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Is the hymen a suitable cut-off point for clinically relevant pelvic organ prolapse?

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ABSTRACT

Objectives: The primary objective was to evaluate the ability of different anatomic cut-off points, as established in specialist urogynecology populations, to identify clinically relevant prolapse in a population of postmenopausal women with pelvic floor symptoms recruited from primary care.
Study design: Cross-sectional study among 890 women (≥55 years) screened for pelvic floor symptoms.
Main outcome measures: The Pelvic Floor Distress Inventory 20 was used to measure symptoms, and the Pelvic Organ Prolapse Quantification (POP-Q) system was used to assess prolapse. Areas under the curves, sensitivity, and specificity were calculated for the hymen as a cut-off point for symptomatic prolapse of the anterior and posterior vaginal wall. For the apical compartment, a cut-off point of −5 cm relative to the hymen was used.
Results: Vaginal bulging was the only symptom reported more often with increasing POP-Q stages. Areas under the curves (95% confidence intervals) to discriminate between women with and without vaginal bulging symptoms were 0.66 (0.61–0.72), 0.56 (0.50–0.63), and 0.61 (0.55–0.66) for the anterior (Ba), posterior (Bp) and apical (C) compartment, respectively. When the hymen was used as the cut-off point, Ba had a sensitivity of 38.1% and a specificity of 82.4%, and Bp had a sensitivity of 13.3% and a specificity of 96.5%. For C, the cut-off point of −5 cm relative to the hymen had a sensitivity of 37.9% and a specificity of 73.1%.
Conclusions: The anatomic cut-off points for clinically relevant prolapse established in the specialist urogynecology population cannot adequately identify symptomatic prolapse in a population of postmenopausal women with pelvic floor symptoms recruited from primary care.

1. Introduction

Pelvic organ prolapse is defined as a descent of the anterior or posterior vaginal wall, or descent of the uterus (or the vaginal vault after hysterectomy) [1], and some degree of prolapse is typically present in approximately 75% of women aged 45–85 years [2]. Prolapse can be associated with symptoms related specifically to the prolapsed structures, such as seeing or feeling a vaginal bulge or pelvic pressure and heaviness, but can also be associated with other symptoms of pelvic floor dysfunction, such as urinary, defecatory, or sexual symptoms [3]. The degree of prolapse is most commonly assessed using the Pelvic Organ Prolapse Quantification (POP-Q) system as advised by the International Continence Society. A POP-Q stage (0–4) is determined for each compartment, with the overall POP-Q stage being equal to the POP-Q stage of the most severely prolapsed compartment [4].

However, because (asymptomatic) mild prolapse is present in large proportions of women in the community [2,5] as well as those attending routine gynecologic examination [6,7], some authors have suggested that POP-Q Stage 1 and Stage 2 (above the hymen) might be better regarded as physiological [7–12].

Several studies have attempted to identify the anatomic thresholds at which prolapse becomes symptomatic or clinically relevant. These studies, all performed in specialist urogynecology settings, agree that symptomatic prolapse can be defined as the presence of either "seeing or feeling a bulge in the vagina" [7,12,13] or "the sensation of a lump or bulge and/or a dragging sensation in the vagina" [7,11]. POP-Q measurements of the anterior vaginal wall (point Ba), the posterior vaginal wall (point Bp), and the apical compartment (point C) have been studied to find the anatomic cut-off points at

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which prolapse becomes symptomatic. These showed that prolapse of the anterior and posterior vaginal wall had optimal cut-off points approximately at or just beyond the hymen (Ba and Bp varying from −0.5 to +1 cm), [7,11–13] while prolapse of the apical compartment became symptomatic at or beyond 5 cm above the hymen. [11]

The cut-off points for the POP-Q measurements Ba, Bp, and C have shown reasonably good sensitivities and specificities in specialist urogynecology clinics [7,11–13]. However, the sensitivity and the specificity of a test may change when applied to different patient populations [14–16]. Selection bias, due to symptomatic patients being referred to specialist urogynecology clinics, means that both the prevalence of vaginal bulging symptoms and the prior probability of (advanced) prolapse will be higher in women seeking surgical treatment for prolapse in urogynecology clinics. Therefore, we cannot validly generalize the cut-off points for clinically relevant (symptomatic) prolapse to the general population if we rely solely on data established in the urogynecology clinic population.

The aim of this study was to evaluate the discriminative value of the anatomic cut-off points for clinically relevant (symptomatic) prolapse, as established in specialist urogynecology settings, in a population of postmenopausal women with pelvic floor symptoms recruited from primary care.

2. Methods

2.1. Study design

This was a cross-sectional sub-study of the "Pelvic Organ Prolapse in Primary Care: Effects of Pelvic Floor Muscle Training and Pessary Treatment Study" (POPPS) [17]. Enrollment was between October 2009 and December 2012, and all participants provided written informed consent. The study was approved by the Medical Ethics Committee of the University Medical Center Groningen (METc2009.215), and was registered in the Dutch Trial Register (www.trialregister.nl, identifier NTR 2047). Women were invited for an assessment if they were aged ≥55 years, registered in one of the 20 Dutch primary care practices involved in the POPPS project, and screened positive for at least one pelvic floor symptom on a postal questionnaire. This five-item screening questionnaire included questions on urinary incontinence, vaginal bulging, pelvic heaviness/pressure, and vaginal splinting to start or complete micturition or defecation, and has been previously published [17]. We applied the following exclusion criteria: current treatment for prolapse or treatment within the past year, pelvic organ malignancy, current treatment for another gynecological disorder, severe/terminal illness, impaired mobility, cognitive impairment, and insufficient command of the Dutch language.

2.2. Assessment

Before pelvic examination, all participants completed the Pelvic Floor Distress Inventory-20 (PFDI-20) to measure the distress they experienced from pelvic floor symptoms. This questionnaire comprises 20 items requiring yes or no responses, and each item addresses a separate symptom. If a " yes" response is given, patients answer "not at all," "somewhat," "moderately," or "quite a bit," to the question: "If yes, how much does it bother you?" The total PFDI-20 score ranges from 0 to 300, with higher scores indicating more distress [18]. During the assessment, data about patient characteristics, including the medical and obstetric history, were collected by a standardized interview.

Prolapse was assessed by physical examination in supine position using the Pelvic Organ Prolapse-Quantification (POP-Q) system. In the POP-Q system, the degree of prolapse of the anterior vaginal wall (Ba), the posterior vaginal (Bp) wall, and the uterus or vaginal vault (following hysterectomy) (C) is measured in centimeters during a maximal Valsalva maneuver, using the hymen as a reference point. Based on these parameters, a POP-Q stage can be calculated for each compartment, from Stage 0 (normal pelvic support) to Stage 4 (complete eversion). The overall POP-Q stage is equal to the POP-Q stage of the most severely prolapsed compartment [4]. POP-Q measurements were performed after voiding, and all POP-Q points (except total vaginal length) were measured on maximal straining. We maximized the women's pushing efforts by asking them to strain as if they wanted to pass a hard bowel movement. Physical examinations were performed by four research physicians who were trained in POP-Q measurement according to the following method. First, the research physicians studied the original publication by Bump et al. to understand the POP-Q procedure [4]. Second, an experienced urogynecologist showed the research physicians how to perform a POP-Q measurement in patients visiting the Pelvic Floor Center of the University Medical Center Groningen. Third, the research physicians performed a number of POP-Q measurements under the supervision of this urogynecologist, who repeated the first of these measurements to see if they agreed with those of the research physicians. When the urogynecologist felt that the research physicians were capable of performing POP-Q measurements independently, they were permitted to start performing study measurements. The research physicians were blinded to the answers on the PFDI-20 questionnaire.

2.3. Analyses

Participants were divided in four groups based on their overall POP-Q stage (Stage 0, 1, 2, and ≥3). The proportion of women reporting each PFDI-20 symptom was compared between groups using the chi squared test for trend (Chi^2_{trend}). A symptom was regarded as present if participants reported the symptom and if it was at least "somewhat" bothersome on the PFDI-20 questionnaire.

Receiver operator characteristic (ROC) curves were constructed for each of the symptoms reported more often with increasing POP-Q stage, using the established Ba, Bp, and C cut-off points to discriminate between women with and without the symptom. The area under the ROC curve (AUC) was then calculated to measure the discriminative ability of the Ba, Bp, or C measurements to distinguish between persons with and without bothersome symptoms. For the interpretation of the AUC, we used the rule of thumb, that a test with an AUC ≥0.9 has high accuracy, that with an AUC of 0.7–0.9 has moderate accuracy, and that with an AUC of 0.5–0.7 has low accuracy. An AUC of 0.5 means that the accuracy of the test is equal to a 50:50 chance (i.e., tossing a coin) [19].

For the anterior (Ba) and posterior (Bp) compartments we calculated the sensitivity and specificity of the hymen as a cut-off point. Sensitivity was calculated as the number of women with Ba/Bp ≥ 0 and symptoms (true positives) divided by the number of women with Ba/Bp ≥ 0 and symptoms (true positives) plus the number of women with Ba/Bp < 0 and symptoms (false negatives). Specificity was calculated as the number of women with Ba/Bp < 0 without symptoms (true negatives) divided by the number of women with Ba/Bp < 0 without symptoms (true negatives) plus the number of women with Ba/Bp ≥ 0 without symptoms (false positives). For the apical compartment (C), we used a cut-off point of −5 cm relative to the hymen (C ≥ -5) to calculate sensitivity and specificity [11].

We also calculated adjusted AUCs, sensitivities, and specificities after excluding women with a higher-stage prolapse in other compartments. For example, if a participant had a Stage 1 anterior vaginal wall prolapse but a Stage 2 posterior vaginal wall prolapse, this participant was excluded from the analyses of Ba versus symptoms on the assumption that in this participant, the Stage 2 posterior vaginal wall prolapse was very likely to confound the rela-