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COST EFFECTIVENESS AND COST UTILITY ANALYSIS OF SACRAL NEUROMODULATION, OPTIMIZED MEDICAL TREATMENT AND BOTULINUM NEUROTOXIN IN THE TREATMENT OF IDIOPATHIC OVERACTIVE BLADDER IN SPAIN.

Hypothesis / aims of study

Sacral neuromodulation (SNM) is an effectiveness therapeutic option for idiopathic Overactive Bladder (OAB) after conservative treatment failure (1, 2). The average time from onset of urinary symptoms to treatment with SNM was 9.6 years suggesting that patients continue to remain on failed drug therapy in combination with the use of pads for a long period of time. In the later years, botulinum neurotoxin A (BoNT) is being used for these patients even without a health authority approval for this indication and with a lack of long-term efficacy data. Recently, the first efficacy data with BoNT reinjections in idiopathic OAB have just been published (3). For these reasons, the aim of this study was to evaluate the projected health benefits, costs and cost-effectiveness of SNM compared with BoNT and Optimized Medical Treatment (OMT) for the treatment of idiopathic OAB in Spain.

Study design, materials and methods

A Markov model representing the treatment practice for drug-refractory idiopathic OAB patients with Urge Urinary Incontinence in Spain was developed to extrapolate long term costs and effectiveness under 3 treatment pathways: SNM, BoNT and OMT (remaining on failed drug therapy plus pads). Patients' response to treatment was defined in terms of 'improvement' (50% or greater reduction in main incontinence or urgency frequency symptoms). Two additional measures of effectiveness were included: quality-adjusted life year (QALY) values and a mean value of incontinence episodes. Effectiveness results and adverse events rates were obtained from literature and validated by an expert panel composed by Spanish urologists. Resource use (drugs, diagnostic tests, procedures, medical visits and adverse events) and treatment pathways were based on expert opinion (by 2 Focus Group meetings and structured interviews of 5 experienced Urologist from the four participanting hospitals). Total healthcare costs were determined from the public payer perspective and calculated by multiplying resource use by Spanish costs (obtained from Spanish database of health costs). The model was adjusted for a 10-year follow-up, to include the battery change for SNM. At the end of the ten-year period, mean cumulative costs and the two cumulative scores of effectiveness facilitated two separate cost effectiveness analyses (CEA) of SNM therapy in comparison with the other therapeutic pathways: incremental cost per QALY gained; and incremental cost per incontinence episode avoided. In line with current recommendations for CEA conducted in European settings, a discount rate of 3% per annum was applied to account for the present value of the future stream of costs and effectiveness. Probabilistic sensitivity analysis was performed, based on Monte Carlo simulations drawing parameter values from the distributions assigned to key uncertain parameters.

Results

Over a ten-year period, the incremental costs for SNM decrease significantly; while it incurs in higher first-year costs, its monthly follow-up costs are lower compared with both, BoNT and OMT.

The percentage of patients' that showed an improvement of the symptoms was higher in those who received SNM than that of patients receiving BoNT and OMT. Overall, Quality-Adjusted of Life Years (QALYs) for all initiated treatments increased progressively in time; however SNM had the highest QALYs values compared with the rest of alternatives and across all periods of analyses, ranging from 0.67 to 6.14; whereas QALYs for treatment with OMT at baseline were lowest for all years of analyses.

OAB management with SNM may be associated with 5.58€ and 1.01€ per incontinence episode avoided and incremental cost-effectiveness ratios (ICERs) of 7,138€ and 658€ per QALY gained compared to OMT, at 5 and 10 years respectively, with ICERs well below 30,000€ per QALY gained at the first year of treatment and thereafter.

SNM may also have a higher mid-long term effectiveness than BoNT at a reasonable cost, with ICERs of 25,996€ and 16.646€ per QALY gained at year 5 and 10, respectively.

SNM vs. BOTOX

	Incremental Cost	Episode avoided	Cost per Episode avoided	QALY gained	Cost per QALY gained
5 years	5.382,45 €	95	56,38 €	0,207	25.995,56 €
7 years	8.180,15 €	108	75,50 €	0,266	30.749,17 €
10 years	4.930,58 €	131	37,74 €	0,296	16.646,01 €

SNM vs. OMT

	Incremental Cost	Episode avoided	Cost per Episode avoided	QALY gained	Cost per QALY gained
5 years	7.097,19 €	1272	5,58 €	0,994	7.137,59 €
7 years	7.043,35 €	1183	5,95 €	1,165	6.048,27 €
10 years	905,09 €	893	1,01 €	1,376	657,85 €

Probabilistic sensitivity analyses demonstrated that the chances the outcomes obtained in this study fall within the acceptable European thresholds of cost-effectiveness are very high (from 86-100%). Variability in the results of SNM vs BoNT was observed,

because BoNT results are based on a single-centre study with a higher number of the patients treated with the first injection but a lower number returning for repeated injections (13 patients with 3 injections).

Interpretation of results

While the first year costs of SNM are higher, lower yearly follow up costs are shown during the ten years. The decrease in the costs combined with higher effectiveness make InterStim a cost-effectiveness option, with ICERs below the Spanish threshold (30,000€ per QALY gained) from year 1 (compared to OMT) and year 5 (compared to BoNT) onwards.

Concluding message

SNM therapy with InterStim provides the highest chances of symptom improvement and a marked improvement in quality of life (as measured with utilities), at relatively reasonable incremental costs for refractory idiopathic OAB patients, showing that this therapy is cost-effectiveness when compared with BoNT and OMT over a 10-year horizon.

References

1. Van Kerrebroeck PE, van Voskuilen AC, Heesakkers JP, Lycklama á Nijholt AA, Siegel S, et al. Results of sacral neuromodulation therapy for urinary voiding dysfunction: outcomes of a prospective, worldwide clinical study. J Urol 2007;178:2029-34

2. Van Voskuilen AC, Oerlemans DJ, Weil EH, van den Hombergh U, van Kerrebroeck PE. Medium-term experience of sacral neuromodulation by tined lead implantation. BJU Int 2007;99:107-10

3. Khan S, Kessler TM, Apostolidis A, Kalsi V, Panicker J, Roosen A, Gonzales G, Haslam G, Elneil S, Fowler CJ, Dasgupta P. What a Patient With Refractory Idiopathic Detrusor Overactivity Should Know About Botulinum Neurotoxin Type A Injection. J Urol 2009; 181: 1773-1778

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