



# Should we combine vaginal prolapse surgery with continence surgery?

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Received: 9 July 2018 / Accepted: 25 October 2018 / Published online: 8 November 2018

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## Abstract

The risk of postoperative stress urinary incontinence (SUI) can be reduced by combining prolapse repair with continence surgery. However, more women face a serious adverse event (SAE) after vaginal prolapse surgery combined with a midurethral sling (MUS). It is difficult to predict a woman's individual postoperative SUI and SAE risk; therefore, weighing the benefits and risks of combination surgery is complex. We offer a concept that might help in considering combination surgery. According to this concept, women whose risk of needing subsequent surgery for postoperative SUI is on average 9% are likely to benefit from combination surgery.

**Keywords** Current opinion · Pelvic organ prolapse · Stress urinary incontinence · Midurethral sling · Combination surgery

## Introduction

After prolapse repair women could need subsequent continence surgery for persisting or de novo stress urinary incontinence (SUI). To reduce the risk of postoperative SUI, prolapse surgery could be combined with a continence procedure. A recently published systematic review including meta-analysis shows that women had lower risk of undergoing subsequent continence surgery for SUI after combination surgery than after prolapse surgery only [1]. Differences in subsequent continence surgery were 0% vs. 40% (RR 0; 95% CI 0–0.2) in women with coexisting SUI before surgery and 1% vs. 15% (RR 0.1; 95% CI 0–0.6) in women with occult SUI [1]. However, pooling data from four randomized trials [2–5] that included 641 women undergoing vaginal prolapse surgery with or without a midurethral sling (MUS) showed more serious

adverse events (SAEs) after combination surgery than with the two-step strategy in which the prolapse is corrected first and postoperative SUI is treated when necessary; 14% vs. 8% (RR 1.7; 95% CI 1.1–2.7) [1]. This might be explained by more women receiving an MUS in the one-step strategy, resulting in more SAEs overall. An SAE was defined as an adverse event requiring an invasive procedure or reoperation or resulting in failure of one or more organ systems or death [6].

When one is considering combination surgery, the risk of undergoing subsequent continence surgery after prolapse repair should exceed the SAE risk in combination surgery. As it is difficult to predict a woman's individual risk to undergo subsequent continence surgery or face an SAE, balancing these risks and benefits is complex. Besides, women weigh risks and benefits differently and there is no best way to do this.

Here we offer a conceptual model for weighing the pros and cons based on the available knowledge that could help health workers and women considering combination surgery. The model also includes our estimate of the threshold at which the benefits of combination surgery are likely to outweigh the risks.

## A conceptual model for considering combination surgery

In balancing the risks and benefits, one could argue that subsequent surgery for postoperative SUI should be regarded as an SAE. The total SAE risk is then defined as the sum of the

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SAE risk related to index surgery, the subsequent surgery risk for postoperative SUI and the SAE risk related to this continence procedure. One can calculate the total SAE risk for combination surgery (one-step strategy) and prolapse surgery only (two-step strategy) and, from this point of view, study which strategy has the overall lowest SAE risk and would therefore be preferable to perform. When the SAE risks are assumed to be low, combination surgery will often be favorable, even when subsequent MUS risk is relatively low. Accordingly, the higher the SAE risks will be, the higher the subsequent MUS risk must be to favor combination surgery.

A problem with this mathematical model is that risk percentages will differ between women, surgeons, institutions and countries and depend on study design and definitions. To overcome this problem, we ran several scenarios involving various risks as presented in Table 1. Based on our studies and the literature, we varied SAE risk during vaginal prolapse repair and MUS surgery among 4%, 7% and 10% [1, 3–5, 7–9]. Combining vaginal prolapse surgery with a MUS increases SAE risk [1]. The relative risk (RR) for an SAE was 1.4 in a database analysis [9], 1.7 in our review [1] and 2.4 in our CUPIDO trials [4, 5]. Therefore, we also varied the SAE risk in combination surgery by multiplying the SAE risk of prolapse surgery by 1.4, 1.7, 2.0 and 2.3, respectively (to use equal intervals 2.4 was rounded off to 2.3). This resulted in 12 scenarios comparing the total SAE risk in the one- and two-step strategy. It is unlikely that true SAE risks will be lower or higher than the supposed percentages.

We assumed that the subsequent MUS risk was 2% after combination surgery [1]. To study the minimal subsequent MUS risk after prolapse surgery only in which combination surgery would still be preferable, we varied the subsequent

MUS risk to an extent at which the risk difference was at least 1% (only rounded percentages were used). The risk difference between a one- and two-step strategy is the difference between the total SAE risks. A positive outcome favors a one-step strategy and a negative outcome favors a two-step strategy.

The results of the 12 scenarios are presented in Table 2. The SAE risk after combination surgery is calculated by multiplying the SAE risk in POP surgery by the assumed RR for an SAE in combination surgery. The total SAE risk in both strategies is calculated as explained above using the minimal subsequent MUS risk in which the risk difference is about 1%. These calculations showed that combination surgery (one-step strategy) was preferable when the subsequent MUS risk was 9% on average. The threshold to prefer combination surgery was obviously low (5%) when SAE risks were low (SAE risk 4%, RR in combination surgery 1.4) and accordingly high (15%) when SAE risks were high (SAE risk 10%, RR in combination surgery 2.3).

## Discussion

We presented a conceptual model for weighing the risks and benefits when combination surgery is considered. The model shows that if a woman's individual risk of undergoing subsequent MUS after vaginal prolapse surgery is about 9%, the benefits of combination surgery are likely to outweigh the risks. The higher the SAE risks, the higher the subsequent MUS risk must be to still favor combination surgery. When the subsequent MUS risk is 15% or higher, each scenario favored combination surgery.

**Table 1** SAE risks used in the scenarios

SAE risk	Literature	CUPIDO trials	Updated review	Assumed risk in several scenarios
MUS surgery	5–6% <sup>a, b</sup>	–	–	4%, 7% and 10%
Vaginal POP surgery only	3% <sup>c</sup> , 12% <sup>d</sup>	5% <sup>c</sup>	8% <sup>f</sup>	
Combination surgery	4% <sup>c</sup> , 17% <sup>d</sup>	12% <sup>c</sup>	14% <sup>f</sup>	Relative risk (RR) <sup>g</sup> : 1.4 <sup>c</sup> ; 1.7 <sup>f</sup> ; 2; 2.3 <sup>e</sup>

MUS midurethral sling, POP pelvic organ prolapse, SAE serious adverse event

<sup>a</sup> Schraffordt Koops, AJOG 2005: 5% (3.5% bladder perforations; 0.1% vascular injury; 1.6% tape loosening; 0.2% tape rejection) [7]

<sup>b</sup> Ford et al., Cochrane Review 2017: 6% [in a comparison between transobturator and retropubic tape Ford et al. found overall: 1.2% (55/4676) vascular/visceral injury; 2.6% (159/6173) bladder/urethral injury; 2.1% (94/4568) vaginal tape erosions; 0.3% (1/374) bladder/urethral lesions] [8]

<sup>c</sup> Erekson et al. 2017: Major postoperative complications for any vaginal prolapse repair without sling occurred in 2.6% (441/16898). This was 3.7% (296/8030) in vaginal prolapse repair with sling: 2.6% vs. 3.7%; RR 1.4; 95% CI 1.2–1.6 ([openepi.com](http://openepi.com)) [9]

<sup>d</sup> Wei et al., OPUS trial, NEJM 2012: SAE risk 12% vs. 17%; RR 1.5; 95% CI 0.9–2.5 ([openepi.com](http://openepi.com)) [3]

<sup>e</sup> CUPIDO trials: SAE risk in vaginal prolapse repair was 5% (CUPIDO-1 4/71; CUPIDO-2 RCT 2/47; CUPIDO-2 FU 7/138) and in combination surgery 12% (CUPIDO-1 10/63; CUPIDO-2 3/43); 5% vs. 12%; RR 2.4; 95% CI 1.2–5.0 ([openepi.com](http://openepi.com)) [4, 5]

<sup>f</sup> Updated review: 8% vs. 14%; RR 1.7; 95% CI 1.1–1.7 [1]

<sup>g</sup> It is assumed that the SAE risk of combination surgery is higher than the risk of vaginal prolapse surgery only. We varied the relative risk (RR 1.4, 1.7, 2.0 and 2.3), resulting in 12 SAE risk percentages for combination surgery ( $4\% \times 1.4 = 5.6\%$ ;  $7\% \times 1.4 = 10.5\%$  (etc.) ...  $10\% \times 2.3 = 23\%$ ). To increase the RR in equal steps in the different scenarios, we rounded RR 2.4<sup>e</sup> down to RR 2.3

**Table 2** Minimal subsequent MUS risk in which the estimated total risk difference still favored combination surgery

SAE risk in POP or MUS surgery	RR for SAE in combination surgery	Estimated SAE risk in combination surgery	Subsequent MUS risk for POSUI after index surgery <sup>a</sup>	Total SAE risk (including subsequent MUS)		Estimated risk difference <sup>b</sup>
				Combination surgery	POP surgery only	
4%	1.4	5.6%	5%	7.68%	9.2%	2%
4%	1.7	6.8%	6%	8.88%	10.24%	1%
4%	2	8%	7%	10.08%	11.28%	1%
4%	2.3	9.2%	8%	11.28%	12.32%	1%
7%	1.4	9.8%	6%	11.94%	13.42%	1%
7%	1.7	11.9%	8%	14.04%	15.56%	2%
7%	2	14%	10%	16.14%	17.7%	2%
7%	2.3	16.1%	11%	18.24%	18.77%	1%
10%	1.4	14%	7%	16.2%	17.7%	2%
10%	1.7	17%	9%	19.2%	19.9%	1%
10%	2	20%	12%	22.2%	23.2%	1%
10%	2.3	23%	15%	25.2%	26.5%	1%
Subsequent MUS risk in which combination surgery was still favorable (average and min-max)			9% (5–15%)			

MUS midurethral sling; POP pelvic organ prolapse, POSUI postoperative stress urinary incontinence, RR relative risk, SAE serious adverse event, SUI stress urinary incontinence

<sup>a</sup> Minimal subsequent MUS risk for POSUI after index surgery in which the estimated risk difference was still 1% or higher favoring combination surgery. Only rounded percentages were used. As a consequence, risk differences are also rounded percentages

<sup>b</sup> Estimated risk difference: calculated total SAE risk in POP surgery only (two-step strategy) minus total SAE risk in combination surgery (one-step strategy). Only rounded percentages

There is no prediction model to calculate a women's individual risk to undergo subsequent MUS surgery after vaginal prolapse surgery. In our recent review we showed that women with coexisting SUI have a 40% risk of undergoing subsequent MUS for postoperative SUI and women with occult SUI have a 15% risk [1]. So, one could roughly state that women with coexisting or occult SUI are very likely to benefit from combination surgery. This should be communicated during preoperative counseling.

Whether a woman chooses combination surgery depends on her individual risk of having postoperative SUI and facing an SAE and, perhaps most importantly, on how she weights the pros and cons. Aspects that might also influence this choice will depend on culture, health system accessibility, insurance and legislation. We used the subsequent MUS risk as outcome because this risk is reasonably clear from the literature and a strong marker for bothersome postoperative SUI. However, not all women with postoperative SUI will choose to undergo a MUS, leaving some women with bothersome SUI beyond our scope. Considering these limitations, the proposed 9–15% threshold should be regarded as an indicative and helpful percentage rather than the only way to choose between combination surgery or not.

## Conclusion

The conceptual model we presented might be useful in considering continence surgery during prolapse repair. According to our model, women with on average a 9% risk of needing subsequent surgery for postoperative SUI are likely to benefit from combination surgery.

## Compliance with ethical standards

**Conflicts of interest** J. Marinus van der Ploeg: the author reports no conflict of interest.

Jan-Paul W.R. Roovers: medical consultant for American Medical Systems (AMS).

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