National Institute for Health and Care Excellence

Draft for consultation

Urinary incontinence and pelvic organ prolapse in women: management

[J] Surgical management of pelvic organ prolapse and stress urinary incontinence

NICE guideline tbc

Evidence reviews

October 2018

Draft for Consultation

These evidence reviews were developed by the National Guideline Alliance hosted by the Royal College of Obstetricians and Gynaecologists

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ISBN:

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Surgical treatment (including mesh and non-mesh procedures) for pelvic organ prolapse associated with stress incontinence

Review question

What is the most effective surgical management for women with both stress urinary incontinence and pelvic organ prolapse, including the sequence of interventions?

Introduction

Women commonly present with both pelvic organ prolapse (POP) and urinary incontinence (UI) and it is unclear what are the most effective sequencing or combination of interventions to achieve optimal outcomes for them. This review focuses on the efficacy of performing surgery for stress urinary incontinence (i) during the same operation as surgery for pelvic organ prolapse, or (ii) following surgery for pelvic organ prolapse.

Summary of the protocol

Please see Table 1 for a summary of the Population, Intervention, Comparison and Outcome (PICO) characteristics of this review.

Table 1: Summary of the protocol (PICO)

Population	Women (aged 18 and over) with both POP and urinary incontinence, who are undergoing surgery Only women with anterior and/or apical POP will be considered, as posterior POP affects a different compartment and should not influence the outcome of continence surgery Women having repeat surgery or those who were treatment naïve will be considered

Intervention	• Concurrent surgery for POP and SUI
	
	The following surgeries for POP will be considered, as long as they are performed concurrently with a surgical option for the management of SUI:
	Anterior prolapse
	• Anterior repair or colporrhapy or cystocele repair
	  ○ With or without mesh, biological or synthetic
	  ○ Mesh kit or inlay mesh
	• Paravaginal repair (open or laparoscopic)
	
	Apical prolapse
	• Vaginal hysterectomy
	• Vaginal sacrospinous hysteropexy
	• Manchester repair
	• Hysteropexy with mesh
	  ○ Laparoscopic or open

	○ Wrap around or posterior attachment • Suture hysteropexy ○ Laparoscopic or open **Vault prolapse** • Posterior IVS • Sacrospinous fixation • Sacrocolpopexy with mesh ○ Laparoscopic or open • Mesh kit or inlay mesh • Colpocleisis • Uterosacral plication ○ Vaginal or laparoscopic The following surgeries for SUI will be considered, as long as they are performed concurrently with any surgical option for the management of POP: • Suburethral slings (synthetic mesh) ○ Retropubic bottom-up ○ Retropubic top-down ○ Transobturator outside-out ○ Transobturator outside-in • Single incision ○ Mini-sling or single-incision sling • Adjustable slings ○ Retropubic ○ Transobturator • Colposuspension ○ Open abdominal retropubic suspension ○ Laparoscopic retropubic suspension • Fascial slings (autologous/pubovaginal sling)/sling on a string/rectus sling/ fascia lata sling • Para or transurethral injections (bulking agents) • Artificial urinary sphincters
Comparison	• Prolapse surgery only • Prolapse surgery followed by SUI surgery
Outcomes	**Critical** • Change in continence status ○ Self-reported symptoms ○ Objective cure rate ○ Negative stress (cough) test ○ Pad test (1-hr or 24-hr) ○ Number of incontinence episodes per day • Repeat surgery (for UI or POP, or mesh complications) • Long-term complications (>12 months) ○ Pain ○ Mesh erosion or extrusion (vaginal, bladder, urethra) ○ Fistula ○ Need for catheterisation ○ Infection (recurrent UTI, wound) ○ De novo overactive bladder symptoms

	○ Occurrence of POP ○ Wound complications (hernia) **Important** • Adverse events (immediate post-op or perioperative) ○ Severe bleeding requiring a blood transfusion ○ Internal organ injury (to bladder or bowel) • Continence specific health-related quality of life (including sexual function) • Patient satisfaction, patient reported improvement (for example, Patient global impression of improvement [PGII])

IVS: Intravaginal Slingplasty; POP: Pelvic Organ Prolapse; SUI: Stress Urinary Incontinence; UTI, Urinary Tract Infection.

For full details see the review protocol in appendix A.

Methods and process

This evidence review was developed using the methods and process described in Developing NICE guidelines: the manual. Methods specific to this review question are described in the review protocol in appendix A and for a full description of the methods see supplementary document C.

Declarations of interest were recorded according to NICE's 2014 conflicts of interest policy until 31 March 2018. From 1 April 2018, declarations of interest were recorded according to NICE's 2018 conflicts of interest policy. Those interests declared until April 2018 were reclassified according to NICE's 2018 conflicts of interest policy (see Register of Interests).

Clinical evidence

Included studies

Four articles reporting data from three RCT were included in this review (Borstad 2010; Constantini 2008; Constantini 2012; and van der Ploeg 2015). Three articles reporting 2 RCTs (n=185) evaluated pelvic organ prolapse (POP) surgery with or without concurrent stress urinary incontinence (SUI) surgery only (Constantini 2008/ 2012; van der Ploeg 2015) in women with POP and SUI. All participants in these studies had at least both POP-Q Stage II prolapse and subjectively-verified SUI. One of the RCT (n=47) compared abdominal sacropexy or hysterosacropexy for POP with or without a Burch colposuspension for SUI and reported data at both mid- and long-term follow up (Constantini 2008; Constantini 2012). The other RCT was a multisite study (n=138) that compared POP surgery with or without a midurethral sling – transobturator or retropubic - for SUI (van der Ploeg 2015); prolapse surgery mainly consisted of anterior vaginal repair but was at the discretion of the surgeons as indicated.

One multisite RCT (n=194) evaluated SUI surgery concurrent to POP surgery with SUI surgery 3 months after POP surgery in women with POP and SUI (Borstad 2010). The majority of women had anterior prolapse and assessed as having POP-Q Stage II. Prolapse surgery mainly consisted of Manchester repair but was at the discretion of the surgeons as indicated. SUI surgery consisted of tension-free vaginal tape (TVT) surgery.

See also the literature search strategy in appendix B, study selection flow chart in appendix C, evidence tables in appendix D, forest plots in appendix E, and GRADE tables in appendix F.

Excluded studies

Studies excluded from the review and reasons for their exclusion are provided in appendix K.

Summary of clinical studies included in the evidence review

The included studies are summarised in

Table **2**.

Table 2: Summary of included RCT studies

Study	Participants	Intervention	Control	Outcomes
Borstad 2010 N = 194	Women with objectively-verified SUI and POP-Q>Stage II[a]	POP (various) + SUI (TVT) surgery[b]	POP (various) surgery then after 3 months SUI (TVT) surgery[b]	• Objective cure of SUI
Costantini 2008/2012 N = 47	Women with ICS-defined SUI and POP-Q>Stage II[a]	POP (Abdominal sacropexy or hysterosacropexy)+ SUI (Burch Colposuspension) surgery	POP (Abdominal sacropexy or hysterosacropexy) surgery	• Objective cure of SUI • Self-reported symptoms of SUI • Repeat surgery • Sexual function • Continence-specific HR QoL • Patient satisfaction/reported improvement
Van der Ploeg 2015 N = 138	Women with subjectively- or objectively-verified (stress test) SUI and POP-Q>Stage II[a]	POP (various) + SUI (MUS) surgery[b]	POP surgery[b]	• Objective cure of SUI • Self-reported symptoms of SUI • Repeat surgery • Adverse events • Continence-specific HR QoL • Patient satisfaction/reported improvement

Notes: a) Objective verification of SUI consisted in stress (cough) test with bladder volume >300 ml without prolapse reduction. Subjective verification of SUI consisted of positive answer to SUI-related item on the Dutch UDI; b), Type of POP surgery performed determined, as indicated, by surgeon. Abbreviations: HR QoL, health-related quality of life; ICS, International Continence Society; MUS, midurethеral sling; POP, Pelvic organ prolapse; POP-Q, Pelvic Organ Prolapse Quantification system; SUI, stress urinary incontinence; TVT, tension-free vaginal tape.

See also clinical evidence tables in appendix D.

Quality assessment of clinical studies included in the evidence review

GRADE analysis was conducted on critical and important outcomes and clinical evidence profiles can be found in appendix F.

Economic evidence

Included studies

A systematic review of the economic literature was conducted but no studies were identified which were applicable to this review question. See supplementary material D for further information.

Excluded studies

No studies were identified which were applicable to this review question.

Summary of studies included in the economic evidence review

No economic evaluations were identified which were applicable to this review question.

Economic model

This question was not prioritised for economic modelling because the evidence to base this on was anticipated to be limited and the committee agreed that other topics were higher priorities for economic evaluation.

Clinical evidence statements

POP and SUI surgery versus POP surgery only

Change in continence status

- Low quality evidence from 1 RCT (n=57) showed there is a clinically important difference favouring combined POP and SUI surgery over POP surgery only on objective cure of SUI at 1 year follow up in women with both POP and SUI: RR 1.49 (95% CI 1.05-2.12).
- Very low quality evidence from 1 RCT (n=47) showed no clinically important difference between combined POP and SUI surgery over POP surgery only on objective cure of SUI at >5 year follow up in women with both POP and SUI: RR 0.75 (95% CI 0.44-1.3).
- Low quality evidence from 1 RCT (n=37) showed no clinically important difference between combined POP and SUI surgery and POP surgery only on the number of women who no longer have self-reported voiding symptoms at >1 year follow up in women with both POP and SUI: RR 1.05 (95% CI 0.87-1.26).
- Low quality evidence from 1 RCT (n=31) showed there is a clinically important difference favouring POP surgery only over combined POP and SUI surgery on the number of women who no longer have self-reported storage symptoms (as per the ICS criteria, which include urgency, urgency incontinence, frequency, nocturia, pain and stress incontinence) >1 year follow up in women with both POP and SUI: RR 0.68 (95% CI 0.47-0.97).
- Moderate to low quality evidence from 1 RCT (n=134) showed no clinically important difference between combined POP and SUI surgery and POP surgery only on self-reported symptoms as assessed by overall UDI-urinary incontinence score (MD -11.0 [95% CI -20.31 to -1.69]), nor on the subscales of UDI-overactive bladder (MD -4.0 [95% CI -11.45 to 3.45]), UDI-obstructive micturition (MD -3.0 [95% CI -11.64 to 5.64]), UDI-

genital prolapse (MD 0 [95% CI -11.59 to 11.59]), and UDI-pain/discomfort (MD -2.0 [95% CI -10.82 to 8.82]) at 1 year follow up in women with both POP and SUI.

- Moderate to low quality evidence from 1 RCT (n=134) showed there is a clinically important difference favouring combined POP and SUI surgery over POP surgery only on the number of women who, according to the UDI at 1 year follow up, self-report that they do not have urinary incontinence at all (RR 2.09 [95% CI 1.39-3.15]), stress urinary incontinence (RR 1.97 [95% CI 1.44-2.71]), and urge urinary incontinence (RR 1.38 [95% CI 1.04-1.85]).

Repeat surgery

- Low to very low quality evidence from 1 RCT (n=134) showed no clinically important difference between combined POP and SUI surgery and POP surgery only on repeat surgery for complications (RR 3.01 [95% CI 0.83-10.84]) and repeat surgery for POP recurrence (RR 1.13 [95% CI 0.29-4.32]) at 1 year follow up in women with both POP and SUI.
- Very low quality evidence from 1 RCT (n=45) showed no clinically important difference between combined POP (abdominal sacropexy or hysterosacropexy) and SUI surgery (Burch colposuspension) and POP surgery (sacropexy or hysterosacropexy) only on repeat surgery for SUI (midurethral sling) at >5 year follow up in women with both POP and SUI: RR 1.91 (95% CI 0.39-9.41).
- Moderate quality evidence from 1 RCT (n=134) showed there is a clinically important difference favouring combined POP and SUI surgery (midurethral sling) over POP surgery (sacropexy or hysterosacropexy) only on repeat surgery for SUI (midurethral sling) at 1 year follow up in women with both POP and SUI: RR 0.04 (95% CI 0-0.74).

Adverse events (immediate post- or peri-operative)

- Very low quality evidence from 2 RCT (n=181) showed no clinically important difference between combined POP and SUI surgery and POP surgery only on the number of women who experienced a post- or perioperative internal bladder injury in women with both POP and SUI: RR 2.25 (95% CI 0.21-24.27).

Continence-specific health-related quality of life

- Very low quality evidence from 1 RCT (n=45) showed no clinically important difference between combined POP and SUI surgery and POP surgery only on the number of women not having sexual intercourse (RR 0.74 [95% CI 0.34-1.65]), the number of women experiencing disturbances during sexual intercourse (RR 0.72 [95% CI 0.18-2.85]), and the number of women not experiencing disturbances during sexual intercourse (RR 1.38 [95% CI 0.75-2.56]) at >5 year follow up in women with both POP and SUI.
- Low to moderate quality evidence from 1 RCT (n=134) showed no clinically important difference between combined POP and SUI surgery and POP surgery only on IIQ-physical functioning (MD 9.0 [95% CI 1.88 to 16.12]), IIQ-mobility (MD 3.0 [95% CI -5.74 to 11.74]), IIQ-social functioning (MD 6.0 [95% CI -0.97 to 12.97]), IIQ-embarrassment (MD 1.0 [95% CI -6.8 to 8.8]), and IIQ-emotional health (MD 0 [95% CI -7.53 to 7.53]) at 1 year follow up in women with both POP and SUI.
- One RCT (n=45) that compared abdominal sacropexy or hysterosacropexy with concurrent Burch colposuspension (median 1 [range 0-11]) and abdominal sacropexy or hysterosacropexy only (median 2 [range 0-17]) reported no significant difference on overall IIQ-7 score at >5 year follow up in women with both POP and SUI.

Patient satisfaction/Patient-reported improvement

- Low quality evidence from 1 RCT (n=133) showed no clinically important difference between combined POP and SUI surgery and POP surgery only on the number of women who have improved on the PGI-I (RR 1.05 [95% CI 0.84-1.32]) and the number of women who have no complaints on the PGI-S (RR 1.14 [95% CI 0.9-1.44) at 1 year follow up in women with both POP and SUI.
- Low quality evidence from 1 RCT (n=45) showed no clinically important difference between combined POP and SUI surgery and POP surgery only on the number of women who would be willing to repeat surgery at >5 year follow up in women with both POP and SUI: RR 1.01 (95% CI 0.8-1.27).
- One RCT (n=45) that compared abdominal sacropexy or hysterosacropexy with concurrent Burch colposuspension (median 8 [range 4-10]) and abdominal sacropexy or hysterosacropexy only (median 8.5 [range 5-10]) reported no significant difference on patient satisfaction, assessed using a visual analogue scale, at >5 year follow up in women with both POP and SUI.

POP and SUI surgery versus POP surgery then SUI surgery

Change in continence status

- Low quality evidence from 1 RCT (n=194) showed no clinically important difference between concurrent POP and SUI surgery and SUI surgery 3 months after POP surgery on objective cure for SUI at 1 year follow up in women with both POP and SUI: RR 1.2 (95% CI 1.04-1.39).

Economic evidence statements

No studies were identified which were applicable to this review question.

Recommendations

J1.1.1 Consider concurrent surgery for stress urinary incontinence (UI) and prolapse in women with anterior and/or apical prolapse and stress UI. **[2019]**

J1.1.2 When offering concurrent surgery for stress UI and prolapse explain to the woman:

- that there is uncertainty about whether the combined procedure is effective for treating stress UI beyond 1 year, and that stress UI might persist despite surgery
- the risk of complications related to having surgery for stress UI at the same time as prolapse surgery compared with the risk of complications related to having sequential surgery. **[2019]**

Research recommendations

What is the most effective surgical management for women with both stress urinary incontinence and pelvic organ prolapse, including the sequence of interventions?

The committee's discussion of the evidence

Interpreting the evidence

The outcomes that matter most

Change in continence status, repeat surgery and complications at more than 12 months were considered to be the critical outcomes for this question. Performing POP surgery on its own to correct prolapse may lead to an improvement in SUI such that SUI surgery is not needed and little is known about whether concurrent surgery is more effective, durable and risky and leads to more complications than POP surgery alone. Repeat surgery was considered to be a critical outcome as many women ask whether not having concomitant surgery means that they will require a second procedure. Post- and peri-operative adverse events, continence-specific health-related quality of life, and patient satisfaction/patient-reported improvement were considered to be important outcomes because surgery for stress incontinence at the same time as prolapse surgery may result in more voiding difficulty and overactive bladder symptoms. If combined surgery is to be performed, surgeons should be clear about what the immediate risks of the surgery are and whether it is acceptable to women who have SUI and POP.

Change in continence status was reported for both comparisons of interest, but repeat surgery, adverse events, incontinence-specific health-related quality of life, patient satisfaction/patient-reported improvement were only reported for the comparison of concurrent pelvic organ prolapse and stress urinary incontinence surgery with pelvic organ prolapse surgery only. No evidence was found for either comparison of interest about the occurrence of complications 12 months after surgery.

The quality of the evidence

The quality of evidence for each outcome was assessed using GRADE.

The quality of evidence for the comparison of simultaneous pelvic organ prolapse and stress urinary incontinence surgery with pelvic organ prolapse surgery alone ranged from very low to moderate for these outcomes: change in continence status, repeat surgery, adverse events, continence-specific health-related quality of life, and patient-satisfaction/patient-reported improvement. Outcomes were downgraded mainly because of the imprecision of the associated confidence intervals. Only one outcome (adverse events) was pooled. One study was at high risk of bias because there was no information about allocation concealment, no blinding of participants/personnel, incomplete outcome data, and significant differences between the arms at baseline on urodynamic assessment measures; although the other study was at low risk of bias, 40% of the sample did not have objectively-verified SUI at baseline and outcomes were therefore downgraded one level for indirectness where relevant.

The quality of evidence for the one outcome reported for the comparison of concurrent pelvic organ prolapse and stress urinary incontinence surgery versus pelvic organ prolapse surgery followed by stress urinary incontinence surgery that could be assessed using GRADE (change in continence status) was low because of the high risk of bias of the 1 contributing study and imprecision of the confidence intervals associated with the effect estimate.

Benefits and harms

There was no clinically important difference between arms on the following outcomes: adverse events, continence-specific health-related quality of life, and patient satisfaction/patient-reported improvement. There was some evidence suggesting that at 1 year follow up, women who have concurrent pelvic organ prolapse and stress urinary incontinence surgery have an increased probability of being (i) objectively cured of stress urinary incontinence (using a negative cough stress test) and (ii) subjectively (i.e. self-reportedly) cured.

Pelvic organ prolapse surgery on its own was favoured over concurrent pelvic organ prolapse and stress urinary incontinence surgery on only one outcome, the resolution of storage symptoms. Although 1 of the RCT reported on outcomes greater than 5 years after surgery, no difference was found between concurrentPOP and SUI surgery and pelvic organ prolapse surgery only on any of the reported outcomes during this period.

The committee discussed that the fact that no difference was found between concurrent POP and SUI surgery and POP surgery only on the risk of experiencing perioperative bladder injury. Even though the evidence was only rated as very low to moderate and because there was evidence to the contrary, the committee agreed that if a woman presents with symptoms of both pelvic organ prolapse and stress urinary incontinence, the possibility of concurrent pelvic organ prolapse and stress urinary incontinence surgery for both conditions should be considered. The committee noted that this approach may also be preferred by women with these conditions because they would undergo only one rather than two surgical procedures. The committee did not want to be prescriptive about any particular surgical procedure, because of the limited quality and quantity of evidence, since any decision would need to be tailored to the particular symptoms, presentation and preferences of the woman.

However, the committee agreed that women should be able to make an informed choice about their treatment. Based on the limitations of the evidence they therefore recommended that it is important to explain that there is a gap in the evidence about longer term efficacy of surgery. It is important that the woman should be informed that there is uncertainty about the risk of complications for undergoing either option, (i.e. having the two surgeries conducted at the same time, or sequentially). They also recommended, based on their experience that the woman be told that concurrent surgery for both stress urinary incontinence as well as pelvic organ prolapse may carry an increased risk of complications because it is likely to be a more complex surgical procedure.

Due to the limited evidence for the surgical management for women with both stress urinary incontinence and pelvic organ prolapse the committee made a research recommendation. This is important because many women have co-existing symptoms of stress urinary incontinence and pelvic organ prolapse and seek surgical treatment for both conditions. It is not known whether there is a benefit to concurrent surgery or sequential surgery for these women and what the adverse effects of these approaches are. There are no long-term data to guide patients in making decisions about surgery and the committee felt that it was important to assess success and complications of both approaches over a 5-year period.

Cost effectiveness and resource use

The committee was of a view that if a woman presents with symptoms of both pelvic organ prolapse and stress urinary incontinence the option of concurrent pelvic organ prolapse and stress urinary incontinence surgery should be considered. The committee noted that even though concurrent surgery is a more major surgical procedure, there is no evidence of an increase in intraoperative complications and there may be potential cost savings to the NHS. For example, a concurrent pelvic organ prolapse and stress urinary incontinence repair procedure would only require one preoperative assessment, one anaesthetic procedure, one recovery period, one admission, and so on; similarly, there would be other economies of

scale such as clinician and operating theatre time, and surgical consumables. There may also be cost savings associated with scheduled follow-up visits. For example, women who are well post-surgery are generally seen only once for follow-up. But if pelvic organ prolapse and stress urinary incontinence repairs are done separately there will be a scheduled follow-up after each surgical procedure. There are also benefits to women in terms of quality of life if they want to avoid the inconvenience of a repeat surgical procedure for stress urinary incontinence after the initial pelvic organ prolapse repair.

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Appendices

Appendix A – Review protocols

Review protocol for review question: What is the most effective surgical management for women with both stress urinary incontinence and pelvic organ prolapse, including the sequence of interventions?

Table 3: Evidence review protocol for what is the most effective surgical management option for women with both SUI and POP

Field (based on PRISMA-P)	Content
Review question	What is the most effective surgical management for women with both stress urinary incontinence and pelvic organ prolapse, including the sequence of interventions?
Type of review question	Intervention
Objective of the review	Women commonly present with both pelvic organ prolapse and urinary incontinence and there is lack of clarity about the sequencing or combination of interventions to achieve optimal outcomes for them.
Eligibility criteria – population/disease/condition/issue/domain	Women (aged 18 and over) with both POP and urinary incontinence, who are undergoing surgery We will include women with stress UI or mixed UI with stress predominance who have failed or declined conservative treatment. We will include women with anterior and/or apical POP, as posterior prolapse is a different compartment and should not influence the outcome of continence surgery. Women having repeat surgery or those that are treatment naïve will be included.

Eligibility criteria – intervention(s)/exposure(s)/prognostic factor(s)	Prolapse surgery combined with concurrent incontinence surgery.
	The following surgical treatments for pelvic organ prolapse will be considered, as long as they are performed concurrently with a surgical option for the management of stress urinary incontinence:
	Anterior prolapse
	• Anterior repair or colporrhapy or cystocele repair:
	  ○ With or without mesh, biological or synthetic
	  ○ Mesh kit or inlay mesh
	• Paravaginal repair (open or laparoscopic)
	
	Apical prolapse

Field (based on PRISMA-P)	Content

	• Vaginal hysterectomy
	• Vaginal sacrospinous hysteropexy
	• Manchester repair
	• Hysteropexy with mesh
	  ○ Laparoscopic or open
	  ○ Wrap around or posterior attachment
	• Suture hysteropexy
	  ○ Laparoscopic or open
	
	Vault prolapse
	• Posterior IVS
	• Sacrospinous fixation
	• Sacrocolpopexy with mesh
	  ○ Laparoscopic or open
	• Mesh kit or inlay mesh
	• Colpocleisis
	• Uterosacral plication
	  ○ Vaginal or laparoscopic
	
	Any of the following surgical options for the management of stress urinary incontinence will be considered in this review, as long as they are performed concurrently with any surgical option for the management of POP:
	• Suburethral slings (synthetic mesh)
	  ○ Retropubic bottom-up
	  ○ Retropubic top-down
	  ○ Transobturator outside-out
	  ○ Transobturator outside-in
	• Single incision
	  ○ Mini sling or single incision sling

Field (based on PRISMA-P)	Content

	• Adjustable slings
	  ○ Retropubic
	  ○ Transobturator
	• Colposuspension
	  ○ Open abdominal retropubic suspension
	  ○ Laparoscopic retropubic suspension
	• Fascial slings (autologous/pubovaginal sling)/sling on a string/rectus sling/ fascia lata sling
	• Para or transurethral injections (bulking agents)
	• Artificial urinary sphincters

Eligibility criteria – comparator(s)/control or reference (gold) standard	Combination vs prolapse only Combination vs prolapse followed by incontinence surgery

Outcomes and prioritisation	**Critical**
	• Change in continence status
	  ○ Self-reported symptoms
	  ○ Objective cure rate (to be examined in NMA and pairwise results to be presented there)
	  ○ Negative stress (cough) test
	  ○ Pad test (1-hr or 24-hr)
	  ○ Number of incontinence episodes per day
	• Repeat surgery (for UI or POP, or mesh complications)
	• Long-term complications (>12 months)
	  ○ Pain
	  ○ Mesh erosion or extrusion (vaginal, bladder, urethra)
	  ○ Fistula
	  ○ Need for catheterisation
	  ○ Infection (recurrent UTI, wound)
	  ○ De novo overactive bladder symptoms
	  ○ Occurrence of POP
	  ○ Wound complications (hernia)

Field (based on PRISMA-P)	Content

	Justification: The rationale for not always doing both together may be that you then do not require a continence procedure when the prolapse is corrected and there may be differences in effectiveness and complications.
	
	Important
	• Adverse events (immediate post-op or perioperative)
	  ○ Severe bleeding requiring a blood transfusion
	  ○ Internal organ injury (to bladder or bowel)
	• Continence-specific health-related quality of life
	  ○ Sexual function
	  ○ King's Health Questionnaire
	• Patient satisfaction, patient reported improvement
	  ○ Patient global impression of improvement (PGI)
	Justification: These are the additional important outcomes which will influence decision making.

Eligibility criteria – study design	• SR of RCT • RCT • Conference abstracts in absence of full-texts of RCT • Comparative cohort studies in the absence of other studies for critical outcomes only.
Other inclusion exclusion criteria	In the absence of RCT evidence, prospective observational studies with follow-up <24 months for critical outcomes only English language only.

Proposed sensitivity/sub-group analysis, or meta-regression	**Population Subgroups**
	• Type of POP (anterior or apical)
	• Severity/Grade of POP
	• Type of UI
	  ○ Pure stress
	  ○ Mixed UI
	• Surgical status
	  ○ Repeat or recurrent surgery
	  ○ Treatment naïve

Field (based on PRISMA-P)	Content
Selection process – duplicate screening/selection/analysis	Dual sifting will be undertaken for this question using NGA STAR software. Sifting, data extraction, appraisal of methodological quality and GRADE assessment will be performed by the systematic reviewer. Dual weeding will be performed by a second systematic reviewer on 5% or 10% of records (depending on database size), with resolution of discrepancies in discussion with the senior reviewer if necessary. Quality control will be performed by the senior systematic reviewer. Dual data extraction will not be performed for this question.
Data management (software)	Pairwise meta-analyses, if possible, will be performed using Cochrane Review Manager (RevMan5). 'GRADEpro' will be used to assess the quality of evidence for each outcome. NGA STAR software will be used for generating bibliographies/citations, study sifting, data extraction and recording quality assessment using checklists.
Information sources – databases and dates	Sources to be searched: Medline, Medline In-Process, CCTR, CDSR, DARE, HTA, Embase Limits (e.g. date, study design): Apply standard animal/non-English language exclusion Limit to RCTs and systematic reviews in first instance but download all results
Identify if an update	This review question is not an update.
Author contacts	Developer: The National Guideline Alliance https://www.nice.org.uk/guidance/indevelopment/gid-ng10035.
Highlight if amendment to previous protocol	For details please see section 4.5 of Developing NICE guidelines: the manual 2014.
Search strategy – for one database	For details please see appendix B.
Data collection process – forms/duplicate	A standardised evidence table format will be used, and published as appendix D (clinical evidence tables) or H (economic evidence tables).
Data items – define all variables to be collected	For details please see evidence tables in appendix D (clinical evidence tables) or H (economic evidence tables).
Methods for assessing bias at outcome/study level	Standard study checklists were used to critically appraise individual studies. For details please see section 6.2 of Developing NICE guidelines: the manual 2014.

Field (based on PRISMA-P)	Content
	The risk of bias across all available evidence was evaluated for each outcome using an adaptation of the 'Grading of Recommendations Assessment, Development and Evaluation (GRADE) toolbox' developed by the international GRADE working group http://www.gradeworkinggroup.org/
Criteria for quantitative synthesis (where suitable)	For details please see section 6.4 of Developing NICE guidelines: the manual 2014l.
Methods for analysis – combining studies and exploring (in)consistency	For details of the methods please see supplementary material C.
Meta-bias assessment – publication bias, selective reporting bias	For details please see section 6.2 of Developing NICE guidelines: the manual 2014. If sufficient relevant RCT evidence is available, publication bias will be explored using RevMan software to examine funnel plots. Trial registries will be examined to identify missing evidence: Clinical trials.gov, NIHR Clinical Trials Gateway
Assessment of confidence in cumulative evidence	For details please see sections 6.4 and 9.1 of Developing NICE guidelines: the manual 2014.
Rationale/context – Current management	For details please see the introduction to the evidence review.
Describe contributions of authors and guarantor	A multidisciplinary committee developed the guideline. The committee was convened by the National Guideline Alliance and chaired by Dr Fergus Macbeth in line with section 3 of Developing NICE guidelines: the manual 2014. Staff from the National Guideline Alliance undertook systematic literature searches, appraised the evidence, conducted meta-analysis and cost-effectiveness analysis where appropriate, and drafted the guideline in collaboration with the committee. For details of the methods please see supplementary material C.
Sources of funding/support	The National Guideline Alliance is funded by NICE and hosted by the Royal College of Obstetricians and Gynaecologists.
Name of sponsor	The National Guideline Alliance is funded by NICE and hosted by the Royal College of Obstetricians and Gynaecologists.
Roles of sponsor	NICE funds the National Guideline Alliance to develop guidelines for those working in the NHS, public health, and social care in England.
PROSPERO registration number	Not registered with PROSPERO.

1

Appendix B – Literature search strategies

Literature search strategies for review question: What is the most effective surgical management for women with both stress urinary incontinence and pelvic organ prolapse, including the sequence of interventions?

Database: Medline & Embase (Multifile)
Last searched on Embase Classic+Embase 1947 to 2017 October 25, Ovid MEDLINE(R) Epub Ahead of Print, In-Process & Other Non-Indexed Citations, Ovid MEDLINE(R) Daily and Ovid MEDLINE(R) 1946 to Present

Date of last search: 26th October 2017.

#	Searches
1	Urinary Incontinence, Stress/ use ppez
2	Stress Incontinence/ use emczd
3	Mixed Incontinence/ use emczd
4	(urine adj2 (loss or leak$)).tw.
5	((stress$ or mix$ or effort$) adj5 incontinen$).tw.
6	SUI.tw.
7	exp Pelvic Organ Prolapse/ use ppez
8	exp pelvic organ prolapse/ use emczd
9	(pelvic$ adj3 organ$ adj3 prolaps$).tw.
10	(urinary adj3 bladder adj3 prolaps$).tw.
11	((vagin$ or urogenital$ or genit$ or uter$ or viscer$ or anterior$ or posterior$ or apical or pelvi$ or vault$ or urethr$ or bladder$) adj3 prolaps$).tw.
12	(splanchnoptos$ or visceroptos$).tw.
13	Rectocele/ use ppez
14	rectocele/ use emczd
15	(hernia$ adj3 (pelvi$ or vagin$ or urogenital$ or uter$ or bladder$ or urethr$ or viscer$)).tw.
16	(urethroc?ele$ or enteroc?ele$ or sigmoidoc?ele$ or proctoc?ele$ or rectoc?ele$ or cystoc?ele$ or rectoenteroc?ele$ or cystourethroc?ele$).tw.
17	1 or 2 or 3 or 4 or 5 or 6 or 7 or 8 or 9 or 10 or 11 or 12 or 13 or 14 or 15 or 16
18	Suburethral Slings/ use ppez
19	Urinary Sphincter, Artificial/ use ppez
20	exp suburethral sling/ use emczd
21	colposuspension/ use emczd
22	bladder sphincter prosthesis/ use emczd
23	retropubic$.ti,ab.
24	"bottom up".ti,ab.
25	"top down".ti,ab.
26	(tension$ adj3 (tape$ or vagina$)).ti,ab.
27	TVT$.ti,ab.
28	((transvagin$ or trans-vagin$) adj3 tape$).ti,ab.
29	(transobturator$ or trans-obturator$).ti,ab.
30	"outside in".ti,ab.
31	"inside out".ti,ab.
32	(single adj incision).ti,ab.
33	(minisling$ or mini-sling$).ti,ab.
34	((sling$ or tape$ or hammock$) adj3 (procedure$ or operat$ or surg$)).ti,ab.
35	((fascia$ or subfascia$ or sub-fascia$ or autologous$ or adjust$ or pubovagin$ or rectus) adj3 (sling$ or tape$ or hammock$)).ti,ab.
36	((midurethra$ or mid-urethra$ or suburethra$ or sub-urethra$ or synthetic$) adj3 (sling$ or tape$ or hammock$)).ti,ab.
37	MUS.ti,ab.
38	(colposuspen$ or colpo-suspen$ or cystopex$ or urethropex$).ti,ab.
39	((retro-pubi$ or retropubi$ or abdomin$ or open or laparoscopic$ or bladder neck) adj3 suspension$).ti,ab.
40	(miniarc or monarc or SPARC).ti,ab.
41	((artificial or prosthes$) adj3 sphincter$).ti,ab.
42	((transurethra$ or trans-urethra$ or paraurethra$ or para-urethra$ or periurethra$ or peri-urethra$) adj3 inject$).ti,ab.
43	(bulk$ adj3 agent$).ti,ab.
44	MMK.ti,ab.
45	(Marshall$ adj Marchett$ adj Krantz$).ti,ab.
46	(anterior adj3 repair).ti,ab.
47	Hysterectomy, Vaginal/ use ppez
48	vaginal hysterectomy/ use emczd
49	abdominal hysterectomy/ use emczd

#	Searches
50	((vagin$ or abdom$) adj3 hysterectom$).tw.
51	(total adj laparoscopic$ adj hysterectom$).tw.
52	(hysteropex$ or sacro-hysteropex$ or sacrohysteropex$ or colpopex$ or sacro-colpopex$ or sacrocolpopex$ or sacropex$ or cervicopex$ or sacro-cervicopex$ or sacrocervicopex$).tw.
53	(colporrhaph$ or perineorrhaph$ or perineoplast$ or culd?plast$).tw.
54	(manchester$ adj3 (repair$ or operation$ or procedure$ or method$ or surger$)).tw.
55	colpocl$.tw.
56	IVS.tw.
57	((intravagin$ or intra-vagin$) adj3 slingplast$).tw.
58	(TSST or STST or TSTS).tw.
59	(transfix$ adj3 (stitch$ or sutur$)).tw.
60	scaffold$.tw.
61	((urethroc?ele$ or enteroc?ele$ or sigmoidoc?ele$ or proctoc?ele$ or rectoc?ele$ or cystoc?ele$ or rectoenteroc?ele$ or cystourethroc?ele$ or vault$ or anter$ or poster$ or apical$ or vagin$ or para-vagin$ or paravagin$ or utero-vagin$ or uterovagin$ or recto-vagin$ or rectovagin$ or utero-sacral$ or uterosacral$ or sacrospin$ or sacro-spin$ or pubourethral or Kelly or Stamey or prolaps$ or POP) adj3 (repair$ or suspen$ or fix$ or plicat$)).tw.
62	((POP or prolaps$ or prolaps$ reduc$) adj (surg$ or operat$)).tw.
63	((vagin$ or pelvi$) adj3 reconstruct$).tw.
64	*Pelvic Organ Prolapse/su use ppez
65	*pelvic organ prolapse/su use emczd
66	*Urinary Incontinence, Stress/su use ppez
67	*Stress Incontinence/su use emczd
68	64 or 65
69	66 or 67
70	68 and 69
71	18 or 19 or 20 or 21 or 22 or 23 or 24 or 25 or 26 or 27 or 28 or 29 or 30 or 31 or 32 or 33 or 34 or 35 or 36 or 37 or 38 or 39 or 40 or 41 or 42 or 43 or 44 or 45 or 46
72	47 or 48 or 49 or 50 or 51 or 52 or 53 or 54 or 55 or 56 or 57 or 58 or 59 or 60 or 61 or 62 or 63
73	17 and 71 and 72
74	70 or 73
75	Surgical Mesh/ use ppez
76	exp surgical mesh/ use emczd
77	(mesh$ or non-mesh$ or nonmesh$).tw.
78	Polypropylenes/ use ppez
79	polypropylene/ use emczd
80	polypropylen$.tw.
81	75 or 76 or 77 or 78 or 79 or 80
82	1 or 2 or 3 or 4 or 5 or 6
83	7 or 8 or 9 or 10 or 11 or 12 or 13 or 14 or 15 or 16
84	81 and 82
85	81 and 83
86	84 and 85
87	74 or 86
88	limit 87 to english language
89	Limit 88 to RCTs and SRs, and general exclusions filter applied

Database: Cochrane Library via Wiley Online

Date of last search: 26th October 2017.

#	Searches
#1	MeSH descriptor: [Urinary Incontinence, Stress] explode all trees
#2	(urine near/2 (loss or leak*)):ti,ab,kw (Word variations have been searched)
#3	((stress* or mix* or effort*) near/5 incontinen*):ti,ab,kw (Word variations have been searched)
#4	SUI:ti,ab,kw (Word variations have been searched)
#5	MeSH descriptor: [Pelvic Organ Prolapse] explode all trees
#6	(pelvic* near/3 organ* near/3 prolaps*):ti,ab,kw (Word variations have been searched)
#7	(urinary near/3 bladder near/3 prolaps*):ti,ab,kw (Word variations have been searched)
#8	((vagin* or urogenital* or genit* or uter* or viscer* or anterior* or posterior* or apical or pelvi* or vault* or urethr* or bladder*) near/3 prolaps*):ti,ab,kw (Word variations have been searched)
#9	(splanchnoptos* or visceroptos*):ti,ab,kw (Word variations have been searched)
#10	MeSH descriptor: [Rectocele] explode all trees
#11	(hernia* near/3 (pelvi* or vagin* or urogenital* or uter* or bladder* or urethr* or viscer*)):ti,ab,kw (Word variations have been searched)
#12	(urethrocele* or urethrocoele* or enterocele* or enterocoele* or sigmoidocoele* or sigmoidocele* or proctocele* or proctocoele* or rectocele* or rectocoele* or cystocele* or cystocoele* or rectoenterocele* or rectoenterocoele* or cystourethrocele* or cystourethrocoele*):ti,ab,kw (Word variations have been searched)
#13	#1 or #2 or #3 or #4 or #5 or #6 or #7 or #8 or #9 or #10 or #11 or #12
#14	MeSH descriptor: [Suburethral Slings] explode all trees

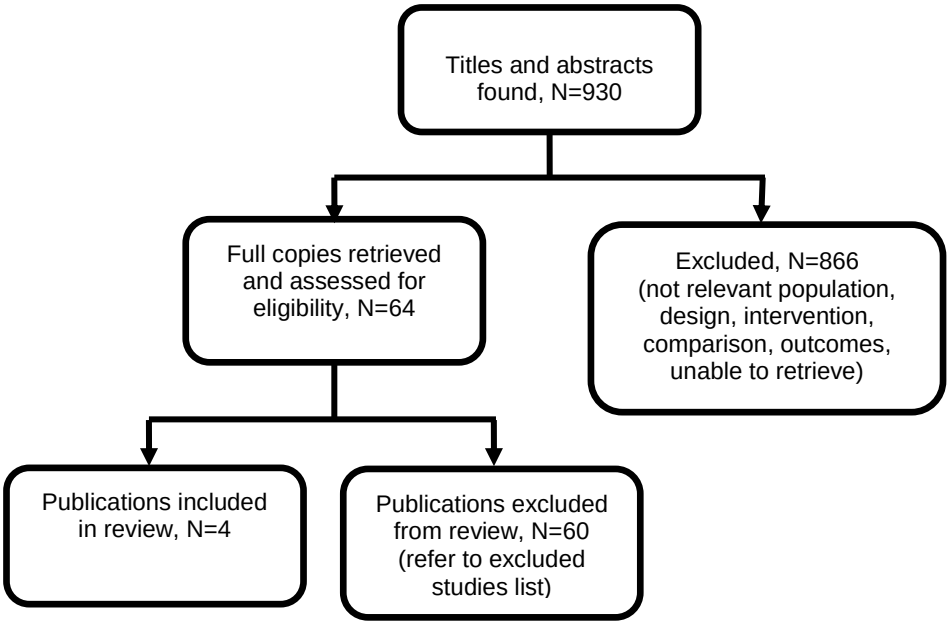
#	Searches
#15	MeSH descriptor: [Urinary Sphincter, Artificial] this term only
#16	retropubic*:ti,ab,kw (Word variations have been searched)
#17	"bottom up":ti,ab,kw (Word variations have been searched)
#18	"top down":ti,ab,kw (Word variations have been searched)
#19	(tension* near/3 (tape* or vagina*)):ti,ab,kw (Word variations have been searched)
#20	TVT*:ti,ab,kw (Word variations have been searched)
#21	((transvagin* or trans-vagin*) near/3 tape*):ti,ab,kw (Word variations have been searched)
#22	(transobturator* or trans-obturator*):ti,ab,kw (Word variations have been searched)
#23	"outside in":ti,ab,kw (Word variations have been searched)
#24	"inside out":ti,ab,kw (Word variations have been searched)
#25	(single next incision):ti,ab,kw (Word variations have been searched)
#26	(minisling* or mini-sling*):ti,ab,kw (Word variations have been searched)
#27	((sling* or tape* or hammock*) near/3 (procedure* or operat* or surg*)):ti,ab,kw (Word variations have been searched)
#28	((fascia* or subfascia* or sub-fascia* or autologous* or adjust* or pubovagin* or rectus) near/3 (sling* or tape* or hammock*)):ti,ab,kw (Word variations have been searched)
#29	((midurethra* or mid-urethra* or suburethra* or sub-urethra* or synthetic*) near/3 (sling* or tape* or hammock*)):ti,ab,kw (Word variations have been searched)
#30	MUS:ti,ab,kw (Word variations have been searched)
#31	(colposuspen* or colpo-suspen* or cystopex* or urethropex*):ti,ab,kw (Word variations have been searched)
#32	((retro-pubi* or retropubi* or abdomin* or open or laparoscopic* or bladder neck) near/3 suspension*):ti,ab,kw (Word variations have been searched)
#33	(miniarc or monarc or SPARC):ti,ab,kw (Word variations have been searched)
#34	((artificial or prosthes*) near/3 sphincter*):ti,ab,kw (Word variations have been searched)
#35	((transurethra* or trans-urethra* or paraurethra* or para-urethra* or periurethra* or peri-urethra*) near/3 inject*):ti,ab,kw (Word variations have been searched)
#36	(bulk* near/3 agent*):ti,ab,kw (Word variations have been searched)
#37	MMK:ti,ab,kw (Word variations have been searched)
#38	(Marshall* next Marchett* next Krantz*):ti,ab,kw (Word variations have been searched)
#39	(anterior near/3 repair):ti,ab,kw (Word variations have been searched)
#40	#14 or #15 or #16 or #17 or #18 or #19 or #20 or #21 or #22 or #23 or #24 or #25 or #26 or #27 or #28 or #29 or #30 or #31 or #32 or #33 or #34 or #35 or #36 or #37 or #38 or #39
#41	MeSH descriptor: [Hysterectomy, Vaginal] this term only
#42	((vagin* or abdom*) near/3 hysterectom*):ti,ab,kw (Word variations have been searched)
#43	(total next laparoscopic* next hysterectom*):ti,ab,kw (Word variations have been searched)
#44	(hysteropex* or sacro-hysteropex* or sacrohysteropex* or colpopex* or sacro-colpopex* or sacrocolpopex* or sacropex* or cervicopex* or sacro-cervicopex* or sacrocervicopex*):ti,ab,kw (Word variations have been searched)
#45	(colporrhaph* or perineorrhaph* or perineoplast* or culdoplast* or culdeplast$):ti,ab,kw (Word variations have been searched)
#46	(manchester* near/3 (repair* or operation* or procedure* or method* or surger*)):ti,ab,kw (Word variations have been searched)
#47	colpocl*:ti,ab,kw (Word variations have been searched)
#48	IVS:ti,ab,kw (Word variations have been searched)
#49	((intravagin* or intra-vagin*) near/3 slingplast*):ti,ab,kw (Word variations have been searched)
#50	(TSST or STST or TSTS):ti,ab,kw (Word variations have been searched)
#51	(transfix* near/3 (stitch* or sutur*)):ti,ab,kw (Word variations have been searched)
#52	scaffold*:ti,ab,kw (Word variations have been searched)
#53	((urethrocele* or urethrocoele* or enterocele* or enterocoele* or sigmoidocoele* or sigmoidocele* or proctocele* or proctocoele* or rectocele* or rectocoele* or cystocele* or cystocoele* or rectoenterocele* or rectoenterocoele* or cystourethrocele* or cystourethrocoele* or vault* or anter* or poster* or apical* or vagin* or para-vagin* or paravagin* or utero-vagin* or uterovagin* or recto-vagin* or rectovagin* or utero-sacral* or uterosacral* or sacrospin* or sacro-spin* or pubourethral or Kelly or Stamey or prolaps* or POP) near/3 (repair* or suspen* or fix* or plicat*)):ti,ab,kw (Word variations have been searched)
#54	((POP or prolaps* or prolaps* reduc*) next (surg* or operat*)):ti,ab,kw (Word variations have been searched)
#55	((vagin* or pelvi*) near/3 reconstruct*):ti,ab,kw (Word variations have been searched)
#56	#41 or #42 or #43 or #44 or #45 or #46 or #47 or #48 or #49 or #50 or #51 or #52 or #53 or #54 or #55
#57	MeSH descriptor: [Pelvic Organ Prolapse] this term only and with qualifier(s): [Surgery - SU]
#58	MeSH descriptor: [Urinary Incontinence, Stress] this term only and with qualifier(s): [Surgery - SU]
#59	#57 and #58
#60	#13 and #40 and #56
#61	#59 or #60
#62	MeSH descriptor: [Surgical Mesh] explode all trees
#63	(mesh* or non-mesh* or nonmesh*):ti,ab,kw (Word variations have been searched)
#64	MeSH descriptor: [Polypropylenes] explode all trees
#65	polypropylen*:ti,ab,kw (Word variations have been searched)
#66	#62 or #63 or #64 or #65
#67	#1 or #2 or #3 or #4
#68	#5 or #6 or #7 or #8 or #9 or #10 or #11 or #12
#69	#66 and #67
#70	#66 and #68
#71	#69 and #70

#	Searches
#72	#61 or #71

Appendix C – Clinical evidence study selection

Clinical evidence study selection for review question: What is the most effective surgical management for women with both stress urinary incontinence and pelvic organ prolapse, including the sequence of interventions?

Figure 1: PRISMA flow chart for review question what is the most effective surgical management for women with both stress urinary incontinence and pelvic organ prolapse.



Appendix D – Clinical evidence tables

Clinical evidence tables for review question: What is the most effective surgical management for women with both stress urinary incontinence and pelvic organ prolapse, including the sequence of interventions?

Table 4: Clinical evidence table

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
Full citation Costantini, E., Lazzeri, M., Bini, V., Del Zingaro, M., Zucchi, A., Porena, M., Burch colposuspension does not provide any additional benefit to pelvic organ prolapse repair in patients with urinary incontinence: a randomized surgical trial, Journal of Urology, 180, 1007-12, 2008 Ref Id 541330 **Country/ies where the study was carried out** Italy **Study type**	**Sample size** N=47 (Intervention=24; Control=23) **Characteristics** Uterus-vaginal prolapse=24 participants, Vault prolapse=13, Cystocele=8, Cystocele + rectocele=2. All patients had subjective and/pure objective UI (pure SUI, mixed UI, occult SUI=4) on stress test both before and after prolapse repositioning. Baseline and other characteristics (data from Constantini 2012 unless otherwise stated) Age (years) - mean (±SD; range) POP (Sacropexy) + SUI (Burch colposuspension) surgery (n=24): 60 (10.6; 35 to 79)	**Interventions** Intervention: POP surgery (Abdominal sacropexy or hysterosacropexy) + SUI surgery (Burch colposuspension) Control: POP surgery (Abdominal sacropexy or hysterosacropexy)	**Details** Follow up at 3, 6 and 9 months, then annually, including urogynaecological history, clinical examination and stress test. No participants lost at first published follow up (Constantini 2008); 2 participants (committed suicide=1 in intervention group; moved abroad + no longer attending scheduled follow ups=1 in control group) lost at 5-year published follow up (Constantini 2012). Twenty participants excluded (refused to participate=15; did not meet inclusion criteria=5) before randomisation. All participants medically assessed with history, clinical examination, UDI-6 and IIQ-7 questionnaire, bladder diary, urine culture, 1-hr pad test and pelvic US. Vaginal inspection performed in gynaecological and standing positions, at rest, and under	**Results** Results from Constantini 2012 unless otherwise as indicated with *. Change in continence status **POP (sacropexy) + SUI (Burch colposuspension) surgery** Dry* Baseline: 0 at 50 months post-operative follow-up (n=24): 11 at 69 months post-operative follow-up (n=23): - Incontinent Baseline: 24 at 50 months post-operative follow-up (n=24): 13 (SUI: 8; MUI: 4; urge UI: 1); Grade I: UI (6); Grade 2/3: UI (7)	**Limitations** **Risk of bias (Cochrane ROB tool)** Overall high risk of bias Random sequence generation: Low (computer-generated randomised block design at Dept. of Statistics, University of Perugia using 1:1 ratio) Allocation concealment: Unclear (Insufficient information) Blinding of participants/personnel: Low for self-report outcomes (participants blinded to group assignment); High for surgical outcomes (personnel (e.g. surgeons) were not blinded to group assignment) Blinding of outcome assessment: Low for immediate post-operative outcomes, High for FU outcomes (Assessors immediately post-operation were blinded to group assignment [Constantini 2008]; assessors at subsequent FU were not blinded to group assignment)

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
RCT **Aim of the study** To evaluate Burch colposuspension combined with abdominal POP repair in women with POP and SUI **Study dates** 1/2002-6/2006 **Source of funding** Not reported	POP surgery (Sacropexy) (n=23): 62.6 (12.8; 27 to 76); p=0.51 Menopause - n POP (Sacropexy) + SUI (Burch colposuspension) surgery (n=24): 18 POP surgery (Sacropexy) (n=23): 18; p=ns Previous urogynaecological surgery - n POP (Sacropexy) + SUI (Burch colposuspension) surgery (n=24): 5 POP surgery (Sacropexy) (n=23): 9; p=0.21 Previous hysterectomy - n POP (Sacropexy) + SUI (Burch colposuspension) surgery (n=24): 5 POP surgery (Sacropexy) (n=23): 8; p=0.34 Previous prolapse repair - n POP (Sacropexy) + SUI (Burch colposuspension) surgery (n=24): 4 POP surgery (Sacropexy) (n=23): 5; p=0.72 Previous SUI surgery - n POP (Sacropexy) + SUI (Burch colposuspension) surgery (n=24): 0 POP surgery (Sacropexy) (n=23): 2; p=0.23 BMI (kg/m2) - median (range)		max straining with full bladder. POP graded using Baden-Walker and POP-Q. Urinary symptoms recorded using ICS criteria and graded using Ingelman Sunderberg scale. In intervention group, abdominal sacropexy/hysterosacropexy was conducted first followed by Burch colposuspension (using non-reabsorbable suture). 'Success' of surgery defined as completely dry (no leakage reported in bladder diary, no pad use, negative stress test).	at 69 months post-operative follow-up (n=23): 13 (SUI: 7; MUI: 4; urge UI: 2); Grade I: UI (6); Grade 2/3: UI (7) Voiding symptoms Baseline: 17 at 50 months post-operative follow-up (n=24): 17/17 cured at 69 months post-operative follow-up (n=23): 16/17 cured Storage symptoms Baseline: 16 at 50 months post-operative follow-up (n=24): 12/16 cured, 4 persistent, 2 de novo at 69 months post-operative follow-up (n=23): 10/15 cured, 5 persistent, 2 de novo UDI-6 score - median (range) Baseline: 16 (16 to 45) at 50 months post-operative follow-up (n=24): 11 at 69 months post-operative follow-up (n=23): - **POP surgery** Dry* Baseline: 0	Incomplete outcome data: Unclear (Insufficient information) Selective reporting: Low (protocol available and all outcomes reported) Other bias: Control group significantly lower on voided volume (p=0.016) and Qmax at uroflowmetry (p=0.005). **Other information** Note: data/tables in Constantini 2008 and 2012 about UDI-6 score and IIQ-7 score inconsistent. Data from Constantini 2012 used.

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
	POP (Sacropexy) + SUI (Burch colposuspension) surgery (n=24): 25.6 (20.8 to 35.2) POP surgery (Sacropexy) (n=23): 26.7 (16 to 31.9); p=0.28 Parity - median (range) POP (Sacropexy) + SUI (Burch colposuspension) surgery (n=24): 2 (0 to 3) POP surgery (Sacropexy) (n=23): 2 (1 to 3); p=1.0 Follow-up (months) - Constantini (2008) - median (mean; range) POP (Sacropexy) + SUI (Burch colposuspension) surgery (n=24): 50 (46.9; 12 to 71) POP surgery (Sacropexy) (n=23): 46 (42.3; 12 to 65) Follow-up (months) - Constantini (2012) - median (range) POP (Sacropexy) + SUI (Burch colposuspension) surgery (n=24): 82 (60 to 107) POP surgery (Sacropexy) (n=23): 80 (60 to 100) Inclusion criteria • POP>2 • UI as defined by International			at 46 months post-operative follow-up (n=23): 14 at 63 months post-operative follow-up (n=22): - Incontinent Baseline: 23 at 46 months post-operative follow-up (n=23): 9 (SUI: 9); Grade 1: UI (6); Grade 2/3: UI (3) at 63 months post-operative follow-up (n=22): 9 (SUI: 6; MUI: 3); Grade I: UI (4); Grade 2/3: UI (5) Voiding symptoms Baseline: 21 at 46 months post-operative follow-up (n=23): 19/21 cured, 2 improved at 63 months post-operative follow-up (n=22): 18/20 cured, 2 improved Storage symptoms Baseline: 17 at 46 months post-operative follow-up (n=23): 15/17 cured, 2 persistent, 1 de novo at 63 months post-operative follow-up (n=22): 16/16 cured, 3 persistent, 2 de novo	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
	Continence Society • Aged 18-75 years-old • Informed consent Exclusion criteria • Benign or malignant uterus lesion (leiomyoma, fibromyoma, cervical or endometrial carcinoma) • Active pelvic inflammatory disease • Known hypersensitivity to synthetic materials (polypropylene, polytetrafluoroethylene, polyethyleneterephtalate, polyglactil acid or polyglycolic acid) • Pregnancy or lactation • Evidence of clinically significant cardiovascular, renal, hepatic or respiratory diseases • Any condition in judgment of			UDI-6 score - median (range) Baseline: 16 (0 to 43) at 46 months post-operative follow-up (n=23): - at 63 months post-operative follow-up (n=22): 2.5 (0 to 14) Repeat surgery Repeat surgery (mediurethral sling) for UI: Intervention at 69 months=4/23. Control at 63 months=2/22. Long-term complications Not reported Adverse events (immediate post-op/perioperative) *Reported no significant major perioperative and early post-operative complications. One women in each group had temporary urinary retention which was resolved in <5 days in each case. Incontinence-specific HR-QoL **POP + SUI surgery** Sexual function* No sexual intercourse Baseline (n=24): 5	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
	investigators that would (i) compromise ability to provide informed consent or comply with study instructions, (ii) place participant at increased risk, or (iii) potentially confound interpretation of results.			69 month long-term follow-up (n=23): 7 Disturbances during sexual intercourse Baseline (n=24): 10 69 month long-term follow-up (n=23): 3 No disturbance during sexual intercourse Baseline (n=24): 9 69 month long-term follow-up (n=23): 13 **POP surgery** Sexual function* No sexual intercourse Baseline (n=23): 10 63 month long-term follow-up (n=22): 9 Disturbances during sexual intercourse Baseline (n=23): 8 69 month long-term follow-up (n=22): 4 No disturbance during sexual intercourse Baseline (n=23): 5 69 month long-term follow-up (n=22): 9 IIQ-7 score - median (range)	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
				POP + SUI surgery Baseline (n=24): 16 (3 to 35) 69 month long-term follow-up (n=23): 1 (0 to 11) **POP surgery** Baseline (=23): 18 (1 to 45) 63 month long-term follow-up (n=22): 2 (0 to 17) *POP + SUI vs SUI: p=ns for all outcome comparisons Patient satisfaction/reported improvement PGI score not reported. Visual analogue score (VAS; 0-10, high scores=more satisfied) reported at long-term FU: Intervention=8 (range 4-10), Control=8.5 (5-10), ns.	
Full citation Costantini, E., Lazzeri, M., Bini, V., Del Zingaro, M., Frumenzio, E., Porena, M., Pelvic Organ Prolapse Repair with and without Concomitant Burch	**Sample size** See Constantini 2008 for details **Characteristics** See Constantini 2008 for details **Inclusion criteria**	**Interventions** See Constantini 2008 for details	**Details** See Constantini 2008 for details	**Results** See Constantini 2008 for details	**Limitations** See Constantini 2008 for details **Other information** See Constantini 2008 for details

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
Colposuspension in Incontinent Women: A Randomised Controlled Trial with at Least 5-Year Followup, Obstetrics & Gynecology International, 2012, 967923, 2012 Ref Id 541329 **Country/ies where the study was carried out** See Constantini 2008 for details **Study type** See Constantini 2008 for details **Aim of the study** See Constantini 2008 for details **Study dates** See Constantini 2008 for details **Source of funding** See Constantini 2008 for details	See Constantini 2008 for details **Exclusion criteria** See Constantini 2008 for details				

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
Full citation Borstad,E., Abdelnoor,M., Staff,A.C., Kulseng-Hanssen,S., Surgical strategies for women with pelvic organ prolapse and urinary stress incontinence, International Urogynecology Journal, 21, 179-186, 2010 Ref Id 100566 **Country/ies where the study was carried out** Norway **Study type** Multisite RCT **Aim of the study** To evaluate efficacy of SUI surgery at same time of POP surgery compared to 3 months after POP surgery	**Sample size** N=194 (Intervention=95, Control=99) **Characteristics** Age (years) - mean (range) POP + SUI (TVT) surgery (n=87): 57.2 (31 to 89) POP then SUI (TVT) surgery (n=53): 59.9 (38 to 85); p=0.2 Previous POP or UI surgery - n POP + SUI (TVT) surgery (n=87): 3 POP then SUI (TVT) surgery (n=53): 5; p=0.3 Previous hysterectomy - n POP + SUI (TVT) surgery (n=87): 7 POP then SUI (TVT) surgery (n=53): 4; p=1.0 Oestrogen use - n POP + SUI (TVT) surgery (n=87): 34 POP then SUI (TVT) surgery (n=53): 24; p=0.1 Weight (kg) - mean (range) POP + SUI (TVT) surgery (n=87): 72.5 (55 to 120) POP then SUI (TVT) surgery (n=53): 72.4 (55 to 118; p=0.9 Parity - mean (range)	**Interventions** Intervention: POP surgery (various as indicated) + concurrent SUI surgery (tension-free vaginal tape [TVT]) Control: POP surgery (various as indicated) then (after 3 months) SUI surgery (TVT)	**Details** Four participants dropped out of intervention group (died=1, rejected surgery on admission=2, no TVT performed=1); 46 dropped out of control group (died=1, refused scheduled appointment after prolapse repair=4, no SUI 3-mo after prolapse repair due to dryness=27, declined TVT despite SUI=14). Four participants were also lost to 1-yr FU in intervention group. In all 7 sites, SUI surgery conducted after completion of POP surgery using separate incision. No dissections beyond bladder neck, no Kelly plications nor mesh procedures were performed during POP surgery. All participants had physical and gynaecological examinations, prolapse evaluated using POP-Q, and all subjectively-symptomatic SUI participants underwent stress cough test in lithotomy position. All participants had same assessment for both SUI and POP 1-year post-surgery. POP surgery conducted as indicated including Manchester anterior repair, sacrospinous fixation, colpocleisis, Le Fort's operation, repairs combined	**Results** **Change in continence status** Objective cure at 12 months (ITT analysis) - n/N POP + SUI (TVT) surgery: 83/95 POP then SUI (TVT) surgery: 72/99 Objective cure at 12 months (On-treatment analysis) - n/N POP + SUI (TVT) surgery: 83/87 POP then SUI (TVT) surgery: 47/53 Repeat surgery Reports that one participant needed repeat prolapse surgery but does not provide her group assignment. Long-term complications Not reported Adverse events (immediate post-op/perioperative) Various minor complications reported in each group (total in intervention=16/87; total in control arm after prolapse repair=2/53;	**Limitations** **Risk of bias (Cochrane ROB tool)** Overall high risk of bias Random sequence generation: Low (permuted block randomisation stratified by site) Allocation concealment: Unclear (independent investigator, used set of sealed, opaque envelopes for each site) Blinding of participants/personnel: High for participants/personnel (not blinded to group assignment) Blinding of outcome assessment: High for surgical outcomes (assessors not blinded) Incomplete outcome data: High (reasons for missing data likely related to true outcome, imbalance in numbers/reasons for missing data across groups) Selective reporting: Unclear (study protocol not available) Other bias: High (recruitment was not consecutive and was left to discretion of recruiting doctor at each site) **Other information**

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
Study dates 2002-2006 **Source of funding** Not reported	POP + SUI (TVT) surgery (n=87): 2.7 (1 to 6) POP then SUI (TVT) surgery (n=53): 2.7 (0 to 6); p=0.9 **Prolapse characteristics** Anterior prolapse - n POP + SUI (TVT) surgery (n=87): 57 POP then SUI (TVT) surgery (n=53): 33; p=0.6 Posterior prolapse - n POP + SUI (TVT) surgery (n=87): 24 POP then SUI (TVT) surgery (n=53): 18; p=NR Apical prolapse - n POP + SUI (TVT) surgery (n=87): 6 POP then SUI (TVT) surgery (n=53): 2; p=NR Stage II prolapse - n POP + SUI (TVT) surgery (n=87): 47 POP then SUI (TVT) surgery (n=53): 32; p=0.5 Stage III or IV prolapse - n POP + SUI (TVT) surgery (n=87): 40 POP then SUI (TVT) surgery (n=53): 21; p=NR **Index surgery** Manchester repair - n POP + SUI (TVT) surgery (n=87): 41		with hysterectomy, and enterocele procedure. SUI surgery in control arm performed as day surgery with local anaesthesia. Cure of SUI defined as no SUI symptoms and no visible leakage when coughing in lithotomy position.	total in control arm after SUI surgery=5/53. Severe bleeding and internal organ injury Not reported. Incontinence-specific HR-QoL Not reported Patient satisfaction/reported improvement Not reported	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
	POP then SUI (TVT) surgery (n=53): 26; p=0.8 Anterior vaginal repair - n POP + SUI (TVT) surgery (n=87): 22 POP then SUI (TVT) surgery (n=53): 11; p=NR Posterior vaginal repair - n POP + SUI (TVT) surgery (n=87): 17 POP then SUI (TVT) surgery (n=53): 13; p=NR Other vaginal repair (e.g. sacrospinous fixation) - n POP + SUI (TVT) surgery (n=87): 7 POP then SUI (TVT) surgery (n=53): 3; p=NR Inclusion criteria Women admitted for vaginal prolapse repair or presenting with symptoms and objectively-verified SUI. Informed consent Women admitted with pessary who experience SUI only after pessary insertion eligible for inclusion. Exclusion criteria Not reported.				
Full citation	**Sample size**	**Interventions**	**Details**	**Results**	**Limitations** **Risk of bias (Cochrane ROB tool)**

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
van der Ploeg, J. M., Oude Rengerink, K., van der Steen, A., van Leeuwen, J. H., Stekelenburg, J., Bongers, M. Y., Weemhoff, M., Mol, B. W., van der Vaart, C. H., Roovers, J. P., Dutch Urogynaecology, Consortium, Transvaginal prolapse repair with or without the addition of a midurethral sling in women with genital prolapse and stress urinary incontinence: a randomised trial, BJOG: An International Journal of Obstetrics & Gynaecology, 122, 1022-30, 2015 Ref Id 541742 **Country/ies where the study was carried out** Netherlands	N=138 (Intervention=67; Control=71) **Characteristics** Age (years) - mean ±SD POP + SUI (n=63): 57 (9.7) POP (n=71): 56 (9.6) BMI (kg/m2) - mean ±SD POP + SUI (n=63): 26.4 (3.6) POP (n=71): 26.4 (3.6) Previous hysterectomy - n POP + SUI (n=63): 4 POP (n=71): 7 POP-Q 3+4 - n/N POP + SUI: 20/61 POP: 25/69 POP≥hymen - n/N POP + SUI: 57/61 POP: 61/69 Leading edge anterior - n/N POP + SUI: 53/61 POP: 53/69 Index surgery Anterior vaginal repair - n POP + SUI: 58 POP: 65 Anterior repair only - n POP + SUI: 16 Apical vaginal repair - n POP + SUI: 40 POP: 46 Apical repair only - n	Intervention: POP surgery (various techniques as indicated) + SUI surgery (midurethral sling) Control: POP surgery (various techniques as indicated)	After randomisation, 3 mistakes were discovered in intervention arm and 1 participant withdrew consent. In intervention group, 1 participant refused combination surgery; in control group, 1 patient was given combination surgery (analysed in control group). All patients completed Dutch-UDI at 12 months, whilst 53 and 61 attended site visit. SUI surgery (i.e. midurethral slings) occurred after vaginal prolapse surgery. Type of vaginal prolapse surgery determined by surgeon at each site on basis of prolapse stage and compartment. Use of range of midurethral slings permitted (e.g. TVT, TVT-O, TOT). Kelly plication, obliterative vaginal procedures and mini-slings not used. Outcomes measured at baseline and at 12-months after index surgery. Subjective data consisted of self-report questionnaire processed centrally; objective data collected by site investigators. Additional treatment for SUI (physiotherapy, surgery, or both) and overactive bladder (e.g. physiotherapy, antimuscarinic drug, or both) was permitted. Note that 12	**Change in continence status at 12 months** **Self-reported symptoms** Absence of UI (measured with validated Dutch-UDI) - n POP + SUI (n=63): 39 POP (n=71): 21; p<0.0001 Absence of SUI (measured with validated Dutch-UDI) - n POP + SUI (n=63): 49 POP (n=71): 28; p<0.0001 Bothersome SUI (response of 'moderately' or 'greatly' on Dutch-UDI item about SUI) - n POP + SUI (n=63): 5 POP (n=70): 14; p=ns Urge UI (measured with validated Dutch-UDI) - n POP + SUI (n=61): 18 POP (n=71): 36; p=ns Bothersome urge UI (response of 'moderately' to 'greatly' on Dutch-UDI item about urge UI) - n POP + SUI (n=61): 4 POP (n=71): 12; p=ns	Overall low risk of bias Random sequence generation: Low (central computer random number generator using blocks of 4, stratified by centre and leading edge of POP, in 1:1 ratio) Allocation concealment: Low (central allocation, sequence list concealed from participants and investigators) Blinding of participants/personnel: Low (not blinded but outcomes not likely to be influenced by this) Blinding of outcome assessment: Unclear (insufficient information) Incomplete outcome data: Low (ITT analysis, reasons for missing outcome data unlikely to be related to true outcome) Selective reporting: Low (protocol available, all outcomes except for cost reported) Other bias: Unclear (insufficient evidence that randomisation mistakes will introduce bias) **Other information**

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
Study type Multicentre RCT **Aim of the study** To compare concurrent midurethral sling and transvaginal prolapse repair with prolapse repair only **Study dates** 11/2008-4/2011 **Source of funding** Unrestricted grant from Dutch Ohra Fund	POP + SUI: 3 Sacrospinous fixation - n POP + SUI: 13 POP: 15 Vaginal hysterectomy - n POP + SUI: 23 POP: 27 Manchester Fothergill - n POP + SUI: 4 POP: 4 Anterior + apical repair - n POP + SUI: 17 POP: 21 Posterior vaginal repair - n POP + SUI: 26 POP: 30 Posterior repair only - n POP + SUI: 0 POP: 0 All 3 compartments repaired - n POP + SUI: 17 POP: 19 Transvaginal MESH repair - n POP + SUI: 0 POP: 3 Retropubic midurethral sling (TVT) - n POP + SUI: 10 POP: 0 Transobturator midurethral sling (TVT-0/TOT) - n POP + SUI: 52		participants in control arm received SUI surgery (midurethral sling). **Additional treatment for SUI** Total - n POP + SUI (n=63): 6 POP (n=71): 26 Physiotherapy - n POP + SUI: 6 POP: 14 Surgery (midurethral sling) - n POP + SUI: 0 POP: 7 Physiotherapy + surgery (midurethral sling) - n POP + SUI: 0 POP: 5 **Total additional treatment for OAB (urgency, frequency, urgency incontinence) - n** Total - n POP + SUI (n=63): 12 POP (n=71): 10 Physiotherapy - n POP + SUI: 4 POP: 3 Antimuscarinic drug - n POP + SUI: 5 POP: 3 Physiotherapy + antimuscarinic drug - n POP + SUI: 3 POP: 4	Frequency (≥10 times/24h) - n POP + SUI (n=48): 13 POP (n=50): 17; p=ns Nocturia (≥2/night) - n POP + SUI (n=63): 20 POP (n=70): 19; p=ns Change in Dutch-UDI incontinence score (mean ±SD) POP + SUI (n=63): -29 (26) POP (n=71): -18 (29); moderate effect favouring control Objective cure rate Negative stress cough test at bladder volume >300 ml - n POP + SUI (n=25): 21 POP (n=32): 18; p=ns Composite endpoint Bothersome SUI, objective SUI and/or any treatment for SUI - n POP + SUI (n=62): 13 POP (n=69): 39; p=ns **Repeat surgery** Total ≥1 repeated interventions Total - n POP + SUI (n=63): 12 POP (n=71): 19 Surgery for complication - n	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
	POP: 1 <u>Inclusion criteria</u> • Genital prolapse POP-Q≥2 • Concurrent SUI (defined as positive stress cough test [300 ml bladder filling without POP reduction] and/or positive response to item about stress on Dutch version of Urogenital Distress Inventory(UDI) ['Do you experience urine leakage related to physical exercise, coughing or sneezing?'). Symptoms of SUI present >1/week and more stress than urge episodes. • Informed consent <u>Exclusion criteria</u> • Aged<18 years-old • Pregnancy in past year, current pregnancy or			POP + SUI (n=63): 8 POP (n=71): 3 <u>Surgery for SUI (midurethral sling) - n</u> POP + SUI (n=63): 0 POP (n=71): 12 <u>Surgery for POP recurrence - n</u> POP + SUI (n=63): 4 POP (n=71): 4 <u>Long-term complications</u> Not reported **<u>Adverse events (immediate post-op/perioperative)</u>** **<u>Complications within first 12 months (defined by EAU Guideline and graded according to Accordion Severity Grading System)</u>** <u>Total severe complications</u> <u>Total - n</u> POP + SUI (n=63): 10 POP (n=710: 4 <u>Urethral tape exposure - n</u> POP + SUI (n=63): 1 POP (n=71): 0 <u>Bladder injury - n</u> POP + SUI (n=63): 2 POP (n=71): 1	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
	desire to become pregnant in the future • Isolated posterior prolapse • Prolapse surgery in last 6 months • Occult SUI • Urinary retention/residual (PMR>300 ml) • Previous surgery of urethra or bladder • Known bladder or urethra diverticulum • Systematic disease that could affect bladder function (e.g. MS) • Current/planned chemotherapy			**Change in incontinence impact questionnaire domain score - mean ±SD** Physical functioning POP + SUI (n=63): -6 (21) POP (n=71): -15 (25); p favours control Mobility POP + SUI (n=63): -10 (28) POP (n=71): -12 (23); p=ns Social functioning POP + SUI (n=63): -5 (21) POP (n=71): -11 (20); p=ns Embarrassment POP + SUI (n=63): -10 (23) POP (n=71): -11 (23); p=ns Emotional health POP + SUI (n=63): -9 (24) POP (n=71): -9 (20); p=ns Sexual function Not reported. **Incontinence-specific HR-QoL**	

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
				Patient satisfaction/reported improvement PGI-I improved at 12 months (7-pt scale, 'improved' defined as much or very much improvement) - n/N POP + SUI: 44/62 POP: 48/71; p=ns PGI-S no complaints at 12 months (dichotomous outcome: no complaints vs mild/moderate/severe complaints) - n/N POP + SUI: 45/63 POP: 44/70; p=ns	

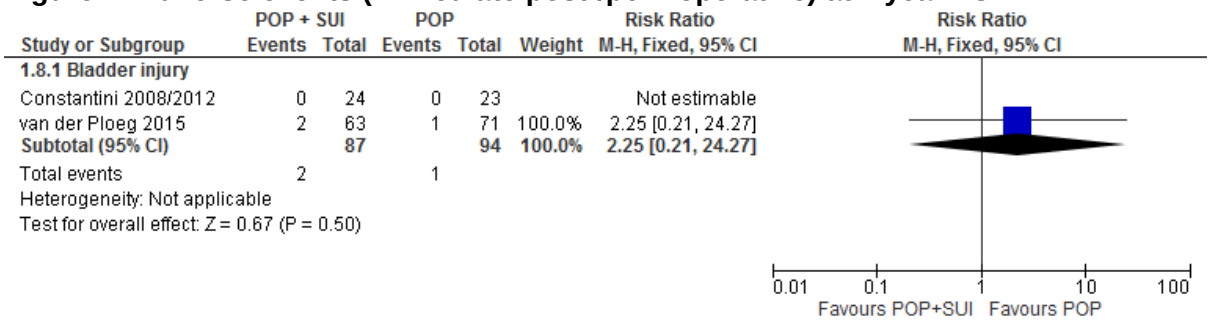
EAU: European Association of Urology; FU: Follow-Up; h: Hours; HR-QoL: Health-Related Quality of Life; IIQ-7: Incontinence Impact Questionnaire-7; ITT: Intention-to-Treat; kg: Kilogram; ml: Millilitre; MUI: Mixed Urinary Incontinence; N: Number; NR: Not Reported; ns:: not significant; OAB: Overactive Bladder; PGI-I: Patient Global Impression of Improvement; PGI-S: Patient Global Impression of Severity; POP: Pelvic Organ Prolapse; POP-Q: Pelvic Organ Prolapse Questionnaire; RCT: Randomised Controlled Trial; ROB: Risk of Bias; SD: Standard Deviation; SUI: Stress Uinary Incontinence; TOT: Transobturator Tape; TVT: Tension-free Vaginal Tape; TVT-O: Tension-free Vaginal tape-Obturator; UDI: Urogenital Distress Inventory; UI: Urinary Incontinence; VAS: Visual Analogue Scale; vs: Versus

Appendix E – Forest plots

Forest plots for review question: What is the most effective surgical management for women with both stress urinary incontinence and pelvic organ prolapse, including the sequence of interventions?

POP and SUI surgery versus POP surgery only

Figure 2: Adverse events (immediate post-/peri- operative) at 1 year FU



POP and SUI surgery versus POP surgery then SUI surgery

It was not possible to conduct meta-analysis as only 1 RCT study was found for this review. Therefore no forest plots for this comparison are included in this appendix.

Appendix F – GRADE tables

GRADE tables for review question: What is the most effective surgical management for women with both stress urinary incontinence and pelvic organ prolapse, including the sequence of interventions?

POP and SUI surgery versus POP surgery only

Table 5: Full clinical evidence profile for POP and SUI surgery versus POP surgery in women with both POP and SUI

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	POP and SUI surgery	POP surgery only	Relative (95% CI)	Absolute		
Objective cure: Negative stress test at 1 year (follow-up 1 years; assessed with: Stress (cough) test with bladder volume >300ml or subjectively-full bladder)												
1	randomised trials	no serious risk of bias	no serious inconsistency	serious[1]	serious[2]	none	21/25 (84%)	18/32 (56.3%)	RR 1.49 (1.05 to 2.12)	276 more per 1000 (from 28 more to 630 more)	⊕⊕OO LOW	CRITICAL
Objective cure: Negative stress test at >5-year follow up (follow-up 5 years; assessed with: Negative stress (cough) test, no reported leakage, and no pad use)												
1	randomised trials	serious[3]	no serious inconsistency	no serious indirectness	very serious[4]	none	11/24 (45.8%)	14/23 (60.9%)	RR 0.75 (0.44 to 1.3)	152 fewer per 1000 (from 341 fewer to 183 more)	⊕OOO VERY LOW	CRITICAL
Self-reported symptoms: No voiding symptoms at >5-years follow up (follow-up 5 years; assessed with: International Continence Society definition)												
1	randomised trials	serious[3]	no serious inconsistency	no serious indirectness	serious[2]	none	16/17 (94.1%)	18/20 (90%)	RR 1.05 (0.87 to 1.26)	45 more per 1000 (from 117 fewer to 234 more)	⊕⊕OO LOW	CRITICAL
Self-reported symptoms: No storage symptoms at >5-years follow up (follow-up 5 years; assessed with: International Continence Society definition)												
1	randomised trials	serious[3]	no serious inconsistency	no serious indirectness	serious[2]	none	10/15 (66.7%)	16/16 (100%)	RR 0.68 (0.47 to 0.97)	320 fewer per 1000 (from 30 fewer to 530 fewer)	⊕⊕OO LOW	CRITICAL

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	POP and SUI surgery	POP surgery only	Relative (95% CI)	Absolute		
Self-reported symptoms: UDI change scores - Overall UI score (follow-up 1 years; measured with: Urogenital Distress Inventory; range of scores: 0-100; Better indicated by lower values)												
1	randomised trials	no serious risk of bias	no serious inconsistency	serious[1]	serious[5]	none	63	71	-	MD 11 lower (20.31 to 1.69 lower)	⊕⊕OO LOW	CRITICAL
Self-reported symptoms: UDI change scores - Overactive bladder (follow-up 1 years; measured with: Urogenital Distress Inventory; range of scores: 0-100; Better indicated by lower values)												
1	randomised trials	no serious risk of bias	no serious inconsistency	serious[1]	no serious imprecision[6]	none	63	71	-	MD 4 lower (11.45 lower to 3.45 higher)	⊕⊕⊕O MODERATE	CRITICAL
Self-reported symptoms: UDI change scores - Obstructive micturition (follow-up 1 years; measured with: Urogenital Distress Inventory; range of scores: 0-100; Better indicated by lower values)												
1	randomised trials	no serious risk of bias	no serious inconsistency	serious[1]	serious[7]	none	63	71	-	MD 3 lower (11.64 lower to 5.64 higher)	⊕⊕OO LOW	CRITICAL
Self-reported symptoms: UDI change scores - Genital prolapse (follow-up 1 years; measured with: Urogenital Distress Inventory; range of scores: 0-100; Better indicated by lower values)												
1	randomised trials	no serious risk of bias	no serious inconsistency	serious[1]	no serious imprecision[7]	none	63	71	-	MD 0 higher (11.59 lower to 11.59 higher)	⊕⊕⊕O MODERATE	CRITICAL
Self-reported symptoms: UDI change scores - Pain/discomfort (follow-up 1 years; measured with: Urogenital Distress Inventory; range of scores: 0-100; Better indicated by lower values)												
1	randomised trials	no serious risk of bias	no serious inconsistency	serious[1]	no serious imprecision[6]	none	63	71	-	MD 2 lower (10.82 lower to 6.82 higher)	⊕⊕⊕O MODERATE	CRITICAL
Self-reported symptoms: UDI score - No UI (follow-up 1 years; assessed with: Negative response to relevant Dutch Urogenital Distress Inventory question)												
1	randomised trials	no serious risk of bias	no serious inconsistency	serious[1]	no serious imprecision	none	39/63 (61.9%)	21/71 (29.6%)	RR 2.09 (1.39 to 3.15)	322 more per 1000 (from 115 more to 636 more)	⊕⊕⊕O MODERATE	CRITICAL
Self-reported symptoms: UDI score - No SUI (follow-up 1 years; assessed with: Negative response to relevant Dutch Urogenital Distress Inventory question)												

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	POP and SUI surgery	POP surgery only	Relative (95% CI)	Absolute		
1	randomised trials	no serious risk of bias	no serious inconsistency	serious[1]	no serious imprecision	none	49/63 (77.8%)	28/71 (39.4%)	RR 1.97 (1.44 to 2.71)	383 more per 1000 (from 174 more to 674 more)	⊕⊕⊕O MODERATE	CRITICAL
Self-reported symptoms: UDI score - No urge UI (follow-up 1 years; assessed with: Negative response to relevant Dutch Urogenital Distress Inventory question)												
1	randomised trials	no serious risk of bias	no serious inconsistency	serious[1]	serious[2]	none	43/63 (68.3%)	35/71 (49.3%)	RR 1.38 (1.04 to 1.85)	187 more per 1000 (from 20 more to 419 more)	⊕⊕OO LOW	CRITICAL
Repeat surgery - For complications (follow-up 1 years)												
1	randomised trials	no serious risk of bias	no serious inconsistency	serious[1]	serious[2]	none	8/63 (12.7%)	3/71 (4.2%)	RR 3.01 (0.83 to 10.84)	85 more per 1000 (from 7 fewer to 416 more)	⊕⊕OO LOW	CRITICAL
Repeat surgery - For POP reoccurrence (follow-up 1 years)												
1	randomised trials	no serious risk of bias	no serious inconsistency	serious[1]	very serious[4]	none	4/63 (6.3%)	4/71 (5.6%)	RR 1.13 (0.29 to 4.32)	7 more per 1000 (from 40 fewer to 187 more)	⊕OOO VERY LOW	CRITICAL
Repeat surgery for midurethral sling after initial Burch colposuspension (follow-up 5 years)												
1	randomised trials	serious[3]	no serious inconsistency[8]	no serious indirectness	very serious[4]	none	4/23 (17.4%)	2/22 (9.1%)	RR 1.91 (0.39 to 9.41)	83 more per 1000 (from 55 fewer to 765 more)	⊕OOO VERY LOW	CRITICAL
Repeat surgery for midurethral sling after initial midurethral sling (follow-up 1 years)												
1	randomised trials	no serious risk of bias	no serious inconsistency	serious[1]	no serious imprecision	none	0/63 (0%)	12/71 (16.9%)	RR 0.04 (0 to 0.74)	162 fewer per 1000 (from 44 fewer to 169 fewer)	⊕⊕⊕O MODERATE	CRITICAL
Adverse events (immediate post-/peri- operative) - Bladder injury (follow-up 1-5 years)												

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	POP and SUI surgery	POP surgery only	Relative (95% CI)	Absolute		
2	randomised trials	no serious risk of bias[3,9]	no serious inconsistency	serious[1]	very serious[4]	none	2/87 (2.3%)	1/94 (1.1%)	RR 2.25 (0.21 to 24.27)	13 more per 1000 (from 8 fewer to 248 more)	⊕OOO VERY LOW	IMPORTANT
Incontinence specific-QoL: Sexual function at >5 years FU - No sexual intercourse (follow-up 5 years)												
1	randomised trials	serious[3]	no serious inconsistency	no serious indirectness	very serious[4]	none	7/23 (30.4%)	9/22 (40.9%)	RR 0.74 (0.34 to 1.65)	106 fewer per 1000 (from 270 fewer to 266 more)	⊕OOO VERY LOW	IMPORTANT
Incontinence specific-QoL: Sexual function at >5 years FU - Disturbances during intercourse (follow-up 5 years)												
1	randomised trials	serious[3]	no serious inconsistency	no serious indirectness	very serious[4]	none	3/23 (13%)	4/22 (18.2%)	RR 0.72 (0.18 to 2.85)	51 fewer per 1000 (from 149 fewer to 336 more)	⊕OOO VERY LOW	IMPORTANT
Incontinence specific-QoL: Sexual function >5 years FU - No disturbances during intercourse (follow-up 5 years)												
1	randomised trials	serious[3]	no serious inconsistency	no serious indirectness	very serious[4]	none	13/23 (56.5%)	9/22 (40.9%)	RR 1.38 (0.75 to 2.56)	155 more per 1000 (from 102 fewer to 638 more)	⊕OOO VERY LOW	IMPORTANT
Incontinence-specific QoL: IIQ at 1 year FU - Physical functioning (measured with: Incontinence Impact Questionnaire; range of scores: 0-100; Better indicated by lower values)												
1	randomised trials	no serious risk of bias	no serious inconsistency	serious[1]	serious[10,11]	none	63	71	-	MD 9 higher (1.88 to 16.12 higher)	⊕⊕OO LOW	IMPORTANT
Incontinence-specific QoL: IIQ at 1 year FU - Mobility (measured with: Incontinence Impact Questionnaire; range of scores: 0-100; Better indicated by lower values)												
1	randomised trials	no serious risk of bias	no serious inconsistency	serious[1]	no serious imprecision[10]	none	63	71	-	MD 3 higher (5.74 lower to 11.74 higher)	⊕⊕⊕O MODERATE	IMPORTANT
Incontinence-specific QoL: IIQ at 1 year FU - Social functioning (measured with: Incontinence Impact Questionnaire; range of scores: 0-100; Better indicated by lower values)												
1	randomised trials	no serious risk of bias	no serious inconsistency	serious[1]	serious[10,11]	none	63	71	-	MD 6 higher (0.97 lower to 12.97 higher)	⊕⊕OO LOW	IMPORTANT

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	POP and SUI surgery	POP surgery only	Relative (95% CI)	Absolute		
Incontinence-specific QoL: IIQ at 1 year FU - Embarrassment (measured with: Incontinence Impact Questionnaire; range of scores: 0-100; Better indicated by lower values)												
1	randomised trials	no serious risk of bias	no serious inconsistency	serious[1]	no serious imprecision[10]	none	63	71	-	MD 1 higher (6.8 lower to 8.8 higher)	⊕⊕⊕O MODERATE	IMPORTANT
Incontinence-specific QoL: IIQ at 1 year FU - Emotional health (measured with: Incontinence Impact Questionnaire; range of scores: 0-100; Better indicated by lower values)												
1	randomised trials	no serious risk of bias	no serious inconsistency	serious[1]	no serious imprecision[10]	none	63	71	-	MD 0 higher (7.53 lower to 7.53 higher)	⊕⊕⊕O MODERATE	IMPORTANT
Incontinence-specific QoL: IIQ-7 overall score at >5 years FU (follow-up 5 years; measured with: Incontinence Impact Questionnaire-7 (short-form); range of scores: 0-100; Better indicated by lower values)												
1	randomised trials	serious[3]	no serious inconsistency	no serious indirectness	no serious imprecision	none	23	22	-	not pooled	⊕⊕⊕O MODERATE	IMPORTANT
Patient-satisfaction/reported improvement - Willingness to repeat surgery at long-term FU												
1	randomised trials	serious[3]	no serious inconsistency	no serious indirectness	serious[2]	none	20/23 (87%)	19/22 (86.4%)	RR 1.01 (0.8 to 1.27)	9 more per 1000 (from 173 fewer to 233 more)	⊕⊕OO LOW	IMPORTANT
Patient-satisfaction/reported improvement - PGI-I Improved at 12 months												
1	randomised trials	no serious risk of bias	no serious inconsistency	serious[1]	serious[2]	none	44/62 (71%)	48/71 (67.6%)	RR 1.05 (0.84 to 1.32)	34 more per 1000 (from 108 fewer to 216 more)	⊕⊕OO LOW	IMPORTANT
Patient-satisfaction/reported improvement - PGI-S No complaints at 12 months												
1	randomised trials	no serious risk of bias	no serious inconsistency	serious[1]	serious[2]	none	45/63 (71.4%)	44/70 (62.9%)	RR 1.14 (0.9 to 1.44)	88 more per 1000 (from 63 fewer to 277 more)	⊕⊕OO LOW	IMPORTANT
Patient-satisfaction/reported improvement - VAS score at >5 years FU (measured with: Visual Analogue Scale; Better indicated by lower values)												

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	POP and SUI surgery	POP surgery only	Relative (95% CI)	Absolute		
1	randomised trials	serious[3]	no serious inconsistency	no serious indirectness	no serious imprecision	none	20	19	-	not pooled	⊕⊕⊕O MODERATE	IMPORTANT

CI: confidence interval; FU: follow-up; IIQ: incontinence impact questionnaire; MD; mean difference; ml: millilitre; no: number; POP: pelvic organ prolapse; QoL: quality of life; RR: relative risk; SUI: stress urinary incontinence; UDI: urogenital distress inventory; UI: urinary incontinence

[1] Only 60% of participants in van der Ploeg et al. 2015 had objectively-verified (i.e. positive stress [cough] test) SUI.
[2] 95% CI crosses 1 default MID for dichotomous outcomes (0.8 or 1.25).
[3] Overall high risk of bias due to: unclear risk of bias about allocation concealment, blinding of participants/personnel, and incomplete outcome data; POP surgery only arm significantly lower at baseline than POP and SUI surgery arm on voided volume and Qmax at uroflowmetry.
[4] 95% CI crosses 2 default MIDs for dichotomous outcomes (0.8 and 1.25).
[5] 95% CI crosses 1 published MID for this outcome (+/- 11 points, from Barber 2010).
[6] The MIDs for the UDI overactive bladder and pain/discomfort subscales, calculated as 0.5 times the SD of the control arm at follow up, were +/- 11.5 points and 13 points, respectively.
[7] MIDs for these outcomes, calculated as 0.5 times the SD of the control arm at baseline, were +/- 12.5 points for obstructive micturition and +/- 14.5 points for genital prolapse.
[8] Very high heterogeneity, i2>=80%.
[9] Overall low risk of bias since there were no events in Constantini et al. 2008/2012.
[10] The MIDs for the IIQ subscales, calculated as 0.5 times the SD of the control arm on the relevant subscales at baseline, were as follows: +/- 11 points for Physical functioning, +/- 12.5 points for Mobility, +/- 9.5 points for Social functioning, +/- 13.5 points for Embarrassment, and +/- 11 points for Emotional health.
[11] 95% CI crosses 1 MID for this outcome.

POP and SUI surgery versus POP surgery then SUI surgery

Table 6: Full clinical evidence profile for POP and SUI surgery versus POP surgery then SUI surgery in women with both POP and SUI

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	POP and SUI surgery	POP surgery then SUI surgery	Relative (95% CI)	Absolute		
Objective cure at 1 year FU - ITT analysis (assessed with: No SUI symptoms and negative stress test)												

1	randomised trials	serious[1]	no serious inconsistency	no serious indirectness	serious[2]	none	83/95 (87.4%)	72/99 (72.7%)	RR 1.2 (1.04 to 1.39)	145 more per 1000 (from 29 more to 284 more)	⊕⊕OO LOW	CRITICAL

CI: Confidence Interval; FU: Follow-Up; IIQ: Incontinence Impact Questionnaire; MD; Mean Difference; ml: millilitre; no: number; POP: Pelvic Organ Prolapse; QoL: Quality of Life; RR: Relative Risk; SUI: Stress Urinary Incontinence; UDI: Urogenital Distress Inventory; UI: Urinary Incontinence

[1] Overall high risk of bias: unclear risk of bias about allocation concealment, blinding of personnel, incomplete outcome data (high drop out in control arm due to refusal of TVT surgery, imbalance in group numbers), selective reporting; recruitment also not consecutive but left to discretion of recruiting doctor at each site.
[2] 95% CI crosses 1 default MID for dichotomous outcomes (0.8 or 1.25).

Appendix G – Economic evidence study selection

Economic evidence study selection for review question: What is the most effective surgical management for women with both stress urinary incontinence and pelvic organ prolapse, including the sequence of interventions?

One global search was conducted for this review question. See supplementary material D for further information.

Appendix H – Economic evidence tables

Economic evidence tables for review question: What is the most effective surgical management for women with both stress urinary incontinence and pelvic organ prolapse, including the sequence of interventions?

No economic evidence was identified which was applicable to this review question

Appendix I – Economic evidence profiles

Economic evidence profiles for review question: What is the most effective surgical management for women with both stress urinary incontinence and pelvic organ prolapse, including the sequence of interventions?

No economic evidence was identified which was applicable to this review question.

Appendix J – Economic analysis

Economic analysis for review question: What is the most effective surgical management for women with both stress urinary incontinence and pelvic organ prolapse, including the sequence of interventions?

No economic analysis was conducted for this review question.

Appendix K – Excluded studies

Excluded studies for review question: What is the most effective surgical management for women with both stress urinary incontinence and pelvic organ prolapse, including the sequence of interventions?

Clinical studies

Table 7: Excluded clinical studies with reasons for exclusion

Study	Reason for Exclusion
Aslam, Mf, Gregory, Wt, Osmundsen, B, Effect of sacrocolpopexy and retropubic sling on overactive bladder symptoms, Journal of the turkish-german gynecological association, 18, 9-14, 2017	Study design does not meet the inclusion criteria - observational study
Atiemo,H.O., Should an anti-incontinence procedure be routinely performed at the time of pelvic organ prolapse repair? An evidence-based review, Current Urology Reports, 11, 304-309, 2010	Narrative literature review
Baessler, K., Aigmuller, T., Albrich, S., Anthuber, C., Finas, D., Fink, T., Funfgeld, C., Gabriel, B., Henscher, U., Hetzer, F. H., Hubner, M., Junginger, B., Jundt, K., Kropshofer, S., Kuhn, A., Loge, L., Nauman, G., Peschers, U., Pfiffer, T., Schwandner, O., Strauss, A., Tunn, R., Viereck, V., Diagnosis and Therapy of Female Pelvic Organ Prolapse. Guideline of the DGGG, SGGG and OEGGG (S2e-Level, AWMF Registry Number 015/006, April 2016), Geburtshilfe und Frauenheilkunde, 76, 1287-1301, 2016	Guideline - references checked for inclusion
Baessler, K., Maher, C., Pelvic organ prolapse surgery and bladder function, International Urogynecology Journal, 24, 1843-52, 2013	Systematic review - references checked for inclusion
Barber, M. D., Brubaker, L., Burgio, K. L., Richter, H. E., Nygaard, I., Weidner, A. C., Menefee, S. A., Lukacz, E. S., Norton, P., Schaffer, J., Nguyen, J. N., Borello-France, D., Goode, P. S., Jakus-Waldman, S., Spino, C., Warren, L. K., Gantz, M. G., Meikle, S. F., Eunice Kennedy Shriver National Institute of Child, Health, Human Development Pelvic Floor Disorders, Network, Comparison of 2 transvaginal surgical approaches and perioperative behavioral therapy for apical vaginal prolapse: the OPTIMAL randomized trial.[Erratum appears in JAMA. 2015 Jun 9;313(22):2287; PMID: 26057298], JAMA, 311, 1023-34, 2014	Intervention/comparator does not meet the inclusion criteria - no combined/sequential prolapse, SUI surgery intervention
Barski, D., Deng, D. Y., Management of Mesh Complications after SUI and POP Repair: Review and Analysis of the Current Literature, BioMed Research International, 2015, 831285, 2015	Systematic review - included studies not relevant, all were retrospective by design
Black, N. A., Downs, S. H., The effectiveness of surgery for stress incontinence in women: A systematic review, British journal of urology, 78, 497-510, 1996	Systematic review - references checked for inclusion
Bradley, C. S., Brown, M. B., Cundiff, G. W., Goode, P. S., Kenton, K. S., Nygaard, I. E., Whitehead, W. E., Wren, P. A., Weber, A. M., Pelvic Floor Disorders, Network, Bowel symptoms in women planning surgery for pelvic organ prolapse, American Journal of Obstetrics & GynecologyAm J Obstet Gynecol, 195, 1814-9, 2006	Study design does not meet the inclusion criteria - observational study

Study	Reason for Exclusion
Bradley, C. S., Nygaard, I. E., Brown, M. B., Gutman, R. E., Kenton, K. S., Whitehead, W. E., Goode, P. S., Wren, P. A., Ghetti, C., Weber, A. M., Pelvic Floor Disorders, Network, Bowel symptoms in women 1 year after sacrocolpopexy, American Journal of Obstetrics & Gynecology, 197, 642.e1-8, 2007	Study design does not meet the inclusion criteria - observational study
Brubaker,L., Nygaard,I., Richter,H.E., Visco,A., Weber,A.M., Cundiff,G.W., Fine,P., Ghetti,C., Brown,M.B., Two-year outcomes after sacrocolpopexy with and without burch to prevent stress urinary incontinence, Obstetrics and Gynecology, 112, 49-55, 2008	Population does not meet the inclusion criteria - women are stress-continent
Bruce, R. G., El-Galley, R. E., Galloway, N. T., Paravaginal defect repair in the treatment of female stress urinary incontinence and cystocele, Urology, 54, 647-51, 1999	Study design does not meet the inclusion criteria - non-randomised
Bump,R.C., Hurt,W.G., Theofrastous,J.P., Addison,W.A., Fantl,J.A., Wyman,J.F., McClish,D.K., Randomized prospective comparison of needle colposuspension versus endopelvic fascia plication for potential stress incontinence prophylaxis in women undergoing vaginal reconstruction for stage III or IV pelvic organ prolapse. The Continence Program for Women Research Group, American Journal of Obstetrics and Gynecology, 175, 326-333, 1996	Population does not meet the inclusion criteria - women are not preoperative stress-incontinent
Chermansky,C.J., Krlin,R.M., Winters,J.C., Selective management of the urethra at time of pelvic organ prolapse repair: An assessment of postoperative incontinence and patient satisfaction, Journal of Urology, 187, 2144-2148, 2012	Population does not meet inclusion criteria - unclear which type of stress UI women have
Chughtai, B., Barber, M. D., Mao, J., Forde, J. C., Normand, S. T., Sedrakyan, A., Association Between the Amount of Vaginal Mesh Used With Mesh Erosions and Repeated Surgery After Repairing Pelvic Organ Prolapse and Stress Urinary Incontinence, JAMA SurgeryJAMA Surg, 152, 257-263, 2017	Study design does not meet the inclusion criteria - observational study
Colaco, M., Mettu, J., Badlani, G., The scientific basis for the use of biomaterials in stress urinary incontinence (SUI) and pelvic organ prolapse (POP), BJU International, 115, 859-66, 2015	Systematic review - references checked for inclusion
Coroleuca, C., Ionescu, C. A., Dimitriu, M., Popescu, I., Coroleuca, C. A., Serbanescu, L., Sexual function and vaginal surgery, Gineco.eu, 13, 5-8, 2017	Systematic review - references checked for inclusion
Costantini, E., Zucchi, A., Giannantoni, A., Mearini, L., Bini, V., Porena, M., Must colposuspension be associated with sacropexy to prevent postoperative urinary incontinence?, European Urology, 51, 788-94, 2007	Population does not meet the inclusion criteria - women are continent
De Tayrac, R., Gervaise, A., Chauveaud-Lambling, A., Fernandez, H., Combined genital prolapse repair reinforced with a polypropylene mesh and tension-free vaginal tape in women with genital prolapse and stress urinary incontinence: A retrospective case-control study with short-term follow-up, Acta Obstetricia et Gynecologica Scandinavica, 83, 950-954, 2004	Study design does not meet the inclusion criteria - observational study
Diwadkar, G. B., Chen, C. C., Paraiso, M. F., An update on the laparoscopic approach to urogynecology and pelvic reconstructive procedures, Current Opinion in Obstetrics & Gynecology, 20, 496-500, 2008	Systematic review - references checked for inclusion
Dmochowski,R.R., Blaivas,J.M., Gormley,E.A., Juma,S., Karram,M.M., Lightner,D.J., Luber,K.M., Rovner,E.S., Staskin,D.R., Winters,J.C., Appell,R.A., Update of AUA Guideline on the Surgical Management of Female Stress Urinary Incontinence, Journal of Urology, 183, 1906-1914, 2010	Guideline - details of included studies not provided

Study	Reason for Exclusion
Drain, A., Khan, A., Ohmann, E. L., Brucker, B. M., Smilen, S., Rosenblum, N., Nitti, V. W., Use of Concomitant Stress Incontinence Surgery at Time of Pelvic Organ Prolapse Surgery Since Release of the 2011 Notification on Serious Complications Associated with Transvaginal Mesh, Journal of Urology, 197, 1092-1098, 2017	Study design does not meet the inclusion criteria - observational study
Ghielmetti,T., Kuhn,P., Dreher,E.F., Kuhn,A., Gynaecological operations: Do they improve sexual life?, European Journal of Obstetrics Gynecology and Reproductive Biology, 129, 104-110, 2006	Systematic review - included studies were not relevant, all were observational by design
Glazener, Cathryn Ma, Cooper, Kevin, Mashayekhi, Atefeh, Bladder neck needle suspension for urinary incontinence in women, Cochrane Database of Systematic Reviews, 2017	Systematic review - references checked for inclusion
Glazener, Cathryn Ma, Cooper, Kevin, Mashayekhi, Atefeh, Anterior vaginal repair for urinary incontinence in women, Cochrane Database of Systematic Reviews, 2017	Systematic review - references checked for inclusion
Handa, V. L., Zyczynski, H. M., Brubaker, L., Nygaard, I., Janz, N. K., Richter, H. E., Wren, P. A., Brown, M. B., Weber, A. M., Pelvic Floor Disorders, Network, Sexual function before and after sacrocolpopexy for pelvic organ prolapse, American Journal of Obstetrics & GynecologyAm J Obstet Gynecol, 197, 629.e1-6, 2007	Population does not meet the inclusion criteria - women are stress-continent
Juul, L., Van Rensburg, J. A., Combined stress urinary incontinence surgery at the time of prolapse surgery - Is it justified?, South African journal of obstetrics and gynaecology, 15, 86-88, 2009	Narrative literature reveiw
Khullar, V., Anding, R., Robinson, D., Castro-Diaz, D., Dmochowski, R., Cardozo, L., Under what circumstances should stress incontinence surgery be performed at the same time as prolapse surgery? ICI-RS 2015, Neurourology and Urodynamics, 36, 909-914, 2017	Narrative literature reveiw
King, A. B., Goldman, H. B., Stress incontinence surgery at the time of prolapse surgery: mandatory or forbidden?, World Journal of Urology, 33, 1257-62, 2015	Narrative literature reveiw
Koch, Y. K., Zimmern, P., A critical overview of the evidence base for the contemporary surgical management of stress incontinence, Current Opinion in Urology, 18, 370-6, 2008	Systematic review - references checked for inclusion
Lamblin,G., Van-Nieuwenhuyse,A., Chabert,P., Lebail-Carval,K., Moret,S., Mellier,G., A randomized controlled trial comparing anatomical and functional outcome between vaginal colposuspension and transvaginal mesh, International Urogynecology Journal and Pelvic Floor Dysfunction, 25, 961-970, 2014	Intervention/comparator does not meet the inclusion criteria - no combined/sequential prolapse, SUI surgery intervention
Lapitan, Marie Carmela M, Cody, June D, Mashayekhi, Atefeh, Open retropubic colposuspension for urinary incontinence in women, Cochrane Database of Systematic Reviews, 2017	Systematic review - references checked for inclusion
Latini, J. M., Kreder Jr, K. J., Associated pelvic organ prolapse in women with stress urinary incontinence: When to operate?, Current Opinion in Urology, 15, 380-385, 2005	Systematic review - references checked for inclusion
MacDonald, S., Terlecki, R., Costantini, E., Badlani, G., Complications of Transvaginal Mesh for Pelvic Organ Prolapse and Stress Urinary Incontinence: Tips for Prevention, Recognition, and Management, European Urology Focus, 2, 260-267, 2016	Unable to obtain full text article

Study	Reason for Exclusion
Maher, C. M., Feiner, B., Baessler, K., Glazener, C. M., Surgical management of pelvic organ prolapse in women: the updated summary version Cochrane review, International Urogynecology Journal, 22, 1445-57, 2011	Systematic review - older version of excluded review (Maher 2016)
Maher, Christopher, Feiner, Benjamin, Baessler, Kaven, Christmann-Schmid, Corina, Haya, Nir, Brown, Julie, Surgery for women with apical vaginal prolapse, Cochrane Database of Systematic Reviews, 2016	Systematic review - references checked for inclusion
Maher, Christopher, Feiner, Benjamin, Baessler, Kaven, Christmann-Schmid, Corina, Haya, Nir, Brown, Julie, Surgery for women with anterior compartment prolapse, Cochrane Database of Systematic Reviews, 2016	Systematic review - references checked for inclusion
Maher,C., Baessler,K., Surgical management of anterior vaginal wall prolapse: An evidence based literature review, International urogynecology journal and pelvic floor dysfunction, 17, 195-201, 2006	Systematic review - references checked for inclusion
McDermott, C. D., Terry, C. L., Woodman, P. J., Hale, D. S., Does tension-free vaginal tape placement at the time of total prolift colpopexy affect distal anterior vaginal support?, Female Pelvic Medicine & Reconstructive Surgery, 16, 353-7, 2010	Study design does not meet the inclusion criteria - observational study
Miklos, J. R., Kohli, N., Laparoscopic paravaginal repair plus burch colposuspension: review and descriptive technique, Urology, 56, 64-9, 2000	Systematic review - references checked for inclusion
Mohsin Rizvi, R., Akhtar, M., Zuberi, N. F., A Review of Comparison of Complications of Vaginal Hysterectomy with and without Concomitant Surgery for SUI: A 5 Years' Experience at a Tertiary Care Hospital of Pakistan, Obstetrics & Gynecology International, 2013, 540646, 2013	Study design does not meet the inclusion criteria - observational study
Nygaard, I. E., McCreery, R., Brubaker, L., Connolly, A., Cundiff, G., Weber, A. M., Zyczynski, H., Pelvic Floor Disorders, Network, Abdominal sacrocolpopexy: a comprehensive review, Obstetrics & Gynecology, 104, 805-23, 2004	Systematic review - references checked for inclusion
Nygaard, I., Brubaker, L., Zyczynski, H. M., Cundiff, G., Richter, H., Gantz, M., Fine, P., Menefee, S., Ridgeway, B., Visco, A., Warren, L. K., Zhang, M., Meikle, S., Long-term outcomes following abdominal sacrocolpopexy for pelvic organ prolapse.[Erratum appears in JAMA. 2013 Sep 11;310(10):1076], JAMA, 309, 2016-24, 2013	Population does not meet inclusion criteria - women are stress-continent
Onwude, J. L., Genital prolapse in women, Clinical Evidence, 2012	Systematic review - references checked for inclusion
Patel,M., O'Sullivan,D., Tulikangas,P.K., Is Burch or mid-urethral sling better with abdominal sacral colpopexy?, International Urogynecology Journal, 20, 787-790, 2009	Study design does not meet the inclusion criteria - observational study
Qatawneh, A., Al-Kazaleh, F., Saleh, S., Thekrallah, F., Bata, M., Sumreen, I., Al-Mustafa, M., Transvaginal cystocele repair using tension-free polypropylene mesh at the time of sacrospinous colpopexy for advanced uterovaginal prolapse: A prospective randomised study, Gynecological surgery, 10, 79-85, 2013	Population does not meet inclusion criteria - fewer than 60% combined POP and SUI sample

Study	Reason for Exclusion
Roovers,J.P.W.R., Oelke,M., Clinical relevance of urodynamic investigation tests prior to surgical correction of genital prolapse: A literature review, International urogynecology journal and pelvic floor dysfunction, 18, 455-460, 2007	Systematic review - references checked for inclusion
Shah, H. N., Badlani, G. H., Mesh complications in female pelvic floor reconstructive surgery and their management: A systematic review, Indian Journal of Urology, 28, 129-53, 2012	Systematic review - references checked for inclusion
Shepherd,J.P., Alperin,M., Meyn,L.A., Frankman,E.A., Zyczynski,H.M., Now or later...Does timing of a midurethral sling in relation to transvaginal prolapse repair affect continence outcomes at 1 year?, Female Pelvic Medicine and Reconstructive Surgery, 16, 299-303, 2010	Study design does not meet the inclusion criteria - observational study
Sohbati, S., Salari, Z., Eftekhari, N., Comparison Between the Transobturator Tape Procedure and Anterior Colporrhaphy With the Kelly's Plication in the Treatment of Stress Urinary Incontinence: a Randomized Clinical Trial, Nephrourology MonthlyNephrourol Mon, 7, e32046, 2015	Population does not meet inclusion criteria - women have a history of SUI without subjective POP
Takahashi,S., Obinata,D., Sakuma,T., Matsui,T., Takenobu,Y., Igarashi,T., Yoshizawa,T., Sato,K., Mochida,J., Sugimoto,S., Transvaginal mesh (TVM) reconstruction with TVT/TOT sling for vaginal prolapse concurrent with stress urinary incontinence, Aktuelle Urologie, 41 Suppl 1, S20-S23, 2010	Study design does not meet the inclusion criteria - observational study
Toz, E., Ozcan, A., Apaydin, N., Uyar, I., Kocakaya, B., Okay, G., Outcomes of vaginal hysterectomy and constricting colporrhaphy with concurrent levator myorrhaphy and high perineorrhaphy in women older than 75 years of age, Clinical interventions in aging, 10, 1009-1015, 2015	Study design does not meet the inclusion criteria - observational study
van der Ploeg, J. M., van der Steen, A., Oude Rengerink, K., van der Vaart, C. H., Roovers, J. P., Prolapse surgery with or without stress incontinence surgery for pelvic organ prolapse: a systematic review and meta-analysis of randomised trials, BJOG: An International Journal of Obstetrics & Gynaecology, 121, 537-47, 2014	Systematic review - older version of excluded review (van der Ploeg 2017)
van der Ploeg, J. M., van der Steen, A., Zwolsman, S., van der Vaart, C. H., Roovers, J. W. R., Prolapse surgery with or without incontinence procedure; a systematic review and meta-analysis, 22, 22, 2017	Systematic review - references checked for inclusion
Visco, A. G., Brubaker, L., Nygaard, I., Richter, H. E., Cundiff, G., Fine, P., Zyczynski, H., Brown, M. B., Weber, A. M., The role of preoperative urodynamic testing in stress-continent women undergoing sacrocolpopexy: The Colpopexy and Urinary Reduction Efforts (CARE) randomized surgical trial, International Urogynecology Journal, 19, 607-614, 2008	Population does not meet the inclusion criteria - women are stress-continent
Visco, A. G., Brubaker, L., Nygaard, I., Richter, H. E., Cundiff, G., Fine, P., Zyczynski, H., Brown, M. B., Weber, A. M., The role of preoperative urodynamic testing in stress-continent women undergoing sacrocolpopexy: The colpopexy and urinary reduction efforts (CARE) randomized surgical trial, Journal of Urology, 184, 1421, 2010	Population does not meet inclusion criteria - women are stress-continent
Wehbe,S.A., Kellogg,S., Whitmore,K., Urogenital Complaints and Female Sexual Dysfunction (Part 2) (CME), Journal of Sexual Medicine, 7, 2305-2317, 2010	Systematic review - references checked for inclusion

Study	Reason for Exclusion
Wu, J. M., Dieter, A. A., Pate, V., Jonsson Funk, M., Cumulative Incidence of a Subsequent Surgery After Stress Urinary Incontinence and Pelvic Organ Prolapse Procedure, Obstetrics & GynecologyObstet Gynecol, 05, 05, 2017	Study design does not meet the inclusion criteria - observational study
Xiromeritis,P., Marotta,M.L., Royer,N., Kalogiannidis,I., Degeest,P., Devos,F., Outcome of laparoscopic sacrocolpopexy with anterior and posterior mesh, Hippokratia, 13, 101-105, 2009	Study design does not meet the inclusion criteria - observational study
Yurteri-Kaplan, L. A., Gutman, R. E., The use of biological materials in urogynecologic reconstruction: a systematic review, Plastic & Reconstructive Surgery, 130, 242S-53S, 2012	Systematic review - references checked for inclusion
Zargham, M., Alizadeh, F., Tadayyon, F., Khorrami, M. H., Nouri-Mahdavi, K., Gharaati, M. R., Izadpanahi, M. H., Yazdani, M., Mazdak, H., Concomitant surgical correction of severe stress urinary incontinence and anterior vaginal wall prolapse by anterior vaginal wall wrap: 18 months outcomes, Journal of Research in Medical Sciences, 18, 588-93, 2013	Intervention/comparator does not meet inclusion criteria - no combined/sequential prolapse, SUI surgery intervention

Economic studies

No economic studies were identified which were applicable to this review question. See supplementary material D for further information.

Appendix L – Research recommendations

Research recommendations for review question: What is the most effective surgical management for women with both stress urinary incontinence and pelvic organ prolapse, including the sequence of interventions?

What is the most effective surgical management for women with both stress urinary incontinence and pelvic organ prolapse, including the sequence of interventions?

Why is this important?

Many women have co-existing symptoms of stress urinary incontinence and pelvic organ prolapse and seek surgical treatment for both conditions. It is not known whether there is a benefit to combination surgery or sequential surgery for these women and what the adverse effects of these approaches are. There are no long term data to guide patients in making decisions about surgery and the committee felt that it was important to assess success and complications of both approaches over a 5 year period.

Table 8: Research recommendation rationale

Research question	What is the most effective surgical management for women with both stress urinary incontinence and pelvic organ prolapse, including the sequence of interventions?
Importance to 'patients' or the population	Prospective randomised trials should be undertaken to compare concurrent POP and SUI surgery with SUI surgery following POP surgery in women with both SUI and POP to determine if symptoms are improved at 5 years or if either approach has an increase in adverse events.
Relevance to NICE guidance	The Committee felt that it would be important to know if there is a benefit in sequential surgery vs combination surgery for women with both SUI and POP in improving the symptoms at 5 years, as no evidence was identified on long-term outcomes for this comparison. Nor was there any evidence on whether long term adverse effects e.g. voiding were greater in either group.
Relevance to the NHS	Concomitant POP and SUI is common and there is no information as to whether surgery should be performed for both conditions at the same time and the possible advantages and disadvantages of this approach. Outcome would be that some women could avoid 2 separate operations for their condition.
National priorities	High
Current evidence base	Minimal
Equality	None known

Table 9: Research recommendation modified PICO table

Criterion	Explanation
Population	Women with apical or anterior POP and stress urinary incontinence who are considering surgery for both conditions
Intervention	POP surgery and continence surgery combined
Comparator	POP surgery with deferred UI surgery
Outcome	Cure of stress incontinence, cure of prolapse, adverse events such as voiding dysfunction, OAB. Long term cure of SUI. Need for repeat POP or SUI surgery
Study design	RCT
Timeframe	5 years

Criterion	Explanation
Additional information	