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Continence outcomes following partial excision of vaginal mesh exposure after mid-urethral tape insertion

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ABSTRACT

Objective: To assess the incidence of recurrent stress urinary incontinence (SUI) following vaginal excision of exposed mid-urethral tape (MUT).
Study design: This was a retrospective observational study in a tertiary urogynaecology unit of an inner city teaching hospital. The population consisted of 41 consecutive women seen with a vaginal mesh exposure following MUT insertion between 2000 and 2009, which failed to resolve with conservative measures. The primary outcome measure was the presence of symptoms of stress urinary incontinence following surgical excision of exposed mesh.
Results: The incidence of recurrent SUI following tape excision was 34.1%. Type of mid-urethral tape, menopausal status, and the time interval between tape insertion and excision were not found to be significantly associated with the risk of recurrent SUI.
Conclusions: Over a third of women experience recurrent SUI after surgical management of vaginal mesh exposure following MUT insertion. Risk factors may be more comprehensively studied using prospectively collected cohorts.

1. Introduction

Stress urinary incontinence (SUI) is a common and debilitating condition, which is estimated to affect 1 in 3 women over the age of 18 [1]. Surgical intervention may be undertaken when conservative measures such as supervised pelvic floor physiotherapy have failed to improve symptoms. The tension-free vaginal tape (TVT) was first described by Ulmsten in 1995 [2], and it is estimated that over a million TVT procedures have been performed since 1996 [3]. The TVT and other mid-urethral tapes aim to restore continence by providing support at the mid-urethra, thus correcting urethral hypermobility secondary to loss of pubourethral ligament support. The latter is the most common mechanism associated with urethral sphincter incompetence and SUI.

Randomised control trial data have confirmed the TVT to have similar long term efficacy to colposuspension [4], whilst being minimally invasive. Subsequent interventions such as the transobturator tape described by Delorme in 2001 have used different techniques for the insertion of a mid-urethral tape (MUT) in order to reduce the risk of trocar-related complications such as bladder perforation, bowel and major blood vessel injury. The common factor in all mid-urethral tape procedures is the introduction of synthetic mesh into the suburethral area. Most mid-urethral tapes are composed of a type 1 macroporous monofilament polypropylene mesh. Although this mesh type is associated with reduced risks of exposure, exposure or extrusion, this is a potential consequence of the introduction of any synthetic sling material. While most tape exposures represent a healing defect or extrusion of the material, true erosion into adjacent organs such as the bladder and urethra have also been described [5,6], but the most common site of tape exposure is the vagina. Vaginal tape exposure rates vary from 0.4% [7] to 5.9% [8], with rates tending to be higher with the transobturator route [9] and with silicone coated tapes [10].

Surgical management of vaginal tape exposure is indicated when conservative management, e.g. with vaginal oestrogen, fails to correct the exposed area. Studies have been published describing risk factors for vaginal exposure but there are very few data specifically on recurrence of incontinence following surgical management as an outcome measure. This is an important

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point to consider since the mechanism of action of mid-urethral tapes may be compromised by excision of a portion of the tape. Increasing numbers of women are undergoing mid-urethral tape procedures, implying that increasing numbers may have vaginal exposure as a complication. The question of whether their stress incontinence will recur will be of concern to all women undergoing vaginal mesh excision, but there are currently no data in the literature to answer this question. An estimate of the proportion of women who will experience recurrent SUI following surgical management would be of value in the pre-operative counselling of such women.

The primary aim of this study was to assess the proportion of women who experience recurrent SUI following surgical treatment of vaginal tape exposure.

2. Methods

This was a retrospective observational chart review study. The study population consisted of 41 consecutive women who were seen between 2001 and 2009 in a tertiary-level urogynaecology unit with a vaginal mesh exposure following mid-urethral sling insertion. Patients were identified from an ongoing departmental audit of operative procedures within the Urogynaecology Department and operating theatre records. Demographic and clinical information were obtained by retrospective review of patient records. Exclusion criteria were SUI at initial presentation and resolution of vaginal exposure with conservative measures alone.

All patients underwent a full urogynaecological history and examination, microscopy and culture of a midstream urine specimen, and a high vaginal swab if any vaginal discharge was present.

All patients were treated initially with local oestrogen cream for 6 weeks. Those with persistent exposure on careful clinical assessment at 6 weeks were offered surgical intervention. All procedures were performed under general anaesthesia in aseptic conditions. A single dose of broad spectrum antibiotic was administered intravenously at induction of anaesthesia. Procedures were performed in the lithotomy position via a vaginal approach with a urethral catheter in situ. The vaginal epithelium was undermined, the edges of the eroded area of tape were mobilised from the vaginal epithelium and the exposed area was excised. The vaginal epithelial incision area was closed with 2/0 vicryl sutures. Cystourethroscopy was performed to exclude bladder or urethral exposure. Patients were discharged the same day if voiding normally. Post-operatively women were advised to continue using vaginal oestrogen and to refrain from tampon use and intercourse for 6 weeks.

Follow-up took place in an outpatient clinic setting. The presence of lower urinary tract and vaginal symptoms was enquired after by direct questioning based on a structured proforma, with the presence of stress incontinence being a dichotomous (yes/no) variable. A clinical examination was undertaken to assess the presence of any persistent areas of exposed mesh. The primary outcome measure was the development of recurrent SUI at any point during follow-up noted on review of the patient records.

Statistical analysis was undertaken using a chi-square test for categorical data and Student's *t*-test for continuous data. All tests were 2-tailed and a *p*-value of less than 0.05 was used to reject the null hypothesis. Under current UK regulations, this study was deemed a service evaluation using the National Research Ethics Service algorithm for requirements for research ethics committee review (last updated August 2011). It was therefore advised that application for formal ethical review was not necessary. This audit was registered with the St. George's Hospital Clinical Audit department.

Table 1
Interval between surgery and detection of exposure.

Time since index surgery	*n* (%)
8 weeks to 6 months	20 (48.8)
6–12 months	12 (29.2)
12–24 months	7 (17.1)
Over 24 months	2 (4.9)

Table 2
Classification of mesh exposures using IUGA/ICS classification system [11].

ICS classification code	*n*
2AaT3S2	16
3AaT3S2	6
2AaT4S2	4
2B T4S2	5
3BcT3S1	2
2BcT3S1	3
2B T3S2	5
Total	41

3. Results

The mean age of patients in the cohort was 58 years (range 38–79 years). Twenty-seven out of 41 (65.9%) were post-menopausal and 7/41 (17.1%) reported using systemic hormone replacement therapy (HRT) at initial presentation. Six out of 40 reported overactive bladder symptoms at presentation. The index procedure was a retropubic tape in 17/41 (41.5%) women and an obturator tape in 24/41 (58.5%) women. The time to presentation with a tape exposure is shown in Table 1.

Five of the women had previously had vaginal exposures of the tape. The presenting symptom was vaginal discharge and/or bleeding in 10/41 women, and vaginal pain/dyspareunia in 5/41 women. In the remaining patients (26/41), the tape exposure was an incidental finding either at routine post-operative follow-up or during an examination for an unrelated reason. The mean duration of follow-up was 20 (range 6–24) months. The tape exposures were defined using the ICS mesh complication classification [11]. The classification codes and proportion of women with each type of mesh complication are given in Table 2.

The incidence of recurrent SUI following surgical management of tape exposure was 34.1% (recurrent SUI reported by 14/41 women). Of the women who experienced recurrent SUI, 9 had undergone a transobtruator tape as an index procedure, and 5 had undergone a retropubic tape as an index procedure. The risk of recurrent SUI following surgical excision of the exposure was not significantly different between obturator and retropubic tapes (5/17 retropubic versus 9/24 obturator, $p = 0.74$). Post-menopasual status was also not found to be a risk factor for recurrent SUI ($p = 0.57$). Using 6 months as a cut-off point, there was no association between time interval between tape insertion and excision, and the risk of recurrent SUI ($p = 0.99$).

Vaginal bleeding/discharge resolved in all women who presented with this symptom. Vaginal pain/dyspareunia resolved in 4/5 women who presented with this symptom.

4. Comment

In this cohort of patients, the incidence of recurrent SUI following surgical management of a mid-urethral tape exposure was 34.1%. The route of insertion of the tape, menopausal status and time interval between tape insertion and excision were not risk factors for recurrent incontinence.

There is a paucity of data concerning vaginal MUT exposure in the literature, beyond simple rates of exposure from clinical trials.