Is It Possible to Diagnose Surgical Uterine Prolapse With Transperineal Ultrasound? Multicenter Validation of Diagnostic Software

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Abbreviations

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

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Objectives—To validate an ultrasound software that uses transperineal ultrasound to diagnose uterine prolapse (UP).

Methods—Multicenter, observational and prospective study with 155 patients that had indications for surgical intervention for dysfunctional pelvic floor pathology. Each patient underwent an examination with Pozzi tenaculum forceps was performed in the operating room with the patient anesthetized, followed by surgical correction of stages II–IV UP. Transperineal ultrasound was used to assess the difference in the pubis–uterine fundus measurement. With a multivariate logistic regression binary model (with the measurement ultrasound at rest, the Valsalva maneuver and age) using nonautomated methods to predict UP. With the purpose of evaluating the model, a table with coordinates of the receiver operating characteristic (ROC) curve, after which sensitivity and specificity were assessed.

Results—A total of 153 patients were included (73 with a diagnosis of surgical UP). It was obtained from the AUC (0.89) of the probabilities predicted by the model (95% confidence interval, 0.84–0.95; $P < .0005$). Based on the ROC curve for the model, obtaining a sensitivity of 91.8% and a specificity of 72.7%, values that were superior to those for the clinical exam for surgical UP (sensitivity: 80.8%; specificity: 71.3%).

Conclusions—We validated software that uses transperineal ultrasound of the pelvic floor and patient age to generate a more reliable diagnosis of surgical UP than that obtained from clinical examinations.

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

There are individual peculiarities that can favor the appearance and progression of pelvic organ prolapse (POP).[1,2] The maintenance of pelvic support mechanisms through physical activity is questionable,[3] which is why surgery sometimes becomes the solution to this pathology. However, hysterectomy has a number of complications[4] including a risk of POP recurrence after the procedure.[5] There are different types of POP recurrences,[6,7] and different surgical techniques have been recommended to avoid such events.[8] There are multiple risk factors that influence the recurrence of POP,[9,10] with the main mechanism being the descent of apical support after vaginal hysterectomy,[11,12] in addition to its association with urinary incontinence.[13,14] Therefore, a correct diagnosis before surgery is crucial for the correct treatment of patients.

The International Continence Society Pelvic Organ Prolapse Quantification (ICS POP-Q) system[15] is the classic method of evaluating uterine prolapse (UP) before surgery. However, imaging tests such as magnetic resonance imaging (MRI) have been shown to be comparable to clinical evaluations for the assessment of UP.[16] However, both diagnostic methods present different limitations because clinic exams only involve the anatomical surface, using the hymen as a mobile point of reference,[15] and MRI, which is a more economical test, is not always available to clinicians for the study of POP.

Pelvic floor ultrasound has become a useful tool in the diagnosis of POP, establishing significant prolapse of each compartment in relation to the postero-inferior margin of the symphysis pubis during the Valsalva maneuver.[17,18] Additionally, the differential diagnosis within each compartment has been defined sonographically, for the anterior[19–21] middle[22,23] and posterior[24] compartments. The ultrasound diagnosis of UP is based on the measurement of the placement of the uterine fundus between rest and Valsalva maneuver with respect to the pubis; UP is defined when this measurement is ≥15 mm (sensitivity: 75% and specificity: 95%).[22] However, UP is a multifactorial entity, and this aspect should be considered when making a diagnosis. For this reason, different multifactorial regression models have been proposed, with transperineal ultrasound used to define the diagnosis of UP.[25] The model that includes the measurement of the difference in the pubis–uterine fundus distance at rest and during the Valsalva maneuver and age has been the model that has demonstrated maximum discriminatory power, with greater simplicity in application in routine clinical practice, correctly diagnosing 96.7% of patients with UP.[25] However, this model has a series of limitations because the populations studied for its development were patients with UP and patients with cervical elongation without UP; furthermore, the model lacks external validation.[25] Therefore, the objective of this multicenter study was to validate an ultrasound software that uses transperineal ultrasound to diagnose UP.

Materials and Methods

Study Population

This was a multicenter, observational and prospective study. Four hospitals participated (Hospital Universitario de Valme of Seville [Spain], University Healthcare Complex of Gran Canaria [Spain], University Healthcare Complex of León [Spain] and Hospital Universitario Virgen de la Victoria of Málaga [Spain]).

A total of 155 patients were consecutively recruited between September 1, 2021, and September 30, 2022.

The patients were recruited during a specialized pelvic floor consultation at each center and had to meet the following inclusion criteria:

- Indication for surgical intervention for dysfunctional pathology of the pelvic floor, for corrective surgery of POP or for anti-incontinence surgery with tension-free tapes; and
- Accept and sign the informed consent form for participation in the study.

All patients who had a history of previous corrective surgery for pelvic floor pathology or previous hysterectomy were excluded.

Examination Method

Assessment in Consultation

All the patients included were evaluated during consultations, where a standardized questionnaire and clinical examination were carried out using the ICS POP-Q system to assess the presence and stage of POP.[15] Clinical UP with surgical indication criteria was defined as stage II-IV UP (symptomatic and affects the quality of life) presented in the consultation. In cases of urinary incontinence, the type of incontinence was determined (stress urinary incontinence [SUI] or urge urinary incontinence [UUI]), and the state of SUI was determined using a simple stress test. When in doubt, a urodynamic test was performed to confirm the type of urinary incontinence.

Assessment in the Operating Room

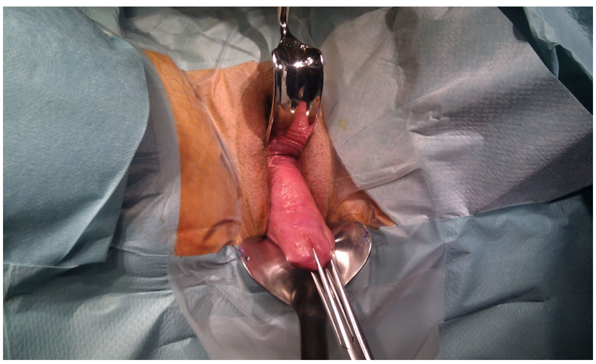
Each patient was anesthetized in the operating room, and before surgery, the surgeons performed a new examination with Pozzi tenaculum forceps to determine the descent of the uterus by applying the ICS

POP-Q system. Surgical correction of UP was performed when the examination with Pozzi tenaculum forceps indicated stages II–IV UP (symptomatic and affects the quality of life) according to the ICS POP-Q system[15] (Figure 1) (diagnosis of UP with Pozzi tenaculum forceps with surgical criteria [gold standard]).

Ultrasound Assessment

Transperineal ultrasounds were performed by experts in pelvic floor ultrasound from each hospital; the experts were unaware of the clinical examination findings. The ultrasound machines used were a Canon i600 Aplio® (Canon Medical Systems Corp., Tokyo, Japan) with a PVT-675MV 3-dimensional abdominal probe and a Voluson E8 (GE Healthcare, Zipf, Austria) ultrasound system with an 8–4-MHz volume transducer. Images were acquired with patients in dorsal lithotomy position with an empty bladder.[26,27] For image capture, the previously described methodology was followed, taking measurements[25] at rest and during the Valsalva maneuver (minimum of 6 s[28]). The movement of the uterus was established by calculating the difference in pubis–uterine fundus measurements (rest and Valsalva)[25] (Figure 2, online supplemental Video 1). Measurements were made inside the posteroinferior pubic, according to the previously established methodology,[25,29] measuring the pubis–uterine fundus measurement and the difference in pubis–uterine fundus measurements at rest and during the Valsalva maneuver.

Figure 1. Diagnosis of UP with Pozzi tenaculum forceps.



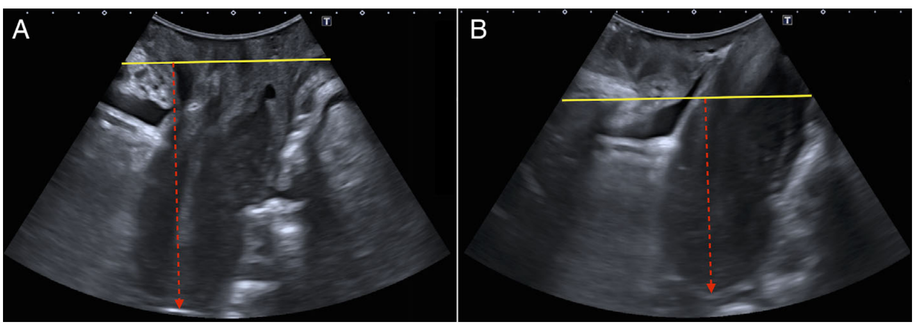
Statistical Study

For the numerical variables, the mean and standard deviation were used, and for the qualitative variables, the percentage. Student's *t*-test or Mann–Whitney *U*-test was used to compare numerical variables and the χ^2 test for qualitative variables. ROC and AUC were used to determine individual predictive abilities. $P < .005$ was considered statistically significant for all comparisons.

With the parameters used in the software described previously,[25] we created a multivariate binary logistic regression model using non-automated methods to predict UP, performing a goodness-of-fit test (−2LL). The calibration of the said model was with the Hosmer and Lemeshow test, and calibration pending were made. The discriminatory power of the model was defined with Harrell's C statistic (obtained as AUC).

A cut-off point was obtained in the table with the coordinates of the ROC curve for the analysis of sensitivity and specificity and to evaluate its use in the diagnosis of PU; 95% confidence intervals (CIs) were

Figure 2. Ultrasound of uterine prolapse. Yellow line delimits the posteroinferior margin of the pubis and red arrow the pubis–fundus distance at rest (**A**) and Valsalva (**B**).



incorporated. Statistical analyzes were performed using IBM SPSS version 28 statistical software (IBM, Armonk, NY).

Sample Size

Based on the Peduzzi formula, considering a minimum number of events per variable of 10 (Harrell, 2005) and a 20% prolapse diagnosis, 101 patients were needed for this study. Of these 101 patients, 20 had UP, and 81 did not have UP. Thus, our study met the aforementioned conditions.

Ethical Approval

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

Results

A total of 155 patients were recruited, 2 of whom were excluded because the assessment was not performed with Pozzi tenaculum forceps. Of the 153 patients who completed the study, 73 presented surgical UP in the examination with Pozzi tenaculum forceps, for which corrective surgery was performed, and 80 did not present surgical UP during the exam using Pozzi tenaculum forceps (Table 1). There was a statistically significant difference between the 2 groups in age (62.3 versus 53.9; $P < .001$), number of vaginal deliveries (2.4 versus 2.0; $P = .041$), presence of stress incontinence (21.9% versus 45.0%; $P = .004$), cystocele (89.0% versus 71.3%; $P = .008$), UP diagnosed during consultation (80.8% versus 28.7%; $P < .001$), rectocele (43.8% versus 26.3%; $P = .027$) and enterocele (15.1% versus 1.3%; $P = .002$).

The pubis–uterine fundus measurements for patients with and without a diagnosis of surgical UP in the examination with Pozzi tenaculum forceps are provided in Table 2. The patients with a diagnosis of surgical UP in the examination with Pozzi tenaculum forceps presented greater pubis–uterine fundus measurements at rest (−70.7 versus −78.1; $P = .015$) and during the Valsalva maneuver (−48.5 versus −71.0; $P < .001$). In addition, the difference in pubis–uterine fundus measurements at rest and during the Valsalva maneuver was also greater for

Table 1. General and Clinical Characteristics of the Patient Included

	With Correct Uterine Prolapse Surgery (n = 73)	Without Correct Uterine Prolapse Surgery (n = 80)	P	95% CI
Age	62.3 ± 10.3	53.9 ± 10.1	<.001	5.1; 11.7
Vaginal deliveries	2.4 ± 1.5	2.0 ± 0.8	.041	0.02; 0.8
Abortions	0.4 ± 0.7	0.5 ± 0.8	.845	−0.27; 0.22
Cesarean sections	0.1 ± 0.5	0.1 ± 0.3	.581	−0.09; 0.17
BMI	27.1 ± 3.7	27.8 ± 4.5	.337	−2.2; 0.7
Stress incontinence	16/73 (21.9%)	36/80 (45.0%)	.004	−37.5; −8.6
Urge incontinence	27/73 (37.0%)	35/80 (43.8%)	.414	−21.7; 8.7
Cystocele	65/73 (89.0%)	57/80 (71.3%)	.008	5.2; 30.4
Stage I	4/65 (6.1%)	3/57 (5.3%)	.027	−8.9; 10.2
Stage II	15/65 (23.1%)	26/57 (45.6%)		−37.9; −5.7
Stage III	46/65 (70.8%)	28/57 (49.1%)		4.3; 37.4
Uterine prolapse	59/73 (80.8%)	23/80 (28.7%)	<.001	38.5; 65.6
Stage I	4/59 (6.8%)	7/23 (30.4%)	.020	−44.5; −6.1
Stage II	14/59 (23.7%)	6/23 (26.1%)		−24.7; 15.9
Stage III	37/59 (62.7%)	10/23 (43.5%)		−4.3; 40.3
Stage IV	4/59 (6.8%)	0/23 (0%)		−8.1; 16.2
Rectocele	32/73 (43.8%)	21/80 (26.3%)	.027	2.5; 32.6
Stage I	13/32 (40.6%)	11/21 (52.4%)	.723	−36.2; 14.6
Stage II	15/32 (46.9%)	8/21 (38.1%)		−17.6; 32.8
Stage III	4/32 (12.5%)	2/21 (9.5%)		−17.8; 20.0
Enterocele	11/73 (15.1%)	1/80 (1.3%)	.002	5.1; 22.6
Stage I	4/11 (36.4%)	1/1 (100%)	.496	−84.8; 20.6
Stage II	6/11 (54.5%)	0/1 (0%)		−29.1; 78.7
Stage III	1/11 (9.1%)	0/1 (0%)		−70.6; 37.7

patients with a diagnosis of surgical UP in the examination with Pozzi tenaculum forceps (22.2 versus 7.1; $P < .001$).

The data obtained for the patients were applied to the previously published model that includes the difference in pubis–uterine fundus distance at rest and during the Valsalva maneuver and patient age[25] (Figure 3). Harrell's C statistic was obtained from the AUC (0.89) of the probabilities predicted by the model (95% CI, 0.84–0.95; $P < .0005$) (Figure 4). The calibration of the model was evaluated by calculating the calibration slope B, obtaining a coefficient of determination of 0.95 (95% CI, 0.86–1.00) (Figure 5). Based on the ROC curve for

Table 2. Measurements Obtained in the Mid-Sagittal Plane at Rest and in Valsalva

	With Correct Uterine Prolapse Surgery (n = 73)	Without Correct Uterine Prolapse Surgery (n = 80)	*P*	95% CI
Pubis–uterine fundus measurement				
Rest	−70.7 ± 18.8	−78.1 ± 18.0	.015	1.5; 13.2
Valsalva	−48.5 ± 21.6	−71.0 ± 19.7	<.001	15.9; 29.1
Pubis–uterine fundus measurement. Difference between rest and Valsalva	22.2 ± 15.2	7.1 ± 6.8	<.001	11.3; 19.0

Figure 3. Example of the use of the binary model based on the difference in the pubis–uterine fundus distance at rest and with the Valsalva maneuver and age as a predictor of UP. **A**, Patient with 45 years of age and with a difference in the pubis–uterine fundus distance at rest and with the Valsalva maneuver of 12 mm has a personalized risk of having a UP of 21.4%. **B**, Patient with 50 years of age and with a difference in the pubis–uterine fundus distance at rest and with the Valsalva maneuver of 17 mm has a personalized risk of having a UP of 74.5%.

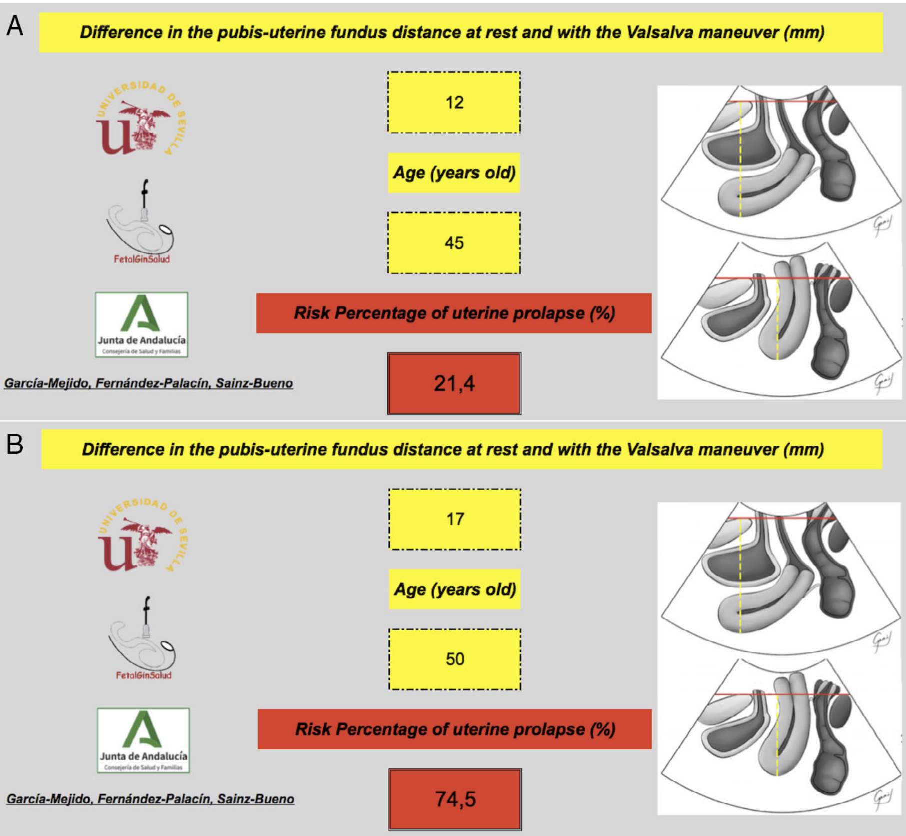
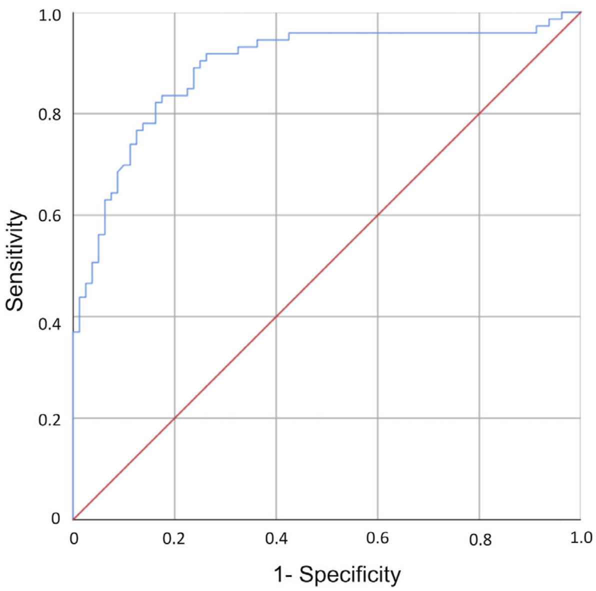


Figure 4. ROC curve for the logistic regression model obtained from the association between the difference in the pubis–uterine fundus distance at rest and with the Valsalva maneuver and age.



the model, 30% was identified as the most suitable cut-off point for the ultrasound diagnosis of surgical UP, with a sensitivity of 91.8% and a specificity of 72.7%, which was higher than those for the clinical exam for surgical UP (sensitivity of 80.8% and a specificity of 71.3%) (Table 3).

Discussion

The main findings are that a model that includes the difference in the pubis–uterine fundus distance at rest and during the Valsalva maneuver and patient age had an AUC of 0.89 and a calibration slope of 0.95. With this model, surgical UP can be defined more reliably than with a clinical exam, presenting greater sensitivity (91.8% versus 80.8) and specificity (72.7 versus 71.3%). Previously, UP has been indicated on ultrasound when the difference in the pubis–uterine fundus distance at rest and during the Valsalva maneuver was ≥15 mm, with a sensitivity of 75%,

Figure 5. Calibration graph of original logistic regression model obtained for the association between the difference in the pubis–uterine fundus distance at rest and with the Valsalva maneuver and age.

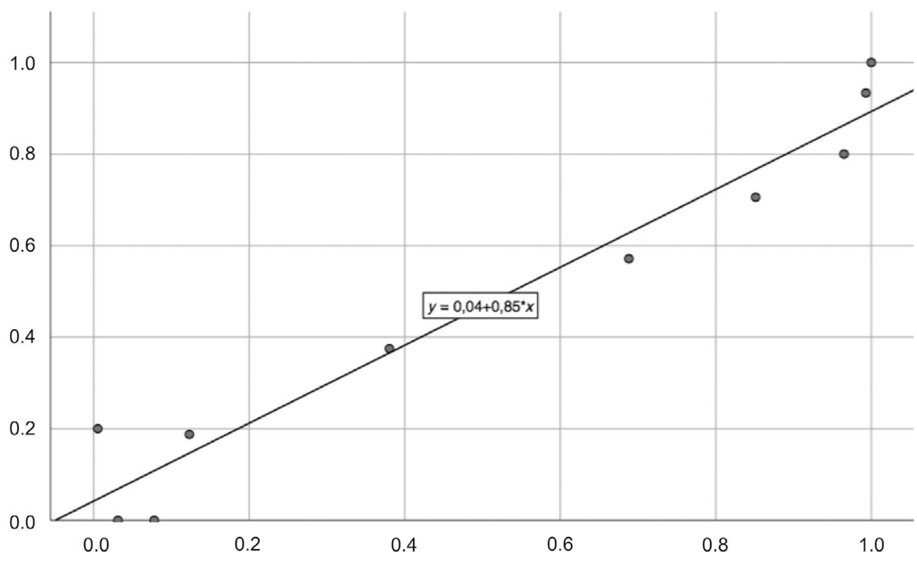


Table 3. Comparison of Diagnostic Capacity Between Ultrasound and Clinical Examination

	Sensitivity (%)	95% CI	Specificity	95% CI
Clinical uterine prolapse with surgical indication criteria	80.8	69.9; 89.1	71.3	60.1; 80.8
Ultrasound uterine prolapse with surgical indication criteria	91.8	82.9; 96.9	72.5%	61.4; 81.9

which is lower than that established in this study.[22] The measurement of ≥15 mm for the difference in the pubis–uterine fundus distance at rest and during the Valsalva maneuver has shown, in this multicenter study, to have very good agreement with clinical exams for UP using the ICS POP-Q system, with a kappa index of 0.826 (0.71; 0.94).[30] The model that is validated in this study presents a series of advantages because of the addition of an isolated cut-off point; the model allows different ultrasound measurements to be included and related to the different ages of patients. In addition, this multicenter study confirms that this technique can be easily applied during consultations by different examiners and in different centers, with excellent interobserver reliability.[23]

The first ultrasound descriptions of significant middle compartment POP were based on measuring the protrusion of the cervix with respect to the posteroinferior rim of the pubis during the Valsalva maneuver.[18] Subsequently, ultrasound was used to describe how to perform the differential diagnosis of POP of the middle compartment via the measurement of the difference in the pubis–uterine fundus distance at rest and during the Valsalva maneuver.[22] Finally, with this same measurement, it was possible to establish software to personalize the risk of UP in patients using ultrasound measurements and age.[25] The measurement of the difference in the pubis–uterine fundus distance at rest and during the Valsalva maneuver allows the indirect assessment of DeLancey level I (uterosacral–cardinal ligament complex), establishing a more reliable diagnosis of UP than that obtained through clinical examinations, as seen in this study. One explanation for this result is that the ICS POP-Q system only provides information on the anatomical surface and uses a mobile soft tissue point as a reference (hymen).[15] Transperineal ultrasound has made it possible to determine the different pathologies that may influence the differential diagnosis of middle compartment POP.[25,30,31] The physiological foundation of these studies is based on the concept that POP is related to ligament support and closure of the levator hiatus.[32] Therefore, in POP patients with apical support failure, cardinal ligaments are 20% larger. During the Valsalva maneuver, these ligaments in patients with POP are twice as long as those in patients with normal support.[33] Identifying patients with apical support outside of the "normal range" is useful to avoid unnecessary surgical treatments.[31] In this study, we validated previously published software that diagnoses patients with surgical PU in a more reliable way than a clinical examination.[25] Other previous studies have not described the superiority of ultrasound to clinical evaluation for POPs less than stage 2, as determined by the POP-Q,[34] or in symptomatic POP.[35] But different correlations have been observed, from good ($r = .77$)[36] to poor results,[37] between clinical exams for POP of the middle compartment and ultrasound.

The main strength of our study resides in the fact that the validation of this model was conducted through a multicenter study and with a cohort of patients who require corrective surgery for different pelvic floor dysfunctions. The software is simple to implement (Figure 3), objective and presents high reliability in detecting the probability of suffering UP,[25,30] making it applicable in typical clinics.

An aspect of this study that can be criticized is the method used to assess apical support.[25] Apical support is defined by the lower end of the cervix; but we believe that when studying the mobility of the uterus, we are indirectly evaluating this support. Furthermore, the conditions in which ultrasound examinations were performed were very specific. It is possible that this position may limit the exiting of the POP, but no differences have been described between the dorsal lithotomy position and standing position in descending POP.[38] We might think that there are cases in which visualization of the uterine fundus could be difficult (such as a retroverted uterus or posterior compartment POP). However, using low frequencies and modifying the gain of the ultrasound machine is enough to obtain an image of the uterine fundus, thus obtaining an excellent interobserver reliability in measurements of the difference in the distance from the pubic symphysis to the uterine fundus at rest and during the Valsalva maneuver.[23]

Conclusion

In conclusion, we have validated software developed using transperineal ultrasound of the pelvic floor and patient age that allows a more reliable diagnosis than that obtained with clinical examinations for surgical UP.

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