

Female stress urinary incontinence surgery: ‘Resurgence of the Titans’

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ABSTRACT

Objective: To evaluate the trends in female stress urinary incontinence (SUI) surgery in a UK tertiary referral center during five years before the July 2018 tape suspension and to compare it with National Health Service (NHS) England data.

Materials and methods: A retrospective study of female SUI procedures (bulking agents, mid-urethral sling [MUS], colposuspension, autologous fascial sling) in a single UK tertiary referral center between 2013 and 2018. The treatment choice was made through shared decision-making on the basis of national standardized information leaflets, patient’s own research, and discussion/clarification with the surgeon. Data on NHS England SUI surgery between 2012 and 2018 were extracted from a retrospective review of the hospital episode statistics.

Results: Between 2013 and 2018, 448 procedures for SUI were performed at our center. In contrast to a significant 31% decline in the total number of SUI procedures in NHS England in that time period, no decline in the number of SUI procedures occurred in our center. However, the distribution of SUI procedures did change significantly. MUS procedures declined significantly (46% total and 45% relative), whereas bulking agents and colposuspensions showed a clear relative rise (+11% and +30%). The distribution of SUI procedures in NHS England also changed significantly with a decline in MUS procedures (39% total and 11% relative) and an increase in bulking agents (82% total and 9% relative).

Conclusion: When all invasive treatment options are transparently presented to female patients with SUI, they prefer other surgical treatments as an alternative to MUS.

Keywords: Female, suburethral slings, mid-urethral sling, urinary incontinence stress/surgery, urethra/surgery

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Introduction

Approximately 10% of adult women report weekly occurrence of urinary incontinence (UI), and 25%–45% report occasional UI.^[1] Isolated stress UI (SUI) is the most common type of UI with a prevalence between 10% and 39%.^[1] First-line treatment of female SUI consists of lifestyle interventions, continence pessaries, and pelvic floor muscle therapy (PFMT). When conservative management fails, surgical management can be offered. Surgery for female SUI has evolved significantly, from autologous fascial slings (AFS) and Burch colposuspensions to the introduction of less invasive synthetic mid-urethral slings (MUS) in the 1990s, which quickly replaced colposuspension as the

gold standard and led to a substantial increase in SUI surgical procedures by 2010.^[2-4]

Mesh^[5] also became a popular surgical treatment for pelvic organ prolapse (POP), using the same synthetic material as tapes^[5] used in SUI surgery. The 2011 Food and Drug Administration safety communication and the up-classification from Class II to Class III in 2016 only applied to mesh in POP surgery. Media reports,^[6] advertisements, and litigation^[7] following the FDA communication, rarely distinguished between mesh for POP and mesh for synthetic slings for female SUI. Furthermore, only 12% of women understand the difference between the use of synthetic material for POP and for SUI.^[6] This led to an increase in report-

ed tape complication rate,^[8] a strong increase in litigation cases between 2012 and 2014^[7] and eventually to a decline in the use of MUS in the UK,^[4] Australia,^[3] and in the USA,^[9] despite a report by the European Scientific Committee on Emerging and Newly Identified Health Risks (SCENHIR), in which the use of tape for female SUI by appropriately trained surgeons and in counseled patients is supported.^[10]

Consensus statements of six international urology and urogynecology societies reviewed the evidence on the safety and outcomes of tape in SUI surgery and concluded to further support its use.^[11, 12] The UK Mesh Oversight Group (established by the National Health Service [NHS] England in 2014), consisting of healthcare professionals, patients, industry, legislation, and regulatory agencies, concluded that tapes are safe and effective to treat women with SUI.^[13] The UK National Institute for Health and Care Excellence (NICE), the British Association of Urological Surgeons (BAUS), the British Society of Urogynecology (BSUG), and the Royal College of Obstetricians and Gynecologists (RCOG) recommended to continue offering patients retropubic MUS alongside colposuspension, AFS, and intramural bulking agents. In contrast, an independent UK medicines and medical devices safety review (initiated in February 2018) recommended an immediate temporary suspension on the use of mesh tape for SUI in July 2018 owing to increasing reports of complications by patients, and conditions for reinstatement were formulated. NHS England followed the recommendation and suspended mesh operations as the conditions for reinstatement have not yet been met till date.^[14] The Cumberlege review published in July 2020 (<https://www.immdsreview.org.uk/Report.html>) has laid the framework and recommendations needed for any reinstatement of mesh usage for SUI surgery in women in the UK.

In this study, we evaluated the trends in SUI surgery during the five years prior to the UK mesh tape suspension, in a single tertiary referral center. These trends were compared with the NHS England data of the same time period.^[4]

Main Points:

- Overall, there is a worldwide decline in female stress urinary incontinence (SUI) surgery.
- Women should be offered all surgical treatment options after failure of conservative and medical therapy for SUI.
- Surgical options for female SUI should not be limited to mid-urethral slings and should include colposuspension, autologous fascial slings, and urethral bulking agents.
- Shared decision making is crucial in SUI surgery.
- Functional urologists need to be trained and be able to offer all surgical options for female SUI surgery as well as manage complications of such operations.

Material and methods

We conducted a retrospective study of female SUI procedures performed in a single UK tertiary referral center between 2013 and 2018. The case volume in adult women (> 18 years of age) of bulking agents, MUS (retropubic/transobturator), colposuspension (open/laparoscopic), and AFS was evaluated.

As a standard of practice in our center, all women with persistent bothersome SUI and failure of conservative and medical therapy are offered urodynamic evaluation (including urethral pressure profilometry), to confirm the diagnosis as urodynamic stress incontinence (USI) and to evaluate for concomitant filling and voiding or post-voiding bladder dysfunctions. All the patients are subsequently discussed at a weekly multidisciplinary team meeting (urologists, urogynecologists, urodynamic practitioners, and pelvic floor physiotherapists). In accordance with the NICE, BAUS, and BSUG guidelines, women are offered surgical therapy and sent BAUS and/or BSUG leaflets on all possible SUI surgical interventions for their review and are clearly informed that no further surgical treatment is also an option. The leaflets have been available throughout the study period, are publicly available (https://www.baus.org.uk/patients/information_leaflets/ and <https://bsug.org.uk/pages/information-for-patients/111>), designed for lay persons to understand, and are frequently updated and overhauled. The patient is then invited to the clinic to further discuss all options and the implications of the diagnostic findings and their patient characteristics on each. Therefore, the type of treatment is chosen through shared decision making on the basis of standardized information leaflets, the patient's own research, diagnostic findings, and their discussion with the surgeon.

The interventions are performed by one urologist and one urogynecologist. Laparoscopic colposuspension was recently introduced in our center in 2017 and is only done by the urogynecologist. AFS on the other hand is only performed by the urologist. The bulking agents used are Deflux® (Red Leaf Medical.) and Bulkamid ® (Contura International A/S). The MUS used are Gynecare TVT™ (Ethicon), RetroArc Retropubic Sling System™ (AMS), Monarc™ sling (AMS), Advantage™ (Boston Scientific), and Advantage Fit™ (Boston Scientific).

For comparison, the trends in inpatient female SUI surgery in England were reviewed on the public domain NHS Digital (<https://digital.nhs.uk/>). A retrospective review of surgery for POP and SUI covering hospital episode statistics (HES) and experimental statistics is publicly available,^[15] and a broad analysis of the 2000–2017 data has been published.^[4] Data tables were used to extract the count of women with a procedure for SUI from April 2012 until March 2017. The following Office of Population Censuses and Surveys (OPCS) 4 procedure codes were

evaluated: M52.1 suprapubic sling operation, M52.3 colposuspension of the neck of bladder, M52.3 + Y75.2 colposuspension of neck of bladder, and laparoscopic approach to abdominal cavity NEC, M53.3 introduction of tension-free vaginal tape, M53.6 introduction of transobturator tape, and M56.3 endoscopic injection of inert substance into outlet of female bladder.

This study was exempt from institutional review board because of its retrospective nature and use of anonymous as well as publicly available data.

Statistical analysis

Statistical analysis was performed using Statistical Package for the Social Sciences 25 (IBM SPSS Corp.; Armonk, NY, USA) and XLSTAT (Addinsoft SARL). Trends in surgery were analyzed with the Mann-Kendall test (XLSTAT). Data distributions were analyzed using Pearson's chi-squared tests with post-hoc Bonferroni analysis. Statistical significance was set at $P < .05$.

Results

Between January 2013 and December 2017, 448 procedures for SUI were performed at our center (Figure 1). No significant trend was found in the total number of SUI procedures performed ($P = .82$). AFS ($P = .21$) and bulking agents ($P = .23$) showed no significant change in trend over the years. There was a decline of 46% in total MUS procedures, which did not reach significance ($P = .08$). However, there was a significant 97% increase in colposuspensions ($P = .02$).

The distribution of SUI procedures performed at our center (Figure 2) changed significantly between 2013 and 2018 ($P < .01$). Post-hoc analysis revealed a significant relative 45% decline in MUS procedures ($P < .01$). There was a clear, but not significant, relative rise in bulking agents (+11%) and colposuspensions (+30%). The overall distributions of 2013 and 2017 did change significantly ($P < .01$), attributable to the decline in MUS procedures ($P < .01$) and rise in colposuspensions ($P < .01$).

Between April 2012 and March 2017, 55,341 procedures for SUI were performed in England (Figure 3). There was a significant 31% decline ($P = .02$) in the total number of SUI procedures. No trend in AFS ($P = .82$), open and/or laparoscopic colposuspension ($P = .23$), and bulking agent procedures ($P = .48$) was noted, but MUS procedures declined significantly by 39% ($P = .02$).

The significant change in distribution of the different SUI procedures as performed in England between April 2012 and March 2017 is represented in Figure 2 ($P < .01$). Post-hoc analysis revealed a significant relative rise of 9% in bulking agents ($P < .01$) and a significant relative decline of 11% in MUS procedures ($P < .01$).

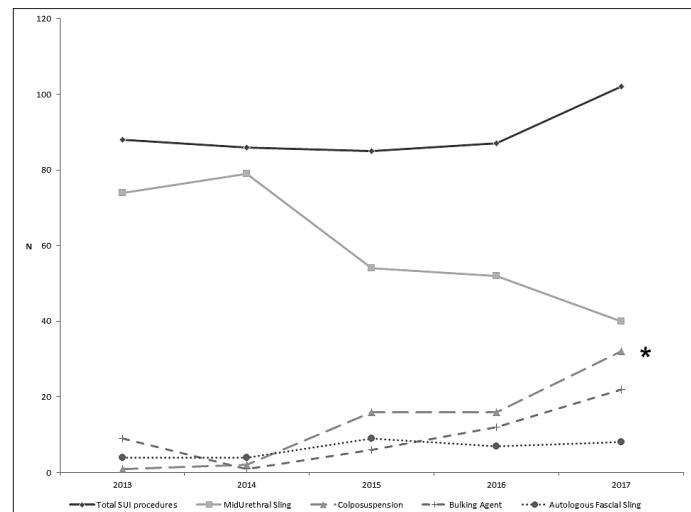


Figure 1. Trends in the procedures for stress urinary incontinence in our tertiary referral center from 2013 to 2018.

*represents a significant trend over the years (Mann-Kendall test, $P < .05$)

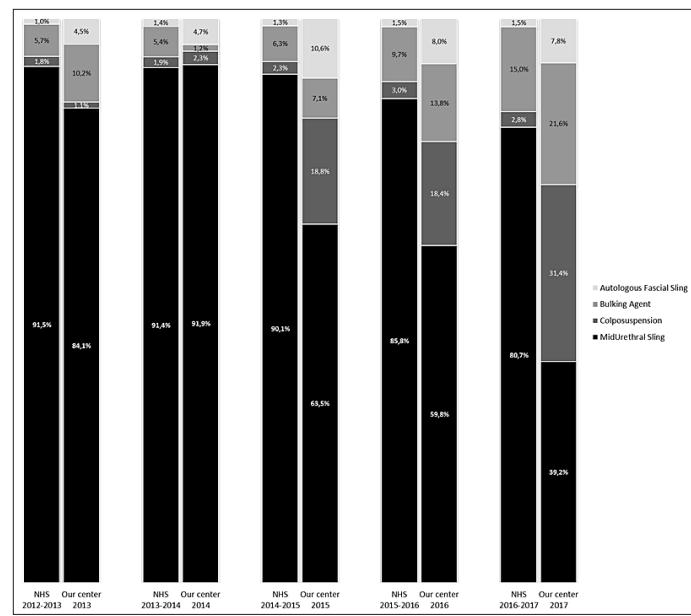


Figure 2. Evolution of the distribution of the procedures for stress urinary incontinence NHS England and in our tertiary referral center between 2012 and 2017.

Discussion

This is, till date, the first report on trends in female SUI surgery from a single UK tertiary referral center during the five years preceding the tape suspension in July 2018.^[14]

A significant 31% decline in SUI procedures was noted in England between April 2012 and March 2017, which is similar to the declines reported by other countries: 39% in academic centers in

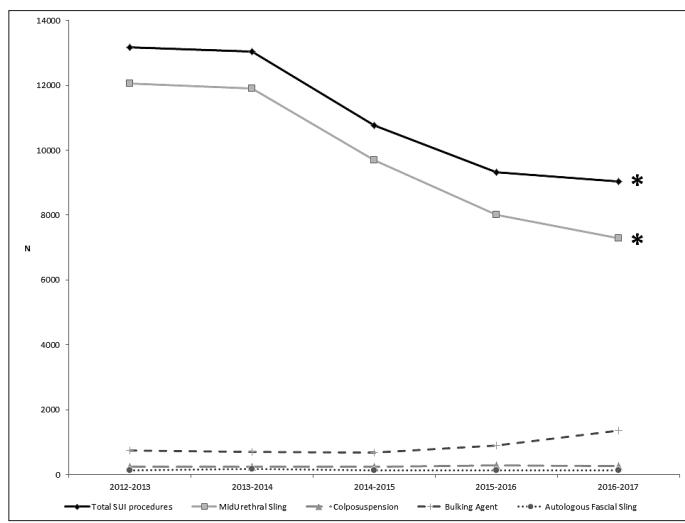


Figure 3. Trends in the procedures for stress urinary incontinence in England (NHS) between April 2012 and March 2017. *represents a significant trend over the years (Mann-Kendall test, $P < .05$)

the USA,^[9] 56% in Ontario, Canada,^[16] and 20% in Australia.^[3] The decline in overall SUI procedures suggests that many women either continue first-line therapy (PFMT)^[3] or do not pursue further SUI treatment owing to fear of life-long complications. PFMT, however, has lower objective and subjective cure rates than MUS (65% vs 91%, respectively) and requires maintenance to sustain continence if achieved.^[17] In contrast to national and international trends in SUI surgery, we found no decline in SUI procedures at our center between 2013 and 2018.

The overall decline in SUI procedures in England and other countries can be attributed to the significant decline in MUS procedures: 39% in England in the past five years, which is comparable to reports from the USA,^[18] Canada,^[16] and Australia.^[3] The 46% decline in MUS procedures at our center is similar to national and international trends, which are likely caused by the increased reporting of mesh complications by the patients and by recent media reports^[6] and litigation^[7] related to complications.^[8] The reported peri-procedural and 30-day complication rates of first-time MUS-surgery was recently reported to be 2.4% and 1.7%, respectively. Within five years, 5.9% of patients were readmitted for further interventions, symptoms, or complications, leading to an overall complication rate of 9.8% within five years.^[19]

As the total number of SUI procedures remained stable at our center, we looked at the procedure distribution to evaluate which ones replaced MUS. There was only a slight relative increase in AFS (+3%) and bulking agents (+11%), but a large (30%) increase in colposuspensions (17% were after introducing the laparoscopic approach in 2017). In contrast, no significant upward trend in other SUI procedures occurred in England, leading

to an overall decline in SUI procedures. This difference could be attributed to the fact that all options (including non-mesh options) were offered in our center, and the decision on type of surgery was made through shared decision making.

Women still considering surgical treatment most likely prefer minimally invasive and safe alternatives to MUS surgery. Minimally invasive procedures offer a faster postoperative recovery and esthetically less apparent and bothersome scars, although scars from modified AFS is about 5 cm and from an open colposuspension is about 7 cm. This could explain the 82% increase in choice for bulking agents in England between 2012 and 2017. However, the effectiveness of bulking agents remains unclear, especially in the long term, and the patients have to be informed on the possible need for repeated injections to achieve urinary continence^[20] with a limitation on the number of times (two or three) the injections can be repeated.

Apart from the preference for minimally invasive procedures by women with SUI, several other reasons may exist why the number of invasive procedures for SUI (open colposuspension and AFS) has not changed between 2012 and 2017 in England.^[15] First, the fast rise in popularity of MUS after its introduction indirectly caused a decline in exposure to these procedures by urologists and urogynecologists in training and to a decline in expertise of the older generation of surgeons. Reintroduction of these techniques would require several months to years to allow for adequate (re-)training, to be able to reliably offer them as a safe alternative to MUS. However, the experience in open colposuspension and AFS was sustained in our center, explaining the increase in invasive procedures between 2013 and 2017.

A second reason may be that MUS procedures have a lower risk of immediate complications and a similar risk of further incontinence surgery and later complications, compared with open colposuspension.^[21] Therefore, women with a fear of MUS complications may not choose an alternative procedure with a different complication risk. Furthermore, MUS surgery was shown in a meta-analysis to have significantly higher objective continence rates in female SUI than colposuspension (80% vs 68%), although high-quality long-term data (> five years) are lacking.^[22] Comparison of MUS with AFS showed similar effectiveness and prevalence of complications.^[22] A report from US academic institutions on trends in SUI surgery following the FDA notifications showed an increase in AFS compensating for the decline in MUS surgery.^[18] Long-term pain, dyspareunia, and erosion are debilitating complications of MUS and have probably contributed to the strong decline in its popularity, but post-AFS scar pain has also been reported.^[23]

The outcomes and complication rates of laparoscopic colposuspension are comparable to the open approach at two years post-

surgery;^[24] and hence, it has a lower cure rate than MUS surgery for SUI in women.^[22,24] However, laparoscopic colposuspension has a trend to lower peri-operative complications and a faster recovery time compared with the open procedure.^[24] It could therefore present as an alternative to the controversial MUS, which may explain the rapid rise in popularity after its introduction in our center. Operation time, however, is longer; and the learning curve steeper.^[24] Colposuspension also uses synthetic sutures that can cause pain, and there is about a 10%–20% risk of developing a posterior vaginal compartment prolapse that needs further surgery.

This retrospective study had several limitations. Data are from a single UK tertiary referral center with experience in both open and minimally invasive procedures for female SUI. This may explain the higher relative numbers in both open colposuspension and AFS compared with NHS England data. Coding for out-patient procedures is not mandatory in NHS England and were, therefore, not included in our analysis. Data from procedures in private hospitals is not publicly available. Both factors might lead to an underestimation of the absolute numbers of MUS and bulking agent procedures in the UK. The effect on the relative distributions and overall trends therefore cannot be determined.

In a tertiary center, the rate of second surgery is probably higher than the overall country's number and may affect the patient's choice and hence the procedure distributions. Data on concomitant POP surgery and the outcome and revision data of our patient population were not presented as we believed they did not belong within the scope of this study. The outcomes of all types of SUI surgery have been studied, analyzed, and reviewed extensively in the past and have been discussed in this manuscript. Furthermore, the subjective postoperative satisfaction of patients undergoing SUI surgery in our center was not evaluated. It is unknown whether the process of shared decision making in female SUI surgery affects the objective and subjective outcomes of these procedures. Finally, we did not present patient data (age, socio-demographic information, etc.), which may influence the decision making process for the type of SUI surgery.^[3]

The data from our tertiary referral center demonstrate that, when, after extensive investigation and multidisciplinary discussion, all surgical options are offered and when the risks and benefits are transparently presented, women will still actively choose and consent for surgical treatment of SUI through shared decision making. Laparoscopic colposuspension, open colposuspension, and AFS^[22] have similar success rates to MUS and are recommended by the European Association of Urology guidelines (2020); however, their different complication profile may be more acceptable to women than the risks of synthetic material and may outbalance the debilitating social and financial consequences of living with SUI.

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