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Autologous fascial slings – efficacy and future challenges. An analytic review

Abstract

Stress urinary incontinence (*SUI)* consists a clinical entity affecting approximately 1/3 of women worldwide. Therefore, management and therapeutic mapping should be planned assiduously.

Surgical treatment for *SUI* has been an optimal surgical intervention for over 50 years, beginning from Burch colposuspension and Kelly's plication, to midurethral slings, tension free vaginal tapes, trans obturator tapes and autologous fascial slings.

Even though synthetic midurethral slings represented the most common surgical approach since the mid 90's, due to their minimally invasive character, nowadays, lots of concerns have been raised among medical community concerning their serious long-term complications such as, mesh erosion, vaginal extrusion, urethral erosion and injury, groin, thigh or pelvic pain, recurrent infections and dyspareunia.

These complications forced *FDA (Food and Drug Administration)* to issue a warning against their use, leading the implementation concerning autologous facial slings come back in to the surface.

Despite the fact that the use of autologous fascial slings depicts a more invasive and challenging approach to treat *SUI*, there are notably more benefits regarding postoperative outcome, as well as decreased rate of potential complications when compared to *TVT (Tension-free Vaginal Tape) and TOT (Trans Obturator Tape)*. Although, more trials and data must be conducted in order to be considered as main approach.

Aim of this analytic review consists efficacy's depiction of the autologous fascial slings according to recent bibliography and the role they could play in the near future concerning optimal therapeutic strategy of *SUI*.

Keywords: stress urinary incontinence, autologous fascial slings, midurethral slings

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Abbreviations: SUI, stress urinary incontinence; FDA, food and drug administration; TVT, tension-free vaginal tape; TOT, trans obturator tape; AFS, autologous fascial slings; APVS, autologous pubovaginal sling

Introduction

Stress urinary incontinence is defined as the involuntary loss of urine during physical movement or activity, raising an incidence rate of 18-26,4%.[1]

Predisposing factors for *SUI* in women consist vaginal delivery and obesity. Studies have reported rates of 46% of women in their fifth and sixth decades of life suffer from urinary incontinence, with *SUI* accounting for at least half of those cases.[2,3]

Over the years, many alternatives regarding surgical treatment of *SUI* have been reported, most commonly using synthetic midurethral slings. Lately though, many concerns have been raised concerning this surgical intervention due to its increased operative complications. (erosion of the synthetic material). Another option regarding surgical treatment of *SUI* represent autologous fascial slings *(AFS)*.

AFS can be used as primary treatment for stress urinary incontinence or in women who already have undergone an unsuccessful surgical intervention with synthetic midurethral slings. In this procedure, patient's own tissue is being harvested as sling's primary material. Usually tissues which being harvested consist rectus fascia and fascia lata with the latter anatomically more familiar due to the similarity of the abdominal wall.[4]

The main advantage of *APVS (Autologous Pubovaginal Sling),* in comparison with synthetic *PVS,* is their minimal inflammatory and foreign body reactions and decreased risk of erosion of the synthetic material. Nevertheless, the disadvantages of *APVS*, such as longer operating time due to the harvesting process and repositioning of the patient, should also be noted. In addition, there are associated morbidities of the harvesting site such as bleeding and infections.[5] Although this surgical intervention depicts more invasive, it managed to diminish all potential operative complications (erosion of synthetic mesh).This decreased rate justifies the increased use of autologous slings as optimal therapeutic mapping of stress incontinence.

Materials and methods

We performed an assiduously analytic review collecting material from medical databases, using the keywords *"autologous slings", "pubovaginal slings", "stress urinary incontinence"* in order to prove the utility of autologous pubovaginal slings in women. Articles published in English between the years 2013 and 2022 were selected by the authors. Animal science was excluded from this review.

Operative technique

The operative technique has previously been described by McGuire, Bang,[6] and Mahdy et al.[7]

Patient is positioned in dorsal lithotomy position and a Foley catheter is inserted. A Pfannenstiel incision is made above the pubis and then carried down to the rectus fascia. The fascia is then freed from the covering subcutaneous fat and the sling outline is marked with dimensions of 10-12cm in length and 1.5-2cm in width. The edges of the sling are dissected and freed from the rectus abdominis muscle and their ends are getting suspended using 0 polypropylene or *PDS* sutures. Then, the graft is placed in a basin filled with saline solution. The abdominal incision is packed with betadine infused gauze sponges left to be closed later on. In the second part of the operation, 50ml of a solution containing 0.5% bupivacaine and 1:10.000 adrenaline are locally injected in the vaginal epithelium for better dissection. A median incision was made in the anterior vaginal wall and the vaginal mucosa was reflected laterally off the posterior urethra and bladder neck.

A linear midline, or inverted U, vaginal incision is made up to the bladder neck (maximum 2cm below the urethra). The vaginal epithelium is then dissected from periurethral and pubocervical fascia so we can enter the retropubic space. At this point, the bladder should be evacuated. Needle passers are used and properly guided from suprapubic space down into the vaginal incision. We then remove the Foley catheter and cystoscopy is performed to check for any urinary bladder injury. The sutures of the graft are now inserted in the tip of the needle passers and the sutures are delivered in an inside-out fashion to the suprapubic region. The sling is secured in the periurethral fascia using 3/0 absorbable sutures. Then the vaginal and abdominal incisions are closed. A vaginal packing, lubricated with xylocaine gel and betadine is placed carefully inside the vagina and a new Foley catheter is inserted again. The vaginal packing should be removed it the first postoperative day and if the patient has no discomfort, Foley catheter should be removed before active voiding trial. If there are no severe complications the patient can be discharged.

Results

On the papers reviewed demographics were taken under consideration but no significant change was shown according to age, and ethnicity.

In a retrospective study by Lee et al.[8] (Table 1), patients undergoing primary *PVS (pubovaginal sling) (PVS1)* were compared to those with secondary *PVS(PVS2)*.[8]

Table 1 Stress urinary incontinence. Analysis of current literature

	Nr of patients	Procedure	Clinical indications	Follow UP	Success definition	Success rate
Dominic lee(5)	84/110	AFPVS	History, Physical examination with POP-Q, urethral hypermobility,SUI, preoperative questionnaires	PSV1(73months) PSV2(85months) 78completed questionnaires	SUIOS (Pad use, definition of success(QoL≤3, UDI-3≤1, no reoperation)	76% in PSV1 52% in PSV2
Jerry Blaivas (9)	31319 AFPVS=5733 SMUS=25586	AFPVS SMUS	Mixed stress and urge incontinence	AFPVS 30m SMUS 34m	SUIOS	Obj: AFPVS 82% SMUS 88% (Pvalue: .22) Sub: AFPVS 79% SMUS 77% (Pvalue: .60)
Sharma(15)	30/35	APPVS SMUS	Positive cough stress test and Bonney test	6months	ICIQ, Urodynamic Study	APPVS(13/15) 100% SMUS(15/15) 100%
Sandy Kim (13)	34/83	AFPVS	Positive cough test, urodynamically proven SUI, questionnaires	PVS1(14,2y) PVS2(14,8y)	UDI-6,IIQ-7, QOL	PVS1 74% PVS2 54%
Khan(24)	162/201	TVT, AFS, Xenograft		10years(median)	Complete dry or improved, BFLUTS, EQ-5D	TVT:31,7% AFS: 50,8% Pelvicol: 15,7%
Shah(31)	21/189(19/21 received ARFS after previous sling excision)	ARFS	LUT mesh perforation after midurethral polypropylene mesh sling	22months(mean)	Patient's continence	80,9%
Mccoy(27)	46	AFPVS	Prior mesh slings for SUI, dyspareunia, refractory MUI or SUI, sling erosion, extrusion, and obstruction	9,3months	Obj: wearing 0-1 dry pads/day Sub: median subjective QoL reported as delighted at first FU	Obj: 91% Sub:76%
Parker(28)	59/288	AFPVS	Prior MUS before AFPVS. Recurrent SUI, sling extrusion, and sling obstruction	1-124m (14.7m mean)		Obj: 54,2% Sub: 52,5%
Aberger(30)	71	ARFS	Failed prior sling procedure. Failure, extrusion, erosion	12-93months(median-29m)	Patient's report of no urinary leakage during physical activity, coughing, or sneezing	61,9%

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PVS1 group was defined as those with no preexisting major procedure for treatment of *SUI,* while *PSV2* group was defined as those with previous major vaginal or abdominal anti incontinence surgery. A number of 110 patients were the initial cohort with 26 of those either lost to follow up or deceased, leaving us with a number of 84 patients. Clinical indications for *AFPVS surgery* were history, physical examination *(with POP-Q, urethral hypermobility, SUI)* and preoperative questionnaires. The *FU* period for the *PSV1* group was 73 months and for *PSV2* was 85months.

Patients were asked about pad use and other questionnaires. *(UDI-6, QoL, re operation)* as treatment definition, leading us to a success rate of 76% for *PVS1* and 52% in *PSV2.* Re-operation was needed for 3 patients in *PSV1* group, all with periurethral bulking agent, and for 9 patients in *PSV2* group, 4 with periurethral bulking agent, 1 with repeat sling, 1 with urethral dilation, 1 with sling mesh excision and 1 with mesh sacrocolpopexy.

In another study performed by Blaiva et al.[9] 31,313 patients were included, 5733 of them being treated with *AFPVS* and 25,386 with *SMUS*.[9]

The indications for surgical treatment were *SUI* symptoms and *SUIOS (dry pad test, voiding diary, questionnaires)* while 75% of the patients had complicated *SUI.* The mean follow-up for patients operated with *AFPVS* was 30months, while for patients treated with *SMUS* was 34months. Using the *SUIOS,* objective success rate measured at 82% for *AFPVS* and 88% *(P-Value .22)* and subjective success rate measured at 79% for *AFPVS* and 77% for *SMUS (P-value .60)*. Considering the complications of *SMUS*, we see a slightly higher prevalence rate of bladder perforation, erosion surgery and refractory pain. On the other hand, the complications with the highest prevalence in *AFPVS* were, urethral obstruction and wound complication. It should be noted that both techniques had similar *De novo OAB rates* (Table 2).

Table 2 Complications of AFPVS use

	Re-Operation	**PSV1(n=3)**		**PSV2(n=9)**
	Periurethral Bulking Agent	3		4
	Repeat Sing			1
Dominic Lee	AVWS			1
	Urethral Dilation			1
	Sling mesh erosion			1
	Mesh sacrocolpopexy			1
	Prevalence (%)	**AFPVS(n=5733)**		**SMUS(25,586)**
	Death	2/5733 (0.034)		2/7762(0)
	Bladder perforation	50/3854 (1.3)		579/19,411 (3.0)
	Bowel perforation	4/2936 (0.1)		4/3820 (0.1)
Jerry blaivas	Wound complications	70/1982 (3.5)		NA
	Urethral obstruction	358/4313 (8.3)		301/9375 (3.2)
	Erosion surgery	8/2786 (0.28)		333/16,619 (2.0)
	De novo OAB	320/2876 (11)		1512/14,765 (10)
	Dyspareunia	4/454		24/324 (7.4)
	Refractory pelvic pain	6/1004 (0.6)		247/7084 (3.5)
		AFPVS(n=15)	**TVT(n=15)**	**Pvalue**
	Urinary retention	7 (46.7%)	1 (6.70%)	0.035
	Urgency	2 (13.3%)	3 (20)	0.99
	Urinary tract infection	1 (6.7%)	0 (0)	0.99
Sharma	Wound hematoma	2 (13.3)	0 (0)	0.483
	Surgical site infection	4 (26.7)	0 (0)	0.01
	Groin pain	0 (0)	4 (26.7)	0.01
	Vesicovaginal fistula	1 (6.7)	0 (0)	0.99
	Urinary retention needing cutting of sling	1 (6.7)	0 (0)	0.99
Sandy Kim	6 women complained of urge incontinence but did not seek medical treatment,			
	6 complained of mild stress incontinence, 1 recurrent UTI, 1 subjective incomplete bladder emptying			
		TVT(n=63)		**AFS(n=61)**
	Re operations(SUI)	2(3,2%)		0
Khan	Use of self-catheterization	3(4,7%)		4(6,5%)
	Sling release	2(3,2%)		2(3,3%)
	Exposure	1(1,6%)		0
	Scar Pain	0		2(3,2%)
Shah	5/21 (24%): UVF, urine retention, and recurrent SUI			
McCoy	6/46 (13%)			
Parker	Any 21/59 (35.6%)			
	Major: 2/59 (3.4%)			
Aberger	12/71(17%)			

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A competitive study of J. B. Sharma et al.,[10] compared short term results of *AFPVS* and *SMUS* in treatment of female *SUI*.[10]

30 patients were divided in 2 groups of 15 people each according to the operation performed. Follow up was conducted using *ICIQ* and lasted for 6 months. The clinical indication for surgical intervention was positive cough test and Bonney test. All women were urodynamically evaluated. A total of 13 women of group1 *(AFPVS)* had cure of *SUI* at 6weeks and 100% were cured at 6 months after operation. Tape was cut in 1 case and *VVF* developed in another one. All women were cured for *SUI* in group2 *(SMUS)* at 6 weeks and 6 months. Prevalence rate of urinary retention, postoperatively, was higher in *AFPVS* (46,7%) and 4 women (26,7%) of group 1 had surgical site infection. Groin pain and urgency were the main complains of patients in group 2.

In the study of Sandy Kim et al.[11] a long-term outcome of *AFPVS* results in women is reported.[11]

The original cohort of the study was 83 women and 34 provided long term follow up (7 in the clinic and 27 by phone interview). Later, patients were divided in 2 groups. *PVS1*(n=18) were women who were operated for the first time with *AFPVS* and *PSV2* (n=16) women with prior surgical operation for treatment of *SUI*. Median follow up for *PVS1* was 14,2 years and for *PVS2* 14,8 years. Clinical indications for *AFPVS* were positive cough test, urodynamically proven *SUI* and questionnaires. Success was defined by *UDI-6, IIQ-7* and *QoL* with rates of 74% for *PVS1* and 54% for *PVS2*.

Khan et al.[12] conducted a comparative study between outcomes of *TVT, AFS and xenograft* slings for management of female *SUI*.[12]

162/201 patients were available for follow up with a median duration of 10years. Treatment for SUI was defined as complete dry or improved incontinence, while *BFLUTS (Bristol Female Lower Urinary Tract Symptoms Questionnaire)* and *EQ-5D* were also assessed. Success rates after 10years were 31,7% for *TVT*, 50,8% for *AFS* and 15,7% for *Pelvicol*. Re-operation rates for persistent *SUI* was 3,2% for *TVT*, 13,1% for *Pelvicol* and non for *AFS*.

Shah et al.[13] performed a retrospective review, analyzing medical records of 139 patients undergoing transvaginal removal of synthetic mesh while focusing on 21 patients with lower urinary tract mesh perforation.[13]

19 of this patients received *ARFS* (*Autologous rectus fascial slings*) after previous sling excision. The clinical indications for the prior sling excision were *LUT (Lower Urinary Tract)* mesh perforation after midurethral polypropylene mesh sling. The mean follow up was 22 months and according to patient's continence, success rate was 80,9%. On the patients with urethral perforation continence was achieved in 71,5% of the cases, while patients with bladder perforation had all been cured. It should also be noted that 5/21(24%) of the women suffered with complications such as UVF *(Ureterovaginal fistula), urine retention and recurrent SUI* (Table 2).

Another study, performed by McCoy et al.[14] reviewed the outcome of *AFPVS* as a salvage procedure for women with recurrent *SUI* after prior *TVS* mesh.[14]

46 patients underwent *AFPVS* following removal of synthetic mesh in simultaneous or staged fashion. Indications for mesh removal and *AFPVS* placement were dyspareunia, refractory *MUI* or *SUI*, *erosion, extrusion and bladder outlet obstruction.* Median follow up was 9,3months where 42/46(91%) of the women had experienced objective success. Objective success rate was defined as using 0 or 1 safety pads daily and subjective success rate was defined as *QoL report* as delighted at first follow up with success rate of 76%.

Parker et al.[15] shares a retrospective experience with *AFPVS* after prior *MUS* in an original cohort of 288 women.[15] This study focuses on 59 women who had undergone prior placement of *MUI* with indications for *AFPVS* being recurrent *SUI*, sling extrusion and obstruction. Median follow up was 14,7 months with a reported objective success rate of 54,2% and subjective success rate of 52,5%. Major complications were reported in 2/59(3,4%) women and minor complications in 21/59(35,6%).

Aberger et al.[16] performed a retrospective study of 224 women with prior intervention for *SUI with retropubic MUS, transobturator MUS, porcine dermis, bladder neck sling and ARF bladder neck sling.*[16] They focused on 71% of women in that *ARF* sling was used for secondary repair after prior sling failure, extrusion and erosion. Follow up was performed for 12-93 months with a median range of 29months. Success was defined as patient's report of no urinary leakage during physical activity, coughing or sneezing with a rate pf 61,9%. Potential complications were reported in 12/71(17%) of women (Table 2).

We should address the fact that new material has now been created to be used as slings. An ideal replacement should be a degradable biomaterial which elicits an *M2* predominant immune response, permits remodelling and exhibits favourable mechanical properties. Allograft and xenograft materials have yielded suboptimal cure rates. Synthetic tissue engineered materials show promising results from in vitro studies and future research should focus on animal and human trials in this area.[17]

Discussion

Women with *SUI* represent a complex patient population and treatment planning can be really challenging. Many options are available for surgical treatment of *SUI*, such as *urethral bulking agents, retropubic suspension, sling placement (autologous or synthetic) and mesh sacrocolpopexy* being some of those. Synthetics midurethral slings are probably the most popular approach when it comes to sling placement for the last 15 years, mostly due to their minimal invasive character. Lately though, warnings have been raised against their use, due to their severe complications, such as erosion of mesh and extrusion, leading the medical community, to look for solutions with other methods.

This study focuses on the use of autologous slings for treatment of *SUI*, analyzing the bibliography in the past 10 years, in order to better understand and estimate the efficacy of autologous slings and its challenges. *AFPVS* have been used for years, not so predominantly though, mostly for complicated cases of *SUI* or after previous failed surgeries with synthetic mid-urethral slings, but according to latest bibliography there is no indication to suggest that autologous slings should only be used as last resort.

A study has shown that the use of *AFPVS* had better success rates compared with *TVT*, while in another study a higher success rate was observed in patients with *AFPVS* procedure as first choice for operations, than those operated with *AFPVS* after a prior failed surgery for treatment of *SUI*.

Furthermore, is should be reported, that autologous fascia slings have a high success rate in cases where they were used as secondary intervention to treat *SUI*, after prior failed synthetic mesh operation. It is clear that surgery for *AFPVS*, is a more invasive procedure due to the fascia harvesting required. This is the reason why more cases of complications, such as wound hematoma and infections, are reported. On the other hand, it seems like some serious complications of *SMU*,

such as *erosion, pelvic pain, dyspareunia and de Novo surgery* have a significantly lower prevalence rate when autologous fascia slings are used.

Conclusion

Autologous fascia slings should be considered as a reasonable primary treatment option for female stress urinary incontinence, mostly in cases of urethral perforation, irradiated urethra, intrinsic sphincter deficiency and following excision of urethral diverticulum. It is also clear that *AFPVS* after synthetic mesh removal can be successfully performed in patients with *SUI* and should be a primary option. We should also note the fact that autologous fascia slings are cost free and don't comply with foreign body complications. As a result, more future studies should be conducted, focusing on standardizing objective and subjective measures and minimalize lost to follow-up population.

While optimal surgical treatment for *SUI* is still to be found, *AFPVS* should always be considered as an option in the future and more medical professionals should be educated about this procedure.

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Conflicts of interest

All authors declare any financial interest with respect to this manuscript.

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