

## GYNECOLOGY

# Comparing the diagnostic accuracy of 3 ultrasound modalities for diagnosing obstetric anal sphincter injuries



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**BACKGROUND:** The optimal imaging modality of obstetric anal sphincter injuries needs to take into consideration convenience, availability, and ability to assess the sphincter morphologic condition. Endoanal ultrasound imaging currently is regarded as the reference standard, but it is not widely available in obstetric units. Exoanal alternatives exist, such as 3-dimensional introital or transperineal ultrasound imaging, which are already readily available in most obstetrics and gynecology units.

**OBJECTIVE:** The primary objective was to evaluate the diagnostic accuracy of 3-dimensional introital and 3-dimensional transperineal ultrasound imaging compared with 3-dimensional endoanal ultrasound imaging as the reference standard for the detection of anal sphincter defects in women who sustained obstetric anal sphincter injuries. The secondary objective was to correlate a diagnosis of anal sphincter defect on imaging to symptoms of anal incontinence, and to assess patient discomfort that is experienced for each imaging modality.

**STUDY DESIGN:** A cross-sectional study was conducted of 250 women who sustained obstetric anal sphincter injuries, all of whom underwent 3-dimensional introital, transperineal, and endoanal ultrasound imaging. Introital and transperineal ultrasound imaging were assessed with tomographic ultrasound imaging. All of the women completed a validated modified St Mark's Score and Visual Analogue Score for discomfort. Optimal cut-off values for a significant defect on tomographic ultrasound imaging were defined as those with the greatest sensitivity and specificity based on receiver operating characteristic curves with endoanal ultrasound imaging as the reference standard. Diagnostic test characteristics of introital and transperineal ultrasound imaging were calculated with the use of these optimal cut-offs.

**RESULTS:** Optimal cut-off for a significant external anal sphincter defect was  $\geq 3$  of 7 slices; sensitivity and specificity were 0.65 and 0.75

on introital imaging and 0.70 and 0.69 on transperineal ultrasound imaging. Optimal cut-off for a significant internal anal sphincter defect was  $\geq 2$  of 5 slices; sensitivity and specificity were 0.59 and 0.84 on introital imaging and 0.43 and 0.97 on transperineal ultrasound imaging. The area under the curve for the diagnosis of external and internal anal sphincter defects ranged from 0.70–0.74 ( $P < .001$ ) for introital and transperineal imaging. Positive predictive value for external and internal sphincter defects ranged from 0.37–0.63, and negative predictive value ranged from 0.85–0.93 for introital and transperineal ultrasound imaging. Endoanal ultrasound imaging was the only modality for a defect to correlate with symptoms; mean modified St. Mark's score for a defect sphincter was 2.4 (standard deviation, 4.1) and for an intact sphincter was 0.9 (standard deviation, 2.7;  $P < .01$ ). Introital and transperineal ultrasound imaging were associated with less discomfort than endoanal ultrasound imaging.

**CONCLUSION:** Endoanal ultrasound imaging remains the most accurate diagnostic imaging modality. With low positive predictive values, introital and transperineal ultrasound imaging are not suitable for the identification of sphincter defects; however, high negative predictive values show a good ability to detect an intact sphincter. The optimal cut-off number of slices on tomographic ultrasound imaging for external and internal anal sphincters allows for standardization of a significant defect. In women with a history of obstetric anal sphincter injuries, introital and transperineal ultrasound imaging are suitable to screen for an intact sphincter if endoanal ultrasound imaging is not available. When defects are found, women should then have endoanal ultrasound imaging to verify the diagnosis.

**Key words:** endoanal ultrasound imaging, introital ultrasound imaging, obstetric anal sphincter injury (OASI), transperineal

Obstetric anal sphincter injury (OASI) is one of the main causes of anal incontinence because it occurs in up to 35% of vaginal deliveries.<sup>1–3</sup> It can impact women's social, psychologic, and physical quality of life significantly and

increasingly is associated with litigation.<sup>4</sup> Endoanal ultrasound (EAUS) assessment of the anal sphincters after OASI has been shown to be useful, particularly in counselling regarding mode of delivery in a subsequent pregnancy.<sup>5–7</sup> Clinical examination is associated with poor detection of sphincter damage<sup>8</sup>; ultrasound diagnostic accuracy is better.<sup>9</sup>

There has been increasing interest in the optimal imaging modality of OASIs, taking into account convenience, availability, and ability to assess the sphincter morphologic condition. To date, most

research has been carried out with the EAUS technique,<sup>1,3,10</sup> currently regarded as the reference standard.<sup>9,11</sup> However, it requires a trained operator and expensive specialized equipment and is relatively intrusive to the patient. Furthermore, it may distort the muscular anatomy of the anal canal.<sup>12</sup> Alternative exoanal approaches include introital ultrasound imaging (IUS)<sup>12,13</sup> and transperineal ultrasound imaging (TPUS),<sup>14–17</sup> which visualize the sphincter in an undisturbed state. Moreover, the equipment for these scans is readily available in most obstetric and gynecology units.

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## AJOG at a Glance

**Why was this study conducted?**

Endoanal ultrasound imaging is regarded as the reference standard for imaging the anal sphincter morphologic condition. Alternatives that are more widely available and accepted by patients include 3-dimensional introital and transperineal ultrasound imaging. However, it is unknown whether they are accurate enough to replace endoanal ultrasound imaging.

**Key findings**

Three-dimensional introital and transperineal ultrasound imaging provide suitable screening tools for an intact anal sphincter but are not sensitive enough to detect defects accurately. Onward referral for endoanal ultrasound imaging would be required if a defect is seen, because this remains the reference standard and correlates best with symptoms.

**What does this add to what is known?**

The cut-off for an external anal sphincter defect on tomographic ultrasound imaging is  $\geq 3$  of 7 slices and for an internal anal sphincter defect is  $\geq 2$  of 7 slices, which provides standardization within the field for reporting and clinical use.

With ultrasound imaging advances, 3- and 4-dimensional technology is also becoming increasingly popular. Advantages include multiplanar imaging, short examination times, and digital volume storage that allow for later reanalysis.<sup>16,17</sup>

The primary aim of this study was to evaluate the diagnostic test accuracy of 3-dimensional IUS and 3-dimensional TPUS compared with 3-dimensional EAUS as the reference standard for the detection of anal sphincter defects in women who sustained OASIs. The secondary aim was to correlate a diagnosis of anal sphincter defect on imaging with symptoms of fecal incontinence and to assess patient discomfort that is experienced for each imaging modality.

**Materials and Methods**

This was a cross-sectional study of 250 consecutive women who had sustained OASIs and undergone primary repairs of the anal sphincter. They were recruited from the perineal clinic of the tertiary urogynecology center of Croydon University Hospital, United Kingdom. All the women were referred from within Croydon University Hospital or the surrounding regions for assessment 6–12 weeks after delivery or were seen in a subsequent pregnancy for counselling regarding mode of delivery. Women were recruited prospectively from

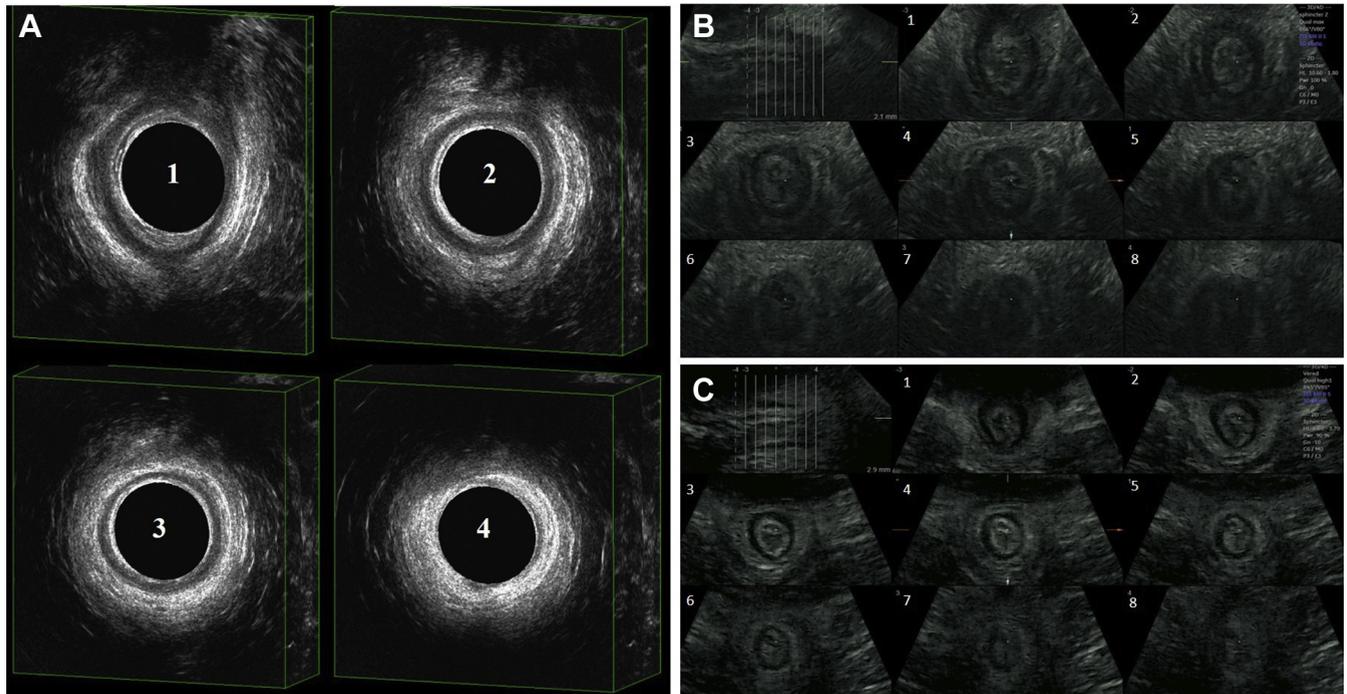
October 2013 to August 2015. Women who were  $\geq 18$  years old and could read and understand English were eligible. The study was approved by the National Research Ethics Service South East London Committee (REC number 13/LO/0232) and local research and development department, IRAS project number 122213, and was registered in [clinicaltrials.gov](http://clinicaltrials.gov) (NCT 02655900). All study participants gave written informed consent.

Demographic data (age, body mass index, ethnicity, and parity) of each patient were collected. Each patient completed a validated modified St. Mark's score,<sup>18</sup> which is a 24-point scoring system for anal incontinence symptoms, that accounts for fecal urgency, flatal incontinence, liquid and solid fecal incontinence, impact on lifestyle, and the use of incontinence pads or constipating medication. For each patient, all ultrasound assessments were performed on the same day. EAUS was performed at rest with the use of the Pro-focus 2202 or Flex-focus 500 ultrasound systems (BK Medical, Herlev, Denmark) fitted with a 12–16 MHz anorectal transducer (type 2052; focal point up to 20 mm and focal range 5–45 mm, with 360-degree acquisition). With the patient lying in the left lateral position, the probe was inserted along the axis of the

anal canal, and the 3-dimensional volume imaged the full length of the anal sphincter, starting proximally at the puborectalis muscle to the most distal aspect of the subcutaneous level of the external anal sphincter (EAS). IUS and TPUS were performed with the GE Voluson I system (GE Medical Systems, Zipf, Austria). Both examinations were performed at rest with the patient in the supine position. IUS was performed with a 3-dimensional 5–9 MHz endocavity probe that was placed with low pressure on the posterior fourchette in a vertical axis towards the anal sphincter complex. TPUS was performed with a 3-dimensional 4–8.5 MHz curved array abdominal probe. The probe was placed transversely on the perineum and inclined to visualize the U shape of the puborectalis muscle and angulated to visualize the full length of the sphincter. Both modalities had an acquisition angle of 85 degrees. All ultrasound examinations were performed by an investigator (I.M.A.vG.) who is experienced in imaging of the anal sphincter.

The 3-dimensional image volumes of all 3 modalities were stored for off-line assessment. Image analysis was performed with the 3-dimensional viewing program (version 5.19; BK Medical) for EAUS and the 4-dimensional View software (version 10.2; GE Medical Systems) for IUS and TPUS by 3 independent investigators who were blinded to clinical and other imaging findings. Every investigator analyzed 30 volumes of each modality; intraclass correlation analysis was performed to assess agreement. After substantial agreement was found, the remaining volumes were analyzed by a single investigator independently (A.T. analyzed EAUS; I.V. analyzed IUS; L.P.A. analyzed TPUS).

The 3-dimensional EAUS volume was assessed by rating the sphincter complex integrity at 3 levels starting after the U shape of the puborectalis muscle: (1) the deep level, up to where the EAS muscle forms anteriorly in the midline, (2) the superficial level, where the internal anal sphincter (IAS; hypoechoic) and EAS (hyperechoic) should be seen as complete rings, and (3) the subcutaneous

**FIGURE 1**  
Intact anal sphincter

**A**, Three-dimensional endoanal ultrasound images of an intact sphincter with the external anal sphincter seen as the complete hyperechoic ring encircling the complete hypoechoic ring of the internal anal sphincter. The puborectalis (1), deep (2), superficial (3), and subcutaneous (4) levels are shown. **B**, Introital tomographic ultrasound imaging shows an intact external (slices 2–8) and internal (slices 2–6) anal sphincter. **C**, Transperineal tomographic ultrasound imaging shows an intact external (slices 2–8) and internal (slices 2–6) anal sphincter.

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level of the EAS, where the IAS is no longer present (Figure 1, A).

IUS and TPUS were both assessed by tomographic ultrasound imaging (TUI). The TUI was adjusted to have 8 slices, with the interslice interval varying according to individual sphincter length. EAS (slices 2–8) and IAS (slices 2–6) were evaluated in the same TUI. Slice 1 corresponds with the puborectalis level. Slice 2 was adjusted to be the most cranial aspect of the EAS (deep level), where the muscle comes together in the midline, with the superficial level ending at slice 6. Slices 7 and 8 covered the subcutaneous level (Figure 1, B and C).

Defect sizes were measured for all 3 modalities with a 3-point angle, with the angle vertex in the middle of the anal canal. The 3-dimensional EAUS volume was assessed in the deep, superficial, and subcutaneous levels for defects, with manipulation of the cube in the axial, coronal, and sagittal planes to aid

diagnosis. Any defect of  $\geq 30$  degrees of partial or full thickness was measured for IAS and EAS and considered significant if present at  $\geq 1$  level<sup>17</sup> (Figure 2, A). The same cut-off angle for EAS and IAS defect was also used for IUS and TPUS for consistency in analysis (Figure 2, B and C). The EAS was evaluated both with and without the subcutaneous level to assess whether diagnostic performance would be affected by the inclusion of this level. In addition, we looked at the deep level independently and calculated sensitivity and specificity of IUS and TPUS in detecting a defect at this level, because this can be the most challenging level to diagnose defects accurately in view of anatomic variations.

Norderval score was calculated for all 3 ultrasound modalities (Table 1), which accounted for the length, depth, and size of both EAS and IAS defects, with 0 being no defect and 7 being maximal defect.<sup>19</sup>

After each scan, women were asked to complete a visual analogue pain assessment tool that ranged from 0 (no discomfort) to 10 (severe discomfort) to determine the discomfort of each modality.

The mean values for demographic variables were calculated. Interclass correlation analysis (absolute agreement between the mean of  $\kappa$  raters, 2-way random-effects model) between the 3 investigators was performed for the Norderval scores of 30 volumes for each imaging modality. Based on the 95% confident interval of the interclass correlation estimate, values of  $<0.50$  indicate poor, of  $0.50$ – $0.75$  indicate moderate, of  $0.75$ – $0.90$  indicate good, and of  $>0.90$  indicate excellent reliability.<sup>20,21</sup>

Spearman's rank correlation was used to test correlation of Norderval scores between different imaging methods. The sensitivity and specificity of IUS and TPUS was calculated with EAUS as the

**FIGURE 2**  
Defect anal sphincter



**A**, Superficial level of endoanal ultrasound imaging shows a defect in the external anal sphincter (*angle*) and internal anal sphincter (*arrows*). **B**, Superficial level (slice 4) of introital tomographic ultrasound imaging shows a defect in the external anal sphincter (*angle*) and internal anal sphincter (*arrows*). **C**, Superficial level (slice 4) of transperineal tomographic ultrasound imaging shows a defect in the external anal sphincter (*angle*) and internal anal sphincter (*arrows*).

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reference standard, and receiver operating characteristic curves were created.<sup>22</sup> The area under the receiver operating characteristic curve (AUC) was calculated, in which 0.50 denotes no clinical application as a test, 0.60–0.70 indicates poor, 0.70–0.80 indicates fair, 0.80–0.90 indicates good, and >0.90 indicates an excellent test.<sup>23</sup> This included all levels for the EAS (slices 2–8) and IAS (slices 2–6) and subsequently excluded the subcutaneous level of the EAS (slices 2–6). The number of slices with the best diagnostic perfor-

mance was selected to define the best cut-off value for the detection of a significant EAS and IAS defect within a population of known OASI. Diagnostic test characteristics for these cut-offs were calculated. Mann-Whitney *U* test was used to test the modified St. Mark's Score against intact or defect sphincters for each imaging modality with the use of the new cut-off values. Mann-Whitney *U* test was used to assess the difference in visual analogue scores of discomfort for IUS and TPUS compared with EAUS.

Sample size calculation was based on the assumption of a 30% prevalence of anal sphincter defects in the population of interest.<sup>16</sup> A sample size of 200 women would provide 60 women with sphincter defects. Sixty women with a sphincter defect would give a confidence interval (CI) of 0.50–0.75, assuming a true rate of sensitivity of 0.64. One hundred and forty women with an intact sphincter would provide a confidence interval of 0.78–0.90, assuming a specificity of 0.85. Recruiting 250 women would allow for unusable volumes for analysis or incomplete data sets.

Statistical analysis was performed with IBM SPSS statistics software (version 23; IBM SPSS, Armonk, NY). A probability value of <.05 was considered statistically significant for all analyses.

## Results

In total, 250 women were examined at a median of 5 months (range, 1–137 months) after the index (OASI) delivery, of whom 88 were pregnant with a subsequent pregnancy at the time of examination. Average age was 31.5 years (standard deviation [SD], 4.5), mean body mass index was 25.3 kg/m<sup>2</sup> (SD, 4.7 kg/m<sup>2</sup>), and 183 of 248 women (74%) had a parity of 1. The main ethnic group was white (116 women; 46%); other ethnicities were Indian (55 women;

**TABLE 1**  
Norderval scoring system for anal sphincter defects<sup>19</sup>

Variable	Score			
	0	1	2	3
<b>External anal sphincter</b>				
Length of defect	≤50%	≥50%		
Depth of defect	None	Partial	Total and ≤90-degree radial extension	Total and >90-degree radial extension
<b>Internal anal sphincter</b>				
Length of defect	≤50%	≥50%		
Depth of defect	None	Total and ≤90-degree radial extension	Total and >90-degree radial extension	

Total score was calculated by the addition of the total length and depth score for both external and internal anal sphincter.  
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TABLE 2

**Sensitivity and specificity per number of tomographic ultrasound imaging slices for detection of external and internal anal sphincter defects using introital and transperineal ultrasound imaging compared with endoanal ultrasound imaging as the reference standard using receiver operator characteristic curves**

Variable	Tomographic ultrasound imaging slices, n	Sensitivity	Specificity	Area under the curve	95% Confidence interval	Pvalue
<b>External anal sphincter</b>						
<i>Without subcutaneous level included</i>						
Introital ultrasound imaging	1	0.76	0.63	0.70	0.63–0.77	<.001
	2	0.68	0.69			
	3	0.53	0.76			
	4	0.41	0.81			
	5	0.18	0.90			
Transperineal ultrasound imaging	1	0.69	0.63	0.68	0.61–0.76	<.001
	2	0.66	0.65			
	3	0.64	0.69			
	4	0.61	0.73			
	5	0.54	0.78			
<i>With subcutaneous level included</i>						
Introital ultrasound imaging	1	0.82	0.61	0.74	0.66–0.81	<.001
	2	0.77	0.65			
	3	0.65	0.75			
	4	0.55	0.80			
	5	0.34	0.86			
	6	0.23	0.89			
	7	0.13	0.93			
Transperineal ultrasound imaging	1	0.73	0.63	0.72	0.64–0.79	<.001
	2	0.73	0.66			
	3	0.70	0.69			
	4	0.66	0.73			
	5	0.61	0.76			
	6	0.49	0.82			
	7	0.37	0.87			
<b>Internal anal sphincter</b>						
Introital ultrasound imaging	1	0.63	0.81	0.72	0.62–0.83	<.001
	2	0.59	0.84			
	3	0.47	0.88			
	4	0.19	0.94			
	5	0.30	0.99			

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(continued)

TABLE 2

**Sensitivity and specificity per number of tomographic ultrasound imaging slices for detection of external and internal anal sphincter defects using introital and transperineal ultrasound imaging compared with endoanal ultrasound imaging as the reference standard using receiver operator characteristic curves** (continued)

Variable	Tomographic ultrasound imaging slices, n	Sensitivity	Specificity	Area under the curve	95% Confidence interval	Pvalue
Transperineal ultrasound imaging	1	0.43	0.96	0.70	0.57–0.82	.001
	2	0.43	0.97			
	3	0.39	0.98			
	4	0.29	0.98			
	5	0.21	0.99			
<i>Any external anal sphincter and/or internal anal sphincter defect in the deep level (slice 2)</i>						
Introital ultrasound imaging		0.36	0.84	0.60	0.52–0.69	.02
Transperineal ultrasound imaging		0.64	0.69	0.67	0.59–0.75	<.001

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22%), other Asian (35 women; 14%), black (27 women; 11%), and mixed or unknown ethnicity (17 women; 7%).

The interclass correlation of the Norderval score among the 3 analysts for 30 volumes showed a significant correlation: 0.83 (95% CI, 0.70–0.92;  $P<.01$ ) for EAUS, 0.76 (95% CI, 0.57–0.88;  $P<.01$ ) for IUS, and 0.86 (95% CI, 0.74–0.93;  $P<.01$ ) for TPUS.

A defect of  $\geq 30$  degrees in  $\geq 1$  level was present in 79 of 248 women (32%) on EAUS, in 134 of 246 women (55%) on IUS, and on 118 of 243 women (49%) on TPUS. Two volumes were missing for different women, and not all volumes had complete data to fully assess the EAS or IAS for IUS or TPUS. The mean (SD) Norderval scores for EAUS, IUS, and TPUS were  $1.2\pm 2.0$ ,  $1.8\pm 1.9$ , and  $1.1\pm 1.5$ , respectively. The correlation of Norderval scores was moderate; between EAUS and IUS, it was  $r_s=0.42$  ( $P<.001$ ), and between EAUS and TPUS, it was  $r_s=0.47$  ( $P<.001$ ).

The AUC for IUS and TPUS and the sensitivities and specificities for each number of TUI slices for diagnosing EAS and IAS defects are indicated in Table 2. The number of slices with the best diagnostic performance for a significant EAS defect was  $\geq 3$  of 7 slices; sensitivity and specificity were 0.65

and 0.75 on IUS and 0.70 and 0.69 on TPUS. Optimal cut-off for significant IAS defect was  $\geq 2$  of 5 slices; sensitivity and specificity were 0.59 and 0.84 on IUS and 0.43 and 0.97 on TPUS. The receiver operating characteristic curves for diagnosis of EAS and IAS defects on IUS and TPUS are presented in Figure 3, A and B. The AUC for EAS defects (with subcutaneous level included) on IUS was 0.74 (95% CI, 0.66–0.81;  $P<.001$ ) and on TPUS was 0.72 (95% CI, 0.64–0.79;  $P<.001$ ). The AUC for IAS defects on IUS was 0.72 (95% CI, 0.62–0.83;  $P<.001$ ) and on TPUS was 0.70 (95% CI, 0.57–0.82;  $P=.001$ ). Both IUS and TPUS had greater AUC for EAS defects when the subcutaneous level was included, although not statistically significant. Table 3 shows a summary of the diagnostic test characteristics of both IUS and TPUS with the use of the optimal cut-off values.

Sixty-one women had anal incontinence symptoms, of whom 30 had a defect on EAUS. EAUS imaging was the only modality for a defect to correlate with the modified St. Mark's Score; mean score was  $2.4\pm 4.1$  for defect sphincter and  $0.9\pm 2.7$  for intact sphincter ( $P<.01$ ). There was no difference in mean modified St. Mark's Score between

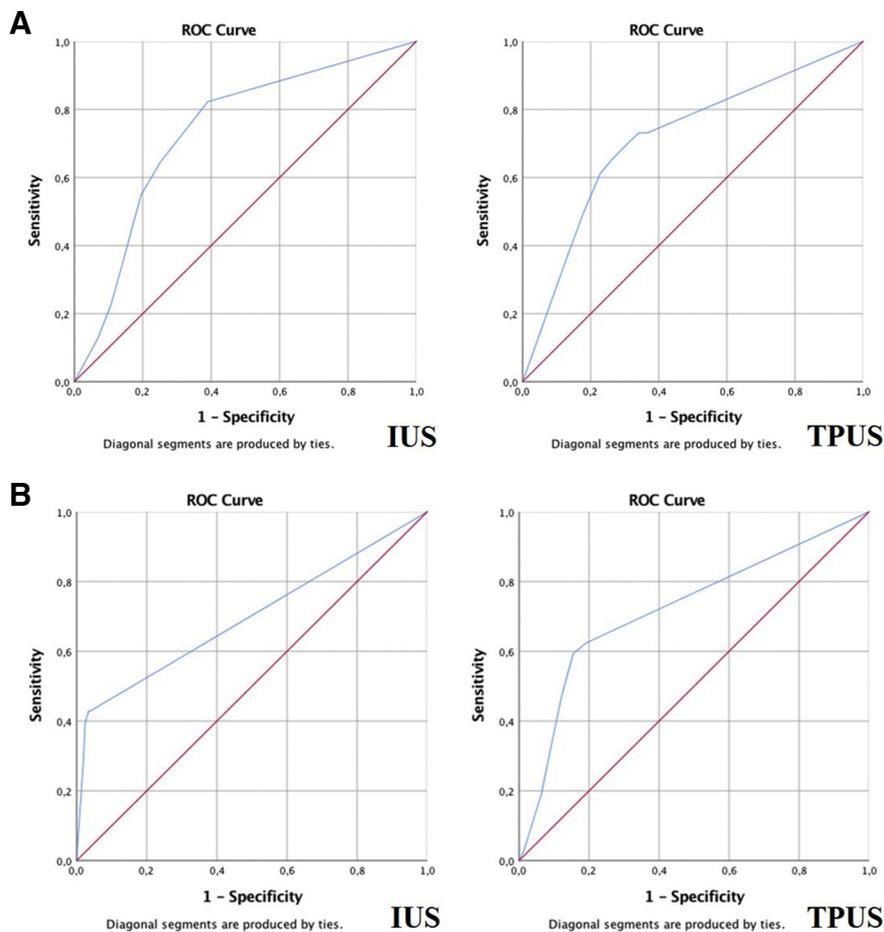
intact or defect sphincter for either IUS or TPUS:  $1.1\pm 2.5$  vs  $1.8\pm 3.8$  ( $P=.40$ ) and  $1.1\pm 2.6$  vs  $1.6\pm 3.5$  ( $P=.17$ ), respectively.

Discomfort scores of the imaging technique were documented for 238 of 250 patients. The mean discomfort scores for IUS ( $1.0\pm 1.8$ ) and TPUS ( $0.0\pm 1.3$ ) were significantly lower when compared with EAUS ( $4.0\pm 2.3$ ; both  $P<.001$ ).

### Comment:

The study aim was to assess diagnostic test accuracy of 3-dimensional IUS and TPUS compared with 3-dimensional EAUS as the reference standard for the detection of anal sphincter defects in women who sustained OASIs. Optimal cut-off for a significant EAS defect was  $\geq 3$  of 7 slices and for significant IAS defect was  $\geq 2$  of 5 slices on TUI. Both IUS and TPUS had AUC that showed fair ability to diagnose EAS and IAS defects. Both had high negative predictive value, which suggests good ability to identify an intact sphincter; but low positive predictive value, which indicates poor detection of sphincter defects. EAUS was the only modality to correlate with anal incontinence symptoms. IUS and TPUS were associated with less discomfort than EAUS.

**FIGURE 3**  
Receiver operator characteristic curves



**A**, Receiver operator characteristic curves for 3-dimensional introital tomographic ultrasound imaging (*left*) and 3-dimensional transperineal tomographic ultrasound imaging (*right*) for diagnosis of external anal sphincter defects (with inclusion of subcutaneous level). **B**, Receiver operator characteristic curves for 3-dimensional introital tomographic ultrasound imaging (*left*) and 3-dimensional transperineal tomographic ultrasound imaging (*right*) for diagnosis of internal anal sphincter defects.

IUS, introital ultrasound imaging; ROC, receiver operator characteristic; TPUS, transperineal ultrasound imaging.

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When first described, IUS suggested good correlation with EAUS.<sup>24</sup> Later, a larger study showed, in fact, low sensitivity, with high specificity,<sup>25</sup> which were comparable with our findings. Two-dimensional IUS and TPUS have been compared with EAUS in a large study that concluded that 2-dimensional TPUS could identify an intact sphincter, but lacked sensitivity to detect defects.<sup>16</sup> Our study found higher sensitivity values using 3-dimensional, which suggests that 3-dimensional imaging can offer improved detection

compared with 2-dimensional. The only other study that compared all 3-dimensional modalities had 55 patients; they substantiated that 3-dimensional technology with TPUS improves the test accuracy compared with 2-dimensional and that 3-dimensional TPUS has potential in screening<sup>26</sup> that is similar to other studies.<sup>27,28</sup> With our significantly larger study, we confidently agree that (with AUC values of 0.70–0.74) 3-dimensional IUS and TPUS are not suitable diagnostic tests to substitute EAUS.

The development of optimal cut-off values for a significant EAS and IAS defect on TUI allows for standardized reporting in clinical and research settings. Although a cut-off of  $\geq 4$  of 6 slices on TUI has been validated against symptoms in urogynecology patients,<sup>29</sup> we are aiming for a cut-off to detect a sphincter defect in women known to have OASI. We know the majority of women with OASI will not have symptoms until later in life, if at all; therefore, a defect can be significant, even if not associated with symptoms. There has been debate about whether the subcutaneous component of the EAS should play a part in defining a defect.<sup>29</sup> We found that its inclusion led towards improved diagnostic performance, although not statistically significant. The subcutaneous part of the EAS contributes to a significant proportion of the sphincter and thus should be included. In the deep level, it was more difficult to diagnose a defect accurately on IUS or TPUS compared with EAUS, which was indicated by lower AUC for this level when isolated. This demonstrates the poor ability of distinguishing a defect from anatomic variation at this level.

We believe that this is the most adequately powered study to date to compare these three 3-dimensional imaging modalities to be able to draw firm conclusions. We also used validated scoring systems for symptoms and scan findings. In addition, the study population is generalizable, and there is low risk of detection bias because all examiners were blinded to other scan results and clinical history. However, the use of 3 examiners, even with good interclass correlation, may have introduced bias. We acknowledge that the quality of the scanning machine for EAUS was superior to that used for IUS and TPUS. It is possible that accuracy could be improved with a new generation scanner. We also acknowledge the heterogeneity of this study population, because some women were pregnant. In addition, there was a large range in follow-up time. Although presence of anal

TABLE 3

**Diagnostic test characteristics of introital and transperineal ultrasound imaging for diagnosis of external and internal anal sphincter defects with the use of endoanal ultrasound imaging as reference standard in 250 women who sustained obstetric anal sphincter injury**

Anal sphincter	Imaging modality	Defect, <sup>a</sup> n/N (%)	Sensitivity	Specificity	Positive predictive value	Negative predictive value	Positive likelihood ratio	Negative likelihood ratio
External	Endoanal ultrasound imaging (N=248) <sup>b</sup>	73/248 (29.4)	N/A	N/A	N/A	N/A	N/A	N/A
	Introital ultrasound imaging (N=248) <sup>b</sup>	80/223 <sup>c</sup> (35.9)	0.65	0.75	0.50	0.86	2.60	0.47
	Transperineal ultrasound imaging (N=246) <sup>b</sup>	96/227 <sup>d</sup> (42.3)	0.70	0.69	0.51	0.85	2.26	0.43
Internal	Endoanal ultrasound imaging (N=248) <sup>b</sup>	34/248 (13.7)	N/A	N/A	N/A	N/A	N/A	N/A
	Introital ultrasound imaging (N=248) <sup>b</sup>	52/241 <sup>c</sup> (21.6)	0.59	0.84	0.63	0.93	3.69	0.49
	Transperineal ultrasound imaging (N=246) <sup>b</sup>	19/238 <sup>d</sup> (8.0)	0.43	0.97	0.37	0.93	14.33	0.59

N/A, not applicable.

<sup>a</sup> With the use of the cut off values of  $\geq 1$  level for external and internal anal sphincter on endoanal ultrasound,  $\geq 3/7$  slices for external anal sphincter or  $\geq 2/5$  slices for internal anal sphincter on introital ultrasound imaging/transperineal ultrasound imaging; <sup>b</sup> 2 volumes for different women were missing; <sup>c</sup> 22 volumes had incomplete data to assess external anal sphincter and or internal anal sphincter fully; <sup>d</sup> 23 volumes had incomplete data to assess external anal sphincter and or internal anal sphincter fully.

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incontinence symptoms may change with time and pregnancy status, these 2 confounders have no effect on sphincter defects or morphologic condition.<sup>3,30</sup> Therefore, because all scans were performed on the same day for each woman, the diagnostic accuracy of each modality or correlation with symptoms should not be affected.

Patient acceptability should be considered. As expected, the less intrusive nature of IUS and TPUS led to reduced discomfort. The IUS probe requires pressure on the posterior fourchette; this and hence tissue proximity could result in reduced visibility of distal defects at the 12 o'clock position. This may support the use of TPUS over IUS.

When applicability is evaluated, cost and equipment availability are important. IUS and TPUS probes already are used widely by obstetricians and gynecologists and provide a cheaper alternative to the more specialized endoanal probe. However, one must appreciate that the interpretation of all techniques requires training and expertise.

This study was carried out in a cohort with a high prevalence of sphincter defects; therefore, the negative predictive value would be expected to be even higher in an unselected cohort of postpartum women. This would support their use to screen for an intact sphincter on labor ward immediately after delivery. Although likely to be highly accepted by patients and reduce undetected OASI, it would require widespread training of obstetricians, instead of improving examination skills. Likely, the most appropriate place for these modalities is in the antenatal setting, assessing women in subsequent pregnancies after OASI to advise mode of delivery.

In conclusion, 3-dimensional EAUS remains the most accurate method for the diagnosis of anal sphincter defects and correlates best with symptoms, hence cannot be substituted by IUS or TPUS. High negative predictive value indicates that, in women with a history of OASI, IUS and TPUS are useful for screening an intact sphincter in situations in which EAUS is not available. However, with a

low positive predictive value, women with defects on IUS or TPUS would need referral for EAUS to verify the diagnosis. ■

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