ONLINE LEARNING FOR 3D/4D TRANSPERINEAL ULTRASOUND OF THE PELVIC FLOOR

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Running headline: **ONLINE LEARNING ULTRASOUND OF THE PELVIC FLOOR**

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Abstract

Introducction: To evaluate the feasibility of an online learning process for performing and analysing 3D/4D transperineal ultrasound imaging of the pelvic floor.

Materials and Methods: A prospective study was conducted with 20 patients. The learning process of three inexperienced examiners (IEs) performing and analysing 3D/4D transperineal ultrasound volumes was evaluated. The learning process for the IEs was conducted online by an expert examiner (EE); no face-to-face tutoring was provided. The IEs' competency and analysis of the volumes were estimated using the intraclass correlation coefficient (ICC).

Results: The interobserver analysis of the levator hiatus dimensions provided by the EE and those from each IE (for the 20 studied cases) had ICCs ranging from 0.81 to 0.96. The dimensions of the levator hiatus performed by the IEs for the first 10 patients showed ICCs ranging from 0.55 to 0.9. However, when the IEs proceeded with the next 10 patients, they obtained ICCs ranging from 0.81 to 0.96.

Conclusions: Conducting 3D/4D transperineal ultrasound of the pelvic floor is a technique that can be learned online in a short period of time. A learning programme designed specifically for this purpose provides excellent reliability.

Keywords: Levator ani muscle, learning, transperineal ultrasound, pelvic floor

Key message: Conducting 3D/4D transperineal ultrasound of the pelvic floor is a technique that can be learned online in a short period of time.

Main test

Introduction:

Pelvic floor pathology is a recurrent entity related to muscle injuries during childbirth. Patients with a levator ani muscle (LAM) injury after delivery are more likely to present pelvic organ prolapse, mainly of the anterior and medial compartments[1], voiding dysfunctions[2] and an increased risk of recurrent prolapse after corrective surgery[3-5]. The most frequent lesion of the LAM after delivery is avulsion, defined as the deinsertion of the LAM at the level of the lower branch of the pubis[6-7]. Avulsion occurs in 12% of eutocic deliveries[8], in 34% of vacuum-assisted deliveries[9] and in 35-64% of forceps-assisted deliveries[10-12].

Initially, magnetic resonance imaging (MRI) was the technique established to study muscle injuries of the pelvic floor. However, due to advances in ultrasound imaging and the possibility of accessing the axial plane, 3D/4D transperineal ultrasound has become an alternative to MRI for pelvic floor imaging[13]. Nevertheless, when a new imaging technique is described, its reliability must be demonstrated before being used in clinic practice. Previous studies have determined the existing adequate inter- and intra-observer correlations for the evaluation of the pelvic floor through 3D/4D transperineal ultrasound[14,15]. However, although some studies have defined the learning process for 3D/4D transperineal ultrasound of the pelvic floor, its knowledge remains limited. These studies have described a learning curve based on the direct tutoring of an inexperienced examiner (IE) by an expert examiner (EE)[16,17]. In this field, the number of EEs for pelvic floor ultrasound is limited; therefore, it is difficult to access face-to-face tutoring for learning how to conduct 3D/4D transperineal ultrasound. In this sense, our objective was to evaluate the feasibility of an online learning process for performing and analysing 3D/4D transperineal ultrasound imaging of the pelvic floor.

Material and Method

A prospective observational study was conducted between 1 September 2015 and 31 January 2016. Twenty primiparous women with vaginal delivery were included. The women were participating in an ongoing cohort study designed to investigate the avulsion of postpartum LAM. The study was conducted at the University Hospital of Valme (Seville, Spain). It was approved by Andalucia's Bioethics Committee.

All nulliparous women at term gestation, without prior pelvic floor corrective surgery, in the active stage of labour, with the foetus in cephalic presentation and with written informed consent were considered suitable for the study and therefore included. Pregnancies with severe maternal or foetal pathology were excluded. Patients with connective tissue disease, a neurological disorder or incapability of performing the Valsalva manoeuvre were also excluded.

The sonographic evaluation was performed 6 months after delivery. Images were acquired with patients in the dorsal lithotomy position, placed on the gynaecological examination table under empty bladder conditions. The transducer was carefully placed on each patient's perineum, applying the minimum pressure possible. Three volume measurements were taken for each patient: at rest, during the Valsalva manoeuvre and during maximum contraction. The 3D/4D ultrasound imaging was conducted in the midsagittal plane using a Toshiba Aplio 500 ultrasound system (Tokyo, Japan) with a 6-8 MHz convex volumetric probe. Subsequently, an analysis of the ultrasound volumes was performed offline.

The study involved three IEs (IE 1, IE 2 and IE 3) and. one pelvic floor ultrasound EE with over 7 years of experience in sonographic studies of the pelvic floor. The IEs were gynaecologists with 4 years of experience, but completely inexperienced in performing or analysing 3D/4D ultrasound imaging of the pelvic floor. However, the IEs possessed previous knowledge on the use of the ultrasound device to be employed for the 3D/4D imaging, as well as at least 4 years of experience in obstetric and gynaecological ultrasound imaging. The IEs were provided the written and audio-visual material regarding handling the ultrasound system by e-mail, as well as instructions to perform the 3D/4D imaging to obtain successful volumes for the offline analysis. In addition, the material specified how to conduct the offline analysis to obtain the pelvic plane of minimal dimensions (PMD). The IEs had a week (training period) to study the audio-visual material and ask the questions to the EE (all questions were answered by e-mail). No face-to-face instruction was provided to the IEs in a practical manner at any time.

Image acquisition

The material provided by the EE specified the following guidelines for a successful acquisition:

1) Prior to initiating the volumetric acquisition, configure the device to a sagittal acquisition angle of 70º and a coronal acquisition angle of 90º (maximum values). Set the depth to 9 cm and the focus to 3.5 cm.
2) Place the sheath on the transducer. Carefully place the transducer with gel on the patient's perineum in such a way that the pubis lies to the right of the image and from top to bottom (figure 1).
3) Divide the screen in two equal halves, as shown in Figure 1. Place the urethra and angulation of the anorectal canal equidistantly to the midline and visualize the pubis (figure 1).
4) Acquire the volume.
5) Perform a quick, deep scan in 'C image' (in the 3D/4D volume processing mode of four images) to verify that the acquisition was successful. Then, record the volume for further analysis.

Each IE independently performed three volumetric acquisitions on each patient (at rest, during the Valsalva manoeuvre and during maximum contraction), and the acquisitions were recorded. The three IEs obtained the volumes corresponding to the first 10 patients. Then, said volumes were sent by e-mail to the EE. Subsequently, the EE analysed the images and reported to each IE the corresponding results on their performance. According to the EE, in regard to obtaining the PMD, volumetric acquisitions with a full approach of the levator hiatus (the pubis, anal region and puboviscеral area should be present) were qualified as *successful* after the analysis[18]. On the other hand, volumetric acquisitions were qualified as a *failure* if any of the anatomical structures described above were missing. Once the IE reviewed the report issued by the EE and acknowledged the failures in their acquisitions regarding the first 10 patients, they resumed the ultrasound imaging with the 10 remaining patients (these acquisitions were later analysed by the EE).

Image processing

The following guidelines for the volumetric analysis were presented in the material provided by the EE:

1) Obtain the PMD from the volume acquired, determined by the most caudal part of the pubic symphysis, urethra, vagina, anal canal and lower part of the LAM at the posterior level.
2) Evaluate the different levator hiatus dimensions: anteroposterior diameter (LHap), transverse diameter (LHt) and area (LHarea)[8].
3) The levator-urethra gap (LUG) should be measured from the centre of the urethra up to the insertion of the LAM, to the left (LUG-l) and to the right (LUG-r)[19].

The offline study was performed with the volumes obtained by the EE from the 20 patients studied. The IEs carried out the offline analysis of the first 10 patients and then compared their values with the measurements provided by the EE, which were made available after the complete volumetric analysis of the first 10 patients. Subsequently, the IEs analysed the volumes for the remaining 10 patients.

Statistical analysis

Based on previous studies, to obtain an intraclass correlation coefficient (ICC) greater than 0.6, with the corresponding 95% confidence interval (CI) for LHarea at rest, a required sample size of 20 patients was calculated[16]. The values were analysed by calculating the ICC with the 95% CI. Interclass correlation coefficient values <0.2 were considered to have poor reliability, 0.21-0.40 fair reliability, 0.41-0.60 moderate reliability, 0.61-0.80 adequate reliability and 0.81-1.00 excellent reliability[20]. The mean difference between the observers ('biases') was calculated using the Bland-Altman and 95% limits of agreement (LOA) methods[20]. To test for significant bias, the 95% CI for the bias in each case was used to determine whether the bias differed from zero. Statistical analyses were performed using IBM SPSS Statistics 23 software.

Results

The 20 primiparous patients included in this study presented a mean age of 30.65 ± 5.08 years, an average BMI of 22.56 ± 2.26 kg/m^2 and a mean gestational age of 39.25 ± 1.02 weeks at delivery. Epidural analgesia was requested by 95% (19/20) of the patients, presenting an average epidural time of 330.79 ± 151.2 minutes; episiotomy was present in 60% (12/20) of the patients, while avulsion occurred in 55% (11/20) of the patients. All deliveries were vaginal; 60% were eutocic (12/20), and 40% (8/20) were vacuum assisted.

Image acquisition

The EE did not present failures in the acquisition of images. Each IE acquired 60 volumes by 3D/4D transperineal ultrasound (20 at rest, 20 during the Valsalva manoeuvre and 20 during contraction). Failures in the volumetric acquisitions of the three IEs for determining the PMD were present for the first 10 acquisitions; the rest of the volumetric acquisitions (patients 10 to 20) were successful. Figure 2 depicts the failures of each IE. Eight acquisition failures were presented by IE 1 (the anus was not visualized in five images, the pubis was not seen in one image, and the LAM was not observed in two images). Six failures were presented by IE 2 (the anus was not visualized in one image, the pubis was not seen in one image, and the LAM was not observed in four images). Nine acquisition failures were presented by IE 3 (the anus was not visualized in six images, the pubis was not seen in one image, and the LAM was not observed in two images).

Image processing

Table 1 shows the means of the different dimensions of the levator hiatus obtained by the EE compared with those obtained by each IE. No statistically significant differences were observed in the levator hiatus dimensions.

Table 2 shows the interobserver study of the levator hiatus dimensions between the EE and each IE for the 20 cases studied. An ICC ranging from 0.81 to 0.96 was estimated. Measurements of the levator hiatus performed by the IEs showed ICCs ranging from 0.55 to 0.91 for the first 10 patients. However, when the IEs studied the 10 remaining patients, ICCs ranging from 0.81 to 0.96 were obtained (Figure 3).

The interobserver study between the EE and each IE in relation to the LUG-l and LUG-r are shown in Table 2. The ICC obtained by the IE for the LUG-l was 0.72 in the first 10 patients and 0.89 in the 10 remaining patients, and the ICC obtained by the IE for the LUG-r was 0.81 in the first 10 patients and 0.82 in the 10 remaining patients.

Discussion

The first study describing the learning process for 3D/4D ultrasound of the pelvic floor was that of Saifarikas et al. in 2013[16]. However, after conducting a PubMed review, no study was found that referred to an online learning process for 3D/4D transperineal ultrasound. The present study shows that it is feasible to conduct a learning process without direct practical tutoring by an EE. However, it is necessary to present specific and didactic material to guide the IE.

It was observed that the three IEs presented failed 3D/4D volumetric acquisitions of the pelvic floor in the first 10 patients studied. These failures were not present in the volumetric acquisitions of the remaining 10 patients. This finding has been described in previous studies. Therefore, it has been established that the learning curve for acquiring successful volumes of the pelvic floor is relatively short[16]. However, in the Saifarikas study, the IE was able to acquire the complete image of the PMD after receiving 3 hours of proper tutoring in volumetric acquisitions[16]. The present work aimed to recreate the learning process from the beginning; for this reason, the three IEs in our study presented failures when attempting to obtain the PMD. It was observed that by not receiving direct tutoring, the orientation in space and the management of 3D/4D transperineal ultrasound became more difficult. Therefore, we believe that a face to face training could have reduced acquisition errors. Most of the failed volumes of the three IEs occurred during the Valsalva manoeuvre (IE 1 = 4/8; IE 2 = 4/6; IE 3 = 6/9) (figure 2). This finding has been previously described by other authors[15,21]. However, this difficulty was overcome by the IEs after the first 10 3D/4D volumetric acquisitions corresponding to the first 10 patients studied. IE1 and IE3 mostly failed to capture the anal canal because they centered the pubis more than necessary in the middle sagittal plane. However, the main error of the IE2 laterally shifted the middle sagittal plane, reason why it did not correctly observe the MEA. The different errors committed by all the IE were due to a deficient interpretation of the middle sagittal plane. However, everyone learned to correctly center the median sagittal plane to obtain a correct image of the PMD after the first 10 3D/4D volumetric acquisitions.

The analysis of the levator hiatus dimensions by the three IEs presented an ICC with excellent reliability after the first 20 patients were analysed (ICCs ranging from 0.82 to 0.96). In a previous study, good results were reported by an IE in the dimensioning of the levator hiatus at rest, during the Valsalva manoeuvre and during contraction, after 2.5 hours of training[17]. However, our results were obtained by three IEs without prior experience with 3D/4D ultrasound imaging of the pelvic floor, only with online tutoring by an EE. In addition, other authors have come to describe excellent reliability for dimensioning the LHap, LHt and LHarea at rest and during contraction[14-16,22,23] and excellent to moderate reliability for LHap and LHarea during the Valsalva manoeuvre[15,23]. These previously described results are consistent with those obtained in our study through online learning for the analysis of 3D/4D pelvic floor imaging.

The ICCs for the LUG estimated by the three IEs presented excellent reliability (Table 2). Previous studies comparing the LUG dimensions obtained by different EEs in women after delivery have shown significant reliability[24]. However, the studies that used IEs for dimensioning the LUG also obtained good results for the LUG ICCs[16,17]; of which, Van Veelen[17] provided the IE with two 2.5-hour sessions and Saifarikas[16] instructed the IE for 20 hours. The online training to which our IEs were submitted was sufficient to obtain a good correlation for the LUG dimensions.

A limitation of our work is that only asymptomatic patients with a vaginal delivery were included during the previous 6 months, not being considered patients with pelvic organ prolapse symptoms. Therefore, we believe that the results of this study should not be extrapolated to patients with pelvic organ prolapse and should be taken into consideration for future studies. Another possible limitation of the study may be that the audio-visual material provided to the IEs was not customized. However, to address this problem, the EE responded to all the questions posed by the IE in a theoretical manner via telematics. The personalized EE reports specifying the failures of the volumetric acquisitions and analysis for the first 10 patients contributed to improving the learning process of each IE.

We believe that an important aspect of our study was the strictness in establishing that at all times, the only training for the IE would be theoretical, conducted online and not tutored in a practical manner by the EE. In addition, three IEs were involved and each one independently carried out their own theoretical learning. Therefore, we believe that these results can be recreated by other IEs, allowing a non-tutored, face-to-face learning process for 3D/4D transperineal ultrasound of the pelvic floor. This learning process can be highly useful in the beginning of the basic education and telematics for 3D/4D transperineal ultrasound of the pelvic floor, providing greater access to a larger proportion of specialists interested in this technique. However, to achieve the successful management of and improvement in this technique, which is applicable in clinical practice, we consider that tutored learning is the best option.

In conclusion, transperineal 3D/4D ultrasound of the pelvic floor is a technique that can be instructed online in a short period of time with excellent reliability through a learning programme designed specifically for this purpose.

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Table 1: Shows the different measurements of the different scanners (n = 20).

	Media (SD)				p
	EE	IE1	IE2	IE3	
LHap					
Rest	62.44 (±6.86)	64.99 (±8.77)	60.21 (±7.51)	62.71 (±10.11)	NS
Valsalva	66.95 (±8.68)	65.96 (±9.16)	64.58 (±9.60)	66.77 (±13.11)	NS
Contraction	59.67 (±8.76)	65.43 (±11.20)	59.32 (±9.35)	59.82 (±10.80)	NS
LHt					
Rest	42.69 (±9.79)	40.44 (±9.58)	40.49 (±8.53)	42.45 (±9.70)	NS
Valsalva	46.46 (±10.06)	44.44 (±10.35)	44.44 (±8.87)	46.33 (±9.21)	NS
Contraction	43.16 (±9.58)	43.58 (±9.59)	41.22 (±8.91)	42.50 (±10.07)	NS
LHarea					
Rest	16.75 (±3.87)	16.68 (±4.30)	15.29 (±4.16)	16.74 (±5.26)	0.028 (EE and EI2)
Valsalva	20.13 (±4.74)	19.68 (±5.34)	18.14 (±5.02)	20.58 (±4.93)	0.037 ((EE and EI2)
Contraction	16.31 (±3.92)	19.24 (±5.50)	15.54 (±3.84)	16.41 (±4.59)	<0.0005 (EE and EI1)
LUG-l	2.12 (±0.29)	2.20 (±0.27)	2.25 (±0.33)	2.10 (±0.28)	NS
LUG-r	2.06 (±0.27)	2.17 (±0.29)	2.11 (±0.27)	2.14 (±0.28)	NS

LHap: Antero-posterior levator hiatus diameter; LHt: Transverse levator hiatus diameter; LHarea: Levator hiatus area, LUG-l: left levator–urethra gap; LUG-r: rigth levator–urethra gap; EE: explorador expert; IE1: inexperienced examiner 1; IE2: inexperienced examiner 2; IE3: inexperienced examiner 3. NS: Not statistically significant values.

Table 2. Interobserver reliability of the elevator hiatus measurements IE (n = 20)

	ICC (95% CI)	Bias (SD)	LOA	p
LHap				
Rest	0.86	0.84	0.73-0.94	<0.0005
Valsalva	0.82	0.79	0.65-0.92	<0.0005
Contraction	0.87	0.85	0.75-0.94	<0.0005
LHt				
Rest	0.94	0.93	0.88-0.97	<0.0005
Valsalva	0.94	0.94	0.89-0.98	<0.0005
Contraction	0.96	0.95	0.91-0.98	<0.0005
LHarea				
Rest	0.96	0.95	0.92-0.98	<0.0005
Valsalva	0.92	0.91	0.84-0.97	<0.0005
Contraction	0.91	0.89	0.81-0.96	<0.0005
LUG-l	0.81	0.78	0.63-0.92	<0.0005
LUG-r	0.90	0.88	0.80-0.96	<0.0005

LHap: Antero-posterior levator hiatus diameter; LHt: Transverse levator hiatus diameter; LHarea: Levator hiatus area; EE: expert examiner; IE: inexperienced examiner; ICC: intraclass correlation coefficient; LOA: 95% limits of agreement.

Figure 1: The middle sagittal plane is visualized. The dashed yellow line indicates in the center of the image. IE places the urethra (§) and angulation of the anorectal canal (⌘) at the same distance perpendicular to the dashed yellow line. The red solid line marks the PMD.

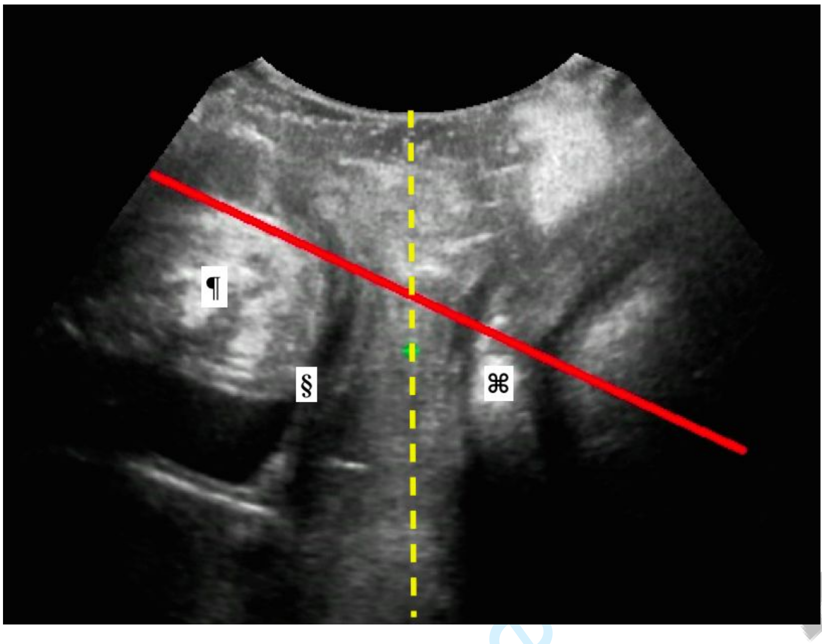


Figure 2: Shows the errors and successes in the image capture of the different IE.

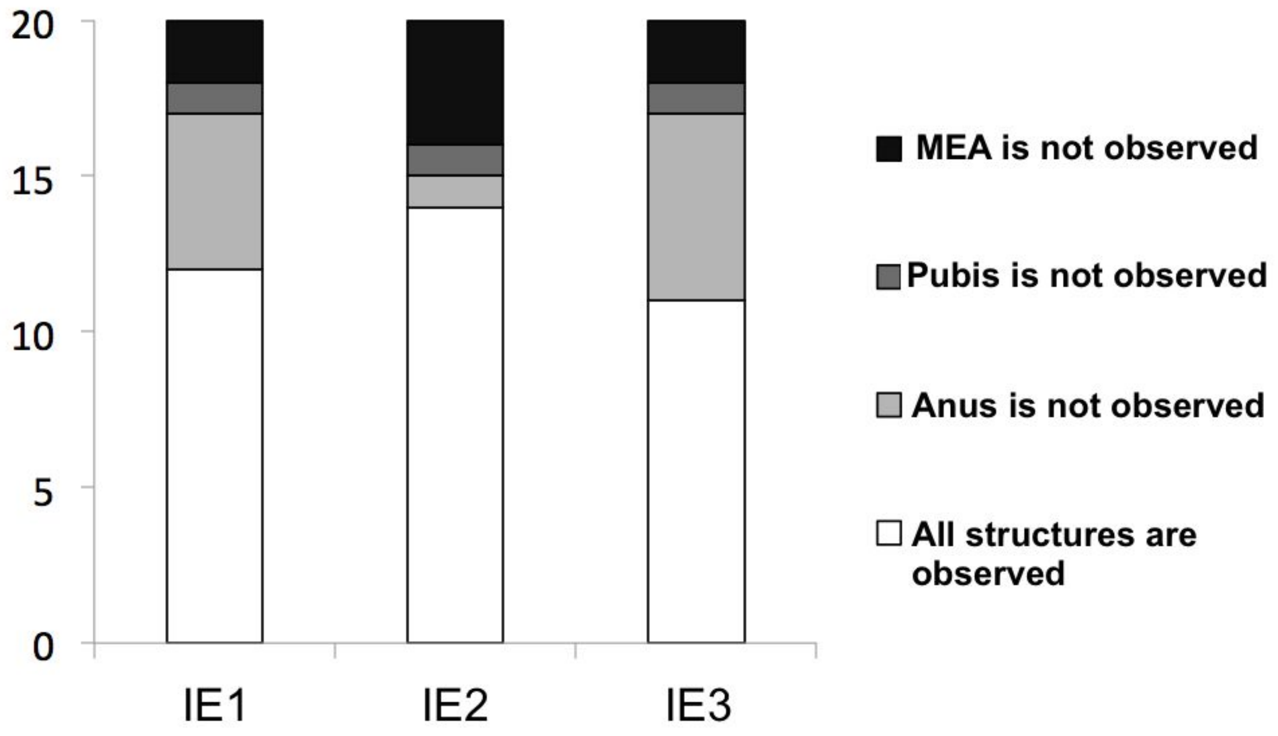
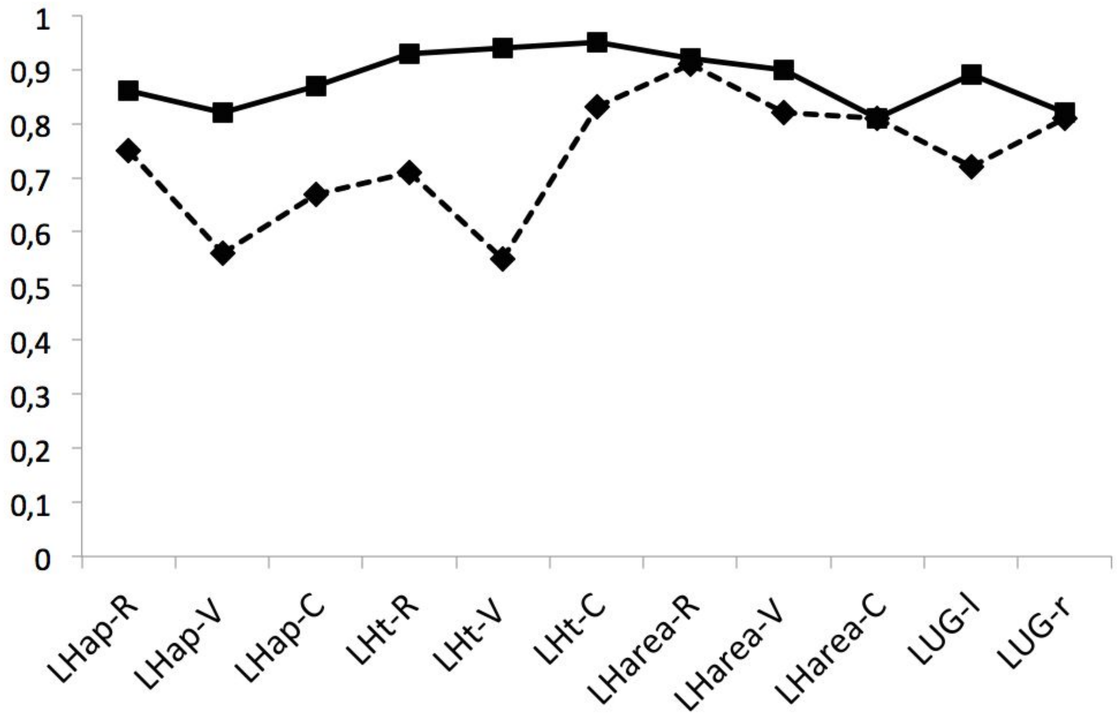


Figure 3: The ICC is observed among the 3 inexperienced explorers in the first 10 patients analyzed (broken line) and in the 10 following patients analyzed (solid line).



LHap: Antero-posterior levator hiatus diameter; LHt: Transverse levator hiatus diameter; LHarea: Levator hiatus area; contraction (-C), at rest (-R) and Valsalva (-V).

Table 2. Interobserver reliability of the elevator hiatus measurements IE

	ICC (95% CI)	Bias (SD)	LOA	p
LHap				
Rest	0.86	0.84	0.73-0.94	<0.0005
Valsalva	0.82	0.79	0.65-0.92	<0.0005
Contraction	0.87	0.85	0.75-0.94	<0.0005
LHt				
Rest	0.94	0.93	0.88-0.97	<0.0005
Valsalva	0.94	0.94	0.89-0.98	<0.0005
Contraction	0.96	0.95	0.91-0.98	<0.0005
LHarea				
Rest	0.96	0.95	0.92-0.98	<0.0005
Valsalva	0.92	0.91	0.84-0.97	<0.0005
Contraction	0.91	0.89	0.81-0.96	<0.0005
LUG-l	0.81	0.78	0.63-0.92	<0.0005
LUG-r	0.90	0.88	0.80-0.96	<0.0005

(n = 20)

LHap: Antero-posterior levator hiatus diameter; LHt: Transverse levator hiatus diameter; LHarea: Levator hiatus area; EE: expert examiner; IE: inexperienced examiner; ICC: intraclass correlation coefficient; LOA: 95% limits of agreement.