**Title page**

Title: Is there a role for transperineal ultrasound imaging of the anal sphincter immediately after primary repair of third degree tears?

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**Financial Disclaimers/Conflict of Interest statement:** None

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**Abstract (250 words)**

**Objective:**

When obstetric anal sphincter injuries are identified, it is crucial that the defects are repaired appropriately to achieve a better outcome. Although the presence of an intact anal sphincter is not the sole mechanism for maintaining continence, and not all women with an anal sphincter defect are symptomatic, there is an association between sphincter defects and anal incontinence. Our aim was to evaluate whether transperineal ultrasound (TPUS) is useful in assessing anal sphincter integrity immediately following primary repair of obstetric anal sphincter injuries (OASIs).

**Study Design:**

This is a prospective observational study of women who sustained OASIs during their first vaginal delivery. Three dimensional (3D) TPUS was performed immediately after repair of OASIs to identify anal sphincter defects*.* A repeat TPUS was performed 12 weeks following repair.

**Results:**

21 women sustained OASIs of whom 20 (95%) attended follow up. Eight (40%) had a grade 3a tear and 12 (60%) a 3b tear.

8/20 (40%) women had residual external anal sphincter (EAS) defects identified by TPUS immediately after repair. Of these eight defects, six (75%) persisted at 12 weeks postpartum. No new defects were seen at follow up among the twelve women in whom no defect was seen immediately following the repair.

Six residual EAS defects were found at 12 weeks postpartum. An EAS defect at 12 weeks postpartum was associated with anal incontinence (p = 0.04). Women with 3b tears were more likely to have anal incontinence (AI) and residual sonographic EAS defects when compared with 3a tears but this was not statistically significant.

**Conclusions:**

Women who had no TPUS defect detected immediately following primary repair of OASIs, remained as such at 12 weeks postpartum. Of those in whom a defect was seen immediately after repair, it persisted in 75% of cases at 12 weeks. We believe that the value of TPUS immediately after repair appears to be limited and would need to be defined if it were to be considered for routine practice. Further research on its role immediately after repair of major tears (Grade 3C/4) is needed. In addition, performing ultrasound would require widespread training of obstetricians to develop expertise. This highlights the importance of adequate training of obstetricians in OASI repair.

**Keywords:** transperineal ultrasound; anal incontinence; obstetric anal sphincter injuries; third-degree tears; childbirth

**Brief summary:**

To evaluate whether transperineal ultrasound is useful in assessing anal sphincter integrity immediately following primary repair of obstetric anal sphincter injuries (OASIs).

**1.1 Introduction**

Anal incontinence (AI), is defined as the involuntary loss of flatus or faeces (1) and can have a devastating effect on women’s social, physical and mental well-being (2). It is a complex multifactorial condition (3) and obstetric anal sphincter injuries (OASIs) play an important role in the development of symptoms (4). The mean prevalence of AI following primary repair of OASIs is 39% [range 15-61%] (5), but this is probably an underestimation due to the embarrassing nature of the problem.

Despite primary repair, up to 92% of women have persistent anal sphincter defects on endoanal ultrasound (EAUS) (7). Although the presence of an intact anal sphincter is not the sole mechanism for maintaining continence (3), there is an association between anal sphincter defects and AI (6, 7). In a prospective study of 806 women, Sioutis et al (8) demonstrated that compared with those with an intact anal sphincter and those with a sphincter scar on EAUS, the St. Mark’s Incontinence Score (SMIS) was significantly higher in women with a residual sphincter defect.

When OASIs are identified, it is crucial that the defects are repaired by an appropriately trained clinician following an evidence based protocol to achieve a better outcome (13).

Endoanal ultrasound (EAUS) is a validated imaging technique (9) and regarded as the gold standard for the anal sphincter complex (1). However, it requires expertise, is expensive and is not readily available in all maternity units. Different imaging modalities have been used to evaluate the anal sphincter. Transperineal ultrasound (TPUS) (10) are widely available, and the images can be stored and analysed at a later date and also allow for imaging of the anal sphincter in all three orthogonal planes simultaneously. Furthermore, TPUS is associated with less discomfort in comparison to EAUS (10) and is likely to be more acceptable to patients.

Our aim was to evaluate whether three dimensional (3D) TPUS is useful in assessing anal sphincter integrity immediately following primary repair of OASIs.

**1.2 Materials and Methods**

All patients were recruited in a prospective longitudinal study over a 16-month period between March 2016 and June 2017 at University Hospital Lewisham, which involved TPUS immediately after primary repair of OASIs and at 12 weeks postpartum.

Women who sustained OASIs underwent a primary repair of their anal sphincter by the duty obstetrician.

3D TPUS was performed by a trained clinical research fellow (KW) immediately after delivery (prior to suturing), immediately after repair of OASIs and at follow up 10-12 weeks postpartum. 3D TPUS was performed at rest using a GE Voluson 730 system with a 4-8 MHz transabdominal curved array volume transducer. Women were scanned in the supine position with knees semi-flexed. A transverse transducer placement allows the probe to keep a minimal distance from the anal sphincter. The probe is then tilted to visualise the ‘U’ shaped puborectalis muscle. It is then angulated to obtain a transverse and longitudinal view of the whole anal sphincter sphincter complex. A minimum of three ultrasound volumes are acquire. Tomographic ultrasound imaging (TUI) is adjusted to obtain eight slices, with the interslice interval varying according to the individual sphincter length. Slice 1 corresponds to the puborectalis, slice 2 the most cranial aspect of the EAS (deep level), slice 3-6 to the superficial level and slice 7-8 images at the subcutaneous level. The EAS is imaged in slices 2-8 and the IAS in slices 2-6. The angle of the discontinuity of the ring of the EAS or IAS is measured immediately after repair of the OASI and at 10-12 weeks postpartum. An EAS defect is diagnosed when four or more of the six slices (between slice 2 and slice 7) show a discontinuity of at least 30 degrees in the ring of muscle of the external sphincter (mixed echoic ring) (11). KW analysed the ultrasound images 3-6 months after delivery, and was blinded to the clinical details. The scan findings were not conveyed to the patients.

Women completed the validated modified St. Mark’s Incontinence Score [SMIS] (12) in early labour to assess their bowel function pre-pregnancy, and this was repeated at 10-12 weeks later. Data was analysed with SPSS version 26 (Chicago, Illinois, USA). The study was approved by the South East Coast - Surrey Research Ethics Committee (REC 16/LO/2140).

**1.3 Results**

Of the 274 women who were invited, 264 (95%) agreed to participate, and 226 (86%) had a vaginal delivery. Twenty one (8%) women sustained an OASIs. Of these, one (5%) patient did not attend follow up at 10-12 weeks postpartum. Therefore, ultrasound volume data of 20 patients were analysed.

Eight (40%) women sustained a 3a tear and 12 (60%) had a 3b tear. The median time to follow-up was 84 days (range 65-109). All these women were delivered vaginally of whom 5 (25%) had a forceps delivery and none a vacuum extraction. All repairs were performed by obstetrician with different levels of experience (Table 1). Three out of the four doctors with less than 5 year’s experience repaired the OASI under supervision. There was no significant relationship between the number of years of experience of doctors and residual sonographic sphincter defects at 12 weeks postpartum.

All women were asymptomatic before labour with a SMIS of 0. The majority (n = 14; 70%) of women were asymptomatic with a SMIS of 0 at 10 -12 weeks postpartum. The mean SMIS was 1.25 (SD 3.1) with a range of 0 - 13. Of the 20 women in this study, six (30%) complained of defaecatory symptoms when using the validated SMIS questionnaire. All six women had AI (with or without faecal urgency). In two, this was solely faecal incontinence. The other four had a combination of, flatus incontinence (three), faecal incontinence (four), faecal urgency (two) and one also had an alteration of lifestyle.

Eight women sustained a grade 3a tear, six were repaired by the end-to-end method and two with the overlap technique. The obstetricians repairing the 3a tears with the overlap technique had seven and nine years clinical experience respectively. One of them was supervised by a more senior clinician with more than 10 years obstetric experience. Of the twelve women with 3b tears, one (8%) had an end-to-end and 11 (92%) an overlap repair. There was no difference in symptoms between the two types of repairs (p=0.41).

There was evidence of repair of the anal sphincter with TPUS. Sutures appeared in 2 patients as hyperechoic spots located at the repair site (Figure 1) but this finding is not consistent in all patients. Of the 20 OASIs that occurred, 19 (95%%) women had an anal sphincter defect identified with TPUS immediately after delivery and prior to suturing. Eight (40%) women had a defect in the EAS immediately after repair (Figure 2). No IAS defects were identified with TPUS immediately after repair.

Of the eight women with a sonographic defect, two (25%) had a 3a tear and six (75%) a 3b tear on clinical examination. Of the eight defects identified immediately after repair, six (75%) were still present at follow up at 12 weeks and the circumferential size of the defect was unchanged. No new defects were seen at follow up 12 weeks following a primary repair. An EAS defect identified immediately after repair was significantly associated with AI symptoms at 12 weeks (p = 0.02). Similarly, persistent EAS defects at 12 weeks postpartum were associated with AI (p = 0.04). Five (62.5%) of the eight women with a sonographic defect immediately after repair were symptomatic and had a mild degree of incontinence (SMIS score: 1-5) at 12 weeks postpartum. Eleven (92%) of the 12 women without a defect immediately after repair on TPUS were asymptomatic with one (8%) having a SMIS of 13.

Eight (40%) women sustained grade 3a tears and 12 (60%) sustained 3b tears based on clinical diagnosis, and there was no difference in symptoms 12 weeks postpartum (Table 2).

**1.4 Discussion**

This is the first study where TPUS was performed immediately after primary repair of OASIs to evaluate the anatomical outcome of the repair. We demonstrated that 40% of women had a residual EAS defect immediately after primary repair, of whom 75% had a persistent defect on TPUS at 12 weeks postpartum. In addition, no new defects were seen at follow up examination among women without a significant defect detected on TPUS immediately following primary repair. Evidence of repair can be seen on TPUS immediately after repair. In addition, there was a significant association between sonographic residual anal sphincter defects and AI.

The use of TPUS for the evaluation of the anal sphincter complex after OASIs has been previously described (13), and compared with EAUS (10, 14). However, there is only one study which has evaluated the anal sphincter in the early postpartum period with TPUS (24). Garcia-Mejido et al used TPUS to evaluate the anal sphincter on 146 women within 48 hours of a vaginal delivery and identified EAS defects in 15 (10.3%) cases. Of these, three (2%) had defects identified with TPUS but not apparent clinically. They found that TPUS was able to visualise evidence of repair as a thickening of the EAS with a more hyperechoic appearance (15). They also reported no residual sphincter defects with TPUS immediately after primary repair of OASIs. In concordance, we also found evidence of primary repair of OASIs immediately after repair but differed in that we found TPUS identified residual EAS defects in 40% of women immediately after primary repair of OASIs. There were however methodological differences between the two studies. In our study, TPUS was performed immediately after repair, whereas Garcia-Mejido et al (15) performed TPUS 48 hours postpartum. In addition, we used tomographic ultrasound imaging volume that covered the entire anal sphincter muscle by adjusting interslice interval individually in each woman according to the length of the anal sphincter. However Garcia-Mejido et al (15) analysed the imaging volume at a fixed interslice interval of 2.5mm. It is therefore likely that they may have not included the entire length of the anal sphincter as the length of anal sphincter varies amongst individuals (16) and therefore might have missed some defects.

We found that no new defects were seen at follow-up examination among women without a significant defect detected on TPUS immediately following primary repair. This implies that there may be a role of TPUS immediately after the repair. If the scan showed that the repair has been adequately repaired and there is no significant defect on TPUS, this finding will persist at 12 weeks. In addition, in 25% of women who were believed to have a sonographic defect immediately after repair, the defect was not identified 12 weeks later. This could have been an artefact created by the oedema and bleeding at delivery giving the appearance of a defect. Therefore, the value of TPUS immediately after repair appears to be limited and would need to be defined if it were to be considered for routine practice.

Despite primary repair of OASIs, between 8.2 (15) and 58.3% (17) of women are known to have a persistent anal sphincter defect on TPUS. This may reflect poor repair technique or failure to repair the anal sphincter at all. There is also incomplete of details of whether a protocol was followed for the repair including the grade of doctor who performed the repair, the type of anaesthesia used, the use of intraoperative and postoperative antibiotics, the surgical technique of repair, the type of sutures that should be used and post operative care. We found that 30% of women had an EAS defect with TPUS at 12 weeks postpartum. In our unit, all OASIs were repaired in accordance with the RCOG Green-Top Guideline (18).

A meta-analysis (19) of 2288 women demonstrated a significant association between OASIs and AI. They reported that compared to women who did not sustain an OASI, the risk of AI for women who had sustained an OASI was 2.66 times higher (95% CI, 1.77-3.98) (19). In keeping with other studies with a mean prevalence of AI of 39% (range 15-61%) (5) following OASIs, our study found 30% of women had AI symptoms at 12 weeks following a primary sphincter repair.

Persistent sonographic anal sphincter defects are associated with an increased risk of faecal incontinence (4, 6, 7, 10), and secondary sphincter repair has been shown to have poor long-term outcomes (20). Therefore, primary repair of OASIs at delivery provides the best opportunity to get an optimal outcome and minimise the risk of faecal continence. Although there are studies in which women were scanned in the early postpartum period (15, 21), the relationship between the sonographic appearance of the anal sphincter immediately following repair and AI symptoms have not previously been evaluated. We found that 63% of the women with a sonographic defect immediately after repair were symptomatic of AI at 12 weeks postpartum, and 67% of those with a persistent sonographic EAS defect at 12 weeks postpartum were symptomatic. Our findings are in keeping with other studies (4, 6, 7) showing a significant association between sonographic residual anal sphincter defects and AI.

The presence of a persistent anal sphincter defect not only predisposes to the development of AI, (22) but also has an impact on the management of subsequent pregnancies and caesarean section rates (23) . The most appropriate place to review these women is in a one-stop perineal clinic (24). Ideally, these clinics should have anal ultrasound and manometry facilities and have access to multidisciplinary professionals who provide holistic care to those with pelvic floor and perineal problems.

There are limitations with our study that need to be acknowledged. Firstly, TPUS findings of the anal sphincter were not compared with the validated EAUS findings. Secondly, the short follow-up interval of 10 to 12 weeks precludes assessment of longer-term assessment of symptoms of AI. The sample size of women who sustained OASIs was small. This was however part of a planned prospective study that commenced during labour and only women who sustained OASI were recruited for this part of the study. As OASI is unpredictable it is difficult to perform such a study where TPUS is performed immediately after an OASI repair. We acknowledge that the rate of OASIs (8%) is quite high, therefore the results may not be generalisable to other centres. This rate is however in keeping with the national rate. Thiagamoorthy et al (25) carried out a questionnaire-based survey of 215 maternity units in the United Kingdom. They found that the incidence of OASIs was 6.1% (range 0-14%) in primiparae.

**1.5 Conclusions**

This is the first study to prospectively evaluate the anal sphincter using TPUS immediately after repair of an OASI and repeated 12 weeks later. We found that no new defects were seen at follow-up examination among women without a significant defect detected on TPUS immediately following primary repair. This implies that there may be a role for TPUS immediately after the repair of 3a or 3b tear. However further research needs to be performed to evaluate the role of TPUS immediately after the repair of major tears (Grade 3c/4) as it has been shown that women with a major tear (Grade 3c/4) had a significantly poorer outcome with respect to the anal incontinence and associated quality of life when compared with minor tears (Grade 3a/b). In contrast, when the 25% of women in whom anal sphincter defects were identified immediately after primary repair of OASIs, the defects were no longer seen at 12 weeks postpartum, suggesting that they could have been artefacts. Therefore, re-exploration of the repair in these women would have been futile. We believe that the value of TPUS immediately after repair appears to be limited and would need to be defined if it were to be considered for routine practice. In addition, performing ultrasound would require widespread training of obstetricians to develop expertise therefore it may not be feasible. This highlights the importance of adequate training of obstetricians in OASI repair. This can be achieved by attending structured hands-on workshops (26, 27) which have been shown to improve the level of knowledge on the diagnosis and repair of OASIs but competence can only be demonstrated by objective structured assessment of technical skills.

**Acknowledgements**

We would like to thank P Bassett, Statistician from the Statsconsultancy Ltd, University of Reading for his help with the statistical analyses.

**Funding**

There are no conflicts of interest or disclosures.

**Table 1 Transperineal ultrasound scan findings in relation to the years of experience of doctors repairing the OASI**

|  |  |  |
| --- | --- | --- |
| Years of experience | TPUS with residual EAS defect  n = 6 | TPUS without residual EAS defect  n = 14 |
| <5 | 0 | 4 (28.6) |
| 5-10 | 5 (83.3) | 9 (64.3) |
| >10 | 1 (16.7) | 1 (7.1) |

Fisher’s Exact test, p=0.32

**Figure 1 Transperineal ultrasound scan findings of the anal sphincter immediately after primary repair of OASIs and at 10-12 weeks postpartum**

Women with OASIs who underwent primary repair

n = 20

*Immediately after delivery prior to suturing*

No defect

1 (5%)

EAS defect

19 (95%)

*Immediately after repair*

Residual EAS defect

8 (40%)

No defect

12 (60%)

Residual EAS defect

6 (75%)

*12 weeks after repair*

No new defect

12 (100%)

No residual EAS defect

2 (25%)

**EAS = external anal sphincter**

**Table 2 Symptoms of anal incontinence and EAS defects 12 weeks postpartum**

|  |  |  |  |
| --- | --- | --- | --- |
| Grades of OASIs | 3a  (n = 8) | 3b  (n = 12) | p value\* |
| Symptoms of anal incontinence at 12 weeks  n (%) | 1 (13) | 5 (42) | 0.61 |
| Defects of EAS on TPUS immediately after repair  n (%) | 2 (25) | 6 (50) | 0.35 |
| Defects of EAS on TPUS at 12 weeks postpartum  n (%) | 1 (12.5) | 5 (42) | 0.6 |

\*Mann-Whitney U test

**Figure 2 Transperineal tomographic ultrasound imaging taken immediately after repair of an OASI demonstrating hyperechoic spots corresponding to PDS sutures located at the EAS repair site.**

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**Figure 3 Transperineal tomographic ultrasound imaging taken immediately after repair of an OASI shows a defect in the external anal sphincter (angle of 60 degrees).**

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