The Effectiveness and Complications of Double-Forced Sling Method in Stress Incontinence Surgery

Stres İnkontinans Cerrahi Tedavisinde Double Forced Sling Yönteminin Etkinliği ve Komplikasyonları

İdrar kaçırmada Double-Forced Sling Yöntemi / Double-Forced Sling Method in Incontinence

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Özet

Amaç: Bu çalışmada, 4 yıllık takip sürecinde stress tipte idrar kaçırmanın cerrahi tedavisinde geniş tabanlı Double Forced sling yönteminin başarısını, etkinliğini ve komplikasyonlarını araştırmayı amaçladık. Gereç ve Yöntem: Kliniğimizde 2005 ve 2007 tarihleri arasında 144 stress tipte idrar kaçırması olan bayan hastaya mono ve multiflaman sentetik meş kullanılarak geniş tabanlı double forced sling ameliyatı uygulandı. Çalışmaya alınan hastalara ayrıntılı öyküsü, sistemik ve pelvik muayene, idrar kültürü, Q-tip ve Boney testi, supine stres testi, işeme günlüğü, 24 saatlik ped testi, sistoskopi ve ürodinami (sistometri ve Valsalva leak point pressure ölçümü) yapıldı. Hastalara idrar kaçırma için ICIQ-SF sorgulama formu ile Korman sorgulama formları dolduruldu. Hasta sonuçları ve ameliyatın başarısı ped testi, ICIQ-SF skorlaması ve Korman sorgulama analizine göre değerlendirildi. Bulgular: Hastaların ortalama yaşı 49.7 ± 8.7 (31-75 arasında) idi. Hiçbir hastada cerrahi sırasında komplikasyon gelişmedi. Tüm hastalarda ameliyat sonrası 6. 12. ve 48. aylardaki ICIQ-SF skoru, pad sayısı ve 24 saatlik pad testi sonuçları ameliyat öncesi döneme göre istatistiksel açıdan anlamlı derecede düşük olarak saptanmıştır ($p<0.05$). Ameliyat sonrası 48.ayda 135 hasta idrarını tutabiliyordu, 125 hasta ise yapılan ameliyattan memnundu. Ameliyat sonrasında hastaların 4'ünde vajinal erozyon ve sütür granülomu, 2'sinde üretral erozyon, 10 hastada yeniden acil işeme semptomları görüldü. Tartışma: Geniş tabanlı Double Forced Sling ameliyatı stres tipte idrar kaçırmanın tedavisinde efektif bir şekilde kullanılabilir. Stres tipte idrar kaçırmanın tedavisinde cerrahi tekniğin yanı sıra kullanılan meş materyalinin tipi ve yeri oldukça önemli olup bu konuda klinik ve deneysel çalışmalara ihtiyaç vardır.

Anahtar Kelimeler

Double Forced Sling; Sentetik Meş; Stres İnkontinans

Abstract

Aim: To determine the clinical results contributions to surgical success and complications of Broad Based Double-Forced Sling (DFS) Technique in the surgical treatment of stress incontinence in a 4 year follow-up. Material and Method: Broad based DFS operations were performed in 144 stress type incontinent women by using semiabsorbable mono and multiflament mesh materials in our department between 2005 and 2007. Detailed history, systemic evaluation and pelvic examination results, urine culture, Q-tip and Boney test, supine stress test, and urination diary, 24-hour pad test, cystoscopy and urodymanics measurements (cystometry and Valsalva leak point pressure) were recorded for each patient. The patients filled out ICIQ-SF and Korman questionnaires for urinary incontinence.The data of the patients and the success of the operation were evaluated based on 24hr pad test, ICIQ-SF scoring,and Korman questionnaire analysis. Results: The mean age of the patients was 49.7 ± 8.7 years (range: 31-75 years). None of the patients suffered intraoperational complications. In all of the patients, the postoperative 6th,12th, and 48th months ICIQ-SF scores, pad counts and pad test were reached to the statistically significant lower than those of the preoperative period ($p<0.05$)Postoperatively, in the 48th month, 135 patients (93.75%) had continence rate and the patient satisfaction rates for all patients were as 125 patients (86.8%). Four patients (2.77%) had vaginal extrusion, and 2 patients (1.38%) had urethral extrusion. Four patients (2.77%) had suture granuloma and ten patients (6.94%) had de novo urgency. Discussion: Broad based double forced sling is an effective technique in the treatment of stress urinary incontinence and type of the mesh used in sling surgery is very critical point and further clinical and experimental studies are needed.

Keywords

Double Forced Sling; Synthetic Meshes; Stress Incontinence

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Introduction

Various surgical techniques that involve supporting and stabilizing the bladder neck and urethra have been defined to provide continence. Among these, sling operations have been used with high success rates for all types of incontinence. Numerous methods and materials have been practiced in sling procedures. Present surgical techniques for the treatment of SUI are continually improved and new techniques are offered. However, there is still no consensus on the best technique.

Recognized complications of synthetic sling procedure include urinary storage and voiding symptoms, such as de-novo urgency,urge incontinence,incomplete bladder emptying and urinary retention,or urethral,bladder and vaginal extrusion [1]. All synthetic materials provide similar success rates, but none is free of complications. Several factors contribute to the wide range of erosion/extrusion rates, including operative technique, implant size, and the specific properties of the sling material, such as pore size, stiffness, elasticity, and basic tissue compatibility [1]. It is important for the surgeon to be familiar with the characteristics of each type of mesh material,as their qualities tend to determine the biocompatibility [2;3]. Macropore monofilament polypropylene mesh material has the most compelling history of host tissue integration, incorporation, safety and biocompatibility compared with polytetrafluoroethylene,polyester, or silicone [4;5].

Double forced sling method is the use of the anterior vaginal wall and synthetic mesh material together in order to support the bladder neck. Thus, it is hypothesized that any potential erosive complications may be averted with the presence of the vaginal wall in between the mesh material and the urethra and the effectiveness and reliability of DFS method has been investigated

Material and Method

a) Study Population

In this study, broad based DFS operation were performed in 144 stress type incontinent womens by using semiabsorbable mono and multiflament mesh materials in our department between 2005 and 2007. The results of four-year follow up were recorded. Patients with failed previous anti-incontinence surgery, clinical and/or urodynamic diagnoses of Stress type urinary incontinence, positive stress test, previous hysterectomy were included in the study. Patients with urodynamically mix type urinary incontinence and detrusor over activity, postvoid residual (PVR) 100 ml or greater, a contraindication to anesthesia, pelvic organ prolapse, pregnancy, neurogenic bladder, bladder outlet obstructions, urinary fistula or active urinary or vaginal infection were excluded from the study.

Detailed history, pelvic examinations, urine culture, Q-tip and Boney test, supine stress test, 24-hour pad test [6], cystoscopy and urodynamic measurements were recorded for each patients. All of the patients had stress incontinence. The patients filled out International Consultation on Incontinence Questionnaire- Short Form (ICIQ-SF) and Korman Questionnaire Form [7;8] for quality of life and urinary incontinence.We used a validated Turkish version of the ICIQ-SF questionnaire [9]. This study was approved by the hospital regional Ethics Committee of Ankara, Turkey.

b) Outcome assessment

Urethral mobility was evaluated with Q tip test and lateral cystogram.If urethral angle was higher than 35 degree,it was defined as hipermobility. In the 24-hour pad test,no need for pad use or pad weight of less than 2 gr was considered as cure;pad weight of 2-8gr were accepted as mild;pad weight of 9-19 gr were accepted as moderate;and pad weight of 20 gr or over were accepted as severe[6].Considering the pad counts,no use of pads was considered as cure;use of fewer than 50% of the number of number of pads that were used preoperatively or use of one pad were accepted as improvement;and use of more than 50% of the number of the pads used preoperatively or use of ≥ 2 pads were accepted as failure.

Korman questionnaire form is shown in the Appendix S1. In the Korman questionnaire analysis, storage and voiding symptoms, and patient satisfaction were questioned.Storage symptoms(questions 6 to 8) and voiding symptoms(questions 2 to 5)were scored.Patient satisfaction was assessed with questions 14 and 15.Each of the questions of voiding and storage symptoms was scored between 0 and 2 and the total scores were evaluated as follows: mild (0-2), moderate (3-5), severe (6-8). Patients having no, mild, moderate and severe symptoms were considered cure, improved, and failed respectively [7;8].

Quality of life and incontinence were evaluated based on ICIQ-SF scores related with incontinence. We used a validated Turkish version of the ICIQ-SF questionnaire.To determine the ICIQ-SF scores of the patients, ICIQ-SF question form consisting of 6 questions on quality of life and incontinence was used. This scoring has done according to Question 3,4,5 and the ICIQ-SF scores of patients has calculated [9].

The patients were first evaluated in the postoperative 2nd month. This evaluation was based on the continence status, vaginal examination, and any findings of infection or extrusion. All these evaluations were repeated in the postoperative 6th,12th, and 48th months. The results of the patients and success of the operation were assessed according to ICIQ-SF scores, pad test, and Korman questionnaire analysis.

c) Operation Technique

With the patients under regional or general anesthesia and in lithotomic position, labia major was temporarily fixed on the inner hip. The urethral 20F Foley catheter was inserted and the balloon was blown up to 20ml.An incision of inverted A shape was inflicted on the anterior wall of the vagina. The upper part of A shaped incision was formed into an island belonging to the vaginal wall. This patch was 3×4cm in most of the patients. Proximal anterior vaginal wall (the lower part of A) was dissected as a flap (Figure 1a).Synthetics mesh materials were first sutured onto the upper part of the A on the vaginal island with absorbable vicryl sutures. Then,with 2 polypropilen sutures,these meshes were fixed on both the right and left sides of this island in a helical manner to form a suspension and using curved Kishner needles,the prolen sutures were transferred to suprapubic area.These sutures were ligated on the fascia of rectus muscle in a crosswise manner (Figure 1b).The mobile lower wing was advanced onto the island and was sutured onto the vaginal skin with intermittent sutures using 3-0 monocryl sutures (Figure 1c).To achieve the control of the bladder and the urethra after the passage of the needle,cystourethroscopy

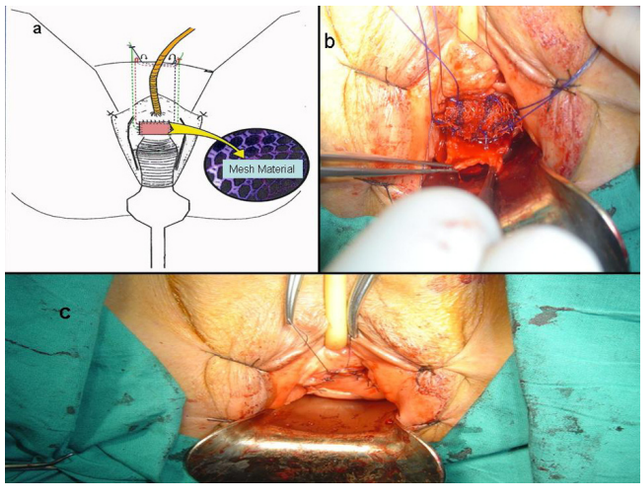


Figure 1. A shaped incision on the anterior vaginal wall. The upper part of A was used for vaginal sling through minimal dissection (A). The division of the vaginal wing, fixation of the mesh onto the vaginal island, and vaginal flap. c. Suturing of the vaginal flap (lower A) on the vaginal mucosa in a manner to cover the island patch that holds the mesh inside (B).

was performed. After confirmation of the bladder and urethra as normal,the prolen sutures were ligated crosswise in the suprapubic region. Special attention was paid not to create much tension on the mesh material. Urethral catheters were removed on the postoperative second day. After removal of the urethral catheters, post-urination residue amount of the patients was measured with suprapubic ultrasound.

d) Statistical Analysis

The data were analyzed by 13.5 version of Statistical Package for Social Science(SPSS Inc,USA). Continuous data were expressed as mean ± standard deviation (SD). Paired sample t test were used to determine statistical significance.Categorical data were expressed as value and percentage.P< 0.05 was considered statistically significant. In table 2, P value, all groups, preoperative versus postoperative 48th months.

Results

The mean operation time was 55 minutes (range:32-80 min.). The hospitalization time was 2 days. The demographic characteristics of the patients have been presented in Table 1. The patients underwent urodynamic test before the operation. No statistically significant differences were determined all of the patients at preoperative urodynamic test. Intraoperatively, none of the patients developed bowel, bladder and/or urethral perforations and any complications.

Table 1. The demographic characteristics of the patients.

Mean ± SD	
Age*	49.7 ± 8.7 (31-75)
Parity*	3.1 ± 1.09 (1-5)
BMI*	27.9 ± 4.1
(Body mass index kg/m2)	(21-40)
DM** (Diabetes Mellitus)	13 (9.02%)
HT** (Hypertension)	26 (18.05%)
Menopause**	29 (20.13%)
Anticolinergic use**	26 (18.05%)
Previous history of incontinence surgery**	13 (9.02%)
previous hysterectomy **	10 (6.94%)

* The data are presented as mean ± Std (minimum-maximum).
** The data are presented as the number of observation (%).

The mean ICIQ-SF scores,24-hour pad test scores and pad counts of the patients in the pre and postoperative 6th,12th,and 48th months are shown in Table 2.In all of the patients, the postoperative ICIQ-SF scores, pad counts and pad test were reached to the statistically significant lower than those of the preoperative period (p<0.05)(Table 2).

Table 2. Comparison of the preoperative and postoperative ICIQ-SF scores, 24-hr pad test and pad counts.

	Preop	Postop 6th month	Postop 12th month	Postop 48th months	P Value
Mean total ICIQ-SF score (± SD)	20.1 ± 0.4	2.1 ± 0.8	1.2 ± 0.6	0.8 ± 0.5	0.0076
24-h pad test (gr)*	32.4 ± 9.3	2.7 ± 6.2	2 ± 1.1	1.3 ± 0.8	0.0069
No Pad use (cure) **	-	137(95.1%)	136 (94.4%)	135 (93.7%)	---
Mean total pad count (± SD)	7.1 ± 1.4	0.83 ± 0.5	0.33 ± 0.2	0.2 ± 0.15	0.018

• Paired sample t test was used in all comparisons, P<0.05.
* The data are presented as Mean ± SD.
* * The data are presented as the number of observations (%).
P, All groups, preoperative versus postoperative 48th months.

The rates of cure, improvement, and failure of the patients in all the groups in the pre and postoperative 6th, 12th, and 48th months for voiding and storage symptoms, continence and patient satisfaction based on Korman analysis have been shown in Table 3. In the 48th postoperative month, 135 patients (93.75%) had continence rate and the patient satisfaction rates for all patients were as 125 patients (86.8%) (Table 3).

Table 3. Korman Questionnaire analysis results

	Preop	Postop 6th month	Postop 12th month	Postop 48th month
Voiding and Storage symptoms				
Mild	30 (20.8%)	12 (8.3%)	8 (5.5%)	6 (4.16%)
Moderate	50 (34.7%)	15 (10.4%)	8 (5.5%)	3 (2.08%)
Severe	64 (44.4%)	8 (5.5%)	-	-
Non-symptomatic	-	109(75.6%)	128 (88.8%)	135(93.75%)
Continence	-	137(95.1%)	136 (94.4%)	135(93.75%)
Patient satisfaction	-	120(83.3%)	113 (78.4%)	125 (86.8%)

* The data are presented as the number of observations (%)

Postoperative complications have been shown in table 4. Postoperatively 10 (6.94%) patients developed denovo urgency symptoms. The urine retention of 5 patients resolved in a mean

Table 4. Postoperative complications.

Vaginal Erosion (n) (%)	4 (2.77%)
Urethral Erosion (n) (%)	2 (1.38%)
Suture Granuloma (n) (%)	4 (2.77%)
Urine Retention (n) (%)	5 (3.47%)
Incontinence (n) (%)	9 (6.25%)
Denovo Urgency (n) (%)	10 (6.94%)

* The data are presented as the number of observation (%).

10.6 days. Four (2.77%) patients had vaginal extrusion. Urethral extrusion was observed in 2 (1.38%) patients. In the postoperative 48thmonths, 9 (6.25%) patients had incontinence (Table 4).

Discussion

Since 1864 when Baker and Brown described "Suprapubic sistostomy" for SUI,more than 100 procedures have been defined [10].Despite the multitude of surgical procedures,no consensus has been obtained on indications and/or effective procedure for SUI surgery. Transvaginal needle suspension technique was first listed among SUI surgery techniques in 1959 when Pereyra [11] showed that with the use of a special needle,paraurethral tissue could be suspended on the abdominal fascia. Literature review showed a success rate of 40 to 100% with needle suspension techniques [12].

The first meta-analysis of incontinence surgery was made by Gary E. Leach et al [13] in 1997.At the end of the analysis, retropubic suspensions (Burch) and sling operations, despite higher rate of complications, were found to be 89% and 92% more effective in the long term follow-up than anterior repair or transvaginal suspensions.

Giacomo Novara et al [14], in their recent meta-analysis, the rates of continence were 65% to 92% with TVT.Burch determined continence rates of 72% to 86%, which were lower than those with TVT.The rates with TVT and pubovaginal slings were equal.The continence rates with retropubic slings (Intravaginal slingplasty(IVS), SPARC) were 78% to 87%.With TVT,higher continence rates were found than the rates with the other retropubic types(IVS, SPARC), while the continence rates with retropubic and Transobturatuar type(TOT) interventions were found to be equal despite lack of sufficient data. TVT, BURCH, Pubovaginal slings and IVS were found to have similar complication rates. Retropubic and transobturator methods were compared and significantly low rates of bladder perforation,pelvic hematoma,and accumulation LUTS symptoms[15].Considering all the meta-analyses and studies in the literature, retropubic suspension and pubovaginal slings seem to have higher complication rates than the rates with TVT and TOT. However, they have been found to be more efficient in the long-term.

Literature review of the studies on midurethral sling reduced efficiency rates of TOT and TVT for low ALPP and immobile urethra. Kayigil et al [16], in their recent studies, ISD was accompanied to urethral hypermobility at a rate of 28%, Particularly in complicated and secondary cases,it should also be remembered that midurethral techniques may be insufficient and it has provoked thought as to the reconsideration of broad-based to be the best choice.

The published incidence rate of urinary retention after single incision sling surgery for incontinence has been reported to be 3.2% [17]. In another study, the incidence rate of urethral obstruction after synthetic sling surgery for incontinence has been reported to be 20% [18]. In our study, however, urinary retention rate was 3.47%, but none of the patients suffered permanent retention. The rate of de novo urgency after synthetic sling surgery ranges from 5% to 25% [19]. In our study,this rate was 6.94%.

The reported extrusion incidence varies from 0.3% to 23% with higher rates when synthetic sling material was used [20]. Several factors contribute to the wide range of extrusion rates, including specific properties of the sling material, local ischemia, poor mesh incorporation, and basic tissue compatibility [1]. In another study, with the use of synthetic materials, this rate ranged between 0% and 12% [21]. In the only randomized controlled equivalence trial comparing extrusions rates between TVT and SPARC, Lord et al [22] reported rates of 4.8% and 10.5% respectively. In our study, however, vaginal extrusion rate was 2.77%.

The exact etiology of urethral extrusion is unknown [23]. The American Urological Association clinical guidelines panel performed a meta-analysis of the literature on anti-incontinence procedures and identified 27 of 1515 (2.7%) patients who had urethral extrusion after synthetic sling placement [13]. In our study, urethral extrusion rate was 1.38%.

Kayigil et al. [24] previously defined broad-based DFS technique. Broad-based sling surgery is preferred choice of treatment because of its high long-term success rate, low complication rate, minimal effects on sexual functions, and high rate of patient satisfaction. DFS methods consist of the use of anterior wall of vaginal wall and synthetic mesh material to support the bladder neck. Thus, presence of the vaginal wall between the mesh material and urethra is thought to possibly reduce potential erosive complications.

Literature presents only one clinical study on the use of broad based sling.Polypropylene mesh and bone fixation were used,yielding a success rate of 82% [25].In our technique,however,rather than fixation on the pubic bone,fixation on rectus fascia method is used. The high success rates and low complication rates in our study where synthetic materials were used may have been due to the characteristics of the mesh material as well as the DFS technique. The rate of erosive complications was lower particularly in the monofilament groups;this can be attributed to vaginal wall blockade,namely the vaginal island located between the sling (mesh) and urethra,which leads to less pressure and lower risk of ischemia,erosion,and infection development. With the contributions of all of these factors,broad-based DFS technique proves to yield high success rates and low complication rates in all types of stress incontinence and in secondary cases.In these patient groups,studies with longer follow-up where broad based sling technique is compared with midurethral sling use are needed.

In conclusion, Broad based double-forced sling surgery is successful technique for treatment of stress incontinence. In the treatment of stress incontinence,as well as the surgical technique,the characteristics of used synthetic mesh materials,their shape,and application method affect the success of surgery. However, randomly controlled, prospective clinical studies with larger series of patients and longer follow-up are needed to determine the long-term effects of this method.

Akcnowledgement

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