Original Article

Is modified Raz technique of midurethral sling a reliable and cost-effective method of treating stress urinary incontinence?

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ABSTRACT

Objectives: We report our experience of pure stress urinary incontinence (SUI) treated by midurethral synthetic sling placement by modified Raz technique.

Materials and Methods: Fifty-three patients with pure SUI operated at our institute between June 2003 and December 2008 were included in this study. Midurethral sling tape, fashioned from commercially available large pore synthetic mesh, was placed using the modified Raz technique. The technique consisted of placing the tape within retropubic space using double-pronged needle, which is passed under finger control through the fascia and retropubic space. Outcomes were assessed on the basis of patient's interview in follow-up OPD.

Results: Mean age was 57.68 (28–69) years. Forty-five (85%) patients were totally dry and eight (15%) socially dry at the end of the follow-up. Mean operative time was 46.5 + 11.3 minutes (35–80 minutes). None of the patients required blood transfusion or had bladder/bowel injury. Mean duration of hospital stay was 2.17 days (2–4 days). Mean duration of follow-up was 46.1 months (12–78 months).

Conclusions: Modified Raz technique is safe and cost-effective for placing midurethral sling for genuine stress incontinence.

Key words: Stress urinary incontinence, midurethral slings, polypropylene, prosthesis and implant.

INTRODUCTION

Stress urinary incontinence (SUI) is defined as the complaint of involuntary leakage on effort or exertion or on sneezing or coughing.[1] Although SUI is not a life-threatening condition, it can greatly affect one's quality of life. Surgical therapy is employed in patients who have severe degrees of SUI or those patients in whom conservative or pharmacological treatments have failed. Sling procedures for genuine SUI are today the mainstay of treatment and have been used for over a century with first procedure reported by Schultze in 1888.[2]

The integral theory of female urinary continence described by Petros and Ulmsten redefined the modern approach to anti-incontinence surgery and ushered the era of the midurethral sling. The concept was applied clinically by placing the sling to a more distal location beneath the urethra then as compared to the previous techniques.[3] Subsequently excellent results were presented using suprapubic arc system (SPARC®, American Medical Systems Inc., Minnetonka, MN) or tension-free vaginal tape (TVT). Some authors have even termed midurethral sling surgery as the new gold-standard for SUI.[4,5]

With the available midurethral slings, the trocar has to be passed blindly either from above (suprapubically) or below (transvaginally), which increases the chances of injury to the pelvic organs and blood vessels.[6,7] In addition, these are also very costly for developing countries. Shlomo Raz modified the technique of sling placement with opening the endopelvic fascia and passing the needle under controlled digital palpation, thereby decreasing the chances of injury to surrounding pelvic organs as well as significantly decreasing

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cost using tailor-made mesh.[8] Their finger-guided passing of needle was similar to the Raz procedure of bladder neck suspension.[9]

We present our experience with the use of large pore polypropylene mesh/polypropylene-polyglactin mesh as a pubovaginal sling (midurethral) in the treatment of SUI with the modified Raz technique.

MATERIALS AND METHODS

A retrospective analysis was performed of consecutive 53 patients of pure SUI who underwent midurethral slings procedure with the modified technique from June 2003 to December 2008 at our institute. Preoperative evaluation included a history, physical examination, urine microscopic examination, and culture. Severity of SUI was defined by the number of pads used by the patients per day as mild (< 2), moderate (2–4), and severe (>4). Patients were examined in lithotomy and standing positions to demonstrate SUI on cough test and Valsalva maneuver. Four patients of our series underwent multichannel urodynamic examination for history suggestive of mixed incontinence in accordance with NICE guidelines.[10]

All patients were counseled regarding the need of postoperative clean intermittent catheterization (CIC) and transient voiding dysfunction.

Forty-five of 53 patients (85%) were post-menopausal. Vaginal tissue was atrophic in four patients and they were preoperatively treated with local estrogen cream. Twenty patients gave previous history of hysterectomy; others had history of undergoing gynecological procedures, details of which were not available. None of the patients had previous history of surgery for incontinence or pelvic organ prolapsed. Eight patients had grade 1 cystocele and two patients had grade 1 rectocele, which did not require treatment. Five patients underwent simultaneous vaginal hysterectomy for gynecological indications.

A polypropylene mesh (Prolene®)/polypropylene-polyglactin mesh (Vipro®) measuring 1 × 10 cm (Ethicon, Johnson and Johnson, USA) was fashioned from commercially available 15 × 7.5 cm mesh. This strip was soaked in antibiotic saline and stitched at all four corners to 1-0 polyglactin suture.

All patients received 1 g amikacin intravenously at the time of induction. 16 Fr Foley catheter was placed in urinary bladder and balloon was palpated at bladder neck to estimate urethral length. Two percent of xylocaine with adrenaline was infiltrated in the vaginal mucosa overlying the urethra. A 1.5–2 cm mid-line incision was made over the midurethra (1.5 cm proximal to external urethral meatus). Vaginal mucosal flaps were dissected on either side extending into avascular plane, until endopelvic fascia was reached. Endopelvic fascia was perforated with scissors bilaterally. Blunt dissection was carried out in retropubic space by inserting a finger and the bladder was swept medially. Two small punctures were made suprapubically and a double-pronged needle (Cook Urological Inc., Indiana, USA) is passed under finger control through the fascia and retropubic space. The previously placed polyglactin sutures from the mesh are transferred to the suprapubic incision. A marking catgut suture is placed in the center of the mesh along its length to ensure that mesh placement is equidistant. Check cystoscopy was done to rule out bladder or urethral injury at this point.

The polyglactin suture was pulled and tension adjusted by placing the tip of an artery forceps while positioning sling against midurethra. The polyglactin suture was tied in air knot fashion. Once equidistant placement of sling was ensured, catgut suture marker was removed. The anterior vaginal wall was closed with continuous running 3-0 polyglactin suture. The suprapubic incision was closed with a 3-0 monofilament suture. Antibiotic solution soaked vaginal pack was inserted, which was removed on day two.

Antibiotic was continued for 3 days postoperatively. Vaginal pack was removed after 24 hours of surgery and providine-iodine vaginal pressary was advised for 5 days. Voiding trial was given after 48–72 hours and uroflow and postvoid residue was checked. If residual urine was more than 50 ml, patient was advised CIC. In sexually active patients, abstinence was advised for 6 weeks postoperatively.

The patients were followed up with history and clinical examination by the operating surgeon in the OPD. Social dryness was defined as patient requiring ≤1 pad per day and acceptable leak while carrying out routine tasks. Satisfaction was assessed on the basis of patient's interview.

RESULTS

Fifty-three patients underwent surgery for stress incontinence. Preoperative urodynamic assessment was done in four patients for indication as cited above. None of them had detrusor over activity or obstructed flow. Mean age of patient was 57.68 (28–69) years. Mean operative blood loss was 100 ± 30 ml. Mean operative time was 46.5±11.3 minutes (35–80 minutes). Five of the patients also underwent simultaneous vaginal hysterectomy for gynecological indications with no increase in morbidity. Mean duration of hospital stay was 2.17 days (2–4 days). Mean duration of follow-up was 46.1 months (12–78 months) [Table 1].

Forty-five (85%) patients were completely dry and eight (15%) were socially dry at the end of the follow-up. Four patients failed voiding trial and were advised CIC, which was later discontinued after 3–8 weeks, when their

Table 1: Patient demographics

Mean age (range)	57.67 (28–69)
Mean number of prior surgeries	0.60 (0–4)
Mean number of vaginal deliveries	3.15 (1–8)
Mean number of pads	3.03 (0–10)
Number of procedures (%)	
Sling alone	48 (91)
Sling + vaginal hysterectomy	5 (9)

Table 2: Complications

Event	No (%)
Stitch line hematoma (managed conservatively)	1 (1.8)
UTI/ Fever (in immediate postoperative period)	2 (3.7)
Urinary retention	4 (7.5)
Lower abdominal pain	2 (3.7)
Dyspareunia	5 (9.4)

PVR fell to <50 ml. None of the patients required sling release. Two patients complained of dull aching lower abdominal pain, which was relieved by administration of oral analgesic agents. Five of our patients complained of mild dyspareunia, which was transient and did not require treatment [Table 2].

One of the patient developed stitch line hematoma which was managed conservatively. There was no incidence of bladder or urethral injury. None of the patients reported significant voiding dysfunction, infection, nonhealing, or erosion of the sling till their last follow-up [Table 2].

DISCUSSION

Over last few years, many procedures using autologous material (rectus sheath, fascia lata) or synthetic material (polypropylene, mersilene) have been reported in literature.[11,12] Continued refinements in materials were sought to identify an ideal compound for use in transvaginal slings that would be inert, sterile, noncarcinogenic, and mechanically durable.[13] Synthetic materials have the advantage of being readily available and do not require harvesting from another site. This decreases the operative time, discomfort, and potential donor site complications after the surgery. Histological[14] and clinical[15,16] studies have shown that polypropylene is a synthetic material that is well-tolerated by the body, with little exposure of the patient to infection and vaginal or urethral erosion. Cure rates using synthetic slings have been shown to be around 73–95%.[17,18]

In a review of contemporary literature, Daneshgari *et al*. have found complication rates ranging from 4.3% to 75.1% for retropubic midurethral slings. They have quoted postoperative obstruction ranging from 1.9% to 19.7% from various series.[19] In these patients, resolution is commonly spontaneous; the intervening period can be managed with CIC or indwelling catheter.

A recent meta-analysis showed that TVT outperformed Burch colposuspension both in terms of postoperative continence rates, whereas success rate efficacies were similar after TVT and pubovaginal slings. Comparing TVT to the other retropubic tension-free midurethral vaginal slings, TVT was more efficacious than both intravaginal slingplasty (IVS) and SPARC.[20] Some authors have even described midurethral slings as the new gold-standard for the treatment of female SUI.[4,5]

The reasons for popularity of these procedures are effectiveness, ease, and low rate of serious complications. A recent meta-analysis of complications of these procedures have highlighted significantly high rates of bladder perforation after TVT.[6] Deng *et al*. have questioned the authenticity of reported complication rates and have described major complications and even 10 deaths as retrieved after systemic search of food and drug administration (FDA) manufacturer and user facility device experience (MAUDE) database.[7]

Rodriguez and Raz have described a mid-distal urethral sling procedure in which distal urethra is defined as anything distal to the pubourethral ligament.[8] They have explained the mechanism of action of TVT procedure by providing support as well as contributing to normal function of distal urethral complex (composed of the pubourethral ligaments, intrinsic sphincteric mechanism, extrinsic sphincter, and levator muscles located immediately distal to the pubourethral ligaments). Furthermore, they have enumerated the drawbacks of current midurethral sling systems as being blind procedures with consequently higher incidences of major complications.

In their modification, a sling is refashioned from commercially available mesh, which is cheap, does not require any special instrumentation, and is placed only within the retropubic space. The optimal surgical approach should minimize the risk of damage to the bladder neck, vagina, and urethra. This is achieved by developing retropubic space with blunt dissection and passing double-pronged needle under finger guidance. The procedure should augment the urethral resistance during sudden increase in the intra-abdominal pressure without preventing normal decreases in urethral pressure during voiding. Placing a sling beneath the urethra increases the urethral compression and provides a plate for receiving the transmitted intra-abdominal pressure to the bladder neck and proximal urethra. The safety of the procedure has also been demonstrated in their series with no incidence of major complications.

Conventional guidelines recommended multichannel

urodynamic studies in SUI patients planned for surgery. With the advent of midurethral slings, which have shown to be effective in all types of urinary incontinence, studies have questioned the routine use of urodynamic parameters like Valsalva leak point pressure in predicting outcome of sling surgery.[21] Houwert *et al*. have proposed that standard use of urodynamic investigation in the preoperative workup of midurethral slings needs to be revisited.[22]

In our series we had cure rate in all the 53 patients till their last follow-up. Sling procedures that are successful at 6 months are likely to remain successful for many years.[23] In our series, all the patients had a follow-up of more than 12 months and all these patients were doing well till their last follow-up.

In a comprehensive meta-analysis of complications of midurethral slings, Novara *et al*. have found the incidences of various complications – bladder/vaginal perforation 2.91–9.31%; hematoma 1.45–3.9%, UTI 3.7–7.5%, and CIC in 7–7.5% of cases in various RCTs and non-randomized studies.[6] Rodriguez *et al*. have described pelvic hematoma (not requiring treatment) in 0.33% and suprapubic pain in 0.66% of cases. Three of their patients required CIC for maximum of 3 months after which they were all spontaneously voiding.[8] In our series, four (7.5%) patients required CIC after failed voiding trial, which was discontinued after a period of 3–8 weeks. We attribute this to be the procedure-related local tissue edema/pain, which gradually subsided. Other minor complications in our series were hematoma (not requiring treatment) in 1.8%, UTI in 3.7%, low back pain in 3.7%, and dyspareunia in 9.4% of cases.

Major concerns about the erosion of the sling into the urinary tract have been diminished as a result of meticulous detail in placing the mesh through a small incision and tying the mesh loosely so as to avoid excessive compression and ischemia. We did not encounter any incidence of mesh erosion into the urethra in our series of patients. We faced none of the major injuries like vascular injury, bowel injury, necrotizing fasciitis, sepsis, or death, a fact emphasized by the Shlomo Raz group.

One standard-sized polypropylene mesh costs around INR 1800 and polypropylene-polyglactin (Vipro®) mesh costs around INR 2300. This is economically friendlier as compared to custom-made mesh systems commercially available, ranging from INR 18,000 to 25,000, especially in developing country like India.

The limitations of this study are lack of objective analysis and quantification of SUI. Outcomes were based on patients' interview on OPD basis by the operating surgeon and not by patient-driven questionnaires, possibly influencing the overall results.[8] Despite the limitations of the study, we believe this procedure is a cost-effective alternative to other minimally invasive procedures using commercially available kits and with comparable outcomes.

CONCLUSIONS

Polypropylene mesh as midurethral slings by modified Raz technique is cost-effective, safe, and has acceptable complication rates. Although our series is a not big enough to draw any formal conclusions, but we can safely infer that the results of this procedure are comparable to other techniques used in patients with pure SUI.

REFERENCES

1. Abrams P, Cardozo L, Fall M, Griffiths D, Rosier P, Ulmsten U, *et al*. The standardisation of terminology of lower urinary tract function: report from the standardisation sub-committee of the International Continence Society. Am J Obstet Gynecol 2002;187:116–26.
2. Barett D, Wein AJ. Voiding dysfunction, diagnosis, classification and management. In: Gillenwater JY, Grayhack JT, Howards ST, Duckett JW, editors. Adult and Pediatric Urology. Chicago: Year Book Medical; 1987. p. 863-962.
3. Petros PE, Ulmsten UI. An integral theory of female urinary incontinence: experimental and clinical considerations. Acta Obstet Gynecol Scand 1997;166:3–8.
4. Bemelmans BL, Chapple CR. Are the slings now gold-standard treatment for the management of female stress urinary incontinence and if so which technique? Curr Opin Urol 2003;13:301-7.
5. Serati M, Salvatore S, Uccella S, Artibani W, Novara G, Cardozo L, *et al*. Surgical treatment for female stress urinary incontinence: what is the gold-standard procedure? Int Urogynecol J Pelvic Floor Dysfunct 2009;20:619-21.
6. Novara G, Galfano A, Boscolo-Berto R, Secco S, Cavalleri S, Ficarra V, *et al*. Complication Rates of Tension-Free Midurethral Slings in the Treatment of Female Stress Urinary Incontinence: A Systematic Review and Meta-Analysis of Randomized Controlled Trials Comparing Tension-Free Midurethral Tapes to Other Surgical Procedures and Different Devices. Eur Urol 2008;53:288–309.
7. Donna Y D, Matthew R, Shlomo R, LarissaV. Rodriguez. Presentation and Management of Major Complications of Midurethral Slings: Are Complications Under-reported? Neurourol Urodynam 2007;26:46-52.
8. Rodríguez LV, Raz S. Prospective analysis of patients treated with distal urethral polypropylene sling for symptoms of stress urinary incontinence: surgical outcome and satisfaction determined by patient driven questionnaires. J Urol 2003;170:857-63.
9. Raz S. Modified bladder neck suspension for female stress incontinence. Urology 1981;17: 82-5.
10. National Institute of Health and Clinical Excellence (NICE) guidelines on management of urinary incontinence in women http://www.nice.org.uk/nicemedia/pdf/CG40NICEguideline.pdf
11. McGuire EI, Lytton B. Pubovaginal sling procedure for stress incontinence. J Urol 1978;119:82.
12. Leach GE, Dmochowski RR, Appell RA, Blaivas JG, Hadley HR, Luber KM, *et al*. Female stress incontinence clinical guidelines panel summary report on surgical management of female stress incontinence. J Urol 1997;158:875-80.
13. Rapp DE, Kobashi KC. The evolution of midurethral slings. Nat Clin Pract Urol 2008;5:194–201.
14. Falconer C, Soˆderberg M, Blomgren B, Ulmsten U. Influence of different sling material on connective tissue metabolism in stress urinary incontinent women. Int Urogynecol J 2001;S19–23.

15. Ulmsten U, Petros P. Intravaginal slingplasty (IVS); an ambulatory surgical procedure for treatment of female urinary incontinence. Scand J Urol Nephrol 1995;29:75–82.
16. Margan PA, Ward KL, Johnson D, Smirni WE, Hilton P, Bibby J. Tension-free vaginal tape for primary genuine stress incontinence: a two-centre follow-up study. BJU Int 2000;86:39–42.
17. Snith T, Daneshgari F, Dmochowski RR . Surgical treatment of incontinence in females. In: Abrams P, Cardozolo L, Khoury S, Wein A, editors. Incontinence 2nd ed Plymouth UK: Health publication Ltd; 2002. p. 823-63.
18. Weber AM, Walters MD. Burch procedure compared to sling procedures for stress urinary incontinence: a decision analysis. Obstet Gynaecol 2000;96:185:32-40.
19. Daneshgari F, Wesley Kong W, Swartz M. Complications of Mid Urethral Slings: Important Outcomes for Future Clinical Trials. J Urol 2008;180:1890-7.
20. Novara G, Ficarra V, Boscolo-Berto R, Secco S, Cavalleri S, Artibani W. Tension-Free Midurethral Slings in the Treatment of Female Stress Urinary Incontinence: A Systematic Review and Meta-analysis of Randomized Controlled Trials of Effectiveness. Eur Urol 2007;52:663–79.
21. Rodri´guez LV, de Almeida F, Dorey F, Raz S. Does Valsalva Leak Point Pressure predict outcome after the distal urethral polypropylene sling? Role or urodynamics in sling era. J Urol 2004;172:210-4.
22. Houwert RM, Venema PL, Aquarius AE, Bruinse HW, Kil PJM, Vervest HAM. Predictive value of urodynamics on outcome after midurethral sling surgery for female stress urinary incontinence. Am J Obstet Gynecol 2009;200:649e1-12.
23. Pesce F. Current management of stress urinary incontinence. BJU 2004;94:8-13.

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