

Systematic review and economic modelling of the effectiveness and cost-effectiveness of non-surgical treatments for women with stress urinary incontinence

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Executive summary

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Executive summary

Description of proposed service

The treatment options for stress urinary incontinence (SUI) can be classified as non-surgical and surgical. Lifestyle changes, such as weight loss, smoking cessation, etc. may reduce the risk of leakage but all need continued adherence. Non-surgical interventions, such as pelvic floor muscle training (PFMT), biofeedback (BF), electrical stimulation (ES), bladder training (BT), vaginal cones (VCs), etc., may also require long-term adherence to the taught programmes in order to produce continued benefit. However, these interventions have few adverse events compared with surgical treatment. Alternatively, the leakage can be contained using absorbent pads, an indwelling urinary catheter or, very rarely, urinary diversion.

Epidemiology and background

Stress urinary incontinence is the involuntary leakage of urine associated with effort or exertion, or on sneezing or coughing. Some women may also have symptoms of urge incontinence (a sudden compelling desire to pass urine, which is difficult to defer). Estimates of prevalence suggest that over 30% of women aged ≥ 40 years have SUI. The annual incidence increases with age (aged > 65 years, annual incidence rates $\approx 9\%$).

Objective

This study aimed to assess the clinical effectiveness and cost-effectiveness of non-surgical treatments for women with SUI.

Methods

The work comprised three distinct elements: (1) a survey of women with SUI to identify outcomes of importance to them [using a Patient Generated Index (PGI)]; (2) a systematic review and a meta-

analysis of non-surgical treatments for SUI to find out which are most effective [this was done in two ways, by comparing results of trials (direct pairwise comparisons) and by modelling results (mixed-treatment comparisons, MTCs)]; and (3) economic modelling of non-surgical and surgical treatments for SUI to find out which combinations of treatments (treatment pathways) are most cost-effective.

The survey identified areas of importance to women who suffer from SUI, using a PGI. A total of 188 women were invited to take part.

Literature searching included the Cochrane Incontinence Group Specialised Register (last searched March 2008), electronic databases (1980 to March 2008) and the websites of relevant professional organisations and manufacturers. Randomised controlled trials (RCTs) and quasi-RCTs (alternate allocation) were eligible. Random effects models were used to derive summary estimates with 95% confidence intervals (CIs) or credible intervals (CrIs) of the odds ratio (OR) for dichotomous variables and standardised mean difference (SMD) for continuous variables (direct pairwise comparison only).

To compare the cost-effectiveness of the treatment pathways, a Markov model was used. The model was developed using data from the review of effectiveness and data on resource use systematically identified as being relevant to the UK National Health Service (NHS). The model estimated cost and quality-adjusted life-years (QALYs) for a 40-year time horizon. Discounting at 3.5% was performed, as was deterministic and probabilistic sensitivity analysis.

Results

Survey

Overall, 38 different areas were reported by respondents on the PGI. These areas were divided into four themes: activities of daily living; sex, hygiene and lifestyle issues; emotional health; and the availability services.

Number and risk of bias in studies included in the systematic review

A total of 88 trials reporting data from 9721 women were identified, considering five generic interventions [PFMT, ES, VCs, BT and serotonin–noradrenaline reuptake inhibitors (SNRI) medications], in many variations and combinations. PFMT data were split into PFMT basic (fewer than two sessions of training per month) and PFMT with extra sessions (more than two sessions per month). Data were available for 37 interventions and 68 treatment comparisons by direct pairwise assessment. Mixed-treatment comparison models compared 14 interventions, using data from 55 trials (6608 women). Included studies were generally small and had short follow-up periods. Fourteen studies (16%) reported both adequate random allocation sequence generation and concealment.

Summary of clinical effectiveness

The direct pairwise comparison analysis and the MTC analysis showed that the treatments were, on average, more effective than no treatment. Delivering PFMT in a more intense fashion, either through extra sessions (more than two per month) or with BF, appears to be the most effective treatment [PFMT extra sessions vs NT odds ratio (OR) 10.7, 95% CrI 5.03 to 26.2; PFMT + BF vs NT OR 12.3, 95% CrI 5.35 to 32.7]. Only when success was measured in terms of improvement was there evidence that PFMT basic was better than no treatment (PFMT basic vs NT OR 4.47, 95% CrI 2.03 to 11.9). Adverse events were uncommon except for SNRI medication.

Costs

The perspective adopted for the analysis is that of the UK NHS. The total costs for each intervention over a 3-monthly period (the cycle length of the Markov model) were lifestyle changes £27, PFMT basic £189, PFMT with extra sessions £351, drug therapy £164, tension-free vaginal tape (TVT) £1135, colposuspension £1396 and containment products £39.

Using cure rates, a strategy of lifestyle changes and PFMT with extra sessions followed by TVT was the least costly (£1644) and the most effective (16.20 QALYs). The strategy that had lifestyle changes followed by TVT (LS–TVT) was the most costly (£1973).

Using improvement rates, the strategy LS–PFMT basic–PFMT extra sessions–TVT was the least costly (£1795). The strategy LS–TVT was the most costly (£2425).

Quality-adjusted life-years

Using cure rates, the strategy that used lifestyle changes and PFMT basic, followed by PFMT with extra sessions, followed by SNRI and then TVT (LS–PFMT basic–PFMT extra sessions–SNRI–TVT), was the least effective (15.89 QALYs).

Using improvement rates, the strategy LS–PFMT extra sessions–TVT was the most effective (16.37 QALYs). The strategy LS–TVT was the least effective (16.2 QALYs) (and, as noted above, the most costly).

Cost-effectiveness

For cure rates, the strategy using lifestyle changes and PFMT with extra sessions followed by TVT (LS–PFMT extra sessions–TVT) had a probability of greater than 70% of being considered cost-effective for all threshold values for willingness to pay for a QALY of up to £50,000.

For improvement rates, LS–PFMT extra sessions–TVT had a probability of greater than 50% of being considered cost-effective when society's willingness to pay for an additional QALY was more than £10,000.

Sensitivity analysis

The results were most sensitive to changes in the long-term performance of PFMT and also in the relative effectiveness of PFMT basic and PFMT with extra sessions. The results were not sensitive to plausible changes in the structure of the model (use of containment products instead of using an active treatment, introduction of vaginal cones and ES into treatment strategies). The results were also insensitive to plausible changes in the age of women, time horizon, discount rates, quality-of-life estimates, and mortality from surgery.

Limitations of the calculations

Few data were available for most comparisons and a pragmatic decision was made to include women with urgency urinary incontinence (UUI) symptoms, but only if the proportion of women

with UUI was less than 50% of the study sample. The definitions of outcomes differed between studies and the interventions were varied in terms of the precise nature of the exercise as well as the duration of therapy.

All of these results need to be considered cautiously as very few data were available for interventions. The 95% central CrIs for these interventions are very wide and indicate that we know very little about their relative effectiveness. There were few long-term data for any of the therapies. These data are important determinants of cost-effectiveness, yet little is known about how quickly symptoms might return.

Other important issues regarding implications

There may not be sufficient trained therapists to provide the potentially more effective and cost-effective intensive non-surgical treatments. For the use of these therapies to increase, staff would need to be recruited, trained and retained.

Within all of the analyses, the preferences of women for the process of care have not been considered. Women are likely to have preferences about who provides the care, where the care is provided, and what risks and costs they face themselves.

The value of the non-surgical treatments depends upon its ability to maintain women's long-term adherence to therapy. How this might be achieved in practice will involve a complex interplay of factors, including who provides the therapy, how it is provided, for how long, the preferences of women, and so on. These issues could not be fully explored in this study because of the limited evidence base.

Implications for practice

Non-surgical treatments for SUI in women are effective and could potentially be cost-effective, but a judgement is required as to whether the benefits are worth the cost.

There is clear evidence that PFMT plus BF and PFMT with extra sessions was effective. Several other treatments (PFMT plus BT and BF; PFMT plus BF and VCs or ES) are promising, but there is insufficient evidence to recommend their routine use.

There is no evidence that PFMT basic is any better than no treatment in terms of cure, although it does improve symptoms compared with no treatment.

The cost-effectiveness of the non-surgical treatments is dependent upon whether their short-term effectiveness is sustained.

Recommendations for further research

Conclusions are based on data from a limited number of small trials.

More intensive forms of PFMT appear worthwhile, but research is required to define an optimal form of more intensive therapy that is feasible and efficient for the NHS to provide.

Further definitive evidence from large, well-designed studies is required in order to provide a definitive answer.

Any further research on long-term outcomes, benefit assessment or costs should be incorporated into an updated economic evaluation, as and when it becomes available.

If an effective and efficient follow-up regimen can be developed then the incentives/disincentives faced by NHS providers may need to be reconsidered to aid its implementation.

Publication

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The research reported in this issue of the journal was commissioned by the HTA programme as project number 06/41/02. The contractual start date was in July 2007. The draft report began editorial review in March 2009 and was accepted for publication in October 2009. As the funder, by devising a commissioning brief, the HTA programme specified the research question and study design. The authors have been wholly responsible for all data collection, analysis and interpretation, and for writing up their work. The HTA editors and publisher have tried to ensure the accuracy of the authors' report and would like to thank the referees for their constructive comments on the draft document. However, they do not accept liability for damages or losses arising from material published in this report.

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