

Determining “abnormal” levator hiatus distensibility using three-dimensional transperineal ultrasound in Chinese women

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Abstract The dimension of the levator hiatus is a possible predictor of pelvic organ prolapse (POP). This retrospective study investigated 360 women who went to urogynecological clinic for pelvic floor discomfort. Levator hiatus dimensions were obtained by three-dimensional transperineal ultrasound and results were compared between women with and without significantly objective prolapse (International Continence Society POP quantification, grade 2 or higher). Receiver operating characteristic (ROC) curve analyses were performed to determine valid screening index for detecting abnormal levator hiatus distensibility. Women with significantly objective prolapse had significantly higher levator hiatus dimensions than those without (all $P < 0.001$). ROC curve analyses confirmed that hiatal area (HA) of 19.5 cm² during Valsalva maneuver can be used as single-screening index for abnormal levator hiatus distensibility with sensitivity of 0.80 and specificity of 0.70. In this study, we used a two-step method and achieved higher sensibility (0.80 vs. 0.87) without reducing specificity (0.70 vs. 0.71) compared with a single-screening index method. As a result, we suggest that $HA \geq 19.5$ cm² during Valsalva maneuver is an indicator of abnormal levator hiatus distensibility in Chinese women and that the two-step method has higher sensitivity in detecting abnormal distensibility.

Keywords three-dimensional transperineal ultrasound; levator hiatus; levator ani muscle; pelvic organ prolapse

Introduction

Pelvic organ prolapse (POP) is a highly prevalent condition that causes discomfort in women because of the descent of pelvic floor organs, such as the bladder, vagina, uterus, or bowels, and significantly affects quality of life [1–3]. In developing countries, POP has a mean prevalence of 19.7% [4], whereas an epidemiological survey in China showed that nearly half the population of Chinese women over 50 years old is susceptible to this condition. Early detection and diagnosis of POP are important because early intervention and treatment may improve symptoms and reduce its degree and operation rate [5,6].

The POP quantification (POP-Q) system was introduced

in 1996 and it considers the hymen as a fixed reference point in evaluating POP severity. Since 2004, it has been the most commonly used method in China, regardless of its complexity [7]. However, as a means of evaluating the degree of prolapse, this system cannot be used to observe injuries of pelvic support structures or dynamic changes in levator hiatus.

Defects of pelvic floor-supporting structures are considered the main causes of POP. In recent years, numerous imaging studies [8–12] have focused on pelvic floor support structures. However, the etiology of POP remains undetermined. Levator hiatus is delimited by the levator ani muscle and is important in pelvic organ support [13]. Three-dimensional (3D) transperineal ultrasound is a convenient method widely used to observe dimensions of the levator hiatus and its distensibility [13–23]. Studies have proposed that an enlarged levator hiatus may be an important indicator of pelvic floor support failure [14,24] and slacking of levator ani muscle. Moreover, increased levator hiatus dimensions is associated with POP severity

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[14,25,26]. Furthermore, studies have confirmed the hypothesis that increased levator hiatus dimensions is associated with high POP possibility not only in women with symptomatic pelvic floor dysfunction but also in asymptomatic nulliparous women [11,12].

Study on abnormal levator hiatus distensibility

The levator hiatus is closely related to occurrence of POP; however, few studies have screened its abnormal distensibility to detect POP. Dietz *et al.* (2008) suggested that hiatal area (HA) > 25 cm² during Valsalva maneuver should be defined as abnormal distensibility or ballooning of the levator hiatus [14]. However, several studies have shown that the levator hiatal dimensions in East Asian women are smaller than in Caucasian women after controlling possible confounders, including body mass index, height, and maternal factors; moreover, they proposed that differences in racial origins may be the only significant factor that can be considered [15–17]. Therefore, in discerning abnormal levator hiatus distensibility in Chinese women through Valsalva maneuver, cautiousness is lacking in defining the cut-off at 25 cm². We conducted this retrospective study to test the validity of using a HA of 25 cm² during Valsalva maneuver and to identify suitable parameters and methods to detect abnormal levator hiatus distensibility in Chinese women.

Research design and methods

This study was approved by the Ethics Committee of Shanghai Jiao Tong University Affiliated Sixth People's Hospital. We retrospectively analyzed data of 360 women who went to the urogynecological clinic of the hospital from May 2013 to September 2016 for consultation of pelvic floor discomfort symptoms, such as incontinence, dysuria, bulging sensation, and heaviness. All patients underwent medical history interview, physical examination for prolapse (International Continence Society POP-Q system), and 3D transperineal ultrasound examination using GE Voluson E8 (GE Medical Systems, Australia) with RAB4-8-D 3D volume probe. POP-Q grade 2 or higher refers to the leading edge of prolapse and is situated < 1 cm above the hymen [27]. Patients with history of pelvic floor surgery and who were unable to perform an adequate Valsalva maneuver were excluded. Imaging was performed on patients after bladder emptying. Patients were placed at rest and on supine position. Maximal Valsalva maneuver was then performed with the probe placed on the perineum in the mid-sagittal plane. Ultrasound data were analyzed offline using GE 4D View by one experienced doctor, who was blinded from all

clinical data. In the midsagittal section, the plane of minimum hiatal dimension was identified between the hyperechoic posterior aspect of the pubic symphysis (PS) and the hyperechoic anterior border of the puborectal muscle (PRM), which is posterior to the anorectal muscle (represented by the green line in Fig. 1A) [28]. Relevant parameters were then measured at the plane of minimal hiatal dimension to evaluate the levator hiatus size; variables included the HA of levator hiatus, anteroposterior diameter of levator hiatus (AP), and coronal diameter of levator hiatus (LR) at rest and under Valsalva maneuver. Differences in HA between rest and Valsalva maneuver (Δ HA r-V) were also calculated. Fig.1 shows an image of the levator hiatus (represented by dotted line in Fig. 1B and 1C).

Statistical analysis was performed using SPSS 13.0 for Windows (SPSS Chicago, IL, USA). Mean values were compared using Student's *t*-test and statistical significance was considered at $P < 0.05$. Receiver operating characteristic (ROC) curve analyses were performed to examine the relationship between hiatal dimensions and significant prolapse (POP-Q grade 2 or higher) to formulate a plausible method of detecting women with abnormal levator hiatus distensibility.

Comparison of hiatal dimension between women with and without significantly objective prolapse

Out of 360 data sets, 37 were excluded because of poor image quality. Thus, only 323 were left for data set analysis. Median age of study population was 59 (range: 27–86) years. A total of 286 (89%) women were parous, and median parity was 2 (range: 1–8). A total of 103 (32%) women complained of lower urinary tract dysfunctions (such as incontinence and dysuria), 83 (26%) complained about symptoms of POP (such as pelvic floor discomfort, bulging sensation, and heavy feeling), and 110 (34%) complained of lower urinary tract dysfunctions and POP. Objective clinical examination using POP-Q system revealed the following results: 102 had grade 2 or higher cystoceles, 24 of which presented grade 2 or higher cystoceles combined with uterine prolapse; 68 exhibited grade 2 or higher uterine prolapse; 18 had grade 2 or higher rectoceles, and six were scored with grade 2 or higher enterocele. In total, 194 (60%) women were diagnosed with prolapse of POP-Q grade 2 or higher.

Table 1 shows comparison of hiatal dimensions between women with and without POP-Q grade of 2 or higher. Overall, women with significantly objective prolapse had higher levator hiatus parameters, including AP, LR, HA, and HA r-V, at rest and under Valsalva maneuver ($P < 0.001$) (POP-Q grade 2 or higher) than those without (Table 1).

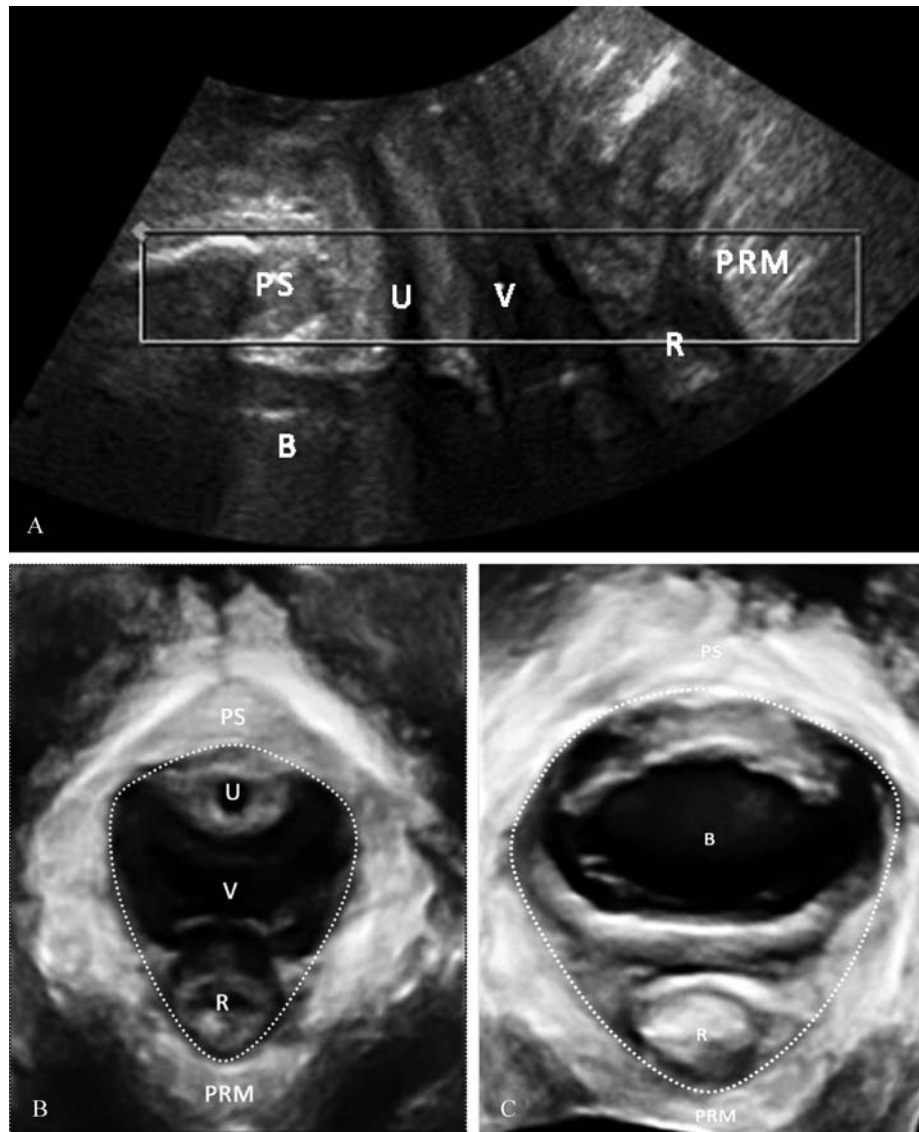


Fig. 1 3D transperineal ultrasound images of levator hiatus in mid-sagittal plane (A) and axial plane (B, C). (A) In mid-sagittal plane, the plane of minimal hiatal dimension was identified between the hyperechoic posterior aspect of PS and the hyperechoic anterior border of PRM (green line in frame). (B) In the axial plane, levator hiatus (dotted line) of a normal woman performing Valsalva maneuver is indicated; urethra, vagina, and rectum are presented from anterior to posterior within the levator hiatus. (C) Levator hiatus (dotted line) of a woman with grade 3 cystocele performing Valsalva maneuver is indicated in the axial plane. Compared with normal woman (B), urethral display in the woman with severe cystocele is unclear, with the bladder visible in the dilated vagina anterior to the rectum. PS, pubic symphysis; PRM, puborectalis muscle; U, urethra; V, vagina; R, rectum; B, bladder.

Efficiency of single-screening index method in detecting abnormal levator hiatus distensibility

ROC curves confirmed association between dimensions of levator hiatus and significantly objective prolapse (POP-Q grade 2 or higher). Area under the curve (AUC) of vHA (19.5 cm^2) (0.79; 95% CI: 0.73–0.86) was highest among all parameters, with sensitivity of 0.80 and specificity of 0.70 (Youden index, 0.51; Fig. 2). Furthermore, 25 cm^2 cut-off during Valsalva maneuver resulted in sensitivity of

0.27 and specificity of 0.83, with a higher specificity but a lower sensitivity than that of 19.5 cm^2 .

Efficiency of two-step method in detecting abnormal levator hiatus distensibility

According to the results of single-screening index method mentioned above, 25 cm^2 cut-off during Valsalva maneuver achieved a high specificity of 0.83 and was selected as the first step of the screening index.

After excluding those with vHA $\geq 25 \text{ cm}^2$, ROC curve

Table 1 Comparison of hiatal dimension between women with and without significantly objective prolapse

Parameter	Grade		P
	≥2	<2	
rAP (cm)	5.60±0.59	4.95±0.65	<0.001
rLR (cm)	3.88±0.58	3.72±0.50	<0.001
rHA (cm ²)	14.53±3.14	12.29±2.52	<0.001
vAP (cm)	6.37±0.73	5.48±0.87	<0.001
vLR (cm)	4.97±0.67	4.37±0.55	<0.001
vHA (cm ²)	22.68±4.42	17.56±4.75	<0.001
ΔHA r-V(cm ²)	8.33±4.17	5.22±3.89	<0.001

rAP, anteroposterior diameter at rest; rLR, coronal diameter at rest; rHA, hiatal area of levator hiatus at rest; vAP, anteroposterior diameter during Valsalva maneuver; vLR, coronal diameter during Valsalva maneuver; vHA, hiatal area of levator hiatus during Valsalva maneuver; ΔHA r-V, difference between HA at rest and during Valsalva maneuver.

analyses were re-conducted for those with vHA < 25 cm² to determine which parameter(s) could be selected as the second step for the screening index except for vHA and confirmed that AUC of rHA (0.71; 95% CI: 0.63–0.79) and ΔHA r-V (0.74; 95% CI: 0.66–0.82) were relatively higher than other parameters; moreover, the rHA of 11.5 cm² (Youden index, 0.38; Fig. 3A) and HA r-V of 5 cm² (Youden index, 0.45; Fig. 3B) yielded sensitivities of 0.83 and 0.81 and specificities of 0.53 and 0.64, respectively. Joint observation of rHA and ΔHA r-V was then selected as second-step screening index.

After multiple data analyses, the best second-step screening index was a combination of rHA = 10 cm² (sensitivity and specificity 0.95 and 0.30, respectively) and ΔHA r-V = 5 cm² (sensitivity and specificity 0.81 and 0.64, respectively) to detect abnormal levator hiatus distensibility in women with vHA < 25 cm²; moreover, the ROC curve confirmed the feasibility of such combination (Fig. 3C). Two-step method of detecting abnormal levator hiatus distensibility yielded a sensitivity of 0.87 and specificity of 0.70 in enrolled women (Table 2).

Comparison of efficiency of single-screening index and two-step method in detecting abnormal levator hiatus distensibility

Table 2 shows the comparison between single-screening index and two-step method for detecting abnormal levator hiatus distensibility. Compared with single-screening index method, the two-step method achieved higher sensibility (0.80 vs. 0.87) without reducing specificity (0.70 vs. 0.71).

Debate

To date, most studies have included imaging studies of levator hiatus and mainly focused on the characteristics of levator hiatus in women with POP or in the relationship between the defects of the levator ani muscle/POP and the levator hiatus [12,14,26,29,30]. By observing the mor-

phology of the levator hiatus, researchers discovered that ballooning occurs in women with POP [14]. The levator ani muscle is considered one of the key components in pelvic organ support [25]. The puborectalis muscle, a part of the levator ani muscle, delimits the levator hiatus and plays an important role in preventing pelvic organs from prolapsing when abdominal pressure increases. Women with major puborectalis muscle defects have large hiatal dimensions [29]. Moreover, studies confirmed that supervised pelvic floor muscle training decreases hiatal area in women with POP [30]. Our study revealed that women with significantly objective prolapse have larger levator hiatus than those without; this result is similar with other researches, which showed that levator hiatus dimensions are strongly correlated with prolapse severity [12,26].

The enlargement of levator hiatus is closely related to POP, thus, it can be reasonably considered as a risk factor for POP. Hence, to prevent POP, methods should be further investigated to screen for abnormal levator hiatus distensibility. Dietz *et al.* first attempted to define normal levator hiatus with 3D ultrasound and considered HA > 25 cm² during Valsalva as abnormal distensibility or ballooning of the levator hiatus. We also used 25 cm² during Valsalva as a screening index for abnormal levator hiatus distensibility in the Chinese population. However, such value was not suitable and has a poor sensitivity of 0.27 and a relatively high specificity of 0.83. We performed statistical analysis and discovered that compared with 25 cm², HA of 19.5 cm² during Valsalva was more preferable for detecting abnormal levator hiatus distensibility in the Chinese population, with a significantly higher sensitivity (0.80 vs. 0.27) but low specificity (0.70 vs. 0.83).

We tested a new two-step method for detecting abnormal levator hiatus distensibility. This method was slightly complex but achieved higher sensitivity (0.80 vs. 0.87) without reducing specificity (0.70 vs. 0.71) compared with single-screening index method.

In using the two-step method to determine abnormal levator hiatus distensibility, the following were concluded:

- vHA ≥ 25 cm² indicates abnormal distensibility.
- when vHA < 25 cm² and r-HA ≥ 10 cm² and

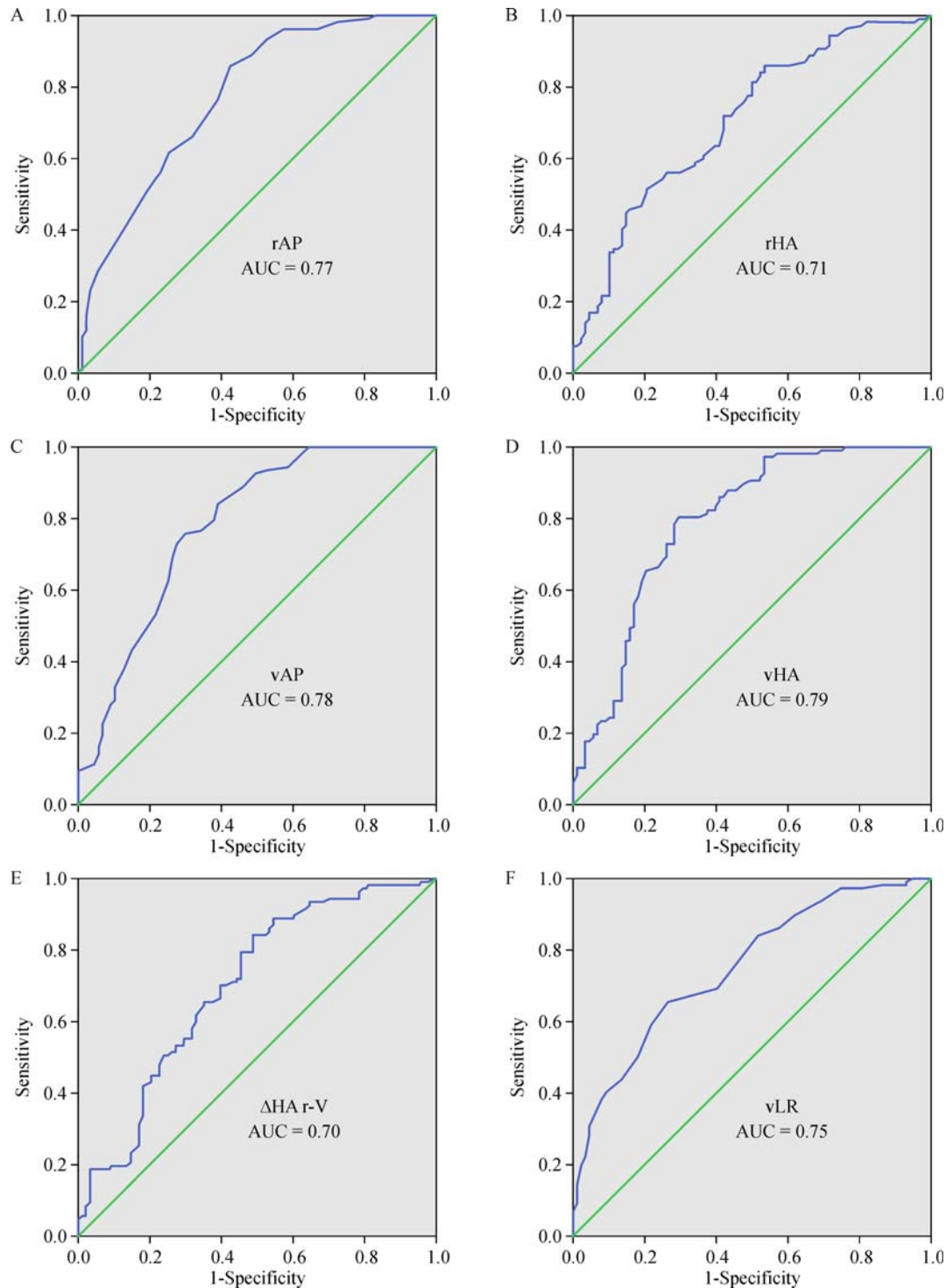


Fig. 2 ROC curves showed association between levator hiatus dimensions, which included rAP (A), rHA (B), vAP (C), vHA (D), Δ HA r-V (E), vLR (F), and significantly objective prolapse (POP-Q grade 2 or higher). AUC of vHA (19.5 cm^2) (0.79; 95% CI: 0.73–0.86) was highest among all parameters, with sensitivity of 0.80 and specificity of 0.70 (Youden index, 0.51).

Δ HA $\geq 5 \text{ cm}^2$ were attained, abnormal levator hiatus distensibility was also detected.

Aside from vHA, the ROC curve also indicated that vAP is a plausible parameter for detecting hiatal abnormal distensibility; this result is consistent with that of an earlier

study [23]. AP measurement is highly convenient as it can be measured on 2D images. However, compared with HA, the AUC of AP was smaller probably because it neglected the influence of LR, which is another important parameter of levator hiatus. As AUC of AP was lower than HA and to

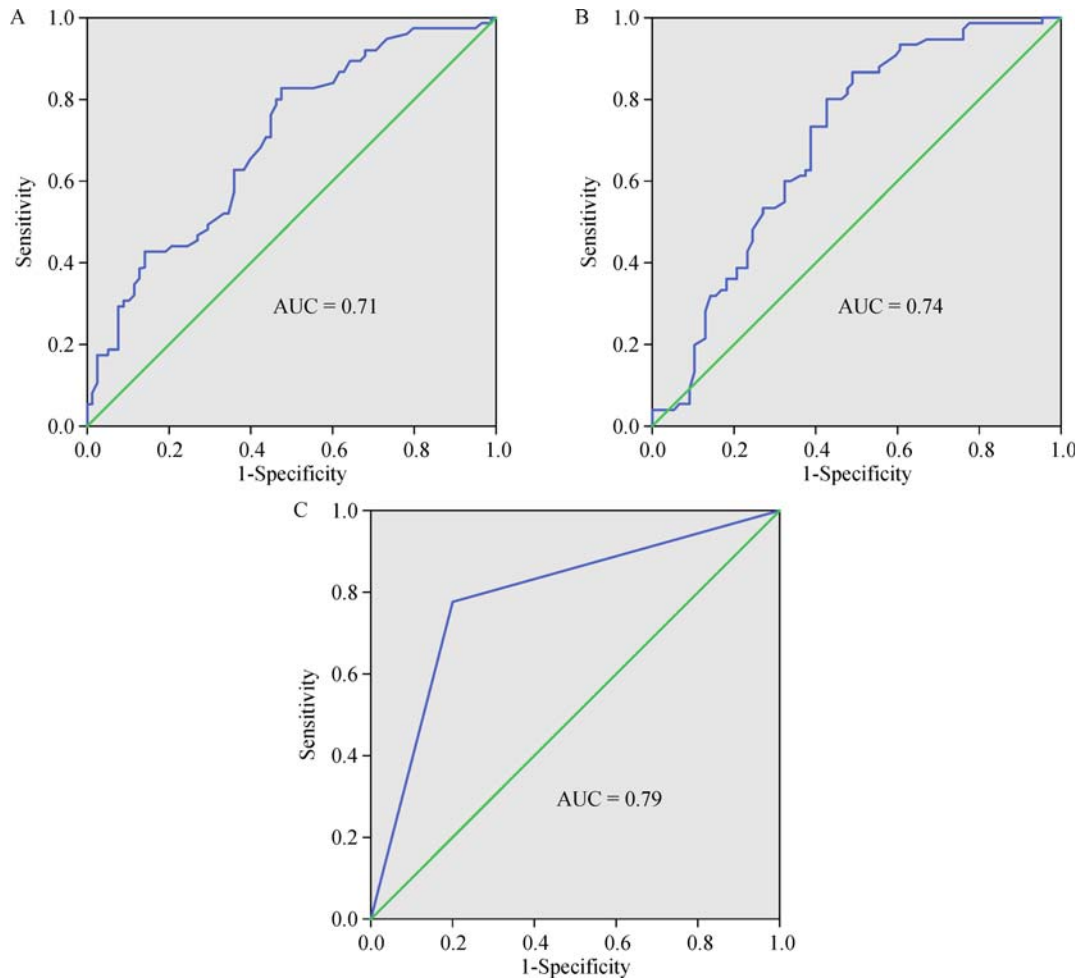


Fig. 3 ROC curves and performance of rHA (A), Δ HA r-V (B), and joint observation of rHA and Δ HA r-V (C) for the detection of abnormal levator hiatus distensibility in women with vHA < 25 cm².

Table 2 Comparison between single-screening index and two-step method for detecting abnormal levator hiatus distensibility

		Grade		Total
		≥ 2	<2	
Single-screening index method	Abnormal (vHA ≥ 19.5 cm ²)	155 (80%)	39 (30%)	194
	Normal (vHA < 19.5 cm ²)	39 (20%)	90 (70%)	129
Two-step method	Abnormal ^a	169 (87%)	37 (29%)	206
	Normal ^b	25 (13%)	92 (71%)	117

Values are *n* (%). ^aAbnormal: (1) vHA ≥ 25 cm² or (2) vHA < 25 cm², but r-HA ≥ 10 cm² and Δ HA ≥ 5 cm² were attained simultaneously. ^bNormal: (1) vHA < 25 cm² and (2) r-HA < 10 cm² or Δ HA < 5 cm².

guarantee higher accuracy, we suggest vHA as the better parameter for detecting abnormal levator hiatus distensibility than AP.

Clinical significance of determining abnormal levator hiatus distensibility

Diagnosis of abnormal levator hiatus distensibility does

not invalidate the consideration of prolapse symptoms or replace the clinical value of the POP-Q system. In this retrospective study, results obtained should be confirmed by further research based with an increased sample population before being applied in the clinical setting. This study aimed to provide a convenient imaging method for screening abnormal levator hiatus distensibility in the early stage. When abnormal levator hiatus is detected during ultrasound examination, POP-Q grading, full

clinical examination, and follow-up observation should be suggested. Further studies should determine the necessity of performing pelvic floor training or other means of treatment and timing of intervention.

A potential limitation of our study may be selection bias because data sets were obtained in patients with urogynecologic signs or symptoms. Hence, our conclusions are limited to the population with these conditions.

Summary

Measurement of hiatal dimension by 3D ultrasound imaging is a valid method to detect abnormal hiatal distensibility. We suggest $HA \geq 19.5 \text{ cm}^2$ during Valsalva maneuver as an indicator of abnormal levator hiatus distensibility in Chinese women. Moreover, the two-step method improved higher sensitivity in detecting abnormal distensibility.

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Compliance with ethics guidelines

Chaoran Dou, Qin Li, Tao Ying, Yulin Yan, Xia Wang, and Bing Hu declare no conflicts of interest. This study was approved by the Ethics Committee of Shanghai Jiao Tong University Affiliated Sixth People's Hospital.

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