**Risk of Obstetric Anal Sphincter Injuries (OASIS) and anal incontinence: A meta-analysis**

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**Running title:**

Anal sphincter defects and incontinence postpartum

**Place of Study**

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**Abstract**

*Background*

Obstetric anal sphincter injuries (OASIS) are the commonest cause of anal incontinence in women of reproductive age. We determined the risk of anal sphincter defects diagnosed by ultrasound, and the risk of anal incontinence in (i) all women who deliver vaginally, (ii) in women without clinical suspicion of OASIS, and (iii) after primary repair of sphincter injury, by systematic review.

*Methods*

We searched major databases until June 2018, without language restrictions. Random effects meta-analysis was used to obtain pooled estimates of ultrasound diagnosed OASIS and risk of anal incontinence symptoms at various time points after delivery, and of persistent sphincter defects after primary repair. We reported the association between ultrasound diagnosed OASIS and anal incontinence symptoms using relative risk RR) with 95% CI.

*Results*

We included 103 studies involving 16,110 women. Of all women who delivered vaginally, OASIS were diagnosed on ultrasound in 26%(95%CI, 21-30, I2=91%), and 19% experienced anal incontinence (95%CI, 14-25, I2=92%). In women without clinical suspicion of OASIS (n = 3688), sphincter defects were observed in 13%(10-17, I2=89%) and anal incontinence experienced by 14%(95% CI: 6-24, I2=95%). Following primary repair of OASIS, 55% (46-63, I2=98%) of 7549 women had persistent sphincter defect with 38% experiencing anal incontinence (33-43, I2=92%). There was a significant association between ultrasound diagnosed OASIS and anal incontinence (RR 3.74, 2.17-6.45, I2=98%).

*Interpretation*

Women and clinicians should be aware of the high risk of sphincter defects following vaginal delivery even when clinically unsuspected, and despite primary repair, the high rate of persistent defects and symptoms.

**Keywords**

Obstetric anal sphincter injuries, endoanal ultrasound, anal sphincter defects, anal incontinence, faecal incontinence, primary repair, systematic review

**Background**

Every year up to 30,000 mothers sustain obstetric anal sphincter injuries (OASIS) in the UK, (1) and this is the commonest cause of anal (faecal and flatus) incontinence in women of reproductive age group. (2) (3) One tenth of all obstetric claims involve perineal trauma including anal sphincter injury, costing the UK National Health Service (NHS) Litigation Authority over £31 million during a period of ten years (2000-2010). (4) The majority of negligence claims were related to missed and inaccurate diagnosis of anal sphincter injury after delivery, or to persistent sphincter defects and incontinence symptoms even after primary repair.

Accurate diagnosis and appropriate management of sphincter injuries is crucial to prevent anal incontinence. (3, 5, 6) and this is now an essential part of obstetric training.

Endoanal ultrasound is a useful tool to identify anal sphincter tears and determine extent of trauma. (7, 8) It is not known if detection of anal sphincter defects by ultrasound differs at various time points after delivery or after repair. Furthermore, the association between obstetric anal sphincter injury and short, medium or long-term anal incontinence is not known. Persistence of sphincter defects or anal incontinence symptoms may vary according to the technique of primary repair such as approximating the torn edges using an end-to-end or an overlap method of repair. Existing studies are small and imprecise, and they do not provide robust estimates on the risk of anal sphincter defects diagnosed by ultrasound at various time periods after delivery, and type of repair. (9)

We undertook a systematic review to determine the burden of anal sphincter defects diagnosed by ultrasound in women following vaginal delivery with and without a clinical diagnosis after delivery and following primary repair of the sphincter injury. We also assessed the association between diagnosis of sphincter defects on ultrasound and anal incontinence symptoms at various time points after delivery.

**Methods**

We undertook the systematic review with a prospective protocol (PROSPERO 42016030199), and reported in line with PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) guidelines. (10)

*Literature search*

We searched PubMed, EMBASE, “Ovid Emcare”, HMIC, “Joanna Briggs Institute EBP Database”, “Books at Ovid”, and “Journals at Ovid Full Text” from inception until June 2018, without any language restrictions. We combined the search terms for the relevant population, risk factors and outcomes such as ‘childbirth’, ‘pregnancy’, ‘delivery’, ‘obstetric anal sphincter injur\*’, ‘anal sphincter damage’, ‘anal sphincter injur\*’ ‘occult trauma’, ‘transanal ultrasound’, ‘endoanal ultrasound’, ‘endoanal ultrasound examination’. We supplemented electronic searches with manual search of the reference lists of the included studies. The detailed search strategy is provided in Appendix 1.

*Study selection*

Two pairs of independent (MS/TM and MS/JH) reviewers selected the studies in two stages. In the first stage, we screened the abstracts to identify potential studies for inclusion. In the next stage, we evaluated the full texts of the identified studies for eligibility. Any disagreement was resolved by the senior author (ST). We included studies that reported on anal sphincter defects in women following vaginal delivery, with or without clinical suspicion of anal sphincter injury, and after primary repair of the tear. The sphincter injuries diagnosed by ultrasound involved external, internal or both sphincters. Defects diagnosed by ultrasound without a clinical suspicion of anal sphincter tear were defined as occult injuries. The outcomes were assessed at various time points after delivery: < 3 months, 3-6 months, 6-12 months and > 1 year.

We excluded studies that did not specify mode of delivery or only included women who delivered with forceps or ventouse; reported only on anal incontinence symptoms and not ultrasound diagnosed sphincter injury; and those that did not provide data on outcomes in the first year postpartum. We also excluded studies with duplicate data, case reports, case series and case control studies.

*Quality assessment and data extraction*

Two pairs of independent reviewers (MS/TM and MS/JH) assessed quality of included studies for internal (bias specific to the study) and external (representativeness of findings) validity. For internal validity, we assessed the study design (prospective, retrospective), selection of participants (consecutive, arbitrary), adequacy of follow up (<80%, >=80%), ascertainment of outcome (two independent blinded assessors for sphincter defect on ultrasound; validated questionnaires for anal incontinence). Although there is no standardization, we also assessed the adequacy of definition of anal sphincter defect. This included clear documentation and justification of what was ultrasound features of what was perceived as anal sphincter defect or equally, reference to another study with the relevant definition (11). We considered the studies to have low risk of bias if they were prospective, consecutively recruited participants, followed-up over 80% of women, and used validated tools to assess outcomes.

External validity was based on documentation of a clear and standardised definition of ultrasound anal sphincter defect and the use of a validated questionnaire to diagnose anal incontinence. Studies with consecutive or randomised recruitment were considered to have a representative population. Studies that did not fulfil three or more of criteria for internal or external validity were classified as high risk for bias.

*Outcomes*

Data were extracted in duplicate using predesigned tables for the relevant outcomes (Appendix 2). We extracted data on the numbers of women diagnosed with anal sphincter defects in three groups: all women after vaginal delivery, women without any clinical suspicion of anal sphincter injury, and women who have undergone primary repair (defined as muscle repair of any type immediately after delivery). We also extracted data on the number of women with anal incontinence symptoms in the above three groups at various time points after delivery. Information was obtained on the type of sphincter repair (end-to-end, overlap or mixed) and obstetric factors that may affect the sphincter integrity such as epidural, episiotomy and instrumental delivery.

*Statistical analysis*

Random effects meta-analysis was used to calculate summary estimates of risk of ultrasound diagnosed anal sphincter defects and anal incontinence symptoms after vaginal delivery with 95% CI at various time points after delivery. When an outcome was reported at more than one time point in the follow-up, we used the longest follow up estimate in our overall meta-analysis. In women who had undergone primary repair, we calculated the risk of ultrasound diagnosed defects and anal incontinence symptoms, according to different types of repair (end-to-end, overlap, mixed), at various time points after delivery using above methods.

We undertook pre-designed subgroup analyses (Appendix 3) to assess if there were any differences in the risk of anal sphincter defects or anal incontinence after episiotomy (≤40% or >40%), epidural (≤50% or >50%), year of publication (≤2000, or >2000), quality of studies (high or low). Additional subgroup analysis was undertaken to determine the risk of sphincter defects and anal incontinence symptoms in only primiparous women. We reported the association between ultrasound diagnosed anal sphincter defect and anal incontinence symptoms as odds ratios (OR) and 95% CI, and the risk of sphincter defects diagnosed on ultrasound following instrumental delivery as relative risk (RR) and 95% CI. Heterogeneity was reported using the I2 statistic, with values <50% indicate minimal, 50-75% moderate and >75% high heterogeneity. Publication bias was assessed using funnel plots, and Begg’s and Egger’s tests. All analyses were performed using Stata software (version 15.0, College Station, Texas).

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*Accuracy of Data*

MS is the guarantor for the quality of data of this study. Corresponding and senior author (ST) made the final decision to submit for publication.

**Results**

Figure 1 provides the flow chart of the study identification and selection (PRISMA).

*Characteristics of included studies*

From 3201 citations, we included 103 studies (7, 11-112). These comprised: 33 studies (4,174 women) with data on ultrasound diagnosed anal sphincter defects +/- anal incontinence symptoms after vaginal delivery; 28 studies (3,688 women) on women without a clinical suspicion of sphincter injury; and 55 studies (7,549 women) on women following primary sphincter repair. Studies were conducted in 23 countries with sample sizes ranging from 15 to 1,495 women. Most studies (82/103) were published after 2000. The most commonly used validated questionnaires to determine anal incontinence symptoms were the Wexner faecal incontinence score (113) or St. Mark’s incontinence score (114).

*Quality assessment (Figure 2)*

About two thirds of the included studies (70/103, 68%) were low risk for representativeness and consecutive participants were selected in 84% (87/103) studies. Sixty-three percent (63%) of studies (58/92) which assessed anal incontinence, used a validated questionnaire; 38% (39/103) had adequate assessment of ultrasound diagnosed sphincter defect. Both anal incontinence and anal sphincter defect outcomes were adequately ascertained in 24% (22/92) of studies. Follow-up was adequate (>80% of participants) in 66% (68/103) of studies.

*Obstetric anal sphincter injury following vaginal delivery*

Overall, a quarter of women who delivered vaginally were diagnosed to have an anal sphincter defect on ultrasound (26%, 95% CI 21-30, I2=91%) (33 studies, 4,174 women). The risk varied significantly (p=0.013) according to the timing of ultrasound, with the highest proportion diagnosed at 3-6 months after vaginal delivery (36%, 93% CI 27-45%) (Figure 3). Subgroup analysis limited to only primiparous women showed that a quarter of these women had anal sphincter defect on ultrasound (27%, 95%CI: 22-33%, I2=88%) (20 studies, 2,266 women).

Subgroup analysis showed a decrease in ultrasound diagnosed sphincter defects in studies published after 2000 than before (p=0.018) (Appendix 3). No differences were observed according to the risk of epidural, episiotomy or quality of studies (Appendix 3). After vaginal delivery, a fifth of women (19%, 95% CI 14-25, I2=92%) reported anal incontinence symptoms (25 studies, 2,523 women). The occurrence of symptoms did not vary over time (p=0.707) (Figure 3). Women who underwent operative vaginal delivery (forceps or ventouse) were 4-times more likely to have anal sphincter defects than those who had spontaneous delivery (OR 4.10, 95% CI 2.36-7.12, I2=68.7%) (15 studies, 1,949 women).

*Women without a clinical suspicion of obstetric anal sphincter injury*

In 13% of women (95% CI 10-17, I2=89%), although anal sphincter injury was not suspected clinically, sphincter defects were diagnosed on ultrasound (28 studies, 3,688 women). The rate of diagnosis varied significantly with the timing of the ultrasound (p=0.011), with the highest rates at 3-6 months (20%, 95% CI: 15-25, I2=76%) after delivery (Figure 3). Overall 14% (95% CI: 6-24, I2=95%) of women without clinical suspicion of sphincter injury reported anal incontinence (13 studies, 1,295 women). The risk of anal incontinence increased over time (p=0.00), with the highest risk observed at 6 months (39%, 95%CI: 17-62, I2=95%) after delivery.

In primiparous women without clinical suspicion of anal sphincter injury, the overall risk of anal sphincter defects is 14% (95% CI: 9-19, I2=92%) (20 studies, 2552 women) (Appendix 4).

*Anal sphincter related outcomes after primary repair*

In over half of all women who had primary repair, persistent sphincter defects were diagnosed on ultrasound (55%, 95% CI 45-63, I2=98%) (55 studies, 7,549 women) (Figure 3). This risk did not vary significantly according to the follow-up period (p=0.363) (Figure 3). In subgroup analysis including only primiparous women, 64% (95% CI 46-80%, I2=97%) were diagnosed with sphincter defects on ultrasound (Appendix 4). Subgroup analysis did not show any statistically significant difference in post repair anal sphincter defects, according to the type of sphincter repair (p=0.052) (Table 1). Post end-to-end repair, the risk of anal sphincter defect was 0.71 (95% CI 0.54-0.85, I2=97%, 1143 women) vs 0.43 post overlap approximation (95% CI 0.21-0.66, I2=96%, 456 women) or 0.49 for mixed repair techniques (95% CI 0.38-0.59, I2=99%, 6,538 women). Over a third of women experienced anal incontinence symptoms following primary repair of the sphincter (38%, 95% CI 33-43, I2=92%) (50 studies, 5,166 women) (Figure 3). This risk did not vary according to the timing of follow-up (p=0.447). Flatus incontinence was reported by a third of all women undergoing repair (31%, 95% CI 25-38, I2=94%), whereas fecal incontinence was reported in 1 out of 10 women (9%, 95% CI 6-12, I2=85%)About one in 4 in 10 primiparous women (40%, 95 CI 30-52, I2=91%) reported anal incontinence after repair of the sphincter (Appendix 4).

There were significant differences according to the type of repair and post repair anal incontinence, with lowest risk in studies where either method of repair was used (overlap or end-to-end) than only end-to-end or only overlap technique (p<0.01) (Table 1).

The findings did not vary according to the study quality. Finally, our data concluded similar risk for isolated defects in the internal and or external sphincters for each technique (table 1).

*Association between ultrasound anal sphincter defects and anal incontinence*

Table 2 shows the relationship between ultrasound diagnosed defect and anal incontinence. Women who had sphincter defect diagnosed on ultrasound following a vaginal delivery were 4-times more likely to have anal incontinence than those with intact sphincter (RR 3.74, 95% CI 2.17-6.45, I2=80%) (19 studies, 2,005 women) (Table 2). In those without a clinical suspicion of sphincter injury, the risk of anal incontinence was 2.5-fold (2.53, 95% CI 1.24-5.13, I2=85%); in those following a primary repair of sphincter injury the same risk was 2.8-fold (RR 2.77, 95% CI 1.95-3.92, I2=42%) respectively. The magnitude of this association varied according to the timing of follow-up in all three groups of women (Table 2).

*Publication bias*

Appendix 5 summarizes the funnel plots for each population and outcome.

**Discussion**

*Key findings*

This systematic review has provided an estimate of risk for anal sphincter defects following vaginal delivery (26%), including those which are missed during routine clinical examination (occult defects – 13%). We noted a variation in the trend of the anal sphincter defects risk at various times postpartum, where 6-month follow up appears to be a representative window; the highest risk is at 3-6 months and the lowest immediately postpartum. We also found that approximately 50% of women will have persistent anal sphincter defects following primary repair of OASIS. Risks of defects following primary repair of OASIS seem stable across the first year (3months-1 year).

Although our data show a clear association between instrumental deliveries and higher risk of anal sphincter defects, we did not find any difference related to the routine use of epidural anaesthesia or episiotomy. Subgroup analysis concluded a marginally higher overall risk of anal sphincter defects in primiparous women. However, most of the included cohorts consisted of primiparous women. Previous evidence shows that in primiparous women the rate of instrumental deliveries or OASIS may be higher, and hence this keeps with our findings.

Our data support that almost 1 out of 5 women on average will develop some symptom of anal incontinence following vaginal delivery (19%); this risk was similar even when OASIS was not suspected clinically (17%). In addition, 2 out of 5 women who underwent primary repair of OASIS (0.39%) will become symptomatic, and 1 out of 10 (9%) will sustain fecal incontinence; however, our data were focused mainly during the first year postpartum.

We also concluded that persisting anal sphincter defects following primary repair of OASIS are directly associated with anal incontinence (OR: 2.77, CI: 1.95-3.92). Further to this, undiagnosed (occult) injuries can increase the likelihood of anal incontinence by 1.33-14.88 times (RR), and this is probably because the vast majority of those defects are left unrepaired. Following any vaginal delivery, the RR for a symptomatic (anal incontinence) anal sphincter defect varies from 3.64 to 9.08 at certain time points and the highest is within the first 3 months postpartum.

Regarding methods of repairing anal sphincter defects, our data suggest that risk for persistent defects is higher for end-to-end approximation technique (71 vs. 43%), but this did not reach a statistically significant level. Nevertheless, both techniques appear to result in equal risk of future risk of anal incontinence symptoms (49 vs. 45% for end-to-end vs. overlap respectively). This is in keeping with a previous meta-analysis (9).

*Clinical Interpretation*

Vaginal delivery has been previously associated with postpartum anal incontinence, and this is the main concern when defects are diagnosed postpartum (3, 115). Several studies support that OASIS can impact long-term quality of life (116, 117). This can result in various socioeconomic consequences with potential medico-legal implications (4). A smaller review has given similar estimate for occult injuries in 2007 (118). Our data pose several important questions:

First, more than 1 in 10 women will sustain occult injuries, and our data indicate association with future development of anal incontinence. This could suggest the need for routine use of endoanal ultrasound postpartum to identify cases for occult injuries if not in all primiparous women, for those who may be deemed at higher risk of such injury e.g. in forceps delivery. This may result in prompt recognition and repair of high-grade occult injuries, however a reduction in long-term risk of anal incontinence will only be achieved by scrutiny of outcome of primary repair as it is being performed, as well as preventative pelvic floor physiotherapy. Given the heterogeneity of the data which come from several countries globally, with different training programs, this scrutiny may need to be specifically tailored.

Secondly, variation in trend of risk of anal sphincter defect’ implies a rising demand for reaching consensus on the optimal follow up window postpartum. This includes the need for identifying patients who would fit criteria for prolonged follow up, to ensure quality of life is not compromised.

Thirdly, half of women with repaired OASIS will have persistent sphincter defects and these are associated with higher risk for anal incontinence. A rising trend was noted in symptomatic women throughout follow up timeline (Figure 3). This questions the need for prolonged follow up and intervention to salvage quality of life. It also raises a question for optimal future delivery plan to avoid deterioration of those symptoms. Although a recent meta-analysis (119) reports similar risk for recurrent OASIS (rOASIS), there is still lack of evidence on how detrimental such events (rOASIS) can be for pelvic floor function. We noted a significant drop in the reported risk of anal sphincter defects in studies published after 2000. This could reflect either a better consensus in ultrasound diagnosis, or equally more robust training culture to decrease or repair effectively OASIS. However, it is difficult to comment whether there is any actual drop in the risk of OASIS, as this could also reflect the rising Caesarean section rate.

Finally, end-to-end or overlap approximation of anal sphincter edges have been practiced globally as primary repair techniques for OASIS. With either method of repair, there is still a high risk of persistent anal sphincter defects. This poses the question as to whether more formal training along with competency assessment may be required to optimize repair outcomes. Cohorts where mixed techniques were used resulted in lower risk of symptomatic women (30% vs. 49% or 45%).

*Strengths of this systematic review*

To our knowledge, this is the largest systematic review to report the above outcomes. We included 103 studies with 16,110 women from 23 countries and used a prospective protocol to draw our conclusions according to PRISMA guidelines. These give our result a global perspective to form the basis of future guidelines in offering OASIS care. Our protocol was designed to capture and assess any possible limitations from data quality. The data analysis was conducted by senior experienced statisticians and the relevant interpretation was performed acknowledging the heterogeneity, scrutinised by an expert panel who are co-authors of this study. During data interpretation we have taken into consideration any risk of bias which is described in detail below.

*Limitations*

We noted significant heterogeneity across majority of our studies which can be attributed to variation in the definition of ultrasound diagnosis of anal sphincter defects, as well as to the fact that studies investigate those defects at different time points. Heterogeneity can also be secondary to the global improvement in diagnosing anal sphincter defects throughout the last two decades. Furthermore, heterogeneity can also arise from different local practices, as well as variation in the diagnosis of anal incontinence, especially in the cases where validated scales were not used.

Forty-one out of 103 included studies (40%) were deemed high risk for bias. This underlines that we should interpret our results sparingly. Out of 103 studies, 18 were conference papers which can introduce additional bias. Further, data extraction for some studies was challenging, mainly because of the different scales used. A future meta-analysis could consider using synthesis of individual patient data. Most of the studies included were primarily observational with small samples and short follow up limited to the first year postpartum. Variation of risk factors reported for anal sphincter defects did not allow further exploration for some of them.

We noted a difference in the risk of defects reported in published studies prior to 2000, and this may be attributed to evolution of ultrasound technical equipment and experience of sonographers or clinicians. However, it is still recognized that there is no standardization of reporting of anal sphincter images with the sphincter tears USS diagnosis is dependent on training and recognition of normal from variant anatomy. Failure to appreciate variations in normal anatomy may mislabel a sphincter as damaged and may explain the discrepancy in the number of women reported to have a defect and those that are symptomatic in the population. For instance, failure to recognise the shorter anterior sphincter in women may lead to over diagnosis of an anterior sphincter injury. Some of the difficulties are related to reporting with various definitions used to describe and injury. The definition of a true defect needs to be defined and may differ between the studies as a quadrant defect, a third defect or simple discontinuity of the muscle. The terms scar, disruption, defect and distortion of the anal sphincter are often used but may not mean the same. This is very important and relevant in counselling a woman with a potential injury but also if litigation arises.

Although we included 103 studies, less than half of them contributed to the calculation of the association of ultrasound sphincter defects with anal incontinence. Finally, we focused on anal sphincter defects as an etiological factor for anal incontinence. However, pelvic floor physiology is complex and anal incontinence is multifactorial and often not solely be related to sphincter integrity.

*Conclusions*:

We provide robust estimates on anal sphincter defects and their association with future development of anal incontinence. Our results show the burden of the problem is higher than previously reported. Therefore, women and clinicians should be aware of the high risk of sphincter defects following vaginal delivery even when clinically unsuspected, and despite primary repair, the high rate of persistent defects and symptoms. Those risks need to be communicated during counselling prior to childbirth, where applicable, in order to make a balanced decision regarding the mode of delivery. This is important as women may opt to make choices regarding mode of delivery based on pelvic floor safety rather than traditional obstetric indications..

In addition, reassessment of diagnosis and the need for secondary repair of anal sphincter injury repair highlights the need for a stringent competency assessment for surgery in this area. Future research should focus on developing a prediction model which could identify high risk cases for routine ultrasound postpartum and evaluate risk factors for failed repairs.

**Disclosure of Interests**

Authors declare no conflict of interest

**Ethical Approval**

Not required for this systematic review

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**Contribution to Authorship**

MS extracted data with TM and JH; MS drafted the manuscript. ST is the senior author of this study, who conceived the protocol of the systematic review, edited the manuscript and designed the analysis model. DAM has performed the data analysis with senior input from JZ. SJ, CC, CK, RT are senior consultants, experts in the field, who have provided valuable input in editing and interpreting the data. All authors have approved final submission.

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