



Changing surgical trends for female stress urinary incontinence in England

Martino Maria Zacche¹ · Sambit Mukhopadhyay¹ · Ilias Giarenis¹

Received: 4 September 2018 / Accepted: 21 November 2018 / Published online: 6 December 2018
© The International Urogynecological Association 2018

Abstract

Introduction and hypothesis Stress urinary incontinence (SUI) surgery has significantly evolved with the introduction of synthetic midurethral slings (MUS). However, following reports from the US Food and Drug Administration and European Commission, the use of vaginal meshes in urogynaecology has been largely scrutinised. We analysed trends in female SUI surgery in England from 2000 to 2017.

Methods The Hospital Episode Statistics database was retrieved from the Health and Social Care Information Centre website. Specific four-character codes of the evolving OPCS-4 coding system were used to quantify SUI operations.

Results We analysed 180,773 admissions from 2000 to 2017. A steep rise in MUS use was noted until 2008–2009, followed by a consistent drop, with a nadir of 6383 procedures in 2016–2017. Removal of MUS has become increasingly popular, with a peak of 591 in 2012–2013. Numbers for traditional continence operations remained low. Colposuspensions markedly decreased to 189 in 2012–2013, with a slight positive trend only in the last few years, while autologous sling use constantly dropped from 262 to 124 throughout the study period. Admissions for urethral bulking agents increased from 650 to 1324 in the last 2 years.

Conclusions MUS represents the most commonly performed procedure for SUI, despite an obvious reduction in the last 8 years. Urethral bulking agents are becoming more popular, while the numbers of colposuspensions and autologous slings are still low. Training programmes should take into account current shifts in surgical practice.

Keywords Stress urinary incontinence · Surgery · Mesh · Trends

Introduction

Stress urinary incontinence (SUI) is a quality-of-life burden for 14.8–31.8% of women [1]. Surgical treatment is considered a valuable option when conservative measures fail. Over the last 2 decades, interventions for SUI have greatly evolved and become less invasive with the introduction of synthetic midurethral slings (MUS) [2]. Robust evidence revealed that MUS were as effective as traditional surgery and have therefore become the procedure of choice for several years [3–5]. However, when counselling patients, the National Institute for Health and Care Excellence (NICE) guidelines recommend a thorough discussion regarding risks and benefits of the

different surgical options available, including not only MUS, but also colposuspension, autologous fascial sling, and injectables [6].

Reports from the US Food and Drug Administration (FDA) in 2008 and 2011, European Commission (SCENIHR) in 2015, and, subsequently, national media have drawn attention to urogynaecological mesh implants and their related complications. Although these mainly focused on transvaginal mesh augmentation for pelvic organ prolapse, the use of synthetic slings for SUI has been extensively scrutinised. This resulted in increasing litigation and debate about the safety of MUS, which led to an official “pause” in vaginal mesh surgery since July 2018 in England [7, 8]. Interestingly, concomitantly with the first FDA warning, a reduction in the admissions for MUS and a rise in their removal were documented in the NHS from 2008 to 2012 [9].

The Hospital Episode Statistics (HES) database includes admissions and procedures of NHS hospitals in England. Interventions are coded with the Office of Population Censuses and Surveys Surgical Operations and Procedures,

✉ Martino Maria Zacche
m.zacche@gmail.com

¹ Department of Urogynaecology, Norfolk and Norwich University Hospital, Norwich, UK

Fourth Edition (OPCS-4). While it was developed for commissioning and reimbursement, its accuracy supports the use for research [10]. HES data have already been used to describe changes in the surgical treatment of female SUI between 2000 and 2012, with a focus mainly on MUS [9, 11]. However, data reflecting current practice are lacking. In view of the more recent safety warnings regarding meshes from scientific committees (FDA and SCENIHR) and media, we hypothesised a further reduction in the admissions for MUS with a concomitant rise of colposuspension, autologous fascial sling and injectables. Thus, we aimed to describe trends of surgery for female SUI in England over the last 17 years.

Methods

We retrospectively analysed public domain information from the HES database available on the Health and Social Care Information Centre website. Different operations were identified using specific four-character codes of the evolving OPCS-4 coding system. This is a classification of procedures and interventions carried out during in-patient stays or day-case surgery within the NHS. Reports on admitted patient care are published every year. We did not include treatments performed in the outpatient setting as their coding is not mandatory. Data were extracted from reports between 2000 to 2017. We included admissions for SUI surgery and also interventions for removal of MUS. As highlighted in Table 1, continence operations were categorised as “traditional surgery”, “MUS”, and “urethral bulking agents” to facilitate the analysis of the trends. We did not seek ethical approval as we used public domain and anonymous data.

Results

Overall 180,773 admissions from 2000 to 2017 were included. SUI procedures initially rose, from 8473 in 2000–2001 to a peak of 13,259 in 2008–2009. Subsequently, numbers gradually fell, with a decrease of 30% in the last 3 years, from 11,666 in 2013–2014 to 8150 in 2016–2017 (Fig. 1). The vast majority were MUS, followed by traditional surgery and injectables, which constituted 80.6%, 10.6%, and 8.8% of the SUI procedures, respectively (Fig. 2).

During the first decade, we recorded a fourfold increase in MUS, from 2706 in 2000–2001 to 11,801 in 2008–2009. However, a negative trend followed as admissions for MUS almost halved, with 6386 tapes performed in 2016–2017. Regarding type of MUS, retropubic tension-free vaginal tape (TVT) has been consistently preferred to transobturator tape (TOT), with respective peaks of 7015 in 2007–2008 and 4506 in 2008–2009 (Fig. 3). Of note, specific codes for TVT (M53.3) and TOT (M53.6) were only added in 2006–2007, while beforehand these were grouped together into “other specified vaginal operations to support outlet of female bladder” (M53.8).

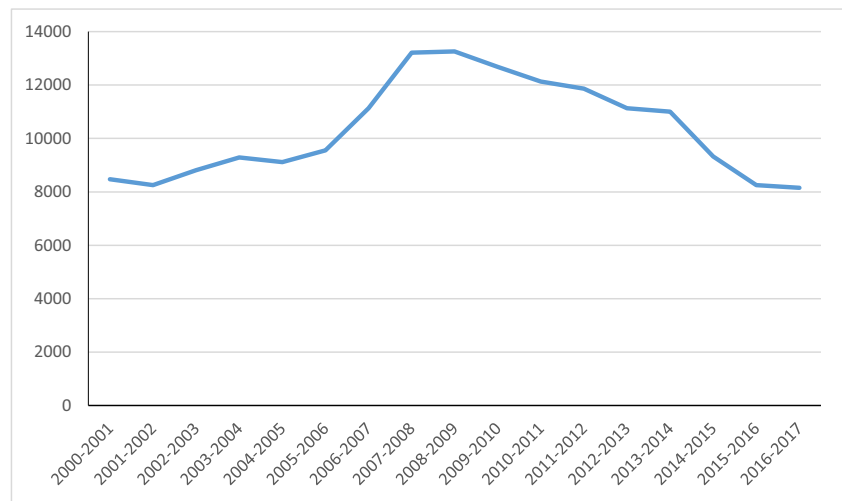
Overall, we counted 107,821 insertions versus 5143 (4.7%) MUS removals since 2006–2007, when coding for total (M53.4), partial (M53.5) removal of TVT and removal of TOT (M53.7) were introduced. Initially, these admissions increased with a total of 591 procedures in 2012–2013 and only recently dropped to 411 in 2016–2017. Specific trends are shown in Fig. 4. Partial removal of TVT represented the predominant group, with a peak of 349 cases in 2012–2013 followed by a gradual decline until 219 in 2016–2017.

Coding for traditional surgery significantly fell, from 4383 in 2000–2001 to < 500 per year since 2008–2009. In

Table 1 SUI procedures and respective four-digit codes

Procedures	OPCS-4 codes	
Traditional surgery	Abdominoperineal suspension of urethra	M51.1
	Endoscopic suspension of neck of bladder	M51.2
	Other specified combined abdominal and vaginal operations to support outlet of female bladder	M51.8
	Suprapubic sling operation	M52.1
	Retropubic suspension of neck of bladder	M52.2
	Colposuspension of neck of bladder	M52.3
MUS	Introduction of tension-free vaginal tape	M53.3
	Introduction of transobturator tape	M53.6
	Other specified vaginal operations to support outlet of female bladder	M53.8
Removal of MUS	Total removal of TVT	M53.4
	Partial removal of TVT	M53.5
	Removal of TOT	M53.7
Urethral bulking agents	Endoscopic injection of inert substance into outlet of female bladder	M56.3

Fig. 1 SUI procedures (total numbers)



particular, colposuspensions steeply dropped from 3758 to 189 between 2000–2001 and 2012–2013. Then, their trend inverted, with 257 procedures coded in 2016–2017. On the other hand, small numbers of autologous slings have been performed throughout the study period. Nevertheless, a gradual decrease was recorded, from 262 in 2000–2001 to 124 in 2016–2017 (Fig. 5).

Regarding injectables, procedures annually coded initially dropped from 1384 (2000–2001) to a nadir of 649 (2004–2005). However, in the last 2 years, a marked increase was noted, with 1324 admissions in 2016–2017 (Fig. 6).

Discussion

Surgical management of female SUI has been evolving over the years. Our study shows a substantial rise in the total number of interventions from 2000 to 2009, followed by a constant decline up to 2017. MUS rapidly increased, becoming the most commonly performed procedure for SUI. However, following safety warnings regarding the use of mesh, the number of MUS has progressively fallen. Admissions for colposuspensions markedly dropped and plateaued in 2007, while the numbers of autologous slings remained persistently low throughout the study period. Of note, despite the obvious

Fig. 2 SUI surgery—categories of procedures performed. *Urethral/bladder neck supporting procedures (including colposuspensions and autologous slings). **Mid-urethral sling

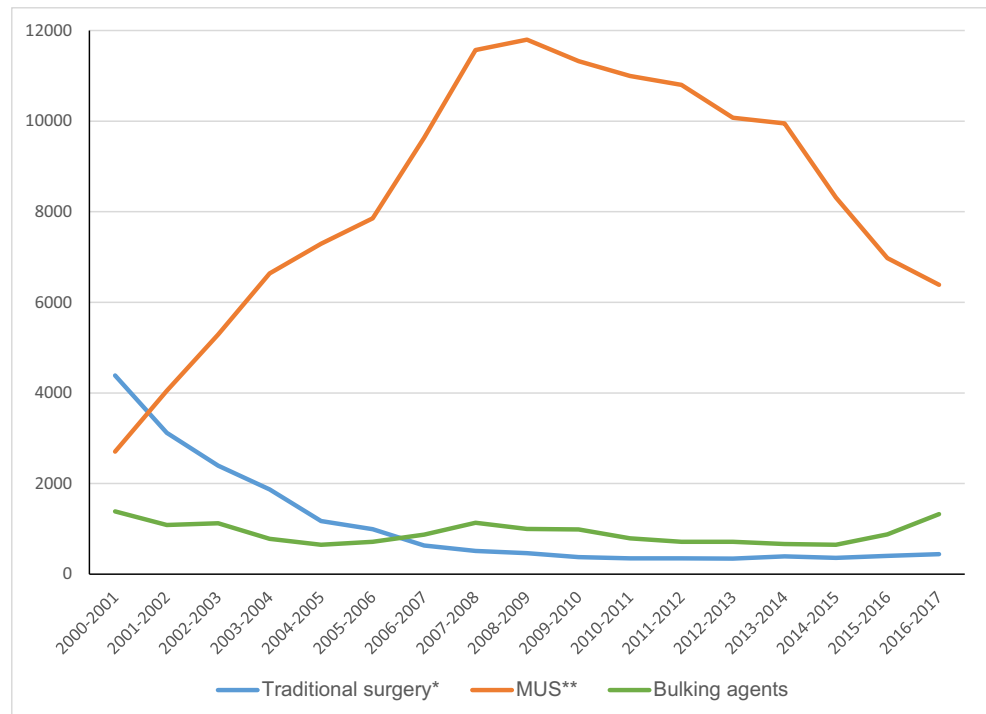
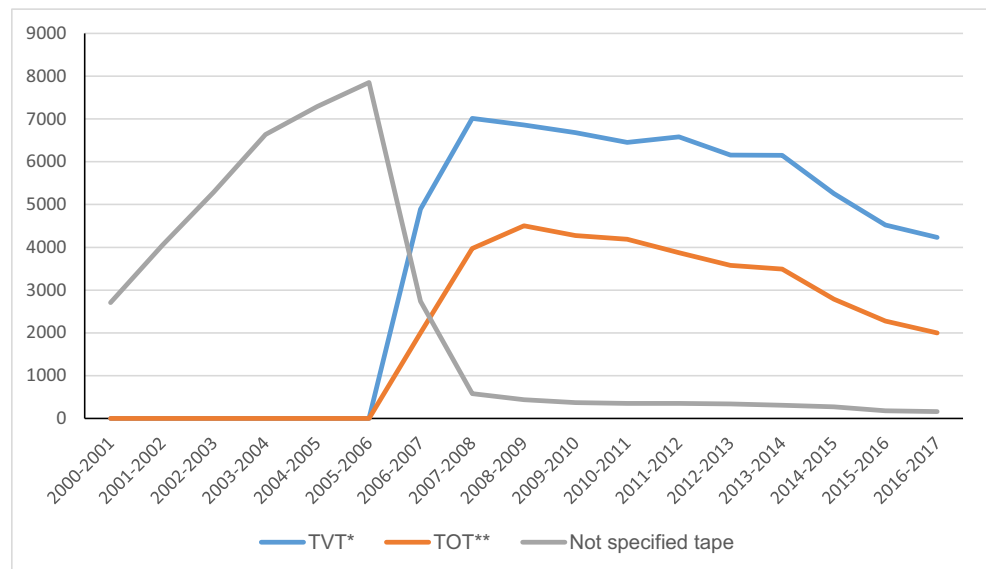


Fig. 3 MUS approach.
*Retropubic tension-free vaginal
tape. **Transobturator tape



negative trend for MUS and traditional surgery, injectables have only recently become more popular.

Since its introduction, a marked increase in MUS surgery has been documented worldwide, including the US (1998–2007) [12], Australia (1994–2009) [13], Taiwan (2006–2010) [14], Belgium (1997–2007) [15], and Finland (1987–2009) [16]. Interestingly, there are very few long-term data regarding practice following FDA warnings. Rac et al. reported on eight academic centres across the US from 2007 to 2013 [17]. A decrease in MUS use was registered, with a concomitant rise of mesh revisions. Also, these trends became more obvious following the second FDA warning in 2011. Recently, Brown et al. analysed data from Medicare Australia, showing

a plateau in MUS surgery between 2009 and 2011 and a subsequent drop between 2012 and 2014 [18]. While these MUS patterns were comparable to our study, other continence procedures showed different trends. In fact, admissions for autologous sling became more popular in the US, representing 21% and 30% of all SUI interventions, in 2007 and 2013, respectively. On the other hand, practice in Australia was more similar to that in England, with an overall reduction of admissions for SUI as alternatives to MUS were performed in a small number of patients.

There are no reports from Europe regarding current practice. We investigated changes in SUI surgery over the last 17 years. We demonstrated a spike in MUS until 2009.

Fig. 4 MUS removal

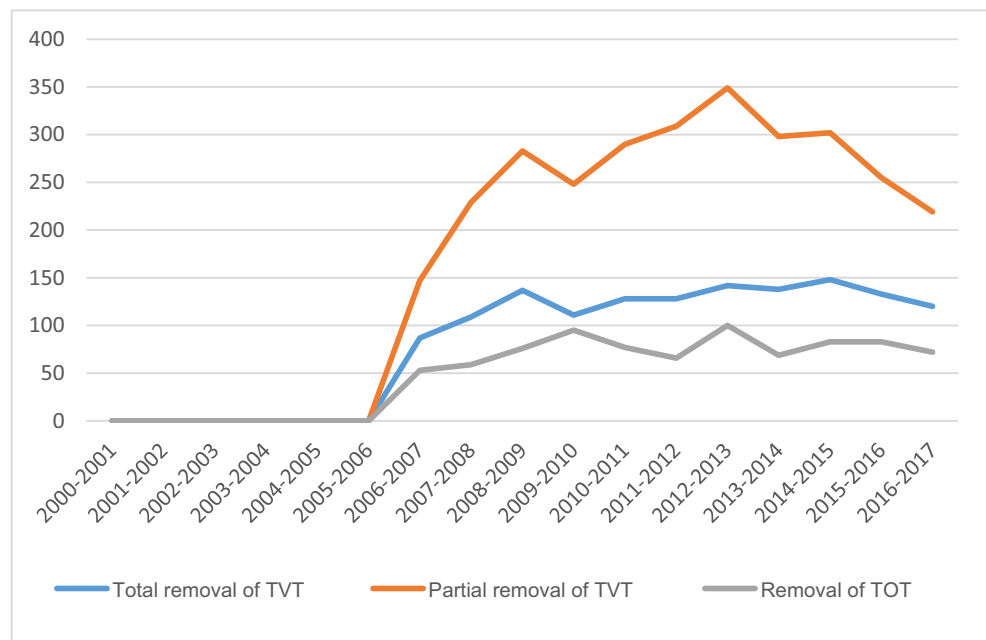
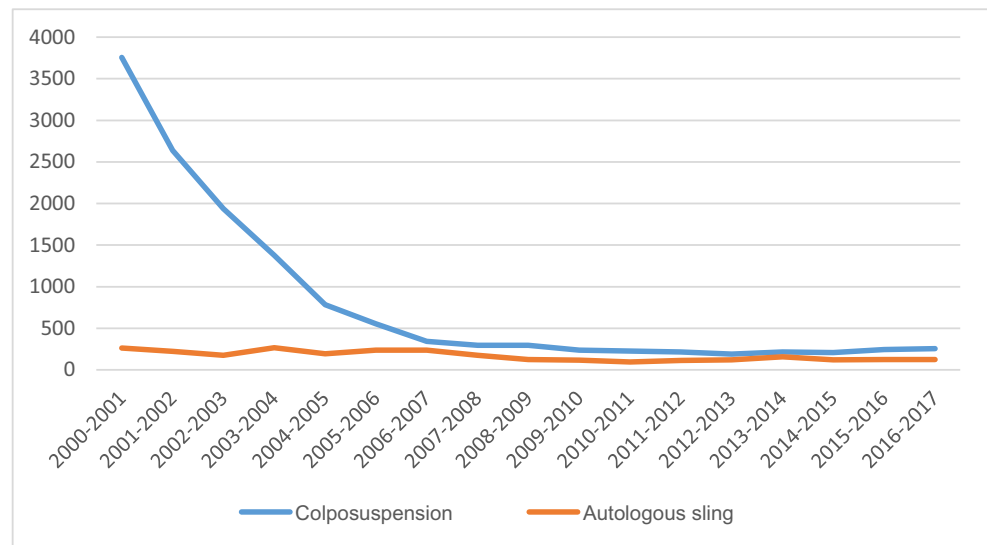


Fig. 5 Traditional surgery



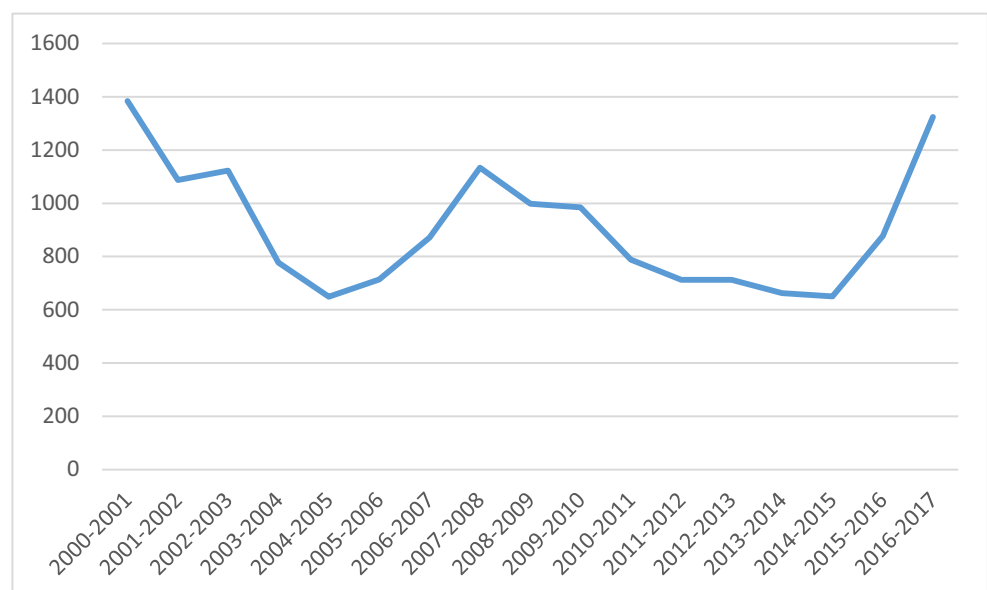
Synthetic slings may have been initially introduced in a large cohort of women with long-standing symptoms of SUI, who were reluctant or not fit for traditional surgery. The development of a minimally invasive approach may have also encouraged clinicians to offer continence surgery. MUS may have appeared a relatively easy procedure to perform, resulting in a lower threshold for treating women with SUI. However, the scenario has drastically changed over the last few years.

SUI surgery has progressively become less popular in England, with a consistent drop of continence procedures performed since 2009. This was mainly a reflection of MUS trends. In fact, despite robust evidence supporting its safety and effectiveness [5], MUS plateaued following the first FDA warning in 2008, while markedly declined after the second FDA communication in 2011. Subsequently, the use of

vaginal synthetic slings has been increasingly the object of negative publicity from the media, medico-legal litigation has become more common, and therefore clinicians might have felt overwhelmed. We showed a twofold increase in MUS revisions over the years. Potential indications for mesh removal include voiding difficulties, vaginal exposure, bladder or urethral perforation, infection, and chronic pelvic or groin pain. In our cohort we were not able to analyse the indication for the removals as this information was not available in the public domain of the HES database.

Interestingly, Rice et al. [19] investigated women's perception of mesh-related issues and noted a significant rise in complaints following the FDA warning in 2011, while the diagnosis rate of mesh complications did not change. Current attention regarding meshes may have led patients to increasingly

Fig. 6 Injectables



demand their removal. On the other hand, concerns about potential lawsuits may have led clinicians to lower the threshold for offering revision surgery. In July 2018, the use of any mesh for SUI was suspended by the English government in order to carry out a thorough investigation on its risks for women [8]. In this environment, SUI surgery is performed less frequently as women may be more reluctant to seek medical advice, relying longer on conservative management for SUI. Of note, a recent Canadian study evaluated awareness of women towards treatment options for SUI. Pelvic floor physiotherapy represented the most appealing remedy, followed by pessary and surgery [20].

We reported an obvious preference for the retropubic compared with the transobturator approach. This is more likely to depend on a surgeons' rather than patients' choice. In particular, groin pain is a well recognised complication specific to TOT. If persisting and debilitating, this may represent a surgical conundrum. Most of the clinicians are not familiar with the complex anatomy of the groin and do not have the necessary expertise to completely remove a tape through the obturator canal. On the other hand, surgeons are more used to eventually exploring the retropubic space, as this is encountered when performing traditional surgery. However, UK trends contrast with practice in the rest of Europe. In Finland, while TVT markedly decreased from 2002, admissions for TOT increased and eventually overtook TVT in 2007 [16]. A recent survey among IUGA members also revealed a definite preference for TOT versus TVT for uncomplicated SUI; notably, almost 40% of the responders were practising in Europe [21].

Despite warnings regarding the use of mesh, alternative interventions have failed to gain popularity. Traditional surgery was performed in < 5% of the cases in 2016–2017. This mainly resulted from the substantial drop of the admissions for colposuspension, which was demonstrated from 2000 to 2001 to 2006–2007. In the last few years we did not record a significant rise in either colposuspension or autologous sling. Compared with MUS, traditional surgery is certainly associated with longer recovery and women may be less prepared to accept it. On the other hand, in view of the small numbers registered in England, training is challenging and few centres may be able to offer this type of surgery.

The use of urethral bulking agents has remained stable over the years, ranging between 649 and 1384. However, they represent the only type of surgery able to show a markedly positive trend in the last 2 years, with procedures performed annually approximately doubling. Injectables constitute the least invasive intervention for SUI, with a significantly lower cure rate compared with other procedures [22]. However, NICE highlight that repeat injections may be required to overcome this limit. Patients may prefer these in order to avoid more invasive surgery, accepting the higher failure/recurrence rate associated with this type of surgery [23]. Of note, we did not report on urethral bulking agents performed in the outpatient

setting; in fact only small numbers are recorded in the database as their coding is not mandatory.

We performed a retrospective analysis of changing trends in female SUI surgery over a 17-year period. This topic has been a subject of research worldwide, but we present the first long-term data following FDA safety warnings regarding the use of vaginal meshes in urogynaecology. Nevertheless, we acknowledge several limitations. In fact, while all the data for inpatient procedures are mandatory from all NHS hospitals in England, their accuracy depends on clinical coders. Also, a national registry including interventions performed in the private sector is not available. Thus, despite large numbers, our analysis is incomplete as we did not consider this population. However, it is likely that this represents a small, but certainly unknown, proportion of SUI interventions. Moreover, further patterns regarding women's characteristics (age, previous continence procedure) and surgeons' subspeciality (gynaecologist, urogynaecologist, or urologist) could not be investigated as these data are not available in public domain reports. Finally, we were unable to comment on the type of sling inserted (conventional, adjustable, or single incision), tape material (polypropylene or polyvinylidene fluoride), and surgical approach for colposuspension (laparotomy or laparoscopy) as the respective codes have not been introduced yet.

Shifts in SUI surgery are of paramount importance. While any intervention carries potential risks, meshes have been the focus of an exceptional debate in England. The recent suspension of vaginal mesh surgery in NHS hospitals warrants an urgent revision of urogynaecologists' training programmes in order to provide adequate care for women who request an operation for SUI. Monitoring of trends is compelling as alternative options to MUS may eventually gain popularity. Finally, further research including patient-level data is needed to show future changes in practice.

Funding No funding was received for this project.

Compliance with ethical standards

Conflicts of interest Martino Zacche does not have any conflict of interest. Sambit Mukhopadhyay accepted cover of travel expensed from Dynamesh, Astellas, Kebomed UK, and Cook Medical. Ilias Giarenis received speaker honoraria from Astellas.

Publisher's note Springer Nature remains neutral with regard to jurisdictional claims in published maps and institutional affiliations.

References

1. Coyne KS, Sexton CC, Thompson CL, Milsom I, Irwin D, Kopp ZS, et al. The prevalence of lower urinary tract symptoms (LUTS) in the USA, the UK and Sweden: results from the epidemiology of LUTS (EpiLUTS) study. *BJU Int*. 2009;104(3):352–60.

2. Cox A, Herschorn S, Lee L. Surgical management of female SUI: is there a gold standard? *Nat Rev Urol*. 2013;10(2):78–89.
3. Ward KL, Hilton P, Uk, Ireland TVTTG. Tension-free vaginal tape versus colposuspension for primary urodynamic stress incontinence: 5-year follow up. *BJOG* 2008;115(2):226–233.
4. Schimpf MO, Rahn DD, Wheeler TL, Patel M, White AB, Orejuela FJ, et al. Society of Gynecologic Surgeons Systematic Review G. sling surgery for stress urinary incontinence in women: a systematic review and metaanalysis. *Am J Obstet Gynecol*. 2014;211(1):71 e1–e27.
5. Ford AA, Rogerson L, Cody JD, Aluko P, Ogah JA. Mid-urethral sling operations for stress urinary incontinence in women. *Cochrane Database Syst Rev*. 2017;7:CD006375.
6. NICE. Urinary incontinence in women: management 2015. [Available from: <https://www.nice.org.uk/guidance/cg171/resources/urinary-incontinence-in-women-management-pdf-35109747194821>].
7. Nager CW. Midurethral slings: evidence-based medicine vs the medicolegal system. *Am J Obstet Gynecol*. 2016;214(6):708 e1–5.
8. Parliament. Update on the Independent Medicines and Medical Devices Safety Review: Written statement-HCWS841 2018. [Available from: <https://www.parliament.uk/business/publications/written-questions-answers-statements/written-statement/Commons/2018-07-10/HCWS841/>].
9. Withington J, Hirji S, Sahai A. The changing face of urinary continence surgery in England: a perspective from the hospital episode statistics database. *BJU Int*. 2014;114(2):268–77.
10. Burns EM, Rigby E, Mamidanna R, Bottle A, Aylin P, Ziprin P, et al. Systematic review of discharge coding accuracy. *J Public Health (Oxf)*. 2012;34(1):138–48.
11. Gibson W, Wagg A. Are older women more likely to receive surgical treatment for stress urinary incontinence since the introduction of the mid-urethral sling? An examination of hospital episode statistics data. *BJOG*. 2016;123(8):1386–92.
12. Wu JM, Gandhi MP, Shah AD, Shah JY, Fulton RG, Weidner AC. Trends in inpatient urinary incontinence surgery in the USA, 1998–2007. *Int Urogynecol J*. 2011;22(11):1437–43.
13. Lee J, Dwyer PL. Age-related trends in female stress urinary incontinence surgery in Australia—Medicare data for 1994–2009. *Aust N Z J Obstet Gynaecol*. 2010;50(6):543–9.
14. Wu CJ, Tong YC, Hsiao SM, Liang CC, Liang SJ, Weng SF, et al. The surgical trends and time-frame comparison of primary surgery for stress urinary incontinence, 2006–2010 vs 1997–2005: a population-based nation-wide follow-up descriptive study. *Int Urogynecol J*. 2014;25(12):1683–91.
15. Cammu H, Saeys F, Haentjens P. Dramatic increase (1997–2007) in the number of procedures for stress urinary incontinence in Belgium. *Int Urogynecol J*. 2010;21(12):1511–5.
16. Kurkijarvi K, Aaltonen R, Gissler M, Makinen J. Surgery for stress urinary incontinence in Finland 1987–2009. *Int Urogynecol J*. 2016;27(7):1021–7.
17. Rac G, Younger A, Clemens JQ, Kobashi K, Khan A, Nitti V, et al. Stress urinary incontinence surgery trends in academic female pelvic medicine and reconstructive surgery urology practice in the setting of the food and drug administration public health notifications. *Neurourol Urodyn*. 2017;36(4):1155–60.
18. Brown J, King J. Age-stratified trends in 20 years of stress incontinence surgery in Australia. *Aust N Z J Obstet Gynaecol*. 2016;56(2):192–8.
19. Rice NT, Hu Y, Slaughter JC, Ward RM. Pelvic mesh complications in women before and after the 2011 FDA public health notification. *Female Pelvic Med Reconstr Surg*. 2013;19(6):333–8.
20. Brennand E, Ruiz-Mirazo E, Tang S, Kim-Fine S. Calgary Women's pelvic Health Research G. urinary leakage during exercise: problematic activities, adaptive behaviors, and interest in treatment for physically active Canadian women. *Int Urogynecol J*. 2018;29(4):497–503.
21. Ghoniem G, Hammett J. Female pelvic medicine and reconstructive surgery practice patterns: IUGA member survey. *Int Urogynecol J*. 2015;26(10):1489–94.
22. Kirchin V, Page T, Keegan PE, Atiemo K, Cody JD, McClinton S. Urethral injection therapy for urinary incontinence in women. *Cochrane Database Syst Rev*. 2012;2:CD003881.
23. Robinson DA, Cardozo K, Bidmead L, Dixon J, Balmforth A, Rufford J. J. What do women want?: interpretation of the concept of cure. *Female Pelvic Med Reconstr Surg*. 2003;9(6):273–7.