Comparison of recovery from postoperative pain utilizing two sling techniques

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HARTANTO VH, DIPIAZZA D, ANKEM MK, BACCARINI C, LOBBY NJ. Comparison of recovery from postoperative pain utilizing two sling techniques. The Canadian Journal of Urology. 2003;10(1):1759-1763.

Purpose: *Bone anchors are used for suture fixation in a wide variety of reconstructive surgeries. They have been in use for pelvic floor reconstruction since 1992. Bone anchors provide a stable point of suture fixation in order to avoid tying over the mobile rectus fascia. The purpose of this study was to compare two sling techniques that utilize bone anchors with respect to recovery from postoperative pain, complete continence, operative time, and length of hospital stay.*

Materials and methods: *A total of 64 women (mean age = 57) were treated for stress urinary incontinence secondary to intrinsic sphincter deficiency or hypermobility between March 1998 to August 2000. Group I (SPWS) consisted of 30 patients who underwent insitu vaginal wall sling with suprapubic placement of bone anchors in the pubic tubercle utilizing the Vesica system. Group II (TVCS) consisted of 34 patients who underwent cadaveric fascia sling with transvaginal placement of bone anchors behind the symphysis pubis utilizing the Precision-TAC system. Phone interviews were conducted by a third party who was blinded to the details of the surgical technique, to assess pain at various postoperative times as well as current level of continence. The pain assessment was done using the Verbal Pain Assessment Scale (VAS). Complete continence was defined as dryness with no pad use.*

Results: *Significant differences were discovered in both days to pain free state and operative time. No other differences were detected in continence or length of hospital stay. Based on the VAS, a pain free state was achieved for the TVCS group in 1.33 days and for the SPWS group in 9.7 days with p=0.00043. Mean operative time for the SPWS group was 96.9 minutes for the sling alone and 106.7 minutes when combined with cystocele repair. Mean operative time for the TVCS group was 75.36 minutes for the sling alone and 98.11 minutes when combined with cystocele repair. No patient in either group developed osteomyelitis, osteitis pubis, removal of the bone anchors for any reason, nor sling erosion. Seventy percent and 83.3% patients were completely dry (mean follow-up 12.5 months, range 3-30 months) in the SPWS and TVCS group, respectively.*

Conclusion: *A pain free state is achieved faster in patients undergoing transvaginal placement of bone anchors compared to bone anchors placed suprapubically. Bone anchors used in sling procedures are safe and achieve acceptable short term continence rates.*

Key Words: incontinence, sling, bone anchors, pain

Accepted for publication December 2002

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Introduction

Pain is rapidly becoming the fifth vital sign. Modification of standard surgical techniques to

minimize pain, operative time and hospital stay while maintaining long-term efficacy is a continuing process. Sling procedures have traditionally been associated with high cure rates in the treatment of stress urinary incontinence.[1,2] The use of bone anchors for suture fixation are used in a wide variety of reconstructive surgery. They have been in use for pelvic floor reconstruction since 1992.[3] The use of bone anchors in incontinence procedures not only provides a rapid way to stabilize the supporting sling to bone, but avoids tying sutures over a mobile rectus fascia, which may increase the possibility of suture pullout from the sling material below.[4]

Based on surgical preference, bone anchors may be placed suprapubically in the pubic tubercle or transvaginally behind the symphysis pubis. Choices of sling material consist of: autologous tissue such as rectus fascia, fascia lata, and full thickness anterior vaginal wall segments; allografts such as cadaveric fascia; and synthetic materials. The use of an in situ vaginal wall sling and cadaveric fascia greatly reduces the surgical manipulation required for sling placement.[5-7] Efficacy rates for various materials have been reported between 77%-95%.[7,8]

Concerns about using bone anchors in sling procedures include increased morbidities such as infection, chronic post operative pain, suture pullout and efficacy. We compare two techniques that use bone anchors for suture fixation with respect to: recovery from pain using the Verbal Pain Assessment Scale, continence, operative time, and length of hospital stay.

Material and methods

A retrospective chart review was conducted on a total of 64 women who were treated for stress urinary incontinence (SUI) secondary to Intrinsic Sphincter Deficiency (ISD) or hypermobility between March 1998 and August 2000. All procedures were performed by one surgeon (NJL). Preoperatively all patients underwent a thorough history and physical examination and multichannel, slow-filling urodynamics performed at lying down and sitting positions. At the time of physical examination, all patients' bladders were filled to 200 ml - 300 ml. Patients were then asked to cough or perform valsalva. Stress incontinence was demonstrated in all patients. If prolapse was identified, it was reduced prior to valsalva.

The patients were divided into two groups sequentially by the procedure performed. Group I consisted of the first 30 patients who underwent insitu vaginal wall sling with suprapubic placement of bone anchors in the pubic tubercle (SPWS). Group II consisted of the consecutive 34 patients who underwent cadaveric fascia sling with transvaginal placement of bone anchors behind the symphysis pubis (TVCS). Each group was subdivided into A and B which were sling without cystocele repair and sling with cystocele repair, respectively.

All patients were given preoperative antibiotics and placed under general or regional anesthesia. A 16 F Foley catheter was employed. Copious amounts of antibiotic solution (Bacitracin) was used throughout the case as an irrigant. Cystocele repair was performed using a Kelly type plication with anterior colporrhaphy.[10] Vaginal incisions were closed with a running 2-0 polyglycolic acid absorbable suture. Vaginal packing was placed at the end of each procedure.

The technique of in situ vaginal wall sling with suprapubic bone anchors has been described elsewhere.[11] In summary, a 1 cm transverse incision was made over each pubic tubercle and dissected down to the periosteum. Using the Vesica Press In ^{TM}Anchor System (Boston Scientific/Microinvasive ^{R}), a titanium bone anchor loaded with #1 Novafil suture was pressed into the pubic tubercle. On the anterior vaginal wall a "block A" was drawn and injected with 10 cc 1% lidocaine with epinepherine. The incisions were carried through the vaginal wall to the level of the pubocervical fascia. Cystoscopy confirmed that sutures were passed into the lateral vaginal lumen. A free Mayo-type needle was used to place a horizontal mattress suture through the wall sling and the suture was transferred to the abdominal wound. The suture was tied over a suture spacer. These steps were repeated on the opposite side.

A brief description of the placement of a Cadaveric fascia sling with transvaginal bone anchors as has been described elsewhere[12] follows. An inverted U-shape is sketched on the anterior vaginal wall, injected with 10 cc 1% lidocaine with epinepherine, and dissected to the level of the pubocervical fascia to create a flap one finger breadth space behind the pubic bone. Using the Precision Tack (Boston Scientific/ Microinvasive^{R}) a titanium bone anchor loaded with #1 Novafil suture is pressed into the pubic bone. The allograft material used was a 2 cm x 4 cm freeze-dried, irradiated cadaveric fascia lata (Tutoplast^{R}, Mentor) which was soaked in antibiotic solution. The previously placed sutures were passed through a folded corner of the graft. Sutures were tied, with a Kelly clamp placed under the graft, to reduce undo tension on the sling.

Phone interviews were conducted by a third party, who was blinded to the details of the surgical

technique, on postoperative day number 3, 7 and 30. Each pain assessment was followed by a detailed interview indicating the estimated pain intensity based on verbal pain assessment scales (VAS, 0-10). Time to painfree condition (VAS = 0) after surgery was evaluated between the two groups. Complete continence, surgery time, and length of hospital stay were also evaluated. Complete continence was defined as dry and using no pads. The data were then analyzed using two-tailed student T-test and X^2 statistical analysis.

Results

A total of 64 women, 34 to 81 years old (mean age 57), were involved in this study. The mean age was not significantly different between the two groups. Group I consisted of 21 patients having sling procedure alone and 9 patients having sling and cystocele repair. Group II consisted of 31 patients having sling procedure alone and 3 patients having sling and cystocele repair. In order to provide sufficient numbers for statistical comparison, patients both with and without cystocele repair were joined. Based on the Verbal Pain Assessment Scale, a pain free state was achieved in 9.7 days for group I and 1.3 days for group II, which was significantly different to P=0.00043. Short term complete continence was not significantly different between groups I and II; with mean follow up of 12.5 months, range of 3-30 months. For each subgroup, the operative time was listed in Table 1. There was no significant difference between subgroups IA and IIA. However, once the patients with cystocele repair were included in the calculations, the OR times were statistically different between groups I and II. No patient in any group developed osteomyelitis, osteitis pubis, removal of the bone anchors for any reason, nor sling erosion. Only 3 of 64 patients in both groups required hospitalization greater than one postoperative day. The length of hospital stay was also not significantly different between groups I and II.

Discussion

To date there have been few reports of postoperative pain assessment in the surgical treatment of stress urinary incontinence in women who undergo a pubovaginal sling procedure. Historically, the earliest sling procedures were designed to prevent urinary leakage by providing circumferential pressure at the level of the bladder neck by means of rotating various muscles and fascia.[13,14] In the last half of the twentieth century, modifications to simplify the procedure resulted in the development of transvaginal approaches and the use of free fascial slings. Harvesting of free fascial slings still requires extensive surgical exposure (rectus fascia) or the use of secondary procedures and incisions (fascia lata), with the potential morbidity of prolonged pain, longer hospital stays and wound infection.[15,16]

The sling procedure continues to undergo modifications through the use of bone anchors and a variety of sling material options. The use of bone anchors where the fascia is tenuous allows the sutures tension to be distributed to the pubic bone rather than the rectus fascia.[3] The vaginal wall sling initially described by Raz[17] uses full thickness anterior vaginal wall segments as the supporting sling. Handa[18] began using banked human fascia lata for the sling in 1994 and since that time several reports have been published on its use.[19-21]

TABLE 1. **Operative time for each subgroup**

		No. patients	Days to painfree	Complete continence	OR time (minutes)	Length of hospital stay (days)
Group 1:	IA	21	9.7 $\pm$ 7.0	70.0%	96.9 $\pm$ 34.1	1.2 $\pm$ 0.4
	IB	9			106.7 $\pm$ 12.6	
Group II:	IIA	31	1.33 $\pm$ 1.15	83.3%	75.36 $\pm$ 13.96	1.1 $\pm$ 0.3
	IIB	3			98.11 $\pm$ 4.29	
P value at 5% level (+/- std dev)			P=0.00043	X^2=0.04072 Df=1 P >0.10	P(1 vs II)=0.043 P(IA vs IIA)=0.155	P=0.469

Pain assessment and management are major clinical problems that have received increasing attention. Verbal pain assessment scales are widely used to assess pain and several studies have validated their use in the postoperative setting.[22,23] Days to a pain free state was achieved significantly faster in the transvaginal bone anchor group (1.33 days), than in the suprapubic bone anchor group (9.7 days). We acknowledge the shortfall of retrospective assessment of days to pain free as judged by the patient. The cause of the delay in days to pain free in the suprapubic bone anchor group is not made clear by this study. The suprapubic incisions made for the bone anchoring or for the fact that Group I has more patients with cystocele repairs as well may be the cause of the prolonged pain compared with Group II.

A procedure may result in decreased pain, decreased operative time, and decreased length of hospital stay, but it must have comparable efficacy. Short term complete continence as defined by dry with use of no pads was achieved in 70% of patients in group I (SPWS) and 83.3% of patients in group II (TVCS). This was not clinically significant between the two groups. Until recently, few studies define a cure rate based on complete dryness. The Female Stress Urinary Incontinence Clinical Guidelines Panel analyzed the literature and determined an 82% (73-89) long term complete continence rates.[26] Other recent studies report a range of complete continence to be 62%[27] to 82%[28] using rectus fascia to construct the pubovaginal sling. Longer follow up may prove our efficacy rates to be somewhat lower, but with a mean follow up of 12.5 months, our strict definition of continence shows both procedures to be acceptable in the management of female stress urinary incontinence.

Our operative time was statistically different between the two groups (p=0.043) with the TVCS group's operative time approximately 20 minutes faster on average. Kaplan[24] reported a mean operative time of 84.2 $\pm$ 17.8 minutes to perform a rectus fascia pubovaginal sling as described by McGuire and Litton.[15] This compares favorably to our reported operative time employing bone anchors. However, in the community setting as in our institution, the operative time for a rectus fascia pubovaginal sling averages 120 minutes.

Only 3 of 64 patients in both groups required hospitalization greater than one postoperative day. The mean hospital stay was 1.2 and 1.1 days for groups I and II, respectively. Several studies report a mean hospital stay of 2.5-3.7days after undergoing a rectus fascia pubovaginal sling.[24,25] Our patient's length of stay was significantly shorter by at least one day which may have reduced the of cost per procedure in comparison based solely on length of stay.

Conclusions

We report on 64 patients who underwent a pubovaginal sling which incorporated bone anchors as a point of fixation for the sling. No patient developed osteomyelitis, osteitis pubis, surgical removal of the bone anchor for any reason, nor sling erosion. Bone anchors used in sling procedures to treat stress urinary incontinence are safe and achieve acceptable continence rates. A pain free state based on verbal pain assessment scale is attained faster in patients undergoing transvaginal placement of bone anchors compared to bone anchors placed suprapubically. □

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