

# Concomitant surgical correction of severe stress urinary incontinence and anterior vaginal wall prolapse by anterior vaginal wall wrap: 18 months outcomes

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**Background:** The aim of this study is to evaluate the outcome of an innovative, minimally invasive sling technique with autologous tissue in women with concomitant incontinence and anterior vaginal wall prolapse (AVWP). **Materials and Methods:** Fifty-six women with stress urinary incontinence (SUI) or mixed urinary incontinence and AVWP were randomly assigned into two groups: In Group A (26 patients), anterior colporrhaphy (Kelly placcation) and sling placement using a strip of anterior vaginal wall were performed, and in Group B (30 patients), transvaginal mesh correction of AVWP and tension-free vaginal tape (TVT) insertion (retropubic – craniocaudal route) using polypropylene mesh were carried out. The patients were followed-up for over 18 months and were assessed objectively using a 48 h frequency-volume chart, a 48 h pad test and a standardized stress test. Related surgical complications and outcomes were recorded and compared. **Results:** Surgical cure rates for Group A and Group B at the first (3 days) and last (18 months) post-operative visits were 62% and 84%; and 54%, and 72%, respectively ( $P = 0.09$  and  $0.31$ ). Complications occurred in 9 patients (44%) of Group B, but only 3 patients (12%) in Group A. **Conclusion:** Vaginal sling surgery using an anterior vaginal wall strip can improve SUI and in comparison with propylene mesh is associated with lower complication rates. Although, the surgical success rate of this technique is lower than T-Sling, larger studies with selected patients will help assess the suitable patients for this pelvic reconstructive surgery.

**Key words:** Autologous sling, prolapsed, tension free vaginal mesh, urinary incontinence

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## INTRODUCTION

Stress urinary incontinence (SUI), is considered as a common and distressing medical condition among one-third of adult women.<sup>[1]</sup> It is estimated that 4-35% of adult women are suffering from SUI, world-wide.<sup>[2,3]</sup>

According to the integral theories urinary incontinence (UI) and pelvic organ prolapse (POP) may be two sides of the same coin: Coexistence of SUI and (POP) is reported in 15-80% of women with pelvic floor dysfunction.<sup>[4]</sup>

Evidences indicate that surgical procedures are more effective to cure SUI than non-surgical procedures, especially in cases with concomitant SUI and POP.<sup>[5]</sup>

The most challenging issue in the treatment of SUI is the choice of surgical procedure for this purpose. Currently, surgeons are trying to modify their techniques to improve efficacy, safety, and cost-effectiveness,

and to minimize invasiveness<sup>[6]</sup> tension-free vaginal tape (TVT). Techniques was first introduced by Ulmsten *et al.* (1995).<sup>[7]</sup> After introducing the “integral theory” by Petros *et al.* (1999), use of polypropylene mesh slings for concomitant treatment of SUI and POP based on the tissue fixation system has become popular.<sup>[8,9]</sup>

From reported procedures, TVT are one of the most widely used methods with acceptable short-term and long-term cure rates and minimal invasiveness for any types of SUI.<sup>[10-12]</sup> Some complications; however have been reported including, mesh erosion, dyspareunia, and de novo urgency for synthetic slings.<sup>[13,14]</sup> Moreover, Food and Drug Administration released a public health notification regarding serious complications associated with transvaginal placement of surgical meshes for the repair of SUI and POP.<sup>[15]</sup>

However, autologous pubovaginal sling is considered the gold standard for the treatment of SUI in women due

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to its appropriate long-term cure rates and low complication rates.<sup>[9,10]</sup>

In this study, we try to find an autologous strip for replacing with mesh that can be used minimal invasively in patients with concomitant SUI and POP. Therefore, the aim of this study is to evaluate the outcome of technique, autologous vaginal wall epithelium and sub-mucosal wrap sling and anterior colporrhaphy, compared with TVT, suprapubic arc route (SPARC)-TVT and colporrhaphy with polypropylene mesh, in patients with concomitant SUI and POP.

## MATERIALS AND METHODS

In this randomized clinical trial, which was held during December 2009-September 2012 in Isfahan, 56 women with concomitant diagnosis of SUI or mixed UI, with prominent stress component and POP who were referred to Al-Zahra and Noor hospitals for surgical intervention were enrolled. The protocol was approved by the Medical Ethics Committee of Isfahan University of Medical Sciences.

Severity of SUI was diagnosed clinically based on a positive stress test (more than 14/21 points on the International Consultation on Incontinence Questionnaire-Short Form [ICIQ-SF]) or a positive 1 h pad test (>10 g urine loss with a full bladder).<sup>[16]</sup>

POP was diagnosed based on halfway classification system (HCS)<sup>[17]</sup> and those with stage 1-3 of POP were selected.

Patients with active urinary tract infection, urolithiasis, neurogenic bladder, urogenital malignancy and high-grade rectocele, enterocele or cystocele (based on the POP - equal or more, than stage 3 were excluded from the study. Selected patients were randomized into two groups based on the file number with computer. Surgical procedures were either anterior colporrhaphy (Kelly placation) or sling placement using a strip of anterior vaginal wall (26 patients/Group A) or transvaginal mesh correction of anterior vaginal wall prolapse and mid-urethral sling using polypropylene mesh (30 patients/Group B).

Pre-operative evaluation included medical history, pelvic examination, 48 h voiding diary, 12 h pad test, basal laboratory tests (complete blood count, renal and liver function tests, serum electrolytes, urine analysis, and culture), genitourinary ultrasonography, and when indicated multichannel urodynamic study.

Peri-operative information, including: Operation time, estimated blood loss, and bladder perforation was obtained from reports completed by the surgeon's assistant.

Objective and subjective cure rate in studied population was evaluated between 3 days and 18 days and 1, 6, 12, and 18 months after surgery.

Urine culture and vaginal examination were carried out at every visit. Surgery was considered successful when there was no post-operative SUI (patients was dry and the stress test was negative) and post-operative cystocele was <2 grade according to the HCS grading system.

Post-operative information regarding objective and subjective cure were analyzed and compared in patients of two studied groups who completed the 18 months follow-up period.

### Operative procedure

All patients received 1 g Ceftriaxon intravenously pre-operative time.

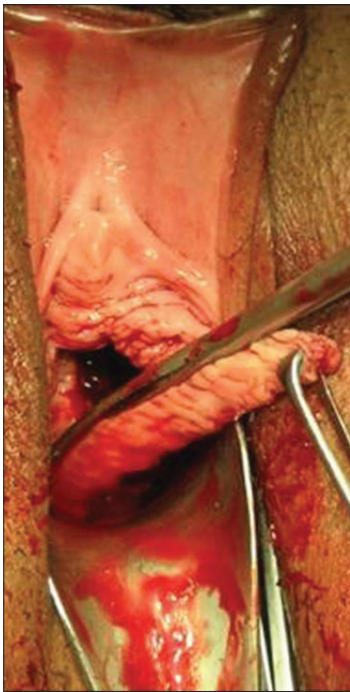
The operation was performed under spinal, epidural or general anesthesia, according to patients and surgeon preference. The same surgeon (MZ) performed all the surgeries. The device design and sling technique were unique to retropubic cranio-caudal mid-urethral sling.<sup>[5,18]</sup>

### Group A (Anterior Vaginal Wall-Sling)

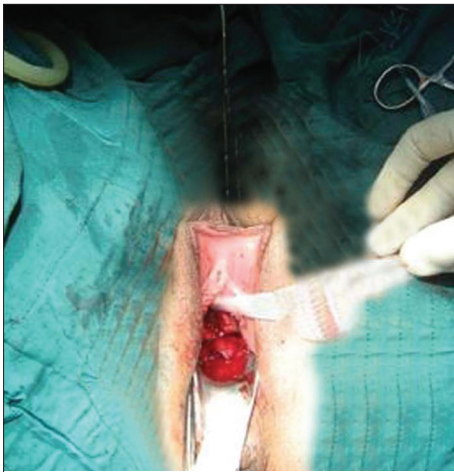
In Group A [Figure 1], the excess, anterior vaginal wall (mucosal, sub-mucosal layers, muscularis, and adventitia) was identified and exposed for the entire length (from mid-urethra to anterior cervical fornix). The vaginal wall was incised vertically for width of 1-1.5 cm in the middle part and length of 12 cm. The sling strip was harvested from one side of the dissected vaginal wall. If the required length of normal vaginal mucosa was not provided, we continued the strip along the opposite vaginal wall edge to achieve the minimum required length for passing the strip from endopelvic fascia bilaterally. Two small punctures were made suprapubically and trocar is passed under finger control through the fascia and retropubic space. Check cystoscopy was carried out to rule out bladder or urethral injury at this point. The previously placed nylon sutures from the sling strip are transferred to the suprapubic incision. Nylon sling traction sutures were tied over the rectus fascia and placed "tension-free" under the mid-urethra. At this time, buttressing of the cystocele was performed with Kelly sutures (0-0 Vicryl sutures).

### Group B (T-Sling)

In Group B [Figure 2], after the passage of retropubic tunnelers and endoscopic control, tension adjusted by placing the tip of an artery forceps while positioning sling against mid-urethra. The edges of the mesh, near perivesical fascia, were sutured laterally to the arcus tendineus fascia pelvic near the obturator foramen.



**Figure 1:** Sling placement using a strip of anterior vaginal wall wrap (Group A or AVW sling)



**Figure 2:** Transvaginal mesh correction of anterior vaginal wall prolapse and mid-urethral sling using polypropylene mesh (Group B)

The T-Sling mesh system was placed between the vagina and the bladder and secured without any vaginal wall trimming. T-Sling mesh kit (Herniamesh Company Polypropylene, Italy) is a tension-free self-fixation sling. The synthetic material provided in this system is monofilament non-woven polypropylene in the arms, but central portion of this mesh is absorbable. It using for SUI and cystocele repair.

The vaginal incision was closed and a hemostatic tampon was placed in the vagina. The urinary catheter was removed 24-48 h after surgery.

**Statistical analysis**

Obtained data were analyzed using the SPSS (version 15) software. Quantitative and qualitative variables were compared in two studied groups using the independent sample *t*-test and Chi-square test, and fisher exact test, respectively. Statistically, significant difference and confidence interval were *P* value of < 0.05 and 95% respectively.

**RESULTS**

All patients had severe SUI as a primary complaint and 28 (56%) had previous vaginal surgery once.

Demographic characteristics and operative details of the studied population in two studied groups are presented in Table 1.

The median of follow-up period in two studied groups was 18 months. All patients in Group B and 24 patients in Group A completed the 18 months follow-up. One patient was lost to follow-up due to the long distance and expense of travel.

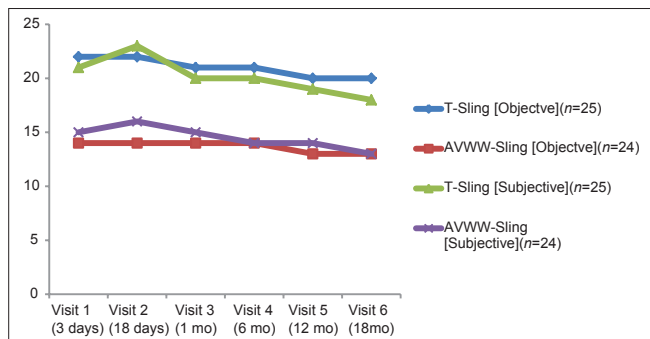
Objective and subjective cure rates are summarized in Graph 1.

Post-operative findings and complications in the Group A and Group B are presented in Table 2.

**DISCUSSION**

Our findings show that AVW-Sling is a safe and cost-benefit, anti-incontinence technique. Advantages of this technique are that there is no need for additional incision for harvesting a strip of fascia, and retro pubic dissection is not necessary versus other classic autologous slings. However, despite the classic sling procedures, harvested tissue is not “fascia” and its integrity and strength is questionable.

In this study, patients with severe SUI (ICIQ-SF more than 25/12) were selected in order to obtain more precise



**Graph 1:** The rate of objective and subjective cure rates in different methods AVW, Anterior vaginal wall wrap

**Table 1: Demographic data and operative details**

	Group B (n=25)	Group A (n=25)	P value
Demographic details			
Age (years) <sup>a</sup>	54.1±4.1	55.9±4.1	NS
BMI (kg/m <sup>2</sup> ) <sup>a</sup>	27.8±4.1	28.1±4.4	NS
Parity (number) <sup>a</sup>	4.3±1.6	4.8±1.7	NS
Previous surgery (POP repair and incontinence surgery) <sup>b</sup> (%)	12 (48) 18 (72)	16 (66) 21 (84)	NS
Operative details			
Mean duration of operation <sup>a</sup> (min)	56±24	42±20	0.04
Mean duration of hospitalization <sup>a</sup> (days)	2.07±0.92	2.88±0.94	NS

<sup>a</sup>Mean±SD; Number (%) results are presented as number (percent); T-sling method (Group B) Anterior vaginal wall sling (Group A); POP=Pelvic organ prolapse; BMI=Body mass index; NS=Non significant

**Table 2: Comparison of complications between two groups**

	Group B (n=25) (%)	Group A (n=25) (%)	P value
Short term complication (before 1 month)			
Vaginal bleeding	3 (12)	5 (21)	NS
Hematoma	2 (8)	0 (0)	NS
Bladder penetration	2 (8)	1 (4)	NS
Long-term complication (after 1 month)			
Cystitis	3 (12)	3 (12)	NS
Vaginal erosion	2 (8)	0 (0)	NS
De nova urgency	2 (8)	0 (0)	NS
Recurrence of SUI	1 (8)	8 (32)	0.009
Chronic urinary retention	4 (16)	0 (0)	0.03

More than 4 weeks  
Results are presented as number (percent); T-sling method (Group B); Anterior vaginal wall sling (Group A); SUI=Stress urinary incontinence; NS=Non significant

and practical results. The subjective outcomes of the two procedures were not significantly different; whereas the objective outcomes were better in the T-Sling group during the medium term (6 months) follow-up period. When compared with the studies that have used facial sling, our autologous tissue shows inferior results.

Sharifiaghdas and Mortazavi have investigated the medium-term subjective and objective outcomes and satisfaction rates of TVT and autologous rectus fascia sling in the treatment of SUI in women. According to their findings, objective and subjective cure rates was not different significantly between studied procedures in the treatment of type II SUI.<sup>[19]</sup>

Amaro *et al.* in Brazil have compared outcomes of autologous fascial sling (AFS), arectus fascia strip, and TVT procedures in women with SUI and indicated that the results were similar between AFS and TVT, except for operative time, which was shorter in TVT. Cure rates were 71% at 1 month, 57% at 6 and 12 months in AVW Sling and 75% at 1 month, 70% at 6 months and 65% at 12 months in T-Sling. The quality of life at 36 months was similar in the two procedures.<sup>[18]</sup>

In AVW Sling technique, not only is the operative time shorter, but also it has all the advantages of an autologous facial sling. It is due to our selected minimal invasive technique.

In another study in Brazil, Sartori *et al.* compared the rates of subjective and objective healing of classic pubovaginal sling and TVT for surgical treatment of SUI. They showed that in medium-term follow-up, the subjective healing was similar in the two groups, but in long-term follow-up (after 15 or 19 months), TVT surgery provided better subjective healing. The rate of objective healing was not different significantly in both procedures.<sup>[20]</sup>

According to the report of American Urological Association, slings are the most effective treatment procedures for severe SUI because of their high long-term success rates.<sup>[17]</sup> Recently, the use of autologous sling has increased due to its low-cost and similar cure rate in compare with synthetic slings, which has been reported in several studies.<sup>[18-24]</sup>

In long-term, the difference between the two procedures (T-Sling and AWV Sling) becomes insignificant and one could conclude that the long-term outcomes are similar.

In fact the procedure could be considered as a modified Raz anterior vaginal wall sling.<sup>[25,26]</sup>

In our method, a 1.5 cm wide strip of the vaginal wall epithelium and sub mucosa was passed through endopelvic fascia, which may be wider fibrosis with similar efficacy that can be expected from a classical anterior vaginal wall suspension with prolene sutures.<sup>[26]</sup>

UI is a multidimensional phenomenon, so in evaluating the outcomes of different treatment methods, various domains should be considered. Though, it seems that both subjective and objective testing are necessary in this field, some studies have indicated that urodynamic findings that evaluate the outcome objectively, have poor correlation with patient's symptoms and subjective improvement that are considered as the most salient outcomes for surgical treatment of SUI.<sup>[27-29]</sup>

Evidence indicates that in cases with scar tissue around the urethra and atrophied pelvic floor including patients with a history of paraurethral surgery or atrophic vaginitis, fibrosis made by the sling could not have a good effect in treating SUI.<sup>[30]</sup>

Many studies have shown that the recurrence of SUI in TVT method is lower than autologous sling procedure.

In our study, 7/8 (87.5%) of patients in AVW. group with recurrence of SUI had a previous history of vaginal surgery

and all of them were older than 55-year-old. Therefore, we could conclude that in younger patients (<55-year-old) with more appropriate vaginal tissue and without history of vaginal surgery, this method is more suitable as mentioned by Raz *et al.* too.<sup>[25]</sup> In addition, though the use of synthetic slings with minimally invasive procedures is growing rapidly, it seems that especially in young women, complication of extensive vaginal mesh prosthesis, for example dyspareunia and tethered vagina, is considered a serious problem. Using the autologous tissue could be an ideal method in this regard.

Despite their low cure rate, traditional methods such as anterior colporrhaphy have reported to produce more satisfaction in affected patients as reported by Freeman *et al.*<sup>[31]</sup>

The rate of de novo urge incontinence as a complication of SUI surgery has reported to vary between 2.2% and 15%.<sup>[20]</sup> Though, de novo urge incontinence in our study was not significantly different between the two groups, the rate was 0% in the autologous sling procedure. This finding may show one of the advantages of the AVW technique; however, more studies are needed to confirm it.

In sum, this pilot study confirms the safety and a 58% effectiveness of the vaginal wall wrap in simultaneous correction of POP stage <3 and severe SUI. Although, the recurrence rate of the vaginal wall wrap was higher than propylene sling, factors like better subjective outcome (that is important in quality of life of patients with SUI) and its low complication rate and cost, makes it an attractive transvaginal procedure for simultaneous correction of POP and SUI.

The anterior vaginal wall epithelium, which its use is safe, could make a sufficient fibrous tissue, which consequently results in reinforcement of pubourethral ligament and restoration of UI.

The success rate of AVW Sling can be improved by selection of young women (with better quality of vaginal mucosa) and exclusion of patient with a history of failed anti-incontinence surgery. For more conclusive results, more studies with larger sample size are recommended.

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