**ORIGINAL ARTICLE** 



# International Urogynecology Consultation: Patient Reported Outcome Measures (PROs) use in the evaluation of patients with pelvic organ prolapse

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#### Abstract

**Introduction and hypothesis** Patient-reported outcome measure instruments include patient-reported outcomes (PROs) and patient-reported goals (PRGs), which allow practitioners to measure symptoms and determine outcomes of treatment that matter to patients.

**Methods** This is a structured review completed by the International Urogynecology Consultation (IUC), sponsored by the International Urogynecological Association (IUGA). The aim of this working group was to evaluate and synthesize the existing evidence for PROs and PRGs in the initial clinical work-up/evaluationand research arena for patients with pelvic organ prolapse (POP).

**Results** The initial search generated 3589 non-duplicated studies. After abstract review by 4 authors, 211 full texts were assessed for eligibility by 2 writing group members, and 199 studies were reviewed in detail. Any disagreements on abstract or full-text articles were resolved by a third reviewer or during video meetings as a group. The list of POP PROs and information on PRGs was developed from these articles. Tables were generated to describe the validation of each PRO and to provide currently available, validated translations.

**Conclusions** All patients presenting for POP should be evaluated for vaginal, bladder, bowel and sexual symptoms including their goals for symptom treatment. This screening can be facilitated by a validated PRO; however, most PROs provide more information than needed to provide clinical care and were designed for research purposes.

Keywords Patient-reported outcomes · Patient-reported goals · Quality of life measures

## Introduction

This report is part of a series of articles that are the product of the International Urogynecology Consultation (IUC), sponsored by the International Urogynecological

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Association (IUGA). This is a 4-year, 4-chapter project with 16 reports dedicated to reviewing and summarizing the world's literature on pelvic organ prolapse. This report is from the second year and chapter of the project, which is focused on evaluation of the patient with pelvic organ

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prolapse. Prior and subsequent years will be devoted to defining the condition, non-surgical management and, finally, surgical treatment of pelvic organ prolapse. This report will focus on reviewing the literature on patientreported outcome measures (PROs) for the evaluation of subjects with pelvic organ prolapse.

Pelvic organ prolapse (POP) is the herniation of pelvic organs into the vagina. When defined by symptomatology there is an incidence of 3-6%; however, upon vaginal examination up to 50% of women have signs of POP [1]. POP significantly impacts a woman's quality of life causing physical, social, psychological, occupational, domestic and/or sexual limitations and affects mental well-being. The Pelvic Organ Prolapse Quantification System (POP-Q) objectively assesses the anatomical support of the vagina; however, prolapse stage may not always correspond to patient symptoms or concerns [2]. Additionally, postoperative POP-Q improvement or worsening does not necessarily correlate with subjective patient outcome. Prior research found that patients reporting the absence of symptoms (urinary, defecatory, pressure) are frequently satisfied with surgery, even with anatomical failure [3]. Patient-reported outcome measure instruments include patient-reported outcomes (PROs) and patient-reported goals (PRGs), which allow practitioners to measure symptoms and determine outcomes of treatment that matter to patients.

According to the International Consultation of Incontinence (ICI), the most useful assessments of the presence, severity and impact of pelvic floor disorders (PFDs) on patients are psychometrically validated PROs [4]. PROs are considered an essential part of patient evaluation and are becoming progressively more important as we strive to make healthcare more patient centered [5]. Not only do PROs help provide personalized clinical care, but they are also a major outcome utilized in clinical trials [6, 7]. The joint terminology report from IUGA and the International Continence Society for reporting outcomes of surgical procedures recommends that PROs are used in clinical trials [8].

However, while PROs assess condition impact, they may not reflect patient treatment expectation and goals, which are at the heart of clinical care for the individual patient. Therefore, evaluation of Patient-Reported Goals (PRGs) and goal attainment will help tailor patient treatment plans, engage in shared-decision making and improve patient satisfaction. In addition, the majority of PROs were not designed for use in the clinical setting but were developed for research purposes.

This chapter will describe the differences and roles of PROs and PRGs in clinical care, research and future directions in POP initial evaluation and treatment.

#### Background

#### What are patient-reported outcomes (PROs)?

A PRO is a validated questionnaire (also referred to as instruments) that assesses health-related quality of life, symptom-specific details, sexual function and global impression of improvement [9]. PROs are completed by patients to measure their perception of functional well-being and health status. PROs describe or reflect how a patient feels, functions, or survives and are used in both clinical practice and research [10]. PROs also ask specific questions about a patient's condition and can be used to evaluate benefits and treatment effect [6]. Careful consideration is required to choose appropriate PROs for both clinical use and research purposes. Most PROs require considerable time for patients to complete and may impose additional workload on clinicians with evaluation and upload into the electronic medical record.

#### What are patient-reported goals (PRGs)?

PRGs are usually written by the patient as free text in the order of goal importance as decided by the patient. Patient goal setting may be the most sensitive and specific way to understand an individual patient's perspective and can be used over time to understand changes in patient priorities. Goals were first described as a prolapse measure in 2003 [11]. The same year, they were used to measure patient satisfaction after surgery for POP and/or incontinence [11]. Others have expanded on this work by having patients not only set goals but rank their level of goal attainment in both surgical and non-surgical management of PFDs over the course of a year [12]. Goal attainment was highly associated with patient satisfaction in these studies. Further qualitative work found that there are five basic types of goals patients list in relationship to pelvic floor disorders: symptom, information seeking, lifestyle, emotional and other [13].

#### Why do we use patient-reported outcomes and patient-reported goals?

Within the constraints of an outpatient clinic visit women may not always divulge clear information about their pelvic floor symptomatology or which symptoms are the most bothersome. For example, a cohort of women undergoing pessary fitting predominantly listed resolution of bladder symptoms as a treatment goal rather than prolapse-related symptoms such as feeling of a bulge [14]. This may be due to the sensitive nature of symptoms, a patient's inability to clearly explain their main concerns, the constraints of a conventional history and examination, or poor understanding of the interrelatedness of pelvic floor symptoms [15].

Patient-reported outcomes, either as a PRO or PRG, fill this gap by encouraging discussion and/or self-expression and disclosure of embarrassing or intimate conditions. They aid with the screening and detection of functional problems that may not be readily volunteered by patients. They also help with monitoring the treatment impact on patient functioning and inform clinical management of patient conditions.

PROs and PRGs can help with personalizing care planning and patient self-management. They facilitate patient involvement in their care and their decision-making and support patients in self-managing long-term conditions. Importantly, they also align surgeon's and patient's expectations.

Another important aspect of PROs and PRGs is their use in research, quality improvement projects, audits and clinical performance evaluations. By including PROs and PRGs in clinical trials, patients' everyday experiences of their condition and subsequent treatment are captured in an objective fashion, data that would not otherwise be captured by traditional physiologic measures. Health-related quality of life measures are important in POP where the goal is improved function (not survival) and treatments often have similar efficacy but may have differing effects on quality of life. Research studies with clinical primary outcomes should incorporate and control for PROs because self-rated health can affect risk behaviors, health utilization and general satisfaction.

### **Materials and methods**

International experts in the field of Urogynecology and PROs were selected through the IUC chairs and steering committee with input from the IUGA executive committee after a competitive application process and invitation. Regular group meetings took place from January 2020–July 2021 to determine the outline and content of the paper. A structured search of the literature from 1980 to May 2020 using Scopus, PubMed and Embase was performed to identify existing PROs for POP using the terms "("Surveys and Questionnaires" [Mesh] OR patient reported outcome\* OR questionnaire OR questionnaire\* OR survey OR surveys) AND ("Pelvic Floor Disorders" [Mesh] OR pelvic floor prolapse[tiab] OR pelvic floor disorder\*[tiab] OR pelvic floor dysfunction[tiab] pelvic floor disorder' OR 'pelvic floor disorders' OR 'pelvic floor dysfunction' OR 'pop (prolapse)' OR 'colpoptosis' OR 'complete external prolapse (genital)' OR 'complete procidentia (genital)' OR 'complete prolapse (genital)' OR 'genital procidentia' OR 'genital prolapse' OR 'genital-urinary prolapse' OR 'genito-urinary prolapse' OR 'genitourinary prolapse' OR 'overt prolapse (vaginal)' OR

'pelvic descent' OR 'pelvic organ descent' OR 'pelvic organ prolapse' OR 'pelvic prolapse' OR 'procidentia, complete' OR 'prolapse, genital' OR 'prolapse, genitourinary' OR 'prolapse, vagina' OR 'total procidentia (genital)' OR 'uro-genital prolapse' OR 'urogenital prolapse' OR 'vagina eversion' OR 'vagina prolapse' OR 'vaginal descensus' OR 'vaginal descent' OR 'vaginal procidentia' OR 'vaginal prolapse' OR 'vaginal ptosis' OR 'vaginal wall descent' OR 'vaginal wall prolapse')

The structured review process was as follows. The initial search generated 3589 non-duplicated studies. After abstract review by 4 authors, 211 full texts were assessed for eligibility by 2 writing group members and 199 studies were reviewed in detail. Any disagreements on abstract or full-text articles were resolved by a third reviewer or during video meetings as a group. The list of POP PROs and information on PRGs was developed from these articles. Each PROM title was used to conduct an additional search in PubMed for validation and translation studies performed on the specific measure. The recommendations obtained from the writing group including PROs in this summative review were decided upon in an iterative process. The IUC peer review process involved four rounds of review including review by the IUC co-chairs, the IUC steering committee members, the IUGA general membership (through an online process) and finally the IUGA executive committee before being submitted for peer review to the International Urogynecology Journal.

#### **Overall objective of report**

The aim of this working group was to evaluate and synthesize the existing evidence for PROs and PRGs in the initial clinical work-up/evaluation and research arena for patients with POP. This paper describes the development of clinical and research usage of PROMs, existing research gaps and current best practices for use of PROs and PRGs.

#### Results

#### Patient-reported Outcomes (PROs)

#### Generic or condition specific

Health-related quality of life measures fall into two major categories: generic and condition-specific. Generic measures are multi-dimensional, capture the overall health of a patient, transcend different specialties and assess a wide range of populations. Generic questionnaires compare health states between patients but are less able to assess patient concerns with specific disease states. Condition-specific measures more specifically assess a particular disease but are not able to be compare differing conditions across disease states. Condition-specific instruments can be further divided into screeners or in-depth questionnaires. Screening surveys allow providers to capture patients experiencing a specific condition and can be followed by in-depth questionnaires for further evaluation of the condition [16]. Condition-specific measures are more responsive inherently than generic PROS in detecting treatment effects [17]. Often, screening questionnaires are utilized to ascertain presence or absence of a condition and are followed by in-depth PROs to further gauge level of bother. Examples of condition-specific POP measures include the Pelvic Floor Distress Inventory (PFDI) and Pelvic organ prolapse/Incontinence Sexual Questionnaire-IUGA Revised (PISQ-IR) [18, 19]. Below is a more in-depth discussion of these classifications.

# Epidemiologic screening versus measurement in specific populations

Screening measures are an ideal method of assessing POP prevalence at the population level when a physical exam and completion of a detailed questionnaire may not be practical because of the sheer volume of subjects screened or the availability of practitioners to perform standardized exams. Tegerstedt et al. developed a five-item questionnaire to identify POP in population-based studies. Items in the questionnaire ask respondents about: (1) sensation of tissue protrusion/vaginal bulging; (2) vaginal pain/discomfort; (3) worsening of symptoms with stress/heavy lifting; (4) need to manually reduce the vagina to void; (5) urgency urinary incontinence along with the patient's age [20].

The second type of screening measure consists of complex questionnaires that evaluate multiple domains of pelvic floor disorders related to pelvic organ prolapse simultaneously, such as the Epidemiology of Prolapse and Incontinence Questionnaire (EPIQ). The EPIQ is a rigorously validated epidemiologic survey capable of screening for pelvic floor disorders in large populations of women, with a high likelihood of identifying women having a particular pelvic floor disorder. It collects a wide range of information on pelvic floor disorders' risk factors; thus, complete information about patients for detailed statistical analyses is obtained. The EPIQ assesses symptoms in the following six domains: SUI, overactive bladder, anal incontinence, vaginal bulge, defecation dysfunction and voiding dysfunction/pelvic pain. The EPIQ should not be used as a diagnostic instrument [21]. Some epidemiologists have used question #35 of EPIQ, a single question, to screen for pelvic organ prolapse in a general population [21].

Screening questionnaires may also be specific to certain populations. For example, pregnancy and the postpartum period are particular times in women's lives which can be associated with pelvic floor disorder symptom onset or aggravation. Instruments that diagnose problems at this time of life would create an opportunity for early identification of symptoms to provide health promotion actions, thus potentially reducing the development of pelvic floor disorders later in life [22]. Examples of instruments used for this purpose include the International Consultation on Incontinence Questionnaire-Vaginal Symptoms (ICIQ-VS) [23] and the Australian Pelvic Floor Questionnaire [24].

#### Multidimensional versus dimension-specific

Most generic and condition-specific instruments are multidimensional, i.e., they measure more than one aspect of health-related quality of life (HRQOL). In contrast, dimension-specific instruments are designed to assess a single component of HRQOL, e.g., emotional distress. The trend in assessing HRQOL outcomes has been toward the use of a multidimensional generic and/or condition-specific instrument, supplemented with dimension-specific instruments, as needed. Dimension-specific instruments should be used when more detail about a specific subdomain of HRQOL is desired. Primary domains of HROOL include physical, psychological and social functioning, overall well-being and perceptions of health status. Secondary domains include symptoms, sleep disturbance, intimacy and sexual functioning and personal productivity (e.g., household, occupational or community activities).

POP, like all pelvic floor disorders, is a multidimensional phenomenon, and treatment outcomes should be evaluated based on patient-reported symptoms in multiple domains [25]. Patients with additional bowel and bladder symptoms may benefit from a global questionnaire like PFDI and PFIQ [6]. Other multidimensional tools include the Prolapse Quality of Life questionnaire (P-QOL) [26], or the electronic Personal Assessment Questionnaire-Pelvic Floor (ePAQ-PF) [27].

#### Symptom measures versus function measures and bother

**Symptom measure** Symptom measures discriminate between women with and without POP and can be useful in accurately estimating prevalence and/or incidence of POP in the general population [28]. Symptom scales are considered condition-specific. Generally, these scales include measurement of a symptom's presence and whether or not it is bothersome. The symptom measures demonstrate spectrum bias. Some patients may present with "typical" or classic symptoms along the clinical spectrum of a condition, while others may present with less severe or even "atypical" symptoms or manifestations [28]. Screening for POP without a physical examination is subject to such spectrum bias and is likely

to only identify women with anatomically advanced POP. Therefore, screener sensitivity decreases in a populationbased sample.

**Functional measure and bother** Symptom distress and life impact are two different aspects covered in questionnaires that measure function and bother. Health-related quality of life is assessed by measuring the degree to which bladder, bowel, or vaginal symptoms affect the daily activities, relationships, and emotions of women with pelvic floor disorders. Examples of function measures include the PFIQ, PFIQ-7 or Prolapse Quality of Life (P-QoL) scale. The P-QoL is a condition-specific instrument for measuring HRQOL in women with POP. The questionnaire consists of 20 items representing nine QoL domains of general health, prolapse impact, role physical and social limitations, personal relationships, emotional problems, sleep/energy disturbances and severity measures [26].

Symptom distress/bother scores usually serve the role of both a symptom inventory and a measure of the degree of bother and distress caused by the broad array of pelvic floor symptoms (i.e., PFDI-46, PFDI-20) [18]. Patients are asked whether they experience symptoms; if so, they indicate on a scale from 1 (not at all) to 4 (quite a bit) the degree to which they are bothersome. Those tools allow for some quantification of the degree of bother to patients from their POP symptoms and bladder and bowel dysfunction. Another instrument that measures the severity of POP symptoms (vaginal and sexual) and related bother is the ICIQ-VS. The bother rating is given on a scale from 0 to 10 [23].

#### Patient-reported goals (PRGS)

Women with pelvic floor disorders have a wide range of personal goals before a treatment or intervention. Achievement of these goals is a primary reason for undergoing treatment. Patient's treatment goals are broadly categorized into:

- Symptom goals: specific symptom relief: prolapse, urinary, bowel and pain/discomfort symptoms;
- 2. Function goals: general lifestyle improvement: physical, social, emotional and sexual [29, 30].

Based on the literature, most patients' goals are symptom resolution goals [13]. Symptom resolution goals ranked the most important and were commonly achieved after surgery [30]. Function goals, such as lifestyle and emotional goals, accounted for only 30% of the goals. They were usually ranked as a lesser priority [13] and were also achieved less frequently [31].

# How are patient-reported outcomes and goals administered?

While generally self-administered, PROs can be administered in multiple formats. Questionnaires may be completed by paper/pen, electronically or telephonically. Different formats of PROM administration require separate validation studies.

To achieve seamless integration of patient-reported outcomes and/or goals in clinical practice, there should be planning, selection and engagement.

**Planning** for what dissemination strategy will be used (e.g., paper, electronic vs telephonic), how the integrated system will be governed, ethical and legal issues, and how data from multiple electronic health records can be pooled across organizations is important. Some PROM measures require permission and/or fees for their use.

Selection identifies the target patient population for patient-reported outcome data collection based on the intended use of the data in the health care system. Selection of PROs should include choosing specific outcomes and their measures to optimize applicability for a target population.

**Engagement** includes how, where and with what frequency patients will respond to patient-reported outcomes measures; how to display patient-reported outcomes data in electronic health records, how clinical teams will act upon patient-reported outcomes data; and how to train, support and encourage clinical teams and patients to incorporate patient-reported outcomes data into care [32].

#### How do we track PROM and PRGs?

The questionnaire link or goal form should ideally be provided before clinical consultation to help the clinician understand patient symptomatology and expectations prior to the appointment. Completed patient data are required to be stored in a secure database through a contracted data supplier responsible for keeping protected information secure. Ideally women should be asked to complete post-treatment PROs, goal attainment scores, or list new goals (if applicable) [33].

#### Validation of PROs

A discussion about the validity of a measure (PRO) must begin with the meaning of validity. Validity refers to the evidence and rationale available to make inference and actions in a specific population based on instrument scores [34]. There are several key components to this definition.

 Table 1
 Validity of questionnaires

| Validity type        |   | Data source   | Data methods   | Evaluative criteria   |
|----------------------|---|---|--|---|
| Internal             | Content or face   | Target population<br>(patients), experts, litera-<br>ture reviews | Focus groups, interviews,<br>cognitive interviews,<br>literature review, sorting or<br>ranking                           |   |
|                      | Internal consistency  | Target population   | Survey   | Tau-equivalence, Cronbach's<br>alpha<br>Item total correlation  |
|                      | Dimensional   | Target population   | Survey-factor analysis   | Kaiser-Guttman rule, eigenval-<br>ues, scree plots, Kaiser-<br>Meyer-Olkin residuals,<br>structural equation models |
|                      | Reliability   | Target population   | Survey test-retest, split half   | Correlation, chi-square, t-tests<br>matched pairs, Bland-<br>Altman,  |
| External (construct) | Convergent, concurrent,<br>discriminant, divergent,<br>Predictive | Target population, external                                       | Patient self-report (surveys,<br>diaries, activity logs),<br>external subjective, exter-<br>nal objective, gold standard | Correlation across data source<br>and data method, ROC, AUC   |
| Responsiveness       | Sensitivity to change   | Target population   | Survey baseline and follow-<br>up  | Effect size, (Cohen's),<br>standardized response mean<br>(SRM), Guyatt (requires<br>MCID be identified)             |

First, the term "specific population" is the acknowledgement that any "validation" efforts may only support the assumption that the instrument is a valid measure for which to draw inference in a population that is comparable to the populations used to validate the measure [35]. For instance, a test that was developed with the intention of being a valid measure of sexual function for women with a prolapse may not be valid to measure sexual function in women with a primary and sole diagnosis of urinary incontinence.

Inference may be intended to be used as a populationbased screen and to indicate only that further evaluation may or may not be warranted. Alternatively, a score may be intended as a clinical tool and indicative of a preferred treatment pathway for an individual patient.

A further consideration in validation approach is the intended use of the measure. The intended use dictates the level of evidence required for inferential validity of a measure [34]. For instance, a measure that is intended to be used as a population screen to discriminate between those considered at risk versus those not at risk is a standard need of public health. For valid measurement, the use of a measure to screen for potential risk requires a less stringent level of evidence than would a measure intended for use as a clinical diagnostic tool, which may require the ability to discriminate between presence and absence of the actual disease state.

The evidence standards that exist for a given measure must be sufficient to support the intended use of the measure, and standards of evidence may shift over time. Reviews and judgment of the adequacy of a measure for its intended use must primarily consider the sufficiency of the level of evidence available to support the intended inference based on test score. The hierarchical levels of evidence may be grossly categorized as corresponding to internal and external validity and are briefly described below as well as described in Table 1.

#### Minimally important difference (MID)

When using overall scores from PROs to compare two time points it is important to report whether the measured change in the score reflects a real change in the patient's clinical condition versus a mere statistical change between values. The minimally important difference (MID) is a measure of change in a PRO total score that suggests an important clinical change, of either improvement or worsening of the condition as measured by the PRO. If the change in the total score of a PRO is greater than the MID, it suggests a significant clinical change; if it is less than the MID then it suggests no change in the clinical condition of the subject/ subjects. There are two main approaches for identifying MIDs: anchor based and distribution based. Anchor-based approaches are preferred and more reliable; however, not all PROS have studies that define the MID. The anchor-based approaches use an external indicator, called an "anchor," and differences can be determined either cross-sectionally or longitudinally. The anchor can be either an objective (e.g.,

| PRO  | Clution   | Further validations  | Country<br>and<br>language  | Intended<br>use of<br>PROM   | Sample<br>composition<br>and size  | Number items<br>in initial<br>item pool for<br>validation<br>sample/psy-<br>chometrics | Content validity:<br>patient focus group or<br>interview, expert focus<br>group or interview;<br>final patient review: | Internal-<br>dimen-<br>sional:<br>EFA, CFA<br>PCA, FA,<br>SEM, IRT,<br>eigenvalues,<br>factor load-<br>ings | Internal con-<br>sistency   | Reli-<br>ability/<br>stability/<br>agree-<br>ment   | Number of<br>items in final<br>PROMS | Sub-scales or domains   | External<br>(construct) valida-<br>tion: construct,<br>convergent, predic-<br>divergent, predic-<br>tive, distriminant,<br>known-group,<br>external criterion:<br>correlation, 1-test,<br>ANOVA, IRT | MID: yes/no;<br>-on/sive-<br>ness                                 | Scoring/outcome<br>data type  |
|--|---|--|-----------------------------|--|--|--|--|---|---|---|--------------------------------------|---|--|---|---|
| Body Image in<br>the Pelvic<br>Organ Prolapse<br>Questionnaire:<br>BIPOP         | Lowder, Jerry L., et al.<br>"Body image in the pelvic<br>organ polyape question-<br>mire: development and<br>validation." <i>American</i><br><i>journed of obstitrics and</i><br><i>givecology</i> 211.2 (2014):<br>174-e1.           |  | US Eng-<br>lish             | Research<br>tool   | Women 18+<br>with POPQ<br>stage $\geq II$<br>and self-<br>report of<br>symptom. N<br>= 20,1                                    | 21   | Patient focus groups;<br>pt. cognitive<br>interviews for item<br>evaluation; expert<br>input                           | EFA (PCA)<br>with<br>varimax  | Cronbach's<br>alpha on<br>factors/<br>sub-<br>scales,<br>with<br>appropri-<br>ate value<br>ranges<br>reported     | Paired<br>Ftesis;<br>ICC  | 2                                    | 2: Attractiveness and<br>Partner  | Yes, primarily<br>convergent, use<br>validated self-<br>administered<br>instruments,<br>correlations<br>why reported<br>p-value  | Not reported  | Mean range 1-5.<br>Option for total<br>use of a strutanty<br>use of a strutanty<br>score by combining<br>partnered and non-<br>partnered women;<br>the Attractiveness;<br>the Attractiveness;<br>across partnered<br>and nonpartnered<br>and nonpartnered |
| Australian Pelvic<br>Floor Question-<br>naire: APQ                               | Baesler, K., et al. (2008).<br>"An interviewer-admin-<br>istered wildande female<br>pelvie floor questionnaire<br>for commity-based<br>research." Menopause<br>15(3): 973-977   | Baessler, K., et al. (2009).<br>"Australian pelvis floor<br>questionatire: a validated<br>interviewer-administered<br>pelvis floor questionatire<br>for routine clinic and<br>research." Int Urogynecol<br>J Pelvis Floor Dystimet<br>20(2): 149–158 Baessler,<br>K., et al. (2010). "A vali-<br>dated self-administered<br>female pelvis floor<br>questionatire." Int<br>Urogynecol J 21(2):<br>163–172                                 | UK Eng-<br>lish             | Research<br>with<br>further<br>work<br>(Bac-<br>clinic<br>use<br>use | Women $18 + with Pelvé floor 18 + with Pelvé floor disorders disorders (n = 4.93) from the Longituindal Suudy of Ageing Women$ | Not reported   | Initial question set<br>by worken<br>by worken<br>Interviews to<br>remove "ambiguous<br>questions"                     | Factor<br>analysis<br>(principal<br>com-<br>ponent<br>analysis,<br>varimax<br>rotation(                     | Cronbach's<br>alpha)  | Bland-<br>Altman<br>plot  | Not reported                         | Bladder function<br>(Q1-5), bowel<br>function (Q16-27),<br>prolapse symptoms<br>(Q23-32) and<br>sexual function<br>(Q33-42) | Spearman correla-<br>tion and K  | 1.3 for blad-<br>der 1.0 for<br>POP1.2:2.2<br>for global<br>score | Total score is out of 40<br>with each question<br>scoring 0.3 based<br>on response  |
| Electronic<br>Personal<br>Assessment<br>Question-<br>naire Pdvic<br>FloorePAQ-PF | Computer interviewing in<br>unrgurenciology: Concept,<br>development and<br>psychometric testing of<br>an electronic paivle floor<br>assessment questionnaire<br>(e-PA) in primary and<br>secondary care, Radley<br>et al. BJOG, 2006 | <ol> <li>Development and<br/>psychometric testing of a<br/>symptom index for pelvic-<br/>organ prolapse. Bradshaw<br/>HD, Hiller L, Furkas AG,<br/>Raddy S, Raddy SC, J<br/>Obstet (Janecol, Apr<br/>2006; 2, Responsive-<br/>ness of the electronic<br/>Personal Assessment<br/>Questionnaire-Pelvic<br/>Floor (ePAQ-PF), Jones<br/>GL, Lumb J, Raddey<br/>SC, Farkas AG In Uno-<br/>Syneol J Pelvic Floor<br/>Devinent 2000</li> </ol> | UK Eng-<br>lish,<br>Italian | Clinical   | Women 18+<br>with and<br>wibbut<br>Pelvic floor<br>disorders. N<br>= 432   | 14 domains<br>with 4<br>dimen-<br>sions  | Questionnaire uses<br>BBUS Q, SPS-Q<br>and FST and ques-<br>tions developed with<br>other experts. No<br>patient input | Factor-<br>analysis   | Crombach's<br>alpha on<br>factors/<br>suctors/<br>scales,<br>with<br>appropri-<br>ate value<br>ranges<br>reported | Test-retest<br>at 1<br>week<br>in pri-<br>mary<br>care<br>popu-<br>lation<br>only<br>wii-<br>wii-<br>coxon<br>rank<br>sum | 20 domains<br>in current<br>version  | Urinary, Bowel,<br>Vaginal, Sexual  | known group<br>difference  | 9   | This is automatically<br>calculated as a<br>percentage  |

| Table 2 (continued)                                       | (nontinited)  |                     |                            |                            |   |  |   |   |                              |  |                                 |                       |   |   |   |
|---|---|---------------------|----------------------------|----------------------------|---|--|---|---|------------------------------|--|---------------------------------|-----------------------|---|---|---|
| РКО   | Citation  | Further validations | Country<br>and<br>language | Intended<br>use of<br>PROM | Sample<br>composition<br>and size   | Number items<br>in initial<br>item pool for<br>validation<br>sample/psy-<br>chometrics | Content validity:<br>patient Keus group or<br>interview, expert focus<br>group or interview.<br>final patient review: | Internal-<br>dimen-<br>sional:<br>EFA, CFA<br>PCA, FA,<br>SEM, IRT,<br>eigenvalues,<br>factor load-<br>ings | internal con-<br>sistency    | Reli- N<br>ability/ it<br>stability/ P<br>agree-<br>ment | Number of titems in final PROMS | Sub-scales or domains | External<br>(construct) valida-<br>construct), valida-<br>convergent,<br>divergent predic-<br>tive, discriminant,<br>tive, discriminant,<br>twon-group,<br>external criterion:<br>correlation, t-text,<br>ANOVA, IRT  | MID: yes/no;<br>responsive-<br>ness                                       | Scoring/outcome<br>data type  |
| Sheffield Prolapse<br>Symptoms<br>Questionnaire:<br>SPS-Q | Bratchaw HD, Hiller L, Fariss<br>AG, Radig S, Radig SC.<br>Development: and psychometric<br>testing of a sympositudes.<br>I of repolse organ pricinges.<br>J October 2016<br>Ap2:66:33-11-82. doi:<br>10.1018/0014456.00320357989.<br>PMID: 16648633.   |                     | UK Eng-<br>lish            | Clinical                   | Women 18+<br>with and<br>without<br>probayes. N<br>= 203  | 23   | Patient review of<br>questionnaire and<br>modificiation of<br>questionnaire   | Factor<br>analysis  | Cronbach's<br>alpha          | Test-retest 2:<br>with<br>kappa                          | 52                              |                       | Wilcoxon-rank<br>sum: Kruskkal-<br>wad-Walis:<br>disciminant or<br>group validity   | MID not<br>reported;<br>Peanson<br>correlation<br>for respon-<br>siveness | 4-point ordinal<br>response scale<br>(new, occusion-<br>ally, most of the<br>time, all of the<br>time, all of the<br>time, all of the<br>time, all of the<br>BFL/JTS-Q, each<br>item also includes<br>a sub-question<br>relating to bother:<br>'How much of a<br>problem is this for<br>you' also recorded<br>on a 4-point ordinal<br>response scale (not<br>a problem, a serious<br>problem, a serious<br>problem, a serious |
| Prolapse and<br>Incontinence<br>Knowkelge<br>Quiz: PIKQ   | Shah A.D. Massagi MP,<br>Kohli N. Rajan SS,<br>Braano RP, Hoye L. A<br>reliable, valid instrument<br>to assess patient knowl-<br>edge about urinary incon-<br>tinence and pelvic organ<br>prolapse, in Urogysneeol<br>J Pavic Floor Dysfunct.<br>2008 Sept.J 9(9): 1283-9<br>doi: 10.107/s00192-008-<br>6031-3 Ept00.7030192-008-<br>6031-3 Ept00.703019-<br>0 Ept00.70301-3 Ept00.70301-<br>0 Ept00.70301-3 Ept00.70301-<br>0 Ept00.70301-3 Ept00.70301-3 Ept00.7030-<br>0 Ept00.70301-3 Ept00.70301-3 Ept00.7030-<br>0 Ept00.70301-3 Ept00.7030-3 Ept00.7030-<br>0 Ept00.7030-3 Ept00.7030-3 Ept00.7030-<br>0 Ept00.7030-3 Ept00.7030-3 Ept00.7030-3 Ept00.7030-<br>0 Ept00.7030-3 Ep |                     | US Eng-<br>lish            | Chnical                    | Women<br>18+, with<br>18+, with<br>18+, with<br>18+, with<br>13+<br>13+ $3and without13+213+3+213+$ | 54   | ž   | Principul<br>compo-<br>nents<br>factor<br>analysis  | Cronbach's<br>alpha ><br>0.8 | Test/retest 2.<br>reli-<br>ability                       | 2                               | 12 urinury, 12 POP    | (Cronbach's alpha<br>> 0.8). Mean<br>test scores were<br>slightlyingher<br>upon retest (UI,<br>0.46, P = 0.046;<br>P = 0.046;<br>P = 0.046;<br>P = 0.126).<br>P = 0.120;<br>P = 0.120;<br>P = 0.120;<br>P = 0.120;<br>P = 0.120;<br>P = 0.040;<br>P | Test-retest<br>Pearson's<br>correla-<br>tions                             | 12-point perfect score<br>for each section (1<br>point per correct<br>answer)   |

 $\underline{\textcircled{O}} Springer$ 

| PRO  | Citation  | Further validations   | Country<br>and<br>language | Intended<br>use of<br>PROM | Sample<br>composition<br>and size   | Number items<br>in initial<br>item pool for<br>validation<br>sample/psy-<br>chometrics | Content validity:<br>patient focus group or<br>interview, expert focus<br>group or interview,<br>final patient review: | Internal-<br>dimen-<br>EFA, CFA<br>PCA, FA,<br>SEM, IRT,<br>eigenvalues,<br>factor load-<br>ings | Internal con-<br>sistency                        | Reli-<br>ability/<br>stability/<br>agree-<br>ment  | Number of<br>items in final<br>PROMS | Sub-scales or domains   | External<br>(construct) valida-<br>tion: construct,<br>convergent, predic-<br>divergent, predic-<br>divergent, predic-<br>tive, discriminant,<br>known-group,<br>external criterion:<br>correlation, t-test,<br>ANOVA, IRT | MID: yes/no;<br>responsive-<br>ness   | Scoring/outcome<br>data type   |
|--|---|---|----------------------------|----------------------------|---|--|--|--|--|--|--------------------------------------|---|--|---|--|
| Birminghum<br>Bowel, Bladder<br>Sunftorin<br>Symptom<br>Questionnaire:<br>BBUSQ    | Hiller L, Radley S, Mann<br>CH, Radley SC, Begum<br>G, Patove SJ, Salaman<br>H, Development and<br>validation of a question-<br>main for the assessment<br>of bowel and lower<br>minary tract symptoms<br>in wome. BJOG. 2002<br>Apr:109(4):412-23.<br>doi: 10.111/j.1471-<br>6228.3002.01.147.x.<br>PMID: 1.2013162.   | L Hiller, HD Bradshuw,<br>SC Radley, S Radley, A<br>scoring system for the<br>assessment of bowel and<br>lower urinary tract symp-<br>toms in women.BOG:<br>An International<br>Optime of Obsterrise and<br>Gynaecology. Volume<br>109, I, Isue 4.2001.Pages<br>0328, 0328N 1470-   | UK Eng-<br>lish            | Clinical                   | Women 18+,<br>with (n =<br>without (n =<br>131) bladder<br>or bowel<br>symptoms | 8  | Yes  | Factor<br>analysis<br>with<br>Varinaax<br>rotation   | Cronthach's<br>alpha<br>exceeded<br>keel<br>keel | Kappa<br>coef.<br>ficients<br>ficeints<br>tepper-<br>senting<br>propor-<br>agre-<br>ment<br>basyond<br>that you<br>chance<br>test<br>test<br>test<br>apart<br>apart<br>apart | 5                                    | Constiputor (01-2),<br>Evacution(77-13,<br>15,1, Incontinence<br>03-6), Liniary<br>(q16-22, q1-4);<br>binary for constipa-<br>tion) | Wilcoxon mark<br>sum or Kruskal-<br>Wallis   | Spearman's<br>rank correlation<br>correlation<br>correlation<br>baseline/6<br>months<br>months                              | For all indi-<br>vidual questions,<br>as 1 to 4 from top<br>to bottom of the<br>responses sets with<br>the exception of<br>question one being<br>coded as 1 to 6 and<br>question 14 as 1 for not<br>(see Appendent 1).<br>All missing<br>coded as 1 to 6 and<br>question 14 as 1 for<br>sets and 14 as 1 for<br>question 14 as 1 for<br>sets and 1 as 1 for<br>the exception ad<br>as 0.Except for a<br>a 10 missing<br>composed enticly<br>of multi-ferm<br>domains with the<br>composition of<br>free domains soft<br>above in 10 for<br>100 where a high<br>secre is indicative<br>symptoms<br>symptoms |
| "Do you Feel a<br>Bulge?"  | Barcher MD, Neubauer NL,<br>Klein-Olarte V, Can<br>we screen for pelvic<br>organ prohapse without a<br>physical examination in<br>privatical examination in<br>physical examination in<br>physical examination in<br>a physical examination in<br>physical examination in<br>a physical examination<br>of the physical<br>2006 Gut 9 (2016) (2016)<br>2006 Muy 8, PMID:<br>16681 989. | <ol> <li>Tan JS, Lukacz ES,<br/>Menefee SA, Powell CR,<br/>Nager CW: San Diego<br/>Pekie Floor Consortium.<br/>Predictive value of<br/>prolapes symptom: a<br/>large databases tudy:<br/>Int Urogymerol J Pelvic<br/>Floor Dysfanct. 2005<br/>May-Jun; 16(3):203-9;<br/>discussion 2004 doi:<br/>12.43-8. Epub 2004 doi:<br/>22.43-8. Epub 2004 doi:</li> </ol> | US Eng-<br>lish            | Screening                  | Women 18+<br>with and<br>without<br>polapse. N<br>= 120                         | -  | Ŝ  |  | Spearman's<br>0.58 (P <<br>0.001)                | Test/retest<br>reli-<br>ability<br>at 1<br>week<br>kappa<br>0.84   | -                                    | Коле  | t-test   | N. N  | Binary   |
| Pelvic Organ<br>Prodapse Simple<br>Screning Inven-<br>tory: POPSSI<br>tory: POPSSI | Tehrani et al. BMC Women's<br>Heatth 2011, 11:48.<br>Streening of pelvice organ<br>prolapse with a physical<br>exam: (A community<br>based study).http://www.<br>biomedcentral.com/1472.<br>6874/11/48  |   | Iran Per-<br>sian          | Clinical<br>screen-<br>ing | Women 18+<br>with and<br>without<br>prolapse. N<br>= 945                        | 4  | Ŷ  | No: descrip-<br>tive study<br>only   |  |  | 4                                    | None  | Yes  | In healthy<br>popula-<br>tion: Sens<br>45.5%, spec<br>87.4%,<br>PPV 72.7,<br>NPV 88%,<br>in POP<br>population:<br>Sens 20%, | Numericat  |

NPV 66%

| Table 2 (continued)   | (manining)   |  |                 |                            |                                  |   |  |  |  |   |  |                                      |   |   |   |   |
|---|--|--|-----------------|----------------------------|----------------------------------|---|--|--|--|---|--|--------------------------------------|---|---|---|---|
| PRO   | Clation  | Further validations  | SUC             | Country<br>and<br>language | Intended<br>use of<br>PROM       | Sample<br>composition<br>and size   | Number items<br>in initial<br>item pool for<br>validation<br>sample/psy-<br>chometrics | <ul> <li>Content validity:<br/>patient focus group or<br/>interview, expert focus<br/>group or interview,<br/>final patient review;</li> </ul> | : Internal-<br>up or dimen-<br>tfocus sional:<br>ww. EFA, CFA<br>ew: PCA, FA,<br>SEM, IRT,<br>eigenvalues,<br>factor load-<br>ings | H Internal con-<br>sistency<br>F:A<br>A,<br>RT,<br>RT,<br>Intres,<br>oad- | on- Reli-<br>ability/<br>agree-<br>ment                                  | Number of<br>items in final<br>PROMS | Sub-scales or domains   | External<br>(construct) valida-<br>tion: construct,<br>convergent,<br>divergent, predic-<br>tive, discriminant,<br>tive, discriminant,<br>external criterion:<br>correlation, t-test,<br>ANOVA, IRT | MID: yes/no;<br>responsive-<br>ness   | Scoring/outcome<br>data type  |
| International<br>Consultation on<br>Incontinence<br>Questionnaire<br>Vaginal Symp-<br>toms Module:<br>ICIQ-VS | Price, N. Jackson, S.R.<br>Avery, K. Brookes,<br>ST, Avtrans, P. 2006.<br>Development and<br>psychometric evaluation<br>of the ICIQ vagainal<br>Symptoms Questionnauri<br>the ICIQ-vS. BJOG Int.<br>J. Obstet. Gynaecol. 113,<br>700–712.  | 5<br>dion<br>Int.<br>113,  |                 | UK Eng-<br>lish            | Clinical                         | Women 18+<br>Symp-<br>comtaic<br>probases<br>(N = 141)<br>and without<br>probase (N = 77) | 21   | Structured interviews<br>with patients   | views Factor<br>analysis   | Cronbach's alpha  | is Kappa   | <u>4</u>                             | 0-53 vaginal symp-<br>toms subscaled-58<br>sexual matters<br>subscaled-58<br>subscaled on one of the<br>one on a subscale<br>subscale subscale are not<br>incorporated in the<br>overall score but<br>indicate impact<br>of individual<br>symptoms for the<br>patient | chi-square  | ton CIM<br>iboroqra<br>avistroqra<br>noitrovranin<br>of an<br>bachitem<br>toxxoliW<br>bachitem<br>toxxoliW<br>toxxoliW<br>toxxoliW<br>toxxoliW<br>toxxoliW<br>toxxoliW<br>toxxoliW<br>toxxoliW<br>toxxoliW<br>toxxoliW<br>toxxoliW<br>toxxoliW<br>toxxoliW<br>toxxoliW<br>toxxoliW<br>toxxoliW<br>toxxoliW<br>toxxoliW<br>toxxoliW<br>toxxoliW<br>toxxoliW<br>toxxoliW<br>toxxoliW<br>toxxoliW<br>toxxoliW<br>toxxoliW<br>toxxoliW<br>toxxoliW<br>toxxoliW<br>toxxoliW<br>toxxoliW<br>toxxoliW<br>toxxoliW<br>toxxoliW<br>toxxoliW<br>toxxoliW<br>toxxoliW<br>toxxoliW<br>toxxoliW<br>toxxoliW<br>toxxoliW<br>toxxoliW<br>toxxoliW<br>toxxoliW<br>toxxoliW<br>toxxoliW<br>toxxoliW<br>toxxoliW<br>toxxoliW<br>toxxoliW<br>toxxoliW<br>toxxoliW<br>toxxoliW<br>toxxoliW<br>toxxoliW<br>toxxoliW<br>toxxoliW<br>toxxoliW<br>toxxoliW<br>toxxoliW<br>toxxoliW<br>toxxoliW<br>toxxoliW<br>toxxoliW<br>toxxoliW<br>toxxoliW<br>toxxoliW<br>toxxoliW<br>toxxoliW<br>toxxoliW<br>toxxoliW<br>toxxoliW<br>toxxoliW<br>toxxoliW<br>toxxoliW<br>toxxoliW<br>toxxoliW<br>toxxoliW<br>toxxoliW<br>toxxoliW<br>toxxoliW<br>toxxoliW<br>toxxoliW<br>toxxoliW<br>toxxoliW<br>toxxoliW<br>toxxoliW<br>toxxoliW<br>toxxoliW<br>toxxoliW<br>toxxoliW<br>toxxoliW<br>toxxoliW<br>toxxoliW<br>toxxoliW<br>toxxoliW<br>toxxoliW<br>toxxoliW<br>toxxoliW<br>toxxoliW<br>toxxoliW<br>toxxoliW<br>toxxoliW<br>toxxoliW<br>toxxoliW<br>toxxoliW<br>toxxoliW<br>toxxoliW<br>toxxoliW<br>toxxoliW<br>toxxoliW<br>toxxoliW<br>toxxoliW<br>toxxoliW<br>toxxoliW<br>toxxoliW<br>toxxoliW<br>toxxoliW<br>toxxoliW<br>toxxoliW<br>toxxoliW<br>toxxoliW<br>toxxoliW<br>toxxoliW<br>toxxoliW<br>toxxoliW<br>toxxoliW<br>toxxoliW<br>toxxoliW<br>toxxoliW<br>toxxoliW<br>toxxoliW<br>toxxoliW<br>toxxoliW<br>toxxoliW<br>toxxoliW<br>toxxoliW<br>toxxoliW<br>toxxoliW<br>toxxoliW<br>toxxoliW<br>toxxoliW<br>toxxoliW<br>toxxoliW<br>toxxoliW<br>toxxoliW<br>toxxoliW<br>toxxoliW<br>toxxoliW<br>toxxoliW<br>toxxoliW<br>toxxoliW<br>toxxoliW<br>toxxoliW<br>toxxoliW<br>toxxoliW<br>toxxoliW<br>toxxoliW<br>toxxoliW<br>toxxoliW<br>toxxoliW<br>toxxoliW<br>toxxoliW<br>toxxoliW<br>toxxoliW<br>toxxoliW<br>toxxoliW<br>toxxoliW<br>toxxoliW<br>toxxoliW<br>toxxoliW<br>toxxoliW<br>toxxoliW<br>toxxoliW<br>toxxoliW<br>toxxoliW<br>toxxoliW<br>toxxoliW<br>toxxoliW<br>toxxoliW<br>toxxoliW<br>toxxoliW<br>toxxoliW<br>toxxoliW<br>toxxoliW<br>toxxoliW<br>toxxoliW<br>toxxoliW<br>toxxoliW<br>toxxoliW<br>toxxoliW<br>toxxoliW<br>toxxoliW<br>toxxoliW<br>toxxoliW<br>toxxoliW<br>toxxoliW<br>toxxoliW<br>toxxoliW<br>toxxoliW<br>toxxoliW<br>toxxoliW<br>toxxoliW<br>toxxoliW<br>toxxoliW<br>toxxoliW<br>toxxoliW<br>toxxoliW<br>toxxoliW<br>toxxoliW<br>toxxoliW<br>toxxoliW<br>toxxoliW<br>toxxoliW<br>toxxoliW<br>toxxoliW<br>toxxoliW<br>toxxoliW<br>toxxoliW<br>t | Each question is<br>scored and then<br>a bother score is<br>also assessed. Total<br>score is reported<br>and the website rec-<br>omments gainst<br>single item scores<br>or assessments     |
| Propase Qual-<br>ity of Life:<br>P-QoL  | P-QOL: a validated<br>questionmate to<br>assess the symp-<br>toms and quality<br>or file of women<br>with ungenital<br>prolapse. Digesu<br>with ungenital<br>prolapse. Digesu<br>Cardozo L, Rob<br>inson D, Salvatore<br>S. Int Urogmeed J<br>Pelvic Floor Dys-<br>funct. 2005 May-<br>Junct. 2005 May-<br>Junct. 2005 May-<br>Junct. 2015 May-<br>discussion 181.<br>discussion 181.<br>discussion 181.<br>discussion 282.<br>discussion 283.<br>discussion |  | English         | Clinical                   | Wome<br>syn<br>and<br>POI<br>POI | Women 18+ with not rel<br>symptomatic<br>POP (n = 140)<br>and without<br>POP (N = 75)     | Not reported   | No putient input<br>reported   | Not reported   | Cronbach alpha<br>and stability   | 2-week tast-<br>retest analysis  | 20 Series 20                         | 3   | Spearman cor-<br>relation   | MID, respon-<br>siveness not<br>reported  | Subscale scores   |
| Epidemiology of<br>prolapse and<br>incontinence<br>questionnatie:<br>EPIQ                                     | Lukacz ES, Lawrence<br>JM, Buckwalter<br>JG, Burchette RJ,<br>Nager CW, Luber<br>KM. Epidemiology<br>of Prodapse and<br>incontinence<br>of prodapse and<br>incontinence<br>verationatics:<br>very International<br>Urogynecology<br>Journal. 2005<br>Aug:16(4):272-84.   | Egger MJ, Lukazz<br>Egger MJ, Lukazz<br>Wang J, Nygand<br>Wang J, Nygand<br>U, Web VS Paper-<br>Baed completion<br>of the Epidemiol<br>of the Epidemiol<br>and Incontinerse<br>Questionmire<br>(EPIQ), Female<br>pelvic medicine<br>& reconstructive<br>argory 2013<br>Jung 90, 17 clec-<br>tronic version | US Eng-<br>lish | Screen for PFDs            |                                  | Symptomatic and 22 "sto<br>nonsymp-<br>ionatic<br>"healthy"                               | 22 "stem" ques-<br>tions,  | Expert review, P<br>focus groups<br>focus groups<br>and nonsymp-<br>tomatic<br>tomatic   | PCA with<br>Varimux,<br>Intreshold<br>criteria given   | Cronbach alpha  | Test-retest<br>2-week<br>interval<br>Kappa and<br>correlations<br>or ICC | - 2                                  | QoL, OPO, SUI,<br>OAB, AI   | Predictive for<br>the following:<br>POPS.UI.<br>OAB, AI.<br>Discriminant<br>between<br>and PFD<br>putients  | Not reported:<br>this study did<br>not evaluate<br>responsive-<br>ness.   | Positive and nega-<br>tives of the predictive<br>values of the EPIQ to detect<br>FPIQ no detect<br>776% and 57%, SUI = 77%,<br>88% and 87% and<br>90% and AI = 61% and<br>91%, respectively |

| Pelvic Floor Dis- Barbe<br>tress Inventory Ku | Barber MD,<br>Kuchibhatla MN. | 1. Barber MD, Chen Z, U<br>Lukacz E. Markland | US Eng-<br>lish | Research and<br>Clinical | Women with<br>nelvic floor | POPDI = 61<br>items: PFIO = | No patient input;<br>expert panel | Not reported | Overall PFDI<br>and PFIO | Test-retest report 93<br>interclass cor- | PFDI is 3<br>subscales: | Yes, Spearman's<br>correlation | 8-UDI scale<br>(non-surgical | Subscale scores<br>for each scale |
|---|-------------------------------|---|-----------------|--------------------------|----------------------------|-----------------------------|-----------------------------------|--------------|--------------------------|--|-------------------------|--------------------------------|------------------------------|-----------------------------------|
|   | Piener CF Rumn                | A Waif Bribaker                               |                 |                          | dvsfimction n              |                             |                                   |              | State and                | relation (it is                          | IIDI POPDI              | comparing                      | SIII treat-                  | are obtained hv                   |
|   | RC. Psychometric              | L. Nygaard I. Wei-                            |                 |                          | = 100                      |                             | urogynecolo-                      |              | subscale                 | not stated but                           | CRADI: PFIO             | scales and                     | ment)                        | takingthe mean                    |
|   | evaluation of 2               | dner A, Janz NK,                              |                 |                          |                            |                             | gists, 1 female                   |              | Cronbach's               | the statistic                            | is 3 subscales:         | subscales                      |                              | value of all items                |
| naire   | comprehensive                 | Spino C. Further                              |                 |                          |                            |                             | urologist, 1                      |              | alpha range              | reported for                             | POPIQ, UIQ,             | to clinical                    |                              | answered within                   |
| (PHQ) cor                                     | condition-specific            | validation of the                             |                 |                          |                            |                             | colorectal                        |              | from 0.84 to             | interclass reli-                         | CRAIQ                   | indicators                     |                              | each subscale.                    |
| dır   | quality of life               | short form versions                           |                 |                          |                            |                             | surgeon and 2                     |              | 0.98                     | ability should                           |                         | of symptom                     |                              | These scores are                  |
| ins   | instruments for               | of the Pelvic Floor                           |                 |                          |                            |                             | psychometri-                      |              |                          | be Pearson's                             |                         | severity and                   |                              | then transformed                  |
| 2WC   | women with pelvic             | Distress Inventory                            |                 |                          |                            |                             | cians                             |              |                          | correlation                              |                         | diagnostic                     |                              | by multiplying                    |
| flo .   | floor disorders.              | (PFDI) and Pelvic                             |                 |                          |                            |                             |                                   |              |                          | coefficient,                             |                         | criteria and                   |                              | the mean score of                 |
| An  | Am J Ubstet                   | Floor Impact Ques-                            |                 |                          |                            |                             |                                   |              |                          | although                                 |                         | bladder dairy                  |                              | each subscale                     |
| ŝ   | Gynecol. 2001                 | tionnaire (PHQ).                              |                 |                          |                            |                             |                                   |              |                          | authors label                            |                         | data                           |                              | by 25; subscale                   |
| De  | Dec;185(6):1388-              | Neurourol Urodyn.                             |                 |                          |                            |                             |                                   |              |                          | it ICC in                                |                         |                                |                              | score - range of 0                |
| 95.   | 95. doi: 10.1067/             | 2011 Apr;30(4):541-                           |                 |                          |                            |                             |                                   |              |                          | summary                                  |                         |                                |                              | to 100. Total                     |
| mc  | mob.2001.118659.              | 6. doi: 10.1002/                              |                 |                          |                            |                             |                                   |              |                          | table) with                              |                         |                                |                              | scale score is                    |
| PA  | PMID: 11744914.               | nau.20934. Epub                               |                 |                          |                            |                             |                                   |              |                          | PFDI and                                 |                         |                                |                              | calculated by                     |
|   |                               | 2011 Feb 22. PMID:                            |                 |                          |                            |                             |                                   |              |                          | PFIQ scale                               |                         |                                |                              | summing the                       |
|   |                               | 21344495: PMCID:                              |                 |                          |                            |                             |                                   |              |                          | and subscale                             |                         |                                |                              | subscale                          |
|   |                               | PMC3750146                                    |                 |                          |                            |                             |                                   |              |                          | correlation                              |                         |                                |                              | scores This gives                 |
|   |                               | 7 Borbor MD Woltons                           |                 |                          |                            |                             |                                   |              |                          | conflictants                             |                         |                                |                              | a total nossihla                  |
|   |                               | 2. Dauga MLD, Wallets                         |                 |                          |                            |                             |                                   |              |                          | COGILICIEILIS                            |                         |                                |                              | a total possible                  |
|   |                               |   |                 |                          |                            |                             |                                   |              |                          | ranging irom                             |                         |                                |                              | SCORE TOT THE ULT                 |
|   |                               | PESSKI Irial                                  |                 |                          |                            |                             |                                   |              |                          | 0.77 to 0.92                             |                         |                                |                              | (0-300), PUPU                     |
|   |                               | Group. Responsive-                            |                 |                          |                            |                             |                                   |              |                          |  |                         |                                |                              | (0-300) each                      |
|   |                               | ness of the Pelvic                            |                 |                          |                            |                             |                                   |              |                          |  |                         |                                |                              | with 3 subscales;                 |
|   |                               | Floor Distress Inven-                         |                 |                          |                            |                             |                                   |              |                          |  |                         |                                |                              | CRADI (0-400)-                    |
|   |                               | tory (PFDI) and                               |                 |                          |                            |                             |                                   |              |                          |  |                         |                                |                              | has 4 subscales                   |
|   |                               | Pelvic Floor Impact                           |                 |                          |                            |                             |                                   |              |                          |  |                         |                                |                              |                                   |
|   |                               | Questionnaire                                 |                 |                          |                            |                             |                                   |              |                          |  |                         |                                |                              |                                   |
|   |                               | (PFIQ) in women                               |                 |                          |                            |                             |                                   |              |                          |  |                         |                                |                              |                                   |
|   |                               | undergoing vaginal                            |                 |                          |                            |                             |                                   |              |                          |  |                         |                                |                              |                                   |
|   |                               | surgery and nessary                           |                 |                          |                            |                             |                                   |              |                          |  |                         |                                |                              |                                   |
|   |                               | treatment for nelvic                          |                 |                          |                            |                             |                                   |              |                          |  |                         |                                |                              |                                   |
|   |                               | onten prolance                                |                 |                          |                            |                             |                                   |              |                          |  |                         |                                |                              |                                   |
|   |                               | Am I Ohstat                                   |                 |                          |                            |                             |                                   |              |                          |  |                         |                                |                              |                                   |
|   |                               | Gamered 2006                                  |                 |                          |                            |                             |                                   |              |                          |  |                         |                                |                              |                                   |
|   |                               | Mar: 104/551407 9                             |                 |                          |                            |                             |                                   |              |                          |  |                         |                                |                              |                                   |
|   |                               | Asi: 10.10166                                 |                 |                          |                            |                             |                                   |              |                          |  |                         |                                |                              |                                   |
|   |                               | oior DOMA 01 076                              |                 |                          |                            |                             |                                   |              |                          |  |                         |                                |                              |                                   |
|   |                               | man incontraction                             |                 |                          |                            |                             |                                   |              |                          |  |                         |                                |                              |                                   |
|   |                               | 2 Borbor MD Spino C                           |                 |                          |                            |                             |                                   |              |                          |  |                         |                                |                              |                                   |
|   |                               | J. Dauloti MLP, Spino C,                      |                 |                          |                            |                             |                                   |              |                          |  |                         |                                |                              |                                   |
|   |                               | Jairz INN, Druoaker                           |                 |                          |                            |                             |                                   |              |                          |  |                         |                                |                              |                                   |
|   |                               | L, INJgaard I, Inager                         |                 |                          |                            |                             |                                   |              |                          |  |                         |                                |                              |                                   |
|   |                               | CW, Wheeler IL;                               |                 |                          |                            |                             |                                   |              |                          |  |                         |                                |                              |                                   |
|   |                               | Pelvic Floor Disor-                           |                 |                          |                            |                             |                                   |              |                          |  |                         |                                |                              |                                   |
|   |                               | ders Network. The                             |                 |                          |                            |                             |                                   |              |                          |  |                         |                                |                              |                                   |
|   |                               | minimum important                             |                 |                          |                            |                             |                                   |              |                          |  |                         |                                |                              |                                   |
|   |                               | differences for the                           |                 |                          |                            |                             |                                   |              |                          |  |                         |                                |                              |                                   |
|   |                               | urinary scales of                             |                 |                          |                            |                             |                                   |              |                          |  |                         |                                |                              |                                   |
|   |                               | the Pelvic Hoor                               |                 |                          |                            |                             |                                   |              |                          |  |                         |                                |                              |                                   |
|   |                               | Distress Inventory                            |                 |                          |                            |                             |                                   |              |                          |  |                         |                                |                              |                                   |
|   |                               | and Pelvic Floor                              |                 |                          |                            |                             |                                   |              |                          |  |                         |                                |                              |                                   |
|   |                               | Impact Question-                              |                 |                          |                            |                             |                                   |              |                          |  |                         |                                |                              |                                   |
|   |                               | naire. AmJ Obstet                             |                 |                          |                            |                             |                                   |              |                          |  |                         |                                |                              |                                   |
|   |                               | Gynecol. 2009                                 |                 |                          |                            |                             |                                   |              |                          |  |                         |                                |                              |                                   |
|   |                               |   |                 |                          |                            |                             |                                   |              |                          |  |                         |                                |                              |                                   |
|   |                               | aioe 2000 02 007                              |                 |                          |                            |                             |                                   |              |                          |  |                         |                                |                              |                                   |
|   |                               | pMID-10375574                                 |                 |                          |                            |                             |                                   |              |                          |  |                         |                                |                              |                                   |
|   |                               | PMCID:  |                 |                          |                            |                             |                                   |              |                          |  |                         |                                |                              |                                   |
|   |                               |   |                 |                          |                            |                             |                                   |              |                          |  |                         |                                |                              |                                   |

| Each of the 3 scales<br>of the PFD/200<br>is scoredfrom 0<br>(catat distress)<br>to 100 (grantest<br>distress). The<br>scores of these<br>3 scales serves<br>summary score<br>of the PFD/20<br>(0-300)   | Scores for each item<br>ange from 0 to<br>5. The total ques-<br>tionnalies acore<br>tanges from 0 to<br>45, with ligher<br>scores and be<br>transformed by<br>transformed by<br>transfo |
|--|---|
| MID = 12;<br>3-6 months<br>post-surgery.<br>releat for<br>matched pairs<br>of difference<br>surgery PFDI<br>and PFIQ<br>scores, effect<br>size, SRM  | No MID<br>reported not<br>reported for<br>reports<br>ness   |
| Correlation of<br>short form<br>with bing<br>form of<br>original PFIQ<br>scales<br>scales  | Construct   |
| Urinury Distress<br>Inventory<br>(UD), Review<br>Organ Pro-<br>lapse Distress<br>Inventory<br>(CRADI)<br>(CRADI)   | Global, Urinary,<br>Polupas,<br>Defeca-<br>Iony, Starction<br>Dysfunction   |
| 20 - 3 scales:<br>UDI (6 iems), Pelvic<br>organ Pro-<br>organ Pro-<br>lapae Distensi<br>(PODDI)<br>(PODDI)<br>Colorectal-<br>maul Distess<br>Inventoy<br>(CRADI 8<br>items)<br>items)  | ō   |
| Paurson cor-<br>relation for<br>test-retest<br>reliability,<br>labeled as<br>ICC by<br>authors   | Fixed effect with<br>ICC: Kappa   |
| ž  | Cronbach's alpha  |
| ž  | input; Not reported<br>anel   |
| Ŷ  | No patient input;<br>expert panel   |
| PFDI has 61<br>items PFTQ<br>has 93 items  | σ.  |
| Women 18+,<br>preopera-<br>tive surgical<br>putients for<br>player floor<br>diagnosis. n<br>= 45   | Women 18+ with<br>pelvic floor<br>disorders. N<br>= 141   |
| Research +<br>Clinkal  | Clinical  |
| US Eng-<br>lish  | US Eng-<br>lish   |
| Zr Lukacz E,<br>Markinad A,<br>Markinad A,<br>Markinad A,<br>L. Nygaurd I,<br>Weidner A, Janz<br>B, Spino C,<br>Furber vialiation<br>of the short form<br>Pelvic Floor<br>Pistress Inventory<br>Pistress Inventory<br>Pistress Inventory<br>Pistress Inventory<br>Distress Inventory<br>Pistress Inventory<br>Distress Inventory<br>Distre |   |
| Barber MD, Walters<br>MD, Junnp RC.<br>Short forms of two<br>orditon-specific<br>quality-of-life<br>quality-of-life<br>quastionities (FPD)-20<br>disordes (FPD)-20<br>disordes (FPD)-20<br>An DObset<br>Gynecol. 2005<br>Juli 193(1):103-13,<br>duil:193(1):103-13,<br>duil:193(1):103-13,<br>duil:193(1):103-13,<br>duil:193(1):103-13,<br>duil:193(1):103-13,<br>duil:193(1):103-13,<br>duil:193(1):103-13,<br>duil:193(1):103-13,<br>duil:193(1):103-13,<br>duil:193(1):103-13,<br>duil:193(1):103-13,<br>duil:193(1):103-13,<br>duil:193(1):103-13,<br>duil:193(1):103-13,<br>duil:193(1):103-13,<br>duil:103(1):103-13,<br>duil:103(1):103-13,<br>duil:103(1):103-13,<br>duil:103(1):103(1):103-13,<br>duil:103(1):103(1):103-13,<br>duil:103(1):103(1):103-13,<br>duil:103(1):103(1):103(1):103(1):103(1);<br>duil:103(1):103(1):103(1):103(1);<br>duil:103(1):103(1):103(1):103(1);<br>duil:103(1):103(1):103(1);<br>duil:103(1):103(1):103(1);<br>duil:103(1):103(1):103(1);<br>duil:103(1):103(1);<br>duil:103(1):103(1);<br>duil:103(1):103(1);<br>duil:103(1):103(1);<br>duil:103(1):103(1);<br>duil:103(1):103(1);<br>duil:103(1):103(1);<br>duil:103(1):103(1);<br>duil:103(1):103(1);<br>duil:103(1):103(1);<br>duil:103(1):103(1);<br>duil:103(1):103(1);<br>duil:103(1):103(1);<br>duil:103(1):103(1);<br>duil:103(1):103(1);<br>duil:103(1):103(1);<br>duil:103(1):103(1);<br>duil:103(1):103(1);<br>duil:103(1):103(1);<br>duil:103(1):103(1);<br>duil:103(1):103(1);<br>duil:103(1):103(1);<br>duil:103(1):103(1);<br>duil:103(1):103(1);<br>duil:103(1):103(1);<br>duil:103(1):103(1);<br>duil:103(1):103(1);<br>duil:103(1):103(1);<br>duil:103(1):103(1);<br>duil:103(1):103(1);<br>duil:103(1):103(1);<br>duil:103(1):103(1);<br>duil:103(1):103(1);<br>duil:103(1):103(1);<br>duil:103(1):103(1);<br>duil:103(1):103(1);<br>duil:103(1):103(1);<br>duil:103(1):103(1);<br>duil:103(1):103(1);<br>duil:103(1):103(1);<br>duil:103(1):103(1);<br>duil:103(1):103(1);<br>duil:103(1):103(1);<br>duil:103(1):103(1);<br>duil:103(1):103(1);<br>duil:103(1):103(1);<br>duil:103(1):103(1);<br>duil:103(1):103(1);<br>duil:103(1):103(1);<br>duil:103(1):103(1);<br>duil:103(1):103(1);<br>duil:103(1):103(1);<br>duil:103(1):103(1);<br>duil:103(1):103(1);<br>duil:103(1):103(1);<br>duil:103(1):103(1);<br>duil:103(1):103(1);<br>duil:103(1);<br>duil:103(1);<br>duil:103(1);<br>duil:103(1);<br>duil:103(1);<br>duil:1                            | Peterson TV, Karp<br>Reterson TV, Karp<br>VC, Davial GW,<br>VL, Davial GW,<br>Valdaulon of a<br>symptom bether<br>questionmatic. Int<br>gressiformatic. Int<br>gressiformatic. Int<br>gressiformatic. Int<br>gressiformatic. Int<br>gressiformatic. Int<br>gressiformatic. Int<br>Strepsilon 1.2007<br>Strepsilon 1.2007<br>Strepsilon 1.2007<br>May 11. PMID:<br>2.0458467.<br>20458467.   |
| Pelvic Hoor Dis-<br>tress Inventory<br>short form<br>(PFDL-20)<br>and PFQ<br>short form<br>(PFIQ-7)  | Pelvic Floor<br>Bother<br>Questionnaire:<br>PFBQ  |

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| A reasonable Higher scores indi- |                |               | PISQ total were calculated | 9              | points scores for each | question, from    | 0 (always) to    | 4 (never), with | the exception   | of question      | 5, which was    | scaled from 0    | (always) to 5 (do | not masturbate). | Individual factor | scores were | calculated by | adding the scores | for the individual | items in each | factor. Reverse | scoring was used | for items 1, 2, 5, | 6, 7, 8, 9, 10, 22, | 23, 24, 26, 27 | and 29. Factor | 1 contained | questions 1, 2, 5, | 6, 7, 8, 9, 10, 12, | 22, 23, 24, 26, | 27 and 29; factor | 2 contained | questions 11, | 13, 16, 17, 18, | 19, 20, 21, 25 | and 30; factor | 3 contained | questions 3, 4, | 14, 15, 28 and | 31. To handle | missing values, | the researcher | calculated the | and the second | sum by multiply- |
|----------------------------------|----------------|---------------|----------------------------|----------------|------------------------|-------------------|------------------|-----------------|-----------------|------------------|-----------------|------------------|-------------------|------------------|-------------------|-------------|---------------|-------------------|--------------------|---------------|-----------------|------------------|--------------------|---------------------|----------------|----------------|-------------|--------------------|---------------------|-----------------|-------------------|-------------|---------------|-----------------|----------------|----------------|-------------|-----------------|----------------|---------------|-----------------|----------------|----------------|---|------------------|
| T-test                           | oral/          | ive,          | cal,                       | er-            | (pc                    |                   |                  |                 |                 |                  |                 |                  |                   |                  |                   |             |               |                   |                    |               |                 |                  |                    |                     |                |                |             |                    |                     |                 |                   |             |               |                 |                |                |             |                 |                |               |                 |                |                |   |                  |
| ppa, 31 items; 3 domains         |                |               | Physical,                  | Partner-       | Related)               |                   |                  |                 |                 |                  |                 |                  |                   |                  |                   |             |               |                   |                    |               |                 |                  |                    |                     |                |                |             |                    |                     |                 |                   |             |               |                 |                |                |             |                 |                |               |                 |                |                |   |                  |
| Cronbach alpha weighted kappa,   |                |               |                            |                |                        |                   |                  |                 |                 |                  |                 |                  |                   |                  |                   |             |               |                   |                    |               |                 |                  |                    |                     |                |                |             |                    |                     |                 |                   |             |               |                 |                |                |             |                 |                |               |                 |                |                |   |                  |
| o Factor                         | loading-MLC    | Principal     | component                  | analysis with  | Verimax                | rotation          |                  |                 |                 |                  |                 |                  |                   |                  |                   |             |               |                   |                    |               |                 |                  |                    |                     |                |                |             |                    |                     |                 |                   |             |               |                 |                |                |             |                 |                |               |                 |                |                |   |                  |
| 8+ 41 No                         | matic          | ulthy         | mal                        | / phase        | 83;                    | 1 with            | UI or POP and    | sexually active | mal             | emal             | / phase         | 66               |                   |                  |                   |             |               |                   |                    |               |                 |                  |                    |                     |                |                |             |                    |                     |                 |                   |             |               |                 |                |                |             |                 |                |               |                 |                |                |   |                  |
| Research Women 18+               |                | and healthy   | for internal               | validity phase | 1, n = 83;             | Women with        | UI or P          | sexually        | for internal    | and external     | validity phase  | 2, n = 99        |                   |                  |                   |             |               |                   |                    |               |                 |                  |                    |                     |                |                |             |                    |                     |                 |                   |             |               |                 |                |                |             |                 |                |               |                 |                |                |   |                  |
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| Pelvic Organ Pro-                | lapse/Urinary  | Incontinence  | Sexual                     | Questionnaire: | PISQ (full             | length)           |                  |                 |                 |                  |                 |                  |                   |                  |                   |             |               |                   |                    |               |                 |                  |                    |                     |                |                |             |                    |                     |                 |                   |             |               |                 |                |                |             |                 |                |               |                 |                |                |   |                  |

| of items by the<br>mean of the<br>answered items |  |
|--|--|
|  | Correlation  |
|  | z  |
|  | <u>1</u>   |
|  | test-retest  |
|  | Cronbuch's<br>alpha  |
|  | None   |
|  | ¥.   |
|  | ñ  |
|  | Women 18 + (n<br>= 90) from<br>prinnary PSQ<br>validation<br>validation<br>additional<br>women TX (N = 46)   |
|  | Research   |
|  | US Eng-<br>lish  |
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|  | Pelvic Organ Pro-<br>lapseUrinary<br>Incontinence<br>Secual<br>Questionnaire:<br>PISQ-12   |
|  |  |

|  |   |  |                            |          |  |        |  |  |                     | 1           |          |   |             |              |  |
|--|---|--|----------------------------|----------|--|--------|--|--|---------------------|-------------|----------|---|-------------|--------------|--|
| Player Organ Pro-<br>Apps/Urinary<br>Incontinence<br>Sexual<br>PISQ-9<br>PISQ-9    | Assikenzi, So,<br>valid Form of<br>Valid Form of<br>Valid Form of<br>PISQ-3, for Use in<br>PISQ-3, for Use in<br>Comparative Stud-<br>ies of Women With<br>and Without Pelvic<br>Organ Prolapse<br>andro Urinary<br>Incontinence."<br>Reconstr Surg<br>Formale Pelvic Med |  | US Eng-<br>lish            | Research | Momen 18+ with<br>and without<br>pelvic floor<br>disorders             | 2      | <<br>2                                     | 9<br>U<br>Q  | crombachs<br>alpha  | Test-retest | 5        | z   | Correlation |              |  |
| Pelvic Organ Pro-<br>Inconstructions<br>sexual<br>auto IUGA<br>Revised:<br>PISQ-IR | Rogers, RG, et al.<br>(2013), ''A new<br>measure of sexual<br>function in women<br>with pelvic floor<br>distortes (FPD);<br>progradmaire,<br>UGA-Revised<br>(PISO-H8)' in<br>Uregiomaire,<br>Uregiorecu J<br>24(7); 1091-1103.  | Pauls, RN, et al.<br>(2015): Sexual<br>function in continence<br>using a new<br>instrument: the<br>program. In<br>Urogynecol J.<br>Constantine, ML,<br>Urogynecol J.<br>Constantine, ML,<br>Urogynecol J.<br>Constantine, ML,<br>et al. (2017),<br>a single summary<br>correction of a<br>guestionnaire-<br>functor et al. (2019),<br>J. (1901–1907,<br>ME, et al. (2019),<br>J. (2023) a strate<br>(PISQ-JRR):<br>J. (2023) a strate<br>projection of<br>the Perice Organ<br>Pulgaschneon-<br>tinence Sexual<br>Pulgared I.<br>(2015) a strate<br>(PISQ-JR)<br>(2015) a strate<br>of the Perice Organ<br>Pulgared I.<br>(2016) Screes<br>for Impated<br>in Women with<br>Pelvic Floor Dis-<br>contrast for Dis-<br>torest's Journal of<br>Clinical Medicine | UK &<br>US<br>Enge<br>Iish | Research | Women 18+ with<br>and without<br>paird floor<br>disorders. n<br>= .589 | 0<br>7 | Cognitive inter-<br>views, expert<br>punel | PCA with<br>trainans,<br>trainans,<br>criteria given | Cronbach's<br>aipha | Test-retest | <u>و</u> | For sexually<br>inactive 2<br>domains:<br>Sexually<br>inactivity<br>(NSA-PR)<br>(NSA-PR)<br>Quality and<br>Satistiction<br>(Global qual-<br>ity, Condition<br>impach, For<br>sexual<br>response (SA-<br>AO, SA-R),<br>Satisticito,<br>Satisticito,<br>Satisticito,<br>Satisticito,<br>Satisticito,<br>Satisticito,<br>Satisticito,<br>Satisticito,<br>Satisticito,<br>Satisticito,<br>Satisticito,<br>Satisticito,<br>Satisticito,<br>Satisticito,<br>Satisticito,<br>Satisticito,<br>Satisticito,<br>Satisticito,<br>Satisticito,<br>Satisticito,<br>Satisticito,<br>Satisticito,<br>Satisticito,<br>Satisticito,<br>Satisticito,<br>Satisticito,<br>Satisticito,<br>Satisticito,<br>Satisticito,<br>Satisticito,<br>Satisticito,<br>Satisticito,<br>Satisticito,<br>Satisticito,<br>Satisticito,<br>Satisticito,<br>Satisticito,<br>Satisticito,<br>Satisticito,<br>Satisticito,<br>Satisticito,<br>Satisticito,<br>Satisticito,<br>Satisticito,<br>Satisticito,<br>Satisticito,<br>Satisticito,<br>Satisticito,<br>Satisticito,<br>Satisticito,<br>Satisticito,<br>Satisticito,<br>Satisticito,<br>Satisticito,<br>Satisticito,<br>Satisticito,<br>Satisticito,<br>Satisticito,<br>Satisticito,<br>Satisticito,<br>Satisticito,<br>Satisticito,<br>Satisticito,<br>Satisticito,<br>Satisticito,<br>Satisticito,<br>Satisticito,<br>Satisticito,<br>Satisticito,<br>Satisticito,<br>Satisticito,<br>Satisticito,<br>Satisticito,<br>Satisticito,<br>Satisticito,<br>Satisticito,<br>Satisticito,<br>Satisticito,<br>Satisticito,<br>Satisticito,<br>Satisticito,<br>Satisticito,<br>Satisticito,<br>Satisticito,<br>Satisticito,<br>Satisticito,<br>Satisticito,<br>Satisticito,<br>Satisticito,<br>Satisticito,<br>Satisticito,<br>Satisticito,<br>Satisticito,<br>Satisticito,<br>Satisticito,<br>Satisticito,<br>Satisticito,<br>Satisticito,<br>Satisticito,<br>Satisticito,<br>Satisticito,<br>Satisticito,<br>Satisticito,<br>Satisticito,<br>Satisticito,<br>Satisticito,<br>Satisticito,<br>Satisticito,<br>Satisticito,<br>Satisticito,<br>Satisticito,<br>Satisticito,<br>Satisticito,<br>Satisticito,<br>Satisticito,<br>Satisticito,<br>Satisticito,<br>Satisticito,<br>Satisticito,<br>Satisticito,<br>Satisticito,<br>Satisticito,<br>Satisticito,<br>Satisticito,<br>Satisticito,<br>Satisticito,<br>Satisticito,<br>Satisticito,<br>Satisticito,<br>Satisticito,<br>Satisticito,<br>Satisticito,<br>Satisticito,<br>Satisticito,<br>Satisticito,<br>Satisticito,<br>Satisticito,<br>Satisticito,<br>Satisticito,<br>Satisticito,<br>Satisticito,<br>Satisticito,<br>Satisticito,<br>Satisticito,<br>Satis | Correlation | Not reported | Either meun<br>clavallation or at<br>transformed sum.<br>For calculation<br>respondent must<br>respondent must<br>auswer more<br>auswer more<br>than one half of<br>the issues in the<br>subscale. |

| Instrument  | Citation   | Language             |
|---|--|----------------------|
| Body Image in Pelvic Organ Prolapse Questionnaire (BIPOP) |  |                      |
|   | Moroni, Rafael M., et al. "Assessment of body image, sexual function,<br>and attractiveness in women with genital prolapse: a cross-sectional<br>study with validation of the Body Image in the Pelvic Organ Prolapse<br>(BIPOP) Questionnaire." <i>The journal of sexual medicine</i> 16.1 (2019):<br>126-136.            | Portuguese-Brazilian |
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|   | PDF Not Available Hou, Y. and D. Hou (2020). "Validation of the Aus-<br>tralian Pelvic Floor Questionnaire in Chinese pregnant and postpartum<br>women." Eur J Obstet Gynecol Reprod Biol 245: 102-106.  | Chinese              |
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|   | Kassa et al. Validation of the Pelvic Organ Prolapse Simple Screening<br>Instrument (POPSSI) in a population of Ethiopian Women. BMC<br>Women's Health (2019) 19:52  | Ethiopian            |
| Incontinence Questionnaire-VS                             |  |                      |
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|   | Stavros, A., Themistoklis, G., Niki, K., George, G., Aristidis, A. (2012).<br>The validation of international consultation on incontinence question-<br>naires in the Greek language. Neurourol. Urodyn. 31, 1141–1144   | Greek                |
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|   | Chattrakulchai, K., Manonai, J., Silpakit, C. et al. Validation of the Thai<br>version of the International Consultation on Incontinence Question-<br>naire-Female Lower Urinary Tract Symptoms (ICIQ-FLUTS). Int<br>Urogynecol J 31, 2603–2610 (2020).  | Thai                 |
|   | Arenholt, L. T. S., et al. (2019). "Translation and validation of the<br>International Consultation on Incontinence Questionnaire Vaginal<br>Symptoms (ICIQ-VS): the Danish version." Int Urogynecol J 30(1):<br>17-22.  | Danish               |

| Instrument                       | Citation   | Language   |
|----------------------------------|--|------------|
| Prolapse Quality of Life (P-QoL) |  |            |
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|                                  | Validation of the French version of the P-QoL questionnaire. Veit-Rubin<br>N, Digesu A, Swift S, Khullar V, Kaelin Gambirasio I, Dällenbach<br>P, Boulvain M. Eur J Obstet Gynecol Reprod Biol. 2015 Sep;192:10-<br>6. doi: 10.1016/j.ejogrb.2015.05.028. Epub 2015 Jun 10. PMID:<br>26142910  | French     |
|                                  | Quality of Life in POP: Validity, Reliability and Responsiveness of the<br>Prolapse Quality of Life Questionnaire (P-QoL) in Spanish Women.<br>Sánchez-Sánchez B, Yuste-Sánchez MJ, Arranz-Martín B, Navarro-<br>Brazález B, Romay-Barrero H, Torres-Lacomba M. Int J Environ Res<br>Public Health. 2020 Mar 5;17(5):1690. doi: 10.3390/ijerph17051690.<br>PMID: 32150963  | Spanish    |
|                                  | <ul> <li>P-QOL questionnaire in Thai version./ Validation of the Prolapse<br/>Quality of Life (P-QOL) questionnaire in Thai version. Manchana T,<br/>Bunyavejchevin S. Int Urogynecol J. 2010 Aug;21(8):985-93. doi:<br/>10.1007/s00192-010-1107-3. Epub 2010 Feb 11.PMID: 20148241</li> <li>Wiwanitkit V. Int Urogynecol J. 2010 Aug;21(8):1039; author reply<br/>1041. doi: 10.1007/s00192-010-1166-5. Epub 2010 May 18. PMID:<br/>20480141</li> </ul>   | Thai       |
|                                  | Validation of the Slovakian version of the P-QOL questionnaire.<br>Svihrova V, Digesu GA, Svihra J, Hudeckova H, Kliment J, Swift S.<br>Int Urogynecol J. 2010 Jan;21(1):53-61. doi: 10.1007/s00192-009-<br>0989-4. Epub 2009 Sep 11. PMID: 19763367   | Slovakian  |
|                                  | Validation of a German version of the P-QOL Questionnaire. Lenz F,<br>Stammer H, Brocker K, Rak M, Scherg H, Sohn C Int Urogynecol J<br>Pelvic Floor Dysfunct. 2009 Jun;20(6):641-9. doi: 10.1007/s00192-<br>009-0809-x. Epub 2009 Feb 13. PMID: 19214361  | German     |
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|                                  | Translation, transcultural adaptation, reliability and validation of the<br>pelvic organ prolapse quality of life (P-QoL) in Amharic. Belayneh<br>T, Gebeyehu A, Adefris M, Rortveit G, Genet T. Health Qual Life<br>Outcomes. 2019 Jan 14;17(1):12. doi: 10.1186/s12955-019-1079-z.<br>PMID: 30642346   | Amharic    |
|                                  | Validation of the Prolapse Quality-of-Life Questionnaire (P-QoL) in<br>Portuguese version in Brazilian women. de Oliveira MS, Tamanini JT,<br>de Aguiar Cavalcanti G. Int Urogynecol J Pelvic Floor Dysfunct. 2009<br>Oct;20(10):1191-202. doi: 10.1007/s00192-009-0934-6. Epub 2009<br>Jul 4. PMID: 19578803  | Portuguese |

| Instrument   | Citation   | Language             |
|--|--|----------------------|
|  | [Assessment of quality of life in women with pelvic organ prolapse:<br>conditional translation and trial of P-QOL for use in Japan]. Fukumoto<br>Y, Uesaka Y, Yamamoto K, Ito S, Yamanaka M, Takeyama M, Noma<br>M. Nihon Hinyokika Gakkai Zasshi. 2008 Mar; 99(3):531-42. doi:<br>10.5980/jpnjurol1989.99.531. PMID: 18404882   | Japanese             |
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| Epidemiology of prolapse and incontinence Questionnaire (EPIQ)           |  |                      |
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| instrument | Citation   | Language              |
|------------|--|-----------------------|
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POPQ stage, pad count) or a subjective measure (e.g., PGI-I). Distribution-based approaches are based on statistical criteria from the PRO scores. When a PRO does not have an anchor-based MID, the MID can be estimated using a distribution approach as half the standard deviation of the baseline score of the measure of interest [36].

### **PROs and PRGs for clinical practice**

#### **Commonly used PRO and PRG measures**

# Patient-reported outcomes: function and symptom bother measures

Below is a list of instruments identified by our structured review of the literature. We aimed to be inclusive of measures specifically for POP or validated for use in this population. These measures are of varied quality and rigor in their validation and reliability testing; please refer to Table 2 for specific details of the PROs specific to POP. The overarching principle in choosing a PRO for clinical or research use is to understand what a PRO is designed to measure (severity, functional impact, sexual health, etc.) and in what population (post-menopausal women, community women, women with PFDs, etc.). Grading of PROs is an arduous process following the COnsensus-based Standards for the selection of health Measurement INstruments (COSMIN) guidance and was outside the scope of this review [37]. Table 3 provides currently available validated languages for each PRO specific to POP.

The health-related quality of life (HRQOL) visual analog scale is a single validated health utility item that captures respondents' perceptions of their current state of health on a scale from 0 to 100 (0 represents death; 100 represents perfect health). This single question has been developed into three condition-specific HRQoL questions for evaluating POP treatment:

- Overall, how satisfied are you with the care you have been getting for your pelvic floor condition? (Responses: very satisfied/somewhat satisfied/neither satisfied nor dissatisfied/somewhat dissatisfied/very dissatisfied).
- (2) In your opinion, has the treatment of your pelvic floor condition been very successful/moderately successful/ somewhat successful/not at all successful?
- (3) Compared with how you were doing before your recent pelvic floor operation, would you say that now you are much better/a little better/about the same/a little worse/ much worse?

Lower scores on the satisfaction items represent a better health state [38].

#### Patient Global Impression of Improvement (PGI-I)

Global impression, single-item scores are another option for measuring POP therapeutic success. Srikrishna et al. validated the Patient Global Impression of Improvement (PGI-I) in 2010 for patients with POP undergoing surgical management. Validation of this scale involved participants listing five goals prior to surgical management. Patient goal achievement measured by a visual analog scale (VAS) determined subjective satisfaction and PGI-I indicated overall satisfaction. The PGI-I correlated with anatomical changes in POP-Q and quality of life changes in the p-QoL [39].

#### Patient global impression of change PGI-C

The Patient Global Impression of Change (PGIC) is a singleitem, self-report question that has been validated in women undergoing vaginal repair augmented with mesh. In this study, 88% of women who perceived "success" on the PGIC also showed improved POP-Q stage [40].

# International consultation on incontinence questionnaire vaginal symptoms module (ICIQ-VS)

The ICIQ-VS is a 14-item scale with weighted scoring that was developed and validated in 2006 to assess the effect of POP on vaginal symptoms, quality of life and sexual function [23]. Instructions for use are maintained on-line at https://iciq.net/iciq-vs (accessed 01/01/2022).

### Pelvic Floor Impact Questionnaire (PFIQ-31)/Pelvic Floor Impact Questionnaire short form-7 (PFIQ-7)/Pelvic Organ Prolapse Impact Questionnaire-7 (POPIQ-7)

The PFIQ is a commonly used condition-specific quality of life questionnaire that assess the impact of bladder, bowel and vaginal symptoms on a woman's daily activities, relationships and emotions [18]. It is psychometrically validated, reliable and responsive to change [41]. The PFIQ is a selfadministered 31-item questionnaire with three subscales addressing bladder [Urinary Impact Questionnaire (UIQ)], bowel [Colorectal-Anal Impact Questionnaire (CRAIQ)] and POP [POP Impact Questionnaire (POPIQ)]. The short form of the PFIQ is shortened to seven questions, hence PFIQ-7. The PFIQ-7 subscale scores range from 0-100, with a summary score of 0-300. Higher scores mean increased distress. Of note, compared to the PFDI, the PFIQ-7 requires a higher reading level (9th to 11th vs 6th to 8th, respectively) [42].

### Pelvic Floor Distress Inventory (PFDI)/Pelvic Organ Prolapse Distress Inventory (POP-DI)/single question for screening: do you feel a bulge?

The PFDI is a 46-item form that evaluates urinary, colorectal and POP distress that asks about specific symptoms related to PFDs over the past 3 months [18]. In the PFDI-46, there are 16 items to evaluate POP distress (POP-DI). This is a complementary PRO to the PFIQ. Like the PFIQ, this was abridged to a short form, the PFDI-20. In the PFDI-20 there are 20 questions sub-divided into: urinary distress inventory (UDI), colorectal and anal distress (CRADI) and POP distress (POPDI). Subscale scores range from 0-100 and the summary score is from 0-300, with higher scores indicating increased distress. Their psychometric characteristics have been evaluated by Gelhorn et al., and the PFDI-20 has been validated by Barber et al. [18, 41, 43]. A mean difference of 24 points in the PFDI-20 or 11 points in the POPDI-6 can be used as a clinically relevant difference between groups [44]. It is written at a sixth to eighth grade reading level [42].

From the original study population a single question on the PFDI-20 accurately and reliably identified those women with POP "Do you usually have a bulge or something falling out that you can see or feel in your vaginal area?" An affirmative answer to this question was 96% sensitive (95% CI 92–100) and 79% specific (95% CI 77–92) for prolapse beyond the hymen, and it is commonly used for populationbased screening [28].

#### Pelvic Organ Prolapse/Urinary Incontinence Sexual Questionnaire (PISQ-IR, PISQ-9, PISQ-12, PISQ-31)

The PISQ-31 was developed in 2001 as the first conditionspecific instrument to assess sexual function in women with pelvic organ prolapse and/or urinary incontinence. The original questionnaire had 31 items but subsequently the short form (PISQ-12) was developed in 2003 [45, 46]. The MID for the PISQ-31 is 6 points, and improvements that meet this threshold may be considered clinically important [47]. The PISQ-31 has three domains that can be reported separately: Behavioral/Emotive, Physical and Partner-Related. PISQ-12 scores cannot be reported at the domain level.

The PISQ-9 is a shortened version and can be used in comparative studies assessing pelvic floor function in women with and without prolapse or incontinence [48].

The Pelvic Organ Prolapse/Incontinence Sexual Questionnaire-International Urogynecologic Association (IUGA) Revised (PISQ-IR) was designed to improve upon prior PISQ versions by including women who experience anal incontinence in its validation and evaluate potential PFD impact on women who are not sexually active [19]. Since 2013 the PISQ-IR has been validated and translated into over 25 languages.

#### Pelvic Organ Prolapse Symptom Score (POP-SS)

The POP-SS is a 7-item symptom index and requires participants to rate the frequency (never, occasionally, sometimes, most of the time or all of the time) of a POP symptom experienced in the 4 weeks before evaluation [49]. Co-existent urinary and bowel problems are not assessed.

This questionnaire was developed to cover symptoms caused or exacerbated by prolapse and was intended to be used as a supplement to other validated scales of urinary, bowel and sexual symptoms associated with POP. The final question asks which symptoms cause the most bother [49].

#### Body Image in Pelvic Organ Prolapse Questionnaire (BIPOP)

The BIPOP is validated to assess body image impact in women with POP and consists of ten items and two subscales: (1) general attractiveness and (2) partner-related POP reactions [50]. The BIPOP refers to an individual's perceptions of and attitudes towards her own body and is a dimension often incorporated with sexual function analyses.

#### Prolapse Quality of Life (P-QOL)

Designed to specifically assess the impact of POP on women's quality of life, the P-QOL is a specific multidimensional tool that has 20 questions over 9 domains: general health perceptions, prolapse impact, role limitations, physical limitations, social limitations, personal relationships, emotional problems, sleep, energy disturbance and measurement of symptom severity [26].

#### Australian Pelvic Floor Questionnaire (APQ)

The APQ is a comprehensive interviewer-administered questionnaire that integrates bladder, bowel and sexual function, pelvic organ prolapse, severity, bother and condition-specific quality of life [51]. It has been validated for self-administration [52].

# Electronic Personal Assessment Questionnaire-pelvic floor (ePAQ-PF)

The ePAQ-PF is a self-administered, interactive, web-based questionnaire that measures the impact of urinary, bowel, vaginal and sexual symptoms. The Birmingham Bowel and Urinary Symptoms Questionnaire (BBUS-Q), Sheffield Prolapse Symptoms Questionnaire (SPS-Q) and Female Sexual Function Index (FSFI) were the initial questionnaires to form the basis of the ePAQ-PF [27]. The core element of ePAQ-PF is standardized multiple-choice questions, which assess both the frequency and impact of pelvic floor symptoms across four dimensions [15, 27].

While there are no specific PROs for vaginal laxity, the ePAQ-PF patient response data have been used to identify the common concern for "vaginal laxity," which shows a strong correlation with reduced vaginal sensation during intercourse [53].

The ePAQ-PF allows for free text to record PRGs. Previous data show 63% of patients (n = 1996) added PRGs. In evaluation of the goals, a potential deficit in the ePAQ-PF questionnaire was identified. Approximately 11% of patients listed goals related to body image. In view of this, body image was incorporated as a domain with the vaginal dimension of ePAQ-PF in the more recent versions (version 18) [15].

#### Pelvic Floor Bother Questionnaire (PFBQ)

The PFBQ is a nine-item questionnaire that includes symptoms and bother related to (1) stress urinary incontinence, (2) urinary urgency, (3) urinary frequency, (4) urgency incontinence, (5) dysuria, (6) pelvic organ prolapse, (7) obstructed defecation, (8) fecal incontinence and (9) dyspareunia [54]. Each answer is scored in a range from 0 to 5 with higher scores indicating more severe bother. The scoring system gives the same weight for all questions [54].

#### Surgical Satisfaction Questionnaire (SSQ)

The SSQ is an 8-item questionnaire validated for women after surgical repair of POP. Responses are recorded on a 5-point Likert-type scale with responses from 0 = "very unsatisfied" to 4 = "very Satisfied" [55].

#### Improvement Satisfaction Scale (ISS)

The ISS a single validated item that assesses satisfaction in women following POP surgery. The item reads:

Check the number that best describes how you are currently compared to before surgery for incontinence/pelvic organ prolapse? Response options are: (1) fixed; (2) greatly improved; (3) improved; (4) not improved; (5) worsened [56].

#### SPS-Q Sheffield Prolapse Symptoms Questionnaire

The SPS-Q assesses symptoms related to POP and the impact they have on QoL. The original validation and development laid the groundwork for the more commonly used computer version (e-PAQ) [57].

#### Patient-reported outcomes: screening

**Epidemiology of Prolapse and Incontinence Questionnaire** (**EPIQ**) This questionnaire was developed to screen for pelvic floor disorders including POP in general populations. The positive predictive value to detect POP is 76% [21]. The questionnaire is valid for both paper and electronic (webbased) administration [58].

**Pelvic Organ Prolapse Simple Screening Inventory (POP-SSI)** The POPSSI is a screening measure for POP and consists of four questions originally from the PFDI: (1) Do you experience urinary incontinence with laughing, sneezing, or coughing? (2) Do you experience urinary urgency? (3) Do you feel pain during defecation? (4) Do you feel or see a bulge in the vagina? [59]. According to the original validation study, the sensitivity and specificity of POPSSI for identification of pelvic organ prolapse in the general population are 45.5 and 87.4%, respectively.

POP Knowledge: Prolapse and Incontinence Knowledge Questionnaire (PIKQ) and the Pelvic Floor Awareness and Knowledge Survey (PFAKS) The PIKQ and PFAKS are knowledge questionnaires. The PFAKS was developed through expert consensus using both qualitative and quantitative methods. Written at an eighth grade reading level, it demonstrates discriminant validity and can be used to uncover patient misconceptions about POP, SUI and OAB [60].

The PIKQ is a valid, reliable and self-administered instrument for assessing knowledge of POP and UI [61].

#### Summary

In summary, the identified PROs for both screening and HRQoL in POP vary in their degree of rigor, utility and intended use. Some of the most widely used PROs still lack validation data in specific populations (such as pregnant women) and specific settings (e.g., community-based populations), and the minimally important clinical difference is still unknown. When choosing PROs for the initial evaluation of POP, attention must be given to the validation and then confirming that the intended use of the PRO aligns with intended use in clinical practice or research.

#### Limitations of patient-reported outcomes

PROs were originally developed for use in research methodology; their extrapolation to clinical practice may make data interpretation inaccurate. Importantly, women may be concerned about the impact of their answers on the care provided by health care providers and adjust responses accordingly. Questionnaires take time to complete, and the response burden may lead to a lower response rate. Clinicians' and researchers' knowledge and familiarity with PROs may also impact their use. Health care organizations often require funding to use PROs on a large-scale basis, potentially limiting usage.

#### Patient-reported goals (PRGs)

In 2005, the term "EGGS" was created to facilitate communication about patient-centered treatment outcomes: E-expectations, G-goal setting, G-goal achievement and S-satisfaction [62]. Patient-reported goals can be used to provide patient-centered care and assess efficacy of treatments.

Patients may be asked to list their personal goals for treatment and prioritize their goals by indicating a rank order of importance from "most important to me" to "not very important" [13, 63]. Goal achievement can also be measured by a 5-point Likert scale (1 = strongly disagree, 5 = strongly agree) or by another 5-point scale (from -2 = strongly disagree that the goal had been met to +2 = strongly agree that the goal had been met) [64]. The 10-point Visual Analog Goal Attainment Scale is another option for reporting goal achievement [65, 66]. The visual analog scale can also be used to compare patients' and surgeons' goals [67].

Goal attainment scaling (GAS) is a technique for measuring goal achievement after therapy that has become commonly used to assess fulfillment of patient-centered goals and outcomes. GAS approaches allow any patient goal to be "anchored" prior to treatment. Patients can judge their own treatment outcomes during follow-up by rating their outcomes on a 5-point scale, with -2 assigned to the worst outcome and +2 to the best [12, 64]. A simpler option is the Global Impression of Improvement Questionnaire (PGI-I), which utilizes a single question and response to gauge goal attainment [29].

While patient goals correlate with satisfaction, they are also associated with improved condition specific QOL measures [68, 69]. Goal studies have also demonstrated that when patients seek care for pelvic organ prolapse they may desire improvement in urinary symptoms illustrating the potential disconnect between anatomical improvement and patient expectations [63]. When evaluating patients with pelvic organ prolapse, overactive bladder symptoms remained a common reason for goal failure [70]. Mamik et al. also found that patient's pelvic organ prolapse surgical goals often centered on urinary symptom resolution while physician goals focused on anatomical correction of bulging illustrating the clinician/patient disconnect often found in surgical studies and outcome measures [71]. Pelvic organ prolapse symptom goals may include resolution of bulge, defecatory improvement, resolution of urinary tract infections, and sexual and emotional aspects. Importantly, symptom goals are often met with anatomical correction, and thus patient's report goal achievement [31, 65, 66]. Surgery has been found to attain greater goal achievement than non-surgical management of pelvic organ prolapse (pessary) [29, 71].

Patients' postoperative satisfaction with surgery is correlated with their goal achievement. Women whose personal goals were not met were often dissatisfied with their surgical outcomes, even though their surgery was considered "successful" based on objective findings [11]. Goal assessment is not identical to quality of life assessment; both provide complementary but independent indications of long-term subjective treatment success [72]. Goals that relate to social roles, sexuality and self-image may take longer to successfully achieve than other types of goals. Longer-term follow-up is crucial to determine whether initial improvements have been maintained [64].

Goals are stable over time; 83% of women continue to report goal achievement 10 years after surgery for pelvic floor disorders [3]. Research on goal setting has also included patient's fears related to surgery, providing insight into the concerns for new symptoms, pelvic organ prolapse recurrence and surgical complications that concern women choosing pelvic organ prolapse surgical management [73].

#### Summary of patient-reported goals

Patient goals are broadly classified into symptomatic and functional goals. Symptomatic goals seem to be most common and are often achieved in pelvic organ prolapse treatment. Understanding patient goals may direct therapy, prevent misunderstanding and allow for effective shared decision making.

#### Limitations of patient-reported goals

Patient-reported goals involve free text, and this can be difficult to track over time. Just like PROs, goals should be evaluated after treatment, and most systems lack simple ways to refer back to initial patient goals or measures of goal attainment.

#### PRO/PRG research recommendations

The appropriate HRQoL instrument for a research study depends on the goals of the intervention and the primary outcomes studied. Important to consider are the concepts measured, target population, assessment frequency and administration. The measure used should be validated in the language and culture of the intended survey population, as these can confound responses. Multiple HRQoL measures can be included in a single study, but staff and participant burden, time constraints and resources are important to consider. HRQoL measures should be assessed, at minimum, at baseline and termination of the study. Additional assessments should be timed based on both the measurement properties of the instrument and the nature of the condition being studied (i.e., the expected changes in function due to the intervention, condition and disease process).

The use of validated HRQoL measures is preferred because it ensures the results obtained are clinically useful. Validation of a HRQoL measure involves a rigorous scientific process that ensures the instrument reliability measures what it is intended to measure for a specific population. The psychometric properties of an instrument are not transferable, and a new validation process must take place for each new language and culture in which it is administered.

Responses to HRQoL measures are on an ordered scale and include Likert scales, visual analog scales, categorized/ anchored visual analog scales, pictorial scales and checklists [74]. Using statistical methods, weights can be added to questions or domains to reflect ideas that may be of greater importance. A validated scoring algorithm is predetermined for each HRQoL measure allowing for a numerical score to be computed based on each patient's responses. Various scoring mechanisms exist including: (1) single rating: single score obtained on a one concept; (2) index: single score obtained on multiple related domains or independent concepts; (3) profile: multiple scores on multiple related domains; (4) battery: multiple scores on an independent concept. Items on the instrument can also be reversed scored to accurately capture negatively worded questions specific to a concept or theme. To aid in the research analysis, Likert scales can be dichotomized although this does result in a loss of response granularity.

Responses to HRQoL instruments are highly variable because they are based on patients' own experiences. Interpretability of scores is enhanced by comparing them against published normative values for specific populations or the minimally important difference (MID). MIDs are the smallest change in score that suggests a benefit or detriment to an intervention and are specific to populations and context. The MID can usually be estimated as half the standard deviation of the baseline score of the measure of interest [36].

Incomplete HRQoL surveys decrease study sample size and potentially impose biased results. In some cases, missing

values make it impossible to generate a score. In the setting of missing survey items, statistical methods must be used to handle the missing data and depend on the missing mechanism. If the data can be assumed to be missing and random, then bias is less of an issue, and it can be presumed the available data may be representative of all data. For missing at random data, a complete case analysis using only available data, maximum-likelihood estimation or multiple imputation can be conducted. Often survey items are missing in patients with similar characteristics, and in these situations, data are considered missing not at random. For missing not at random data, sensitivity analyses should be conducted. Psychometrically, the number of allowed missing values can be determined where the remaining items no longer predict a global score. Some measures, such as the PISQ 12, provide this scoring advice.

More disease-specific HRQoL measures in FPMRS are needed. In particular, validated measures on vaginal laxity and its impact on relationship happiness and sexual function are lacking (Pauls 2013).

PRGs are also important to consider as a research outcome and represent individualized patient-centered outcomes. As previously discussed, there are validated ways to assess goal attainment or achievement; however, this is an area that needs further development and is an emerging field at this time.

# Translation/validation: considerations when validating a PROM in another language/cultural context

A clinical trial can be invalidated if proper data collection was not done because of ambiguous or incorrect translation of a PROM; for this reason, instruments must undergo a more rigorous translation process than simple translation.

The past decades have seen big changes in cross and multi-cultural research methods. Historically, translation work focused on establishing 'linguistic equivalence' or word-for-word translation. Linguistic equivalence does not always establish "cultural equivalence," and translation work has turned its' focus towards establishing cultural equivalence. The importance of cultural equivalence in translation means that the translation goal is to identify terminology which would convey a specific meaning; in some languages this might be achieved by a simple phrase, and in others this may require more detailed elaboration. On a practical level, for every item in a PROM an annotation is added that identifies the intent of the item as well as additional information around words or terminology that might be particularly problematic in the translation process [36].

Word-for-word translation is further verified for meaning with both forward and backward translation. Forward translation means the translation from the source language to the target language. Creating a minimum of two forward translationsis recommended by professional translators able to read/write the source and the target language. The two translations must be "reconciled" in one final translation. Then, a new translator transforms the final translation "backward" or back into the original language to confirm content stability [75].

Prior to using the translated PROs, there should be qualitative research with the overall objective of linguistic validation to ensure that the translated documents are conceptually appropriate and linguistically accurate. By this process, the translated text is actively tested with patients to confirm conceptual equivalence and content validity based on clinician review and/or cognitive interviews (CI) in the target population. The general purpose of a CI is to find out how respondents understand questions and what they are thinking when they try to answer questions and perform the response tasks. The basic CI process involves reading the question to the respondent, or having the respondent read the question, and then using a strategy to find out what the respondent was thinking about the question. There are two basic strategies: think-aloud and verbal probing. Think-aloud typically requires a fair amount of interviewer training and is often conducted by cognitive psychologists, and respondents vary in their ability to perform the think-aloud task. Verbal probing is conducted by a member of the research team, not a professional interviewer. The person conducting the CI should be familiar with the objectives of the research and the specific questions recommended for CI for this questionnaire [75].

Once an instrument has been translated and linguistically validated, a study should be conducted to evaluate the psychometric properties of the translated questionnaire. Ideally, new PROs should be developed simultaneously in multiple languages to allow for inclusive research and clinical care.

# Conclusion

PROs and PRGs are essential in urogynecology clinical care and research. The challenge is integrating these tools into clinical care with the ability to track and obtain repeated measures over time. Research should focus on using PROs that are short, applicable to the study question and validated for the intended population. There remains a deficit in PROs for specific populations (such as post-partum people), languages/cultures and conditions (vaginal laxity). In addition, most of the PROs that have been developed for prolapse were developed for use in research, not clinical settings. Research aimed at identifying best practice use of PROs in a clinical setting for individual use would be helpful to establish their utility in clinical care.

# **Summary of recommendations**

All patients presenting for POP should be evaluated for vaginal, bladder, bowel and sexual symptoms including their goals for symptom treatment. Minimum recommendations for evaluation are as follows:

- (1) **Vaginal symptoms** including bulging, pressure, laxity, discomfort and digitation or splinting for urination or defecation.
- (2) **Bladder symptoms** including dysfunction (both stor-age/voiding) and incontinence.
- (3) **Bowel symptoms** including accidental bowel leakage, defecatory dysfunction, fecal urgency and constipation.
- (4) Sexual function including evaluation of sexual activity, presence of pain, concerns they would like to discuss and whether their pelvic floor dysfunction is affecting their sexual function or body image or preventing sexual relationships.

This screening can be facilitated by a validated PROM; however, most PROs provide more information than needed to provide clinical care and were designed for research purposes.

Based on the committee's literature review and expertise, we make the following recommendations divided into clinical care for POP, research for POP and future directions for PRGs and PROs related to POP.

I. PRGs and PROS for POP clinical care

- a. The most specific information needed for the initial evaluation of POP is patient-reported goals. The evaluation of POP requires investigation and questions into the multiple dimensions of the pelvic floor, and this complexity can be simplified with goals. Patient goals may or may not relate to POP and thus will align the clinician and patient, allowing for shared decision making and avoiding dissatisfaction with treatment plans.
  - i. Goals should be recorded in a way that allows for re-evaluation of goal attainment over time particularly after surgical or non-surgical management for POP.
  - ii. Goals may change over time as POP or symptoms related to POP are treated.
  - As a main principle, the most bothersome symptom, as identified by the question "What bothers you most?," can help guide goal-setting.
     However, the provider must consider that pelvic floor disorders tend to co-exist and patients

may have multiple equally important goals to address in a treatment plan.

- iv. Goals help delineate the primary expectation or concern for the patient of the clinical encounter. Examples include: "What problem do you hope the treatment will address?," "What is your goal for bladder or bowel outcomes?," and "What are your fears regarding bladder or bowel function after POP treatment?"
- b. If PROs are used during the clinical encounter
  - i. Use instruments validated for measurement of the patient's specific symptoms (bowel, bladder, vaginal and/or sexual)
  - ii. Use the instruments during the clinical encounter or inform the patient if these are being completed for research.
  - iii. Choose short instruments to collect the minimum information necessary to decrease patient burden
  - iv. If PROs are used to record the presence or absence of bowel, bladder, vaginal and sexual symptoms, the instrument(s) should include a bother score for symptoms.
  - iii. PROs offer standardized measurement of POP symptoms, quality of life, etc., but do not replace individualized patient goals.
- iv. PROs may help unmask pre-existing PFDs prior to the treatment of POP.
  - II. PROs and PRGs for POP Research
- a. Generally, PROs were developed for research rather than patient care.
- b. Understanding the population as well as the condition for which the PROM is valid for inference is essential when applying it to a given research project.
- c. Validated PROs should be used whenever possible and should be chosen based on project objectives.
- d. Be familiar with scoring and confirm accuracy in reporting PROM scores and interpretation. Identify rules for missing values and whether scores can be reported on the total measure, domain or individual item level.
- e. For some measures on-line scoring programs have been published and can help avoid errors. If you are scoring the measure yourself particularly attention should be

paid attention to reverse scoring, weighted scoring or errors in scoring coding.

- f. In general, PROs should be administered and reported both before and after a research intervention.
- g. Evaluate the appropriateness and rigor of PROs including psychometric properties and compatibility with the project prior to initiating the project.
- h. In clinical research the primary objective should match primary outcome or endpoint. Example: If your research is about the approach of surgery (vaginal versus abdominal) and how it relates to sexual function then your main outcome needs to be a measure of sexual function.
- i. Minimum clinical important differences (MICDs) are more meaningful in reporting PROs after interventions than *p*-values.
- j. Patient-reported goals and goal attainment are also an important part of POP research.

III. Gaps in current literature:

- a. New terms are emerging in patient description of vaginal symptoms such as laxity or openness, and PROs are needed to help quantify the impact of these symptoms on quality of life and bother.
- b. Most PROS are used for group-level research rather than assessing outcome on an individual level, and there is need to define MICD and responsiveness for most PROs.
- c. Few PROs assess the psychological distress associated with POP. This is a research gap.
- d. Few PROs assess patient-specific knowledge about POP, and this represents another research gap.
- e. There is need for more translations of PROs allowing for broader research populations.
- f. There are few POP screening questionnaires that could easily be used in primary care settings.
- g. POP PROs are generally designed for use in subspecialty clinics, and POP PROs for the general population need to be developed.

#### Declarations

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#### SPECIAL CONTRIBUTION



# International Urogynecological Consultation Chapter 2.2: Imaging in the Diagnosis of Pelvic Organ Prolapse

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#### Abstract

**Introduction and Hypothesis** This section of Chapter 2.2 of the International Urogynecology Consultation on Pelvic Organ Prolapse (POP), reviews the literature on the role of imaging in the diagnosis of POP.

**Methods** An international group of nine urogynecologists and one university-based medical librarian adhered to the framework of the scoping review. The group performed a search of the literature using pre-specified search terms in Scopus, OVID Medline, and PubMed. Publications were eliminated if not relevant to the diagnostic value of POP imaging. The remaining articles were evaluated for quality using the Joanna Briggs Institute Checklist for Diagnostic Test Accuracy Studies. The resulting list of articles was used to perform a comprehensive narrative review of the diagnostic value of imaging modalities for the diagnosis of POP.

Results The original search yielded 3,289 references, 135 of which were used by the writing group.

**Conclusions** Most imaging studies utilized in the diagnoses of POP lacked standardization in the definition of POP. Most imaging studies lack standardization in the protocols used to diagnose POP within each imaging technique. Ultrasound- and MRI-related studies are most represented in the literature, compared with fewer CT- and X-ray-/fluoroscopy-related studies. Therefore, radiographic imaging is of limited value in the diagnosis of POP.

Keywords Imaging  $\cdot$  Ultrasound  $\cdot$  MRI  $\cdot$  CT scan  $\cdot$  Fluoroscopy  $\cdot$  Pelvic organ prolapse  $\cdot$  Diagnosis

#### Abbreviations

| AUGS | American Urogynecologic Society             |
|------|---|
| ICS  | International Continence Society            |
| IUC  | International Urogynecological Consultation |
| IUGA | International Urogynecological Association  |

- POP Pelvic organ prolapse
- POP-Q Pelvic Organ Prolapse Quantification
- SGS Society for Gynecologic Surgeons

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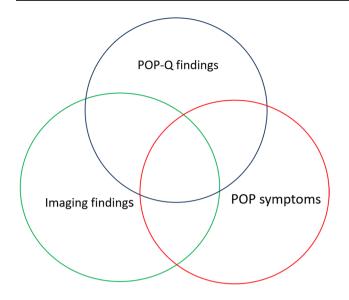
#### Introduction

This report is part of the series of articles that are produced by the International Urogynecological Consultation (IUC), a project sponsored by the International Urogynecology Association (IUGA) on the management of pelvic organ prolapse (POP). This is a four-chapter project with 16 reports. The present article is from the second chapter reporting on the evaluation of POP. It focuses on the role of imaging in the diagnosis of POP. POP is defined as the descent of any one or more of the vaginal walls, cervix, or vaginal vault after hysterectomy [1]. The correlation of this examination finding with the symptom of being able to see or feel a vaginal bulge is necessary for the diagnosis of POP. This relationship mostly happens at or below the level of the hymenal plane. Chapter 1.1 of the IUC evaluated the definition of POP and stressed that it should only be made in a patient with the complaint of a vaginal bulge or in a patient with a medically morbid condition directly related to POP [2]. As symptoms play a major role in the diagnosis it can be difficult to appreciate various symptoms and the diagnosis becomes more complex when the patient's symptoms are disproportionate to the level of descent seen on examination. It has been postulated that imaging techniques, such as ultrasound or magnetic resonance imaging (MRI), can provide additional information to assist in those instances where the diagnosis is not straightforward [3, 4]. Imaging techniques can show and measure the degree of the displacement of pelvic organs and their descent against a defined reference point. Hence, imaging can assist in both the diagnosis and quantification of prolapse. For example, the reference points commonly used to assess POP on MRI are the pubo-coccygeal line (PCL) and midpubic line (MPL), which are fixed bony lines [3, 5, 6]. Translabial/transperineal ultrasound (TPUS) uses a transverse line along the inferior border of pubic symphysis as a reference line for diagnosing POP in different compartments [7–9]. On the other hand, the reference plane of the hymen, which is used for clinical examination, is a soft-tissue plane, which moves with the movement of the pelvic floor. The findings of clinical examination and imaging techniques may or may not correlate with each other or with the patient's symptoms [10-12]. The variation in landmarks used for reference lines also means that different methods of imaging are not comparable. Imaging, however, can be used to understand how POP and associated symptoms interact. As an example, it is commonly used to assess anorectal symptoms, especially bowel evacuation disorders. The dilation and anterior ballooning of the rectum seen on MRI may not cause descent of the posterior vaginal wall and POP by physical examination. Indeed, the term "rectocele," which is used to describe this MRI finding, is also commonly used to describe posterior vaginal wall prolapse. This often

leads to confusion in the diagnosis and management of the conditions by different specialties. Clinical examination can visualize the vaginal wall descent, but it might be difficult to assess the visceral involvement [13]. Imaging techniques can identify the organs within the vaginal wall prolapse and hence improve the diagnostic accuracy of what the POP represents from an organ-based pathology. For example, it can help to differentiate the small bowel versus rectal descent in the settings of the clinically diagnosed posterior vaginal wall prolapse. The stage of POP may vary in the sitting up or standing position [12]. The non-invasive nature of imaging and convenience of assessment in a weight-bearing position are additional advantages of imaging for POP [3, 5, 6, 14]. Another question that arises is whether clinical examination or imaging might be more efficient in diagnosing POP of a particular compartment [15–17]. For example, a prolapse of the upper vagina, which may not be seen easily on clinical examination, may be better diagnosed using imaging techniques [18]. On the other hand, clinical examination may diagnose POP more accurately than imaging alone, and, more importantly, physical examination has been shown to correlate with POP symptoms [4, 17].

The value of any diagnostic testing is traditionally assessed by non-experimental cross-sectional or cohort studies, which compare a test's classification of a diagnosis with that of a reference standard. The conceptual starting point of a diagnostic test study is to apply the reference (or gold) standard to determine which study participants have the prolapse and which participants do not. In the case of prolapse, the Pelvic Organ Prolapse Quantification (POP-Q) examination is considered the gold standard among the urogynecology scientific community. However, although this view is widely accepted, it is not universally agreed upon. For example, in the colorectal literature, some studies call for other imaging modalities as a gold standard in assessing POP [19, 20]. The diagnosis of POP is further complicated by the fact that not all prolapse diagnosed by POP-Q is bothersome. Typically, the presence of symptoms is required to identify prolapse as clinically significant. Therefore, diagnostic studies should consider the fact that not all forms of prolapse identified on physical examination or imaging are symptomatic (Fig. 1).

A well-designed POP imaging accuracy study will need to include a clear definition of prolapse by POP-Q and symptoms, set up clear definitions of radiological findings identified as positive, calculate sensitivity and specificity, and ideally report likelihood ratio and receiver-operating curves (ROCs), which will allow the derivation of evidence-based cut-offs for this particular diagnostic modality. The area under the curve (AUC) on ROCs defines the accuracy of the test: the closer the AUC approaches 1, the more discriminatory value the test carries in distinguishing prolapse from normal controls. This chapter reviews different imaging



**Fig. 1** Venn diagram of pelvic organ prolapse (POP) physical findings, symptoms, and imaging findings. *POP-Q* Pelvic Organ Prolapse Quantification

techniques available for assessing POP and compares them with the clinical examination findings using a clinical diagnosis of prolapse according to either the POP-Q system or the Baden–Walker (BW) grading system. The BW half-way system preceded POP-Q and consisted of four grades: grade 0, no prolapse; grade 1, halfway to the hymen; grade 2, to the hymen; grade 3: halfway past the hymen; grade 4, maximum

 Table 1
 MeSH search terms

descent. It was included in the review to avoid exclusion bias, as the colorectal literature was late to adopt POP-Q and continued using the BW system long after it was introduced in 1994 into the urogynecology community.

# **Materials and Methods**

This manuscript is a narrative review. Nine international urogynecology experts in radiographic imaging in POP were assembled. The chair of the writing group was selected by the IUC chairs, the IUC steering committee with input from the IUGA Executive Committee. A competitive application process and invitation were developed for the other members (authors) of the writing group.

To complete an in-depth literature search on this topic, the authors assembled the search terms that they found most relevant to the imaging of POP. This list of terms was presented at the IUGA annual scientific meeting in 2020 for input from the membership. The additions from membership input made at that meeting were incorporated in the final search terms presented in Table 1. Regular meetings allowed for the group to collaborate on the outline and layout components of this narrative review. The PubMed, OVID Medline, and Scopus Databases were queried for the search terms noted in Table 1, between January 1990 and July 2020. The initial search, performed on 29 July 2020, produced 2,961 unique references. The references were uploaded into Covidence software and divided among the authors for

| Section 1 | Introduction   | ultrasound, pelvic organ prolapse imaging, fluoroscopy, pelvic floor disorders, pelvic<br>floor imaging, mri pelvic floor, vaginal prolapse, rectocele, cystocele, defecography,<br>proctography, radiology pelvic prolapse   |
|-----------|--|---|
| Section 2 | Role of Imaging in Prolapse  | ultrasound, pelvic organ prolapse imaging, fluoroscopy, pelvic floor disorders, pelvic floor imaging, mri pelvic floor, vaginal prolapse, rectocele, cystocele, defecography, proctography, radiology pelvic prolapse   |
| Section 3 | MRI—Technique and Evaluation of Prolapse                                     | mri pelvic prolapse, magnetic resonance imaging prolapse, mri pelvic floor, mri pelvic<br>laxity, mri pelvic relaxation, mri cystocele, mri rectocele, mri anterior compartment,<br>mri posterior compartment   |
| Section 4 | Role of X-ray and CT scan  | x-ray abdomen, barium, computed tomography pelvis, CT scan pelvis, CT scan<br>uterovaginal prolapse, radiologic imaging prolapse, radiographic imaging pelvis,<br>fluoroscopy pelvis, contrast imaging, cysto-urethrography   |
| Section 5 | Ultrasound—Overview of Techniques:<br>Transperineal, Introital, Transvaginal | transperineal ultrasound, translabial ultrasound, transvaginal ultrasound, pelvic prolapse, three dimensional ultrasound pelvic floor, 3 D ultrasound, 4 D ultrasound pelvic floor, introital ultrasound  |
| Section 6 | Ultrasound Anterior Compartment  | ultrasound bladder, ultrasound urethra, bladder imaging, ultrasound anterior compart-<br>ment, ultrasound cystocele, urethrocele, anterior vaginal defect, levator hiatus   |
| Section 7 | Ultrasound Middle Compartment  | uterine prolapse, vaginal vault prolapse, levator hiatus, levator ani muscle, posthys-<br>terectomy prolapse, ultrasound vaginal prolapse, ultrasound uterovaginal prolapse,<br>ultrasound vaginal vault prolapse, apical prolapse, cervical prolapse, ultrasound<br>genital hiatus, levator ballooning |
| Section 8 | Ultrasound Posterior Compartment   | transperineal ultrasound, introital ultrasound, rectocele, ultrasound posterior compart-<br>ment, levator ani imaging, ultrasound levator hiatus, enterocele, rectocele, posterior<br>vaginal defect, perineal hypermobility  |

initial screening. Each reference underwent an inclusion or exclusion criteria assessment by two independent reviewers (writing group members), with a third reviewer as a referee for tie-breaking inconsistencies. The Joanna Briggs Institute (JBI) scoping review guidelines were followed.

Following the initial review, all abstracts were reviewed by two reviewers independently, and conflicts were resolved by a third team member, with the aim of eliminating the studies where the primary focus of imaging use was not the diagnosis of POP and where physical examination (POP-Q or other prolapse grading system) was not used as a goldstandard reference for POP diagnosis. This process resulted in 581 manuscripts relevant to the goal of the narrative review. The full-text manuscript reviews were performed by two reviewers independently rated for inclusion or exclusion, according to the JBI checklist. The final inclusion list consisted of 112 manuscripts and was made as a consensus discussion among all reviewers. Figure 2 shows the Preferred Reporting Items for Systematic Reviews and Meta-Analyses diagram of the article selection process.

Next, the data extraction from the manuscripts was performed, using a standardized data extraction sheet developed specifically for this project. The data collected included study geographic location, study design, number of participants, relevant imaging technique details, types of reference lines used (if any), prolapse compartment (anterior, apical, posterior), and testing validation methods. The sections were divided into different imaging techniques and included X-ray/fluoroscopy, CT scan, MRI, and ultrasound. At least two team members contributed to the data synthesis of each section.

The writing group members produced versions of the manuscript incorporating the edits provided by all members until a final first draft was achieved. This was then circulated to several chosen referees before undergoing peer review. The IUC peer review process involved four rounds of review, including review by the IUC co-chairs, the IUC steering committee members, the IUGA general membership (through an online process), and finally the IUGA board members. The manuscript was then submitted for peer review to the *International Urogynecology Journal*.

### Results

#### X-Ray/Fluoroscopy

A total of 4 cohort studies met the inclusion criteria. Three studies used the POP-Q system for the diagnosis of prolapse [13, 21, 22] and one study used the BW grading system [23]. Three studies focused on posterior wall compartment prolapse (defecography) [13, 22, 23] and one addressed the anterior compartment [21].

#### Variation in Technique

All studies were performed in the sitting position on a commode, with maximum straining, squeezing, and at rest

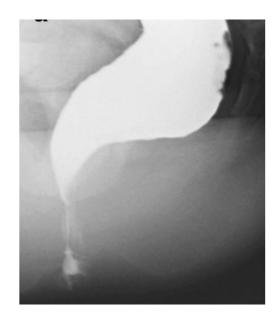
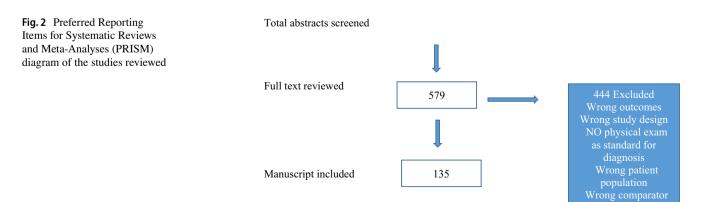


Fig. 3 Normal fluoroscopy with rectal barium opacification



(Fig. 3). The biggest variation in the technique was evident in the methods used for opacification of the rectum, vagina, bladder. and small bowel. For posterior prolapse imaging, Altman et al. used oral barium contrast medium, intraperitoneal and intravesical omnipaque solution, and barium paste contrast medium in the vagina and the rectum during defecoproctography (DCP) [13]. Finco et al. also used barium paste opacification of the rectum and vagina but added barium paste to the perianal skin, and used iothalamic acid for bladder opacification [23]. Groenendijk et al. limited opacification to the small bowel and rectum by using barium sulfate suspension meal and barium enema [22]. The only study reporting on anterior compartment prolapse described the extensive opacification technique involving intraperitoneal and intravesical omnipaque administration in addition to vaginal and rectal barium paste [21].

#### Definition of Cases and Controls and Radiographic Markers

Three studies reported on symptoms associated with prolapse but did not use those symptoms in defining clinically significant prolapse. The clear clinical definition of prolapse was used only in one study: Groenendijk et al. defined clinically significant prolapse of the posterior wall as  $\geq$  POP-Q stage II [22]. The clear definition of an abnormal radiographic finding in the anterior compartment was reported by Altman et al., describing the descent of opacified urinary bladder below the pubococcygeal line as abnormal [21]. Studies focusing on the posterior compartment used definitions of abnormal radiographic findings describing the apex of the rectocele as a common reference point. Groenendijk et al. measured the distance from the rectocele apex to the expected rectal lining of the anterior rectal wall [22]. Finco et al. and Altman et al. measured the distance between the rectocele apex and the line extended through the anal canal axis [13, 23]. In addition, Finco et al. classified radiographic findings of rectocele as grades I, II, and III, using this distance, and defined radiographic rectocele as grade I when it was less than 2 cm long, grade II for 2-4 cm, and grade III when it was over 4 cm [23].

#### **Diagnostic Accuracy Reporting**

There were no studies clearly reporting on the sensitivity or specificity of fluoroscopic testing, in relationship to clinical examination. Studies examined only the correlation between clinical and radiological findings. There was a moderate correlation between the clinical and radiological diagnosis of anterior wall prolapse (degree of correlation r=0.67) [13]. There was poor correlation between fluoroscopic imaging of the posterior compartment and clinical examination for posterior vaginal prolapse (degree of correlation r=0.49) [21]. Although increasing the size of the rectocele on

defecography moderately correlated with difficulty in rectal emptying (r=0.59), there were no other significant associations between symptoms and anatomical findings on imaging [23].

#### **Computerized Tomography**

Only one study was identified reporting on the diagnostic value of computerized tomography (CT) [24]. The study included only seven patients and commented on all compartments. The authors did not use POP-Q as the gold standard for POP diagnosis but rather identified the presence or absence of prolapse in specific compartments during surgical correction as an ultimate reference point. They used extension of the bladder base past the PCL as a radiographic marker for anterior prolapse, and the distance between the line from the anterior margin of the anal canal and the anterior wall of the rectum greater than 2 cm as the radiographic definition of posterior prolapse. CT findings were false negative for all three sites of prolapse in one patient. There were no false-positive cases on CT, when compared with surgical findings.

Because of the small number of studies identified using search terms specific to fluoroscopic and CT imaging of prolapse, the original search was extended past January 2000 to include manuscripts published as early as January 1990. The extended search added no additional manuscripts for CT and one additional manuscript in fluoroscopy [25]. Brubaker et al. evaluated 30 women with prolapse beyond introitus straining in a sitting position with oral contrast medium, and vaginal, rectal, and bladder opacification [25]. The specific radiographic findings consistent with prolapse were not clearly defined and cystocele and rectoceles were reported as present or absent. Radiographic markers were described as heterogeneous with comments on their appearance such as "hour glass shaped." The study did not report on the sensitivity or specificity of testing but the authors concluded that 11 patients had a modification of their surgical plan based on the information obtained from imaging.

#### Conclusion

There is no standardization in CT and fluoroscopic imaging techniques with regard to diagnosing POP. Opacification modalities vary greatly, and the definitions of radiographic findings consistent with prolapse are often unclear. There are no appropriately designed studies describing the diagnostic accuracy of fluoroscopy or CT in the diagnosis of POP. The summary of studies is presented in Table 2.

### **Magnetic Resonance Imaging**

A total of 25 studies met the inclusion criteria for assessing prolapse via MRI. Most studies were cohort cross-sectional,

| Reference               | Technique                         | Physical examination | POP symptoms<br>considered in the<br>analysis | Main reported outcome   |
|-------------------------|-----------------------------------|----------------------|---|---|
| Altman et al. [13]      | Cystodefecoperitoneography, video | BW                   | UDI, DDI                                      | History of pelvic surgery, size of<br>prolapse of the posterior vaginal<br>wall, and the presence of constipa-<br>tion (assessed by a questionnaire)<br>are predictors of the presence of<br>abnormal defecography  |
| Altman et al. [21]      | Cystodefecoperitoneography, video | BW                   | None  | Moderate correlation between<br>clinical and radiological findings<br>in patients with anterior vaginal<br>wall prolapse. New definition of<br>cystocele with lead markers at<br>the introitus did not improve the<br>correlations  |
| Finco et al. [23]       | Colpocystodefecography            | BW                   | KESS  | Proportions of patients diagnosed<br>with rectocele radiographically<br>and with BW did not differ before<br>surgical intervention, but they did<br>differ after surgery for POP  |
| Groenendijk et al. [22] | Defecography                      | POP-Q                | DDI, UDI, CRADI                               | Two groups with rectocele (stage II<br>and higher and stage I and lower)<br>were compared. Symptoms were<br>compared in groups defined by<br>PE and by defecography. No<br>relation was found between bowel<br>complaints and posterior wall<br>prolapse evaluated by clini-<br>cal examination ( $p = 0.33$ ), nor<br>between bowel complaints and<br>rectocele ( $p = 0.19$ ) assessed by<br>defecography |
| Brubaker et al. [25]    | Dynamic fluoroscopy               | Physical examination | None  | Dynamic fluoroscopy improved pre-<br>surgical evaluation by identifying<br>enterocele in 26 out of 30 patients  |
| Pannu et al. [24]       | СТ                                | Surgical exploration | None  | CT findings were false negative for<br>all three sites of prolapse in one<br>patient. There were no false-posi-<br>tive cases on CT when compared<br>with surgical findings   |

Table 2 Computerized tomography (CT) and fluoroscopy

BW Baden–Walker, POP-Q Pelvic Organ Prolapse Quantification, UDI Urinary Distress Inventory, DDI Defecatory Distress Inventory, KESS Knowles Eccersley Scott Symptom Score, CRADI ColoRectal-Anal Distress Inventory, POP pelvic organ prolapse, PE physical examination, CT computerized tomography

with 5 out of 19 describing cohorts of patients planning surgical intervention for prolapse. All but two studies [18, 26] used POP-Q for describing patient prolapse type and severity.

#### Variation in Technique

With the exception of one study, all studies used a T2-weighted basic pulse sequence, which enhances the signal of water (Figs. 4, 5) [26]. The strength of a magnetic field in an MRI machine varied from 0.25 to 3 Tesla with approximately half of studies reporting on the 1.5-Tesla

MRI technique. All studies were performed in the supine position and images obtained at rest and during straining. Some studies added images obtained during squeezing and contraction of the pelvic floor muscles [6, 17, 27]. One study examined patients in the supine position during defection [18]. Delaney et al. hypothesized that prolapse in one vaginal wall can be obscured by a competing defect in the opposite vaginal wall in cases of multicompartmental prolapse. The authors examined the effect of the reduction of the opposing vaginal wall with the vaginal speculum blade and concluded that in cases of advanced POP, the speculum pressing onto the most dependent portion of



Fig. 4 Magnetic resonance image at rest with no prolapse

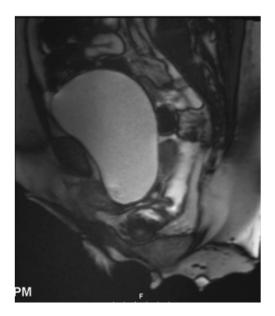


Fig. 5 Magnetic resonance image demonstrating a posterior defect with enterocele containing small bowel and small bowel mesentery

the vaginal wall prolapse reveals additional prolapse in the opposing compartment in 59% of the patients [28]. Abdulaziz et al. evaluated the effect of positioning (standing, sitting, and supine) on the diagnostic accuracy of MRI in POP quantification and concluded that the maximal extent of prolapse is best evaluated in the standing position [29]. Tumbarello et al. established that 95% of women extended their prolapse further in the supine position with repetitive Valsalva maneuvers [30]. About half of the studies used vaginal and/or rectal gel to enhance opacification and one study was specifically aimed at assessing the effect of the addition of vaginal and rectal gel on POP MRI imaging by comparing opacified and non-opacified imaging techniques [31]. Oral contrast medium was used only in the study with T1-weighted images [26]. One study reported on the use of intramuscular butylscopolamine to reduce intestinal mobility [32] and one study described gadolinium solution infused into the bladder in addition to using vaginal and rectal gel. [33]

#### Definition of Cases and Controls and Radiographic Markers

Only four studies collected data on the symptoms of prolapse and used validated questionnaires [32, 34-36]. The most commonly used questionnaires were the Urinary Distress Inventory (UDI), the Defecatory Distress Inventory (DDI), the Incontinence Impact Questionnaire (IIQ), and the ColoRectal-Anal Distress Inventory. One study included correlation of prolapse and symptoms, but did not use a validated questionnaire [37]. All but one of the studies did not utilize questionnaires in defining POP as symptomatic or clinically significant [36]. The biggest variation existed in definitions of MRI findings: multiple midsagittal pelvic reference lines were described to quantify prolapse using MRI (Table 3). An attempt was made to standardize MRI lines, by introducing the sacrococcygeal-inferior pubic point line; however, this proposed reference line was not universally accepted. Subsequently, radiographic definitions of prolapse in reference to multiple lines varied greatly. Largely, studies reported either on distances between the pre-determined or leading portions of the prolapsing organ and the selected reference line or on different radiographic stages of prolapse using arbitrary cut-off values (Table 4). Xie et al. introduced the term "exposed vaginal length," measured from the point where the posterior vaginal wall separates from the anterior wall to the ventral tip of the perineal body, as a potential tool to diagnose posterior compartment prolapse [36]. Rodrigues Jr et al. explored the value of estimated levator ani volume (LASV) in prolapse staging and found that LASV can be estimated using MRI and shows good correlation with 3D images on MRI; the clinical relevance of this finding needs to be studied [38]. Lammers et al. used pubovisceral muscle avulsions on MRI to correlate with prolapse in different compartments and found that pubovisceral avulsions, presence, and severity correlated with signs and symptoms of prolapse. [32]

#### **Diagnostic Accuracy Reporting**

The majority of the studies reported on the association or correlation of prolapse with physical examination findings but did not have sensitivity or specificity calculated or ROC reported. Findings of advanced prolapse stages appear to correlate better with MRI POP diagnosis than POP-Q stages I and II. The correlation of POP-Q prolapse diagnosis is

| Table 3         Magnetic resonance imaging reference lines | e imaging reference lines   |   |
|--|---|---|
| Line   | Definition  | References  |
| Pubococcygeal line   | Extending from the inferior-most portion of the symphysis pubis to the tangent<br>of the last coccygeal joint. Points of interest are measured as a vertical distance<br>to the reference line corresponding to the levator muscles | Abdulaziz et al. [29], Agildere et al. [26], Broekhuis et al. [17], Delaney et al. [28], Etlik et al. [14], Grob et al. [3], Hodroff et al. [33], Lakeman et al. [34], Lin et al. [18], Pannu et al. [31], Pollock et al. [68], Siegmann et al. [37], Singh et al. [61], Torricelli et al. [62] |
| Midpubic line  | Drawn across the midsagittal aspect of the pubic bone through the approximate level of the vaginal hymen corresponding to the level of the hymen  | Abdulaziz et al. [29], Barakat et al. [6], Cortes et al. [63], Fauconnier et al. [64], Lakeman et al. [34], Pannu [31], Singh et al. [61], Woodfield et al. [65], Xie et al. [36]   |
| Horizontal line  | Measures the width of the pelvic floor hiatus in the anteroposterior dimension.<br>Measured from the inferior tip of the pubic symphysis to the posterior circular fibers of the anorectal junction                                 | Xie et al. [36], Lin et al. [18], Lakeman et al. [34], Gupta et al. [16], Broekhuis<br>et al. [17], Abdulaziz et al. [29]   |
| Mid-anal line  | Line extending through the middle of the anal canal in a resting position of the anorectal junction 2 cm above the plane of the ischial tuberosities  | Xie et al. [36], Lin et al. [18], Abdulaziz et al. [29], Sayed et al. [66]  |
| Internal anal sphincter line<br>Hiatus line                | Internal anal sphincter line Reference line placed through the ventral aspect of the internal anal sphincter<br>Hiatus line Measures the distance from the pubis to the posterior anal canal  | Xie et al. [36]<br>Xie et al. [36], Comiter et al. [67]   |
| Perineal line  | Reference line from the inside of the pubic symphysis to the front tip of the perineal body   | Xie et al. [36], Lakeman et al. [34], Fauconnier et al. [64], Abdulaziz et al. [29]   |
|  |   |   |

slightly better in the anterior compartment than in the apical and posterior compartments. Only one study reported ROCs for different radiographic markers assessing posterior compartment prolapse [36]. The study compared the diagnostic value of eight existing reference lines and a new parameter, the "exposed vaginal length," in the diagnosis of posterior compartment prolapse. The study focused on the ability of MRI to detect the size and not the POP-Q stage of prolapse, as the authors believed that POP-Q is not designed to assess the prolapse size, which is the parameter that the authors felt most consistently correlated with bothersome symptoms. The exposed vaginal length outperformed the traditional reference lines in diagnosing prolapse size, with an AUC of 0.95. This measurement can discriminate large posterior compartment prolapse from small, with a cut-off value of 2.9 cm. The "perineal line-internal pubis" showed the highest sensitivity and specificity among traditional lines, with an AUC of 0.91 [36].

# Conclusion

Magnetic resonance imaging findings appear to correlate somewhat better with POP-Q staging in the anterior compartment and in more advanced stages of prolapse. The lack of standardized definitions for reference lines and a lack of reporting on test accuracy made it difficult to compare study results.

# Ultrasound

Out of the 50 studies that met the inclusion criteria for assessing POP via ultrasound, 44 explored the perineal ultrasound technique, consistent with AIUM/IUGA practice guidelines [39]. The remainder of the studies focused on endovaginal, endoanal, and trans-abdominal ultrasound.

# **Transperineal Ultrasound**

The vast majority of the TPUS studies were cohort crosssectional, with only 10 studies designed as case–control cross-sectional. Two studies used the BW or the Green classification of cystoceles, with the remainder reporting POP according to the POP-Q. The Green classification of cystocele takes into account the urethrovesical angle and the level of urethral involvement in anterior vaginal wall descent [40]. Three studies included patients planning surgery for prolapse.

**Variation in Technique** Technique variation in transperineal ultrasound was minimal in the studies published after 2004 following a standardized protocol popularized by Dietz et al. (Figs. 6, 7) [41, 42]. Most of the studies were performed in supine position with no organ opacification. The transducer

| Table 4         Radiographic definitions of prolapse  |  |   |                        |
|---|--|---|------------------------|
| Radiographic distance to the reference line   | Reference  | Radiographic staging of POP   | Reference              |
| Difference between the coordinates of maximal prolapse<br>for anterior and posterior vaginal wall and apex and<br>reference line  | Barakat et al. [6], Fauconnier et al. [64], Lake-<br>man et al. [34], Tumbarello et al. [30], Xie<br>et al. [36] | Stages of prolapse ranging from I to IV as referenced<br>by the distance from the mid-pubic line: stage I<br>MPL <-1 cm (less than 2-cm descent); stage II between<br>-1 and +1 distance from the MPL (between 2- and 4-cm<br>descent); stage III more than +1 cm from the MPL but<br>less than + (TVL-2) (more than 4-cm descent), stage IV<br>more than + (TVL-2) or more than 4-cm descent   | Cortes et al. [63]     |
| In the anterior compartment, the posterocaudal-most point<br>of the anterior vaginal wall was used; in the central<br>compartment, the distal-most point of the cervix or the<br>vaginal vault; and in the posterior compartment, the<br>anterocaudal-most point of the posterior vaginal wall<br>using reference | Broekhuis et al. [17]  | Modified Sigh et al.: 1st 0.5–2 cm movement of the pelvic organs during straining, 2nd 2–4 cm movement, but not below the PCL, 3rd>4 cm movement or below the PCL, 4th>10 cm movement below the PCL   | Etlik et al. [14]      |
| The positions of the bladder neck, bladder base, and uter-<br>ine cervix (or vaginal apex) were recorded as positive if<br>above and negative if under the PCL  | Delaney et al. [28]  | HMO classification for MRI grading of pelvic organ<br>prolapse: 0 above the H line; 1, 0–2 cm below the H line;<br>2, 2–4 cm below the H line; 3, more than 4 cm below the<br>H line  | Gupta et al. [16]      |
| Distances to the anterior part of the cervix, bladder neck, and pouch of Douglas were measured to the PCL   | Grob et al. [3]  | Stage I: all organs lying above the MPL; stage II: pelvic<br>organs lying < 1 cm proximal to or distal from the MPL;<br>stage III: distal-most portion of the prolapse is > 1 cm<br>below the MPL but protrudes no further than 2 cm less<br>than the total vaginal length; stage IV: complete eversion   | Singh et al. [61]      |
| Measures bladder neck height or the perpendicular distance from the bladder neck to the reference line, the posterior urethrovesical angle, and the posterior levator plate angle relative to the PCL   | Hodroff et al. [33]  | Mild: organ descended < 3 cm below the PCL, moderate:<br>between 3 and 6 cm below the PCL; severe: if more than<br>6 cm below the PCL. Rectocele was classified as mild if<br>protruding less than 2 cm past the line tangential to the<br>anterior wall of the anal canal, moderate if protruding<br>2–4 cm, and severe if protruding more than 4 cm   | Torricelli et al. [62] |
| Cystoccle: any portion of the bladder herniated below the PCL. Rectocele anterior bulging (> 1 cm) of the anterior rectal wall compared with static imaging   | Lin et al. [18]  | Anterior compartment, the reference point was the poste-<br>rior- and inferior-most aspect of the bladder base. In the<br>apical compartment, the reference point was the anterior<br>cervical lip or the posterior superior vaginal apex if the<br>woman was post-hysterectomy. In the posterior compart-<br>ment, the anterior aspect of the anorectal junction served<br>as the point of reference. Organ prolapse < 3 cm below<br>the PCL small, 3 to 6 cm below moderate, and > 6 cm<br>below the PCL large prolapse | Woodfield et al. [65]  |
| Bladder: cystocele defined as 1) below the PCL, 2) below<br>the MPL or $< = 3$ cm above the MPL; apical POP: 1)<br>below the PCL, 2) below the MPL or $< = 5$ cm above<br>the MPL; small bowel: 1) below the apical third of the<br>vagina; rectum: more than 3-cm anterior bulge relative to<br>the anal canal   | Pannu et al. [31]  | No staging system proposed  |                        |

Table 4 (continued)

| Radiographic distance to the reference line   | Reference   | Radiographic staging of POP   | Reference |
|---|---|---|-----------|
| Organ prolapse (O line) was used to categorize cystocele,<br>when a portion of the bladder prolapsed below the PCL.<br>Apical prolapse was measured with respect to the PCL.<br>Rectocele was defined as anterior bulging > 1 cm of the<br>anterior wall of the rectum compared with static imaging | Pollock et al. [68]                               | No staging system proposed  |           |
| Cystocele was diagnosed if the bladder base descended below the PCL on straining. Rectocele was present if the anterior rectal wall was pouching out $\geq 2$ cm at defecation  | Siegmann et al. [ <i>37</i> ]                     | No staging system proposed  |           |
| Anterior compartment—the distal-most part of the blad-<br>der. Apical compartment—the leading edge of the vagi-<br>nal cuff or the location of the cervix. Posterior compart-<br>ment—the anorectal junction in relation to the PCL   | Van der Weiden et al. [35]                        | No staging system proposed  |           |
| PCL pubo-coccygeal line, MPL midpubic line, POP pelvic o  | organ prolapse, TVL total vaginal length, HMO H l | PCL pubo-coccygeal line, MPL midpubic line, POP pelvic organ prolapse, TVL total vaginal length, HMO H line, M line, organ prolapse, MRI magnetic resonance imaging | 00        |

was applied to the perineum lightly placed to minimize pressure so as not to reduce maximal descent. The technique's sensitivity to positional changes was examined by Rodriguez-Mias et al. who studied the effect of standing position on US accuracy, to assess if established diagnostic cut-offs for POP need to be changed. The authors concluded that parameters describing organ descent are not affected by the standing position but hiatal diameters change enough to consider a new cut-off [43]. Braverman et al. demonstrated that diagnostic performance of sonographic markers predicting prolapse is only marginally better in standing position [12].

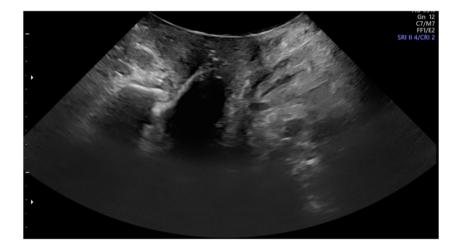
Definition of Cases and Controls and Radiographic Markers Two thirds of the studies included assessments of symptoms, but only five used validated questionnaires. The most commonly used questionnaire was the Pelvic Floor Distress Inventory (PFDI-20) [44]. Most of the studies did not use symptoms or validated questionnaires in the definition of clinically significant prolapse, but rather explored the association between ultrasound diagnosis of POP and the presence of clinical symptoms, without quantifying severity. However, several studies focused on the diagnostic accuracy of ultrasound in relationship to POP symptoms, rather than the POP-Q, and attempted to define cut-offs for significant pelvic organ descent on the basis of prolapse symptoms [7]. Ten studies used the definition of POP-Q stage II as clinically significant. There were two main categories of sonographic markers utilized to predict POP: the measurements of descent describing organ position relative to the inferior margin of the symphysis pubis and measurements relative to the levator plate (Table 5). The most frequently quoted topographic organ descent cut-offs were  $\geq 10 \text{ mm and} \geq 15 \text{ mm}$ below the symphysis pubis for the bladder and rectal ampulla [7]. In studies focusing on uterine prolapse, the clinical definition of prolapse was defined as descent of the cervix to 15 mm above the symphysis pubis or lower. The highest variation was amongst the cut-off values describing the apical compartment. They varied between 15 mm above the symphysis pubis to 0 mm (symphysis pubis level). However, some studies explored other sonographic markers such as tenting of the paravaginal fornices in the axial plane (presumably describing a paravaginal defect) [45], discontinuity in the anterior anorectal muscularis that resulted in a diverticulum of the rectal ampulla extending into the vagina ("true rectocele") [46], vaginal canal shape described as H, U, and eye shaped [47] or morphology and axial orientation variations of the levator plate [48].

**Diagnostic Accuracy Reporting** Fifteen out of 44 studies commenting on the value of transperineal ultrasound in the diagnosis of POP reported measures of diagnostic test accuracy (area under the curve for ROC analysis). Five studies reported on topographic sonographic markers and eight

Fig. 6 Transperineal ultrasound at rest



**Fig. 7** Transperineal ultrasound at rest with Valsalva demonstrating anterior compartment prolapse



focused on the measures of the levator plate, with two studies exploring both measures. Although the sonographic definitions were fairly consistent across the literature, the studies used heterogeneous definitions of prolapse as reference standards. Some studies focused on detecting the symptoms of prolapse and some attempted to report on diagnostic test discrimination between POP-Q stages. Others defined clinically significant prolapse as  $\geq$  POP-Q stage II (Table 6). The definition of clinically significant prolapse by POP-Q varied by compartment, with the majority of studies making the distinction for  $\geq$  POP-Q stage II for anterior and posterior compartments and  $\geq$  POP-Q stage I for the apical compartment. None of the studies used validated questionnaires to define clinically significant POP. All studies were cohort cross-sectional by design and included a large number of participants, but were limited to two populations: predominantly white in Australia and Asian in China. AUCs ranged from 0.59 for an ultrasound topographic marker predicting

uterine POP symptoms in the case of uterine prolapse, to 0.94 for hiatal area at Valsalva predicting POP-Q stage III. It is worth noting that an AUC of 0.5 carries no diagnostic value in detecting a pathological condition and indicates that the test is performing no better than flipping a coin.

Receiver-operating characteristic curves appear to be similar for both anterior and posterior compartments, although the relationship between organ descent and symptoms was slightly stronger for the anterior compartment. Topographic markers appear to detect symptoms of POP only slightly better than the marker of the levator plate. ROC analysis indicates that the probability of transperineal ultrasound (TPUS) in detecting symptomatic prolapse increases with increasing POP stage [49]. Studies reporting the diagnostic value of TPUS in an Asian Chinese population report slightly better diagnostic accuracy than studies originating in Australia. The sensitivities and specificities of TPUS in detecting symptoms of POP and physical evidence of POP

| Table 5         Sonographic markers for pelvic organ prolapse                          | rolapse  |   |   |
|--|--|---|---|
| Topographic imaging of organ descent   | References   | Measurements of the levator plate                             | References  |
| Anterior: bladder descent below the symphysis  | <ul> <li>Xuan et al. [69], Lone et al. [4, 70], Dietz et al.</li> <li>[8, 11, 71], Kluivers et al. [72], Lai et al.</li> <li>[73], Rodriguez-Mias et al. [43], Wen et al.</li> <li>[53], Bu et al. [74], Chantarasorn and Dietz</li> <li>[9], Najjari et al. [75], Schettino et al. [76],<br/>Barakat et al. [6], Braverman et al. [12],<br/>Broekhuis et al. [17], Zhu et al. [77]</li> </ul> | Levator muscle avulsion]                                      | Trutnovsky et al. [78], Dietz and Beer-Gabel<br>[79], Lai et al. [73], Pattillo Garnham et al.<br>[80], Ying et al. [48], Zhuang et al. [50], Huang<br>et al. [60], Zhu et al. [77]   |
| Posterior: the anterocaudal-most point of the anterior rectal wall below the symphysis | Xuan et al. [69], Volloyhaug et al. [15], Lone<br>et al. [4, 70], Dietz et al. [11, 71, 81], Dietz<br>and Steensma [82], Dietz and Lekskulchai<br>[7] Dietz and Korda [83], Barakat et al. [6],<br>Rodrigues et al. [38], Kluivers et al. [84], Lai<br>et al. [73], Rodriguez-Mias et al. [12], Broekhuis<br>et al. [17], Zhu et al. [77]  | Levator diameter (vertical and horizontal)                    | Levator diameter (vertical and horizontal) Majida et al. [85], Kozma et al. [86], Dietz and<br>Beer-Gabel [79], Pineda et al. [87], Huang<br>et al. [60], Wen and Zhou [51], Ying et al. [48],<br>Zhuang et al. [50], Wen et al. [88] |
| Apical: uterine descent in relation to the sym-<br>physis                              | Xuan et al. [69], Volloyhaug et al. [15], Lone<br>et al. [4, 70], Dietz et al. [8, 11, 71], Kluivers<br>et al. [84], Lai et al. [73], Rodriguez-Mias<br>et al. [43], Wen et al. [47, 53], Wu et al. [49],<br>Barakat et al. [6], Braverman et al. [12],<br>Broekhuis et al. [17], Shekand Dietz [89], Zhu<br>et al. [77]   | Levator hiatal area (also described as<br>levator ballooning) | Xuan et al. [69], Abdool et al. [90], Athanasiou<br>et al. [57], Dietz and Beer-Gabel [79], Lai et al.<br>[73], Pattillo Garnham et al. [80], Rodriguez-<br>Mias et al. [43], Speksnijder et al. [91], Zhuang<br>et al. [50]          |
|  |  |   |   |

| 0                                     | -                 |   |   |   |
|---------------------------------------|-------------------|---|---|---|
| Reference                             | Ultrasound marker | Details   | Prolapse reference standard definition  | ROC statistics  |
| Trutnovsky et al. [78]                | Levator plate     | Scoring system for puborectalis avulsion:<br>6-point and 12-point systems   | Symptoms and signs of POP in all com-<br>partments dichotomized as presence or<br>absence   | AUCs were 0.619 and 0.633 for the 6-point<br>and the 12-point scales respectively. The<br>discrete variable "avulsion" a cut-off<br>value of "6" was chosen for the 12-point<br>scale on the basis of these ROC curves.<br>This resulted in 32.8% sensitivity and<br>86.0% specificity for predicting signifi-<br>cant POP on ultrasound. The association<br>between avulsion and physical findings<br>of POP (POP-Q) was stronger than the<br>association of avulsion with ultrasound<br>findings of POP |
| Dietz et al. [81]                     | Topographic       | Measurement of rectal descent relative to<br>the symphysis, rectocele depth measure-<br>ment  | Posterior compartment prolapse associ-<br>ated with symptoms of vaginal digitation<br>and incomplete bowel emptying                                     | AUCs are 0.61 for detecting vaginal digita-<br>tion and 0.614 for incomplete bowel<br>emptying on the one hand and rectocele<br>depth on the other. The cut-off depth of<br>15 mm provides sensitivities of 66% for<br>vaginal digitation and 63% for incomplete<br>emptying, and specificities of 52 and 57%<br>respectively   |
| Dietz and Lekskulchai [7] Topographic | Topographic       | Measurement of rectocele and cystocele descent below the symphysis pubis  | Dominant compartment POP associated<br>with the feeling of a vaginal lump or<br>bulge, or a dragging sensation  | AUCs 0.857 vs 0.821 for anterior vs poste-<br>rior compartment for predicting symp-<br>toms of POP  |
| Kluivers et al. [72]                  | Topographic       | Maximum descent of the leading edge of<br>the bladder, the cervix or vaginal vault<br>and rectum in millimeters   | Symptomatic prolapse confirmed by<br>POP-Q or BW and associated with the<br>feeling of a vaginal lump or bulge, or a<br>dragging sensation              | AUCs indicating the probability of symp-<br>toms of prolapse with increasing stages,<br>was 0.778 for the POP-Q, 0.783 for BW<br>ordinal stages and 0.715 for ultrasound<br>quantification. The cut-off point, with<br>equal costs of misclassification, was at<br>the hymen (0 cm) in the POP-Q, stage 2<br>in the ordinal stages and 14 mm below<br>the reference line through the symphysis<br>pubis for ultrasound  |
| Lai et al. [73]                       | Levator plate     | The depth of discontinuity between the<br>insertion of the muscle and the rami<br>pubis in the case of abnormal insertion<br>of the puborectalis muscle. Measured in<br>the plane of minimal hiatal dimension | POP symptoms were defined as a vaginal<br>lump/bulge or a dragging sensation.<br>Significant clinical prolapse was defined<br>as POP stage II or higher | AUC 0.82 for POP stage II or higher, 0.84 for POP symptoms, 0.77 for significant POP on ultrasound, and 0.79 for hiatal ballooning. ROC showed that a cut-off depth for levator muscle injury of 7 mm yielded sensitivity of 62% and specificity of 80% for POP symptoms  |

| Table 6 (continued)        |  |  |   |  |
|----------------------------|--|--|---|--|
| Reference                  | Ultrasound marker  | Details  | Prolapse reference standard definition  | ROC statistics   |
| Pineda et al. [87]         | Levator plate  | Midsagittal diameter of the hiatus on<br>Valsalva  | Significant clinical prolapse was defined<br>as POP stage II or higher  | AUC of 0.637 for AP diameter on Valsalva.<br>AUC 0.71 for the relationship between<br>midsagittal AP diameter and clinical<br>findings of significant prolapse, 0.751 for<br>significant prolapse diagnosed on ultra-<br>sound. A cut-off of 6 cm of the AP hiatal<br>diameter on Valsalva yielded a specificity<br>of 0.64 and a sensitivity of 0.7 for detect-<br>ing significant prolapse on ultrasound   |
| Rodriguez-Mias et al. [43] | Rodriguez-Mias et al. [43] Topographic and levator plate | Maximum descent of the leading edge of<br>the bladder, the cervix or vaginal vault<br>and rectum in millimeters in the stand-<br>ing position. Levator hiatus area in the<br>standing position   | Symptoms of POP with clinically signifi-<br>cant POP as POP-Q stage II and above<br>for the anterior and posterior compart-<br>ments and POP-Q stage $\geq I$ for the apical<br>compartment   | AUCs 0.698 for cystocele, 0.593 for uterine AUCs 0.698 for cystocele, 0.593 for uterine descent, 0.635 for the rectal ampulla, and 0.706 for levator hiatal area respectively vs symptoms of POP. A hiatal area on Valsalva of $29 \text{ cm}^2$ was found to be the optimal cut-off when imaging is performed in the standing position  |
| Wen et al. [47]            | Topographic  | Maximal uterine descent and shape of the vaginal canal   | Symptoms of POP with clinically signifi-<br>cant POP as POP-Q stage II and above  | The AUC was 0.69 for apical prolapse. The ROC curve proposed a cut-off of 10 mm above the symphysis pubis for uterine prolapse (POP stage $\geq$ I) with sensitivity of 74% and specificity of 64%. An eye-shaped vaginal canal with an AP diameter of greater than 10 mm in the rendered axial plane was a sign of uterine prolapse   |
| Wen et al. [53]            | Measures of levator plate                                | Hiatal area, AP diameter of hiatal area and<br>width of hiatal area measured in cen-<br>timeters at rest, on Valsalva maneuver,<br>and on pelvic floor muscle contraction.<br>All measures transformed in Z-score.<br>Z-score 5 (measured value – predicted<br>mean value)/predicted standard devia-<br>tion | POP-Q stage II or higher defined as symp-<br>tomatic prolapse. Symptomatic POP is<br>defined as subjective symptoms of the<br>bulge. Substantial POP on translabial<br>ultrasound defined as a cystocele to at<br>least 10 mm below the symphysis, uter-<br>ine descent to 15 mm above the symphy-<br>sis or lower, rectal ampulla/enterocele<br>descent to at least 15 mm below the<br>symphysis, or a combination thereof | AUCs of 0.69, 0.87, and 0.86 for Z-scores<br>for POP-Q stage II or higher substanti-<br>ate POP on translabial ultrasound, and<br>symptomatic POP. The levator hiatal area<br>cut-off was $20 \text{ cm}^2$ with sensitivity of<br>81% and specificity of 58% for POP-Q<br>stage II or higher, sensitivity of 86% and<br>specificity of 70% for symptomatic POP,<br>and sensitivity of 87% and specificity of<br>73% for substantiate POP on translabial<br>ultrasound. ROC analysis illustrated that<br>no diagnostic cut-off value can be used<br>to distinguish the normal state and POP<br>stage I. Patients with POP stage I were<br>always clinically asymptomatic |

| Table 6 (continued) |                           |  |  |   |
|---------------------|---------------------------|--|--|---|
| Reference           | Ultrasound marker         | Details  | Prolapse reference standard definition   | ROC statistics  |
| Wen et al. [52]     | Measures of levator plate | Hiatal area, AP diameter of the hiatal area<br>and width of the hiatal area measured<br>in centimeters at rest, on Valsalva<br>maneuver, and on pelvic floor muscle<br>contraction. All measures transformed<br>into Z-score   | POP-Q stages I, II, III dichotomized as present or absent  | AUCs of 0.65 and 0.69 for hiatal area at<br>Valsalva and hiatal length at Valsalva<br>respectively for POP stage I. AUC of 0.77<br>and 0.72 for hiatal area at Valsalva and<br>hiatal length at Valsalva respectively for<br>POP stage II. AUC of 0.94 for hiatal length at<br>Valsalva for POP stage III. ROC illus-<br>trated that no ideal cut-off to distinguish<br>between "normal" and POP stage I. If<br>we consider women who had no POP or<br>had asymptomatic POP (stage I) to be<br>"normal" and those with symptomatic<br>POP (stage II or more) to be "abnormal,"<br>the ROC proposes a maximal hiatal area<br>of 20 cm <sup>2</sup> or an AP of 6 cm (Z-score of<br>1.0) as cut-off with sensitivity of 79%<br>and specificity of 65% for hiatal area<br>sensitivity of 71% and specificity of 58%<br>for hiatal length |
| Wen and Zhou [51]   | Measures of levator plate | AP diameter was measured in the mid-<br>sagittal plane as the minimal distance<br>between the hyperechoic inferoposte-<br>rior aspect of the pubic symphysis and<br>the hyperechoic anterior border of the<br>pubovisceral muscle. The hiatal area<br>was measured in the minimal axial plane<br>with minimal dimensions | POP-Q stage II or higher defined as clini-<br>cally significant prolapse. Symptomatic<br>POP is defined as subjective symptoms<br>of a bulge | AUCs 0.63 for the AP diameter and 0.66 for the hiatal area according to POP-Q stage II and higher. AUCs 0.75 for the AP and 0.82 for the hiatal area against prolapes symptoms. A cut-off of 6.0 cm for the AP diameter against POP-Q stage II and higher yielded sensitivity of 73% and specificity of 54%. For prolapse symptoms, the cut-off of 6.0 cm for the AP diameter had sensitivity of 74% and specificity of 54%, and the cut-off of 20 cm <sup>2</sup> for the hiatal area against VOP-Q stage II and higher produced sensitivity of 76% and specificity of 54%. For prolapse symptoms, the cut-off of 6.0 cm for the AP diameter had sensitivity of 74% and specificity of 64%, and the cut-off of 20 cm <sup>2</sup> for the hiatal area had sensitivity of 78% and specificity of 68%                                  |

Table 6 (continued)

| Wu et al. [49] To         |                               |  |   |   |
|---------------------------|-------------------------------|--|---|---|
|                           | Topographic                   | Uterine descent was measured relative to<br>the horizontal line positioned through<br>the posteroinferior margin of the sym-<br>physis pubis on maximal Valsalva                       | POP-Q stages I and above and stage II<br>and above for the apical compartment.<br>Symptomatic POP is defined as subjec-<br>tive symptoms of the bulge                   | AUCs for POP symptoms 0.75. AUCs for<br>POP-Q stage I and above 0.83; for POP-Q<br>stage II and above 0.85. Cut-off values:<br>4.79 mm above the symphysis pubis for<br>POP symptoms; cut-off 6.63 mm above<br>the symphysis pubis for POP-Q stage 1+;<br>cut-off 8.42 mm below the symphysis<br>pubis for POP-Q stage II+. Likelihood<br>ratio + 1.91 for symptoms; 2.72 for<br>POP-Q stage 1+; 8.67 for POP-Q stage<br>II+. Likelihood ratio 0.34 for symptoms;<br>0.25 for POP-Q stage 1+; 0.39 for POP-Q<br>stage II+ |
| Braverman et al. [12] Toj | Topographic and levator plate | Maximal caudal displacement of pelvic<br>organs in relation to the symphysis pubis<br>on maximal Valsalva maneuver supine<br>and standing. Hiatal area on maximum<br>Valsalva maneuver | Clinically significant prolapse defined as<br>POP-Q stage II or higher in the anterior<br>and posterior compartments or stage I or<br>higher in the central compartment | AUCs for the anterior compartment: 0.64<br>supine and 0.67 standing; for uterine<br>descent: 0.64 supine and 0.67 stand-<br>ing; for the posterior compartment: 0.57<br>supine and 0.6 standing; for the hiatal<br>area: 0.68 supine and 0.72 standing  |
| Shekand Dietz [89] To     | Topographic                   | Apical descent was measured relative to<br>the posteroinferior margin of the sym-<br>physis pubis  | Symptomatic POP is defined as subjective symptoms of the bulge  | AUC 0.68 with sensitivity $0.7$ and specific-<br>ity $0.57$ for a cut-off of $-15$ mm $(15$ mm<br>above the symphysis pubis). AUC $0.74$<br>with sensitivity $0.7$ and specificity $0.64$<br>for a cut-off of $-15$ mm $(15$ mm above<br>the symphysis pubis) after patients with<br>anterior- and posterior-dominant prolapse<br>were excluded   |
| Zhuang et al. [50] Lev    | Levator plate                 | Levator-urethra gap, levator-symphysis gap, and puborectalis attachment  | MRI diagnosis of unilateral or bilateral avulsion   | AUC 0.906 by levator-urethra gap for<br>the diagnosis of levator avulsion with a<br>cut-off of 23.65 mm (sensitivity, 92%;<br>specificity, 95%). AUC 0.906 by levator-<br>symphysis for the diagnosis of levator<br>avulsion with a cut-off of 28.7 mm (sensi-<br>tivity, 84.6%; specificity, 69.7%)  |

AP anteroposterior, POP pelvic organ prolapse, POP-Q Pelvic Organ Prolapse Quantification, BW Baden–Walker, ROC receiver-operating characteristic, AUC area under the curve

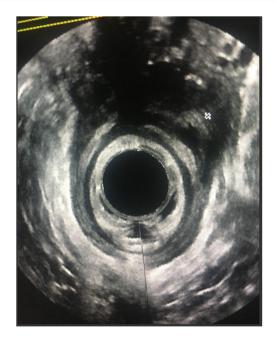
range from high 60 to low 80 and depend on the population, definition of POP, POP compartment assessed in the study, and POP severity [47, 49-53]. Only one study reported a likelihood ratio, the parameter that allows the assessment of an individual patient's probability of having POP [49]. The likelihood ratio (LR) describes the chance of a positive sonographic marker being expected in a patient with POP compared with the likelihood of the same result being expected in a patient without POP. LR close to 1 means that the test result does not appreciably change the likelihood of POP. Ideally, the LRs should be either above 10 or below 0.1 to provide strong evidence to rule POP in or out. The positive LRs were 1.91 for ultrasound detecting symptoms of POP, 2.72 for detecting  $\geq$  POP-Q stage I, and 8.6 for detecting  $\geq$  POP-Q stage II. The negative LRs were 0.34, 0.25, and 0.39 respectively, indicating that ultrasound performs marginally better in ruling in advanced-stage POP than ruling in it out. LRs showed a rather small effect in predicting symptoms of POP or less advanced POP. This study focused on detecting uterine prolapse only [49].

**Conclusion** The standardized technique of TPUS for POP detection is generally accepted; however, the accuracy of transperineal ultrasound in detecting symptoms or the anatomical finding of POP is moderate at best. The accuracy slightly improves in the standing position and with increasing POP severity. TPUS assessment in the standing position can be performed in cases where false-negative findings are suspected after a supine assessment. TPUS findings need to be interpreted with caution in patients with milder forms of POP. Reports on the diagnostic accuracy of TPUS findings are limited to two specific populations, as most studies originated in Australia and Asia. There is significant variation in diagnostic cut-offs for POP detection with regard to uterine descent between the two populations.

# Other Types of Ultrasound

Six studies evaluated the diagnostic significance of alternative ultrasound modalities for the diagnosis of POP. Three studies attempted to assess endoanal ultrasound, two studies commented on endovaginal ultrasound, and one study explored the value of transabdominal ultrasound.

**Endoanal Ultrasound** All three studies utilizing endoanal ultrasound in the diagnosis of POP were performed among patients awaiting surgical intervention for POP (Fig. 8). The technique was not standardized, and the ultrasound evaluations were performed in lithotomy, lateral decubital, or supine positions with the use of a tilting table. One study used a Foley balloon inserted in the bladder to better delineate the anterior compartment POP [54]. As POP-Q is not commonly accepted among colorectal surgeons as a gold



 $\ensuremath{\mathsf{Fig.8}}$  Endoanal ultrasound with internal and external anal sphincter defect

standard reference for POP diagnosis, the diagnostic accuracy of endoanal ultrasound was described in correlation with intraoperative findings during POP surgery. Vierhout et al. focused on the posterior compartment and identifying enteroceles [54]. The authors described a sonographic marker of peristaltic loops of small bowel protruding into the vagina as evidence of an enterocele herniation of the pouch of Douglas. They concluded that rectal ultrasonographic findings were in good accordance with intraoperative anatomical diagnosis of enterocele. In 27 out of 29 patients (93%), when an enterocele was diagnosed by endoanal ultrasound, it was confirmed during surgery. Karaus et al. also focused on diagnosing enterocele, and defined an enterocele sonographic marker as the opening of a cul-de-sac into the vagina [55]. Only 4 patients out of the entire cohort of 17 underwent surgery, and enterocele was confirmed for all of them. Minagawa et al. explored all compartments for prolapse using the endoanal technique and compared ultrasound against intraoperative findings in 31 patients. This study used postural change from supine to standing position on a tilting table and defined any descent of the bladder neck from the baseline supine position as cystocele, descent of the vaginal vault of more than 3 cm as apical prolapse, and descent of the posterior vaginal wall of more than 1 cm as rectocele. The authors reported sensitivity, specificity, and accuracy of 90%, 83%, and 74% for anterior, apical, and posterior prolapse respectively [56].

**Endovaginal Ultrasound** Two studies describing endovaginal ultrasound use in POP diagnosis focused on two different aspects of POP. Lone et al. aimed to assess if ultrasound findings can aid in diagnosing additional POP, which would lead to a change in planned surgical intervention. They concluded that clinical examination is better at diagnosing cysto-urethrocele, rectocele, and uterine prolapse. In addition, endovaginal ultrasound also diagnosed two intussusceptions and a combined enterocoele and intussusception in one woman, but overall did not have an impact in the planned management approach [4]. Athanasiou et al. reported on the ability of endovaginal ultrasound to assess the levator hiatal area and correlated it with POP-Q findings. The authors concluded that the hiatal area, and not levator thickness, is in strong correlation with POP-Q measurements in all compartments [57].

**Transabdominal Ultrasound** One study that utilized the transabdominal ultrasound technique, attempted to use it to diagnose paravaginal defects. The role of the paravaginal defect in POP is debated in the literature and the defect itself is not adequately reflected by the POP-Q measuring system [58]. The authors attempted to evaluate if the lateral bladder base "sagging" below level of the central bladder correlates with the physical examination diagnosis of a paravaginal defect established with the use of ring forceps reducing the apical prolapse. The authors concluded that the sonographic paravaginal defects identified in this study were artificially created by the ultrasound technique, utilizing a balloon placed in the vagina to enhance vaginal forces. Hence, this technique cannot accurately diagnose paravaginal defects.

**Conclusion** The diagnostic value of endovaginal and endoanal ultrasound is limited to the detection of enterocele, likely because insertion of the probe into the vaginal or rectal cavity distorts the descent of the prolapsing organs by adding a space-occupying effect. There is no adequately described transabdominal ultrasound technique that can aid the diagnosis of prolapse.

# Head-to-Head Comparison of Different Imaging Techniques

Seven studies included a second imaging technique in the assessment of patients' POP, while attempting to define the value of the index imaging technique in POP diagnosis. Some of the studies used another technique to define cases of POP, as they found POP-Q alone inadequate as a standard reference for testing accuracy. For example, Van Gruting et al. used a composite reference standard to define POP + cases: DCP, MRI, and physical examination findings needed to agree in order to meet the definition of the positive reference case for POP [19]. Other studies provided insight

into how the techniques compare in POP detection. Martellucci and Naldini reported good correlation between DCP and ultrasound when assessing patients with rectocele (88% agreement) [20]. Beer-Gabel et al. demonstrated that DCP and the ultrasound techniques showed good concordance for the diagnosis of enterocele [59].

Broekhuis et al. aimed to evaluate agreement between MRI and TPUS in detecting prolapse in all compartments and concluded that the two imaging techniques correlate moderately to well only in the anterior compartment [17]. Barakat et al. performed a true blinded head-to-head comparison of MRI and TPUS in detecting POP defined via POP-Q, and concluded that both techniques perform similarly in POP detection in all three compartments, but these findings are limited only to high-grade (POP-Q stage III and IV) POP [6]. Finally, Zhuang et al. focused on the ability of MRI and TPUS to assess levator avulsion and reported 92% agreement, with a kappa of 0.79 between the two techniques [50].

# Conclusion

Transperineal ultrasound has a moderate correlation with DCP in diagnosing enteroceles. MRI and TPUS can be used interchangeably in the diagnosis of levator avulsion but differ in their detection of POP in individual compartments, especially in cases of mild POP.

# Role of Imaging Techniques in the Clinical Management of POP

In 6 studies (3 on MRI and 3 on TPUS) the authors attempted to evaluate the role of imaging in surgical or conservative POP management.

# Magnetic resonance imaging

Van der Weiden et al. reported on MRI measurements before and 6 months after sacrocolpopexy and concluded that MRI only revealed significant improvement for the apical compartment, with no correlation between changes in MRI measurements, POP-Q measurements, and validated questionnaires [35]. Siegmann et al. reported on the MRI assessment of patients before and after pelvic floor repair with transvaginal mesh, demonstrating clinically occult POP cases in 73.3% of patients at 3 months after repair, but this finding did not correlate with clinical symptoms [37]. Attenberger et al. focused specifically on the ability of MRI to provide additional information not evident according to the physical examination [27]. The latter study evaluated if the MRI diagnosis of POP had an impact on the treatment strategy or altered the surgical procedure: the treatment plan was changed in 13 out of 50 cases (26%). In 12 cases, an enterocele was diagnosed by MRI, but was not detected on physical examination. In 4 cases, an enterocele and in 2 cases a rectocele were suspected clinically but were not confirmed by MRI. The study did not have a comparison group and did not provide any data on patient-centered surgical outcomes.

# **Transperineal Ultrasound**

Lone et al. studied whether baseline assessment with ultrasound in addition to routine physical examination added diagnostic value leading to management change in patients with POP in a prospective cohort study with normal controls [4]. Although TPUS enhanced the visualization of additional pelvic floor abnormalities and identified a higher number of additional ultrasound pathological conditions in the POP group (11.3% enteroceles and 3.4% intussusceptions), it did not lead to a change in the clinical treatment plan, as the majority of abnormalities (mainly enteroceles) were small. Huang et al. assessed the role of TPUS in patients undergoing transvaginal mesh and native tissue repair surgery for anterior compartment POP and commented on the ability of ultrasound parameters to predict surgical failure [60]. They reported that preoperatively, patients with and without POP recurrence were similar in the POP-O staging and ultrasound measures of levator hiatus. On 12-month postoperative ultrasound, patients with POP recurrence in the anterior compartment demonstrated a higher rate of complete levator avulsion (OR 14.2; CI 4.8–42.2). Gillor et al. performed a similar study focusing on sonographic outcomes of posterior compartment correction with and without mesh augmentation [46]. They reported that clinical recurrent posterior vaginal wall prolapse (defined as point  $Bp \ge -1$ ) was seen in 20% of patients, whereas POP diagnosed by ultrasound (defined as descent of the rectal ampulla  $\geq 15$  mm below the symphysis pubis) was noted in 12% of patients. An additional 6% exhibited enterocele findings on ultrasound (diagnosed if an enterocele sac was seen at or below the level of the symphysis pubis on imaging) [46]. There was no difference in sonographic levator avulsion between the mesh-augmented and native tissue repair groups in this study [46]. In those without significant posterior compartment descent on clinical examination, a substantial minority still showed a "true rectocele," (defined as defect of the rectovaginal septum). This was the case after both mesh (29%) and native tissue repair (18.5%).

# Conclusion

In comparison trials, no imaging modality appeared superior to another. Overall, the value of diagnostic imaging in POP management remains unclear and understudied.

# Recommendations

- Computerized tomography and fluoroscopic imaging such as defecography should not be used routinely to diagnose POP, as there are not enough well-designed studies reporting on their accuracy for POP detection.
- The value of defecography is in the detection of enterocele and intussusception.
- The value of MRI in diagnosing multicompartment POP is unclear, as studies reporting diagnostic accuracy are very heterogeneous in technique, reference lines used, and definitions of POP reference standards.
- Exposed vaginal length with a cut-off value of 2.9 cm can be used to detect large rectocele on MRI with good accuracy.
- Transperineal ultrasound can be used to detect clinically significant POP and symptomatic POP with moderate accuracy. Accuracy decreases as POP-Q stages decrease.
- Cut-off values for uterine POP are population specific and need to be used with caution in populations other than white Australian or Asian Chinese women.
- The value of endovaginal and endoanal ultrasound in prolapse detection and quantification is limited to the detection of enteroceles.
- Both MRI and TPUS can be used in the diagnosis of levator ani avulsion.
- High-quality studies should be performed to evaluate the utility of imaging in the clinical management of POP.

# **Discussion Points**

The intended use of imaging test can be diagnosis, screening, staging, monitoring, surveillance, prediction, or prognosis. This narrative review focuses on the diagnostic value of different imaging modalities in POP. Our working group identified a significant gap in the current literature surrounding imaging use. There is a lack of well-designed studies with clear definitions of reference standard defining POP as disease. Largely, it is stemming from the lack of consensus of what defines "clinically significant POP." Imaging techniques appear to perform moderately well in the diagnosis of advanced POP stages, but those POP cases are easily diagnosed on pelvic examination. An ideal study would be a large cohort focusing on low-grade POP, where the "clinically significant prolapse" is diagnosed as a combination of pelvic examination evidence of POP and the presence of symptoms determined by validated questionnaires. The studies with a similar design will need to be repeated in diverse patient populations. Only after this evidence is obtained can we gain a better insight into the diagnostic abilities of different imaging modalities.

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# Declarations

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# SPECIAL CONTRIBUTION



# International Urogynecology consultation chapter 2 committee 3: the clinical evaluation of pelvic organ prolapse including investigations into associated morbidity/pelvic floor dysfunction

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# Abstract

**Introduction and hypothesis** This manuscript from Chapter 2 of the International Urogynecology Consultation (IUC) on Pelvic Organ Prolapse (POP) reviews the literature involving the clinical evaluation of a patient with POP and associated bladder and bowel dysfunction.

Methods An international group of 11 clinicians performed a search of the literature using pre-specified search MESH terms in PubMed and Embase databases (January 2000 to August 2020). Publications were eliminated if not relevant to the clinical evaluation of patients or did not include clear definitions of POP. The titles and abstracts were reviewed using the Covidence database to determine whether they met the inclusion criteria. The manuscripts were reviewed for suitability using the Specialist Unit for Review Evidence checklists. The data from full-text manuscripts were extracted and then reviewed. **Results** The search strategy found 11.242 abstracts, of which 220 articles were used to inform this narrative review. The main themes of this manuscript were the clinical examination, and the evaluation of comorbid conditions including the urinary tract (LUTS), gastrointestinal tract (GIT), pain, and sexual function. The physical examination of patients with pelvic organ prolapse (POP) should include a reproducible method of describing and quantifying the degree of POP and only the Pelvic Organ Quantification (POP-Q) system or the Simplified Pelvic Organ Prolapse Quantification (S-POP) system have enough reproducibility to be recommended. POP examination should be done with an empty bladder and patients can be supine but should be upright if the prolapse cannot be reproduced. No other parameters of the examination aid in describing and quantifying POP. Post-void residual urine volume >100 ml is commonly used to assess for voiding difficulty. Prolapse reduction can be used to predict the possibility of postoperative persistence of voiding difficulty. There is no benefit of urodynamic testing for assessment of detrusor overactivity as it does not change the management. In women with POP and stress urinary incontinence (SUI), the cough stress test should be performed with a bladder volume of at least 200 ml and with the prolapse reduced either with a speculum or by a pessary. The urodynamic assessment only changes management when SUI and voiding dysfunction co-exist. Demonstration of preoperative occult SUI has a positive predictive value for de novo SUI of 40% but most useful is its absence, which has a negative predictive value of 91%. The routine addition of radiographic or physiological testing of the GIT currently has no additional value for a physical examination. In subjects with GIT symptoms further radiological but not physiological testing appears to aid in diagnosing enteroceles, sigmoidoceles, and intussusception, but there are no data on how this affects outcomes. There were no articles in the search on the evaluation of the co-morbid conditions of pain or sexual dysfunction in women with POP. **Conclusions** The clinical pelvic examination remains the central tool for evaluation of POP and a system such as the POP-Q or S-POP should be used to describe and quantify. The value of investigation for urinary tract dysfunction was discussed and findings presented. The routine addition of GI radiographic or physiological testing is currently not recommended. There are no data on the role of the routine assessment of pain or sexual function, and this area needs more study. Imaging studies alone cannot replace clinical examination for the assessment of POP.

Keywords Pelvic organ prolapse · Clinical evaluation · Urinary tract dysfunction · Gastrointestinal dysfunction

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# Introduction

This report is part of a series of articles that are the product of the International Urogynecology Consultation (IUC), which is sponsored by the International Urogynecological Association (IUGA). This is a 4-year, four-chapter project, with 16 reports dedicated to reviewing and summarizing the world's literature on pelvic organ prolapse (POP).

This report is from the 2nd year and chapter of the project, which is dedicated to the evaluation of POP. This year/chapter is divided into three reviews, the other two involve the radiographic evaluation of POP and the use of patient-reported outcomes (POP condition-specific quality-of-life questionnaires) in the evaluation of POP. This report focuses on the clinical evaluation of women with POP and describe how to use the physical examination to describe pelvic organ support or prolapse. In addition, the associated testing to evaluate comorbid conditions of the urinary and gastrointestinal tracts (GITs) is described and evaluated. Radiographic testing to evaluate comorbid lower urinary tract and gastrointestinal conditions is part of this report.

It is recommended that every patient with POP has a thorough clinical examination. Describing and evaluating the patient for POP, although it at first seems straightforward, is in fact very complex. First, there are several classification systems currently in use to describe and quantify POP. The clinician is then left to determine the relative benefits of using one system over another. In addition, it is recognized that many patients with POP often have pelvic floor comorbidities involving other pelvic/abdominal organ systems [1]. Choosing how best to use clinical resources to properly investigate these conditions in patients with POP can be confusing. In addition, the interpretation of test results in a patient with POP may be different than interpretation of the same studies in a patient with normal pelvic organ support. Finally, this paper addresses the question as to which additional testing is necessary and should be routine versus which testing should only be performed if there are associated symptoms present. This review is not meant to be an exhaustive paper regarding the evaluation of lower urinary tract or gastrointestinal symptoms in women, except as they are uniquely influenced by POP.

In this review, the components of a clinical examination and the conditions under which they should be performed are assessed and the best practices described. Any additional testing of co-morbid conditions that should be routinely undertaken, and the conditions under which they are best performed, are evaluated and the best practices described. Knowledge gaps and areas that require further study are also noted.

# Materials and methods

This manuscript is a narrative review that includes a systematic search of the literature using terms from the Pub-Med and Embase databases (January 2000 to August 2020). Only human studies involving adult women and limited to the English language were included. The terms for searching the literature were developed by the authors of this report and were presented to the IUGA membership at the annual scientific meeting in 2020; progress was reported at subsequent meetings. These are shown in Table 1 the titles and abstracts were reviewed using the Covidence database to determine whether they met the inclusion criteria. In the event of uncertainty, this was discussed at regularly scheduled meetings. The manuscripts were next reviewed for suitability using the Specialist Unit for Review Evidence checklists for cohort, cross-sectional, and case-control epidemiological studies. This was done to assess data presentation, population description, and bias. Only studies that included populations with clear definitions of patients with symptomatic POP, which described examination findings, were included. The full-text manuscripts were extracted and then reviewed. Those manuscripts that qualified were reviewed in depth and the process is summarized in the Results section (Fig. 1).

# Results

The search strategy found 11,242 abstracts, which were reviewed and led to the extraction of 940 full-text articles, of which 220 articles were used to inform this narrative review. The results and the PRISMA figure for each are reported in three areas:

- 1. Clinical physical examination
- 2. The urinary tract (LUTS), and
- 3. The gastrointestinal tract (GIT).

Other comorbid conditions such as pain and sexual dysfunction are better evaluated and recorded using patient-reported outcomes, which are covered in a separate manuscript of the IUC [2].

# Clinical physical examination of a woman with POP

A review of the existing literature on the examination of a patient with POP and the impact of various parameters on the examination findings was performed. The initial search identified more than 7,155 abstracts of which around 96 studies were included in the final review (Fig. 2) This review of the clinical examination is divided into four sections:

- 1. General aspects of examination of a woman with POP
- 2. Examination of the anterior compartment
- 3. Examination of the posterior compartment
- 4. Examination of the apical compartment

#### Table 1 Keywords used for searching the literature

| Number | Evaluation of POP                   | Evaluation of LUTS                                 | Evaluation of GIT                 | Evaluation of pelvic floor muscle function, sexual function, and pelvic pain |
|--------|-------------------------------------|--|-----------------------------------|--|
| 1.     | Genital prolapse                    | Assessment of urinary symp-<br>toms                | Assessment of defecation symptoms | Assessment of sexual dysfunc-<br>tion  |
| 2.     | Uterovaginal prolapse               | Urinalysis   | Proctoscopy                       | Vaginal laxity   |
| 3.     | Cystocele                           | Urinary incontinence, stress/<br>cough stress test | Digital anorectal examination     | Pelvic floor muscle strength   |
| 4.     | Cystourethrocele                    | Post-void residual                                 | Anal sphincter tone               | Oxford Scale   |
| 5.     | Anterior wall prolapse              | Uroflow  | Digital rectal examination        | Clitoral sensation   |
| 6.     | Rectocele                           | Urodynamics or urodynamic studies                  | Bowel diary                       | Blood flow   |
| 7.     | Posterior wall prolapse             | Cystometry   | Bristol Stool Chart               | Assessment of pelvic pain  |
| 8.     | Enterocele                          | Pressure-flow study                                | Sigmoidoscopy                     | Evaluation of pelvic pain  |
| 9.     | Recto-enterocele                    | Occult stress incontinence                         | Anorectal manometry               | Cotton-swab test   |
| 10.    | Perineocele                         | Bladder diary                                      | Defecography                      | Sensory examination  |
| 11.    | Procidentia                         | Frequency volume chart                             | Defecography with MRI             | Trigger points   |
| 12.    | Apical prolapse                     | Pad-weight test                                    | Rectal prolapse                   | Pelvic floor muscle tenderness   |
| 13.    | Vault prolapse                      | Cystoscopy   | Intussusception                   | Pelvic floor resting tone  |
| 14.    | Cervical elongation                 | Urethral mobility                                  |                                   | Neuromuscular examination  |
| 15.    | Pelvic organ prolapse               | Q-tip  |                                   |  |
| 16.    | Uterine prolapse                    | Cotton swab test                                   |                                   |  |
| 17.    | Anterior compartment prolapse       | Pessary reduction test                             |                                   |  |
| 18.    | Posterior compartment prolapse      | Urethral pressure profilometry                     |                                   |  |
| 19.    | Perineal descent                    | Leak point pressure                                |                                   |  |
| 20.    | Joint hypermobility and<br>prolapse | Detrusor overactivity                              |                                   |  |
| 21.    | Striae                              | Non-obstructive voiding dif-<br>ficulty            |                                   |  |
| 22.    | Urethral mucosal prolapse           |  |                                   |  |
| 23.    | Paravaginal defect                  |  |                                   |  |

POP pelvic organ prolapse, LUTS lower urinary tract symptoms, GIT gastrointestinal tract

#### General aspects of examination of a woman with POP

**Methods to describe/quantify examination of POP** A variety of systems have been devised to classify and quantify POP. Eight studies focused on assessing the reliability and reproducibility of various staging systems (Table 2). It was found that the Baden–Walker Halfway Grading System had moderate reproducibility, making it unsuitable for clinical care or research [3]. The Pelvic Organ Prolapse Quantification (POP-Q) system, on the other hand, was found to have good interobserver agreement and was found to be particularly useful in the research setting [4].

Owing to the complexity of the POP-Q, a simplified POP-Q (S-POP) system was devised. This system retains the ordinal stages of the POP-Q but simplifies the terminology and reduces the number of points measured. Three studies evaluated the validity, interobserver agreement, and intersystem agreement between the simplified POP-Q and POP-Q [5–7]. The authors concluded that a substantial intersystem

association exists between S-POP and POP-Q, and S-POP, being simpler, may be more applicable to clinical practice worldwide. It was also found that the simplified POP-Q system retains its inter-examiner agreement across centers of varying degrees of expertise and is a valid, user-friendly alternative to POP-Q. For a complete description of the POP-Q please refer to the article by Bump et al. [8]. For a complete description of the S-POP please refer to the article by Swift et al. [9].

One study described and evaluated the validity of the novel "eye-ball" POP-Q technique (POP-Q by estimation) [10]. In this technique, the points along the anterior and posterior vaginal walls (Aa, Ba, Ap, and Bp) and on the perineum genital hiatus (GH) and perineal body (Pb) were visually estimated. Determination of vaginal depth (total vaginal length, or TVL) and apical descent (points C and D) were assessed by both visual estimation and palpation with the examiner's dominant hand. The authors suggested that estimating POP-Q values provided comparable results to

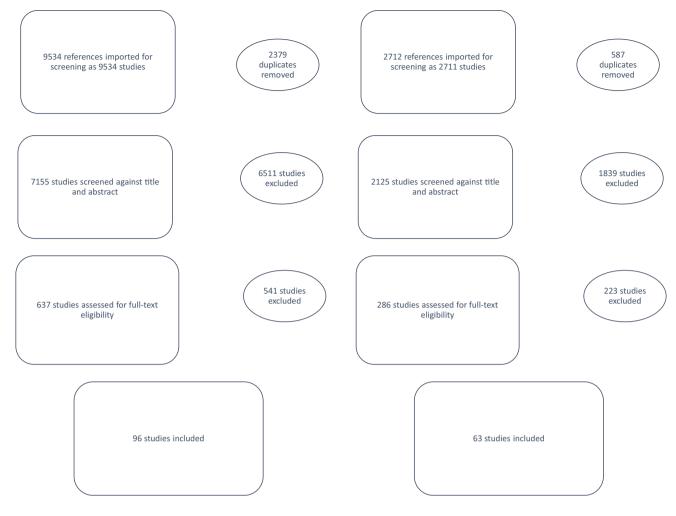


Fig. 1 Preferred Reporting Items for Systematic Reviews and Meta-Analyses diagram for prolapse and examination findings

measuring them when performed by physicians well versed with the standard POP-Q.

**Impact of various parameters on POP examination** When examining a patient with suspected POP, it is critical that the examiner sees and describes the maximal extent of the POP as experienced by the woman. This may be impacted by many variables including the patient's age, parity, body mass index (BMI), position, bladder volume, rectal fullness, the timing of the day of the examination, examination performed at rest or Valsalva/straining, and effect of anesthesia in the case of examination in operating rooms. The correlation of examination findings with these variables was examined separately in nine studies. The conclusions of these are summarized below.

1. Age, parity, and BMI: there is no literature on how any of these impacts the ability of a woman to aid in her examination to identify the bothersome extent of her POP.

Fig. 2 Preferred Reporting Items for Systematic Reviews and Meta-Analyses diagram for lower urinary tract symptoms

- 2. Bladder volume and rectal fullness: the effect of bladder volume on examination of POP was evaluated by two studies [11, 12]. Both concluded that the maximal extent of POP should always be assessed with an empty bladder. This could be because a full bladder does not allow maximal straining and also distorts the anatomy of the vaginal wall, especially of the anterior and central compartments. Similarly, a full rectum may cause confounding of findings by competing for space. One study commented that all patients with POP should be examined with an empty rectum if possible [13]. However, there is a lack of evidence to support this.
- 3. Patient position: there is a lack of standardized recommendations regarding patient position during a POP examination. Three studies examined the effect of patient position on the staging of POP [14–16]. It was found that the severity of POP demonstrated is greater when the examination is done in the upright position on a birthing chair or in the standing position rather than

| Staging system   | Number of studies | Interobserver repeatability | Intersystem agreement<br>with POP-Q | Validity | Simplicity/complexity                                     |
|------------------|-------------------|-----------------------------|-------------------------------------|----------|---|
| Baden–Walker     | 2                 | Moderate (kappa 0.50)       | Fair to moderate                    | +        | -   |
| POP-Q            | 1                 | Good                        | _                                   | +        | Complex   |
| Simplified POP-Q | 3                 | Perfect (kappa 0.87)        | Good                                | +        | Simple  |
| Eye ball POP-Q   | 1                 | Perfect (kappa 0.84)        | Good                                | +        | Simple for physicians<br>well versed in standard<br>POP-Q |

Table 2 Results of studies assessing the different staging systems for pelvic organ prolapse

POP-Q Pelvic Organ Prolapse Quantification

in the supine or lithotomy position. The inter-observer repeatability and correlation with the quality of life scores were also greater for examination findings in the upright position. In cases where the examination is not possible in an upright position, validation of POP-Q in a left lateral position was also assessed and the authors found a high degree of inter-observer reliability of POP-Q findings in this position [12].

- 4. Time of examination: the effect of the time of the day (morning versus afternoon) on POP-Q measurements, was assessed in a prospective observational study on 32 subjects [17]. No correlation was found between time of the day and extent of POP on examination. The authors concluded that for patients complaining of POP extending beyond the hymen there is no need to repeat an examination late in the day to confirm the full extent of prolapse.
- 5. Rest or straining: one study examined the predictive value of GH and Pb measurements obtained at rest and with straining for signs and symptoms of POP[18]. GH and Pb measured on straining were consistently stronger predictors of prolapse symptoms and objective prolapse (by clinician examination and by ultrasound) than at Gh and Pb measured at rest.
- 6. Anesthesia/neuromuscular blockade: the effect of neuromuscular blockade on POP staging was examined by one study [19]. It was found that neuromuscular blockade during anesthesia led to a significant increase in POP-Q measurements, especially in the apical compartment. The authors highlighted that in asymptomatic women with up to stage II POP, the surgical procedure should be limited to that planned preoperatively rather than allowing intraoperative findings to affect surgical management.
- Role of cervical traction in prolapse examination: one study compared the degree of uterine prolapse between POP-Q with cervical traction and POP-Q in the standing position. They also assessed patient-reported pain and acceptability scores between the two examinations [20]. The median point C in the standing position was -4 (-7 to +2) and with cervical traction -0.5 (-3 to +4). Forty

percent reported visual analog scale (VAS) pain scores of  $\geq 5$  under examination with cervical traction. Surprisingly, there was no significant difference in acceptability scores between the groups.

**Relation of POP stage to GH length, Pb, and TVL** Two studies were aimed at describing the relationship between GH and Pb measurements with increasing POP stage [21, 22]. It was found that as the extent of POP increases, GH measurements also increased until stage 4 POP, where mean GH decreased. Also, the POP-Q measurement GH  $\geq$  3.75 cm is highly associated with and predictive of apical vaginal support loss. One study found that measurement of the TVL improved the correlation between the C-point measurement and POP symptoms [23].

Evaluation of pelvic floor muscle function in women with POP Different methods have been used to study the pelvic floor muscle function (PFMF) and its correlation with severity of POP and pelvic symptoms. One study assessed whether POP severity, pelvic symptoms, quality of life, and sexual function differ based on PFMF (assessed by the Brink scale score; Table 3) by re-analyzing preoperative assessments of 317 of the 322 women enrolled in the Colpopexy and Urinary Reduction Efforts (CARE) trial [24]. They found that women with the highest Brink scores (n=75), suggesting enhanced pelvic floor muscle tone, had less advanced POP and smaller GH measurements, than those with the lowest Brink scores (n=56), suggesting weak pelvic floor muscle tone.

Two other studies tested the correlation between the PFMF, using the Oxford grading scale (Table 4), and the severity of POP. In one study 1,037 women were evaluated by assessing the POP-Q and the Oxford assessment of the PFMF. The muscle contraction was graded according to the modified Oxford grading system (Table 4): 0 = no contraction, 1 = flicker, 2 = weak, 3 = moderate, 4 = good, 5 = strong [25]. The levator hiatus (LH) size and GH were measured by digital examination [26]. Severity of POP correlated moderately with GH (r = 0.5, *p*<0.0001) and with LH (transverse r = 0.4, *p*<0.0001; longitudinal r = 0.5, *p*<0.0001), but

| Muscle function dimension   | Score  |
|-----------------------------|--|
| Squeeze pressure            | 1 = None   |
|                             | 2 = Weak squeeze, felt as a flick at various points along the finger surface: not all the way around |
|                             | 3 = Moderate squeeze; felt all the way around the finger surface                                     |
|                             | 4 = Strong squeeze; full circumference of fingers compressed   |
| Muscle contraction duration | 1 = None   |
|                             | 2 = Less than 1 s  |
|                             | 3 = Greater than 1 s but less than 3 s   |
|                             | 4 = Greater than 3 s   |
| Vertical displacement       | 1 = None   |
|                             | 2 = Finger moves anteriorly  |
|                             | 3 = Whole length of finger move anteriorly   |
|                             | 4 = Whole fingers move anteriorly, are gripped, and pulled in  |
| Total                       | Range 3–12   |

 Table 3
 Brink scoring system

weakly with the modified Oxford grading scale (r = 0.16, p < 0.0001). In the second study, it was seen that POP stage had a significant influence on effective involuntary pelvic floor muscle contraction to counteract a sudden increase in intra-abdominal pressure during coughing. Women with POP stages II or more were significantly less able to achieve effective involuntary muscle contraction during coughing (which resulted in stabilization of the perineum; 37.7%) than women without POP (75.2%) [27].

**Neurological examination in women with POP** There are very few data on neurological assessment in patients with POP. In a case–control study, the vaginal and clitoral sensory thresholds were assessed in 66 women with (n=22) and without POP (n=44) using a thermal and vibration Genito-Sensory Analyzer [28]. They found that women with POP exhibited significantly lower sensitivity in the genital area to vibratory and thermal stimuli than women without POP.

Association of spine curvature with POP and bony dimensions of the pelvis Three studies evaluated the relationship of spinal curvature with POP. One study assessed the relationship of spinal curvature and POP, specifically, the loss of lumbar

 Table 4
 Modified
 Oxford
 Grading
 scale
 for
 muscle
 (PFM)
 strength
 Strength</th

| Grading | Description                    |
|---------|--------------------------------|
| 0       | No discernible PFM contraction |
| 1       | Very weak PFM contraction      |
| 2       | Weak PFM contraction           |
| 3       | Moderate PFM contraction       |
| 4       | Good PFM contraction           |
| 5       | Strong PFM contraction         |

lordosis or pronounced thoracic kyphosis in 363 patients with symptomatic POP [29]. They found that patients with abnormal spinal curvature were 3.2 times more likely to develop POP than patients with a normal curvature (odds ratio, 3.18; 95% confidence interval, 1.46 to 6.93; p=0.002) and identified an abnormal change in spinal curvature as a significant risk factor in the development of POP. In the other two studies no differences in the mean T or L spine angles were found between women with and those without POP symptoms ( $p \ge 0.05$ ) and bony dimensions on MRI at the level of the pelvic floor in matched cohorts were similar [30, 31].

#### Examination of different pelvic compartments in POP

Examination of anterior vaginal wall compartment for paravaginal defects With respect to the clinical examination of the anterior vaginal wall defects, using the standardized POP-Q examination and a clinically defined technique for describing the presence of paravaginal defects, right and/or left lateral, central or superior defects have been described. To differentiate a midline or central defect from a paravaginal defect, an index finger or ring forceps must be placed vaginally toward each ischial spine separately. If the prolapse becomes reduced, the woman is clinically diagnosed with a paravaginal defect on that side. In a prospective study, the sensitivity to detect left, right, and bilateral paravaginal defects was reported to be 48%, 40%, and 23.5% respectively, whereas the specificities for each side were 71%, 67%, and 80% respectively compared with intraoperative findings. The overall prevalence of paravaginal defects in patients with at least POP-Q stage II POP of the anterior vaginal wall was 38% [32].

Another study assessed the inter-examiner and intraexaminer reliability of the evaluation of the anterior vaginal wall, including the evaluation of paravaginal defects, using the POP-Q examination and a standardized evaluation of paravaginal defects [33]. The clinical examination of anterior vaginal wall support defects displayed poor inter-examiner and intra-examiner agreement. Overall inter-examiner agreement was 42%, with a kappa of 0.16.

**Correlation of anterior and apical compartment prolapse** The relationship or coexistence of anterior vaginal wall prolapse with apical prolapse was investigated in one study [34]. Women with a POP-Q Point Ba value  $\geq -1$  were retrospectively analyzed for the presence of apical POP defined as POP-Q point C value  $\geq -3$ . The finding of POP-Q stage II or greater anterior vaginal wall prolapse was highly suggestive of clinically significant apical vaginal descent to -3 cm or greater. Furthermore, as the anterior vaginal wall POP-Q stage increased, the predictive value of apical POP increased. In women with POP-Q stage II anterior vaginal wall prolapse there was associated apical descent (defined as POP-Q point C  $\geq -3$ ) in 42%; in stage III anterior vaginal wall POP, apical descent was found in 85%; and in POP-Q stage IV anterior vaginal wall POP it was 100%.

# Examination of the posterior compartment and the need for a rectovaginal examination

Three studies were identified that specifically evaluated the posterior vaginal wall and its relationship to GI dysfunction. A prospective cohort study used a variety of validated questionnaires and standardized examination measures, including Bp, AP, GH, and Pb, transverse GH, Pb at rest, with strain in addition to a "pocket" noted on rectal examination [35]. Inter- and intra-rater reliability for these were assessed by two independent examiners. This study demonstrated the reliability of these measurements of the posterior vaginal compartment and a weak association between obstructed defecation and pelvic organ prolapse.

Another study evaluated the association between defecatory symptoms such as constipation, painful defecation, fecal incontinence, and flatus incontinence and posterior vaginal wall examination using the POP-Q and by defecography [36]. The authors found no association between defecation disorders and posterior wall prolapse (evaluated by POP-Q) or rectocele (assessed by defecography) and that clinical examination missed most enteroceles. They concluded that most anatomical measures of posterior compartment prolapse are reliable and reproducible; however, they do not correlate well with defecatory symptoms.

One study assessed the evaluation of the rectovaginal septum (RVS) using a digital rectal examination [37]. The authors concluded that extending the clinical examination of prolapse to include rectal examination to palpate defects in the RVS may reduce the need for a defecatory proctogram or ultrasound for the assessment of obstructive defection and may help to triage patients in the management

of posterior compartment prolapse. Larger rectoceles were easier to identify and true rectoceles may be best diagnosed by rectal examination.

#### Examination of the apical compartment

Normal values for the apical component of the POP-Q One study assessed normal values for the apical component of the POP-Q (points C, D, and TVL) in asymptomatic women by re-analyzing data from the original 2005 Pelvic Organ Support Study using a data set of 1,011 women [38]. In patients without POP defined as all POP-Q points above the hymenal remnants, they found mean POP-Q values to be: point C (vaginal cuff)  $-7.3 \pm 1.5$  cm, point C (cervix)  $-5.9 \pm 1.5$ , point D -8.7 cm  $\pm 1.5$  cm, TVL (no hysterectomy) 9.8 cm  $\pm 1.3$  cm, and TVL (hysterectomy) 8.9 cm  $\pm 1.5$  cm.

**Clinical evaluation of cervical elongation** A study evaluating 39 consecutive patients who had a preoperative POP-Q and a pathology report that documented the cervical length was performed. The comparison was between estimated cervical length (eCL) on the preoperative POP-Q (by subtracting point D from point C) to the actual cervical length (aCL) reported in the pathology report. The authors found a statistically significant difference between the eCL (mean 5.6  $\pm$  2.91 cm) and the mean aCL (3.2 cm  $\pm$  0.99; *p*<0.0001). However, there was not a statistically significant difference between the eCL (mean 5.6  $\pm$  2.91 cm) and the mean aCL (3.2 cm  $\pm$  0.99; *p*<0.0001). However, there was not a statistically significant difference between the eCL and aCL in patients whose prolapse was proximal to the hymen (3.5  $\pm$  2.21 cm vs 3.1  $\pm$  1.06 cm; *p* = 0.475). The authors concluded that the cervical length measured using POP-Q may not be accurate at more advanced stages of prolapse [39].

Apical descent in the office compared with evaluation in the operating room One study compared the assessment of apical prolapse in the office and assessment in the operating room [40]. The office assessment was conducted using a standard POP-Q examination with measurement at straining. The intraoperative assessment was performed by placing traction on the cervix with a tenaculum. The mean difference in the C point between the two clinical settings was 3.5 cm with a difference of  $\geq 5$  cm in 33% of subjects. Of note, the mean difference was larger for women with lesser stages of prolapse: 5.8 cm at stage 1, 3.0 cm at stage 2, and 1.4 cm at stages 3/4 (p<0.001). A difference of  $\geq$ 5 cm in point C with cervical traction was more commonly noted with lower stages of prolapse; it was noted in 70.3% of women with stage 1 versus only 9.3% of women with stage 2, and 8.5% in women with stage 3 (p < 0.001).

Association of posterior and anterior prolapse with apical support Two studies evaluated the association of anterior and posterior compartment prolapse with apical support. In the first study the authors found that the mean point C location was  $-6.9 \pm 1.5$  (mean  $\pm$  standard deviation) in control patients without POP. In patients with posterior prolapse point C was  $-4.7 \pm 2.7$  cm. In patients with anterior prolapse point C was  $-1.2 \pm 4.1$  cm, p values were <0.001 for all comparisons [41]. The authors concluded that posteriorpredominant prolapse involved threefold less apical descent than in patients with anterior-predominant prolapse. In the second study the authors analyzed 196 subjects and performed a standard POP-Q examination, and then assessed anterior and posterior prolapse in each subject before and following support of the apex using the posterior half of a Graves speculum [42]. Their POP-Q stages before apical support were stage 2 prolapse in 36% of patients, stage 3 in 55%, and stage 4 in 10%. With simulated apical support from the Graves speculum, point Ba changed to stage 0 or 1 in 55% and Bp changed to stage 0 or 1 in 30% (p<0.001 for both). The mean change in Ba with apical support was 3.5  $\pm$  2.6 cm and for point Bp the mean change was 1.9  $\pm$  2.9 cm (p<0.001). These findings suggest a greater relationship between the anterior vaginal wall and apical prolapse.

**Summary of clinical examination of a woman with POP** The clinical evaluation of a patient suspected of having POP by presenting symptoms should start with a thorough pelvic examination. The POP-Q system is the most studied POP classification system for describing and quantifying POP. It should be used clinically in settings where clinicians have extensive experience and comfort in its use. In clinicians with extensive experience, POP-Q values can often be reliably and adequately obtained by "eyeballing." The POP-Q should be used in all research settings. In settings that do not have extensive experience with the POP-Q, or in settings that find it cumbersome to use, substituting the S-POP is acceptable as a means of describing and quantifying POP. The use of other systems currently in the literature should be discouraged unless more literature is published demonstrating their utility.

To optimally perform a physical examination on a patient with suspected POP several parameters should be met:

- 1. The subject should have an empty bladder (and empty rectum, if possible.
- 2. If the subject cannot confirm the extent of their POP by examination in the supine or left lateral position, the examination should be repeated in a more upright or standing position.
- 3. The time of day of the examination is not important in most cases.
- 4. The examination should be done during straining or coughing.
- 5. Cervical traction or examination under the effects of a neuromuscular blockade may overstate the degree of apical POP and should not be relied upon.

Other parameters of a thorough pelvic examination and imaging for pelvic anatomy are less well investigated but may provide some clinical assistance in planning therapy.

- Noting the dimensions of the GH or vaginal introitus plays a role in the evaluation of a patient with POP. A large GH as documented by a POP-Q examination ≥ 3.75 cm is associated with greater degrees of POP. Understanding what information this provides to the clinician in staging and quantifying POP is less clear and requires more study. Of note, recording the size of the GH is part of the POP-Q but not the S-POP.
- 2. A greater pelvic floor muscle contraction strength has been associated with less severe POP by both POP-Q examination and various POP symptom scores. In addition, patients with POP appear to have some degree of neurological deficit in other pelvic structures. Therefore, evaluating and recording pelvic floor muscle contraction strength and the presence or absence of neurological deficits, although encouraged, does not currently play a recognized role in the evaluation or quantification of POP.
- 3. Evaluation of the spine in patients with POP may lead to better understanding of the epidemiology and pathophysiology of POP but does not play any specific role in the evaluation of patients with POP.
- 4. Clinical examination to identify and characterize sitespecific defect of the anterior vaginal wall prolapse has not been studied enough to draw robust conclusions. However, although reporting these clinical findings may aid the individual surgeon in preoperative planning, is too nonspecific for widespread adoption into current clinical grading schemes.
- 5. Evaluation of posterior vaginal wall prolapse can be complemented by a rectovaginal examination as there is evidence that it can help to distinguish between true rectoceles and enteroceles. There is poor correlation between posterior vaginal prolapse by clinical examination and GI dysfunction.
- Evaluation and grading of apical (cervical/vaginal vault) 6. POP is complex and currently there is very little information from which to draw clinically relevant information. It appears that in normal subjects the cervix (POP-Q point C) is 4.5 to 7.5 cm above the hymenal remnants, the posterior vaginal fornix (POP-Q point D) is 7 to 10 cm above the hymenal remnants, and in hysterectomized patients the vaginal cuff (POP-Q point C in hysterectomized patients) is 6 to 8.5 cm above the hymen. The TVL in patients with a uterus is 8.5 to 11 cm and in hysterectomized patients it is 7.5 to 10.5 cm. The determination of a cut-off point beyond which apical values represent true POP or clinical symptomatic disease is unknown although any compartment prolapse at or beyond the hymen is more likely to be symptomatic.

- 7. Repeating a POP-Q examination under anesthesia often overestimates apical prolapse and although useful for surgical planning, currently should not be recommended. It is not known whether there is a long-term prognostic value for this apical assessment.
- Using a tenaculum to provide traction on the cervix in the clinical setting can overestimate uterine prolapse, is deemed uncomfortable by patients, and therefore should be discouraged.

# **Further research**

- 1. Future research needs to determine the predictive value of a large GH as a sign of impending POP that may require prophylactic therapeutic measures. Further, is a large GH a risk factor for POP or a side effect of having the vaginal bulge protruding through and physically dilating the vaginal opening?
- 2. Future research on what represents true uterine or vaginal vault prolapse is critical. There are some data on the normal range of values for POP-Q points C and D. However, what is not known is if patients with POP-Q point C and D values below these ranges but still above the hymenal remnants have a type of POP that requires therapeutic measures, particularly if that patient is undergoing surgery to correct anterior or posterior vaginal wall prolapse.
- 3. If a paravaginal defect is detected what is the role of anterior vaginal repair? To what degree does a paravaginal defect contribute to anterior vaginal wall recurrence?
- 4. Further study on how physical examination under the effects of neuromuscular blockade (anesthesia) affects future outcomes. For example, if a subject has significant cervical or apical POP identified in the operating room that was not noted during clinical physical examination, are they at a greater risk of future apical POP, particularly if nothing is done to address this apparent apical defect at the time of surgery for another form of POP?
- 5. Future research should better define the role of weak pelvic floor muscle tone or contraction strength as a predictor of the subsequent development of POP. A complete discussion of the role of pelvic floor muscle strength training and its role in treating POP will be included under another report in the IUC that has been published as part of this series entitled "International Urogynecology Consultation chapter 3 committee 2; conservative treatment of patients with pelvic organ prolapse: pelvic floor muscle training" [43].

# Assessment of lower urinary tract function in women with POP

A review of the existing literature on the assessment of lower urinary tract function in women with POP was performed. The initial search identified 2,711 titles and abstracts, of 2665

which 63 studies were included in the final review of this section (Fig. 2).

This section is presented in three sub-sections: the assessment of voiding dysfunction, assessment of detrusor overactivity (DO), and assessment of stress urinary incontinence (SUI).

#### Assessment of voiding dysfunction in women with POP

The prevalence of voiding dysfunction in women with prolapse varies depending on the definition but ranges from 6 to 60%. Assessment of voiding difficulty in women with prolapse was addressed in 11 papers. Six papers had voiding difficulty as the focus [44–49], 4 papers addressed voiding difficulty as part of LUTS assessment [50–53], and 1 paper addressed the accuracy of ultrasound in measuring bladder volume [54]. Six themes were identified in these studies.

**Post-void residual urine volume** Post-void residual urine volume (PVR) was the most utilized measure to define voiding dysfunction in the studies reviewed; however, there was no agreement on the cut-off value at which retention was diagnosed ranging from 50 to 200 ml, as shown in Table 5.

To find a cut-off value for PVR that could predict postoperative voiding trial results more accurately than a predetermined value of 100 ml, one study used a receiver operating curve, but no PVR value was better than 100 ml (the predetermined value used in the study) [49].

The accuracy of translabial ultrasound scan formulae used for PVR measurement in patients with prolapse was examined in one paper [54]. It found that the results obtained by the three published formulae correlated with the cathetermeasured PVR.

**Urine flow studies** These included free-flow studies (noninstrumented flow studies) and pressure-flow studies (instrumented urodynamic flow studies). Different measurements were used to define voiding dysfunction, as shown in Table 5.

One study [46] examined the correlation between freeflow and pressure-flow studies. It concluded that the peak and average flow rates in women with POP are dependent on voided volume and the correlation between free-flow and pressure-flow studies decreases as the prolapse stage increases.

**Detrusor contractility measures** The concept of detrusor underactivity was addressed in two papers [45, 50] to predict the potential course of postoperative voiding difficulty. The Bladder Contractility Index (BCI), as defined by Abrams [55], was used in one paper [45]. BCI <100 was associated with higher PVR and a more severe stage of prolapse, but it failed to predict postoperative resolution of voiding difficulty. The second study [50] used a six-class grading of detrusor contractility based on Schafer's nomograms [56].

Table 5Measures for theassessment of voiding difficulty

|  | Number of studies | Reference numbers of the studies |
|--|-------------------|----------------------------------|
| Post void residual volume                    | 10                |                                  |
| >50 ml                                       | 1                 | (46)                             |
| >100 ml                                      | 6                 | (39, 41, 43–48, 47)              |
| >150 ml                                      | 1                 | (38)                             |
| >200 ml                                      | 1                 | (42)                             |
| >25% of total bladder volume                 | 1                 | (40)                             |
| Urin flow studies                            |                   |                                  |
| Q max  | 4                 |                                  |
| <12 ml/s                                     | 1                 | (47)                             |
| <15 ml/s                                     | 3                 | (38, 42, 45)                     |
| Bladder outlet obstruction                   |                   |                                  |
| Pdet Max >40 cm $H_2O$                       | 1                 | (45)                             |
| Pdet Qmax >20 cm $H_2O$ with Qmax <12        | 1                 | (47)                             |
| Detrusor underactivity                       |                   |                                  |
| Bladder Contractility Index                  | 1                 | (39)                             |
| Schafer's grading                            | 1                 | (50)                             |
| Pdet Max <10 cm H <sub>2</sub> O             | 1                 | (42)                             |
| Prolapse reduction during voiding assessment | 3                 | (41, 42, 46)                     |

*Qmax* maximum flow rate, *Pdet Max* maximum detrusor pressure as measured during pressure flow studies, *Pdet Qmax* pressure detrusor at maximum flow rate, *DU* detrusor underactivity

They reported women with weak detrusor contractility having increased PVR in the immediate postoperative period, with resolution after 1 month.

**Bladder trabeculation on cystoscopy** One study addressed the cystoscopic finding of trabeculation in women with POP. Trabeculations were scored from 0 to 4, representing increasing severity from none, slight, moderate, severe, and severe with diverticula. They reported significantly higher prevalence of symptoms of voiding difficulty and increased PVR (>100 ml) in women with any degree of trabeculations compared with women with no trabeculations [53].

**Prolapse reduction in assessing voiding dysfunction** Prolapse reduction using a pessary or gauze pack was used to assess the impact of prolapse on voiding difficulty in three papers [47, 48, 52]. One study used pessary reduction of prolapse to predict postoperative resolution of voiding difficulties [47]. Authors reported that the resolution of voiding difficulty with pessary reduction of prolapse has 89% sensitivity and 80% specificity in predicting post-repair resolution [47]. In another study, pessary reduction of prolapse was used routinely in all patients while performing urodynamics [48] to assess voiding dysfunction and occult SUI. This resulted in the diagnosis of voiding dysfunction defined as post-void residual of >50 ml or 20% of voided volume in 27%, which reduced to 10% postoperatively. The authors did not test the value of pessary in predicting postoperative

voiding dysfunction. The third study used vaginal packing for prolapse reduction and found that PVR decreased significantly after vaginal packing [52].

**Risk factors for postoperative voiding dysfunction** Five studies looked at the assessment of potential risk factors to predict postoperative persistence of voiding dysfunction [45, 47–50]. In two studies, no potential risk factors were found [45, 50]. Three papers reported various potential risk factors to include history of diabetes, PVR >200 ml and detrusor pressure at maximum flow (Pdet Max) <10 cm H<sub>2</sub>O, all of which were found to have some impact on postoperative voiding dysfunction [48]. Persistence of voiding difficulty after pessary reduction of prolapse was associated with a 67% chance of persistent postoperative voiding difficulty [47]. Patient age was reported as the only risk factor for postoperative elevated PVR [49].

#### Assessment for detrusor overactivity in patients with POP

The effect of POP on detrusor overactivity (DO) was addressed in ten papers [50–53, 57–62]. Table 6 demonstrates the measures used to assess DO, the aim of assessment, and the use of prolapse reduction.

Assessment methods for DO Urodynamic assessment [50–55] trabeculation on cystoscopy [53] and artificial neural network analysis of clinical assessment [62] were used to assess for DO. However, even when other methods of

| Table 6Studies addressingdetrusor overactivity (DO)in patients with pelvic organ |   | Number of studies | Reference numbers of the studies |
|--|---|-------------------|----------------------------------|
| prolapse (POP)   | Method of assessing for DO                              |                   |                                  |
|  | Urodynamics (cystometry)                                | 8                 | (44-46, 51-55)                   |
|  | Trabeculations on cystoscopy                            | 1                 | (47)                             |
|  | Artificial neural network analysis                      | 1                 | (56)                             |
|  | Aim of assessing for DO <sup>a</sup>                    |                   |                                  |
|  | Assessment for DO as co-morbidity with POP              | 3                 | (46, 47, 56)                     |
|  | Assessing the value of urodynamics in patients with POP | 5                 | (44, 45, 52, 53, 55)             |
|  | Assessment for risk factors predicting DO post-repair   | 3                 | (44, 51, 54)                     |
|  | Prolapse reduction during assessment                    | 2                 | (46, 54)                         |

<sup>a</sup>Some papers had more than one aim and were included in more than one group

assessment of DO were used, urodynamic assessment was carried out as the gold standard for comparison, despite no evidence that urodynamics are the gold standard.

The importance of urodynamic studies in the assessment of DO in patients with POP Five studies were designed to evaluate the role of preoperative urodynamic assessment of DO (uninhibited detrusor contractions on a cystometrogram) in women with POP. Two studies examined the impact of urodynamic assessment on changing patient management [58, 59]. Two other studies examined the role of urodynamic assessment in predicting postoperative DO [50, 61] whereas the last study focused on the role of urodynamic assessment in diagnosing asymptomatic DO [51]. Not surprisingly, they came to different conclusions regarding the importance of preoperative urodynamic assessment in women with POP and two of the three found no benefit of urodynamic assessment in the preoperative evaluation of patients with POP.

Predicting post-repair overactive bladder Three papers considered the preoperative risk factors for persistent or de novo overactive bladder (OAB; symptom of urinary frequency and urgency with or without the complaint of urgency incontinence) following surgical repair. Two studies used symptoms to assess for postoperative OAB [50, 57], one used urodynamic assessment post-operatively to assess for DO [60]. Pre-operative DO was not predictive of post-repair OAB or DO; however, one study found that preoperative OAB symptoms are more likely to resolve in the absence of preoperative DO [50].

# Summary: assessment of voiding dysfunction in women with **POP** Voiding dysfunction in patients with POP is common but evaluation techniques provide limited information.

1. The post-void residual volume estimation is commonly used for assessment of voiding dysfunction. The most commonly used value for diagnosing an elevated postvoid residual is 100 ml by catheter or ultrasound.

- 2. Severity of POP is associated with reduced maximum and average flow rate, and voiding dysfunction is associated with the cystoscopic finding of trabeculation; however, there is no demonstrated benefit for using any of these methods in the routine assessment of the patient with POP.
- 3. Reduction of POP by pessary or packing often resolves voiding dysfunction and if this is noted on evaluation, it has a high predictive value for resolution of voiding difficulty after surgical POP repair.
- 4. Postoperative persistence of voiding dysfunction was found to be associated with diabetes, age, PVR >200 ml, P det max <10 and failure of a pessary to resolve voiding difficulty.
- 5. Preoperative urodynamic assessment was the most commonly utilized diagnostic tool for DO. Preoperative urodynamic diagnosis of DO did not change management, but the absence of preoperative urodynamic DO suggests that symptoms of OAB are more likely to resolve after surgery.

# Further research

- 1. Further research is needed in the development of predictive models for persistence of voiding difficulty or DO postoperatively to aid in patient counseling.
- 2. Understanding how varying degrees of POP and how prolapse of different compartments affects voiding is poorly understood and needs further research.
- 3. Further study to assess the effect of voiding dysfunction on the patient both from a symptomatic and a morbidity perspective (recurrent UTIs, upper urinary tract disease) is not currently well understood

# Assessment for SUI in women with POP

A substantial proportion of women presenting with POP report SUI symptoms. Preoperative SUI can either resolve or persist after POP surgery. Furthermore, a significant proportion of preoperatively continent women develop de novo SUI after POP surgery. SUI was addressed, either exclusively or as part of LUTS assessment, in 47 papers. Three main themes were identified: assessment of preoperative SUI, prediction of postoperative SUI, and prediction of de novo SUI.

# Assessment of preoperative SUI

- 1. Stress test: the significance of patient position and prolapse reduction during the cough stress test was demonstrated in a study performed on 297 women waitlisted for POP surgery, with a third of them reporting SUI symptoms. Five different cough stress tests were performed with a subjectively full bladder (standing, semilithotomy, with and without reduction, reduction with speculum, and pessary). The test with the fewest positive results (34%) was the one performed without POP reduction in a semi-lithotomy position; the test with the most positive results (80%) was the one performed with pessary reduction in a semi-lithotomy position. With the full battery of tests, 93% of women with SUI symptoms demonstrated leakage; only 50% demonstrated leakage without reduction. Eighty-nine percent of the women with a positive stress test were diagnosed when performing at least two of the three tests with prolapse reduction, and 98% were diagnosed when performing all three tests with prolapse reduction (speculum and pessary reduction in the semi-lithotomy position, pessary reduction in the standing position). The authors also emphasized the importance of adequate bladder volume (200 ml) [63]. The findings were not compared with postoperative outcomes.
- 2. Q-tip angle: one study concluded that the Q-tip test is affected by POP. The angles were smaller with the prolapse reduced and with a full bladder [64]. A substantial correlation (r=0.68) between POP-Q point Aa and Q-tip angle was noted in a study on women presenting predominantly with SUI and anterior wall prolapse [65].
- 3. Importance of urodynamic studies in the assessment of preoperative SUI: one study concluded that a computer-based model including preoperative symptoms and patient's baseline characteristics cannot predict preoperative urodynamic diagnosis and, as a consequence, cannot replace a preoperative urodynamic study [62]. In another retrospective study, preoperative urodynamic testing in patients with POP changed the management or counseling in only 3% (11 out of 316) in a cohort of women, with the indication for the study being OAB symptoms, mixed, or insensible urinary incontinence, or voiding difficulty (i.e., not occult SUI evaluation only). Major management alterations occurred mostly in women with SUI and concurrent voiding difficulty.

The authors inferred that it might be in these patients that preoperative urodynamic study has its greatest value [58]. These two studies did not correlate the preoperative examination with postoperative outcomes.

**Prediction of postoperative SUI** Postoperative SUI can represent persistent or de novo SUI. In this section, some studies approached postoperative SUI as persistent SUI [66] specifically, whereas some studies included women with any preoperative continence status and their results on postoperative SUI include both persistent and de novo SUI. De novo SUI specifically is addressed separately in the following section.

- Predictive value of preoperative stress test: five studies provided data to calculate the predictive value of a negative stress test during preoperative urodynamic study for postoperative SUI in an unselected POP population (i.e., any preoperative continence status) [67–70]. All studies included stress tests with prolapse reduction. The negative predictive value ranged between 45 and 90% (median 78%; Table 7).
- 2. Other predictors for postoperative SUI:

Three studies looked at other predictors of postoperative SUI. One study included only women with preoperative urodynamic SUI and the predictive urodynamic parameters for persisting urodynamic stress incontinence were overt (versus occult) urodynamic SUI, below normal maximum urethral closure pressure (MUCP, defined by the authors as <60 mmHg), and functional urethral length (FUL) < 2 cm [71].

Two further studies included all women, regardless of preoperative incontinence status. The only two urodynamic parameters predictive of postoperative SUI in the one study were preoperative urodynamic stress incontinence and low P det Max [72]. In the other study, none of the investigated urodynamic parameters was associated with postoperative SUI [61].

**Prediction model for postoperative SUI** A model developed to predict postoperative SUI for women regardless of preoperative continence status considers subjective urinary incontinence symptoms, stress test with and without prolapse reduction, age, point Ba, vaginal parity, and insertion of a mid-urethral sling during surgery [73]. The strongest predictor for postoperative SUI was preoperative SUI. The model's ability to discriminate women at low or high risk for bothersome postoperative SUI or treatment for SUI during the first postoperative year was at a "useful level" (defined as area under the curve 0.76; interpretation: 0.5 not better than chance—1 perfect discrimination). However, the study does not report the extent to which the model correctly estimates the absolute risk (i.e., calibration), making it difficult to use it in counseling International Urogynecology Journal (2023) 34:2657–2688

Table 7 Predictive value of a negative preoperative stress test for postoperative stress urinary incontinence after pelvic organ prolapse surgery

| Reference              | Type of<br>surgery | Study design  | Follow-up<br>(months) | Baseline<br>continence | n <sup>a</sup> | Preoperative<br>test  | Postoperative SUI<br>outcome  | Rate of<br>postoperative<br>SUI after a<br>negative test,<br>n (%) | NPV <sup>b</sup> % |
|------------------------|--------------------|---------------|-----------------------|------------------------|----------------|---|---|--|--------------------|
| Alas et al. [67]       | Any                | Retrospective | Median 53             | Any                    | 274            | UDS up to<br>capacity with<br>and without<br>reduction<br>(speculum)                          | Subjective (non-<br>validated) or<br>objective SUI<br>(not specified)                               | 27/274 (10)  | 90                 |
| Jeon et al. [68]       | SCP                | Prospective   | 24                    | Any                    | 112            | UDS up to<br>capacity with<br>reduction<br>(swab)   | Bothersome<br>subjective SUI<br>(UDI-6) or objec-<br>tive SUI (CST)<br>or additional SUI<br>surgery | 32/112 (29)  | 71                 |
| Kasturi et al.<br>[69] | TVM                | Retrospective | 6                     | Any                    | 60             | UDS with<br>reduction<br>(speculum or<br>pessary)   | Subjective (non-<br>validated) and<br>objective SUI<br>(CST or UDS)                                 | 15/60 (25)   | 75                 |
| Leruth et al. [66]     | SCP                | Retrospective | Mean 25               | Any                    | 55             | Stress test at capacity with  | Subjective SUI (nonvalidated)   | 30/55 (55)   | 45                 |
|                        |                    |               |                       |                        |                | and without<br>reduction<br>(manual) and<br>UDS up to<br>capacity with<br>reduction<br>(swab) | Need for sling<br>surgery   | 9/55 (16)  | 84                 |
| Park et al. [70]       | SCP                | Retrospective | Mean 11               | Any                    | 70             | UDS up to<br>capacity with<br>reduction<br>(pessary or<br>speculum)                           | Need for SUI<br>surgery   | 13/70 (19)   | 81                 |

SUI stress urinary incontinence, NPV negative predictive value, UDS urodynamic study, SCP sacrocolpopexy, CST cough stress test, TVM transvaginal mesh, UDI-6 Urinary Distress Inventory Short Form

<sup>a</sup>Only women without concomitant anti-incontinence surgery included

<sup>b</sup>Negative predictive value calculated based on numbers provided in the original studies

patients regarding operative options. Furthermore, our search did not identify any external validation studies for the model.

**Prediction of postoperative SUI (occult SUI)** Occult SUI is defined as urine loss observed during a cough stress test with the POP reduced in a patient with POP who reports no urinary incontinence [74]. It is used as a preoperative test with the intention to identify women at risk of developing de novo SUI after prolapse surgery. Table 8 summarizes the studies that address the predictive value of occult SUI for de novo SUI.

Twenty-five studies provided either the diagnostic accuracy measures or data enabling the calculation for positive and/or negative test [50, 67, 75–97]. Baseline continence status, diagnostic criteria for occult SUI, methods to reduce the prolapse, surgical procedures, and the definition of de novo SUI varied widely among the studies, making the comparison challenging. Most studies defined occult SUI clearly as

SUI demonstrated only during prolapse reduction, whereas some also included demonstrable urodynamic SUI without prolapse reduction in symptomatically continent women. The diagnostic accuracy of occult SUI differed greatly, likely because of the heterogeneity in the studies. The medians (and ranges) for sensitivity were 39% (5–100), for specificity they were 86% (57–97), for positive predictive value they were 91% (51–100).

**Importance of urodynamic studies for diagnosis of occult SUI** One study reported similar occult SUI rates with stress testing during physical examination and urodynamic studies. In 76%, occult SUI was identified with both tests, in 11% with urodynamic studies only, and in 13% during physical examination only (kappa 0.648). They did not correlate the findings with postoperative de novo SUI rates [98].

| Reference                     | Type of POP | Study design          | Follow-up | Baseline  | n <sup>a</sup> | Test for OSUI  | Definition of de  | Rate of de novo SUI     | 'o SUI                 | Sensitivity, | , Specificity, PPV, % NPV, % | PPV, % | NPV, % |
|-------------------------------|-------------|-----------------------|-----------|---|----------------|--|---|-------------------------|------------------------|--------------|------------------------------|--------|--------|
|                               | surgery     |                       | (months)  | continence  |                |  | novo SUI  | Test positive,<br>n (%) | Test negative, $n$ (%) |              | %                            |        |        |
| Alas et al. [67]              | Any         | Retrospective ]       | Median 53 | No subjective<br>(nonvalidated) or<br>objective SUI (stress<br>test, UDS) | 210            | UDS up to capacity;<br>reduction with<br>speculum                                | Subjective<br>(nonvalidated)<br>or objective SUI<br>(not specified)                 | N/A                     | 12/210 (4)             | N/A          | N/A                          | N/A    | 94     |
| Araki et al.<br>[ <b>50</b> ] | TVM         | Retrospective         | 6         | No subjective SUI<br>(ICIQ-UI + pad                                       | 62             | CST at 300 ml;<br>reduction with   | SUI symptoms + pad usage  | 8/13 (62)               | 2/49 (4)               | 80           | 90                           | 62     | 96     |
|                               |             |                       |           | usage)  |                | gauze pack or<br>pessary   | Need for SUI<br>surgery   | 3/13 (23)               | 0/49 (0)               | 100          | 83                           | 23     | 100    |
| Ballert et al.<br>[75]        | Any vaginal | Retrospective Mean 17 | Mean 17   | No subjective (non-<br>validated) or objective<br>SUI (UDS)               | 24             | UDS up to capacity;<br>reduction with<br>pessary or vaginal<br>pack              | Need for interven-<br>tion for SUI  | N/A                     | 2/24 (8)               | N/A          | N/A                          | N/A    | 92     |
| Costantini et al.<br>[76]     | SCP         | RCT                   | 9         | No subjective (UDI)<br>or objective SUI<br>(stress test, UDS)             | 32             | Stress test with full<br>bladder; reduction<br>both with fingers<br>and speculum | Subjective (UDI)<br>+ objective SUI<br>(stress test)                                | N/A                     | 3/32 (9)               | N/A          | A/A                          | N/A    | 91     |
| Ellström Engh<br>et al. [77]  | Vaginal NTR | Prospective           | 12        | No subjective<br>(nonvalidated) or<br>objective SUI                       | 74             | CST at 300 ml;<br>reduction with<br>speculum                                     | Subjective SUI<br>(nonvalidated)  | 3/7 (43)                | 5/67 (7)               | 38           | 94                           | 43     | 93     |
|                               |             |                       |           |   |                | Quantification test<br>and 48-h pad test;<br>reduction with<br>pessary           | Subjective SUI<br>(nonvalidated)  | 2/6 (33)                | 6/68 (9)               | 25           | 94                           | 33     | 91     |
| Ennemoser<br>et al. [78]      | Any vaginal | Retrospective Mean 68 | Mean 68   | No objective SUI<br>(CST)   | 57             | Stress test at 300 ml<br>sitting and standing;<br>reduction with<br>speculum     | Subjective (non-<br>validated) and/<br>or objective and/<br>or treatment for<br>SUI | 16/57 (28)              | N/A                    | N/A          | N/A                          | 28     | N/A    |
|                               |             |                       |           |   |                |  | Need for SUI<br>surgery   | 3/57 (5)                | N/A                    | N/A          | N/A                          | S      | N/A    |
| Goessens et al.<br>[79]       | Vaginal NTR | Retrospective         | 7         | No bothersome<br>subjective SUI<br>(nonvalidated)                         | 132            | Subjective SUI (non-<br>validated) revealed<br>during ring pessary<br>home test  | Bothersome<br>subjective SUI<br>(nonvalidated)<br>warranting<br>treatment           | N/A                     | 12/132 (9)             | N/A          | N/A                          | N/A    | 91     |
| Hafidh et al.<br>[80]         | Vaginal NTR | Retrospective         | 12        | No subjective (non-<br>validated) or objective<br>SUI (UDS)               | 52             | UDS; reduction with pessary/sponge stick   | Subjective SUI<br>warranting any<br>treatment                                       | N/A                     | 2/52 (4)               | N/A          | N/A                          | N/A    | 96     |
| Karateke et al.<br>[81]       | Vaginal NTR | Retrospective         | 20        | No subjective SUI<br>(UDI-6)  | 54             | UDS up to 200 ml;<br>reduction with<br>two ring forceps<br>bilaterally           | Objective SUI<br>(UDS)  | N/A                     | 8/54 (15)              | N/A          | N/A                          | N/A    | 85     |

| Table 8 (continued)                     | inued)  |               |             |  |                |   |  |                          |                          |              |                       |          |          |
|---|---|---------------|-------------|--|----------------|---|--|--------------------------|--------------------------|--------------|-----------------------|----------|----------|
| Reference                               | Type of POP                                     | Study design  | Follow-up   | Baseline   | n <sup>a</sup> | Test for OSUI   | Definition of de   | Rate of de novo SUI      | /o SUI                   | Sensitivity, | , Specificity, PPV, % | PPV, %   | NPV, %   |
|   | surger y  |               | (similoini) | contractor   |                |   | 100 0001   | Test positive, $n$ (%)   | Test negative,<br>n (%)  |              | 9/                    |          |          |
| Kleeman et al.<br>[82]                  | Vaginal NTR                                     | Retrospective | Mean 5      | No subjective SUI<br>(UDI)   | 53             | CST, retrograde filling<br>to subjectively full<br>bladder, reduction<br>with speculum                              | Subjective SUI<br>(not specified)                                  | N/A                      | 1/53 (2)                 | N/A          | N/A                   | N/A      | 86       |
| Klutke and<br>Ramos [83]                | Vaginal NTR                                     | Retrospective | Mean 42     | No subjective SUI<br>(nonvalidated)                                    | 20             | UDS up to capacity;<br>reduction with<br>Gellhorn pessary   | Subjective (non-<br>validated) and<br>objective SUI<br>(UDS)       | N/A                      | 0/20 (0)                 | N/A          | N/A                   | N/A      | 100      |
| Liang et al.<br>[84]                    | Vaginal NTR                                     | Prospective   | 3–6         | No subjective SUI<br>(nonvalidated)                                    | 47             | UDS up to capacity;<br>reduction with<br>pessary  | Subjective SUI<br>(nonvalidated)                                   | 11/17 (65)               | 0/30 (0)                 | 100          | 83                    | 65       | 100      |
| Manodoro et al. Vaginal NTR<br>[85]     | Vaginal NTR                                     | Retrospective | Mean 18     | No subjective SUI<br>(nonvalidated)                                    | 120            | UDS up to capacity;<br>reduction with ring<br>pessary   | Objective SUI<br>(CST) or need<br>for SUI surgery                  | 10/43 (23)               | 15/77 (19)               | 40           | 65                    | 23       | 81       |
|   |   |               |             |  |                |   | Need for SUI<br>surgery  | 0/43 (0)                 | (0) 1/10                 | N/A          | 64                    | 0        | 100      |
| Misraï et al.<br>[86]                   | SCP   | Retrospective | Mean 20     | No subjective (non-<br>validated) or objective<br>SUI (UDS)            | 53             | UDS; reduction with<br>sponge-holding<br>forceps  | Objective SUI<br>(not specified)<br>+ pad usage                    | N/A                      | 7/53 (13)                | N/A          | N/A                   | N/A      | 87       |
| Reena et al.<br>[87]                    | Vaginal NTR                                     | Prospective   | 1.5         | No subjective<br>(nonvalidated) or<br>objective SUI (not<br>specified) | 78             | Pyridium pad test;<br>reduction with ring<br>pessary  | Objective SUI<br>(not specified)                                   | 34/53 (64)               | 0/25 (0)                 | 100          | 57                    | 64       | 100      |
| Schierlitz et al.<br>[88]               | Vaginal NTR or RCT<br>SCP                       | RCT           | Q           | No subjective SUI<br>(nonvalidated)                                    | 39             | UDS up to capacity;<br>stress test with or<br>without reduction;<br>reduction with<br>speculum or opened<br>forceps | Need for SUI<br>surgery  | 3/39 (8)                 | N/A                      | N/A          | N/A                   | ×        | A/A      |
| Sierra et al.<br>[89]                   | Any including<br>anterior/apical<br>compartment | Retrospective | 9           | No objective SUI on<br>clinical examination                            | 76             | UDS up to capacity;<br>reduction with ring<br>pessary, speculum,<br>or scopette                                     | Subjective SUI<br>(nonvalidated)                                   | N/A                      | 2/97 (2)                 | N/A          | N/A                   | N/A      | 98       |
| Song et al. [90]                        | Vaginal NTR                                     | Prospective   | Q           | No subjective<br>(nonvalidated) or<br>objective SUI (CST)              | 206            | Stress test with full<br>bladder and 1-h pad<br>test; reduction with<br>ring pessary                                | Subjective SUI<br>(UDI-6, IIQ-7)<br>Need for SUI<br>surgery        | 18/45 (40)<br>10/45 (22) | 30/161 (19)<br>3/161 (2) | 38<br>77     | 83<br>82              | 40<br>22 | 81<br>98 |
| Srikrishna et al. Not specified<br>[91] | Not specified                                   | Prospective   | 24          | No objective SUI<br>(video-urodynamics)                                | 48             | Video-urodynamics<br>up to capacity;<br>reduction with ring<br>pessary  | Subjective<br>SUJ (KHQ)<br>confirmed<br>with video-<br>urodynamics | 2/5 (40)                 | 1/43 (2)                 | 67           | 93                    | 40       | 98       |

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| Bindentity from the problem of the problem | Table 8 (continued)          | tinued)     |              |           |   |                  |  |   |                         |                        |              |    |        |        |
|--|------------------------------|-------------|--------------|-----------|---|------------------|--|---|-------------------------|------------------------|--------------|----|--------|--------|
| matry         matry <t< td=""><td>Reference</td><td>Type of POP</td><td>Study design</td><td>Follow-up</td><td></td><td>n<sup>a</sup></td><td></td><td>Definition of de</td><td>Rate of de nov</td><td>o SUI</td><td>Sensitivity,</td><td></td><td>PPV, %</td><td>NPV, %</td></t<>   | Reference                    | Type of POP | Study design | Follow-up |   | n <sup>a</sup>   |  | Definition of de  | Rate of de nov          | o SUI                  | Sensitivity, |    | PPV, % | NPV, % |
| Way         Froperior         Manual control   |                              | surgery     |              | (suniom)  | conunence   |                  |  | 10.6 0/01   | Test positive,<br>n (%) | Test negative, $n$ (%) | 9,           | 9, |        |        |
| Any vgluid         RCT         1,2         Compaction SULCSD         1,3         Resurp relation at<br>300 and         1,3         Resurp relation at<br>300 and         1,3         Resurp relation at<br>300 and         1,3         1,3         9         9         9         9         2           Any vgluid         RCT         1,2         Subjective SUL         1,3   | Svenningsen<br>et al. [92]   | Any         | Prospective  | Mean 5    | No subjective (not<br>specified) or   | 137              |  | Subjective SUI<br>(validated)   | (40)                    | (16)                   | 6            | 76 | 40     | 84     |
| $ \label{eq:relations} \mbox{An vagial} k r \ k \ k \ k \ k \ k \ k \ k \ k \ k$   |                              |             |              |           | objective SUI (CST)   | 135              | Pessary reduction at<br>100 ml   |   | (22)                    | (17)                   | 6            | 94 | 22     | 83     |
| Any vaginal<br>Any vaginalRCT12Subjective SU1<br>and no objective<br>and no objective<br>sU123244771298471297129Any vaginalRCT12Subjective SU1<br>and no objective<br>and no objective<br>sU1R411/135 (8)12121332Any vaginalRCT12Subjective SU1<br>and no objective<br>sU1R410110311/135 (8)121220Any vaginalRCT12Subjective SU1<br>and no objective<br>subjective<br>to and no objective<br>  |                              |             |              |           |   | 107              | Pessary reduction at 300 ml  |   | (50)                    | (13)                   | 28           | 94 | 50     | 87     |
| Any vaginal<br>Any vaginalRCT12Subjective SUL<br>maximum oncoverset24Any of the above<br>and no obtive<br>control many non-control many non-contro many non-control many non-contr   |                              |             |              |           |   | 62               | Pessary 1 week   |   | (47)                    | (11)                   | 50           | 88 | 47     | 89     |
| Any vaginal         RCT         12         Subjective SUI<br>and non-molecked<br>and on-plective<br>BUICST with full         12         Office evaluation stress         Both encourse SUI<br>and non-molecked<br>and on-plective<br>BUICST with full         12         Office evaluation stress         Both encourse SUI<br>and non-molecked<br>BUICST with full         12         Office evaluation stress         Both encourse SUI<br>and non-molecked<br>BUICST with full         12         Office evaluation stress         Both encourse SUI<br>and non-molecked<br>BUICDD         Both encourse<br>and non-molecked<br>and non-molecked<br>BUICDD         12         Office evaluation stress         Both encourse SUI<br>and non-molecked<br>BUICDD         Both encourse SUI<br>and non-molecked<br>BUICDD         12         Office evaluation stress         Both encourse<br>BUICDD         12         Subjective SUI<br>and non-molecked<br>BUICDD         13         13/41         13   |                              |             |              |           |   | 74               | Any of the above<br>positive   |   | (39)                    | (6)                    | 73           | 71 | 39     | 91     |
| Any vaginalRCT12Subjective UI172Office evaluation stressBothersome SUI $9.22$ (28) $7140$ (5)568528and no bothersomeut (UD)util hadder; viewutil view <td>Van der Ploeg<br/>et al. [93]</td> <td>Any vaginal</td> <td>RCT</td> <td>12</td> <td>Subjective SUI<br/>maximum once/week<br/>and no objective<br/>SUI (CST with full<br/>bladder)</td> <td>182</td> <td></td> <td>Bothersome SUI<br/>(UDI), objective<br/>SUI (CST at<br/>300 ml) and/or<br/>any treatment<br/>for SUI</td> <td>18/47 (38)</td> <td>11/135 (8)</td> <td>62</td> <td>81</td> <td>38</td> <td>92</td>  | Van der Ploeg<br>et al. [93] | Any vaginal | RCT          | 12        | Subjective SUI<br>maximum once/week<br>and no objective<br>SUI (CST with full<br>bladder) | 182              |  | Bothersome SUI<br>(UDI), objective<br>SUI (CST at<br>300 ml) and/or<br>any treatment<br>for SUI | 18/47 (38)              | 11/135 (8)             | 62           | 81 | 38     | 92     |
| T7UDS up to capacity:<br>with or without322 (14) $455 (7)$ $43$ $73$ $14$ SCPRCT3Subjective SUI never4UDS 300 ml; reduction $1/2 (50)$ $19/46 (41)$ $5$ $96$ $50$ SCPRCT3Subjective SUI never8UDS 300 ml; reductionSUI (stress text $1/2 (50)$ $19/46 (41)$ $5$ $96$ $50$ SCPRCT3Subjective SUI never6UDS 300 ml; reductionSUI (stress text $1/2 (50)$ $19/46 (41)$ $5$ $96$ $50$ Scial Aspects of<br>Aging questionnaire61UDS 300 ml; reduction $1/10 (stress text1/10 (stress te$  | Van der Ploeg<br>et al. [94] | Any vaginal | RCT          | 12        | Subjective UI<br>maximum once/week<br>and no bothersome<br>UI (UD1)                       | 172              |  | Bothersome SUI<br>(UDI) and/or<br>any treatment<br>for SUI                                      | 9/32 (28)               | 7/140 (5)              | 56           | 85 | 28     | 95     |
| SCPRCT3Subjective SUI never48UDS 300 ml; reductionSubjective SUI $1/2$ (50) $19/46$ (41)59650rarely (Medical,<br>Epidemiological, and<br>Social Aspects of<br>Aging questionnaire)with support<br>range transmentSUI (stress test<br>at 300 ml) and/<br>$4/8$ (50) $19/46$ (41)59650Replicitiesentertion<br>range transmentat 300 ml, manual<br>or any treatment $4/8$ (50) $19/46$ (41)59050Aging questionnaire)reductionreductionentertion $at 300$ ml, manual<br>or any treatment $4/8$ (50) $18/53$ (34) $189050Aging questionnaire)reductionfor SUI11/14 (79)22/63 (35)339379Aging questionnaire)with swabfor SUI11/14 (79)22/63 (35)339379Aging questionnaire)with swabfor SUI11/14 (79)20/41 (49)178450Aging questionwith swabfor SUI11/14 (79)20/41 (49)178450Aging questionwith speculumfor SUI11/14 (79)307455Advin Archfor SUI11/12 (55)17/42 (40)397455Advin Archwith speculumfor SUI11/20 (55)17/42 (40)7456Advin Archfor SUIfor SUIfor SUIfor SUIfor SUIfor SUIfor SUIAdvin Archfor SUIfor SUIfor SUI$   |                              |             |              |           |   | <i>LT</i>        | UDS up to capacity;<br>with or without<br>reduction; reduction<br>with swab on forceps |   | 3/22 (14)               | 4/55 (7)               | 43           | 73 | 14     | 93     |
|  | Visco et al.<br>[95]         | SCP         | RCT          | б         | Subjective SUI never<br>or rarely (Medical,<br>Epidemiological, and                       | 48               |  | Subjective SUI<br>(PFDI), objective<br>SUI (stress test   | 1/2 (50)                | 19/46 (41)             | 5            | 96 | 50     | 59     |
| UDS 300 ml: reduction         Iot SUI         11/14 (79)         22/63 (35)         33         93         79           with swab         uDS 300 ml; reduction         4/8 (50)         20/41 (49)         17         84         50           UDS 300 ml; reduction         4/8 (50)         20/41 (49)         17         84         50           UDS 300 ml; reduction         11/20 (55)         17/42 (40)         39         74         55           With speculum         31/52 (60)         96/245 (39)         24         88         60  |                              |             |              |           | Social Aspects of<br>Aging questionnaire)   | 61               | UDS 300 ml; manual reduction   | at 300 ml) and/<br>or any treatment   | 4/8 (50)                | 18/53 (34)             | 18           | 06 | 50     | 99     |
| UDS 300 ml; reduction         4/8 (50)         20/41 (49)         17         84         50           with forceps         with forceps         11/20 (55)         17/42 (40)         39         74         55           UDS 300 ml; reduction         11/20 (55)         17/42 (40)         39         74         55           with speculum         31/52 (60)         96/245 (39)         24         88         60   |                              |             |              |           |   | LL               | UDS 300 ml; reduction<br>with swab   | for SUI   | 11/14 (79)              | 22/63 (35)             | 33           | 93 | 62     | 65     |
| UDS 300 ml; reduction         11/20 (55)         17/42 (40)         39         74         55           with speculum         31/52 (60)         96/245 (39)         24         88         60   |                              |             |              |           |   | 49               | UDS 300 ml; reduction<br>with forceps  |   | 4/8 (50)                | 20/41 (49)             | 17           | 84 | 50     | 51     |
| All methods 31/52 (60) 96/245 (39) 24 88 60  |                              |             |              |           |   | 62               | UDS 300 ml; reduction<br>with speculum   |   | 11/20 (55)              | 17/42 (40)             | 39           | 74 | 55     | 60     |
|  |                              |             |              |           |   | 297 <sup>b</sup> | All methods  |   | 31/52 (60)              | 96/245 (39)            | 24           | 88 | 60     | 61     |

| Veletellee            | Type of POP                          | Study design Follow-up Baseline   | Follow-up                                | Baseline  | n <sup>a</sup> | Test for OSUI  | Definition of de  | Rate of de novo SUI     | o SUI   | Sensitivity, | Sensitivity, Specificity, PPV, % NPV, % | PPV, % | NPV, % |
|-----------------------|--------------------------------------|---|--|---|----------------|--|---|-------------------------|---|--------------|---|--------|--------|
|                       | surgery                              |   | (monuns)                                 | (monus) conunence                                   |                |  | 100 0 VOI   | Test positive,<br>n (%) | Test positive. Test negative, $n$ (%) $n$ (%) | <u>%</u>     | %                                       |        |        |
| Wei et al. [96]       | Wei et al. [ <b>96</b> ] Any vaginal | RCT   | en e | No subjective SUI<br>(PFDI)                         | 170            | <ul> <li>170 Stress test at 300 ml; Stress, urgency, or 41/57 (72) 43/113 (38) 49 reduction with swab mixed UI defined as a positive CST, bottersome symptoms, and/ or treatment for UI</li> </ul> | Stress, urgency, or<br>mixed UI defined<br>as a positive<br>CST, bothersome<br>symptoms, and/<br>or treatment<br>for UI | 41/57 (72)              | 43/113 (38)                                   | 49           | 8                                       | 72     | 62     |
| Yamada et al.<br>[97] | Anterior colpor-<br>rhaphy           | Anterior colpor- Retrospective Mean 58 No subjective<br>thaphy (nonvalidate<br>objective SU | Mean 58                                  | No subjective<br>(nonvalidated) or<br>objective SUI | 10             | 1-h pad test and stress<br>test; reduction with<br>ring pessary or<br>vaginal pack   | Subjective SUI<br>(nonvalidated)  | N/A                     | 0/10 (0)                                      | N/A          | V/A                                     | N/A    | 100    |

CST cough stress test, SCP sacrocolpopexy, RCT randomized controlled trial, NTR native tissue repair, UI urinary incontinence. ICIO-UI International Consultation on Incontinence Ouestionnaire-Urinary Incontinence, UDI Urinary positive predictive value, NPV negative predictive value, UDS urodynamic study, N/A not applicable, TVM transvaginal mesh flagnostic accuracy values; some studies provided rates of de novo SUI after positive and/or negative test, and diagnostic accuracy values were calculated based on these data Impact Questionnaire Short Form, KHQ King's Health Questionnaire POP pelvic organ prolapse, OSUI occult stress urinary incontinence, SUI stress urinary incontinence, PPV Inventory Short Form, IIQ-7 Incontinence Distress Distress Inventory, UDI-6 Urinary

were included <sup>a</sup>Only women without concomitant anti-incontinence surgery 'Total number of women 165; each subject underwent two different prolapse reduction methods

Another study compared the predictive value of demonstrable SUI during basic office evaluation versus urodynamic study for de novo SUI. Stress tests were performed in the lithotomy position with (swab on forceps) and without reduction of the prolapse. During basic office evaluation women were examined with a subjectively full bladder and during urodynamic studies with 300-ml bladder filling and at maximal bladder capacity. More women demonstrated SUI during urodynamic study, but the diagnostic accuracy for bothersome de novo SUI or treatment for de novo SUI was not improved by the addition of the urodynamic study [94].

Other predictors of de novo SUI Two studies were aimed at identifying other risk factors for de novo SUI. Urodynamic markers that were associated with de novo SUI were low MUCP [99]. low FUL [99], and bladder outlet obstruction [100].

Two studies demonstrated that occult SUI is also seen in posterior wall prolapse [101, 102] up to the same extent as with anterior wall prolapse [101].

Prediction model for de novo SUI A model and risk calculator developed to predict de novo SUI among women without preoperative SUI symptoms contains seven predictors: age, number of previous vaginal births, urine leakage associated with urgency, history of diabetes, BMI, preoperative reduction stress test result, and placement of a midurethral sling during surgery. The model predicted absolute risk accurately, with slight tendencies to overestimate the risk when the probability reached 50% or greater. The concordance index (interpretation: 0.5, not better than chance to 1, perfect discrimination) was 0.73 in the original study [103], and it outperformed both expert opinion and preoperative stress testing in discriminating between women who developed de novo SUI during 12 months followup and not. However, when the model was applied to other samples (external validation), the results for the concordance index or area under the curve decreased to 0.62, 0.63, and 0.69 [103–105]. One study assessed the model's performance as a diagnostic test using a probability of de novo SUI of >50% as a cut-off for a positive test. Using this cut-off, a positive test had a predictive value of 27% (i.e., 27% of women with an estimated risk of 0.5 or higher actually developed SUI). This illustrates how the model overestimates the risk when the baseline risk is lower than in the original sample [105].

Summary: assessment of SUI in patients with POP The evaluation of SUI in patients with POP is very complex and recommendations vary widely.

In women with POP and SUI, the cough stress test 1. should be performed with at least 200-ml bladder volume and with the prolapse reduced either with a speculum or pessary in order to have the highest chance of identifying a positive result.

- 2. Assessment of UDS in women prior to POP surgery has been shown to change management in a small percentage of cases, for example, when SUI (clinical or occult) coexists with voiding dysfunction. The management may change by the avoidance of a concomitant continence procedure or the choice of one with a perceived lower risk of associated voiding dysfunction.
- 3. There are no comparative data on different diagnostic alternatives correlating with postoperative outcomes as studies such as VALUE [106] and VUSIS [107] excluded women with prolapse beyond the hymen.
- 4. In an unselected POP population, a negative reduction stress test during preoperative urodynamic assessment has a median negative predictive value of 78% (range 45–90%) for postoperative SUI. There is conflicting evidence regarding the predictive value of further urodynamic parameters such as MUCP and FUL.
- 5. More preoperatively continent women will demonstrate occult SUI during a urodynamic assessment compared with office evaluation stress test but this does not have greater accuracy for bothersome de novo SUI or treatment for de novo SUI. The demonstration of preoperative occult SUI during urodynamic assessment has a positive predictive value for de novo SUI of 40% (0–79%) and its absence has a negative predictive value of 91% (51–100%) respectively.
- 6. A de novo SUI prediction model that incorporates seven variables and outperforms pure chance, expert opinion, and reduction cough stress test alone. However, in follow-up studies the model performed poorly, overestimating the risk when compared with the original study.

To sum up, the most useful information from the evaluation of a patient with POP with regard to postoperative stress incontinence is the high negative predictive value of a negative stress reduction test.

# **Further research**

- 1. Future research should look to improve the performance of current prediction testing, and develop new predictive parameters. These could probably be identified by deepening our understanding of the biological and biomechanical explanations behind de novo and persistent SUI.
- 2. The prognostic value of MUCP and FUL should be reassessed in further studies.
- 3. Persistent and de novo SUI probably have different prognostic factors, thus developing separate models may be feasible and increase accuracy.
- 4. Researchers should follow The Transparent Reporting of a Multivariable Prediction Model for Individual Prognosis or Diagnosis statement when presenting a new or validating an existing prediction model [108].

# Evaluation of hydronephrosis and hematuria in patients with POP

There were two studies that discussed the prevalence of hydronephrosis and hematuria in women with POP. The study on hydronephrosis evaluated 180 patients and found some degree of hydronephrosis in 30%. A multivariate statistical analysis revealed only the two following factors associated with hydronephrosis. First, anterior compartment prolapse, as defined by POP-Q point Ba; noting that for every 1-cm increase, the relative risk of hydronephrosis increases by 1.68. Second, cystometric capacity; it was found that every 100-ml increase in maximum cystometric capacity increases the relative risk of hydronephrosis by 1.5. However, the model only predicted about 30% of the hydronephrosis [109].

The study evaluating microscopic hematuria (defined as  $\geq$  red blood cells per high power field) noted its presence in 20.1% in a population of 1,040 women. This population is at a very low risk of urinary tract malignancy and the authors suggested that the cut-off for significant microscopic hematuria in this population should be re-evaluated [110].

To summarize: the severity of anterior vaginal wall prolapse and cystometric capacity are associated with hydronephrosis in a limited number of studies; prediction models are not well developed.

# Assessment of gastrointestinal tract symptoms in women with POP

A review of the existing literature on the assessment of GIT symptoms in women with POP identified 2,251 titles and abstracts, of which 17 studies were included in the final review of this section (Fig. 3). Studies were included whose primary population or a significant portion of the study population were women with POP, who then underwent evaluation of the GIT other than or in addition to symptom assessment and clinical examination (Table 9).

# Defecography

Several studies compared various defecography imaging modalities with each other [112, 118, 124, 125]. Difficulties in evaluation of the existing literature included the use of various methods for the assessment of prolapse on physical examination, including the Baden–Walker halfway system, the POP-Q system, and several manuscript-specific nonstandardized examination techniques. In addition, various methods of performing the imaging and interpretation of results were described. In studies of fluoroscopic defecography, there was variability in which compartments were opacified with contrast; although the rectum was universally opacified, other possible compartments included the bladder, vagina, perineum, peritoneum, and small bowel.



Fig. 3 Preferred Reporting Items for Systematic Reviews and Meta-Analyses diagram for gastrointestinal radiographic/physiological testing

Three studies of fluoroscopic defecography found that this imaging modality detected more enteroceles than physical examination [111, 113, 117]. Two studies found that MRI defecography was able to diagnose enteroceles more readily than physical examination, and one of these found that MRI defecography was also able to diagnose more enteroceles than fluoroscopic defecography [122, 125]. Two studies found that sigmoidoceles were not diagnosed on examination but were identified by fluoroscopic defecography [112, 117]. One study found that the size of the posterior vaginal wall prolapse, as assessed by physical examination, was associated with the finding of enterocele and/or rectal intussusception on fluoroscopic defecography [114].

Patient symptoms were assessed in two studies that found that defecatory symptoms were not significantly associated with findings on radiographic imaging or examination [115, 116]. One study found no relationship between defecatory symptoms in women with posterior vaginal wall prolapse and abnormal defecography. The other found no relationship between defecatory symptoms and posterior vaginal wall prolapse on examination or rectocele or enterocele on defecography [115, 116]. One study found that two thirds of women with a rectocele and symptoms of obstructed defecation or anal incontinence had intussusception (13.5% Oxford Grade I, 41% Grade II, and 13.5% Grade III) on MR defecography and were more likely to have an enterocele [119].

# Anal physiological testing and anal ultrasound versus physical examination

Anal physiology and anorectal endosonography testing added limited information to the routine physical examination evaluation of POP patients for identifying intussusception [126, 127].

Patients with fecal incontinence may benefit from this testing. In terms of the clinical consequences of the imaging investigation, two studies found that the imaging results led to a change in surgical plan for 22–41% of patients [112, 117].

#### Definitions/interpretation of radiographic imaging studies

Consensus on definitions and interpretations of fluoroscopic defecography and MRI defecography have been developed by multiple stakeholder societies including the IUGA [128, 129]. Although these documents represent consensus on the use of these imaging modalities in patients with defecatory disorders, they "do not" contain information pertinent to patients with pelvic organ prolapse regarding specific methods and measurements. There is no consensus on whether or not patients with prolapse and no GI symptoms should undergo any testing beyond a thorough physical examination. It has been agreed upon that imaging should include measurements performed during the defecation phase rather than only with strain to improve sensitivity [123, 128, 129]. Studies in which there was no defecography phase have limited applicability.

Summary: assessment of GIT symptoms in women with POP Summary of supplemental evaluation for GI dysfunction in women with POP is an area requiring a significant amount of research before any concrete recommendation can be made.

 There were no studies that reported on patient outcomes in those evaluated by fluoroscopic defecography, MRI defecography, or anal physiology testing, and those who did not undergo this evaluation. Therefore, the clinical significance of this testing, particularly in asymptomatic patients, remains uncertain. It does seem that some ana-

| Reference                 | Study design         | Population  | Method(s) of clinical<br>assessment   | Results   |                                    |                           |           | Discussion   |
|---------------------------|----------------------|---|---|---|------------------------------------|---------------------------|-----------|--|
| Fluoroscopic defecography | efecography          |   |   |   |                                    |                           |           |  |
| Kelvin et al.             | Retrospective cohort | n=170 consecutive   | BW ±POP-Q   | Only 74% POP-Q—POP-Q not used for analysis  | d for analysis                     | _                         |           | Descriptive study showing that   |
| [111]                     | study, USA           | women with<br>eventoms of nelvic                          | ,   | Findings on BW vs DCP   | •                                  |                           |           | cystoceles and rectoceles are<br>similarly diamosed by both RW and   |
|                           |                      | floor dysfinction   |   |   | BW                                 | DCP                       | Both      | DCP, but more enteroceles diagnosed  |
|                           |                      | referred for dynamic                                      |   | Rectocele   | 91%                                | 76%                       | 70%       | by examination   |
|                           |                      | cystoproctography   |   | Enterocele  | 40%                                | 28%                       | 14%       |  |
|                           |                      |   | DCP   | Cystocele   | 81%                                | 94%                       | 78%       |  |
| Kaufman et al.            | 2                    | n=22 women with   | Questionnaires  | 86% had previous pelvic surgery   |                                    |                           |           | Low concordance of findings between  |
| [112]                     | tive cohort study,   | symptomatic prolapse                                      |   | 41% patients had a change in surgical plan owing to imaging results   | cal plan owing                     | g to imagin,              | g results | modalities   |
|                           | ACU                  | went on to pervic<br>reconstructive surgery               |   | POP-Q vs DCCP vs dMRI   |                                    |                           |           |  |
|                           |                      |   |   |   | p-qoq                              | DCCP                      | dMRI      |  |
|                           |                      |   |   | Cystocele   | 68%                                | 45%                       | 41%       |  |
|                           |                      |   |   | Rectocele   | 86%                                | 82%                       | 50%       |  |
|                           |                      |   | Physical examination,<br>POP-Q  | Enterocele  | 36%                                | 41%                       | 36%       |  |
|                           |                      |   | DCCP  | Sigmoidocele  | %0                                 | %6                        | %0        |  |
|                           |                      |   | Had defecography phase  | Levator ani defect  | %0                                 | %0                        | 18%       | Levator ani defects only diagnosed by dMRI   |
|                           |                      |   | dMRI  | Internal rectal prolapse  | 6%                                 | 45%                       | %0        | Sigmoidocele only diagnosed by DCCP  |
|                           |                      |   | No defecography phase   | Full-thickness rectal prolapse  | %6                                 | %0                        | %0        | Lack of defecography phase during<br>MRI likely contributes to findings  |
| Lopez et al.              | Prospective cohort   | n=25 women with POP                                       | Clinical examination  | No statistical analysis   |                                    |                           |           | Descriptive study suggesting CDP   |
| [113]                     | study, Sweden        | on clinical examination<br>planning to undergo<br>surgery | (no POP-Q or BW)  | Pre-operatively: cystocele on clinical examination vs CDP 28% vs 88%  | al examinatio                      | ų                         |           | might contribute to characterization<br>of prolapse, but limited by lack of<br>use of either POP-Q or BW and small |
|                           |                      |   | Questionnaires  | Pre-operatively: rectocele on clinical examination vs CDP 96% vs $84\%$   | al examinatio                      | sv n                      |           | numbers  |
|                           |                      |   | CDP   | Enterocele on clinical examination vs CDP 8% vs $24\%$  | vs CDP 8% v                        | 's 24%                    |           | CDP may be helpful in diagnosing enteroceles   |
| Takano and                | Prospective cohort,  | n=66, which included                                      | Clinical examination (no  | No statistical analysis   |                                    |                           |           | Descriptive study limited by lack of   |
| натада<br>[114]           | Japan                | oo remare pauents, 11<br>male patients                    | POP-Q OF BW)  | 75% of patients with symptoms of vaginal prolapse showed descent of the vagina on DCR   | vaginal prola                      | ose showed                |           | statistical analysis, lack of POP-Q or<br>BW, mixed sex population, and lack<br>of defecography phase              |
|                           |                      |   | DCR: opacification of<br>the ileum, bladder,<br>vagina, rectum, and<br>perineum | 78% of patients with uterine descent had an enlarged angle<br>between the vaginal axis and horizontal line at the superior<br>border of the sacrum on DCR | nt had an enla<br>ontal line at tl | rged angle<br>he superior |           |  |
|                           |                      |   | No defecography phase   | *68% of patients with symptoms of descent of the rectum or<br>obstructed defecation had descent of the rectum on DCR                                      | f descent of th                    | ie rectum o<br>on DCR     |           |  |

Table 9 Evidence table for the evaluation of prolapse in women with symptoms of obstructed defecation and anal incontinence

| Reference                   | Study design                                 | Population   | Method(s) of clinical<br>assessment                           | Results  | Discussion  |
|-----------------------------|--|--|---|--|---|
|                             |  | Symptoms of prolapse,<br>defecatory dysfunction,<br>incontinence NOS                   |   | *Female + male   | Study does not demonstrate benefit of DCR   |
| Roovers et al.<br>[115]     | Prospective cohort study,<br>The Netherlands | =u   | Physical examination,<br>POP-Q                                | Abnormal defecography was defined as presence of an enterocele, rectal intussusception, or both  | Applying the proposed scoring system<br>may predict the probability that an<br>enterocele or rectal intussusception |
|                             |  | planned for surgery  |   | Abnormat= 32%<br>Enterocele = 28%  | is found; for scores >1 and <8,<br>defecography may be more useful  |
|                             |  |  |   | Rectal intussusception 11%   | i.e., for patients with some predictive<br>factors but not others, imaging may                                      |
|                             |  |  |   | Both = $7\%$   | add to clinical assessment  |
|                             |  |  |   | History of pelvic surgery, size of the posterior vaginal wall prolapse, and the presence of constipation predicted abnormal defecography (i.e., enterocele, rectal intussusception)                              |   |
|                             |  |  |   | Used to create a formula to predict probability = $3+3 \times$ history of pelvic surgery* + Ap (in cm) +3 × constipation*  |   |
|                             |  |  | Questionnaires<br>(standardized)                              | *Present = 1, $absent = 0$   |   |
|                             |  |  |   |  |   |
|                             |  |  | Fluoroscopic defecog-<br>raphy with vaginal<br>also opacified | Patients with probability less than $20\%$ (score $\leq 1$ ) or g<br>reater than $70\%$ (score $\geq 8$ ) of abnormal defecation do<br>not get additional information from this study                            |   |
| Groenendijk<br>et al. [116] | Prospective cohort study,<br>The Netherlands | n=59, women with<br>primary pelvic organ<br>prolapse: 68 enrolled;<br>5 dropped out; 4 | Physical examination,<br>POP-Q<br>DDI                         | No significant relationship was found between defecatory symptoms<br>and presence of posterior vaginal wall prolapse on examination<br>(p=0.33), rectocele $(n=0.19)$ , or enterocele $(n=0.99)$ on defecography | Clinical examination may overestimate<br>posterior vaginal wall prolapse and<br>underestimate enterocele            |
|                             |  | defecography incorrectly   | щ   | Clinical examination diagnosis of a rectocele compared with defecography   |   |
|                             |  | million  | raphy with vagina<br>also opacified                           | Sensitivity 1.0, 95% CI 0.82 to 1  |   |
|                             |  |  |   | Specificity 0.23 95% CI -0.11 to 0.38  |   |
|                             |  |  |   | Clinical examination diagnosis of enterocele compared with defecography  |   |
|                             |  |  |   | Sensitivity 0.07, 95% CI 0.002 to 0.32   |   |
|                             |  |  |   | Specificity 0.95, 95% CI 0.85 to 0.99  | No correlation of bowel symptoms<br>with posterior wall prolapse<br>on examination or rectocele or                  |
|                             |  |  |   |  | enterocele on defecography  |

Table 9 (continued)

| Monome sub dealers from the field of claims and   |                     |                                    |   |   |   |                                     |                       |              |             |                |  |
|---|---------------------|------------------------------------|---|---|---|-------------------------------------|-----------------------|--------------|-------------|----------------|--|
| The properties of the diagone entenceds. signal data in the result of the diagone entenceds. signal data in the result of the diagone entenceds. signal data in the result of the diagone entenceds. signal data in the result of the diagone entenced is a field of the diagone entenced in the diagone entenced is a field of the diagone entenced in the diagone entenced entenced in the diagone entenced entence entenced entenced entence entenced entenced entenced entence entenced entenced entenced entence entenced entence entenced entence entenced entence entenced entence entenced entenced entence entenced entence entenced entenc   | Reference           | Study design                       | Population                              | Method(s) of clinical assessment  | Results                                       |                                     |                       |              |             |                | Discussion   |
| Plate solution soluti solution solution solution solution solution solution solution so  | Kim et al.<br>[117] | Prospective cohort,<br>South Korea | <i>n</i> =109                           | Physical examination,<br>POP-Q  | Physical examinatior<br>The surgical plan cha | ı did not diagno<br>anged in 22% of | se enteroce.<br>cases | le, sigmoide | ocele, or F | п              | Clinical examination misses<br>enteroceles, sigmoidoceles, and rectal<br>intussusception found by DCCP |
| Ending on continuition vs DCCP     Examination vs DCCP     Examination vs DCCP     Examination vs DCCP     Examination vs DCP     Examination     Examination vs DCP     Examination  |                     |                                    |   |   | Patients with a change symptoms $(p=0.023)$   | ged surgical pla                    | n had a high          | ler prevalen | ice of bow  | el             |  |
| Induction          Induction <t< td=""><td></td><td></td><td></td><td></td><td>Findings on examina</td><td>tion vs DCCP</td><td></td><td></td><td></td><td></td><td></td></t<>  |                     |                                    |   |   | Findings on examina                           | tion vs DCCP                        |                       |              |             |                |  |
| $ \begin{array}{llllllllllllllllllllllllllllllllllll$   |                     |                                    |   |   |   | Examination                         | DCCP                  |              |             | <i>p</i> value |  |
| Cystocele total         Negative         20         10         30         400           113 enrolled         Positive         20         79         79         79           113 enrolled         Retocele total         Negative         27         58         50         400           113 enrolled         Retocele total         Negative         27         58         70         50           113 enrolled         Retocele total         Negative         27         58         70         50           113 enrolled         Retocele total         Negative         20         10         70         50         4000           113 enrolled         Retocele total         Negative         27         58         20         20         20           113 enrolled         Retocele total         Negative         10         2         10         2         10         2         10         2         10         2         10         2         10   |                     |                                    |   |   |   |                                     | Negative              | Positive     |             |                |  |
| $ \begin{array}{llllllllllllllllllllllllllllllllllll$   |                     |                                    |   |   | Cystocele total                               | Negative                            | 20                    | 10           | 30          | <0.001         |  |
|   |                     |                                    |   |   |   |                                     | 0                     | 79           | 62          |                |  |
| 113 enrolled       Recorecte total       Negative       27       39       60001         103       Pasitive       27       5,820       09       6001         4dropped out       Rt total       Negative       101       8       109         4dropped out       Rt total       Negative       101       8       109         Vomen with stage 2I1       DCCP       Enterocte total       Negative       101       8       109         Vomen with stage 2I1       DCCP       Enterocte total       Negative       107       2       109         Vomen with stage 2I1       DCCP       Enterocte total       Negative       107       2       109         Vomen with stage 2I1       DCCP       Pasitive       107       2       109       0       0         reconstructive sugery       also opacified       Signoidocce total       Negative       107       2       109       0   |                     |                                    |   |   |   | Positive                            | 20                    | 89           | 109         |                |  |
| $ \begin{array}{l lllllllllllllllllllllllllllllllllll$  |                     |                                    | 113 enrolled                            |   | Rectocele total                               | Negative                            | 27                    | 32           | 59          | <0.001         |  |
| Positive       27       5,820       109         4 dropped out       R1 total       Negative       101       8       109         4 dropped out       R1 total       Negative       101       8       109         4 dropped out       R1 total       Negative       101       8       109         4 dropped out       DCCP       Enterocele total       Negative       101       8       109         4 dropped unodynamic       DCCP       Enterocele total       Negative       107       2       109         4 dropped unodynamic       Bladder and vaginal       Sigmoidocele total       Negative       107       2       109         7 reconstructive surgery       also opacified       Sigmoidocele total       Negative       107       2       109         7 adderee of pelvic floor       (no POP-Q or BW)       O       0       0       0       0         7 adderee of pelvic floor       (no POP-Q or BW)       Compared with MRL, CCD II diagnoses additional defectors       4       109         7 adderee of pelvic floor       (no POP-Q or BW)       O       0       0       0       0         7 adderee of pelvic floor       (no POP-Q or BW)       Compared with MRL, CCD II diagnoses additional defectors   |                     |                                    |   |   |   |                                     | 0                     |              | 50          |                |  |
| 4 dropped out     R1 total     Negative     101     8     109       7     2     0     0     0     0       7     7     Positive     101     8     109       7     7     2     109     109     109       7     7     2     109     109     109       7     7     2     109     109     109       7     7     2     109     109     109       7     7     100     105     109     109       7     7     100     105     109     109       7     100     105     105     109     109       7     100     105     105     109     109       7     100     105     105     109     109       7     100     105     105     109     109       7     100     105     105     109     109       7     100     105     105     109     109       7     100     105     105     109     109       7     100     105     105     109     109       7     100     105     105     109  |                     |                                    |   |   |   | Positive                            | 27                    | 5,820        | 109         |                |  |
| Nomen with stage $\geq II$ DCCPEnterocele totalPositive1018109Women with stage $\geq II$ DCCPEnterocele totalNegative1072109POP and unodynamic<br>confirmed urinary<br>incontinenceMethod totalNegative1072109Without HO pelvicBladder and vaginal eSigmoidocele totalNegative1072109Without HO pelvicBladder and vaginal eSigmoidocele totalNegative1072109n=35 women with clinical<br>descutUo POPQ on BW)All patients underwent both imaging studies000n=35 women with clinical<br>descutUo POPQ on BW)All patients underwent both imaging studies4109n=35 women with clinical<br>descutUo POPQ on BW)Compared with MRL CCD II diagnoses additional defects:1054109n=35 women with clinical<br>descutUo POPQ on BW)Compared with MRL CCD II diagnoses additional defects:109109n=10CCDW and to CCDI aWithout (CCDI) aWithout (CCDI) aNegative20109n=10CCD with (CCDI aNegativeNegative103109109n=10CCDW and to CCDI aNegative103109109n=10NegativeNegative108109109109n=10NegativeNegative108109109109n=10NegativeNegativeNegative106109109n=10Nega  |                     |                                    | 4 dropped out                           |   | RI total                                      | Negative                            | 101                   | 8            | 109         |                |  |
| Women with stage $\geq II$ DCCPEnterocele totalNegative1018109POP and unodynamic<br>confirmed urinary<br>incontinenceDCCPEnterocele totalNegative1072109POP and unodynamic<br>confirmed urinary<br>incontinenceBladder and vaginal =Enterocele totalNegative1072109Without HO pelvic<br>reconstructive surgeryBladder and vaginal =Sigmoidocele totalNegative1072109T=35 women with clinical<br>descent(no POP-Q or BW)<br>   |                     |                                    |   |   |   |                                     | 0                     | 0            | 0           |                |  |
| Women with stage 2 IDCCPDCCPEnterocele totalNegative1072109POP and urodynamic<br>confirmed urinary<br>incontinenceWithout HO pelvicBladder and vaginal =Sigmoidocele totalNegative1072109Without HO pelvicBladder and vaginal =Sigmoidocele totalNegative1072109Without HO pelvicalso opacifiedAllPostive1054109n=35 women with clinicalClinical examinationAll patients underwent both imaging studies4109n=35 women with clinicalClinical examinationAll patients underwent both imaging studies4109n=35 women with clinicalClinical examinationAll patients underwent both imaging studies4109n=35 women with clinicalClinical examinationAll patients underwent both imaging studies4109n=35 women with clinicalClinical examinationAll patients underwent both imaging studies4109n=35 women with clinicalClinical examinationAll patients underwent both imaging studies4109n=35 women with clinicalClinical examinationAll patients underwent both imaging studies4109n=35 women with clinicalClinical examinationAll patients underwent both imaging studies4109n=35 women with clinicalClinical examinationAll patients underwent both imaging studies4109n=4CCD with (CCDI) andRecocele = 13All patients4109 <td< td=""><td></td><td></td><td></td><td></td><td></td><td>Positive</td><td>101</td><td>8</td><td>109</td><td></td><td></td></td<>  |                     |                                    |   |   |   | Positive                            | 101                   | 8            | 109         |                |  |
| POP and unodynamic<br>confirmed urinary<br>incontinence       0       0       0       0       0         Without HO pelvic       Bladder and vaginal       Sigmoidocele total       Negative       107       2       109         Without HO pelvic       Bladder and vaginal       Sigmoidocele total       Negative       107       2       109         reconstructive surgery       also opacified       All patients underwent both imaging studies       0       0       0         n=35 women with clinical       Clinical examination       All patients underwent both imaging studies       4       109         n=35 women with clinical       Clinical examination       All patients underwent both imaging studies       4       109         n=35 women with clinical       Clinical examination       All patients underwent both imaging studies       4       109         n=35 women with clinical       Clonical examination       All patients underwent both imaging studies       4       109         n=45       Clonical examination       Compared with MRI, CCD II diagnoses additional defects:       4       109         n=45       CD with (CCDI) and with order e = 13       Yaginal vault prolapse = 20       5       5         n=46       Phase       Phase       Phase       7       7  |                     |                                    | Women with stage ≥II                    | DCCP  | Enterocele total                              | Negative                            | 107                   | 2            | 109         |                |  |
| incontinence Positive 107 2 109<br>Without HO pelvic also opacified also opacified 105 4 109<br>reconstructive surgety also opacified 100 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0   |                     |                                    | POP and urodynamic<br>confirmed urinary |   |   |                                     | 0                     | 0            | 0           |                |  |
| Without HO pelvic<br>reconstructive surgeryBladder and vaginal =<br>also opacifiedSigmoidocele total<br>NegativeNegative1054109n=35 women with clinical<br>evidence of pelvic floor<br>widence of pelvic floorClinical examination<br>(no POP-Q or BW)<br>Compared with MRL, CCD II diagnoses additional defects:<br>Cystocele = 14Positive1054109n=35 women with clinical<br>woidence of pelvic floor<br>descentAll patients underwent both imaging studies4109n=35 women with clinical<br>woidence of pelvic floor<br>descentConPO-Q or BW)<br>(no POP-Q or BW)All patients underwent both imaging studies4109n=35 women with clinical<br>descentConPO-Q or BW)<br>(no POP-Q or BW)Compared with MRL, CCD II diagnoses additional defects:<br>  |                     |                                    | incontinence                            |   |   | Positive                            | 107                   | 2            | 109         |                |  |
| reconstructive surgery also opacified 0 0 0 0 1=35 women with clinical Clinical examination vidence of pelvic floor (no POP-Q or BW) compared with MRI, CCD II diagnoses additional defects: Cystocele = 14 Cystocele = 14 Cystocele = 13 vithout (CCDI) and Rectorele = 13 vithout (CCDI) and vithout (CCDI) and vithout (CCDI) and voiding and defection base   |                     |                                    | Without HO pelvic                       | Bladder and vaginal =   | Sigmoidocele total                            | Negative                            | 105                   | 4            | 109         |                | This may influence surgical planning   |
| Positive     105     4     109       n=35 women with clinical     Clinical examination     All patients underwent both imaging studies     C       evidence of pelvic floor     (no POP-Q or BW)     Compared with MRI, CCD II diagnoses additional defects:     C       evidence of pelvic floor     (no POP-Q or BW)     Compared with MRI, CCD II diagnoses additional defects:     C       descent     C     Vaginal vault prolapse = 20     Enterocele = 14       CCD with (CCDI) and without (CCDI) and without (CCDI) and without (CCDI) and base     Rectocele = 13   |                     |                                    | reconstructive surgery                  | also opacified  |   |                                     | 0                     | 0            | 0           |                |  |
| n=35 women with clinical     Clinical examination     All patients underwent both imaging studies     C       evidence of pelvic floor     (no POP-Q or BW)     Compared with MRI, CCD II diagnoses additional defects:     C       descent     Cystocele = 14     Vaginal vault prolapse = 20     Enterocele = 4     C       CCD with (CCDI) and without (CCDI) and voiding and defection of the original and defection of the original and defection of the original and defection     Rectocele = 13     Notifing and defection of the original and defection  |                     |                                    |   |   |   | Positive                            | 105                   | 4            | 109         |                |  |
| study, Belgum evidence of pelvic floor (no POP-Q or BW) Compared with MRI, CCD II diagnoses additional defects:<br>descent Cystocele = 14<br>Vaginal vault prolapse = 20<br>Enterocele = 4<br>CCD with (CCDI) and Rectocele = 13<br>without (CCDI) and Rectocele = 13<br>without (CCDI) and Petcocele = 13<br>without | Vanbeckevoor        | t Prospective cohort               | n=35 women with clinical                | Clinical examination  | All patients underwe                          | nt both imaging                     | studies               |              |             |                | Cystocele, vaginal vault prolapse,   |
| Cystocele = 14<br>Vaginal vault prolapse = 20<br>Enterocele = 4<br>Rectocele = 13   | et al. [118]        |                                    | evidence of pelvic floor descent        | (no POP-Q or BW)  | Compared with MRI                             | , CCD II diagne                     | ses addition          | nal defects: |             |                | rectocele, enterocele, and rectal<br>descent most readily seen on CCD                                  |
| _   |                     |                                    |   |   | Cystocele = 14                                |                                     |                       |              |             |                | with voiding and defecation phase  |
| _   |                     |                                    |   |   | Vaginal vault prolaps                         | se = 20                             |                       |              |             |                |  |
| _   |                     |                                    |   |   | Enterocele = $4$                              |                                     |                       |              |             |                |  |
|   |                     |                                    |   | CCD with (CCDII) and<br>without (CCDI) a<br>voiding and defecation<br>phase | Rectocele = 13                                |                                     |                       |              |             |                |  |

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Table 9 (continued)

| Table 9 (continued)     | ltinued)                       |   |   |   |  |          |  |
|-------------------------|--------------------------------|---|---|---|--|----------|--|
| Reference               | Study design                   | Population  | Method(s) of clinical<br>assessment   | Results   |  | Disc     | Discussion   |
|                         |                                |   | Dynamic, single-shot<br>MRI sequence<br>without defecography<br>phase   | Rectal descent = 5  |  |          |  |
| MR defecography         | phy                            |   |   |   |  |          |  |
| Hausammann              | д.                             | n=37 women  | BW  | 2/3 patients had moderate to large rectocele on MRD   | ele on MRD   | Patio    | Patients with a rectocele on examina-  |
| et al. [ 119]           | study, Switzerland             |   |   | No significant association between size of rectocele on MRD and constipation or fecal incontinence  | f rectocele on MRD and const                         |          | tion may have other pelvic floor<br>defects as well  |
|                         |                                |   |   | 67.5% of women with a rectocele had a concomitant intussusception   | oncomitant intussusception                           |          |  |
|                         |                                |   |   | Significantly more likely to have an enterocele $(p=0.013)$   | ocele ( <i>p</i> =0.013)                             |          |  |
|                         |                                |   | Symptom questionnaires<br>(Cleveland clinic<br>constipation score<br>and Wexner faecal<br>incontinence score) | Obstructed defectation symptoms did not differ between isolated rectocele and rectocele + intussusception   | differ between isolated rectoco                      | sle and  |  |
|                         |                                | Patients with rectocele<br>and defecatory<br>dysfunction  | MRD (open)  | Higher grade intus<br>susception was associated with FI ( $p=0.048$ )   | ated with FI ( $p=0.048$ )                           |          |  |
| Aziz et al.<br>[120]    | Case series                    | <i>n</i> =7 patients with<br>pelvic floor disorder<br>symptoms and a history<br>of cysterectomy and<br>hysterectomy referred<br>for MRD | Physical examination<br>POP-Q   | <ol> <li>5 POP-Q stage II or III</li> <li>2 POP-Q stage 0</li> <li>MRD findings:</li> <li>4 patients = anterior enterocele (small bowel), moderate</li> </ol> | we), moderate  | MR<br>pa | MRD may be useful in post-cystectomy<br>patients with vaginal bulge                            |
| Pollock et al.<br>[121] | Retrospective cohort<br>study, | <i>n</i> =54 women  | Physical examination  | <ul> <li>patients = ametror significancere, inocerate</li> <li>Symptoms</li> <li>96% bothersome POP</li> </ul>  |  | BW<br>BW | oundy minined by very spectaric population<br>MRD not significantly correlated with<br>BW      |
|                         |                                |   |   | Spearman correlation coefficient between MRD grading compared with examination  | 1 MRD grading  |          |  |
|                         |                                |   |   | Ó   | Overall Anterior wall                                | lle      |  |
|                         |                                | 170 patients with POP screened  | POP-Q or BW   | BW th   | тю —0.001; <i>p</i> =0.998 тю 0.197; <i>p</i> =0.154 | 0        | Overall POP-Q stage and anterior wall<br>correlated positively and significantly<br>with MRD   |
|                         |                                | 116 excluded because of<br>incomplete examination<br>or MRD information   | MRD   | POP-Q   | tho 0.305; $p=0.025$ tho 0.436; $p=0.001$            |          | MRD may provide different information<br>than clinical examination, particularly<br>BW staging |

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| Table 9 (continued)  | inued)                                |   |                                     |  |                                 |  |  |
|--|---------------------------------------|---|-------------------------------------|--|---------------------------------|--|--|
| Reference  | Study design                          | Population  | Method(s) of clinical<br>assessment | Results  |                                 |  | Discussion   |
| Lin et al. [122]<br>(same group<br>as Pollock<br>et al. [121]) | Retrospective cohort<br>study,<br>USA | и=178   | Physical examination,<br>BW         | Patients with POP specifically not reported                          | orted                           |  | MRD may provide additional information<br>on the presence of an enterocele     |
|  |                                       |   |                                     | Physical examination compared with MRD for enterocele detection      | MRD for enterocele de           | etection   |  |
|  |                                       |   |                                     | Sensitivity 0.300, specificity 0.926                                 |                                 |  | Anterior wall had the best correlation<br>between examination and MRD          |
|  |                                       |   |                                     | Spearman correlation coefficient between MRD grading and BW grading  | een MRD                         | Agreement between<br>BW grade 3,4 and<br>MRD moderate to<br>severe | Findings impacted by how MRD grading<br>is defined                             |
|  |                                       |   |                                     | Anterior   | rho=0.652,<br>moderate positive | 84.6%  |  |
|  |                                       | 274 patients with POP or<br>other pelvic floor disor-<br>der underwent MRD                          |                                     | Apical   | tho=0.195, poor                 | 63%  |  |
|  |                                       | 96 excluded for male sex,<br>incomplete examination<br>or MRD, inability to<br>defectate rectal gel | MRD                                 | Posterior  | tho=0.277, poor                 | 78.7%  |  |
| Arif-Tiwari<br>et al. [123]                                    | Retrospective cohort<br>study, USA    | n=237   | Dynamic MR with<br>Valsalva only vs | 56% prior surgery for POP or UI<br>Vaginal prolapse 22.8%            |                                 |  | Suggests that dynamic MRI for patients<br>with POP should include defecography |
| (same group<br>as Lin et al.                                   |                                       |   | derecography phase                  | 67.4% prior hysterectomy   |                                 |  | pnase  |
| [122] and<br>Pollock et al.                                    |                                       |   |                                     | 0% prolapse detected by Valsalva only but not defecography phase     | / but not defecography          | / phase  |  |
| above [121])   |                                       |   |                                     | Percentage POP detected by defecography phase but not Valsalva only: | aphy phase but not Va           | lsalva only:   |  |
|  |                                       |   |                                     | Cystocele 37.6%  |                                 |  |  |
|  |                                       |   |                                     | Rectocele 25.7%  |                                 |  |  |
|  |                                       | 274 with symptoms of POP  |                                     | <i>p</i> <0.0001   |                                 |  |  |
|  |                                       | 37 patients excluded for<br>male sex or inability<br>to tolerate or defecate<br>rectal gel          | No physical examina-<br>tion data   |  |                                 |  |  |

| Table 9 (continued)       | ttinued)                       |   |  |   |   |                           |   |
|---------------------------|--------------------------------|---|--|---|---|---------------------------|---|
| Reference                 | Study design                   | Population  | Method(s) of clinical assessment                             | Results   |   |                           | Discussion  |
| Faucheron                 | Prospective cohort             | n=50 patients with                                | Physical examination   | Peritoneocele   |   |                           | MRD and DCCP had good interobserver   |
| et al. [124]              | study, France                  | posterior vaginal wall<br>prolapse who ultimately |  | DCCP  |   |                           | agreement for rectocele and posterior<br>colpocele  |
|                           |                                | had surgical repair                               |  | Sensitivity 0.833; specificity 1.000                                    | ecificity 1.000   |                           |   |
|                           |                                |   | POP-Q  | MRD   |   |                           |   |
|                           |                                |   | DCCP   | Sensitivity 0.633, specificity 1.000                                    | ecificity 1.000   |                           |   |
|                           |                                |   | MRD  | Detection of defects and interobse<br>surgery and radiographic findings | Detection of defects and interobserver agreement of findings at surgery and radiographic findings | t of findings at          |   |
|                           |                                |   | Findings at surgery  |   | DCCP  | MRD                       |   |
|                           |                                |   | Studies undergone by<br>all patients but not<br>reported on: | Posterior colpocele   | 89%; kappa=0.69, good   | 91%; kappa=0.76, good     |   |
|                           |                                |   | Colonic transit time study                                   | Rectocele   | 91%; kappa=0.69, good   | 93%; kappa=0.79, good     |   |
|                           |                                |   | Anal manometry   | Peritoneocele   | 87%; kappa=0.72, good   | 76%; kappa=0.54, moderate |   |
|                           |                                |   | Endoanal US  | Full-thickness<br>rectal prolapse                                       | 95%; kappa=0.80, good   | 91%; kappa=0.56, moderate |   |
|                           |                                |   | Colonoscopy  | Internal rectal<br>prolapse   | 93%; kappa=0.85,<br>excellent   | 87%; kappa=0.69, good     | DCCP was better at detecting peritone-<br>ocele, full-thickness, and internal rectal<br>prolapse, possibly because of more<br>physiological nositioning for DCP |
| Lienemann<br>et al. [125] | Case-control study,<br>Germany | <i>n</i> =66                                      | Physical examination   | Diagnosis of<br>enterocele  | Examination   | MR-CCRG                   | MR-CCRG was better than DCP at<br>diagnosing enteroceles  |
|                           |                                |   |  | Present   | 43  | 53                        |   |
|                           |                                |   |  | Absent  | 12  | 2                         |   |
|                           |                                |   |  | Diagnosis of<br>enterocele  | Examination   | DCP                       |   |
|                           |                                |   |  | Present   | 23  | 14                        |   |
|                           |                                |   |  | Absent  | 11  | 20                        |   |
|                           |                                |   |  | Diagnosis of<br>enterocele  | MR-CCRG   | DCP                       |   |
|                           |                                | 55 patients with POP                              | DCP  | Present   | 29  | 14                        |   |
|                           |                                | 11 controls without POP                           | MR-CCRG  | Absent  | 5   | 20                        | MR-CCRG detected enteroceles missed<br>on examination   |

| Table 9 (continued)  | inued)  |  |  |  |  |
|--|---|--|--|--|--|
| Reference  | Study design  | Population   | Method(s) of clinical assessment   | Results  | Discussion   |
| Anal physiology testing<br>Groenendijk Prospec<br>et al. [126] The N | y testing<br>Prospective cohort study, <i>n</i> =59 women with pri-<br>The Netherlands mary POP stage ≥II<br>68 enrolled<br>68 enrolled<br>4 dropped out<br>5 had testing done<br>incorrectiv | n=59 women with pri-<br>mary POP stage ≥II<br>68 enrolled<br>4 dropped out<br>5 had testing done<br>incorrectly      | Symptom questionnaire<br>(defecation distress<br>inventory)<br>POP-Q<br>AFT: manometry,<br>sensation, PNTLT<br>AES                 | Patients with POP vs health controls reference values<br>Lower squeezing pressure<br>Delayed first sensation, desire, capacity<br>Prolonged PNTLT<br>p<0.01<br>Patients with FI had significantly lower resting ( $p=0.036$ ) and squeezing<br>pressures ( $p=0.046$ ) and increased risk of external sphincter defect<br>OR = 12.75; 95% CI 2.40–66.67<br>Manometry was not different between patients with and without   | AFT and AES add limited information to<br>the routine evaluation of POP patients.  |
|  |   | <b>6</b>   |  | Anorectal sensation and sensitivity were not related to the stage<br>of posterior wall prolapse  | Patients with fecal incontinence may<br>benefit from this testing  |
| Zbar et al.<br>[127]   | Prospective cohort<br>study, UK   | <i>n</i> =73 women (14 isolated rectocele aka type 1, 26 rectocele and apical POP aka type 2, 33 controls) controls) | BW<br>Defecography<br>Anorectal manometry,<br>vector manometry,<br>parametric assess-<br>ment of the rectonal<br>inhibitory reflex | All patients with rectocele had this finding on examination and defecography<br>Reduced resting and squeeze pressure in type 2 rectoceles<br>p-0.001<br>Elevated resting pressure in type 1 rectocele<br>p-0.001<br>But squeeze pressure not significantly different<br>Reduced inhibitory slope in RAIR measurements in both rectocele types<br>compared with controls (type 1 $p$ -0.001, type 2 $p$ =0.002)<br>Maximum inhibitory pressure lower in type 1<br>n=0.006   | There are few consistent, differences<br>in anal physiology between isolated<br>rectoceles and those associated with<br>other prolapse   |
| <i>BW</i> Baden–W<br>resonance im<br><i>CCD</i> colpocy              | 'alker prolapse grading<br>aging, CDP cystodefec<br>stodefecography, MRD  | system, POP-Q Pelvic C<br>operitoneography, NOS<br>magnetic resonance def  | Jrgan Prolapse Quantifi<br>not otherwise specified<br>fecography, FI fetal inc   | <i>BW</i> Baden–Walker prolapse grading system, <i>POP-Q</i> Pelvic Organ Prolapse Quantification, <i>DCP</i> dynamic cystoproctography, <i>DCCP</i> dynamic cystoproctography, <i>dMRI</i> dynamic magnetic resonance imaging, <i>CDP</i> cystodefecoperitoneography, <i>NOS</i> not otherwise specified, <i>DCR</i> dynamic contrast roentgenography, <i>DDI</i> defecation distress inventory, <i>HO</i> heterotopic ossification, <i>CCD</i> colpocystodefecography, <i>MRD</i> magnetic resonance defecography, <i>FI</i> fetal incontinence, <i>MR-CCRG</i> magnetic resonance colpocystorectography, <i>PNTLT</i> pudendal nerve terminal latency | roctography, <i>dMRI</i> dynamic magnetic<br>iventory, <i>HO</i> heterotopic ossification,<br><i>TLT</i> pudendal nerve terminal latency |

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time, AFT anorectal function testing, AES anal endosonography, RAIR renoanal inhibitory index

tomical defects, including enterocele, sigmoidocele, and intussusception, are better visualized with either fluoroscopic defecography or MRI defecography, but how this relates to clinical decision-making or more specifically outcomes, remains unclear.

2. In patients where these diagnoses are in question or in patients who present with GI symptoms, it is reasonable to obtain further imaging and testing beyond a routine clinical examination. However, these additional studies can be expensive and uncomfortable to patients, and currently there is no apparent benefit to identifying an underlying condition that would influence treatment decisions and outcomes. Until a benefit is established, their routine use in asymptomatic women with POP should be discouraged outside of research protocols.

**Further research** Future studies comparing imaging and physiological testing with clinical examination need to compare their results with standardized clinical evaluation in the form of the POP-Q. Standardized minimum criteria for imaging and physiological testing need to be established, as well as a standardized reporting system to allow for comparison between studies. Until these are drawn up it will remain almost impossible to evaluate the literature.

Studies in patients with POP and no GI complaints comparing radiographic/physiological testing with no testing need to be evaluated with meaningful outcome measures.

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## Declarations

## Conflicts of interest None.

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