Original article

A prospective randomized controlled trial of the transobturator tape and tissue fixation system minisling in 80 patient with stress urinary incontinence - 3 year results

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Abstract: INTRODUCTION: We aimed to perform a randomised controlled trial (RCT) comparing the efficiency of transobturator tape (TOT) operation against an adjustable minisling, the tissue fixation system (TFS), in the treatment of urodynamically proven stress urinary incontinence. METHODS: The trial comprised 80 patients with urodynamically proven stress urinary incontinence. The patients were randomly allocated to either TOT group (group I) or TFS group (group II). Total follow period was 36 months. The objective cure rates in TFS group and TOT group were 90% and 84%, respectively, and the difference was statistically significant ($p<0.05$). Operation time: 5±1 min in TFS group, 12± 1 in TFS group ($p<0.05$). Postoperative groin pain was significantly high in TOT group (12 patients). Both operations had positive effects on the quality of life (QoL) measures.
CONCLUSION: The TFS showed better objective outcomes in comparison to TOT.

Key words: Minisling, tissue fixation sysytem, transobturator tape

INTRODUCTION

In 1990 Petros & Ulmsten described a prototype intravaginal slingplasty operation, later known as the "TVT", which was based on their "Integral Theory"[1]. A Mersilene tape was inserted below the midurethra, exiting unattached through the lower abdominal muscles. Post-operative xrays demonstrated no change in the position of bladder neck in patients cured of their SI, thereby invalidating the pressure transmission theory[2]. This method was revolutionary in that it was a minimally invasive day-care operation, with minimal pain and no significant post- operative urinary retention. However, scattered reports of small bowel and external iliac artery perforations, albeit infrequent, were major causes of concern, inviting calls for zero tolerance for such surgery[3]. Delorme's transobturator (TOT) approach to the midurethral sling in 2001 significantly decreased such complications with an almost equivalent cure rate[4]. However, the TOT was subject to its own major complications, such as obturator nerve and artery damage, groin pain, even bladder perforation. Though infrequent, these complications were cause for concern. In 2005, the 1st midurethral minisling sling, the Tissue Fixation System (TFS) was described in a preliminary report[5]. A polypropylene sling was inserted below the midurethra entirely per vaginam, without entry to the retropubic or obturator space, without the need for cystoscopy, and with minimal post-operative pain.

The Urogynecology clinic of Ankara Etlik Zubeyde Hanim Women's and Maternity Research Hospital, Turkey performed the TFS minisling soon after the first report in 2005[6].

Our aim was to compare the efficacy of the TFS and TOT in a prospective randomized control study (RCT) in a group of patients who had urodynamically proven SUI.

MATERIALS AND METHODS

This single blind prospective randomized controlled trial was carried out in the urogynecology clinic of Ankara Etlik Zubeyde Hanim Women's and Maternity Training and Research Hospital, Turkey. All operations were undertaken between September 2005-September 2006. The study comprised 80 patients with only urodynamically proven stress urinary incontinence cases. The cases were randomly allocated for TOT (group I) or TFS operation (group II) according to a computer generated programme. Each group consisted of 40 patients. Two patients in TOT group and 1 patient in TFS group lost follow up and these patient were not included in the study. The study flow chart has been given in figure 1.

The patients were evaluated with a full clinical history, a validated incontinence impact questionnaire 7 (IIQ 7), pelvic and urogynecologic examination, pelvic ultrasound, cough stress pad test (CSPT) and urodynamics before and after the operations.

Supine cough stress pad test (CSPT).

A preweighed pad was placed on the vulva. The patient coughed 10 times with a full bladder, the pad was reweighed and the increased amount is noticed as leaked urine. A urine loss greater than 1 gm was regarded as positive for stress incontinence (SI), and a loss less than 1 gm as a negative result (no SI).

Inclusion criteria were 1) patients with genuine stress incontinence (GSI) with a Valsalva leak point pressure (VLPP) less than 60 cm H_2O[7], 2) patients treated surgically for the first time for stress urinary incontinence, 3) patients who failed to respond to conservative management as physiotherapy or drugs.

Exclusion criteria were 1) overflow incontinence, 2) neurological lesions, 3) overactive bladder, 4) transient causes of urinary incontinence such as urinary tract infection, 5) pure urge incontinence, 6) mixed incontinence, 7) patients with pervious surgery for the correction of urinary incontinence.

All patients participated to the study after informed consents had been taken and the local ethics committee of the hospital accepted the study.

All operations were performed by the first author after the accomplishment of 10 previous TFS surgeries for learning curve. The author already had a wide experience in TOT incontinence surgery.

Surgery

Surgery was performed in the lithotomy position, with legs placed in stirrups. All patients received preoperative antibiotic prophylaxis, 1 gm intravenous cephazolin. The standard "outside in" method was used for the TOT, with

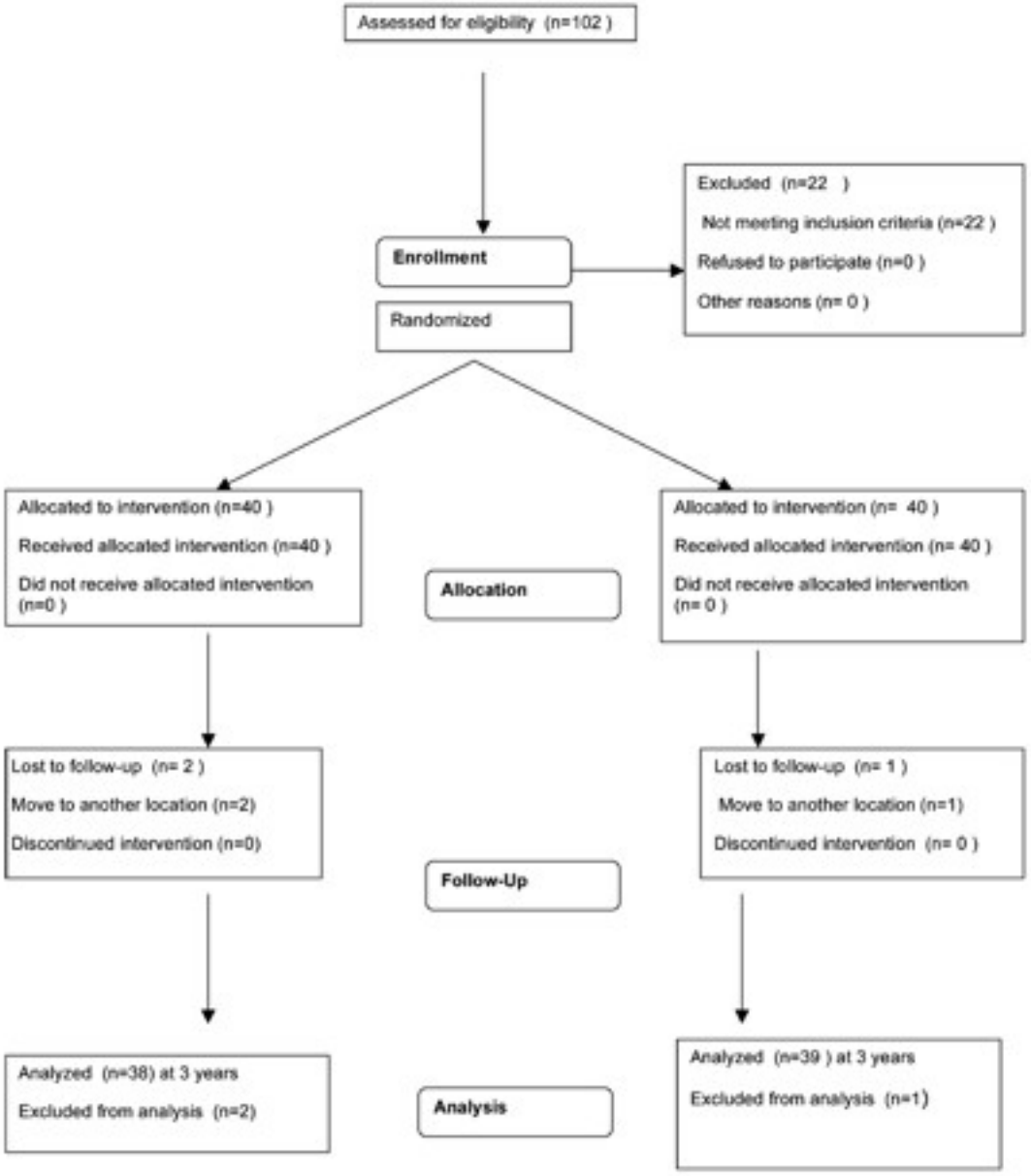

Fig. 1. – Study flow chart.

the tape inserted at the level of the clitoris. The TFS (TFS Surgical Adelaide SA) consists of two anchors attached to an adjustable sling (fig.2). It consists of an 11mm X 4mm anchor with 4 prongs, with a one-way trapdoor at its base which allows tightening of the laterally displaced fascia. The tape is macroporous, non-stretch, 7.5 mm wide, individually knitted from 80 micron monofilament threads.

Technique of TFS

A small channel was made between the vagina and urethra to perforate the urogenital diaphragm (perineal membrane), exactly like the first part of a TVT. The anchors were inserted into the inferior surface of the pubovaginalis muscles, immediately behind the urogenital diaphragm (fig. 3). The tape was tightened over an 18 gauge rigid Foley catheter until it touched, but did not indent, the urethra, fig. 2. The TOT also had a non-stretch 10 mm wide monofilament tape, and was performed with a standard "outside in" protocol.

The patients were reevaluated at 2 weeks, 3 months, 6 months, 1 year, 2 years and at 3 years. The postoperative assessment was done by a senior surgeon of the urogynecology clinic who did not take part in the operations. The first author was not involved in the follow up process.

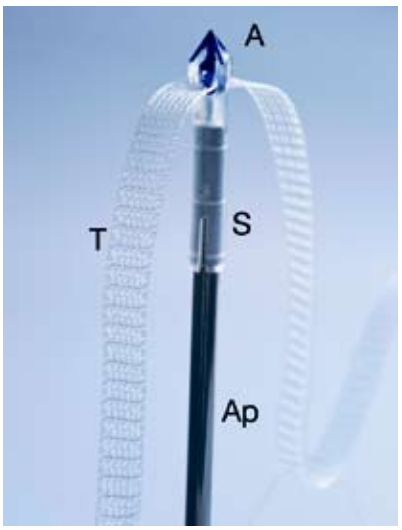

Fig. 2. – The polypropylene anchor (A) is held in a saddle (S) on an applicator (Ap). A macroporous polypropylene tape (T) is threaded through the base of the anchor to provide a one way tightening system.

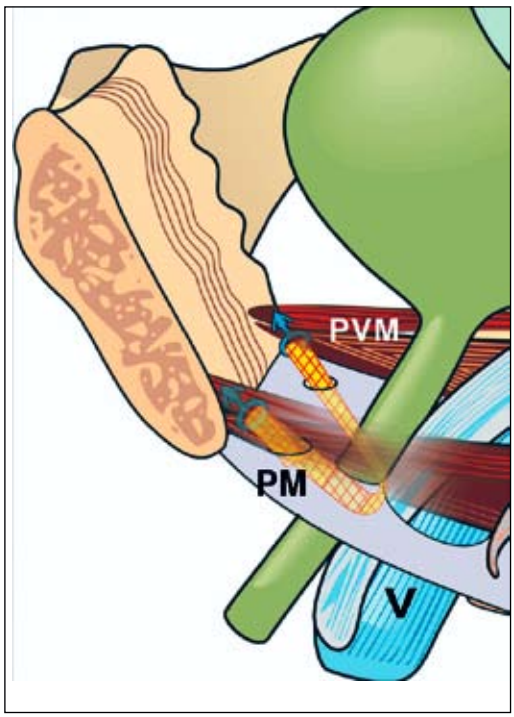

Fig. 3. – The TFS midurethral sling. The sling is inserted just behind the perineal membrane (PM) into the undersurface of the pubovaginalis muscle (pubococcygeus and puborectalis), below the Space of Retzius.

Our primary outcome measure was objective cure rate after 3 years of antiincontinence surgery. Secondary outcome measures were duration of procedures, postoperative comfort of the patients (e.g groin pain) and quality of life (OoL) scores.

If the CSPT was negative after the operation and the patient reported the restoration of urinary continence, then it was regarded as "objective cure". If the patient reported the restoration of urinary incontinence but the supine cough stress test was positive, then it was regarded as "subjective cure". If no change in the incontinence complaint after the operation then it was regarded as ''failure''

Total follow period was 36 months (36± 1 month).

Table 1. – Patient characteristics.

Variable	TOT *n*=38	TFS *n*=39	p value
Age	51.5 ±12.5	54 ±13.6	0.6
Body mass index	29.6 ± 2.7	28.7±3.1	0.7
Parity	2.5±1.7	2.7±1.3	0.4
Postmenopausal	27 (71%)	29(74%)	0.3
Hormone replacemet therapy	5 (13%)	7(18%)	0.6
Duration of SUİ (in years)	4.7±1.3	5.1± 0.3	0.5

Mean±standard deviation and *n* (%)

Table 2. – Operation duration, intra and postoperative complications

Variable	TOT *n*=38	TFS *n*=39	p value
Duration of procedure(min)	12±1	5±1	0.001
Bladder injury	0	0	Not applicable
Bleeding exceeding 100 ml.	0	0	Not applicable
Urinary retention	2 (5%)	0	0.3
Postop groin pain	12 (31.5%)	0	0.04
Anchor displacement	0	1 (2.5%)	Not applicable

Mean ± standard deviation and *n* (%)

To have 80% power to detect this difference and to limit the chance of type I error to 5%, the number of patients for each group was estimated to be 36. We decided to add approximately 10% to this concerning loss to follow up. Therefore, the total sample size was calculated to be 80 patients (40 in each arm) (α=0.1).

All the data were recorded using standard forms. We used SPSS 11.5 (Statistical Package for Social Sciences) for Windows for statistical analysis. We gave the results as mean±standard deviation and as numbers and percents. The Student's t test and Fischer Exact test were used where appropriate.

For all comparisons, $p < 0.05$ was considered statistically significant.

RESULTS

The groups were similar in terms of age, body mass index, parity, menopausal status, hormone replacement therapy, and the duration of SUI (Table 1).

The analysis of the data showed that the duration of the operation was significantly shorter in the TFS group (5±1 min) compared to the TOT group (12±1min, $p < 0.001$) (Table 2). No intraoperative complications such as bladder injury or/and bleeding exceeding 100 ml were seen. However, there were 2 urinary retentions in TOT group. In addition postoperative groin pain was significantly high in TOT group (12 patients) (Table 2).

During the preoperative assessment period, the VLPP (cystometry) and cough stress pad tests were carried out. Both tests were also carried out at the 3 years follow up. There were no statistically significant difference between groups in terms of preoperative and postoperative CSPT values (Table 3). Whereas, there were statistically significant difference within groups in terms of preoperative and postoperative CSPT values (Table 4).

Table 3. – Pre and postoperative assessment of and CSPT in both groups.

Variable	TOT *n*=38	TFS *n*=39	p value
Preop. CSPT (gr)	67±24	75±14	0.7
Postop CSPT (gr)	0.46±0.5	0.75±0.2	0.4

Table 4. – Pre and postoperative assessment of CSPT within groups

	Preoperative	Postoperative	p value
TOT Group			
CSPT(gm)	67±24	0.46±0.5	0.0002
TFS Group			
CSPT(gm)	75±14	0.75±0.2	0.0001

Table 5. – Cure rates after the operations

Variable	TOT *n*=38	TFS *n*=39	p value
Objective cure rate	84% (32 cases)	90% (35)	0.036
Subjective cure rate	5% (2 cases)	2% (1)	0.812
Failure	11% (4 cases)	8% (3)	0.674

Table 6. – Pre and postoperative QoL(mean of scores) comparisons within groups

	Preoperative	Postoperative	p value
TOT Group			
Mean of QoL	14±7	4±1	0.006
TFS Group			
Mean of QoL	15±6	3±1	0.005

For analysis of cure rates at the end of 3 years, 38 patients were available for the TOT group and 39 patients were available for the TFS group (fig. 1). The objective cure rate, subjective cure rate and failure rate in TFS group were 90% (35 cases), 2% (1 case) and 8% (3 cases), respectively. The objective cure rate, subjective cure rate and failure rate in TOT group were 84% (32 cases), 5% (2 cases), and 11% (4 cases), respectively (Table 5). There was statistically significant difference between groups in terms of objective cure rate ($p>0.05$).

There were no statistically significant difference between groups in terms of the mean of the preoperative QoL scores ($p>0.05$). However, statistically significant differences were obtained when the preoperative and postoperative mean of QoL scores were compared within groups ($p<0.05$) (Table 6). The mean of the QoL scores have improved in both of the groups.

The total follow up period was 36±1 months.

TOT group complications

Urinary retentions were resolved with a 3 days long catheterization. Postoperative groin pain lasted 2 weeks in 9 patients. Two patients needed anti-inflammatory medications and their complaint stopped within 1 month. One patient refused any intervention for her groin pain and at 3 years follow up she reported that she had been feeling a nasty pain sometimes (particulary in long distance walking) but she did not want any intervention.

TFS group complications

Anchor displacement in the left side was observed in 1 patient at her 1 year control. The anchor was removed under local anesthesia and the patient remained continent.

There were no tape erosions in either group.

DISCUSSION

As far as we know, this is the first study comparing a minisling with a more conventional anti-incontinence operation, the TOT. The objective cure rate in TFS group was higher than the TOT group and the difference was statistically significant ($p<0.05$). In addition the TFS was significantly superior with regard to the secondary outcome measures. The TOT group had a significant incidence of groin pain (31%), higher urinary retention (5%), and longer operating time (12 minutes vs 5 minutes).

A major concern in planning this study was to ensure equivalence in the surgical protocols, and to remove as much bias as possible. Our methodology aimed to narrow these variables. All the operations were performed by the same surgeon who was experienced in both the TOT and the TFS midurethral sling operations. The populations were similar. A non-stretch tape was used in both operations which were all performed under spinal anesthesia. Evaluation of the operated patients was performed by an independent observer and it was based on objective criteria, weighed loss by means of cough pad tests. Another concern was whether a learning curve of 10 was sufficient training for the TFS. The results indicate that 10 was a sufficient number.

The anatomical restoration of the TFS is almost identical to that of the TVT. The TFS is inserted retropubically in a vertical position, exactly the same axis as the TVT. Unlike the TVT, however, the TFS at all times remains below the space of Retzius. Post-operative ultrasound studies indicate that it is very close to the origin of the pubourethral ligament[8,9], which it seeks to reinforce. The anatomical studies of Zacharin demonstrate a vertically disposed pubourethral ligament[10]. On the other hand Scherlitz et al.'s study suggest that TOT may be inferior to the TVT in the treatment of stress urinary incontinence[11]. The study showed 14 of 67 patients (21%) in the TVT group had stress incontinence demonstrated during repeat urodynamic assessment compared with 32 of 71 (45%) in the TOT group ($p<0.05$). They concluded that retropubic TVT is a more effective operation than the transobturator tape sling in women with urodynamic stress incontinence.

QoL scores have improved after the operations. Both operation types had good effects on the QoL measures.

In our study; the TFS showed better objective outcomes in comparison to TOT, hence; low complication rate, high postoperative compliance with TFS and the ease of TFS technique herald that TFS deserves wide utilization. However; more randomized studies with larger samples are needed to corroborate these findings.

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