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THE COST-UTILITY OF SACRAL NEUROMODULATION VERSUS BOTULINUM TOXIN A FOR THE TREATMENT OF REFRACTORY IDIOPATHIC OVERACTIVE BLADDER (WITH URGENCY URINARY INCONTINENCE) IN SWEDEN

Hypothesis / aims of study

The overactive bladder syndrome (OAB) is defined as urinary urgency, usually with urinary frequency and nocturia, with or without urgency urinary incontinence [1,2]. In Sweden, OAB (with urinary incontinence) has been estimated to affect about 470.000 people, representing a total annual cost of 206 mln EUR (cost of diagnosis, medications, pad use, consultations, and treatment of clinical depression associated with OAB) [3]. Conventional management of OAB consists of lifestyle modification, behavioural therapies and medication. If these fail, specialized treatments as Sacral Neuromodulation (SNM) or repeated injections of Botulinum Toxin A (BTX-A) can be offered. In Sweden, there is currently a lack of consensus in relation to the use of SNM. Thus, an analysis of the clinical benefit and the associated costs of the therapeutic options, could be a valuable part of a basis for decision for the relevant stakeholder. The purpose of this study was therefore to evaluate the cost-utility of SNM in comparison with BTX-A in patients with OAB (with urgency urinary incontinence) in Sweden.

Study design, materials and methods

The analysis was performed by adapting to the Swedish setting an existing decision analytic model, using discrete event simulation method. Outcomes (expressed in Quality Adjusted Life Years, QALYs) and costs (including: device and drug acquisition costs, pre-procedural and procedural costs, follow-up and management of adverse events) were gathered in order to derive incremental cost-utility ratios. Clinical data were based on literature and. Resource use for treatment of complications was based on expert opinion, whilst cost data were based on hospital costs and on Swedish national tariff lists (SEK 2014). In accordance with the Swedish national reimbursement guidelines, the analysis was performed over a lifetime horizon and results were interpreted against a willingness-to-pay threshold of 400.000 SEK/QALY. One-way deterministic and probabilistic sensitivity analyses were performed. Different time horizons (5, 10 and 15 years) were tested as well.

Results

Over the lifetime horizon, SNM led to higher costs (incremental costs of 135.043 SEK) and superior benefits (incremental QALYs of 0.93) compared with repeated injections of BTX-A. The corresponding cost-utility ratio was 145.562 SEK/QALY, well below the accepted willingness-to-pay threshold in Sweden. A one-way sensitivity analysis were performed to assess the impact of the results at each of the model parameter between a minimum and a maximum value (Figure 1). Over the lifetime horizon, SNM remained cost-effective (i.e. below the threshold) in all the scenarios, reaching a maximum ratio of 185.859 SEK/QALY when the cost of the battery replacement was increased of the 25%. When assessing the impact of the time horizon, SNM appeared to be cost-effective after 10 years (257.473 SEK/QALY).



Figure 1. Tornado diagram over lifetime horizon

In the probabilistic sensitivity analysis every parameter was randomly assigned a value based on a pre-specified distribution; SNM had 84.3% probability of being cost-effective.

Interpretation of results

The study results are consistent with those obtained in Italy, UK, the Netherlands, Spain. The thorough deterministic and probabilistic sensitivity analysis showed the robustness of the model. However, the basic limitations to modelling exercises should be acknowledged: clinical data were based on multiple sources with different level of evidence and were artificially extrapolated

over a longer time horizon, resource consumption and adverse event management were partly based on expert opinion, simplifications in the treatment patterns and assumptions on different parameters were made (e.g.resource use for SNM procedure for OAB was assumed to be identical to that for fecal incontinence).

Conclusion

In this analytic model, Sacral Neuromodulation was shown to offer good value-for-money to the Swedish healthcare system when compared with repeated injections of Botulinum toxin A in the treatment of overactive bladder patients with urgency urinary incontinence.

References

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Disclosures

Funding: Analysis is funded by Medtronic A/B Clinical Trial: No Subjects: NONE