Learning curve for the detection of pouch of Douglas obliteration and deep infiltrating endometriosis of the rectum

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STUDY QUESTION: How long does it take to be proficient in diagnosing pouch of Douglas (POD) obliteration and deep infiltrating endometriosis (DIE) of the rectum with transvaginal sonography (TVS)?

SUMMARY ANSWER: Sonographers familiar with the general use of TVS are expected to be proficient in the diagnosis of endometriosis nodules of the rectum and the detection of POD obliteration using the ‘sliding sign’ after ≏40 examinations, performed in a referral clinic for pelvic pain.

WHAT IS ALREADY KNOWN: With rectal DIE, the reasons for the obvious diagnostic problems are complex. Menstrual pain or cramps are still considered to be ‘normal’ and do not provide a reason for patients and even health-care providers to seek expert help. Furthermore, the performance of TVS for diagnosing pelvic endometriosis has been shown to be accurate only in experienced hands.

STUDY DESIGN, SIZE AND DURATION: This prospective study included 121 selected patients with suspected endometriosis.

PARTICIPANTS/MATERIALS, SETTING, METHODS: Symptomatic patients, referred to a pelvic pain clinic, were examined by an expert sonographer (E.S.) and consecutively by two trainees (T1/2).

MAIN RESULTS AND THE ROLE OF CHANCE: The learning curve using the cumulative sum shows that the trainees, listed as T1/T2, reached the predefined level of proficiency in detecting bowel nodules after examining 42 and 37 patients, for T1 and T2, respectively. The prevalence rate of bowel nodules demonstrated by the ES was 21%. The sensitivity, specificity, positive and negative predictive values (PPV, NPV) as well as the accuracy for TVS of T1 and T2 in comparison with the results of ES were 72 and 89, 96 and 95, 87 and 80, 90 and 98, and 89 and 94%, respectively. The prevalence rate of POD obliteration, as demonstrated by a negative sliding sign, was 27%. The trainees reached the predefined level of proficiency after examining 42 and 33 patients, for T1 and T2, respectively. The sensitivity, specificity, PPV, NPV as well as the accuracy for TVS for T1 and T2 in comparison with the results of the ES were 83 and 89, 95 and 95, 91 and 80, 90 and 98, and 91 and 94%, respectively.

LIMITATIONS, REASONS FOR CAUTION: We performed this analysis in a tertiary referral centre with a high number of advanced cases of DIE, not reflecting a standard population.

WIDER IMPLICATION OF THE FINDINGS: Integrated in TVS training courses, typical sonographic video clips for DIE of the rectum, including the use of disease-specific signs, could help to improve diagnostic accuracy in DIE and shorten diagnostic delays.

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Key words: learning curve / transvaginal sonography (TVS) / bowel nodule / uterine sliding sign / deep infiltrating endometriosis (DIE)

Introduction

Endometriosis is one of the most common benign gynaecological diseases with a prevalence rate ranging between 3 and 15% (Melis et al., 1994; Child and Tan, 2001; Oehmke et al., 2007). The predominant symptoms of endometriosis are dysmenorrhoea, dyspareunia, infertility, dyschezia or dysuria. In addition, chronic pelvic pain can be the consequence of infiltration of pelvic nerves (Fauconnier and Chapron, 2005). Diagnostic tools consist of the patient’s past gynaecological history, speculum examination and bimanual palpation,
transvaginal sonography (TVS) and magnetic resonance imaging (MRI) (Bazot et al., 2011a,b). Nevertheless, endometriosis cannot be excluded after negative imaging results.

Despite the high prevalence of the disease, the average diagnostic delay after the onset of symptoms until the definitive diagnosis has been reported to be as long as 6.7–12.1 years, which could be confirmed recently by our study group (Husby et al., 2003; Ballard et al., 2006; Nnoaham et al., 2011; Hudelist et al., 2012). Pain and infertility issues have a strong impact on quality of life for the individual, and lead to enormous direct and indirect costs for national economics (Nnoaham et al., 2011; Simoens et al., 2011a,b). As a consequence, there is a strong need for easy access to fast and accurate diagnostic facilities in order to shorten the diagnostic delay and to triage patients for therapy in specialized centres in cases of extensive disease.

The reasons for the obvious diagnostic problems are complex. First, menstrual pain or cramps are still considered to be ‘normal’ and do not give a reason for patients and even health-care providers to seek expert help or assistance (Ballard et al., 2006). Secondly, the performance of TVS for diagnosing pelvic endometriosis has been shown to be accurate only in experienced hands (Hudelist et al., 2011a,b).

With regard to this, specific sonographic signs associated with bowel nodules and the loss of sliding of the bowel against the posterior uterine wall reflecting obliteration of the pouch of Douglas (POD) (‘negative sliding sign’) have been shown to exhibit high accuracy for the non-invasive, sonographic diagnosis of deep infiltrating endometriosis (DIE), either reflecting endometriotic bowel infiltration or utero-rectal adhesions (Guerriero et al., 2008; Hudelist et al., 2011a,b, 2013; Reid et al., 2013).

The question how much experience is needed to become proficient in certain skills is an issue of increasing importance in diagnostic and therapeutic procedures (Weersinghe et al., 2006; Balsyte et al., 2010; Smith and Greaves, 2010; Bazot et al., 2011a,b; Goldman et al., 2011; Hefler et al., 2012; Michalopoulos et al., 2012).

Surgery for endometriosis becomes much more complicated when POD obliteration or bowel nodules are present and requires an interdisciplinary, centralized therapeutic approach. The role of an accurate pre-operative diagnostic work-up, particularly focusing on the presence or absence of POD obliteration and bowel nodules, is crucial.

In order to evaluate the number needed to gain competence or to review the level of competence, a special statistical tool has been reported previously (Wohl, 1977; Biau et al., 2008a,b). The so-called learning curve using the cumulative sum (LC-CUSUM), deriving from evaluation of an industrial quality process, has been suggested to assess when an individual learning curve can be completed after reaching a predefined level of performance.

The purpose of this prospective study was to evaluate the learning curve of TVS for the diagnosis of DIE of the rectum and POD obliteration.

**Methods**

Patients participating in the study were referred to our pelvic pain clinic and consecutively evaluated via TVS by three examiners (G.H., A.T. and A.K.) from January 2012 to October 2012. The study was approved by the local institutional review board and informed consent was obtained from all patients. Premenarchal and post-menopausal women as well as oncological patients, virgins and women with previous surgery for endometriosis or surgically diagnosed and non-operated endometriosis were excluded from the study.

The learning curves of two trainees (T1: A.T. and T2: A.K.) were evaluated for the diagnosis of bowel nodules and the detection of POD obliteration by assessing the sliding sign.

The trainees were generally trained gynaecologists without specialized experience in TVS concerning endometriosis, having performed an approximate number of 2500 TV scans in general gynaecology, which may reflect the TVS experience of a gynaecologist in central Europe. The test was defined by an expert sonographer (ES: G.H.), with a proficient experience in diagnosing DIE of a gynaecologist as demonstrated previously (Hudelist et al., 2009). In brief, TVS was carried out with an Accuvix XQ (Accuvix, Sonoace) scanner using a 5–9-MHz transducer. The probe was first introduced in the posterior vaginal fornix and withdrawn backwards to assess the POD, uterosacral ligaments (USL), urinary bladder and the vagina. Following this, the probe was advanced for visualization of the uterus and the adnexal regions in sagittal and horizontal planes. Finally, the probe was moved upwards in order to achieve full visualization of the rectosigmoidal wall layers. Rotation of the probe and up and down movements was necessary to visualize the rectosigmoid colon in women with an axial or anteverted uterus. In patients with a fixed and/or retroverted uterus, we tried to extend the visualization of the bowel as far as technically feasible. The bowel was not prepared prior to the investigation which has been favoured by other groups (Valenzano et al., 2008; Savelli et al., 2011). Sonographic features of endometriotic disease of the rectosigmoid included the presence of a regular or irregular hypoechoic mass distorting and replacing the normal appearance of the muscular layer of the rectal wall (a hypoechoic thin line in the mid-sagittal plane adjacent to a hyperechoic layer representing the rectal submucosa). We considered all lesions that were visible by TVS, i.e. the rectum plus the portion of the sigmoid. In a cohort of 200 patients, the ES has shown that TVS can be a valuable preoperative diagnostic tool for DIE of the rectum with the sensitivity, specificity, positive and negative predictive values (PPV, NPV) of 98, 99, 98 and 99%, respectively.

Furthermore in this study, the second hand of the examiner was placed on the lower abdomen to allow ballottement of the uterus between the vaginal probe and the palpating hand, as in a bimanual gynaecological examination. In normal anatomy, the smooth movement of the anterior rectal wall against the posterior aspect of the uterus can be observed, when moving the uterus between the vaginal probe and the palpating hand on the lower abdomen. If this physiological movement cannot be provoked, the so-called ‘sliding sign’ is defined to be negative (Hudelist et al., 2013; Reid et al., 2013) and this has been shown to reflect obliteration of the POD due to bowel endometriosis and/or secondary adhesions consistent with POD obliteration.

Education for the trainees started with a theoretical introduction on DIE. This included typical sonographic pictures and video sequences of the normal anatomy of the rectum followed by five typical videos with DIE of the rectum and associated specific signs as described above. Consecutively, the trainees were present during five routine TVS examinations of the ES as demonstrated previously (Hudelist et al., 2011a,b).

Each patient’s clinical history, symptoms and result of TVS were obtained and documented on a case report form by the ES. Additional sonographic changes related to endometriosis in different anatomical regions were evaluated and documented and are in accordance with studies published previously by the ES. Trainees were blinded to patient’s clinical history, and the bimanual palpation and TVS examination of the ES. Trainees were absent during the first examination performed by the ES (TVS followed by bimanual examination) and were chosen randomly. Following this, either T1 or T2 did a second TVS examination on the patient scanned by the ES (only one trainee performed TVS after the ES in each respective patient). The ES was present during the TVS examination of the trainee. In cases of incongruent findings, the TVS was repeated by the ES and findings were explained either to
T1 or T2 in order to enhance the diagnostic skills of T1 or T2. The main outcome measure was the degree of correlation between the TVS performed by T1 or T2 and the TVS performed by ES with regard to the detection of bowel nodules and the assessment of the sliding sign. In addition, all patients underwent MRI for non-invasive, additional confirmation or exclusion of DIE. No attempt was made to confirm the results with surgical or histological findings in the overall patient cohort.

Statistical analysis
Continuous variables are expressed as means ± SD. Categorical variables are presented as frequencies and percentages. Sensitivity, specificity, PPV, NPV, test accuracy and positive and negative likelihood ratios (LHRs) were calculated for the presence or absence of uterine sliding using Catmaker® statistical software.

The LC-CUSUM test was designed to monitor the performance of sequential interventions. Hereby the Null hypothesis (H0, performance is inadequate) is continuously tested against the alternative hypothesis (H1, performance is adequate). Negative scores for correct interventions and positive scores for incorrect results are calculated as previously reported by Biau et al. (2008a,b). Once the summation score reaches a predefined level (h) the test rejects the null hypothesis in favour of the alternative hypothesis indicating that the performance is adequate. We have chosen $h = 1.25$, $P_0 = 0.175$ as an unacceptable failure rate, and $P_1 = 0.1$, as an acceptable failure rate.

Results
Out of the 121 patients included and examined as depicted previously, 5 patients did not give their consent, 2 patients were excluded due to virginity and 8 patients refused to be examined twice. The patients’ demographics and presenting symptoms are depicted in Table I. The patients’ symptoms are also described in Table I.

TVS and bowel nodules
Out of 106 patients, 22 (21%) had rectal DIE as diagnosed by TVS by the ES. Suspected DIE of the rectum could not be confirmed by MRI in two patients. However, the sonographic diagnosis could be confirmed by histological specimens after those two patients underwent surgery for DIE. In contrast, MRI exhibited a false-positive diagnosis of rectal DIE in one patient. This could not be confirmed by the ES, nor by laparoscopy, which exhibited recto-uterine adhesions. Only 50 patients underwent surgery for symptomatic endometriosis. As a consequence, we did not choose laparoscopy as a possible gold standard test.

Furthermore, there were typical sonographic signs for adenomyosis and for endometriotic involvement of the ovaries, the vagina, the USL, the rectovaginal septum (RVS) and the bladder which are shown in Table II, as demonstrated by the ES.

The LC-CUSUM shows that the trainees (T1/2) reached the predefined level of proficiency for diagnosing rectal DIE using typical features of bowel nodules after 42 and 37 patients, respectively. Moreover, the choice of 1.25 as the predefined LC-CUSUM score could be confirmed as a threshold for reaching expertise in diagnosing DIE of the rectum (Fig. I).

T1 and T2 did 64 and 53 examinations, respectively. The sensitivity, specificity, PPV, NPV as well as the accuracy of TVS of T1 and T2 in comparison with the results of ES were 72 and 89, 96 and 95, 87 and 80, 90 and 98, and 89 and 94%, respectively (Table III).

Table I
Demographic data and symptoms in 106 patients submitted to transvaginal sonography (TVS).

<table>
<thead>
<tr>
<th>Symptom</th>
<th>Cases (n, %)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient age (mean, SD)</td>
<td>32.5 years (SD: 6.4)</td>
</tr>
<tr>
<td>Dysmenorrhea</td>
<td>97/106 (89)</td>
</tr>
<tr>
<td>Dyspareunia</td>
<td>66/106 (62)</td>
</tr>
<tr>
<td>Dyschezia</td>
<td>24/106 (23)</td>
</tr>
<tr>
<td>Dysuria</td>
<td>11/106 (10)</td>
</tr>
<tr>
<td>Chronic Pelvic Pain</td>
<td>29/106 (27)</td>
</tr>
<tr>
<td>Subfertility</td>
<td>26/106 (25)</td>
</tr>
<tr>
<td>Total patient number</td>
<td>106 (100)</td>
</tr>
</tbody>
</table>

Table II
TVS findings in 106 patients with suspected pelvic endometriosis as demonstrated by the ES.

<table>
<thead>
<tr>
<th>Site of disease</th>
<th>Cases (n, %)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rectal DIE by TVS: bowel nodules</td>
<td>22/106 (21)</td>
</tr>
<tr>
<td>Rectal DIE by TVS: negative ‘sliding sign’</td>
<td>29/106 (27)</td>
</tr>
<tr>
<td>Other locations of DIE and adenomyosis</td>
<td></td>
</tr>
<tr>
<td>Utterus</td>
<td>46/106 (43)</td>
</tr>
<tr>
<td>Ovaries</td>
<td>25/106 (24)</td>
</tr>
<tr>
<td>Vagina</td>
<td>25/106 (24)</td>
</tr>
<tr>
<td>USL</td>
<td>17/106 (16)</td>
</tr>
<tr>
<td>RVS</td>
<td>5/106 (5)</td>
</tr>
<tr>
<td>Urinary Bladder</td>
<td>1/106 (1)</td>
</tr>
</tbody>
</table>

ES, expert sonographer; DIE, deep infiltrating endometriosis.

Figure I
Learning curve of TVS for bowel nodules.
Discussion

The obvious diagnostic delay of endometriosis has been reported by a number of studies as already mentioned in the introduction. Apart from insufficient awareness of this disease amongst patients and doctors, insufficient diagnostic and surgical skills may lead to a high percentage of false-negative results or underestimation of the severity of endometriosis (Donnez, 2012; Hudelist et al., 2012). The relatively high prevalence of endometriosis, and the significant individual and socioeconomic burden are reasons to increase efforts to optimize the diagnostic and therapeutic process.

Due to major changes in techniques and software and the rising level of experience in sonography, this technique has made a substantial progress and has been proposed as first-line diagnostic test together with clinical examination for non-invasive diagnostics of endometriosis of the female pelvis (Bazot et al., 2004; Hudelist et al., 2009; Piketty et al., 2009). There are various entities and clinical subspecialties within the field of gynaecology, which use ultrasound for specific and highly specialized indications. Endoanal ultrasound in follow-up after obstetric sphincter tears, bladder-neck mobility in urogynaecological assessment of urine incontinent patients and first trimester screening for early detection of chromosome aberration and major malformations of the fetus are all examples of the need for a structured education of ultrasound. In contrast, ultrasound diagnosis of endometriosis is covered in less detail than any other subspecialty educational programme.

Recently, Bazot et al. (2011a,b) published their results of the learning curve of four inexperienced trainees in the diagnosis of endometriomas. Although there was a large inter-trainee variability, the statistical method (LC-CUSUM) was shown to be adequate for this purpose.

Using the same method, we evaluated the learning curve for the sonographic features associated with diagnosis of DIE of the rectum with TVS using two specific ultrasound signs. The present work demonstrates, as the first of its kind, that ~40 TVS examinations are mandatory to transfer TVS expertise to trainees and/or other units. This number could be valid in specialized tertiary referral clinics which provide structured educational programmes.

Nevertheless, the present study has some limitations. First and foremost, we performed this analysis in a tertiary referral centre with a high number of advanced cases of DIE, not reflecting a standard population. Second, the lesion size and position may also influence diagnostic accuracy of TVS. Thirdly, surgical diagnosis of DIE was omitted and MRI was performed as an additional diagnostic test. Laparoscopy should only be seen as a final gold standard test if radical surgery with full dissection of all possibly involved anatomical spaces is performed. Since many patients were not suitable for surgical resection (asymptomatic endometriosis etc.), we also included women without a final histological proof of rectal DIE. Although MRI and TVS performed by an ES cannot be seen as a full substitute for histological proof of DIE, we would like to emphasize the high accuracy of TVS if performed by highly trained staff. Furthermore, the primary question of this study was not to add additional data on the accuracy of TVS for diagnosis of DIE but to investigate the learning curve of this diagnostic tool.

In our opinion, accurate preoperative staging of endometriosis is a conditio sine qua non in order to adequately counsel patients especially in cases of DIE and is highly influential for planning interdisciplinary surgery.

In conclusion, sonographers who are familiar with the general use of TVS are expected to be proficient in the diagnosis of DIE of the rectum after ~40 TVS examinations, performed in a tertiary referral centre setting.
Table IV  Sensitivity, specificity, PPV, NPV, accuracy and positive and negative LHR for negative 'sliding sign'.

<table>
<thead>
<tr>
<th>Trainees</th>
<th>Sensitivity (%)</th>
<th>Specificity (%)</th>
<th>PPV (%)</th>
<th>NPV (%)</th>
<th>Accuracy (%)</th>
<th>+ve LHR</th>
<th>−ve LHR</th>
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<tbody>
<tr>
<td>T1 (n = 64)</td>
<td>83</td>
<td>95</td>
<td>91</td>
<td>90</td>
<td>91</td>
<td>16.64</td>
<td>0.18</td>
</tr>
<tr>
<td>95% CI</td>
<td>68–98</td>
<td>88–100</td>
<td>79–100</td>
<td>82–99</td>
<td>4.27–65.11</td>
<td>0.07–0.43</td>
<td></td>
</tr>
<tr>
<td>T2 (n = 53)</td>
<td>89</td>
<td>95</td>
<td>80</td>
<td>98</td>
<td>94</td>
<td>19.56</td>
<td>0.12</td>
</tr>
<tr>
<td>95% CI</td>
<td>68–100</td>
<td>89–100</td>
<td>55–100</td>
<td>93–100</td>
<td>4.95–77.24</td>
<td>0.02–0.74</td>
<td></td>
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</tbody>
</table>

PPV, positive predictive value; NPV, negative predictive value; +ve LHR, positive likelihood ratio; −ve LHR, negative likelihood ratio; CI, confidence interval.

Authors’ roles
A.T.: chief scientist, was involved in preparation of the manuscript; N.F. was involved in data analysis and preparation of the manuscript; G.S. was involved in statistical analysis. A.K. was involved in recruitment of patients; H.S was involved in preparation of the manuscript; G.H. was involved in preparation of the manuscript, logistic coordination and supervision of the work.

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Conflict of interest
None declared.

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