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The Anterior Vaginal Wall Suspension Procedure: Mid-Term Follow-Up of a Native Tissue Vaginal Repair for Stress Urinary Incontinence

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Abstract

Objective: To report the outcomes of the anterior vaginal wall suspension (AVWS) procedure for stress urinary incontinence (SUI).

Materials and Methods: Following institutional review board approval, a long-term pelvic organ prolapse database of non-neurogenic patients who underwent AVWS for bothersome SUI and ≤ stage 2 anterior vaginal compartment laxity was reviewed. Any patient with prior SUI surgery or < a 6-month follow-up were excluded. Preoperative evaluation included detailed history, validated questionnaires [Urogenital Distress Inventory-Short form, visual analog quality of life score (QoL)], physical examination, and standing lateral voiding cystourethrogram (VCUG). Follow-up included VCUG at 6-12 months postoperatively, yearly examinations, and questionnaires. Failure was measured by a Kaplan-Meier curve using time to reoperation for SUI.

Results: Between 1996 and 2016, 171 patients met the study criteria. The median follow-up was 4.2 years, with 26 (15%) patients having over a 10-year follow-up. Median (interquartile range): age 64 (53-70), body mass index 26 (22-30), and parity 2 (2-3). Ninety-one (53%) patients underwent AVWS with a concomitant procedure, hysterectomy being the most common. Aa and Ba points, questionnaire results, and QoL improved post-operatively and remained improved over time. VCUG findings also improved for urethral support and bladder base reduction. SUI reoperation occurred in 9 (5%) patients, including: fascial sling placement (3) or injectable agents (6).

Conclusion: The AVWS procedure can correct SUI secondary to urethral hypermobility by restoration of the vaginal anatomic support to the bladder neck and bladder base.

Keywords: Anterior vaginal wall suspension, native tissue repair, burch suspension

Introduction

There is an overall paucity of available literature on the long-term outcomes for native tissue repair in the setting of stress urinary incontinence (SUI). The anterior vaginal wall suspension (AVWS) procedure is a modification of the four-corner suspension technique described by Raz in 1989 and has been performed at our institution since 1996 (1-4). The central concept originally put forth by Raz is to address the vaginal wall laxity as a whole, thus restoring support to the anterior vaginal compartment prolapse, which in turn corrects SUI secondary to urethral hypermobility (4). The previously described procedures either addressed anterior vaginal wall prolapse (e.g. Kelly-type plication) or urethral hypermobility (e.g. Marshall-Marchetti-Krantz or Burch culposuspension, Raz bladder neck suspension, or sling), but not both (5).

Initial results of the four-corner suspension were promising, however longer follow-up revealed a significant cystocele recurrence rate (6). It was hypothesized that failure occurred due to inadequate anchoring of the suspension sutures or gradual tissue pull-through. In 1989, Bruskewitz et al. (7) reported that helical loops of suture material in the abdominal rabbit fascia-minimized tissue pull-through compared with other-anchoring methods. Based on this concept, Zimmern et al. (8) published on the AVWS technique using suture placement in a helical fashion to broadly incorporate the full thickness of the anterior vaginal wall supporting the bladder neck and bladder base. This modification improved the durability of the

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repair, which similar to the Burch suspension, depends on the retropubic scar formation. Previous publications reported the outcomes of AVWS for > stage 2 anterior prolapse, uterine preservation, and concomitant hysterectomy (1-3). This study describes our experience with AVWS for SUI secondary to urethral hypermobility induced by anterior vaginal wall laxity.

Materials and Methods

Study Criteria

Following IRB approval, a single-surgeon database was reviewed for patients who had undergone AVWS procedure for the past 20 years. Included patients had bothersome SUI and stage ≤2 anterior vaginal compartment laxity on Pelvic Organ Prolapse Quantification System (POP-Q). Patients with less than 6-months follow-up, prior SUI surgery, or neurogenic bladders were excluded. The database has been prospectively maintained since 2004; data before that year were collected retrospectively. The data were collected by a third-party reviewer not involved in the care of these patients.

Preoperative Evaluation

Preoperative evaluation included a detailed history, validated questionnaires [Urogenital Distress Inventory-Short Form (UDI-6), visual analog quality of life score (QoL)], physical examination (using Baden-Walker grading until the POP-Q was adopted in 1999), and standing lateral voiding cystourethrogram (VCUG) (9). During physical examination, the conversion from Baden-Walker to POP-Q for Aa/Ba points was made using the following scale: grade 0 = Aa/Ba -3, grade 1 = Aa/Ba -2, grade 2 = Aa/Ba -1 or 0.

Regarding VCUGs, a previously standardized protocol was used (10,11). At a fixed bladder volume of 125 mL, the lower edge of the pubic symphysis was used as a reference point to compare lateral views of the urethral angle at rest and during straining to assess for urethral hypermobility, which has previously been defined as approaching a 20-degree gradient (12). The VCUG was also used to measure the lateral height of the cystocele below the lower edge of the pubic symphysis. Grade 0 corresponded to a lateral height of 0 cm or any positive value, grade 1: 0 to - 2 cm, grade 2: <-2 to -5 cm, and grade 3: <-5 cm.

AVWS Procedure

The AVWS procedure is a vaginal native tissue repair that corrects the anterior vaginal wall laxity from the bladder neck to the vaginal apex. The indication for this procedure is women with SUI secondary to urethral hypermobility from anterior vaginal wall laxity. The procedure has been previously described in the literature in detail and has remained unchanged over time (5,13). It is a modified Burch procedure done vaginally. In brief, bilateral longitudinal vaginal incisions are start lateral to the bladder neck and extended to the vaginal apex or cervix. Typically, two sets of #1 Prolene suspension sutures are placed broadly into the vaginal wall, excluding the epithelium, proximally and distally on each side at the level of the bladder neck and cystocele base, respectively. Suture placement is performed in a helical fashion to provide an even distribution of suture tension and prevent suture pull-through. A short, <2 cm midline suprapubic incision is then made to gain access to the tendinous portion of the rectus fascia inserted on the pubis. Then through each vaginal incision, using a blunt and sharp dissection, the endopelvic fascia is perforated to gain access to the retropubic space. Once the retropubic space is freed, a double-pronged ligature carrier is passed under finger control from the suprapubic incision down to the level of the vagina where the suspension sutures are threaded into the eyes of the ligature carrier before being withdrawn back suprapubically. Cystoscopy with 30° and 70° lenses is performed to assess for suture entry anteriorly or ureteric injury. The vaginal incisions are subsequently closed with running absorbable sutures. The suspension sutures are tied 1.5-2 cm above the tendinous portion of the rectus fascia without tension to provide support, but avoid over-correction of the anterior vaginal wall laxity.

Postoperative Follow-up

Postoperative visits were scheduled at 6 weeks, 6 months, 1 year, and then annually. One standing VCUG was performed for 6-12 months postoperatively to determine the degree of improvement in the anatomic support of the urethra and bladder base achieved by AVWS. Were examined by various clinicians, including Female Pelvic Medicine and Reconstructive Surgery (FPMRS) faculty, fellows, or FPMRS-trained physician assistants. Patients not seen in the clinic within the last 2 years were contacted using a structured telephone interview by a third party not involved in the care of these patients. The telephone interviews used questionnaires (UDI-6, QoL), questions about recurrent SUI symptoms, and inquires about SUI reoperation elsewhere.

The primary outcome was AVWS failure, defined as the need for reoperation for SUI. Secondary outcomes included long-term POP-Q scores based on prospective examinations and functional outcome based on questionnaire results, specifically the UDI6-Q3 (SUI) scores. The safety of the procedure was examined in terms of peri-operative complications.

Statistical Analysis

Descriptive statistics are given for continuous measures with medians and interquartile ranges; and for categorical measures with frequencies and percentages. Differences in characteristics between women who underwent another SUI surgery after AVWS and women who did not were tested using the Fisher's Exact test for categorical variables and either the t-test (age,

body mass index, parity) or the Kruskal-Wallis test (years of follow-up, visits per year).

A Kaplan-Meier curve determined UDI-6 Q3 failure-free survival (failure for score of 3) and reoperation-free survival over time for this population, as well as for subgroup comparisons of AVWS with concomitant hysterectomy vs. AVWS alone, and elderly patient >65 years old vs. those younger. Success rates included a loss to follow-up (LTF) analysis (14) considering the patients lost to follow-up as all success, all failure, or comparable to the followed population.

Mixed model analysis was used to determine whether there were trends in physical examination and questionnaire responses over time while controlling for baseline values. The "baseline" p-values refer to baseline values compared to the values during follow-up visits. The "years since AVWS" p-values refer to trends in post-AVWS values over time. All tests were two-sided and completed at the 0.05 significance level using SAS 9.4 (SAS Institute Inc., Cary NC).

Results

Patient Characteristics

Between 1996 and 2016, 171 of 274 patients met the study criteria. Excluded patients had prior SUI surgery (n=53), prior autologous or synthetic slings (n=16), less than 6-month follow-up (n=31), or neurogenic bladder (n=3).

Of the 73 patients not seen in the clinic within the last two years, 29 (40%) were reached by telephone interview. For those, the average distance from our tertiary care facility was 65 miles (standard deviation ±94 miles). Overall lost to follow-up rate was 29% (n=49/171), including deceased (n=5) or unreachable by telephone (n=44).

The median follow-up was 4.2 years, with the median number of visits per year at 1.0. Those with reoperation (n=9) had slightly increased follow-up time (median: 9.8, IQR: 4.4-10.3) compared to those with no reoperation (n=162, median: 4.1, IQR: 1.7-8.0) (p=0.0495). Fifteen percent of the total patients had over a 10-year follow-up. Patient characteristics are summarized in (Table 1).

Outcomes

Perioperatively, the most common complication was intraoperative bleeding (3%), with no blood transfusions required. Early complications (<6 weeks) included suprapubic wound infection (1%) and temporary urinary retention (1%). Late complications (≥6 weeks) included wound infection (1%) and pain (1%). There were no incidences of bladder perforation, erosion of sutures into the vagina, or delayed cystocele recurrence.

Postoperatively, all physical examination points and questionnaire results improved and remained so over time (Table 2). Though the trends were significant for some outcomes, there were no meaningful changes between the 1,

Table 1. Patient demographics

	Total Patients (%) (n=171)	No Reoperation (n=162)	Reoperation (n=9)	p
Age at AVWS, years (median, IQR)	64 (53-70)	64 (53-70)	68 (57-72)	0.5800
Follow-up, years (median, IQR)	4.2 (1.7-8.2)	4.1 (1.7-8.0)	9.8 (4.4-10.3)	**0.0495**
Visits/year of follow-up (median, IQR)	1.0 (0.6-1.5)	1.0 (0.6-1.5)	0.8 (0.6-1.1)	0.8141
Race				
Black	5 (3)	5 (3)	0 (0)	1.0000
Hispanic	4 (2)	4 (2)	0 (0)	
White	156 (91)	147 (91)	9 (100)	
Other	6 (4)	6 (4)	0 (0)	
BMI (median, IQR)	25.6 (22.3-30.1)	25.5 (22.3-29.9)	30.1 (27.3-31.9)	**0.0354**
Parity (median, IQR)	2 (2-3)	2 (2-3)	3 (2-3)	0.3171
Hysterectomy status				
Uterine sparing	24 (14)	22 (14)	2 (22)	0.2403
Concomitant hysterectomy	60 (35)	59 (36)	1 (11)	
Prior hysterectomy	87 (51)	81 (50)	6 (67)	
Concomitant surgery	91 (53)	89 (55)	2 (22)	0.0844
Post-AVWS SUI surgery	9 (5)	0 (0)	9 (100)	

AVWS: Anterior vaginal wall suspension, IQR: Interquartile range, BMI: Body mass index, SUI: Stress urinary incontinence

3, and 5 years post-AVWS time points. Standing VCUG findings were also significantly improved when compared pre- versus post-operatively (Table 3).

The overall success rate was 93% (n=113/122). Nine of 122 patients who required reoperation: Urethral bulking agents (6) and autologous sling placement (3) had a successful SUI outcome. The success rate assuming the LTF patients (n=49) were all successes was 95%, but 66% when assuming all were failures. Assuming the LTF patients (n=49) had a similar success/failure rate as the patients with follow-up (n=122), the overall success rate would be 93%.

As a secondary outcome, UDI-6 question 3 (SUI) results at the last encounter indicated that over half (52%) who completed the questionnaire were completely dry (score=0), while three-quarters (79%) had a score of 0-1.

The Kaplan-Meier 5-year UDI-6 Q3 failure-free survival rate and the reoperation-free survival rate was 94.3% [95% confidence interval (CI) 89.1, 97.0] and 94.7% (95% CI 89.0, 97.5), respectively (Figure 1). There was no significant difference between the Kaplan-Meier curves of patients with concomitant hysterectomy, prior hysterectomy, and uterine sparing AVWS procedure (p=0.33) (Figure 2). The age at the time of AVWS did not affect the time to reoperation (p=0.48) (Figure 3).

Discussion

This study aimed to report the outcomes of AVWS for treatment bothersome SUI secondary to urethral hypermobility from anterior vaginal wall laxity. For 171 patients with a median follow-up of 4.2 years, the success rate was 93% (66% LTF all failures, 95% LTF all successes), with success defined as no reoperations for SUI. Based on post-operative well-supported urethra by VCUG and urodynamic findings, recurrent SUI was most often due to secondary intrinsic sphincteric deficiency (ISD).

Both objective and subjective outcome measures showed significant improvement after AVWS that were maintained over time. Objective outcomes included POPQ Aa, Ba points and VCUG data, which had statistically significant improvement after AVWS and at 1, 3, 5-year follow-up with linear mixed model analysis. Subjective outcomes included UDI-6 (with a

Table 2. Linear mixed model estimates for physical exam and questionnaire data over time, controlling for baseline values

	Mean estimate (standard error)				LMM p-values	
	Baseline	1 Year	3 Years	5 Years	Baseline value	Years since AVWS
Physical Exam	(n=171)	(n=171)	(n=66)	(n=59)		
Aa (-3, +3)	-0.9 (0.1)	-2.8 (0.0)	-2.8 (0.0)	-2.8 (0.0)	0.0001	0.0675
Ba (-3, +8)	-0.8 (0.1)	-2.8 (0.0)	-2.7 (0.0)	-2.7 (0.0)	<0.0001	0.0001
Questionnaires	**(n=99)**	**(n=99)**	**(n=54)**	**(n=40)**		
UDI total (0-100)	44.2 (2.2)	21.0 (1.6)	23.3 (1.4)	25.7 (1.6)	0.0076	0.0008
UDI Q2 (0-3)	1.6 (0.1)	0.7 (0.1)	0.9 (0.1)	1.0 (0.1)	0.0045	<0.0001
No OAB Tx	1.5 (0.1)	0.6 (0.1)	0.8 (0.1)	0.9 (0.1)	0.0363	<0.0001
OAB Tx	1.9 (0.3)	1.3 (0.2)	1.4 (0.2)	1.6 (0.3)	0.1685	0.2547
UDI Q3 (0-3)	1.7 (0.1)	0.6 (0.1)	0.7 (0.1)	0.8 (0.1)	0.0011	0.0043
UDI Q5 (0-3)	0.8 (0.1)	0.4 (0.1)	0.4 (0.0)	0.5 (0.1)	0.9195	0.1048
	(n=97)	**(n=97)**	**(n=54)**	**(n=40)**		
QoL (0 - 10)	6.1 (0.3)	1.9 (0.2)	2.2 (0.2)	2.5 (0.2)	0.0022	0.0080

AVWS: Anterior vaginal wall suspension, LMM: Linear mixed model, Aa, Ba: Points, POP-Q: Pelvic organ prolapse quantification system, UDI: Urinary distress inventory, OAB: Overactive bladder, Tx: Treatment, QoL: Visual analog quality of life score, 1 year, 3 year, and 5 year mean estimates were calculated from LMM model estimates at the mean baseline value

Table 3. Mixed model least square means for baseline versus post-AVWS mean score comparison

	Patients	Baseline vs. Post-AVWS		
		Baseline	Post	p
VCUG				
UAR (degrees)	123	33.5	16.9	<0.0001
UAS (degrees)	122	53.5	23.5	<0.0001
UAR-UAS (degrees)	122	20.2	6.5	<0.0001
Lateral height (cm)	125	-2.4	-0.3	<0.0001

AVWS: Anterior vaginal wall suspension, VCUG: Voiding cystourethrogram, UAR: Urethral angle at rest, UAS: Urethral angle during straining

focus on UDI-6-Q3 related to SUI) and QoL questionnaire scores, which also showed sustained improvement.

These favorable results are similar to the previously published long-term data on a different cohort of women undergoing AVWS for stage >2 anterior prolapse and uterine preservation (1-3).

Other groups have published comparable success rates with AVWS. The original Raz et al. (15) bladder neck suspension had a reported success rate of 90.3% (mean FU 15 months, n=206). A study (n=82) on the 2 or 4 corner Raz et al. (15) bladder suspension revealed an 88% improvement rate (mean FU 4 years, n=48) (16). Another study on AVWS with bone anchors (mean FU 2 years, n=20) reported a cure rate of 95% with no recurrent cystocele, paravaginal defects, or detrusor overactivity (17,18).

A comprehensive review of >10-year follow-up studies for all open anti-incontinence procedures (tension free vaginal tape, transobturator sling, retropubic suspensions, Burch, fascial sling, Stamey needle suspension) reported SUI reoperation rates of 2%-37% (19). Therefore, our rate of reoperation was consistent with other standard anti-incontinence procedures (20).

In addition to providing a durable repair, the AVWS procedure resulted in minimal complications. Intraoperatively, bleeding risk, bladder perforation [previously reported risk 1.6% (1)], or ureteric injury did not occur in this cohort. Postoperatively, urinary tract infection, urinary retention, and wound infection was also uncommon. Because this procedure does not directly affect the urethra or change the voiding dynamics, secondary detrusor over activity is seldom observed (21), as confirmed by relatively unchanged UDI-6 Q2 results over time. The *de novo* damage that occurred in 12 patients was treated with medications. Suture extrusion along the anterior vaginal wall (not encountered in this series) has been previously described post-operatively. An exposed suture can be easily cut with no changes in the anterior vaginal wall support once the retropubic scar has developed. There is a low risk of POP recurrence, consistent with previous reports (1-3).

Lastly, in this series, no information regarding sexual activity before or after AVWS was collected. However, in a previous study (n=56, mean follow-up 24 months), postoperative sexual function was not affected, as AVWS preserves the caliber and length of the vaginal canal (22).

The study strengths include a well-characterized population of women with bothersome SUI and early anterior compartment

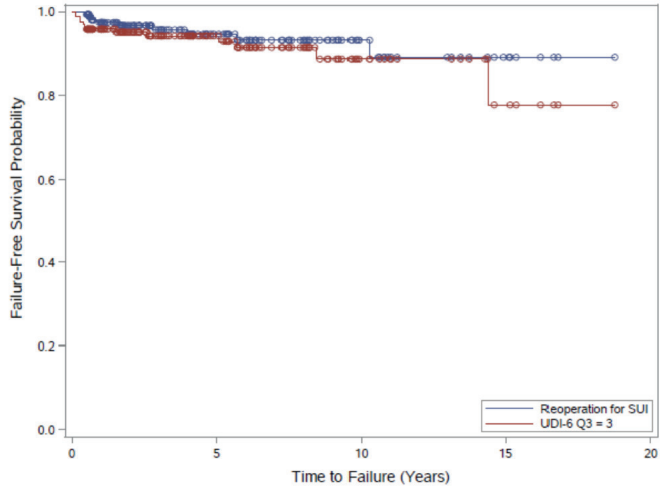

Figure 1. Kaplan-Meier Curve: UDI-6 Q3 failure-free survival and reoperation-free survival after anterior vaginal wall suspension

SUI: Stress urinary incontinence, UDI: Urinary distress inventory

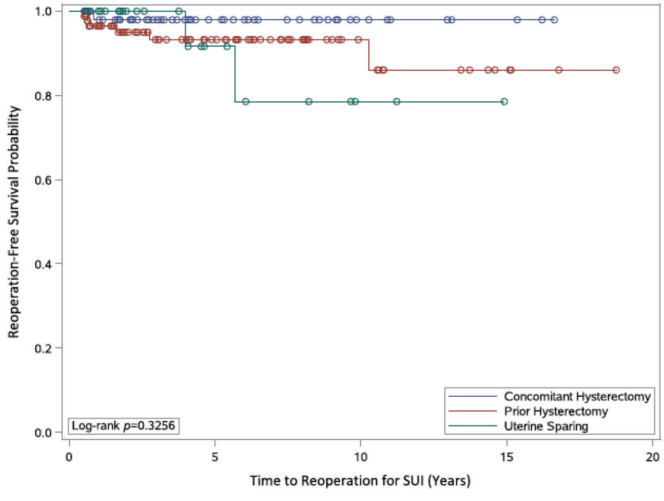

Figure 2. Kaplan-Meier Curve: Reoperation-free survival based on hysterectomy status during anterior vaginal wall suspension procedure

SUI: Stress urinary incontinence

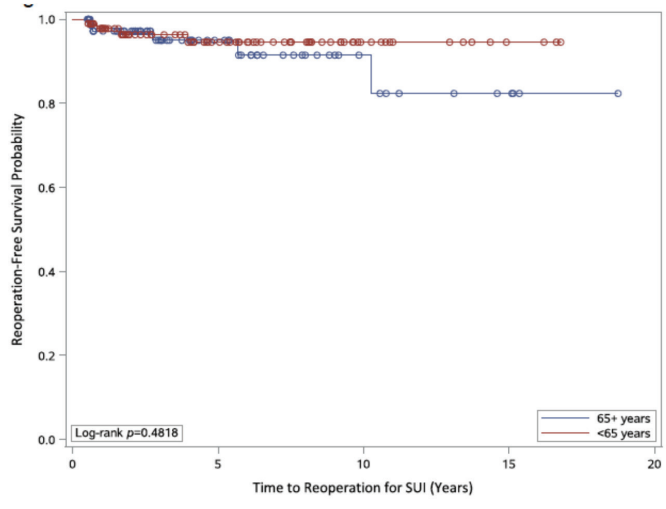

Figure 3. Kaplan-Meier Curve: Reoperation-free survival based on age at the time of anterior vaginal wall suspension procedure

SUI: Stress urinary incontinence

prolapse treated with AVWS with adequate median follow-up. The outcomes included objective and subjective parameters. The data were collected retrospectively before 2004, but since then has been prospective.

Study Limitations

Limitations to this study include being a single surgeon series and patients lost to follow-up. Travel for repeat follow-up appointments can be difficult in this aging population and may seem unnecessary to those doing well and satisfied with their operative results. Alternatively, LTF patients could have sought out care elsewhere for recurrent SUI management.

Additionally, defining failure as the need for reoperation secondary to recurrent bothersome SUI provides a definitive data point. It is our experience that, like in other long-term studies (23), patients who did not pursue reoperation were overall satisfied with their postoperative quality of life even if they had mild SUI recurrence.

Native tissue repair techniques for anterior POP should be part of the female pelvic surgeon's armamentarium, especially in the current state of synthetic vaginal mesh controversy (24). This study supports the that the AVWS procedure is an attractive management technique for surgeons and patients alike given its durability, simplicity, and low morbidity. It is a less than one-hour surgery which can be associated with other procedures (hysterectomy, apical suspension, posterior repair (25), with no negative effects on success rates. It is also very suitable for obese patients since a vaginal approach carries less morbidity than a retropubic approach. Lastly, AVWS is cost-effective compared with other vaginal anti-incontinence procedures (26).

Conclusion

In this mid-term follow-up study, the AVWS procedure was shown to be a durable, simple, and safe non-mesh repair alternative to treat SUI secondary to urethral hypermobility by restoring the vaginal anatomic support to the bladder neck and bladder base.

Ethics

Ethics Committee Approval: XX

Informed Consent: Retrospective study.

Peer-review: Externally peer-reviewed.

Authorship Contributions

Surgical and Medical Practices: A.K., A.T. R., A.L.C., P.E.Z., Concept: A.K., A.T. R., A.L.C., P.E.Z., Design: A.K., A.T. R., A.L.C., P.E.Z., Data Collection or Processing: A.K., A.T. R., A.L.C., P.E.Z., Analysis or Interpretation: A.K., A.T. R., A.L.C., P.E.Z., Literature Search: A.K., A.T. R., A.L.C., P.E.Z., Writing: A.K., A.T. R., A.L.C., P.E.Z.

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