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Risk factors of recurrence of stress urinary incontinence after single-incision sling at 5 years

Abstract

Introduction and hypothesis: Stress urinary incontinence (SUI) affects 5-35% of women, especially at menopause. In severe cases or when conservative treatment fails, a tensión-free suburethral band is indicated. Similar short-medium term cure rates have been reported with mini-sling (SIS) compared to retropubic and transobturator band. But the long-term information is scarce and it seems that the risk of recurrence is not negligible (4-37%).

There is little literatura that studies the posible predisposing factors for the recurrence of SUI after SIS. The objective is to identify factors associated with the risk of relapse of SUI at 5 years, after SIS.

Methods: A prospective five-years follow-up observational study (2015-2019) was performed in women who underwent SUI using SIS. The sample was 115 patients with relapse of SUI.

Statistics: T-Student or U-Mann and ROC for quantitative variables, Chi-Squared and OR for qualitative variables.

Results: L25 patients (21.74%) had recurrence during the study period.

Of all the variables analyzed, they only showed a significant association with the recurrence of SUI: height, weigth and BMI, a history of fetal macrosomia and the number of compresses used.

The patients who presented recurrence of SUI had a lower heigth, greater weight, and therefore a higher BMI.

The obstetrics history of a vaginal delivery with a fetus >4 kg, was associated with a higher risk of recurrence (OR: 4.05, IC 95%=1.09-15.03), and the use of a greater number of compresses was also associated with an increased risk of relapse, obtaining an area under the curve of 0.659.

Conclusion: The 5-year recurrence rateo f SUI after mini-sling in our setting was 21.74%.

A lower height, a greater weight and BMI, macrosomic delivery and greater number of purses have shown a significant association with the risk of relapse of SUI after mini-sling at 5 years.

Therefore, it is essential to adecuately advise patients according to their personal factors of the potencial risk of recurrence after SIS.

Keywords: stress urinary incontinence, recurrence, risk factors

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Abbreviations: AH, arterial hypertension; BMI, body mass index; CMA, outpatient major surgery unit; MUI, mixed urinary incontinence; OR, odds ratio; PGI, patient global impression of improvement; POP, pelvic organ prolapse; ROC, receiver operating characteristic; SIS, single incision sling or mini-sling; SUI, stress urinary incontinence; TO, transobturator band; TVT, retropubic band, UDS, urodynamic study

Introduction

Urinary stress incontinence (SUI) is defined as the leakage of urine during physical exertion, sneezing or coughing. It has a high prevalence of between 5 and 35% in women, mainly in postmenopause, affecting their quality of life.[1,2]

Initial treatment as recommended by the European Urological Association (UAE) should be based on exercises to strengthen the pelvic muscles, associated with treatment with local estrogens.[3]

Patients with severe urinary incontinence, or who do not respond to conservative medical treatment, require surgical treatment, which has undergone multiple changes over the past decades. Burch's retropubic colposuspension, considered the gold standard decades ago, has been replaced by new minimally invasive surgical techniques based on the use of suburethral tapes: the retropubic tension-free vaginal tape (TVT), the transobturator suburethral tape (TO), and more recently the single incision sling (SIS).

SIS represents the third generation of suburethral tapes and differs from the previous ones in that they require only a vaginal incision for insertion, the dissected tissue is smaller, and the band used is shorter (6 to 12cm). SIS was designed with the aim of minimizing major complications such as bladder, vaginal and urethral erosions or perforations, and chronic pain associated with the use of suburethral tapes, reducing costs and surgical time.

Multiple studies have compared the efficacy of SIS versus TVT and

TO, with similar cure rates being observed. A comprehensive meta-analysis published in 2014, concluded that there were no differences in terms of objective and subjective cure, impact on quality of life and sexual activity, between SIS and conventional tapes at 18 months of study.[4]

Regarding the SIS results, Oliveira's group obtained an objective cure rate of 80% at 12 months,[5] Palmieri's 86.5% at 23 months,[6] and T. Lo's 90%, with a subjective cure rate of 86% at 12 months.[7] Other publications reaffirm the good results of SIS, observing a drop in success rates as the years after surgery pass.[8]

However, despite the general efficacy, the failure rate of suburethral tape surgery remains between 4% and 37%.

Very few studies have investigated the risk factors associated with SUI recurrence after SIS, although many have been proposed, including increasing age, obesity, associated comorbidities, overactive bladder, immobility of the bladder neck, mixed urinary incontinence (MUI), pelvic organ prolapse (POP) surgery and previous anti-incontinence surgery.[6]

The objective of our study is to establish possible risk factors for relapse of SUI in our population after mini-sling band placement.

Material and methods

A prospective observational study was conducted through a 5-year follow-up (2014-2019) in 115 women who underwent surgery with a SIS with the aim of identifying patients with recurrence of SUI, and trying to establish the risk factors associated with this recurrence.

All the patients were operated on at the Universitary Clinic Hospital of Valladolid and evaluated at the Pelvic Floor Unit. SUI was explored in consultation, in lithotomy and/or supine position and with a bladder filled (250-300 ml) checked by ultrasound, using the cough test and the positive Bonney test to confirm urethral hypermobility.

SIS surgery was indicated to patients with pure SUI or associated with MUI. The only exclusion criteria were the need for concomitant prolapse surgery. Urodynamic studies (UDS) were only performed in relapsed SUI, when SUI was suspected due to intrinsic sphincter deficit and in complex urine incontinence.

A follow-up was carried out in consultation at 6, 12 and 24 months, and by telephone interview at 3, 4 and 5 years, assessing objective cure through the cough test, and anamnesis on symptoms related to SUI, and subjective cure using the PGI scale (Patient Global Impression of Improvement).

The presence of ananmesis compatible with symptoms of SUI (with a frequency of more than once a week or the daily need for compresses) was established as a diagnosis of relapse of SUI.

The patients were also evaluated according to other variables such as age, size, weight, body mass index (BMI), daily physical activity, obstetric history (parity, forceps delivery, vaginal delivery of fetus >4kg), comorbidity (AH, respiratory, psychiatric or neurological pathology), concomitant medication (diuretics, antihypertensive, or psychiatric), smoking, previous anti-incontinence surgery, previous mixed urinary incontinence, severity of SUI (Grade I, II, III), no. compresses/24h, presence of POP and previous UDS.

The meshes used were Ophira® (Promedon, Córdoba, Arg.) and Altis® (Coloplast, UK, Ltd).

65 Altis and 50 Ophira were placed. All were placed by two gynecologists in the Outpatient Major Surgery Unit (CMA) without admission, under mild sedation and with local infiltration of 0.25% Svedocain® (bupivacaine+epinephrine) diluted 50% with physiological saline.

This study was authorized by the ethics and research committee of the eastern health area of Valladolid (Code: FO-P07-12, date: 13/02/2015) (appendice-1).

The Kolmogorov-Smirnov test was applied for quantitative variables to determine the type of distribution. The T-Student test was used to study quantitative variables with a normal distribution, and the U-Mann-Witney test otherwise. The Chi-square test with Yates correction was used to study qualitative variables. In all cases, less than 0.05 was the value taken as statistically significant. For quantitative variables with a statistically significant relationship, ROC curve was constructed and the area under the curve was calculated, and for qualitative variables the OR was calculated with a 95% confidence interval. SSPS v. 23 was the stadistic software used.

Results

The sample was composed of 115 patients monitored during 5 years. Twenty-five of them (21.74%) had recurrence during the study period, 9 Altis and 16 Ophira.

From all variables analyzed (Table 1) those that showed a significant association with the recurrence of SUI in the univariate analysis were height, weight and BMI, a history of fetal macrosomia and the number of compresses used.

Table 1 Univariate association between anthropometric, obstetric, medical variables, previous gynecological surgery, type and grade of urinary incontinence, number of purses, previous urodinamic study and type of SIS, and the development of relapse of SUI

Variable (n)	Recidive		P
	No	Yes	
Age (115)	-90	-25	0.073[1]
Median (Range Q1-Q3)	67,00 (41-80)	75,00 (64-85)	
Height (m) (112)	-89	-23	0.02[1]
Mean±Standard deviation	1,6±0,69	1,55±0,05	
Weight (kg) (113)	-90	-23	0.037[2]
Mean±Standard deviation	66,76±11,19	72,65±11,70	
BMI (111)	-88	-23	0.001[1]
Mean±Standard deviation	26,11±4,13	30,18±5,32	
Daily physical activity (46)	38	8	0.489[3]
Parity (≥1) (111)	87	24	0.278[1]
Fórceps (≥1) (9)	7	2	0.307[3]
Fetal macrosomy (81)			
0 delivery >4kg	54	5	0.028[3]
≥1 deliveries >4kg	16	6	
Arterial hypertension (34)	23	11	0.074[3]

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Table Continued

Variable (n)	Recidive		P
	No	Yes	
Respiratory pathology (13)	8	5	0.121[3]
Psychiatric pathology (38)	28	10	0.403[3]
Tobacco ≥5 per day (14)	12	2	0.421[3]
Previous gynecological surgery (17)			
Type of incontinence (115)			
Pure SUI (61)	48	13	0.906[3]
MUI (54)	42	12	
SUI grade (115)			
II (93)	82	21	0.304[3]
III (12)	8	4	
No. of purses (110)	-87	-23	0.017[3]
	3,64±1,96	4,61±2,12	
UDS prior to surgery (19)	18	1	0.057[3]
Type of sis (115)			
Ophira (50)	34	16	0.0243[3]
Altis (65)	56	9	

They did not appear significant, suffering a MUI, or the degree of incontinence, nor parity, neither perform UDS prior to surgery.

Having a history of gynecological surgery was also not related to the risk of recurrence. Furthermore, no patient had previous anti-incontinence surgery.

From the analysis carried out, we infer that there are no significant differences regarding the presence of early (1-6 days), intermediate (≥7-29 days) or late (≥30 days) complications between both types of mini-sling.

Bivariate analysis of the variables that showed a significant association with relapse of SUI was performed.

The Ophira tape was related with a 2.77-fold higher risk of recurrence than Altis (OR: 2.77, IC 95%=1.10-6.92).

The patients who presented recurrence of SUI had a lower height, greater weight, and therefore a higher BMI than those who did not recur, as can be seen in Figures 1–3, with an area under the ROC curve of 0.295, 0.658 and 0.733, respectively.

The obstetric history of a vaginal delivery with a fetus >4 kg, was associated with a higher risk of recurrence (OR: 4.05, IC 95%=1.09-15.03), and the use of a greater number of compresses was also associated with an increased risk of relapse (Figure 4), obtaining an area under the curve of 0.659.

Discussion

Around 15% of women who undergo SUI surgery will require subsequent treatment of its persistence or recurrence.[9] Multiple variables have been associated with this primary surgery failure, including advanced age, urge urinary incontinence, POP or concomitant surgery, obesity and diabetes mellitus, among others.

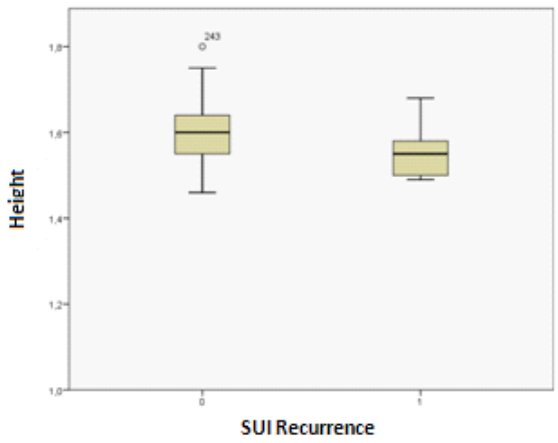

Figure 1 Relationship between height and risk of SUI recurrence.

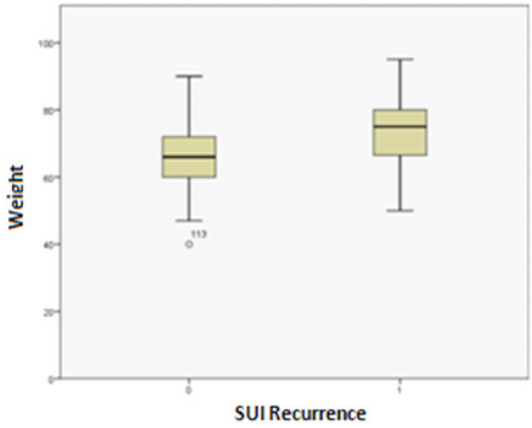

Figure 2 Relationship between weight and risk of SUI recurrence.

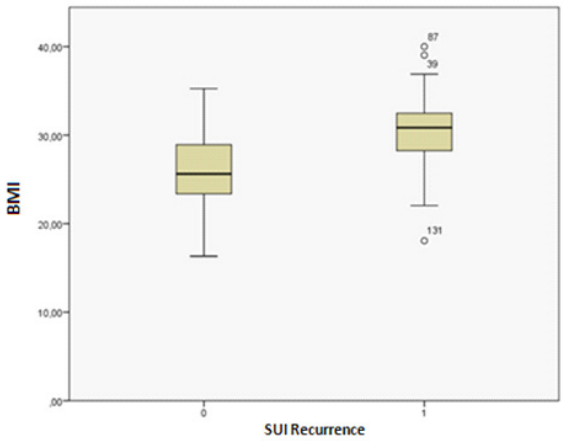

Figure 3 Relationship between BMI and risk of SUI recurrence.

However, despite of its increasing popularity and promising results, there are few studies focused on establishing clinical predictors, wich are associated with the failure of surgery with SIS.

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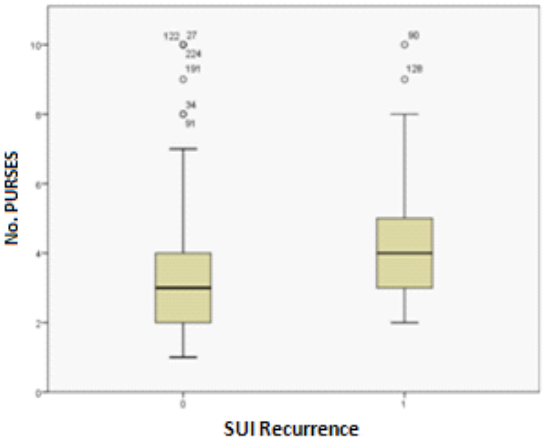

Figure 4 Relationship between the number of compresses used and risk of SUI recurrence.

The existing bibliography shows contradictory results, because these studies are very heterogeneous respect to the type of study used (prospective,[5,8] retrospective[6,7]), years of follow-up, inclusion and exclusion criteria and other factors.

Our study was a prospective observational study with a 5-year follow-up, which included all patients who were operated with a SIS due to SUI. The inclusion criteria were that the patient presented SUI, associated or not with MUI. Patients who need concomitant prolapse surgery were excluded.

Some publications establish prolapse or previous anti-incontinence surgery, neurogenic disease, constipation, intrinsic sphincter deficit or maximum preoperative urethral closure pressure <40cm H_2O as risk factors for recurrence.[7]

Nevertheless, other studies only considered independent risk factors for recurrence, a detrusor pressure <20cm H_2O at peak flow during the emptying phase, and the presence of a severe SUI identified by the ICIQ-SF questionnaire.[6]

This last factor was also conclusive for the Oliveira group after 12 months of surgical follow-up.[5]

In our study, the percentage of SUI recurrence was 21.74% at 5 years, slightly higher than those published for TOT, which vary from 9 to 20% at 5-9years.[10–14]

Our work finds a significant association between SUI recurrence and weight, height, BMI, having had a delivery with a fetus >4kg, and high use of compresses. Reviewed studies have also found a relationship between SUI relapse and BMI, but not between recurrence with fetal macrosomia and prior high use of compresses.

However, as previously stated, the results are contradictory. It has been widely debated, whether obese patients should be considered for this type of surgery, without any of the previously cited studies being able to establish that BMI affected the outcome of SIS, nor to establish a specific BMI from which the option surgical would be with TO instead of mini-sling.[5]

Another key point is to establish the most appropriate mesh type in terms of length, type of anchorage, and adjustment system. Our results conclude that the risk of SUI relapse is significantly higher with Ophira than with Altis SIS (OR=2.77). Establishing universal risk factors for recurrence of urinary incontinence after SIS insertion is a difficult task at the moment, and we also do not know whether or not this type of tape implies a higher risk of recurrence compared to conventional ones.[4]

Conclusion

The non-negligible failure rate after surgery does not contraindicate the use of SIS as a treatment for SUI, but it does require correct pre-surgical advice, especially in obese or with a history of macrosomal delivery patients.

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Conflicts of interest

The authors declare that they have no conflict of interest.

References

1. Haylen BT, de Ridder D, Freeman RM, et al. An international urogynecological association (IUGA)/International continence society (ICS) joint report on the terminology for female pelvic floor dysfunction. *Neurourol Urodyn*. 2010;21(1):5–26.
2. Luber KM. The definition, prevalence, and risk factors for stress urinary incontinence. *Rev Urol*. 2004;6 Suppl 3:S3–S9.
3. Capobiancoa G , Madoniab M , Morellia S, et al. Management of female stress urinary incontinence: A care pathway and update. Maturitas. 2018;109:32–38.
4. Mostafa A, Phay Lim Ch, Hopper L, et al. Single-incision mini-slings versus standard midurethral slings in surgical management of female stress urinary incontinence: an Updated systematic review and meta-analysis of effectiveness and complications. *Eur Urol*. 2014;65(2):402–427.
5. Oliveira R, Botelho F, Silva P, et al. Single-incision sling system as primary treatment of female stress urinary incontinence: prospective 12 months data from a single institution. *BJU Int*. 2011;108(10):1616–1621.
6. Palmieri S, Frigerio M, Spelzini F, et al. Risk factors for stress urinary incontinence recurrence after single-incision sling. *Neurourol Urodyn*. 2018;37(5):1711–1716.
7. Lo T, Shailaja N, Chua S, et al. Evaluation of clinical outcome and risk factors for failure of single-incision midurethral short tape procedure (solyx tape) for stress urinary incontinence. *J Minim Invasive Gynecol*. 2019;26(4):688–694.
8. Mira Gon L, Luis C, Riccetto Z, et al. Mini-sling ophira at 8 years follow-up: does it sustain results? *Urol Int*. 2019;102(3):326–330.
9. Morgan D. Stress urinary incontinence in women: Persistent/recurrent symptoms after surgical treatment. 2020.
10. Barber MD, Kleeman S, Karram MM, et al. Risk factors associated with failure 1 year after retropubic or transobturator midurethral slings. *Am J Obstet Gynecol*. 2008;199(6):666.e1–667.

11. Groutz A, Rosen G, Gold R, et al. Long-term outcome of transobturator tension-free vaginal tape: efficacy and risk factors for surgical failure. *J Womens Health*. 2011;20(10):1525–1528.

12. Serati M, Bauer R, Cornu JN, et al. TVT-O for the treatment of pure urodynamic stress incontinence: efficacy, adverse effects, and prognostic factors at 5-year follow-up. *Eur Urol*. 2013;63(5):872–878.

13. Jonsson Funk M, Siddiqui NY, Kawasaki A, et al. Long-term outcomes after stress urinary incontinence surgery. *Obstet Gynecol*. 2012;120(1):83–90.

14. Ashok K, Wang A. Recurrent urinary stress incontinence: an overview. *J Obstet Gynaecol Res*. 2010;36(3):467–473.

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