

# Complications of Mid-Urethral Tape Insertion

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## Abstract

**Background:** Urinary stress incontinence is a health condition affecting millions of women globally with an incidence reaching 35%. The initial management is usually of conservative nature in the form of pelvic floor muscle training. If this fails then surgical management is offered. There are different methods of managing urinary stress incontinence like mid-urethral tape (MUT) insertion, colposuspension or the use of urethral bulking agents. In our unit, MUT insertion has been the conventional method of surgical management.

**Methods:** The data were obtained from retrospective auditing of our practice in our Trust that was conducted on three different phases over 4 years (2011 to 2015). The source of information was the database and clinical notes.

**Results:** A total of 221 patients underwent MUT insertion. Thirty-five procedures were performed by urologists and 185 by gynecologists. Twenty-three surgeries were performed by gynecologic trainees under senior supervision. All the MUT insertions performed by urologists were performed by consultants. Fifty patients (22.6%) experienced urinary retention, 18 had to use clean intermittent catheterization (CISC) (8%), and 41 patients (13%) developed symptoms of over-active bladder. There have been four bladder perforations (1.8%) all associated with tension-free vaginal tape (TVT) procedures and two cases of tape erosions (1%). Four patients (5%) complained of groin pain post-operatively; all of them had undergone tension-free obturator tape (TVT-O) procedure. There have been no buttonhole injuries, pelvic hematomata, or bleeding complications. In addition to that there have been no post-operative infections.

**Conclusions:** Our complication rates have been concomitant with those described in literature. A surgical database proves helpful not only in auditing surgical effectiveness but also in comparing the surgical managements between different surgeons and departments.

**Keywords:** Mid-urethral tapes; Urinary stress incontinence; Complications

## Introduction

Urinary stress incontinence (USI) is a very common gynecological health condition affecting 4-35% of women worldwide [1]. The initial management suggested by the National Institute for Health and Care Excellence (NICE) guidelines involves conservative measures, mainly in the form of pelvic floor muscle training (PFMT) [2, 3]. This approach can be successful in the majority of affected women [4]. However, when conservative measures fail then surgical approaches are necessary [2]. There are different methods of operative management of USI, mainly in the form of mid-urethral synthetic tape (MUT) insertion, colposuspension, the use of autologous slings or injecting urethral bulking agents [5].

In our unit the conventional method of surgical management being used in the recent years was the insertion of MUT, either of tension-free vaginal tape (TVT) and tension-free obturator tape (TVT-O).

Following the national guidance [3], surgeons performing surgical management of USI maintain audit data and submitted their results in the British Society of Urogynecologists (BSUG) registry. This data allow auditing of the urogynecologic practice and comparison of the outcomes between different departments.

In our department, we audited the surgical practice of surgical management for USI and compared our rate of complications to those cited in literature.

## Materials and Methods

The data were collected from a retrospective audit conducted in the hospitals of the United Lincolnshire Hospitals NHS Trust for MUT insertions from 2011 to 2015. The data were collected from the BSUG Audit database and/or clinical notes. The audit was conducted in three phases. The first phase (phase 1) was the initial audit and that was followed by two re-audits (phase 2 and 3). Phase 1 was the period when the audit was initiated and covered all the procedures performed between February and December 2011. Phase 2 was a stage of re-auditing of our practice and comparing it the previous audit results. So, phase 2 covered the period from January to December 2012. Phase 3 was a further re-auditing, from January 2013 to January 2015, where the surgical results were audited again and the results compared to the previous two audit results.

The complication rates of MUT insertion is known to vary considerably between different surgical units and surgeons [6]. As a result the rates of our complications were compared to

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**Table 1.** Numbers and Rates of Complications Over the 4-Year Period in Our Trust

Complication	Phase 1		Phase 2		Phase 3		All patients		Literature
	N = 41	Rate	N = 98	Rate	N = 82	Rate	N = 221	Rate	Rates
Urinary retention	14	34%	26	28%	10	12%	50	22.6%	2.3-19.7%
CISC	9	23%	6	6%	3	3%	18	8%	4.6%
Bladder perforation	0	0%	2	2%	2	2%	4	1.8%	2.7-13.8%
<i>De novo</i> OAB symptoms	9	23%	22	22%	10	12%	41	18.5%	0.2-15%
Vaginal tape erosion	0	0%	0	0%	2	2%	2	1%	0.3-23%
Groin pain	0	0%	0	0%	4	5%	4	5%	0.8-5%

The data are presented in different auditing phases and then collectively as "All patients". Literature rates were obtained from various international studies and meta-analyses [7-13].

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As the data were from retrospective audits no institutional review board approval was indicated and ethical compliance with human study was not indicated.

## Results

Over the 4-year period, 221 patients underwent MUT insertion. Thirty-five procedures were performed by urologists and 185 by gynecologists. Of these 185 procedures, 23 surgeries were performed by gynecologic trainees, under senior supervision. All the MUT insertions performed by urologists were performed by consultants.

Fifty patients (22.6%) experienced urinary retention and 18 had to use clean intermittent catheterization (CISC) (8%) (Table 1, [7-13]).

Symptoms of over-active bladder complicated 41 patients (13%), while there have been bladder perforations (1.8%) all associated with TVT procedures, and two cases of tape erosions (1%).

Four patients (5%) complained of groin pain post-operatively; all of them had undergone TVT-O procedure.

There have been no buttonhole injuries, pelvic hematomata, or bleeding complications. In addition to that there have been no post-operative infections.

## Discussion

The data show that our complication rates were similar, if not slightly better, to the rates described in literature. The cumulative results can lead, initially, to the erroneous conclusion that our complication rates are higher than those stated in literature (Table 1, "All patients"). This is mainly due to the rates of urinary retention and *de novo* overactive bladder (OAB), as their collective rates are higher than those cited in literature.

However, after examining the rates of these complications, over the different phases of the auditing, there is an evident reduction in the number of these complications. In more details, the rates of urinary retention in phases 1 and 2 were 34% and 28% respectively, but the following year they dropped to 12%. The same applies to the rates of *de novo* OAB symptoms

which gradually kept going down from 23% in phase 1 to 12% in phase 3.

Even the complications that appeared in the later phases of the audit (phases 2 and 3, Table 1), like bladder perforation, tape erosion and groin pain, their rates were still similar to those rates mentioned in the literature. Most complications were commoner with junior trainees rather than with experienced surgeons.

It is important to take into account that the available indices for complication rates in literature come from individual departmental assessments. As a result, there is big diversity and lack of consistency in the frequency of any complication. For example, for the TVT procedures the cited complication rates, in general, have an extensive range between 4.3-75%, while for TVT-O is 10.5-31.3% [14]. Not surprisingly, with certain complications that cover very large ranges (e.g. vaginal erosion: 0.3% to 23%), this can make our assessment and monitoring of surgical success quite challenging.

There is no doubt that learning curves play a pivotal role in the success of surgical procedures and avoidance of complications [15]. This became evident in our findings moving from phase 1 to phase 3.

MUT procedures were thought, initially, to be "easy" and "straightforward", and their complications easily managed, but time proved this contemplation to be mistaken [16, 17]. It is conventionally accepted that to reach a surgical dexterity of low complications every surgeon needs to perform 20 to 80 procedures [18]. Understandably, the risk of surgical complications always remains present, like with any surgical procedure, but with trainee surgeons might be even higher.

Consequently, patients need proper counselling preoperatively, something that counts on doctor-patient communication. Reassurance and the sense of support are derived from good communication [19]. In the case of MUT surgeries, the communication should cover adequate explanation, provision of information leaflets and addressing all the concerns by the patients [7].

On a parallel aspect, it has been suggested before that the most consistent method of measuring the management efficacy and complication rates of a surgical procedure is by keeping a surgical database [20].

The BSUG database since its launch has offered the opportunity to surgeons to input their surgical procedures and

any relevant complications. Accordingly, it has proven to be an invaluable tool for auditing and monitoring urogynecologic practice [21]. On a larger scale, the IUGA database is an international example where surgeons can audit their own procedures, revise their practice, and compare it to other departments all over the world.

Even though the sling procedures are the widely examined surgical management of USI, there are still reservations on their long-term outcomes, with global suggestions of the necessity of longstanding data [22]. Moreover, the recent media-generated polemics against the use of synthetic meshes have raised a lot of questions about the efficacy and safety of the procedures [23]. Nevertheless, none of the available surgical procedures can offer an absolute treatment and none is risk-free [3]. Furthermore, there are advocates that believe MUT procedures have been the “victim” of the vaginal mesh fiasco [24]. Such a point is worth of consideration, especially as there is evidence that MUT excels to Burch colposuspension [25].

Nevertheless, taking into consideration the different complications, success rates and invasiveness of the alternative surgical procedures [26-28], it proves the point regarding the need for proper preoperative counselling and the necessity of a detailed database.

## Conclusions

Our complication rates with MUT insertion, in a district general hospital, have been improving with time. Some complications rates were higher at the early stages but they improved with time. A surgical database proves helpful not only in monitoring surgical efficacy but also in comparing the surgical managements between different departments nationally and globally.

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## Financial Disclosure

Not applicable.

## Conflict of Interest

None to declare.

## Informed Consent

Not applicable.

## Author Contributions

PB and MS collected the data. PB wrote the primary manu-

script and MS has revised it.

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