Received: 17 September 2018 | Revised: 1 March 2019 | Accepted: 23 April 2019

DOI: 10.1002/nau.24030

REVIEW ARTICLE

Neurourology Urodynamics ICS SUFU WILEY

Midurethral slings for treatment of stress urinary incontinence review

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Abstract

Purpose: The midurethral sling (MUS) has largely been regarded as the "gold standard" in treatment of stress urinary incontinence (SUI). Recently the safety and use of the MUS has come under scrutiny following concerns about the use of mesh implants. The aim of this review was to detail the background to SUI which has led to the development of MUS, to highlight the issues surrounding the use of mesh under the current climate of mesh controversies and to provide an update on current evidence on the use of MUS.

Materials and methods: We conducted a review of the literature looking at the efficacy and safety of MUS.

Results: MUS has good rates of subjective cure in the short and into the longer term. The overall rates of complications are low including those associated with the use of mesh implants. When compared to other continence procedures, MUS is equally effective in regard to cure but has lower rates of complications and more favorable operative outcomes. The use of mesh has been supported by major Urogynaecological Societies along with the reports from government driven enquiries into the use of mesh.

Conclusions: Overall, MUS have been shown to be an effective and safe surgical treatment for management of stress urinary incontinence.

KEYWORDS

mesh, midurethral slings, stress urinary incontinence, surgical complications, surgical treatment

1 | INTRODUCTION

The midurethral sling (MUS) has largely been regarded as the "gold standard" in treatment of stress urinary incontinence (SUI). This procedure was introduced in the late 20th century following on from the use of Burch colposuspension after attempts were made to develop a less invasive approach to treatment of SUI.[1]

Urinary incontinence is a prevalent and debilitating problem affecting approximately 50% of women during their lifetime. SUI is thought to affect 50% of those women with incontinence making it the most prevalent cause of urinary leakage.[2] It is associated with significant physical and psychological morbidity, sexual dysfunction, and loss of independence with consequent decreased participation in social and domestic activities. SUI is defined by the International Continence Society as the "complaint of involuntary leakage of urine on effort or exertion, or sneezing or coughing."[3] Urodynamic stress incontinence (USI) is the "involuntary leakage of urine observed during filling cystometry. It is associated with increased intra-abdominal pressure, in the absence of a detrusor contraction."[4] Given the high prevalence of the condition, it has significant cost implications to both the individuals affected

and the healthcare service. The estimated annual cost to the healthcare system in the UK exceeds GBP 700 million and in the USA, it is over USD 20 billion.[5-7]

The aim of this review was to detail the background to SUI which has led to the development of MUS, to highlight the issues surrounding the use of mesh under the current climate of mesh controversies and to provide an update on current evidence on the use of MUS.

2 | PATHOPHYSIOLOGY OF STRESS URINARY INCONTINENCE

Continence is maintained when the closing pressure of the urethra is higher than the pressure within the bladder.[8] SUI occurs when urethral pressure is reduced by lack of muscular support, leading to higher abdominal pressure, and resultant urinary leakage.

Two mechanisms for development of stress urinary incontinence have been recognized. First, urethral hypermobility or significant displacement of the urethra and bladder neck during exertion, and second, intrinsic urethral sphincter deficiency.[9] Historically, SUI was classified by Green[10] into two types: type I is caused by the loss of the posterior urethrovesical angle, and type II is the loss of the posterior urethrovesical angle in association with urethral hypermobility. The term hypermobility refers to the downward displacement of the urethra with a maximal straining angle of 30° or more from baseline.[11] A subsequent modification to the classification of SUI was made by McGuire et al[12,13] and emphasizes the principle of intrinsic sphincter deficiency (ISD) as a cause of SUI. This then became known as type III. ISD involves leakage of urine in association with very low urethral closure pressures and can occur in both the presence or absence of urethral hypermobility. Standardization of a definition of ISD has been difficult but is widely accepted to be maximal urethral closure pressure (MUCP) less than 20 cmH_2O or Valsalva leak-point pressure (VLPP) of less than 60 cmH_2O. However, the European Association of Urology (EAU) guidance is such that the value of the MUCP or the VLPP should not be used to determine the severity of SUI. This diagnosis often makes treatment more difficult and is associated with much lower rates of surgical success.[12,14]

3 | DEVELOPMENT OF MUS

The tension-free vaginal tape (TVT) is a minimally invasive procedure which was first described by Ulmsten[1] in 1995. It was introduced as a minimally invasive, ambulatory standardised surgical procedure and has largely replaced the open Burch Colposuspension owing to its minimally invasive approach and good safety profile.[1]

Since its introduction multiple other commercially available types of MUS have been introduced including the mini-sling or single-incision sling. In general, these sling types share the common characteristics of using a monofilament type 1 polypropylene synthetic mesh, which is inserted at the level of the mid-urethra and is applied without tension. However various new devices that have undergone technical modifications, predominantly alterations to the technique and route used for sling insertion, have also been trialed.[15]

There are two main surgical approaches to insertion of the MUS. The retropubic approach to tape insertion involves the vertical passage of two needles, one either side of the urethra, through the retropubic space blindly from the vagina to the abdomen or from the abdomen to the vagina, so called "bottom to top" or "top to bottom" technique.[1] In the transobturator approach the tape is inserted in a horizontal plane at the level of the mid-urethra between the two obturator foramina. The ends of the tape are tunneled percutaneously with a curved needle either side. Neither approach requires suture fixation.[16] Shortly after the development of this technique a similar operation was described in which a tape is passed percutaneously through the obturator foramina, using an inside-to-outside technique, that is, mediolateral.[17]

4 | OUTCOME OF MUS AND COMPARATIVE STUDIES

Given the duration of use, this procedure has more than 17 years of evidence-based studies reporting on global outcomes of usage. Randomized controlled trial evidence is limited in the longer term as most studies detail short-term follow-up of patients up to 12 months. There are however evermore studies reporting on the long-term efficacy and effects of the TVT procedure beyond 5 years.

A 2015 Cochrane review has detailed many of the outcomes occurring following MUS surgery. With evidence from 55 randomized controlled trials, subjective cure was reported at 62% to 98% in those undergoing transobturator approach, and from 71% to 97% in those undergoing a retropubic approach. In the long term (beyond 5 years of follow-up), subjective cure rates ranged from 43% to 92% with a transobturator approach, and from 51% to 88% with a retropubic approach. There was found to be no statistically significant difference in the cure rates of either approach. Beyond 5 years, four trials (714 women) reported subjective cure rates ranging from 43% to 92% in the transobturator group and from 51% to 88% in

the retropubic group. The average long-term subjective cure rate across both groups was reported as 84.3% and the difference between the groups was found to be not statistically significant (risk ratio or relative risk [RR], 0.95; 95% confdence interval [CI], 0.80-1.12).[18]

In terms of complications following surgery the rate of bladder perforation was significantly lower following a transobturator approach with rates of 0.6% vs 4.5% if a retropubic approach was adopted. Vaginal tape erosion was assessed in 31 trials with 4743 participants and found the average rate of vaginal tape erosion across both groups to be 2.09%, with no significant difference demonstrated whether a retropubic or transobturator approach was adopted (RR, 1.13; 95% CI, 0.78-1.65). Groin pain was reported to be significantly higher in women who underwent a transobturator procedure than in women who underwent a retropubic procedure (RR 4.12; 95% CI, 2.71-6.27). The average rate of groin pain across both groups was 4.51% and, using this as the assumed control rate in the retropubic group, there were 163 more cases per 1000 in the transobturator group (95% CI from 94 to 266 per 1000 more). The review concluded that groin pain was found to be short-lasting, with most cases resolving within the first 6 months following surgery. The reported duration of pain ranged from 2 to 52 weeks, with a median duration of 8 weeks. Postoperative voiding dysfunction rates were found to be 5.53% and in the short term the average rate of de novo urgency/urgency urinary incontinence was 8.35%. Sexual function was assessed using validated questionnaires in 10 trials. In each of these trials there was a significant improvement from baseline scores that spanned a follow period between 6 and 24 months with no difference between a transobturator or retropubic approach. At 24 months, the rate of dyspareunia was low in each group with no significant difference noted between either group.[18]

More recently Constantini et al[19] published the long-term results of their randomized controlled trial of 87 women undergoing retropubic or transobturator approach. Subjective and objective cure rates were 59.6% and 70.2% in the transobturator group and 75% and 87.5% in the TVT group over a median follow-up period of 100 months. They concluded that both groups were highly satisfied at long-term follow-up. This is highlighted as one of only a few trials that have reported on longer-term outcomes beyond 5 years.

Nilsson et al[20] reported results of their study following 90 women after TVT procedures over a 17-year duration. Objective cure, defined as a negative stress test, was reported at 91.3% and subjective cure, assessed using PGII questionnaires, found 87.2% of women felt they were significantly better than before surgery. Only one woman had undergone a repeat continence procedure and one experienced mesh exposure during this time period. The authors concluded the procedure to be "a durable procedure with efficacy lasting beyond 17 years."[20]

Reporting 10-year outcomes of transobturator tapes in 160 women, Serati et al[21] found that 97% of women declared themselves as subjectively "cured" and 92% were found to be objectively cured demonstrating no significant decrease in objective cure rates over the 10-year follow-up. Fourteen percent of women reported de novo overactive bladder symptoms but no other adverse events were reported. The authors concluded that the TVT-O procedure was highly effective and a safe treatment for SUI.[22]

5 | MUS COMPARED TO OTHER CONTINENCE PROCEDURES

5.1 | MUS compared to open Burch colposuspension

Having previously been the treatment of choice for SUI, open Burch colposuspension was then overtaken by the introduction of the TVT. However, with the current issues surrounding the use of mesh devices it is possible surgeons may revert back to older techniques with a consequent increase in the number of Burch colposuspension procedures performed, both open and laparoscopic.

The results of a recent Cochrane systematic review and meta-analysis have shown with evidence from 5 randomized controlled trials that there was no significant difference in cure rates in the short (RR, 088; 95% CI, 0.67-1.16) and medium term (up to 5 years). Data were not available for long-term follow-up beyond 5 years. There was little difference in the rates of adverse events overall, although bladder perforation was found to occur more frequently during TVT and voiding dysfunction was reported to be 40% lower in those undergoing colposuspension although the results appeared to be influenced by one large trial. De novo or recurrent prolapse was reported to be eight times higher in patients undergoing colposuspension as opposed to sling procedures. Surgical outcome measures favored the TVT above the open colposuspension.[22]

5.2 | MUS compared to laparoscopic Burch colposuspension

Following the introduction of the minimally invasive MUS, a move towards a more minimally invasive approach to colposuspension was made. The aim being to avoid major abdominal incisions, enable shorter hospital stays, and faster resumption of normal activities in keeping with the benefits of the MUS. A 2017 Cochrane review[23] compared MUS with laparoscopic Burch colposuspension. Twenty-two trials were identified

using either TVT or SPARC procedures and concluded that at 18 months follow-up, there was no significant difference between cure rates of laparoscopic Burch colposuspension and slings procedures (RR, 0.91; 95% CI, 0.8-1.02). This remained the case in the longer term of up to 8 years where Paraiso et al[24] reported TVT and laparoscopic Burch colposuspension continued to have similar rates of cure (RR, 1.18; 95% CI, 0.36-3.81). One trial reported reoperation rates at 1 year, with three out of 38 women in the TVT group and one out of 32 woman in the laparoscopic colposuspension group undergoing repeat surgery for "noncure." They reported no difference in the perioperative complication rates between laparoscopic colposuspension and vaginal sling procedures (RR, 0.99; 95% CI, 0.60-1.64) but surgical outcome measures, specifically length of hospital stay and return to normal activities, favored the MUS group.[25]

5.3 | MUS compared to autologous fascial slings

As one of the first procedures described to treat SUI, the modern autologous fascial sling was introduced in the 1940s and adapted into the 20th century.[26] Still recommended as a treatment for SUI today, a recently updated Cochrane[26] review details the efficacy of this procedure compared to the MUS. Twelve trials addressed the comparison and found them to be equally effective in the short term (up to 1 year) (RR, 0.97; 95% CI, 0.78-1.20) but MUS was found to have the advantage of a shorter operating time, fewer perioperative complications (excluding bladder perforation) and some evidence suggesting less postoperative voiding dysfunction and de novo detrusor overactivity.

5.4 | MUS compared to periurethral injections

A recent Cochrane review found no randomized controlled trials comparing MUS with periurethral injections.[27] A current ongoing randomized controlled trial is near completion[28] and there are several other ongoing studies assessing the use of injectables in the treatment of SUI.[29-33] A further literature search identified no published studies directly comparing the outcome measures for these two procedures.

6 | THE MESH CONTROVERSY

After the Food and Drug Administration (FDA) issued a warning about the use of transvaginal meshes for pelvic organ prolapse (POP) in 2011, there has been much debate about the use of mesh in the MUS continence procedures. Concern is increasing that the use of transvaginal mesh devices to treat SUI and POP have exposed women to avoidable harms following complications such as infection, tissue extrusion, mesh exposure, mesh shrinkage, and side effects such as severe pain, sexual dysfunction, and repeat surgical interventions.[34]

Vocal patient groups and numerous medical negligence lawsuits following severe complications with this procedure have meant that many MUS devices have been withdrawn from the market and some countries have precluded the use of MUS devices altogether. Consequently the number of MUS procedures performed in the recent past have declined with one recent US-based study seeing a decrease in the number of synthetic mesh sling procedures performed for SUI over the past 7 years. They concluded this was the likely effect of the FDA public health notifications regarding implantable mesh on surgical practice for SUI.[35]

As a result of patients calling upon clinicians to defend the use of MUS, along with political pressures and statement opinions from relevant medical societies, this has led to a large-scale inquiry on the use of implantable mesh for both POP and SUI treatment.

The results of the inquiry have been drawn from several organizations conducting reviews of current evidence base literature. The Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR)[36] has advised that mesh implanted for continence be viewed differently to mess implanted for POP as a result of far fewer mesh-related complications. They have recommended "synthetic sling SUI surgery is an accepted procedure with proven efficacy and safety in the majority of patients with moderate to severe SUI when used by an experienced and appropriately trained surgeon."[36]

A Scottish report believes "women should be offered all appropriate treatments (mesh and nonmesh) as well as the information to make informed choices." It also states, "when surgery involving polypropylene or other synthetic mesh tape is contemplated, a retropubic approach is recommended."[37]

Most, if not all, major international societies devoted to treating SUI (including International Urogynecology Association, the American Urogynecologic Society, the American Urologic Association, the Society for Urodynamics and Female Pelvic Medicine and Urogenital Reconstruction,[38] the Royal Australian and New Zealand College of Obstetricians and Gynecologists, the EAU, the American Congress of Obstetrics and Gynecology) have all issued statements supporting the use of MUS as the preferred first-line surgical treatment for SUI. This conclusion was made after summarizing the evidence from many prospective trials that have demonstrated

MUS devices to have equal or improved efficacy over other surgical procedures used to treat SUI and that mesh-specific complication rates as a result of SUI surgery remain low.[38]

A recent study by Chapple et al[39] has concluded that it is essential to evaluate the various treatment options available including colposuspension, bulking agents, and autologous slings alongside the MUS device. It suggests that MUS polypropylene slings have good efficacy and acceptable morbidity and should remain a viable treatment option available to women with SUI. Taking into consideration the recommendations of this review and statements released by the aforementioned societies, the consensus opinion appears to be to support the continued use of MUS devices. When comparing MUS with autologous facial slings and colposuspension procedures there is evidence enough to support their effective and safe use, and indeed in many aspects of patient recovery and post procedure complications rates, the MUS seems to offer a safer approach to SUI treatment than the alternative options. By retracting the use of the MUS altogether, it would appear we are denying women of what is generally regarded a safe and efficacious procedure that has clearly been shown to benefit the majority of women who undergo the procedure. It is clear that there is potential to cause harm with patients experiencing chronic pelvic pain, groin pain, and tape erosion, and that the long-term outcomes of these procedures are yet to be proven. We therefore believe that there is a need for MUS to be carried out by surgeons with the experience to help limit this risk as much as possible.

7 | CONCLUSION

MUS have been shown to be an effective and safe surgical treatment for stress urinary incontinence. The efficacy has been shown to decline over time but it still remains efficacious over long-term follow-up. Controversies over the use of implantable mesh for the treatment of pelvic organ prolapse and stress urinary incontinence has impacted on the use of MUS in recent years with a decline in the number of MUS procedures being performed. Clinicians have to exercise caution when using implantable mesh to treat SUI and perhaps consideration of an informed consent checklist as published by Digesu et al[38] could help ensure appropriate patient selection and counseling. To aid the long-term surveillance of implanted mesh for treatment of SUI patient registries have been proposed as a tool for monitoring adverse events.[35]

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How to cite this article: Ford AA, Taylor V, Ogah J, Viet-Rubin N, Khullar V, Digesu GA. Midurethral slings for treatment of stress urinary incontinence review. *Neurourology and Urodynamics*. 2019;1-6. https://doi.org/10.1002/nau.24030