Australian and New Zealand Journal of Obstetrics and Gynaecology 2014; **54:** 462–468 DOI: 10.1111/ajo.12242

Original Article

Can anyone screen for deep infiltrating endometriosis with transvaginal ultrasound?

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Background: Surgical treatment of deep infiltrating endometriosis (DIE) is complex, and preoperative diagnosis benefits both surgeon and patient. Studies in expert centres have reported high accuracy for transvaginal ultrasound (TVUS) diagnosis of DIE. External validation of these findings has been limited, and no information is available on how quickly these skills can be acquired. The aim of this study was to measure the learning curve of DIE-TVUS and to identify the causes for inaccuracies in the diagnosis of bowel lesions and Pouch of Douglas (POD) obliteration.

Methods: Following one week of training at the University of São Paulo (Brazil), 205 consecutive women with a history of endometriosis symptoms were prospectively assessed by TVUS after minimal bowel preparation. TVUS findings were correlated with laparoscopic findings in eighty-five cases to assess the accuracy. The LC-CUSUM and CUSUM were used to assess the learning curve and maintenance of competency, respectively.

Results: The sensitivity and specificity for DIE of the bladder, vagina and bowel were 33% and 100%, 80% and 100%, and 88% and 93%, respectively. The sensitivity and specificity for the presence of POD obliteration were 88% and 90%, respectively. LC-CUSUM analysis confirmed that competency for DIE-TVUS was achieved within 38 scans for the detection of POD obliteration and within 36 scans for the detection of bowel nodules. Competency was maintained for the remainder of the scans as assessed by the CUSUM.

Conclusions: After one week of DIE-TVUS training, competency can be achieved within forty procedures, allowing diagnosis of DIE with similar diagnostic accuracy as reported by centres of excellence.

Key words: bowel, deep endometriosis, diagnosis, learning curve, transvaginal ultrasonography.

Introduction

Endometriosis is a challenging gynaecological condition affecting 10-15% of women in the reproductive age group.[1] The majority of women with endometriosis have superficial lesions which can be treated by simple operative laparoscopy. A subgroup of women has deeply infiltrating endometriosis (DIE). This is defined as endometriotic lesions that penetrate under the surface of the peritoneum by more than 5 mm in the uterosacral ligaments (USL), rectosigmoid, rectovaginal septum or bladder[2] and can be associated with Pouch of Douglas (POD) obliteration. The treatment is significantly more complex.[3] Preoperative diagnosis of DIE greatly benefits the woman as it allows early referral to an endometriosis specialist, better preoperative counselling and preparation, and the opportunity to arrange for a multidisciplinary team to be present at surgery.[4,5]

Several studies have reported high accuracy for the diagnosis of DIE with TVUS.[6–12] These studies were all conducted by very experienced sonologists who developed the techniques in selected women with a high pretest risk for DIE.

The aim of this study was to assess whether a diagnostic accuracy for DIE could be obtained comparable to that of the experts. In addition, we assessed the learning curve associated with acquiring these skills and identified the causes for inaccuracies in the diagnosis of those lesions that make surgery significantly more complex.

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Received 18 February 2014; accepted 26 June 2014.

Material and Methods

In November 2009, the corresponding author spent one week of training at the University of São Paulo Medical School and at Digimagem Diagnósticos Médicos, São

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Paulo, Brazil, to learn the transvaginal scanning technique published by Goncalves *et al.* in 2009.[13] The technique includes a mild bowel preparation, consisting of an oral laxative on the eve of the examination and a rectal enema consisting of 120 mL of sodium diphosphate (Fleet, C.B. Fleet Company, Lynchburg, VA, USA) 1 hour before the examination. The corresponding author is a gynaecologist with a subspecialty degree in ultrasound and more than 10 years of experience, but no prior experience in detecting DIE. This study commenced immediately upon the corresponding author's return from Brazil. Between November 2009 and September 2011, 205 consecutive women with symptoms of endometriosis were referred for TVUS. Each examination was carried out with an iU22 ultrasound machine (Koninklijke Philips, N.V.) using a c8-4 vaginal transducer and interpreted in real time but also recorded on DVD. All examinations were performed by a single operator (SP) who was not blinded to the symptoms and history of the woman.

In addition to routine analysis of the uterus and ovaries, the examination protocol included visualisation of the peritoneal surface covering the vesicouterine pouch and the POD, the rectosigmoid, the vagina and the retrocervical area. Bladder nodules (Fig. 1) were recorded if a hypoechoic nodule was seen in the vesicouterine pouch or the bladder wall. If the vaginal wall was thickened with a hypoechoic nodule (Fig. 2), a vaginal nodule was recorded. Bowel involvement was established when a hypoechoic solid appearing lesion was seen adherent to the bowel wall (Fig. 3). The layers of the bowel wall were examined (Fig. 4). When bowel endometriosis was identified, the number of lesions, their size in three dimensions and the distance to the anus were documented.

Mobility of the pelvic organs was assessed. Particular attention was paid to the assessment of movement between the bowel and the posterior surface of the uterus, cervix and vagina to diagnose POD obliteration. This has also been described as the sliding sign.[14,15]

At the time of the ultrasound, a score sheet was completed.

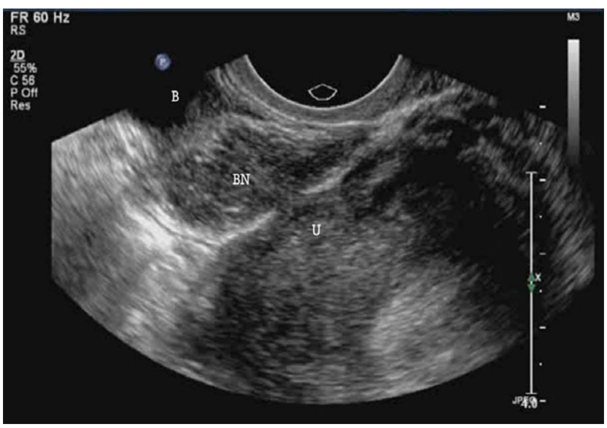

Figure 1 Bladder nodule (BN), uterus (U) and bladder (B).

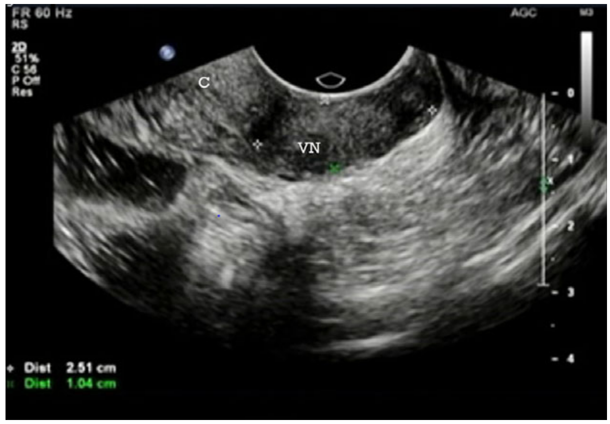

Figure 2 Vaginal nodule (VN) and cervix (C).

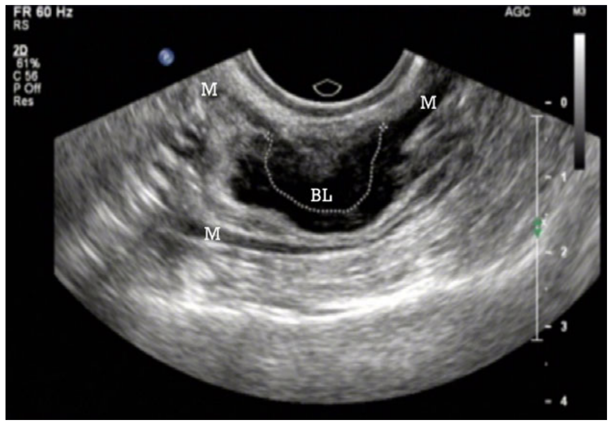

Figure 3 Bowel nodule (BL), different from the normal muscularis propria (M).

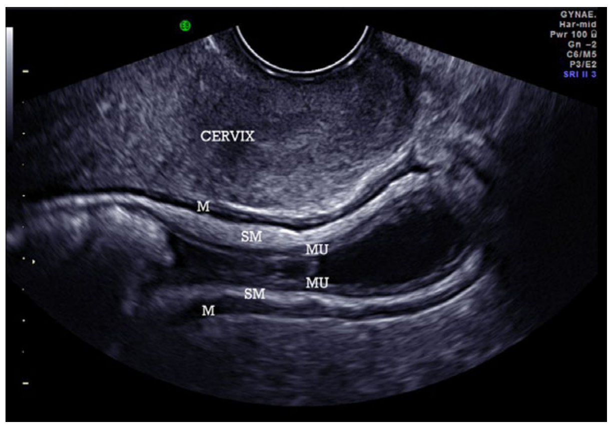

Figure 4 Different layers of the bowel: muscularis propria (M), submucosa (SM), and mucosa (Mu).

Eighty-five women underwent surgery, and these were all included in the analysis. The laparoscopic images, operation reports and histology reports were assessed by the corresponding author who was blinded to the ultrasound report at the time of analysis, and a surgical score sheet was completed. This was later compared to the ultrasound score sheet. Lesions that were not confirmed by histology were not excluded from being entered on the surgical score sheet. Although a visual diagnosis is associated with a certain error rate,[16] histological confirmation also depends on the experience of the pathologist, the extent of tissue sectioning and the degree of fibrosis and diathermy artefacts within the specimen.[17] More importantly, the value of DIE-TVUS to the surgeon is the accurate description of the anatomical changes in the pelvis. Consequently, the surgeon's preoperative and intraoperative planning does not depend on the histological confirmation as this is a post hoc finding.

When there was discordance between ultrasound and laparoscopy, the ultrasound DVD and laparoscopic images were studied to identify the cause of the discordance, but the initial scoring was not altered.

Ethics approval was obtained from the Monash Health Human Research Ethics Committee (Project No. 13417Q).

Statistical analysis

Sensitivities, specificities, positive and negative predictive values (PPV and NPV) and accuracy were calculated for the diagnosis of POD obliteration, vaginal nodules, bowel and bladder involvement and endometriomas, the results of the laparoscopy being considered the gold standard.

The LC-CUSUM (learning curve–cumulative sum) test was used to assess the learning curve for the TVUS detection of POD obliteration and bowel nodules. The LC-CUSUM sequentially tests the null hypothesis 'performance is unacceptable' against the alternative hypothesis 'performance is acceptable'.[18–20] Once the summation score reaches a preset level (h), the test rejects the null hypothesis, indicating that the performance is adequate.

The acceptable failure rate for our study was set at 10% and the unacceptable failure rate at 20%. A simulation of 10 000 replicates of 100 procedures was performed with a 10% and 20% failure rate, respectively, to select the h-value that optimised the type I error (declaring competency in an 'out-of-control' scenario,) and type II error (not declaring competency in an 'in-control' scenario).[18] Table 1 shows a summary of these simulations. An h-value of −1.25 was chosen as it is associated with an optimal trade-off between the 14.9% risk of a type I error and a 12.1% risk of a type II error.

Once the LC-CUSUM declared competency, ongoing performance was measured with the CUSUM, which is designed to detect a shift from adequate to inadequate performance. Once the score crosses the h limit, performance is considered inadequate and an audit can then take place to determine the reason. Simulations as previously described were used to choose an h-value of 1.5 that was chosen with a risk of a type I error of 16.6% and a risk of type II error of 6.6% (Table 1).

Results

Women were between 18 and 48 years of age. Of the 85 women who underwent surgery, 61 had a past history of endometriosis (72%). Presenting symptoms were

Table 1 Type I and type II errors for LC-CUSUM and CUSUM associated with different h levels

h LC−CUSUM	−1	−1.1	−1.2	**−1.25**	−1.3	−1.4	−1.5	−1.6
P1	0.10	0.10	0.10	**0.10**	0.10	0.10	0.10	0.10
Total alarms	9525	9273	8952	**8794**	8705	8247	7834	7363
Type II error (%)	4.8%	7.3%	10.5%	**12.1%**	13.0%	17.5%	21.7%	26.4%
P2	0.20	0.20	0.20	**0.20**	0.20	0.20	0.20	0.20
Total alarms	3193	2238	1737	**1487**	1271	940	675	434
Type I error (%)	32.0%	22.4%	17.4%	**14.9%**	12.7%	9.4%	6.8%	4.3%
h CUSUM	1.25	1.3	1.4	**1.5**	1.6	1.7	1.8	1.9
P1	0.10	0.10	0.10	**0.10**	0.10	0.10	0.10	0.10
Total alarms	1289	1174	935	**655**	468	351	246	215
Type II error (%)	12.9%	11.7%	9.4%	**6.6%**	4.7%	3.5%	2.5%	2.2%
P2	0.20	0.20	0.20	**0.20**	0.20	0.20	0.20	0.20
Total alarms	9030	8838	8652	**8338**	8043	7755	7410	7063
Type I error (%)	9.7%	11.6%	13.5%	**16.6%**	19.6%	22.5%	25.9%	29.4%

For each value h and for both performance levels (P1 acceptable failure rate of 10%; P2 unacceptable failure rate of 20%), 10 000 simulations of 100 scans are performed for the LC-CUSUM and CUSUM. Total alarms represent the number of times the cumulative sum reaches the h level in the 10 000 simulations. For the LC-CUSUM, the proportion of simulated trainees with adequate performance (P1) that do not reach the h level within 100 scans represents the type II error and the proportion of simulated trainees with inadequate performance (P2) that do reach the h level represents the type I error. Conversely, for the CUSUM, the proportion of simulated trainees with adequate performance (P1) that do reach the h level within 100 scans represents the type II error and the proportion of simulated trainees with inadequate performance (P2) that do not reach the h level represents the type I error. The h-values selected for the LC-CUSUM and CUSUM are shown in bold.

dysmenorrhoea (63%), dyschezia (53%), dyspareunia (44%), infertility (22%), abnormal bleeding (20%), chronic pain (21%) and rectal bleeding (8%).

In this series, 29% of women had bowel nodules, 7% had bladder nodules, 40% had POD obliteration, 18% had a vaginal nodule, and 20% had endometriomas.

The sensitivity, specificity, PPV, NPV and accuracy for the TVUS diagnosis of endometriomas, POD obliteration, vaginal nodules, bladder nodules and bowel nodules are summarised in Table 2.

These results compared well with the results published in the literature[6–12] and were in keeping with a systematic review by Hudelist which showed that the sensitivity, specificity, PPV and NPV for the diagnosis of bowel nodules is 91%, 98%, 98% and 95%, respectively.[12] Goncalves *et al.* reported that for the detection of bowel nodules, the sensitivity was 98%, specificity 100%, PPV 100%, NPV 97% and accuracy 99%.[11]

The LC-CUSUM shows that 38 scans were required to achieve competency for the detection of POD obliteration (Fig. 5) and 36 scans were required to achieve competency for the detection of bowel nodules (Fig. 6). After performance was deemed proficient, continuing monitoring with CUSUM showed ongoing adequate performance (Figs 5 and 6).

Discussion

The results of this study confirm that after one week of observing DIE-TVUS and a short learning curve, ultrasound skills can be acquired which match published diagnostic accuracy in expert centres.

Although the results in this study compare favourably with the published literature,[9,10,12] the diagnostic accuracy is less than that obtained by the group of Abrão *et al.*[11] whose technique was used. There are several possible reasons for this. The unit of Prof Abrão is a tertiary referral centre with a high case load allowing for the rapid accumulation of experience. There is a higher prevalence of severe disease, possibly having a favourable impact on the reported test characteristics. Thirdly, there is daily feedback between surgeons and imaging specialists leading to constant fine-tuning of the interpretation of ultrasound findings. For most centres, that degree of communication is difficult to achieve. Nonetheless, our study demonstrates that after 1 week of training and a short learning curve, TVUS in the hands of someone with prior TVUS experience allows for the diagnosis of DIE with a high diagnostic accuracy.

The high diagnostic accuracy of TVUS for the detection of endometriomas has been widely reported,[10,21–24] and this study provides further confirmation.

Table 2 Diagnostic test characteristics for the transvaginal ultrasound diagnosis of endometriomas, Pouch of Douglas obliteration, vaginal nodules, bladder nodules and bowel nodules in 85 women

Localisation	Sensitivity (%)	Specificity (%)	PPV (%)	NPV (%)	Accuracy (%)
Right/left ovary	100/100	92.9/92.9	66.7/66.7	100/100%	93.8/93.8
POD obliteration	88.2	90	85.7	91.8	89.3
Vagina	80	100	100	95.5	96
Bladder	33.3	100	100	95.1	95.2
Bowel	88	93.3	81	95	91.7

PPV, positive predictive value; NPV, negative predictive value.

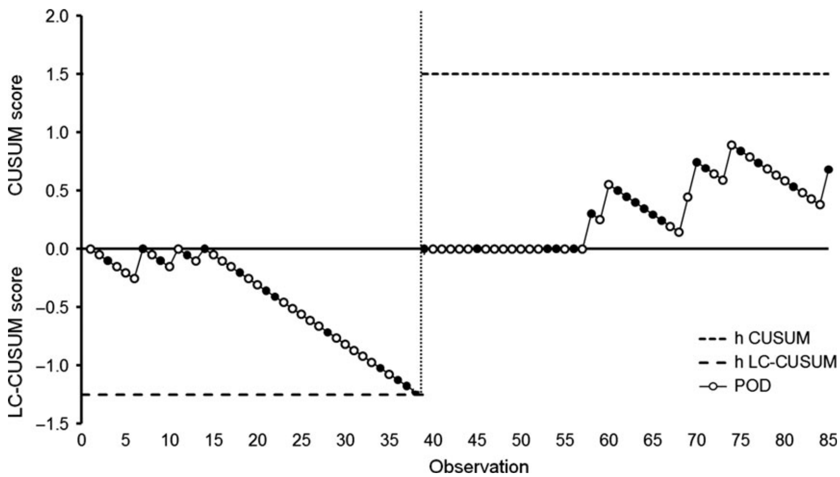

Figure 5 LC-CUSUM followed by CUSUM for the detection of Pouch of Douglas obliteration. The *x*-axis shows the sequential number of procedures. The *y*-axis shows the LC-CUSUM, followed by the CUSUM score for each procedure. Full circles represent true-positive results.

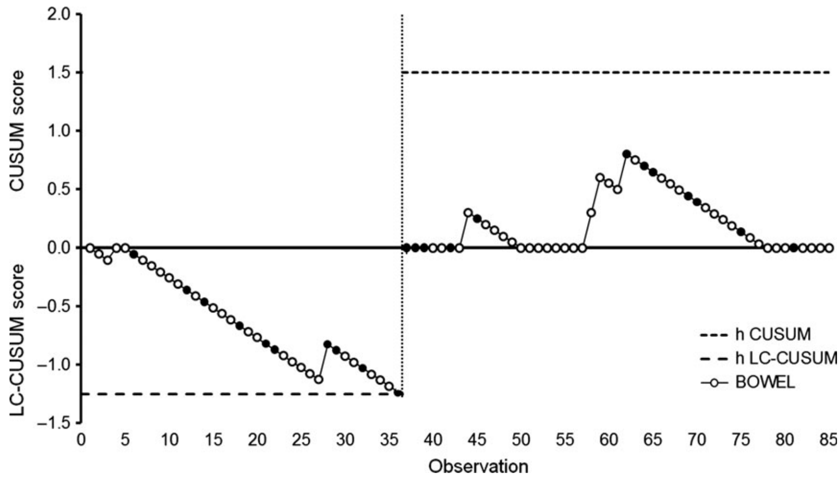

Figure 6 LC-CUSUM followed by CUSUM for the detection of bowel nodules. The *x*-axis shows the sequential number of procedures. The *y*-axis shows the LC-CUSUM, followed by the CUSUM score for each procedure. Full circles represent true-positive results.

Bladder nodules are easy to identify, and therefore, the low sensitivity is disappointing. A review of the false-negative results demonstrated that insufficient time was spent scanning the bladder. Given the uncommon occurrence of bladder nodules, the bladder is easily overlooked. The poor sensitivity highlights the importance of a systematic approach including a detailed study of the bladder.

From a surgical point of view, the preoperative diagnosis of POD obliteration and bowel involvement greatly assists in the preoperative decision-making.[5] Inaccuracies in the preoperative diagnosis of bowel nodules and POD obliteration were therefore reviewed in detail.

Our results indicate that the TVUS diagnosis of POD obliteration and bowel nodules is learned quite quickly, yet we identified a number of pitfalls. When reviewing the false-negative and false-positive results for POD obliteration, it became obvious that the 'inaccuracies' centred predominantly around differences in terminology used. The discordances occurred more commonly after proficiency had been reached as can be seen on the CUSUM (Fig. 5). In the initial learning phase, only three mistakes were made, all false-negative results (Fig. 5). This was followed by forty-four consecutive correct results including fourteen cases of correctly identified POD obliteration. Later, six further mistakes were made: one false-negative and five false-positive results (Fig. 5). We speculate that the ability to detect more subtle changes in the POD improved with experience and less severe forms of POD obliteration were being reported. When the laparoscopic and ultrasound images were reviewed for those incorrect results, there usually was agreement between the ultrasound description and the laparoscopy. However, it became apparent that the sonologist and the surgeon use a different definition for POD obliteration and that POD obliteration is defined differently by different surgeons. It stresses the need for unambiguous terminology and the importance of good communication between surgeons and sonologists. Until agreement on terminology is reached, it may be preferable to carefully describe the location and extent of the adhesion(s) in the POD rather than interpreting them as 'complete' or 'partial' POD obliteration.

There were three false negatives for bowel lesions. In each case, the bowel had been reported to be densely adherent to a large USL nodule; however, on ultrasound, there was no other evidence of invasion of the bowel wall. These three women had preoperative bowel preparation, and a colorectal surgeon assisted during the procedure. One woman had a segmental resection, one had a disc resection, and the third woman had the bowel released from the USL nodule with subsequent removal of the USL nodule, but no bowel resection. The two bowel resections confirmed endometriosis in the bowel on histology. The third one was only described as a bowel nodule on laparoscopy, but histological confirmation of bowel endometriosis was not obtained.

There were also four false-positive results for bowel nodules. The first two occurred very early and are considered part of the real learning curve (Fig. 6). Looking at the bowel is a completely new concept in gynaecological imaging and is initially confusing. Later, review in these two cases demonstrated that the bowel wall appeared thickened only because the bowel looped back causing the bowel wall to be 'bunched up' on the inside turn. Once the first real bowel nodule was observed, that same mistake was not repeated.

There were two false-positive findings later in the series. Review of the ultrasound images (Figs 7 and 8) confirmed convincing ultrasound images of bowel nodules raising the possibility that these were actually present but missed at laparoscopy. Lesions on a free-lying loop of bowel in particular can be easily missed. The nodule may be rotated away from the laparoscope, or the loop of the

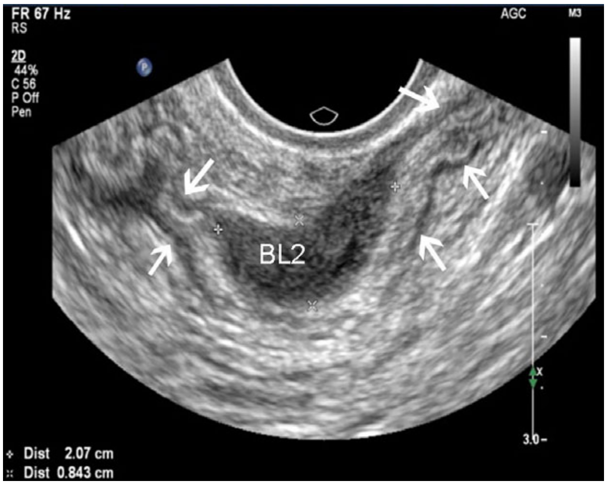

Figure 7 Ultrasound image of a presumed bowel nodule (BL2) that was not noted on laparoscopy and therefore classified as a false-positive result. The normal muscularis propria is visible (arrows).

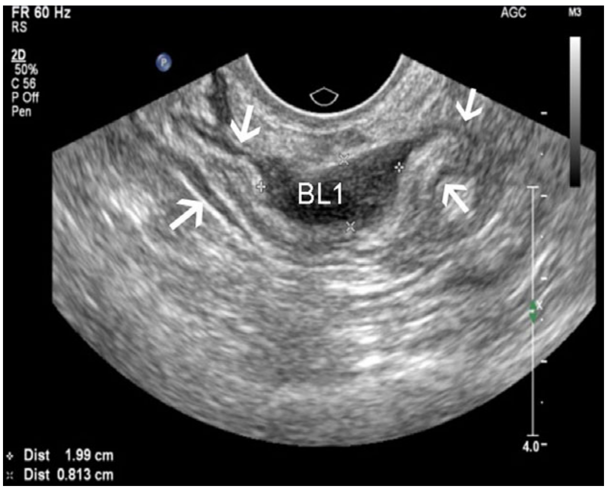

Figure 8 Ultrasound image of a presumed bowel nodule (BL1) that was not noted on laparoscopy and therefore classified as a false-positive result. The normal muscularis propria is visible (arrows).

bowel may have been pushed out of the pelvis with the patient in Trendelenburg position, making it more difficult to recognise such lesions.

One of the strengths of this study is that the learning curve was assessed using a validated statistical model. Furthermore, the learning curve was not assessed against the subsequent interpretation of ultrasound images by another sonologist, but against laparoscopic findings.

Nonetheless, a number of possible limitations of this study also need to be acknowledged. Firstly, the primary investigator had extensive gynaecological ultrasound experience, and this may have shortened the learning curve. However, Biau *et al.* have demonstrated that the learning curve as measured by the LC-CUSUM is not greatly influenced by unknown start performance.[19] Furthermore, because the learning curve was assessed against laparoscopy, the feedback was not instantaneous. Whether immediate feedback by an expert sonologist may result in a shorter learning curve is unknown and the subject of further study.

Secondly, not all women who underwent an ultrasound had surgery, and therefore, the accuracy of the ultrasound could not be tested in that group. There was a variety of reasons why some women did not have surgery. In the group who underwent surgery versus the group who did not, bowel nodules and POD obliteration were noted on ultrasound in 30% and 40%, and 42% and 55%, respectively. Given the similarity between the ultrasound findings of both groups, it is unlikely that the ultrasound findings in the nonsurgical group would have significantly affected the results.

Finally, surgeons were also not blinded to the ultrasound results. This could lead to bias in that surgeons may be more likely to agree with a finding described on ultrasound. If such bias was present, increased concordance would lead to an overestimation of the diagnostic accuracy and a shortening of the learning curve.

Conclusion

In conclusion, this study provides evidence that the required skills to diagnose DIE can be attained by experienced sonologists after a brief learning period. The study also provides further external validation of the high diagnostic accuracy of DIE-TVUS. Both findings support the proposition that DIE-TVUS should become part of the standard ultrasound training. The diagnostic accuracy can be furthered improved by regular communication with the laparoscopic surgeons and general agreement on terminology between surgeons and sonologists.

Acknowledgement

The authors thank David J Biau for his kind advice on the simulations to estimate the type I and type II errors for the LC-CUSUM and CUSUM.

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