DOI: 10.1111/1471-0528.14943 www.bjog.org **Systematic review** 

# Prolapse surgery with or without incontinence procedure: a systematic review and meta-analysis

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**Background** To reduce the risk of postoperative stress urinary incontinence (POSUI) prolapse repair might be combined with incontinence surgery.

**Objectives** Compare efficacy and safety of prolapse surgery with and without incontinence surgery.

**Search strategy** Including our earlier review a systematic search in PubMed, EMBASE, the Cochrane Library and the Register of Current Controlled Trials was performed from 1995 to 2017.

**Selection criteria** Randomised trials comparing prolapse surgery with a midurethral sling (MUS) or Burch colposuspension.

**Data collection and analysis** Two reviewers selected eligible articles and extracted data. Stress urinary outcomes were pooled for preoperative SUI. Urgency incontinence and adverse events were pooled for incontinence procedure.

Main results Ten trials were included. Women with preoperative SUI symptoms or occult SUI had a lower risk to undergo subsequent incontinence surgery for POSUI after vaginal prolapse surgery with a MUS than after prolapse surgery only: 0 versus 40% [relative risk (RR) 0.0; 95% CI 0.0–0.2] and 1 versus 15%

(RR 0.1; 95% CI 0.0–0.6), respectively. These differences were not significant in continent women not tested for occult SUI or without occult SUI. Serious adverse events were more frequent after vaginal prolapse repair with MUS (14 versus 8%; RR 1.7; 95% CI 1.1–2.7), but not after sacrocolpopexy with Burch colposuspension. Combination surgery did not increase the risk of overactive bladder symptoms, urgency incontinence and surgery for voiding dysfunction.

**Conclusions** Vaginal prolapse repair with MUS reduced the risk of postoperative SUI in women with preoperative SUI symptoms or occult SUI, but serious adverse events were more frequent.

**Keywords** Burch colposuspension, concomitant, meta-analysis, midurethral sling, occult, pelvic organ prolapse, review, stress urinary incontinence.

**Tweetable abstract** Less stress incontinence after vaginal prolapse repair with sling, but more adverse events.

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#### Introduction

After prolapse surgery women could need subsequent incontinence surgery for persisting or de novo postoperative stress urinary incontinence (SUI). Women with pelvic organ prolapse and coexisting SUI face the highest risk of postoperative SUI. However, women without symptoms of SUI can develop de novo SUI after prolapse repair. The risk of de novo SUI is higher in women with occult SUI

compared with women without occult SUI.<sup>1,3,4</sup> Occult SUI is defined as visible urinary leaking with prolapse reduction in women without symptoms of SUI.<sup>5</sup>

There is strong evidence that prolapse surgery combined with incontinence surgery reduces the risk of postoperative SUI. <sup>1,6</sup> The extent to which this risk is reduced is less clear and it depends on the risk of developing SUI after prolapse surgery only. Besides other predictors, preoperative incontinence is probably the most important risk factor for

postoperative SUI.<sup>7,8</sup> When considering prolapse repair with incontinence surgery, a woman's individual risk of developing postoperative SUI should be predicted as well as possible. Moreover, this should be balanced against the possible risks of combining prolapse and incontinence surgery. Although safety concerns have gained increased attention since the release of the 2011 US Food and Drug Administration health notification on serious complications associated with transvaginal Mesh, only a few randomised trials have reported serious adverse events (SAEs) after combination surgery with a midurethral sling (MUS).<sup>1</sup> Therefore, balancing risks and benefits is still difficult, hampering adequate decision making.

In 2014 we published a systematic review with meta-analysis of the evidence, comparing prolapse surgery only with combination surgery in women with pelvic organ prolapse. Because the evidence was not always clear and new randomised trials have since been published on the subject, we have updated the review with the aim of gaining more understanding of the risks and benefits of prolapse surgery with or without an incontinence procedure.

#### **Methods**

Published previously, our methods are summarised below (see also www.studies-obsgyn.nl/cupido).<sup>1</sup> Randomized clinical trials (RCTs) published in English that compared prolapse repair with and without MUS or Burch colposuspension were eligible for inclusion. All inclusion and exclusion criteria are presented in Appendix S1 of the Supporting Information.

The following databases were searched: MEDLINE (via PubMed), EMBASE, the Cochrane Library and the Register of Current Controlled Trials. The search strategies consisted of keywords related to pelvic organ prolapse and SUI (see Appendix S2). For this update the publication date was limited to January 2013–January 2017, resulting in a complete search for the period 1995–2017. Reference lists of selected full-text articles and reviews were checked for additional articles.

Titles and/or abstracts were independently screened by AS and MP. The full text of potentially relevant articles was assessed for eligibility. Study data were independently extracted using a data extraction sheet as advised by the Cochrane Consumer and Communication Review Group. Any disagreement about inclusion or data was resolved by a consensus meeting. Authors of selected publications were asked whether any further outcome measures not reported were available and the final data extraction sheet was presented to them as a final check to limit the risk of human error.

Because preoperative incontinence is an important predictor for postoperative SUI, and MUS and Burch colposuspension are thought to be equally effective in treating incontinence, we pooled stress urinary outcome measures for women with coexisting symptomatic SUI and women asymptomatic for SUI before surgery. <sup>10</sup> In women without SUI symptoms we differentiated also between women with and without occult SUI. We pooled possible adverse effects for MUS and Burch colposuspension, independently from preoperative incontinence in the study subjects. Urgency UI was considered a potential adverse event.

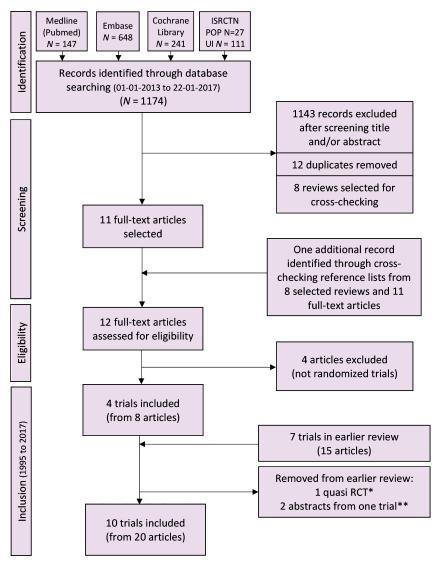
The primary outcome was SUI. We use 'persisting SUI' when SUI symptoms persisted after prolapse surgery. In the case of women without SUI symptoms before prolapse surgery reporting postoperative SUI, we use the term 'de novo SUI'. Secondary outcomes included treatment for SUI, bladder storage symptoms, obstructive voiding and adverse events. Definition depended on the descriptions used in the studies. We decided that prolonged catheterization of the bladder should have lasted at least 1 week. Where possible, we used the terminology proposed by the International Urogynecological Association (IUGA) and International Continence Society (ICS).<sup>5</sup> When outcome data of more than one follow-up period after index surgery were available we used the longest follow-up period, unless otherwise stated.

Data were pooled when at least two trials were available. For dichotomous outcomes, we reported relative risk with 95% confidence intervals. Because of the few available studies and sometimes substantial statistical heterogeneity ( $I^2$  of more than 25%), we applied a random-effects model in Review Manager 5.3 for all analyses. The risk of bias of the selected studies was judged using the 'risk of bias' table developed by the Cochrane Collaboration.<sup>9</sup> Risk of bias is categorised as a low, high or unclear risk of bias. Trial quality was downgraded from high-quality evidence to moderate- or low-quality evidence, depending on the presence of random sequence generation, allocation concealment, blinding, incomplete outcome data and selective reporting.

#### **Results**

#### **Study selection**

Figure 1 summarizes the process of literature identification and study selection (references are added in the Figure S1). Of 1174 titles, 12 publications were potentially relevant and assessed for eligibility. Based on the abstract or full article, four were excluded because the subjects in the studies were not randomised. Statistically 11 The publication by Bastani et al. Was included after communication with the authors clarifying their randomisation method, blinding and follow up. The selection of eight articles included four new trials, Atlanta three publications with long-term follow up from two previously included trials and one correction to an earlier publication. We excluded one study from our earlier review, because we falsely included this as a quasi-RCT, whereas it



**Figure 1.** Review flow diagram. In Figure S1 (see Supporting information) the figure is presented with references. \*The trial of Liapis et al.<sup>21</sup> was reconsidered for inclusion and judged as being not a radomised trial because enough information was lacking. \*\*The trial of Schierlitz et al.<sup>33</sup> was included as a full-text article. Two earlier extracts were then excluded.

should have been considered a cohort.<sup>21</sup> Adding the six trials from our earlier review, the updated review includes a total of ten RCTs (from 20 articles).<sup>3,4,14,16–19,22–33</sup>

#### Study characteristics

Details of the studies are summarised in Table 1. Three studies compared prolapse surgery with and without an incontinence procedure in women with coexisting symptomatic UI (Borstad and CUPIDO-1 in vaginal prolapse repair with a MUS and Costantini in sacrocolpopexy with Burch colposuspension). Seven RCTs studied combination surgery in symptomatically continent women: one trial did not test for occult SUI, the CARE and OPUS trial included women with or without occult SUI, state of the studies of the studies are summarised in Table 1. Three studies are surgery with and without an incompared to the studies of the stu

trials studied women with occult SUI<sup>4,17,33</sup> and one included only women without occult SUI.<sup>30</sup> Although the definition differed widely, all studies reported on (S)UI after surgery (see Table S1).

#### Study and data quality

Appendix S3 summarizes the risk of bias of the trials and this is also added to the forest plots in the Supporting Information. Two studies were considered to be of high quality<sup>23,31</sup> and two were assessed to be low-quality trials.<sup>14,17</sup> The other six trials were assessed to be of moderate quality. Overall the quality of evidence is rated moderate, mainly because of possible selection bias and lack of blinding. All authors were approached for possible additional

Table 1. Included randomised trials								
First author (acronym)	Continence status*	Surgery	POPQ stage	Number intervention versus control (total)	Follow up	Trial quality		
Bastani <sup>14</sup>	No symptomatic SUI	$VPR \pm TOT$	≥3	35 versus 37 (72)	3 months	Low		
Borstad <sup>29</sup>	SUI (a)	$VPR\pmTVT$	≥2	87 versus 94 (181)	1 years	Moderate		
Brubaker (CARE trial) <sup>3,18,20,22–24,26</sup>	No symptomatic SUI (b)	ASC $\pm$ Burch	≥2	157 versus 165 (322)	7 years	High		
Costantini, no (occult) SUI <sup>25,30</sup>	No (occult) SUI (c)	ASC $\pm$ Burch	≥3	34 versus 32 (66)	8 years	Moderate		
Costantini, Ul <sup>27,32</sup>	UI (d)	ASC $\pm$ Burch	≥3	24 versus 23 (47)	7 years	Moderate		
Fuentes <sup>17</sup>	Occult SUI (e)	$VPR\pmTVT\text{-}O$	≥3	27 versus 33 (60)	1.7 years	Low		
Schierlitz <sup>19,33</sup>	Occult SUI (e)	$VPR\pmTVT$	≥2	37 versus 43 (80)	6 years	Moderate		
Van der Ploeg (CUPIDO-1) <sup>15,16</sup>	SUI (f)	$VPR\pmMUS$	≥2	63 versus 71 (134)	1 years	Moderate		
Van der Ploeg (CUPIDO-2) <sup>4,15</sup>	Occult SUI (g)	$VPR\pmMUS$	≥2	43 versus 47 (90)	1 years	Moderate		
Wei (OPUS trial) <sup>28,31</sup> Total	No symptomatic SUI (h)	$VPR\pmTVT$	≥2	165 versus 172 (337) 672 versus 717 (1389)	1 years	High		

ASC, abdominal sacrocolpopexy; Burch, Burch colposuspension; FU, follow-up; MUI, mixed urinary incontinence; MUS, midurethral sling; PFDI, Pelvic Floor Distress Inventory; TOT, transobturator tape; TVT, tension-free vaginal tape (retropubic); TVT-O, transobturator tape; VPR, vaginal prolapse repair.

a: symptomatic SUI (94% had also objective SUI without reduction of the prolapse, 6% occult SUI with reduction of the prolapse); b: no symptomatic SUI (however: 20% had subjective SUI at PFDI, 10% bothersome SUI at PFDI, 4% had objective SUI and 36% had occult SUI); c: no SUI (no subjective, objective or occult SUI); d: symptomatic urinary incontinence (13 pure SUI, 30 MUI and 4 occult SUI); e: continent women with urodynamic SUI with or without reduction of the prolapse; f: 96% reported subjective SUI more than once a week, 47% reported bothersome SUI and 78% showed objective SUI without reduction of the prolapse; g: no subjective or objective SUI without reduction of the prolapse, but urinary leakage at a stress reduction test (however, 48% reported subjective SUI at UDI and 8% bothersome SUI at UDI); h: No symptomatic SUI (33% had objective SUI, probably with reduction of the prolapse).

information. One author could not be reached<sup>17</sup> and one author did not confirm the data presented in the extraction sheet.<sup>33</sup> From two studies no power-analysis was available.<sup>14,17</sup> The other trials were powered for urinary incontinence (UI). One study did not achieve the required sample size.<sup>4</sup>

### Postoperative SUI: women with pelvic organ prolapse and coexisting symptomatic SUI

Three studies compared prolapse surgery with and without an incontinence procedure in women with coexisting SUI symptoms before surgery (Table 2.1). 16,27,29 In the smallest study Costantini et al.<sup>27</sup> compared sacrocolpopexy with and without Burch colposuspension in women with preoperative UI. The two other studies compared vaginal prolapse repair with and without MUS in women with symptomatic SUI. 16,29 Pooling the three studies in Table 2.1 showed no significant difference in objective SUI and subsequent surgery for persisting SUI. However, the trials had important clinical and methodological differences and statistical heterogeneity was high. Costantini et al.<sup>27</sup> studied sacrocolpopexy with Burch colposuspension in women with preoperative UI (SUI, mixed UI or occult SUI). The other two trials showed more similarities and studied vaginal prolapse repair with MUS in women with coexisting SUI. 16,29 Pooling these two trials reduced statistical heterogeneity and showed less subsequent surgery for persisting SUI after prolapse surgery with MUS [0 versus 40%; relative risk (RR) 0.0; 95% CI 0.0–0.2; which was statistically significant]. In women with prolapse and coexisting SUI; one should combine vaginal prolapse repair with MUS in 2.5 women to prevent one woman needing subsequent MUS after prolapse surgery only [numberneeded-to-treat (NNT) 2.5] (see also Figure S2).

## Postoperative SUI: women with pelvic organ prolapse without symptomatic SUI

Women with prolapse, but without SUI complaints, might be tested for the presence of occult SUI. According to the included RCTs we divided these continent women into (1) women with unknown occult SUI; (2) women with occult SUI; and (3) women without occult SUI.

Women in the first group represent the clinical situation in which a woman without SUI symptoms considers prolapse surgery without further testing for occult SUI. Two RCTs did not report on occult SUI in their primary analysis and one did not test for occult SUI. 14,23,31 The CARE trial reported on data from 3 months, one, two and 7 years. 18,23,24,26 We used the 7-year data for UI and subjective SUI. The number of incontinence procedures at 5-year and 7-year follow up are cumulative numbers with also a significant number lost to follow up. Therefore

<sup>\*</sup>Letters refer to the following notes:

40% (38/96)

15% (18/123)

0.2

0.1

0.1-0.4

0.0-0.6

Table 2. Combination surgery compared to prolapse repair only: postoperative SUI*							
	Subjects (N)	Intervention (n/N)	Control (n/N)	RR	95% CI	l² (%)	
2.1 Women with co-existing SUI symptoms							
Objective SUI	102	23% (11/48)	37% (20/54)	0.7	0.2-2.0	63	
Surgery for POSUI	360	2% (4/173)	36% (68/187)	0.1	0-6.3	89	
Surgery for POSUI (subgroup: vaginal prolapse repair with or without MUS)	315	0% (0/150)	40% (66/165)	0.0	0-0.2	0	
2.2 Women without SUI symptoms (with or without occult SUI)							
Subjective SUI	245	50% (60/116)	67% (84/126)	0.8	0.7-0.9	0	
Objective SUI	544	6% (16/259)	14% (40/285)	0.5	0.1-4.1	0	
Surgery for POSUI	708	2% (8/348)	6% (23/360)	0.4	0.1-1.1	0	
2.3 Women without SUI symptoms, but with occult SUI (vaginal prola	apse repair	with or withou	t MUS)				

 $l^2$  statistical heterogeneity, the percentage of the variability in effect estimates that is due to heterogeneity rather than chance; MUS, midurethral sling; POSUI, postoperative SUI.

229

5% (5/93)

1% (1/106)

Objective SUI

Surgery for POSUI

percentages are inappropriate and we used the 2-year data for the outcome surgery for postoperative SUI. Objective SUI figures were available only at 2-year follow-up. Pooling the studies (Table 2.2) showed less subjective SUI after combination surgery compared with prolapse surgery only (50 versus 67%; RR 0.8; 95% CI 0.7–0.9). Although we found a tendency towards less subsequent surgery for de novo SUI (2 versus 6%; RR 0.4; 95% CI 0.1–1.1), differences were not statistically significant. We found no difference in objective SUI. The comparisons are also presented in the Figure S2.

Three trials reported on de novo SUI in women without preoperative SUI symptoms, but with occult SUI. Although occult SUI was not uniformly defined, the studies were pooled. All compared vaginal prolapse repair with or without MUS. Pooling showed in Table 2.3 that in women with occult SUI, a prophylactic MUS significantly reduces the risk of objective SUI (5 versus 40%; RR 0.2; 95% CI 0.1-0.4), and undergoing subsequent surgery for de novo SUI (1 versus 15%; RR 0.1; 95% CI 0.0-0.6) (see also Figure S2). The NNT to prevent one woman with occult SUI undergoing subsequent surgery for de novo SUI was seven. Each trial favoured combination surgery, and heterogeneity was low. For women with occult SUI, a sub analysis in the CARE and OPUS trials reported only an incontinence end point and could therefore not be included in these analyses. Although outcomes differed slightly, in both trials the risk of postoperative incontinence was almost halved by a prophylactic incontinence procedure.<sup>3,31</sup>

Costantini et al.<sup>25</sup> were the first to perform an RCT comparing sacrocolpopexy with or without Burch colposuspension in symptomatically continent women without occult SUI. The authors found no difference in de novo

UI, therapy for de novo UI and change in urogenital distress inventory (UDI) score. The OPUS trial reported in a sub-analysis on a UI end point (bothersome UI or objective SUI) in continent women without occult SUI and found less UI 12 months after prolapse repair with MUS compared with prolapse repair only, but differences were not statistically significant (28 versus 41%; RR 0.7; 95% CI 0.5-1.0).31 A similar comparison was done in the CARE trial for an SUI end point (objective SUI, bothersome SUI or treatment for SUI) and showed significantly less SUI after sacrocolpopexy with Burch colposuspension versus no Burch colposuspension (21 versus 38%; RR 0.6; 95% CI 0.4-0.9).3 In the CUPIDO-2 trial, continent women without occult SUI were not randomised, but underwent vaginal prolapse surgery only and were followed in a cohort.4 One year after prolapse surgery, 8% of these women reported bothersome SUI, showed objective SUI and/or underwent treatment for postoperative SUI. Due to differences in outcome, pooling of trials in women without symptomatic SUI and without occult SUI, was not possible.

## Urgency incontinence and adverse events: vaginal prolapse repair with or without MUS

Seven trials studied vaginal prolapse repair with or without MUS. 4,14,16,17,29,31,33 Preoperative incontinence differed. Pooling the data showed that urgency incontinence was less frequent after combination surgery compared with vaginal prolapse repair only (28 versus 42%; RR 0.7; 95% CI 0.5–0.99) (Table 3). We found no differences in prolonged bladder catheterization and surgery for voiding dysfunction, although both analyses showed a tendency towards more voiding problems after combination surgery. Adverse

<sup>\*</sup>Supporting information: see Forest plots in Figure S2.

Table 3. Combination surgery compared to prolapse repair only: adverse events\*

	Subjects (N)	Intervention (n/N)	Control (n/N)	RR	95% CI	<i>I</i> <sup>2</sup> (%)			
3.1 Vaginal prolapse repair with or without MUS									
Urgency UI	288	28% (38/134)	42% (65/154)	0.7	0.5–0.99	0			
Prolonged bladder catheterization	885	8% (33/427)	4% (18/458)	2.3	0.97-5.5	31			
Surgery for voiding dysfunction	822	1.3% (5/395)	0.2% (1/427)	2.4	0.4–16	12			
Adverse events**	557	28% (74/265)	15% (45/292)	1.8	1.3-2.4	0			
Serious adverse events***	641	14% (43/308)	8% (26/333)	1.7	1.1–2.7	0			
3.2 Sacrocolpopexy with or without Burch colposuspension									
Urgency UI	409	6% (13/202)	9% (19/207)	1.0	0.3-3.7	28			
Prolonged bladder catheterization	113	3% (2/58)	0% (0/55)	4.7	0.2–95	NA			
Adverse events	424	30% (63/211)	31% (67/213)	1.1	0.5–2.4	45			

 $l^2$  statistical heterogeneity, the percentage of the variability in effect estimates that is due to heterogeneity rather than chance; MUS, midurethral sling; NA, not applicable.

events (AEs) were not always defined clearly and definitions varied between trials (see Table S1 and S2). Pooling the data shows that AEs occurred more often after vaginal prolapse repair with MUS compared with prolapse repair only: 28 versus 15%; RR 1.8; 95% CI 1.3-2.4 (Table 3.1). The OPUS trial was excluded in this pooling because the study reported only on SAEs and not on AEs.31 To improve clinical relevance we also pooled SAEs. The original data from three trials were used because these studies clearly defined SAEs.4,16,31 In two trials the definition of an AE was unclear. 29,33 Based on the definition from the European Association of Urology guideline (SAE: an AE requiring an invasive procedure or reoperation, or resulting in failure of one or more organ systems or death), it was possible to make a crude estimate of SAEs from one trial (see Table S2).33,34 Pooling these data showed more SAEs after vaginal prolapse repair with MUS: 14 versus 8% (RR 1.7; 95% CI 1.1-2.7). SAEs that occurred more in combination surgery included bladder perforations, ureteral injuries, tape exposures, MUS-related pain, long-term voiding difficulties and tape loosening for this. All comparisons are also presented in the Figure S3.

## Urgency incontinence and adverse events: sacrocolpopexy with or without Burch colposuspension

Three trials studied sacrocolpopexy with or without Burch colposuspension. <sup>23,25,27</sup> Pooling the trials in Table 3.2 showed no difference in urgency UI after sacrocolpopexy with or without Burch colposuspension (see Figure S3). Also, prolonged catheterization and AEs were similar. Data on SAEs were only available from the CARE trial and showed no difference. <sup>26</sup>

#### Disease-specific and generic quality of life

Overactive bladder symptoms as measured by a validated questionnaire improved in women undergoing prolapse surgery both with or without the combination of an incontinence procedure. 4,16,23,31,33 In all studies the improvement was slightly better after combination surgery, but differences were not statistically significant.

Four trials reported obstructive voiding symptoms 1 year postoperatively and found no differences between prolapse surgery with or without an incontinence procedure. 4,16,23,31

The OPUS trial and CUPIDO trials reported on generic health and quality of life. 4,16,31 Although trials were not powered for this, no differences in generic health and quality of life were found between vaginal prolapse repair with or without MUS.

#### **Discussion**

#### Main findings

Most studies showed fewer women having postoperative SUI after prolapse surgery with an incontinence procedure compared with prolapse surgery only. In women with preoperative SUI symptoms or with occult SUI, the meta-analysis showed statistically significantly fewer women with SUI after vaginal prolapse repair with MUS than after prolapse repair only. But SAEs were also more frequent after vaginal prolapse repair with MUS. No differences were found in postoperative urgency UI, bladder storage symptoms and voiding dysfunction, although there was a tendency towards more prolonged bladder catheterisation and surgery for voiding dysfunction in women undergoing vaginal prolapse repair with MUS.

<sup>\*</sup>Supporting information: see Forest plots in Figure S3.

<sup>\*\*</sup>Adverse event (AE): we used the definition as used in the separate trials.

<sup>\*\*\*</sup>Serious adverse event (SAE): an AE requiring an invasive procedure or reoperation or resulting in failure of one or more organ systems or death.

#### Strengths and limitations

Possible limitations of this review are that only English literature was eligible and we might have failed to locate other trials reported in the non-English literature. A more important limitation lies possibly within the trials themselves. Only two of the ten RCTs were assessed as high quality<sup>23,31</sup> and two trials were judged to be of low quality. 14,17 Selected trials seem especially at risk for selection bias. Two trials were not powered and one trial did not reach the intended sample size. Details on study and patient characteristics were not reported equally well. Due to important differences in patient characteristics (e.g. preoperative incontinence) and study size, statistical heterogeneity was sometimes high. Finally, pooling of data was limited, mainly because of differences in outcome measures. A few of these limitations might be confined by performing an individual patient data meta-analysis. Nevertheless, even without individual patient data, we believe this is the most comprehensive meta-analysis on this topic, in that the categorisation of women facilitates clinical application of the results.

#### Interpretation

In this update to our initial review we extended our search period from 1995 to 2017 and added four RCTs. This improved overall evidence, increased the number of comparisons and made it possible to distribute RCTs more adequately among predefined patient groups, reducing clinical diversity and statistical heterogeneity. One trial could be included as a full-text article instead of mere abstracts and the CARE-trial reported on more than the 2-year follow up. Evidence improved, especially in women with prolapse and coexisting SUI symptoms and on AEs.

Two other important reviews have been published on the subject and their results are roughly in line with a reduced SUI risk after combination surgery. 6,35 Maher et al.<sup>6</sup> published a Cochrane meta-analysis concerning surgery for pelvic organ prolapse, including a comparison between prolapse surgery with or without incontinence surgery. They also conclude that the combination of prolapse surgery with an incontinence procedure is likely to be beneficial in women with coexisting or occult SUI. The authors state that these benefits have to be weighed against potential risks, but that these risks are poorly reported. With the inclusion of more recent trials and excluding incontinence procedures other than MUS or Burch colposuspension, we improved evidence concerning benefits and risks allowing better balancing of pros and cons. The other review from Matsuoka et al. 35 included symptomatic continent women only. They found a similar preventive effect of vaginal prolapse repair with an MUS, but not for sacrocolpopexy with Burch colposuspension. The authors also conclude that adding an incontinence procedure to prolapse repair increases the likelihood for an SAE. The increase of SAEs in combination surgery seems logical. After all, fewer women will undergo incontinence surgery after prolapse surgery only compared with prolapse surgery combined with an incontinence procedure and so fewer women are exposed to the possible risks of an MUS or Burch colposuspension.

The positive effect of adding an MUS to vaginal prolapse repair seemed to increase with the severity of preoperative incontinence: 0% versus 40% needed subsequent surgery for postoperative SUI (NNT 2.5) in women with coexisting SUI symptoms; 1 versus 15% (NNT 7.1) in continent women with occult SUI; and 2 versus 6% (not significant difference) in all continent women. This benefit must be balanced against the increased risk of facing an SAE from 8 to 14% (number needed to harm 17). Whereas benefits clearly exceed risks in coexisting SUI, they are in balance in women with occult SUI and risks even exceed benefits when all continent women are considered. Moreover, several studies showed no difference in generic health and quality of life between vaginal prolapse surgery with or without an MUS supporting selective use of combination surgery.4,16,31

Although women with occult SUI were more at risk to develop de novo SUI than women without occult SUI, occult SUI is limited in predicting de novo postoperative SUI. Jelovsek et al.<sup>7</sup> showed that other risk factors influence the risk of postoperative SUI (e.g. age, body mass index, performing anterior colporrhaphy) and developed an excellent online calculator to predict a woman's individual risk to have postoperative SUI. This study group developed another appealing online calculator for balancing risks and benefits for women considering MUS in SUI without prolapse.<sup>36</sup> A similar tool would be helpful in considering combination surgery in women with pelvic organ prolapse.

#### **Conclusion**

Women undergoing prolapse repair are at risk of having persisting or de novo SUI after surgery. Vaginal prolapse surgery with MUS reduces the risk of postoperative SUI in women with SUI symptoms or occult SUI before surgery, but more SAEs also occur after combination surgery. Therefore, risks and benefits should be balanced for the individual woman. According to the principle of 'first, do no harm' we would be conservative in performing preventive incontinence surgery in symptomatic continent women, especially without occult SUI. Further research should focus on prediction models that allow women to balance risks and benefits more adequately. Physicians should be aware that perceptions of risks and benefits will differ between individuals, emphasising the importance of shared decision making.

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#### Disclosure of interests

None declared. Completed disclosure of interests form available to view online as supporting information.

#### Details of ethics approval

Ethical approval was not applicable.

#### Contribution to authorship

All authors were closely involved in the study design. MP and AS reviewed the literature and extracted data. MP contacted all authors for further information. MP and SZ performed data analysis and assessed the quality of studies and risk of bias. HV and JP assisted in the literature review and analysis. MP wrote the first draft and all were closely involved in revising the article and consented with the final version.

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#### **Supporting Information**

Additional Supporting Information may be found in the online version of this article:

Figure S1. Flow diagram with references.

Figure S2. Forest plots.

Figure S3. Forest plots.

Table S1. Study characteristics.

Table S2. Reported adverse events and serious adverse events.

Appendix S1. Inclusion and exclusion criteria.

Appendix S2. Search strategy.

**Appendix S3.** Risk of bias. ■

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