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SINGLE-INCISION MINI SLING COMPARED WITH TRANSOBTURATOR SLING FOR TREATING STRESS URINARY INCONTINENCE IN WOMEN

By

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ABSTRACT

Background: Stress urinary incontinence (SUI) is a common disorder that affects a large number of women and their quality of life. It is defined as the involuntary leakage of urine on effort or exertion, or on sneezing or coughing according to the standardized terminology of the International Continence Society.

Objective: The aim of this study was to compare both the efficacy and safety of the single-incision mini-sling (SIMS) against the traditional trans-obturator (TOT) sling for the surgical management of SUI in women including; objective and subjective cure rates, patient's satisfaction, and complication rates.

Patients and methods: This study was a prospective, double-blind clinical trial conducted on 100 women complaining of symptoms of stress urinary incontinence, with or without urge incontinence, based on patient complaint, cough stress test and ICIQ-SF score. Attended the outpatient clinic of the Obstetrics and Gynecology Department of Al- Hussein hospital, Al-Azhar University, Cairo, during from March 2016 to March 2019.

Results: Regarding the cough stress test after one year follow up, the number of participants who reported negative results showed continuous progress in group (B) [42 women (89%)] after 38 (79.2%) in 6th month visit. On the other hand, group (A) women showed a little drop [44 women (91.7%)] after 46 (93.9%) in 6th month visit. Yet, the two groups showed insignificant difference at this follow up stage (P= 0.74).

Conclusion: The 1-year follow-up results of this prospective trial indicate that both procedures appear to be equally effective for the treatment of SUI as regard the objective cure rates, whereas the SIMS procedure showed higher subjective cure rates than the TOT procedure.

Keywords: Single-Incision Mini Sling, Transobturator Sling, Stress Urinary Incontinence, Women, clinical trial.

INTRODUCTION

Management options vary between conservative and surgical procedures. Conservative approaches for treatment of stress urinary incontinence (SUI) include pelvic floor exercises, electrical stimulation, laser application and duloxetine therapy. Although there is renewed interest in conservative therapies for stress urinary incontinence, surgery remains the primary choice in managing this condition. Surgical options include paravaginal defect repair, the Marshall-Marchetti-Krantz procedure, open and laparoscopic Burch urethropexy, and sling procedures *(Capobianco et al., 2018)*. As regards sling use, it was found that

midurethral slings techniques achieved high cure rates in women with SUI and have become the mainstay for surgical treatment of SUI in women over the last 2 decades *(Mostafa et al., 2013)*. One of the modalities of such procedures is the transobturator midurethral tape (TOT). It was introduced to minimize the complications of the previous retropubic tapes, which include injury to the bladder, major vessels, and bowel. TOT has shown similar safety and efficacy to Tension-free vaginal tape (TVT) in a recently published randomized trials and meta-analyses *(Novara et al., 2010).*

In an effort to maintain efficacy while eliminating some of the side effects, a new generation of tapes has been developed, called 'single incision tapes or 'mini-slings'. They are designed to be shorter (in length) than standard mid-urethral slings and do not penetrate the tissues as deeply as standard slings. It was therefore thought that they would cause fewer side effects while being effective *(Nambiar et al., 2017).* Single incision tapes have a number of potential advantages that attracted the attention of many surgeons worldwide: shorter length polypropylene mesh, insertion through a single vaginal incision, avoiding both retropubic and groin trajectories (in retropubic tension-free vaginal tape (RP-TVT) and transobturator tension-free vaginal tapes (TO-TVT)); and the ability to perform the procedure under local anaesthesia and therefore a shorter recovery and earlier return to normal activities *(Mostafa et al., 2013).*

The aim of this study was to compare both the efficacy and safety of the single-incision mini- sling against the traditional trans-obturator sling for the surgical management of SUI in women including; objective and subjective cure rates, patient's satisfaction, and complication rates.

PATIENTS AND METHODS

This study was a prospective, double-blind clinical trial conducted on 100 women complaining of symptoms of stress urinary incontinence, with or without urge incontinence, based on patient complaint, cough stress test and ICIQ-SF score. Attended the outpatient clinic of the Obstetrics and Gynecology Department of Al- Hussein hospital, Al-Azhar University, Cairo, during from March 2016 to March 2019.

Ethical consent: An approval of the study was obtained from Al- Azhar University Academic and Ethical Committee. Every patient signed an informed written consent for acceptance of the operation.

Measured Outcome:

The objective cure was defined as a negative cough stress test, and the subjective cure was defined as zero incontinence episodes on the ICIQ-SF. The primary outcome of this study was to test the hypothesis that there was no difference between SIMS and TOT regarding both the objective and the subjective cure rates. The secondary outcome was pain perception (VAS score) and complications incurred at one-year follow up between the two procedures.

Inclusion Criteria:

Women diagnosed with stress or mixed urinary incontinence based on the patient's main complaint of involuntary leakage of urine upon coughing, sneezing,

straining or lifting heavy objects) and/ or urgency were eligible for the study. Stress incontinence had to be the main bothering symptom defined as more episodes of leakage due to coughing or physical exertion than with urgency. Positive cough stress tests with the bladder holding 300 to 400 mL and fulfilling the International Consultation on Incontinence Questionnaire – Short Form (ICIQ-SF) were used to confirm the diagnosis.

Exclusion criteria:

Women with history of previous mid urethral sling procedure, presence of a connective tissue disorders, advanced pelvic organ prolapse (Pelvic Organ Prolapse Quantification. stage 3), residual urine volume >100 mL, previous pelvic radiotherapy, chemotherapy or pregnancy were excluded from the study.

Preoperative Considerations:

All patients were subjected to the following baseline assessment by history, clinical examinations, investigation as well as answering questionnaires.

History Taking: This was carried out to detect the presenting and the dominating symptoms of stress incontinence. The evaluation included age, residency, educational level, menstrual history and obstetric history including obstetrical complications. The past history of diseases which might elevate intra-abdominal pressure as chronic cough and constipation, neurological diseases, medical disorders of significance as diabetes, surgical operations whether abdominal or vaginal and any medications used were considered.

Clinical Examination: All patients were subjected to complete clinical examination including both general and local examinations. In the standing position, the cough stress test was performed at a bladder volume of 300 mL. The results of the cough stress test were considered positive if urine leakage occurred with a cough or negative if no urine leakage was seen and the bladder volume was recorded.

Preoperative Laboratory Investigations: Blood samples were drawn from each patient in the study as a routine preoperative protocol. Blood tests were; complete blood count (CBC), liver function tests, renal function tests, fasting and 2 hours- postprandial blood sugar and coagulation profile. Moreover, a midstream urine samples were collected for analysis and culture if needed. Also, an ECG was requested for each patient older than 35 years old for anesthetic purposes.

Randomization: On the day of surgery, all women were randomized into two groups; the first group were subjected to the single-incision mini-sling; (SIMS) Altis sling (Coloplast Corp, Minneapolis Minnesota, USA) and the second had the standard trans-obturator tape; (TOT) (Obtryx II Transobturator Sling System - Halo— Boston Scientific, Natick, MA, USA) using a computer- generated block randomization sequence, with allocation to each group being performed via a series of opaque envelopes.

Surgical Procedures: All surgeries were performed by a single surgeon (A.E.). Prior to surgery, parenteral antibiotics were injected (1.5 gm Ampicillin/ Sulbactam or 80 mg Gentamicin).

Following induction of anesthesia (whether general or spinal) the patients were carefully placed in a slightly exaggerated dorsal lithotomy position with appropriate pressure points adequately padded. The operative field was cleaned with a standard antiseptic agent and draped, with care being taken to keep the groin folds in the operative field. A 14-Gauge urethral catheter was inserted into the bladder and the bladder was emptied.

The surgical procedure was performed either alone or in combination with other surgical procedures e.g. anterior colporrhaphy, posterior colpoperineorrhaphy or perineal repair. Diagnostic cystoscopy was not routinely performed.

Duration of anti-incontinence surgery was recorded dependently from other concomitant procedure. Any complications were recorded and managed accordingly.

Surgical technique of SIMS:

The Altis sling is made of a 0.8mm diameter monofilament polypropylene mesh, knitted into a sling 1. 1 cm wide by 7.75 cm long. One end of the sling assembly connects to a short length of USP size I monofilament polypropylene suture and to a polypropylene static (non-tensioning) anchor. Whereas, the second side of the sling assembly terminates to a longer section of USP size I monofilament polypropylene suture. This suture is then positioned through the second anchor that is dynamic with an integrated tensioning system. The tensioning capability is accomplished by threading the suture through a polyurethane tensioning collar which is assembled onto the anchor. The anchor/suture assembly wraps around the anchor, resulting in a gap between the anchor and the collar providing constant pressure on the suture, preventing it from moving on its own, or during a pelvic stress event. Tensioning is achieved by pulling on the suture loop, thus applying increased tension of the sling to the urethra until desired support is achieved. The Altis anchors perform an acute mechanical role of maintaining the desired position and tension through the acute post- operative tissue healing and in-growth phase (Adopted from Altis single-incision sling system product brochure, Coloplast).

Surgical technique of TVT-O:

The Obtryx Sling System - Halo is a sterile, single use system consisting of a polypropylene knitted mesh protected by a disposable plastic sleeve. At the distal ends of the mesh assembly there are association loops designed to be placed in the needle slot of the distal end of the delivery device. The disposable delivery device consists of a handle with a stainless steel needle. The needle is designed to facilitate the passage of the mesh assembly through bodily tissues for placement through the obturator foramen (Adopted from Obtryx™ -Transobturator Mid-Urethral Sling System, Product Review for the Purchasing Committee).

Post-Operative Care and Follow-Up:

Post operatively, vital signs, vaginal bleeding or hematomas were monitored and recorded. Pain was assessed by Visual Analogue Scale (VAS) which is a continuous scale comprised of a horizontal (HVAS) or vertical (VVAS) line, 10 centimeters (100 mm) in length, anchored by 2 verbal descriptors, one for

each symptom extreme. Hospital discharge occurred 24-h after surgery after three spontaneous micturitions with post voiding residual (PVR) <100 ml evaluated by ultrasound and/ or catheterization.

Complications were managed accordingly. Intraoperative bladder injury was managed by urgent cystoscopy and repair of injured site by Vicryl 2/0 sutures if needed. Transurethral bladder drainage by Foley catheter was maintained for 7 days postoperatively. In case of hematoma, it was evacuated and the feeding vessel was secured. The procedure was postponed for another sitting and the case was excluded from the study. Follow-up visits were scheduled by a physician not involved with the surgeries. Follow-up were at day 7, and then 1, 3, 6, and 12 months after the procedure. On the 7th day visit, a brief history of the patient pain profile, fever, inability to void easily, frequency, urgency, dysuria, leakage of urine with cough and appearance of vaginal discharge were discussed and recorded. Examination of signs of inflammation or infection with cough stress test and post voiding residual were assessed and recorded.

The 1st, 3rd, 6th and 12th - month follow up visits aimed to ask the patients about the modifications in voiding habits regarding number of micturitions, incontinence episodes during the day, pain score (VAS) and if they faced voiding difficulties coinciding with fulfilling of (ICIQ-SF). Moreover, a cough stress test was performed as an objective measure for surgical success. All the data was collected in a specially designed sheet for each patient.

Statistical Analysis:

The collected data were coded, processed and analyzed using the SPSS (Statistical Package for Social Sciences) version 22 for Windows® (IBM SPSS Inc, Chicago, IL, USA). For quantitative data, the Shapiro-Wilk test for normality was performed. For normally distributed data, values were expressed as mean ± standard deviation and Independent Samples T test was performed for comparison between two groups. For data that were not normally distributed median and interquartile range (expressed as 25th-75th percentiles) were calculated and Mann-Whitney test was used for comparison between the two groups and Friedman's two-way analysis of variance for repeated measurements. As regards qualitative data, they were represented as frequency (number and percentage) and either Pearson's Chi square test for independence, Fisher’s exact test or Fisher- Freeman-Halton exact test was used to examine association between two variables. Significance was adopted at $p < 0.05$ for interpretation of results of tests. Independent-samples t-test of significance was used when comparing between two means. Chi-square (x2) test of significance was used in order to compare proportions between two qualitative parameters. The confidence interval was set to 95% and the margin of error accepted was set to 5%. P value < 0.05 was considered significant.

RESULTS

In total, 100 women fulfilled the inclusion criteria. They were randomly divided in two groups whereas group (A) was subjected to SIMS insertion, while the second group (B) was subjected to TOT for the treatment of stress urinary incontinence. During the study, some patients missed the follow up visits; consequently, they were excluded from the study if two consecutive visits were missed **(Figure 1)**.

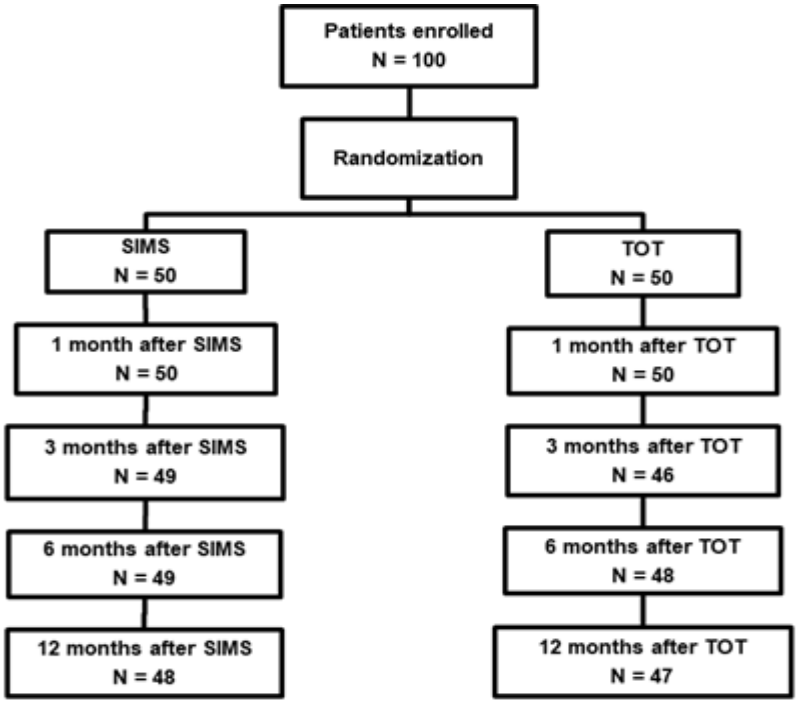

Figure (1): Flow-chart of study population. SIMS, single-incision mid-urethral sling; TOT, trans- obturator tape.

The socio-demographic data of the studied groups regarding age, residence, occupation and education level showed insignificant difference between both groups.

The age of women included in this study ranged between 27 and 65 years with a mean of 46.3± 10.5 years. This mean was 44.3 years in group (A) (SIMS procedure) while 48.3 years in group (B) (TOT procedure) without any statistically significance (P= 0.057). There was nearly equal distribution of women regarding their residency either from urban areas 56% or rural areas 44% (p= 0.17). The great majority of women on both groups had no jobs (90 %). Despite ranging from 86% in group (A) to 94% in group (B), however, this was statistically insignificant. According to educational level, the highest percentage of the studied groups was in women with mid- level of education in both group A and B (56.0% & 54.0 % respectively) followed by those with high education (26 % in both groups). While, the lowest percentage of educational level was about 19% in both groups. Most of the studied women were non- smokers; representing about 92% in group (A) and 94% in group (B). Otherwise, other special habits were irrelevant **(Table 1)**.

Table (1): Descriptive data of the 100 women participating in the two study groups

Variables \ Groups		TOT (n = 50)		SIMS (n = 50)		Total (n = 100)		p
Age	**Min- Max**	30.0 - 65.0		257.0 - 65.0		27.0 - 65.0		0.057
	Mean ± SD	48.3 ± 10.8		44.3 ± 9.8		46.3 ± 10.5		
Residency	**Urban**	32	64.0%	24	48.0%	56	56.0%	0.107
	Rural	18	36.0%	26	52.0%	44	44.0%	
Occupation	**Working**	3	6.0%	7	14.0%	10	10.0%	0.182
	Not working	47	94.0%	43	86.0%	90	90.0%	
Educationallevel	**Illiterate**	12	24.0%	7	14.0%	19	19.0%	0.377
	Mid-level	27	54.0%	28	56.0%	55	55.0%	
	High level	11	22.0%	15	30.0%	26	26.0%	
Special habits	**None**	47	94.0%	46	92.0%	93	93.0%	0.695
	Smoker	3	6.0%	4	8.0%	7	7.0%	

The duration of hospital stay was almost 24 hours after surgery in most of cases (88% in group (A) and 84% in group (B)). Only 6 women in group (A) (12%) and 8 women in group (B) (16%) needed more than 24 hours (P= 0.564).

Regarding post-operative groin pain (first day), it ranged from 3 to 7 on the visual analogue scale (VAS) with a mean of 4.7 ± 1.2 in group (A) and from 4 to 7 with a mean of 5.5 ± 1.1 in group (B) which represented a statistically significant difference (P=0.001) as shown in table (2).There was no statistically significant difference between both groups regarding; cough stress test, post-voiding residual urine and urine retention (P= 0.207, 0.893 and 0.692, respectively).

Eleven women from group (A) and nine from group (B) complained early postoperative partial urinary outlet obstruction, leading to increased residual bladder volume (>100 mL). This was treated using intermittent bladder catheterization for up to 1 week **(Table 2)**.

Table (2): Comparison between both studied groups as regard post-operative complications and hospital stay

Variables \ Groups		TOT (n = 50)		SIMS (n = 50)		Total (n = 100)		p
Pain 1 (VAS)	**Min- Max**	4.0 - 7.0		3.0 - 7.0		3.0 - 7.0		0.001*
	Mean ± SD	5.5 ± 1.1		4.7 ± 1.2		5.1 ± 1.2		
Cough stress test 1	**Positive**	23	46.0%	17	34.0%	40	40.0%	0.207
	Negative	22	44.0%	30	60.0%	52	52.0%	
	Cath	5	10.0%	3	6.0%	8	8.0%	
Post Voiding residual1	**Less 100**	35	70.0%	36	72.0%	71	71.0%	0.893
	More 100	10	20.0%	11	22.0%	21	21.0%	
	Catheter	5	10.0%	3	6.0%	8	8.0%	
Hospital Stay	**24 hrs**	42	84.0%	44	88.0%	86	86.0%	0.564
	> 24 hrs	8	16.0%	6	12.0%	14	14.0%	
Urine retention 1	**Positive**	9	18.0%	11	22.0%	20	20.0%	0.692
	Negative	36	72.0%	36	72.0%	72	72.0%	
	Catheter	5	10.0%	3	6.0%	8	8.0%	

One week post-operatively, the statistically significant difference in the level of the groin pain (VAS) was still existed between the two groups (despite much improvement) with a mean of 2.2 ± 1.5 for group (A) and 3.6 ± 1.7 for group (B) (P= <0.001). Additionally, the presence of groin pain itself showed extreme variability between the two groups (6% in group (A) compared to 70% in group (B)) (P= <0.001) as shown in table (3).Moreover, there was no statistically significant difference between both groups regarding; cough stress test, post-voiding residual urine, excessive vaginal discharge, subjective emptying problems, urge incontinence and wound infection (P> 0.05).

Variable degrees of urge incontinence were presented among women in both groups. Six women in group (A) and four women in group (B) were prescribed medications due to severe urge incontinence **(Table 3)**.

Table (3): Comparison between both studied groups as regard one-week post-operative pain score and complications

Variables \ Groups		TOT (n = 50)		SIMS (n = 50)		Total (n = 100)		p
Pain 2 (VAS)	**Min- Max**	0.0 - 6.0		0.0 - 5.0		0.0 - 6.0		<0.001
	Mean ± SD	3.6 ± 1.7		2.2 ± 1.5		2.9 ± 1.7		
Cough stress test 2	**Positive**	23	46.0%	20	40.0%	43	43.0%	0.545
	Negative	27	54.0%	30	60.0%	57	57.0%	
Post Voiding residual 2	**Less 100**	40	80.0%	42	84.0%	82	82.0%	0.603
	More 100	10	20.0%	8	16.0%	18	18.0%	
	Absent	32	64.0%	45	90.0%	77	77.0%	
Vaginal discharge	**Excessive**	16	32.0%	20	40.0%	36	36.0%	0.405
	Usual	34	68.0%	30	60.0%	64	64.0%	
Subjective emptying problems 2	**Present**	7	14.0%	9	18.0%	16	16.0%	0.585
	Absent	43	86.0%	41	82.0%	84	84.0%	
Urge incontinence 2	**Present**	21	42.0%	18	36.0%	39	39.0%	0.539
	Absent	29	58.0%	32	64.0%	61	61.0%	
Groin Pain 2	**Present**	35	70.0%	3	6.0%	38	38.0%	<0.001
	Absent	15	30.0%	47	94.0%	62	62.0%	
Wound infection 2	**Present**	6	12.0%	5	10.0%	11	11.0%	0.749
	Absent	44	88.0%	45	90.0%	89	89.0%	

Follow up was performed at 1st, 3rd, 6th and 12th month. At these recalls, the participants were asked to fill the ICIQ-SF about persistent urinary stress incontinence, amount of leaked urine, interference with everyday life, difficulties in micturition i.e. voiding dysfunction, urgency and other OAB symptoms and changes occurred in voiding habits.

Both the cough stress test (objective cure) and the ICIQ-SF score (subjective cure) were statistically insignificant for both groups in the first month (P= 0.205 and 0.110) **(Table 4)**.

Table (4): Comparison between both studied groups as regard post-operative urinary symptoms and pain scores at the 1st month follow up

Variables \ Groups		TOT (n = 50)		SIMS (n = 50)		Total (n = 100)		P
Cough stress test 1m (objectivecure)	**Positive**	20	40.0%	14	28.0%	34	34.0%	0.205
	Negative	30	60.0%	36	72.0%	66	66.0%	
ICIQ-SF score 1m	**Min-Max**	0.0 - 21.0		0.0 - 18.0		0.0 - 21.0		0.110
	Median(IQR)	9.0 (0.0-11.0)		5.0 (0.0-10.0)		8.0 (0.0-10.5)		
	Mean rank	55.0		46.0				
ICIQ question 3--1m	**Never**	16	32.0%	20	40.0%	36	36.0%	0.106
	once/week	5	10.0%	6	12.0%	11	11.0%	
	2-3 times/week	16	32.0%	19	38.0%	35	35.0%	
	Daily	5	10.0%	5	10.0%	10	10.0%	
	Several	2	4.0%	0	0.0%	2	2.0%	
	All time	6	12.0%	0	0.0%	6	6.0%	
Number of Micturitions per day 1m	**Min-Max**	5.0 - 8.0		5.0 - 8.0		5.0 - 8.0		0.013
	Mean ± SD	6.8 ± 0.9		6.4 ± 0.9		6.6 ± 0.9		
Incontinence episodes per day 1m	**Min-Max**	0.0 - 6.0		0.0 - 5.0		0.0 - 6.0		0.080
	Median(IQR)	1.0 (0.0-4.0)		1.0 (0.0-2.0)		1.0 (0.0-2.5)		
	Mean rank	55.4		45.6				
Groin Pain 1m	**Present**	27	54.0%	0	0.0%	27	27.0%	<0.001
	Absent	23	46.0%	50	100.0%	73	73.0%	
Post Voiding residual 1m	**Less 100**	46	92.0%	47	94.0%	93	93.0%	1.000
	More 100	4	8.0%	3	6.0%	7	7.0%	
Subjective emptying problems 1m	**Present**	0	0.0%	0	0.0%	0	0.0%	1.000
	Absent	0	0.0%	0	0.0%	0	0.0%	

At the third month, the cough stress test (objective cure) showed statistically significant difference between both groups (89.8% negative test in group (A) compared to 67.4% in group (B) (P= 0.007) as shown in table (5). The ICIQ-SF score (subjective cure), however; was statistically insignificant for both groups as shown in table (5).Persistently, the frequency of micturition before and after surgery in both groups represented a statistically significant difference at the third month. Moreover, the percentage of women experienced groin pain in group (B) shrunk to 45.7%, though, the statistically significant difference was still presented **(Table 5)**.

Table (5): Comparison between both studied groups as regard post-operative urinary symptoms and pain scores at the 3rd month follow up

Variables \ Groups		TOT (n = 46)		SIMS (n = 49)		Total (n = 95)		p
Cough stress test 3 (objective cure)	**Positive**	15	32.6%	5	10.2%	20	21.1%	0.007
	Negative	31	67.4%	44	89.8%	75	78.9%	
ICIQ-SF score 3	**Min-Max**	0.0 - 21.0		0.0 - 18.0		0.0 - 21.0		0.194
	Median (IQR)	4.0 (0.0-10.0)		0.0 (0.0-8.0)		4.0 (0.0-8.0)		
	Meanrank	51.6		44.6				
ICIQ question 3—3	**Never**	16	34.8%	25	51.0%	41	43.2%	0.003
	once/week	14	30.4%	6	12.2%	20	21.1%	
	2-3 times/week	6	13.0 %	12	24.5%	18	18.9%	
	Daily	2	4.3%	6	12.2%	8	8.4%	
	Several	2	4.3%	0	0.0%	2	2.1%	
	All time	6	13.0%	0	0.0%	6	6.3%	
Number of micturitions per day 3	**Min-Max**	5.0 - 8.0		6.0 - 9.0		5.0 - 9.0		0.001
	Mean ± SD	6.7 ± 0.9		7.4 ± 0.9		7.1 ± 1.0		
Incontinence episodesper day 3	**Min-Max**	0.0 - 6.0		0.0 - 4.0		0.0 - 6.0		0.215
	Median (IQR)	1.0 (0.0-2.0)		1.0 (0.0-1.0)		1.0 (0.0-1.0)		
	Meanrank	51.4		44.8				
Groin Pain 3	**Present**	21	45.7%	0	0.0%	21	22.1%	<0.001
	Absent	25	54.3%	59	100.0%	74	77.9%	
Post Voiding residual3	**Less 100**	46	100.0%	46	93.9%	92	96.8%	0.243
	More 100	0	0.0%	3	6.1%	3	3.2%	
Subjective emptying problems 3	**Present**	3	6.5%	3	6.1%	6	6.3%	1.000
	Absent	43	93.5%	46	93.9%	89	93.7%	

The sixth month follow-up:

At this visit, the proportion of women experienced negative cough stress test (objective cure) continued to rise in both groups. Despite the bounce in group (B) percentage (79.2% after 67.4% at the third month) compared to group (A) rise (93.3% after 89.8% at the previous visit), yet there was statistically significant difference between both groups (P= 0.033).

Simultaneously, the ICIQ-SF score (subjective cure) showed lower results than the previous visit for both groups, yet, without significant difference in both groups (P= 0.165).

Additionally, a statistically significant difference occurred between the two groups regarding the incontinence episodes per day with an inter quartile range (IQR) of (0.0-0.0) for group (A) and (0.0-2.0) for group (B) (P= 0.037).

Regarding the groin pain, the percentage of women experienced such pain continued to drop in group (B) with time and the statistically significant difference between the two groups was still presented (P <0.001) **(Table 6)**.

Table (6): Comparison between both studied groups as regard post-operative urinary symptoms and pain scores at the 6th month follow up

Variables \ Groups		TOT (n = 48)		SIMS (n = 49)		Total (n = 97)		p
Cough stress test (objective cure) 6	**Positive**	10	20.8%	3	6.1%	13	13.4%	0.033
	Negative	38	79.2%	46	93.9%	84	86.6%	
ICIQ-SF score 6	**Min-Max**	0.0 – 18.0		0.0 – 16.0		0.0 – 18.0		0.165
	Median(IQR)	0.0 (0.0-6.0)		0.0 (0.0-0.0)		0.0 (0.0-6.0)		
	Mean rank	50.6		44.3				
ICIQ question 3-6	**Never**	34	70.8%	38	77.6%	72	74.2%	0.301
	once/week	3	6.3%	6	12.2%	9	9.3%	
	2-3 times/week	3	6.3%	1	2.0%	4	4.1%	
	Daily	5	10.4%	4	8.2%	9	9.3%	
	Several	3	6.3%	0	0.0%	3	3.1%	
	All time	0	0.0%	0	0.0%	0	0.0%	
Number of Micturitionsper day 6	**Min- Max**	6.0 - 8.0		5.0 - 8.0		5.0 - 8.0		0.591
	Mean ± SD	6.9 ± 0.8		7.0 ± 1.1		6.9±1.0		
Incontinence episodes per day 6	**Min-Max**	0.0 - 4.0		0.0 - 4.0		0.0 - 4.0		0.037
	Median(IQR)	0.0 (0.0-2.0)		0.0 (0.0-0.0)		0.0 (0.0-1.0)		
	Mean rank	53.7		44.4				
Groin Pain 6	**Present**	19	39.6%	0	0.0%	19	19.6%	<0.001
	Absent	29	60.4%	49	100.0%	78	80.4%	
Post Voiding residual 6	**Less 100**	48	100.0%	49	100.0%	97	100.0%	NA
	More 100	0	0.0%	0	0.0%	0	0.0%	
Subjective emptying problems 6	**Present**	3	6.3%	3	6.1%	6	6.2%	1.000
	Absent	45	93.8%	46	93.9%	91	93.8%	

- **The twelfth month follow-up:**

Regarding the cough stress test after one year follow up, the number of participants who reported negative results showed continuous progress in group (B) (42 women (89%) after 38 (79.2%) in 6th month visit). On the other hand, group (A) women showed a little drop (44 women (91.7%) after 46 (93.9) in 6th month visit). Yet, the two groups showed insignificant difference at this follow up stage (P= 0.74).

Contrarily, there were significant difference between the two groups regarding; ICIQ-SF score, the episodes of incontinence and the groin pain (P= 0.019, 0.015 and <0.001, respectively) **(Table 7)**.

Table (7): Comparison between both studied groups as regard post-operative urinary symptoms and pain scores at the 12th month follow up

Variables \ Groups		TOT (n = 47)		SIMS (n = 48)		Total (n = 95)		p
Cough stress test (objective cure) 12	**Positive**	5	10.6%	4	8.3%	9	9.5%	0.740
	Negative	42	89.4%	44	91.7%	86	90.5%	
ICIQ-SF score 12	**Min-Max**	0.0 - 18.0		0.0 - 16.0		0.0 - 18.0		0.019
	Median (IQR)	0.0 (0.0-5.0)		0.0 (0.0-0.0)		0.0 (0.0-4.0)		
	Mean rank	53.1		43.0				
ICIQ question 3-12	**Never**	30	63.8%	41	85.4%	71	74.7%	0.009
	once/week	4	8.5%	3	6.3%	7	7.4%	
	2-3 times/week	5	10.6%	3	6.3%	8	8.4%	
	Daily	8	17.0%	0	0.0%	8	8.4%	
	Several	0	0.0%	1	2.1%	1	1.1%	
	All time	0	0.0%	0	0.0%	0	0.0%	
Number of micturitions per day 12	**Min- Max**	6.0 - 9.0		5.0 - 8.0		5.0 - 9.0		0.392
	Mean ± SD	7.3 ± 0.7		7.1 ±1.0		7.2 ±0.9		
Incontinence episodes per day 12	**Min-Max**	0.0 - 4.0		0.0 - 4.0		0.0 - 4.0		0.015
	Median (IQR)	0.0 (0.0-1.0)		0.0 (0.0-0.0)		0.0 (0.0-1.0)		
	Mean rank	53.3		42.8				
Groin Pain 12	**Present**	12	25.5%	0	0.0%	12	12.6%	<0.001
	Absent	35	74.5%	48	100.0%	83	87.4%	
Post Voiding residual 12	**Less 100**	47	100.0%	48	100.0%	95	100.0%	NA
	More 100	0	0.0%	0	0.0%	0	0.0%	
Subjective emptying problems 12	**Present**	3	6.4%	0	0.0%	3	3.2%	0.117
	Absent	44	93.6%	48	100.0%	92	96.8%	

DISCUSSION

After fulfilling the inclusion criteria, there was no significant difference between both groups (SIMS as group (A) and TOT as group (B)) regarding the mean age of the participants (46.3± 10.5 years) which was in agreement with *Rudnicki et al. (2017)* and *Basu and Duckett (2010)*. In parallel, a slight increase in mean age was found in a study by *Chang et al. (2015)* with a mean age of 59.9 years. There was significant association of increasing age and presence of urinary incontinence in women *(Agarwal and Agarwal, 2017)*.

Additionally, there were no statistically significant differences between the two groups regarding the other personal descriptive parameters such as the women's weight, height, body mass index, parity and menopausal status. This was also the case in *Chang et al. (2015), Rudnicki et al. (2017)* and *Neuman et al. (2011)* studies.

Regarding the women main complaint, the principle symptom in both groups was leakage of urine with cough or sneezing (97%) and only 3 women in group (B) reported both urgency and involuntary leakage. This was statistically insignificant between both groups. In the contrary, the mixed urinary incontinence represented up to 23.9% in the study *Rudnicki et al. (2017)* and rose up to 58% in *Bianchi-Ferraro et al. (2013)* study. In our study, we preferred to prescribe medical treatment -initially- for women complaining of mixed urinary incontinence in order to reduce the bias and the heterogeneity of results, especially, the ICIQ-SF scores. Specially, this trend was recommended by *NICE Guideline (2019).*

The local examination of the studied women showed non-significant difference between both groups. There was an agreement to exclude women needing extensive concomitant surgery in order not to add bias in the results of the study. The duration of the studied procedure was calculated separately from other concomitant surgery if indicated.

As it was the main inclusion criterion in our study, all women presented with positive cough stress test, and this was in accordance with *Kocjancic et al. (2014)*.

Conversely, women included in our study reported a mean of 5.2 ± 0.4 to 5.4 ± 0.8 visits to the bathroom for micturition (group (A) and (B), respectively). These figures were quite higher in other studies, where number of micturition's per day reached a mean of 7.2± 2.2 *Rudnicki et al. (2017)*. This difference may be attributed to increased percentage of women complaining mixed incontinence in Rudnicki's trial (23.9% rather than 16% in our study) which necessitate more frequent bathroom visits due to urgency.

In our study, a statistically significant difference was found between both groups regarding the duration of the procedure. While it ranged between 12 to 17 minutes in SIMS group with a mean of 14.1 ±1.4 minutes, it reached 15 to 22 minutes with a mean of 17.7 ± 2.0 in TOT group. The SIMS was superior to TOT in terms of shorter operative time in many trials *Chang et al. (2015)* and *Rudnicki et al. (2017)*.

In the contrary, in a study by *Neuman et al. (2011),* there was no difference between the groups regarding the duration of the procedure.

This study aimed to compare the safety between the two tapes SIMS and TOT. Though, we failed to find a significant difference between the two groups regarding surgical complications. This finding was in agreement with *Chang et al. (2015), Neuman et al. (2011)* and *Rudnicki et al. (2017)*. Unsurprisingly, the encountered complications in most of studies – including the current study- were mostly in the form of bladder injury in case of TOT and localized hematomas in case of SIMS *(Minaglia et al., 2010)*. Consequently, the SIMS was produced to

reduce such morbidity *(Morán et al., 2019)*.

Regarding post-operative groin pain, the current study showed a statistically significant difference in favor of SIMS with VAS scores around 5/10. Other studies proved the same results regarding both vaginal and thigh pain, with scores higher than 5/10 in TOT rather than SIMS (16). Moreover, even in low scores (VAS scores 3/10), the pain scores were still lower with SIMS than with the TOT procedure *(Neuman et al., 2011)*.

Conversely, no significant difference in VAS scores between the two procedures was found after each postoperative follow-up in other trials *(Chang et al., 2015)*.

Regarding other one-week post-operative parameters, there were no statistically significant differences between both groups regarding; cough stress test, post-voiding residual urine, excessive vaginal discharge, subjective emptying problems, urge incontinence and wound infection. These findings came in accordance with other studies by *Neuman et al. (2011)*, *Rudnicki et al. (2017)* and the systematic review and meta- analysis by *Mostafa et al. (2014)*.

Most of the studies scheduled the follow up visits at 3rd, 6th and 12th months. Contrarily, the first month follow-up was added in this study. There was a statistically significant difference between the frequencies of micturition before and after surgery in both groups and this trend was resulted from the advice of increasing the frequency of micturition as a sort of bladder training. Additionally, the percentage of women experienced groin pain in group (B) outnumbered their counterparts in group (A).

Regarding the objective and subjective cure rates at the third month, the cough stress test (objective cure) showed statistically significant difference between both groups despite that the ICIQ-SF score (subjective cure) failed to achieve the same result. These differences were quite different from those of *Rudnicki et al. (2017)* which showed no difference between the groups.

Regarding the safety (complication rates), the percentage of women experienced groin pain in group (B) continued to decrease, though, the statistically significant difference was still presented.

The objective cure rate continued to rise in both groups. Yet, there was statistically significant difference between both groups (93.3% in SIMS compared to 79.2% in TOT). Conversely, these results were totally different from those in both *Chang et al. (2015)* and *Basu and Duckett (2010)* studied which showed better results in favor of non-SIMS tapes. However, in another non-comparative studies, the cough stress test was negative for up to (92.2%) of cases at 6 months using the same SIMS as the current study *Kocjancic et al. (2014)*.

Regarding the cough stress test (objective cure), no significant difference was found between the two groups after one-year follow-up. The TOT group showed continuous progress to achieve 89% against 91.7% in SIMS group. These statistics were in agreement with *Rudnicki et al. (2017)* who found equal objective cure rate in both groups.

Consequently, regarding the objective cure measure, there were insignificant differences between the two groups in the absolute risk reduction (ARR) (2.3%, CI: 0 – 15.28%, p = 0.555), relative risk (RR) (0.78, CI: 0.22 – 2.74, p = 0.702) and relative risk reduction (RRR) (0.22, CI: 0 – 0.78, p = 0.271). This calculation was in agreement with *Rudnicki et al. (2017)*, where relative risks (RR) calculation indicated no difference between the two groups regarding objective [RR 0.938, 95% confidence interval (CI) 0.705–1.249, p = 0.691; no leakage vs. leakage]and subjective cure rate (RR 0.88; 95% CI 0.696– 1.112, p = 0.627; never leakage vs. any leakage).

However, regarding the subjective cure measure (ICIQ-SF score), a significant difference was found between both groups in ARR (21.6%, CI: 4.1 – 37.7%, p = 0.012), RR (0.4, CI: 0.2 – 0.9, p = 0.023) and RRR (0.60, CI: 0.12 – 0.82, p = 0.001).

This unexplained difference between both the subjective and objective cure rates in each group might be attributed to the definition of cure and the individual expectations between the research team and the candidates as reported by *Hilton and Robinson (2011).*

Moreover, in accordance with *Chang et al. (2015)*, women in the SIMS group had less frequency of intent to treat than those in the TOT group. Whereas, this figure was 43 based upon objective cure, it dropped to only 5 women needed to be treated based upon subjective cure measure.

After one year follow up, the post-operative pain profile was significantly lower in the SIMS group than the TOT group. This is because that the standard TOT requires three incisions (one vaginal, two in the groin) and the passage of trocars through adductor muscles which is not presented in SIMS *(Chang et al., 2015)*. This difference in pain perception was in agreement with most of previous studies *Chang et al. (2015), Mostafa et al. (2014)* and *Rudnicki et al. (2017)*.

Regarding other far complications, no reports were found of mesh erosion, or foreign body sensation through 12 months. These data were in agreement with *Kocjancic et al. (2014)*.

CONCLUSION

The 1-year follow-up results of this prospective trial indicate that both procedures appear to be equally effective for the treatment of SUI as regard the objective cure rates, whereas the SIMS procedure showed higher subjective cure rates than the TOT procedure. Regarding pain perception, the SIMS showed less post- operative groin pain compared to the TOT.

Moreover, the operative time was shorter in the SIMS compared to the TOT. Both procedures were associated with a similar incidence of perioperative and postoperative complications. Overall complication rates were also similar, with the exception of groin pain.

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إستخدام الشريط الأصغر أحادي الشق مقارنة بإستخدام شريط عبر الثقبة السدادية لعلاج سلس البول الإجهادى لدى السيدات

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خلفية البحث: يعد سلس البول الإجهادي من الأمراض شائعة الحدوث بين السيدات لاسيما وانه يؤثر على حياتهن الصحية والاجتماعية. ويعرف هذا النوع من السلس البولي على أنه تسرب البول–لا إراديأً- عند بذل مجهود، أو عند العطس أو السعال. ويصيب هذا النوع حوالي 4٪ من النساء الذين تتراوح أعمارهم بين 20 و24 سنة وترتفع هذه النسبة لتصل إلى 35 ٪ في النساء اللاتي تجاوزن سن الأربعين.

الهدف من البحث: هو مقارنة فعالية وسلامة الشريط الأصغر أحادي الشق بشريط عبر الثقبة السدادية كحل جراحي لعلاج سلس البول الإجهادي لدي السيدات بما في ذلك؛ معدلات الشفاء سواء اكلينيكياً أو التحسن التي قد تقره السيدات بعد الجراحة وكذلك معدلات حدوث المضاعفات.

المريضات وطرق البحث: كانت هذه الدراسة تجربة سريرية مستقبلية مزدوجة التعمية أجريت على 100 امرأة يشكون من أعراض سلس البول الإجهادي، مع أو بدون سلس البول الإلحاحي، بناءً على شكوى المريض، واختبار إجهاد السعال ودرجة (ICIQ-SF)، حضور إلي العيادة الخارجية لقسم أمراض النساء والولادة بمستشفى الحسين، جامعة الأزهر، القاهرة، خلال الفترة من مارس 2016 إلى مارس 2019.

نتائج البحث: فيما يتعلق باختبار إجهاد السعال بعد عام واحد من المتابعة، أظهر عدد المشاركين الذين أبلغوا عن نتائج سلبية تقدمًا مستمرًا في المجموعة (ب) [42 امرأة (89٪)] بعد 38 (79.2٪) في زيارة الشهر السادس. من ناحية أخرى، أظهرت نساء المجموعة (أ) انخفاضًا طفيفًا [44 امرأة (91.7٪)] بعد 46

(93.9٪) في زيارة الشهر السادس. ومع ذلك ، أظهرت المجموعتان اختلافًا ضئيلًا في مرحلة المتابعة هذه (P = 0.74).

الاستنتاج: تشير نتائج المتابعة لمدة عام لهذه التجربة المرتقبة إلى أن كلا الإجراءين يبدو أنهما فعالان بشكل متساوي في علاج سلس البول الإجهادي فيما يتعلق بمعدلات العلاج الموضوعي، في حين أظهر إجراء الشريط الأصغر أحادي الشق معدلات شفاء ذاتية أعلى من إجراء تدريب المدربين.

الكلمات الدالة: الشريط الأصغر أحادي الشق، الشريط عبر الثقبة السدادية، سلس البول الإجهادي، نساء.

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