

Should prophylactic anti-incontinence procedures be performed at the time of prolapse repair? Systematic review

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Abstract

Introduction and hypothesis Women with high-grade pelvic organ prolapse (POP) are considered at risk of developing postoperative stress urinary incontinence (SUI) once the prolapse has been repaired. The probable explanation for patients remaining subjectively continent is that POP can cause urethral kinking or compression. We hypothesized that performing prophylactic anti-incontinence procedures during surgical POP correction in women with no symptoms for urinary incontinence (UI) may prevent SUI postoperatively.

Methods A systematic review of randomized trials was performed. Participants were women with severe POP and no symptoms of SUI. The primary outcomes were UI or treatment for this condition after the surgical procedure. Results are presented as relative risk (RR), with 95 % confidence interval (95 %).

Results Initially, 5,618 studies were identified by the search strategy, but only seven trials met the inclusion criteria. We performed a meta-analysis with common variables of studies and with the same scale of quantification. We found that performing an anti-incontinence procedure at the same time of prolapse repair reduced the incidence of SUI postoperatively (RR 0.51; 95 % CI 0.38–0.68). However, when the types of anti-incontinence procedure were analyzed separately, we found different results. The subgroup of patients who underwent retropubic midurethral sling surgery was the only group that benefited from the anti-incontinence procedure,

with a decrease in the incidence of SUI (RR 0.09; 95 % 0.02–0.36).

Conclusions Prophylactic treatment of women with severe POP using retropubic midurethral sling was the only procedure that reduced the risk of UI.

Keywords Pelvic organ prolapse · Occult urinary incontinence · Systematic review · Stress urinary incontinence · Meta-analysis

Introduction

Stress urinary incontinence (SUI) is defined as involuntary loss of urine during physical activity, coughing, or sneezing, according to the International Continence Society (ICS) [1]. In addition to SUI, pelvic organ prolapse (POP) is another pelvic floor dysfunction. The risk factors for both entities are the same and may be present simultaneously, especially in the presence of more severe forms of prolapse [2]. However, when a clinically continent patient with advanced prolapse develops urinary incontinence (UI) after reduction of genital prolapse, this condition is called occult stress incontinence [1]. The probable explanation for the fact that these patients were continent prior to surgery may be urethral kinking or even extrinsic compression of the urethra by the genital prolapse, which acts as a mechanism that increases urethral resistance to the passage of urine [3]. Therefore, when the obstructive factor is removed by surgical correction or prolapse reduction, patients may present leakage of urine during physical stress. Some authors recommend treating occult stress incontinence in a second procedure, after correcting the genital prolapse [4]. Nevertheless, other authors, with the purpose of reducing costs involved in a new hospitalization and risks arising from a new surgical procedure, have conducted a considerable series of studies assessing the effectiveness of correcting

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occult stress incontinence and treating genital prolapse in a single procedure [3].

Therefore, in view of such a controversial topic, we hypothesized that performing prophylactic anti-incontinence procedures during surgical POP correction in women with no UI symptoms may prevent SUI postoperatively.

Materials and methods

This systematic review of controlled clinical trials was conducted in accordance with the systematic review guidelines provided by the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) checklist. We selected studies with clinically continent adult women with anterior genital or vaginal vault prolapse classified as grade 3 or 4 according to the Pelvic Organ Prolapse Quantification (POP-Q) system or the Baden–Walker system. A group of patients who underwent surgical correction of genital prolapse only was compared with another group in which this correction was associated with a concomitant prophylactic surgery to prevent UI. The primary outcome evaluated was the incidence of SUI after surgical correction of prolapse or the need of surgical treatment for SUI. Secondary outcome comprised adverse events related to these surgical procedures.

Strategy for literature review

We performed a systematic literature review of articles published in PubMed, Embase, Cochrane Library, and Lilacs databases up to 12 January 2014. For this purpose, we developed a research strategy based on descriptors and synonyms for UI and genital organ prolapse, with no limitations regarding study research design, time of publication, language, or country of origin. The study screening process was performed by two independent researchers. At the end of this stage, their selections were compared, and discrepant cases were solved by consensus. All selected studies were assessed by two researchers for their methodological quality and risk of bias using the technique developed by Jadad et al. in 1996 and the levels of evidence established by the Oxford Centre for Evidence-Based Medicine [5, 6]. The evaluation of methodological quality was used to analyze the strength of evidence provided by each study rather than as an inclusion criterion for the literature review.

Statistical analysis

Noncontinuous variables were expressed as weighted mean difference and continuous variables as relative risk (RR), both with a confidence interval of 95 % (95 %). The value used for rejecting the null hypothesis was 5 %. After the systematic review, a meta-analysis was performed using the Cochrane

RevMan software, version 5.1. Dichotomous variables were analyzed using the Mantel–Haenszel statistical method in a random-effects model of RR with 95 %. Study heterogeneity was calculated by I^2 . Articles were divided into subgroups according to type of anti-incontinence procedure performed.

Results

Initially, 5,618 studies were identified by the formulated search strategy. This included articles retrieved from each database searched, related articles, and references analyzed in the selected studies. Of those, 2,645 articles were retrieved from MEDLINE via PubMed, 2,862 from Embase, 95 from Cochrane Library, and 16 from LILACS. We selected 66 articles for full-text analysis, but only seven eligible trials fulfilled the necessary prerequisites for this systematic review according to PRISMA checklist (Fig. 1) [7–16]. In this review, there were 956 patients [7–17]. Altogether, the review included trials of four different types of anti-incontinence procedures: midurethral sling (retropubic and transobturator), Burch colposuspension, needle colposuspension, and cystopexy with posterior pubourethral ligaments plication [7–16].

Surgeries for prolapse correction were not standardized and included the following techniques: vaginal hysterectomy, anterior repair, paravaginal anterior repair, posterior repair, sacrospinous ligament vaginal suspension, bilateral iliococcygeus vaginal suspension, culdoplasty,

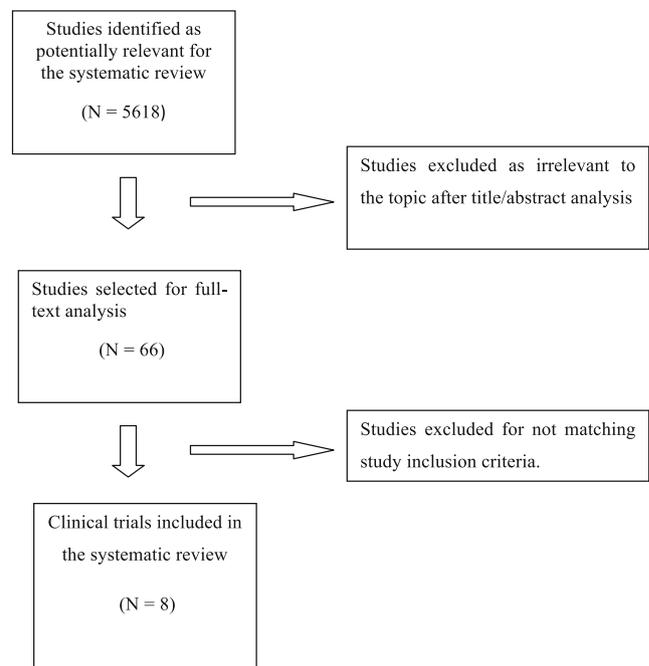


Fig. 1 Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) flow diagram

sacrocolpopexy, perineoplasty, colpocleisis, and prolapse surgery with Prolift [7–16]. Methodological analysis of the studies is summarized in Table 1. Methods of diagnosing occult stress incontinence in each study were not similar, and the number of patients diagnosed with it is listed in Table 2.

A meta-analysis calculus was performed with common variables of studies and the same scale of quantification. First, we analyzed the global effect of anti-incontinence procedures in terms of incidence of UI after surgical procedure (Fig. 2) [7, 8, 11–16]. It is important to emphasize that we only included five clinical trials in this first analysis, because they had similar outcomes [7, 8, 11–16].

We found that performing any prophylactic anti-incontinence procedure at the same time as prolapse repair reduced the incidence of SUI postoperatively (RR 0.51; 95 % CI 0.38–0.68). However, when types of anti-incontinence

procedures were analyzed separately, we found different results. In the subgroup of patients who underwent a retropubic midurethral sling procedure, it was beneficial in reducing the incidence of surgical treatment of SUI postoperatively (RR 0.09; 95 % CI 0.02–0.36) (Fig. 3) [7–9]. On the other hand, there was no significant difference between the subgroup that underwent Burch colposuspension and the control group in terms of the incidence of SUI postoperatively (RR 1.47; 95 % CI 0.28–7.79) [11–15].

Surgical adverse effects are listed in Table 3. We performed a meta-analysis of clinical trials that showed similar outcomes and analyzed studies that used tension-free vaginal tape (TVT)—from Schierlitz et al. and Wei et al. Adverse effects of TVT in terms of bladder perforation showed 24 times greater chance of bladder perforation compared with prolapse correction only (RR 24.12; 95 % CI 1.43–405.55) and two

Table 1 Methodological analysis of included clinical trials

Author	Year	Oxford CEBM scale	Jadad score	Loss to follow-up	Primary outcome	Follow-up times	Intervention (n)	Control (n)	Study
1 Wei et al. [7]	2012	1b	5	Intervention: 3 Control: 7 (in 1 year)	In 3 months, symptoms, stress test or treatment for SUI. In 12 months, symptoms or treatment for SUI.	3 months, 12 months	Prolapse repair + TVT (165)	Prolapse repair + sham (172)	Article
2 Khelaia et al. [8]	2010	2b	1	Not reported	De novo SUI	Mean de follow-up time: intervention (51 months), control (53 months)	Anterior colporrhaphy + TVT (46)	Anterior colporrhaphy (46)	Abstract
3 Schierlitz et al. [9]	2014	1b	1	Intervention: 2 Control: 4 (in 6 months)	Need of subsequent SUI surgery	6 months, 27 months	Prolapse repair + TVT (37)	Prolapse repair (43)	Article
4 Fuentes et al. [10]	2011	2b	1	Not reported	Need of subsequent SUI surgery	6 months, 15 months	Prolapse repair + TVTo (27)	Prolapse repair (33)	Abstract
5 Brubaker et al. [11–14]	2008	1b	5	Intervention: 5 Control: 12 (in 1 year)	SUI (stress test or urgency symptoms) sacrocolpopexy (165)	3 months, 1 year, 2 years, 7 years Article	Burch colposuspension with abdominal sacrocolpopexy (157)	Abdominal	Article
6 Costantini et al. [15]	2007	2b	1	No losses (in 6 months)	SUI (UDI questionnaire and stress test)	3 months, 6 months, 12 months	Burch colposuspension with sacropexy (34)	Colposacropexy (32)	Article
7 Colombo et al. [16]	1996	1b	3	Not reported	Patients history of SUI symptoms and stress test	12 months	Cystopexy with posterior pubourethral ligaments plication (50)	Cystopexy alone (52)	Article

Oxford CEBM Oxford Centre for Evidence-Based Medicine, *SUI* stress urinary incontinence, *TVT* tension-free vaginal tape, *POPQ* Pelvic Organ Prolapse Quantification, *ICIQ* International Consultation on Incontinence Modular Questionnaire–Lower Urinary Tract Symptoms Quality of Life, *TVTto* tension-free vaginal tape transobturator tape, *UDI* Urogenital Distress Inventory

Table 2 Methods of diagnosing and number of patients with occult stress incontinence (OSI) in each clinical trial

Study number	Author	Year	Intervention (n)	Control (n)	OSI diagnosis	OSI
1	Wei et al. [7]	2012	Prolapse repair + TVT (165)	Prolapse repair + sham (172)	URD reduction with swabs	111 patients with OSI
2	Khelaia et al. [8]	2010	Anterior colporrhaphy + TVT (46)	Anterior colporrhaphy (46)	Reduction with pessary	46 patients with OSI (group TVT)
3	Schierlitz et al. [9]	2014	Prolapse repair + TVT (37)	Prolapse repair (43)	Prolapse reduction with Sims' speculum or opened sponge forceps	Not detailed
4	Fuentes et al. [10]	2011	Prolapse repair + TVT (27)	Prolapse repair (33)	Does not report how prolapse was reduced in URD	60 patients with OSI
5	Brubaker et al. [13]	2008	Burch with abdominal sacrocolpopexy (157)	Abdominal sacrocolpopexy (165)	No standardization for prolapse reduction (speculum, hands, swabs, pessary)	Not detailed
6	Costantini et al. [15]	2007	Burch colposuspension with sacropepy (34)	Colposacropexy (32)	URD: prolapse reduction with Sims' speculum positioned at the anterior fornix and with fingers	0 patients with OSI
7	Colombo et al. [16]	1996	Cystopexy with posterior pubourethral ligaments plication (50)	Cystopexy alone (52)	URD: prolapse reduction with Sims' speculum positioned at the anterior fornix (Bump et al. [18])	102 patients with OSI

SUI stress urinary incontinence, TVT tension-free vaginal tape, URD urodynamics, TVT_o tension-free vaginal tape transobturator tape

times greater risk of major bleeding (RR 2.31; 95 % CI 0.11–47.74) [7, 9].

Discussion

Currently, when it comes to therapeutic interventions, it is unacceptable that a treatment indication is not based on the best level of scientific evidence, along with physician clinical experience and patient expectations. When focusing specifically on the best level of scientific evidence to determine the effectiveness of an intervention, the systematic review of randomized controlled trials combined with meta-analysis is

the research design that shows the highest degree of recommendation and the highest level of evidence [17, 19].

The indication to perform an anti-incontinence procedure during prolapse repair in asymptomatic patients is one of the most controversial topics in urogynecology. Therefore, the strength of this systematic literature review with meta-analysis is that it was conducted specifically to assess the impact of anti-incontinence procedures during surgical correction of prolapse in women who had severe genital prolapse and no symptoms of stress incontinence. An important aspect of this study is that it was possible to analyze the type of anti-incontinence procedure and compare the impact of each one individually, considering that Burch and retropublic

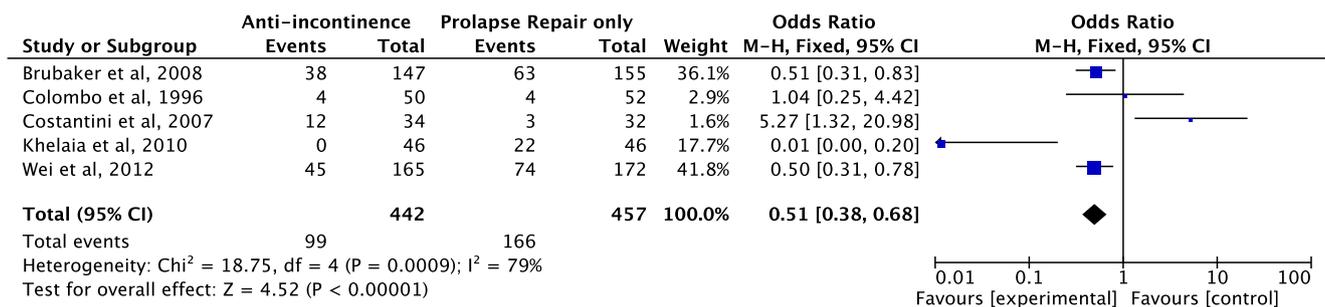


Fig. 2 Global effect of anti-incontinence procedures on the incidence of urinary incontinence (UI) after surgical treatment for prolapse correction. 95 % CI 95 % confidence interval. Anti-incontinence group patients who

underwent surgical correction of genital prolapse associated with an anti-incontinence prophylactic surgery. Control group patients who underwent surgical correction of genital prolapse

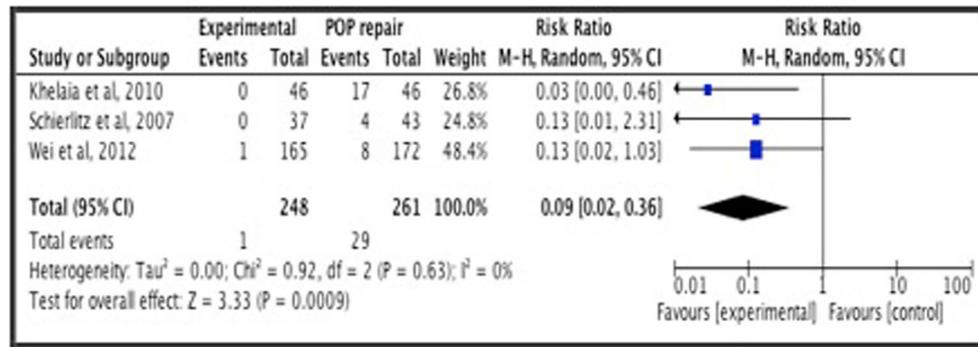


Fig. 3 Effect of retropubic midurethral sling procedure on the incidence of surgical treatment for urinary incontinence (UI) after surgical treatment for prolapse correction. 95 % CI 95 % confidence interval. *Experimental*

group patients who underwent surgical correction of genital prolapse associated with anti-incontinence prophylactic surgery. *POP group* patients who underwent surgical correction of genital prolapse

midurethral slings have very different mechanism of action and different complications.

We chose investigations that assessed only patients with no clinical signs of UI before prolapse reduction. It is known that

prolapse reduction during preoperative urodynamic studies may reveal occult stress incontinence in 36–80 % of women with severe genital prolapse [2, 20]. In these circumstances, in patients with urinary loss after prolapse reduction, it is

Table 3 Adverse effects of surgical treatment

Study number	Author	Intervention (n)	More common adverse effects	Severe adverse effects
1	Wei et al. [7]	Prolapse repair + TVT (165)	Rates of bladder perforation, urinary tract infection, major bleeding complications, and incomplete bladder emptying in the first 6 weeks after surgery were all higher in the sling group than in the sham group. There were no mesh erosions resulting from sling placement. Bladder perforations due to sling placement were all managed during surgery without long-term consequences	Intervention group: 28 of 165 and control 20/172
2	Khelaia et al. [8]	Anterior colporrhaphy + TVT (46)	Not described	Not described
3	Schierlitz et al. [9]	Prolapse repair + TVT (37)	Complications reported in the TVT/non-TVT groups were hemorrhage (blood loss >500 ml) with 1 (4 %) vs. 2 (7 %) (although no blood transfusion was required in any patient), voiding difficulty postoperatively with urethral catheterization in 1 (4 %) vs. 1 (3.7 %), or intermittent clean self-catheterization in 2 (8 %) vs. 0 (0 %) for 6–10 days postsurgery	No
4	Fuentes et al. [10]	Prolapse repair + TVT (27)	Not described	Not described
5	Brubaker et al. [11]	Burch colposuspension with abdominal sacrocolpopexy (157)	There were no statistically significant differences between groups in any obstructive symptoms at 1 year. Fewer women in the Burch group had urge incontinence symptoms than in the no-Burch group (14.5 vs. 26.8 %, $p=0.048$). No other statistically significant differences were found between groups in terms of irritative symptoms, including irritative subscale score, bothersome irritative symptoms, any irritative symptoms, or composite urge endpoint after 1 year	Percentage of women who had serious adverse events within 3 months after surgery was similar in the two groups (14.6 % in the Burch group and 14.5 % in the control group, $p=0.79$).
6	Costantini et al. [15]	Burch colposuspension with sacrocolpopexy (34)	Wound hematoma: Intervention 1/34 and control 0/32 Voiding disturbances: Intervention 3/34 and control 0/32	Blood transfusion: Intervention 3/34 and control 3/32
7	Colombo et al. [16]	Cystopexy with posterior pubourethral ligaments plication (50)	12 (23 %) control vs. 14 (28 %) patients required intermittent self-catheterization for 11 and 16 days, respectively ($p=0.002$); voiding difficulties in zero and five (10 %) patients, respectively ($p=0.02$). One patient in the intervention group was readmitted 29 days after surgery to undergo urethral dilation	No

SUI stress urinary incontinence, TOT transobturator tape, TVT tension-free vaginal tape, TVT_o tension-free vaginal tape transobturator tape

suggested that a prophylactic anti-incontinence procedure should be performed during prolapse repair to prevent postoperative SUI [2, 3, 21]. Our meta-analysis found that retropubic midurethral sling was the only anti-incontinence procedure that leads to a significant reduction in the incidence of UI [7–10]. However, methods of reducing the prolapse in the urodynamic evaluation were different between studies.

Assessing occult stress incontinence is still controversial. Visco et al. studied five different methods of prolapse reduction: pessary, manual, swab, forceps, and speculum. Detection rates of SUI with prolapse reduction varied significantly by reduction method. However, although sensibility and sensitivity among methods varied, the authors found that positive predictive value for postoperative leakage did not differ statistically among the methods [22]. Additionally, it is important to note that the number of patients diagnosed with occult stress incontinence in each study varied. Probably, preoperative urinary loss during the reduction test was associated with a higher risk for postoperative SUI [22]. In this systematic review, the studies presented disproportional number of patients with occult UI. This distribution imbalance could lead to biased conclusions in the studies. An alternative to solving this risk of bias would be to evaluate the impact of prophylactic anti-incontinence procedure separately in patients with occult UI and compare them with patients with no preoperative urine loss after reducing the prolapse.

It is essential, therefore, to balance all benefits and adverse effects of performing an anti-incontinence procedure. A concern related to additional TVT in patients with occult UI is the possibility of a higher rate of intraoperative complications, which are primarily associated with the risk of bladder perforation; however, recent literature provides increasing evidence that more serious complications may arise, such as hemorrhage in the space of Retzius, laceration of external iliac vessels, bowel perforation, or even obturator nerve injury [23]. In our study, adding an anti-incontinence procedure concomitant with prolapse surgery increases the likelihood of adverse events. Preventing SUI is an important surgical goal when treating POP. However, when this is associated with other bothersome urinary symptoms, it can decrease postoperative patient satisfaction [24, 25]. Another issue to be considered was the fact procedures for genital prolapse correction varied greatly between studies, which may have influenced treatment effectiveness. Moreover, these studies did not have a standardized follow-up time. Differently from the meta-analysis performed by Maher et al. [26], our study included only randomized clinical trials published up to January 2014, in addition to the studies by Fuentes et al. and Schierlitz et al. [9–11].

It is possible to conclude that retropubic midurethral sling was the only anti-incontinence surgery that significantly reduced postoperative SUI rates. Burch procedure did not show a significant decrease, while transobturator slings and needle

colposuspension did not allow meta-analysis because they had different outcomes. However, more randomized studies with standardized surgical techniques and outcomes are needed to evaluate better the prophylactic treatment of occult SUI.

Conflicts of interest None.

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