Thieme

Surgical Procedures for the Treatment of Stress Urinary Incontinence (SUI) in the Light of the Updated FDA-Warning and its Effects on Practice Patterns in Germany between 2010 and 2021

Operative Eingriffe zur Behandlung der Belastungsharninkontinenz nach der Aktualisierung der FDA-Warnung und deren Auswirkung auf die Praxis in Deutschland zwischen 2010 und 2021

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Keywords

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Schlüsselwörter

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ABSTRACT

Introduction

Changes in surgical practice patterns to cure stress urinary incontinence (SUI) became evident after FDA warnings regarding vaginal mesh were issued. The primary aim was to describe nationwide numbers of suburethral alloplastic slings (SAS) inserted in 2010, 2015, 2018 and 2021 in Germany. Secondary, numbers were related to SUI specific non-alloplastic alternatives and bulking agents. Additionally, age distribution and overall inpatient surgeries in women were subject to analysis.

Materials and Methods

Descriptive study utilizing data gathered from the German Federal Statistical Office (www.destatis.de). Included were the following procedures of inpatient surgery: A. SAS; B. non-allplastic slings; C. open/laparoscopic colposuspension; D. Bulking agents; overall changes and changes in age distribution (groups of 5-years intervals) are described.

Results

Overall, n = 3599466 female inpatient procedures were analyzed. There was a considerable decrease of SAS surgeries of 28.49% between 2010 (n = 23464) and 2015 (n = 16778), and a decrease of 12.42% between 2015 and 2018 (n = 14695) and an additional decrease of 40.66% between 2018 and 2021 (n = 8720). Over time a 55.03% continuous decrease in non-alloplastic slings was observed (n = 725 in 2010 to n = 326 in 2021). Open and laparoscopic

colposuspension numbers went down with a rate of 58.23 % (n = 4415 in 2010, n = 1844 in 2021). Between 2010 and 2018, only bulking agent procedures increased with a rate of 5.89 % from n = 1425 to n = 1509.

Conclusions
There was a considerable decrease in inpatient surgical procedures using SAS. Alternatives not only failed to compensate, but experienced also a major decline.

ZUSAMMENFASSUNG

Einleitung
Nachdem die FDA Warnungen zu Vaginalnetzen herausgegeben hat, hat sich die chirurgische Praxis zur Behandlung der Belastungsharninkontinenz deutlich geändert. Das Hauptziel dieser Arbeit war, die Anzahl bundesweit durchgeführter Eingriffe mit suburethralen alloplastischen Schlingen (SAS) in den Jahren 2010, 2015, 2018 und 2021 in Deutschland zu beschreiben. Sekundär wurde die Anzahl belastungsharninkontinenzspezifischer, nicht-alloplastischer Alternativen und der Einsatz von Bulking Agents geprüft. Die Altersverteilung der Patientinnen und die Gesamtheit der stationären operativen Eingriffe bei Frauen wurden ebenfalls analysiert.

Material und Methoden
Es handelt sich um eine deskriptive Studie, die sich auf Daten des Statistischen Bundesamts in Deutschland (www.destatis.de) stützt. Eingeschlossen wurden folgende stationäre operative Eingriffe: A. SAS; B. nicht alloplastische Schlingen; C. die offene/laparoskopische Kolposuspension; D. Bulking Agents; allgemeine Veränderungen und Änderungen in der Altersverteilung (Gruppen wurden in 5-Jahres-Intervalle eingeteilt) werden beschrieben.

Ergebnisse
Insgesamt wurden 3 599 466 stationäre Eingriffe bei Frauen analysiert. Es gab einen erheblichen Rückgang an SAS-Eingriffen (28,49 %) zwischen 2010 (n = 23 464) und 2015 (n = 16 778); zwischen 2015 und 2018 (n = 14 695) betrug der Rückgang 12,42 % und zwischen 2018 und 2021 (n = 8720) sank der Prozentsatz zusätzlich um 40,66 %. Im Laufe der Zeit wurde ein kontinuierlicher Rückgang von 55,03 % bei Einsatz nicht alloplastischer Schlingen beobachtet (von n = 725 im Jahre 2010 zu n = 326 in 2021). Die Anzahl offener und laparoskopischer Kolposuspensionen ging ebenfall um 58,23 % zurück (von n = 4415 im Jahre 2010 auf n = 1844 in 2021). Zwischen 2010 und 2018 stieg nur die Anzahl der Eingriffe mit Bulking Agents um 5,89 % von n = 1425 auf n = 1509.

Schlussfolgerungen
Es kam zu einem erheblichen Rückgang der stationären operativen SAS-Eingriffe. Alternative Prozeduren schafften nicht nur keinen Ausgleich, sondern erlebten auch einen erheblichen Rückgang.

Introduction

Alloplastic materials improved urogynecologic surgery regarding stress urinary incontinence (SUI) for more than two decades [1]. The invention of the tension free vaginal tape (TVT) revolutionized the surgical therapy of women suffering from SUI [2]. Different surgical approaches to insert suburethral alloplastic slings (SAS) (retropubic vs. transobturatorial) as well as different types of SAS (materials, inside-out vs. outside-in techniques) have emerged over the years [3]. Promising data on success, low complications and high long-term improvement of quality of life have given the SAS a “gold standard” status in many countries, such as Germany, Austria and Switzerland [1, 4, 5, 6, 7, 8].

Vaginal parity, overweight and increasing age are known risk factors for SUI [9]. Therefore, demographic changes in our aging population may lead to increased numbers of urogynecologic patients and consequently surgical procedures [10].

In 2011, the US Food and Drug Administration (FDA) released a safety communication update regarding transvaginal mesh for surgical therapy of pelvic organ prolapse (POP) [11]. Even though SAS were not primarily addressed in the FDA’s warning, the awareness of surgeons regarding the use of vaginal mesh for prolapse repair causing certain serious problems such as pain, dyspareunia and erosion, had been intermingled into the field of SAS surgery unfortunately. Although national [12] and international [13] statements have clearly described the safety of SAS, the FDA warning influenced practice patterns worldwide, even resulting in banning the SAS in general in some countries such as UK [14].

The aim of this study was to analyze if the attitudes of surgeons regarding surgical procedures for SUI using SAS were affected by the FDA warning in Germany, even though there have not been any national limitations or restrictions to use SAS.

Materials and Methods

Data acquisition

Data have been gathered retrospectively from the German Federal Statistical Office (www.destatis.de). Four different time points were subject to analysis: The year 2010, prior to the updated FDA warning that led to a considerable decrease of the use of vaginal mesh in pelvic organ prolapse surgery [11, 14], the years 2015 and 2018, in which potential effects of the FDA warnings might have become recognizable, and the year 2021, in which numerous recommendations reassured the use of SAS in Germany and other countries [4, 5, 12, 15]. Although the 2021 numbers were highly

▶**Table 1** Nationwide inpatient OPS codes used for data extraction of all four groups subject to analysis.

	A. suburethral alloplastic slings SAS	B. non-alloplastic slings	C. open or laparoscopic colposuspension	D. bulking agents
Codes	5–593.20 5–593.2x 5–593.x 5–593.y 5–594.30 5–594.31 5–594.x	5–593.00 5–593.01 5–593.02 5–593.0x 5–593.10 5–593.11 5–593.1x 5–594.0 5–592.2	5–595.0 5–595.10 5–595.11 5–595.1x 5–595.20 5–595.21 5–595.22 5–595.23 5–595.24 5–595.25 5–595.2x 5–595.3	5–596.00 5–596.01 5–596.02 5–596.0x

affected by the SARS-CoV-2-pandemic, the authors decided to include 2021. The included OPS codes can be seen in ▶**Table 1**. The German Federal Statistical Office provides all inpatient surgery cases over the country of Germany. In addition, age distribution in 5 years' intervals was provided.

Definition of outcomes

We defined our primary outcome parameter as the number of nationwide inpatient procedures for SUI with SAS. Secondary, surgical alternatives such as non-alloplastic slings, Burch colposuspension and bulking agents were analyzed. Age distribution could be analyzed by the use of 5 years intervals. Overall inpatient female surgical procedures were described to provide context information.

Statistics and analyses

All analyses were performed using Microsoft Excel for Mac, Version 16.78 (Microsoft, Redmond, Washington, US). Outcomes had been analyzed with descriptive statistics, respectively.

Ethics

Since these data were anonymous OPS codes only without any patients' information, ethical approval was not mandatory for this retrospective study.

Results

Overall numbers and primary results

In 2010, 2015, 2018 and 2021 there were a total of 33 599 466 female inpatient surgical procedures in Germany. Out of those, SAS for SUI were placed in 63 657 women. After the FDA-warning in 2011 there was considerable decrease of 28.49 % in between the years 2010 (n = 23 464) vs. 2015 (n = 16 778). Further on, numbers decreased about 12.42 % in 2018 (n = 14 695) and about additional 40.66 % in between 2018 and 2021 (n = 8720) There was an overall 62.84 % decrease of SAS surgery between 2010 and 2021 in total. See ▶**Fig. 1** for details.

Surgical alternatives

Regarding alternatives such as non-alloplastic slings, there was an 55.03 % continuous decrease over time as well (n = 725 in 2010 to n = 326 in 2021). Open and laparoscopic colposuspension numbers went down 58.23 % (n = 4415 in 2010, n = 1844 in 2021). In between 2010 and 2018, only bulking agent procedures increased slightly from n = 1425 to n = 1509 (5.89 %). In 2021, bulking agents decreased about 21.6 % from n = 1509 to n = 1183). See ▶**Fig. 2** for SAS alternatives.

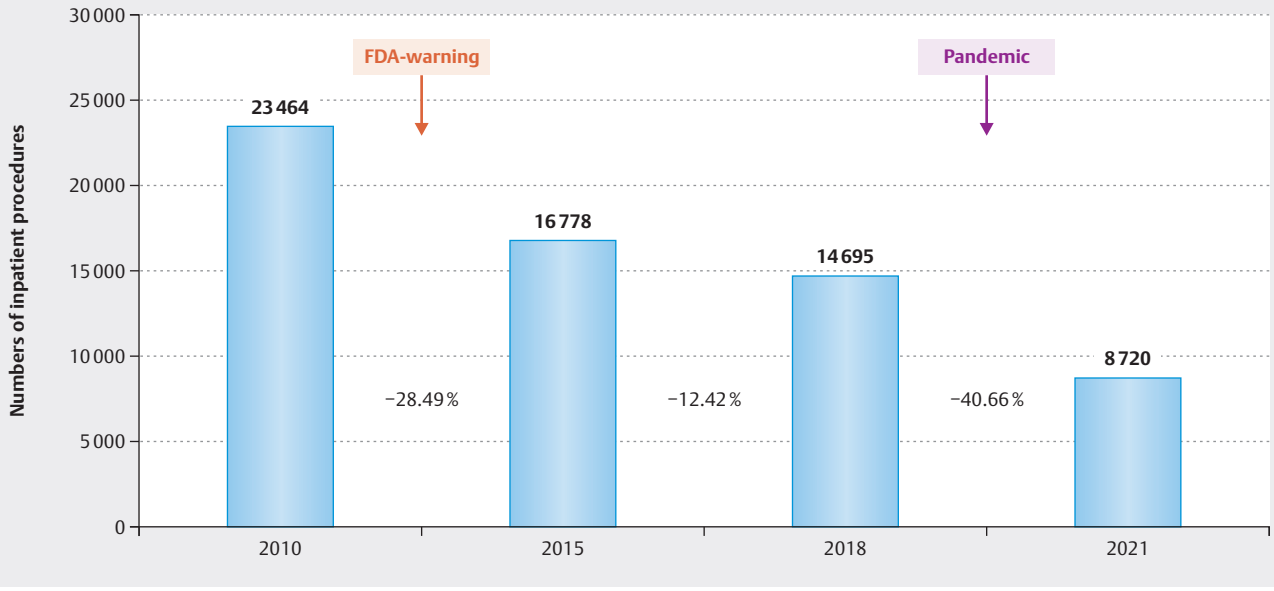
Overall inpatient numbers

The number of female inpatient surgical procedures increased over time: 2010 (n = 7 976 794), 2015 (n = 8 595 727; + 7.76 %) and 2018 (n = 8 793 074; + 2.30 %). In 2021, numbers decrease to n = 8 233 871 (− 6.36 %). ▶**Fig. 3** illustrates all female inpatient surgery cases in Germany. Regarding age distribution of all female inpatient surgical procedures, we could identify two age peaks at 30–35 years constantly over the time periods analyzed between 2010 and 2021 and at 70–75 years in 2010, 75–80 years in 2015 and 2018 and 80–85 years in 2021 (▶**Fig. 4**).

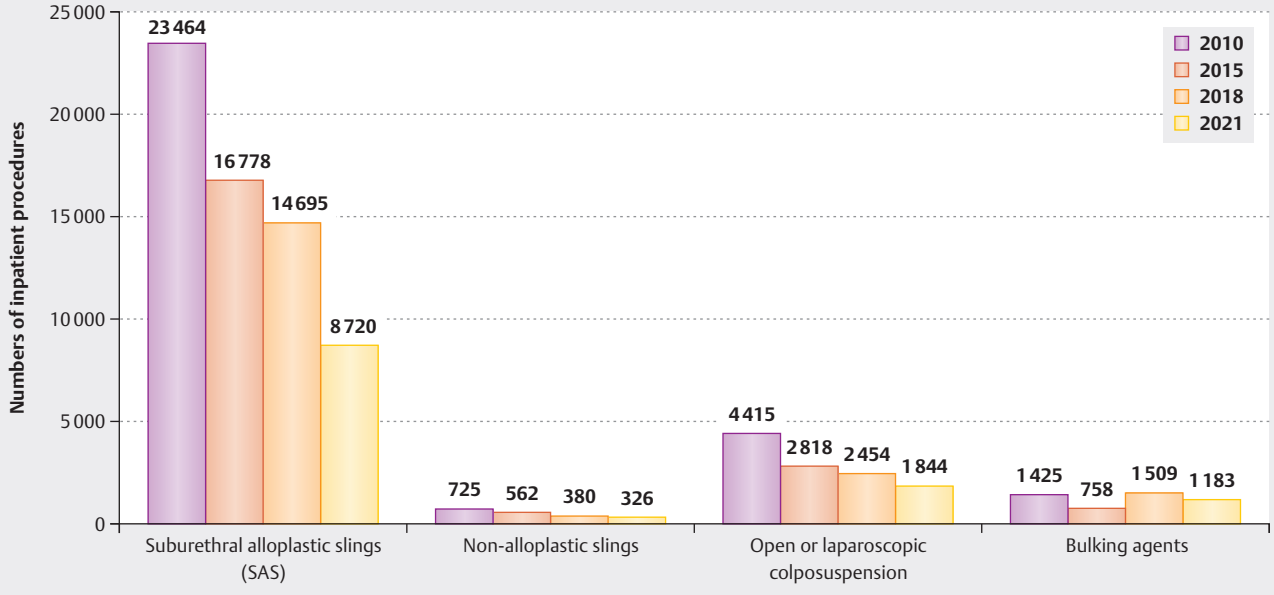
Discussion

SUI is one of the most common pelvic floor disorders in women and the SAS procedure is supposed to be the therapeutic "gold standard" in many countries. We could identify a dramatic decrease in the use of SAS in Germany between the years 2010 and 2021 of 62.84 %. Several reasons for this decline may be considered, however, it is most likely that the FDA warnings and both patients and health care providers attitude toward alloplastic material used in urogynecologic surgery might have influenced this trend, especially in the years prior to the SARS-CoV-2-pandemic.

There is a solid body of evidence showing the SAS safety and efficacy [4]. Guidelines of the German-speaking countries on urinary incontinence still define the SAS as being "gold standard" to treat female SUI [6]. Ford et al. concluded that: "Mid-urethral sling operations have been the most extensively researched surgical treatment for stress urinary incontinence (SUI) in women and have



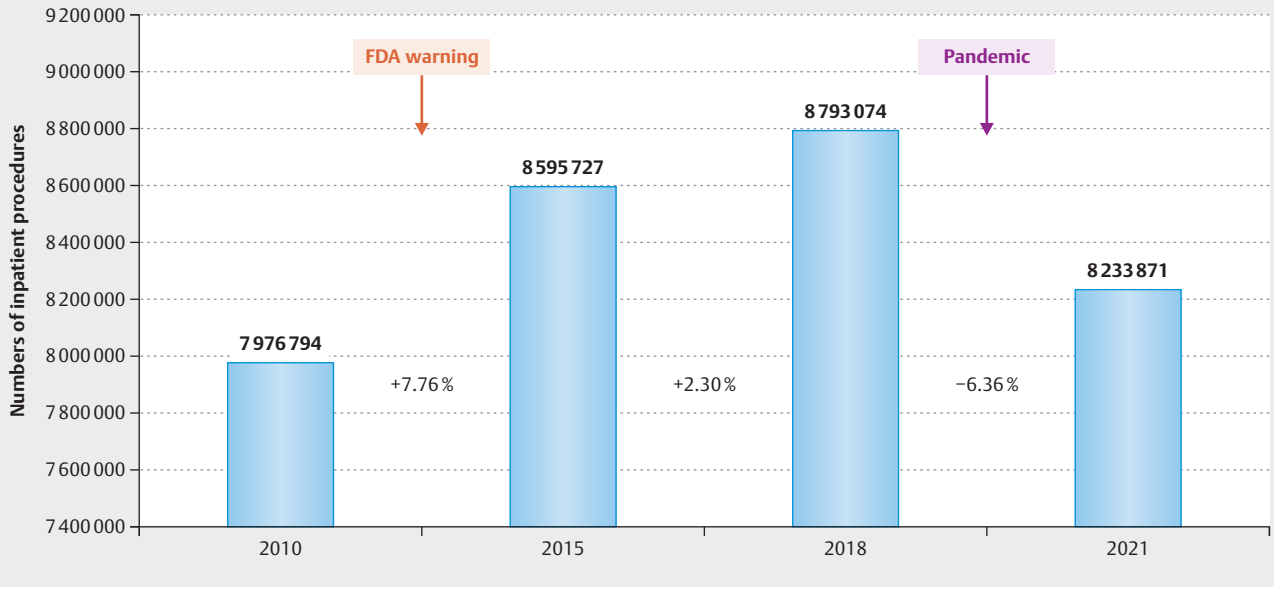
▶ **Fig. 1** Changes over time in suburethral alloplastic sling (SAS) surgeries (female inpatients only) between 2010 and 2021. Mind the FDA-Warning in 2011 and the potential effects of the pandemic between 2018 and 2021.



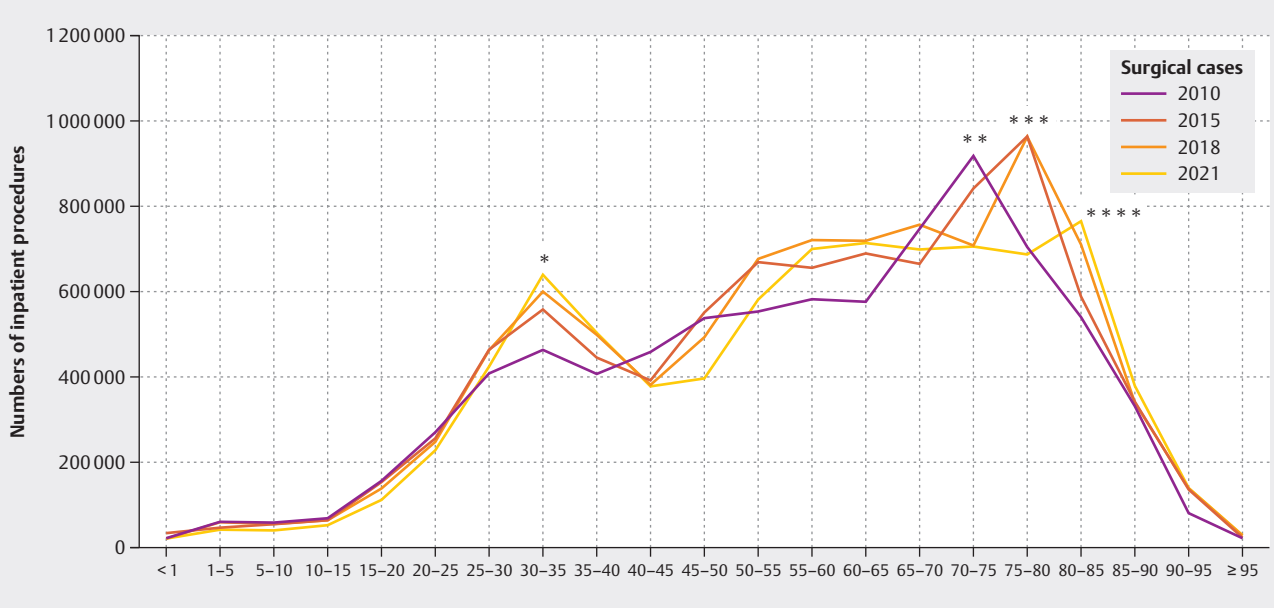
▶ **Fig. 2** Alternatives to the suburethral alloplastic slings. Note the decrease that goes along with the reduced numbers of the SAS procedure. Only bulking agents increased between 2015 and 2018.

a good safety profile." [4] This Cochrane analysis included 81 trials with 12113 women. Ford et al. describe a subjective cure rate in the short term of less than one year of 84.4%, medium term (1–5 years) of 88.1% and long term (> 5 years) of 70.7% [4] Nilsson et al. proved long lasting effects of more than 90% objective cure on continence and quality of life of the TVT [8]. Furthermore, there is a wide national consensus about offering the SAS procedure to women with SUI in Germany and the German speaking countries [1, 5, 6, 12] even though alloplastic material is needed.

In their systematic review, Guillot-Tantay et al. state "There is wide discrepancy between the literature and the various warnings coming from both health agencies and administrative databases" [16].



▶ **Fig. 3** Overall female inpatient cases in Germany between 2010 and 2021.



▶ **Fig. 4** Age distribution of all female inpatient cases in groups of 5 years intervals. Note there are two age peaks. One (*) at 30–35years, staying constantly over the years 2010, 2015, 2018 and 2021. Then three other peeks (**, ***, and ****) showing an increase in age over time.

The FDA warning did not primarily address SUI procedures but rather alloplastic materials for POP surgery [11]. Subsequently numbers of POP vaginal surgical procedures using these materials decreased over time [17]. Nevertheless, SAS cases decreased as well in many countries [18, 19, 20]. Obviously, there might be different reasons to explain this decline. Berger et al. found a significant reduction in SAS placement between 2011 and 2016 in the US [18]. Although numbers in total were declining, it was actually fewer surgeons performing the same number of slings. Other studies by Palmerola et al. and Brown et al. found a similar decline after the FDA-warning in both the US and Australia [21, 22]. Interestingly, an AUGS-survey published by Clemons et al. could not find any decline in SAS in 507 AUGS members who responded [23].

One possible explanation could be the fact that more experienced surgerons with higher volumes were confident enough to maintain SAS in their portfolios, whereas others who did lower numbers stopped performing the SAS procedures completely.

Another explanation for the decline could be the fact that we actually "overtreated" women suffering from SUI in the time of raising numbers of implanted SAS prior to the FDA warning. The awareness of physiotherapy being a sufficient first line treatment increased over the same time [24], leading to a more guideline associated treatment pathway to start with pelvic floor muscle training prior to surgery [6]. In addition, adding an SAS as a concomitant procedure during prolapse repair is subject to intensive discussion. A more critical view on this topic might have decreased SAS numbers as well [25].

Ng-Stollmann et al. provide a thorough analysis of mesh procedures affected by the FDA warnings concluding to establish a critical use of alloplastic materials in urogynecology [14].

When specific surgical procedures are subject to analysis, the analysis should provide a general view of all surgical procedures in women with respect to changes over predefined time periods. The present study shows that the dramatic decrease of SUI cases fell in a time of steadily increasing female inpatient cases in Germany. Solely between 2018 and 2021 a 6.36% decrease in overall female inpatient surgeries was found, which can be attributed to the SARS-CoV-2-pandemic [26]. Gray et al. also found a decrease in some both conservative and surgical therapies during the SARS-CoV-2-pandemic [26]. The authors are aware of the fact, that any changes in numbers between 2018 and 2021 are mainly driven by the SARS-CoV-2-pandemic. Nevertheless, these numbers seem worthwhile reporting.

Regarding alternatives to SAS such as pubovaginal slings, Burch colposuspension or bulking agents, one would assume that increasing numbers did compensate for the decreasing SAS in Germany. However, this was surprisingly not a finding of the present study. Except bulking agents, that doubled their numbers between 2015 and 2018, all other procedures decreased over time. Furthermore, the increasing numbers of surgical procedures with bulking agents were not able to compensate the decrease of SUI procedures. Itkonen Freitas et al. analyzed Bulkamid's status being an alternative to the TVT procedure in their RCT with less adverse events but less efficacy as well [27]. However, bulking agents could not compensate for the decline of suburethral slings in our study.

One potential explanation for the missing increase of SAS-alternatives could be the fact that while surgeons were very experienced and successful using SAS, alternatives were not subject to training anymore. There was no need to be capable of performing Burch procedures. Therefore, there might have been hospitals that did not offer colposuspension or non-alloplastic slings at all. In addition, a worsening of the general urogynecological care in Germany should at least be discussed, although increasing numbers of certified pelvic floor centers show a different picture.

While the FDA warnings are likely to be at least one of the reasons for the decline in SAS surgeries, a strong support of this hypothesis could be given by a considerable increase of surgical alternatives. Lacking this increase as in our presented data, this could be an indication that the observed decline in urogynecologic surgeries in total has nothing to do with the FDA warning in 2011 at all. Therefore, other reasons for changes in practice patterns need to be subject to future research. Whether a market saturation has occurred in Germany over the time needs to by analyzed carefully.

Urogynecologic care in Germany is constantly aiming for increasing its quality. This can be identified in rising numbers of certified pelvic floor centers as well as rising numbers of surgeons certified by the national urogynecologic society AGUB. Therefore, training of evidence based procedures such as SAS and colposuspension should be in the center of enhancing our patient care rather than developing experimental uncontrolled techniques.

While the authors are aware of the fact that the artificial sphincter could be an alternative procedure to treat SUI in special cases, low numbers identified do not seem to change the overall view of negative trends without sufficient alternatives (artificial sphincters implanted 2010: 29; 2015: 38; 2018: 24; 2021: 17). In addition, in some cases suprapubic permanent catheterization or an urostoma could be an alternative in a few cases as well, however, low numbers do not alter the broad picture described in this study.

Strengths of this study are an independent analysis of all female inpatient surgeries at four different time points. Out of those, 2010 is neither affected by the FDA warnings, 2015 and 2018 can be recognized as potentially being influenced by the FDA warnings and 2021, that needs to be seen in the light of both both the FDA warning as well as the SARS-CoV-2-pandemic. More than 33 million women were included in this analysis providing a broad overview of surgical practice patterns in Germany at the four defined timepoints.

However, there are obviously weaknesses as well. The German Federal Statistical Office (www.destatis.de) provides the OPS codes for all inpatient procedures in Germany. Usually, urogynecologic surgery is not performed in an outpatient setting in Germany due to unsatisfying reimbursement patterns. Therefore, there might be an insignificant minority only of cases that could have been performed in an outpatient clinic. In addition, we were unable to address these cases in our analysis since the German Federal Statistical Office (www.destatis.de) does not provide data on outpatient cases. Further, the OPS code database strongly relies on the accuracy of coding itself. There was no way to control for any type of miscoding or other errors. Patient specific data on demographics, diagnoses, information on previous surgeries, symptoms, bother, combination of other surgical options or conservative treatment was not subject to analysis in this study. In addition, the German Federal Statistical Office does not provide any information on how many procedures had been performed in which hospitals in Germany. Therefore, we cannot provide information about individual surgeons' preferences.

Even without the effects of the SARS-CoV-2-pandemic the dramatic decline of surgical cases treating women suffering of SUI need to be addressed. It is not very likely that demographic changes have led to decreasing numbers of patients in the field of urogyneclogy, the opposite is much more likely to be truth [10].

Conclusions

The present study shows that inpatient surgeries using alloplastic slings for SUI decreased dramatically in the time of the FDA warnings. Whereas our data does not prove cause and effect, the FDA warnings have to be taken into account for being a potential reason for this decline. Surprisingly, the number of surgical alternatives for SUI such as pubovaginal slings, Burch colposuspension or bulking agents did not a show compensatory increase. Whether or not we have a situation of undersupply in our urogynecologic patients or whether we experienced a market saturation needs to be subject for ongoing and future research projects.

Acknowledgement

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Conflict of Interest

The authors declare that they have no conflict of interest.

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