Clinics of Surgery

Research Article ISSN: 2638-1451 | Volume 8

Comparison of Results after 9 Years of Stress Urinary Incontinence Treatment with Transobturator Tape and Single Incision Sling

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Received: 07 Oct 2022
Accepted: 17 Oct 2022
Published: 21 Oct 2022
J Short Name: COS

Citation:

De-Miguel-Manso S. Comparison of Results after 9 Years of Stress Urinary Incontinence Treatment with Transobturator Tape and Single Incision Sling. Clin Surg. 2022; 8(2): 1-8

Keywords:

Stress urinary incontinence; Transobturator suburethral band; Single-incision sling; Long-term follow-up; Complications; Continence

1. Abstract

1.1. Introduction and Hypothesis: Surgical treatment of stress urinary incontinence (SUI) is performed using a tension-free suburethral band, and the most recent is the single-incision sling (SIS) developed to reduce surgical time and minimize the complications associated with retropubic and transobturator bands.

The objective of this study is to compare the SIS bands with the transobturator (TO) bands, in terms of efficacy (objective and subjective continence) and long-term post-surgical complications

1.2. Methods: Prospective observational study, with a 9-year follow-up (2012-20121) at the University Clinical Hospital of Valladolid (Spain), in women who underwent surgery for SUI using suburethral bands, TO or SIS.

1.3. Results: 271 patients were included, 133 TO and 138 SIS.

The TO group was older and had a higher frequency of hypertension and previous gynecological surgery, including an anti-incontinence technique. SIS patients performed physical activity more frequently and associated a higher percentage of psychiatric pathology.

Surgery time was lower with SIS and TO was significantly associated with POP corrective surgery.

There are no significant differences in immediate (<7 days), intermediate (≥7-30 days) or late (≥1 month) complications.

No significant differences were found in relation to objective or subjective healing using the satisfaction scale, the ICIQ-SF questionnaire, and the PGI-1.

1.4. Conclusions: Although the evidence currently does not place SIS as the gold standard treatment for SUI, in our study we did not observe differences between the two procedures (SIS and TO) during the 9-year follow-up, neither in objective nor subjective cure.

1.5. Brief summary: Surgical treatment of urinary stress incontinence can be treated, with similar results at 9 years, using transobturator suburethral band and single-incision sling, after proper patient selection.

2. Introduction

Stress urinary incontinence (SUI) is usually due to a mechanical or anatomical defect, or weakness of the urethra or pelvic floor; the therapeutic approach is usually focused on mechanical therapies,

such as surgery. But this is indicated when conservative therapies fail. There are numerous corrective surgical techniques: retropubic and transobturator tension-free suburethral bands, single-incision suburethral bands, or Burch colposuspension1. The choice of one technique or another usually depends on the criteria of the surgeon and the characteristics of the patient, although in recent years attempts have been made to opt for minimally invasive surgeries, displacing laparotomic and laparoscopic colposuspension to the background and turning synthetic suburethral bands into the "gold standard"

The most recent suburethral bands are the single-incision sling (SIS) that were developed with the aim of reducing surgical time and minimizing the complications associated with traditional suburethral bands (erosions or perforations of the bladder, vagina or urethra, or chronic pain). To achieve this goal, the SIS are shorter and their fixation system does not pass through the obturator hole.

The objective of this study is to compare mini-sling bands with transobturator bands, in terms of efficacy (objective and subjective continence) and long-term post-surgical complications.

3. Material and Methods

A prospective observational study, from a single center, was carried out for 9 years (2012-20121) at the Valladolid University Clinical Hospital (Spain), in women who underwent surgery for SUI using suburethral bands. Two study groups were established:

- TO: Patients operated on by inserting a tension-free transobturator suburethral band (TO), both in-out and out-in.

- SIS: Patients who received a minisling band (SIS).

The inclusion criteria were: presenting SUI, associated or not with mixed urinary incontinence (MUI), with predominance of SUI symptoms, a positive cough stress test for urethral hypermobility, and previous unsuccessful or undesired conservative treatment for SUI.

The following exclusion criteria were applied: diagnosis of neurogenic bladder and postvoid residue >100ml. Age and body mass index (BMI) did not limit inclusion in this study.

In the initial visit, the patients were evaluated clinically and ultrasoundally, based on validated questionnaires such as the ICIQ-IU-SF and PGI-1. Urodynamic study (UDS) was performed in complex incontinence, recurrence or in patients with previous incontinence surgery. In the first two years of follow-up, the patients were evaluated in the Pelvic Floor Unit through exhaustive anamnesis, physical and ultrasound examination, assessing the effectiveness of the band and analyzing immediate (<7 days), intermediate (≥7-30 days) and late (≥30 days) complications. Rates of total and stress continence (objective cure) were analyzed using the cough test. The subjective cure rate was assessed using the ICIQ-SF questionnaire, the PGI-I scale, and the degree of personal satisfaction, expressed on an analog scale from 0 to 10. The patients who gave scores between 7 and 10 were considered very satisfied. Subsequently, annual follow-up was carried out, exhaustively evaluating the same variables by telephone.

Recurrence of SUI was defined as the appearance of more than 1 episode of SUI Grade II per week, after a period of more than 3 months from the insertion of the anti-incontinence band.

Statistical analysis: The Kolmogorov-Smirnov test was applied for quantitative variables to determine the type of distribution. For the study of quantitative variables with normal distribution, the T-Student test was used and otherwise the U-Mann-Witney test was used. For the study of qualitative variables, the Chi-square test with Yates correction was used. In all cases, less than 0.05 was the value taken as statistically significant. SSPS v. 23 was the statistical software used.

Ethical approval: authorization of the study by the ethics and research committee of the East Valladolid health area (Code: FO-P07-12). Verbal consent was obtained from the included patients.

4. Results

A total of 271 patients were included, 133 TO and 138 SIS.

The mean age was significantly higher in the TO group (p=0.000), with no significant differences in BMI. More patients performed some physical activity in the SIS group (p=0.001).

Regarding obstetric history, both groups had similar percentages of nulliparity, forceps, and vaginal deliveries with fetus > 4 kg. Regarding the medical pathology, a significantly higher frequency of arterial hypertension was found in TO patients (p=0.023) and more psychiatric pathology in the SIS group (p=0.023).

TO patients had a higher frequency of previous gynecological surgery (p=0.023) and also had a significant history of another anti-incontinence band, both TO (n=7, p=0.006) and SIS (n=8, p=0.003).

Regarding the types of bands used, the in-out insertion was more frequent for the TO (100 vs 33) and with respect to SIS, 77 Altis® and 58 Ophira® were inserted, among others.

When analyzing the distribution of bands per year, we verified that between 2014 and 2017 more SIS were placed than TO (p=0.000), in 2018 the figures were similar, and from 2019 the insertion of SIS drastically decreased.

When comparing the symptoms of the patients, significant differences were found in the type of urinary incontinence (UI) and in the degree of SUI (more frequent MUI in TO and SUI in SIS, and higher percentage of SUI degree III in TO), but not in the number of pads used before surgery, nor in the UDS previously performed. The initial ICIQ-SF score was significantly higher in SIS (Table 1).

Significant differences were found in the association of anterior, middle, and posterior compartment POP (pelvic organ prolapse) surgery, in favor of TO (Table 1).

The surgery time was significantly lower with SIS, and with statis-

tical significance TO was associated with more corrective surgery of POP (Table 1).

There are no significant differences in immediate (<7 days), intermediate (≥7-30 days) or late (≥1 month) complications (Table 2).

Among the immediate complications, we found 1 bladder perforation and 1 inferior epigastric artery hemorrhage into the space of Retzius with TO that required urgent surgical repair.

Although there are no global differences, some events are individually significant, such a higher incidence of bladder retention as an immediate complication with TO and as late complications, greater de novo urgency and recurrence of SUI with SIS. A non-significant trend is observed towards a higher frequency of extrusion with SIS, and a higher percentage of late pain with TO.

Table 3 describes the number of patients who were reviewed each year, with respect to the total number included in the study.

No significant differences were found between both groups at the 9-year follow-up in relation to objective cure. A tendency to decrease objective healing was observed after the sixth year with TO, while SIS remained at 70% between the fourth and seventh year (Figure 1).

The total continence rate trend´s was to decrease from the fifth year with SIS and from the sixth year with TO. Significant differences were only found between both groups at the third year (p=0.013) (Figure 2).

When evaluating subjective healing through the degree of satisfaction, it remained between 8-10 throughout the follow-up with both bands, but with TO it decreased after the seventh year (Figure 3), without finding significant differences between the two groups.

The score on the ICIQ-SF questionnaire increases with both bands from the fourth year and especially from the seventh, with no significant differences between them (Figure 4).

Improvement after treatment was assessed using the PGI-1 questionnaire, which was maintained throughout follow-up between scores [1-2] (very much better and much better), with no differences between the two bands (Figure 5).

Table 1: Comparison of the type of UI, degree of SUI, number of compresses, previous urodynamic study, associated POP, initial ICIQ-SF, concomitant prolapse surgery and surgery time.

Variable	TO (133)	SIS (138)	p
UI* type			
SUI^ (128)	49 (36.8%)	79 (57.2%)	0,000[a]
MUI[t] (131)	72 (54.1%)	59 (42.8%)	
Hidden (12)	12 (9.1%)	0	
SUI degree			
I ((6)	6 (4.5%)	0	0.006[a]
II (221)	100 (75.2%)	121 (87.7%)	
III (44)	27 (20.3%)	17 (12.3%)	
Number of compresses			
Median (range)	3 (10)	3 (9)	NS[b]
Urodynamic study (34)	14	20	NS[a]
Initial ICIQ-SF: median (range)	15 (21)	16 (11)	0.005[b]
Concomitant prolapse surgery (95)	91 (68.4%)	4 (2.9%)	0.000[c]
Vaginal hysterectomy (39)	39	0	0.000[c]
Anterior colporrhaphy (74)	72	2	0.000[c]
Posterior prolapse mesh (41)	41	0	NS[a]
Manchester (3)	3	0	0.000[c]
Enterocele (5)	5	0	0.027[c]
Ritcher (1)	1	0	NS[a]
Sacrocolpopexy (1)	1	0	NS[a]
Perineorrhaphy (75)	71	4	0.000[c]
Surgery time: median (range) minutes	65 (125)	30 (55)	0.000[b]

* Urinary incontinence, ^ Stress urinary incontinence, [t]Mixed urinary incontinence, [a] Chi-Cuadrado test, NS: not significant, [b] Mann–Whitney U test, [c] Fisher's exact test

Table 2: Complications with TO and SIS, immediate, intermediate and late.

Variable	TO (133)	SIS (138)	p
Immediate complication (29)	17 (12.8%)	12 (8.7%)	NS[a]
Hematoma (3)	0	3	NS[a]
Bladder perforation (2)	2	0	NS[a]
Urinary tract infection (4)	2	2	NS[a]
Bladder retention (15)	11 (8.3%)	4 (2.9%)	0.053[a]
Urinary catheter (6)	4	2	NS[a]
Pain (1)	1	0	NS[a]
Hemorrhage surgery (1)	1	0	NS[a]
Vaginal perforation (5)	2	3	NS[a]
Intermediate complication (15)	7 (5.3%)	8 (5.8%)	NS[a]
Hematoma (3)	1	2	NS[a]
Urinary tract infection (7)	3	4	NS[a]
Bladder retention (3)	2	1	NS[a]
Urinary catheter (2)	1	1	NS[a]
Pain (2)	1	1	NS[a]
Late complication (96)	40 (30.1%)	56 (40.6%)	NS[a]
De novo urinary urgency (35)	11 (8.3%)	24 (17.4%)	0.025[a]
Bladder retention (5)	3	2	NS[a]
Extrusion mesh (8)	3 (2.3%)	5 (3.6%)	NS[a]
Pain (22)	13 (9.8%)	9 (6,5%)	NS[a]
Urethrolysis (3)	3	0	NS[a]
Recurrence SUI (49)	16 (12%)	33 (23.9%)	0.011[a]

NS: not significant, [a] Chi-Cuadrado test

Table 3: Number of patients with a response each year of follow-up.

YEAR OF FOLLOW-UP	TO	SIS
1 year	133	138
2 years	117	131
3 years	97	127
4 years	65	98
5 years	48	66
6 years	41	35
7 years	21	20
8 years	3	4
9 years	1	4

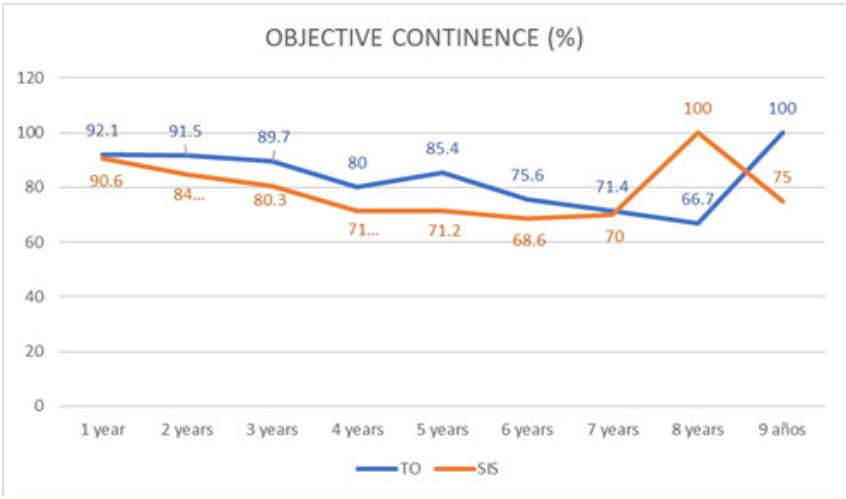

Figure 1: Objective continence (cough test or telephone survey of SUI symptoms) during the follow-up of both groups, TO and SIS.

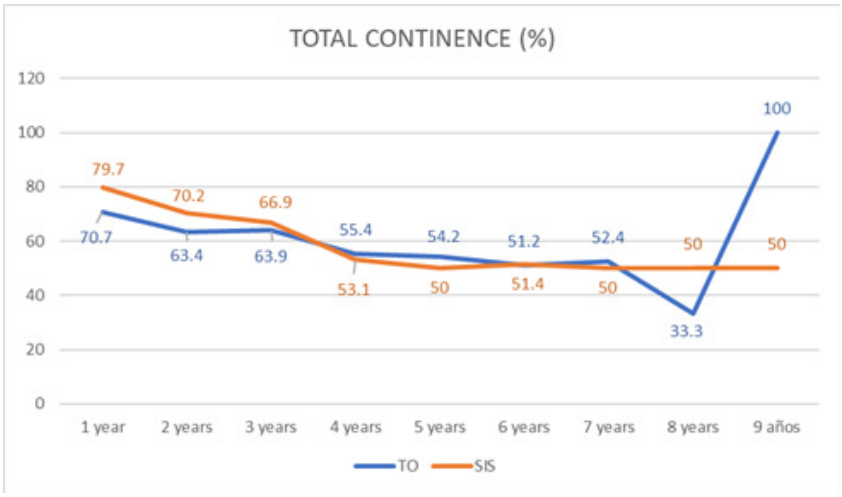

Figure 2: Total continence (stress and urgency) during the follow-up of both groups, TO and SIS.

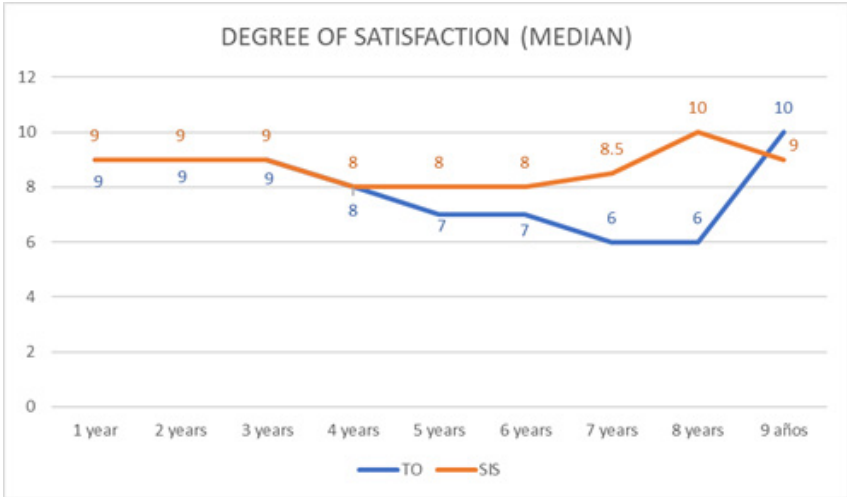

Figure 3: Degree of patient satisfaction during follow-up, after TO and SIS (analog scale between 0-10).

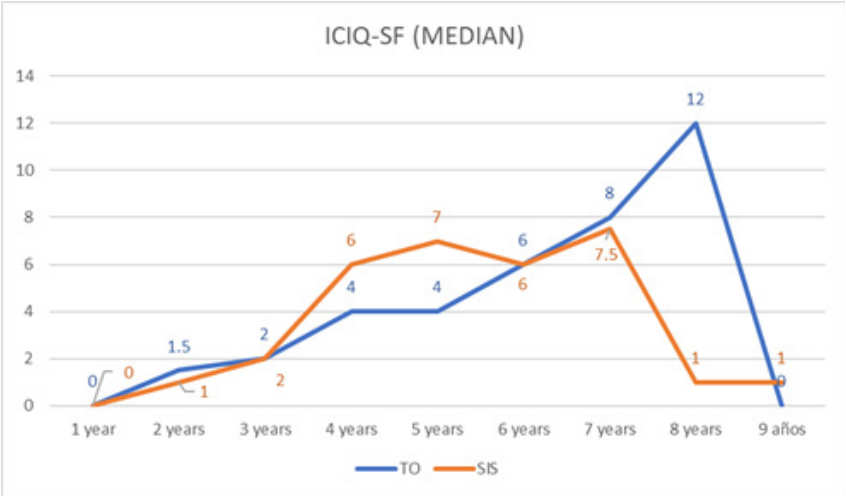

Figure 4: Comparison of the score on the ICIQ-SF questionnaire throughout the follow-up, between both groups.

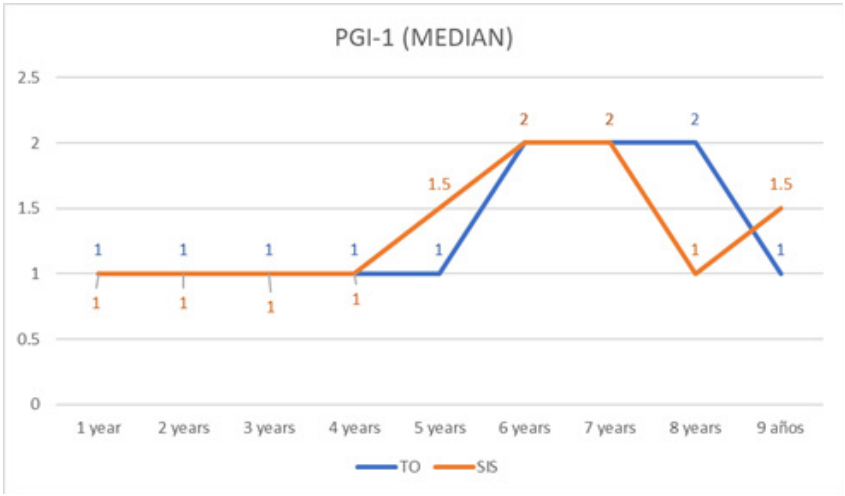

Figure 5: Results of the PGI-1 improvement questionnaire after surgery with TO and SIS, over the years.

5. Discussion

In the last decade, at least a dozen articles have been published comparing SIS bands with TO, of which the vast majority study in-out TO.

These publications focus primarily on comparing objective cure, subjective cure, and surgical complications; and although most of them are randomized clinical trials (RCT), follow-up is usually short-term (1-3 years) [3-12], finding only one RCT at 5 years [13]. Prospective studies at 714 and 1015 years, and one retrospective at 9 years16 have also been reported.

In our sample, the patients in the SIS group were younger (58.4 years vs. 65.6 years, p<0.001) and practiced physical activity more frequently (41.1% vs 19.3%, p<0.001) than those in the TO group. In contrast, a higher percentage of patients operated on with TO presented hypertension (41.3% vs 29.4%, p=0.039), possibly because they were older.

Regarding the type of incontinence, pure SUI was more diagnosed in SIS (63.9% vs 34.9%, p<0.001) and IUM in TO (55.1% vs 36.1%, p<0.001). In both groups, the most frequent SUI Grade was II, but there were significant differences regarding SUI Grade III, which was higher in TO (22.0% vs 9.4%, p=0.001). These differences could also be due to the fact that the patients in the TO group have a higher mean age.

The initial ICIQ-SF score was higher in SIS (16 vs 15, p=0.005), possibly due to their younger age and greater impact of SUI on their quality of life.

Patients with TO associated significantly more concomitant POP surgery of the 3 compartments, compared to SIS. When the surgical indication was a recurrence of SUI, a TO band was inserted more frequently than a SIS band (13.8% vs 0.6%, p<0.001).

The higher frequency of POP surgery associated with OT was due to the fact that, in our center, when a POP requires surgical repair and also corrects an SUI, an OT band is placed in the same act and, exceptionally, an SIS band.

In our setting, SIS bands are inserted in a Major Ambulatory Surgery regimen without admission, with local anesthesia and light sedation, so they are indicated for the treatment of SUI without symptomatic POP.

It is striking how more patients with SIS were operated on between 2014-2017, and since 2019 more TO have been inserted, with a

significant decrease in SIS. In 2019, we carried out a study of recurrences of SUI with SIS at 5 years17, and we verified how they were related to BMI. Since then, we carefully select the candidates for SIS, limiting its indication if BMI ≥30 and between 25-30 we assess other possible risk factors for recurrence (SUI grade, associated pathology...).

Our study reveals that the objective cure rate at 1, 2 and 3 years is high for both bands, but without significant differences (TO vs SIS, 1 year: 90.5%-90.1%, 2 years: 87.3%- 83.1% and 3 years: 89.7%-80.3%); this result is also found by other authors for follow-up at 1 year7,9-11, 2 years [6,8] and 3 years [12]. Some authors report significant differences in objective continence at one year in favor of TO, such as Hinoul4 (TO 97.6% vs SIS 83.6%, p<0.05), Amat3 (TO 90% vs SISI 87.5%, p=0.015) and Hota5 (TO 90.0% vs SIS 47.6%, p<0.05).

We found no significant differences in terms of objective cure between TO and SIS during the 9-year follow-up, but we did find a tendency to worsen after the sixth year for TO and the seventh year for SIS (OT vs SIS, 6 years: 70%- 64.3% and 7 years: 64.3%-50%).

A 5-year RCT13 does not report significant differences in objective continence either, being 82.6% for TO and 68.4% for SIS (p>0.05), very similar figures to ours at 5 years (TO 84.3% and SIS 64.4%, p>0.05).

Our group in a 7-year follow-up publication [14] describes, without significant differences, high objective cure rates for both bands, with a tendency to worsen from the sixth year with TO and the seventh with SIS (TO vs SIS, 6 years: 70 %-64.3% and 7 years: 64.3%-50%).

A 9-year retrospective study, with 68 TO and 54 SIS, also found no significant differences in the objective cure rate [16], and another 10-year prospective design, with 31 TO and 33 SIS, shows a similar objective cure rate between both bands, but greater decrease in success from the second to the tenth year with SIS [15].

When examining total continence, the rates are lower than the objective cure and we found no significant differences between both bands over 7 years. It is striking how drastically it drops after 3 years for TO (59.2%) and after 4 years for SIS (48.2%). We postulate as possible causes, the higher frequency of MUI and older age in women with TO band, and the appearance of de novo urgency as a late complication, more frequent after SIS band than after TO.

The subjective cure rate was evaluated by the degree of satisfaction (visual scale from 0 to 10) and we found no significant differences between bands. The trend describes a high satisfaction during the first 2 years (TO vs SIS, 1 year: 8 and 8.6, 2 years: 7.8 and 7.9) and subsequent progressive decrease, with a greater decrease at the sixth year, but with scores for both bands not under 6 the seventh year.

The reviewed literature also finds no significant differences in subjective healing, assessed by different scales (PGI-I, KHQ, ICIQ-UI, I-QOL, PFDI-20, UDI-6) neither in the short term (1 year3-5.7, 9-11, 2 years6,8 and 3 years12) nor in the medium and long term (5 year13, 7 years14, 9 years6 and 10 years15).

The shorter surgery time associated with SIS in our environment is significant, a finding also reported by Xin10 and Wu16, but in our study, TO women more frequently associated concomitant POP repair, which lengthens surgical time. It could be postulated that the insertion of SIS is faster than TO, due to the less dissection of the paraurethral space that it requires, but some authors do not find differences in these times, such as Grigoriadis8.

The frequency of complications of both procedures did not differ globally or by periods. In a non-significant way, they were more frequent in the immediate period with TO (12.8% vs 8.7%, p>0.05) and in the long term with SIS (40.6% vs 30.1%, p>0.05).

In general, the complications were classified as minor (Clavien-Dindo Grade I and II18), except for 2 major complications with TO (Clavien-Dindo G III): bladder injury and inferior epigastric artery perforation.

In both cases, it is observed how they tend to be more frequent after the month (30.1% TO and 40.6% SIS, p<0.05). Among patients with late complications, we found significant differences in de novo urgency, more frequent with SIS (17.4% vs 8.3%, p=0.023) and in recurrence of SUI, also higher with SIS (23.9% vs 12%, p= 0.011), and in a non-significant way, urethrolysis (9.68% vs 0%, p>0.05), and late pain (9.8% vs 6.5%, p>0.05) with TO, and extrusion of the mesh with SIS (3.6% vs 2.3%, p>0.05).

In general, the reviewed authors do not observe significant differences in relation to complications [6,7,10-12]. Only significantly less postoperative pain [3,4,7,10,12] and a trend towards a higher frequency of de novo urgency7 and extrusion6 of mesh with SIS have been reported.

These findings agree with our results.

A possible limitation of our study would be that we only obtained the results of an TO patient at 9 years.

6. Conclusions

• Although current evidence does not place SIS as the gold standard treatment for SUI, in our study, we did not observe differences between both procedures in objective or subjective cure during the 9-year follow-up.

• For both bands, objective continence is high but we see how it decreases over the years, starting from the sixth year with TO and from the seventh year with SIS.

• The safety of both bands is very high, but there has been a greater risk of de novo urgency and recurrence of SUI with SIS.

• In our environment, SUI is treated with both bands, avoiding SIS in women with a BMI greater than 30 and between [25-30], assessing other possible risk factors for band failure.

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