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Risk factors of long-term complications after Tension-Free Vaginal Tape (TVT) procedure in Chinese patients with stress urinary incontinence.

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Abstract

This study evaluated the safety profile and also the contributing risk factors of tension-free vaginal tape (TVT) in the management of stress urinary incontinence in Chinese patients. Clinical data of the patients who received TVT procedure in Renji Hospital were retrospectively reviewed and the contributing risk factors for long-term complications were analyzed. The incidence of overactive bladder symptoms and vaginal tape erosion after TVT procedure was found to be higher than that was reported earlier. Risk factor analysis showed that year of TVT experience, preoperative urinary frequency and prior pelvic surgery contributed independently to the overactive bladder complication. Year of TVT experience, urinary voiding difficulty, number of vaginal childbearing and diabetes history were proposed as independent risk factors of vaginal tape erosion. Chinese female patients undergoing TVT procedure suffered from higher incidence of long-term complications such as overactive bladder symptoms and vaginal tape erosion.

Key words: Tension-free vagina tape, complication, risk factor, stress urinary incontinence

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Introduction

Stress urinary incontinence (SUI), is one of the common diseases in elderly women and has impacted negatively to patient's quality of life and sociability. Ulmsten et al. [1] introduced the tension-free vaginal tape (TVT) in 1996, which has become the gold standard for treatment of SUI. While the high efficacy rate of this interventional therapy has been confirmed by many studies [2-6], the safety profile has also been a hot spot of discussion in recent years. Bulent et al. [7] summarized the incidence of immediate, short-tem and long-tem complications, and also explored the risk factors influencing the incidence of TVT complications. Urge incontinence and overactive bladder symptoms developed in 9.1 % and 4.3 % of the patients, respectively with possible risk factors such as prior-anti-incontinence surgery, tighter tape, etc. [8,9]. A recent meta-analysis of postoperative complications has shown that the tape erosion rate was in average of 1.1 % (0.2-22 %) [10]. The possible risk factors were also identified to be excessive tension of the sling on the urethra and technical errors during dissection of the plane beneath the urethra [11,12].

However, the rare data published so far to describe the situation in Chinese female SUI patients who underwent TVT procedure and the risk factors in eastern female patients are still unclear as well. In our study, we retrospectively reviewed the data from 349 Chinese SUI patients who received TVT procedure from 2000 to 2007. The incidences of postoperative de-novo urgency, overactive bladder symptoms and vaginal tape erosion were examined and risk factors were analyzed by an epidemiological survey.

Materials and Methods

Patients: Patients suffered from SUI for more than 6 months and underwent suburethral tension-free vaginal tape (TVT) procedure in our department from September 2000 to November 2007. Gynecare TVT system (Johnson & Johnson) was used for all the patients under spinal or general anesthesia. Patients in which the other tape was used have been excluded from the retrospective study.

TVT procedure: The TVT procedure was as follows: a vaginal incision approximately 1 cm from the external urethra meatus with blunt dissection produced a space lateral to the urethra. Two abdominal incisions were made first at the intended exit points with the needles just superior to the pubic symphysis. Metzenbaum scissors were used to mobilize a flap of the vaginal mucosa on

each side of the urethra. The TVT Rigid Catheter Guide was inserted into an 18 Fr Foley catheter, which was then reinserted into the bladder. With the guide in place in the bladder, the handle was moved toward the ipsilateral leg, which would be on the same side that the needle would be passed. The TVT needle was inserted into the vaginal incision, through the periurethral fascia, into the retropubic space (Space of Retzius) and upward until the needle came through the abdominal incisions. After each pass of needle, cystoscopy was performed with needle in place extending from the vagina to the abdomen. After bladder integrity was confirmed, the TVT needles were pulled through the tissues and placed on the abdomen. The TVT sling was placed prior to removal of the protective plastic sheath covering the Prolene mesh sling. The goal was to position the tape so that during the cough test only one or two drops of urine leaked. To prevent over-correction, a blunt instrument was placed between the tape and the urethra. Then the plastic sheath was removed and excess abdominal tape was cut off. Vaginal and abdominal incisions were sutured, with a urethral catheter reserved.

Follow up: All patients were followed up for 24-48 months (mean 38.4 13.6 months) after TVT procedure and they were interviewed on demographic data, dietary habit, life style, concomitant drug history, family and personal anamnesis, surgery history, 24h pads test before and one as well as six months after TVT procedure. All patients received preoperative assessments including query of detailed history, comprehensive pelvic examination, and urodynamic test. Patients without informed consent to cooperate with the interview and failed to fully recall their information related to the study and those who had personality disorder or the tendency of misleading or speculated about the interviewer's intention were all excluded from the study.

Statistical analysis: SAS 8.02 software was used for statistical analysis. Descriptive statistics of measurement data were expressed as mean standard deviation. Wilcoxon's test was applied for analysis of the measurement data if these data were not normally distributed. Enumeration data were analyzed by the Chi-square test. Wilcoxon's test was used for ranked data. Logistic stepwise regression was performed for screening of the potential independent risk factors.

Results

There were 349 female patients who underwent TVT procedure and their data were reviewed as valid. Aged from 42-71 years (mean 55.4 11.2 years), these patients suffered from SUI for 5 months to 8 years (medium 3.8 years). The incontinence symptom disappeared or partially recovered shortly after operation, whereas 4.3 % (15/349) patients developed de-novo urge incontinence 6-12 months after TVT procedure. In total, no immediate, short-term or long-term complications occurred in 246 patients.

Peri-operative blood loss over 200 ml was observed in 2.3% (8/349) patients, with an average of 249.4+35.6 ml. The remaining (341/349) had blood loss of 40-200 ml with an average of 65.5 ±45.8 ml. All the bleeding cases were successfully managed conservatively with bimanual compression. Bladder perforation occurred in 1.7 % (6/349) patients.

Urinary infection and wound infection after TVT procedure occurred in 3.7 % (13/349) and 1.4 % (5/349) patients, respectively. 12.3% (43/349) patients reported minor voiding difficulty and 2.9 % (10/349) patients reported complete urinary retention but all recovered after 3 weeks to 2 months by encouraging them self voiding intermittently.

14.6 % (51/349) patients suffered from overactive bladder symptoms after operation and all were prescribed with oral anticholinergics. 3.7 % (13/349) patients experienced vaginal tape erosion 6 months to 13 months after TVT procedure and another 2 cases of vaginal tape erosion were diagnosed 21 and 26 months after TVT procedure, respectively. Among those 15 patients who suffered from tape erosion, 73.3 % (11/15) complained vaginal discharge, bleeding, dyspareunia, urinary, vaginal or groin pain, and 26.7 % (4/15) were diagnosed when the tape was palpable by patients herself and/or families. Four of the 15 cases were defective suburethral wall healing with central tape extrusion while the other 11 cases were lateral vaginal wall tape erosion. Six of the 15 cases presenting with signs of inflammation (4 of whom swab culture was positive) were managed by complete removal of the tape. The remaining cases were managed by partial excision of the eroded tape.

The incidence rates of overactive bladder symptoms and vaginal tape erosion before 2003 were statistically higher than that of after 2003 (Table 1).

Aged patients with preoperative urinary frequency and patients with prior pelvic surgery (including the vaginal surgery) were more likely to suffer from postoperative overactive bladder symptoms. The pelvic surgery includes the vaginal surgery, anti-incontinence surgery, hysterectomy, prolapse repair, etc (Table 2).

Age, urinary voiding difficulty after TVT procedure, number of vaginal childbearing, atrophic vaginal epithelium, and high blood glucose are risk factors for urethral/vaginal erosion were shown in Table 3.

Logistic stepwise regression analysis was conducted for multivariate analysis ($P<0.1$ was set as the level of significant difference). The results showed that year of

TVT experience (OR=2.74; 95% CI= 1.24, 3.24) and prior pelvic surgery (OR=4.01, 95% CI=2.38, 5.64) were independent risk factors of overactive bladder complication.

And year of TVT experience (OR=4.55, 95%CI=3.01, 7.07), urinary voiding difficulty (OR=2.01; 95%CI= 1.44, 2.67), number of vaginal childbearing (OR=3.56; 95% CI=1.84, 5.32) and diabetes history (OR=4.92; 95% CI=2.96, 6.87) were independent risk factors of vaginal tape erosion.

Discussion

The overall incidence of complications following TVT procedure in Chinese patients is comparable to that of western women. Interestingly, we found two cases of late tape erosion happened 21 and 26 months after operation, respectively. These findings suggested that long-term follow up was very much necessary after TVT procedure, if we considered together with the similar findings from the study of Messens et al [13]. Couples of studies have shown that the TVT (macropronous monofilament polypropylene tape) had the most compelling history of safety and biocompatibility compared with other sling materials. The incidence of erosion complications after TVT procedure was 0.2-1.2 % [14,15]. We proposed the reason why the incidence in our study was higher was that learning curve played a very important role to prevent such complication, which was evident by the decreased rate of such complication in patients who underwent TVT procedure after 2003. But we still speculated that there might be difference between western and Chinese women patients in terms of tape biocompatibility.

The 2nd International Consultation on Incontinence proposed three complication groups as immediate, short-term and long-term complications. Bulent and Oktay [7] had summarized the risk factors accordingly. In our study, we haven't found any risk factors of the immediate and short-term complications even if we have included many variables from different angles. But we did find out some independent ones in long-term complications such as overactive bladder complication and vaginal tape erosion. Although Allahdin et al. [16] suggested postoperative urgency and vaginal wall erosion were more common in older-aged patients with TVT procedure, other authors had conflicting results [17,18]. In our study, age appeared to be statistically significant in univariate analysis in both overactive bladder and tape erosion complication but turned to be dependent after multivariate analysis. We recommend that patients with symptoms of urinary frequency should take anticholinergic medications before surgery, and receive TVT procedure after urinary frequency symptoms have been controlled for 1 month, otherwise overactive bladder or urge incontinence may occur after surgery. It has been suggested that technical reasons, such as vaginal wall dissection in the wrong plane, inadequate dissection and inadequate vaginal incision suturing could result in vaginal erosion [18,19], but the authors are not convinced themselves that the learning curve appears to be a risk factor as some of the complications occurred after considerable experience on the TVT procedure has been accumulated. In our study, all the TVT procedures have been done by a small group of urologists in the past 7 years. Undoubtedly, their experience had been accumulated by years. The decreased incidence rate of vaginal tape erosion and postoperative bladder urgency demonstrated that the learning curve could be one of the risk factors for such complications, which was reconfirmed by the multi-variable risk factor analysis.

We also found prior pelvic surgery contributed to overactive bladder symptoms. Johnson et al. [20] suggested previous incontinence surgery should be considered as a risk factor of tape erosion as this intervention would destroy the sub-urethral tissue. More interestingly, one of the short-term complications, i.e. post-operative urinary function difficulty turned to be one of the risk factors of tape erosion. Other authors proposed multiple factors such as vaginal and pelvic surgery, type of anesthesia, tape elasticity for voiding difficulty contributed to the urinary retention after TVT operation [21-24]. We speculated that the extent of abnormality of supportive sub-urethral issue had greater weight in determining the event of voiding difficulty. Considering another fact that number of vaginal childbearing of patients, a condition that will also destroy the sub-urethral tissue, turned to be a risk factor of tape erosion. We strongly recommended further investigation on association between sub-urthral tissue abnormality and long-term complications of TVT procedure.

Our study proposed number of vaginal childbearing and high blood glucose as two new indicators for atvta procrdure. Their validity needs to be verified from larger-scale studies. Anyhow, it supports the agreement that many factors could possibly influence the appearance of tape erosion proposed by other authors [8,12,19,20].

In conclusion, the Chinese SUI patients presented the similar profile of efficacy and complications with western patients. Multiple factors are screened to be valid as independent risk factors of the long-term complications. As these two complications have much more negative impact on patients than others, these findings are very meaningful for us to predict complication incidence.

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Conflict of interest statement

We declare that we have no conflict of interest.

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