A Randomized Controlled Trial of Pubovaginal Sling *versus* Vaginal Wall Sling for Stress Urinary Incontinence

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Abstract

Purpose : To compare the results of Pubovaginal sling and Vaginal wall sling for the treatment of stress urinary incontinence in females.

Material and Method : Between February 2001 and December 2001, a randomized controlled trial was done to compare safety and efficacy of pubovaginal sling *versus* vaginal wall sling in the management of women with urinary incontinence. Fifteen women 42-68 years old (mean age 51.3 years) were treated with fascial sling (group A) and 11 women 45-60 years old (mean age 50.4 years) with vaginal wall sling (group B). Twenty-one patients had type II SUI and 5 patients had type III SUI (ISD); none had pre-operative detrusor instability. Measures of outcome included efficacy based on SEAPI-QMN, post-operative presence of stress or urge incontinence, frequency of complications, operative time, post-operative pain, length of hospitalization, length of clean intermittent catheterization (CIC) time and mean global evaluation.

Results : All patients were followed for at least 3 months after surgery (median 7 months). A total of 20 and 6 women received spinal and general anesthesia, respectively. SEAPI-QMN decreased from a median of 6.3 to 0.8 for group A and from 6.1 to 0.9 for group B. No patient in either group had persistent stress incontinence. Urge incontinence was present in 2 of group A patients and 1 of group B patients. No serious post-operative complications were encountered in both groups. Post-operative pain and operative times for group B patients were significantly lower than for group A patients. Length of hospitalization, length of CIC time and mean global evaluation were not significantly different between the two groups.

Conclusion : In the short-term, both pubovaginal sling and vaginal wall slings were effective in the treatment of women with SUI. However, the use of vaginal wall sling resulted in significantly shorter operative times and lower post-operative pain compared with pubovaginal sling. Therefore, the vaginal wall sling should be the prefered treatment for SUI.

Key word : Stress Urinary Incontinence, Surgery, Pubovaginal Sling, Vaginal Wall Sling, Randomized Controlled Trial

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Stress urinary incontinence (SUI) is a devastating condition that affects 10 per cent to 20 per cent of females in the general population(1). Excessive urethral mobility appears to be the most prevalent factor associated with urinary leakage in the presence of increased abdominal pressure(2). The surgical management of SUI has been based on the tenet of creating urethral coaptation with restoration of passive continence. A variety of methods have been described for the correction of SUI. These have included the use of a urethral sling. A sling for the correction of SUI may be fashioned from autologous fascial strips (rectus fascia and fascia lata), donor strips (dura), synthetic materials (polypropylene, polytetrafluroethylene or polyester fiber mesh graft) or by burying the vaginal wall(3,4).

The fascial pubovaginal sling has enjoyed limited success in the management of SUI. Although the success rates are high, the relative complexity of the procedure, long surgical wound, post-operative pain and slow recovery have precluded this technique from being more widely used(5).

The simplified vaginal wall sling which involves the creation of a vaginal flap and uses permanent sutures placed in the periurethral supporting structures was developed and is a modification of the Raz bladder neck suspension. Raz et al reported an 88 per cent success rate at 5 years of follow-up using this technique(5).

The present study compares the efficacy of the fascial sling *versus* the vaginal wall sling in a series of 26 consecutive patients treated for SUI.

MATERIAL AND METHOD

Between February 2001 and December 2001, 26 women with anatomical incontinence or intrinsic sphinctor dysfunction were randomized into two groups. The first 15 patients (group A) underwent a pubovaginal sling operation using rectus fascia; the remaining 11 patients (group B) underwent a vaginal wall sling operation. All procedures were performed by the same surgeon. The mean age was 51.3 (SD : 1.8) and 50.4 (SD : 2.3) years in groups A and B respectively. A detailed voiding and pregnancy history, duration of SUI, physical examination, urinalysis, lateral cystography, urodynamic study and SEAPI incontinence classification (stress activity related incontinence, emptying ability, degree of anatomical defect, protection use and instability)(6) were obtained pre-operatively for all patients. Patients with other genitourinary abnormalities or with detrusor instability were excluded from the study.

Surgical technique

The patients were placed in the dorsal lithotomy position. A weighted vaginal speculum and silk labial retraction sutures were used to aid in the exposure of the anterior vaginal wall.

Vaginal wall sling

After infiltration of the anterior vaginal wall with 1 per cent xylocaine with adrenaline (allowing decreased bleeding and easier dissection of the vaginal sling from surrounding tissue), a rectangular incision (2 x 3 cm) was made in the anterior vaginal wall (Fig. 1). Using both blunt and sharp dissection, the urethropelvic ligament was detached from the tendinous arc at the pelvic wall. The urethra was free from remaining attachments, so that the rectangular sling lay over the urethra distally and the bladder neck proximally. Each corner of the sling was anchored with 1-0 Prolene incorporating vaginal wall, pubocervical fascia, and proximally urethropelvic ligament and periurethral fascia and distally vaginal wall and periurethral fascia (Fig. 2). A 1 to 2 cm suprapubic incision was made through which two Stamey's needles were passed into the vaginal transferring the Prolene sutures. As already described, cystoscopy was performed to rule out bladder or urethral injury from either the sutures or passage of the Stamey's needles. As with the fascial sling, tension of the sutures was monitored by visual examination of both the bladder neck and proximal urethra. Care was taken to coapt but not obstruct the urethra. The vaginal flap was advanced and closed using interrupted 4-0 Dexon® (Fig. 3). The abdominal wall was closed with 3-0 plain catgut and 4-0 Nylon.

Fascial sling

An inverted U incision was made at the anterior vaginal wall and the vaginal wall was dissected free from the underlying periurethral fascial tissue. Blunt and sharp dissection was performed to gain access into the retropubic space bilaterally. Care was taken to free both the endopelvic and pubocervical fascia from either side of the urethra. An extended Pfannensteil incision was made and a 2 x 6 cm strip of rectus fascia was harvested (Fig. 4). Each end of the sling was oversewn in a transverse fashion with

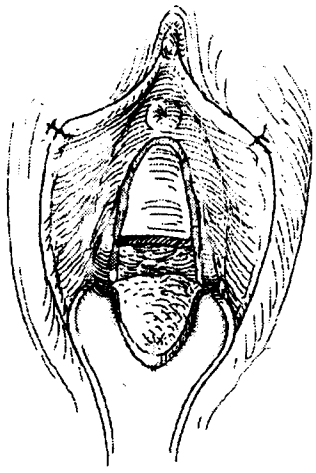

Fig. 1. Starting at the level of the bladder neck, the proximal vaginal wall is dissected to create a pediculated flap of adequate length to cover the urethra in a later step of the operation. This creates a rectangular island of anterior vaginal wall that underlies the bladder neck and urethra, retains its own vascular supply, and will function as the sling.

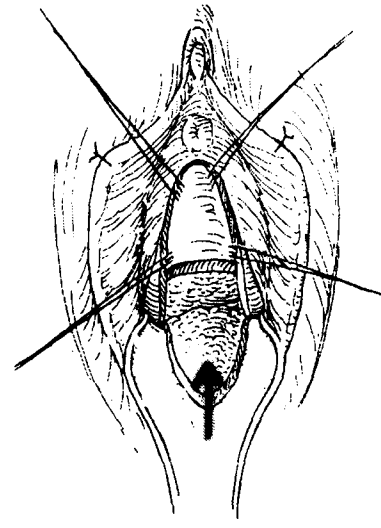

Fig. 2. The four corners of the rectangular island of the vaginal wall are anchored with individual sutures of number 1 prolene applied in a helical fashion.

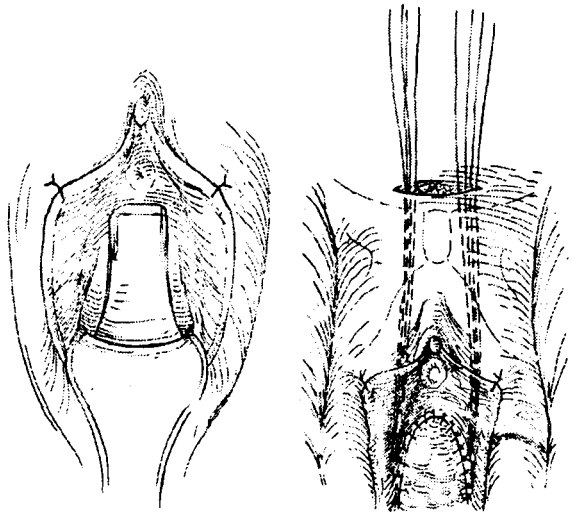

Fig. 3. The proximal vaginal wall flap, previously developed and mobilized, is advanced over the sling to provide an epithelial cover and restore the integrity of the vagina. All prolene sutures are tied individually and then to each other across the midline without undue tension. The suprapubic incison is closed.

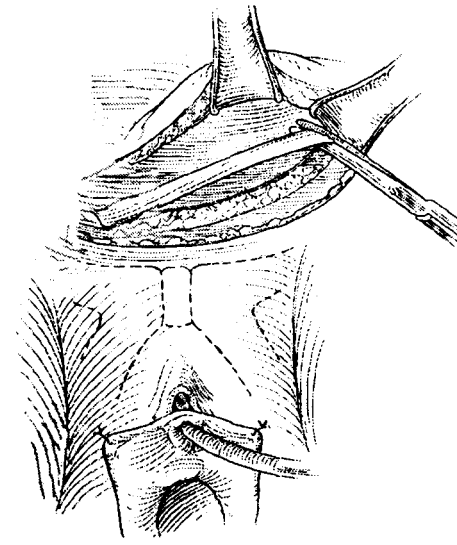

Fig. 4. Pfannensteil incision is made over the suprapubic area, exposing the anterior abdominal fascia. The incision for the retrieval of the fascia graft is outlined. A strip of fascia 2 x 6 cm is harvested.

zero Prolene sutures. Further dissection of the retropubic space allowed connection of the space previously created by vaginal dissection. A Stamey's needle was passed from the rectus fascia into the retropubic space. Prolene sutures of the sling were passed back and the sling was positioned across the bladder neck and secured to the periurethral tissue (Fig. 5). Using cystoscopic guidance to visualize the bladder neck, tension was adjusted by securing the Prolene ends to either side of the rectus fascia. The goal was to coapt but not obstruct the urethra and bladder neck. The vaginal wound was closed with interrupted 4-0 Dexon® and a vaginal pack was placed. The rectus fascia was repaired with running 2-0 Dexon® sutures, subcutaneous tissue was sutured with interrupted 3-0 Plain catgut and the skin was closed with interrupted 4-0 Nylon.

After both procedures, a foley catheter was retained for three days. After catheter removal, if patients could not void or had postvoid residual urine $\geq$ 100 ml, clean intermittent catheterization (CIC) was used until no residual urine was detected.

Outcomes assessed included operative time (in minutes), 24 h post-operative pain by visual analogue score (from 1-10), CIC time (in days), and length of hospitalization (in days). Post-operative persistence of SUI, subjective SEAPI outcome (as described by Raz and Eriksen[6]), development of *de novo* urge or urge incontinence and global evaluation by the patient [very satisfied (1), satisfied (2), no change (3), dissatisfied (4), very dissatisfied (5)] were assessed every 3 months in the first year.

Statistical method

Age and post-operative pain score were compared between the two groups using independent samples *t*-test. The number of previous pregnancies, SEAPI score, global evaluation score, duration of incontinence and operative time were compared between the two groups using the Wilcoxon ranksum test. Persistence of incontinence (yes/no) and *de novo* urge incontinence (yes/no), were compared using Fisher's exact test. Significant true-failed p-value was set at ≤ 0.05.

RESULTS

The median follow-up time was 7 months (range 3 to 12). Twenty-one patients had type II SUI

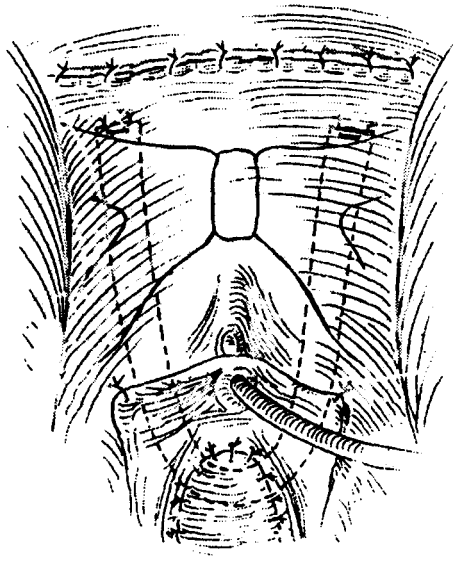

Fig. 5. Prolene sutures of the sling are passed back and the sling is positioned across the bladder neck and secured to the periurethral tissue, the end of the sling is anchored to the suprapubic area with the previously placed prolene sutures.

and 5 patients had type III SUI (ISD). The mean age was 51.3 years in group A and 50.4 years in group B. The median number of previous pregnancies was 2 in group A and 2 in group B, The median SEAPI-QMN was 6 in both group A and group B. The median duration of incontinence was 24 months in group A and 48 months in group B. (Table 1)

There were no statistically significant differences at baseline for patients who underwent fascial *versus* vaginal wall sling.

Operative time was significantly lower for group B compared with group A (64.2 ± 8 *versus* 98.2 ± 17.3) ($p < 0.01$). Post-operative pain was also signi-ficantly lower for group B (3.2 ± 1.4 *versus* 4.8 ± 1.6) ($p = 0.02$). (Table 2)

In group A, 2 (13%) patients required CIC for 5 and 7 days; in group B, 2 (18%) patients required CIC for 7 and 14 days. Duration of hospitalization was not significantly different between both groups (median 6.8 days in group A and 6.5 days in group B). SEAPI-QMN decreased from 6.3 to 0.8 for group A and from 6.09 to 0.9 for group B. Of the 15 group A patients, 1 (6.6%) had persistent stress incontinence, but the severity decreased with time. No group B patients had post-operative stress incontinence. When globally evaluated for satisfaction after surgery, groups A and B patients had median scores of 2 and 1 respectively ($p = 0.02$). *De novo* urgency incontinence developed in 2 patients in group A and 1 patient in group B.

Overall complications were minor and included vaginal bleeding that required prolonged vaginal packing (1), suprapubic wound infection that resolved with oral antibiotics and wound dressing (1), recurrent stress urinary incontinence (2) and prolonged initiation of voiding (3). No patients had permanent urinary retention. (Table 3)

DISCUSSION

There is still considerable debate on the best surgical approach for the treatment of stress urinary incontinence (SUI). The earliest documented surgical approach to SUI was in 1864 by Baker Brown[7]; since his description, more than 200 different surgical procedures have been designed to correct SUI[8]. Unfortunately, it is often difficult to compare the results published in the literature because of important differences in the surgical techniques and in the selection of the patients. Also, most authors generally report only short-term results, whereas it would be more meaningful to analyse long-term cure at 5 years (preferably, 10 years) after surgery. In addition, ran-

Table 1. Baseline parameters of patients undergoing surgical repair of SUI.

	Fascial slings (Group A) (n = 15)	Range	Vaginal slings (Group B) (n = 11)	Range	P-value
Age (years) (mean ± SD)	51.3 ± 7.3		50.4 ± 7.6		0.76*
Number of previous pregnancies (median)	2	1-4	2	0-4	0.56+
SEAPI-QMN (median)	6	4-9	6	4-8	0.71+
Duration of incontinence (months) (median)	24	4-120	48	6-120	0.57+

* Student's *t*-test, + Wilcoxon rank sum test

Table 2. Parameters of evaluation.

	Fascial slings	Vaginal slings	P value
Operative time (mins) (mean ± SD)	98.2 ± 17.3	64.2 ± 8	< 0.01*
Post-operative pain (mean ± SD)	4.8 ± 1.6	3.2 ± 1.4	0.02*

* Student's *t*-test

Table 3. Post-operative efficacy evaluation.

	Fascial slings (n = 15)	%	Vaginal slings (n = 11)	%	P-value
SEAPI-QMN (median)	0.8		0.9		
Patients required CIC (no)	2	13	2	18	
Duration of CIC (day)	5, 7		7, 14		
Persistence of stress incontinence (number)	1	6.7	0	0	0.58*
De novo urge incontinence (number)	2	13.3	1	9.1	0.62*
Median global evaluation (score)	2		1		0.02+
1 = very satisfied (no)	6	40	8	72.7	
2 = satisfied (no)	6	40	3	27.3	
3 = no change (no)	2	13.3	0	0	
4 = dissatisfied (no)	1	6.7	0	0	
5 = very dissatisfied (no)	0	0	0	0	

* Fisher's exact test, + Wilcoxon rank sum test

domized controlled studies comparing different surgical procedures are rare.

In 1949, Marshall, Marchetti and Krantz described vesicourethral suspension, and this urethropexy technique constituted the first step in the history of the surgical management of female sphincter incompetence *via* an abdominal approach. The development of needle suspension techniques became the next logical step to avoid the abdominal approach and open retropubic dissection and, thus, to minimize patient morbidity[9,10].

Sling procedures have been used since the early part of the 20th century, first described by Von Giordano in 1907. There have been many modifications in the tecnique but the same concepts still hold true to this day. The pubovaginal sling procedure has become the gold standard for the treatment of SUI. Most surgical procedures are done with autologous fascia. The morbidity of the procedure is usually low, although some patients complain of pain after fascial harvesting. In some patients the rectus fascia may not be available due to previous surgery. The vaginal wall sling technique described in 1992 by Raz provides a new method for treating SUI. To date, reports of efficacy and other outcomes of pubovaginal sling and vaginal wall sling revealed an 88 per cent success rate at 5 years of follow-up[5] and 95 per cent success rate at 17 months of follow-up[11] respectively. The present study was a randomized controlled study comparing the results of these two procedures.

In the present study the two procedures were performed by a single surgeon to minimize variations in technique. There were no statistically significant differences at baseline between the two groups. The vaginal wall sling procedure required a shorter operative time than pubovaginal sling. Thus, patients treated with vaginal wall sling should have a small risk of peri-operative complications. In the present study post-operative pain was evaluated at 24 hours post-operation to make sure that the recovery after anesthesia was complete. Vaginal wall sling patients had less post-operative pain than fascial sling patients so the former patients enjoyed a more rapid convalescence. Other outcomes were not significantly different between the groups. The reasons for the patients' dissatisfication were prolonged wound discomfort, post-operative CIC or persistent incontinence.

One criticism of the vaginal wall sling is that vaginal shortening may result in decreased sexual function in sexually active women. Although the authors routinely counsel patients on this potential problem, no patients in the present series have expe-

rienced any post-operative sexual problem. In post-menopausal women, the routine use of topical estrogens allows easier surgical dissection and also helps to prevent significant surgical shortening.

SUMMARY

The vaginal wall sling is an easy, reliable method of correcting SUI. The success rates are excellent and are equivalent to fascial slings. The incidence of post-operative stress and urge incontinence and the rate of post-operative complications are low. More importantly, the procedure requires a shorter operative time. Thus, patients will have a minimal risk of peri-operative complications, less post-operative pain, and enjoy a relatively rapid convalescence. Longer follow-up will be required to establish the longevity of these results. However, since the procedure has been shown to be safe and effective on short-term follow-up, the vaginal wall sling should be the preferred surgical method for the treatment of SUI.

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การศึกษาเปรียบเทียบผลของการผ่าตัดรักษาผู้ป่วยที่มีภาวะไอ จาม มีปัสสาวะเล็ดราด (stress incontinence) โดยวิธี pubovaginal sling กับวิธี vaginal wall sling โดยศึกษาแบบสุ่มไปข้างหน้า

วิทย์ วิเศษสินธุ์, พบ, วชิร คชการ, พบ*, วราภรณ์ ไวคกุล, พบ**, อุบลรัตน์ รุ่งเรืองศิลป์, วทบ, วทม***, ณิชา ศิริพรภิญโญ, วทบ, นศม***, วีระ วิเศษสินธุ์, พบ***

วัตถุประสงค์ : ศึกษาเปรียบเทียบผลของการผ่าตัดรักษาภาวะ ไอ จาม มีปัสสาวะเล็ดด้วยวิธีการยกรั้งหลอด-ปัสสาวะด้วยพังผืดกล้ามเนื้อหน้าท้อง (pubovaginal sling) ให้เป็นกลุ่ม A กับการใช้ผนังช่องคลอด (vaginal wall sling) ให้เป็นกลุ่ม B

วัสดุและวิธีการ : เป็นการศึกษาแบบสุ่มไปข้างหน้า โดยศึกษาระหว่าง กุมภาพันธ์ 2544 ถึง ธันวาคม 2544 ผู้ป่วย-หญิงที่มารับการรักษาภาวะไอ จาม ปัสสาวะเล็ด จำนวน 26 ราย (21 รายเป็นแบบชนิด 2 และอีก 5 รายเป็นแบบชนิด 3) ทำการผ่าตัดโดยวิธีใช้พังผืดกล้ามเนื้อหน้าท้อง 15 ราย อายุระหว่าง 42–68 ปี (เฉลี่ย 51.3 ปี) และใช้ผนังช่องคลอด 11 ราย อายุระหว่าง 45–60 (เฉลี่ย 50.4 ปี) การประเมินผลจะใช้ SEAPI–QMN, ภาวะไอ จาม ปัสสาวะเล็ด และ ภาวะ Urge incontinence หลังผ่าตัด ภาวะแทรกซ้อน ระยะเวลาการผ่าตัด ความเจ็บปวดหลังผ่าตัด ระยะเวลาในการนอนพักรักษาตัวในโรงพยาบาล ระยะเวลาที่ต้องทำการสวนปัสสาวะหลังผ่าตัด และความพึงพอใจของผู้ป่วย

ผลการศึกษา : ผู้ป่วยทุกรายจะได้รับการติดตามผล อย่างน้อย 3 เดือนหลังผ่าตัด (โดยเฉลี่ย 7 เดือน) SEAPI–QMN ลดลงจาก 6.3 เหลือ 0.8 ในผู้ป่วยกลุ่ม A และลดลงจาก 6.09 เหลือ 0.9 ในผู้ป่วยกลุ่ม B ไม่มีผู้ป่วยรายใดที่ยังมีอาการไอ จาม ปัสสาวะเล็ดอยู่หลังผ่าตัด มีผู้ป่วย 2 รายในกลุ่ม A และ 1 รายในกลุ่ม B มีภาวะ urge incontinence ไม่มีภาวะแทรกซ้อนที่รุนแรงในทั้งสองกลุ่ม ระยะเวลาในการผ่าตัดและ ความเจ็บปวดหลังผ่าตัดในกลุ่ม B น้อยกว่ากลุ่ม A อย่างมีนัยสำคัญทางสถิติ ระยะเวลาในการพักรักษาตัวในโรงพยาบาล ระยะเวลาที่ต้องทำการสวนปัสสาวะ และความพึงพอใจของผู้ป่วยของทั้งสองกลุ่มไม่แตกต่างกันอย่างมีนัยสำคัญทางสถิติ

สรุป : จากการติดตามผู้ป่วยในระยะเวลาสั้น สามารถรักษาภาวะไอ จาม ปัสสาวะเล็ดโดยใช้พังผืดกล้ามเนื้อหน้าท้องและผนังช่องคลอดได้ผลดีเท่ากัน อย่างไรก็ตามการใช้ผนังช่องคลอดจะใช้เวลาในการผ่าตัดที่สั้นกว่า และมีอาการเจ็บปวดหลัง-ผ่าตัดน้อยกว่าอย่างมีนัยสำคัญ เมื่อเปรียบเทียบกับการใช้พังผืดกล้ามเนื้อหน้าท้อง ดังนั้นการใช้ผนังช่องคลอดอาจจะเป็นวิธี-ผ่าตัดที่ใช้ในการรักษาภาวะไอ จาม ปัสสาวะเล็ดที่เหมาะสมกว่า

คำสำคัญ : ภาวะไอ จาม ปัสสาวะเล็ด, การผ่าตัด, พูโบวาจัยน่าสลิงค์, วาจัยน่าวอลล์สลิงค์

วิทย์ วิเศษสินธุ์, วชิร คชการ, วราภรณ์ ไวคกุล,
อุบลรัตน์ รุ่งเรืองศิลป์, ณิชา ศิริพรภิญโญ, วีระ วิเศษสินธุ์
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