

READJUSTABLE SLING PROCEDURES FOR TREATMENT OF IN FEMALE STRESS URINARY INCONTINENCE WITH INTRINSIC SPHINCTER DEFICIENCY

Readjustable Sling Procedures for Treatment of in Female Stress Urinary Incontinence with Intrinsic Sphincter Deficiency

Propose: The REMEEX (Mechanical External Regulation; Neomedic International) sling as a bladder neck sling that allows adjustment of the sling tension in the postoperative period. We evaluated the early outcomes of Remeex procedures in the management of women in SUI patients by intrinsic sphincter deficiency (ISD).

Materials and Methods: 20 women underwent Remeex procedures to treat stress urinary incontinence (SUI) and all patients had ISD. The patients were divided into three groups according to their preoperative Valsalva leak point pressure (VLPP) and maximum urethral closure pressure (MUCP): Parameters of evaluation included a comprehensive medical history, physical examination and urodynamic study that included determining the VLPP and MUCP, operation time and complication. Further, we asked about lower urinary tract symptoms (LUTSs) with using a female bladder questionnaire. After treatment, the same questionnaires were repeated. The objective and subjective success rate were evaluated during the postoperative period.

Results: The mean age was 55.66 ± 9.58 years and the mean follow-up period was 9.3 months (6-16 months) For the operation outcome results, in ISD all group no failures occurred and success rates (cure + improvement) was 100% (20 patients had full recovery). The postoperative satisfaction (including very satisfaction) rate of patients according to ISD group was 100% in the all group ($p > 0.05$). Also, these results show that the REMEEX procedure improves LUTSs exception voiding pain in the all patients ($p < 0.05$).

Conclusions: We consider the REMEEX procedure to be an effective treatment female SUI with ISD.

Key Words: suburethral sling, urinary Stress incontinence

Introduction

SUI is an important problem in health which may cause functional disorder to elderly people. It has been reported that the prevalence of urinary incontinence is increasing proportionately with age and 65% of women over 50 have it [1]. According to its mechanism, it is categorized into anatomic urinary incontinence due to urethra hypermobility and ISD [2]. A variety of surgical techniques have been developed based on research on SUI and tension-free vaginal tape (TVT) introduced in 1996 has been frequently used. Since then, outside-in MONARC subfascial hammock, an American Medical System (Monarc) which was introduced in 2001 in which transobturator route passes outside in has been frequently used. An obturator system, Ethicon (TVT-O), which was suggested two years later and in which transobturator route passes inside out have also been frequently used with TVT. It has been reported that their success rates were above 80-100% [3-6]. Those in SUI with ISD were 24-84% though it was differently reported according to research in comparison with the success of anatomical urinary incontinence to treat urinary incontinence and complications such as voiding difficulty occurred after surgery [7-9].

REMEEX are the Spanish initials for Mechanical External Regulation. This is a re-adjustable sling system for the surgical treatment of female SUI. This procedure permits the adjustment and readjustment of sling tension intra-operatively or during the postoperative period with minimally invasive ambulatory surgery, which can be performed under local anesthesia months or even years after the first procedure. Therefore, it has advantages that urinary retention can be obtained and incontinence can be minimized. This study analyzed results of REMEEX surgery for female SUI caused by ISD to determine whether it is effective for SUI with ISD.

MATERIALS AND METHODS

1. Patient group

This study observed 20 subjects who were diagnosed with ISD in urodynamic study (UDS) at the urology department and had REMEEX from February, 2006 to April, 2009 for more than six months.

For the study, we implemented prospective studies of medical records by phone or personal interviews for medical examination using a questionnaire to identify the success rates of surgeries, satisfaction rates, differences in success rates according to degrees of ISD, satisfaction in lower urinary tract symptoms and complications. All the patients had interviews for medical examination before surgeries, and UDS including vasalva leak point pressure (VLPP) and Maximal urethral closure pressure (MUCP). Based on VLPP and MUCP conducted at UDS, ISD was categorized as follows:

Mild ISD is defined as $40\text{cmH}_2\text{O} \leq \text{VLPP} < 60\text{cmH}_2\text{O}$, moderate ISD as $\text{MUCP} \leq 20\text{cmH}_2\text{O}$ or $30\text{cmH}_2\text{O} \leq \text{VLPP} < 40\text{cmH}_2\text{O}$, and severe ISD as $\text{MUCP} \leq 10\text{cmH}_2\text{O}$ or $\text{VLPP} \leq 30\text{cmH}_2\text{O}$. Then the subjects were divided into mild ISD group: (Group I = 11), moderate ISD group: (Group II = 6) and severe ISD group: (Group III = 3). Objective judgment after surgical treatment was based on Stamey standards. When the subjects had no incontinence after surgery, they were defined as cured, When they had insignificant incontinence after surgery, they were defined as improved. When the degree of incontinence did not change after surgery, it was defined as a failure. Success rates included complete recovery and improvement. Patients' subjective satisfaction was investigated using a questionnaire and it was categorized into four phases; very satisfactory, satisfactory, usual

and unsatisfactory. The lower urinary tract symptoms included frequency, nocturia, and urgency, urge incontinence, residual urine sensation and dysuria. To quantify overall satisfaction in urination before and after surgery in respect with each lower urinary tract symptom, a visual analog scale test (VAT) was used and the following marks are presented: 0 for very satisfactory and 10 for very unsatisfactory to compare changes of VAT points before and after surgery. This study conducted student's t-test, one-way ANOVA and Chi-square test on the results of the study with use of SPSS 10.0. For an analysis of interview results after surgery, this study used Kruskal-Wallis Test and when groups were compared and the p-value was below 0.05, it was judged as significant.

2. Operation technique

REMEEX system consists of regulation prosthesis (varitensor) and a short Polypropylene sling (35 x 12mm) with suspension suture threads. The REMEEX Mechanical Regulation part is a subcutaneous permanent implant with the "varitensor," which permits adjustment of the sling support from outside the body by means of an external manipulator (EM). The varitensor also has a mechanical connecting point for the EM on its upper side. These components are made of biocompatible materials such as titanium and ultra-high-molecular-weight polyethylene (Chirulen®). First we made a 3cm abdominal incision just over the pubis. The sling is placed at the level of the bladder neck through a vaginal incision, and the suspension threads are passed through the Retzius space by a suture passer needle driven by a passer handle. After checking the bladder integrity, the suspension threads are introduced into the varitensor. The tension of the sling can now be regulated. Clockwise rotation elevates the sling, and counterclockwise rotation lowers the sling. The adjustment can be made at the OR based on surgical experience. The following morning the catheter is removed, and after filling the bladder with 300 c.c. of saline, we control the incontinence level, with the patient standing up and doing incontinence maneuvers, and regulating the sling elevation accordingly. Then we ask the patient to urinate and we measure the residual urine. The EM is a disposable part of the set that is removed once the desired continence level is achieved. If this is > 100 cc, we lower the sling tension. When there is no incontinence and the residual is < 100 cc, we disconnect the manipulator and discharge the patient.

RESULTS

The mean age of the subjects of the study was 55.66±9.58. The mean age of the mild ISD group was 54.63±8.56, that of the moderate ISD group was 56.21±8.46, and that of the severe ISD group was 58.81±3.70. The numbers of the patients who had hysterectomy and incontinence operation (TVT) were 4 and 2 respectively. The mean number of the patients who had natural childbirth was 2.6 and the mean observing period was 9.3 months (6-16). The operation time for the procedure was 35 minutes (25-45), and the mean duration of the postoperative urethral catheterization was 2.6 days (2-4). No patient needed catheterization for more than 4 days. After the urethral catheter was removed, postoperative regulation was necessary for 6 of 20 patients. Postoperatively, in 4 of the 20 patients, the stress test with 300 ml volume in bladder was positive after catheter removal and we needed to increase the sling tension by rotating the Manipulator of the Varitensor clockwise a mean of 5mm. In 2 of the 20 patients the residual was abnormal, and we had to decrease the sling tension by rotating the Manipulator counterclockwise a mean of 4 mm. Fourteen subjects completely recovered from incontinence, and 6 improved. No failures occurred and success rates (full recovery + improvement) was 100% (20 patients had full recovery). In ISD Group, the full recovery rate of group 1 was 81.8%, that of group 2 was 66.6%, and that of group 3 was 33.3%. As ISD was worse, the cure rate decreased, but it was not statistically insignificant. Four subjects (20%) answered that they were very satisfied and 16 answered (80%) that they were satisfied. Three groups answered that they were 100% satisfied.

In VAT point change of urinary tract symptom after surgery, the following results were obtained: frequency (5.2->1.9), nocturia (5.5->1.8), urgency (3.1->1.7), urge incontinence (3->1.3), and residual urine sensation (5.4->2.9). The subjects showed significant improvement in all the symptoms and dysuria was somewhat worsened (2.9->3.6), it was statistically significant exception dysuria. They showed no significant complications such as damages in the urinary bladder, the intestines, blood vessels, and hematoma. However, they had the following short-term complications: 4 had transient urgency (20%), 1 had wound infection (5%), and 2 had difficult emptying (10%), but all of them improved after manipulator control. For long-term complications, one subject (5%) had chronic pain due to the wound, but no other complications were found.

DISCUSSION

SUI is the most common female urethral incontinence. Urine leakage occurs when the bladder neck opens as abdominal pressure increases without contraction of the detrusor muscle. Its causes are categorized into urethra hyper mobility and ISD [2]. In 1996, Ulmsten et., al. introduced TVT which is a variant of sling surgery. As this method requires less incision and exfoliation of vaginal wall, the operating period and hospitalization are shorter, recovery is faster and fewer side effects are found in comparison with previous sling operations. It has been extensively used for treatment of SUI [10]. Short-term results of TVT currently reported is 80-100% satisfactory [3,10,11], and Olsson, Kroon and Ulmsten et., al. reported a success rate of more than 90% by observing a female SUI patient who had TVT surgery for three years [4,5], Nilsson et., al. reported 81.3% success rate by observing 80 patients for seven years [12]. However, according to the report by Mazouni, 60% had voiding difficulty after TVT surgery, [13], and severe complications such as misplacement of tape in the bladder or urethra due to bladder perforation or urethral erosion, vessel injury and bowel perforation have been reported [14,15]. Then in 2001, Delorme suggested using the midurethra sling with polypropylene mesh passing through the obturator foramen instead of the Retzius space. TOT surgery is categorized into outside-in Monarc and inside-out TVT-O suggested by De Laval two years later [16]. Liapis et., al. reported full recovery rates of Monarc and TVT-O were 90% and 87% after 1 year follow-up observation [17], and Lee et., al. once reported full recovery rates were 92% and 86% after 1 year follow-up observation of 100 Korean patients [18]. In a study by Seok et., al. 14% complained of mild voiding difficulty after TOT surgery, but it was lower in comparison with those who had TVT [19] and it caused less bladder, abdominal cavity, and vessel injury [20]. As TOT is easy to learn, takes a short period for actual surgery and hospitalization, has no risk of perforation because of not passing through the Retzius space, has no need of cystoscopy, and shows good long-term results, it has been used most extensively [19]. ISD means insufficiency of urethral sphincter regardless of anatomical locations, which was suggested by McGuire [9]. There are some controversial definitions of ISD, but when VLPP is below 60cmH₂O, intrinsic insufficiency of urethral sphincter was determined [21]. To diagnose ISD, we usually measure VLPP. When the urinary bladder is filled with 150-200ml and VLPP is below 60cmH₂O,

severe ISD is determined. When VLPP is 60-90 cmH₂O, ISD is suspected, and when VLPP is above 90cmH₂O, no ISD is determined. To clearly diagnose ISD, this study targeted patients whose VLPP was below 60cmH₂O. There have been controversies on whether lower VLPP causes lower success rate of surgery and lots of studies on the results of TVT for ISD patients have been conducted. Rodriguez et. al. categorized patients who had TVT into four groups according to urine leakage pressures and evaluated them for one year. Then he discovered all the groups showed 92-96% success rates and urine leakage pressure did not affect the success of the treatment [22]. Kim et. al. categorized patients who had TVT into a group with above 60cmH₂O of VLPP and a group with below 60cmH₂O and evaluated them for 5 years. As significant difference in success rates between the two groups were not found, he reported that VLPP is not a factor that affects the success of TVT [23]. Paick et. al. categorized 221 patients who had TVT into a group whose VLPP is above 60 cmH₂O and a group whose VLPP is below 60cmH₂O and observed them for a mean period of 10.5 months. Success rates were 93.1% and 82% and the group with lower VLPP showed lower success rates of TVT [7]. Rezapour et. al, determined the following cases as high-risk factors of failure: when patients are older than 70, MUCP is below 10 and they have immotile urethra. After surgery of TVT for SUI with ISD, 74% (36 out of 49 patients) showed success and 12% (12) improved. The success rate was 86%, which was lower in comparison with TVT for patients with anatomic urinary incontinence [24]. In 2006, Doo et. al. conducted TVT targeting 31 patients with below 60cmH₂O of VLPP and 64 with above 60cmH₂O of VLPP and five years later, full recovery rates were 51.6% and 82.8% respectively. The success rate of IDS group was significantly lower [25]. When MUCP is below 20cmH₂O the success rate of TVT was 73% [26]. It is believed that the reasons why opposite results on SUI with ISD have been reported probably are that there are no standards on how to measure urinary leakage pressure and outcomes of TVT may be different according to tension of TVT surgery. It is suggested that further studies on it are needed. Recently, TOT has been used for treatment of SUI patients along with TVT, but there have been only a few reports on its outcomes for SUI with ISD. O'Connor et. al. categorized 43 patients who had TOT into a group with above 60cmH₂O of VLPP and a group with below 60cmH₂O and observed them for six months. They reported that full recovery rate of the former was 25%, which was significantly lower than that of the former, 77%. It was because the mesh tape of TOT which was more horizontally placed lacks support as it wraps a smaller part of the urethra in comparison with that of TVT [9].

Surgical procedures to treat SUI generally aim at lifting and supporting the urethrovesical junction. Sub-urethral slings serve this purpose well. The overall goal of sling operation is to produce adequate urethral resistance to prevent stress incontinence allowing voluntary and complete bladder emptying.

Slings that are too tight are associated with voiding dysfunction and De Novo urge incontinence. Slings that are too loose may still allow stress incontinence. The most common problem of sling surgery has been the excess tension of the sling and concern over postoperative bladder outlet obstruction has led to the development of a number of methods in order to determine the proper sling tension.

Many factors may produce recurrence of SUI after surgery: insufficient neck elevation at rest or stress, pelvic surgery or complicated delivery, endogenous hormonal changes, age-related collagen alteration, significant weight gain, or the presence of a hidden ISD. If SUI reappears or the patient suffers persistence of urinary leakage after surgery, it will lead us to perform a new intervention to correct it. However, the success rate of incontinence reoperations is between 20% and 40% lower than that of first-time operations, and these procedures present a greater number of complications. The sub-urethral sling has traditionally been considered a procedure of last resort for previous surgical failures and for those patients with severe ISD [27]. The REMEEEX system allows postoperative adjustment of the sling tension. This sling system allows the surgeon to leave it very loose at the time of surgery with the ability to tighten or loosen the sling easily in the post-operative period to achieve continence and still maintain adequate voiding function. This system is composed of a sub-urethral sling with two traction thread sutures connected to a regulation device (varitensor) positioned above the fascia of the abdominal muscle. The varitensor and the sling remains implanted to allow bladder suspension level readjustment. The re-adjustability avoids post surgical urinary retention and assures long term continence. Mantovani et. al. conducted REMEEEX on 32 SUI women patients who had fixed urethra, urethra hyper mobility, ISD or failed in previous surgery and observed them for three years. It was reported that 31 were fully recovered except one patient who had an instrument removed due to infection [28], Araco et. al. conducted surgery on 38 patients with ISD and controlled tension of three patients (7.9%) six months after the surgery. It was reported all of them showed successful results one year after the surgery [29]. Success rate of Groups 1, 2 and 3 including patients who showed improvement in this study was 100%, which was a higher success rate in comparison with the results of TVT or TOT for ISD patients.

Therefore, it is suggested that this method is effective to decrease voiding difficulty which was found to be higher in TVT and can supplement the low success rate of TOT for female SUI caused by ISD.

CONCLUSION

We provided REMEEEX to 20 women patients with ISD and evaluated the early outcomes of REMEEEX procedures. This study targeted a small number of the subjects and the follow-up period was short, but they showed higher success rates while they were evaluated for more than six months. Success rates are at least similar to those obtained with synthetic slings (TVT and TOT). Though its incision wound size was larger and urethra catheter indwelling period was somewhat longer in comparison with those of previous methods. As it caused less infection and side-effects except chronic pain, it is believed to be effective for treatment of SUI with ISD. This study suggests that more subjects and a longer follow-up period are needed for more exact evaluation.

REFERENCES

1. Seo JB, Lee JZ. The epidemiologic study of the urinary incontinence in community-dwelling women over 50 years old. *Korean J Urol* 1999;40:1025-30
2. Blaivas JG, Romanzi LJ, Heritz DM. Urinary incontinence: pathophysiology, evaluation, treatment overview and nonsurgical management. In: Walsh PC, Retik AB, Vaughan ED Jr, Wein AJ, editors. *Campbell's urology*. 7th ed. Philadelphia: Saunders; 1998;1007-43
3. Ulmsten U, Falconer C, Johnson P, Jomaa M, Lanner L, Nilsson CG, et al. A multicenter study of tension-free vaginal tape (TVT) for surgical treatment of stress urinary incontinence. *Int Urogynecol J Pelvic Floor Dysfunct* 1998;9:210-3

4. Olsson I, Kroon U. A three-year postoperative evaluation of tension-free vaginal tape. *Gynecol Obstet Invest* 1999;48:267-9
5. Ulmsten U, Johnson P, Rezapour M. A three-year follow up of tension free vaginal tape for surgical treatment of female stress urinary incontinence. *Br J Obstet Gynaecol* 1999;106: 345-50
6. Zullo MA, Plotti F, Calcagno M, Marullo E, Palaia I, Bellati F, et al. One-year follow-up of tension-free vaginal tape (TVT) and trans-obturator suburethral tape from inside to outside (TVT-O) for surgical treatment of female stress urinary incontinence. *Eur Urol* 2007;51:1376-82
7. Paick JS, Ku JH, Shin JW, Son H, Oh SJ, Kim SW. Tension-free vaginal tape procedure for urinary incontinence with low Valsalva leak point pressure. *J Urol* 2004;172:1370-3
8. Razapour M, Ulmsten U. Tension free vaginal tape (TVT) in women with recurrent stress urinary incontinence: a long term follow-up. *Int Urogynecol J Pelvic Floor Dysfunct* 2001;12 Suppl 2:S9-11
9. O'Connor RC, Nanigian DK, Lyon MB, Ellison LM, Bales GT, Stone AR. Early outcomes of mid-urethral slings for female stress urinary incontinence stratified by valsalva leak point pressure. *Neurourol Urodyn* 2006;25:685-8
10. Moran 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
11. Nilsson CG. The tension free vaginal tape procedure (TVT) for treatment of female urinary incontinence. A minimal invasive surgical procedure. *Acta Obstet Gynecol Scand* 1998;168:34-7
12. Nilsson CG, Kuuva N, Falconer C, Rezapour M, Ulmsten U. Long-term results of the tension-free vaginal tape (TVT) procedure for surgical treatment of female stress urinary incontinence. *Int Urogynecol J Pelvic Floor Dysfunct* 2001;12 (Suppl 2):S5-8
13. Mazouni C, Karsenty G, Bretelle F, Bladou F, Gannerre M, Serment G. Urinary complications and sexual function after the tension-free vaginal tape procedure. *Acta Obstet Gynecol Scand* 2004;83:955-61
14. Zilbert AW, Farrell SA. External iliac artery laceration during tension free vaginal tape procedure. *Int Urogynecol J Pelvic Floor Dysfunct* 2001;12:141-3
15. Amna MB, Randrianantenaina A, Michel F. Colic perforation as a complication of tension-free vaginal tape procedure. *J Urol* 2003;170:2387
16. De Leval J. Novel surgical technique for the treatment of female stress urinary incontinence: transobturator vaginal tape inside-out. *Eur Urol* 2003;44:724-30
17. Liapis A, Bakas P, Creatsas G. Monarc vs TVT-O for the treatment of primary stress incontinence: a randomized study. *Int Urogynecol J Pelvic Floor Dysfunct* 2008; 19:185-90
18. Lee KS, Choo MS, Lee YS, Han JY, Kim JY, Jung BJ, et al. Prospective comparison of the 'inside-out' and 'outside-in' transobturator-tape procedures for the treatment of female stress urinary incontinence. *Int Urogynecol J Pelvic Floor Dysfunct* 2008;19:577-82
19. Seok NS, Suh HJ, Lee DH. Clinical outcome of transobturator Monarc procedures for treating of women with stress urinary incontinence: 2-year follow up. *Korean J Urol* 2006;47:835-40
20. Delorme E. Transobturator urethral suspension: mini-invasive procedure in the treatment of stress urinary incontinence in women. *Prog Urol* 2001;11:1306-13
21. Bristow SE, Hilton P. Assessment and investigations for urinary incontinence. *Bail- lieres Best Pract Res Clin Obstet Gynaecol* 2000;14:227-49
22. Rodriguez LV, de Almeida F, Dorey F, Raz S. Does Valsalva leak point pressure predict outcome after the distal urethral polypropylene sling Role of urodynamics in the sling era. *J Urol* 2004;172:210-4
23. Kim NS, Bae JH, Lee JG. long-term follow-up of the tensionfree vaginal tape (TVT) procedure for treating female stress urinary incontinence. *Korean J Urol* 2006;47:729-33
24. Rezapour M, Falconer C, Ulmsten U. Tension-Free vaginal tape (TVT) in stress incontinent women with intrinsic sphincter deficiency (ISD)--a long-term follow-up. *Int Urogynecol J Pelvic Floor Dysfunct* 2001;12 Suppl 2:S12-4
25. Chin Kyung Doo, Jin Bum Kim, W an Seok Kim, Jin Sung Park, Byung Joo Chung Predictive Factors Affecting Long-term Cure and Patient Satisfaction of the Tension-free Vaginal Tape Procedure for the Treatment of Female Stress Urinary Incontinence. *J. Korean Continence Society* 2006;10:9-16
26. Liapis A, Bakas P, Salamalekis E, Botsis D, Creatsas G. Tension-free vaginal tape (TVT) in women with low urethral closure pressure. *Eur J Obstet Gynecol Reprod Biol* 2004;116:67-70
27. Amaye-Obu FA, Drutz HP 1999 Surgical management of recurrent stress urinary incontinence: a 12-year experience. *Am J Obstet Gynecol* 181:1296-309
28. Mantovani F, Castelnovo C, Bernardini P. ReMeEx device (External echanical Regulator) for incontinence: implantation and regulation procedure, complications and results at 3 years follow.up. *Arch Ital Urol Androl.* 2004 Mar;76:49-50
29. Araco F, Gravante G, Dati S, Bulzomi' V, Sesti F, Piccione E. Results 1 year after the Reemex system was applied for the treatment of stress urinary incontinence caused by intrinsic sphincter deficiency. *Int Urogynecol J Pelvic Floor Dysfunct.* 2007 Dec 11 [Epubahead of print]

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