Identification of Surgical Uterine Prolapse in Premenopausal Patients With Clinical or Ultrasound Criteria? A Multicenter Comparative Study

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Abbreviations

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

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Objectives—It is unknown whether diagnosing uterine prolapse (UP) via ultrasound or surgical criteria is superior. Our objective is to determine whether the diagnostic capacity of ultrasound with surgical criteria differs from that of surgical criteria only.

Methods—This was a multicenter prospective observational study with 54 premenopausal patients with surgical criteria for a dysfunctional pelvic floor pathology who were consecutively recruited for 1 year. Clinical UP with surgical criteria was defined when UP stage II–IV was identified (during pelvic floor consultation), and UP diagnosed by ultrasound with surgical criteria was established when a difference ≥15 mm was found between rest and Valsalva applied to the pubis-uterine fundus. The sensitivity, specificity and positive and negative predictive values were determined to evaluate clinical and ultrasound methodologies as diagnostic tests.

Results—UP diagnosed by ultrasound with surgical criteria presented better sensitivity (78.57 vs 35.71%), specificity (92.11 vs 81.58%), positive predictive value (61.83 vs 23.99%), and negative predictive value (96.35 vs 11.37%) than UP diagnosed by surgical criteria only.

Conclusion—Ultrasound with surgical criteria is superior to surgical criteria alone when diagnosing UP.

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

Introduction

Pelvic organ prolapse (POP) is a condition that decreases patients' quality of life but can improve with surgery.[1] The preoperative diagnosis of POP has traditionally been performed by clinical examination according to the International Continence Society Pelvic Organ Prolapse Quantification (ICS POP-Q) system.[2] Additionally, ultrasound has been used to study the affected compartment in POP[3,4] and to perform the differential diagnosis within each compartment.[5–10] In fact, a transperineal ultrasound study of the pelvic floor showed that measurement of the difference in the pubis-uterine fundus distance at rest and with the Valsalva maneuver can confirm ultrasound-diagnosed uterine prolapse (UP) with surgical criteria when it is symptomatic and the value is ≥15 mm (sensitivity of 75% and specificity of 95%).[9]

There are biological differences in the support of the pelvic organs between premenopausal and postmenopausal women.[11,12] In addition, the premenopausal state is a risk factor for POP recurrence after corrective surgery,[13] reflecting the importance of its correct diagnosis. To aid in the diagnosis of UP, transperineal ultrasound has been included with measurement of the difference between the pubis-uterine fundus distance at rest and with the Valsalva maneuver, indirectly assessing apical support failure in these patients.[9] Accordingly, transperineal ultrasound may also be a useful technique to assess surgical UP in premenopausal patients. However, it is unknown whether ultrasound with surgical criteria is superior to clinical UP with surgical criteria (when UP is stage II–IV and symptomatic). Therefore, our objective is to determine whether the diagnostic capacity of ultrasound with surgical criteria differs from that of surgical criteria alone when diagnosing UP.

Materials and Methods

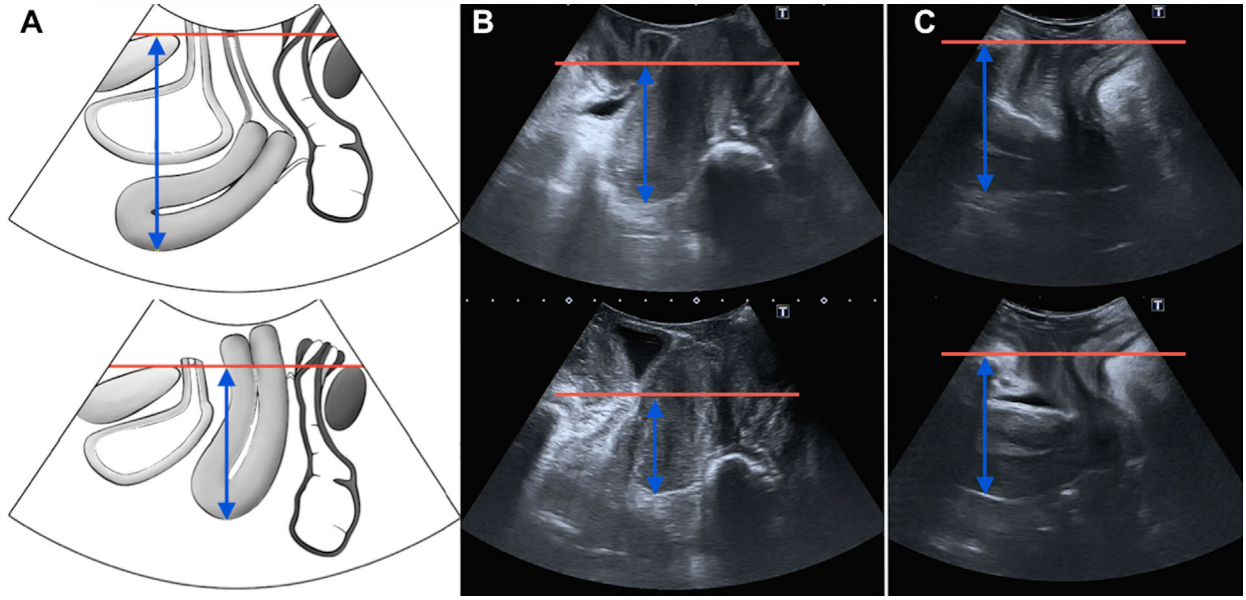
A multicenter prospective observational study was conducted with 54 premenopausal patients recruited consecutively between September 1, 2021, and September 30, 2022. The hospitals included in the study were the University Hospital of Valme of Seville (Spain), University Health Care Complex of Gran Canaria (Spain), University Health care Complex of León (Spain), and University Hospital Virgen de la Victoria of Málaga (Spain).

Recruited patients had to be premenopausal, candidates for surgery for dysfunctional pelvic floor pathology (POP correction surgery or anti-incontinence surgery with tension-free vaginal tape) and provide written informed consent to participate in the study. Patients with previous corrective surgery for pelvic floor pathology or hysterectomy were excluded. All patients underwent a standardized interview and a clinical examination using the ICS POP-Q system to assess POP.[2] A diagnosis of UP with surgical criteria was considered when POP stage II–IV was present (symptomatic and affects quality of life). In cases of urinary incontinence, a standardized interview was conducted, which included questions about stress urinary incontinence (SUI), urge urinary incontinence (UUI) or mixed urinary incontinence (MUI) and an examination to determine the state of SUI (simple stress test). In clinically doubtful cases, a urodynamic test was performed to confirm the diagnoses. The clinical parameters included in the study were age, vaginal deliveries, abortions, caesarean sections, body mass index (BMI), SUI, UUI, MUI, cystocele, the degree of cystocele, rectocele, the degree of rectocele, enterocele, the degree of enterocele, UP, the degree of UP, and clinical UP with surgical criteria (when UP is stage II–IV, symptomatic and affects quality of life).

Transperineal ultrasound was performed after the clinical examination by different examiners and experts in pelvic floor ultrasound. The sonographers were unaware of the data regarding the clinical examination. The ultrasound machines used were a Toshiba 500 Aplio® (Toshiba Medical Systems Corp., Tokyo, Japan) with a PVT-675MV three-dimensional abdominal probe and a Voluson E8 (GE Healthcare, Zipf, Austria) ultrasound system with an 8- to 4-MHz volume transducer. Transperineal ultrasound was performed in the dorsal lithotomy position following a previously described methodology.[9,14] The descent of the uterus was established by determining the uterine fundus and its relationship with the posteroinferior pubic margin[4] between rest and Valsalva application (minimum of 6 s) (Figure 1). Measurements within the posteroinferior margin of the pubis were defined as negative values, and measurements outside were defined as positive values.[15] Ultrasound-diagnosed UP with surgical criteria was defined when the difference in the pubis-uterine fundus distance between rest and Valsalva application was ≥15 mm.[9] The ultrasound parameters studied were the pubis-uterine fundus distance (rest and Valsalva) and the difference in the pubis-uterine fundus distance between rest and Valsalva application. There is 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.[10]

Before the surgical procedure and with the patient anaesthetized, the surgeons were allowed to perform a new examination of the uterine support mechanisms by performing controlled traction with

Figure 1. A, Pubis-uterine fundus measurement. Difference between rest (up) and Valsalva (down). **B**, Ultrasound-diagnosed UP with surgical criteria (rest [up] and Valsalva [down]). **C**, Without ultrasound-diagnosed UP with surgical criteria (rest [up] and Valsalva [down]).



Pozzi tenaculum forceps to determine the descent of the uterus (Figure 2) (a diagnosis of UP with Pozzi tenaculum forceps with surgical criteria was established if UP was stage II–IV, symptomatic, and affects quality of life). The criteria of the ICS POP-Q system[9] were followed, and surgical correction of UP was performed when stage II–IV UP was present.

Statistical Study

The numerical variables are summarized as the means and standard deviations, while the qualitative variables are summarized as frequencies and percentages. This analysis was performed for the groups defined by the UP variable (yes/no). To compare the quantitative variables between the two study groups (UP [yes/no]), the parametric Student's *T* test or the nonparametric Mann–Whitney *U* test was used according to the normality of the data (Shapiro–Wilk test). On the other hand, to analyze the relationships between qualitative variables and UP, χ^2 tests, Fisher's exact test or nonasymptotic Monte Carlo methods, and exact tests were performed. The sensitivity, specificity, and positive and negative predictive values were determined to evaluate clinical and ultrasound methodologies as diagnostic tests. All results were complemented with 95% confidence intervals (CIs). Data analysis was performed with the statistical package IBM SPSS Statistics 28.0 for Windows.

Figure 2. Diagnosis of UP with Pozzi tenaculum forceps.

Sample Size
To detect a difference in sensitivity between the two tests (clinical and ultrasound) of 50% (30 vs 80%) (obtained from a pilot study), an α error of 5% and a power of 85%, we needed 16 patients per group. For calculation of the sample size, the program nQuery Advisor Release 7.0 was used.

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

Results

Of the 54 patients recruited, two were excluded; one patient was excluded because the assessment was not performed with Pozzi tenaculum forceps, and the other was excluded because informed consent for the surgical intervention was revoked. Of the 52 patients included, 16 underwent corrective UP surgery (with a diagnosis of UP with Pozzi tenaculum forceps with surgical criteria), and 36 did not undergo any corrective surgery. The general characteristics of the patients according to the examination performed during the consultation for clinical UP are reflected in Table 1. No statistically significant differences in the presence of urinary incontinence or other associated POPs were observed between the groups.

Table 2 shows the measurements obtained in the mid-sagittal plane at rest and during Valsalva of the patients according to the examination performed during the consultation for UP and according to the degree of UP. We did not find differences in the pubis-uterine fundus measurements in patients with UP and those without UP. We also found no differences in the pubis-uterine fundus measurements according to the degree of UP.

When we compared the measurements obtained in the mid-sagittal plane of the patients with and without a diagnosis of UP with Pozzi tenaculum forceps with surgical criteria (Table 3), we observed statistically significant differences in the pubis-uterine fundus distance between rest and Valsalva (17.27 ± 8.90 vs 7.44 ± 6.74; $P < .0005$) between the two groups.

The comparison of diagnostic capacity between surgical criteria alone and ultrasound with surgical criteria in relation to the realization of corrective surgery for UP (diagnosis of UP with Pozzi tenaculum forceps with surgical criteria [gold standard]) is shown in Table 4. We observed that UP diagnosis by ultrasound with surgical criteria presented better sensitivity (35.71 vs 78.57%), specificity (81.58 vs 92.11%),

Table 1. General and Clinical Characteristics of the Patient Included

	UP (n = 16)	Without UP (n = 36)	*P*	95% CI
Age	49.69 ± 8.99	46.83 ± 7.91	.196	−1 to 0
Vaginal deliveries	1.81 ± 0.83	1.92 ± 0.69	.522	−1 to 0
Abortions	0.38 ± 0.62	0.28 ± 0.66	.388	0 to 0
Caesarean sections	0.13 ± 0.34	0.08 ± 0.28	.641	0 to 0
BMI	27.63 ± 4.60	26.62 ± 3.75	.479	−1.83 to 3.84
Stress incontinence	7/16 (43.75%)	19/36 (52.78%)	.764	−38.27 to 20.27
Urge incontinence	6/16 (37.50%)	14/36 (38.89%)	1	−29.97 to 27.17
Mixed incontinence	5/16 (31.25%)	14/36 (38.89%)	.829	−35.35 to 20.15
Cystocele	11/16 (68.75%)	25/36 (69.44%)	1	−27.84 to 26.64
Grade I	0/11 (0%)	2/25 (8.00%)	.489	−38.50 to 19.50
Grade II	6/11 (54.54%)	16/25 (64.00%)		−10.96 to 45.97
Grade III	5/11 (45.45%)	7/25 (28.00%)		−35.35 to 20.15
Rectocele	5/16 (31.25%)	14/36 (38.89%)	.829	−35.35 to 20.15
Grade I	1/5 (20.00%)	7/14 (50.00%)	.241	−55.51 to 4.49
Grade II	3/5 (60.00%)	7/14 (50.00%)		−19.03 to 39.03
Grade III	1/5 (20.00%)	0/14 (0%)		0.40 to 39.60
Enterocele	1/16 (6.25%)	0/36 (0%)		−5.61 to 18.21
Grade I	0/1 (0%)	0/0 (0%)	—	—
Grade II	0/1 (0%)	0/0 (0%)		—
Grade III	1/1 (100%)	0/0 (0%)		—

Table 2. Measurements Obtained in the Mid-Sagittal Plane at Rest and in Valsalva of the Patients According to Examination Performed in the Office With or Without UP and According to the Degree of UP

	UP (n = 16)	Without UP (n = 36)	P	UP (Grade I) (n = 4)	UP (Grade II) (n = 4)	UP (Grade III) (n = 8)	P
Pubis-uterine fundus measurement							
Rest	−89.36 ± 19.61	−83.14 ± 17.95	.268	−95.23 ± 27.71	−86.93 ± 23.12	−87.64 ± 16.88	.458
Valsalva	−78.27 ± 25.12	−73.50 ± 20.63	.475	−89.26 ± 37.49	−80.54 ± 28.55	−71.65 ± 16.67	.483
Pubis-uterine fundus measurement. Difference between rest and Valsalva	11.08 ± 9.01	9.64 ± 8.38	.578	5.97 ± 12.47	6.39 ± 6.32	15.99 ± 5.91	.136

positive predictive value (23.99 vs 61.83%), and negative predictive value (11.37 vs 96.35%) than that by surgical criteria alone.

Discussion

We observed that in premenopausal patients, ultrasound with surgical criteria was superior to surgical criteria alone when diagnosing UP, with higher sensitivity (35.71 vs 78.57%), specificity (81.58 vs 92.11%), positive predictive value (23.99 vs 61.83%), and negative predictive value (11.37 vs 96.35%). In a previous study, a difference in the pubis-uterine fundus distance at rest and with the Valsalva maneuver ≥15 mm was verified to define UP, with a sensitivity of 75% (95% CI: 64–86%), a specificity of 95% (95% CI: 89–100%), a positive predictive value of 86% (95% CI: 78–95%), and a negative predictive value of 89% (95% CI: 82–97%).[7] However, in this study, the ultrasound diagnosis was compared with the clinical diagnosis established with the ICS POP-Q in premenopausal women. We observed that when using ultrasound, we obtained a more reliable examination than the clinical examination to plan surgical UP correction in premenopausal patients, possibly because using surgical criteria alone for the diagnosis may result in underestimation due to the characteristics of premenopausal patients with UP. When performing ultrasound, we used a diagnostic technique that targets the descent of the uterine fundus, indirectly assessing the state of DeLancey's level I (cardinal–uterosacral ligament complex).[2] On the other hand, the clinical assessment of UP through the ICS POP-Q system is mainly limited by providing information only on the anatomical surface and using a mobile reference point (hymen). Ultrasound has been established as a superior test to the clinical test for the assessment of POP less than stage 2 of the POP-Q system.[16] Different types of correlations have been defined between the symptoms of central compartment POP and ultrasound-diagnosed UP.[17,18] However, the concordance of transperineal ultrasound with the diagnosis of UP by the ICS POP-Q system is very good, with a kappa index of 0.826,[19] thus allowing the differential diagnosis of POP of the central compartment.[19,20] The physiological explanation is that POP is related to ligament support,[21] and in cases of apical support failure, a 20% increase in the length of the cardinal ligaments is observed,[22] which implies that patients with POP present during the Valsalva maneuver have an increase of twice the

Table 3. Measurements Obtained in the Mid-Sagittal Plane of the Patients With and Without Diagnosis of UP With Pozzi Tenaculum Forceps

	With Diagnosis of UP With Pozzi Tenaculum Forceps (n = 16)	Without Diagnosis of UP With Pozzi Tenaculum Forceps (n = 36)	P	95% CI
Pubis-uterine fundus measurement				
Rest	−86.83 ± 21.05	−84.40 ± 17.75	.680	−14.14 to 9.30
Valsalva	−69.56 ± 27.23	−76.96 ± 19.74	.285	−6.37 to 21.18
Pubis-uterine fundus measurement. Difference between rest and Valsalva	17.27 ± 8.90	7.44 ± 6.74	<.0005	7.10 to 14.72

Table 4. Comparison of Diagnostic Capacity Between Diagnosis of UP With Surgical Criteria and Uterine Prolapse Diagnosed by Ultrasound With Surgical Criteria

	Sensitivity	95% CI	Specificity	95% CI	Positive predictive value	95% CI	Negative predictive value	95% CI
Clinical uterine prolapse with surgical indication criteria	35.71%	12.76–64.86	81.58%	65.67–92.26	23.99%	1.25–46.73	11.37%	0–23.94
Ultrasound uterine prolapse with surgical indication criteria	78.57%	49.29–95.34	92.11%	78.62–98.34	61.83%	29.58–94.09	96.35%	0–8.45

length of these ligaments compared to patients without POP.[22] In premenopausal patients, we have been able to more effectively detect apical support failure through ultrasound, improving the diagnostic capacity in cases of UP that must be corrected surgically.

When we compared the pubis-uterine fundus distance, we observed no differences between patients with UP and patients without UP or between patients with different degrees of UP. However, this examination was performed during a consultation and focused on premenopausal patients (Table 2). When these same patients were examined in the operating room and under anesthesia, we observed that the pubis-uterine fundus distance between rest and Valsalva differed between patients with and without a diagnosis of UP with Pozzi tenaculum forceps (Table 3) because during the examination of premenopausal patients, no complete decrease in apical support was observed during application of the Valsalva maneuver, as occurs during an examination with a patient anaesthetized with Pozzi tenaculum forceps. However, we can detect this decrease by using transperineal ultrasound in a more reliable manner without the need to use Pozzi tenaculum forceps under anesthesia.

The main strength of the study resides in its multicentricity, including the involvement of different professionals in diagnosis by surgical criteria only, ultrasound with surgical criteria and Pozzi tenaculum forceps. In addition, we allowed surgeons to change the surgical criteria established during consultation for the diagnosis established by them with the patient anaesthetized with Pozzi tenaculum forceps; we did not observe any surgical complication or additional difficulty during surgical interventions. This aspect allowed comparison of the diagnoses established in both clinical and ultrasound consultations with those established in anaesthetized patients with Pozzi tenaculum forceps. A potentially questionable aspect is the number of patients who were included, but we must consider that the number of premenopausal patients with POP is sometimes restricted and that the population recruited is sufficient to establish the pre-established objectives.

Conclusion

In conclusion, ultrasound with surgical criteria is superior to surgical criteria alone when diagnosing UP.

Data Availability Statement

Research data are not shared.

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