

Original Article

A Randomised Prospective Study of Treatment Efficacy of Stress Urinary Incontinence with Newer ‘Sling on String’ Method Versus Conventional Trans-Obturator Tape TOT-O (Outside In)

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ABSTRACT

BACKGROUND: Mid urethral sling operation is the most effective surgical procedure for the stress urinary incontinence. Unfortunately cost is a major drawback for the commercially available slings. The aim of the study was to evaluate the comparative results of surgical management of SUI using newer ‘Sling on String’ method versus TOT-O (Trans-obturator tape outside in).

METHODS: Polypropylene macroporous (pore size more than 40 micron) mesh 6" X 3", Modified (outside-in) needle (made at our institution), No 1 polypropylene suture, and 2-0 polyglactin suture for the ‘Sling on String’ group and conventional LOTUS^{VM} tape was used in the ‘TOT-O’ group. Women aged between 40-70 years were included in this study. They were divided in 2 groups - TOT-O group and ‘Sling on String’ group. Statistical analysis was performed with the aid of Statistic XL v 1.8 and SISA. *P* values <0.05 were considered as statistically significant.

RESULTS: Total 71 women participated - 35 (49.3%) TOT-O group and 36 (50.7%) ‘Sling on String’ group. The only statistically significant factor was: longer mean operative time for ‘Sling on String’ group i.e. 33.3 ± 10.9 minutes compared to TOT-O group i.e. 19 ± 5.5 minutes. But the overall cost was very low in ‘Sling on String’ group than that of the TOT-O group.

CONCLUSIONS: ‘Sling on String’ method is a very effective low cost alternative for the treatment of stress urinary incontinence.

Key-words: Stress, Sling on String, Trans-obturator tape, Urinary Incontinence

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Introduction:

Stress Urinary incontinence is one of the common forms of urinary incontinence in women.¹ International continence society (ICS) clearly defines stress incontinence as “involuntary leakage of urine per urethra during increased intra-abdominal pressure (like coughing, sneezing or exercise), when intra-vesical pressure exceeds maximum urethral closure pressure in absence of detrusor contraction or urinary tract infection”.² It has a significant impact on the health related quality of life (HRQoL).³ The reported prevalence rate of stress incontinence is in between 20 to 40% for middle-aged and older women.⁴ In 1990 Delaney, as one of the first researchers, concluded that its pathophysiology is associated with a defect in bladder neck and urethra due to the laxity of surrounding tissues and the insufficiency of the internal sphincter of urethra.⁵ The current surgical treatments for stress incontinence are minimally invasive tension-free transobturator tape by outside-in (TOT-O) and tension-free vaginal tape (TVT).⁶ In 1996 Ulmsten and colleagues had published a report describing the tension-free vaginal tape technique in the treatment of SUI.⁷ A few years later, trans-obturator tape method was described in which the tape is carried out between the obturator foramina.⁸ Both methods are now widely used for surgical treatment of SUI but the TVT needs additional cystoscopy after the completion of the procedure.⁹

Both TOT-O and TVT are somewhat costly and the cost is variable depending on the manufacturer of the TAPE.¹⁰ These items are not readily available in many centres. The need for development of in-house (Indigenous) methods has been practiced in many places.^{11, 12} Similarly in our facility also we have developed a new method wherein a strip of polypropylene macroporous mesh (Sling) attached to a thread of polypropylene suture (String) was used for placing under

the mid urethra for the correction of SUI as low cost alternative method. The aim of the study was to evaluate the comparative results of surgical management of SUI in women using either the newer ‘Sling on String’ or the conventional TOT-O method. Conventional TOT-O was preferred in our study group as it did not require routine (additional) cystoscopy after the completion of procedure.

Materials & Methods:

It was a prospective randomised controlled study involving gynaecology department at College of Medicine and JNM Hospital, Kalyani. Total duration of the study was two years. After taking informed consent a total of 71 women aged between 40-70 years were included in the study that fulfilled the inclusion criteria (See Below). The sample size was determined by fulfilling the inclusion and exclusion criteria 35 were required per group in order to detect the difference of significance with 80% power & 5% probability of type I error, assuming a standard deviation with 95% confidence interval both sided. Before undertaking the study the proposal was duly approved by the Institutional Ethics Committee vide number F-24/PR/COMJNMH/IEC/18/939. All patients, before treatment, were carefully examined and ascertained on the basis of: physical examination, uro-gynaecological examination (stress test), compilation of two questionnaires on quality of life namely Impact Incontinence Quality of life (IIQ-7) and the Incontinence Severity Index (ISI), urinalysis including urine culture and abdominal ultrasound. They were prospectively randomized, by means of a predetermined computer-generated table. Inclusion criteria were: between 40-70 years of age, suffering from SUI, positive stress test, associated pelvic organ prolapse (POP) up to POP-Q stage I. The exclusion criteria were : surgery for incontinence earlier, mixed variety of Urinary Incontinence, any existing neurological disease, pelvic

organ prolapse (POP) greater than POP-Q stage I and those who were lost at any point during follow up. 'TOT-O' group included 35 patients (49.3%) and 'Sling on String' group included 36 patients (50.7%). Conventional LOTUS^{VM} tape was used in the 'TOT-O' group for surgical treatment. Patients were followed-up at first, third and sixth month postoperatively and thereafter annually for up to two years. They were evaluated with standardized urogynaecologic questions on urinary symptoms as well as on quality of life (IIQ-7 and ISI) and were also made to undergo detail urogynaecological examination at each follow up visit.

Statistical analysis used: Statistical analysis was performed with the aid of Statistic XL v 1.8 and SISA. *P* values <0.05 were considered as statistically significant. Numerical variables were compared between groups by Mann-Whitney's u-test and for paired comparisons the paired t-test were used.

Surgical Technique (Sling on String):

Materials Used: Polypropylene macroporous (pore size more than 40 micron) mesh 6" × 3", Modified (outside – in) needle (made at our institution), No 1

polypropylene suture, and 2-0 polyglactin suture.

Description of the Modified (outside – in) needle: It is a 23 cm long stainless steel needle having three parts; handle (10 cm), shaft (4 cm), and needle body (9 cm semi-circular in a radius of 4.5 cm). It has an eye at tip of 1 mm diameter for the passing polypropylene string to attach it with the needle during passage through the trans-obturator region.

Surgical steps:

- Dissect mid-urethral region 1 cm below the external urethral meatus in Lithotomy Position and make a stab incision, about 1.5 cm in length, at the junction of a line where clitoris touches labiocrural fold and 1.5 cm below the point of insertion of adductor longus;
- remove the mesh from the packet and make a 1 cm wide longitudinal strip from the mesh;
- attach 1-0 polypropylene suture thread about 15 cm long on both side to make the cumulative length more than 30 cm as only total 6" (15 cm mesh length available from one side to other side) (**Fig 1**);

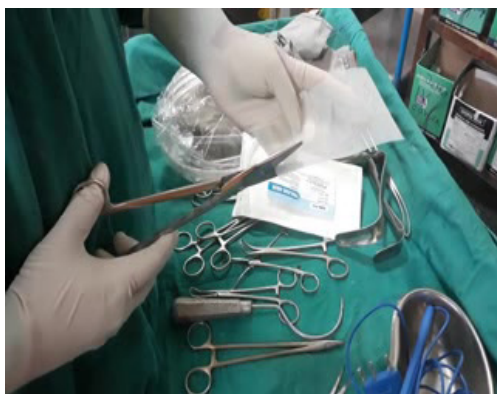


Fig 1: Polypropylene macroporous (pore size more than 40 micron) mesh 6' × 3' and cutting of a mesh strip of 1 cm breadth and attaching polypropylene suture No 1 with the mesh end both side to make the length of the "Sling on String" system at least 30 cm (required from one obturator foramina to other side)

- d) insert modified (outside –in) needle through stab incision site in the right side from outside-in (**Fig 2**);
 - e) when tip seen at sub-urethral region attach polypropylene suture thread to needle tip →then withdraw the needle following the route of entry;
 - f) till the suture will comes out of the stab wound entry point and then hold the suture end with an artery forceps;
 - g) repeat the same procedure on the contra lateral side until the needle tip emerges at the sub-urethral region where the other end of the suture is attached to and thereafter the needle is withdrawn until the thread comes out of the stab-
- h) Stretch the suture string on either side simultaneously while keeping an artery forceps in between urethra and mesh sling so that the mesh does not fit too snugly on the urethra-vesical angle (**Fig 3**);
 - i) cut the excess suture on both side a few mm below the skin level → close sub-urethral incision with 2-0 polyglactin suture.

Results:

The study included 71 women who met the inclusion criteria and gave informed consent.



Fig 2 : Dissection of mid-urethral zone and insertion of modified needle through the stab incision

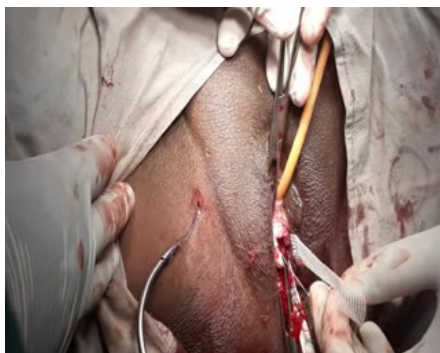


Fig 3: Removal of modified needle through the stab incision opposite side & placement of sling

No significant inter-group differences were noted in terms of menopausal status, mean age, parity, mean BMI, degree of utero-vaginal prolapse, positive stress test, abdominal leak point pressure, Impact Incontinence Quality of life (IIQ-7) Score, Incontinence Severity Index (ISI) Category as described in Table 1. No patient presented with detrusor over activity (Dys-synergia). The follow-up was at one three and six

month and thereafter at the end of first and second year for both groups. Table 2 shows intra-operative and immediate post-operative data, which revealed significantly longer mean operative time for 'Sling on String' group i.e. 33.3 ± 10.9 minutes as compared to the TOT group i.e. 19 ± 5.5 minutes. However, the cost per patient was approximately INR 6000 for the TOT-O group availing the most economical price in

Table 1: Baseline Pre-operative data in study groups

Parameters		'Sling on String' group (n=36)	'TOT-O' group (n=35)	P value
Post menopausal		19 (52.7%)	17 (48.6%)	0.168
Mean age (years)		58.8 ± 6.1	60.6 ± 11.0	0.196
Parity (Vaginal)		4.0 ± 1.9	4.4 ± 2.7	0.642
Mean BMI (kg/m ²)		22.5 ± 3.1	22.8 ± 2.1	0.818
Prolapse (POP-Q –I)		14 (38.9%)	15 (42.8%)	0.952
Positive stress test		36 (100%)	35 (100%)	0.515
Abdominal Leak Point Pressure (ALPP) (cm H ₂ O)		45.2 ± 11.3	44.6 ± 14.7	0.147
Impact Incontinence Quality of life (IIQ-7) Score		23.6 ± 4.4	22.5 ± 5.2	0.582
Incontinence Severity Index (ISI) Category	Dry	0	0	0.667
	Slight	0	0	
	Moderate	20 (55.56%)	18 (51.4%)	
	Severe	16 (44.44%)	17 (48.6%)	

Table 2: Comparison of Peri-operative (intra – operative and immediate post-operative) parameters

Parameters	'Sling on String' group (n=36)	'TOT-O' group (n=35)	P value
Mean operative time (Min)	33.3 ± 10.9	19 ± 5.5	0.001
Intra operative bladder injury	0	0	—
Length of hospital stay	4.2 ± 1.2	4.6 ± 1.0	0.671
Urinary Retention	1 (2.78%)	1 (2.85%)	—
Perineal Pain	2 (5.5%)	0	
Procedure related cost (INR)	500	6000	< 0.0001

the market, whereas the corresponding data for the Sling on string was only INR 500. The market price of 6" × 3" (15 cm X 7.5 cm) mesh is approximately INR 600¹³ which can be used for as many as 5 patients since only a 1.5 cm breadth longitudinal strip (Sling) is required for one patient. Along with that one No 1 polyglactin suture (String) which costs about INR 150-200¹⁴ and another 2-0 polyglactin suture costs about INR 200-250¹⁵ are also required for the closure of the sub-urethral incision. Two cases in 'Sling on String' group suffered from perineal area pain (5.5%) in the immediate postoperative period. One patient in each group underwent intermittent self-catheterization for urinary

retention. As shown in Table 3, during the entire follow-up of up to two years in both the groups all patients were found to be negative for stress. In each group there were significant improvement on IIQ-7 questionnaire and Incontinence Severity Index (ISI). More than 80 % patients were found to be dry as per ISI (Incontinence Symptom Index) at the "third" month follow up in both the group. During final follow up at the end of two years more than 95% patients were found dry. No significant intergroup differences were noted in terms of clinical examination (stress test) and questionnaires (IIQ-7 and ISI) in either group during follow up.

Table 3: Comparison of Post-operative parameters at follow up:

		'Sling on String' group (n=36)	'TOT-O' group (n=35)
Positive Stress Test	Pre -OP	100%	100%
	1 Month	0% (<.001)	0% (<.001)
	3 Month	0% (<.001)	0% (<.001)
	6 Month	0% (<.001)	0% (<.001)
	1 st Year	0% (<.001)	0% (<.001)
	2 nd Year	0% (<.001)	0% (<.001)
Mean IIQ-7 Score	Pre -OP	23.6 ± 4.4	22.5 ± 5.2
	1 Month	0.71 ± 2.5 (<.001)	0.78 ± 2.7 (<.001)
	3 Month	0.35 ± 1.2 (<.001)	0.42 ± 1.1 (<.001)
	6 Month	0.18 ± 1.4 (<.001)	0.19 ± 1.2 (<.001)
	1 st Year	0.08 ± 0.9 (<.001)	0.11 ± 0.9 (<.001)
	2 nd Year	0.06 ± 0.92 (<.001)	0.05 ± 0.93 (<.001)
Dry ISI	Pre -OP	0 %	0 %
	1 Month	83.3 % (<.001)	82.6 % (<.001)
	3 Month	92.3 % (<.001)	90.6 % (<.001)
	6 Month	94.6 % (<.001)	93.9 % (<.001)
	1 st Year	91.8 % (<.001)	94.7 % (<.001)
	2 nd Year	95.4 % (<.001)	95.8 % (<.001)

* Figure in parenthesis denotes *p*-values comparing pre-op and post-op parameters in same study group. ISI = Incontinence Symptom Index, IIQ = Incontinence Impact Questionnaire

Discussion:

Our study compared the outcome of surgical management of SUI using either newer 'Sling on String' method or the conventional TOT-O. Almost half of the patients in both the groups were in the post-menopausal. The prevalence of urinary incontinence increases with age, whereas the SUI is a major concern for its effect on the day to day life in the group of women aged over 50 years.¹⁶ History of Previous Vaginal delivery emerged as one of the risk factors in SUI.¹⁶ In our study mean parity was four in both groups. Pelvic organ prolapse is often associated with SUI.¹⁷ Approximately, 40% patients in both groups suffered from utero-vaginal prolapsed (POP-Q Stage I) in our study. It has been documented in literature that type I and type III collagen are the main support structures of the urethra, para-urethral tissues, cardinal ligament as well as uterosacral ligament. Mean diameters of collagen fibres are greater in patients suffering from SUI and prolapse.¹⁷ Patients in this study were included with demonstrable stress urinary incontinence. It is a very effective method for preoperative evaluation and not inferior than advanced urodynamic testing. It is also very effective for evaluation of post-operative patients who had undergone stress incontinence surgery.¹⁸ Abdominal leak point pressure (ALPP) estimation by Valsalva manoeuvre is another effective method to assess the patients preoperatively where the video-urodynamic studies are not easily available. When ALPP is less than 60 cm of H₂O, it indicates intrinsic sphincter deficiency. If it is more than 90 cm of H₂O, then urethral hypermobility is probably the cause of SUI.¹⁹ Intrinsic sphincter deficiency group get benefit from mid-urethral sling procedure whereas hypermobile urethra requires colpo-suspension. Our study populations were having ALPP less than 60 cm H₂O and therefore underwent sling procedure for correction of SUI.¹⁹

The mean operative time was significantly longer for 'Sling on String' group i.e. 33.3 ± 10.9 minutes than TOT-O group i.e. 19 ± 5.5 minutes. As in the literature it is also documented that mean operative time for TOT-O procedure is around 20 min.²⁰ No intraoperative bladder injury was reported in our study group. Only one patient in each group underwent intermittent self-catheterization for relief of urinary retention. Post-Operative patients were considered to be having Transient Urinary Retention when post-void residual urine volume (PVR) exceeded 100 mL following mid urethral sling operation.²¹ Several factors may be responsible for it like age, history of previous pelvic surgery, co-existence of cystocele, number of previous vaginal deliveries and urodynamic parameters etc.²¹ Perineal pain is sometimes seen after these sling procedures and in our study group this complication was encountered in two patients following 'Sling on String' surgery.²²

The major advantage of 'Sling on String' technique for SUI was its cost effectiveness. It was developed indigenously in our institution as in house method. Using commercially available TOT-O tapes turns out to be quite costlier than the 'Sling on String' procedure.²³ Quality of life and relief of symptoms were identical in both the group. In our study there was significant decrease in IIQ-7 score in identical number in each group and more than 90% of patient became "dry" as per ISI index scoring system in the first follow up after one month. In our study we had used non elastic polypropylene macroporus (>40 micron diameter) mesh. The results obtained from both techniques, during follow-up up to 24 months, were similar (p < 0.001) in terms of patients' symptomatic relief, IIQ-7 and ISI scoring.

Conclusion:

'Sling on String' and TOT-O both procedures are effective equally for treatment of female

SUI. The only flip side is that the ‘Sling on String’ procedure takes longer operative time. Long term results up to 24 months are similar for both the procedures. ‘Sling on String’ procedure is an economical alternative way for surgical treatment of SUI, more so, in a low-resource set up like that of ours. Duration of time for the ‘Sling on String’ process will be reduced in future with time of more learning and practising this procedure.

References:

1. Moldovan CP, Marinone ME, Staack A. Transvaginal retropubic sling systems: efficacy and patient acceptability. *Int J Womens Health*. 2015; 7:227-37.
2. Abrams P, Cardozo L, Fall M et al. The standardization of terminology in lower urinary tract function: Report from the standardization sub-committee of the International Continence Society. *Urology*. 2003; 61:37–49.
3. Xu D, Zhao M, Huang L, Wang K. Overactive bladder symptom severity, bother, help-seeking behavior, and quality of life in patients with type 2 diabetes: a path analysis. *Health Qual Life Outcomes*. 2018; 16: 1.
4. Sousa A, Jesus A, Carvalho M et al. Transobturator slings for female stress urinary incontinence. *Acta Med Port*. 2014; 27(4):422-7.
5. DeLancey JO. Anatomy and physiology of urinary continence. *Clin Obstet Gynecol*. 1990; 33(2):298-307.
6. Zyczkowski M, Nowakowski K, Kuczmik W et al. Tension-free vaginal tape, transobturator tape, and own modification of transobturator tape in the treatment of female stress urinary incontinence: comparative analysis. *Biomed Res Int*. 2014; 2014: 347-56.
7. Ulmsten U, Henriksson L, Johnson P, Varhos G. An ambulatory surgical procedure under local anesthesia for treatment of female urinary incontinence. *Int Urogynecol J Pelvic Floor Dysfunct*. 1996; 7(2):81-5.
8. E. Delorme. Transobturator urethral suspension: mini-invasive procedure in the treatment of stress urinary incontinence in women. *Prog Urol*. 2001; 11(6):1306-13.
9. Sandhu JS, Karan SC, Maiti GD, Dudeja P. To evaluate the safety and efficacy of the TVT-Secur procedure in the treatment of stress urinary incontinence in women. *Med J Armed Forces India*. 2017; 73(1):36-41.
10. Ross S, Robert M, Lier D, Eliasziw M, Jacobs P. Surgical management of stress urinary incontinence in women: safety, effectiveness and cost-utility of trans-obturator tape (TOT) versus tension-free vaginal tape (TVT) five years after a randomized surgical trial. *BMC Women’s Health*. 2011;11:34.
11. Ben-Zvi T, Moore K, Haidar N, Gregoire M. An in-house Composix™-based pubovaginal sling trial for female stress urinary incontinence: Five-year comparative followup to tension-free and transobturator vaginal tapes. *Can Urol Assoc J*. 2017;11(8):275-80.
12. Abdel-Fattah M, MacLennan G, Kilonzo M, et al. The SIMS trial: adjustable anchored single-incision mini-slings versus standard tension-free midurethral slings in the surgical management of female stress urinary incontinence. A study protocol for a pragmatic, multicentre, non-inferiority randomised controlled trial. *BMJ Open*. 2017;7(8):e015111.
13. <https://www.indiamart.com/proddetail/prolene-mesh-14435587491.html>. Accessed on 26.06.2018 (Online).

14. <https://pinkblue.in/sutures-india-trulene-1-suture.html>. Accessed on 26.06.2018 (Online)
15. <https://pinkblue.in/sutures-india-trusynth-2-0-suture.html>. Accessed on 26.06.2018 (Online)
16. Varella LRD, Bezerra da Silva R, Eugênia de Oliveira MC, Melo PHA, Maranhão TM de O, Micussi MTABC. Assessment of lower urinary tract symptoms in different stages of menopause. *J Phys Ther Sci*. 2016; 28(11):3116-21.
17. Han L, Wang L, Wang Q, Li H, Zang H. Association between pelvic organ prolapse and stress urinary incontinence with collagen. *Exp Ther Med*. 2014; 7(5):1337-41.
18. Nager CW, Brubaker L, Litman HJ et al. A randomized trial of urodynamic testing before stress-incontinence surgery. *N Engl J Med*. 2012; 366(21):1987-97.
19. Ghoniem G, Stanford E, Kenton K, et al. Evaluation and outcome measures in the treatment of female urinary stress incontinence: International Urogynecological Association (IUGA) guidelines for research and clinical practice. *Int Urogynecol J Pelvic Floor Dysfunct*. 2008; 19(1):5-33.
20. Magon N, Chopra SV. Transobturator Tape in Treatment of Stress Urinary Incontinence: It is Time for a New Gold Standard. *N Am J Med Sc*. 2012; 4(5):226-30.
21. Kim JH, Shin SH, Oh MM, Park JY, Lee JG, Bae JH. Factors affecting transient urinary retention after transobturator tape mid-urethral sling surgery for female patients with stress urinary incontinence: a single center experience. *Eur J Obstet Gynecol Reprod Biol*. 2013; 168(1):107-11.
22. Sun X, Yang Q, Sun F, Shi Q. Comparison between the retropubic and transobturator approaches in the treatment of female stress urinary incontinence: a systematic review and meta-analysis of effectiveness and complications. *Int Braz J Urol*. 2015; 41(2):220-29.
23. Rawlings T, Zimmern PE. Economic analyses of stress urinary incontinence surgical procedures in women. *Neurourol Urodyn*. 2016; 35(8):1040-45.