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Research

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Cost Effectiveness analysis of Surgical Treatment of Stress Urinary Incontinence Using Single-Incision Mini-Slings *vs.* Tension-Free Vaginal Obturator in Spain

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ABSTRACT

Objectives: Stress Urinary Incontinence (SUI) is highly prevalent, noticeably deteriorating quality of life. The current surgical treatment is performed through minimally invasive techniques that are quite rapidly evolving. The objective of this study is to analyze the comparative efficiency, from the perspective of the health system, of surgical treatments for patients with SUI through the use of the single-incision mini-sling (SIMS), MiniArc™ (American Medical Systems, Inc), in relation to the transobturator sling, TVT-O.
Methods: Cost-effectiveness analysis based on the results of interventions performed with TVT-O (2005-2008) and MiniArc™ (2008-2011) in women with a diagnosis of SUI. The clinical result was an objective cure at 12 months (pad-test <1 g/h). The costs were the direct healthcare costs (diagnostic and surgical procedures, medical devices, medications, hospital stay times and staff). Later, different sensitivity analyses were conducted.
Results: The two groups were homogenous regarding the principal base characteristics. No statistically significant difference in effectiveness between MiniArc™ (93.2%) and TVT-O (86.5%) was observed. The total annual cost per patient was less with MiniArc™ (2,059€, 95% CI: 1,914; 2,285; 2,543$, 95% CI: 2,364; 2,822) than with TVT-O (2,821€, 95% CI: 2,661; 2,997; 3,484$, 95% CI: 3,287; 3,701), causing an estimated savings of 762€, 95% CI: 516; 987 (-941$, 95% CI: -1,219; -637). The sensitivity analysis showed that the probability of association MiniArc™ with the lowest cost was close to 100% in almost all the cases.
Conclusions: The use of MiniArc™ is associated with a 762€, 941$ per patient reduction in the average annual cost, compared to TVT-O, while maintaining a similar effectiveness.

KEYWORDS: Cost-effectiveness; Single-incision mini-sling; Transobturator.

ABBREVIATIONS: SIMS: Single-incision mini-sling; TVT-O: Tension-free Vaginal Tape Obturator; SUI: Stress Urinary Incontinence; ICIQ-SF: International Consultation on Incontinence Questionnaire-Short Form; ICER: Incremental Cost Effectiveness Ratio; 95% CI: 95% Confidence Interval; SD: Standard Deviation.

INTRODUCTION

Stress Urinary Incontinence (SUI) is the involuntary loss of urine triggered by physical activity such as coughing, laughing, etc., which coincides with an increase in abdominal pressure. It is most commonly caused when the urethra is hyper mobile because of problems with the muscles of the pelvis and hyperactivity of the detrusor. This pathology affects a significant proportion of women, especially beginning at 30 years of age, notably deteriorating

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quality of life.[1] The objective of its treatment is improving the patients' quality of life. Once pharmacological treatment or muscular rehabilitation of the pelvic floor is not enough, surgery is used.[2] In 1996, Ulmstein et al[3] used a tension-free suburethral vaginal sling (Tension-free Vaginal Tape, TVT), performing an intraoperative review cystoscopy to test bladder integrity. Later, to reduce complications associated with retropubic placement of the TVT, Delorme et al[4] approached the technique more simply as it did not require the review cytoscopy, by implanting a transobturator sling (Tension-free Vaginal Tape, TVT-O). Finally, a third generation of slings appears, with a single incision as well as reduced size, called mini-slings,[5,6] among which are TVT-Secur™ and MiniArc™, which are affixed using an obturator needle.

The Spanish National Health System presents a universal coverage, and it is funded from taxes and predominantly operates within the public sector. Provision is free of charge-with the exception of the drugs prescribed. Nowadays, knowledge of the efficiency of new technology has become indispensable, for the sake of a rational allocation of health resources. For this reason, the objective of the present study is to estimate the incremental cost effectiveness ratio of surgical treatment of patients with SUI using the MiniArc™ compared to TVT-O, from the perspective of the health system.

MATERIAL AND METHODS

Data obtained from medical records of patients who had undergone interventions consecutively in one hospital for SUI between 2005 and 2011 were analyzed retrospectively. The follow-up period for data collection was 12 months. All patients signed the corresponding informed consent form; additionally, prior approval from the hospital's corresponding Research Ethics Committee was obtained. The basal severity was measured with Sandvick's test[7] (consists of two questions, regarding frequency and amount of leakage), and the International Consultation on Incontinence Questionnaire-Short Form, ICIQ-SF[8] (that provides a measure to assess the impact of symptoms of incontinence on quality of life and outcome treatment by using 4 items, being severe incontinence if there is an score bigger than 12). An economic evaluation of the surgical options, MiniArc™ and TVT-O, was performed to estimate the incremental costs and benefits of surgical treatments for the patients who presented with stress urinary incontinence. The analysis was carried out in a 1 year time horizon and from the perspective of the Spanish National Health System. The type of analysis was cost effectiveness; a cost minimization analysis would be carried out if there was not a significant statistical difference of clinical result. The result of the analysis is expressed as the Incremental Cost Effectiveness Ratio (ICER), calculated using:

$$ICER \frac{= \left[Cost_{MiniArc} - Cost_{TVT-O} \right]}{= \left[Effectiveness_{MiniArc} - Effectiveness_{TVT-O} \right]}$$

In the case of performing a cost minimization analysis, the final result corresponds to the difference between the costs of each option.

A mathematical model was designed to estimate the overall cost per patient during 12 months of follow-up. The model was based on the flow of follow-up processes in care of patients in the hospital (Figure 1)

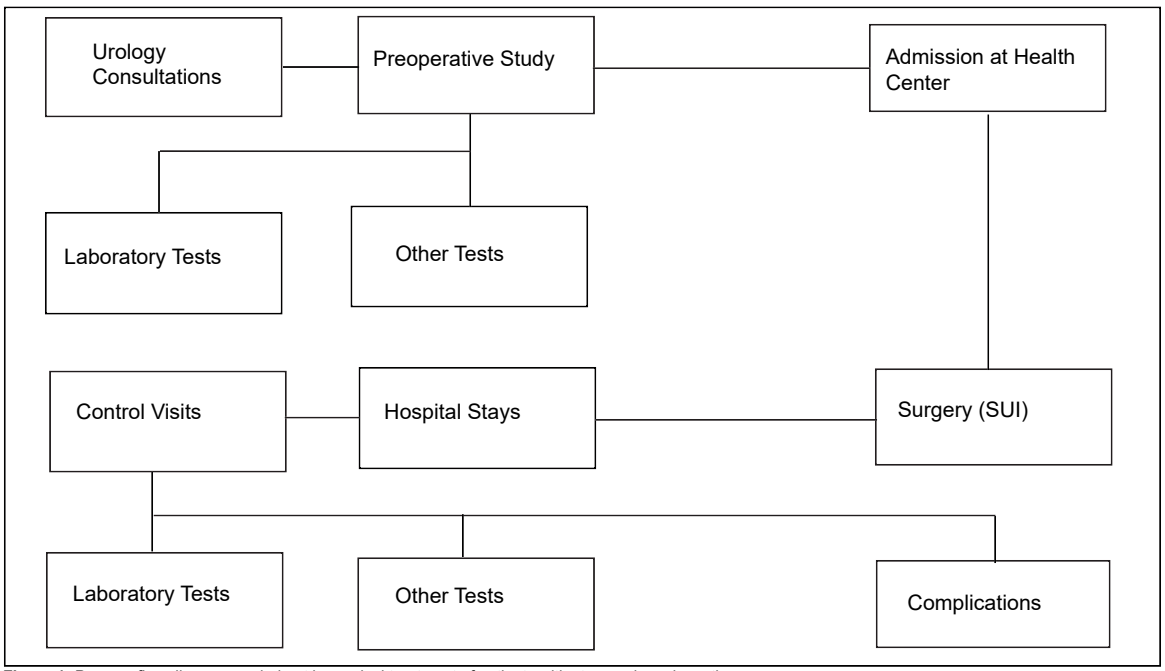

Figure 1: Process flow diagram carried out in surgical treatment of patients with stress urinary incontinence

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Given the health system's perspective, only direct healthcare costs were included.[9] The cost analysis was carried out using the *bottom-up* method. Briefly, this method identifies, quantifies and evaluates the individual costs of each phase of the process:

a) Preoperative, which includes everything from the visit when the decision to surgical intervention is made (consultations for clinical history and overall evaluation, diagnostic and laboratory tests and urodynamic evaluation);

b) Interventional, including everything from the moment of the intervention until patient's discharge from the hospital (time of the surgical intervention and the health professionals and hospital stay);

c) Post-operative, where the events that have occurred since hospital discharge after surgery up to 12 months follow-up (consultations, diagnostic and laboratory tests, and management of complications) are analyzed.

The unit prices of consultations, diagnostic testing and laboratory tests are taken from the hospital's analytical accounting; the prices of medications used were extracted from the BOT Plus database from the General Council of Spanish Pharmacists;[10] operating room times and the times of the health professionals were taken from the hospital registries of each patient who underwent surgery. All costs are expressed in 2013 euros (and US dollars), updating them to that year if necessary, according to the general CPI of the National Statistics Institute of Spain.

The total cost (T_c) is calculated using the corresponding cost of each phase (i):

$$T_c = \sum_{1}^{n} q_{(i)} * c_{(i)}$$

q being the frequency of use of each resource and c the unit price.

Once the total cost was estimated, the bootstrap method[11,12] was used to analyze the uncertainty associated with the obtained result of each surgical option. Briefly, bootstrap is a nonparametric method, which, through a resampling process with replacement, generates a large quantity of samples with the same size as the original, allowing one to estimate a probabilistic distribution to calculate the statistic of interest, in our case, the dispersion of the average cost using its confidence interval at 95% (95% CI).

Finally, the average cost of the difference between the use of TVT-O and MiniArc™ was calculated, then proceeding to estimate the probability that MiniArc™ was less costly than TVT-O, analyzing for each iteration obtained in the bootstrap:

$$[Prob\{(Cost_{MiniArc} - Cost_{TVT-O}) < 0\}$$

Clinical effectiveness was expressed using the objective cure rate at 12 months follow-up, defined as the absence of urine loss, manifested with a negative pad test result (urine loss of <1g in 1 hour).[13] Additionally, the secondary complications of each surgical option were analyzed: intraoperative complications such as bladder perforation, early complications (in the first month after surgery) such as hematoma, groin pain or urethral obstruction, and late complications (after the first month) such as vaginal erosion, difficulty urinating, new urgency or urinary tract infection (UTI) (repeated).

When comparing the two groups, continuous variables were analyzed using the Student's t test, and categorical ones using Chi-square test; difference between proportions was estimated using Wald method. The statistical package used was SPSS 17.

Different sensitivity analyses were performed, evaluating the robustness of the result through variation of the value of the most relevant variables. As such, the hospital stay of patients who received the TVT-O was reduced to bring it in line with the stay of MiniArc™ patients (0 days), the cost of the hospital stay was varied within a wide margin (±25%), attending to the variability existing between different centers; additionally, taking the variability of the price of the devices into account, the corresponding price of MiniArc™ varied some ±25%.

RESULTS

Patient Characteristics

The information corresponding to 81 patients was collected, 37 of whom had undergone surgery through the available technique at the time of the TVT-O (2005-2008) and the remaining 44 of whom with MiniArc™, beginning when this device was available (2008-2011). The patients' clinical parameters that were most relevant to the economic study are included in Table 1.

	MiniArc™ (SD)	TVT-O (SD)	*p*
Number of patients	44	37	
Age (yr)	58.9 (11.0)	58.3 (11.3)	0.816
Body Mass Index (kg/m²)	27.9 (4.7)	31.1 (5.7)	0.009
Parity (n)	2.5 (1.2)	2.3 (1.3)	0.547
Sandvik's test	4.32 (1.22)	4.38 (1.32)	0.833
ICIQ-SF Questionnaire	14.50 (1.77)	14.95 (1.39)	0.208

Table 1: Baseline characteristics of patients who underwent the surgical interventions

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Clinical Results

The principal clinical result, objective cure of the patient at 12 months, was slightly greater with MiniArc™ (41/44; 93.2%; SD: 3.8) than with TVT-O (32/37; 86.5%; SD: 5.6), although a significant statistical difference was not present (6.7%, 95% CI: -6.6; 20.0; χ^2: 0.40; p: 0.527). For that reason, the adopted economic analysis was cost minimization, exclusively evaluating the costs associated with each surgical option, since there was a statistical equivalence of clinical results.

No intraoperative complications were observed in either of the analyzed surgical options. Only 3 cases of early complications were observed (1 with MiniArc™ and 2 with TVT-O) without showing a statistically significant difference between the two techniques p: 0.553). With regard to late complications, statistically different differences in vaginal erosion (1 case with TVT-O) difficulty urinating (2 with MiniArc™ and 3 with TVT-O; p: 0.506), new urgency (6 with MiniArc™ and 10 with TVT-O; p: 0.131) were not observed either. The only difference was with repeated UTIs (1 with MiniArc™ and 13 with TVT-O; $p<0.05$)

Costs

The relevant resources used in patients with one or the other therapeutic option, as well as the average number of units used are expressed in Table 2.

	MiniArc ™	TVT-O	*p*
Preoperative phase			
Gynecological visit	1.00	1.14	0.129
Ultrasound scan	1.09	1.00	0.061
Urodynamic test	1.05	0.97	0.095
Urine sediment	0.98	0.58	0.013(*)
Rehabilitation	4.91	2.54	0.097
Intervention phase			
Theater (min)	39.66	54.24	<0.001(*)
Gynecologist (min)	24.68	42.65	0.001(*)
Anaesthetist (min)	57.57	50.68	<0.001(*)
Nurse (min)	46.61	54.38	<0.001(*)
Hospital stay (days)	0	3.14	<0.001(*)
Post-operative phase			
Gynecologist (visit)	4.09	3.84	0.046(*)
Ultrasound scan	2.18	2.41	0.345
Urodinamic test	1.02	1.08	0.535
Urine sediment	1.98	0.00	<0.001(*)
Rehabilitation	0	0.65	<0.001(*)

Table 2: Healthcare resources used for patient management with each therapeutic option. (*): statistically significant difference

The main difference is found in the intervention phase, showing a significant reduction in resources used during that phase with MiniArc™.

To estimate the overall cost of patient care, the unit prices described in Table 3 were used, which multiplying the frequency of use of each to estimate the cost of each phase.

Health Resource	Unit Price (€; ($))
Gynecologist visit	35.00€ ; (43.23$)
Ultrasound scan	43.00€ ; (53.11$)
Urodynamic test	201.72€ ; (249.14$)
Urine sediment	7.00€ ; (8.65$)
Rehabilitation Session	14.07€ ; (17.38$)
Theater (min)	2.50€ ; (3.09$)
Gynecologist (min)	0.81€ ; (1.00$)
Anaesthetist (min)	0.90€ ; (1.11$)
Nurse (min)	0.46€ ; (0.57$)
Nurse's Assistant (min)	0.29€ ; (0.36$)
MiniArc™	680.40€ ; (840.34$)
TVT-O	646.76€ ; (798.79$)
AMS Room	76.17€ ; (94.07$)
Hospital stay (days)	288.90€ ; (356.81$)

TVT-O: Tension free Vaginal Tape Obturator; MAS: Major ambulatory surgery

Table 3: Unit prices of the principal resources used (€; ($), 2013).

The result of the analysis after performing the bootstrap indicated that the average cost associated with MiniArc™ was lower (2,059€; 2,543$), showing a statistically significant difference with respect to TVT-O (2,821€; 3,485$), with an average savings of 762 euros (941$) (t: -5.6636; p: 1.99) per patient in the first year of follow-up (Table 4). Additionally, a 100% probability of producing this cost savings was estimated.

Therapeutic Alternative	Cost (€;$) (95% CI)	Difference (95% CI)
MiniArc™	2,059€ (1,914; 2,285); 2,543$ (2,364; 2,822	-762€ (-987; -516); -941$ (-1,219; -637)
TVT-O	2,821€ (2,661; 2,997); 3,484$ (3,287; 3,701)	

Table 4: Results of costs obtained with MiniArc™ and TVT-O in the base case

The results of the costs, disaggregated according to the previously defined phases, show that the intervention phase constitutes the cost determinant in the group of patients who had MiniArc™ placement (Table 5).

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Phase	Alternative	Cost (95% CI)	Difference (95% CI)
Preoperative	MiniArc™	369 (339; 399)	51 (11; 90)
	TVT-O	317 (293; 344)	
Intervention	MiniArc™	950 (941; 961)	-984 (-988; -817)
	TVT-O	1,832 (1,770; 1,934)	
Post-Operative	MiniArc™	740 (591; 915)	64 (-135; 286)
	TVT-O	676 (583; 820)	

Table 5: Average cost disaggregated by time components of the process

That is essentially due to the fact that the surgery is performed as an outpatient procedure, which is less normal in the case of TVT-O (mean stay: 3.14 days, range: 2-9) because of pain.

Sensitivity Analysis

In the univariate sensitivity analysis, a reduction of costs associated with the use of MiniArc™ was maintained when the hospital stay was reduced by 25% (555€, 95% CI: 252; 779; 685$, 95% CI: 311; 962) or was increased by the same proportion (966€, 95% CI: 692; 1,242; 1,193$, 95% CI: 855; 1,534). Additionally, given that the length of the hospital stay forms a relevant variable in the cost, a sensitivity analysis was carried out, modifying the time in an interval of 2 to 0 days, estimating that the probability of cost savings with MiniArc™ was 100%, 90% and 9% for an average stay of patients treated with TVT-O of 2, 1, and 0 days, respectively (Figure 2). On the other hand, if the cost of MiniArc™ were reduced by 25% the reduction of the overall cost would increase to 919€ (95% CI: 651; 1,163),1,134$ (95% CI: 804; 1,436) ; in the case of a 25% increase in the price of the device, there would still be a cost savings, estimated at 575€ (95% CI:313; 832), 710$ (95% CI%: 387; 1,028). (Figure 2)

DISCUSSION

Based on the results found, surgical treatment with-MiniArc™ for patients diagnosed with stress urinary incontinence is associated with a comparable clinical effectiveness to that obtained with Tension-free Vaginal Tape Obturator (TVT-O),without any significant difference in the occurrence of complications observed, except for repeated UTIs, which were fewer in patients who had undergone surgery with MiniArc™. However, the use of MiniArc™ produces a significant reduction of 762€ (95% CI: 516; 987), 941$ (95% CI: 637; 1,219), in the total cost.

The equivalent effectiveness between the two surgical options has already been shown previously. An exploratory, randomized phase 2 study[14] analyzed the objective response, measured using the pad test at 12 months, and shows a slight difference in favor of MiniArc™. Later, a randomized controlled trial,[15] which has evaluated the objective cure rate of MiniArc™ compared to the transobturator standard midurethral sling,

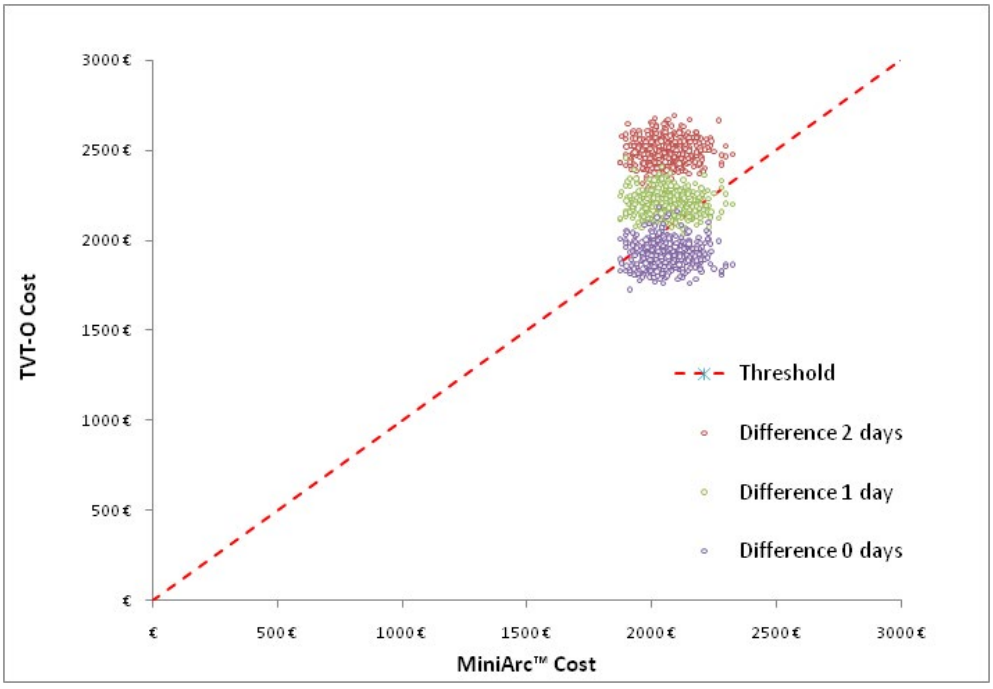

Figure 2: Graphic representation of the bootstrap (after 1000 iterations) to estimate the probability that the treatment with MiniArc™ would be less costly with respect to the different stays with TVT-O. The points above the threshold indicate a lower MiniArc™ cost; those below indicate a greater cost.

Monarc™, concludes that MiniArc™ presents an objective cure rate that is not inferior to the other option (89% v. 91%, respectively; p: 0.65) nor subjective cure (83% v. 86%, respectively; p: 0.46) while post-operative pain is greater ($p<0.01$). Additionally, systematic reviews have been performed that confirm this fact: Mostafa et al[16] have compared the effectiveness of the single-incision minislings *vs*. TVT-O and similar slings, concluding that there is no significant difference in the objective cure rate (RR: 0.98; 95% CI: 0.94; 1.01 at 18.6 months) although MiniArc™ shows a shorter recovery time to return to daily activities (5.08 v. 7.20 days). The demonstration of equivalence in the effectiveness results is essential for the choice of the type of economic analysis.[17] This fact led to the decision to perform a cost minimization analysis, for which the variable in the result is the difference between the total average cost of each evaluated option, having estimated a reduction of costs associated with the use of MiniArc™.

The cost determinants, which explain the result, consist of the shorter intervention time and the performance of the surgery with MiniArc™ as an outpatient procedure. The hospital stay is a relevant factor in the cost difference, which is why that variable was analyzed in depth. On one hand, the duration obtained in our study is in accordance with other practices in our country, as is shown in the recent study from Castroviejo-Royo et al,[18] who indicated a stay of 3.83±2.46 days in patients treated using TVT-TOT. Girvent et al[19] analyzed interventions with TVT-O, obtaining an average stay of 2.7 days, equal to what was reported by others, such as Úbeda et al[20] or Álvarez Cañadas et al.[21] A slightly shorter stay was described by Navazo et al[22] (1.5 days, range: 1-5) or Zullo et al[23] (1, 1±0.3 days). However, the performance of the technique under anesthesia-sedation as an outpatient procedure has been described,[24] for which there was no stay. Thus a great variability can be observed in our country regarding hospitalization time after surgical intervention. For these reasons, the sensitivity of the obtained result to the length of the hospital stay was analyzed, estimating the average cost associated with TVT-O according to different lengths of hospital stays (between 3 and 0 days), showing a higher probability of a lower cost with MiniArc™ in almost all analyzed cases.

We have not found an economic study that compares the cost of MiniArc™ with that of TVT-O. Nevertheless, Montesino et al[25] have recently evaluated the efficiency of surgical treatment – with mini-slings or TVT-O, compared to no surgery in a sample of women with stress urinary incontinence, mixed urinary incontinence, and incontinence associated with prolapse. However, as comparison of the evaluated procedures is not the objective of their study, they did not disaggregate the result by type of procedure or incontinence. They concluded, however, that surgery with minis lings is an efficient option for the National Health System. In another recent study, Boyers et al[26] had estimated the relative efficiency of TVT-O and another single-incision minis ling, Ajust™, showing a higher cost of TVT-O in comparison; the said increase in cost is still greater when the investigators carried out the study from a social perspective, based on a faster recovery with the single-incision minisling, a fact that has also been indicated for MiniArc™ in a recent systemic review.[16]

The study carried out presents some limitations. The sample size is not enough to give the study a large statistical power. For that reason, although the average value of effectiveness was higher with MiniArc™, it could not be demonstrated that there was a significant difference. Nevertheless, a nonparametric bootstrap has been applied to the costs, allowing us to more precisely estimate the measure of interindividual dispersion. A second limitation is the retrospective nature of the study, since the TVT-O group corresponds to a historical control, which could reduce homogeneity between the patients according to some variation in clinical practice. However, this fact was minimized, since the same group of professionals treated all the patients in both groups, which minimizes variability in clinical practice; residents were not involved. Finally, randomized assignment of the surgical options was not done; it was made sequentially in two time periods, before and after the appearance of MiniArc™, which could have an influence in that the samples were not perfectly homologous; however, the samples faithfully reflect common practice, which increases its external validity.

For future investigations, it is suggested that prospective studies are designed with a large enough sample size and that the studied options are randomly assigned to patients. Also, the follow-up times should be longer to analyze the relative efficiency of the two surgical options in the medium and long term.

In conclusion, the results obtained indicate that the use of MiniArc™ in surgical intervention for patients with stress urinary incontinence shows a comparable effectiveness as well as a 762€, 941$ reduction of the annual cost per patient, in comparison with TVT-O. The results suggest that MiniArc™ isa dominant alternative in comparison with TVT-O due to its lower cost and comparable effectiveness.

FINANCIAL DISCLAIMER / CONFLICT OF INTEREST

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OBSERVATIONS

Preliminary results of this study are presented at the ISPOR 17th Annual Congress. 8-12 November, 2014. Amsterdam, The Netherlands.

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