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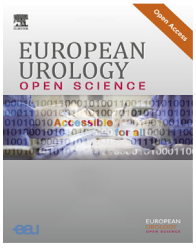

European Association of Urology

Review – Incontinence

Long-term Safety of Synthetic Midurethral Sling Implantation for the Treatment of Stress Urinary Incontinence in Adult Women: A Systematic Review

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Article info

Article history:
Received 24 December 2022
Revised 3 April 2023
Accepted May 16, 2023

Associate Editor:
Véronique Phé

Keywords:
Urinary incontinence
Stress urinary incontinence
Midurethral slings
Systematic review

Abstract

Context: Midurethral slings (MUSs) are the most used therapy for the treatment of stress urinary incontinence (SUI). While warning signals about potential complications have been raised worldwide, there is a lack of safety data especially in the long term.
Objective: Our objective was to evaluate synthetic MUS safety outcomes at long term in adult women.
Evidence acquisition: We included all studies evaluating MUSs in adult women with SUI. All synthetic MUSs have been considered: tension-free vaginal tape (TVT), transobturator tape (TOT), and mini-slings. The primary outcome was the reoperation rate at 5 yr.
Evidence synthesis: Of 5586 references screened after duplicate removal, 44 studies (8218 patients) were included. Among these, nine were randomized controlled trials and 35 were cohort studies. The overall reoperation rates at 5 yr varied between 0% and 19% for TOT (11 studies), 0% and 13% for TVT (17 studies), and 0% and 19% for mini-slings (two studies). The overall reoperation rates at 10 yr varied between 5% and 15% for TOT (four studies) and between 2% and 17% for TVT (four studies). There were few safety data beyond 5 yr: 22.7% of the articles reported a follow-up at $\geq$10 yr and 2.3% at $\geq$15 yr.
Conclusions: The incidence rates of reoperations and complications are heterogeneous, and data beyond 5 yr are rare.

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https://doi.org/10.1016/j.euros.2023.05.013

Patient summary: There is an urgent need to improve safety monitoring of mesh as our review highlights that available safety data are heterogeneous and of insufficient quality to guide the decision.

1. Introduction

Stress urinary incontinence (SUI) is defined by the International Continence Society as "the complaint of involuntary loss of urine on effort or physical exertion including sporting activities, or on sneezing or coughing" [1]. Within <30 yr after their introduction, midurethral slings (MUSs) have become the first-line and the most used therapy for the treatment of this functional disease, with 3.7 million meshes implanted between 2005 and 2013 worldwide [2]. There are two main types of slings: tension-free vaginal tape (TVT) and transobturator tape (TOT). TVTs were the first to be developed in 1996 in Sweden [3] followed by TOTs in the early 2000s [4]. Both are synthetic medical devices with implanted material made of polypropylene [5]. With TVTs, sling passers are advanced behind the pubic symphysis, and this procedure is mainly performed by urologists because of the per-operative cystoscopy. TOTs exclude entry into the retropubic space [6] and can be performed by urologists, gynecologists, and general surgeons. In 2012, a third type of sling has been commercialized: mini-sling, which aims to reduce sling length and surgical trauma behind the pubic bone or within the obturator space [7]. As TOTs, these can be performed by urologists, gynecologists, and general surgeons [8,9].

Despite their wide use, safety data are missing to clearly inform patients as part of a shared medical decision with no clear rate of reoperation available, especially in the long term (ie, $\geq$5 yr after the implantation). A systematic review and meta-analysis published in 2007 evaluated the short-term safety of MUSs, but there was no analysis of reoperations and complications beyond 2 yr [10]. However, complications of surgical mesh procedures were initially described for pelvic organ prolapse repair, such as mesh erosion or infection, and urinary retention, overactive bladder, or chronic pain. MUSs being also considered as mesh, these have led to legal cases against manufacturers worldwide and to national inquiries for these slings.

Initially, because of insurance issues, some countries have even removed TOTs and TVTs from their guidelines, such as the National Institute for Health and Care Excellence in the UK [9].

The objective of this systematic review was to evaluate synthetic MUS long-term safety outcomes in adult women with SUI.

2. Evidence acquisition

This systematic review was conducted according to the Preferred Reporting Items for Systematic Reviews (PRISMA) statement [11]. The protocol is registered on PROSPERO (CRD42020223627).

2.1. Data sources

We carried out a literature search in Medline via PubMed, Embase, and Cochrane Central databases from January 1, 1996, when the first MUS was described, to October 31, 2022 [3,12]. The different surgical procedures for MUSs did not change markedly during this period [8]. We considered only studies with at least 5 yr of follow-up [13].

We developed a search algorithm (reported in the Supplementary material) including keywords and free-text words around *stress urinary incontinence*, *midurethral sling*, AND *female* without language restriction. We also searched for conference abstracts of scientific societies (European Association of Urology, American Urological Association, and International Continence Society) using the aforementioned keywords from 1996 to 2022. We also searched ClinicalTrials.gov for ongoing or completed studies assessing MUSs. Finally, we screened reference lists of relevant studies for any additional reference.

2.2. Eligibility criteria

2.2.1. Study type and patient characteristics

We included all studies evaluating MUSs in adult women with SUI (comparative or not, randomized or not, and retrospective or prospective). Studies reporting case reports, pediatric and male populations, or cohorts of fewer than five women, or based on cadavers or animals have been excluded. Abstracts reporting relevant data have been considered. When a same cohort was reported in different articles, we focused on the article reporting the longest follow-up. We considered only studies with at least 5 yr of follow-up [13].

2.2.2. Intervention types

All synthetic MUSs have been considered: TVTs, TOTs, and mini-slings. Colposuspension and autologous sling procedures, which are alternative nonsynthetic surgical procedures for the treatment of SUI, were not considered in this systematic review.

2.2.3. Outcomes

Our outcomes of interest are defined as follows:

1. Primary outcome: reoperation rate at 5 yr including the following: incision of the sling, ablation of the sling, closure of the erosion, and reoperation for incontinence. We chose to focus on the reoperation rate at 5 yr as the primary outcome because it indicates a severe complication.
2. Secondary outcomes:

(a) Reoperation rates at 7 and 10 yr including the following: incision of the sling, ablation of the sling, closure of the erosion, and reoperation for incontinence
(b) Complication rates at 5, 7, and 10 yr as a whole and for each of the following complications:
(i) Sling erosion
(ii) Sling infection
(iii) Urinary retention
(iv) Urinary infection
(v) Overactive bladder

2.3. Selection process

Two reviewers (G.T. and V.K.) independently screened all retrieved citations first based on their titles and abstracts, and then full texts. Disagreements have been solved by discussion with a third researcher (C.K.) to reach a consensus on the studies to include.

2.4. Data extraction

Two reviewers (G.T. and V.K.) independently extracted the following characteristics:

1. General characteristics: year of publication and journal
2. Study design: comparative or not, randomized or not, prospective or retrospective, and whether the study was single or multicenter
3. Patient characteristics: age, menopause or postmenopause status, neurogenic or non-neurogenic bladder, Valsalva leak point pressure and maximal urethral closure pressure (MUCP) on the urodynamic evaluation if reported, and the type and number of procedures undergone previously for SUI
4. Surgical approach: TOT, TVT, or mini-sling
5. Setting: specialty of the operator (urologists, gynecologists, or urogynecologists) and type of setting (primary, secondary, or tertiary care center)
6. Outcomes as described above
7. Follow-up duration

2.5. Risk of bias assessment

We evaluated the risk of bias [14] of each included study using the Critical Appraisal Skills Programme (CASP) checklist for cohort studies [15] and the ROB tool v2 developed by Cochrane for randomized controlled trials (RCTs) [16].

2.6. Analysis

We described included studies in terms of general characteristics, study design, patient characteristics, surgical approach, setting, and follow-up. Missing data were not replaced.

For each outcome, we represented the event rate graphically in forest plots using R (R Core Team, 2021) [17] by type of slings (TOT, TVT, or mini-sling) and by follow-up time (5, 7, or 10 yr). The analysis was also stratified by study type (RCTs or cohort studies).

Owing to the high heterogeneity of included studies, no meta-analysis was performed.

3. Evidence synthesis

3.1. Literature search

The PRISMA flow chart is presented in Figure 1. Of 5586 references screened after exclusion of duplicates, 482 papers were eligible for a full-text analysis and 44 studies (8218 patients) were finally selected for qualitative synthesis. The study year of publication ranged from 2007 to 2020. None of the abstracts of conferences matched the inclusion criteria, and thus none was included.

3.2. Study characteristics

Among the 44 included articles, nine reported the long-term follow-up results of RCTs and 35 were cohort studies. Their characteristics are summarized in Table 1. Most studies were single-center studies (35 studies, 79.5%), conducted in Europe (28 studies, 63.6%) and in tertiary centers (39 studies, 88.6%). Safety was rarely the primary outcome of the studies (three studies, 6.8%: two RCTs and one cohort study). The median number of patients included was 140 (all studies) with an interquartile range (IQR) of 129 (124 [IQR = 145] for cohort studies and 144 [IQR = 153] for RCTs).

3.3. Patient and sling characteristics

The focus of this study was TVT implantation in 29 (65.9%), TOT implantation in 20 (45.5%), and mini-sling in three (6.8%) studies. In most cases, the implantation was performed by gynecologists (30 studies, 61.3%).

Patients' mean age ranged from 50.7 to 65.3 yr and mean body mass index from 23.4 to 30.3 kg/m^2. In 22.7% of the studies, patients suffered from mixed urinary incontinence and in two articles (4.5 %) from intrinsic sphincter deficiency. Regarding urodynamic parameters, the mean MUCP was reported in 11 studies, in which it ranged from 14.6 to 59.7 cmH_2O. The details of the general characteristics are reported in Table 2.

3.4. Follow-up

The median follow-up ranged between 60 and 162 mo, and was not reported in 21 studies.

Of the 44 articles, 22 (50%) reported the 5-yr reoperation rate.

Loss to follow-up was reported in 23 papers (52.2%), more in randomized clinical trials (nine articles, 100%) than in cohort studies (14 studies, 40%). The median percentage of loss to follow-up at the end of the study was 17% (IQR 23%): 15% for cohort studies (IQR 25%) and 17% (IQR 13%) for RCTs. These data are reported in Table 1.

3.5. Risk of bias assessment

The assessment of the risk of bias is presented in the Supplementary material for the CASP (cohort studies) and in Supplementary Figure 1 for the ROB tool (RCTs). In cohort studies, the risk of bias was high. Most RCTs were rated at

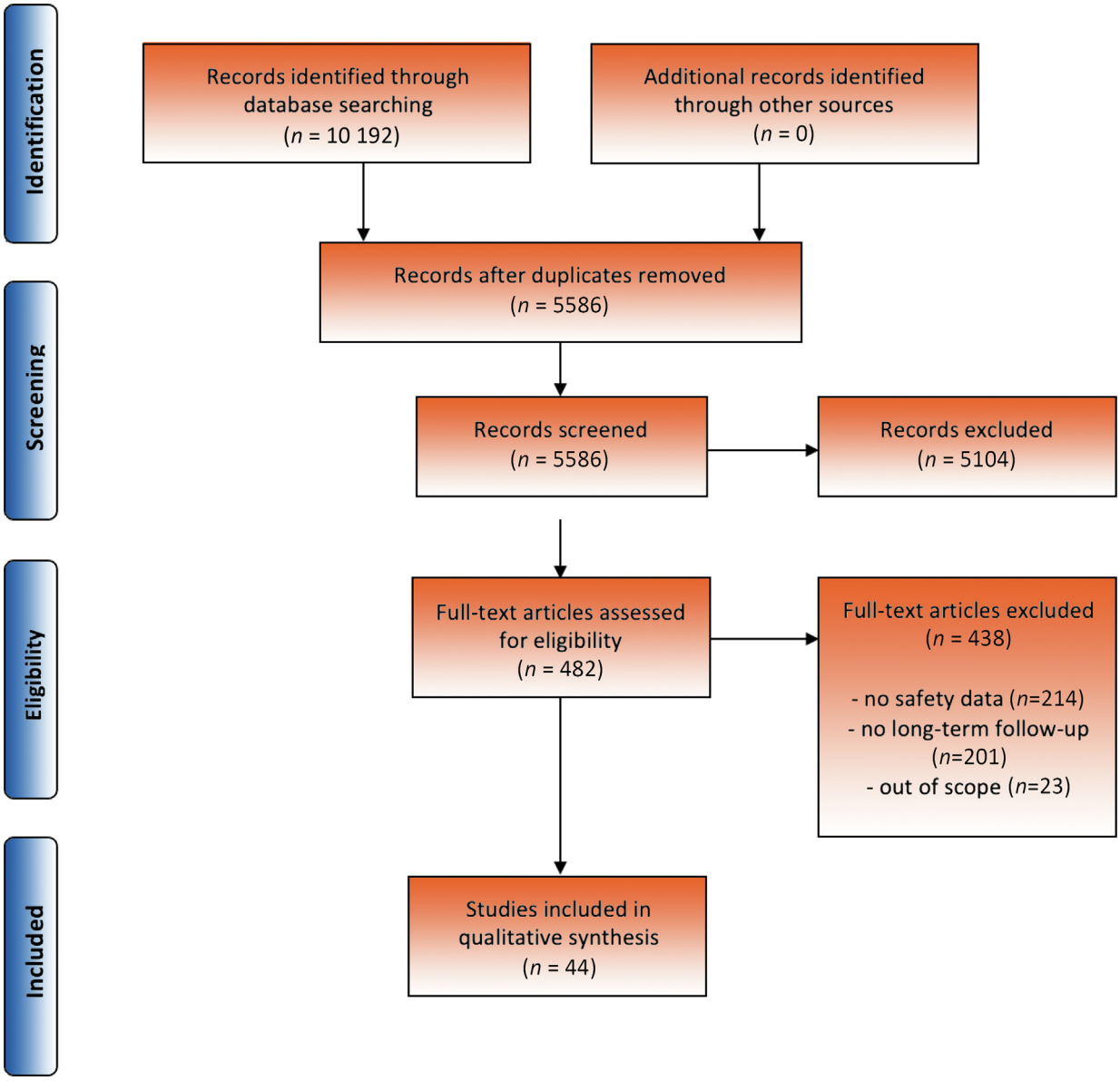

Fig. 1 – Flow chart of the selection process.

some concerns, regarding deviations from intended interventions and selection of reported results. For the measurement of the outcome, two trials were rated to be at a high risk.

3.6. Safety

3.6.1. Reoperation rates

Global reoperation rates are reported in Figure 2 and reoperation rates by type of reoperation in Supplementary Figure 2. The time points at which reoperations are reported differ between studies, as well as the type of reoperation for which incidence rates are reported. Moreover, the type of reoperations for persistent urinary incontinence was not reported in the different studies.

In cohort studies, the overall reoperations rates at 5 yr (reported in Fig. 2) varied between 0% and 19% for TOTs (four studies), 0% and 13% for TVTs (11 studies), and 0% and 19% for mini-slings (two studies). Overall, in the cohort studies, the reported reoperation rate at 5 yr was <5% for 50% of the studies investigating TOTs and 81% of the studies investigated TVTs. In RCTs, the overall reoperation rates at 5 yr varied between 0% and 12% for TOTs (seven studies), 0% and 7% for TVTs (four studies), and 0% and 19% for mini-slings (two studies). Of the trials, 85% reported a reoperation rate at 5 yr of <5% (six out of seven studies) for TOTs and 75% of the studies for TVTs (three out of four studies). The most frequent reoperations reported were ablation of the sling and incision of the sling. Moreover, at 5 yr, reoperation rates for incontinence vary from 0% to 3.2% for TVTs (eight studies), from 0% to 12% for TOTs (ten studies), and from 14.8% to 19.5% for mini-slings (two studies).

In cohort studies, the overall reoperation rates reported at 10 yr were 5% and 15% for TOTs (two studies) and varied

Table 1 – Characteristics of included studies

	Total (*N* = 44)	Cohort studies (*N* = 35)	Randomized controlled trials (*N* = 9)
Median year of publication (IQR)	2015 (7)	2013 (6)	2015 (2)
Median number of patients (IQR)	140 (129)	124 (145)	144 (153)
Location, *n* (%)			
Europe	28 (63.6)	23 (65.7)	5 (55.6)
North America	2 (4.5)	0 (0.0)	2 (22.2)
Asia	12 (27.3)	10 (28.6)	2 (22.2)
Middle East	2 (4.5)	2 (5.7)	0 (0.0)
Centers, *n* (%)			
Single center	35 (79.5)	30 (85.7)	5 (55.6)
Multi center	9 (20.5)	5 (14.3)	4 (44.4)
Setting, *n* (%)			
Secondary care	5 (11.4)	5 (14.3)	0 (0.0)
Tertiary care	39 (88.6)	30 (85.7)	9 (100.0)
Slings, *n* (%) [a]			
TVT	29 (65.9)	23 (65.7)	6 (66.7)
TOT	20 (45.5)	11 (31.4)	9 (100)
MINI	3 (6.8)	1 (2.9)	2 (22.2)
Specific indications, *n* (%)			
Mixed urinary incontinence	10 (22.7)	9 (25.7)	1 (11.1)
Intrinsic sphincter deficiency	2 (4.5)	2 (5.7)	0 (0.0)
Specialty of the surgeons, *n* (%)			
Urologists	12 (27.3)	11 (31.4)	1 (11.1)
Gynecologists	30 (61.3)	21 (60.0)	9 (100.0)
Urogynecologists	5 (11.4)	4 (11.4)	1 (11.1)
Primary outcome, *n* (%)			
Efficacy	21 (47.7)	16 (45.7)	5 (55.6)
Safety	3 (6.8)	1 (2.9)	2 (22.2)
Not specified or unclear	20 (45.5)	18 (51.4)	2 (22.2)
Follow-up, *n* (%)			
From 5 to 10 yr	33 (75.0)	27 (77.1)	6 (66.7)
>10 yr	10 (22.7)	7 (20.0)	3 (33.3)
>15 yr	1 (2.3)	1 (2.9)	0 (0.0)
Loss to follow-up			
Articles that reported data, *n* (%)	23 (52.2)	14 (40.0)	9 (100)
Median percentage of loss to follow-up (IQR)	17% (23%)	15% (25%)	17% (13%)

IQR = interquartile range; MINI = mini-sling; TOT = transobturator tape; TVT = tension-free vaginal tape.
[a] The same article can study several types of slings (the percentages can exceed 100%).

between 2% and 17% for TVTs (four studies). In RCTs, the overall reoperations rates at 10 yr were 0% and 1% for TOTs (two studies), and no study was published for TVTs.

3.6.2. *Complication rates*

Complication rates are reported in Figure 3 and complication rates by type of complication in Supplementary Figure 2. The time points at which complication incidence rates are reported differ between studies, as well as the type of complication for which incidence rates are reported. In cohort studies, the overall complication rates at 5 yr varied between 5% and 48% for TOTs (four studies) and 13% and 67% for TVTs (11 studies). In RCTs, the overall complication rates varied between 10% and 30% for TOTs (seven studies), and 14% and 40% for TVTs (four studies).

The most frequent complications reported were erosions (from 0% to 7% at 5 yr for TVTs and from 0% to 19% for TOTs), overactive bladder (from 2% to 34% at 5 yr for TVTs and from 2% to 43% for TOTs, without distinction between de novo and residual bladder overactivity), and retention (from 0% to 29% at 5 yr for TVTs and 0% to 6% for TOTs), as reported in Supplementary Figure 2.

4. Conclusions

This study is the first systematic review to focus on the long-term safety outcomes of MUSs for the treatment of urinary incontinence in women. In the 44 studies analyzed, the rate of reoperations at 5 yr varies from 0% to 19% depending on the studies and the slings implanted. Indeed, the slings may have different safety profiles. However, our results do not allow us to say which slings have the best safety profile.

Included studies had a small sample size with wide 95% confidence intervals. These were mainly single-center studies, at a high risk of bias for the cohorts, which were most frequent. Only 22 studies provided reoperation rates at 5 yr and eight at 10 yr. The different types of reoperations and complications were inconsistently reported across studies. Results were heterogeneous across studies, with reoperation rates ranging from 0% to 19% at 5 yr and from 0% to 17% at 10 yr, depending on the studies and the slings implanted. Heterogeneity was even more important for complication rates that ranged from 5% and 67%. Owing to this high heterogeneity of included studies, no meta-analysis was performed.

A previous review of the literature, by Latthe et al [10], focusing on complications of slings did not report any long-term data but only short-term data (within 2 yr). The reoperations and complication rates reported were lower than those in our study, which is not surprising because the risk of reoperation increases over time.

In many studies included in this systematic review, there were few or no reoperations reported, which contrasts with the clinical experience. The majority of the studies (50–85%

Table 2 – Details of the studies and population

Study	Year	Design	No. of centers	Place	Median follow-up (mo)	Indication	Slings	Outcome	*N*	Patient characteristics				Urodynamics	
										Age (yr)		BMI (kg/m^2)	Par. *N*	MUCP (cmH_2O)	VLPP (cmH_2O)
										M (SD)	m (IQR)	M (SD)		M	M
Abdel-Fattah [24]	2016	C	1	UK	108	MUI	TOT	Efficacy	83		52 (21)	28.7 (4.7)			
Angioli [25]	2010	RCT	1	IT	60	SUI	TVT, TOT	Safety	72	53.2		26.1		55	59.4
Ankardal [26]	2006	C	1	SE	60	SUI	TVT	Efficacy	707	59.8		27.1			
Athanasiou [27]	2013	C	1	GR	90.3	SUI	TOT	Efficacy	145	61 (10)		27 (3.7)	2		
Bakas [28]	2018	C	1	GR	204	SUI	TVT	Efficacy	61	58.1		27.3			
Cañete [29]	2013	C	1	ES	60	SUI	TOT	Efficacy	93	58					
Celebi [30]	2008	C	1	TR	63.1	SUI	TVT		600	51.7 (11.7)		31.7 (3.0)			
Chêne [31]	2006	C	1	FR	60	MUI	TVT	Efficacy	94	54.6		24.5	1.1	15	
Cheng [32]	2012	C	1	CN	60	SUI	TOT	Efficacy	103	52.4 (11.1)		20.5 (2.7)	2	26	26
Chung [33]	2017	C	1	KR	43.93	MUI	TVT	Efficacy	151	60.5 (10.4)		25.8 (3.0)			42.1
Deffieux [34]	2007	C	1	FR	83	MUI	TVT		61		52	24.1 (13.5)	2.16		
Doo [35]	2006	C	3	KR	60	MUI	TVT	Efficacy	138	52.3		24.2		53.3	79.5
Errando-Smet [36]	2017	C	1	ES	89	SUI	TVT		205	65.3 (10)		29 (5)	3.2		
Giberti [37]	2016	C	1	IT	83.8	ISD	TVT		50	67.8		23.8	2.2	15.1	43.5
Giberti [38]	2011	C	1	IT	60.6	ISD	TVT		30	66.3		24.5		14.6	41.1
Glavind [39]	2011	C	1	DK	60		TVT		173	54			2.1		
Groutz [40]	2011	C	1	IL	60		TOT	Efficacy	61	56.6					
Heidler [41]	2009	C	1	AT	62.4	MUI	TVT		42	59		28.2 (5)			
Karmakar [42]	2017	C	1	UK	110.4		TOT	Efficacy	341	61					
Kenton [43]	2015	RCT	11	USA	60		TVT, TOT	Efficacy	597	53.7 (10.5)		30.3 (6.6)			
Laurikainen [44]	2014	RCT	7	FI	60		TVT, TOT		273	53 (10)		26 (3)			
Lee [45]	2010	C	1	KR	85.5	MUI	TVT		141	55.9 (9.3)		26.5 (1.7)		59.7	81.8
Li [46]	2012	C	1	CN	81.85		TVT		55	56.0 (12.6)		25.4	3		
Liapis [47]	2008	C	1	GR	84		TVT	Efficacy	70	58.1 (10.4)		26.8 (2.3)	2		
Lo [48]	2016	C	1	CN	80.3		TOT		60	52.9 (14.1)		25.4 (3.6)	2	72.2	72.2
Losco [49]	2015	C	1	UK	62.4	NEU	TOT		27	56					
Manso [50]	2020	C	1	PT	113		MINI	Efficacy	172	52 (11)					
Olsson [51]	2010	C	1	SE	138		TVT		147	54.4 (11.6)		25.1 (3.7)			
Reich [52]	2011	C	1	DE	102		TVT		157	63		28.0 (4.3)			
Ross [53]	2015	RCT	1	CA	60		TVT, TOT	Safety	199	52.2 (10.4)		28 (5.5)			
Sabadell [54]	2019	C	1	ES	103.2	SEC	TVT		41		62.7	29.6		28	
Serati [55]	2015	C	1	IT	156		TVT		207		58 (21)				
Serati [56]	2020	C	5	CH	156		TOT	Efficacy	168		60 (16)				
Serdinšek [57]	2018	RCT	1	SI	122.4	MUI	TOT		120	61.9 (9)		27.6 (7)	2.6		
Song [58]	2009	C	3	KR	84	MUI	TVT	Efficacy	364	50.7		23.7		67.1	66.5
Song [59]	2015	C	1	KR	162.4	MUI	TVT		364	59.2		23.4	2.8	66.1	64.5
Sun [60]	2019	RCT	1	CN	120		TOT, MINI		94	58,7		23.8	2.8		
Svenningsen [61]	2013	C	4	NO	129		TVT	Efficacy	603		64	26			
Tammaa [62]	2017	RCT	25	AT	60		TVT, TOT	Efficacy	569	59.8 (11.5)		28.1 (6)	2.2	51.8	53.1
Tommaselli [63]	2015	RCT	2	IT	60		TOT, MINI	Efficacy	144	60.4 (8.4)		28.8 (6)	2.2		
Ulrich [64]	2016	C	2	AT	120		TOT		124	60 (7)		25 (4)			
Zhang [65]	2015	RCT	1	CN	95		TVT, TOT	Efficacy	140	51 (10)		25 (4)	1		
Zhang [66]	2019	C	1	CN	144		TOT		87	53 (12)		25 (4)	2		
Zhang [67]	2018	C	1	CN	156		TVT	Safety	85	52 (11)		25 (3)			

AT = Austria; BMI = body mass index; C = cohort study; CA = Canada; CN = China; DE = Germany; DK = Denmark; ES = Spain; FI = Finland; FR = France; GR = Greece; IL = Israel; IQR = interquartile range; ISD = intrinsic sphincter deficiency; IT = Italy; KR = Korea; M = mean; m = median; MINI = mini-sling; MUCP = maximal urethral closure pressure; MUI = mixed urinary incontinence; NO = Norway; PT = Portugal; RCT = randomized controlled trial; SD = standard deviation; SE = Sweden; SI = Slovenia; SUI = stress urinary incontinence; TOT = transobturator tape; TR = Turkey; TVT = tension-free vaginal tape; VLPP = Valsalva leak point pressure.

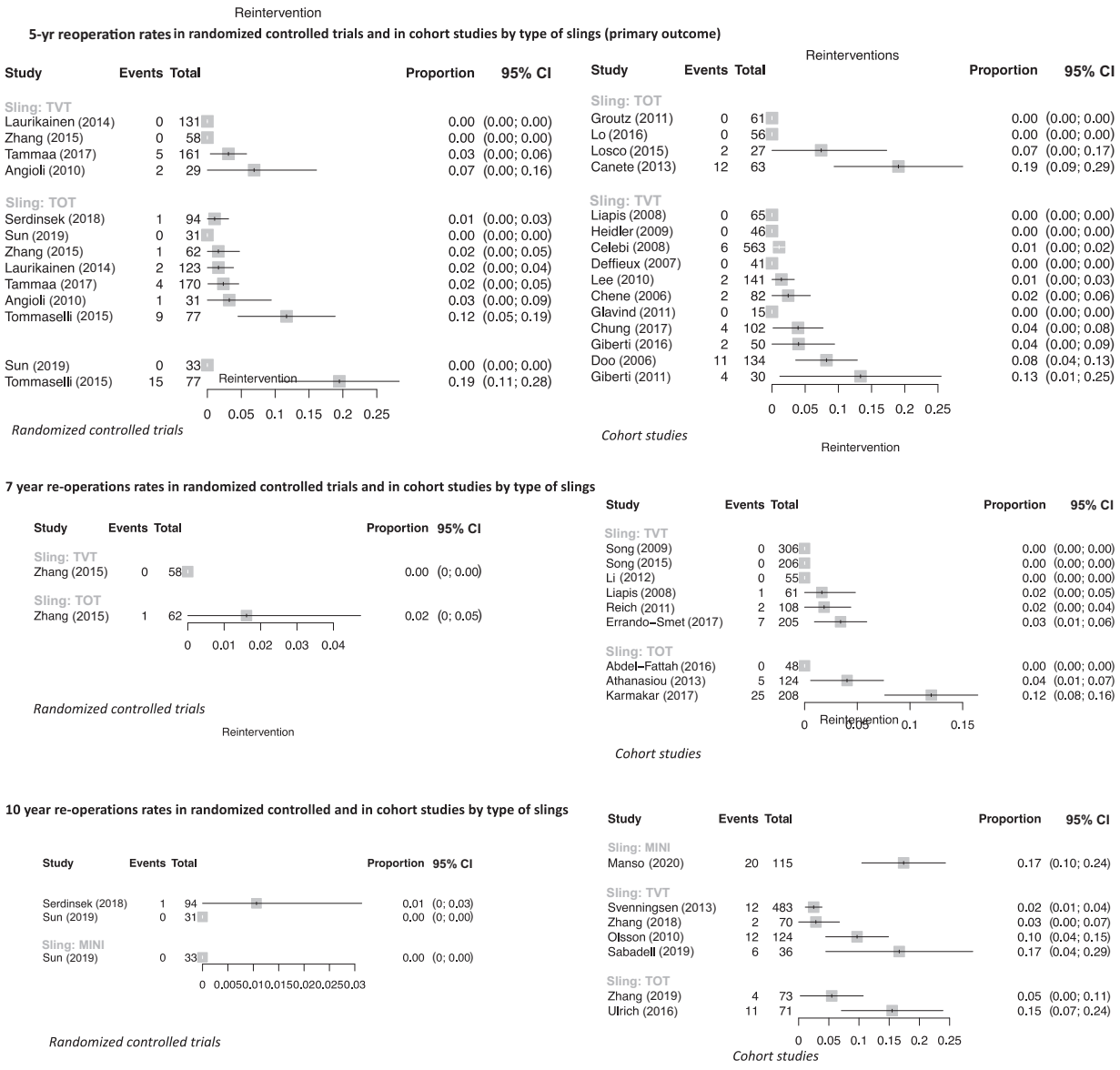

Fig. 2 – Reoperation rates in randomized controlled trials and cohort studies by type of slings. "Events" is the number of reoperations. "Total" is the number of patients included in the study. CI = confidence interval; MINI = mini-sling; TOT = transobturator tape; TVT = tension-free vaginal tape.

of studies for TOTs and 75–81% for TVTs) report a 5-yr reoperation rate of <5%.

There is wide discrepancy between the literature and the various warnings coming from both health agencies and administrative databases [18]. Such discrepancies can be explained in different ways. First, there may be an important attrition bias in long-term cohort studies, and it is likely that patients needing to be reoperated went elsewhere and are therefore considered lost to follow-up if no specific effort has been made to collect the long-term follow-up information. This may underestimate the rate of reoperation and complications in these studies. Second, most of the long-term data were issued from small single-center cohorts providing a low level of evidence. There are very few RCTs that report data of up to 5 yr of follow-up.

Our results reveal the heterogeneity in the reoperation or complication types for which incidence rates are reported. For example, it was not possible to distinguish between de novo and residual overactive bladder, or to list the different operations included for treating persistent urinary incontinence after sling implantation. The standardization of outcomes to be reported is important for comparing results across studies and conducting meta-analyses. This highlights the need for the elaboration of a core outcome set to be systematically collected and reported, on which the urologists and gynecologists' community has agreed.

Some secondary data sources covering a large and quasiexhaustive population and having an exhaustive follow-up irrespective of the patient trajectory may be of particular interest for enhancing the postmarketing surveillance of these devices because of their ability to limit selection and attrition biases. Studies on national healthcare databases (such as SNDS—"National Health Data System" [19,20] in France) seem to be particularly interesting for identifying the complications of these implantable medical devices in the real-life setting. These databases combine

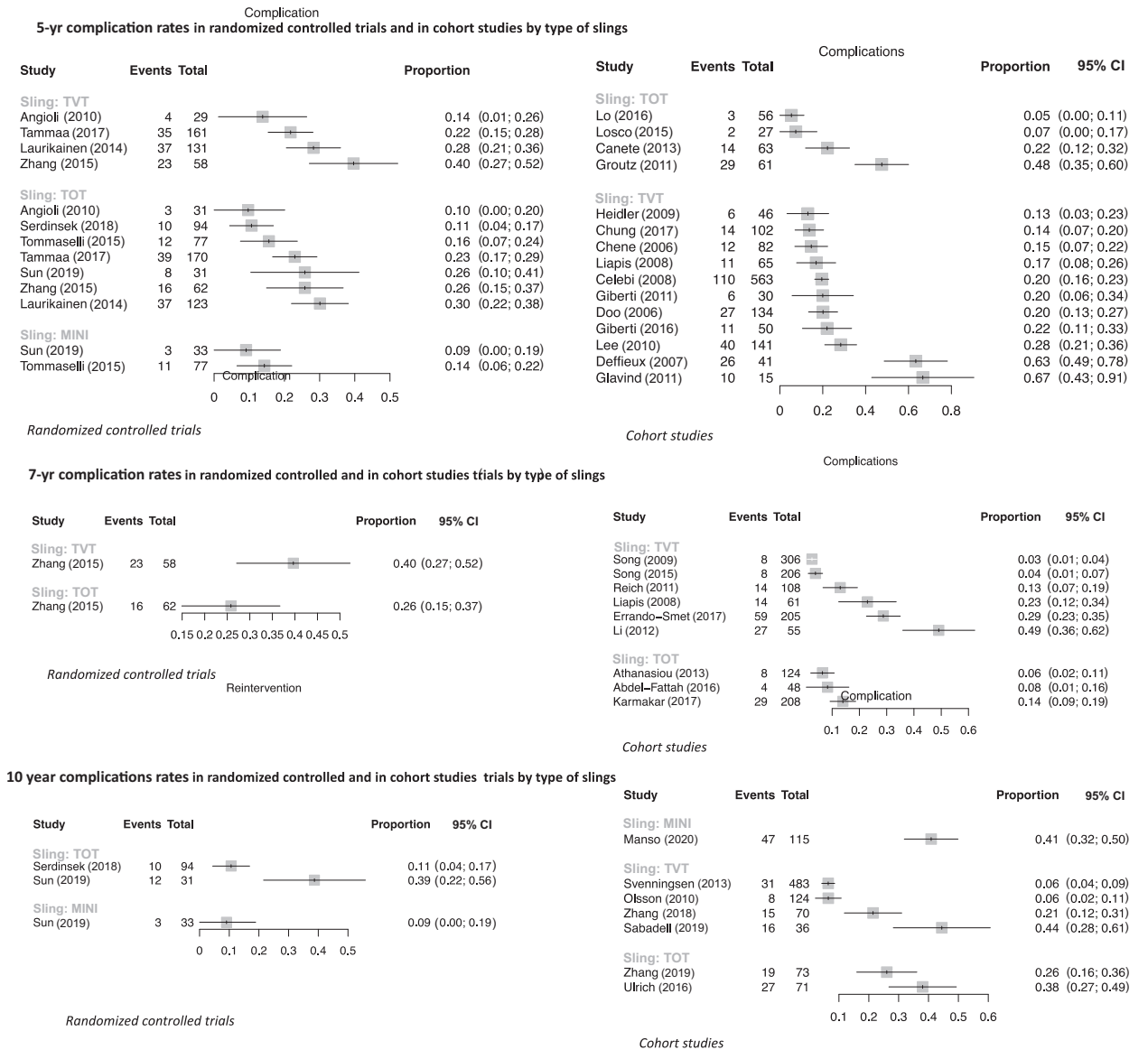

Fig. 3 – Complication rates in randomized controlled trials and cohort studies by type of slings. "Events" is the number of complications. "Total" is the number of patients included in the study. CI = confidence interval; MINI = mini-sling; TOT = transobturator tape; TVT = tension-free vaginal tape.

claims data from health insurance and medical summary of hospitalizations for all individuals covered by health insurance. In our systematic review, we did not find any study based on healthcare databases assessing the safety of these devices.

Moreover, follow-up obligations in studies on surgical techniques with implantable medical devices can also provide interesting and exhaustive data. For instance, the *MAUDE* registry [21,22] in the USA includes all medical device reports submitted to the Food and Drug Administration by mandatory reporters (manufacturers, importers, and device user facilities) and voluntary reporters such as healthcare professionals, patients, and consumers who can also contribute. However, both these data sources (healthcare databases and mandatory follow-up data) are not intended for clinical research purposes and therefore have inherent limits, particularly the lack of detailed clinical evaluation.

Last, we could rely on large-scale, standardized postmarket studies including medically validated data, physician- and patient-reported data, and follow-up data collected with sustained and proactive efforts , such as the *VIGIMESH* [23] register in France. This is a multicenter prospective observatory of women after surgery for urinary incontinence or genital or rectal prolapse with standardized data aiming to estimate the incidence of serious complications. In 2021, >7000 patients were included in VIGIMESH, and this register is still ongoing.

Our systematic review has some limitations. First, our search may not be completely up to date with the last study being included in 2020, but to our knowledge, no relevant study was published recently. In addition, additional studies would not alter our main message regarding the heterogeneous results with a possible underestimation of the reoperation rate. In addition, the heterogeneity of the data did not allow us to perform a meta-analysis.

To conclude, there is an urgent need to improve safety monitoring of MUSs as our systematic review highlights that the safety data available at 5 yr and beyond are heterogeneous and of insufficient quality to guide the decision. Recommendations on standardized reporting of complications are therefore necessary. There is a lack of RCT data and heterogeneity outcomes.

Recent access to national healthcare databases for research, constitution of large national observatories (such as VIGI-MESH), or mandatory postmarketing surveillance (-such as MAUDE) are key opportunities to greatly enhance the long-term assessment of MUS safety, and more generally of medical devices, and their use must be supported.

In practice, better-quality data would be needed to adequately assess the safety of medical devices and thus inform patients, surgeons, and health authorities. A first step could be the definition of a core set of outcomes to be reported in each study. In addition, studies using real-world evidence from medicoadministrative databases may be very useful to document some long-term safety, so their use should be promoted as research findings for long-term safety assessment in these databases. However, our results encourage us to be cautious about the message delivered to patients about the long-term complications of these devices, which are poorly reported in the available literature.

***Author contributions*:** Cyrille Guillot-Tantay had full access to all the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.

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Acquisition of data: Guillot-Tantay, Van Kerrebroeck.
Analysis and interpretation of data: Guillot-Tantay, Dechartres, Tubach.
Drafting of the manuscript: Guillot-Tantay, Dechartres, Tubach.
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Statistical analysis: Guillot-Tantay, Dechartres, Tubach.
Obtaining funding: None.
Administrative, technical, or material support: None.
Supervision: Chartier-Kastler, Tubach, Dechartres.
Other: None.

Financial disclosures: Cyrille Guillot-Tantay certifies that all conflicts of interest, including specific financial interests and relationships and affiliations relevant to the subject matter or materials discussed in the manuscript (eg, employment/affiliation, grants or funding, consultancies, honoraria, stock ownership or options, expert testimony, royalties, or patents filed, received, or pending), are the following: None.

***Funding/Support and role of the sponsor*:** None.

Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.euros.2023.05.013.

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