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Original Article

A new surgery for recurrent or persist stress urinary incontinence in females after primary mid-urethral slings

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Abstract: Objective: To retrospectively evaluate the efficacy of a new complementary mid-urethral sling surgery (Tong's hammock anterior, THA) in treatment of recurrent or persist stress urinary incontinence (SUI) in females after primary synthetic mid-urethral slings (MUSs). Methods: THA was performed in 27 females with recurrent or persist SUI after primary MUSs from June 2005 and July 2010. These patients were followed up for one year, and clinical data including main complaints, operation duration, blood loss, efficacy and complications were reviewed. Results: All 27 SUI patients were treated with THA surgery, a trans-vaginal mid-urethral sling on the descending pubic ramus. The average operation time was 39 min (range: 25-70 min), average blood loss was 70 ml (range: 20-120 ml). After urinary catheter removal, all patients could micturate and their average residual urine was 25.2 ml (range: 0-80 ml). The average hospital stay was 4.7 days (rage: 3-7 days). SUI symptom was persistent in 2 patients after THA surgery and the effective rate reached 92.5%. At 3 months, 6 months and 1 year after surgery, the effective rate was 92.5% (25/27), 92% (23/25) and 87.5% (21/24), respectively. 6 months after THA surgery, 2 were lost to follow up; 1 had recurrent SUI at 1 year and 1 had mesh erosion, 1 died of other diseases, and operative complications were absent after surgery. Conclusions: THA surgery is an effective method for treating recurrent or persistent SUI after primary MUSs. It is cheap, efficient, and easy to handle.

Keywords: Tong's hammock anterior, stress urinary incontinence, trans-vaginal mid-urethral sling, mesh

Introduction

Synthetic mid-urethral slings (MUSs) have been well recognized as golden standard in the surgical therapy of stress urinary incontinence (SUI) in females. Tension free vaginal tape (TVT) is a simple, effective and minimally invasive surgery for the treatment of USI in females. Numerous SUI females have been effectively treated and their quality of life is improved after TVT. As new materials and equipment emerging, other safe and simplified operations have been invented: such as tension free vaginal tape-obturator (TVT-O) and TVT-SECUR. These operations have their own surgical complications. In the surgical treatment of female SUI, to resolve the patients' complaints is as important as to repair their anatomic defects. Some SUI symptoms might be recurrent or persistent after primary surgery. We invented an effective and simple surgical method, Tong's hammock anterior (THA) surgery, for the treatment of persistent or recurrent SUI symptoms after primary surgery. This surgery has been applied in our hospital achieving favorable effectiveness. In the present study, patients receiving THA surgery due to persistent or recurrent SUI symptoms after MUSs were retrospectively reviewed aiming to evaluate the therapeutic efficacy of THA surgery in these patients.

Material and methods

Patient information

Twenty-seven patients who received primary MUSs between June 2005 and July 2010 in 6 different hospitals had recurrent or persistent SUI symptoms after surgery. These patients were transferred into our department and then received THA surgery. The mean age was 58.4 years (range: 44-72 years). Among them, 22 patients were postmenopausal women; 22 were diagnosed with SUI; 5 with mixed urinary

Table 1. Clinical characteristics

Variable	Value
No. pts*	27
Mean age (range)	58.4 (44-72)
Mean body mass index (range) kg/cm^2	53 (47-78)
No. menopausal** (%)	22 (81.5)
Comorbidity (%)	
Diabetes mellitus	3 (11.1)
Hypertension	4 (14.8)
Paralytic	1 (3.7)
Symptom (%)	
Persistent	8 (29.6)
Recurrent	19 (70.4)
Mean time to Recurrence (Month)	9.6 (6-16)
Previous surgeries, n (%)	
TVT	2 (7.4)
IVS	4 (14.8)
TVT-O	13 (48.1)
TOT	3 (11.1)
Others	5 (18.5)

*No. pts: number of patients. **No. menopausal: number of menopausal women.

incontinence (MUI). Diabetes mellitus was found 3 patients, hypertension in 4, and sequela of stroke in 1. Their primary surgeries included TVT (n=2), IVS (n=4), TVT-O (n=13), TOT (n=3), T-SLING (n=1), and other MUSs (n=4). Eight patients had persistent symptoms shortly after surgery and were not improved at 6 months after surgery; 19 had recurrent symptoms at 6 months, which at 1 year were similar to those before surgery in the severity. The average time to recurrence was 9.6 months (rang: 6-16 months). Uro-dynamic examination was done in 10 patients of whom 8 were diagnosed with SUI without OAB or internal sphincter defect and 2 with MUI. The remaining 17 patients received SUI provocation test and Valsalva test. Results from both test together with their symptoms supported the diagnosis of SUI in 15 patients and MUI in 2. Before primary MUSs, moderate and severe urinal leakage was found in 13 patients and 14 patients, respectively; after primary MUSs, moderate and severe urinal leakage was found in 15 patients and 12 patients, respectively. Their symptoms did not aggravate after primary MUSs (**Table 1**).

Confirmation of recurrence or persistence of symptoms

There is no golden standard for the diagnosis of persistent or recurrent SUI symptoms after primary surgery. Chapple [1] concluded on the basis of a multi-center study that outcome of SUI after surgical intervention could be divided into two categories: 1) cure: pad weight test and leakage test showed negative; no urine leakage or urine leakage related symptoms was present within consecutive 3 days; provocation test showed negative. 2) Failure: pad weight test and leakage test show positive at 6 months after surgery; urine leakage and urine leakage related symptoms are observed within consecutive 3 days; provocation test shows positive. El-Hefnawy [2] proposed that the evaluation of surgical efficacy should be done at 6 months after primary surgery, and the outcome could be divided into: 1) cure: no incontinence under any condition, including no SUI symptoms; stress test shows negative, one hour pad weight test and leakage test show negative; further treatment of SUI is not necessary. 2) Failure: stress test shows positive; one hour pad weight test and leakage test show >2 g or the anti-SUI evaluation shows >2. However, both classifications cannot differentiate symptoms due to surgical failure from those persistent symptoms. In the present study, the recurrent or persistent symptoms were defined according to the following criteria: 1) persistent symptoms: Patients complained non-response to therapy, follow-up was done once every 3 months for 6 months, provocation test showed positive, symptoms were not improved; 2) recurrent symptoms: patients reported cure or significant improvement, but symptoms recurred at as early as 6 months after surgery, deteriorated and were comparable to those before surgery, follow up was done every 3 months for 6 months, and symptoms remained unchanged when compared with those before surgery.

Pre-operative preparations and evaluations

All 27 patients received routine physical examination, vagina examination, urine culture test, cotton-swab test of bladder neck, ultrasonography of the bladder and detection of residual urine in the bladder, and examinations of the uterine and appendix. Other tests included blood routine test, blood coagulation test, liver and kidney function test, and electrocardiogram (ECG). Patients who had concomitant hypertension and diabetes mellitus received surgical intervention after the diseases were controlled. Every patient was informed with the

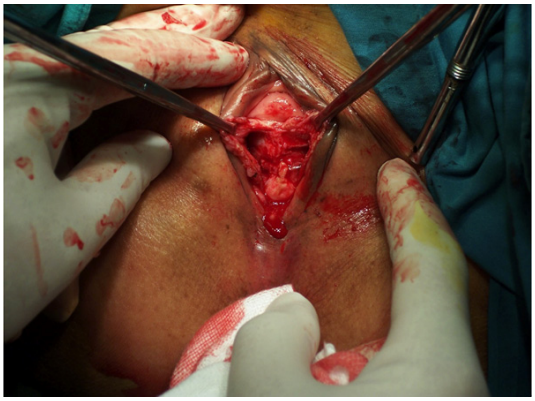

Figure 1. Separation of vaginal mucous and sub-mucous tissues to the descending pubic ramus.

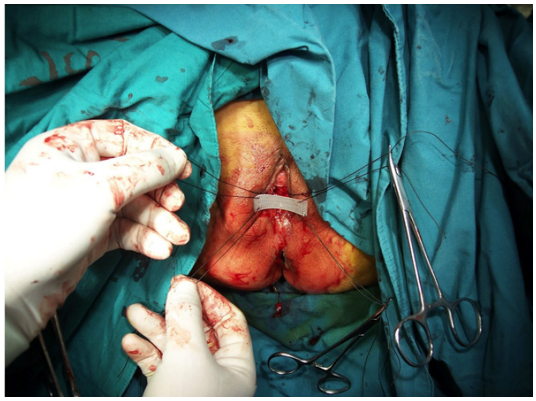

Figure 2. Fixation of sling with tissues on the descending pubic ramus.

examination results, surgical efficacy, re-operation difficulty and re-operative complications. An individual operation method was determined before each operation. Each patient was trained to perform provocation test before operation in order to adjust the sling elasticity during the operation. Pre-operative skin preparation was not needed. Antibiotics were administered once at 30 min before operation or after operation.

Timing of surgery

THA surgery was done at >6 months after primary surgery. For premenopausal patients, surgery was done at 2 weeks after the menstruation stopped; for postmenopausal women who received hormone replacement therapy (HRT), surgery was done at 1 month after discontinuation of HRT. Local vaginal inflammation was treated before operation. Blood pressure and blood glucose were controlled to normal level.

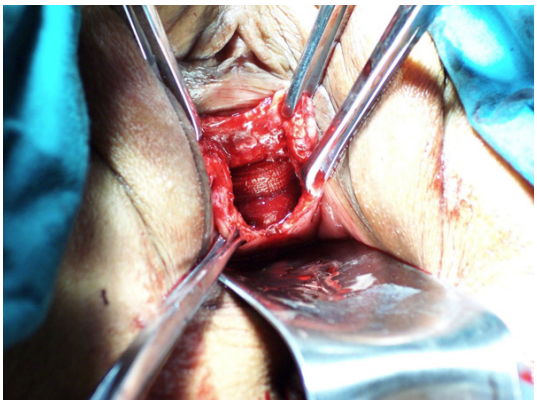

Figure 3. Provocation test was done to adjust the sling tightness.

Anesthesia

Operations were carried out under a local anesthesia with 0.4 g of lidocaine in 80 ml of sodium chloride or saddle block anesthesia was performed in several patients. ECG monitoring was done during the operation. After emptying bladder, diluted anesthetic was injected at 11, 1, 3 and 9 o'clock 0.8-1.0 cm away from the urethral orifice towards the descending pubic ramus, and then infiltration anesthesia was done at the vaginal mucosa 1-3 cm below the external urethral orifice of. The dose of lidocaine was lower than 0.6 g to avoid drug poisoning.

Surgical procedures

All patients were placed in a lithotomy position. A 2-3-cm vertical incision was made in the vaginal anterior wall over 1 cm distant from the external urethral orifice, followed by separation of mucosa and sub-mucosa tissues to the descending pubic ramus. Then, fascia tissues on descending pubic ramus were exposed and the interspace between vagina and bladder was separated (**Figure 1**). The non-absorbable suture was used to suture the fascia tissue at the descending pubic ramus for 2 stitched, with an interval of 0.5 cm. The mesh (Tyco. Healthcare USSC, Norwalk, Connecticut, USA) is cut into a butterfly shaped sling by Professor Tong XW. Fix slings with tissue on descending pubic ramus by 4 sutures (**Figure 2**). The 4 corners of the slings were fixed with non-absorbable sutures. The space between 2 needles near to the pubic symphysis was smaller. Then, the tightness of sling was adjusted as follows: 250-300 ml of sodium chloride was injected

Table 2. Characteristics of surgery

Variable	Value
Anesthesia (%)	
Local anesthesia	9 (33.3)
Saddle block	18 (67.7)
Average operation duration (min)	39 (25-70)
Average blood loss (ml)	70 (20-120)
Residual urinal volume (B-ultradsound detection ml)	25.2 (0-80)
Bladder/urethral/vessal injury	0
Average in-patient duration (d)	4.7 (3-7)

into the bladder, the patient was asked to cough, and the fourth stitch was used to adjust the sling tightness until no urine leakage was observed (**Figure 3**). All the stitches were tightened to form a hammock. The vaginal submucosa was first closed to avoid the mesh erosion by the absorbable suture. Then, the incision at the vaginal wall was closed with absorbable sutures. Oily gauzes were put into the vagina and stayed for 2 h. Urinary catheterization was done with 14# Foley, which stayed for 6 h. Then, patients were encouraged to micturate. If patients could not micturate after catheter removal, a 16# Foley urinary catheter stayed for 48 h.

Follow-up

Data of operation time, blood loss, surgery difficulty, postoperative efficacy and complications were recorded. The patients were followed up at 3 months, 6 months and 12 months after THA surgery. According to patients' complaints, the outcome was classified as follows: 1) cure of urinary incontinence: patients had no or limited amount of urine leakage, and pressure test showed negative; 2) ineffectiveness: patients could not control the urine leakage, and pressure test showed positive.

Results

Informed consent was obtained from 27 patients before surgery. Nine received THA surgery under local anesthesia, and 18 under saddle block anesthesia. The average operation time was around 39 min (rang: 25-70 min). The median intra-operative blood loss was 70 ml (20-120 ml). Damage to the bladder and urethra and hematoma were not found in the operation. Urethral catheter stayed for 6 h in 25 patients, and for 48 h in 2. The mean residual urine volume was 25.2 ml (range: 0-80 ml) at 72 h after surgery, and the average hospital stay was 4.7 days (rang: 3-7 days). Cure was found in 22 patients, significant improvement in 3, and persistent symptoms in 2. The subjective efficacy was 92.5%. Three had symptoms of slightly frequent and urgent micturition, and four had unilateral or bilateral vulva pain. Post-operative infection and deterioration of pre-existing diseases were absent. At 3 months, 6 months and 1 year after surgery, the effectiveness rate was 92.5% (25/27), 92% (23/25), and 87.5% (21/24), respectively. 3 months and 6 months after THA surgery, 2 patients and 1 patient developed urgent micturition, respectively. 6 months after THA surgery, none had local pain, and 2 were lost to follow-up at 6 months after THA surgery. At 1 year after THA surgery, recurrent symptoms were observed in 1 patient and mesh erosion in 1, and 1 died of other diseases (**Tables 2** and **3**).

Discussion

Incidence of recurrent or persistent symptoms

SUI is a common disease in females, and its morbidity varies among different areas and different age groups. Botlero [3] reported that the incidence of SUI was 12.8%-46% in Australian women. SUI may influence the daily life and social activity of women. In the past decade, increasing clinicians and researchers have conducted a variety of studies aiming to develop appropriate clinical strategies for the management of SUI. Conservative treatment and drugs may improve the symptoms in a fraction of patients. With the increase in age and presence of other factors, the quality of life of these patients is significantly influenced, and thus surgery is required. To date, MUSs has been regarded as golden standard in the surgical intervention of SUI. However, recurrent and/or persistent symptoms are also observed after these MUSs, which seriously affects the confidence of both physician and patients on the surgical intervention of SUI, and limits the wide application of this surgery. Thus, a lot of patients lose the opportunity of surgery. The incidence of recurrent symptoms varies among studies. Ashok [4] systematically reviewed the

Table 3. Information collected in the follow-up period

Variable \ Number of patients	Time points: After THA	3 months	6 months	12 months
	n=27	n=27	n=25	n=24
Subjective feel remedied	25	25	23	21
Persistent	2	2	2	2
Recurrent	0	0	0	1
Organ injury	0	0	0	0
Urgent urinary incontinence	3	2	1	0
Mesh erosin	0	0	0	1
pain	4	2	0	0
infection	0	0	0	0

symptoms after primary MUSs, and results showed the recurrence rate was 10-20%. Richter [5] conducted a multi-centered randomized study. Their study showed the TVT and TOT had an effectiveness of 80.8% and 77.7%, respectively, at 12 months after surgery, which suggests that about 20% had recurrence or persistence of symptoms. Most reports have shown that TVT is better than the surgery via sling trans obturator. Novara [6] concluded that TVT had higher objective effectiveness rate than TOT, but the subjective effectiveness rate was comparable. Most reports have shown that surgery via the trans obturator has a cure rate of around 80% [2, 7]; Houwert [8] reported that the Monarc surgery had a subjective failure rate of around 35%. Its recurrence or persistence rate of symptoms was higher than that after retropubic sling. Another kind of mini-invasive surgery for SUI is TVT-SECUR. Masata [9] had showed that in the 2-year follow-up, the cure rate after TVT-O was 92.6%, that after TVT-S H was 68.8% and that after TVT-S U was 69.2%. In line with findings in the Masata's study, Cornu [10] reported a high recurrence rate after TVT-SECUR and they recommended that TVT-SECUR should not be used as a first-line surgery for SUI. All these findings demonstrate that MUSs have a risk for recurrence and persistence of some symptoms. It is imperative to improve the surgery procedures. In the present study, therapeutic efficacy of THA surgery was investigated in SUI women [11] and our results demonstrated that it was an effective surgery for SUI when patients non-responded to MUSs. The effectiveness rate was as high as 92.5% (25/27), 92% (23/25) and 87.5% (21/24) at 3 months, 6 months and 1 year after THA surgery, respectively. Recurrence was noted in 1 patient, mesh erosion was observed in 1, and the failure rate was much lower than that of other surgeries.

Causes of recurrence and persistence of symptoms

MUSs have been widely used worldwide, and the main indication for MUSs is SUI with or without MUI. Operation indications, surgical procedures, way of surgery, materials and inter-individual variation might be factors causing the recurrence and persistence of symptoms after MUSs. The main cause of surgery failure might be inappropriate operative indications, and the operation procedures are also a contributor. For example, loss or disposition of the sling is common after MUSs. In addition, the way of operation may also influence the recurrence or persistence of symptoms. The materials of the mesh are often associated with erosion, but not with surgical efficacy. Meschia [12] in their study mentioned that, among the numerous risk factors for failed anti-incontinence surgery, only urethral hypomobility and recurrent SUI were significantly associated with the failure of TVT procedures. Furthermore, TVT failure might be associated with the angle of ≤30 degrees in the Q-tip test, because the symptoms of these patients were not caused by urethral support weakness. Poon [13] proposed that the persistent SUI after pubovaginal sling (PVS) placement could occur after positioning of the graft excessively proximally on the bladder neck. The failure in some cases may also be caused by sling's gradual gression after operation. In the study of Gilchrist [14], they found that the main cause of MUSs failure was the incorrect location of the sling relative to the mid-urethra. In the failed MUSs, the sling is very close to the bladder neck or the lower urethra. All these studies indicate that the sling must be located in the mid-urethra and be appropriately tightened in the MUSs. In addition, these studies also provide theoretical evidence for the new complementary surgery after failed MUSs. In our department, the mesh was fixed on the descending pubic ramus, which avoids the closeness of the sling to the

bladder neck in the retropubic operation as well as the closeness of the sling to the lower urethral in the obturator operations. Because this suture is relatively fixed, the possibility of migration reduces. The effectiveness of our THA surgery is also supported by the anatomical structure. Meanwhile, provocation test is required to adjust the sling tightness securing the mesh in a proper hammock for SUI.

Treatment of recurrent or persistent symptoms

Physical examination and psychological evaluation are helpful to identify the factors causing the recurrence or persistence of symptoms, especially the pathological factors. If the pre-existing diseases are involved in recurrence or persistence of SUI symptoms, these diseases should be controlled before and after surgery. If the SUI symptoms were improved after controlling of underlying diseases, a physical or electrical stimulation therapy should be used. Other therapies are also reported to be effective: local injection, medication, and stem cell therapy. If the SUI symptoms are not improved, after the patients are fully informed, a second operation may be performed. However, this is also a psychological challenge for both patients and physicians. To find simple, mini-invasive, cheap and repeatable surgery for the recurrent or persistent SUI symptoms is vital. Rardin [15] used the TVT in the treatment of recurrent SUI, and the cure rate reached 75-91%. Since TVT is a retropubic sling, the sling has the possibility to locate close to the bladder neck after a second operation, and it may have a high operative complication than the primary operation. Lo [16] described a surgical method to shorten the sling after TVT for the treatment of recurrent SUI and they called this method as "figure-of-eight sutures". However, this method cannot adjust the sling to the mid-urethra and the persistent or recurrent SUI may not be cured (cure rate: 71.4%). In the present study, the THA surgery fit for the theory of pelvic hammock, in which the mesh is anchored onto the descending pubic ramus. This makes the fixation reliable and long lasting. Meanwhile, the operative wound is small, and there is no deep dissection and puncture, which avoids surgical injuries through the obturator or retropubic. In our surgery, only a small mesh is needed, which reduces the mesh-related complications. The operation is easy to handle and the medical cost also reduces. Thus, this method can be accepted by both patients and physicians, and has a wide application in clinical practice.

Novelties of this study

This study aimed to treat the recurrent or persistent symptoms after primary MUSs with a novel surgery. In addition, we also provided subjective diagnostic criteria for recurrent or persistent symptoms, but objective diagnostic criteria are still required. The THA surgery is a simple, safe and easy-handling method for the treatment of SUI, and has relatively high efficacy. Our findings also emphasized that a detailed pre-operative evaluation was quite important for improving the therapeutic efficacy. To avoid the damage to the bladder, urethral and other organs during the operation is important to reduce the morbidity of recurrent or persistent symptoms after a second surgery. Studies with longer follow-up period and large sample size are needed to confirm our findings.

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Disclosure of conflict of interest

The authors declare that there were no conflicts of interest.

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