

Documentos de Trabajo

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USING SLINGS**

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ABSTRACT

Objective. To determine the cost-utility and cost-effectiveness of the surgical treatment of female urinary incontinence using suburethral slings compared with therapeutic abstention.

Study Design. An economic analysis was performed on 69 women receiving surgical treatment for urinary incontinence using suburethral slings. To calculate the procedure’s cost-effectiveness, an incremental analysis up to 1 year was performed using the incremental cost-effectiveness ratio (ICER). The costs were calculated using a cost-by-process model. Answers to the health-related quality of life questionnaires EQ-5D (generic) and International Consultation Incontinence Questionnaire Short-form (specific) were collected before the operation and as well as 1 month and 1 year post-operation to calculate the utility, using quality-adjusted life years (QALY), and the effectiveness, respectively. A sensitivity analysis was performed by calculating the Incremental Cost-Effectiveness Ratio (ICER) at 5 years post-operation. To complete the economic evaluation, we derived confidence ellipses and acceptability curves. The analysis was conducted for the entire sample and also for each type of urinary incontinence.

Results. In total, 45 women presented with stress incontinence, 15 with mixed incontinence and 9 with incontinence associated with prolapse. The average cost per patient at 1 year post-

operation was 1,220 €. The QALY achieved at 1 year was 0.046. The results reveal an ICER at 1 year of 26,288 €/QALY, which is below the cost-effectiveness threshold considered acceptable, and this value was lower for stress incontinence (21,191 €/QALY). To achieve greater temporal perspective, we examined the ICER at 5 years, which was 10,141 €/QALY, demonstrating that the programme is clearly efficient. The cost-effectiveness was 106.5 €/International Consultation Incontinence Questionnaire Short-form unit.

Conclusion. Surgery for female urinary incontinence using slings is cost-effective compared with abstention in our public health environment.

Key Words. Female urinary incontinence. Surgical treatment. Cost-utility analysis. Cost-effectiveness analysis. QALY.

INTRODUCTION

The introduction at the end of the last century of the surgical treatment of female urinary incontinence (UI) by TVT-type suburethral slings, which achieves excellent results has stimulated cost-effectiveness studies to compare this minimally invasive technique with traditional procedures, including slings, colposuspension (1-7), or pharmacological treatments (8).

In this study, a cost-effectiveness analysis (CEA) and a cost-utility analysis (CUA) were conducted for the surgical treatment of female UI using slings compared with abstention.

MATERIALS AND METHODS

1.-INCREMENTAL STUDY

We performed an economic evaluation of surgery (compared with no surgery) by estimating the incremental costs of the surgical treatment of UI and its incremental effectiveness. The results are presented in terms of the incremental cost-effectiveness ratio (ICER) from the perspective of the service provider and in the frame of a public health care system in Navarra (Spain). Cost-effectiveness acceptability curves (CEAC) and confidence ellipses were also calculated.

Cost measurement

The costs were evaluated using the cost-by-process methodology previously described (9). The costs included medical consultations before surgery, urodynamic and pre-operative studies, hospital stays in Major Outpatient Surgery (MOS) or in a hospital ward, surgical costs (healthcare personnel, material including slings), and medical consultations and drugs after surgery, including re-interventions if required for the first year, which were individualised per patient. The costs outside of the programme were considered to be 0 €. Because the study perspective is that of the Health System provider, there was no additional cost if the patient did not undergo an operation.

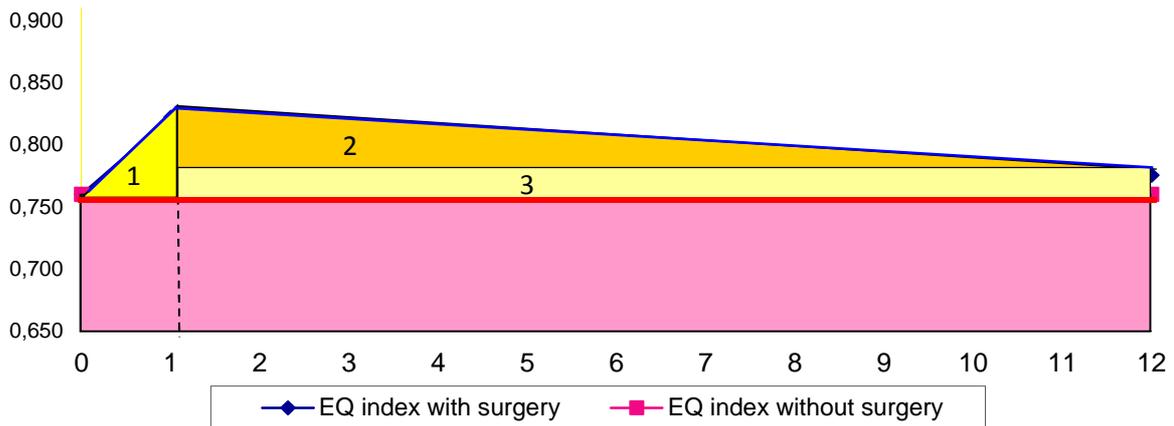
Utility and effectiveness measurement

For the cost-utility analysis (CUA), we used quality-adjusted life years (QALY) as a utility measure, with one QALY equal to one year in full health. This measure was obtained by a health-related quality of life generic questionnaire (HRQL), EQ-5D (10), which provides a value or index (EQ-index) between 0 and 1 and uses the time trade-off (TTO) method (11). For

the incremental calculation of QALY one year after the surgery, we used the formula for the area under the curve (12, 13), assuming that patients who were not treated maintained the same EQ-index during the period considered (Figure 1).

Figure 1

QALYs gained with the intervention. 1= Area under the curve at 1 month after intervention; 1+2+3= Area under the curve at 1 year after intervention using monthly means



For the CEA, we used changes in the ICIQ-SF (International Consultation Incontinence Questionnaire Short-form) specific questionnaire as the effectiveness measure. Its values range from 0 (absence of UI) to 21 (the worst possible status of UI).

The patients were invited to complete both the EQ-5D and ICIQ-SF before the surgery and at 1 month and at 1 year after the surgery.

Calculation of ICER

The formula for the incremental calculation (ICER) is as follows:

$$\text{ICER} = \frac{\text{Cost of surgery} - \text{Cost without surgery}^*}{\text{Effectiveness after surgery} - \text{Effectiveness before surgery}}$$

(*): Null initial costs estimated. Cost in €. Effectiveness: Effectiveness in EQ-index or ICIQ-SF.

The reference value of 30,000 €/QALY was taken as the threshold of cost-effectiveness for efficiency (14).

This method was applied to a global model including all patients and for 1 year of evolution using the average of the costs and effectiveness with multiple imputations (that is, in the case of missing data, the group average was applied). Moreover, models were developed for each type of incontinence: stress urinary incontinence (SUI), mixed urinary incontinence (MUI) and incontinence associated with pelvic organ prolapse (POP).

Economic assessment tools

An analysis of the ratio of the estimated cost-effectiveness was performed by developing confidence ellipses at 50%, 75%, and 95% and using cost-effectiveness acceptability curves (CEAC) as a graphical representation to quantify the uncertainty (15). For this purpose, we employed only the data of those patients with complete information (analysis by complete cases) at 1 year after the surgery.

The models employed were the following: global (Model 1), including models with the value of the EQ-index (Model 1.1) and with ICIQ-SF (Model 1.2); and by the type of UI (Model 2), including models with the value of the EQ-index and ICIQ-SF (Models 2.1 and 2.2, respectively). The functions are as follows:

Model 1:

$$\text{Costs}_i = \alpha_0 + T_i \alpha_1 + u_{1i};$$

$$\text{Effectiveness}_i = \beta_0 + T_i \beta_1 + u_{2i};$$

with $T = 0$, before surgery, and $T = 1$, one year after surgery;

Model 2:

$$\text{Costs}_i = \text{SUI}_i \alpha_{01} + \text{MUI}_i \alpha_{02} + \text{POP}_i \alpha_{03} + T_i \text{SUI}_i \alpha_{11} + T_i \text{MUI}_i \alpha_{12} + T_i \text{POP}_i \alpha_{13} + u_{1i};$$

$$\text{Effectiveness}_i = \text{SUI}_i \beta_{01} + \text{MUI}_i \beta_{02} + \text{POP}_i \beta_{03} + T_i \text{SUI}_i \beta_{11} + T_i \text{MUI}_i \beta_{12} + T_i \text{POP}_i \beta_{13} + u_{2i}$$

where:

α_{0a} = cost before surgery;

α_{1a} = cost after surgery

β_{0a} = effectiveness before surgery;

β_{1a} = effectiveness after surgery,

and estimated with the econometric technique known as SURE (seemingly unrelated regression estimator).

2.-SENSITIVITY ANALYSIS

Because most of the costs were concentrated around the surgical intervention and the data for the HRQL and effectiveness remained equivalent after the first 2 years (16, 17), we extrapolated the calculation of the ICER 5 years with the following considerations based upon our data (18-20) and those of the medical literature(16, 21-24):

- 1.- Outcomes: EQ-index (or ICIQ-SF as applicable) remains equal after the first year; and
- 2.- Costs: patients undergo a 1-year consultation with 6% “de novo” urinary urgency requiring pharmacological treatment with antimuscarinic agents and 6% new interventions (re-interventions).

The future costs and effectiveness were discounted at an annual rate of 3%(25, 26).

3.-Data

We included 69 patients in this study: 45 with SUI, 15 with MUI, and 9 with incontinence associated with POP. All of the patients underwent a complete economic cost analysis.

With respect to the response rate of the HRQL of the EQ-5D questionnaires, we had 67 preoperative, 61 early post-operative and 67 late postoperative registers at 1 year. We removed two patients with MUI because they developed an associated acute illness (lumbosciatica and exacerbation of Parkinson´s disease, respectively) that significantly affected their quality of life, and they were treated as outliers.

With respect to the ICIQ-SF, all patients answered the pre-operative survey, 62 answered the post-operative survey, and 67 answered the 1-year survey.

We implanted 47 mini-slings (39 TVT-Secur and 8 Mini-Arc), 14 transobturator (11 TOT and 3 TOA), 3 Prolift, 4 Prolift with associated TOT and 1 Apogee with TOT. Additionally, at the re-interventions, 1 Mini-Arc and 1 Remeex were implanted.

The following procedures were used during the first year: 69 first visits and 250 successive visits, 22 urodynamic evaluations, 57 pre-operative studies, MOS hospital stay in 69 pre-surgical and 66 post-surgical cases, 71 anti-incontinence surgeries, 43 local anaesthesia treatments, 10 local anaesthesia plus sedation treatments, 22 spinal anaesthesia treatments and 4 hospital inpatient admissions.

RESULTS

1.-COSTS

The full cost of the surgical treatment of the 69 patients was 84,145€ at the end of the year, with an average of 1,220 €/patient: 1,067 in SUI, 1,628 in MUI and 1,664 for POP.

2.-COST-UTILITY AND COST-EFFECTIVENESS ANALYSIS

The results of the incremental cost-utility analysis are shown in Tables 1 and 2. The ICER at 1 year was 26,288 €/QALY, which was lower than the acceptable cost-effectiveness threshold. Thus, the programme can be considered efficient.

Table 1

Results of the incremental cost-effectiveness ratio (ICER) of the surgical treatment for female urinary incontinence using sling placement, with the EQ-5D-index. (N=67)

	Cost (€)	QALY before surgery	QALY after surgery	Δ QALY (EQ-5D)	ICER (€/QALY)
1st year	1,222.42	0.7585	0.8050	0.0465	26,287.99
5th year	1,501.44	3.5781	3.7261	0.1480	10,140.93

Table 2 presents the incremental results with the EQ-index and by the type of incontinence at 1 and 5 years. The SUI exhibited a better ICER at 1 year, with an incremental cost-effectiveness ratio that was lower than the threshold reference of 30,000 €/QALY.

Table 2

ICER of the surgical treatment for female urinary incontinence using sling placement by the type of UI.

Type of UI (n)	Year	Cost (€)	QALY before surgery	QALY after surgery	Δ QALY (EQ-5D)	ICER (€/QALY)
SUI (45)	1 st	1,067.70	0.7570	0.8073	0.0504	21,191.50
	5 th	1,339.93	3.5706	3.6889	0.1192	11,242.08
MUI (13)	1 st	1,628.18	0.7186	0.7683	0.0498	32,714.02
	5 th	1,900.41	3.3896	3.7020	0.3124	6,083.79
POP (9)	1 st	1,664.60	0.8231	0.8384	0.0153	108,877.63
	5 th	1,916.26	3.8826	3.9347	0.0520	36,817.79

SUI: stress urinary incontinence; MUI: mixed urinary incontinence; POP: urinary incontinence associated with pelvic organ prolapse

The results of the ICER after the cost-effectiveness analysis with the ICIQ-SF are presented in Tables 3 and 4. The ICER with the ICIQ-SF was 106.5 €/unit.

Table 3

The **ICER** of the surgical treatment for female urinary incontinence using sling placement of slings, with the ICIQ-SF. (N=69).

	Cost (€)	Auc* before surgery	Auc* after surgery	Δ Auc* ICIQ-SF	ICER (€/specific unit)
1 st year	1,220.22	15.101	3.646	11.455	106.52
5 th year	1,492.46	80.175	26.141	54.034	27.62

(*)Auc: area under the curve.

Table 4

The **ICER** of the surgical treatment for female urinary incontinence using sling placement of slings by the type of UI, with ICIQ-SF.

SUI: stress urinary incontinence; MUI: mixed urinary incontinence; POP: urinary incontinence associated with pelvic organ prolapse. (*)Auc: area under the curve.

Type of UI (n)	Cost €	Auc* sin cirugía	Auc* poscirugía	Δ Area ICIQ-SF	ICER (€/specific unit)
SUI (45)	1,067.70	15.444	2.752	12.692	84.11
MUI (15)	1,411.12	14.733	4.664	10.069	140.13
POP (9)	1,664.66	14	6.57	7.430	224.03

3.-SENSITIVITY ANALYSIS

With a longer temporary perspective, the ICER at 5 years was reduced to 10,141 €/QALY (Table 1), demonstrating that the programme was clearly efficient. Similarly, at 5 years, the ICER for each type of UI was reduced (Table 2), with the ICER of POP being the only one above the efficiency threshold.

The CEA by means of the ICIQ-SF is presented in Table 3 for the global model and in Table 4 for each type of UI.

4.-RESULTS WITH THE ECONOMIC ASSESSMENT TOOLS

To help develop a more intuitive interpretation of the results, the coefficients of the ICIQ-SF were obtained by subtracting the real value from the maximum of 21 and dividing by 100.

Tables 5 and 6 present the global results (Model 1) and the results by the type of UI (Model 2), with respect to the costs and effectiveness.

Table 5

Model 1, the basal and incremental costs and effectiveness by the type of questionnaire.

	EQ-5D (n=118)		ICIQ-SF/100 (n=122)	
	Coefficient (s.d.)	P	Coefficient (s.d.)	P

Equation 1

Basal cost	0.000 (27.989)	1.000	0.000 (43.589)	1.000
Incremental cost	1166.19 (39.582)	0.000	1230.51 (61.644)	0.000

Equation 2

Basal Effectiveness	0.757 (0.021)	0.000	0.059 (0.004)	0.000
Incremental Effectiveness	0.038 (0.030)	0.211	0.115 (0.006)	0.000

Table 6

Model 2, the basal and incremental costs and effectiveness by the type of questionnaire and type of UI.

	EQ-5D (n=118)		ICIQ-SF/100 (n=122)	
	Coefficient (s.d.)	p	Coefficient (s.d.)	P

Equation 1

Basal cost	*SUI	0.000 (25.649)	1.000	0.000 (47.225)	1.000
Basal cost	*MUI	0.000 (46.24)	1.000	0,000 (87.292)	1.000
Basal cost	*POP	0.000 (56.632)	1.000	0,000 (106.911)	1.000
Incremental cost	*SUI	1040.90 (36.273)	0.000	1078.49 (66.787)	0.000
Incremental cost	*MUI	1266.69 (65.393)	0.000	1486.10 (123.45)	0.000
Incremental cost	*POP	1626.22 (80.09)	0.000	1626.22 (151.195)	0.000

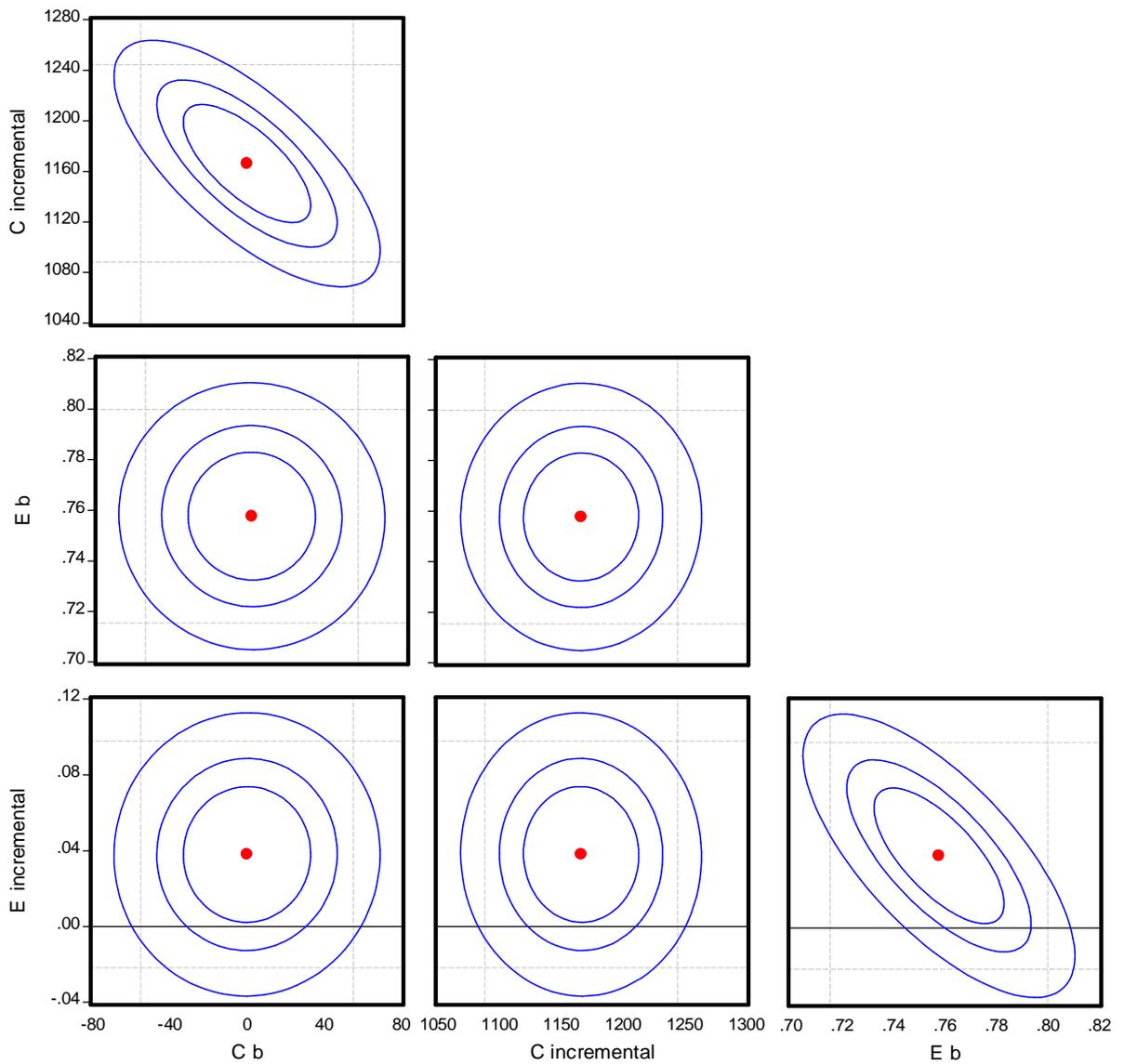
Equation 2

Basal effectiveness	*SUI	0.752 (0.025)	0.000	0.054 (0.005)	0.000
Basal effectiveness	*MUI	0.731 (0.046)	0.000	0.067 (0.010)	0.000
Basal effectiveness	*POP	0.82 (0.057)	0.000	0.072 (0.012)	0.000
Incremental effectiveness	*SUI	0.049 (0.036)	0.178	0.127 (0.007)	0.000
Incremental effectiveness	*MUI	0.011 (0.066)	0.864	0.098 (0.014)	0.000
Incremental effectiveness	*POP	0.021 (0.081)	0.792	0.079 (0.017)	0.000

(*) SUI: stress urinary incontinence; MUI: mixed urinary incontinence; POP: urinary incontinence associated with pelvic organ pr

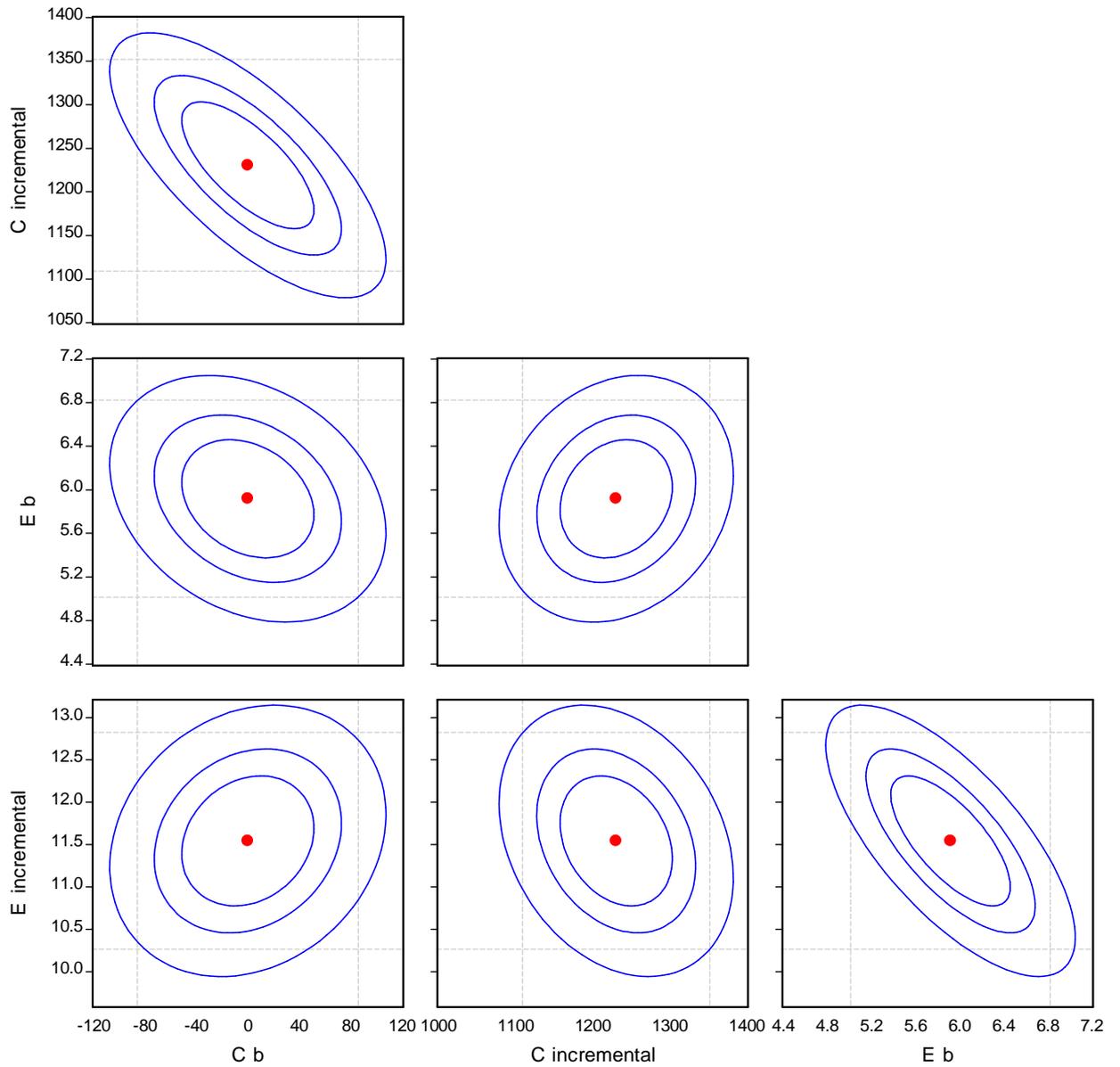
The confidence ellipses of Model 1.1 at 50%, 75% and 95% relative to the effectiveness with the EQ-index (Figure 2) indicate that the increment in costs does not indicate a proportional increase in the effectiveness, and the baseline effectiveness does not determine the incremental costs.

Figure 2
 (Model 1.1) EQ-index confidence ellipses
 (E=effectiveness; C= cost; b= basal)



For Model 1.2, the confidence ellipses (Figure 3) demonstrate that the increase in cost has a tendency towards a lower increment in effectiveness and a high basal effectiveness implies higher cost increments.

Figure 3
 (Model 1.2) ICIQ-SF confidence ellipses
 (E=effectiveness; C= cost; b= basal)



The CEAC for the EQ-index establishes that for a 50% probability of obtaining an Incremental Net Benefit (INB), the increment in the willingness to pay is 30,674 €/QALY (Figure 4) with 20,961 €/QALY for SUI, 112,216 €/QALY for MUI and 76,116 €/QALY for that associated with POP (Figure 5).

Figure 4

Cost-effectiveness acceptability curve with EQ-5D

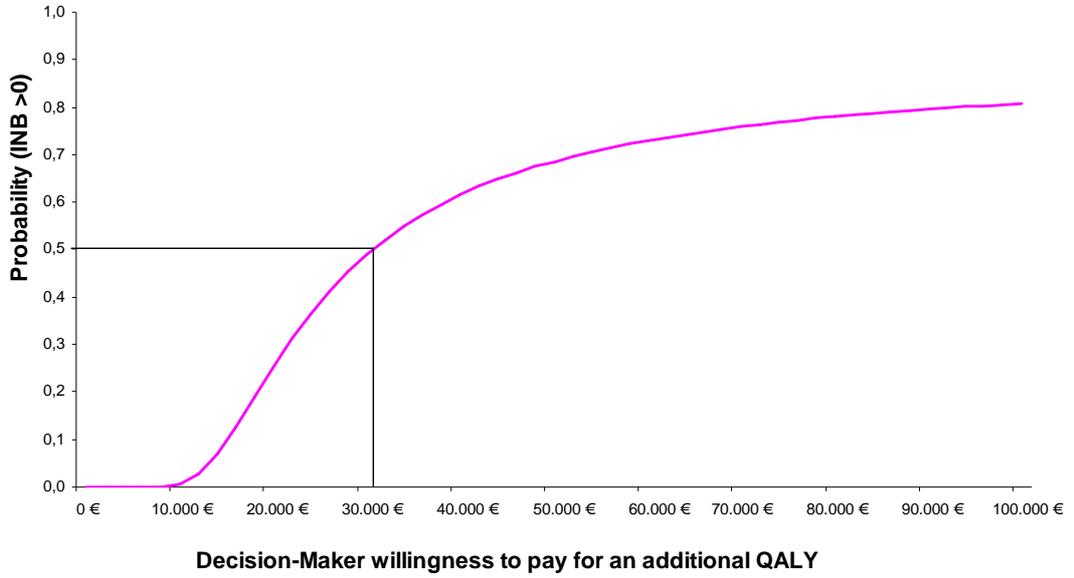
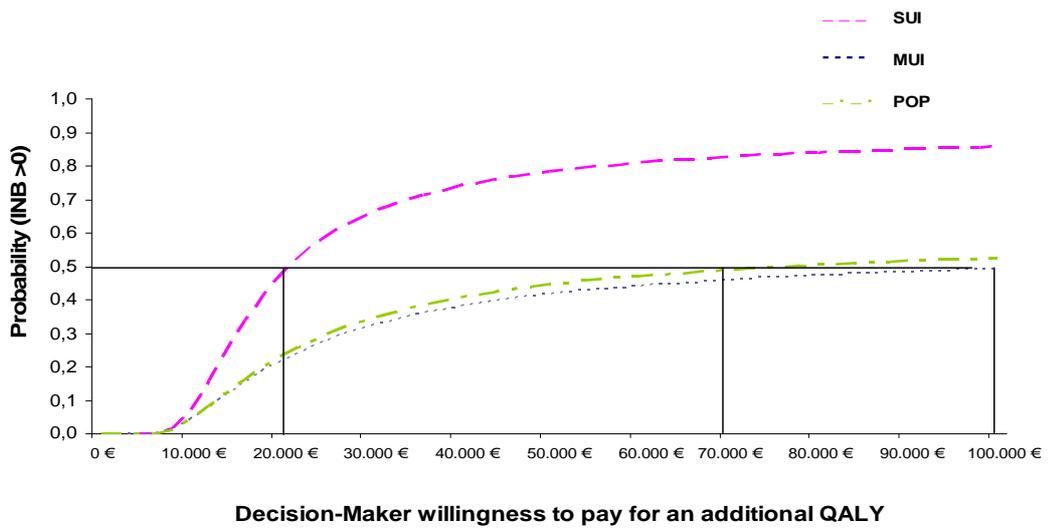


Figure 5

Cost-effectiveness acceptability curve with the EQ-5D by the type of UI.



The CEAC with ICIQ-SF indicates a 50% probability of INB of 10,659 €/incremental area of modified ICIQ-SF (Figure 6), with 8,460, 15,145 and 20,394 €/incremental area of modified ICIQ-SF for SUI, MUI and POP, respectively (Figure 7).

Figure 6

Cost-effectiveness acceptability curve with the ICIQ-SF

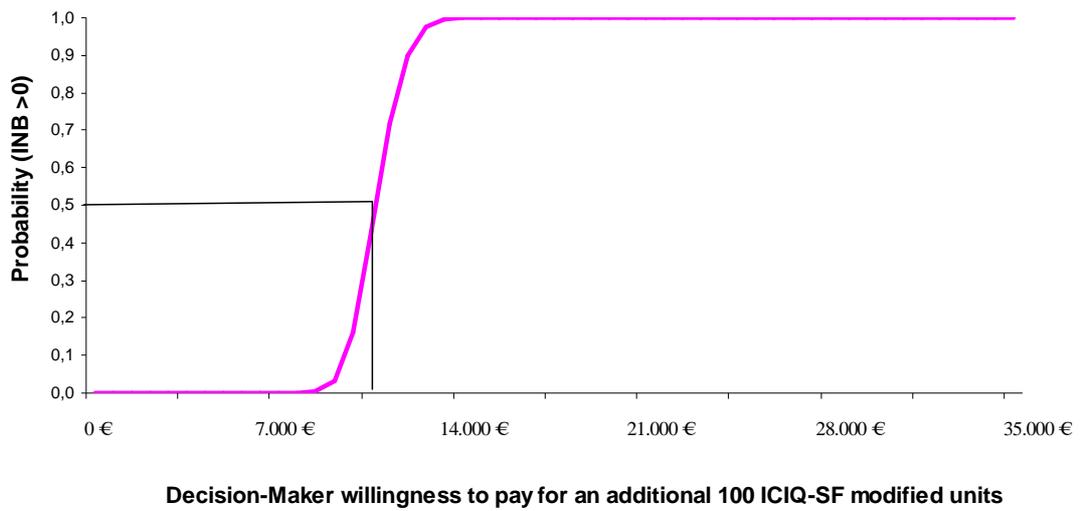
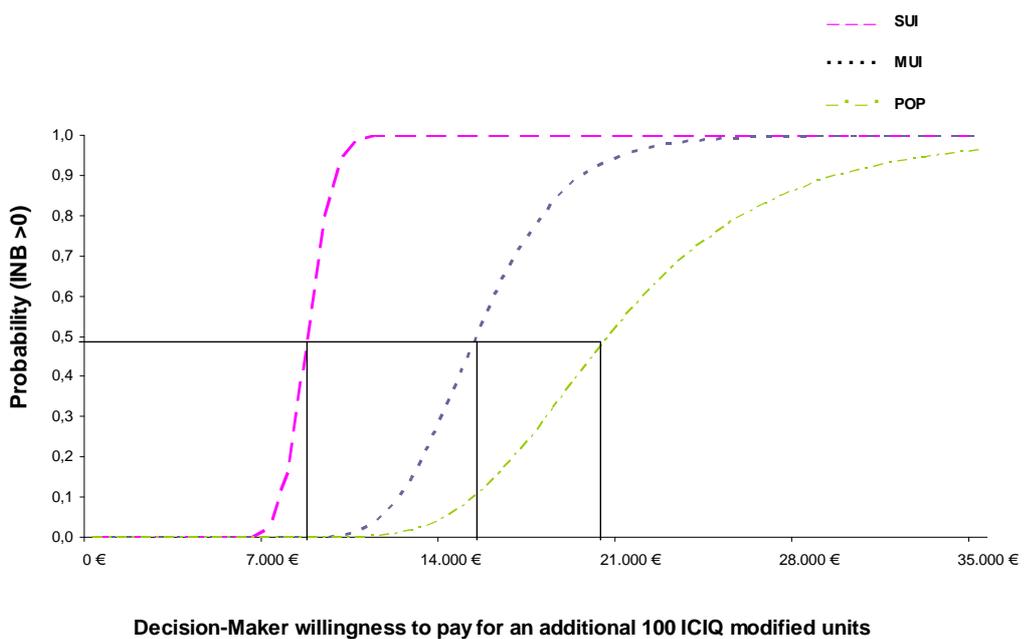


Figure 7

Cost effectiveness acceptability curve with the ICIQ-SF by the type of UI



The analysis allows detecting how SUI obtains probabilities at 50% of INB more cost-effective in each of the models.

COMMENTS

The economic literature concerning the surgical treatment of UI uses different HRQL questionnaires for the calculation of QALY. Manca et al (1) and Dumville et al (3) used the generic questionnaire, EQ-5D. The first obtained increments of QALY at 6 months of 0.397 and 0.387 with TVT and laparoscopic colposuspension, respectively. The second obtained QALY for open colposuspension and laparoscopic colposuspension of 0.421 and 0.416 at 6 months, respectively, and of 0.818 and 0.833 at 1 year, respectively. Performing a literature review to compare TVT with open colposuspension, Wu et al (5) applied utility values published by other authors (27, 28) based on HRQL in chronic diseases or in women who underwent surgery for urinary incontinence using the Health Utilities Index (HUI). The HUI for urinary incontinence was 0.73 and 0.95 after treatment, a value that was significantly different from the one attained by the EQ-index.

Recently, Lier et al (29) compared TVT with TOT using an HRQL with 15 dimensions (15-D)(30). The index values were 0.878 and 0.864 at baseline and 0.899 and 0.897 at 1 year for TOT and TVT, respectively. At 6 weeks, the index values were higher (0.917 and 0.902), indicating an early “euphoria” caused by of the remission of UI and the negative effects that time can have.

There are several HRQL generic questionnaires that can be used to evaluate effectiveness. However, for orthodoxy and to establish comparisons with other health programmes, the reference is EQ-5D, which is used most often to determine the QALY(31).

It is important to note the need to use intermediate results of the effectiveness measures, as we have done herein at 1 month after the surgery, to adjust the calculation of the QALY according to the area under the curve (13). The exclusive application of annual measures can lead to an under- or overestimation of the impacts on the quality of life (32). Intermediate results become essential for the measurement of effectiveness in pathologies such as UI, for which there are short-term results of treatment; in these cases the HRQL questionnaires would better reflect the changes.

For the long-term calculation of effectiveness and costs, we applied an annual discount rate of 3%, the same as that published by Wu et al (5). This rate was also proposed by the US

Panel on Cost-Effectiveness (26) and was assumed by the Spanish Health Economics Association as the rate for the reference case (25).

The ICER results in the literature indicated better cost-utility ratios for laparoscopic surgery techniques or slings compared with traditional surgery and for TOT compared with TVT. In the review by Cody et al(2), at 5 years, TVT exhibited a lower cost (267£ less) than traditional surgical techniques with an equal or higher QALY (+ 0.00048). The probability that TVT was cost-effective was 95% for 20,000 £/QALY. Manca et al(1) demonstrated a lower cost (243£ less) and a higher utility (0.01 QALY) for TVT compared with colposuspension. At 6 months, the probability that TVT was more cost-effective was 94.6% for an ICER of 30,000 £/QALY. However, the review by Kilonzo et al (33) revealed that 5 years must elapse for the TVT results to be cost-effective compared with colposuspension.

We have not found any CEA in the literature that calculates an ICER specific for UI. This study could serve as the first such reference: 106.52€ per unit measured with ICIQ-SF at one year. In their study of CEA, Valpas et al (6) did not calculate an ICER; their results were evident: TVT is less expensive (- 1,180.1€) and more effective (1.9 points with the specific UISS) than colposuspension.

Although the threshold of the ICER has been adopted as 30,000 €/QALY, this aspect is not free from discussion. This reference was suggested for Spain by Sacristán et al (14) and endorsed by Ortún in 2004 (34). In 2010, NICE established (35) that a cost per treatment higher than 20,000-30,000 £/QALY cannot be considered cost-effective. A practical analysis for the monetary estimation of QALY was published by Baker et al (36), who proposed the approximation of the observations of NICE and public opinion surveys regarding the willingness to pay. In the Spanish population, Pinto et al (37) tried to estimate the monetary value per QALY and concluded that obtaining a unique value is difficult.

The generalisation of our results might not be possible because they have been obtained in a specific population and at a public medical centre. The results of surgery and the re-interventions either for the extrusion or persistence of incontinence reflect the experiences of this centre. Additionally, the cost figures cannot be considered typical because of standardised practices, such as local anaesthesia or outpatient surgery, the latter being crucial for Manca et al (1) to establish the superiority of TVT in terms of cost-effectiveness. Moreover, the variations in the costs of personnel and anti-incontinence devices can vary between countries and between hospitals.

There are some limitations to this study: the number of patients, the different types of UI and the different surgical techniques employed. The follow-up collected herein was only

conducted at 1 year, the results at 5 years were based on data from our experience and from other series and should be considered only as an approximation. However, we used utility indices measured from validated questionnaires in specific patients with a specific pathology and after a surgical procedure, with individualised costs per patient not based only on the average, thereby offering additional opportunities to reduce costs (38). However, as we used ICIQ-SF, the study can be used as a reference to compare the results of the cost-effectiveness of treatments for UI and in both sexes with specific questionnaires without needing to run complex studies of cost-utility with the determination of QALY.

Eventually, the assumption made that the untreated patients maintain the same EQ-index during the period considered instead of the experiencing a reduction in their quality of life, a more likely outcome, implies that the estimates of QALYs gained represent a lower bound. Moreover, taking into account our assumption of an initial costs of 0 €, any other consideration should lead to a lower ICER value.

CONCLUSIONS

We can affirm that the surgical treatment of female urinary incontinence with slings is cost-effective compared with abstention in our public health environment. At 1 year, surgery for SUI is more cost-effective than that for the other two types of incontinence, MUI and that associated with POP.

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