Does Dominant Prolapse in Other Compartments Affect the Assessment of Bladder Prolapse on Translabial Ultrasound?

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Abstract

Objective: To explore the impact of dominant prolapse in other compartments in assessing bladder prolapse, and to establish cutoffs for staging bladder prolapse among Chinese women using translabial ultrasound. Design: Prospective multicentre observational study. Setting: Tertiary referral urogynaecology unit. Population: A total of 741 women with symptoms of lower urinary tract dysfunction and/or pelvic floor dysfunction were included. Methods: Women underwent interview, pelvic organ prolapse quantification (POP-Q) examinations and 4D translabial ultrasounds. Main outcome measures: The ROC statistic was used to assess accuracy and define the optimal cutoffs. Results: The mean patient age was 42.7 years (range, 18-82). There were 456 women without dominant prolapse in the apical/posterior compartments. Among patients without and with dominant prolapse, similar cutoffs (-10.9 mm vs. -9.1 mm) were determined for predicting POP-Q stage [?] 2 in the anterior compartment, with AUCs of 0.87 and 0.79, respectively. In contrast, significantly different cutoffs (-5.7 mm vs. +3.5 mm) were determined for predicting POP-Q stage [?] 1 among patients with and without dominant prolapse, with AUCs of 0.85 and 0.77, respectively. Conclusion: Dominant prolapse in the apical/posterior compartments affected the accuracy and cutoffs of translabial ultrasound for staging bladder prolapse. Thus, competition of various organs in women with multi-compartment prolapse should be considered as a potential complicating factor in assessing pelvic organ prolapse. Funding: The study is supported by grants from the National Natural Science Foundation of China (No. 91859115). Key words: Bladder prolapse; translabial ultrasound.

Title: Does Dominant Prolapse in Other Compartments Affect the Assessment of Bladder Prolapse on Translabial Ultrasound?

Short title: Assessment of Bladder Prolapse on Ultrasound

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Abbreviations: FPOP, Female pelvic organ prolapse; ICS POP-Q, International Continence Society pelvic organ prolapse quantification; AUC, the area under the receiver operating characteristic curve.

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Structured Abstract

Objective: To explore the impact of dominant prolapse in other compartments in assessing bladder prolapse, and to establish cutoffs for staging bladder prolapse among Chinese women using translabial ultrasound.

Design: Prospective multicentre observational study.

Setting: Tertiary referral urogynaecology unit.

Population: A total of 741 women with symptoms of lower urinary tract dysfunction and/or pelvic floor dysfunction were included.

Methods: Women underwent interview, pelvic organ prolapse quantification (POP-Q) examinations and 4D translabial ultrasounds.

Main outcome measures: The ROC statistic was used to assess accuracy and define the optimal cutoffs.

Results: The mean patient age was 42.7 years (range, 18-82). There were 456 women without dominant prolapse in the apical/posterior compartments and 285 women with dominant prolapse in the apical/posterior compartments. Among patients without and with dominant prolapse, similar cutoffs (-10.9 mm vs. -9.1 mm) were determined for predicting POP-Q stage [?] 2 in the anterior compartment, with AUCs of 0.87 and 0.79, respectively. In contrast, significantly different cutoffs (-5.7 mm vs. +3.5 mm) were determined for predicting POP-Q stage [?] 1 among patients with and without dominant prolapse, with AUCs of 0.85 and 0.77, respectively.

Conclusion: Dominant prolapse in the apical/posterior compartments affected the accuracy and cutoffs of translabial ultrasound for staging bladder prolapse. Thus, competition of various organs in women with multi-compartment prolapse should be considered as a potential complicating factor in assessing pelvic organ prolapse.

Funding: The study is supported by grants from the National Natural Science Foundation of China (No. 91859115).

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Tweetable abstract

Dominant prolapse in other compartments affects the accuracy and cutoffs of translabial ultrasound for staging bladder prolapse.

Main body of text

Introduction

Female pelvic organ prolapse (FPOP), defined as the descent of one or more of the female pelvic organs, is a common gynecological condition¹. Symptomatic FPOP significantly impacts quality of life among women, with an estimated risk as high as 20% for the need of gynecological surgical intervention². FPOP has been shown to be significantly associated with symptoms of issues such as stress incontinence, voiding dysfunction, fecal incontinence, and others³⁻⁵.

If FPOP is considered as a possible form of hernia⁶, the levator hiatus could be regarded as the largest potential hernia portal in the human body, allowing for the descent of female pelvic organs. Unsurprisingly, there may exist competition between different compartments during pelvic organ descent, so the evaluation of pelvic organ prolapse within one compartment could potentially be affected by prolapse occurring in another compartment.

Imaging techniques have played an important role in the investigation of FPOP⁷. Of the available techniques, translabial ultrasound is currently regarded as one of the most promising modalities in the evaluation of prolapses⁶. The development of translabial ultrasound has contributed greatly to the understanding of FPOP, and it has also helped settle some arguments in the field. However, research appears to be limited on the subject of translabial ultrasound and potential competition between different compartments in multi-compartment prolapse. In one study⁸, it was suggested that the optimal cutoffs for uterine prolapse on translabial ultrasound were not affected by dominant prolapse in other compartments. However, to date there are no known studies regarding the impact of dominant prolapse in other compartments on the assessment of bladder prolapse. Additionally, the best cutoffs for defining bladder prolapse among the Chinese population have not been well established on translabial ultrasound.

Therefore, this study aimed to explore the impact of dominant prolapse in other compartments on the assessment of bladder prolapse on translabial ultrasound. This study also sought to establish the best cutoff values for bladder prolapse among Chinese women on translabial ultrasound.

Patients and Methods

Study population

This prospective, multicenter study involved ten clinical centers located in Mainland China (Chinese Clinical Trial Registration No. ChiCTR ROC 16009855). The study protocol was approved by the local Institutional Human Research Ethics Committee. Informed consent was obtained from each study participant. For quality control, the data from the entire study was controlled and analyzed by the principal investigator.

For this study, women were recruited who were seen at tertiary gynecological centers for lower urinary tract symptoms and/or symptoms of pelvic organ prolapse between February 2017 and September 2018. All participants went through a local standardized interview, a clinical examination using the ICS POP-Q assessment, and a 4D translabial ultrasound examination. For the purposes of the research, prolapse symptoms were defined as "the sensation of a lump in the vagina and/or a dragging sensation in the vagina" ⁹. Women with either a history of hysterectomy or pelvic floor surgery for prolapse or incontinence was excluded from the data.

The ICS POP-Q assessment

The clinical examinations at each center were assessed using the International Continence Society (ICS) POP-Q method^{10,11}by experienced gynecologists (each with [?] 2 years of experience with ICS POP-Q examinations). The gynecologists who performed the assessments were blinded to the patients' clinical data, as well as the results of the 4D translabial ultrasound examinations.

The ICS POP-Q examination assessed anterior, central, and posterior compartment descent by measuring the maximum downward displacement of the anterior vaginal wall, the cervix, and the posterior vaginal wall relative to the hymen with the patient in a maximal Valsalva maneuver. The quantitative descriptions of the ICS POP-Q assessments from this study were recorded using the five stages of pelvic organ support according to the ICS POP-Q system (Table S1). Dominant prolapse in the apical and/or posterior compartment was defined as follows: (a) apical compartment prolapses had the same or higher POP-Q stage than the anterior compartment prolapse; and/or (b) the posterior compartment prolapse had the higher POP-Q stage than the anterior compartment. This is because based on previous findings¹², stage 1 uterine prolapse is just as significant in predicting prolapse symptoms as stage 2 anterior or posterior compartment prolapse on ICS POP-Q assessments.

4D translabial ultrasound examination

The 4D translabial pelvic floor ultrasound examinations were performed using a GE Voluson S6 or S8 ultrasound device with a 4-8MHz curved array volume transducer and with an acquisition angle of 85° (GE, Kretztechnik, GmbH, Zipf, Austria). All ultrasounds were conducted by senior sonographers (each trained for at least 50 consecutive examinations). The sonographers had no access to the patients' other clinical data. The patients were examined in the supine position after bladder emptying and defecation, as previously described. Volume acquisitions were obtained at rest, on contraction, and on Valsalva, and at least three volumes were acquired on Valsalva. Great care had to be taken to have the Valsalva maneuver performed for a minimum duration of 6 seconds without levator coactivation^{13,14}.

Archived 4D translabial ultrasound datasets were analyzed offline at a later date using 4D View software (version 10.0, GE Medical Systems) by two investigators, who each had at least two years of experience with 4D translabial pelvic floor ultrasound examination. These investigators were both blinded to all other data. Using the offline system, they evaluated anterior, central, and posterior compartment descent by measuring the leading edge of the bladder, cervix, and rectum relative to the inferior margin of the symphysis pubis. Positions above the symphysis pubis were given as positive values, while positions below were given as negative values.

Statistical methods

Statistical analysis was performed using IBM SPSS Statistics 22 software for Windows (SPSS Inc., Chicago, IL, USA) and Medcalc (version 11.2; 2011 MedCalc Software Bvba, Mariakerke, Belgium).

The quantitative variables (age and body mass index) were found to be normally distributed using a onesample Kolmogorov-Smirnov test and therefore were expressed as mean values and standard deviations. The qualitative variables were expressed as counts and percentages. Comparisons of the quantitative variables between the cohorts were assessed using an unpaired t-test. A chi-squared test was performed for comparisons of the qualitative variables between the cohorts. The performance of measuring bladder descent on translabial ultrasound in order to predict a POP-Q stage [?] 1 and POP-Q stage [?] 2 for the anterior compartment in clinical examination was evaluated using the area under the receiver operating characteristic curve (AUC) and a 95% confidence interval (CI). Differences between the AUCs of separate cohorts were compared using the Z-test¹⁵, according to the following formula: $Z=|AUC1-AUC2|/sqrt[SE(Standard Errors)1^2+SE^2]$. The sensitivity, specificity, and 95% CIs were also presented and compared using a chi-squared test. The highest Youden index was used to generate the optimal cutoffs of bladder descent on Valsalva for the prediction of different POP-Q stages: Youden's index = sensitivity + specificity – 1¹⁶. P < 0.05 was considered statistically significant.

Results

Participant Characteristics

Between February 2017 and September 2018, a total of 967 women were initially recruited for the study. Women less than one year postpartum were excluded (n = 159). Seventeen women were excluded for either a previous history of hysterectomy or pelvic floor surgery for prolapse or incontinence. Two were excluded

for being under the age of 18, and five others declined to participate in the study. Forty-three data sets were further excluded due to missing POP-Q information, missing US data, or technically suboptimal ultrasound volume data. In total, 741 women were included in the final analysis (76.6%, 741/967).

Table S2 presents the demographic data and symptom assessments of the total cohort. The mean age of the 741 study participants was 42.7 years (range, 18-82), and the mean body mass index was 29.4 kg/m² (range, 15.4–35.5). There were 204 post-menopausal women (27.5%, 204/741) who participated in the study. A total of 293 women, or 39.5% of the cohort, reported prolapse symptoms (a lump or drag felt in the vagina). Of the 293 symptomatic participants, 38 cases were classified as POP-Q stage 0 in clinical examinations, leaving 255 who were actually experiencing symptomatic prolapse. One hundred and ninety-seven women presented symptomatic multi-compartment prolapse, while 58 women showed symptomatic single compartment prolapse. Numbers for isolated symptomatic cystoceles, uterine prolapses, and rectoceles were 41, 15, and 2, respectively. Symptomatic isolated cystoceles descended on average to 8.2 mm below the symphysis pubis (range, 20.6 mm above to 31.9 mm below). There were no cases of isolated enteroceles in this study.

To better evaluate the impact of dominant prolapse in the apical/posterior compartments on the assessment of bladder prolapse using translabial ultrasound, the study participants were divided into two groups: a cohort excluding dominant prolapse (N = 456), and a cohort including dominant prolapse (N = 285). Comparisons of the demographic data and symptom assessments from both cohorts are shown in Table 1. Participants in the cohort including dominant prolapse tended to be older compared to those in the cohort excluding dominant prolapse(mean age: 44.5 years old vs. 41.5 years old). The percentage of women who reported prolapse symptoms in the cohort including dominant prolapse was higher than in the cohort excluding dominant prolapse (49.5% vs. 33.3%). There were no statistical differences in other demographic data or symptom assessments between the two cohorts.

Assessment of bladder descent on translabial ultrasound

In the total population, the receiver operating characteristic curve (ROC) statistics proved that measuring bladder descent using translabial ultrasound showed solid performance for predicting both ICS POP-Q stage [?] 1 and ICS POP-Q stage [?] 2, with AUCs of 0.82 (95% CI: 0.80-0.85) and 0.84 (95%: 0.81-0.87), respectively (Table S3). Optimal cutoff values of 5.7 mm below the symphysis public and 9.1 mm below the symphysis public were determined on translabial ultrasound for predicting ICS POP-Q stage [?] 1 and ICS POP-Q stage [?] 2, respectively (Table S3).

Table 2 shows the comparisons of the optimal cutoff values and AUCs of bladder descent for predicting ICS POP-Q stages in different cohorts. Figure 1 and 2 present the examples of translabial ultrasound images (midsagittal plane) in woman with multi-compartment prolapse. The ROC statistics suggested an optimal cutoff value of 5.7 mm below the symphysis pubis of bladder descent on the ultrasound for ICS POP-Q stage [?]1 in the cohort excluding dominant prolapse (AUC: 0.85; 95% CI: 0.81-0.88), while they pointed to a markedly different optimal cutoff value of 3.5 mm above the symphysis pubis of bladder descent on the ultrasound for ICS POP-Q stage [?]1 in the cohort including dominant prolapse (AUC: 0.77; 95% CI: 0.71-0.81). In contrast, comparable cutoffs of bladder descent on ultrasound images for ICS POP-Q stage [?] 2 were obtained through ROC analysis in both cohorts, with an optimal cutoff value of 10.9 mm below the symphysis pubis in the cohort excluding dominant prolapse, and a cutoff value of 9.1 mm below the symphysis pubis in the cohort including dominant prolapse, respectively. The AUCs for staging bladder descent in the cohort including dominant prolapse were significantly impaired compared to the cohort excluding dominant prolapse (*P* values < 0.001).

Discussion

Main findings

This prospective multicenter study mainly focused on the impact of dominant prolapse in the apical and/or posterior compartments on the assessment of bladder descent in clinical examinations. The data suggested

that dominant prolapse in other compartments significantly impaired the performance of ultrasound parameters for staging bladder prolapse. Interestingly, dominant prolapse in other compartments seemed to have no impact on the optimal cutoffs of bladder descent for predicting POP-Q stage [?] 2 on translabial ultrasound, but it might affect the optimal cutoffs for POP-Q stage [?] 1 according to ROC statistics.

This study also aimed to determine the optimal cutoffs of bladder descent using translabial ultrasound to assess signs of prolapse among Chinese women for the first time. Similar to a previous finding¹⁷ for the definition of significant bladder descent on pelvic floor ultrasound (descent of the bladder to [?]10 mm below the symphysis public on maximal Valsalva), this study proposed that significant bladder descent on an ultrasound should be defined as a descent of the bladder to 10.9 mm or more below the symphysis public on Valsalva, excluding patients with dominant prolapse in the apical or posterior compartments.

Interpretation

Multi-compartment prolapse is commonly seen in real-world clinical practice. Indeed, female pelvic organ prolapse is like a form of hernia, and the levator hiatus is a space that allows for the downward displacement of organs from different compartments¹⁸. Dominant prolapse in other compartments is a particularly interesting confounder for the diagnosis of bladder descent on a translabial ultrasound. This study confirmed that dominant prolapse in other compartments might reduce the accuracy of the assessment of pelvic organ prolapse using translabial ultrasound. Concerning the impact on the optimal cutoffs of bladder descent, the data suggested that dominant prolapse in other compartment(s) did not change the cutoffs of bladder descent for predicting significant POP, which is consistent with the results of previous research⁸. However, the descent of the bladder was less pronounced on Valsalva for POP-Q stage [?] 1 among patients with dominant prolapse in other compartments, according to ROC statistics. Possible reasons for this difference are complex. One thing to consider, for example, is that participants with dominant prolapse in the apical and/or posterior compartments in this study presented higher POP-Q stages compared to those without dominant prolapse, which suggested that these patients might present larger areas of levator hiatus for the downward displacement of various organs. Slight bladder descent might be masked with a smaller area of levator hiatus. Future studies are needed to better explore the reason for this discrepancy.

Different from a previous study mainly conducted on Caucasian women¹⁷, the percentage of participants with multi-compartment prolapse in this study was higher than the percentage with single compartment prolapse among those with prolapse symptoms. Additionally, in the data from the current study, women who presented uterine prolapse or rectocele were also usually accompanied by bladder prolapse. Such differences could possibly be explained by the ethnic differences in the female pelvic floor¹⁹⁻²². It has been demonstrated that Asian women tend to present apical compartment prolapse, while Caucasian women are more likely to have posterior compartment prolapse²¹.

Also worth mentioning is that women with dominant prolapse in the apical and/or posterior compartments in this study were found to be older and among a higher percentage of patients who reported prolapse symptoms. This phenomenon might suggest that older Asian women are more likely to present a larger levator hiatus area and therefore, possibly have more severe apical compartment prolapse. The larger the size of the hernia, the higher the risk the women might have severe apical compartment prolapse^{23,24}. Unsurprisingly, among such women, prolapse symptoms were usually more serious.

Strengths and limitations

To the best of our knowledge, this prospective, multicenter study was performed with the largest sample size conducted among Chinses women. Unlike other studies which only sought to establish the optimal cutoffs on translabial ultrasound, the current study also aimed to explore the confounders for assessing prolapses. However, this study had several limitations. First, there exists a possibility of selection bias in the study population, as there might yet be other potential confounders in the assessment of bladder prolapse on translabial ultrasound. Second, this study was limited in scope to examining those of Chinese nationality. However, the optimal cutoffs determined in this study for defining bladder prolapse on translabial ultrasound among Chinese women are similar to the definitions established among an Australian population

by a previous study¹⁷, which might suggest that anterior prolapse assessment does not vary much among different ethnic groups.

Conclusion

In summary, this study proposed that dominant prolapse in other compartments might significantly impair the diagnostic accuracy for bladder descent on ultrasound, and therefore should be considered as a potential confounder. This study also suggested that the descent of the bladder to 10.9 mm or more below the symphysis pubis on Valsalva should be proposed as an optimal cutoff for the ultrasonic prediction of significant anterior compartment prolapse among the Chinese population. Great caution should be taken when examining women with multi-compartment prolapse in order to more accurately assess their prolapse. Future studies will be needed to explore other potential confounders in the assessment of pelvic organ prolapse during the translabial pelvic floor ultrasound procedure.

Disclosure statement :

The authors report no conflict of interest.

Contribution to authorship:

Manli Wu and Xudong Wang: Concept and design of data; Formal analysis, Writing - Original Draft; Approval of the version of the manuscript submitted.

Zhijuan Zheng, Junyan Cao and Jing Xu: Concept and design of data; Project administration; Approval of the version of the manuscript submitted.

Shuangyu Wu and Ying Chen: Analysis and interpretation of data; Project administration; Approval of the version of the manuscript submitted.

Jiawei Tian: Concept and design of data; Supervision; Project administration; Approval of the version of the manuscript submitted.

Xinling Zhang: Concept and design of data; Supervision; Project administration; Funding; Writing - Review & Editing; Approval of the version of the manuscript submitted.

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Details of ethics approval:

Ethics approval was obtained from Human Research Ethics Committee of the principle clinical centre (the Second Affiliated Hospital of Harbin Medical University, KY2016-203, approved on 7 November 2016).

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Table Legends

 Table 1 Comparison of demographic data and symptoms assessments between cohorts with and without dominant prolapse in apical/posterior compartments

Table 2 Influence of dominant prolapse in apical/posterior compartments on the assessment of bladder descent on Valsalva using translabial ultrasound for predicting POP-Q stage [?] 1 and POP-Q stage [?] 2

Figure Legends

Figure 1 Translabial ultrasound images (midsagittal plane) in a woman with dominant prolapse in the anterior compartment (POP-Q stage 3 for anterior compartment and POP-Q stage 1 for apical compartment) at rest (a) and on maximal Valsalva maneuver (b). The leading edge of the bladder relative to the inferior margin of the symphysis public was -19 mm. *POP-Q, pelvic organ prolapse quantification.*

Figure 2 Translabial ultrasound images (midsagittal plane) in a woman with a severe symptomatic, multicompartment compartment prolapse (POP-Q stage 3 for anterior compartment, POP-Q stage 4 for apical compartment and POP-Q stage 3 for posterior compartment) at rest (a) and on maximal Valsalva maneuver (b). The leading edge of the bladder, cervix, and rectum relative to the inferior margin of the symphysis public were -21 mm, -26 mm and -19 mm, respectively. *POP-Q, pelvic organ prolapse quantification*.

Supplementary Table Legends

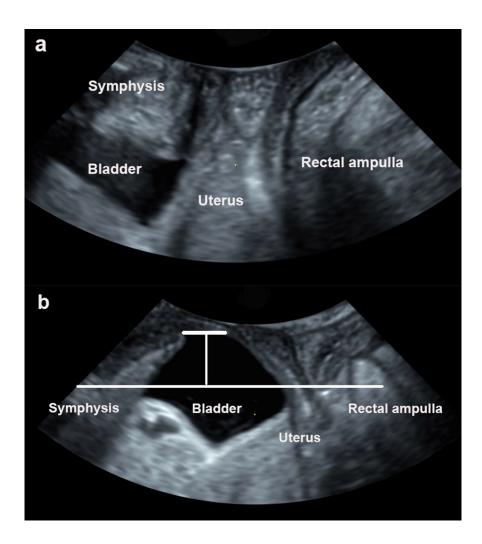
Table S1 The five stages of pelvic organ support using ICS POP-Q system

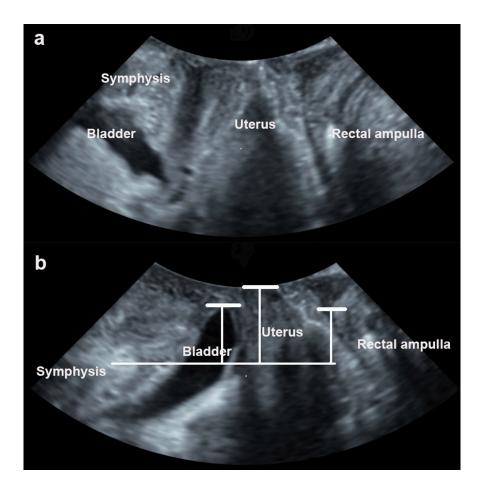
 Table S2 Demographic data and symptoms assessments of the total cohort

Table S3 Assessment of bladder descent on Valsalva using translabial ultrasound for predicting POP-Qstage [?] 1 and POP-Q stage [?] 2 in the total population

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