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ECONOMIC MODELLING OF THE EFFECTIVENESS AND COST-EFFECTIVENESS OF NON-SURGICAL TREATMENTS FOR WOMEN WITH STRESS URINARY INCONTINENCE

Background

While rarely life-threatening, incontinence may seriously influence the physical, psychological and social wellbeing of affected individuals. The impact on the families and carers of women with Urinary Incontience (UI) may be profound, and the resource implications for the health service considerable[1]. Although there have been many literature reviews of individual treatments for stress urinary incontinence it is generally accepted that there is no "perfect" therapy for stress urinary incontinence. For most women it is sensible to attempt the most reversible, simplest, least invasive, and least expensive interventions, such as lifestyle changes and pelvic floor muscle training (PFMT) in the first instance. Compared with surgical treatments, non-surgical treatments, such as lifestyle changes and physical therapies such as PFMT, are associated with limited side-effects and do not preclude future changes in management. From a health service perspective however it is important to balance short and long-term effectiveness against the potential adverse effects and costs of treating stress urinary incontinence. A study[2] was conducted to estimate the effectiveness and cost–effectiveness of the non surgical treatment for women with stress urinary incontinence (SUI).

KEY MESSAGES

1. The impact of stress urinary incontinence on women with the condition, their families and carers and on the NHS as a whole is considerable.
2. From a health service perspective it is important to balance short and long-term effectiveness against the potential adverse effects and costs of treating stress urinary incontinence.
3. Despite the limitations of the evidence base there is evidence that PFMT plus biofeedback and PFMT with extra sessions are likely to be considered cost-effective

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Methods

The perspective of the model was based on the NHS (the health service provider in the UK). A Markov model portraying the temporal and logical sequence of the clinical decision problem was used to provide estimates of costs, effectiveness (measured in quality adjusted life years) and cost-effectiveness. The health states within the model are considered to reflect possible outcomes of therapy e.g. successful treatment (i.e. cure or improvement), failure (i.e. incontinence) and recurrence of incontinence. Graduation in the severity of incontinence was not considered in the model due to paucity of the available data on effectiveness.

In the model women receive an initial treatment, then move into one of three states: Success, failure or death. If a woman considers herself cured (or sufficiently improved so that she no longer feels the need for further treatment) then the treatment is successful. If the treatment does not result in cure (or sufficient improvement) then the woman enters the failure state. Finally, there is always a small chance that over any period of time that a woman would die, either due to surgery, or other causes at any point in time.

In the model people stay in a state for a minimum period of three months, that represents the recommended/widely used duration of PFMT before reassessment. Women can continue moving through states in the model for a maximum of 40 years (equivalent to 160 cycles) which takes into account the life expectancy of women who enter the model at the age of 45. The discount rate used is the recommended rate of 3.5% for both costs and benefits. The clinical effectiveness data were based on an indirect model comparison results, costs were identified from published data. Long term follow- up, failure and recurrence rates were based on extrapolations of existing data.

There are many potential methods for treating stress urinary incontinence which might be used alone or as part of a management strategy. There is some evidence of the relative effectiveness of individual treatments but little information on how the various interventions might be combined into management strategies. Plausible treatment strategies comprising sequences of non-surgical and surgical interventions were identified following consultation with health care professionals and patient group representatives involved in the study. Surgery was considered as an alternative to non-surgical treatments and also as an option should non-surgical treatments fail to satisfactorily resolve symptoms.

Table 1: Management strategies

	Treatment sequence					
	First treatment	**Second treatment**	**Third treatment**	**Fourth treatment**	**Fifth treatment**	**Sixth treatment**
1	Lifestyle + PFMT basic	TVT/ TVTO	2nd surgery	Containment		
2	Lifestyle + PFMT basic	PFMT extra sessions	TVT/ TVTO	2nd surgery	Containment	
3	Lifestyle + PFMT basic	PFMT extra sessions	SNRI	TVT/ TVTO	2nd surgery	Containment
4	Lifestyle + PFMT extra sessions	TVT/ TVTO	2nd surgery	Containment		
5	Lifestyle + PFMT extra sessions	SNRI	TVT/ TVTO	2nd surgery	Containment	
6	Lifestyle	TVT/ TVTO	2nd surgery	Containment		
7*	Lifestyle + PFMT basic	VC	TVT/ TVTO	2nd surgery	Containment	
8*	Lifestyle + PFMT basic	ES	TVT/ TVTO	2nd surgery	Containment	

* Two strategies reported in sensitivity analyses only

VC = vaginal cones; ES = electrical stimulation; SNRI= Serotonin and noradrenaline reuptake inhibitors; TVT= tension free vaginal tape; TVTO= transvaginal oburator tape

The potential management strategies compared within the model are described in Table 1. It is assumed that all women are initially given advice, if appropriate, about modifying their lifestyles. The interventions included in the management strategies are thus: lifestyle changes; basic PFMT (PFMT basic 6 sessions in 3 months); PFMT with extra sessions (PFMT extra sessions 12 sessions in 3 months); electrical stimulation; vaginal cones; drug treatment: Serotonin and noradrenaline reuptake inhibitors (SNRI), surgery tension free vaginal tape(TVT) or other similar self fixing sling e.g. trans vaginal oburator tape (TVTO), and the second surgery. Once all treatments are exhausted it is assumed that women have to manage their symptoms using containment products

Table 2: Base case results of costs and effects using cure rates from the mixed treatment model

Strategy	Cost	Incremental Cost	QALYs	Incremental QALY	ICER
LS-PFMT extra sessions - TVT	£1644		16.2		
LS-PFMT extra sessions - SNRI-TVT	£1727	£82	16.06	-0.13	Dominated
LS-PFMT basic - PFMT extra sessions - TVT	£1758	£113	16.02	-0.17	Dominated
LS-PFMT basic - PFMT extra sessions - SNRI-TVT	£1842	£197	15.89	-0.3	Dominated
LS-PFMT basic - TVT	£1886	£242	16.03	-0.17	Dominated
LS-TVT	£1973	£328	16.08	-0.12	Dominated
Results without dominated and extendedly dominated options					
LS-PFMT extra sessions - TVT	£1644		16.2		

Results

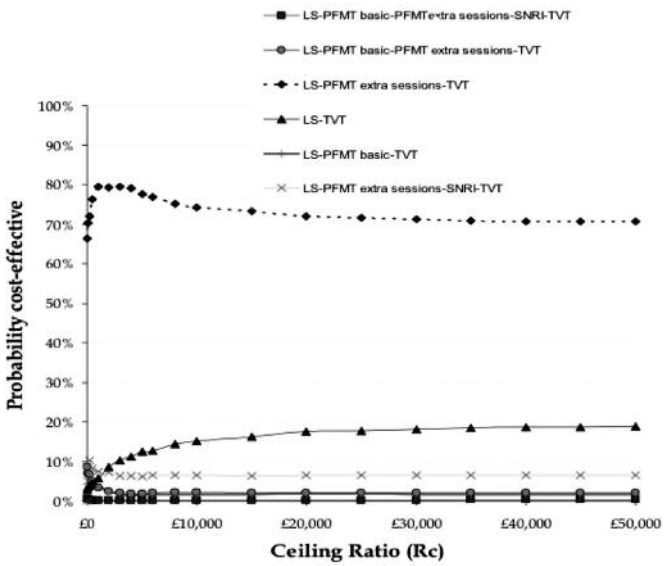
The strategy of lifestyle changes (LS) and pelvic floor muscle training (PFMT) with extra sessions followed by Tension free vaginal tape (TVT) was the least costly (£1644) and the most effective (16.20 QALYs) (Table 2). All other strategies were more costly and less effective (i.e. were dominated).

As the cost-effectiveness point estimates do not provide any information of uncertainty surrounding the model parameters, probabilistic sensitivity analysis using Monte Carlo simulations was also performed. The results of the probabilistic analysis are presented in the form of cost-effectiveness acceptability curves (CEACs) in Figure 1. The LS-PFMT extra sessions-TVT strategy had more than a 70% probability of being considered cost-effective for all threshold values of willingness to pay for a QALY up to £50,000. The other five strategies each have a probability of less than 20% of being considered cost effective.

Sensitivity analysis

The results were somewhat sensitive to changes in the long term cure rates. However, these changes did not alter the main conclusion that LS-PFMT extra sessions-TVT is the preferred strategy. The results were not sensitive to other changes in the model, e.g. different values of quality of life and proportion of patients that used containment products after failure or recurrence for non-surgical or surgical treatments.

Figure 9.8 Cost-effectiveness acceptability curves determined by society's willingness to pay for a QALY for the six strategies



Discussion

The economic model presented in this paper has considered eight different management strategies which were derived following lengthy discussions with health care professional experts and patient representatives. They were chosen, because they were believed to be relevant to the NHS and they might potentially be cost-effective. Hitherto no such analysis existed. The least costly and most effective strategy was lifestyle intervention, followed by PFMT with extra sessions (or PFMT plus biofeedback) and then surgery if necessary.

There were relatively modest differences between treatments in terms of both QALYs and costs and one interpretation of these results might be that any of these treatment strategies could be equally well provided by the NHS. Nevertheless, when the incremental cost-effectiveness was estimated then it was highly likely that lifestyle changes followed by PFMT with extra sessions followed by surgery if necessary would be cost-effective (there was an over 70% chance that this intervention would be considered cost-effective at a threshold value of £20,000 per QALY).

Strategies involving drug management were unlikely to be considered cost-effective, primarily due to the non-adherence to SNRI treatment caused by the side effects of the drugs. Using surgery rather than trying non-surgical treatments was not likely to be cost-effective nor were strategies involving vaginal cones or electrical stimulation. It was also found that the interpretation of the cost-effectiveness results did not greatly change when the model was adapted to allow women to exercise preference not to seek surgery or repeat surgery, should cure or sufficient improvement not be achieved.

Conclusions

The evidence suggests that LS-PFMT extra sessions-TVT is a cost effective strategy. The cost-effectiveness of the non-surgical treatments is dependent upon whether their short-term effectiveness is sustained. 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. Overall, the results of the economic evaluation suggests that further research to develop and test a more intensive PFMT intervention that is acceptable to women and feasible for the NHS is warranted. This research findings led to the National Institute for Health Research (NIHR) Health Technology Assessment (HTA) commissioned call for proposals for "Intensive pelvic floor muscle training to treat female urinary incontinence" trials that are currently under review.

Reference

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