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The one-year experience of tape and mesh removal at a urological tertiary referral centre

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Abstract

Objective: There is increasing controversy surrounding the use of synthetic materials in transvaginal tape and vaginal mesh for stress incontinence and pelvic organ prolapse. The aim of this study was to review the case load and operative management of a tertiary referral urology centre dealing with surgical complications of these procedures within Scotland.

Participants/patients (or materials) and methods: A retrospective review of patients undergoing removal of products and analysis of their symptom, operative findings and postoperative status was conducted.

Results: Twenty-five patients were identified in a one-year period. Eighty per cent of initial procedures were performed by a gynaecologist. Patients presented with a variety of symptoms including pain, infections and haematuria. The most common device needing removal was a tension-free vaginal tape obturator (TVTO). Intraoperative findings were classified using an online calculator with the most common location for complications being within the urethra. Most patients underwent successful removal of all parts of the tape and a small number required combined abdominal and vaginal approach. Postoperatively there was significant symptom resolution for most women with recurrent urinary infections and pain. Over 50% of women were continent postoperatively.

Conclusion: We have demonstrated the benefit of performing operative management of these patients in a tertiary referral centre in terms of outcomes regarding improvement of symptoms and continence rates.

Keywords

Mesh, tape, complications, incontinence, prolapse, surgery

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Introduction

The use of synthetic tape and mesh for stress urinary incontinence and pelvic organ prolapse surgery is a topical and controversial area.

It is estimated that between 2000 and 2014 in Scotland, almost 1500 women with stress urinary incontinence and 350 with pelvic organ prolapse had synthetic mesh implanted each year.[1]

Whilst many women have had great success from the use of synthetic products, unfortunately some have experienced complications with a varying degree of severity and adverse consequences on their lives. There has been concern that inaccurate and inadequate reporting of these complications has led to the full extent of the problem being under-reported not only in Scotland but the rest of the United Kingdom.

In October 2015 the Scottish government published an interim report from the 'independent review of the use,

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safety and efficacy of transvaginal mesh implants in the treatment of stress urinary incontinence and pelvic organ prolapse in women'. This report was instigated by the concerns raised over complications by the Scottish Mesh Survivors group who campaigned to the government for an investigation into the insertion of these synthetic mesh and tape products within Scotland.

Our institution is a tertiary referral centre offering expert assessment and operative intervention for complications surrounding these procedures. The aim of this study was to review the caseload of the centre dealing with complications in terms of operation performed and clinical outcomes for patients.

Experimental/Materials and methods

A prospective database was collected of patients undergoing removal of transvaginal tape and/or vaginal mesh between March 2015 and February 2016. Using the electronic clinical notes system, a retrospective review of case histories was obtained to identify key information regarding date of insertion, type of product, symptoms and indications for removal. We were also able to establish the original operating speciality and year of insertion.

After surgical removal of transvaginal tape and/or vaginal mesh, all patients were reviewed by the operating surgeon in person or via telephone consultation for review of symptoms and postoperative complications.

We analysed the data using descriptive statistics and the International Continence Society International Uro-Gynaecology Association (ICS IUGA) online calculator for mesh complications.

Results

Over the 12-month period, 25 patients underwent surgery in the tertiary referral centre. All were female with an age range of 46 to 81 years old.

Patients presented to both the urology and gynaecology services with a variety of symptoms. Forty-eight per cent ($n = 12$) of patients complained of pain in a variety of locations including abdominal and vaginal. Twenty-eight per cent of patients had recurrent urinary tract infections, a further 28% complained of lower urinary tract symptoms and four women had persistent vaginal discharge. Incontinence, dyspareunia and visible haematuria were each present in 12% of patients. It is interesting to note that one patient requested removal despite being asymptomatic following the media reports regarding tape and mesh complications in Scotland. In regards to self-catheterisation, three patients performed this preoperatively and two had failed attempts due to tape obstructing the urethra.

Assessment of the patients when they re-presented with symptoms of tape complications included initial flexible or rigid cystoscopy, and 68% ($n = 17$, 10 by urologists) had this prior to onward referral to the specialist centre. Furthermore, three patients had initial endoscopic attempts using laser to remove the tape, all of which failed.

Review of the original operation for insertion of tape and mesh revealed 40% ($n = 10$) of patients had a tension-free vaginal tape obturator (TVTO), 32% ($n = 8$) retropubic TVT, 16% ($n = 4$) vaginal mesh only and 12% ($n = 3$) had combined tape and anterior vaginal mesh removal. Twenty per cent of initial procedures were performed by urologists and 80% by gynaecologists. The earliest date of insertion was 2000 and this continued up 2014. Nine of the original procedures were performed in health boards different from the tertiary referral centre (two under urology, seven by gynaecology).

The ICS IUGA prosthesis/graft calculator was used to classify tape and mesh position intraoperatively. It also classified length of time since insertion and symptom location. See Table 1.

In regards to location of the tape, of the 18 patients having only tape removed, five were noted to be transecting the urethra and three had elements found in the bladder. Four patients had palpable tape and two had obvious vaginal erosion. Amongst the four patients having removal of vaginal mesh only, three had vaginal erosion and one had mesh within the bladder. Of those having combined tape and mesh removal, one patient had tape across the urethra and one had a vaginal erosion.

Analysis of the operative procedures performed revealed 64% of patients had complete removal of mesh or tape, of whom three required a combined vaginal and abdominal approach due to location of the tape. Five patients underwent partial removal of tape (either arm or urethral section only) depending on symptoms and location of the surgical issue.

One patient had a concurrent autologous fascial sling placed to manage expected incontinence and 12% of patients required a martius fat graft as part of the repair due to a significant defect within the urethra.

One case had to be abandoned due to anaesthetic difficulties making it unsafe to continue. To date this patient awaits definitive treatment of her tape complications; however, ongoing anaesthetic issues negate this.

Of the remaining 24 women, 54% are continent. Within this cohort of 13 women, two desire further surgical intervention for prolapse repair and the remaining one does not require or wish anything further. Forty-six per cent of patients are incontinent and of these 11 women, one manages with containment devices, three do not wish any further intervention and seven seek further operative intervention in the form of colposuspension, autologous fascial sling or urethral bulking agents.

In regards to resolution of symptoms post-tape and mesh removal, eight of 12 patients who initially reported pain noted a significant improvement following surgery. Unfortunately four stated their pain was now worse than

Table 1. International Continence Society International Uro-Gynaecology Association classification of tape and mesh complications.

Stage	Definition	*N*
1A	Vaginal no epithelial separation, abnormal prosthesis	1
1B	Vaginal no epithelial separation, symptomatic	5
1C	Vaginal no epithelial separation, infection	1
3B	Vaginal larger than 1 cm exposure, symptomatic	4
3C	Vaginal larger than 1 cm exposure, infection	3
4B	Urinary tract, lower	9
6B	Skin or other musculoskeletal, symptomatic	2
T4	Over 12 months	25
S1	Vaginal suture line	5
S2	Vaginal away from suture line	8
S3	Trochar passage	1
S4	Other skin or other musculoskeletal site	3
S5	Intra-abdominal	8

before. Six of seven of patients with recurrent infections had complete resolution following surgery. We have not identified any postoperative fistulae in our follow-up to date.

Discussion

Our data demonstrate a small but significant cohort of women with complications following the insertion of synthetic products for incontinence and prolapse. We operated on an average of two patients per month during a one-year period, which is representative of our current practice with the majority for removal of TVTO.

It is of interest to note the identification of the one patient who requested removal of tape despite having no complaints or evidence of complications. It is unsure what the motivation was behind her desire for tape removal but it is likely to have been influenced by the public campaign within the Scottish media by the support groups.

The wide variety of symptoms that patients present with correlates to the significant amount of damage and disruption that can be caused by problems with insertion or failure of the products, and this was reflected in our results. It is clear to see that abnormal position of the tape, transection of the urethra, positions within the bladder and inadequate skin coverage within the vagina could all lead to the variety of complaints experienced by the patients.

The need for self-catheterisation in a small number of the patients may be due to obstruction of the tape causing impaired bladder emptying and leading to symptoms or infections. The reasons two patients could specifically not perform self-catheterisation became evident intraoperatively when they were found to have urethras completely transected by tape.

The most common location for complications was the identification of tape across the urethra but there were a significant number of women with vaginal erosion. This is unsurprising given the operative techniques for insertion of both mesh and tape. It is, however, concerning that four women had synthetic products in the bladder as it should be standard practice to perform cystoscopy during the initial procedure to ensure no breach of the bladder wall and allow repositioning of the trochar before completion of the operation.

The majority of patients successfully underwent removal of all components of their tapes by a vaginal approach. In a small number a combined approach via the abdomen was required in order to successfully remove foreign material located within the bladder, and all patients consented with this possibility in mind prior to surgery. Unfortunately one patient still awaits ongoing treatment for her complications; however, her instability under anaesthetic and other multiple medical comorbidities are currently deferring her surgical management and she is likely to not be fit for definitive surgery.

It is reassuring to note from our data that more than 50% of patients were found to be continent of urine postoperatively. Within this group of 13 patients, the two that desire further surgery have in fact developed a significant vaginal prolapse that they seek surgical management for and the other continue with no complaints or symptoms. For those who are incontinent, despite significant complications and difficulties with their initial procedures, 64% desire further surgery to help improve their symptoms. As patients become informed of the alternative surgical options for ongoing management of their incontinence such as colposuspension, autologous fascial sling and bulking agents, it is expected that this number may well increase. We performed one synchronous autologous fascial sling in a patient who specifically requested to have any potential incontinence managed at the same time as her removal of tape. However, our standard practice has been to allow tissues to heal and patients to establish the severity of any ongoing incontinence along with repeat urodynamic assessment before addressing further incontinence surgery.

Our results have also demonstrated the resolution of the most significant symptoms that patients were presenting with. Seventy-five per cent of women presenting with pain had resolution or significant improvement on follow-up questioning. Those who in fact had worsening of their

pain had it attributed to ongoing surgical scarring within the vagina and peri-urethral area. Similarly removal of the synthetic products resulted in 86% of women with recurrent urinary tract infections having complete resolution, and this is believed to be due to removal of exposed foreign bodies and improved bladder emptying. The lack of identification of the development of any postoperative fistulae to date can be credited to surgical techniques and the use of martius fat grafts when appropriate for urethral closure.

The main limitation of this study is at present the relatively short follow-up for patients having removal of synthetic products. However, these women are regularly seen back in clinic for ongoing assessment and management of their subsequent incontinence and symptoms.

Conclusion

In conclusion, we believe the removal of tape and mesh due to complications arising from insertion should be performed in a specialist centre with experience of assessment and management of these complex patients. It is essential that close and accurate follow-up is implemented to assess continence and resolution of the original symptoms postoperatively.

The question as to whether concurrent incontinence procedures are required is ongoing as our data demonstrate more than half of women to be dry after removal of tape and mesh products. However, it should be noted that for patients who continue to be incontinent, the majority do in fact desire further surgical intervention despite experiencing complications from initial procedures.

Conflicting interests

The Authors declare that there is no conflict of interest.

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Informed consent

None.

Ethical approval

None.

Guarantor

PG.

Contributorship

PG conceived the study. HB collected, reviewed and analysed patient information. HB researched the literature and wrote the background to the paper. HB prepared the first draft of the manuscript. PG edited and reviewed the manuscript and both authors approved the final version.

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Reference

1. The Scottish Independent Review of the use, safety and efficacy of transvaginal mesh implant in the treatment of stress urinary incontinence and pelvic organ prolapse in women: Interim report, www.gov.scot.uk/publication/2015/10/8485 (accessed September 2016).