Cost-effectiveness analysis of surgical management of stress urinary incontinence with a single incision mini-sling (MiniArc™) versus tension-free vaginal tape obturator in Spain

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ABSTRACT

OBJECTIVES

To analyze the cost-effectiveness of surgical management of stress urinary incontinence (SUI) in women with a single-incision mini-sling (MiniArc™) compared with tension-free vaginal tape obturator (TVT-O).

RESULTS

A cost-effectiveness analysis based on the results of intervention carried out with TVT-O (2005-2008) and MiniArc™ (2008-2011) in women with a diagnosis of SUI was performed. The clinical effectiveness was defined as an objective cure at 12 months (pad-test <1 gH2O). A perspective of the hospital payer was adopted; therefore, only direct healthcare costs (diagnostic and surgical procedures, medical devices, medications, hospital stay time and staff wages) considered. Costs of total cost was estimated by bootstrapping; later, different sensitivity analyses were conducted.

Methods

Procedures were carried out in 83 women (44 in the MiniArc™ group and 39 in the TVT-O group). A small difference (6.7%) in clinical effectiveness was observed in favor of MiniArc™; however, it was not statistically significant (MiniArc™: 93.3%; TVT-O: 96.5%). The total annual cost per patient with MiniArc™ was lower (2,025.75; CI95%: 1,914.2-2,145.2) than with TVT-O (2,821.46; CI95%: 2,663.2-2,989.7), showing a statistically significant cost saving of 762€ (CI95%: 516-987). In the base case, the probability of MiniArc™ is less costly than TVT-O was 100%. The sensitivity analysis showed that the cost determinant was the length of the hospital stay, observing that an equivalent cost was only achieved if there was no cost for any hospital stay with TVT-O.

Conclusions

The use of a single-incision mini-sling MiniArc™ is associated with a comparable clinical effectiveness but with a 762€ per patient reduction of the average annual cost. The MiniArc™ cost is lower for women than for men. Therefore, the results suggest that, over a post- intervention period of twelve months, the single-incision mini-sling MiniArc™ is a dominant alternative to tension-free vaginal tape because of a lower cost and a comparable effectiveness.

INTRODUCTION

Stress Urinary Incontinence (SUI) is the involuntary loss of urine associated with physical effort, such as coughing, laughing, etc., which causes an increase in abdominal pressure; this pathology affects a significant proportion of women, especially starting at 30 years, noticeably deteriorating one’s quality of life. When pharmacological treatment or muscle reinnervation of the pelvic floor is not enough, surgery is used. First, a Tension-Free Vaginal Tape (TVT) was used, performing an intraoperative cough test to check the integrity of the bladder. Later, a transobturator sling (Tension-Free Vaginal Tape, TVT-O) that did not require the cystoscopy, was implanted. Finally, a new generation of slings appeared, with a single incision, allowing the single-incision mini-sling (3,2), among which are TVT-Secure™ and MiniArc™, which are fixed in the obturator foramen (Fig. 1).

Methods

Cost-effectiveness analysis, from the perspective of the hospital payer, of surgical treatment of patients with SUI through the use of MiniArc™ in relation to TVT-O.

Analyzed Population

The data obtained from all medical records of surgical interventions for SUI in the hospital between 2005 and 2011 were included in the retrospective analysis. The follow-up period for data collection was 12 months.

Characteristics of the Economic Study

A cost-effectiveness analysis was conducted to compare the clinical and economic results of surgical treatments. The evaluated options were MiniArc™ and TVT-O. The time frame was 1 year, and the adopted perspective was that of the hospital center. The result of the economic analysis is expressed as the Incremental Cost-Effectiveness Ratio (ICER).

Description of the Model

A Markov model was designed to estimate the cost per patient from the moment of surgical up to a time between 12 months after surgical intervention. This model was based on the flow of processes followed in patients with SUI (Fig 1)-based on the resources used were identified. A data collection sheet was designed.

RESULTS

Information on the Use of Resources

According to the adopted perspective of the hospital, only direct healthcare costs were included. Two phases were defined: pre-operative (from the decision to perform surgical intervention), intervention (from the surgical intervention until the patient’s discharge from the hospital), and post-operative (from hospital discharge after the surgery up to 12 months later). The cost per unit of consultations, diagnostic tests, laboratory tests, medications and operating rooms time and staff were taken based on private and public Spanish costs and from publications of studies conducted in our country (Econ, 2011;14). The use of resources information included in the collection sheets was informed from the information on all patients. A bootstrap with 1,000 iterations was conducted for the average cost and its confidence interval at 95% (CI95%) for each analyzed surgical option.

Effectiveness Information

The main clinical result at 12 months was defined as the absence of escape of urine, shown by a negative Pad test result (loss of urine less than ±1 g in 3 hours).

Sensitivity Analysis

Different sensitivity analyses were conducted, evaluating the robustness of the result through variation of the value of the relevant variables.

Clinical Results

Recovery of the patient at 12 months, was slightly better with MiniArc™ (n: 41/44; 93.3%) than with TVT-O (n: 32/47; 86.9%), even though it did not present a significant difference (6.7%); CI95%: -6.6; 20.0). The studied economic model was used for cost minimization. Baseline data are in Table 2.

The use of the MiniArc™, in surgical intervention in patients with stress urinary incontinence, is associated with lower total cost per patient than TVT-O, (statistically significant reduction of 762€ per patient in the first year) but with comparable effectiveness, so it is considered a dominant option.

Even in the case of TVT-O patients were only a 2 day hospitalization, MiniArc™ is associated with cost saving.

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