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REVIEW ARTICLE

De novo overactive bladder following midurethral sling procedures: a systematic review of the literature and meta-analysis

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Abstract
Introduction and hypothesis De novo overactive bladder (OAB) is a known complication of midurethral sling surgery for the treatment of stress urinary incontinence. To date, differences in the incidence of de novo OAB following the use of different types of midurethral sling remain relatively unknown. The purpose of the present systematic review was to evaluate this incidence and summarize current evidence.
Methods We systematically searched the literature using the MEDLINE, Embase, Scopus, ClinicalTrials.gov, LILACS and Cochrane Central Register of Controlled Trials databases as well as the grey literature and references from the electronically retrieved articles. For comparisons of proportions, we used the chi-squared test. All reported analyses were designed as two-tailed. Statistical significance was set at $p < 0.05$.
Results Finally, 32 studies were included in this systematic review, with a total of 3,139 patients who had undergone midurethral sling procedures that included transobturator tapes (TOT), retropubic tapes (TVT) or single-incision tapes (mini-slings). The overall incidence of de novo OAB was 11.5% in nonrandomized studies (280 women) and 6.4% in randomized studies (50 women). In relation to the type of midurethral sling, the incidence of de novo OAB was 9.7% for mini-slings, 11.2% for TVT-O, 8.7% for TOT and 9.8% for TVTs. The chi-squared test did not reveal significant differences ($p = 0.58$).
Conclusions Current evidence suggests that the overall incidence of de novo OAB following midurethral sling procedures is approximately 9%. There is not enough evidence to support differences in the effects of the different types of sling with regard to this particular postoperative complication.

Keywords Incontinence · Stress urinary incontinence · Overactive bladder · Urgency · Urethral slings

Introduction

The joint terminology report of the International Urogynecological Association (IUGA) and the International Continence Society (ICS) defines overactive bladder (OAB) as "urinary urgency, usually accompanied by frequency and nocturia, with or without urgency urinary incontinence, in the absence of urinary tract infection (UTI) or other obvious pathology" [1]. Infection or other pathological conditions (such as bladder tumours, stones or outlet obstruction) should be excluded. Detrusor overactivity refers to a pattern of bladder muscle contractions that are observed during urodynamic investigations.

The most common risk factors for developing OAB are increasing age and body mass index, smoking, menopause, pelvic organ prolapse and pre-existing stress urinary incontinence. Prolapse surgery and continence surgery have also been shown to affect OAB incidence. Prolapse repair resulted in improvement in OAB symptoms in over 80% of the patients in a study that evaluated the influence of prolapse stage on the resolution of urgency symptoms and urgency

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incontinence after prolapse correction [2]. OAB has a direct impact on the patients' quality of life (QoL). Women with OAB report significantly decreased health-related QoL and high levels of anxiety and depression, and are more likely to seek treatment for nocturia, frequency and urgency [3]. OAB also seems to affect sleep, general health perception, coping capacity and severity of urinary problems [4].

OAB is common in patients with urinary incontinence. Its aetiology is unclear; however, it is often associated with excessive contractile activity of the detrusor muscle. Surgery in patients with mixed urinary incontinence has been shown to improve the urge component of the incontinence, but not as much as the improvement in the stress component [5]. De novo OAB in patients with no previous findings of urgency incontinence has been seen following placement of a midurethral sling. This poses a significant problem as women with previous stress incontinence and surgery have already suffered a significant impact on their QoL, and therefore having a bothersome lower urinary tract symptom replaced by another one following surgery is something that should ideally be avoided or at least quantified in terms of its prevalence to assist preoperative counselling. To date, it remains unclear whether different types of sling are associated with different outcomes. The purpose of the present systematic review is to summarize current evidence on the specific outcome of de novo OAB following stress incontinence surgery and possibly provide directions for clinical practice and future research.

Materials and methods

Study design

The present study was designed according to the PRISMA guidelines [6]. Eligibility criteria were predetermined by the authors. No language or date restrictions were applied during the literature search. All prospective and retrospective observational studies which investigated the incidence of de novo OAB after insertion of a midurethral sling were considered as eligible for inclusion. The definition of OAB was based on the definitions used by the authors of the different studies. Case reports, reviews and animal studies were excluded. Articles that failed to report information on de novo OAB after these surgical procedures were excluded, along with those that dealt only with urinary incontinence after surgical procedures and those that included patients having bladder neck surgery for urinary incontinence. Studies that enrolled patients with symptoms of mixed urinary incontinence preoperatively and those that included patients who had undergone simultaneous surgery for pelvic organ prolapse (including vaginal hysterectomy, colporrhaphy and vaginal mesh procedure) were also excluded to avoid bias due to unmasking of pre-existing urgency after improvement of stress urinary symptoms. Whenever data from a particular study sample appeared in more than one publication, the article with the most complete follow-up data was used. Stratification for follow-up was not predesigned and was therefore not performed as it was anticipated that the studies would have different lengths of follow-up. No language restrictions were applied. Any discrepancies between the authors during data collection were resolved by the consensus of all authors.

Literature search and data collection

We systematically searched the literature using the MEDLINE (1966–2016), Embase (1947–2016), Scopus (2004–2016), ClinicalTrials.gov (2008–2016), LILACS (1982–2016), and Cochrane Central Register of Controlled Trials (CENTRAL) databases as well as the grey literature and the references from the electronically retrieved articles.

Specifically MEDLINE, Scopus, and ClinicalTrials.gov were searched using the keywords "TOT", "TVT", "TVT-O", "TVT-S", "TVT-secure", "sling surgery" and "(anti)incontinence surgery" in combination with "overactive bladder". Embase was searched using the keywords TOT", "TVT", "TVT-O", "TVT-S", "TVT-secure" and "sling surgery" in combination with "overactive bladder", the CENTRAL database was searched using the keyword "overactive bladder", and the LILACS database was searched using the term "de novo overactive bladder". The search strategy is summarized in Fig. 1.

Quality assessment

The methodological quality of all the included studies was assessed using the Oxford Level of Evidence criteria and the GRADE list [7]. The randomized trials were evaluated using the modified Jadad score, which briefly assesses the description of studies as randomized along with details of the randomization, the description of studies as double-blind and the details of the double blinding procedure, information on withdrawals and allocation concealment (Fig. 2) [8].

Statistical analysis

The chi-squared and Fisher's exact tests were used to compare proportions. All reported analyses were designed as two-tailed. Statistical significance was set at $p < 0.05$. The SPSS version 22.0 was used for the analyses (IBM Corp., Armonk, NY).

Meta-analysis

Meta-analysis of proportions was undertaken and a separate subgroup analysis according to the type of sling used was performed using MedCalc® (MedCalc Software, Ostend, Belgium). The heterogeneity among the studies was assessed using the chi-squared and the I^2-statistic tests. Statistical

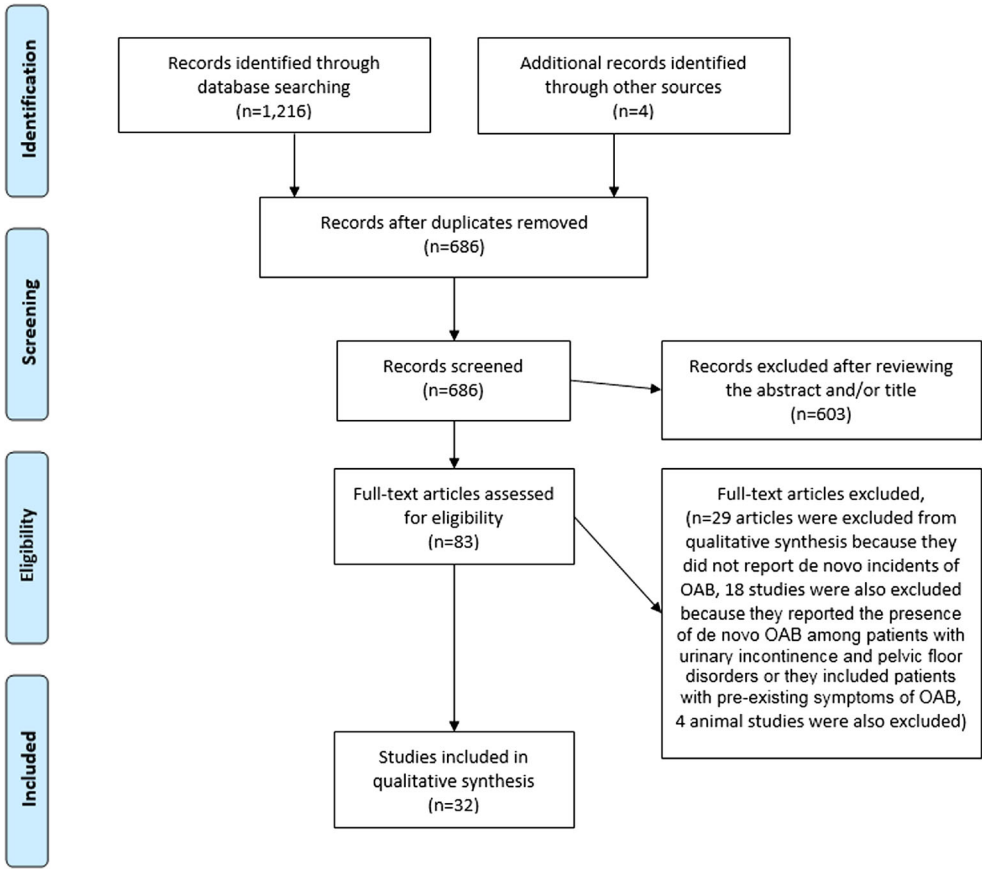

Fig. 1 Search strategy for identifying studies for inclusion

significance was set at $p < 0.05$ for the analysis of heterogeneity. Pooled odds ratios and 95% confidence intervals (CI) for all primary and secondary outcomes were calculated using both the Mantel-Haenszel fixed effects and the DerSimonian-Laird random effects models. Specifically, for all analyses, the results from fixed effects model are presented when both the chi-squared and I^2-statistic tests indicated no heterogeneity among the studies. When statistically significant heterogeneity was present, the results were analysed using the random effects model.

Results

Excluded studies

Five randomized trials were excluded because they reported the presence of de novo OAB among patients with urinary incontinence and vaginal prolapse, corrected either with simple colporrhaphy or with the use of synthetic mesh [9–13]. Ten nonrandomized studies were also excluded for the same reason [14–23]. Another study was excluded because it included patients with pre-existing OAB [24].

Included studies

Finally, 32 studies were included in this systematic review, with a total of 3,139 patients who had undergone midurethral sling procedures including transobturator tapes (TOT), retropubic tapes (TVT) or single-incision tapes (mini-slings) [25–55]. The data from these studies were tabulated in two structured tables. Table 1 shows the details of the randomized controlled trials and Table 2 shows the details of the nonrandomized studies.

	2010; Lee	2014; Laurikainen	2016; Masata
Was the study described as random?	+	+	+
Was the randomization scheme described and appropriate?	+	+	+
Was the study described as double-blind?	–	–	–
Was the method of double blinding appropriate?	–	–	–
Was there a description of dropouts and withdrawals?	+	+	+

Fig. 2 Jadad scores for the methodological evaluation of the randomized trials included (Lee et al. [26], Laurikainen et al. [31], Masata et al. [32])

Table 1 Characteristics and outcomes of the randomized controlled studies

Reference	No. of patients	Type of procedure	De novo OAB	Method of assessment	Type of treatment	Comparison	Mean follow up
[26]	285	Mini-sling	21	ICIQ-FLUTS, VAS	Midurethral sling	TVT-Secur U-shaped vs. hammock	12 months
[31]	131	TVT	4	UISS, VAS	Midurethral sling	TVT vs. TVT-O	5 years
[31]	123	TVT-O	3	UISS, VAS	Midurethral sling	TVT vs. TVT-O	5 years
[32]	47	TVT-O	4	ICIQ-SF	Midurethral sling	TVT vs. TVT-Ajust	12 months
[32]	49	Mini-sling	5	ICIQ-SF	Midurethral sling	TVT vs. TVT-Ajust	12 months

TVT tension-free vaginal tape, *TVT-O* tension-free vaginal tape-obturator, *ICIQ-FLUTS* International Consultation on Incontinence Questionnaire–Female Lower Urinary Tract Symptoms, *ICIQ-SF* International Consultation on Incontinence–Short Form, *UISS* Urinary Incontinence Severity Score, *VAS* visual analogue scale

The overall incidence of de novo OAB was 11.5% in the nonrandomized studies (280 women) and 6.4% in the randomized studies (50 women) ($p = 0.024$). In relation to the type of midurethral sling, the incidence of de novo OAB was 9.7% for mini-slings, 11.2% for TVT-O, 8.7% for TOT and 9.8% for TVTs. The chi-squared test did not reveal significant differences ($p = 0.58$). The meta-analysis of proportions revealed significant heterogeneity among the nonrandomized studies (OAB in 11.76% of women, 95% CI 9.351–14.406, data from 2,570 women; Supplementary Fig. 1). Subgroup analysis revealed the following: OAB in 14.91% of women treated with TVT (95% CI 9.578–21.169, data from 768 women; Supplementary Fig. 2), OAB in 8.45% of women treated with TOT (95% CI 5.115–12.714, data from 716 women; Supplementary Fig. 3), OAB in 11.04% of women treated with mini-sling (95% CI 6.769–16.200, data from 500 women; Supplementary Fig. 4), and OAB in 12.66% of women treated with TVT-O (95% CI 7.305–19.217, data from 520 women; Supplementary Fig. 5).

The meta-analysis of proportions revealed moderate heterogeneity In the randomized studies (OAB in 5.88% of women, 95% CI 3.321–9.127, data from 635 women; Supplementary Fig. 6).

Discussion

The incidence of de novo OAB following sling surgery for stress urinary incontinence, ranges between 5% and 22%. The overall prevalence of OAB has been reported to be 16.9% in the USA [56, 57]; in Europe, the prevalence in the general population aged over 40 years is similar (16.6%) [58]. Billions of dollars are spent annually in the USA alone on its management [59]. OAB and urinary urgency incontinence can have a detrimental negative impact on QoL [60]. This is why it is always important to advise the patient about the risks of stress urinary incontinence surgery and the probability of developing OAB later on. According to Boustead, de novo OAB, urinary urgency incontinence and persisting urgency are the most troublesome complications following midurethral tape surgery [61].

This review summarizes the existing data in the literature on de novo OAB following midurethral sling surgery. This will enable the clinician to appropriately advise patients preoperatively on the benefits and risks of the procedure so that the outcome of surgery will better meet patient expectations. During the design of the present systematic review we hoped that current data would be sufficient to reach definitive conclusions regarding differences in the risk of de novo OAB with the different types of sling. However, to date, evidence remains inconclusive and the design of randomized trials, which will specifically include de novo OAB as one of the primary outcome measures, seems to be important, as the majority of studies included in the present systematic review reported de novo OAB as a secondary outcome with a variety of assessment tools.

Previous clinical studies and reviews have proposed various potential pathophysiological mechanisms that may contribute to this pathology. Therefore, postoperative OAB may be part of mixed preoperative incontinence which becomes more prominent for the patient after the cure of stress urinary incontinence. Alternatively, surgery may affect part of the nerve supply to the lower urinary tract leading to OAB. Bladder outlet obstruction is another possible cause of de novo OAB after continence procedures. Sling division may be required in some patients if the symptoms are very bothersome; this is the case for 2–3% of midurethral or pubovaginal slings [15, 62].

Limitations of the study

A number of possible limitations should be considered in the assessment of the results of the present review. Firstly, the nonrandomized design of the majority of studies included introduced several potential biases, including selective reporting, attrition and publication bias. The wide variation in the definitions and terminology made the selection and assessment of the current literature difficult. OAB is often

Table 2 Characteristics and outcomes of the observational studies

Reference	No. of patients	Type of procedure	De novo OAB	Method of assessment	Mean follow up (months)
[39]	45	Midurethral sling	11	Not specified	6
[37]	21	Midurethral sling	0	KHQ	12
[29]	76	TVT	16	Not specified	>12
[38]	98	TVT	5	IIQ-7, UDI-6	6
[43]	45	TVT	13	Validated Likert scale	3
[43]	118	TVT	13	Validated Likert scale	12
[44]	28	TVT	9	Validated Likert scale	3
[44]	18	TVT	4	Validated Likert scale	3
[40]	55	TVT	10	Not specified	12
[28]	70	TVT	2	KHQ	6
[48]	42	TVT	7	IIQ-7, UDI-6	24
[51]	20	TVT	6	IIQ-7, UDI-6	12
[49]	128	TVT	5	GRA, ICIQ-SF	144
[30]	70	TVT	7	PFIQ-7, PISQ-12	12
[27]	91	Mini-sling	9	ICIQ-SF, W-IPSS	12
[34]	106	Mini-sling	6	KHQ, VAS	12
[33]	87	Mini-sling	6	Not specified	12
[35]	37	Mini-sling	2	ICIQ-SF, KHQ, UISS, VAS	12
[36]	45	Mini-sling	5	PGI-I	6
[25]	82	Mini-sling	20	ICIQ-SF, VAS	12
[50]	52	Mini-sling	7	ICIQ-SF, ICIQ-OAB	12
[44]	23	TOT	5	Validated Likert scale	3
[40]	49	TOT	8	Not specified	12
[41]	92	TOT	4	Not specified	12
[42]	128	TOT	19	Not specified	12
[52]	27	TOT	2	Not specified	60
[46]	30	TOT	0	Not specified	12
[49]	202	TOT	12	GRA, ICIQ-SF	>60
[54]	42	TOT	1	OAB V8	60
[55]	123	TOT	11	KHQ	12
[35]	38	TVT-O	1	ICIQ-SF, KHQ, UISS, VAS	12
[45]	91	TVT-O	10	Not specified	12
[45]	106	TVT-O	10	Not specified	12
[47]	160	TVT-O	23	ICIQ-SF, PGI-I, validated Likert scale	120
[53]	55	TVT-O	18	KHQ, IOQ, FSFI, PGI-I	120
[30]	70	TVT-O	6	PFIQ-7, PISQ-12	12

TOT transobturator tape, *TVT* tension-free vaginal tape, *TVT-O* tension-free vaginal tape-obturator, *FSFI* Female Sexual Function Index Questionnaire, *GRA* Global Response Assessment Scale, *KHQ* King's Health Questionnaire, *OAB V8* Overactive Bladder-Validated 8 questionnaire, *PFIQ-7* Pelvic Floor Impact Questionnaire, *PGI-I* Patient Global Impression of Improvement scale, *PISQ-12* Pelvic Organ Prolapse/Urinary Incontinence Sexual Function Questionnaire–Short Form, *ICIQ-OAB* International Consultation on Incontinence Overactive Bladder symptoms questionnaire, *ICIQ-SF* International Consultation on Incontinence–Short Form, *IIQ-7* Incontinence Impact Questionnaire score, *IOQ* Incontinence Outcome Questionnaire, *UDI-6* Urinary Distress Inventory score, *UISS* Urinary Incontinence Severity Score, *VAS* visual analogue scale, *W-IPSS* Women's Irritative Prostate Symptom Score

termed urinary urgency, frequency, nocturia, detrusor instability and detrusor overactivity, which makes a literature review on this subject even more puzzling. Furthermore, in the majority of included studies, the follow-up was limited to a maximum of 12 months; therefore, our review provides information mainly about short-term "de novo" OAB. In this context, it would be of interest to evaluate the course of OAB with time from surgery. All the studies included evaluated urinary

symptoms but with different, albeit validated, questionnaires. It is therefore possible that some of the studies underestimated the impact of sling surgery on the occurrence of OAB.

Conclusions

Current evidence suggests that the overall incidence of de novo OAB following midurethral sling procedures is approximately 9%. There is not enough evidence to support the beneficial effect of specific types of sling. Given the fact that bladder overactivity may significantly affect the QoL of patients, physicians should inform women prior to midurethral sling procedures for the treatment of uncomplicated stress urinary incontinence about this possible side effect and its anticipated incidence rate.

Compliance with ethical standards

Funding None.

Conflicts of interest S. Doumouchtsis has received travel grants and sponsorship to attend conferences from Speciality European Pharma. He has also received speaker Honorarium from Astellas. The other authors have no conflicts of interest to report.

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