National Institute for Health and Care Excellence

Final

Urinary incontinence and pelvic organ prolapse in women: management

[G] Evidence review for assessing pelvic organ prolapse

NICE guideline NG123

Evidence reviews

April 2019

Final

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

Disclaimer

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Contents

Assessing pelvic organ prolapse

Review question

What is the most effective strategy for assessing pelvic organ prolapse (POP)?

Introduction

The initial diagnosis of prolapse often occurs when a woman presents to her general practitioner (GP) with symptoms (such as a lump or bulge, or of a dragging sensation in the vagina, or with incontinence) and with visual identification on examination. However, prolapse can also be asymptomatic and be discovered incidentally, for example, during a smear test.

The objective of this review is to determine the most effective strategy for assessing POP to inform appropriate management options. This review aims to examine details that should be recorded about patient symptoms as well as to set basic standards of assessment for any healthcare provider (generalist or specialist).

Summary of the protocol

See Table 1 for a summary of the Population, Index test, Reference standard and Outcome (PIRO) characteristics of this review.

Table 1: Summary of protocol (PIRO table)

Population	Women 18 years of age or older with suspected pelvic organ prolapse (POP) (symptomatic or asymptomatic), and who are undergoing initial investigation.

Index test	Reference standard is a specialist physical examination using an assessment tool that quantifies the prolapse (POP-Q or Baden Walker)
	• Full POP-Q or simplified POP-Q
	• For women without symptoms: Full POP-Q or Baden Walker *versus* Generalist assessment: physical examination alone
	• For women with symptoms: Full POP-Q or Baden Walker *versus* Generalist assessment: physical examination and clinical history of symptoms
	• Full POP-Q or Baden Walker *versus* Patient symptoms assessed using validated symptom scales or questionnaires:
	  ○ E-PAQ
	  ○ ICIQ-VS
	  ○ POP-SS
	• For complex cases: Full POP-Q or Baden Walker *versus.* Imaging:
	  ○ Ultrasound
	  ○ Proctogram, X-ray or magnetic resonance imaging (Dynamic)

Reference standard	Reference standard is a specialist physical examination using an assessment tool that quantifies the prolapse (POP-Q or Baden Walker)
Outcome	**Critical** • Sensitivity • Specificity • Positive likelihood ratio

	• Negative likelihood ratio.
	
	Important
	• Patient satisfaction
	• Symptom improvement:
	  ○ Self-reported
	  ○ Assessed using validated questionnaire
	• Change in management option
	• Pain associated with test/assessment
	• Anxiety associated with test/assessment

E-PAQ: Electronic Personal Assessment Questionnaire; ICIQ-VS: International Consultation on Incontinence Questionnaire Vaginal Symptoms; POP-Q: Pelvic Organ Prolapse Quantification system; POP-SS: Pelvic Organ Prolapse Symptom Score

For further details see the full 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 2014. 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

Five studies were included in the review (Kelvin 1999; Kim 2014; Lone 2014; Reimers 2017; Tan 2005).

- Kelvin 1999 and Kim 2014 compared the diagnostic accuracy of dynamic cystoproctography or dynamic colpocystoproctography, respectively, with data previously acquired on physical examination in women with pelvic floor dysfunction. Kim 2014 specifically assessed women with urinary incontinence (UI) and POP planned for combined surgery.
- Lone 2014 was a non-randomised controlled trial comparing the diagnostic accuracy of pre-operative pelvic floor ultrasound with clinical assessment.
- Reimers 2017 assessed the diagnostic accuracy between self-reported ICIQ-VS and clinical assessment for vaginal bulge.
- Tan 2005 compared the diagnostic accuracy of a standardised questionnaire and physical examination (POP_Q examination).

For a summary of included studies see Table 2.

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

Excluded studies

Studies excluded from this review and reasons for their exclusions are provided in appendix K.

Summary of clinical studies included in the evidence review

Table 2 provides a brief summary of the included studies.

Table 2: Summary of included studies

Study	Population	Index Test	Reference Standard	Outcomes	Comments
Kelvin 1999 Cohort study USA	170 women with symptoms of pelvic floor dysfunction, referred for dynamic cystoproctography and with radiologic examinations and medical records available for review. Age range 24 to 85, with a mean age of 58. Mean parity 2.8 and 4 participants were nulliparous. Sixty six percent of participants had undergone hysterectomy, and 51% had undergone other forms of pelvic floor reconstructive surgery.	Dynamic cystoproctography Preparation: 500 ml barium; bladder catheterisation. Position: Radiograph of pelvis in lateral position. Two lateral radiographs of filled bladder obtained with patient in seated position, at rest, and straining.	Physical examination Position: Upright and straining maximally. Size of prolapse graded as small, moderate, or large according to the half-way system of Baden Walker.	Presence or absence of rectocele, enterocele, and cystocele (%). Comparison of positive and negative findings between dynamic cystoproctography and physical examination for detection of rectocele, enterocele, and cystocele.	Dynamic cystoproctography was carried out and compared with retrospective data on physical examination acquired previously.
Kim 2014 Cohort study South Korea	109 women with UI confirmed by urodynamic study and with Stage II or greater POP confirmed by physical examination.	Dynamic cystoproctography Preparation: Suppository retention for at least 10 minutes; dilute	Physical examination Preparation: Empty bladder. Position:	Comparison of positive and negative findings between dynamic colpocystopro ctography and physical examination	Dynamic colpocystopro ctography was carried out and compared with retrospective data on physical examination

Study	Population	Index Test	Reference Standard	Outcomes	Comments
	Women were excluded if they had a history of surgery for UI and POP. Mean age of participants was 62.28 years. Mean parity was 3.87 and 27.5% of participants had undergone hysterectomy.	barium suspension. Women supine in lithotomy position, and bladder emptied using catheter. Gauze with dilute barium suspension placed into vagina and advanced to cervix. Position: Seated and dynamic colpocystodefecography performed at rest and straining, voiding, and defecation phases.	Dorsal lithotomy position. Supine stress test, postvoid urine measurement, urethral mobility test with cotton swab, and bimanual pelvic examination.	for detection of rectocele, enterocele, and cystocele. Sensitivity (%) and specificity (%), and positive and negative predictive rate for cystocele, rectocele and enterocele. Change in surgical plan (%).	acquired previously.
Lone 2014 Non-randomised controlled study UK	105 women with POP and/or UI 53 of participants had other gynaecological symptoms Mean age of participants – 49.5 years. Median parity 2. Moreover, 13.7% of participants had undergone hysterectomy, 8.1% had had previous surgery for pelvic organ prolapse, and 10% had had previous surgery for	Pelvic floor ultrasound Two-dimensional (2D) transperineal ultrasound (TPUS) Position: Supine position, without using rectal or vaginal contrast. High frequency 2D/3D endovaginal ultrasound (EVUS) Position:	POP-Q Measurements of POP-Q points Ba, Bp and C used to describe maximum descent of anterior, posterior and middle compartments respectively. Position: Left lateral and standing position. Examination completed using bimanual pelvic palpation.	Positive and negative findings of cystocele, rectocele, cervix/vault diagnosed on POP-Q and 2D TPUS. Sensitivity (%) and specificity (%) for diagnosing cystocele, rectocele, and cervix/vault using 2D TPUS. Additional diagnoses for enterocele, intussusception, bladder calcification, vaginal cyst on 2D TPUS +	Reference line used to measure enterocele may not have been representative.

Study	Population	Index Test	Reference Standard	Outcomes	Comments
	urinary incontinence.	Midsagittal line on the perineum between the mons pubis and anal canal to visualise the pubic symphysis, urethra, vagina, anal canal and rectum. Performed at rest and on maximal Valsalva manoeuvres.		3D EVUS at 1-year follow-up with interventions during study period.	
Reimers 2017 Cohort study Norway	300 pregnant (primigravida) women undergoing routine ultrasound in the second trimester.	International Consultation on Incontinence Modular Questionnaire vaginal symptoms (ICIQ-VS) Vaginal bulge was dichotomised and women were in the 'no bulge' group or 'bulge' group.	Clinical examination with standardised POP-Q Performed in a standardised fashion according to the ICS/IUGA guidelines with women sitting upright at 45º.	Diagnostic accuracy (sensitivity, specificity, positive and negative predictive values) at 6 weeks postpartum - symptom vaginal bulge to diagnose anatomical POP. Comparison of symptom vaginal bulge and anatomical POP (sensitivity, specificity, positive and negative predictive values) during pregnancy (gestational weeks 21 and 37) and postpartum (week 6, and at 6 and 12 months).	1) Lack of validated POP diagnostic tool for pregnant women. 2) ICIQ questionnaire not yet validated in Norwegian. 3) Inability to detect and exclude women with very early new pregnancies in the postpartum period.
Tan 2005 Cohort study	Women with pelvic floor disorders,	Standardised pelvic floor	POP-Q examination	Diagnostic accuracy (sensitivity,	Instrument used to collect patient data

Study	Population	Index Test	Reference Standard	Outcomes	Comments
USA	1912 of which had analysable data. University of California-San Diego (UCSD): n=122 Kaiser Permanente-San Diego: n=769 Naval Medical Centre-San Diego: n=1021	dysfunction questionnaire Including 51 items on main complaint, review of urinary and bowel symptoms, and past gynaecologic, medical, and surgical history. In addition, the Urogenital Distress Inventory (UDI) and Incontinence Impact Questionnaire (IIQ-7).	Posterior blade of a bivalve speculum used for appropriate visualisation, and 9 POP-Q measurements determined. Position: Patient in the dorsal lithotomy position.	specificity, positive and negative predictive values) of 3 symptoms (urinary splinting, digital assistance (splinting, digitation/disimpaction), and bulge.	was not formally validated and primarily directed at the presence of rectoceles.

Ba: Leading edge on anterior vaginal wall; Bp: Leading edge on posterior vaginal wall; C: Leading edge of cervix or vaginal vault; EVUS: High frequency 2D/3D endovaginal ultrasound; ICIQ: International Consultation on Incontinence Questionnaire: ICIQ-VS: International Consultation on Incontinence Questionnaire Vaginal Symptoms IIQ-7: Incontinence Impact Questionnaire; ICS/IUGA: International Continence Society/International Urogynecological Association; POP: Pelvic Organ Prolapse; POP-Q: Pelvic Organ Prolapse Quantification; TPUS: Transperineal Ultrasound; UDI: Urogenital Distress Inventory; UI: Urinary incontinence.

Also see clinical evidence tables in appendix D.

Quality assessment of clinical studies included in the evidence review

The GRADE quality assessment, modified for diagnostic reviews, was conducted. The full clinical evidence profiles for this review are presented in appendix F.

Economic evidence

Included studies

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

Excluded studies

No studies were found which were applicable to this review question,

Summary of studies included in the economic evidence review

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

Economic model

No economic modelling was undertaken for this review because the committee agreed that other topics were higher priorities for economic evaluation.

Evidence statements

Sensitivity and specificity

Dynamic cystoproctography versus physical examination (Baden Walker technique)

Very low quality evidence from 1 observational study (N = 170) showed that the overall sensitivity and specificity for dynamic cystoproctography compared to Baden Walker was 94% (89 to 98) and 18% (8 to 33) to detect rectocele in adult women.

- Very low quality evidence from 1 observational study (N = 170) showed that the overall sensitivity and specificity for dynamic cystoproctography compared to Baden-Walker was 35% (24 to 48) and 77% (68 to 85) to detect enterocele in adult women.
- Very low quality evidence from 1 observational study (N = 170) showed that the overall sensitivity and specificity for dynamic cystoproctography compared to Baden-Walker was 96% (92 to 99)and 18% (7 to 35) to detect cystocele in adult women.

Dynamic colpocystoproctography versus physical examination (POP-Q)

- Very low quality evidence from 1 observational study (N = 109) showed that the overall sensitivity and specificity for dynamic cystoproctography compared to POP-Q was 100% (93 to 100) and 46% (33 to 59) to detect rectocele in adult women.
- Very low quality evidence from 1 observational study (N = 109) showed that the overall specificity for dynamic colpocystoproctography compared to POP-Q was 98% (94 to 100) to detect enterocele in adult women. Sensitivity for this test against POP-Q was not estimable.
- Very low quality evidence from 1 observational study (N = 109) showed that the overall sensitivity and specificity for dynamic cystoproctography compared to POP-Q was 100% (95 to 100) and 67% (47 to 83) to detect cystocele in adult women.

2D transperineal ultrasound versus physical examination (POP-Q)

- Very low quality evidence from 1 observational study (N = 145) showed that the overall sensitivity and specificity for 2D transperineal ultrasound compared to POP-Q was 39% (28 to 52) and 96% (89 to 99) to detect rectocele in adult women.
- Very low quality evidence from 1 observational study (N = 153) showed that the overall sensitivity and specificity for 2D transperineal ultrasound compared to POP-Q was 59% (46 to 71) and 100% (96 to 100) to detect cystocele in adult women.
- Very low quality evidence from 1 observational study (N = 140) showed that the overall sensitivity and specificity for 2D transperineal ultrasound compared to POP-Q was 69% (53 to 82) and 95% (88 to 98) to detect cervix/vault prolapse in adult women.

Self-reported vaginal bulge versus physical examination (POP-Q)

- Very low quality evidence from 1 observational study (N=300) showed that the overall sensitivity and specificity for self-reported vaginal bulge (as measured by the ICIQ-VS) compared to POP-Q to detect anatomical changes during pregnancy at 21 weeks gestation was 31% (9 to 61) and 85% (80 to 89) and at 37 gestational weeks [N=270] was 50% (1 to 99) and 83% (78 to 87) in women having their first child.
- Very low quality evidence from 1 observational study (N=280) showed that the overall sensitivity and specificity for self-reported vaginal bulge (as measured by the ICIQ-VS) compared to POP-Q to detect anatomical changes during pregnancy was 52% (31 to 72) and 83% (78 to 87) at 6 weeks after childbirth, 20% (1 to 72) and 77% (70 to 83) 6 months after childbirth (N=195), and 0% (0 to 60) and 81% (74 to 86) at 12 months after childbirth (N=176), in women having their first child.

- Very low quality evidence from 1 observational study (N = 1912) showed that the overall sensitivity and specificity for self-reported vaginal bulge compared to POP-Q, was 67% (63 to 70) and 87% (85 to 89) to detect signs of prolapse in adult women.

Self-reported urinary splinting versus physical examination (POP-Q)

- Very low quality evidence from 1 observational study (N = 1912) showed that the overall sensitivity and specificity for self-reported urinary splinting compared to POP-Q was 18% (15 to 21) and 97% (96 to 98) to detect signs of prolapse in adult women.

Self-reported digital assistance versus physical examination (POP-Q)

- Very low quality evidence from 1 observational study (N = 1939) showed that the overall sensitivity and specificity for self-reported digital assistance compared to POP-Q was 32% (27 to 37) and 87% (86 to 89) to detect signs of prolapse in adult women.

Economic evidence statements

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

The committee's discussion of the evidence

Interpreting the evidence

The outcomes that matter most

The committee considered sensitivity and specificity to be critical outcomes because they are the preferred method for assessing the accuracy of diagnostic tests and because they wanted to minimise the false positive and false negative rates. Women incorrectly receiving a diagnosis of pelvic organ prolapse would receive unnecessary further tests or treatments and women who were incorrectly classified as not having pelvic organ prolapse may be falsely reassured and would not get the treatment that they need. The committee also considered positive and negative likelihood ratios to be critical outcomes. The committee considered patient satisfaction, symptom improvement (self-reported and assessed using validated questionnaires), change in management option, and pain or anxiety associated with test/assessment. Evidence on patient satisfaction and pain or anxiety associated with test/assessment was not found from the literature search.

The quality of the evidence

The risk of bias of individual studies was assessed using the QUADAS-2 checklist, and the quality of the evidence for each index test was assessed by adapting the GRADE approach to a systematic review of diagnostic test accuracy. The quality of the evidence for all comparisons was very low, meaning there is limited confidence in the results presented. The evidence comparing dynamic cystoproctography with Baden Walker and self-reported vaginal bulge with POP-Q was downgraded because it was indirect and included small sample sizes; more than half the women included in Kelvin (1999) had undergone previous hysterectomy or other reconstructive pelvic floor surgery (i.e. they were not undergoing initial investigation of POP); women included in Kim (2014) were planned for combined surgery for confirmed POP and UI; it was unclear whether women enrolled in Reimers (2017) were consecutive or a random sample. In addition, the evidence was downgraded because of a significant risk of bias, including a lack of blinding to the interpretation of index test and/or reference standard results; an unclear interval between index test and reference standard; and exclusion of women from the analyses.

Benefits and harms

The committee discussed the evidence that self-reported symptoms showed high specificity in detecting signs of prolapse, but also noted that prolapse was frequently an incidental finding. They agreed that the evidence presented did not show the benefit of relying only on self-reported symptoms or imaging techniques in the routine assessment of women with suspected pelvic organ prolapse.

Based on their expertise and by consensus, they emphasised the importance of the GP taking a clear history and carrying out a careful examination to inform the initial discussion and to rule out other differential diagnoses, before referring for specialist assessment if appropriate.

Based on their experience, the committee emphasised that vaginal prolapse can be diagnosed incidentally during examination in secondary care. The committee decided that in this situation it was important that women are referred to a clinician with a special interest in prolapse for an assessment and management plan.

Evidence indicated that none of the index tests reached the diagnostic accuracy of the POP-Q reference standard. Based on this and consensus, the committee decided that the POP-Q should be the tool of choice when assessing women suspected of having pelvic organ prolapse. This tool created by the International Continence Society can provide a reliable and reproducible measure of pelvic organ prolapse. Although this instrument is generally thought to be the reference standard, it is possible that not all clinicians use it in practice. As a validated instrument, the POP-Q can provide an objective and standard measure of pelvic organ prolapse during the physical examination, enabling continuity of care if women are referred to a different healthcare setting or healthcare provider. Based on their experience and expertise, the committee also agreed that in specialist settings, it is important to assess the integrity of a woman's pelvic floor muscles and the presence of vaginal atrophy, and to rule out the presence of a pelvic mass or any other gynaecological pathology, as these factors need to be considered. The committee agreed that a validated pelvic floor symptom questionnaire could aid assessment.

The committee noted that, compared to the reference standard, the evidence presented did not show any added benefit from using imaging techniques (cystoproctography and 2D ultrasound) for the assessment of pelvic organ prolapse. Based on this and their experience and expertise the committee noted that vaginal prolapse can be diagnosed on physical examination alone and when this occurs women should not be routinely referred for imaging because this would delay management and add unnecessary costs.

The committee was aware that on physical examination the apparent severity of prolapse can change with straining or with a change in position (lying or standing) and noted that assessment should take this into account.

The committee agreed, by consensus, that further investigation should be considered when other pelvic floor symptoms are present such as urinary or faecal incontinence, pain or obstructed defecation. Or when the symptoms are not adequately explained by the findings on physical examination.

Cost effectiveness and resource use

There was no published evidence found on the cost effectiveness of different strategies for assessing pelvic organ prolapse in women.

The committee explained that taking a history to include symptoms of prolapse, urinary, bowel, and sexual function; performing an examination to rule out a pelvic mass, other gynaecology pathology and to document presence of prolapse; and discussing treatment

preferences with women is standard care and providing this would not incur significant extra costs for the NHS.

Similarly, the recommendation of a specialist evaluation for women referred to secondary care for an unrelated condition who have incidental symptoms or finding of vaginal prolapse is reinforcing standard practice and providing such assessment would not incur significant extra costs for the NHS.

The committee discussed the time it takes to administer validated pelvic floor symptom questionnaires. For example, a questionnaire such as ICIQVS, EPAQ, PFDI, and PFIQ can take 5-15 minutes to administer. The committee expressed their view that the additional time required to administer such questionnaires is negligible given the extremely complex nature of pelvic floor disorders and the potential health benefits associated with having an appropriate assessment.

The use of the most appropriate assessment tools for individual women and their symptoms is likely to minimise the unnecessary use of such assessment tools and may result in cost savings to the NHS. Examples of such targeted investigation include performing urodynamics before surgery for prolapse only when urinary symptoms are bothersome, proctography only if there are symptoms of obstructed defecation or faecal incontinence, and anorectal manometry and ultrasound only if there is faecal incontinence. Importantly, some of these assessment tools are very invasive and may adversely affect health-related quality of life.

The committee explained that if a strategy improves the assessment of women with POP and leads to quicker and more appropriate treatment, the additional costs of this assessment would probably be outweighed by both the improvements in health outcomes and the possible future cost savings to the NHS, especially as delayed and inappropriate treatment can exacerbate symptoms which may require expensive treatment in secondary care at a later time.

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Appendices

Appendix A – Review protocols

Review protocol for review question: What is the most effective strategy for assessing pelvic organ prolapse?

Table 3: Review protocol for assessing pelvic organ prolapse

Field (based on PRISMA-P	Content
Review question	What is the most effective strategy for assessing pelvic organ prolapse?
Type of review question	Diagnostic
Objective of the review	Initial diagnosis of prolapse often occurs when a woman presents to the GP with symptoms (such as a lump or bulge or of a dragging sensation in the vagina or with incontinence) and with visual identification on examination. However, prolapse can also be asymptomatic and be discovered incidentally. For example, during a smear test. Identification of a prolapse may not be possible during examination and may require different positioning (standing or lying), examination at different times of day or even examination under anaesthetic. A generalist assessment is likely to consist of visible confirmation and documentation of the presence or not of a prolapse. Specialist assessment is more detailed using an assessment tool that quantifies the prolapse. The POP-Q measures 9 points in the vagina or pelvic floor and quantifies the degree and type of prolapse from 1-4. The Baden-Walker quantification system is simpler for clinicians to perform and hence is still used by clinicians where, for example, conservative management is the treatment option rather than surgery. Physical examination involves investigation of the 3 different vaginal compartments and vaginal walls and noting where they come to when the patient strains or coughs. Decisions about management take into account the woman's symptoms as well. If the woman is asymptomatic, then treatment or referral to a specialist may not be requested by the woman or required.

Field (based on PRISMA-P	Content
	The objective of this review is to determine the most effective strategy for assessing pelvic organ prolapse in order to inform appropriate management options. This review aims to examine details that should be recorded about patient symptoms as well as to set basic standards of assessment for any healthcare provider (generalist or specialist).
Eligibility criteria – population/disease/condition/issue/domain	Women over 18 years with suspected pelvic organ prolapse (symptomatic or asymptomatic) undergoing initial investigation.

Eligibility criteria – intervention(s)/exposure(s)/prognostic factor(s)	Reference standard is a specialist physical examination using an assessment tool that quantifies the prolapse (POP-Q or Baden Walker)
	• Full POP-Q or simplified POP-Q;
	• For women without symptoms: Full POP-Q or Baden Walker * vs. Generalist assessment: physical examination alone
	• For women with symptoms: Full POP-Q or Baden Walker vs. Generalist assessment: physical examination and clinical history of symptoms
	• Full POP-Q or Baden Walker vs. Patient symptoms assessed using validated symptom scales or questionnaires:
	  ○ Electronic Personal Assessment Questionnaire (EPAQ);
	  ○ International Consultation on Incontinence Questionnaire Vaginal Symptoms (ICIQ-VS);
	  ○ Pelvic Organ Prolapse Symptom Score (POP-SS).
	• For complex cases: Full POP-Q or Baden Walker vs. Imaging:
	  ○ Ultrasound
	  ○ Proctogram, X-ray or magnetic resonance imaging (MRI) (Dynamic)

Eligibility criteria – comparator(s)/control or reference (gold) standard	Reference standard is a specialist physical examination using an assessment tool that quantifies the prolapse (POP-Q or Baden Walker)
Outcomes and prioritisation	For studies reporting diagnostic outcomes: **Critical** • Sensitivity • Specificity

Field (based on PRISMA-P	Content

	• Positive likelihood ratio
	• Negative likelihood ratio.
	
	Important
	If conducting meta-analysis: area under the curve.
	
	For studies reporting patient outcomes:
	• Patient satisfaction
	• Symptom improvement:
	  ○ Self-reported
	  ○ Assessed using validated questionnaire.
	• Change in management option
	• Pain associated with test/assessment
	• Anxiety associated with test/assessment.

Eligibility criteria – study design	Test and treat studies Systematic reviews of studies with diagnostic outcomes Cross sectional studies Cohort studies
Other inclusion exclusion criteria	Women with mesh complications will be excluded as they will be captured in a separate review.

Proposed sensitivity/sub-group analysis, or meta-regression	**Population subgroups**
	• Symptomatic
	• By particular symptoms?
	  ○ Prolapse
	  ○ Incontinence
	  ○ Bowel
	• Asymptomatic
	• Complex cases

Field (based on PRISMA-P	Content
	Special consideration will be given to the following groups for which data will be reviewed and analysed separately if available: • Older women • Women with physical disabilities or cognitive impairment Special consideration of women who are considering future pregnancy was not prioritised for this question.
Selection process – duplicate screening/selection/analysis	Formal duplicate screening will not be undertaken for this question, although there will be senior supervision of the selection process. Hard copies of retrieved papers will be read by two reviewers and any disputes will be resolved in discussion with the Topic Advisor. Data extraction will be supervised by a senior reviewer. Draft excluded studies and evidence tables will be discussed with the Topic Advisor, prior to circulation to the Topic Group for their comments. Resolution of disputes will be by discussion between the senior reviewer, Topic Advisor and Chair.
Data management (software)	Pairwise meta-analyses, if possible, will be performed using Cochrane Review Manager (RevMan5). Diagnostic meta-analysis, if possible, will be performed using R '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): No limits in order to capture evidence for Baden Walker assessment tool and as this is a new area for the guideline Apply standard animal/non-English language exclusion
Identify if an update	New area of the guideline.
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.

Field (based on PRISMA-P	Content
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 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 2014.
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.

Field (based on PRISMA-P	Content
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.

Appendix B – Literature search strategies

Literature search strategy for review question: What is the most effective strategy for assessing POP?

Database: Medline & Embase (Multifile)
Last searched on Embase Classic+Embase 1947 to 2017 October 03, 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: 5th October 2017.

#	Searches
1	exp Pelvic Organ Prolapse/ use ppez
2	exp pelvic organ prolapse/ use emczd
3	(pelvic$ adj3 organ$ adj3 prolaps$).tw.
4	(urinary adj3 bladder adj3 prolaps$).tw.
5	((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.
6	(splanchnoptos$ or visceroptos$).tw.
7	Rectocele/ use ppez
8	rectocele/ use emczd
9	(hernia$ adj3 (pelvi$ or vagin$ or urogenital$ or uter$ or bladder$ or urethr$ or viscer$)).tw.
10	(urethroc?ele$ or enteroc?ele$ or sigmoidoc?ele$ or proctoc?ele$ or rectoc?ele$ or cystoc?ele$ or rectoenteroc?ele$ or cystourethroc?ele$).tw.
11	1 or 2 or 3 or 4 or 5 or 6 or 7 or 8 or 9 or 10
12	Baden-Walker$.tw.
13	(Baden and Walker$).tw.
14	(Baden$ adj5 (system$ or classif$ or tool$ or scor$ or grad$)).tw.
15	(Walker$ adj5 (system$ or classif$ or tool$ or scor$ or grad$)).tw.
16	12 or 13 or 14 or 15
17	11 and 16
18	*"Surveys and Questionnaires"/ use ppez
19	*questionnaire/ use emczd
20	(POP-Q$ or POPQ$).tw.
21	"pelvic organ prolapse quantification".tw.
22	((POP or prolaps$) adj5 (system$ or classif$ or tool$ or scor$ or grad$)).tw.
23	18 or 19 or 20 or 21 or 22
24	11 and 23
25	17 or 24
26	letter.pt. use emczd
27	LETTER/ use emczd
28	Letter/ use ppez
29	editorial.pt. use emczd
30	EDITORIAL/ use ppez
31	NEWS/ use ppez
32	exp HISTORICAL ARTICLE/ use ppez
33	note.pt. use emczd
34	ANECDOTES AS TOPIC/ use ppez
35	COMMENT/ use ppez
36	CASE REPORT/ use ppez
37	CASE REPORT/ use emczd
38	CASE STUDY/ use emczd
39	(letter or comment*).ti.
40	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	RANDOMIZED CONTROLLED TRIAL/ use ppez
42	RANDOMIZED CONTROLLED TRIAL/ use emczd
43	random*.ti,ab.
44	41 or 42 or 43
45	40 not 44
46	ANIMALS/ not HUMANS/ use ppez
47	ANIMAL/ not HUMAN/ use emczd
48	exp ANIMALS, LABORATORY/ use ppez
49	exp ANIMAL EXPERIMENTATION/ use ppez

#	Searches
50	exp MODELS, ANIMAL/ use ppez
51	exp RODENTIA/ use ppez
52	NONHUMAN/ use emczd
53	exp ANIMAL EXPERIMENT/ use emczd
54	exp EXPERIMENTAL ANIMAL/ use emczd
55	ANIMAL MODEL/ use emczd
56	exp RODENT/ use emczd
57	(rat or rats or mouse or mice).ti.
58	45 or 46 or 47 or 48 or 49 or 50 or 51 or 52 or 53 or 54 or 55 or 56 or 57
59	exp "SENSITIVITY AND SPECIFICITY"/ use ppez
60	"SENSITIVITY AND SPECIFICITY"/ use emczd
61	(sensitivity or specificity).ti,ab.
62	((pre test or pretest or post test or posttest) adj probability).ti,ab.
63	(predictive value$ or PPV or NPV).ti,ab.
64	likelihood ratio$.ti,ab.
65	LIKELIHOOD FUNCTIONS/ use ppez
66	STATISTICAL MODEL/ use emczd
67	(ROC curve$ or AUC).ti,ab.
68	diagnos$.ti.
69	(diagnos* adj2 (performance* or accurac* or utilit* or value* or efficien* or effectiveness)).ti,ab.
70	gold standard.ab.
71	*DIAGNOSTIC ACCURACY/ or DIAGNOSTIC TEST ACCURACY STUDY/ use emczd
72	59 or 60 or 61 or 62 or 63 or 64 or 65 or 66 or 67 or 68 or 69 or 70 or 71
73	International Classification of Diseases/ use ppez
74	Classification/ use ppez
75	exp *disease classification/ use emczd
76	exp classification/ use emczd
77	Terminology as Topic/ use ppez
78	nomenclature/ use emczd
79	Severity of Illness Index/ use ppez
80	Disease Progression/ use ppez
81	"severity of illness index"/ use emczd
82	disease severity/ use emczd
83	disease course/ use emczd
84	staging/ use emczd
85	(disease adj2 (grad$ or classif$ or index$ or indices or stage? or staging or score? or scoring or categor$)).tw.
86	73 or 74 or 75 or 76 or 77 or 78 or 79 or 80 or 81 or 82 or 83 or 84 or 85
87	72 or 86
88	25 and 87
89	exp Magnetic Resonance Imaging/ use ppez
90	exp nuclear magnetic resonance imaging/ use emczd
91	magnet$ resonance.mp.
92	(MR adj (imag$ or scan$)).tw.
93	(magnet$ adj (imag$ or scan$)).tw.
94	(magneti?ation adj3 imaging).tw.
95	(MRI or MRI$1 or NMR$1).tw.
96	exp Ultrasonography/ use ppez
97	exp echography/ use emczd
98	exp ultrasound/ use emczd
99	(ultrasound$ or ultrasonograph$ or sonogra$ or endosonogra$).mp.
100	exp Radiography/ use ppez
101	exp radiography/ use emczd
102	(radiograph$ or xray or x-ray).mp.
103	exp Defecography/ use ppez
104	exp defecography/ use emczd
105	(proctogra$ or def?ecogra$).tw.
106	(digit$ adj3 rect$ adj3 exam$).tw.
107	(EPAQ$ or e-PAQ$).tw.
108	"Personal Assessment Questionnaire".tw.
109	(POPSS$ or POP-SS$).tw.
110	"Pelvic Organ Prolapse Symptom Score".tw.
111	ICIQ$.tw.
112	(international consultation adj3 incontinen$ questionnaire$).tw.
113	((assessment or symptom$ or quantification) adj (question$ or scale$ or index$ or inventor$ or measure$ or score$ or system$)).tw.
114	Physical examinations/ use ppez
115	exp physical examination/ use emczd

#	Searches
116	clinical examination/ use emczd
117	Medical History Taking/ use ppez
118	exp medical history/ use emczd
119	anamnesis/ use emczd
120	((physical or clinical) adj (exam$ or inspect$)).tw.
121	((medical or clinical or patient) adj history).tw.
122	(history adj2 (take or taking)).tw.
123	anamnesis.tw.
124	palpat$.tw.
125	17 and 23
126	simplified.tw.
127	24 and 126
128	114 or 115 or 116 or 120 or 124
129	25 and 128
130	117 or 118 or 119 or 121 or 122 or 123
131	129 and 130
132	107 or 108 or 109 or 110 or 111 or 112 or 113
133	25 and 132
134	89 or 90 or 91 or 92 or 93 or 94 or 95 or 96 or 97 or 98 or 99 or 100 or 101 or 102 or 103 or 104 or 105 or 106
135	25 and 134
136	125 or 127 or 129 or 131 or 133 or 135
137	exp Pelvic Organ Prolapse/cl, di use ppez
138	exp pelvic organ prolapse/di use emczd
139	*Diagnosis/ use ppez
140	*diagnosis/ use emczd
141	Classification/ use ppez
142	classification/ use emczd
143	139 or 140 or 141 or 142
144	11 and 143
145	137 or 138 or 144
146	88 or 136 or 145
147	limit 146 to english language
148	remove duplicates from 147
149	58 and 148
150	148 not 149

Database: Cochrane Library via Wiley Online

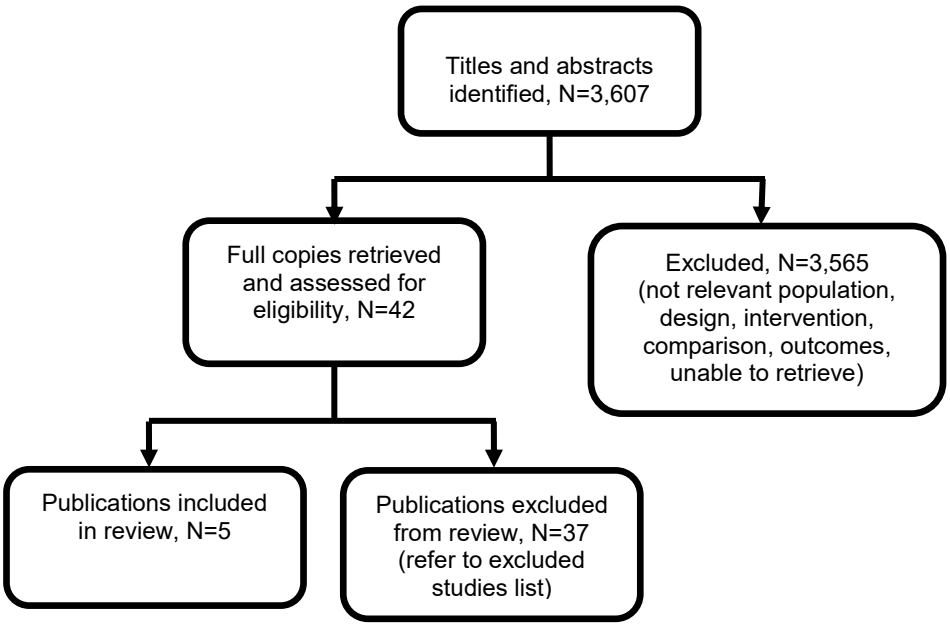
Date of last search: 5th October 2017.

ID	Search
#1	MeSH descriptor: [Pelvic Organ Prolapse] explode all trees
#2	(pelvic* near/3 organ* near/3 prolaps*):ti,ab,kw (Word variations have been searched)
#3	(urinary near/3 bladder near/3 prolaps*):ti,ab,kw (Word variations have been searched)
#4	((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)
#5	(splanchnoptos* or visceroptos*):ti,ab,kw (Word variations have been searched)
#6	MeSH descriptor: [Rectocele] explode all trees
#7	(hernia* near/3 (pelvi* or vagin* or urogenital* or uter* or bladder* or urethr* or viscer*)):ti,ab,kw (Word variations have been searched)
#8	(urethrocele* or urethrocoele* or enterocele* or enterocele* or sigmoidocoele* or sigmoidocele* or proctocele* or proctocoele* or rectocele* or rectocele* or cystocele* or cystocoele* or rectoenterocele* or rectoenterocele* or cystourethrocele* or cystourethrocoele*):ti,ab,kw (Word variations have been searched)
#9	#1 or #2 or #3 or #4 or #5 or #6 or #7 or #8
#10	Baden-Walker*:ti,ab,kw (Word variations have been searched)
#11	(Baden and Walker*):ti,ab,kw (Word variations have been searched)
#12	(Baden* near/5 (system* or classif* or tool* or scor* or grad*)):ti,ab,kw (Word variations have been searched)
#13	(Walker* near/5 (system* or classif* or tool* or scor* or grad*)):ti,ab,kw (Word variations have been searched)
#14	MeSH descriptor: [Surveys and Questionnaires] this term only
#15	(POP-Q* or POPQ*):ti,ab,kw (Word variations have been searched)
#16	"pelvic organ prolapse quantification":ti,ab,kw (Word variations have been searched)
#17	((POP or prolaps*) near/5 (system* or classif* or tool* or scor* or grad*)):ti,ab,kw (Word variations have been searched)
#18	#10 or #11 or #12 or #13 or #14 or #15 or #16 or #17
#19	#9 and #18
#20	MeSH descriptor: [Pelvic Organ Prolapse] explode all trees and with qualifier(s): [Classification - CL, Diagnosis - DI]
#21	#19 or #20

Appendix C – Clinical evidence study selection

Clinical evidence study selection for review question: What is the most effective strategy for assessing POP?

Figure 1: PRISMA flow chart for review question: What is the most effective strategy for assessing POP?



Appendix D – Clinical evidence tables

Clinical evidence tables for review question: What is the most effective strategy for assessing pelvic organ prolapse?

Table 4: Clinical evidence tables

Bibliographic details	Participants	Tests	Methods	Outcomes and results	Comments
Full citation Kelvin, F. M., Hale, D. S., Maglinte, D. D. T., Patten, B. J., Benson, J. T., Female pelvic organ prolapse: Diagnostic contribution of dynamic cystoproctography and comparison with physical examination, American Journal of Roentgenology, 173, 31-37, 1999 **Ref Id** 690876 **Country/ies where the study was carried out** USA **Study type** Prospective cohort study **Aim of the study** To compare the diagnostic accuracy of dynamic cystoproctography with	**Sample size** N = 170 **Characteristics** Age - mean (SD not reported) (years) 58 (range 24 to 85) Parity - Mean (range) 2.8 (0 to 10) Previous surgery - n (%) Hysterectomy n=112 (66) Pelvic floor reconstructive surgery other than hysterectomy (performed at other institutions) n=86 (51) **Inclusion Criteria** • Consecutive patients with symptoms of pelvic floor dysfunction, referred	**Tests** Dynamic cystoproctography Use of a large (12-French) catheter to facilitate bladder filling and emptying, with emphasis on achieving cystocoele drainage. Examination included cystographic and proctographic phases. Physical examination Performed by an experienced urogynaecologist or a urogynaecology fellow, and using the Baden-Walker system.	**Methods** Dynamic cystoproctography Patients ingested 500 ml of barium to make pelvic small bowel opaque. Radiograph of pelvis in lateral position obtained and bladder catheterised. Two lateral radiographs of filled bladder obtained with patient in seated position, at rest and straining. Physical examination Performed with patient in upright birthing chair and straining maximally, and patient assessed for rectocele, enterocele, or sigmoidocele, cystocele, and vaginal vault prolapse. Size of prolapses graded as small, moderate, or large according to the half-way system of Baden and Walker. Data using International Standard of pelvic organ prolapse quantification on physical examination were available for 125 (74%) of patients. Vaginal vault prolapse on physical	**Results** Presence or absence of rectocele - n (%) Proctography: 155 (91): small (n=18, 11%); moderate (n=91, 59%); large (n=46, 30%) Physical examination: 126 (74): small (n=28, 22%); moderate (n=63, 50%); large (n=35, 28%) **Comparison of dynamic cystoproctography and physical examination for the identification of rectocele** Physical examination findings (using Baden-Walker) - positive Cystoproctography findings (+): 119 Cystoproctography findings (-): 7 Total: 126 Physical examination findings (using Baden-Walker) - negative Cystoproctography findings (+): 36	**Limitations** **A. Risk of Bias Patient Sampling** Was a consecutive or random sample of patients enrolled? Yes Was a case-control design avoided? Yes Did the study avoid inappropriate exclusion? Yes Could the selection of patients have introduced bias? Low risk **B. Concerns about applicability Patient characteristics and setting** Are there concerns that the included patients and setting do not match the review question? High concern (more than half of the patients had undergone

Bibliographic details	Participants	Tests	Methods	Outcomes and results	Comments
physical examination in the diagnosis of pelvic organ prolapse in women **Study dates** October 1994 to May 1998 **Source of funding** Not stated	for dynamic cystoproctography. • Women with radiologic examinations and medical records available for review. **Exclusion Criteria** Not stated		examination was assessed only using this method and because data were obtained only for 74% of women, and these data were incomplete, no comparison was made between the findings of vaginal vault prolapse on cystoproctography and evaluation using this method. **Randomisation** Not applicable **Statistical analysis** Not reported (presence or absence of POP summarised as text and in tables). **Power calculation** None reported **Intention to treat analysis** Not applicable	Cystoproctography findings (-): 8 Total: 44 <u>Presence or absence of enterocele - n (%)</u> Proctography: 47 (28): small (n=5, 11%); moderate (n=16, 34%); large (n=26, 55%) Physical examination: 68 (40): small (n=26, 38%); moderate (n=20, 29%); large (n=22, 32%) **Comparison of dynamic cystoproctography and physical examination for the identification of enterocele** <u>Physical examination findings (using Baden-Walker) - positive</u> Cystoproctography findings (+): 24 Cystoproctography findings (-): 44 Total: 68 <u>Physical examination findings (using Baden-Walker) - negative</u> Cystoproctography findings (+): 23 Cystoproctography findings (-): 79 Total: 102 <u>P</u> <u>resence or absence of cystocele - n (%)</u>	previous hysterectomy or other form of reconstructive pelvic floor surgery) **Index Test** **A. Risk of Bias** Were the index test results interpreted without knowledge of the results of the reference standard? No If a threshold was used, was it pre-specified? No threshold used. Could the conduct or interpretation of the index test have introduced bias? High risk **B. Concerns about applicability** Are there concerns that the index test, its conduct, or interpretation differ from the review question? Low concern **Reference Standard** **A. Risk of bias** Is the reference standard likely to correctly classify

Bibliographic details	Participants	Tests	Methods	Outcomes and results	Comments
				Proctography: 159 (94): small (n=36, 23%); moderate (n=77, 48%); large (n=46, 29%) Physical examination: 137 (81): small (n=36, 26%); moderate (n=41, 30%); large (n=60, 44%) **Comparison of dynamic cystoproctography and physical examination for the identification of cystocele** <u>Physical examination findings (using Baden-Walker) - positive</u> Cystoproctography findings (+): 132 Cystoproctography findings (-): 5 Total: 137 <u>Physical examination findings (using Baden-Walker) - negative</u> Cystoproctography findings (+): 27 Cystoproctography findings (-): 6 Total: 33	target condition? Unclear Were the reference standard results interpreted without knowledge of the results of index test? No Could the reference standard, its conduct, or interpretation have introduced bias? High risk **B. Concerns about applicability** Are there concerns that the target condition as defined by the reference standard does not match the question? Low concern **Flow and Timing** **A. Risk of Bias** Was there an appropriate interval between index test and reference standard? Unclear Did all patients receive the same reference standard? Yes Were all patients included in the analysis? Yes Could the patient flow have

Bibliographic details	Participants	Tests	Methods	Outcomes and results	Comments
					introduced bias? Low risk **Other information**
Full citation Kim, J. H., Park, S. J., Yi, B. H., Lee, K. W., Kim, M. E., Kim, Y. H., Diagnostic effectiveness of dynamic colpocystoproctography in women planning for combined surgery with urinary incontinence and pelvic organ prolapse, Gynecologic and Obstetric Investigation, 77, 231-239, 2014 **Ref Id** 690891 **Country/ies where the study was carried out** Korea **Study type** Prospective cohort study **Aim of the study** To assess the diagnostic accuracy of dynamic colpocystoproctography in women with urinary	**Sample size** N =113 (4 patients lost to follow-up; n=109) Follow-up - mean ± SD (months) 6.21 (2.32) **Characteristics** Age - mean ± SD (years) 62.28 (10.78) BMI - mean ± SD 21.57kg/m^2 (2.17) Menopausal - n (%) 86 (78.8) Previous hysterectomy - n (%) 30 (27.5) Parity - mean ± SD 3.87 (1.75) POP on physical examination - n (%) Cystocoele (n=79, 51.6%) Stage II: 40 (26.1) Stage III: 33 (21.6) Stage IV: 7 (4.6)	**Tests** Dynamic colpocystoproctography Women retained suppository for at least 10 minutes, then received dilute barium suspension to make the small bowel opaque Physical examination Pelvic examinations using POP-Q and performed in the dorsal lithotomy position; patients had empty bladders	**Methods** Dynamic colpocystoproctography Women positioned supine in lithotomy position, and bladder emptied using catheter. Gauze with dilute barium suspension placed into vagina and advanced to the cervix. Participant seated and dynamic colpocystodefecography performed at rest and straining, voiding, and defecation phases. Physical examination All patients underwent supine stress test, postvoid urine measurement, urethral mobility test with cotton swab, and bimanual pelvic examination. Each anatomic compartment (anterior, apical, posterior) of the pelvic floor were assessed using Graves speculum and ring forceps. All points for POP-Q (except total vaginal length) recorded at maximal protrusion with the Valsalva manoeuver.	**Results** **Diagnostic accuracy for diagnosing cystocele - %** Sensitivity: 88.7 Specificity: 100 Positive predictive value: 100 Negative predictive value: 66.6 **Comparison of dynamic colpocystodefecography (DCP) with physical examination for identification of cystocele** Physical examination - negative Dynamic DCP negative: 20 Dynamic DCP positive: 10* Total: 30; p<0.001 Physical examination - positive Dynamic DCP negative: 0 Dynamic DCP positive: 79 Total: 79 **Diagnostic accuracy for diagnosing rectocele - %** Sensitivity: 60.9 Specificity: 100 Positive predictive value: 100 Negative predictive value: 45.7 **Comparison of dynamic colpocystodefecography (DCP) with physical**	**Limitations** **A. Risk of Bias** **Patient Sampling** Was a consecutive or random sample of patients enrolled? Yes Was a case-control design avoided? Yes Did the study avoid inappropriate exclusion? Yes Could the selection of patients have introduced bias? Low risk **B. Concerns about applicability** **Patient characteristics and setting** Are there concerns that the included patients and setting do not match the review question? High concern (study was conducted on patients that were planned for combined surgery

Bibliographic details	Participants	Tests	Methods	Outcomes and results	Comments
incontinence (UI) and pelvic organ prolapse (POP) planning for combined surgery **Study dates** April 2005 to May 2010 **Source of funding** Supported by Soonchunhyang University Research Fund	Rectocele (n=50, 32.7%) Stage II: 10 (6.5) Stage III: 28 (18.3) Stage IV: 11 (7.2) Uterovaginal prolapse (n=18, 16.5%) Stage II: 11 (7.2) Stage III: 7 (4.6) Vaginal vault prolapse (n=3, 2.75%) Stage II: 3 (2.75) Lower urinary tract symptoms - n (%) Stress UI: 57 (52.2) Urgency: 26 (23.9) Mixed UI: 52 (47.7) Strain to void: 24 (22.0) Frequency: 42 (38.5) Bowel associated symptoms - n (%) Constipation: 30 (27.5) Faecal incontinence: 12 (11.0) Discomfort with defecation: 18 (16.5) Feeling of incomplete defecation: 25 (22.9) Rectal protrusion during or after defecation: 2 (1.83) **Inclusion Criteria** • Consecutive women with UI confirmed by urodynamic study		**Randomisation** Not applicable **Statistical analysis** Sensitivity, specificity, and positive predictive value of physical examination and POP calculated. X^2 test used to investigate differences in rate of change in surgical plan. **Power calculation** None reported **Intention to treat analysis** Not applicable	**examination for identification of rectocele** Physical examination - negative Dynamic DCP negative: 27 Dynamic DCP positive: 32* Total: 59; p<0.001 Physical examination - positive Dynamic DCP negative: 0 Dynamic DCP positive: 50 Total: 50 **Comparison of dynamic colpocystodefecography (DCP) with physical examination for identification of enterocele** Physical examination - negative Dynamic DCP negative: 107 Dynamic DCP positive: 2* Total: 109 Physical examination - positive Dynamic DCP negative: 0 Dynamic DCP positive: 0 Total: 0 *Newly diagnosed POP in dynamic DCP. **Change in surgical plan - n (%)** 24 (22.1); rectocele (n=10); enterocele (n=2); sigmoidocele (n=4); rectal intussusceptions (n=8) Changed surgical plan included rectocele repair, sacral or transvaginal mesh colpopexy.	for confirmed pelvic organ prolapse and urinary incontinence) **Index Test** **A. Risk of Bias** Were the index test results interpreted without knowledge of the results of the reference standard? No If a threshold was used, was it pre-specified? No threshold used. Could the conduct or interpretation of the index test have introduced bias? High risk **B. Concerns about applicability** Are there concerns that the index test, its conduct, or interpretation differ from the review question? Low concern **Reference Standard** **A. Risk of bias** Is the reference standard likely to correctly classify target condition? Unclear

Bibliographic details	Participants	Tests	Methods	Outcomes and results	Comments
	• Stage II or greater POP confirmed by physical examination **Exclusion Criteria** Women with a history of surgery for UI and POP			For newly diagnosed rectal intussusception, surgical correction with rectocele repair was abandoned for further examination.	Were the reference standard results interpreted without knowledge of the results of index test? No Could the reference standard, its conduct, or interpretation have introduced bias? High risk **B. Concerns about applicability** Are there concerns that the target condition as defined by the reference standard does not match the question? Low concern **Flow and Timing** **A. Risk of Bias** Was there an appropriate interval between index test and reference standard? Unclear Did all patients receive the same reference standard? Yes Were all patients included in the analysis? Yes Could the patient flow have introduced bias? Low risk

Bibliographic details	Participants	Tests	Methods	Outcomes and results	Comments
					Other information The authors acknowledged the following limitations: • Different reference points for the two tests were not explored (hymenal ring and symphysis pubis) • Use of reference line that may overstage prolapses • No investigation of the relationship between DCP findings and surgical outcomes • Lack of data from normal controls and significance of comparing a test at Valsalva with a test during micturition and defecation
Full citation Lone, F., Sultan, A. H., Stankiewicz, A., Thakar, R., The value of pre-operative multicompartment pelvic floor ultrasonography: a 1-year prospective study,	**Sample size** N = 160 (158 had POP-Q and US assessments) POP and/or UI: 105 Controls: 53 At 1-year follow-up: 125/160 (78%); 81 (76.4%) from	**Tests** <u>POP-Q</u> Assessment conducted in the left lateral and standing position and examination completed using bimanual pelvic palpation. Measurements of POP-Q	**Methods** **Randomisation** Not applicable **Statistical analysis** POP-Q point measurement converted to mms and US in mms rounded to nearest zero.	**Results** **Cystocele diagnosed on POP-Q and analysable 2D TPUS at baseline** <u>Prolapse on POP-Q - negative</u> Prolapse on 2D TPUS negative: 92	**Limitations** **A. Risk of Bias** **Patient Sampling** Was a consecutive or random sample of patients enrolled? Unclear

Bibliographic details	Participants	Tests	Methods	Outcomes and results	Comments
British Journal of Radiology, 87, 20140145, 2014 **Ref Id** 690994 **Country/ies where the study was carried out** United Kingdom **Study type** Non-randomised controlled study **Aim of the study** To determine whether pre-operative pelvic floor ultrasound can diagnose additional conditions compared to clinical assessment in women complaining of pelvic floor dysfunction, and whether pre-operative diagnoses of additional conditions would have changed the outcome. **Study dates** July to October 2009 **Source of funding** Not stated	prolapse group and 44 (83.0%) from control group). **Characteristics** Age - mean ± SD (years) 49.5 (14.1) BMI - mean ± SD (kg/m-²) 29.3 (6.5) Parity - median (range) 2 (0 to 6) Previous surgery - n (%) Hysterectomy: 22 (13.7) POP surgery: 13 (8.1) Surgery for UI: 16 (10.0) **Inclusion Criteria** • Women with symptoms of POP and/or UI • Women with other gynaecological symptoms were eligible for inclusion as controls **Exclusion Criteria** Women with pelvic masses (e.g. ovarian cysts or fibroids),	points Ba, Bp and C in cms used to describe maximum descent of anterior, posterior and middle compartments, respectively. Pelvic floor US Two-dimensional (2D) transperineal ultrasound (TPUS) performed on same day as POP-Q assessment. Patients scanned in supine position and without using rectal or vaginal contrast. High frequency 2D/3D endovaginal ultrasound (EVUS) positioned in the midsagittal line on the perineum between the mons pubis and anal canal to visualise the pubic symphysis, urethra, vagina, anal canal and rectum. Performed at rest and on maximal Valsalva manoeuvres.	**Power calculation** None reported **Intention to treat analysis** Not applicable	Prolapse on 2D TPUS positive: 0 Prolapse on 2D TPUS sensitivity (%): 59.0 Prolapse on 2D TPUS specificity (%): 100.0 Prolapse on POP-Q - negative Prolapse on 2D TPUS negative: 25 Prolapse on 2D TPUS positive: 36 **Rectocele diagnosed on POP-Q and analysable 2D TPUS at baseline** Prolapse on POP-Q - negative Prolapse on 2D TPUS negative: 76 Prolapse on 2D TPUS positive: 3 Prolapse on 2D TPUS sensitivity (%): 39.3 Prolapse on 2D TPUS specificity (%): 96.2 Prolapse on POP-Q - negative Prolapse on 2D TPUS negative: 40 Prolapse on 2D TPUS positive: 26 **Cervix/vault prolapse diagnosed on POP-Q and analysable 2D TPUS at baseline** Prolapse on POP-Q - negative Prolapse on 2D TPUS negative: 93 Prolapse on 2D TPUS positive: 5	Was a case-control design avoided? No Did the study avoid inappropriate exclusion? Yes Could the selection of patients have introduced bias? High risk **B. Concerns about applicability** **Patient characteristics and setting** Are there concerns that the included patients and setting do not match the review question? Low concern **Index Test** **A. Risk of Bias** Were the index test results interpreted without knowledge of the results of the reference standard? Yes If a threshold was used, was it pre-specified? Unclear Could the conduct or interpretation of the index test have introduced bias? High risk **B. Concerns about applicability**

Bibliographic details	Participants	Tests	Methods	Outcomes and results	Comments
	which may impact on pelvic floor assessment			Prolapse on 2D TPUS sensitivity (%): 69.0 Prolapse on 2D TPUS specificity (%): 94.9 Prolapse on POP-Q - negative Prolapse on 2D TPUS negative: 13 Prolapse on 2D TPUS positive: 29 None of the women with additional diagnoses of POP on 2D TPUS required surgical intervention for POP at baseline or at 1-year follow-up. 1/78 women (1.3%) with POP on clinical examination opted for pessary treatment, and the remaining women opted for pelvic floor muscle exercises only. **Additional diagnoses on PFUS (2D TPUS + 3D EVUS) at baseline and at 1-year follow-up with interventions during study period - enterocele** At baseline (controls) - median (range) (mm) Enterocele (n=2/54): 10 (7 to 13) At baseline (prolapse group) - median (range) (mm) Enterocele (n=9/89): 10 (-9 to 16) Intervention - n=1 At 1 year (controls) - median (range) (mm) Enterocele (n=12/44): -10 (-20 to 6)	Are there concerns that the index test, its conduct, or interpretation differ from the review question? Low concern **Reference Standard** **A. Risk of bias** Is the reference standard likely to correctly classify target condition? Unclear Were the reference standard results interpreted without knowledge of the results of index test? Yes Could the reference standard, its conduct, or interpretation have introduced bias? Low risk **B. Concerns about applicability** Are there concerns that the target condition as defined by the reference standard does not match the question? Low concern **Flow and Timing** **A. Risk of Bias**

Bibliographic details	Participants	Tests	Methods	Outcomes and results	Comments
				At 1 year (prolapse group) - median (range) (mm) Enterocele (n=16/81): 9 (-16 to 16) **Additional diagnoses on PFUS (2D TPUS + 3D EVUS) at baseline and at 1-year follow-up with interventions during study period - other diagnoses** At baseline (controls) - n/N Intussusception: 1/54 Bladder calcification: 1/54 Vaginal cyst: 4/54 Enterocele + intussusception: 0/54 At baseline (prolapse group) - n/N Intussusception: 3/89 Bladder calcification: 3/89 Vaginal cyst: 2/89 Enterocele + intussusception: 1/89 Intervention - n=1 Intussusception: 1 stapled transanal rectal resection At 1 year (controls) - n/N Intussusception: 2/44 Bladder calcification: 1/44 Vaginal cyst: 2/44 Enterocele + intussusception: 0/44 At 1 year (prolapse group) - n/N Intussusception: 7/81 Bladder calcification: 2/81 Vaginal cyst: 2/81 Enterocele + intussusception: 2/81	Was there an appropriate interval between index test and reference standard? Yes Did all patients receive the same reference standard? Yes Were all patients included in the analysis? Unclear Could the patient flow have introduced bias? High risk **Other information** The authors acknowledged the following limitations: • Small sample size • Most women had prolapse of more than one compartment • Reference line used to measure enterocele may not have been representative

Bibliographic details	Participants	Tests	Methods	Outcomes and results	Comments
				Of 89 women with symptomatic prolapse: Surgery for POP: 43 (48.3%): Vaginal hysterectomy + anterior repair: 12 Anterior repair: 18 Posterior repair: 5 Vaginal hysterectomy: 2 Posterior repair + vaginal hysterectomy: 2 Sacrocolpopexy: 2 Posterior repair + sacrospinous fixation: 2 Pessaries: 10 (11.2%) No treatment: 34 (40.4%)	
Full citation Reimers, C., Staer-Jensen, J. E., Siafarikas, F., Bo, K., Engh, M. E., Association between vaginal bulge and anatomical pelvic organ prolapse during pregnancy and postpartum: an observational study, International Urogynecology Journal, 11, 11, 2017 **Ref Id** 691265 **Country/ies where the study was carried out** Norway **Study type**	**Sample size** N = 300 (n=177 women with eligible data for analysis at last visit) **Characteristics** Age - mean ± SD (years) 28.7 (4.3) Maternal pre-pregnant BMI - mean ± SD (kg/m²) 23.9 (3.9) **Inclusion Criteria** • Pregnant women with their first single pregnancy undergoing routine	**Tests** International Consultation on Incontinence Modular Questionnaire vaginal symptoms (ICIQ-VS) Vaginal bulge was dichotomised and women were in the 'no bulge' group or 'bulge' group. Clinical examination with standardised POP-Q Performed in a standardised fashion according to the ICS/IUGA guidelines with women sitting upright at 45º.	**Methods** Women underwent clinical examinations and completed electronic questionnaires at 5 visits relative to time of birth (i.e. at gestational weeks 21 and 37, and at 6 weeks, and 6 and 12 months postpartum). International Consultation on Incontinence Modular Questionnaire vaginal symptoms (ICIQ-VS) Vaginal bulge was dichotomised and women were in the 'no bulge' group if they stated 'never' for the question 'are you aware of a lump or bulge coming down in your vagina?' and 'do you feel a lump or bulge coming out of your vagina, so that you can feel it on the outside or see it on the outside?'. Otherwise	**Results** Diagnostic accuracy at 6 weeks postpartum - symptom vaginal bulge to diagnose anatomical POP Sensitivity: 52% Specificity: 83% Positive predictive value: 23% Negative predictive value: 95% At the four remaining visits, the diagnostic sensitivity ranged from 0 to 50%, specificity from 77 to 85%, the positive predictive values were below 10%, and the negative predictive values were above 95%. **Comparison of the symptom vaginal bulge and anatomical POP during pregnancy and postpartum** Visit 1 (gestational week 21) - n=300	**Limitations** **A. Risk of Bias** **Patient Sampling** Was a consecutive or random sample of patients enrolled? Unclear Was a case-control design avoided? Yes Did the study avoid inappropriate exclusion? Yes Could the selection of patients have introduced bias? Unclear risk **B. Concerns about applicability** **Patient characteristics and setting** Are there concerns that the included

Bibliographic details	Participants	Tests	Methods	Outcomes and results	Comments
Prospective cohort study **Aim of the study** To explore the relationship between the symptom vaginal bulge and anatomical POP and to compare the diagnostic accuracy of the two tests in women having their first child **Study dates** January 2010 to October 2012 **Source of funding** South-Eastern Norway Regional Health Authority and the Research Council of Norway	ultrasound in the second trimester • Scandinavian speaking **Exclusion Criteria** • Women giving birth before gestational week 32 • Intrauterine foetal death • New pregnancy of more than 6 weeks' gestation at the postpartum visits • Women participating in the intervention group of a randomised controlled trial exploring the effect of pelvic floor muscle training after vaginal delivery		they were considered to be in the 'bulge' group. <u>Clinical examination with standardised POP-Q</u> The variables point B anterior (Ba), cervix (C), point B posterior (Bp), genital hiatus (Gh), and perineal body (Pb) were chosen for analysis. **Randomisation** Not applicable **Statistical analysis** Diagnostic sensitivity and specificity and the positive and negative predictive values of the vaginal bulge were calculated from cross tabulation showing distribution of vaginal bulge and anatomical POP. **Power calculation** No a priori power calculation was performed. **Intention to treat analysis** Not applicable	Vaginal bulge (+): POP (+) 4; POP (-) 44 Vaginal bulge (-): POP (+) 9; POP (-) 243 Sensitivity of bulge (%): POP (+) 31 Specificity of bulge (%): POP (+) 85 Positive predictive value of bulge (%): POP (+) 8 Negative predictive value of bulge (%): POP (+) 96 <u>Visit 2 (gestational week 37) - n=270</u> Vaginal bulge (+): POP (+) 1; POP (-) 45 Vaginal bulge (-): POP (+) 1; POP (-) 223 Sensitivity of bulge (%): POP (+) 50 Specificity of bulge (%): POP (+) 83 Positive predictive value of bulge (%): POP (+) 2 Negative predictive value of bulge (%): POP (+) >99 <u>Visit 3 (6 weeks postpartum) - n=280</u> Vaginal bulge (+): POP (+) 13; POP (-) 44 Vaginal bulge (-): POP (+) 12; POP (-) 211 Sensitivity of bulge (%): POP (+) 52 Specificity of bulge (%): POP (+) 83 Positive predictive value of bulge (%): POP (+) 23 Negative predictive value of bulge (%): POP (+) 95	patients and setting do not match the review question? High concern **Index Test** **A. Risk of Bias** Were the index test results interpreted without knowledge of the results of the reference standard? Yes If a threshold was used, was it pre-specified? No threshold Could the conduct or interpretation of the index test have introduced bias? High risk **B. Concerns about applicability** Are there concerns that the index test, its conduct, or interpretation differ from the review question? Low concern **Reference Standard** **A. Risk of bias** Is the reference standard likely to correctly classify

Bibliographic details	Participants	Tests	Methods	Outcomes and results	Comments
				Visit 4 (6 months postpartum) - n=195 Vaginal bulge (+): POP (+) 1; POP (-) 44 Vaginal bulge (-): POP (+) 4; POP (-) 146 Sensitivity of bulge (%): POP (+) 20 Specificity of bulge (%): POP (+) 77 Positive predictive value of bulge (%): POP (+) 2 Negative predictive value of bulge (%): POP (+) 97 Visit 5 (12 months postpartum) - n=176 Vaginal bulge (+): POP (+) 0; POP (-) 33 Vaginal bulge (-): POP (+) 4; POP (-) 139 Sensitivity of bulge (%): POP (-) 0 Specificity of bulge (%): POP (+) 81 Positive predictive value of bulge (%): POP (+) 0 Negative predictive value of bulge (%): POP (+) 97	target condition? Unclear Were the reference standard results interpreted without knowledge of the results of index test? Yes Could the reference standard, its conduct, or interpretation have introduced bias? Low risk **B. Concerns regarding applicability** Are there concerns that the target condition as defined by the reference standard does not match the question? Low concern **Flow and Timing** **A. Risk of Bias** Was there an appropriate interval between index test and reference standard? Yes Did all patients receive the same reference standard? Yes Were all patients included in the analysis? Unclear

Bibliographic details	Participants	Tests	Methods	Outcomes and results	Comments
					Could the patient flow have introduced bias? High risk **Other information** The authors acknowledged the following limitations: • Lack of a priori power calculation • Lack of pre-pregnancy and early pregnancy data • Lack of validated POP diagnostic tool for pregnant women • ICIQ questionnaire not yet validated in Norwegian • Inability to detect and exclude women with very early new pregnancies in the postpartum period
Full citation Tan, J. S., Lukacz, E. S., Menefee, S. A., Powell, C. R., Nager, C. W., Albo, M. E., Luber, K. M., Predictive	**Sample size** N = 2666 (n=754 excluded due to incomplete data or lack of informed consent) N = 1912	**Tests** Standardised pelvic floor dysfunction questionnaire Including 51 items on main complaint, review of urinary	**Methods** Women completed mailed questionnaire at home or when in the waiting room prior to their exam room visit.	**Results** **Diagnostic accuracy of urinary splinting and POP for prolapse at or past the hymen**	**Limitations** **A. Risk of Bias** **Patient Sampling** Was a consecutive or random sample

Bibliographic details	Participants	Tests	Methods	Outcomes and results	Comments
value of prolapse symptoms: A large database study, International Urogynecology Journal, 16, 203-209, 2005 **Ref Id** 691471 **Country/ies where the study was carried out** USA **Study type** Prospective cohort study **Aim of the study** To compare the relationship between and diagnostic accuracy of patient symptoms reported using a standardised questionnaire and the quantitative degree of POP on physical examination in women with pelvic floor disorders **Study dates** 1 July 2000 to 1 August 2003 **Source of funding** Not stated	University of California-San Diego (UCSD): n=122 Kaiser Permanente-San Diego: n=769 Naval Medical Centre-San Diego: n=1021 **Characteristics** Age - mean ± SD (years) 55.7 (14.7) (n=1880) Weight - mean ± SD (lbs) 164.3 (46.7) (n=1734) Parity - median 2 (n=1897) Previous hysterectomy - % 42.6 (n=1799) Postmenopausal - % 66.7 (n=1808) **Inclusion Criteria** Not stated **Exclusion Criteria** Women with missing data for: Aa, Ba, C, Ap, Bp, or symptom report of urinary splinting, digital assistance, or bulge symptoms	and bowel symptoms, and past gynaecologic, medical, and surgical history. In addition, the Urogenital Distress Inventory (UDI) and Incontinence Impact Questionnaire (IIQ-7). POP-Q examination Posterior blade of a bivalve speculum used for appropriate visualisation, and 9 POP-Q measurements determined with patient in the dorsal lithotomy position.	Standardised pelvic floor dysfunction questionnaire Urinary splinting: Do you ever have to push tissue back into the vagina to urinate? Digital assistance splinting: Do you have to use your fingers to apply pressure on the vagina or rectum to have a bowel movement? Digitation/disimpaction: Do you have to manually remove stool with a finger in the rectum to have a bowel movement? Bulge: Do you ever feel a bulge or that something is 'falling out' of the vagina? POP-Q examination Maximum value of prolapse given on POP-Q exam for values Aa, Ba, C, D, Ap, and Bp. Predictive calculations were performed by dichotomising women into groups based on their maximum POP-Q values. The optimal blend of reasonably high (>70%) positive and negative predictive values for the 3 symptoms (urinary splinting, digital assistance, bulge) occurred when prolapse was defined as ≥0cm. Patients were determined to have anterior, posterior, or general prolapse if their maximum Ba, Bp, or any POP-Q values were ≥0cm	POP-Q ≥0cm - US Anterior prolapse: 112 No anterior prolapse: 40 POP-Q ≥0cm - No US Anterior prolapse: 508 No anterior prolapse: 1252 Sensitivity (%): 18.1 Specificity (%): 96.9 Positive predictive value (%): 73.7 Negative predictive value (%): 71.1 Likelihood ratio: 5.83 **Diagnostic accuracy of digital assistance and POP for prolapse at or past the hymen** POP-Q ≥0cm - DA Posterior prolapse: 103 No posterior prolapse: 200 POP-Q ≥0cm - No DA Posterior prolapse: 219 No posterior prolapse: 1390 Sensitivity (%): 32.0 Specificity (%): 87.4 Positive predictive value (%): 34.0 Negative predictive value (%): 86.4 Likelihood ratio: 2.54 **Diagnostic accuracy of vaginal bulge and POP for prolapse at or past the hymen** POP-Q ≥0cm - Bulge Prolapse: 573 No prolapse: 133 POP-Q ≥0cm - No Bulge	of patients enrolled? No Was a case-control design avoided? Yes Did the study avoid inappropriate exclusion? Yes Could the selection of patients have introduced bias? High risk **B. Concerns regarding applicability** **Patient characteristics and setting** Are there concerns that the included patients and setting do not match the review question? Low concern **Index Test** **A. Risk of Bias** Were the index test results interpreted without knowledge of the results of the reference standard? No If a threshold was used, was it pre-specified? No threshold Could the conduct or interpretation of the index test have

Bibliographic details	Participants	Tests	Methods	Outcomes and results	Comments
			past the hymen. Women were considered to be prolapse free if their POP-Q values for each compartment were above the hymen. **Randomisation** Not applicable **Statistical analysis** X^2 statistic with Yates' continuity correction used to determine sensitivity and specificity of prolapse symptoms to predict the presence of POP. **Power calculation** None reported **Intention to treat analysis** Not applicable	Prolapse: 288 No prolapse: 918 Sensitivity (%): 66.6 Specificity (%): 87.3 Positive predictive value (%): 81.2 Negative predictive value (%): 76.1 Likelihood ratio: 5.26 **Vaginal bulge** Although sensitivity of urinary splinting was quite low, urinary splinting was rarely reported in the absence of anterior prolapse, with a specificity of 96.9%. The positive and negative predictive values of urinary splinting were high at 73.7% (p<0.001) and 71.1% (p<0.001), respectively. **Urinary splinting, digital assistance, and vaginal bulge** Although the sensitivity of having all 3 symptoms was quite low, the specificity for the test was 99.4% (p<0.001). The positive predictive value of having prolapse with all 3 symptoms was quite high at 89.1% (p<0.001). **Diagnostic accuracy for having POP when reporting all 3 symptoms of prolapse** POP-Q ≥0cm - 3 prolapse symptoms Prolapse: 49	introduced bias? High risk **B. Concerns regarding applicability** Are there concerns that the index test, its conduct, or interpretation differ from the review question? Low concern **Reference Standard** **A. Risk of bias** Is the reference standard likely to correctly classify target condition? Unclear Were the reference standard results interpreted without knowledge of the results of index test? No Could the reference standard, its conduct, or interpretation have introduced bias? High risk **B. Concerns regarding applicability** Are there concerns that the target condition as defined by the reference

Bibliographic details	Participants	Tests	Methods	Outcomes and results	Comments
				No prolapse: 6 POP-Q ≥0cm - No 3 prolapse symptoms Prolapse: 812 No prolapse: 1045 All 3 prolapse symptoms Sensitivity (%): 5.70 Specificity (%): 99.40 Positive predictive value (%): 89.10 Negative predictive value (%): 56.30 Likelihood ratio: 9.97	standard does not match the question? Low concern **Flow and Timing** **A. Risk of Bias** Was there an appropriate interval between index test and reference standard? Unclear Did all patients receive the same reference standard? Yes Were all patients included in the analysis? No Could the patient flow have introduced bias? High risk **Other information** The authors acknowledged the following limitations: • Large number of excluded women • Instrument used to collect patient data was not formally validated and primarily directed at the presence of rectoceles

Bibliographic details	Participants	Tests	Methods	Outcomes and results	Comments
					• The study was not blinded

Appendix E – Forest plots

Forest plots for review question: What is the most effective strategy for assessing POP?

Figure 2: Dynamic cystoproctography/colpocystoproctography to detect rectocele in adult women

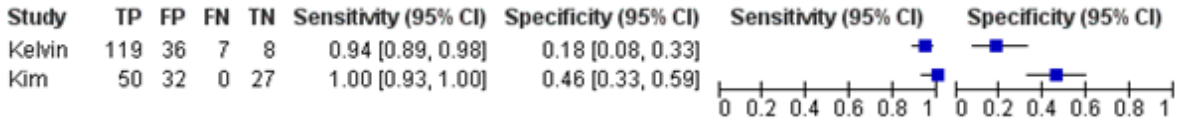


Figure 3: Dynamic cystoproctography/colpocystoproctography to detect enterocele in adult women

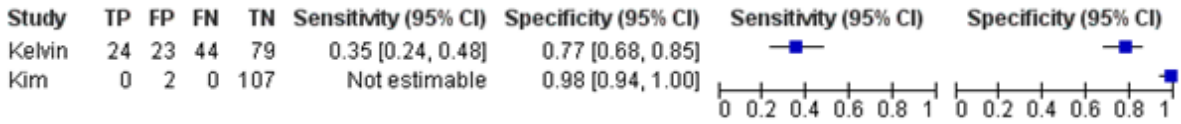
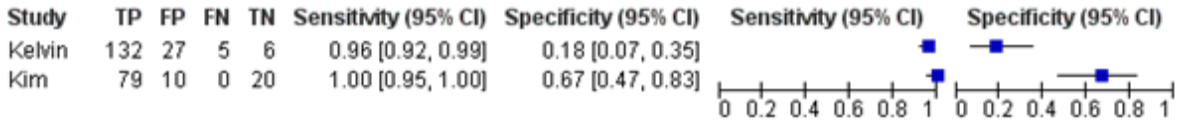


Figure 4: Dynamic cystoproctography/colpocystoproctography to detect cystocele in adult women



Appendix F – GRADE tables

GRADE tables for review question: What is the most effective strategy for assessing POP?

Table 5: Clinical evidence profile (using modified GRADE for diagnostic reviews) for diagnostic tests to assess pelvic organ prolapse.

Index test	Number of studies	Number of participants	Risk of bias[1]	Inconsistency[2]	Indirectness[3]	Imprecision[4]	Sensitivity (95% CI)	Specificity (95% CI)	Quality of the evidence (GRADE)	Importance
Dynamic cystoproctography/colpocystoproctography										
Dynamic cystoproctography to detect rectocele[5]	1	170	Very serious[6]	Not applicable	Serious[7]	Not serious	0.94 (0.89 – 0.98)	0.18 (0.08 – 0.33)	⊕⊖⊖⊖ VERY LOW	CRITICAL
Dynamic colpocystoproctography to detect rectocele[8]	1	109	Very serious[9]	Not applicable	Serious[10]	Not serious	1.00 (0.93, 1.00)	0.46 (0.33, 0.59)	⊕⊖⊖⊖ VERY LOW	CRITICAL
Dynamic cystoproctography to detect enterocele[5]	1	170	Very serious[6]	Not applicable	Serious[7]	Serious	0.35 (0.24, 0.48)	0.77 (0.68, 0.85)	⊕⊖⊖⊖ VERY LOW	CRITICAL
Dynamic colpocystoproctography to detect enterocele[8]	1	109	Very serious[9]	Not applicable	Serious[10]	Not applicable	Not estimable	0.98 (0.94, 1)	⊕⊖⊖⊖ VERY LOW	CRITICAL
Dynamic cystoprotogra	1	170	Very serious[6]	Not applicable	Serious[7]	Not serious	0.96 (0.92, 0.99)	0.18 (0.07, 0.35)	⊕⊖⊖⊖ VERY LOW	CRITICAL

Index test	Number of studies	Number of participants	Risk of bias[1]	Inconsistency[2]	Indirectness[3]	Imprecision[4]	Sensitivity (95% CI)	Specificity (95% CI)	Quality of the evidence (GRADE)	Importance
phy to detect cystocele[5]										
Dynamic colpocystopr otography to detect cystocele[8]	1	109	Very serious[9]	Not applicable	Serious[10]	Not serious	1.00 (0.95, 1.00)	0.67 (0.47, 0.83)	⨁⊖⊖⊖ VERY LOW	CRITICAL
2D transperineal ultrasound compared to POP-Q										
2D transperineal ultrasound compared to POP-Q to detect rectocele	1	145	Very serious[11]	Not applicable	Not serious[12]	Serious	0.39 (0.28, 0.52)	0.96 (0.89, 0.99)	⨁⊖⊖⊖ VERY LOW	CRITICAL
2D transperineal ultrasound compared to POP-Q to detect cystocele	1	153	Very serious[11]	Not applicable	Not serious[12]	Serious	0.59 (0.46, 0.71)	1.00 (0.96, 1.00)	⨁⊖⊖⊖ VERY LOW	CRITICAL
2D transperineal ultrasound compared to POP-Q to detect cervix/vault prolapse	1	140	Very serious[11]	Not applicable	Not serious[12]	Serious	0.69 (0.53, 0.82)	0.95 (0.88, 0.98)	⨁⊖⊖⊖ VERY LOW	CRITICAL

Index test	Number of studies	Number of participants	Risk of bias[1]	Inconsistency[2]	Indirectness[3]	Imprecision[4]	Sensitivity (95% CI)	Specificity (95% CI)	Quality of the evidence (GRADE)	Importance
Self-reported vaginal bulge (as assessed through the ICIQ-VS) to detect anatomical and functional changes during and after pregnancy										
21 weeks gestation	1	300	Very serious[13]	Not applicable	Very serious[14]	Very serious	0.31 (0.09, 0.61)	0.85 (0.80, 0.89)	⨁⊖⊖⊖ VERY LOW	CRITICAL
37 weeks gestation	1	270	Very serious[13]	Not applicable	Very serious[14]	Very serious	0.50 (0.01, 0.99)	0.83 (0.78, 0.87)	⨁⊖⊖⊖ VERY LOW	CRITICAL
6 weeks after birth	1	280	Very serious[13]	Not applicable	Very serious[14]	Very serious	0.52 (0.31, 0.72)	0.83 (0.78, 0.87)	⨁⊖⊖⊖ VERY LOW	CRITICAL
6 months after birth	1	195	Very serious[13]	Not applicable	Very serious[14]	Very serious	0.20 (0.01, 0.72)	0.77 (0.70, 0.83)	⨁⊖⊖⊖ VERY LOW	CRITICAL
12 months after birth	1	176	Very serious[13]	Not applicable	Very serious[14]	Very serious	0.00 (0.00, 0.60)	0.81 (0.74, 0.86)	⨁⊖⊖⊖ VERY LOW	CRITICAL
Self-reported vaginal bulge* compared to POP-Q**										
Self-reported vaginal bulge*** compared to POP-Q to detect POP	1	1912	Very serious[15]	Not applicable	Not serious[16]	Not serious	0.67 (0.63, 0.70)	0.87 (0.85, 0.89)	⨁⊖⊖⊖ VERY LOW	CRITICAL
Self-reported urinary splinting* compared to POP-Q										
Self-reported urinary splinting* compared to	1	1912	Very serious[15]	Not applicable	Not serious[16]	Not serious	0.18 (0.15, 0.21)	0.97 (0.96, 0.98)	⨁⊖⊖⊖ VERY LOW	CRITICAL

Index test	Number of studies	Number of participants	Risk of bias[1]	Inconsistency[2]	Indirectness[3]	Imprecision[4]	Sensitivity (95% CI)	Specificity (95% CI)	Quality of the evidence (GRADE)	Importance
POP-Q to detect POP										
Self-reported digital assistance compared to POP-Q**										
Self-reported digital assistance** compared to POP-Q to detect POP	1	1939	Very serious[15]	Not applicable	Not serious[16]	Not serious	0.32 (0.27, 0.37)	0.87 (0.86, 0.89)	⊕⊖⊖⊖ VERY LOW	CRITICAL

1. *Risk of bias was assessed using the QUADAS-2 checklist (without taking into consideration the applicability domain)*
2. *Inconsistency was assessed by inspection of the 95% prediction region in a summary ROC plot if a diagnostic meta-analysis was conducted. If between 2 and 3 studies, inconsistency was assessed by visual inspection of the point estimates of sensitivity and specificity. If only 1 study, then inconsistency is not applicable*
3. *Indirectness was assessed using the QUADAS-2 checklist items referring to applicability*
4. *Imprecision was based on the width of the confidence interval of test sensitivity as this was considered to be the primary measure of interest. A width in the 95% CI of up to 20% was considered as not serious imprecision, a width between 20 and 40% was considered as serious imprecision, and a width of more than 40% was considered as very serious imprecision*
5. *Reference standard: Baden-Walker*
6. *Low risk for patient selection; high risk for index test and reference standard; Unclear risk for flow and timing*
7. *High concerns of patient selection: more than half of the patients had undergone previous hysterectomy or other form of reconstructive pelvic floor surgery*
8. *Reference standard: POP-Q assessment*
9. *Unclear risk for all domains: patient selection, index test, reference standard, flow and timing*
10. *High concerns: patient selection (study was conducted on patients that were planned for combined surgery for confirmed pelvic organ prolapse and urinary incontinence)*
11. *High risk for patient selection (not consecutive patients); high risk for index test; low risk for reference standard and high risk for flow and timing*
12. *Low concerns for all domains: patient selection, index test and reference standard*
13. *Unclear risk for patient selection; high risk for index test, low risk for reference standard, high risk for flow and timing*
14. *High patient selection concern as this study focused on changes throughout pregnancy and up to 12 months after childbirth. Evidence might not be generalisable to the wide range of women who experience pelvic organ prolapse*
15. *High risk for all domains: patient selection, index test and reference standard, flow and timing*
16. *Low concerns for all domains*

**Defined as an affirmative answer to the question pushing tissue back into the vagina to urinate in a standardised pelvic floor dysfunction questionnaire.*

*** Defined as an affirmative answer to the following questions on a standardised pelvic floor dysfunction questionnaire: (i) Do you have to use your fingers to apply pressure on the vagina or rectum to have a bowel movement? (ii) Do you have to manually remove stool with a finger in the rectum to have a bowel movement?*

**** Defined as an affirmative answer to the following question on a standardised pelvic floor dysfunction questionnaire: Do you ever feel a bulge or that something is falling out of the vagina?*

Appendix G – Economic evidence study selection

Economic evidence study selection for review question: What is the most effective strategy for assessing POP?

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 strategy for assessing POP?

No economic studies were found which were applicable to this review question.

Appendix I – Economic evidence profiles

Economic evidence profiles for review question: What is the most effective strategy for assessing POP?

No economic studies were found which were applicable to this review question.

Appendix J – Economic analysis

Economic analysis for review question: What is the most effective strategy for assessing POP?

No economic analysis was conducted for this review question.

Appendix K – Excluded studies

Excluded studies for review question: What is the most effective strategy for assessing POP?

Clinical studies

Table 6: Excluded studies and reasons for their exclusion

Study	Reason for Exclusion
Altman, D., Lopez, A., Kierkegaard, J., Zetterstrom, J., Falconer, C., Pollack, J., Mellgren, A., Assessment of posterior vaginal wall prolapse: Comparison of physical findings to cystodefecoperitoneography, International Urogynecology Journal, 16, 96-103, 2005	Outcomes not relevant to the protocol
Altman, D., Mellgren, A., Kierkegaard, J., Zetterstrom, J., Falconer, C., Lopez, A., Diagnosis of cystocele - The correlation between clinical and radiological evaluation, International Urogynecology Journal, 15, 3-9, 2004	Outcomes not relevant to the protocol
Baden, W. F., Walker, T. A., Genesis of the vaginal profile: a correlated classification of vaginal relaxation, Clinical Obstetrics and Gynecology, 15, 1048-1054, 1972	Study design not relevant to the protocol
Baden, W. F., Walker, T. A., Statistical evaluation of vaginal relaxation, Clinical Obstetrics and Gynecology, 15, 1070-1072, 1972	Study design not relevant to the protocol - case series
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 paper - reference standard not relevant to the protocol
Blain, G., Dietz, H. P., Symptoms of female pelvic organ prolapse: Correlation with organ descent in women with single compartment prolapse, Australian and New Zealand Journal of Obstetrics and Gynaecology, 48, 317-321, 2008	Reference standard comparison not relevant to the protocol
Broekhuis, S. R., Futterer, J. J., Barentsz, J. O., Vierhout, M. E., Kluivers, K. B., A systematic review of clinical studies on dynamic magnetic resonance imaging of pelvic organ prolapse: the use of reference lines and anatomical landmarks, International Urogynecology Journal, 20, 721-9, 2009	Outcomes not relevant to the protocol
Broekhuis, S. R., Futterer, J. J., Hendriks, J. C. M., Barentsz, J. O., Vierhout, M. E., Kluivers, K. B., Symptoms of pelvic floor dysfunction are poorly correlated with findings on clinical examination and dynamic MR imaging of the pelvic floor, International Urogynecology Journal, 20, 1169-1174, 2009	Outcomes not relevant to the protocol

Study	Reason for Exclusion
Broekhuis, S. R., Kluivers, K. B., Hendriks, J. C. M., Futterer, J. J., Barentsz, J. O., Vierhout, M. E., POP-Q, dynamic MR imaging, and perineal ultrasonography: Do they agree in the quantification of female pelvic organ prolapse?, International Urogynecology Journal, 20, 541-549, 2009	Outcomes not relevant to the protocol
Cespedes, R. Duane, Diagnosis and treatment of vaginal vault prolapse conditions, Urology, 60, 8-15, 2002	Narrative literature review
Chantarasorn, V., Dietz, H. P., Diagnosis of cystocele type by clinical examination and pelvic floor ultrasound, Ultrasound in obstetrics & gynecology : the official journal of the International Society of Ultrasound in Obstetrics and Gynecology, 39, 710-714, 2012	Outcomes not relevant to the protocol
Claydon, C. S., The evaluation of pelvic organ prolapse, Journal of Pelvic Medicine and Surgery, 10, 173-192, 2004	Narrative literature review
Cortes, E., Reid, W. M. N., Singh, K., Berger, L., Clinical examination and dynamic magnetic resonance imaging in vaginal vault prolapse, Obstetrics and Gynecology, 103, 41-46, 2004	Outcomes not relevant to the protocol
Dalpiaz, O., Curti, P., Role of perineal ultrasound in the evaluation of urinary stress incontinence and pelvic organ prolapse: a systematic review, Neurourology & Urodynamics, 25, 301-6; discussion 307, 2006	Narrative literature review
Dietz, H. P., Haylen, B. T., Broome, J., Ultrasound in the quantification of female pelvic organ prolapse, Ultrasound in Obstetrics and Gynecology, 18, 511-514, 2001	Outcomes not relevant to the protocol
Etlik, O., Arslan, H., Odabasi, O., Odabasi, H., Harman, M., Celebi, H., Sakarya, M. E., The role of the MR-fluoroscopy in the diagnosis and staging of the pelvic organ prolapse, European Journal of Radiology, 53, 136-41, 2005	Outcomes not relevant to the protocol
Groenendijk, A. G., De Blok, S., Birnie, E., Bonsel, G. J., Interobserver agreement and intersystem comparison of the halfway system of baden and walker versus the pelvic organ prolapse-quantitation prolapse classification system in assessing the severity of pelvic organ prolapse, Journal of Pelvic Medicine and Surgery, 11, 243-250, 2005	Outcomes not relevant to the protocol
Gupta, S., Sharma, J. B., Hari, S., Kumar, S., Roy, K. K., Singh, N., Study of dynamic magnetic resonance imaging in diagnosis of pelvic organ prolapse, Archives of Gynecology and Obstetrics, 286, 953-958, 2012	Outcomes not relevant to the protocol
Hodroff, M. A., Stolpen, A. H., Denson, M. A., Bolinger, L., Kreder, K. J., Dynamic magnetic resonance imaging of the female pelvis: The relationship with the pelvic organ prolapse quantification staging system, Journal of Urology, 167, 1353-1355, 2002	Outcomes not relevant to the protocol
Kelvin, F. M., Maglinte, D. D. T., Dynamic cystoproctography of female pelvic floor defects and their interrelationships, American Journal of Roentgenology, 169, 769-774, 1997	Narrative literature review

Study	Reason for Exclusion
Kelvin, F. M., Maglinte, D. D. T., Hale, D. S., Benson, J. T., Female pelvic organ prolapse: A comparison of triphasic dynamic MR imaging and triphasic fluoroscopic cystocolpoproctography, American Journal of Roentgenology, 174, 81-88, 2000	Outcomes not relevant to the protocol
Kluivers, K. B., Hendriks, J. C. M., Shek, C., Dietz, H. P., Pelvic organ prolapse symptoms in relation to POPQ, ordinal stages and ultrasound prolapse assessment, International Urogynecology Journal, 19, 1299-1302, 2008	Outcomes not relevant to the protocol
Kobashi, K. C., Leach, G. E., Pelvic prolapse, Journal of Urology, 164, 1879-90, 2000	Narrative literature review
Lakeman, M. M. E., Zijta, F. M., Peringa, J., Nederveen, A. J., Stoker, J., Roovers, J. P. W. R., Dynamic magnetic resonance imaging to quantify pelvic organ prolapse: Reliability of assessment and correlation with clinical findings and pelvic floor symptoms, International Urogynecology Journal and Pelvic Floor Dysfunction, 23, 1547-1554, 2012	Outcomes not relevant to the protocol
Lienemann, A., Anthuber, C., Baron, A., Kohz, P., Reiser, M., Dynamic MR colpocystorectography assessing pelvic-floor descent, European Radiology, 7, 1309-1317, 1997	Reference standard not relevant to the protocol
Lone, F. W., Thakar, R., Sultan, A. H., Stankiewicz, A., Accuracy of assessing Pelvic Organ Prolapse Quantification points using dynamic 2D transperineal ultrasound in women with pelvic organ prolapse, International Urogynecology Journal and Pelvic Floor Dysfunction, 23, 1555-1560, 2012	Outcomes not relevant to the protocol
Manonai, J., Mouritsen, L., Palma, P., Contreras-Ortiz, O., Korte, J. E., Swift, S., The inter-system association between the simplified pelvic organ prolapse quantification system (S-POP) and the standard pelvic organ prolapse quantification system (POPQ) in describing pelvic organ prolapse, International Urogynecology Journal, 22, 347-352, 2011	Outcomes not relevant to the protocol
Najjari, L., Hennemann, J., Larscheid, P., Papathemelis, T., Maass, N., Perineal ultrasound as a complement to POP-Q in the assessment of cystoceles, BioMed Research International, 2014, 740925, 2014	Outcomes not relevant to the protocol
Nguyen, J. K., Current concepts in the diagnosis and surgical repair of anterior vaginal prolapse due to paravaginal defects, Obstetrical & Gynecological Survey, 56, 239-46, 2001	Narrative literature review
Pizzoferrato, A. C., Nyangoh Timoh, K., Fritel, X., Zareski, E., Bader, G., Fauconnier, A., Dynamic Magnetic Resonance Imaging and pelvic floor disorders: how and when?, European Journal of Obstetrics, Gynecology, & Reproductive Biology, 181, 259-66, 2014	Narrative literature review

Study	Reason for Exclusion
Raizada, N., Mittal, P., Suri, J., Puri, A., Sharma, V., Comparative study to evaluate the intersystem association and reliability between standard pelvic organ prolapse quantification system and simplified pelvic organ prolapse scoring system, Journal of Obstetrics & Gynaecology of India, 64, 421-4, 2014	Outcomes not relevant to the protocol
Rovner, E. S., Pelvic organ prolapse: a review, Ostomy/wound management, 46, 24-37, 2000	Narrative literature review
Schettino, M. T., Dato, E., Rossi, C., Panariello, A., Vascone, C., Coppola, G., Iervolino, S. A., D'Assisi, D., Mainini, G., Torella, M., Possible role of perineal ultrasound in the diagnosis of cystocele, Clinical and Experimental Obstetrics and Gynecology, 42, 321-326, 2015	Outcomes not relevant to the protocol
Swift, S., Morris, S., McKinnie, V., Freeman, R., Petri, E., Scotti, R. J., Dwyer, P., Validation of a simplified technique for using the POPQ pelvic organ prolapse classification system, International Urogynecology Journal, 17, 615-20, 2006	Outcomes not relevant to the protocol
Thiagamoorthy, G., Zacche, M., Cardozo, L., Naidu, M., Giarenis, I., Flint, R., Srikrishna, S., Robinson, D., Digital assessment and quantification of pelvic organ prolapse (DPOP-Q): a randomised cross-over diagnostic agreement trial, International Urogynecology Journal, 27, 433-7, 2016	Outcomes not relevant to the protocol
Trutnovsky, G., Kamisan Atan, I., Ulrich, D., Martin, A., Dietz, H. P., Levator ani trauma and pelvic organ prolapse - a comparison of three translabial ultrasound scoring systems, Acta Obstetricia et Gynecologica Scandinavica, 95, 1411-1417, 2016	Reference standard not relevant to the protocol
Wiegersma, M., Panman, C. M. C. R., Kollen, B. J., Berger, M. Y., Lisman-van Leeuwen, Y., Dekker, J. H., Is the hymen a suitable cut-off point for clinically relevant pelvic organ prolapse?, Maturitas, 99, 86-91, 2017	Study design not relevant to protocol - no diagnostic comparison to POP-Q

Economic studies

No economic evidence was found for this review question. See supplementary material D for further information.

Appendix L – Research recommendation

Research recommendations for review question: What is the most effective strategy for assessing POP?

No research recommendation was made for this topic.