

Endoanal ultrasound for detection of sphincter defects following childbirth

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Abstract

Introduction and hypothesis The objectives of this study were to estimate the rates of sonographically detected anal sphincter defects within 72 h of childbirth and to evaluate intra- and interobserver agreement using three-dimensional (3-D) endoanal sonography data.

Methods This is a prospective observational study of primiparous women delivered vaginally. Women without clinically identified anal sphincter lacerations underwent endoanal ultrasonography within 72 h of delivery. Intra- and interobserver agreement for diagnosis of sphincter defects using 3-D endoanal sonography data was calculated using kappa statistics.

Results The rate of sphincter defects in 107 women undergoing 3-D endoanal sonography was 12 %. Characteristics of women with sonographically detected sphincter defects, compared to those without, included a significantly increased rate of clinically diagnosed second-degree lacerations (54 vs 20 %, p 0.008). The intra- and interobserver agreement for diagnosis of sphincter defects using 3-D

endoanal sonography data was 0.82 [confidence interval (CI) 0.66–0.99] and 0.72 (CI 0.54–0.92), respectively.

Conclusions Anal sphincter defects detected using endoanal sonography are common, occurring in 12 % of primiparous women, and are significantly associated with other less severe perineal lacerations. Overall and combining sonographically detected defects with clinically diagnosed lacerations, we estimate that 17.8 % of primiparous women delivered vaginally sustain anal sphincter injuries. The intra-observer agreement for diagnosis of sphincter defects is very good and the interobserver agreement is good.

Keywords Anal sphincter defects · Endoanal sonography · Occult anal sphincter injury

Introduction

Obstetric anal sphincter injuries are powerful markers for subsequent anal incontinence [1–5], and fear of these injuries has likely contributed to the almost 60 % increase in cesarean deliveries in the USA [6]. The reported incidence of clinically diagnosed anal sphincter injuries, which refer to third- and fourth-degree perineal lacerations, ranges from 6 to 18 % [7, 8]. Extrapolating this incidence to the approximately 3,000,000 annual vaginal births in the USA, up to 540,000 women sustain anal sphincter lacerations each year. Anal incontinence, a socially debilitating condition, affects up to 53 % of young healthy women who sustain anal sphincter lacerations during childbirth despite having these lacerations diagnosed and repaired at delivery [9–12].

In addition to clinically recognized third- and fourth-degree lacerations, *occult* anal sphincter injuries have been reported in up to 35 % of primiparous women and have also been associated with increased risk of anal incontinence [13]. Occult anal sphincter injuries refer to anal sphincter

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defects that are not visible at delivery but can be detected with ultrasound imaging of the anal sphincter immediately postpartum. However, results of recent investigations suggest that most anal sphincter injuries previously classified as occult represent misclassification of perineal lacerations and that true occult anal sphincter injuries are rare [14]. These findings highlight the importance of provider education and accurate diagnosis of anal sphincter injury at the time of delivery [14–18]. Consequently, prior to the start of this study, we instituted a formalized provider training program that emphasized accurate clinical diagnosis of perineal lacerations [16, 19].

Whether anal sphincter injuries diagnosed using sonography represent true occult defects or misclassified lacerations, postpartum anal incontinence is reported in approximately 30 % of women diagnosed with sonographic anal sphincter defects postpartum [13]. Furthermore, Fynes et al. showed that 42 % of women with asymptomatic occult anal sphincter defects develop fecal incontinence after a subsequent vaginal delivery [20]. Thus, accurate identification of both clinically diagnosed and sonographically detected anal sphincter injuries would be necessary in investigations aimed at identifying potential modifiable childbirth practices targeted to reducing anal incontinence later in life. The objectives of this study were (1) to describe the rates of both clinically diagnosed and sonographically detected anal sphincter injuries in concert with a formalized provider training program that emphasized accurate clinical diagnosis of perineal lacerations and (2) to determine the intra- and interobserver agreement for the diagnosis of anal sphincter disruption using stored three-dimensional (3-D) endoanal sonography data obtained within 72 h of childbirth.

Materials and methods

Primiparous women who delivered vaginally at Parkland Hospital from 9 June 2009 to 30 November 2009 were screened for possible participation in this prospective observational study. Parkland Hospital serves the medically indigent in Dallas County, Dallas, TX, USA. The rate of deliveries ranges from 12,000 to 15,000 per year. Eligible women were those ≥ 16 years old who delivered a singleton fetus in cephalic presentation at ≥ 37 weeks without a clinically diagnosed third- or fourth-degree perineal laceration. Multiparous women and women with a prior history of fecal incontinence, anal sphincter surgery, or trauma were excluded. The Institutional Review Board for the University of Texas Southwestern Medical Center approved this study. Written consent was obtained from each participant. Eligible women were approached by research staff on the postpartum ward on Monday, Wednesday, and Friday. These were days when the sonography equipment and technician were available.

Training program for perineal anatomy and lacerations

Prior to initiation of this study, we developed, distributed, and reviewed with all providers, which included house officers and certified nurse midwives, an educational video that described the normal perineal anatomy, proper classification of perineal lacerations, and layered repair of a fourth-degree laceration. This instructional video was presented at the American Congress of Obstetricians and Gynecologists Annual Clinical Meeting [19].

Standardized documentation of perineal findings

As part of a quality assurance effort to accurately capture perineal lacerations at our hospital, we developed and introduced a standard schematic diagram of labeled perineal structures (Fig. 1) that is completed by providers at each vaginal delivery. This diagram prompts the provider to mark with a “V” the deepest structure of the perineum that is involved in a laceration. Based on the diagram, research staff annotated and computerized the severity of perineal lacerations, i.e., first-, second-, third-, and fourth-degree [21], for each patient as part of this study. Rectal examinations are not routinely performed unless there has been a perineal laceration.

Endoanal sonography procedure

The ultrasonographer (MMC) was unaware of the specific degree of perineal laceration, if any, recorded at delivery and of specific obstetric and intrapartum events. Prior to the endoanal ultrasound exam, a digital rectal exam was performed to estimate the orientation of the anal canal and to evaluate the anorectum for gross abnormalities that may not have been detected at the time of delivery. Ultrasound assessment of the anal canal was performed with women in the supine position with the legs resting in the stirrups of a gynecologic exam table. The foot of the table was lowered to allow positioning of the endoanal sonography probe along the axis of the anal canal.

Anal endosonography was performed using a 3535 Ultrasound Scanner (BK Medical, Denmark) with an 1850 axial endoscopic probe and 10-MHz transducer. The external diameter of the probe was 17 mm. The focal range of the transducer was set at 2.8 cm. Other acquisition settings were adjusted as deemed appropriate for each examination.

The endoscopic probe was covered with a lubricated condom and introduced along the axis of the anal canal until the puborectalis muscle sling was visualized. The probe was rotated so that the rectovaginal wall was in the mid and upper portion of the screen, symmetrically positioned between the right and left portions of the puborectalis sling. The probe was withdrawn manually along the longitudinal

To be completed by delivering physician or midwife.

1. Episiotomy performed?
 - Yes No

2. Lacerations?
 - Yes No

3. Legs positioned in stirrups during delivery?
 - Yes No

Attach label or enter patient information:

Medical record number:

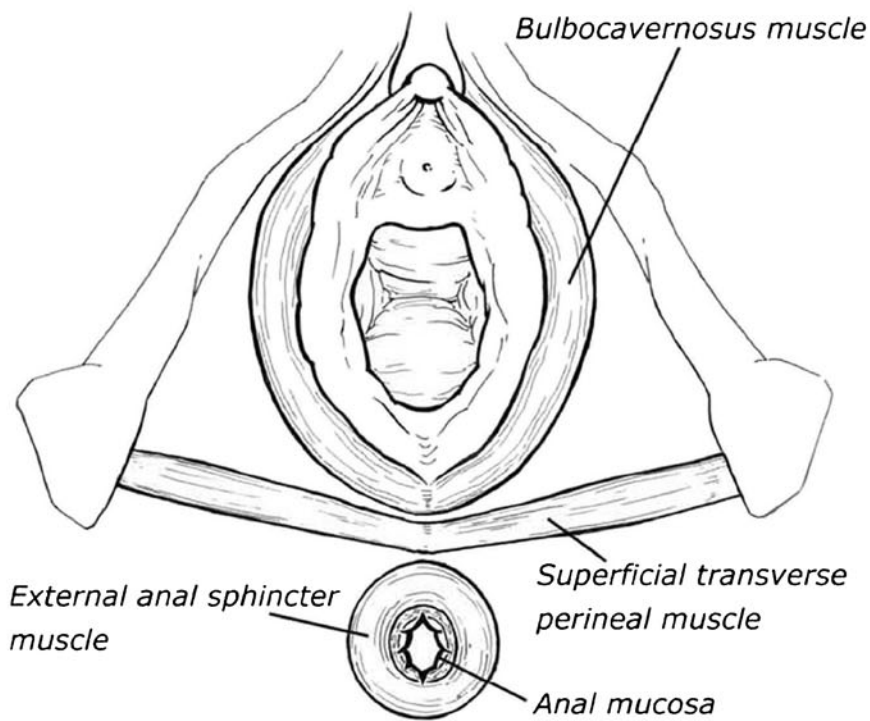
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Patient name: _____

Delivery date:

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4. In the drawing of the perineum below, mark with one or more V's the muscles, anal mucosa, and/or any other structures that the episiotomy or laceration extended into. Place the base of the V on the deepest portion of the structure cut.



Office use only:

Fig. 1 Schematic diagram of labeled perineal structures that is completed by providers at each vaginal delivery

axis of the anal canal to the lowest extent where the external anal sphincter was visualized. The anal canal, which measures approximately 3 cm in length in women, was divided into three sonographically distinct levels: high, mid, and low (Fig. 2). Prespecified study criteria, as described below, were used to define these three levels and for classification of external and internal anal sphincter defects. Following real-time examination of the anal canal, the probe was reinserted in the high anal canal and positioned in an automated pulley for acquisition of 3-D data and image storage. The data from a series of closely spaced endoanal ultrasound images (0.25 mm) were combined to create a 3-D volume displayed as a cube. The 3-D stored data were reviewed by the two examiners (MMC and DMT) using their own personal computers and the same 3-D viewing software (BK Medical). This was done so that both observers examined the same data obtained from each examination.

Interpretation of ultrasound findings

The *high anal canal* was defined as the approximately 5 mm region from the lowest level at which the puborectalis

muscle sling was visualized to the level just above where the external anal sphincter formed a complete ring anteriorly (Fig. 2A). Discontinuity of the external anal sphincter anteriorly at this level was not considered a defect, as this is a common variation of normal sphincter anatomy in women [22]. The *mid anal canal* was defined as the region where the external anal sphincter formed a complete ring around the internal anal sphincter (Fig. 2B) and extended inferiorly to the most distal end of the internal anal sphincter. The *low anal canal* was defined as the region below the end of the internal anal sphincter where only the external anal sphincter muscle was visualized (Fig. 2C).

The *internal anal sphincter* was defined as the concentric hypoechoic band or ring surrounding the anal submucosa (Fig. 2). The *external anal sphincter* was defined as the concentric ring of hyper or mixed echogenicity lateral to the internal sphincter in the mid anal canal and to the anal submucosa in the low anal canal. This ring incorporated the longitudinal muscle, as this muscle is difficult to distinguish from the surrounding external anal sphincter sonographically (Fig. 2).

An *internal anal sphincter defect* was defined as a loss of continuity in the concentric hypoechoic ring surrounding the

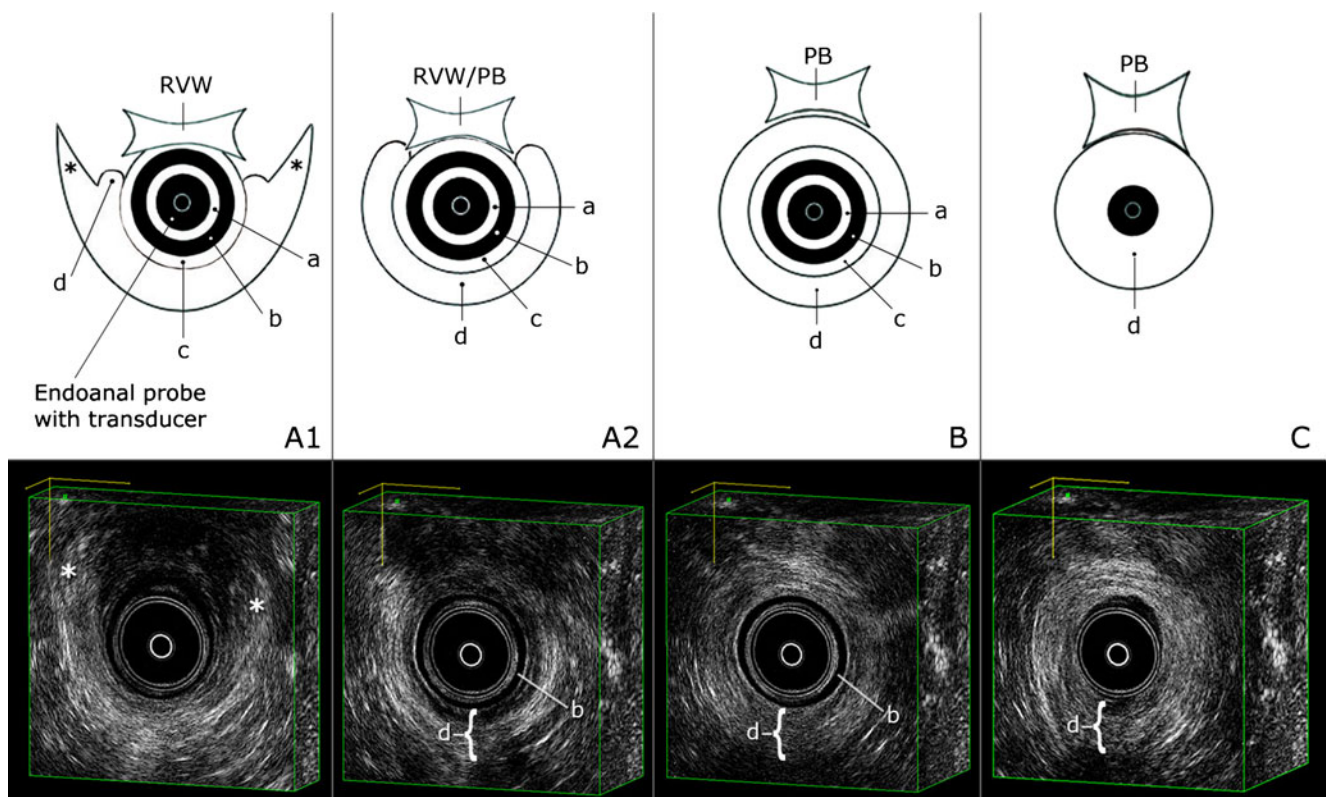


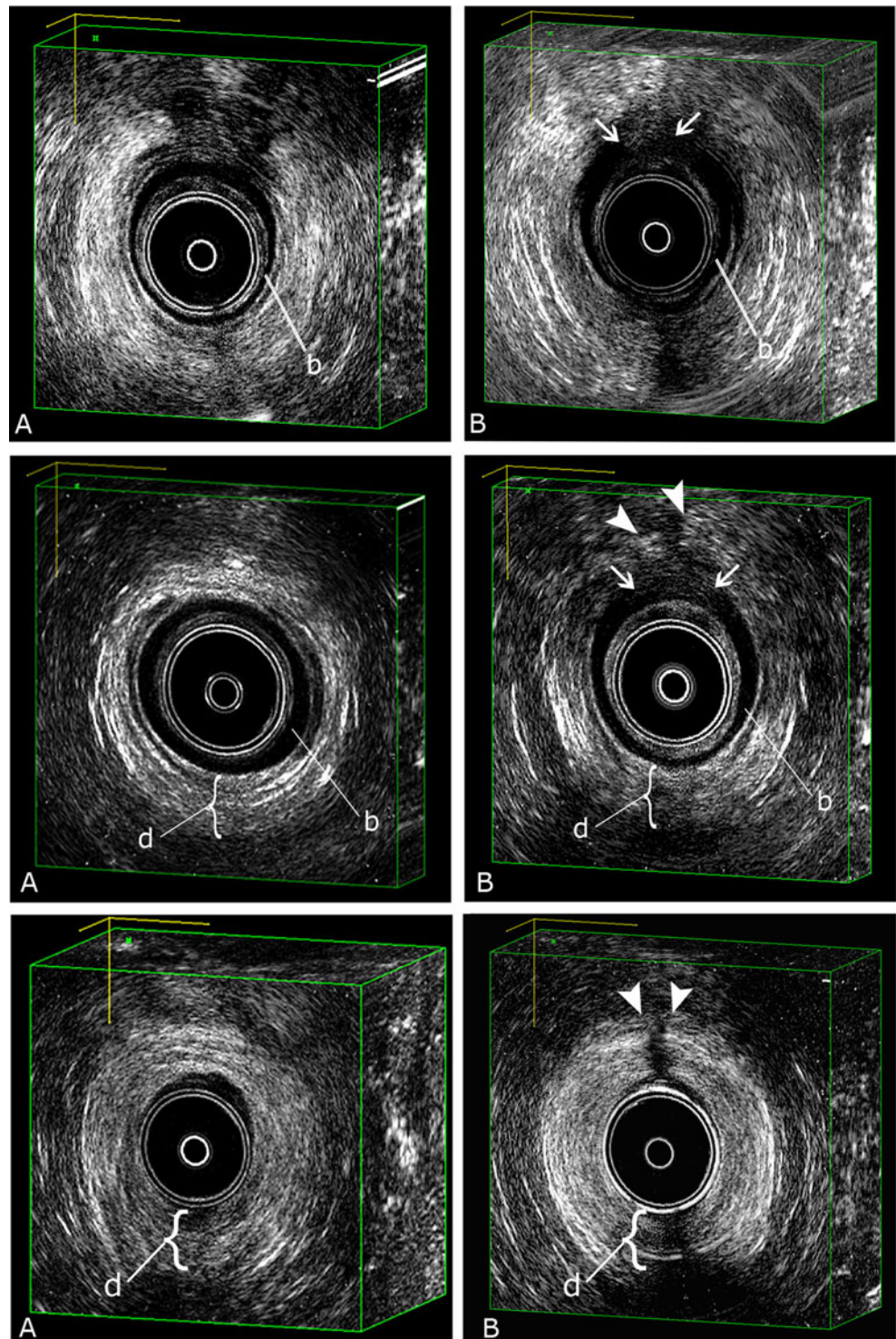
Fig. 2 Line drawings (*top panel*) and representative ultrasound images (*bottom panel*) of anal canal levels evaluated by endoanal sonography (cross-sectional views). High anal canal (A). Drawing and image on the *left* (A1) depicts the lowest level at which puborectalis muscle sling (*) is noted, and drawing and image on the *right* (A2) illustrates the high anal canal 1–5 mm below the puborectalis sling. Mid anal canal (B).

Low anal canal (C). From inner to outer, anatomic structures labeled on the line drawings include: anal submucosa (a), internal anal sphincter (b), longitudinal muscle (c), and external anal sphincter (d). RVW rectovaginal wall, PB perineal body. Note that on the ultrasound images, evaluation of the external anal sphincter (d) included the longitudinal muscle (c)

anal submucosa in the high or mid anal canal level (Fig. 3). An *external anal sphincter defect* was defined as a loss of continuity in the concentric hyper or mixed echogenic ring surrounding the internal sphincter in the mid anal canal, or as a loss of continuity of the external anal sphincter ring in the low anal canal (Fig. 3). If the external anal sphincter did not form a complete ring anteriorly prior to the termination

of the internal anal sphincter, this was also classified as an external anal sphincter defect in the mid anal canal. Anal sphincter defects were only recorded if noted in the anterior half of the anal canal, as defects in this location are most likely associated with obstetric injury [1]. Defects were also annotated by clock face position to the nearest hour, with anterior midline as the 12 o'clock position. The primary

Fig. 3 Representative cross-sectional images of normal (A) and abnormal (B) findings at each of the three levels of the anal canal evaluated. *Top panel* depicts the high anal canal, *mid panel* the mid anal canal, and *lower panel* the low anal canal. Internal anal sphincter (b); external anal sphincter (d). Arrows indicate lateral borders of internal anal sphincter defects and arrowheads indicate borders of external anal sphincter defects



outcome of this study was the overall number of anal sphincter defects (internal and/or external) diagnosed using stored 3-D endoanal sonography data. *Partial* defects of the internal anal sphincter, i.e., defects noted in the high or mid anal canal only, were annotated as an internal anal sphincter defect. Similarly, *partial* external anal sphincter defects, i.e., those noted in the mid or low anal canal only, were recorded as external anal sphincter defects.

Statistical analysis

The primary outcome measure is any anal sphincter defect (internal and/or external sphincter) diagnosed using stored 3-D endoanal sonography data obtained within 72 h of childbirth. Assuming a rate of occult anal sphincter defects of 20 % in primiparous women, which is approximately the midpoint rate reported in the literature [13], 96 participants provided a point estimate with a degree of precision of $\pm 10\%$ at a confidence level of 95 %. We increased this sample to 114 in anticipation of a 15 % dropout rate. Statistical analyses included standard analysis for rates and proportions including Pearson chi-square. A p value < 0.05 was considered significant. Assessment of agreement for categorical data was made using the kappa statistics [23] and 95 % confidence intervals (CI). Kappa values of < 0.40 were considered poor to slight agreement, 0.41–0.60 fair to moderate, 0.61–0.80 good, and 0.81–1.00 very good agreement [24].

The intraobserver agreement in diagnosing any sphincter defect (internal and/or external) was based on repeated interpretation of stored 3-D volumes obtained by the sonographer (MMC). A minimum of 8 weeks was allowed between readings in order to minimize recall bias. For assessment of interobserver agreement, an independent examiner (DMT), unaware of the sonographer's readings, interpreted the 3-D data. The sonographer, a female pelvic medicine and reconstructive surgeon, and the independent examiner, a radiologist, had extensive experience in interpreting endoanal sonography data. The data entered by the second examiner were compared to the first 3-D reading by the sonographer. All data were entered in a study form developed for this study.

Statistical analyses were performed using SAS, version 9.2 (SAS Institute, Cary, NC, USA).

Results

A total of 1,392 consecutive primiparous women delivered vaginally at term were screened for participation in this study and 1,301 without anal sphincter lacerations were identified. A total 206 of these women were approached and 114 were enrolled in this study (Fig. 4). Of the 114 women who underwent endoanal sonography, 107 had stored 3-D data that were deemed interpretable by the

sonographer. The remaining seven 3-D studies were not interpretable due to technical errors during the data saving stage at the completion of the procedure. The endoanal ultrasound examination was completed in an average of 5 min and all enrolled women tolerated the procedure well. None of the 107 women who underwent endoanal sonography reported episodes of anal incontinence after delivery.

Demographic characteristics for the women who underwent endoanal sonography as well as those who did not are shown in Table 1. Shown in Table 2 are obstetric characteristics possibly related to anal sphincter defects. Fifty-four percent of women with sonographic sphincter defects had second-degree lacerations compared to 20 % in those without, p 0.008. In 2009, the year during which the study was conducted, 14,343 women were delivered at Parkland Hospital. Of these, 4,333 (30 %) were delivered by cesarean, 7,353 (51 %) received epidurals, 311 (3 %) were instrumental deliveries, and 358 (4 %) had an episiotomy.

As shown in Fig. 4, 13 (12.1 %) women had sonographic anal sphincter defects detected by initial examination of the stored 3-D data. Anal sphincter defects were consistently identified between the 10 and 2 o'clock positions. As also shown in Fig. 4, we extrapolated the rates of sonographically detected defects and clinically diagnosed anal sphincter lacerations to the entire screening cohort of eligible women and estimated that approximately 17.8 % of the cohort overall sustained anal sphincter injury.

The intraobserver agreement for the diagnosis of anal sphincter defects (internal and/or external) using 3-D sonographic data was 0.82 (CI 0.66–0.99) and the interobserver agreement was 0.72 (CI 0.54–0.92) (Table 3).

Discussion

The central finding in this study is that sonographic anal sphincter defects were more common than sphincter lacerations identified clinically. Specifically, about 12 % of women evaluated by 3-D endoanal sonography were diagnosed with sphincter disruption compared to 6.5 % clinically diagnosed at delivery. In the aggregate, we estimate that almost 18 % of primiparous women delivered vaginally at term sustained either clinical or sonographic anal sphincter injury.

Intra- and interobserver agreement with respect to overall sphincter defects diagnosed by examination of stored 3-D images was very good and good, with kappa values of 0.82 and 0.72, respectively [24]. These results are similar to those by Gold et al. who reported a very good interobserver agreement (kappa = 0.80) for diagnosis of sphincter disruption in 51 consecutive patients examined with two-dimensional (2-D) endoanal sonography for possible sphincter abnormalities [25]. Although earlier data on sphincter defects largely relied on evaluation of 2-D axial ultrasound images, 3-D

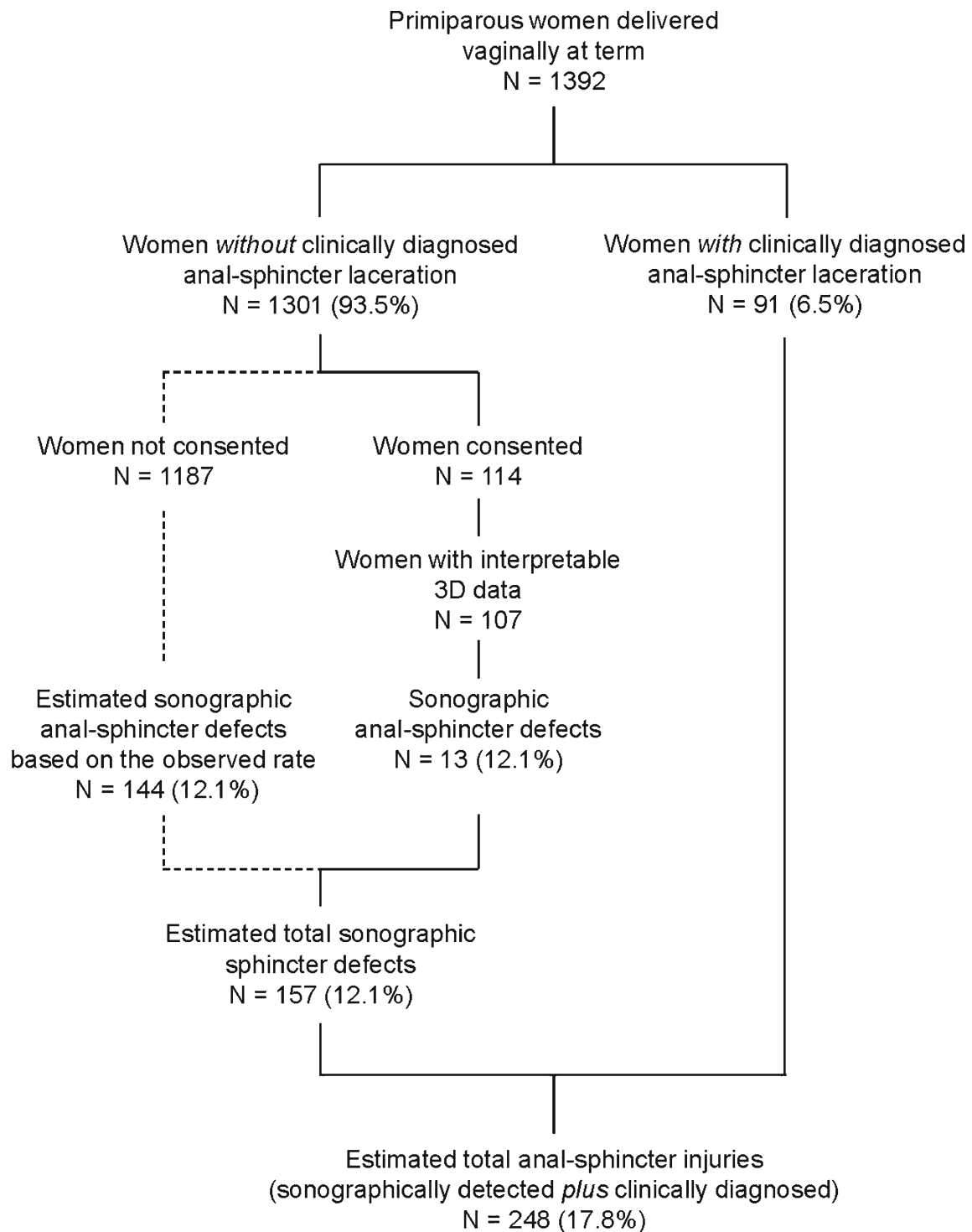


Fig. 4 Distribution of eligible women delivered during the study period

imaging provides the opportunity to obtain axial, sagittal, coronal, and oblique sectional images of the anal canal. It also allows easy management of the data set, which is obtained as a vector volume from different angles, to define the precise location and extension of the sphincter defect(s). In addition,

the length of various anal canal structures and subsequent volume measurements can be obtained.

Another significant finding in this study was the association of sonographically detected anal sphincter defects with second-degree perineal lacerations. A possible interpretation

Table 1 Demographic characteristics of 107 primiparous women who underwent three-dimensional endoanal sonography and all other primiparous women who delivered within the study period

Characteristic	3-D US, <i>n</i> =107	All other, <i>n</i> =1,187	<i>p</i> value
Age, years	21.4±4.3	22.8±5.3	0.01
Race/ethnicity			0.44
Hispanic	89 (83)	928 (78)	
African-American	13 (12)	152 (13)	
White	4 (4)	71 (6)	
Other	1 (1)	36 (3)	
BMI, kg/m ²	30.1±4.7	31.2±6.1	0.08

All data shown as *n* (%) or mean (± SD)

BMI body mass index

of this finding is that second-degree lacerations are “markers” for perineal trauma sufficient to cause anal sphincter injury. This could be of value in signaling the need to further digitally explore the anal canal for all second-degree lacerations in order to minimize misdiagnosis of anal sphincter lacerations. Indeed, Groom and Paterson-Brown showed that the rate of third-degree lacerations rose to 15 % when all *second-degree* lacerations were reevaluated [26]. Similarly, Andrews et al. showed that the prevalence of anal sphincter lacerations increased from 11 to 24.5 % when primiparous women were reexamined [14]. Exploration of second-degree lacerations can be done by placing the index finger of the nondominant hand in the anal canal and distal rectum and using the index

Table 2 Selected obstetric characteristics in women with and without ultrasonographic (US) anal sphincter defects diagnosed by examination of stored 3-D data

Characteristic	US sphincter defect, <i>n</i> =13	No US sphincter defect, <i>n</i> =94	<i>p</i> value
Forceps	0	0	–
Midline episiotomy ^a	2 (15)	5 (5)	0.169
Second stage labor >2 h	1 (8)	3 (3)	0.423
Epidural analgesia	11 (85)	69 (73)	0.383
Birth weight ≥4,000 g	1 (8)	5 (5)	0.727
First-degree ^b perineal laceration	9 (69)	50 (53)	0.276
Second-degree ^b perineal laceration	7 (54)	19 (20)	0.008

All data shown as *n* (%)

^a Midline episiotomy was defined as an intentional second-degree laceration. Episiotomies are not routinely performed at Parkland Hospital

^b First-degree perineal lacerations were those with vaginal epithelium and/or perineal skin interruption; second-degree lacerations included those extending into the bulbospongiosus and/or superficial transverse perineal muscles

Table 3 Agreement between the two observers for the presence of external and internal anal sphincter defects using stored 3-D endoanal sonography data

Observer 2 (MMC)	Observer 1 (DMT)			Total
	Intact IAS & EAS	IAS defect	EAS defect	
Intact IAS & EAS	93	1	0	94
IAS defect	2	2	1	5
EAS defect	1	1	6	8
Total	96	4	7	107

Simple kappa = 0.72

EAS external anal sphincter, IAS internal anal sphincter

and middle fingers of the dominant hand to separate the edges of the laceration in order to expose the deepest extent of the tear.

There is wide variation in the reported incidence of sonographic anal sphincter defects in primiparous women with rates ranging from 11 to 35 % [13]. Similar to clinically diagnosed sphincter lacerations, variations in rates of sonographic defects likely reflect variations in obstetric practice, including episiotomy use, which was shown in a previous study to vary between 20 and 70 % in individual units in the USA [27]. The episiotomy rate, a powerful marker for anal sphincter lacerations, is very low at Parkland Hospital compared to US rates. Specifically, about 6 % of women delivered at Parkland receive episiotomies. This, in concert with a formalized provider training program on anal sphincter lacerations and standardized reporting of endoanal sonography findings, may account for the lower rates of sonographic defects found in this study.

A limitation of this study is the lack of antepartum anal sphincter sonographic assessment. However, in a previous study that evaluated 100 primiparous women using endoanal sonography, no sphincter defects were detected before delivery [1]. Another study limitation is the lack of functional outcomes, specifically anal incontinence in the women with sonographic evidence of sphincter disruption. However, postpartum anal incontinence is reported in approximately 30 % of women diagnosed with sonographic anal sphincter defects postpartum [13]. In addition, the effects of suture material and edema in the perineum on sonographic findings are not known. Nonetheless, this study establishes very good and good intra- and interrater agreement, respectively, using stored 3-D data analyzed by two evaluators from different subspecialties. Lastly, the use of an automated pulley to acquire 3-D images of the anal canal has increasingly been replaced with newer technology that uses an endocavitary probe or motor action within the transducer itself so there are no moving parts in contact with the patient. Although the technology for scanning the anal canal is older, the frequency of the transducer (10 MHz) and

acquisition settings are similar to those used with the newer equipment and probes. In addition, initial data on the use of 3-D endoanal sonography for evaluation of the anal sphincter anatomy were largely obtained using the motorized withdrawal system [28, 29].

The burden of anal incontinence on women's health and well-being is large. Anal sphincter injury sustained during childbirth is a known risk factor for postpartum anal incontinence. Indeed, approximately 50 % of women with clinically diagnosed sphincter lacerations go on to develop anal incontinence later in life [9–12]. This highlights the need for further research where labor management interventions that could prevent or reduce the rates of such injuries are examined. Our results suggest that sonographically detected anal sphincter defects in primiparous women may be important in designing clinical trials that evaluate the role of obstetric interventions intended to reduce anal sphincter injury. Our results should not however be construed to mean that all primiparous women without clinical anal sphincter lacerations should undergo ultrasound examination postpartum. Rather, emphasis should continue to be placed on accurate classification of perineal lacerations at the time of delivery, with thorough examination of the rectovaginal wall and perineum in all women following delivery.

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Conflicts of interest None.

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