

ORIGINAL ARTICLE



Management of mid-urethral tape complications: a retrospective study

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Abstract

Background/purpose of the study Following mid-urethral tape insertion, for stress urinary incontinence (SUI), a proportion of women experience complications such as voiding dysfunction or tape erosion which fail to respond to conservative management approaches. These women thus require further surgical treatment. Our objective was to describe the outcomes of the surgical management of complications in these women.

Methods This retrospective study describes the results obtained following the surgical management of mid-urethral tape complications. Twenty-nine consecutive women who required mid-urethral tape lysis, loosening or excision for tape-related complications in the period 2007–2017 were included. Primary outcomes were improvement in voiding dysfunction and resolution of pain, while secondary outcomes were evaluation of the recurrence of stress urinary incontinence and patient satisfaction. Patient outcomes were measured using the Patient Global Impression of Improvement questionnaire.

Results There were 1459 mid-urethral tape procedures performed in the study period. Twenty-nine women (1.99%) who had revision surgery for tape complication were identified. Interventions included tape loosening or lysis in 19 women and tape excision in ten women. Twenty-three of the 29 patients reported a significant improvement in their symptoms post-operatively. Two women had a recurrence of SUI in the tape excision cohort; all patients following tape loosening or lysis remained continent.

Conclusions Tape revision surgery is a safe and effective treatment for mid-urethral tape complications with the majority of women maintaining continence following revision. Early intervention and proactive management of complications, by the appropriate specialist, will improve outcomes.

Keywords Voiding dysfunction · Mid-urethral tape procedure · Stress urinary incontinence · Tape exposure

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Introduction

A temporary pause has been placed on all vaginal mesh procedures in England as a consequence of the controversies surrounding the complications associated with vaginal mesh surgery. The mid-urethral tape procedure was the generally accepted surgical management option for stress urinary incontinence (SUI) when conservative methods have failed [1]. First introduced in the late 1990s, this technique has good efficacy (85–90% continence rate) and a significantly reduced post-op morbidity compared to the Burch colposuspension [2–5]. Anti-incontinence procedures, however, come with complications, the most frequently described being voiding dysfunction and de novo overactive bladder symptoms. Other reported complications include wound infections, recurrent urinary tract infections (UTI) or failure to improve incontinence. Complications unique to the mid-urethral tape procedures include mesh exposure with dyspareunia and chronic groin pain [6–8].

There is therefore a small group of patients who require further management. The most common indications for further surgery are voiding dysfunction or mesh exposure [9]. There are currently no guidelines for the best approach to the surgical management of these patients. The clinical impact of sling loosening, lysis or excision is not clear. The aim of the study was to evaluate the outcomes of corrective surgery for the mid-urethral tape-related complications such as voiding dysfunction and tape exposure. In addition, we aimed to evaluate the risk factors for tape complications by comparing the cohort of patients with tape complications with a cohort of patients without complications.

Materials and methods

This study was performed in our hospital, which is a tertiary referral center, with a Royal College of Obstetricians and Gynecologists Urogynecology Subspecialty accreditation. Approval was granted by the Audit, Assurance and Effectiveness Department of the Hospital. A retrospective cohort analysis of the demographics, clinical manifestations, urodynamic evaluation and medical course of all patients who required tape loosening, lysis or excision surgery after the placement of a mid-urethral tape for the treatment of SUI in the period 2007-2017 was performed. Patients were identified through the hospital theater records list. Patient hospital records were analyzed, and a detailed medical and surgical history review between the primary surgery and the followup tape complication surgery was undertaken. A note was made of conservative management techniques and their efficacy prior to the surgical management. These included trial of catheter, vaginal estrogens and low-dose antibiotics. Voiding dysfunction was categorized into types as follows [10]:

- i. Hesitancy: difficulty in initiating micturition
- ii. Slow stream: reduced urine flow usually compared to previous performance
- iii. Intermittency: urine flow which stops and starts
- iv. Feeling of incomplete emptying.

For trial of catheter for voiding dysfunction, a urethral catheter was inserted for 5 days and the patient discharged. The patient subsequently returned to the urodynamic suite, and a trial without catheter was performed: Patients had to achieve two voids of > 2/3rds of bladder volume. If this was not achieved, the patient was referred for subsequent management.

Urodynamic examination was performed in all patients prior to placement of a mid-urethral tape as per International Continence Society Guidelines [10]. Comparative analysis was performed between the study group of patients who required a return to theater and a cohort of 50 (every third) patients without tape complications (between the years 2007 and 2017) in order to study any preexisting factors for voiding dysfunction. The following comparisons were made:

- 1. Patient demographics
- 2. Preoperative urodynamic parameters
- 3. The odds ratio of developing voiding dysfunction in all patients with or without detrusor overactivity pre-op was calculated.
- 4. Uroflow parameters: maximal urethral closure pressure, functional urethral length and maximal pressure flow rates were compared between patients with voiding dysfunction and the control group.

The surgical management of tape-related complications was narrowed to tape loosening, lysis and excision. For tape loosening, the vagina at the mid-urethral margin was dissected open and the tape identified. A straight dilator was inserted between the tape and the mid-urethra, and tension was applied to loosen the tape. For tape lysis, the vagina at the mid-urethral margin was dissected open, slightly lateral to the urethra on the one side. The tape was identified and cut. For tape excision, the vagina at the mid-urethral margin was dissected open. Excision of the eroded mesh portion was performed by excising the whole of the vaginal portion of the mesh. The retropubic portion was not excised. The outcomes of the revision surgery were analyzed for all patients. This included a review of telephone consultation records as well as follow-up clinic visit consultations. The primary outcome being assessed post-revision surgery was resolution of voiding dysfunction and pain. Secondary outcomes were resolution of urinary tract infections (UTI) and assessment of stress urinary incontinence (SUI) recurrence, both in the immediate postoperative period and 6 months later. The overactive bladder was defined as urinary urgency, accompanied by frequency and nocturia, with or without urgency urinary incontinence, in the absence of infection or other identifiable diseases of the lower urinary tract [10]. Detrusor overactivity was a urodynamic finding described as involuntary contractions of the detrusor muscle during the filling phase of the urodynamic examination. These contractions may be spontaneous or provoked [10]. Detrusor underactivity is reduced strength bladder contraction, resulting in prolonged or incomplete bladder emptying [10]. All patients completed the Patient Global Impression of Improvement (PGI-I) questionnaire post-revision surgery (Online Appendix 1).

Statistical analysis of the urodynamic outcomes was performed using the chi-squared test, with a pvalue of < 0.05 as statistically significant. Odds ratio and confidence intervals were calculated for the complete cohort assessing voiding dysfunction in mixed incontinence.

Results

There were 1459 mid-urethral tape procedures performed in our hospital in the study period. Twenty-nine women (1.99%) who required revision surgery for tape complication were identified ("test" group) and compared with 50 women without surgical complications ("controls"). Of the 29 patients undergoing revision surgery, 19 presented with voiding dysfunction and ten had mesh erosion. Of the patients with voiding dysfunction, all were categorized as obstruction. We had no cases of detrusor underactivity. Trial of catheter was first attempted in all patients, followed by referral for tape loosening or lysis.

Ten women presented with tape exposure; conservative management with vaginal estrogen was tried in all. Among those that presented with tape exposure, two required treatment with anticholinergic medication due to severe overactive bladder symptoms, as well as longterm low-dose antibiotics for recurrent UTI. Conservative management failed, and these patients were referred for tape excision. 98% of all mid-urethral tape procedures either had no complications or were successfully managed conservatively.

Surgical technique

Three consultant urogynecologists using the same techniques for either retropubic GYNECARE (TVT) or transobturator MONARC (TOT) insertion performed the primary surgery as well as all revision procedures. There were no differences in complication rates between surgeons. Patients presenting with voiding dysfunction within 3 weeks of the primary surgery were categorized for tape loosening. Patients, presenting with voiding dysfunction, who had the tape for longer than 3 weeks of the primary surgery were categorized for tape lysis. Sixteen of the 19 women with voiding dysfunction had tape loosening (three of these had pelvic floor pain). The remaining three women had tape lysis. Patients with tape exposure were categorized for tape excision. Along with tape exposure, these women complained of de novo overactive bladder symptoms, voiding dysfunction, recurrent UTI and pain. There were no transobturator procedures requiring tape excision. Ten women had tape excision. There were no surgical complications following any of the secondary procedures.

 Table 1
 Demographics of test patients and controls. *Others=utero

 vaginal prolapse and recurrent urinary tract infection. ^Concomitant

 procedures=vaginal anterior or posterior fascial repair procedures.

 BMI=body mass index

	Test group	Control group
Total number of patients	29	50
Mean age, years	56	54
% BMI≥25	72%	66%
Presenting symptoms		
Stress urinary incontinence alone	7	36
Mixed incontinence	15	14
Stress urinary incontinence + others*	7	0
Primary surgical procedures		
Retropubic tape procedure	26	40
Transobturator tape procedures	3	10
No. of concomitant procedures ^	8	7
Stress urinary incontinence cure rates	90%	78%

Table 2 Urodynamic assessment: There is a significantly higher incidence of detrusor overactivity in the test group compared to controls: 51.7% vs. 28%, p = 0.0349, chi-squared statistic 4.4464. USI = urodynamic stress incontinence, DO = detrusor overactivity

Urodynamics	Test group	Control group
Urodynamic stress inconti- nence alone	14	36
USI and DO	15	14
Total	29	50

Demographics of the test versus control groups

The test and control groups were comparable in terms of age and body mass index (Table 1). More retropubic than transobturator procedures were performed in our hospital. There were a significantly higher number of patients with urodynamic mixed incontinence in the test group than in the controls: 52% test group vs. 28% controls, p = 0.0349 (Table 2). The rates of concomitant vaginal procedures at the time of mid-urethral tape insertion were comparable in both cohorts: 25.7% test group vs. 17.5% controls. Subgroup analysis of the test group revealed that 31.6% of patients with voiding dysfunction had concomitant procedures, while only 20% of patients with tape exposure had concomitant pelvic floor procedures.

Urodynamic examination of the test versus control groups

A review of the urodynamic examination was performed to evaluate the risk of developing voiding dysfunction prior to the primary mid-urethral tape insertion procedure (Table 3). This showed an odds ratio of 3.23 for

Table 3 Review of the urodynamic profiles of the complete cohort of patients.		Voiding dysfunc- tion	
Odds ratio = 3.23, 95% CI [1.07, 9.78]		Present	Absent
	Detrusor overactivity		
	Present	10	19
	Absent	7	43

Table 4Subgroup uroflowmetry analysis: Voiding difficulty vs. controls.Student's t test for comparison

Uroflowmetry	Voiding dysfunction $n = 19$	Controls $n = 50$	p value
Maximal urethral closure pressure	51.1 cmH ₂ O	50.64 cmH ₂ O	0.945
Functional urethral length	3.55 cm	3.11 cm	0.381
Maximal pressure flow rates	20.46 mls/s	25.9 mls/s	0.034

voiding dysfunction in patients with mixed incontinence, 95% CI [1.07, 9.78]. A subgroup analysis of the uroflow parameters (before insertion of the mid-urethral tape) of the patients who developed voiding dysfunction (n = 19) was compared with that of controls (n = 50). There was a significantly lower maximal pressure flow rate in the cohort that developed voiding dysfunction compared to controls: 20.46 vs. 25.86, p = 0.0343. All other uroflowmetry parameters were comparable between the groups (Table 4).

Outcome following secondary surgery

Tape loosening: n = 16

Mean time from the primary surgery to tape loosening for patients with voiding dysfunction was 15 days: average, $STD = 14.9, \pm 8.1$ days. Six months after tape loosening, 14 of these reported their symptoms were either "very much better" or "much better" and all had normal voiding. 100% of patients were dry (according to selfreport), with no recurrence of SUI post-tape loosening. Two patients had ongoing voiding dysfunction post-tape loosening. One required supra-pubic catheter insertion, and the other resolved after 3 months of intermittent self-catheterization (ISC). There was no improvement in pelvic floor pain symptoms in the three affected women. Two women had recurrent UTI prior to tape revision surgery. This resolved in both patients post-tape loosening.

Tape lysis: n = 3

Mean time from tape insertion to tape division for these patients with voiding dysfunction was 15 months: average, $STD = 15, \pm 10.15$ months. All three reported symptoms that were "much better" post-tape lysis. Six-month followup revealed no SUI recurrence in all patients post-tape division. Despite improved symptoms, one patient had residual voiding dysfunction and required insertion of a supra-pubic catheter. She had a background history of anxiety and depression. She had developed a loss of sensation of bladder fullness 17 months following the primary surgery. Tape lysis did not relieve this complaint. Two of the three women had recurrent UTI prior to tape revision surgery. This resolved in both patients post-tape lysis.

Tape excision: n = 10

Mean time from the primary tape insertion surgery for tape excision for patients with tape erosion was 2.6 years, STD = 3.65 years. All ten patients had an uncomplicated post-op recovery. Six months post-op, 80% of patients reported their symptoms as either "very much better" or "much better," they had no recurrence of SUI, their pain was resolved, and they made a full recovery, with the aid of vaginal estrogens. Two patients reported recurrence of SUI, for which they required urethral bulking agents. One patient required ISC due to residual voiding dysfunction. Another had an unrelated prolapse repair procedure. Two patients with recurrent UTI had symptom resolution following the tape excision.

Discussion

The findings of this study reveal that tape revision surgery successfully restores the quality of life in patients with the mid-urethral tape complications such as voiding dysfunction and tape exposure, with 84% of patients with voiding dysfunction and 80% of patients with erosion reporting improved symptoms. Recurrence of stress urinary incontinence is not a significant finding, with only 2 out of 29 patients reporting SUI post-revision surgery. Detrusor overactivity prior to tape insertion is identified as a significant risk factor in patients who developed voiding dysfunction.

This study demonstrated a complication rate of 2% requiring a return to theater post-mid-urethral tape insertion in the 10-year period studied. This is comparable to that in the published literature, which ranges from 0.6 to 6.4% [11, 12]. Of these, 3% are reported to require surgical revision [13]. Review of the urodynamic examination of the patient cohort with voiding dysfunction revealed that there was a significantly higher incidence of preexisting detrusor overactivity, as well as a reduced flow rate compared to controls. Tape insertion at the mid-urethral region predisposes to de novo overactive bladder symptoms [14]. This case series suggests that the presence of preexisting detrusor overactivity significantly increases the risk of voiding dysfunction by more than threefold. This brings into question the appropriateness of the use of mid-urethral tape procedures in patients with mixed urinary incontinence. It is therefore imperative that patients are counseled about the potential risk of worsening bladder function following the tape insertion.

Ten patients (0.68%) in the 10-year period studied had tape exposure requiring tape excision. Pain, dyspareunia or partner discomfort, voiding dysfunction and recurrent UTI represented the most common reasons patients with mesh exposure required further management. Local vaginal estrogen treatment, though useful in alleviating symptoms, did not lead to symptom resolution in this cohort. The average time from primary surgery to tape excision surgery was two and half years, with one woman presenting with tape exposure 10 years post-op. A clinical examination at follow-up is thus of great importance [15]. Of the ten patients with tape exposure, only two had concomitant pelvic floor surgery at the time of mid-urethral tape insertion. This rate of concomitant procedure is comparable to the control population, who did not require a return to theater with tape exposure. However, four of these ten patients (40%) had previously had pelvic floor surgery. This finding suggests that extensive vaginal surgery at the time of mid-urethral tape insertion does not predispose to tape exposure. But a deficient vaginal environment with extensive scarring and reduced blood supply secondary to previous surgery is a greater risk predictor for tape exposure. This finding is supported by the published literature [15]. Careful past surgical history assessment and vaginal examination therefore is required to reduce the risk of tape exposure.

Our study SUI recurrence rate post-mesh excision is 20%. None of the patients who required tape loosening or lysis developed SUI post-procedure. This finding suggests that unless there is tape exposure which requires excision, tape loosening or lysis is a feasible option for the management of voiding dysfunction without an increased risk of SUI recurrence. This is in contrast to mesh excision for mesh exposure, with the literature suggesting an SUI recurrence rate of 30% to 42% [16, 17].

The limitations of our study include a retrospective study design and a small sample size. In addition, the short-term follow-up post-tape revision surgery for mesh complication (6 months post-procedure) is a limitation of the study as a longer-term review of outcomes may highlight further consequences of revision surgery. In addition, the authors are unaware of any complications which may have been managed in other hospital units. A larger population-based prospective longitudinal study of several urogynecology unit outcomes of the mid-urethral tape procedure complications would be warranted to confirm our findings.

Conclusion

The majority of women (98%) post-mid-urethral tape insertion have no problems requiring the surgical management. Proactive surgical management is an effective approach for patients with the tape-related complications such as voiding dysfunction and tape exposure. Management provides a return of quality of life, with maintenance of continence in the majority. The urodynamic finding of mixed incontinence represents a significant risk factor for voiding dysfunction post-tape insertion. Thus, if the temporary suspension of the mid-urethral tape procedure is lifted, it is crucial that improved patient selection, careful counseling prior to tape insertion and prompt management of complications are practiced in order to avoid patient dissatisfaction.

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Compliance with ethical standards

Conflict of interest Ifeoma Offiah, Suneetha Rachaneni and Anupreet Dua declare that they have no conflict of interest.

Ethical standard The study was approved by the Audit, Assurance and Effectiveness Department of the University Hospitals Plymouth NHS Trust and performed with Good Ethical Standards. Reference Number: CA_2018-19-184. This department has an ethics committee for the approval of studies on humans.

Informed consent Informed consent was obtained from all participants. The references should not be more than 10 years old.

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