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Recurrence of stress urinary incontinence in women treated with transobturator suburethral mesh: 9-year follow-up

Abstract

Objectives: The recurrence of SUI after surgery with TO represents a frequent complication whose etiology has not been clarified.

Our study aims to establish the SUI recurrence rate in patients operated on at our center as well as to analyze the possible factors associated with the risk of recurrence, during a 9-year follow-up.

Methods: Prospective descriptive observational study, conducted at the Hospital Clínico Universitario de Valladolid, between January 2012 and March 2021, including 133 patients.

Results: Our study describes a recurrence rate of SUI after TO of 12%, with a statistically significant relationship (p 0.009) between the year of postoperative follow-up and the risk of recurrence.

The risk of recurrence at 9 years was related to advanced age, macrosomic delivery, and multiparity.

Conclusions: We must identify those patients whose risk factors allow us to anticipate a torpid evolution, considering therapeutic alternatives, for example, in young women or who have not completed their reproductive desire.

Keywords: SUI recurrence, risk factors, long-term follow-up, TO mesh complications

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Introduction

It is estimated that the prevalence of stress urinary incontinence (SUI) ranges between 16-40% in the adult female population.

The treatment of this depends on the degree of severity, starting with hygienic-dietary measures and rehabilitation of the pelvic floor muscles.

For cases that require surgery, tension-free suburethral bands represent the "gold standard",[1–3] with transobturator bands (TO) being the most widely used today, having shown high cure rates (similar to colposuspension) and retropubic mesh), especially in the short and medium term, with a lower percentage of associated complications.

However, recurrence of SUI after surgery with TO, mainly in the long term, continues to be a complication of unknown etiology. Given that SUI can recur after TO, the investigation and study of its possible causes should be a priority, with the aim of identifying and properly selecting the candidates for correction of their SUI with TO.

The objectives of our study were, on the one hand, to establish the recurrence rate of SUI in patients operated on with TO at our center, and secondly, to identify the factors associated with the risk of recurrence of SUI after surgical treatment with TO in a 9-year follow-up.

Material and methods

Prospective descriptive observational study, which included 133 patients. It was carried out at the Hospital Clínico Universitario of Valladolid, between January 2012 and March 2021.

The inclusion criteria were: diagnosis of SUI or mixed with a predominance of exertion, with or without associated pelvic organ prolapse (POP) surgery, operated with a TO band.

The exclusion criteria were postvoid residual >100 ml and neurogenic bladder. The urodynamic study (UDS) was performed in complex, recurrent incontinence or in patients with previous incontinence surgery.

All the patients were evaluated in the Pelvic Floor Unit.

During the first 2 years, follow-up was carried out in the clinic through anamnesis, physical and ultrasound examination, assessing the efficacy of TO and analyzing immediate (<7 days), intermediate (≥7-30 days) and late (≥30 days) complications.). Subsequent follow-up was carried out through an annual telephone survey.

The rate of total and stress continence (objective cure) was analyzed using the cough test. The subjective cure rate was assessed using the ICIQ-IU-SF questionnaire, PGI-I scale, and the degree of personal satisfaction, expressed using an analog scale from 0 to 10, considering patients who gave scores between 7 and 10 to be very satisfied.

The main variable studied was the recurrence of SUI (positive cough test with a frequency of at least several times a week), and as secondary results we studied possible variables associated with the risk of recurrence.

Statistical analysis: continuous quantitative variables with normal distribution are described by mean and standard deviation, and those with non-normal distribution by median and interquartile range. Qualitative variables are described by n and percentage.

For the analysis of the quantitative variables, the Kolmogorov-Smirnov test was used, determining the type of distribution. For those with a normal distribution, the T-Student test was applied and in the opposite case the test used was the U-Mann-Whitney. For the study of qualitative variables, the test chosen was Chi-square with Yates

correction. As occurs in most scientific studies, 0.05 was established as the value below which we rejected the null hypothesis and concluded that there is a statistically significant relationship between the variable and the risk of SUI recurrence. The statistical software used was SSPS v. 23.

The ethics and research committee of the Valladolid Este health area (Code: FO-P07-12) authorized the study. Verbal informed consent was obtained from all included patients.

Results

133 patients were included: 100 TO inside-out, (61 I-Stop® C-Medical, 17 InGyne-S IO® Dipromed, 13 Gynecare®, Johnson-Ethicon, 9 TOA® Presurgy), and 33 TO out-inside (1 InGyne-S® Dipromed, 32 Monarc® AMS).

12% of our patients (16) presented recurrence of SUI (7 In-Out and 9 Out-In).

After analyzing different variables and their association with the risk of recurrence, a decrease in the total cure rate (mean rate 83.6%) and objective continence (cough test or telephone survey with SUI symptoms) was observed as the time since surgery increased.

Both total continence and the recurrence rate were significantly affected after the sixth year (Figure 1) (Figure 2), which showed that there is a statistically significant relationship ($p < 0.009$) between the year of follow-up after surgery and the risk of recurrence.

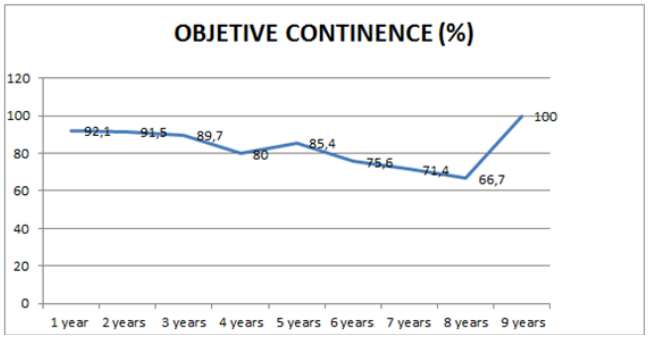

Figure 1 Objective continence with TO band throughout follow-up.

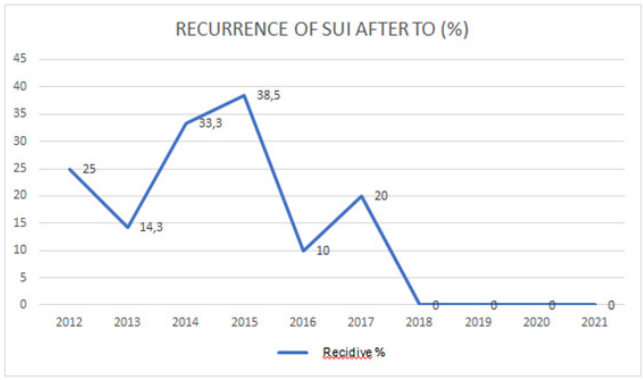

Figure 2 Percentage of recurrence of SUI after TO band during follow-up.

Regarding demographic and obstetric data, only age (median 70 vs 65, p 0.022), parity (12.6% of multiparous women relapsed vs 0% of nulliparous women, p 0.022) and macrosomia (32.1% vs 0%, p 0.000), showed an association for the risk of recurrence (Table 1).

Regarding the data from the clinical examination, neither the type of urinary incontinence (SUI, MUI, or occult), degree of severity, need for prior EUD, or concomitant POP surgery were related to recurrence.

Table 1 Relation of the risk of recurrence after TO with demographic variables, obstetric history, concomitant pathology, and previous gynecological surgery

Variable (N)	Recurrence		P
	No	Si	
Age: median (P25-P75) (133)	65 (40-81)	70 (45-85)	0.022[a]
BMI: mean ± SD (133)	27.4 ± 4.3	28.1 ± 4.1	Ns*
Non-domestic physical activity (30)	29	1	Ns
Parity (132)			
0(5)	5	0	0.008[b]
≥1 (127)	111	16 (12.6%)	
Fórceps (12)	10	2	Ns
Macrosome			
No (71)	71	0	0.000[b]
Si (28)	19	9 (32.1%)	
AHT (53)	46	7	Ns
Respiratory disease (8)	7	1	Ns
Psychiatric illness (28)	23	5	Ns
Neurological disease (4)	3	1	Ns
Tobacco ≥ 5 cigarretes per day (11)	9	2	Ns
Previous gynecological surgery (42)	35	7	Ns
Abdominal hysterectomy (15)			
Vaginal hysterectomy	13	2	Ns
Not (125)			Ns
Yes (8)	112	13 (10.4%)	0.055[b]
Anterior colporrhaphy (15)	5	3 (37.5%)	
Posterior colporrhaphy (11)	13	2	Ns
Burche (1)	9	2	Ns
Marshall-Marchetti (3)	0	1	Ns
	2	1	Ns

[a]Mann-Whitney U test, b Chi-Square test, *Ns: no statistical significance

They did, however, the number of pads that the patients needed before undergoing surgery (median 4 vs 3, p 0.031), the history of vaginal hysterectomy (37.5% recurred vs 10.4% in women not previously operated, p 0.055) or the presence of associated rectocele (21.1% vs 8.4%, p 0.046) (Table 2).

Table 2 Relationship of clinical examination variables with the risk of recurrence after TO

Variable (N)	Recurrence		P
	No	Si	
Type of incontinence			
SUI(49)	44	5	Ns
Mixed (72)	61	11	
Occult (12)	12	0	
Degree of SUI			
I (6)	6	0	Ns
II (100)	89	11	
III (27)	22	5	
Number of compresses			
Median (P25-P75) (133)	3 (0-8)	4 (1-10)	0.031a
UDS (14)	13	1	0.474c
Associated POP (102)	89	13	Ns
Urethrocele (62)	53	9	Ns

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Table2 Continued...

Variable (N)	Recurrence		P
	No	Si	
Cystocele (82)	73	9	Ns
Uterus prolapse (44)	39	5	Ns
Vaginal vault prolapse (1)	0	1	Ns
Enterocele (6)	4	2	Ns
Rectocele			
Not (95)	87	8 (8.4%)	0.046b
Yes (38)	30	8 (21.1%)	
Grade II perineal tear (75)	66	9	Ns
Initial ICQ-SF: Median (P25-P75)	15 (0-21)	15.50 (12-20)	Ns

[a] Mann-Whitney U test, [b] Fisher exact test, *Ns: no statistical significance

When we analyze the data from postoperative complications (Table 3), urinary retention as an immediate complication showed a significant association with the risk of recurrence, with 36.4% recurrence vs 9.8% in patients who did not present said complication (p 0.028); late complications also did (recurrence of 40% vs 0%, p 0.000), unlike the intermediate ones, which turned out not to influence recurrence.

Table 3 Recurrence ratio of SUI after TO with complications

Variable (N)	Recurrence		P
	Not	Yes	
Immediate complication			
Not (116)	105	11 (9.5%)	0.034a
Yes (17)	12	5 (29.4%	
Bladder perforation (1)	1	0	Ns*
Fever (1)	0	1	Ns
UTI (2)	2	0	Ns
Bladder retention			
Not (122)	110	12 (9.8%)	0.028a
Yes (11)	7	4 (36.4%)	
Bladder catheter at discharge(4)	2	2	Ns
Pain (1)	1	0	Ns
Surgery for hemorrhage** (1)	1	0	Ns
Vaginal piercing (1)	1	0	Ns
Intermediate complication (7)	6	1	Ns
Fever (1)	1	0	Ns
Hematoma (1)	1	0	Ns
UTI (3)	3	0	Ns
Bladder retention (2)	1	0	Ns
Bladder catheter (1)	0	1	Ns
Pain (1)	1	0	Ns
Late complication			
Not (93)	93	0	0.000a
Yes (40)	24	16 (40%)	
New IUU (11)	9	2	Ns
Bladder retention (3)	3	0	Ns
Mesh extrusion (3)	3	0	Ns
Pain (13)	10	3	Ns
Urethrolysis (3)	3	0	Ns

[a] Chi-Square Test, * Ns: no statistical significance, ** Hemorrhage from the inferior epigastric artery in the space of Retzius, which required urgent surgical repair

Conclusion

Our study describes a recurrence rate of SUI after TO similar to that described by other authors in the literature reviewed.[4–6]

Multiple variables have been evaluated and proposed as risk factors for this recurrence, without being able to establish a solid relationship, given the variability in the design of the studies carried out, and the scarcity of publications referring to long-term follow-up with this type of mesh.

In our population, the risk of recurrence at 9 years was related to advanced age, as other authors had already concluded,[5,7] macrosomic delivery and multiparity.

The implication of age could be explained by the physiological changes associated with tissue aging, which would also justify a higher risk of recurrence with a longer evolution time after surgery, and although most of the reviewed publications support this relationship between age, years of evolution and recurrence, some authors disagree.[8–10]

On the other hand, despite it being clear that childbirth is considered a risk factor for the development of SUI, some studies have not found a relationship between obstetric history and evolution of SUI after surgery.[11]

Regarding the association between recurrence and the use of a high number of pads, a plausible pathophysiological explanation would be the relationship between the use of pads and the degree of severity of SUI, despite the fact that in our study the latter did not reach statistical significance. In addition, the use of these devices is conditioned by other factors such as age, physical activity, lifestyle.

A history of vaginal hysterectomy probably determines worse long-term results, due to the alteration of the pelvic floor both before and after this surgery.

Rectocele as a risk factor for recurrence could be justified by its association with constipation, causing damage to the pelvic floor muscles, which would influence urethral support.

Given such a disparity in results, it is essential to carry out long-term follow-up and analyze the data, with the aim of offering adequate pre-surgical advice.

Although a high percentage of women who are candidates for surgery with TO will benefit from an improvement in their quality of life, we must identify those whose risk factors allow us to anticipate a torpid evolution, and consider therapeutic alternatives, for example, in young women or who have not completed their birth wish.[12]

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Conflicts of interest

The authors declare that they have no conflict of interest.

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