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SACRAL NERVE STIMULATION AND BOTULINUM TOXIN A FOR THE TREATMENT OF REFRACTORY IDIOPATHIC OVERACTIVE BLADDER: AN INDEPENDENT COST-EFFECTIVENESS ANALYSIS IN THE PERSPECTIVE OF ITALIAN NATIONAL HEALTH CARE SERVICE.

Hypothesis / aims of study

Overactive Bladder (OAB) is a disabling chronic condition posing a significant burden on societies (1). If first-line treatments fail, according to international clinical guidelines the second line should include specialized treatments, such as Sacral Nerve Stimulation (SNS) and Botulinum Toxin A (BTX-A). Both therapies are included into the Italian clinical pathway for refractory idiopathic OAB-wet. Nevertheless, given the limited healthcare resources, decision-makers must weigh up costs against clinical benefits before deciding the best clinical pathway including these new techniques. A research support was found to perform an independent cost-effectiveness analysis. The objective of this study was to assess the cost-effectiveness of two alternative clinical pathways, including both SNM and BTX-A: “SNM strategy”, starting with SNM, and “BTX-A strategy”, starting with BTX-A injections.

Study design, materials and methods

A cost-effectiveness analysis was adapted to current Italian practice using an existing Markov analytic model developed for Spain and running over a 10-year time frame divided into 12-months cycles each (2). A panel of clinical experts in Italy reviewed the model structure, providing treatment transitions rates and resource consumption as well as validating treatment outcomes, adverse events rates and model assumptions based on published literature. Evaluation of resource consumption was conducted from the perspective of the Italian National Healthcare Service. In order to reflect the real costs incurred by hospitals, inpatient procedures were valued through a micro-costing approach. Outpatient resources were quantified with public tariffs and prices. Effectiveness was measured in term of Quality Adjusted Life Years (QALYs) gained, therefore the primary outcome was the incremental total cost per QALY, expressing the additional costs (or savings) implied by the adoption of “SNM strategy” instead of “BTX-A strategy” in order to gain an additional life year in perfect health. A 3% discount rate was applied to costs and outcomes. One-way and probabilistic sensitivity analyses were conducted to assess the robustness of the model.

Results

At year five and year seven (including the SNM device replacement), the “SNM strategy” requires additional costs for QALY gained equal to €4,189.55 and €5,165.06, respectively. These costs position themselves below a conservative €40.000 threshold that an Italian decision-maker may regard as cost-effective. At year ten a 0.75 QALY gain corresponds to a cost-saving of €208.50, making the “SNM strategy” economically dominant. According to this willingness-to-pay level, the probability that the “SNM strategy” is cost-effective against the “BTX-A strategy” would be 99.8% already from year five.

Interpretation of results

The present findings suggest that a clinical pathway considering an early adoption of Sacral Neuromodulation for the treatment of refractory idiopathic OAB-wet may not only be a value-for-money but also a cost-saving strategy for the Italian National Healthcare Service.

Concluding message

SNS and BTX-A represent specialized treatments for refractory OAB. Given the wide use of the two therapies in Italian clinical practice and the scarcity of health care resources, it appeared necessary to inform decision-makers on the relative costs and effects of these therapies to optimise the use of the limited healthcare budgets available. Our independent Cost-Effectiveness analysis shows that an early adoption of SNM in the clinical pathway of refractory idiopathic OAB-wet patients may represent a value-for-money option for Italian decision-makers.

References

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