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WHAT'S NEEDLING US ABOUT THE MANAGEMENT OF REFRACTORY OVERACTIVE BLADDER? AN ECONOMIC ANALYSIS OF THE USE OF PERCUTANEOUS TIBIAL NERVE STIMULATION AND BOTULINUM TOXIN.

Hypothesis / aims of study

Overactive Bladder (OAB) syndrome, defined as 'Urinary urgency, usually accompanied by frequency and nocturia, with or without urgency urinary incontinence, in the absence of urinary tract infection or other obvious pathology'(1), is a prevalent condition known to adversely affect quality of life (QoL). Antimuscarinic therapy remains integral in the management of OAB although problems with adverse effects may affect compliance and persistence. For those who have intractable or refractory symptoms intravesical Botulinum Toxin may offer an efficacious and minimally invasive alternative to reconstructive surgery or sacral neuromodulation (2).More recently Posterior Tibial Nerve Stimulation (PTNS) has been shown to offer an effective and well tolerated alternative treatment approach (3) and may be useful in a similar group of refractory patients (3). The aim of this study was to perform a cost utility analysis of Botulinum Toxin and PTNS in the management of refractory idiopathic OAB.

Study design, materials and methods

A decision analytic Markov model was developed to compare the cost-utility of PTNS and Botulinum Toxin in the management of refractory idiopathic OAB patients. The timeframe was based on a 2 year follow-up period and costing took an NHS perspective. Entry into the model followed an initial consultation and similar investigations for both treatment alternatives.

For PTNS the cost of treatment was estimated using standard NHS sources and for equipment and disposables (Urgent PC, Uroplasty). The annual equivalent cost of the device was calculated assuming a lifespan of 5 years. A cost per use of the device was then estimated under the assumption that the equipment would be used 5 times per week. The treatment algorithm comprised 12 weekly visits over an initial three month period and subsequent maintenance therapy of one session per month. For Botulinum Toxin drug costs were estimated using the British National Formulary (BNF 59, March 2010) for Botox 200iu (Allergan, USA). It was assumed that patients would have repeat treatments every 8 months under local anaesthesia in the out-patient setting and self catheterisation rates (CISC) were assumed to be 20% with patients catheterising for 4 months. Efficacy rates for both procedures were estimated from previously published studies (3) and it was assumed that patients would drop out following unsuccessful treatment. In line with standard NICE (National Institute of Health and Clinical Excellence) methodology costs and effects in year 2 were discounted at 3.5%. It was assumed that a patient would have a 0.02 increase in health state utility as a result of improvement and a 0.05 gain from cure. The incremental cost effectiveness ratio (ICER) of each treatment was calculated relative to the next most effective treatment or 'do nothing'. Sensitivity analysis was undertaken to explore the impact of assumptions about the gains in health state utility from successful treatment.

Results

The base case input values are shown below **[Table 1].** The model was designed to allow these input values to be varied.

PTNS	**Value**	**Range**	**Botulinum Toxin**	**Value**	**Range**
Equipment Cost (£)	960.00	700-1200	Drug cost (£)	276	100-500
Life-span	5	1-5	Procedure (£)	955	500-2000
Patients per week	5	2-10	OPD Visit (£)	87	50-150
Disposable lead (£)	37.00	20-50	CISC Cost/d (£)	4.5	2-10
Hourly nursing (£)	44.00	20-60	CISC Rate (%)	20	0-50
Initial Treatments	12	6-20	Days CISC (%)	50	0-100
Maintenance Visits	21	5-30	Success Rate (%)	80	0-100
Duration of visit (hrs)	0.5	0.2-1.0	Cure Rate (%)	50	0-100
Cure Rate (%)	4.5	0-100	Improvement (%)	50	0-100
Improvement (%)	75	0-100			

Table 1: Model inputs for cost minimisation comparison for PTNS and Botulinum Toxin

In the base case analysis comparison PTNS therapy was found to be cheaper than Botulinum Toxin (£1700.00 and £4067.00 respectively; difference - £2367.00). The incremental cost effectiveness analysis suggested that PTNS had a lower incremental cost effectiveness ratio (£50,133 versus £111,953) although neither would be considered cost-effective using the advisory willingness to pay threshold often adopted in NICE guidance (£20,000 to £30,000 per QALY). **[Table 2]**

Intervention	**Cost**	**QALY**	**Incremental Cost**	**Incremental QALY**	**ICER**
PTNS	£1 700	0.0399	£1 700	0.034	£50 133
BOTOX	£4 067	0.0951	£2 366	0.021	£111 953

Table 2: Incremental cost-effectiveness - Botulinum Toxin relative to PTNS (Base Case)

Sensitivity analysis (SA) using an increased health state utility gain with cure (0.1) and improvement (0.05) is shown below **[Table 3]**

Intervention	**Cost**	**QALY**	**Incremental Cost**	**Incremental QALY**	**ICER**
PTNS	£1 700	0.0826	£1 700	0.083	£20 590
BOTOX	£4 067	0.1180	£2 366	0.035	£66 861

Table 3: Incremental cost-effectiveness of Botulinum Toxin relative to PTNS (SA)

That cost effectiveness is sensitive to health state utility gain is illustrated by the two-way sensitivity analysis shown below **[Figure 1]**.

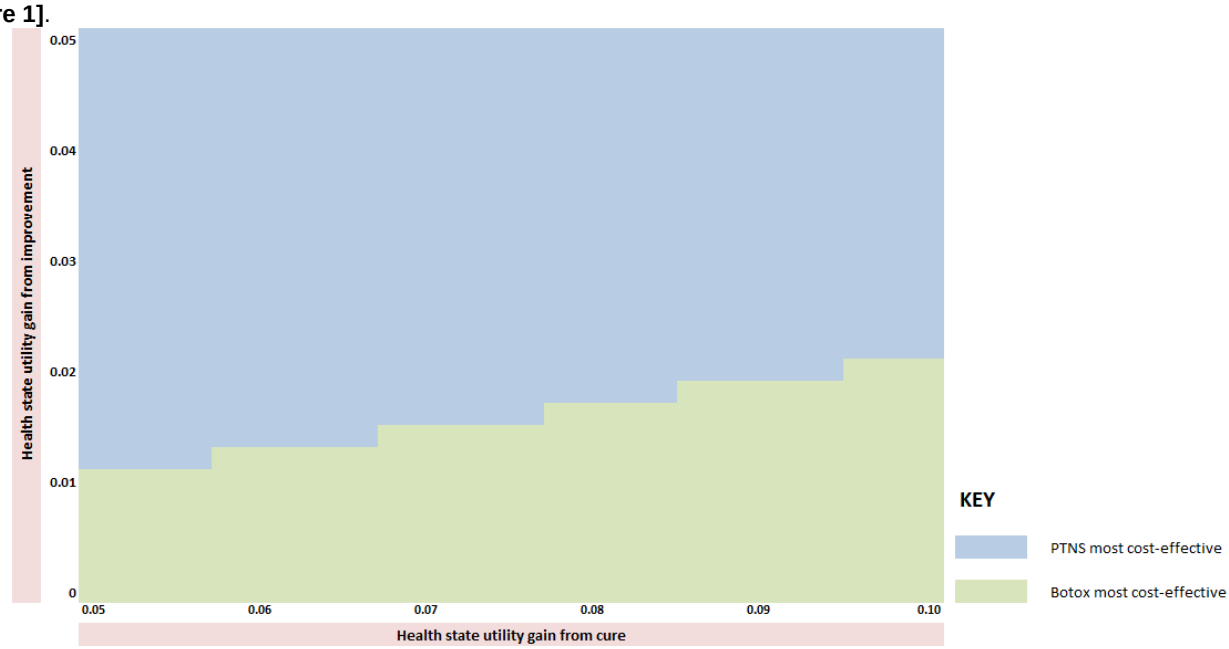

Figure 1: Two way sensitivity analysis varying QALY gain from cure and improvement

Interpretation of results

The evidence from this analysis suggests that PTNS therapy remains cheaper than treatment with Botulinum Toxin in women with refractory idiopathic OAB. In the base case analysis PTNS is more cost effective than Botulinum Toxin according to advisory NICE willingness to pay thresholds. This finding is highly sensitive to the assumptions about the extent to which cure and improvement would improve health related quality of life. If a relatively low improvement in health state utility is assumed neither treatment would appear to be cost effective. However, the sensitivity analysis also showed that if a greater improvement in health state utility is assumed, then PTNS could be considered cost-effectiveness by NICE criteria. It should be noted that the model does not include any adjustment for loss of health state utility associated with complications in the Botulinum Toxin group.

Concluding message

This analysis suggests that PTNS is more cost-effective than Botulinum Toxin in the treatment of refractory OAB providing the gains from cure don't considerably outweigh the gains from improvement short of cure. PTNS may be considered to be cost-effective relative to no treatment if, when successful, it generates a sufficiently large improvement in health related quality of life.

References

1. Int Urogynecol J 2010; 21: 5-26.
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3. Poster presentation. Meeting of AUA, Orlando, Florida. USA. 2008

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