benefits used in the economic analysis
The proportion of women cured of incontinence by initial and secondary treatment was 96.4% with BOA and 96.5% with UT.

Cost results
The average cost of care was $5,042 with BOA and $5,046 with UT.

Synthesis of costs and benefits
Average and incremental cost-effectiveness ratios were calculated to combine the costs and benefits of the two diagnostic approaches.

The average cost per successfully treated patient was $4,693 with BOA and $4,811 with UT.

The cost per unsuccessfully treated patient was $5,771 with BOA and $5,281 with UT.

The incremental cost per one additional patient cured with UT relative to BOA was $3,847.

One-way sensitivity analyses showed that the cost per successfully treated patient was sensitive to variations in the prevalence of types of incontinence (GSI, DI and mixed). When the prevalence rate was greater than 80%, the BOA was the most cost-effective strategy (with a rate greater than 85%, BOA dominated UT). With a rate lower than 79%, UT was the preferred strategy (less costly and more effective).

Threshold values for the costs of UT and primary surgery, cure rate of medical treatment and surgery for mixed incontinence, and sensitivity of UT for mixed incontinence, were also identified.

The study results were robust to variations in the remaining model inputs.

Authors' conclusions
Urodynamic testing (UT) proved to be as costly and effective as the standard basic office assessment (BOA) in the diagnostic preoperative assessment of adult women with stress urinary incontinence (SUI). This conclusion was particularly sensitive to the disease prevalence rate.

CRD COMMENTARY - Selection of comparators
The rationale for the choice of the comparator was clear. BOA was selected as the basic comparator because it was the first diagnostic approach for women with SUI. UT, on the other hand, was usually reserved for more complicated cases. You should decide whether they represent widely used diagnostic approaches in your own setting.

Validity of estimate of measure of effectiveness
The effectiveness evidence came from a review of the literature, the methods and conduct of which were clearly reported. The authors rated the quality of the evidence, although the design of the primary studies was not reported. Therefore, details on the patients and treatments were not provided. The authors did not state the method used to combine the primary estimates. The authors also made some assumptions when the data were not available in the literature. The issue of uncertainty surrounding these variables was addressed in the sensitivity analyses, which were conducted on all variables.

Validity of estimate of measure of benefit
The benefit measure was calculated from the decision model. It represented a disease-specific measure, and it appears that it would be difficult to compare it with the benefits of other health care interventions. The authors stated that quality-adjusted life-years were not used because there was no evidence on changes in quality of life with the treatment...
of urinary incontinence.

**Validity of estimate of costs**
It appears that all the costs relevant to the health care provider have been included in the analysis, although the authors stated that a societal perspective was adopted. The indirect costs were not included due to problems in their measurement. Only limited details of the cost analysis were reported, such as the source of the cost data and some unit costs. Resource use (probability values) was estimated from published data. The price year was not given. No statistical tests were conducted on the costs or quantities. The cost estimates were specific to the study setting but several sensitivity analyses were conducted, thus enhancing the generalisability of the results.

**Other issues**
The authors did not compare their findings with those from other studies, stating that other similar studies had not been carried out to date. They also did not address the issue of the generalisability of the study results to other settings. However, sensitivity analyses were conducted. The authors noted some limitations of their analysis. In particular, the use of decision modelling and a limited study population (including women more likely to have GSI than other complications).

**Implications of the study**
The authors suggested that future randomised trials should be carried out to confirm the results of their study, and that these trials should focus on quality of life issues.

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