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Underdiagnosis of internal anal sphincter trauma following vaginal delivery

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KEYWORDS: birth trauma; endoanal ultrasound; fecal incontinence; OASI; obstetric anal sphincter injury; perineal trauma

CONTRIBUTION

What are the novel findings of this work?

In a contemporary cohort of women with anal sphincter injury, 10% of women referred with a Grade-3a/3b tear have some degree of damage to their internal anal sphincter (IAS) and sphincter tone is reduced in women with IAS trauma 6 months after delivery, regardless of tear grade at referral.

What are the clinical implications of this work?

These findings indicate that a significant proportion of IAS trauma is missed at the time of initial diagnosis of obstetric anal sphincter injury. Clinicians should have a high index of suspicion for IAS trauma in any woman who has reduced sphincter tone following the repair of a Grade-3a/3b tear diagnosed after a vaginal delivery.

ABSTRACT

Objective Damage to the anal sphincter during childbirth remains the leading cause of fecal incontinence in women. Defects in the internal (IAS) or external anal sphincter, alongside symptoms and sphincter tone, will generally dictate the suggested mode of delivery in any successive pregnancy. This study aimed to examine using endoanal ultrasonography the prevalence of IAS damage in women referred with Grade-3a or -3b obstetric anal sphincter injury (OASI) in a tertiary-referral perineal clinic.

Methods This was a retrospective observational study of all women referred to a tertiary-referral perineal clinic after primary repair of OASI (Grade 3a-c, 4) diagnosed for the first time following vaginal delivery between January 2016 and December 2019, inclusive. Women were assessed using the Wexner bowel continence questionnaire, digital examination of sphincter tone and endoanal ultrasound. Injuries in each sphincter were classified as a scar ($\leq 30^{\circ}$) or defect (> $30-90^{\circ}$ or > 90°) on endoanal imaging in the axial plane.

Results In total, 615 women were referred following primary repair of OASI. Sonographic evidence of damage to the IAS was seen in 9.1% (46/506) of women diagnosed with a Grade-3a/3b injury. In women referred with a Grade-3a/3b tear, symptom scores were statistically higher (P = 0.025) in those with an IAS defect $> 30^{\circ}$ compared to those with an intact or scarred IAS, although the median score was zero in both groups. The proportion of women in each group with severe symptoms (score > 9) was similar (2.6% vs 6.5%; P = 0.148). Among women referred with a Grade-3a/3b tear, sphincter tone was reduced more frequently in those with a defect of the IAS than in those with an intact or scarred IAS (52.2% vs 11.7%; odds ratio, 8.14 (95% CI, 4.26-15.67); P < 0.001). Regardless of the reason for referral, women with reduced sphincter tone on rectal examination were four times as likely to have had an IAS defect $> 30^{\circ}$ than were those with normal resting tone (risk ratio, 4.58 (95% CI, 3.25–6.45); P < 0.001).

Conclusions One in 11 women diagnosed with a Grade-3a or -3b tear have evidence of damage to their IAS on endoanal ultrasound. Damage to this muscle is linked to fecal incontinence in women and can have a significant impact on the planning of any future deliveries. This study highlights the importance of established perineal clinics with access to ultrasound. Nonetheless, if reduced sphincter tone is felt on rectal examination, a clinician should have a high index of suspicion for an occult IAS injury. © 2022 The Authors. Ultrasound in Obstetrics & Gynecology published by John Wiley & Sons Ltd on behalf of International Society of Ultrasound in Obstetrics and Gynecology.

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INTRODUCTION

Anal sphincter trauma during childbirth represents the most important risk factor for the development of fecal incontinence in women¹. Damage to the anal sphincter complex occurs in 1-3% of vaginal deliveries, and functional outcomes are linked to the severity of the tear¹. Damage to the internal anal sphincter (IAS) has been highlighted as a risk factor for anal incontinence², although this is debated³. Misdiagnosis of IAS trauma following vaginal delivery has been reported internationally⁴. The importance of this muscle and its repair has been recognized for more than 20 years, and dedicated training programs have been shown to increase the rate of successful repair⁵.

There is growing interest in multiple imaging modalities, such as translabial or introital ultrasound, for the diagnosis of obstetric anal sphincter injury (OASI), especially for use in a 'rule-out' capacity⁶. Endoanal⁷ and translabial⁸ ultrasound have been found to be in good agreement for the diagnosis of sphincter trauma^{9,10}, though validation of both for the IAS is limited¹¹. Despite these advances in imaging technology, the diagnosis of OASI immediately following delivery is based on clinical suspicion and the accoucheur's clinical acumen. As with all obstetric skills, there is variation in awareness of OASI among clinicians, thus there is the potential for anal sphincter injuries to be underdiagnosed or 'overlooked'5. This study aimed to examine the prevalence of IAS damage in women referred with Grade-3a or -3b OASI using endoanal ultrasonography and the effect of IAS damage on symptom scores and clinical findings in a tertiary-referral perineal clinic.

METHODS

This was a retrospective observational study of all women referred to a tertiary-referral perineal clinic following primary repair of OASI (Grade 3a-c, 4) diagnosed for the first time following vaginal delivery between January 2016 and December 2019, inclusive. As part of their initial clinic visit, each patient was evaluated in the following standardized order: medical history, completion of a bowel continence questionnaire¹², clinical examination, including assessment of sphincter tone, and endoanal ultrasound. These assessments were typically made by the same person, who was therefore blinded to neither the clinical information nor clinical assessment before performing endoanal ultrasound. Women attended the clinic 6 months after delivery and repair of the OASI. Examinations and ultrasonography were performed by an experienced consultant, advanced midwifery practitioner or senior urogynecology trainee.

Women were coded in the database according to the referring healthcare professional's opinion of the grade of the tear. Sphincter injuries were classified as Grade 3a, 3b, 3c or 4 depending on the thickness of the tear and any involvement of the IAS or rectal mucosa, as per the guidelines of the Royal College of Obstetricians and Gynaecologists (RCOG)¹³. While we do not have details for each case, in Ireland, the diagnosis of OASI is generally made, or confirmed, by an obstetrician with more than 3 years of postgraduate experience in obstetrics. Maternal demographics, obstetric variables related to delivery, sphincter tone on rectal examination and endoanal ultrasound findings were extracted from the database. Patients with a known history of anorectal disease, previous anal sphincter injury, irritable bowel disease or inflammatory bowel disease were not included in the study. This review used irrevocably anonymized data from an institutional hospital database and was sanctioned by the Research and Ethics Committee of the National Maternity Hospital, Dublin, Ireland (reference: EC. 34 2020).

Continence questionnaire

Each woman who attended the clinic completed a bowel function questionnaire devised by Jorge and Wexner¹². A Wexner score (0, perfect continence; 20, complete incontinence) was assigned based on the presence of flatal incontinence, fecal soiling, fecal incontinence and fecal urgency, and the impact of these symptoms on daily activities. Previous research has shown that a score > 9 indicates severe symptoms sufficient to impair significantly the patient's quality of life¹⁴.

Assessment of sphincter tone

Sphincter tone was assessed digitally by the examiner following history taking but before endoanal ultrasonography. Resting tone was recorded as either 'normal' or 'reduced' based on the examiner's assessment. Anal manometry was not performed.

Endoanal ultrasound

Endoanal ultrasound was conducted using a BK3000 scanner with a 20R3 rectal endoprobe (Bruel and Kjaer, Naerum, Denmark). The endoanal probe has a motorized rotating transducer, which captures 360° axial images within the anal canal⁷. Axial images were recorded at the level of the puborectalis sling and IAS, and at the superficial and subcutaneous levels of the external anal sphincter (EAS) complex, with the woman in the left lateral position, as described previously¹⁵. Injuries in each sphincter were recorded separately and were classified as a scar if $\leq 30^{\circ}$ or as a defect if $> 30^{\circ}$ in an axial image. If the injury was $> 30^{\circ}$, it was classified either as $\leq 90^{\circ}$ or $> 90^{\circ}$ (Figure 1).

Study outcomes

The primary outcome of this study was the proportion of women referred with Grade-3a/3b OASI who had a defect of their IAS on endoanal ultrasonography at 6 months postdelivery. Secondary outcomes were differences in



Figure 1 Endoanal ultrasound images at superficial level of internal anal sphincter, showing intact muscle (a) and 180° defect (b).

demographics, symptom scores and sphincter tone between women with different degrees of OASI and IAS damage. Results were analyzed for our entire cohort and in vaginally primiparous women separately.

Statistical analysis

No formal sample size or power calculations were performed. Instead, the sample size for this study was based on the availability of clinical referrals in our hospital database between January 2016 and December 2019 when the degree of OASI diagnosed at the time of the original repair was recorded for each woman. Before this period, women were recorded as 'OASI', with the degree of tear not specified. After December 2019, there was a change in the maintenance of our hospital database due to software issues and the coronavirus-19 pandemic.

Symptom scores had a non-normal distribution and were right-skewed, that is, most women had a score of zero, and so were compared between groups using the Mann-Whitney U-test. Endoanal ultrasound findings were classified as intact, scar $(0-30^{\circ})$, $> 30-90^{\circ}$ and $>90^{\circ}$, and were analyzed using the χ -square test. For the analysis of residual defects or 'missed Grade-3c tears', Grade-3a/3b tears were reclassified according to IAS integrity. The clinical referral was recorded in our database as per RCOG guidelines, but was categorized into minor (Grade 3a/3b, IAS supposedly intact) and major (Grade 3c/4, IAS disrupted) injuries. Categorical variables were analyzed using the χ -square test or Fisher's exact test, as appropriate. Maternal age and neonatal birth weight were analyzed using Student's t-test. Two-tailed P-values were used throughout, and P < 0.05 was considered to indicate statistical significance. Statistical analysis was performed using R version 4.0.2 (R Foundation for Statistical Computing, Vienna, Austria).

RESULTS

Demographics

Between January 2016 and December 2019, 615 women were referred with OASI. The median age was 33 years (mean, 33 years; range, 18-45 years) and median parity was 1 (range, 1-4). Of the 615 women, 437 (71.1%) were primiparous. Regarding mode of delivery, 58.5% (360/615) of women had a spontaneous vaginal delivery, 17.1% (105/615) were delivered by vacuum extraction only, 14.1% (87/615) were delivered using forceps alone and 10.2% (63/615) were delivered using sequential instruments (failed vacuum then forceps delivery). Of the 615 women, 258 (42.0%) were referred with a Grade-3a tear, 248 (40.3%) with a Grade-3b tear, 67 (10.9%) with a Grade-3c tear and 42 (6.8%) with a Grade-4 tear. A summary of the demographic characteristics of our study population according to grade of tear at referral is given in Table 1.

Primary outcome

Of 506 women referred with a Grade-3a/3b tear, 46 (9.1%) had an IAS defect of $> 30^{\circ}$ on endoanal ultrasonography (Table 1). Of 460 women with a Grade-3a/3b tear and an IAS defect of $\leq 30^{\circ}$, 18 (3.9%) had evidence of scarring of their IAS.

Secondary outcomes

Of those women referred with a Grade-3a/3b tear, 6.5% (33/506) had an intact EAS, while 40.4% (44/109) of those diagnosed with a Grade-3c/4 tear had an intact IAS and 2.8% (3/109) had an intact EAS. Among women diagnosed with a Grade-3a/3b tear at referral, a higher number of significant EAS defects were noted in those with IAS damage.

 Table 1 Demographic and clinical characteristics of women referred with Grade-3a/3b tear and those referred with Grade-3c/4 tear

	Stage of tear			
Parameter	3a/3b (n = 506)	3c/4 (n = 109)	Р	
Maternal age (years)	33 ± 4	33.5 ± 4	0.252+	
Primiparous	362 (71.5)	75 (68.8)	0.649	
Mode of delivery	× ,	. ,	0.028	
Spontaneous vaginal	306 (60.5)	54 (49.5)		
Vacuum	87 (17.2)	18 (16.5)		
Forceps	69 (13.6)	18 (16.5)		
Sequential instrumental*	44 (8.7)	19 (17.4)		
Episiotomy	206 (40.7)	41 (37.6)	0.641‡	
Birth weight (g)	3709 ± 459		0.216	
Symptom score	0(0-2)	1(0-4)	< 0.001	
Severe incontinence	15 (3.0)	8 (7.3)	0.046¶	
(score > 9)				
Endoanal ultrasound				
External anal sphincter			< 0.001	
Intact	33 (6.5)	3 (2.8)		
$\leq 30^{\circ}$	397 (78.5)	64 (58.7)		
> 30-90°	71 (14.0)	35 (32.1)		
> 90°	5 (1.0)	7 (6.4)		
Internal anal sphincter			< 0.001	
Intact	442 (87.4)	44 (40.4)		
$\leq 30^{\circ}$	18 (3.6)	14 (12.8)		
- 30-90°	39 (7.7)	35 (32.1)		
> 90°	7 (1.4)	16 (14.7)		
Reduced anal tone	78 (15.4)	38 (34.9)	< 0.001‡	

Data are given as mean \pm SD, *n* (%) or median (interquartile range). *Failed vacuum and proceeded to forceps. †Student's *t*-test. χ -square test. Mann-Whitney U-test. ¶Fisher's exact test.

Table 2 Demographic and clinical characteristics of women				
referred with Grade-3a/3b tear, according to integrity of internal				
anal sphincter (IAS)				

Parameter	Intact IAS or $\leq 30^{\circ} scar$ (n = 460)		Р
Maternal age (years)	33 ± 4	33 ± 4	0.480†
Primiparous	334 (72.6)	28 (60.9)	0.131‡
Mode of delivery			0.573‡
Spontaneous vaginal	278 (60.4)	28 (60.9)	
Vacuum	81 (17.6)	6 (13.0)	
Forceps	60 (13.0)	9 (19.6)	
Sequential instrumental*	41 (8.9)	3 (6.5)	
Episiotomy	192 (41.7)	14 (30.4)	0.172§
Birth weight (g)	3708 ± 465	3714 ± 404	0.924†
Symptom score	0 (0-2)	0 (0-3)	0.025¶
Severe incontinence (score > 9)	12 (2.6)	3 (6.5)	0.148‡
External anal sphincter on ultrasound			< 0.001
Intact	33 (7.2)	0 (0)	
\leq 30°	383 (83.3)	14 (30.4)	
- > 30-90°	43 (9.3)	28 (60.9)	
> 90°	1 (0.2)	4 (8.7)	
Reduced anal tone	54 (11.7)	24 (52.2)	< 0.001§

Data are given as mean \pm SD, *n* (%) or median (interquartile range). *Failed vacuum and proceeded to forceps. †Student's *t*-test. ‡Fisher's exact test. χ -square test. ¶Mann–Whitney *U*-test.

The median symptom score was higher in women referred with a Grade-3c/4 tear than in those with a Grade-3a/3b tear (1 *vs* 0; P < 0.001), and the proportion of women with severe symptomatology (score > 9) was higher in the Grade-3c/4 group (7.3% *vs* 3.0%; P = 0.046). Among women referred with a Grade-3a/3b tear, symptom scores were statistically higher (P = 0.025) in those with an IAS defect of > 30° than in those with an intact or scarred IAS, although the median score was zero in both groups (Table 2). However, the proportion of women in each group with severe symptoms was similar (2.6% *vs* 6.5%; P = 0.148).

Among women referred with a Grade-3a/3b tear, sphincter tone was more frequently reduced in those with an IAS defect of > 30° than in those with an intact or scarred IAS (52.2% *vs* 11.7%; odds ratio (OR), 8.14 (95% CI, 4.26–15.67); P < 0.001). Sphincter tone was recorded as reduced in 34.9% of women referred with a Grade-3c/4 tear, compared with 15.4% of women with a Grade-3a/3b tear (OR, 2.93 (95% CI, 1.84–4.65); P < 0.001). Regardless of tear characterization at referral, women with reduced sphincter tone on rectal examination were four times as likely to have had an IAS defect of > 30° than were those with normal resting tone (risk ratio, 4.58 (95% CI, 3.25–6.45); P < 0.001).

When the analysis based on grade of tear at referral was repeated in vaginally primiparous women, the findings were similar to those of the overall cohort (Table S1). However, incontinence symptoms, as measured by median symptom score and proportion of those with a score of > 9, did not differ significantly in primiparous women referred with a Grade-3a/3b tear according to IAS integrity (Table S2). As seen in our overall cohort, there was a higher rate of EAS defects in the group with IAS damage (Table S2).

DISCUSSION

Principal findings

This study has shown that one in 11 cases of clinical Grade-3a and -3b OASI involves an undiagnosed sonographic defect in the IAS. Given the size of our unit and the long-term nature of the data collection, this underdiagnosis probably represents a systematic issue, rather than poor diagnosis by a limited number of clinicians. Among women referred with Grade-3a/3b OASI, those with IAS damage noted on endoanal ultrasound had worse symptom scores than did those without IAS damage, although the proportion of women with severe symptoms was similar and these effects were not seen in vaginally primiparous women. Additionally, women with undiagnosed IAS defects had a higher number of significant EAS defects, which may have affected symptom scores. Reduced sphincter tone on rectal examination was associated with a four-fold increase in the risk of injury to the IAS.

A UK study reported that 11.4% of women referred with a Grade-3a/3b tear had some degree of defect in their IAS⁴. This study used three-dimensional imaging and the Starck score¹⁶, unlike the two-dimensional imaging presented here. Despite this, women diagnosed incorrectly as having a Grade-3a/3b tear had higher symptom scores than did those with an intact IAS, as reported in our work. A Scandinavian study reported that IAS defects were overlooked in only 3% of tears repaired according to a standardized protocol involving thorough examination of the IAS and EAS, compared with 10.7% of those repaired conventionally¹⁷. This study suggests that the rate of unrecognized IAS injuries can be minimized with h formal training.

Overdiagnosis of OASI has been highlighted previously¹⁸, although the precise reason for this remains unclear. Our data showed that 6.5% of women referred with a Grade-3a/3b tear and 2.8% of women referred with a Grade-3c/4 tear had no evidence of sphincter injury on endoanal ultrasound. Physician anxiety relating to a 'missed' injury may be contributory, however the cause of this phenomenon is likely to be multifactorial and may be institution-specific.

In units without access to ultrasound or manometry diagnostic modalities, an IAS defect may easily be missed. While women without anal sphincter compromise are unlikely to develop *de-novo* anal incontinence post-natally^{19,20}, one analysis reported that up to 75% of women with sphincter compromise will go on to develop anal incontinence if they deliver vaginally¹⁹, though the number of women with IAS defects in this study was small. While the optimal management of women following OASI remains unknown, the status of the IAS should play a part in planning any future deliveries.

Decreased tone on examination of the anal sphincter was highlighted as a marker for IAS damage in our analysis, and previous studies using anal manometry have shown reduced resting pressures in women with IAS defects^{1,21}. In the present study, women referred with a Grade-3a/3b tear with evidence of IAS damage had a higher number of EAS defects than did those with an intact or scarred IAS, which may have contributed to the decrease in sphincter tone. The findings here suggest that reduced resting tone on rectal examination should prompt further investigation and ultrasound imaging of the anal sphincter complex.

The association between tear severity and symptomatology has not been observed in the longer term^{22,23}, and indeed the etiology of long-term fecal incontinence is multifactorial, with incontinence being seen even in nulliparous women²⁴. Despite this, a recent study strongly linked OASI to anal or fecal incontinence in later life²⁵. This study did not examine grades of OASI specifically and so could not discern the effect of IAS injury on long-term functional outcomes. Future work should assess the integrity of both sphincter muscles separately.

Strengths and limitations

We used a well-validated imaging modality^{7,9} to assess any sphincter defects and a validated symptom scoring system¹². While endoanal ultrasound is a recommended form of imaging, the appearance of a 'normal' IAS has not been examined as thoroughly as that of a 'normal' EAS. The specificity of endoanal ultrasound to rule out IAS injury is unclear, which may have influenced our results. Thus, while we found significant IAS defects in women with supposedly intact sphincters, our imaging of the IAS, and that done in other centers using endoanal ultrasound, should be interpreted with caution. Image sets were analyzed by a limited number of experienced clinicians with training in endoanal ultrasonography. Similarly, rectal examinations were performed by the same limited number of clinicians, which should decrease interobserver variability.

No standardized definition exists for a missed IAS tear. We utilized the criterion of a defect of $> 30^{\circ}$ and applied this criterion consistently, highlighting what we feel to be a group of 'true' missed IAS tears. While this measurement is included in the widely used Starck score for three-dimensional imaging¹⁶, it may have potentially underestimated the incidence of undiagnosed IAS trauma. Similarly, while measures of defect length are included in both the Starck¹⁶ and Norderval²⁶ scores, these were not available in our cohort. These criteria are used widely and correlate well with symptom scores, but may not be appropriate for two-dimensional imaging and should be validated clinically in future research. Study investigators were not blinded to clinical details before performing ultrasound. A review of image sets by a blinded reviewer could alleviate this. Moreover, sphincter tone was assessed by digital examination rather than by manometry and so could be subject to bias. Finally, owing to the nature of our institutional database, we were not able to analyze individual components of the total Wexner score.

Conclusions

One in 11 women diagnosed with Grade-3a or -3b OASI suffered damage to their IAS, damage to this muscle being linked to poorer functional outcomes. Diagnosis of IAS trauma can be made definitively using endoanal or translabial ultrasonography, and this study highlights the importance of a perineal clinic with access to one of these imaging modalities. Regardless of ultrasound findings, if reduced tone is felt on rectal examination, a clinician should have a high index of suspicion for an IAS injury.

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SUPPORTING INFORMATION ON THE INTERNET

The following supporting information may be found in the online version of this article:

Table S1 Demographic and clinical characteristics of vaginally primiparous women referred with Grade-3a/3b tear and those referred with Grade-3c/4 tear

 Table S2 Demographic and clinical characteristics of vaginally primiparous women referred with Grade-3a/3b

 tear according to integrity of internal anal sphincter