

Reported complications of tension-free vaginal tape procedures: A review

The tension-free vaginal sling procedure, a contemporary anti-incontinence procedure, has complications as well as benefits.

ABSTRACT: Stress urinary incontinence is a common condition that is often treated effectively with surgical procedures. While several surgical options exist, tension-free vaginal tape procedures have gained popularity in the last decade due to relatively diminished invasiveness. Long-term data are only now becoming available. The significant reported complications of tension-free tape procedures include bleeding, *du novo* urgency and voiding dysfunction, and tape erosion and bladder perforation. Overall, complication rates are similar to that of other accepted incontinence procedures. Only surgeons who have been properly trained in the use of this procedure should be performing this surgery, as surgeon experience is one of the only significant predictors of successful outcome. Cystoscopy should be performed during tension-free vaginal tape procedures, and candidates for the procedure must be carefully selected. Patients must be informed about the success rates and complications of the various surgical procedures.

Stress urinary incontinence (SUI) is a common problem in women, with an estimated incidence of 29% in the community.¹ More than 100 different surgical procedures for the treatment of incontinence have been described in the surgical literature.² Two of the more popular procedures in this group are the retropubic and the vaginal sling and tape procedures. Other procedures such as the anterior repair, bone anchor suspension, and laparoscopic bladder neck repair have not proven to be as satisfactory and are no longer commonly used.

In 2005, guidelines were published with regard to surgical management of stress urinary incontinence. The Canadian Urological Association guidelines state “the retropubic suspension is an effective treatment for primary stress incontinence” and that “tension-free tapes have good short-term results but await long-term and comparative studies to establish their merit.”³ Similarly, the Society of Obstetricians and Gynecologists of Canada guidelines recommended that “according to the current available evidence, a retropubic procedure provides the best assurance of durable cure” and that the tension-free vaginal tape (TVT) “has demonstrated short-term equivalency to retropubic procedures”

but “has not been rigorously tested for long-term equivalency.”⁴

The retropubic procedures, specifically the Burch repair, have been available for more than 40 years and are considered by many to be the gold standard. Several studies with long-term follow-up have shown subjective cure or improvement in 80% to 90% of patients.^{5,6} Complication rates are well documented. The transfusion rate is less than 5% and bladder or ureteric injury is less than 2%.³ Urinary retention occurs in less than 5% of patients and almost never requires surgical revision.³ Vaginal prolapse occurs in 9% to 38% of patients.⁵

Recently, vaginal tension-free slings have been popularized and have been shown to be very effective. This procedure was first described by Ulmsten in 1996.⁷ It has been well studied and researched and has become a common surgical procedure for urinary incontinence. Various techniques have been used, including an ascending or descending retropubic procedure as well as transobturator approaches.⁸ Short and intermediate-term results

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suggest similar efficacy to that of the retropubic suspension.⁶ Long-term results are only now starting to appear. Because the TVT was adopted and used widely before long-term data were available, there has been a relative lag in published reports of complications of the procedure. Now that more than 600 000 TVT have been done in North America, a review of the literature with regard to complications of the procedure is now possible.

Overview of complications

The reported complications of TVT surgery are summarized in **Table 1**. There is some difficulty in synthesizing the published TVT complications data due to a lack of standardization of definitions and differences in reporting between studies. With this in mind an overview of the data is presented.

Overall, complication rates of TVT series appear to be in a similar range to that of other accepted incontinence procedures. In the largest published series, the most common complications reported included bladder perforation, urinary tract infection, *de novo* urge incontinence, and urinary retention. Erosions of the tape into the bladder, urethra, or vagina were rare but serious events. In general there appears to be no consensus on optimal management of the several reported complications. **Table 2** summarizes the frequency of complications in the major series reported in the literature.⁹⁻¹⁴

Bleeding

The Austrian Working Group for Urogynecology performed a post hoc analysis to further delineate the frequency and management of bleeding complications. They found an overall incidence of 2.7% of perioperative hemorrhage identified by questionnaire at the time of their original prospective study. Most hematomas were of a delayed presentation (>24 hours) and

were considered to be of venous origin, while acute hematomas, which were more likely to require surgical management, were of arterial origin. Overall, about two-thirds of hematomas were conservatively managed while one-third required reoperation or conversion of the TVT operation. Transfusion was required in 15% of the patients having bleeding complications (0.3% in the series overall).¹⁵ In the Finnish registry of 1445 TVT operations, Kuuva and Nilsson¹⁰ reported 27 intraoperative bleeds of >200 mL (1.7%), 34 delayed hematomas (2.3%) and only three patients requiring intervention. In a randomized trial of retropubic culposuspension and TVT in the UK and Ireland, Ward and Hilton¹¹ reported a significantly higher estimated intraoperative blood loss with culposuspension. However, postoperative bleeding and hematomas were more common in the TVT group. One patient in the TVT group required reoperation and transfusion for a lacerated obturator artery.

In general, serious bleeding complications requiring intervention are rare events and usually occur intraoperatively. Delayed pelvic hematomas are more common but rarely require intervention.¹⁵

Du novo urgency and voiding dysfunction

Development of new and persistent storage and voiding symptoms have been described in several series. In one of the earlier TVT series, de Tayrac and colleagues reviewed 144 patients treated between May 1998 and December 2000.¹⁶ They noted voiding disorders postsurgery affecting 31.5% of patients. Urgency and pelvic floor discomfort appear to be significant post-op complications in this patient population. Twenty-five percent of patients developed transient urinary retention, which resolved with

prolonged catheterization in all cases. They concluded that informed consent and preoperative information should be presented to patients prior to these procedures.

Table 1. Reported complications of tension-free vaginal tape.⁹⁻¹⁴

Timing	Complication
Perioperative	Hemorrhage Adjacent organ injury (GU, GI, vascular, nerve) Mortality
Postoperative	Urinary retention Frequency/Urgency/dysuria Wound complications Pelvic hematoma Urinary tract infection Tape infection Vaginal erosion Bladder/urethral erosion Vesicovaginal fistula Dyspareunia

Table 2. Frequency of reported tension-free vaginal tape complications in large published series.⁹⁻¹⁴

Complication	Reported frequency
Perioperative	
Hemorrhage	0.6–2.5%
Bladder injury	2.7–13.8%
Urethral injury	0.0–0.1%
Vascular injury (iliac)	0.1–0.6%
Postoperative	
Pelvic hematoma	0.7–3.4%
Urinary retention	2.3–19.7%
Urinary tract infection	0.7–22.3%
<i>De novo</i> overactive bladder	0.2–15%
Vaginal erosion	0.5–1.3%
Bladder/urethral erosion	0.02%

Sokol and colleagues¹⁷ reviewed 267 patients with the aim of identifying predictors of voiding dysfunction after TVT placement. In particular they found that concomitant prolapse surgery did not have an effect on post-operative voiding function. Only a history of previous incontinence surgery was found to significantly correlate

and management have not been well defined. It is evident that this is a common occurrence and needs to be discussed in the process of gaining informed consent. Clinical risk factors for post-TVT voiding dysfunction need further definition so that this difficult problem may be prevented.

Erosion and bladder

subjective cure in 49 patients who had bladder perforations identified at the time of procedure compared with those who had no perforation. Perforations were managed with proper placement of the tape intraoperatively and slightly longer duration of indwelling catheter. Surgeon experience is the only factor that has been consistently associated with bladder perforation, while other evidence is conflicting for other factors such as BMI, previous hysterectomy, and vaginal prolapse.²⁵⁻²⁷

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with post-TVT urinary retention. Age and postoperative urinary infection predicted prolonged time to adequate voiding. Preoperative urodynamic parameters did not have any predictive value.

Despite being described as a tension-free procedure, persistent urinary retention has been reported in up to 19% of patients in large published TVT series.^{9-14,18-20} Nguyen reported a 6% incidence of urinary retention beyond 3 days in 163 women who had a TVT with concomitant supra-pubic tube placement to facilitate voiding trials.²¹ All were able to regain voiding function with tape mobilization between days 3 and 10, with no long-term follow-up described. On the other hand, others have described excellent results with conservative management of urinary retention, with return of complete bladder emptying up to 6 weeks postoperatively.¹⁰

Unfortunately, reporting of voiding disorders after TVT varies widely between studies and its optimal evalu-

perforation

A rare but alarming delayed complication is erosion of the tape into the vagina, urethra, or bladder. The symptoms of vaginal erosion are often non-specific and may include vaginal discharge, dyspareunia, pelvic pain, and urinary symptoms. Urethral and bladder erosion usually present with hematuria, voiding symptoms, and recurrent infections. Bladder erosion is usually the result of an unidentified bladder perforation at the time of surgery, while vaginal and urethral erosions usually present 18 months later, on average, and are the result of multiple factors including tape tension, atrophic tissues, and poor vascularity.²²⁻²³

The value of cystoscopy performed during the TVT procedure was demonstrated by Duckett and colleagues.²⁴ In 100 consecutive cases, five bladder perforations were identified and dealt with. LaSala and colleagues²⁵ found no difference in rate of

Tape erosion into the urethra or vagina is a potentially devastating complication of TVT procedures. Contributing factors include compromised urethral blood supply (estrogen deficiency or radiation), excess tape tension, dissection too close to urethra, or intraoperative urethral injury, and traumatic catheterization or urethral dilation.²⁸ Surgical management is usually required. Both open and endoscopic procedures have been described.^{9, 10, 14} In contrast, Kobashi and Gouvier have described successful conservative management of vaginal erosions in a small series of four patients.²⁹ No such studies have been published for bladder or urethral erosions.

Tsivian and colleagues observed five vaginal tape erosions in their series of 200 patients.²⁰ Four patients had excision of the tape, while one asymptomatic patient was observed. All five patients were dry at last follow-up, with one patient requiring repeat TVT. Similarly, Kuuva and Nilsson found 10 vaginal erosions in their review of 1455 patients in the Finnish registry.¹⁰ Three were managed without surgery, four had the vaginal mucosa resutured over the exposed tape, and two required tape excision. Continence was preserved in all.

Prevention

Based on our review of the literature

and clinical experience with various complications of tape procedures, a number of recommendations can be made. First, only surgeons who have been properly trained in the use of this procedure should be performing the surgery. Recent studies have shown surgeon experience to be one of the significant predictors of successful outcome.³⁰ The learning curve and the increased incidence of early complications has been described by other studies but requires further characterization.^{14, 26, 27, 30}

Second, cystoscopy should be performed during the procedure to be certain that there is no bladder or urethral perforation. Studies have shown the feasibility of this maneuver which avoids delayed recognition of a potentially morbid complication that can be dealt with simply if identified at the time of surgery.

Third, caution should be exercised with certain patient populations. Those who have had multiple previous failed surgical procedures vaginally in the retropubic space may theoretically have an increased risk of complication with bowel and bladder perforation. Also, women who have a previous history of voiding disorders, urethral syndrome, interstitial cystitis, pelvic pain, and obstructive uropathy may have an increased incidence of postoperative voiding dysfunction.

Fourth, patients should be informed preoperatively about the success rates and complications of the various surgical procedures to allow for informed consent. Some women, for instance, will object to an abdominal incision, whereas others are leery about a permanent foreign body underneath the urethra or relative lack of long-term data.

A recent editorial by Dr Deborah J. Lightner in the *Journal of Urology* summarized the essence of the current literature regarding complications of

urethral sling procedures.³¹ She noted that the incidence of complications varies with operative experience, the procedure, and the centre reporting, and that there is a learning curve that requires further delineation. She notes that this is recognized by the American Urological Association and efforts are increasingly directed to establishing the volume of urological cases required for competency. Complications are not limited to certain types of pelvic procedures, but have been reported with all minimally invasive procedures, including those without violation of the retropubic space such as the transobturator tape. She concludes that although this does not imply that mesh is a poor material for pelvic floor reconstruction, it does mean that a cavalier attitude toward a simple outpatient procedure is unacceptable.

Summary

The various tape procedures offer an innovative approach to the treatment of urinary stress incontinence and offer good clinical results in the hands of the well-trained, experienced surgeon. Nonetheless, there are complications that have been noted in the literature and in our experience. Some compli-

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cations can be very difficult to treat, such as post-op pelvic discomfort and voiding dysfunction, and patients should be aware of these complications prior to surgery.

Competing interests

None declared.

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