

A comparison between adjustable single-incision sling and tension-free vaginal tape-obturator in treating stress urinary incontinence

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Abstract

Purpose To compare the subjective and objective cure rates, postoperative pain, postoperative complications, and postoperative quality of life of adjustable single-incision sling (Ajust[®]) versus tension-free vaginal tape-obturator (TVT-OTM) in the treatment of female stress urinary incontinence (SUI).

Methods Female patients with SUI ($N = 368$) were randomized to receive either Ajust[®] ($N = 184$) or TVT-OTM procedure ($N = 184$) between January 2012 and October 2013. Efficacy was evaluated using cure rate, postoperative complications, postoperative pain profile (using Visual Analogue Scale), Patient Global Impression of Improvement Scale, and International Consultation on Incontinence Questionnaire-Short Form.

Results The patients from Ajust[®] and TVT-OTM groups had no statistically significant difference in subjective and objective cure rates (94.4 vs 90.7 %, $P = 0.171$; 97.2 vs 90.7 %, $P = 0.195$). Compared with the TVT-OTM group, patients in the Ajust[®] group had significantly less postoperative pain, shorter operative duration, and less intraoperative blood loss (all P values < 0.05). No significant difference in perioperative complications was observed between these two groups. Patients in Ajust[®] group had shorter recovery time ($P < 0.001$) compared to TVT-OTM

group. The postoperative quality of life of patients in these two groups was significantly improved compared to baseline; however, no significant difference was observed in the average improvement of life between these two groups ($P = 0.115$).

Conclusions Ajust[®] procedure is simple, safe, and effective for the treatment of SUI. Compared with TVT-OTM, patients receiving Ajust[®] had less intraoperative blood loss, less postoperative pain, and shorter recovery time.

Keywords Stress urinary incontinence (SUI) · Postoperative pain · Postoperative complications · Postoperative cure rate · Adjustable single-incision sling (Ajust[®]) · Tension-free vaginal tape-obturator (TVT-OTM)

Introduction

Stress urinary incontinence (SUI) is the most common type of urinary incontinence in perimenopause women, with an incidence as high as 50 % [1]. The symptoms of SUI include leakage of urine at cough, sneeze, or even during walk or recumbent, which seriously affect a woman's daily life and mental health.

Therapy for SUI includes physical and surgical treatments. Conservative treatment includes pelvic floor muscle training (PFMT) and biofeedback and electrical stimulation. Recent studies [2] have suggested that early surgical treatment is superior to physical treatment alone. Currently, the surgical treatment for SUI is more common, and had shown good curative effects. The most common procedure for surgical treatment of SUI is the standard mid-urethral slings (SMUS), including retropubic tension-free vaginal tape (RP-TVT) and transobturator tension-free vaginal tape

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(TO-TVT) [3–5]. The main complication of RP-TVT is the intraoperative bladder injury, and the main concern of TO-TVT is the postoperative pain in the inner thigh.

Introduction of minimally invasive mid-urethral slings has changed the surgical approach of SUI [6]. Adjustable single-incision sling (Ajust[®]) procedure is a more advanced surgical approach for the treatment of SUI. The sling is a non-absorbable polypropylene material with a width about 1.2 cm. The sling is inserted through a single incision in the anterior vaginal wall and suspends the middle part of urethra; the sling is anchored in the obturator membrane using anchoring device. The tightness of the sling is adjusted intraoperatively to obtain appropriate tension. The advantages of this approach include minimal injury, good tolerance, and shorter operative time. The other advantages are as follows: The surgery can be performed under local anesthesia, and the sling can be fixed firmly, with low incidence of postoperative pain, short hospital stay, and rapid recovery [7]. The present study was aimed to compare the subjective and objective cure rates, postoperative pain, postoperative complications, and postoperative quality of life after the surgical treatment of female SUI by Ajust[®] versus tension-free vaginal tape-obturator (TVT-O[™]).

Patients and methods

Study design

This prospective study included 368 patients undergoing simple surgery for SUI in the ward of pelvic disease of Gynaecology Department in Shengjing Hospital between January 2012 and October 2013. The patients were simply randomized using table of random numbers, and they received Ajust[®] (Bard) procedure or TVT-O[™] (Johnson & Johnson) procedure; patients were followed up for 12 months. The study protocol was approved by the ethical committee of our hospital. All patients provided a written informed consent.

All surgeons were highly experienced and had performed more than 200 surgeries of TVT-O[™] and more than 20 surgeries of Ajust[®] individually.

Patients

Study inclusion criteria were as follows: Patients with body mass index (BMI) < 35 kg/m² and age > 18 years; patients with corresponding clinical symptoms (leakage of urine at cough and sneeze) and urodynamically diagnosed with SUI; and patients who received PFMT but failed to achieve efficacy or patients refused to receive PFMT (ineffective conservative therapy).

Study exclusion criteria were as follows: Patients with Pelvic Organ Prolapse Quantification score ≥ 2 ; patients with history of urinary incontinence surgery (such as Burch surgery and mid-urethral sling surgery) or history of pelvic irradiation; patients with mixed incontinence (SUI < urge urinary incontinence); patients who received prolapse therapy; and patients with disseminated sclerosis and other neurologic diseases.

Preoperative assessment

Preoperative assessment included patients' medical history, pelvic examination, urodynamic assessment, 3-day urinary diary, and International Consultation on Incontinence Questionnaire-Short Form (ICIQ-SF).

Postoperative assessment

Visual analog scale (VAS) was used to measure the patients' pain at 1 day, 1 week, 2 weeks, and 1 month after the surgery, where a VAS > 5/10 was considered severe pain. The bladder catheter was pulled out 24 h after surgery, and patients were asked to train for voluntary micturition; bladder scan (BladderScan[®] BVI9400; Verathon) was used to test the post-void residual volume (PVRV). In this study, a PVRV > 100 ml at 24 h after the surgery was considered urinary retention.

One year after the surgery, patients who had undergone standing cough stress test were guided to complete the Patient Global Impression of Improvement (PGI-I) and ICIQ-SF scales. In the PGI-I scale, patients with significant improvement or improvement in urinary incontinence were considered as "subjective cure." Scale filling and VAS measurement were conducted by trained professionals, and they were blinded to the surgical approaches. The intraoperative blood loss was estimated by weighing the gauze pre- and post-operatively, together with the measurement of the amount of blood in the aspirator.

Surgical approaches

Ajust procedure

Normal saline was injected through anterior vaginal wall. Then the anterior vaginal wall was dissected longitudinally between inferior urethra and urethral lower ditch, and bilaterally dissected in urethral space till obturator. Along the tunnel on the right side created by previous dissection, the fixed anchor was passed behind the ischium pubic ramus before being pivoted through the obturator internus muscle and membrane by rotating the handle towards the obturator internus muscle to basically align the sling mid-line marker and middle urethra. The anchor was then

released by pushing the release lever, the inducer was retracted, and gentle sling traction was applied to test for the quality of anchoring. The adjustable anchor was then introduced in the contralateral side in the same manner as described previously and the sling was adjusted. A flexible probe was inserted into the handle, and the sling lock was pushed to the adjustable anchor. Then the probe was removed, and the excessive mesh was cut off. The anterior vaginal incision was continuously sutured using 2–0 absorbable strands. After confirming no active bleeding, vagina was filled with two pieces of Anergian gauzes, which were removed 24 h later.

TVT-OTM procedure

Normal saline was injected through anterior vaginal mucosa. Then the anterior vaginal wall was dissected longitudinally between inferior urethra to urethral lower ditch, and bilaterally dissected in urethral space till obturator. The left sling was inserted under the guidance of inducer, whose outlet was located about 3 cm parallel to and 1 cm below the urethra. The right sling was inserted in the same manner, and the sling was adjusted. Anterior vaginal wall was continuously sutured using absorbable strands. Then the puncture incision was also sutured, and two pieces of Anergian gauzes were filled into vagina, which were removed 24 h later.

The primary endpoint was the subjective cure (defined as “very much improved” or “much improved” on the PGI-I scale) at 12 months after surgery.

The secondary endpoints were as follows: Objective cure (negative stress test: If there is no leakage of urine during the involuntary cough, the test is negative, indicating an objective cure.) at 12 months after surgery; PVRV at 24 h after surgery; VAS scores at 1 day, 1, 2, and 4 weeks after surgery; and surgery data and perioperative complications.

Sample size and statistical analysis

It was intended to enroll a total of 360 patients in this study. An estimated subjective cure rate of 80 % in the TVT-O group might obtain a difference of 10 % or above between the two groups with a certainty of 80 % ($\beta = 0.2$), $\alpha = 0.05$.

Statistical analysis was performed using SPSS19.0 software. Measurement data analyses were performed using *t* test, and count data analyses were performed using Chi square test, where $P < 0.05$ was considered statistically significant.

Result

General characteristics of patients

A total of 534 patients were recruited in this study, and 368 patients with SUI who met the inclusion criteria were randomized into two groups, namely, Ajust[®] ($N = 184$) and TVT-OTM ($N = 184$) procedures (Fig. 1). Patients in

Fig. 1 Patients flow

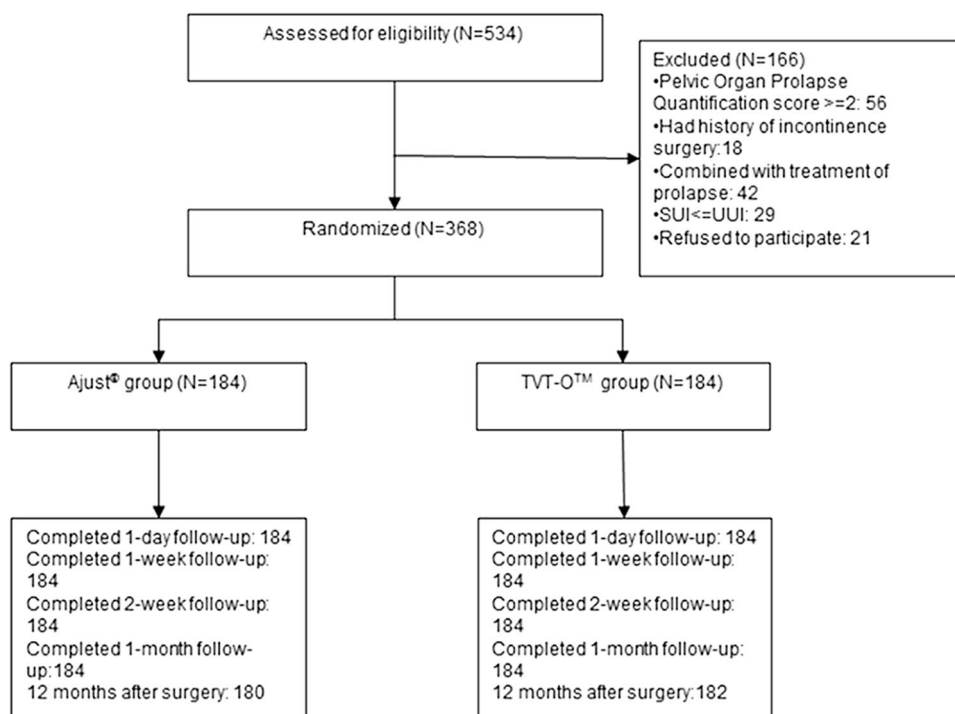


Table 1 General characteristics of patients

Characteristics	Ajust [®] group (N = 184)	TVT-O TM group (N = 184)	P value
Age (years)	57.6 ± 6.8	56.5 ± 5.7	0.093
BMI	26.5 ± 5.1	27.4 ± 5.8	0.115
Duration of SUI (month)	4.1 ± 2.4	4.4 ± 1.9	0.185
Daily urinal pad (N)	3.4 ± 2.1	3.0 ± 1.8	0.051
Urination at night (N)	0.9 ± 1.1	1.0 ± 1.0	0.362
Type of incontinence, % (N)			
SUI	162	169	0.225
MUI	22	15	0.225
Preoperative residual urine volume (ml)	14.7 ± 7.2	16.1 ± 6.7	0.054
Hormone replacement therapy, % (N)	9 (4.9)	6 (3.3)	0.429
Menopause, % (N)	169 (91.8)	173 (94.0)	0.416
PFMT, % (N)	58 (31.5)	63 (34.2)	0.579
Hysterectomy, % (N)	14 (7.6)	18 (9.8)	0.459
Smoking, % (N)	7 (3.8)	9 (4.9)	0.609
Chronic cough, % (N)	10 (5.4)	9 (4.9)	0.814
Hypertension, % (N)	50 (27.2)	47 (25.6)	0.723
Constipation, % (N)	19 (10.3)	16 (8.7)	0.594
Diabetes, % (N)	39 (21.2)	35 (19.0)	0.603

BMI body mass index, Ajust[®] adjustable single-incision sling, TVT-OTM tension-free vaginal tape-obturator, SUI stress urinary incontinence, MUI mixed urinary incontinence, PFMT pelvic floor muscle training

Table 2 Primary and secondary outcomes in Ajust[®] and TVT-OTM group

	Ajust [®] group (N = 184)	TVT-O TM (N = 184)	P value
Rate of subjective cure (PGI-I) at 12 months	170 (94.4)	165 (90.7)	0.171
Rate of objective cure (negative CST) at 12 months	175 (97.2)	172 (94.5)	0.195
PVRV at 24 h after surgery	57.2 ± 23.2	54.4 ± 30.7	0.324
VAS > 5 in 24 h postoperative period, % (N)	2 (1.1)	9 (4.9)	0.032
Postoperative length of stay (days)	2.25 ± 0.74	2.34 ± 0.65	0.216
Time to restore to normal life (days)	14.84 ± 1.17	19.89 ± 1.26	0.000
Average improvement of ICIQ-SF ($\bar{x} \pm s$)	13.20 ± 5.43	12.35 ± 4.87	0.115

Ajust[®] adjustable single-incision sling, TVT-OTM tension-free vaginal tape-obturator, PGI-I Patient Global Impression of Improvement Scale, ICIQ-SF International Consultation on Incontinence Questionnaire-Short Form, CST contraction stress test, PVRV post-void residual volume, VAS Visual Analogue Scale

the two groups had no statistically significant differences in age, BMI, daily urinal pad, duration of SUI, preoperative PVRV, hormone replacement therapy, history of hysterectomy, smoking, and other baseline data, as shown in Table 1.

Primary endpoint

All patients received 12 months' follow-up, and the patients from Ajust[®] and TVT-OTM groups had no statistically significant difference in the subjective cure rate (94.4 vs 90.7 %, $P = 0.171$), as shown in Table 2.

Secondary endpoint

In the 12 months' follow-up, the patients from Ajust[®] and TVT-OTM groups had no statistically significant difference in the objective cure rate (97.2 vs 90.7 %, $P = 0.195$).

PVRV was measured at 24 h after the surgery, and the results showed that the Ajust[®] and TVT-OTM groups had no statistically significant difference in the objective cure rate (57.2 ± 23.2 vs 54.4 ± 30.7, $P = 0.324$).

Incidence of severe pain (VAS > 5/10) at 24 h after surgery in the Ajust[®] group was significantly lower than that in the TVT-OTM group (1.1 vs 4.9 %, $P = 0.032$).

Patients in the Ajust[®] group had shortening trend of postoperative hospital stay compared with the TVT-OTM group ($P = 0.216$), and had significantly shorter time to restore normal life (14.84 ± 1.17 vs 9.89 ± 1.26 , $P = 0.000$).

In the 12 months' follow-up, the average improvement in the Ajust[®] and TVT-OTM groups had no statistical significant difference (3.20 ± 5.43 vs 12.35 ± 4.87 , $P = 0.115$), as shown in Table 2.

Postoperative pain was tested at 1 day, 1 week, 2 weeks, and 1 month after the surgery, and the results showed that the pain within 2 weeks after the surgery in the Ajust[®] group was significantly lower than the TVT-OTM group, and the pain in the two groups basically disappeared 1 month after surgery, with no statistically significant difference (Fig. 2; Table 3).

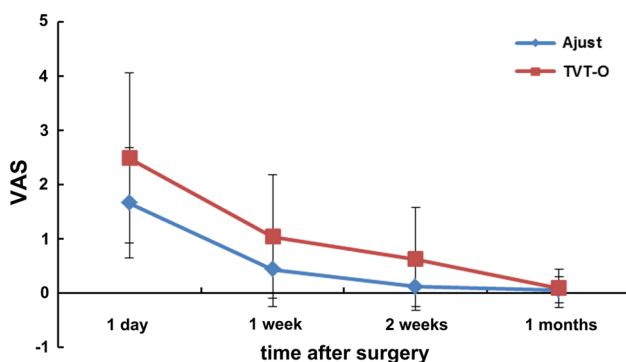


Fig. 2 Visual Analogue Scale (VAS) at 1 day, 1, 2, and 4 weeks after surgery

Table 3 Postoperative pain score (Visual Analog Scale, VAS)

Group	Ajust [®]	TVT-O TM	<i>t</i> (<i>P</i>)
Postoperative day 1	1.66 ± 1.02	2.49 ± 1.56	0.00
Postoperative week 1	0.44 ± 0.68	1.04 ± 1.14	0.00
Postoperative week 2	0.12 ± 0.37	0.63 ± 0.94	0.00
Postoperative month 1	0.06 ± 0.24	0.09 ± 0.35	0.34

Ajust[®] adjustable single-incision sling, TVT-OTM tension-free vaginal tape-obturator

Table 4 Surgical data and perioperative complications

	Ajust [®] group (<i>N</i> = 184)	TVT-O TM group (<i>N</i> = 184)	<i>P</i> value
Surgery time (min)	14.4 ± 7.8	25.2 ± 8.6	0.000
Estimated blood loss	14.6 ± 2.6	22.3 ± 1.7	0.000
Bladder/urethral injuries, % (<i>N</i>)	0	0	0
Voiding dysfunction			
Requiring catheterization	4 (2.2)	10 (5.4)	0.102
CISC at 4 months	0	0	0
Vaginal erosion	0	3 (1.6)	0.082

CISC clean intermittent self-catheterization, Ajust[®] adjustable single-incision sling, TVT-OTM tension-free vaginal tape-obturator

Intraoperative state and perioperative complications

Compared with the TVT-OTM group, the patients in Ajust[®] group had significantly shorter operative time (14.4 ± 7.8 vs 25.2 ± 8.6 , $P < 0.001$) and had significantly smaller amount of intraoperative blood loss (14.6 ± 2.6 vs 22.3 ± 1.7 , $P < 0.001$). No significant intraoperative and postoperative complications were found in the two groups and no bladder, vessel, and nerve damages were found after surgery. Urinal catheter was removed 24 h after surgery in both groups, and four and ten patients had urinary retention, respectively, from Ajust[®] and TVT-OTM groups; they required indwelling bladder catheter. One month after the surgery, the patients' PVRV restored to normal level and they did not require self-catheterization. Three patients in the TVT-OTM group had vaginal sling erosion and they underwent surgery for partial removal, as shown in Table 4.

Discussion

The present study results suggested that compared with the TVT-OTM group, patients receiving Ajust[®] surgical approach had significantly less pain, shorter operating time, smaller amount of blood loss, and shorter recovery time.

Postoperative subjective and objective cure rates

Retrospective study on RP-TVT and TO-TVT as well as meta-analysis did not confirm that there were significant differences in the subjective and objective cure rates between the two groups [8, 9]. However, RP-TVT was more likely to damage bladder, leading to postoperative voiding dysfunction. Meanwhile, the incidence of postoperative pain in the inguinal region and in thigh was significantly increased after TO-TVT surgery.

Numerous studies on short-term follow-up showed that the objective cure rate at 3 months after Ajust surgery was 89.7 % [10], and those at six and 12 postoperative months were 91.4 % [11] and 82–86 % [7, 12], respectively. In

Nauman et al. [6] study, patients with SUI ($N = 52$) received Ajust[®] surgery and 29 months' follow-up. The results showed that the postoperative objective cure rate was 86.3 %, patient's quality of life was significantly improved, and good long-term efficacy was achieved. Tantanasis et al. [13] reviewed the surgical techniques, with long-term success rates ranging from 84 to 95 %.

Postoperative pain

The present study results indicated that compared with TVT-O, patients receiving Ajust procedure had less postoperative pain within 2 weeks, and they might require less recovery time to perform activity and restore normal life. These results were consistent with previous study results [7, 8, 11, 12, 14–17]. In TVT-O surgical approach, postoperative pain was severe, long-lasting, covering large area, and often accompanied by pain in lower limbs, which was further aggravated during activity of lower limbs. It was suspected that the pain could be associated with the adductor tendon injury. Interestingly, in Ajust procedure, the postoperative pain was mild, short-lasting, and the recovery time was shorter compared to TVT-O. It was speculated that the less pain might be due to limited puncture was made only in obturator membrane without any penetrations in obturator internus, leading to no tendon injury. In a multicentre prospective study [10], patients with SUI ($N = 137$) were randomized to receive Ajust ($N = 69$) or TVT-O ($N = 68$) procedures, and the follow-up results showed that the postoperative pain in Ajust group was significantly lower than the TVT-O group within 4 weeks after the surgery.

Postoperative quality of life

Patients receiving Ajust procedure had significantly shorter time to restore their normal life. Multicenter prospective large sample studies [6, 10, 11] indicated that Ajust surgery can significantly improve quality of life of patients. In the present study, the ICIQ-SF survey suggested that the quality of life of patients in the two groups were both significantly improved.

Postoperative urination and sling exposure

The present study showed that the incidence of urinary retention in the Ajust group was lower than the TVT-O group; however, the difference was not statistically significant ($P > 0.05$). A total of 14 patients in the two groups had PVRV > 100 ml at postoperative day 1, and they used indwelling catheter for a duration of 1–14 days; the patients' PVRV reached the normal level at 4 weeks after the surgery. In Mostafa et al. [10] study, it was reported that the incidence of catheterization requirement

in postoperative period in the Ajust group was 4.3 %, which was comparable with the present study results. In Meschin et al. [11] study, one patient had urinary retention at 9 days after the Ajust surgery, and then the sling was removed; 151 patients were followed up for 6 months in another study [18]. Ten patients (6.1 %) had de novo urge incontinence in their post-operative follow-ups which was resolved using anti-cholinergic drugs and two patients (1.2 %) required sling sections due to prolonged bladder outlet obstruction. In previous studies, more attention has been paid to tightness of sling, which is no objective indicator and is mostly associated with the experience of surgeons and training of surgical approach. In the present study, it was found that although the sling tightness was different, postoperative subjective and objective cure rates were not significantly different between the two treatment groups. Based on our operation experience and postoperative outcomes we found that a sling position in SUI surgical approach could affect the outcome, likely, sling position too close to the external urethral orifice might result in postoperative urinary retention and urinary thinning, while a sling position too far from the external urethral orifice might lead to failure of continence surgery and leakage of urine. Hence, it is believed that the core success of surgery is dependent on sling position rather than its tightness, and the use of too tight a sling should be avoided. The incidence of postoperative vaginal sling erosion had no statistically significant difference between the two groups, but was significantly lower than the results previously reported in early type SIMS [19, 20].

Limitation of the study

The major limitations in this study were intraoperative use of epidural anesthesia and use of normal saline for hydrodissection. Moreover, the follow-up duration was short (1 year).

Conclusion

Ajust[®] procedure is simple, safe, and effective for the treatment of SUI. Compared with TVT-O[™], patients receiving Ajust[®] had less intraoperative blood loss, less postoperative pain, and shorter recovery time. However, the efficacy of Ajust[®] surgical approach needs to be further verified using multicenter, large sample, and long-term follow-up studies.

Compliance with ethical standards

Conflict of interest None.

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