Salvage Autologous Fascial Sling After Failed Anti-Incontinence Surgeries: Long Term Follow Up

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Purpose: To evaluate long term outcomes of autologous pubovaginal fascial sling (AFPVS) as a salvage procedure following different types of failed anti-incontinence surgeries.

Material and method: We retrospectively reviewed medical records of patients who had undergone salvage AFPVS after any kind of anti-incontinence surgery from 2005-2015 at our medical center. Patients were contacted by telephone. Revised Urinary Incontinence Scale (RUIS) was used to determine the success rate.

Result: A total of 40 patients out of 51 were successfully contacted. Mean patient age was 50.8 ± 9.8 years (range30-75) and mean follow up was 62.6 ± 32.4 months (range12-120). Of 40 patients, 14(35%) had pure SUI and 26(65%) complained of mixed urinary incontinence. A total of 15(37.5%) patients had a failed Burch colposuspention, 5(12.5%) TVT, 8(20%) TOT, 3 (7.5%) AFPVS and five (12.5%) patients had history of failed mini-sling procedure. Four (10%) patients had undergone more than one anti incontinence surgeries. Overall success rate was 65% in our study. New onset urge urinary incontinence was detected in 25% of patient which was negatively associated with satisfaction and recommendation. There was no statistically significant correlation between mixed urinary incontinence, type or number of previous failed surgeries with success however presence of pure SUI had a strong

Conclusion: Autologous pubovaginal fascial sling might be considered as a safe and efficacious salvage surgical option following failed midurethral slings, Burch colposuspention and even AFPVS itself. It will provide reasonable long term results with no major complications.

Keywords: stress urinary incontinence; salvage fascial sling; failed midurethral sling; anti-incontinence surgery; redo sling

INTRODUCTION

Stress urinary incontinence (SUI) is a common condition which affects up to 40% of women[1]. SUI is defined as involuntary urinary leakage on effort or exertion or on sneezing or coughing. This condition might be due to intrinsic sphincter deficiency (ISD) and/or urethral hypermobility[2]. The surgical treatment of female SUI has evolved over the last century with different techniques and modalities. These include pubovaginal slings (PVS), urethral bulking agents, transvaginal urethral suspensions, retro pubic suspensions and most recently, mid urethral slings (MUS)[3].

In spite of the wide spectrum of options available, treatment fails in 10-20% of patients[4]. Patients who have failed a prior anti-incontinence surgery for SUI, represent a challenging population. Although several studies have been published, to date there is no general consensus on the procedure of choice for treating recurrent SUI (rSUI)[5]. Given lack of quality data on the optimal management and "rescue" procedure for treatment of rSUI, most surgeons rely on their own experience or opinion[6].

Autologous fascial PVS (AFPVS) was first described in the early 20th century and was brought into popular use again by McGuire and Lytton in 1978[3-7]. Success rates of salvage procedures for rSUI including MUS, Burch colposuspention and PVS are respectively 68.5%, 76% and 82.5% [5].

In the present study, we evaluated the clinical usefulness and success rate of AFPVS as a salvage surgery for management of rSUI following anti- incontinence procedures. To our best knowledge this is the first study assessing success rate of redo AFPVS in traditional and new techniques simultaneously.

MATERIALS AND METHODS

We retrospectively reviewed medical records of all patients who had undergone salvage AFPVS after any kind of anti-incontinence surgery from 2005-2015 at our medical center. Failure was defined as either rSUI or mixed urinary incontinence. The patients with history of previous pelvic radiation therapy, diabetes melli-

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Table 1. Demographic and clinical information according to RUIS Score.

Variables	Overall Sample (n = 40)	RUIS Score unsuccessful (n = 14)	RUIS Score Successful (n = 26)	*P*-value
Age(years)	50.8 ± 9.8 (30-75)	50.8 ± 8.1 (33-67)	50.8 ± 10.7 (30-75)	0.99
BMI	27.8 ± 4.5 (20-36)	28.1 ± 4.7 (21-34)	29.1 ± 4.4 (20-36)	0.52
Follow up length(months)	62.6 ± 32.4 (12-120)	54.9 ± 25.8 (24-108)	66.8 ± 35.2 (12-120)	0.27
Time from initial to salvage surgery(months)	71.2 ± 73.9 (3-300)	49.3 ± 50.2 (3-144)	83 ± 82.4 (4-300)	0.17
Parity	3.7 ± 1.8 (0-9)	3.9 ± 1.8 (0-6)	3.6 ± 1.9 (1-9)	0.66
Menopause at the time of surgery	21 (52.5%)	8 (38%)	13 (62%)	0.66
Previous POPa repair	5 (12.5%)	2 (40%)	3 (60%)	0.81
Prior abdominal hysterectomy	9 (22.5%)	4 (44.5%)	5 (55.5%)	0.50
Prior vaginal hysterectomy	1 (2.5%)	-	1 (100%)	0.45
Mixed urinary incontinence(yes)	26 (65%)	11 (42%)	15 (58%)	0.53
Pure SUI(yes)	14 (35%)	3 (21%)	11 (79%)	0.00

a: pelvic organ prolapse

tus and those with concomitant surgery were excluded from the study. All patients underwent physical and pelvic examination, urodynamic study (UDS), Q-tip test, cough stress leak (Marshall) test and cystoscopic evaluation. Before performing salvage AFPVS, all the patients were offered conservative treatments like lifestyle advise on weight loss, adequate fluid intake, kegel exercises and they received appropriate medical treatment (such as anticholinergic drugs, alpha-adrenoreceptor agonists, tricyclic antidepressants or selective serotonin reuptake inhibitors) as needed for at least three months.

Recorded parameters included: age and body mass index (BMI) at the time of salvage surgery, parity, type and number of previous failed surgeries, history of pelvic organ prolapse repair, presence of mixed urinary incontinence, menopause and comorbidities (asthma, chronic obstructive pulmonary disease).

All information regarding the surgery including time, hospital stay, kind of anesthesia, foley catheter removal and probable peri- and post-operative complications was obtained as well.

Salvage AFPVS was carried out using a harvested 2x8 cm rectus fascial strip through a pfannensteil incision. The urethrovesical junction was exposed transvaginally through a submucosal tunnel in anterior vaginal wall. The endopelvic fascia was perforated and sharp dissection was used to develop the retro pubic space up to the abdominal wall. We used No.1 vicryl sutures at either end of the strip for suspending the fascial graft through a tunnel behind the pubis bone. The strip was anchored on to the rectus sheath without any tension and with two finger breadths distance from symphysis pubis. Then the urethra was examined with a 16 French single use Nelaton catheter to rule out any angulation of the urethra.

Follow up evaluation was performed via telephone call using validated Revised Urinary Incontinence Scale (RUIS) questionnaire (unpublished data)[8-9] for assessing urinary continence status and satisfaction of the patients.

The RUIS is a short, reliable and valid five item scale questionnaire that can be used to assess urinary incontinence and to monitor patient outcomes following treatment. It was originally developed by selecting the best performing urinary incontinence items which were included in a large community survey of 2,915 Australians in 2006. The RUIS has recently been validated in clinical settings[10-11]. These studies have shown that the RUIS is a valid and reliable measure of urinary incontinence. With only 5 items the RUIS is short and simple to use and score. Most patients will only take a minute to complete it. A score of less than 3 indicates that the patient has no urinary incontinence. A score of 4-8 is considered mild, a score of 9-12 is considered moderate and a score of 13 or above indicates severe incontinence symptoms.

We used SPSS 22.0 (IBM. Armonk, NY) for statistical evaluation with p-values reported for two tailed assessments and groups were compared utilizing standard x2 and Student's t-test. Normality for quantitative variables were assessed by Kolmogorov-Smirnov (K-S) test and descriptive analysis was reported as Mean and standard deviation.

RESULTS

A total of 51 patients were identified with rSUI or mixed urinary incontinence after anti incontinence surgeries (Burch colposuspention, MUS or PVS). Forty patients who had undergone salvage AFPVS without concomitant surgery, were successfully contacted by telephone and completed the planned study. Mean patient age was 50.8 ± 9.8 years (range30-75) and mean follow up was 62.6 ± 32.4 months (range12-120). None of them had comorbidities like asthma or chronic obstructive pulmonary disease. Demographic and clinical data is summarized in (**Table 1**).

A total of 15(37.5%) patients had a failed Burch colposuspention, 5(12.5%) TVT, 8(20%) TOT, 3 (7.5%) PVS and five (12.5%) patients had history of failed mini-sling procedure. Four (10%) patients had undergone more than one anti incontinence surgeries. These included two patients with prior failed mini-sling and Burch colposuspention, one with failed TVT, TOT, PVS and one patient with history of failed TOT, mini-sling, PVS and Burch colposuspention.

Based on UDS, eight (20%) women had detrusor over activity. Maximum urinary flow rate was 17.9 ± 3.9 ml/sec (range 10-25). Cystoscopic evaluation and vaginal examination was done for all patients. Cough stress leak test was positive in lithotomy position in 37 (92.5%) patients and it was positive in remaining three (7.5%) patients in upright position.

Average operational time including positioning and preparation of the patients was 124.5±35.6 (range 70-220) minutes. There were no perioperative blood transfusions. We had one perforation of the bladder at the

Table 2. Para-clinic and Surgical Information

Variables	Overall sample(n=40)
Urodynamic Evaluation	
OABa (Yes)	8 (20%)
VLPPb≤60	2 (5%)
VLPP (61-89)	21 (52.5%)
VLPP≥90	17 (42.5%)
Maximum flow rate ml/sec	17.9±3.9(10-25)
Surgical Information	
Operation time (minute)	124.5±35.6 (70-220)
General anesthesia (yes)	4 (10%)
Spinal anesthesia (yes)	36 (90%)
Hospital stay (days)	2.2±0.9 (1-4)
Catheterization (days)	2.1±0.8 (1-5)
Peri- and Post-operative Complications	
Bladder perforation	1 (2.5%)
Fever	4 (10%)
Wound infection	4 (10%)
Urinary retention	3 (7.5%)
Need for CICc	3 (7.5%)
Urethrolysis	1 (2.5%)

a: Overactive bladder

b: Valsalva leak point pressure

c: Clean intermittent catheterization

time of surgery and 4 patients had postoperative fever and subsequent wound infection due to subcutaneous seroma collection that required surgical intervention and drainage. Three women had urinary retention, two of them were treated well with 2 weeks intermittent catheterization and one of them underwent urethral dilatation and urethrolysis. Ten (25%) patients suffered from de novo urge urinary incontinence. We did not have any delayed postoperative complications (**Table 2**).

Vaginal exposure of TOT mesh was detected in one patient and it was removed at the time of the salvage surgery. Success rate was defined by RIUS score less than eight. According to RUIS score, 10(twenty five percent) patients were completely cured (RUIS□3) and 40 %(16 women) had mild urinary incontinence (RUIS 4 to 8). Overall success rate was 65% in our study. Nine (22.5%) patients had RUIS score of 9 to 12 who were considered to have moderate urinary incontinence symptoms. Five (12.5%) women had RUIS score more than 13 which means they suffered from severe urinary incontinence symptoms. Failure was defined by RUIS score more than 9(35%) in our study.

Fourteen (35%) patients were not satisfied with the surgery, while14 (35%) were partially satisfied and 12(30%) women were completely satisfied with outcome of the procedure. Twenty-two (55%) patients recommended the salvage AFPVS to others. Assessing sexual function needs validated questionnaires before and after the surgery. There was no significant association of age, BMI, parity, previous hysterectomy or POP repair with success.

Unfortunately, we didn't have any recorded data about sexual function of the patients prior to salvage surgery but we asked them about sexual satisfaction after the procedure and surprisingly all of them mentioned no change in their sexual life.

There was no statistically significant correlation between mixed urinary incontinence, type or number of previous failed surgeries with success however presence of pure SUI had a strong correlation with success ($P = 0.005$).

The association of RUIS score with hypermobility of the urethra and urodynamic findings including VLPP value or presence of detrusor over activity didn't reach statistical significance. De novo urge urinary incontinence was negatively associated with satisfaction and recommendation ($P < 0.005$).

DISCUSSION

According to our results, pure SUI might be a good predictor of success rate even in complex cases. Like many other studies, we didn't find any correlation between age, parity, BMI, menopause and previous POP surgeries with success rate [13,16,29,30]. Persistence of urge urinary incontinence was not a major cause of dissatisfaction, however new-onset urge urinary incontinence seemed to be a very important and bothersome factor affecting satisfaction and recommendation.

Therefore, appropriate pre-operation counselling of the patients to set realistic outcomes is highly recommended. Finding a suitable surgical technique for management of rSUI is a very challenging topic. Available options for these patients include: a repeat mesh sling, AFPVS or urethral bulking agents.

A recent systematic review and meta-analysis of randomized controlled(RCT) trials on the surgical management of rSUI, examined data on 350 women in 10 RCT trials with a mean follow up of 18.1 months. The authors of this review concluded that there is "a poor level of evidence in this field"[12].

However there are no prospective randomized trials assessing the optimal treatment approach for rSUI. In present study we decided to choose AFPVS as salvage procedure for treatment of rSUI hoping for a different and durable outcome. There is a paucity of data to strongly recommend one salvage treatment over another[13-15].

AFPVS is typically not considered as first line treatment for uncomplicated SUI as it is more invasive than MUS but it is our choice when MUS or other surgical procedures have failed since theoretically placing a sling more proximally and correcting ISD should cure the residual incontinence [16]. However AFPVS is not without potential complications. In the literature the most common post-operative complications include urgency and obstruction, with rates ranging between 16-27% for urgency and 14-18% for obstruction requiring intermittent catheterization[1,17,18].

Despite a reported high success rate for TOT and TVT slings, in the most recent Cochrane review, complications are significant and likely under reported[19-20]. Recurrent or persisted SUI occurs after MUS in up to 12-20% of cases[20-21]. MUS also occasionally requires removal or division due to complications such as obstruction, mesh exposure or vaginal pain[20,22,23]).

In a recent review of literature by Nadeau et al, success rate of PVS in the patient population who failed other procedures was reported to be 66-90% [2,24-26]. Bulking agents are another available option for treatment of rSUI. They may provide short-term improvement in symptoms but no cure[27].

Their favorable side effect profile and minimally invasive nature make them a viable alternative for "carefully selected" patients[2].

Petrou et al. have reported a success rate of 76.2% in 21 patients with median follow up of 74 months following salvage AFPVS[13].

In a large retrospective study, Milose et al. reported 69.7 % overall SUI cure rate of AFPVS after failed MUS slings in 66 women with mean follow up of 436 days. Complete cure of all incontinence was achieved in 37.9% patients[16].
Welk and Herschorn identified 33 patients treated with salvage PVS after failure of a median of 2 prior anti incontinence surgeries. Median follow up was 16 months and success rate was reported to be 64%[3].
Walsh CA. et al in a separate series of 7 patients contacted retrospectively, reported a cure rate of 71% with 86% satisfaction of the patients with their outcome [28].
Our overall success rate in the present study is 65% which is comparable to previous available studies in this era. It is logical to consider that second line surgical procedures are likely to be inferior to first line treatment, both in terms of reduced benefit and increased risk of harm[2,27]. Most of the patients in our study were referred to us from other medical centers and we didn't have a background or clinical evaluation of their initial surgeries. Presuming that they were all appropriate candidates for their previous surgeries, our success rate would be acceptable. Although there was no statistically significant correlation between type or number of previous surgeries, we noticed 10 out of 15 patients with history of Burch colposuspention and all of the women with previous failed PVS had RUIS score □8, which means redo AFPVS is not only suitable for more recently invented procedures (MUS) but also can serve as a reasonable option for treatment of traditional surgeries or even failed PVS itself. Our relatively long term follow up time (mean: 62.6, range12-120 months) indicates that positive effects of redo AFPVS is durable. We performed UDS for all patients however, symptoms of overactive bladder were only seen in 20% of them. We didn't find any statistical correlation between UDS findings and our success rate in this study. Perhaps it is time to design a powerful prospective study to reevaluate the usefulness of performing UDS as a routine para-clinical test in "all" incontinent patients with history of failed anti-incontinence procedures. The major limitations of the present study are its retrospective design and subjective outcomes. Relatively large sample size from single institution and long term follow up are the strengths of our study.

CONCLUSIONS

Appropriate management of recurrent stress urinary incontinence after anti-incontinence surgeries is a challenging topic. Our retrospective study supports the use of AFPVS in complex patients. Our data imply that salvage AFPVS provides durable and acceptable continence rates. There are no serious peri- and post-operative complications. Since there is no general consensus on the procedure of choice for treating recurrent SUI, well-designed prospective studies and collaboration in multi-center studies are highly recommended to choose a reasonable approach.

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CONFLICT OF INTEREST

The authors have no conflicts of interest to declare.

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