Is the Presence of Levator Ani Muscle Avulsion Relevant for the Diagnosis of Uterine Prolapse?

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Abbreviations

BMI, body mass index; CIs, confidence intervals; ICS POP-Q, International Continence Society Pelvic Organ Prolapse Quantification; LAM, levator ani muscle; POP, pelvic organ prolapse; SUI, stress urinary incontinence; UP, uterine prolapse

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Objective—To determine if the addition of the assessment of levator ani muscle (LAM) avulsion to the measurement of the difference in the pubis-uterine fundus distance between rest and with the Valsalva maneuver could increase the diagnostic capacity of ultrasound for uterine prolapse (UP).

Methods—This multicenter, observational and prospective study included 145 patients. Ultrasound assessment was performed, establishing the diagnosis of UP as a difference between the pubic-uterine fundus distance at rest and during the Valsalva maneuver ≥15 mm (standard technique), while LAM avulsion was defined as an abnormal LAM insertion in three central slices using multislice ultrasound. A binary multivariate logistic regression model was made using non-automated methods to predict surgical UP (general population, premenopausal, and postmenopausal patients), including the difference between the pubis-uterine fundus distance at rest and with the Valsalva maneuver as well as LAM avulsion.

Results—A total of 143 patients completed the study. The addition of LAM avulsion criteria to the standard dynamic distance-based protocol for the diagnosis of UP resulted in a higher sensitivity for the general population (79.7 vs 68.1%) as well as for premenopausal (89.3 vs 79.9%) and postmenopausal patients (76 vs 66.1%). In contrast, the standard technique showed a higher specificity than the model based on the standard technique associated with LAM avulsion for the general population (89.2 vs 74.3%) and premenopausal women (91.7 vs 63.2%). For postmenopausal patients, the model based on the standard technique associated with LAM avulsion had a higher sensitivity (76 vs 66.1%) and specificity (91.7 vs 86.8%) than the ultrasound diagnosis of UP.

Conclusion—The implementation of the assessment of LAM avulsion in the ultrasound diagnosis of UP is useful in postmenopausal patients, increasing sensitivity and specificity relative to the ultrasound assessment based only on the difference between the pubis-uterine fundus distance at rest and with the Valsalva maneuver.

Key Words—3D transperineal ultrasound; pelvic floor; pelvic organ prolapse; uterine prolapse

Pelvic organ prolapse (POP) affects 50% of patients who have previously gone through pregnancy and delivery,[1] requiring corrective surgery in 10 to 20% of cases.[2,3] The classic diagnosis of POP is based on the International Continence Society Pelvic Organ Prolapse Quantification (ICS POP-Q) system.[4] However, it has been described that the diagnosis may be made

based on transperineal ultrasound.[5–12] Regarding specifically uterine prolapse (UP), the ultrasound diagnosis is made by measuring the difference between the pubic-uterine fundus distance at rest and during the Valsalva maneuver, for which the values of sensitivity and specificity are 75 and 95%, respectively.[10]

Additionally, it is important to remember that POP is related to the closure of the levator ani muscle (LAM) hiatus.[13] LAM hiatus is the largest potential hernial site of the human body, whose lateral and posterior border is the LAM and whose anterior limit is the pubic symphysis. The LAM hiatus undergoes alterations throughout life, increasing its size due to LAM injuries.[14] There is a direct relation between LAM avulsion, enlargement of the genital hiatus and POP, both in clinical and ultrasound measurements.[15,16] Furthermore, LAM avulsion can promote the development of POP.[15,17–20] Nonetheless, there is controversy regarding the risk of POP recurrence, as some authors affirm that it is related to LAM avulsion,[21,22] while others disagree.[23,24]

Considering the current evidence and given that ultrasound provides a reliable diagnosis of UP,[10] we believe that adding LAM avulsion might help to increase the diagnostic capacity of ultrasound for UP. Thus, our aim was to determine if the addition of the assessment of levator ani muscle (LAM) avulsion to the measurement of the difference in the pubis-uterine fundus distance between rest and with the Valsalva maneuver could increase the diagnostic capacity of ultrasound for uterine prolapse (UP).

Materials and Methods

A multicenter, observational and prospective study was carried out between September 1, 2021, and September 30, 2022. The participant hospitals were Valme University Hospital of Seville (Spain), University Health care Complex of Gran Canaria (Spain), University Healthcare Complex of Leon (Spain), and Virgen de la Victoria University Hospital of Malaga (Spain).

A total of 145 patients were consecutively recruited during a specialized pelvic floor consultation at each participant center. The inclusion criteria were as follows: patients with pelvic floor dysfunction with indication for corrective surgery of POP or surgery with tension-free vaginal tapes for stress urinary incontinence. Patients with a previous history of pelvic floor dysfunction surgery or hysterectomy were excluded from the study. All patients accepted and signed written informed consent to participate in the study.

Clinical Assessment

General and clinical characteristics of patients were registered (age, vaginal deliveries, abortions, cesarean sections, body mass index (BMI)). Afterward, a standardized interview was conducted, including questions regarding stress urinary incontinence (SUI), urge urinary incontinence, or mixed urinary incontinence, followed by a pelvic examination using the International Continence Society Pelvic Organ Prolapse Quantification (ICS POP-Q) system to assess the presence and stage of POP.[4] Finally, a bladder stress test was performed to determine the presence of SUI. If the presence of SUI was unclear, a urodynamic test was performed to determine the diagnosis.

Ultrasound Assessment

Ultrasound evaluation was conducted by expert ultrasonographers from each hospital who were blinded to the clinical data of the patients. Images were acquired from the midsagittal plane,[10,25] taking the posteroinferior margin of the pubic bone and the uterine fundus as Reference [10]. The distance was measured at right angles from the posteroinferior margin of the symphysis pubis to the top of the uterine fundus. The diagnosis of UP was established as a difference between the pubic-uterine fundus distance at rest and during the Valsalva maneuver ≥15 mm[10,26] (Figure 1).

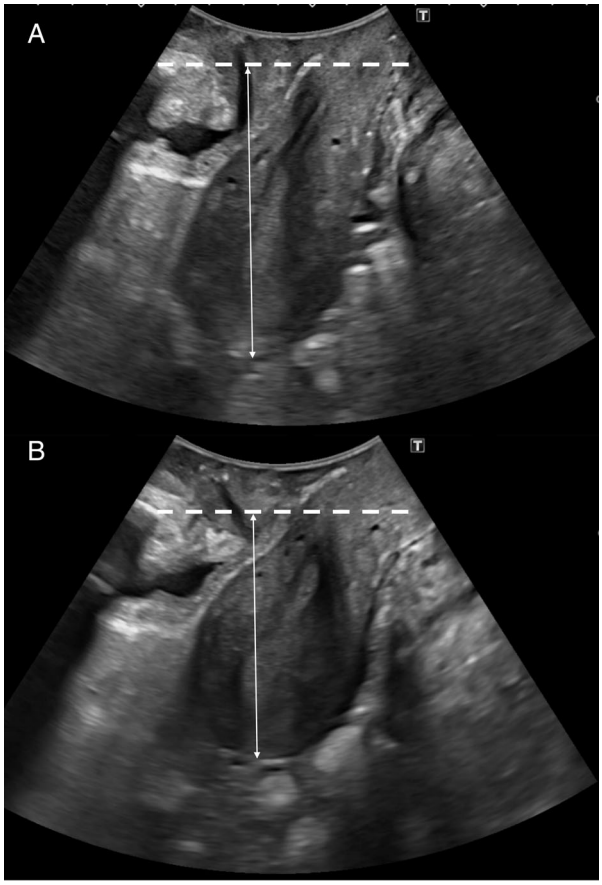
LAM avulsion was assessed during maximum contraction using multislice ultrasound (2.5 mm slice intervals) in the plane of minimal hiatal dimensions[27] (Figure 2). LAM avulsion was defined as an abnormal LAM insertion in three central slices. In borderline cases, abnormal insertion was defined as a levator-urethral gap >2.5 cm.[28]

Clinical Assessment in the Operating Room

In the operating room, once regional anesthesia was used on patients, surgeons performed a clinical examination with Pozzi tenaculum forceps for controlled uterine traction to determine the level of uterine

descent. If the prolapse stage was between II and IV according to the ICS POP-Q system, corrective UP surgery was performed.

Figure 1. Ultrasound of uterine prolapse. Dashed line delimits the posteroinferior margin of the pubis and arrow the pubis-fundus distance at rest **(A)** and with the Valsalva maneuver **(B)**.



Statistical Analysis

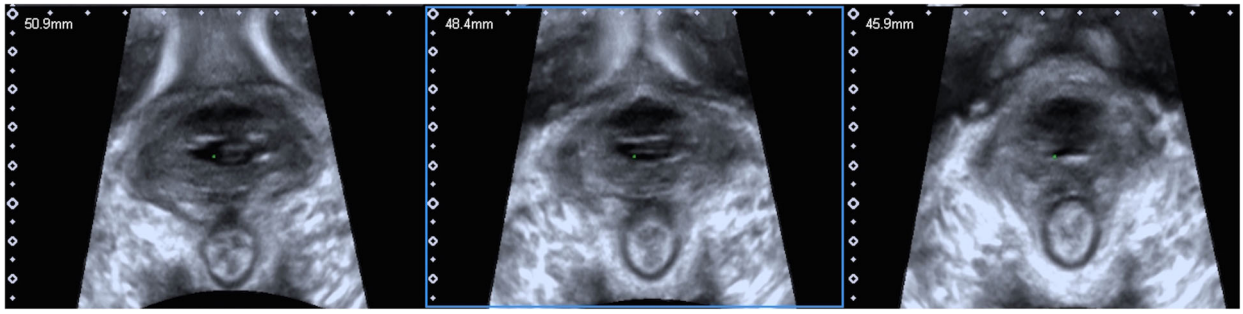
Quantitative variables were expressed as the means and standard deviations, while percentages were used for qualitative variables. The normality of the quantitative data was determined using the Shapiro-Wilk test; then, Student *t* test for independent samples was used for normally distributed data, while the Mann-Whitney *U* test was used for non-normally distributed data. For qualitative variables, either contingency tables and χ^2 tests or nonasymptotic Monte Carlo methods and exact tests were used. Statistical comparisons were made using two-tailed tests, considering $P < .05$ as statistically significant for all comparisons.

A binary multivariate logistic regression model was made using nonautomated methods to predict surgical UP, including the difference between the pubis-uterine-fundus distance at rest and with the Valsalva maneuver as well as LAM avulsion. A goodness-of-fit test (−2LL) was performed, and the model was calibrated using the Hosmer and Lemeshow test, with graphs created for the calibration slopes. Harrel's C-index, obtained as the area under the curve (AUC), was obtained to evaluate the discriminatory power. To apply the model for clinical use, a cutoff point was identified to establish sensitivity and specificity. When possible, 95% confidence intervals were used. All statistical analyses were carried out using the statistical software IBM SPSS version 28 (IBM, Armonk, NY).

Sample Size

Following the Peduzzi formula, considering a minimum number of events per variable of 10 (Harrell, 2005) and a 20% UP diagnosis, we

Figure 2. LAM avulsion with abnormal insertion of the LAM in three central slices.



would need 101 patients for the study, of whom 20 should have UP.

Ethical Approval

The study was approved by the Biomedical Ethics Committee of the Junta de Andalucía (1259-N-20).

Results

A total of 145 patients were recruited, two of whom were excluded due to the lack of clinical examination under regional anesthesia in the operating room. Thus, a total of 143 patients completed the study. Sixty-nine of them underwent UP corrective surgery, while 74 did not require it. The general and clinical characteristics of the patients, depending on the need for corrective UP surgery, are displayed in Table 1. We observed a statistically significant difference between groups regarding age (62.1 ± 10.2 vs 53.6 ± 9.9; $P < .0005$), presence of SUI (18.8 vs 44.6%; P: .001), presence of mixed urinary incontinence (18.8 vs 35.1%; P: .029), cystocele (88.4 vs 71.6%; P: .013), rectocele (43.5 vs 25.7%; P: .034) and enterocele (15.9 vs 1.4%; P: .002).

A model was created based on the difference between the pubis-uterine-fundus distance at rest and with the Valsalva maneuver and the presence of LAM avulsion. The AUC of the probabilities predicted by the model was 0.84 (95% CI: 0.77–0.91; $P < .0005$; Figure 3) for the general population. For premenopausal patients, the AUC of the probabilities predicted by the model was 0.81 (95% CI: 0.64–0.99; P: .001; Figure 4), while the AUC of the probabilities predicted by the model for postmenopausal patients was 0.86 (95% CI: 0.78–0.93; $P < .0005$; Figure 5). Based on the ROC curve for the model for the general population, we identified 60% as the most suitable cutoff point for the ultrasound diagnosis of surgical UP according to the defined models.

Comparing the diagnosis of UP by ultrasound with the diagnosis by the model combining LAM avulsion and the difference in the pubis-uterine-fundus-distance at rest versus with the Valsalva maneuver, we observed that the ultrasound diagnosis of UP had a lower sensitivity in the general population (68.1 vs 79.7%) as well as in premenopausal (79.9 vs 89.3%) and postmenopausal patients (66.1 vs 76%). In contrast, the ultrasound diagnosis of UP showed a higher specificity than the model in the general

Table 1. General and Clinical Characteristics of the Patient Included

	With Corrective Uterine Prolapse Surgery (n = 69)	Without Corrective Uterine Prolapse Surgery (n = 74)	*P*	95% CI
Age	62.1 ± 10.2	53.6 ± 9.9	<.0005	5.0 to 13.0
Vaginal deliveries	2.4 ± 1.5	2.0 ± 0.8	.259	—
Abortions	0.4 ± 0.7	0.5 ± 0.8	.609	—
Caesarean sections	0.1 ± 0.5	0.1 ± 0.3	.866	—
BMI	27.2 ± 3.8	27.8 ± 4.4	.408	−2.1 to 0.9
Stress urinary incontinence	13/69 (18.8%)	33/74 (44.6%)	.001	−0.39 to −0.11
Urge urinary incontinence	25/69 (36.2%)	31/74 (41.9%)	.488	−0.21 to 0.10
Mixed urinary incontinence	13/69 (18.8%)	26/74 (35.1%)	.029	−0.30 to −0.02
Cystocele	61/69 (88.4%)	53/74 (71.6%)	.013	0.04 to 0.29
Grade I	4/61 (6.6%)	3/53 (5.6%)	.040	−0.09 to 0.11
Grade II	14/61 (23.0%)	24/53 (45.3%)		−0.38 to −0.05
Grade III	43/61 (70.4%)	26/53 (49.1%)		0.03 to 0.38
Rectocele	30/69 (43.5%)	19/74 (25.7%)	.034	0.02 to 0.32
Grade I	12/30 (40.0%)	9/19 (47.4%)	.871	−0.33 to 0.19
Grade II	14/30 (46.7%)	8/19 (42.1%)		−0.23 to 0.30
Grade III	4/30 (13.3%)	2/19 (10.5%)		−0.19 to 0.21
Enterocele	11/69 (15.9%)	1/74 (1.4%)	.002	0.06 to 0.25
Grade II	4/11 (36.4%)	1/1 (100%)	.496	−0.85 to 0.21
Grade III	6/11 (54.5%)	0/1 (0%)		−0.29 to 0.79
Grade IV	1/11 (9.1%)	0/1 (0%)		−0.71 to 0.38

population (89.2 vs 74.3%) and among premenopausal women (91.7 vs 63.2%); however, among postmenopausal patients, the proposed model had a higher sensitivity (76 vs 66.1%) and specificity (91.7 vs 86.8%) as shown in Table 2.

Figure 3. ROC curve for the logistic regression model was obtained from the association between the difference in the pubis-uterine fundus distance at rest and with the Valsalva maneuver and LAM avulsion in general population.

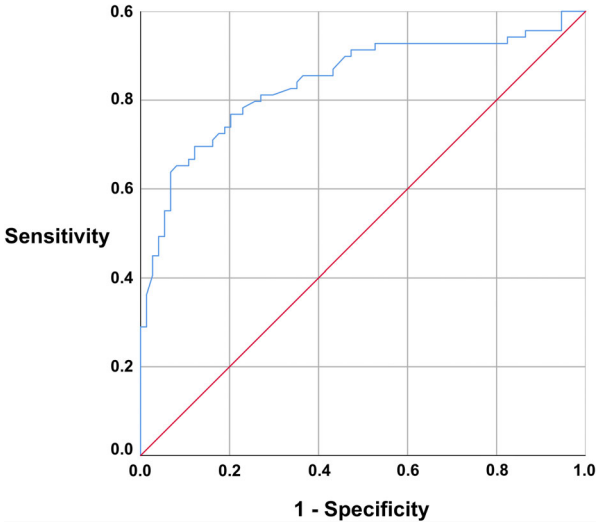
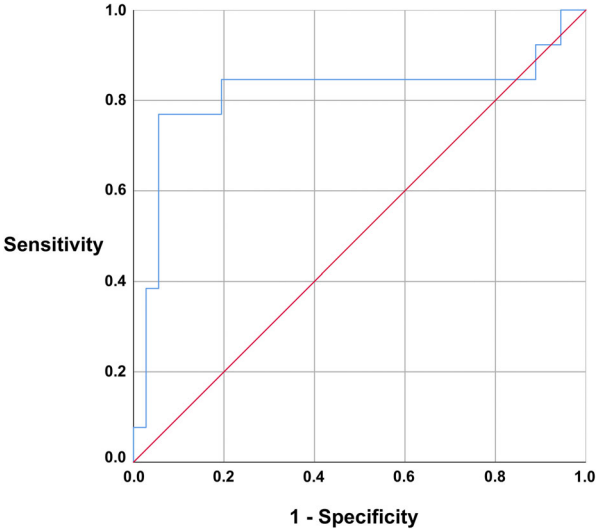


Figure 4. ROC curve for the logistic regression model was obtained from the association between the difference in the pubis-uterine fundus distance at rest and with the Valsalva maneuver and LAM avulsion in premenopausal patients.



Discussion

The proposed model based on the difference between the pubis-uterine-fundus distance at rest and with the Valsalva maneuver and the presence of LAM avulsion has been shown to possess a higher sensitivity (76 vs 66.1%) and specificity (91.7 vs 86.8%) in postmenopausal patients than the ultrasound diagnosis of UP. Nevertheless, in the case of postmenopausal patients, the proposed model is undoubtedly the most specific assessment tool for the diagnosis of UP (91.7 vs 63.2%).

The use of the difference in the pubis-uterine fundus distance at rest and with the Valsalva maneuver ≥15 mm for the ultrasound diagnosis of UP has a sensitivity and specificity of 75 and 9%, respectively.[10] Moreover, this assessment method has shown a very good concordance (Kappa index 0.826 [0.71–0.94]) with the clinical diagnosis of UP based on the ICS POP-Q.[29] Another positive point to mention of this technique is its excellent interobserver reliability, which makes it highly reproducible.[11] Due to these features, software has been developed to customize the risk of UP according to the ultrasound measurements and the age of the patient.[30] Changes occurring during the Valsalva maneuver to the pubis-uterine

Figure 5. ROC curve for the logistic regression model was obtained from the association between the difference in the pubis-uterine fundus distance at rest and with the Valsalva maneuver and LAM avulsion (A) in postmenopausal patients.

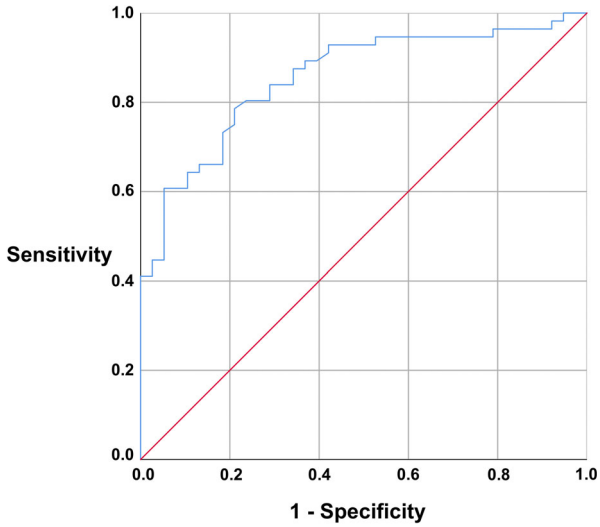


Table 2. Comparison Between Standard Technique Using the Ultrasound Diagnosis of UP (Difference Between the Pubic-Uterine Fundus at Rest and During the Valsalva Maneuver ≥15 mm) and the Proposed Model Using Standard Technique and LAM Avulsion

	Sensitivity	95% CI	Specificity	95% CI
General population				
Standard technique	68.1%	55.8%–78.8%	89.2%	79.8%–95.2%
Standard technique and LAM avulsion	79.7%	68.3%–88.44%	74.3%	62.8%–83.8%
Premenopausal patients				
Standard technique	76.9%%	46.2%–94.9%	91.7%	77.5%–98.3%
Standard technique and LAM avulsion	89.3%	78.1%–95.9%	63.2%	45.9%–78.2%
Postmenopausal patients				
Standard technique	66.1%%	52.2%–78.2%	86.8%	71.9%–95.6%
Standard technique and LAM avulsion	76.9%%	46.2%–94.9%	91.7%	77.5%–98.3

fundus distance in cases of UP are caused by the failure of DeLancey level I (uterosacral-cardinal ligament complex). This failure of apical support leads to a 20% increase in the cardinal ligament length and up to a twofold increase during Valsalva when compared with patients with normal apical support.[31] The identification of patients with failed apical support is basic for optimal surgical procedures.[32,33]

Nevertheless, we should keep in mind that the origin of POP depends not only on the failed apical support but also on the closure of the LAM hiatus.[13] LAM avulsion is associated with anterior and central POP[15,17,20] and has been established as an independent risk factor for symptoms and signs of prolapse.[33] The relationship that exists between pregnancy, childbirth, and changes in the pelvic floor has been described by different authors,[34,35] determining an association between LAM avulsion and prolapse symptoms.[36–38] Hence, the early diagnosis of LAM after childbirth is important, even when screening techniques are applied.[39] In our study, the detection of LAM avulsion was shown to be especially useful in the case of postmenopausal patients, improving the diagnostic capacity achieved by only the difference in the pubis-uterine fundus distance at rest and with the Valsalva maneuver. We believe it is possible that LAM avulsion and injuries of the uterosacral-cardinal ligament complex can occur in most cases at the same time and for the same cause (vaginal delivery). Therefore, older patients with LAM avulsion are more likely to suffer from true UP, and this aspect has been described in previous studies relating age and the ultrasound diagnosis of UP.[30,40]

The main strength of our study is the comparison of the ultrasound diagnosis of UP with the clinical examination in the operating room, with the patient under regional anesthesia, unlike in our previous work, where the clinical diagnosis was based on the examination made during consultation.[10] This allows for a direct contrast between the ultrasonographic findings and the examination at the time of the surgical procedure. Another compelling aspect of our work is its multicentric design and the divided study of patients depending on menopausal stage. However, this could also be a point of criticism, as the division of the population studied in subgroups decreases the power of the findings made. We consider that the evaluation of LAM avulsion could play a role in the assessment of postmenopausal patients with UP and, as such, should be considered in future studies in this field.

Conclusion

In conclusion, the implementation of the assessment of LAM avulsion in the ultrasound diagnosis of UP is useful in postmenopausal patients, increasing the sensitivity and specificity of the ultrasound assessment based only on the difference between the pubis-uterine fundus distance at rest and with the Valsalva maneuver.

Data Availability Statement

Data sharing not applicable to this article as no datasets were generated or analysed during the current study.

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