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ORIGINAL ARTICLE

Translabial ultrasound assessment of the anal sphincter complex: normal measurements of the internal and external anal sphincters at the proximal, mid-, and distal levels

Rebecca J. Hall · Rebecca G. Rogers · Lori Saiz · C. Qualls

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Abstract The purpose of this study was to measure the internal and external anal sphincters using translabial ultrasound (TLU) at the proximal, mid, and distal levels of the anal sphincter complex. The human review committee approval was obtained and all women gave written informed consent. Sixty women presenting for gynecologic ultrasound for symptoms other than pelvic organ prolapse or urinary or anal incontinence underwent TLU. Thirty-six (60%) were asymptomatic and intact, 13 symptomatic and intact, and 11 disrupted. Anterior–posterior diameters of the internal anal sphincter at all levels and the external anal sphincter at the distal level were measured in four quadrants. Mean sphincter measurements are given for symptomatic and asymptomatic intact women and are comparable to previously reported endoanal MRI and ultrasound measurements.

Keywords Translabial ultrasound · Anal sphincter complex · Internal anal sphincter · External anal sphincter

Rebecca G. Rogers is a consultant for Pfizer.

R. J. Hall (✉) · R. G. Rogers · C. Qualls
Department of Ob/Gyn, Division of Urogynecology,
University of New Mexico HSC,
Albuquerque, NM, USA
e-mail: rjhall@salud.unm.edu

L. Saiz
Women's Specialists of New Mexico,
Albuquerque, NM, USA

R. J. Hall · R. G. Rogers · L. Saiz · C. Qualls
Informatics/Biostatistical Support,
University of New Mexico HSC,
Albuquerque, NM, USA

Introduction

Evolving imaging techniques are an integral part of the anal incontinence workup. Clinically, they aid in identifying those patients with sphincter tears that may be amenable to surgical repair. Current diagnostic imaging tools available for evaluation of the anal sphincter complex (ASC) include pelvic floor fluoroscopy, defecography, computed tomography (CT), magnetic resonance imaging (MRI), and diagnostic ultrasound (endoanal, endovaginal, and translabial). Many of these modalities are either not widely accessible or require specialized equipment, are invasive, and may be poorly tolerated by patients [1–8]. The current gold standard for the evaluation of anal sphincter anatomy is considered to be endoanal sonography. Correlations between endoanal sonography and surgical findings of ASC defects have proven to be excellent and measurements of the ASC by endoanal ultrasound correlate well with MRI findings [9–11].

Translabial ultrasound (TLU) offers an alternative imaging modality of the anal sphincter complex and has proven to be well-tolerated by patients. It has been used to describe anal sphincter complex integrity [12, 13]. The equipment needed to perform TLU is readily available to all gynecology and radiology imaging laboratories. Aside from the actual modality utilized, MRI, TLU, and endoanal studies of the anal sphincter complex are quite varied in terms of reporting measurements both with regard to which levels of the ASC were measured and how specific anatomic structures were described [5, 14].

The purpose of the current study was to provide anterior–posterior diameter measurements of the normal anal sphincter complex at the proximal, mid, and distal levels as described by Delancey et al. [15] in asymptomatic women with intact anal sphincters.

Methods

The Institutional Review Board approved our study protocol. Women presenting at Women's Imaging, Prenatal Diagnosis, and Genetics Center for gynecologic ultrasound with symptoms other than pelvic organ prolapse, urinary, or anal incontinence (AI) were recruited and underwent translabial ultrasound using a 4- to 8-MHz curvilinear endovaginal transducer. Since we do not have a small aperture (5- to 12-MHz) transducer in our unit, the high-frequency (4- to 8-MHz) endovaginal transducer was chosen to assess the anatomy and access the highest operating frequency, since the focal zone will be placed at a very superficial level of less than 3–4 cm. Inclusion criteria were any patient older than 18 presenting for gynecologic ultrasound assessment. Women with history of rectovaginal fistula, rectal surgery or trauma, radiation or genital or colorectal cancer, or inflammatory bowel disorders were excluded.

All participants gave written informed consent. Women completed a demographic questionnaire and the Wexner Fecal Incontinence scale, which evaluates anal incontinence symptoms. For purposes of this study, AI was defined as a Wexner Fecal Incontinence scale score >0.

The ultrasound exam was performed by an investigator experienced in translabial imaging of the pelvic floor using a Philips IU22 (Bothell, Washington) ultrasound system. The examiner was blinded to the patient history at the time of the exam. Clinical history information was obtained after the examination via questionnaires as described. After voiding, the patient was placed in the lithotomy position and an endovaginal 4–8 MHz transducer covered with lubricant gel plus a transducer cover also covered with gel was placed at the introitus. To obtain optimal images, the transducer was directed posteriorly toward the anal sphincter complex and aligned nearly perpendicularly to the floor, though this was fine-tuned according to patient habitus and level of ASC assessment. The write zoom capability of the ultrasound system was optimized to enhance spatial resolution. Total examination time was approximately 10 min.

A general survey of the perineal anatomy was performed in sagittal and axial planes. Measurements of the internal and external anal sphincters were taken in the axial plane at three levels. At all levels, the internal anal sphincter (IAS) appears as a symmetric concentric hypoechoic ring surrounding a more echogenic central mucosa. The external anal sphincter appears as a hyperechoic ring surrounding the IAS and is visible only at the distal level. At the proximal ASC level, superior to the puborectalis muscle, the IAS is also identified (Fig. 1a). The midlevel cut is taken at the puborectalis muscle. The puborectalis can be visualized as a multilayered echogenic sling lying posterior to the anal sphincter complex. At this level, again, only the IAS is seen (Fig. 1b). The most distal level is taken where both the IAS and external anal sphincter (EAS) can be visualized, with the IAS seen as hypoechoic, surrounded by a concentric hyperechoic EAS at its widest point (Fig. 1c,d). These planes assess the entire rectum superiorly to inferiorly with slight movement of the transducer at the introitus enabling undistorted visualization of the ASC at each level [16, 17].

Measurements of the IAS and EAS were taken in four quadrants as if describing a clock with the 12 o'clock position anterior, the 3 o'clock position to the patient's left, the 6 o'clock position posterior, and the 9 o'clock position to the patient's right. IAS thickness was measured for the proximal and mid levels, and measurements for both IAS and EAS were obtained distally. At each level, integrity of the sphincter and, additionally, mucosal contour and centrality were noted. The range of defect size was described as related to the clock, with a clock range of disruption reported, for example, a disruption from 10 to 12 o'clock. Images of each level were recorded.

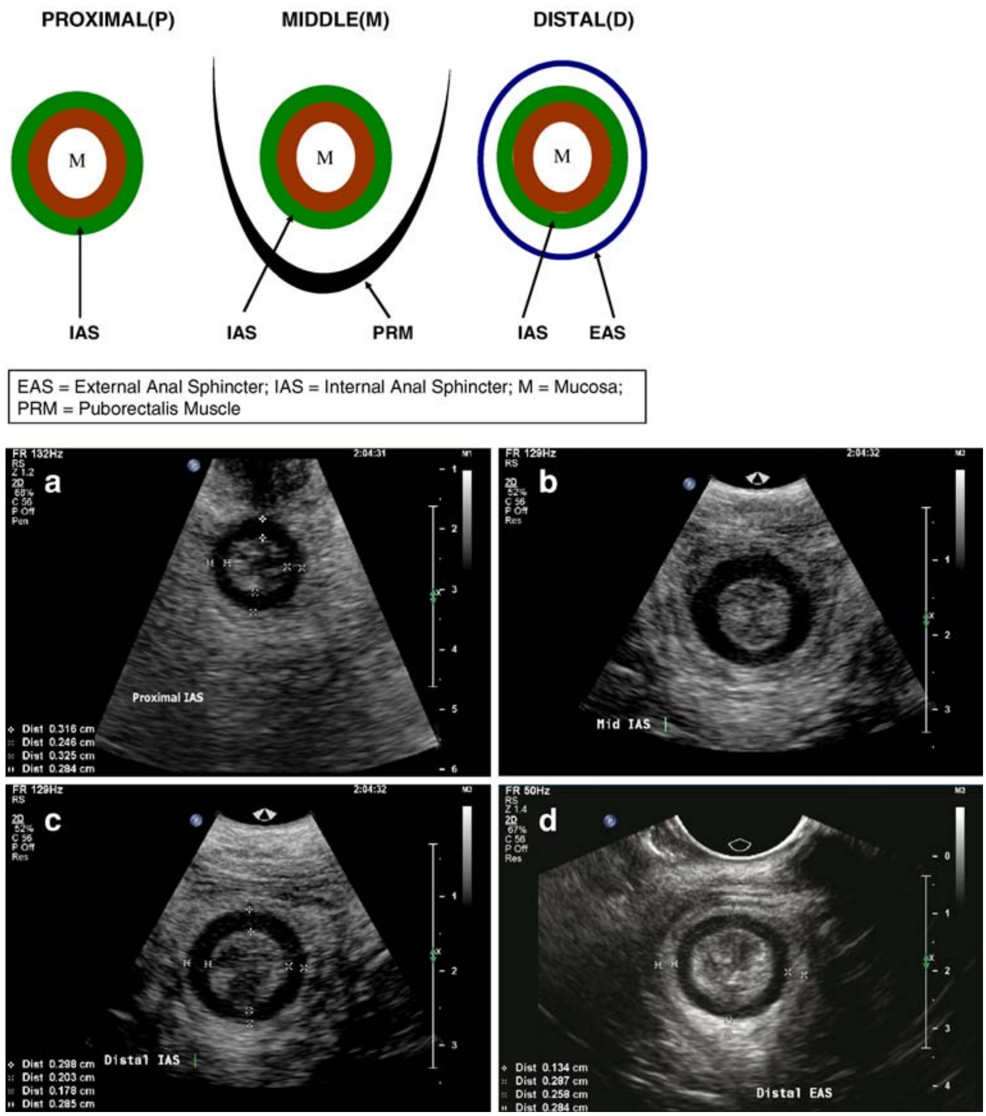
Statistical analysis included univariate analysis of binary and ordinal outcomes by Fisher's exact test and Wilcoxon two-sample test, respectively. Continuous variables were analyzed using analysis of variance. Logistic regression was used for multivariate analysis of binary outcomes. Statistical analysis was performed using Epi-Info Version 6 (Centers for Disease Control and Prevention; Atlanta, GA) and the Statistical Program/SAS (SAS Institute, Cary, NC) with $P<0.05$ significant. An additional ten subjects were recruited to assess inter- and intra-rater reliability. Sixteen different anatomic measurements per patient were all made by reader 1, by a blinded reader 2 at a separate time, and again by reader 1, making a second set of blinded measurements at a third point in time. Interclass correlations (ICC) was performed to calculate intra-observer and interobserver reliability by the formula of Shrout and Fleiss (Model 2,1) [18].

Results

Sixty women gave informed written consent to participate. Of the 60 patients, 11 (18%) had disrupted IAS, EAS, or both. These women were excluded from calculated mean values. No nulliparous women were in the disrupted group.

Of the 49 women with intact anal sphincter complexes, 13 (27%) reported anal incontinence and were also excluded from mean sphincter measurement values. (Fig. 2) In the final cohort of asymptomatic intact women (n=36), the mean age was 34.3±11.3, the mean body mass index was 29.4±11.9, the majority of women were parous [22/36 (61%)] and premenopausal [30/36 (83%)]. Most

Fig. 1 Schematic drawing of Proximal (P), Mid (M) and Distal ASC levels. Corresponding TLU images: **a.** Proximal IAS **b.** Mid IAS **c.** Distal IAS **d.** EAS



women were Hispanic [24/36 (66%)] or Caucasian [10/36 (28%)]. Four patients (11%) complained of chronic constipation and 3(8%) of irritable bowel symptoms.

All four quadrants at three levels were measured for all patients. No differences in measurements were noted between nulliparous and parous patients (all P=NS). Mean sphincter measurements among intact asymptomatic and symptomatic intact women are described in Table 1.

Intact symptomatic women (n=13) differed from intact women who were asymptomatic (n=36) only by age (34.3± 11.3 vs 48.9±12.6 years; P=0.002). Comparison of ASC measurements of asymptomatic and symptomatic intact women revealed differences at the proximal 9 o'clock (P= 0.04) and 12 o'clock (P=0.02) IAS, and the mid 12 o'clock (P=0.012) and the distal 6 o'clock (P=0.02) IAS positions. Adjusted for age in a multivariate analysis, however, these differences were not significant. (all P>0.05) Shrout and Fleiss ICC (2,1) between the two separate readings of reader 1 (intra-rater reliability), which were computed for each of the 16 measurements, showed excellent reliability in 11 measurements, 4 with fair to good reliability, and 1 measurement with poor reliability. The median across the 16 measurements was 0.88 or excellent reliability. This classification of excellent (>0.75), fair to good (0.40–0.75), and poor (<0.45) follows Fleiss criteria [18, 19]. The comparison between the two readers (inter-rater reliability) shows excellent reliability in nine measurements, six with fair to good reliability and one with poor reliability. The median across the 16 measurements was 0.75, which is also excellent reliability. The single measurement that was "poor" for both intra- and inter-rater reliability was the 6 o'clock distal IAS position. Why this measurement had consistently poor reliability is unclear. It may be due to the fact that at the level of the puborectalis, the 6 o' clock position may be too close to the internal anal sphincter to distinguish between the two interfaces.

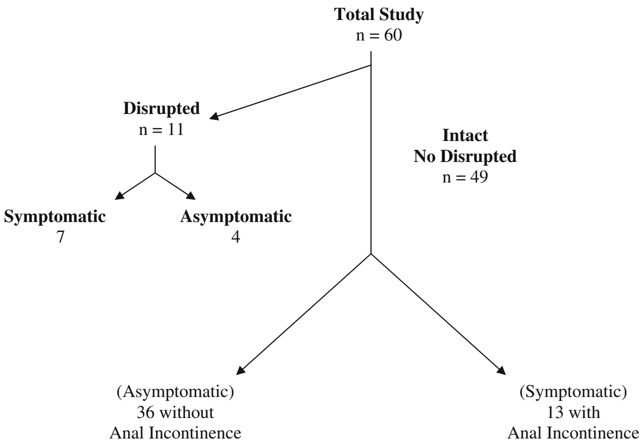


Fig. 2 Algorithm of study population

Among the 11 women with disrupted sphincters, all disruptions were at the 12 o'clock position. All 11 women had disruption of the IAS; four of these disruptions were only seen at the proximal level (above the puborectalis muscle). Two women had disruption of both the IAS and EAS. Seven of the women with disruptions had symptoms of AI, while four did not. It is of note that with those patients who had defects (18%), the central mucosa was elevated toward the defect in 9 (82%) of the 11 women, regardless of the position of the disruption in the anal sphincter complex.

Table 1 Mean EAS and IAS measurements in women with intact EAS and IAS

	Asymptomatic (*n*=36)	Symptomatic (*n*=13)	*P* value
IAS			
Prox 12 o'clock	2.54±1.04	3.29±0.92	0.02
Prox 3 o'clock	2.63±0.75	3.13±1.19	0.17
Prox 6 o'clock	2.16±0.68	2.47±1.03	0.33
Prox 9 o'clock	2.59±0.72	3.20±0.97	0.04
IAS			
Mid 12 o'clock	2.49±0.88	3.18±0.79	0.02
Mid 3 o'clock	2.67±0.68	3.03±0.85	0.19
Mid 6 o'clock	2.08±0.58	2.40±0.72	0.17
Mid 9 o'clock	2.73±0.71	3.00±1.15	0.43
IAS			
Distal 12 o'clock	2.29±0.72	2.67±0.90	0.19
Distal 3 o'clock	2.45±0.74	2.97±0.83	0.07
Distal 6 o'clock	2.20±0.65	2.72±0.60	0.02
Distal 9 o'clock	2.48±0.74	3.02±1.10	0.12
EAS			
12 o'clock	1.45±0.41	1.78±0.69	0.14
3 o'clock	1.84±0.90	1.97±0.76	0.62
6 o'clock	1.79±0.69	1.91±0.65	0.56
9 o'clock	1.84±0.68	1.80±0.69	0.87

Discussion

Anal incontinence is the involuntary loss of flatus or either liquid or solid stool that is a social or hygienic problem [2, 20]. It is underreported, under recognized, and poorly understood. Prevalence estimates for fecal incontinence vary from 0.5–18% in the general population, with 30–50% occurring in the geriatric population. Women are affected six to eight times more commonly than men. Treatment of anal incontinence is expensive, with up to $400 million spent yearly on absorptive devices [2, 21].

Anal continence is maintained by a complex interrelationship between the anal and pelvic floor musculature although the relative importance of each muscle is controversial. Besides the IAS and EAS, which both contribute to the tonic resting pressure, the puborectalis muscle (PRM) may also help to maintain continence [22, 23]. Both neurologic injury to the pudendal nerve (stretch injury) and mechanical injury to the anal sphincter (morphologic injury) are considered the most common pathophysiological factors for anal incontinence. The majority of morphological injuries are thought to be the result of obstetrical trauma. Other causes include history of other anal trauma, hemorrhoidectomy, chronic manual disimpaction, prostatectomy, spinal cord injury, chronic constipation, and laxative abuse [24]. Anal sphincter injury can occur in up to one-third of women after vaginal delivery with greatest risk at first delivery [2, 17, 25, 26].

Clinical evaluation of the anal sphincter complex alone can be unreliable and ancillary testing can aid in the diagnosis of sphincter defects [22, 23]. Electromyography (EMG) can identify sphincter dysfunction but cannot confirm whether it is due to a loss of sphincter anatomic integrity or neuropathy. Manometry does not consistently match clinical or imaging information and is not well-tolerated by patients [27, 28]. Both endoanal ultrasound and MRI provide reliable images of the anal sphincter complex and can diagnose disruptions; however, both are invasive and require specialized equipment. Having the ability to identify appropriate surgical candidates who would benefit from anal sphincter repair using less invasive and well-tolerated imaging techniques may be beneficial to patients suffering from AI [28].

The anatomy of the ASC is complex. The entire complex extends for a distance of approximately 4 cm and, therefore, cannot be fully evaluated in a single sagittal slice [15]. The IAS is a continuation of the circular smooth muscle of the anal wall from the anorectal junction to just below the dentate line. The IAS extends superior and inferior to the puborectalis, so it can be assessed at multiple levels above and below the PRM landmark. Delancey et al. [15] has described several points of interest regarding the anal sphincter complex: the IAS always extends cranially beyond the EAS by more than

10 mm, there is an IAS/EAS overlap of approximately 17 mm and the distal location is where the EAS is its thickest. The EAS, with striated fibers that encircle the rectum, is contiguous at its superior segment with the puborectalis. The distal segment extends 1cm inferiorly beyond the IAS where it inserts anteriorly onto the perineal body. The EAS has been described as being divided into three layers: the deep, superficial, and subcutaneous; however, division of the EAS is controversial with two layers more commonly described as being reproducible by imaging [29]. More recently, Hsu et al. [30] described convincing evidence that coronal MRI images demonstrate lateral extensions of the distal EAS.

Between the IAS and the EAS lies the longitudinal muscle, which is a continuation of the longitudinal muscle of the rectal wall. There is a fibroelastic component that invests both the IAS and EAS. The intersphincteric space is a plane composed of fat, located between the longitudinal muscle and the external anal sphincter, and ends in the subcutaneous layer of the EAS [17, 31].

Multiple imaging techniques have been utilized to assess anal sphincter complex integrity, though fine degree interfaces of anatomic subcomponents described above are not being seen by various imaging techniques or appreciated by interpreting examiners [17]. There have been concerns about whether the various imaging modalities should be compared [32]. This is a logical concern since patient positioning on the exam table has varied with different modalities and the ability to manipulate the transducer, endocoil, or system to accommodate patient anatomy may be limited by patient position. These differences may distort anatomy from one patient to the next [1, 6, 8, 28, 33, 34]. As imaging evolves and identification of correct precise surrounding anatomy improves, there will be more consistent assessment of the ASC [6].

Precise imaging of structural defects using endoanal ultrasound may enhance patients' expected benefit from surgery [35]. Endoanal ultrasound and MRI both demonstrate high soft-tissue resolution in imaging the pelvic floor anatomy. In a prospective study of 90 patients with fecal incontinence, Liberman et al. reported that the addition of endoanal ultrasound changed the management plan from medical to surgical treatment in 11% of patients and that 7% of surgical patients had treatment changed from one surgical technique to another [27]. MRI can provide excellent visualization of the anal sphincter complex, but it is costly and its use is restricted to specialty centers.

A handful of small studies have compared the efficacy of endoanal ultrasonography and MRI in imaging the anal sphincter complex; however, the results determining which of the imaging modalities most accurately visualize the anal sphincter complex have been conflicting [1, 13, 36–38]. Schäfer et al. [32] reported that endoanal sonography was better at differentiating between IAS and EAS than MRI, and muscle diameters were measured more accurately. This was thought to be because MRI images tend to be oblique to the anatomy imaged. Contrarily, Enck et al. [14] reported that endoanal ultrasound does not provide reliable and reproducible morphometric data. Malouf et al. [11] published another study, which found endoanal sonography comparable to MRI. Rociu et al. [37] found only moderate correlation between MRI and endoanal ultrasound. Ultrasonography also appears to be appreciated for its functional dynamic imaging capabilities [16, 39–41].

Endoanal imaging requires a specialized ultrasound system with expensive transducers that are not widely available [9, 10, 13, 42, 43]. Most ultrasound studies have concentrated on endoanal ultrasound in identifying sphincter defects and comparing accuracy to EMG, manometry, and surgery [44, 45]. For both MRI and endoanal ultrasonography, reports are quite varied regarding which levels of ASC assessment were done and which specific anatomic structures were visualized or measured. Both MRI and endoanal imaging carry the disadvantage of requiring that the transducer be placed in the anal canal, which, in and of itself, may distort anatomical findings.

TLU utilizes equipment available in most ultrasound laboratories, it is noninvasive, and it does not distort the anal canal. It has been reported by some to be a feasible alternative or correlative to anal endosonography [16, 40]. Description of TLU imaging of the pelvic floor is scarce [40, 46]. Peschers et al. [13] showed that translabial imaging was capable of identifying the normal anatomy of the ASC and that diagnosed defects were confirmed at the time of reconstructive surgery. Another study found that TLU and endoanal ultrasound had findings that were equally efficacious [46].

We measured the IAS and the EAS at three levels in four quadrants to obtain anterior–posterior diameters of the entire circumference. The IAS was clearly visualized at all our levels, the echo pattern a diffusely hypoechoic ring surrounding the central mucosa/submucosa. The puborectalis was the landmark we used for the mid IAS segment, as the widened u-shaped sling appearance is readily seen posterior to the IAS. Since the anterior EAS occupies only the distal 30% of the anal canal, we measured both the distal IAS and the EAS at the widest segment of that level.

Our mean measurements for intact asymptomatic women of the proximal IAS are comparable to both endoanal or MRI measurements previously published. Maximum thickness of the IAS was seen at the 3 and 9 o'clock locations, similar to findings by Gold et al. using three-dimensional endoanal sonography. The mean IAS and EAS thicknesses of 2.6 and 1.9 mm, respectively, reported by Schäfer, were similar to our range of findings of 2.1–2.7 mm for the IAS thickness and 1.5–1.8 mm for the EAS thickness [44]. Also, our measurements are consistent with reported endoanal MRI measurements with average IAS thickness of 2.5 mm [17]. As compared to a small study of eight patients by Schäfer et al., our measurements of the IAS, again, correlated well with both their MRI and endoanal ultrasound measurements, though all other studies were limited in total measurements and usually limited to one level [32] (Table 2).

We found that among women presenting for ultrasonography for reasons other than pelvic floor disorders, a significant portion had either symptoms or disruptions in the anal sphincter complex. Some of the disruptions were at the proximal level, which may be overlooked with evaluation of only the more distal EAS. In fact, four of our disrupted patients had defects above the PRM, the most common location being at the proximal 12 o'clock position, underlining the importance of surveying the entire anal sphincter complex. We suspect that there are more occult injuries to the anal sphincter complex than may previously have been thought to occur. Our prevalence rate of external anal sphincter defects is consistent with previously described prevalence in the literature; however, if the internal anal sphincter is evaluated only at this distal level, higher lacerations may be missed. Because we are evaluating the sphincter at three levels, the proximal, mid, and distal levels, we suspect that the injuries that we are observing at proximal levels were missed by those assessing the anal sphincter complex more distally.

Limitations of our study include that our measurements in a population of Hispanic and Caucasian women might not represent anatomy of women with different ethnicities. Other studies of normative values of different ethnicities are indicated. We included both nulliparous and multiparous women in our study; but subanalyses revealed no differences in mean sphincter measurements between the two groups. We wished to describe measurements in asymptomatic intact women and found that a significant propor-

Table 2 Comparison of ASC measurements in multiple studies

	Authors									
	Hall	Enck [14]	Voyvodic [31]	Zetterström [12]	Rociu [36]	Beets-Tan [38]			Schäfer [32]	
Patient position	Lithotomy	Left Lateral decubitus (LLD)	LLD	LLD	Supine	LLD	Supine	Supine	LLD	Supine
Type imaging	Translabial ultrasound	Endoanal ultrasound	Endoanal MRI	Endoanal ultrasound	Endoanal ultrasound	Endoanal ultrasound	Endoanal MRI	Phased array MRI	Endoanal ultrasound	Phased array MRI
Number of patients	36	10	62	13	100	60	60	60	8	8
Proximal IAS										
12 o'clock	2.54±1.04									
3 o'clock	2.63±0.75									
6 o'clock	2.16±0.68									
9 o'clock	2.59±0.72									
Mid IAS										
12 o'clock	2.49±0.88	1.27±0.26 to 2.30±0.48			2.92±0.06	3.8±1.2	2.0±0.4	3.2±0.7	1.96±0.61	1.72±0.13
3 o'clock	2.67±0.68									
6 o'clock	2.08±0.58									
9 o'clock	2.73±0.71		2.49±0.9							
Distal IAS										
12 o'clock	2.29±0.72									
3 o'clock	2.45±0.74			2.0±0.6						
6 o'clock	2.20±0.65			1.6±0.4						
9 o'clock	2.48±0.74			2.0±0.7						
EAS				1.9±0.4						
12 o'clock	1.45±0.41	5.52±1.37 to 7.93±1.47		5.9±1.0		7.2±2.3	1.2±0.3	1.3±0.2	6.4±1.07	3.99±0.99
3 o'clock	1.84±0.90			6.7±1.1						
6 o'clock	1.79±0.69		6.1	6.3±1.0	4.09±0.11					
9 o'clock	1.84±0.68		5.85	6.6±1.2						

tion of women presenting for ultrasonography for reasons other than pelvic floor disorders complained of anal incontinence. We screened for anal incontinence using a validated symptom severity measure, but may have under- or overdiagnosed anal incontinence symptoms. Finally, we do not have our own comparative measurements using endoanal ultrasound in these women. We believe that it was important to completely describe normative values and methodology of visualization of the anal sphincter complex before initiating comparative studies. We have recently obtained a National Institutes of Health grant to assess and compare the anal sphincter complex in both translabial 3-D assessment and endoanal imaging of women. This will allow a head on comparison of the two imaging modalities.

The diagnostic imaging community would benefit by adding the urethra and anal sphincter complex to their exam protocol. Because most diagnostic imaging centers have the equipment necessary to do these studies, patients can be initially assessed with improved referrals to specialty centers; additionally, researchers can utilize equipment that their departments already own to further investigate anatomical changes to the anal sphincter complex.

Conclusion

Translabial ultrasound (TLU) is capable of reliably assessing the anal sphincter complex (ASC) with precise measurements and optimal patient comfort, and is widely available to practicing gynecologists. Our study describes measurements of four quadrants at three levels, which yields a thorough assessment of the entire intact anal sphincter complex. Translabial ultrasound using a high frequency endovaginal transducer can be manipulated to optimize planar cuts through the ASC. This serves as an argument for standardized translabial assessment of the ASC, given that most obstetric and gynecologic imaging laboratories already have high-frequency endovaginal transducers on their ultrasound systems.

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