

STUDY PROTOCOL

TITLE OF THE STUDY

Diagnosis of Obstetric Anal Sphincter Injuries (OASIs) using Transperineal Ultrasound Scan (TPUS)

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STUDY SUMMARY

Study Title	Diagnosis of Obstetric Anal Sphincter Injuries (OASIs) using Transperineal Ultrasound Scan (TPUS)
Study Design	Prospective observational study
Study Participants	Women who undergoing their first vaginal delivery
Planned Size of Sample (if applicable)	216
Planned Study Period	January 2017 to April 2018
Research Question/Aim(s)	<p>1) HYPOTHESIS</p> <p>- Transperineal Ultrasound Scan (TPUS) at delivery will increase the detection of Obstetric Anal Sphincter Injuries (OASIs).</p>

2) PRIMARY AIM

- To determine whether the use of the transperineal ultrasound will improve the detection of OASIs immediately following vaginal delivery.

3) SECONDARY AIMS

- To measure hiatal dimensions during labour and correlate to levator detachments.
- To correlate intrapartum fetal head position and station identified using three-dimensional (3D) transperineal and transabdominal ultrasound with levator injury.
- To assess anal sphincter integrity immediately after primary repair of OASIs with transperineal ultrasound.

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STUDY PROTOCOL

BACKGROUND

Obstetric Anal Sphincter Injuries (OASIs)

The incidence of anal incontinence - “the involuntary loss of flatus, liquid or stool that is a social or hygienic problem” (1) is reported to occur in 20-68 % of women after Obstetric Anal Sphincter Injuries (OASIs) (2) (3) (4). Obstetric related anal incontinence was previously believed to be due to pudendal neuropathy (5) (6) (7). However with the advent of Endoanal Ultrasound Scan (EAUS) it has become apparent that mechanical trauma to the anal sphincter is the major aetiological factor.

Three dimensional (3D) EAUS is the gold standard tool to detect OASIs (8). It is however not available in most obstetric units. A potential alternative imaging modality is Transperineal Ultrasound Scan (TPUS) (9) (10) (11) (12) (13). TPUS is readily

available in all obstetric units and therefore potentially can be used as a diagnostic tool to detect OASIs. In addition, it allows assessment of the levator ani muscle (LAM), which is believed to play an important role in the maintenance of anal incontinence (14).

Comparative studies have been done between TPUS and EAUS and have shown a moderate to good correlation between the two imaging modalities for the evaluation of the anal sphincter complex (15) (16). Roos et al (17) compared TPUS with EAUS on women who had an OASIs or symptoms of anal incontinence without OASIs over 12 months following delivery. They found that TPUS is good at detecting normal anal sphincters. However, when an anal sphincter defect is detected with TPUS it requires further clinical assessment to determine whether an OASIs has actually occurred. The authors therefore recommended that if TPUS reveals an intact anal sphincter then no further test is necessary; however if TPUS reveals a defect, a clinical examination and EAUS should be performed to confirm damage to the anal sphincter. In a study by Oom et al (15), TPUS was able to detect 70% of cases with external anal sphincter (EAS) defects and all cases of internal anal sphincter (IAS) defects identified on EAUS. Roche et al (18) scanned 20 primiparous women found and found that two dimensional (2D) TPUS detected all defects identified using 2D EAUS. Ros et al (19) also demonstrated a good correlation with 3D EAUS when 3D TPUS is used to detect residual anal sphincter defects 3 months to 6 years after primary repair of OASIs.

It is known that OASIs can lead to anal incontinence especially when damage to the anal sphincter is not recognised at the time of delivery (20) (21). The incidence of clinically undetected OASIs has been shown to vary between 13 to 87% (11) (22) (23). Two clinical studies have demonstrated that when a trained doctor re-examined the perineum and anal sphincter that the rate of OASIs doubled (22) (24). This highlights the need to improve education of obstetricians and midwives in perineal anatomy and clinical diagnosis of OASIs. However despite training, doctors and midwives still fail to identify all OASIs (11) (25). Although EAUS can increase the detection rate of OASIs (22), it is not widely available in most UK obstetric units. In contrast, TPUS is available in most obstetric units and we therefore wish to determine whether TPUS in addition to a routine clinical examination will increase the detection rate of OASIs.

Anal incontinence can occur if OASIs are not repaired adequately (26) (27) (28). There is a significant correlation between the extent of an anal sphincter defect and the degree of anal incontinence (29). Ultrasound assessment between one week and one year after primary repair of OASIs has shown that between 16 to 90% (12) (28) (26) (15) (27) (30) have a residual anal sphincter defect. Women with a residual anal sphincter defect have significantly more symptoms of anal incontinence than those without a demonstrable defect (26). It is therefore not unreasonable to assume that some of these residual defects on scans represent injuries that were either not or incompletely repaired at the time of delivery. We therefore wish to investigate whether the use of TPUS immediately after primary repair of OASIs may be able to detect an inadequate repair which will be confirmed at the six to eight weeks follow-up.

The reported rates of anal incontinence following primary repair of OASIs range between 15 and 61% (31). Women with anal incontinence are more likely to have an EAS defect (26). We wish to perform a TPUS at six to eight weeks postpartum to assess the anal sphincter, and determine whether there are differences in the morphology compared to TPUS findings at delivery.

Hiatal dimension and levator ani avulsion

The incidence of levator ani muscle (LAM) avulsion is between 10 and 35% (32) (33) (34) (35) and can occur in up to 28% (33) of women undergoing their first vaginal delivery (32) (33). LAM avulsion can have a significant impact on faecal (13) (36) (37) (38) and urinary incontinence (39) (32) (40) (41) (42) (43) and sexual function (44) and is a major contributing factor to the development of pelvic organ prolapse (45) (46) (47) (34). Repairing LAM avulsion has been proven to be unsuccessful (48) (49). There have been attempts to try and find ways to prevent pelvic floor damage during vaginal delivery e.g EPI-NO ® (Tecsana GMBH, Muenchen, Germany). It is a mechanical device which is inserted into the vagina antenatally and stretches the vagina and perineum. However a recent randomized controlled trial has shown it to be of no benefit (50). Given that surgical repair and mechanical devices have been unsuccessful, research needs to focus on a better understanding of when these injuries occur in labour, with a view to preventing them happening in the first place.

A computerised model has demonstrated that the pelvic floor muscles undergo extensive stretching during a vaginal delivery (51). Several forms of injury have been described including avulsions, traumatic over-distension and hematomas (39) (52) (53). LAM avulsion have been investigated in labour and seem to only occur at delivery and not during the first and second stages of labour (54). However it is also known that smaller hiatal dimensions during the third trimester are found to be associated with a higher intervention rate for both instrumental deliveries and caesarean sections (55). Given that smaller hiatal dimensions in the third trimester lead to more obstetric intervention, it may be that particular dimensions or changes to these muscles in labour have an impact on the mode of delivery. Therefore performing TPUS in labour will give us a better understanding of the changes that occur in normal labour, and this may prove to be useful in prediction of mode of delivery.

Computerised models suggest that with the descent of the fetal head that there is distension of the pelvic floor muscles (51). The descent of the fetal head is usually determined by digital vaginal examination (DVE) in relation to the ischial spines and is called the fetal head station (56). This is however a subjective measure but can be measured objectively with TPUS (57) (58) (59) (58) (60). Therefore we wish to investigate changes to the pelvic floor muscles in relation to fetal head station objectively using TPUS.

Forceps delivery (61) (62) (63) (41) (64) (65) (45), prolonged second stage (66) (62) (67) and occipito-posterior (OP) position (33) are risk factors for LAM avulsion. The study evaluating OP with LAM avulsion were done as the baby was being delivered

when one can see the position of the baby's head (33). In labour the diagnosis of OP position was made by a DVE. However there is good evidence that diagnosing the position of the head by DVE can be difficult (68) and that ultrasound diagnosis is more accurate (69) (70) (71). Given that there have been no studies evaluating the position of the fetal head in labour and its relation to LAM avulsion, we propose to accurately diagnose fetal head position in labour and correlate it with LAM avulsion using TPUS.

In summary LAM avulsion and hiatal dimensions are associated with pelvic organ prolapse (45) (46) (47) (34) and both anal (13) (36) (37) (38) and urinary incontinence (39) (32) (40) (41) (42) (43). TPUS can be used to evaluate changes to these muscles in labour and also objectively measure fetal head station and position. This will be the first to study to evaluate these changes during normal labour. Understanding this is important so that preventative strategies can be developed to try and improve the quality of life for women.

HYPOTHESIS

- Transperineal ultrasound at delivery will increase the detection of OASIs.

AIMS OF THE STUDY

Primary Aim

- To determine whether the use of the transperineal ultrasound will improve the detection of OASIs immediately after vaginal delivery.

Secondary Aims

- To measure hiatal dimensions during labour and correlate to levator detachments.
- To correlate intrapartum fetal head position and station identified using three-dimensional (3D) transperineal and transabdominal ultrasound with levator injury.
- To assess anal sphincter integrity immediately after primary repair of OASIs with transperineal ultrasound.

DESIGN AND METHODOLOGY

Prospective study to be conducted between January 2017 and April 2018 at University Hospital Lewisham. Recruitment will start in January 2017 and stop in April 2018.

Sample identification

All women attending the hospital for routine anomaly ultrasound examinations between 20 and 22 weeks of gestation will be invited to participate and will be given an information leaflet at that stage. The initial approach will be made by a member of the clinical care team when women are admitted for induction of labour or are in labour on the delivery suite and the research team can then approach if the potential participant agrees to be approached. The research fellow (KW) will invite eligible women to participate in the study. The source of identifiable personal information that will be used to identify potential participants will be their maternity notes.

Patients inclusion criteria

The inclusion criteria are:

- women who are undergoing their first vaginal delivery
- 37 weeks of gestation or more
- a singleton pregnancy

- cephalic presentation
- maternal age 18 years old or more and being able to read and understand English.

Patients exclusion criteria

Exclusion criteria are those who do not fit in the inclusion criteria.

Size of sample

Power calculation: The incidence of clinically identified OASIS in nulliparous women is 6%. With increased surveillance with transperineal ultrasound and a detailed examination by a trained doctor we predict the detection rate of OASIS will be 12%. Assuming that 10% of the subjects will have discordant responses, and also assuming a 5% significance level and 80% power, it is calculated that 216 women would be required for the study.

Statistics

Due to the paired binary nature of the data (i.e. two measurements for each subject), the McNemar test will be used for the data analysis.

Method of evaluation

The research fellow (KW) will assess fetal head station and hiatal dimensions by TPUS and fetal head position by transabdominal ultrasound.

Perineal and anal sphincter trauma will be assessed and classified by the accoucher following vaginal delivery. Women will be re-examined by the research doctor (KW) who is trained in performing a detailed vaginal, perineal and rectal examination. When an OASIs is identified by the research fellow that is missed by the accoucher it will be verified by the consultant between 08.00 and 20.30 and by the ST6-7, specialty doctor or consultant out of hours and repaired.

Secondly TPUS will be performed to assess anal sphincter and hiatal dimension in the immediate postpartum period on all women in the study. TPUS will be repeated after the primary repair of OASIs to check the integrity of the anal sphincter. Images will be stored for independent assessment by experts in TPUS.

A follow-up appointment will be arranged for six to eight weeks later. At follow-up, all patients will be asked to complete a standardised questionnaire including symptoms of anal incontinence according to the St. Mark's Incontinence Score (SMIS) and undergo a repeat TPUS to assess the anal sphincter and hiatal dimensions.

Demographic and obstetric data will be collected prospectively from the maternity notes, including: maternal age, gestational age at delivery, parity, body mass index, history of previous caesarean section, spontaneous or induced labour, duration of first and second stage of labour, indication for operative vaginal delivery, final mode of delivery, mediolateral episiotomy, and neonatal weight. The following ultrasonographic data will also be collected: fetal head position, angle of progression, hiatal dimension, signs of levator avulsion, anal sphincter integrity.

ETHICAL CONSIDERATION

This study is a self-funded project. Information about the study will be given to women during the antenatal period. Those who agree to participate will be consented on admission to labour ward.

CONSENT

Informed consent will be obtained prior to participating. A discussion will be carried out between the potential participants and the research fellow (KW) about the nature and objectives of the study and possible risks associated with their participation. An

opportunity will be given to potential participants to ask questions. Written material (e.g. information leaflet and consent document) will be given.

REGULATORY COMPLIANCE

Before enrolling patients into the study, the chief investigator (KW) will apply for NHS permission from the NHS Research & Development (R&D). If there are any amendments that will potentially affect a site's NHS permission, the chief investigator will confirm with R&D department that NHS permission is on going.

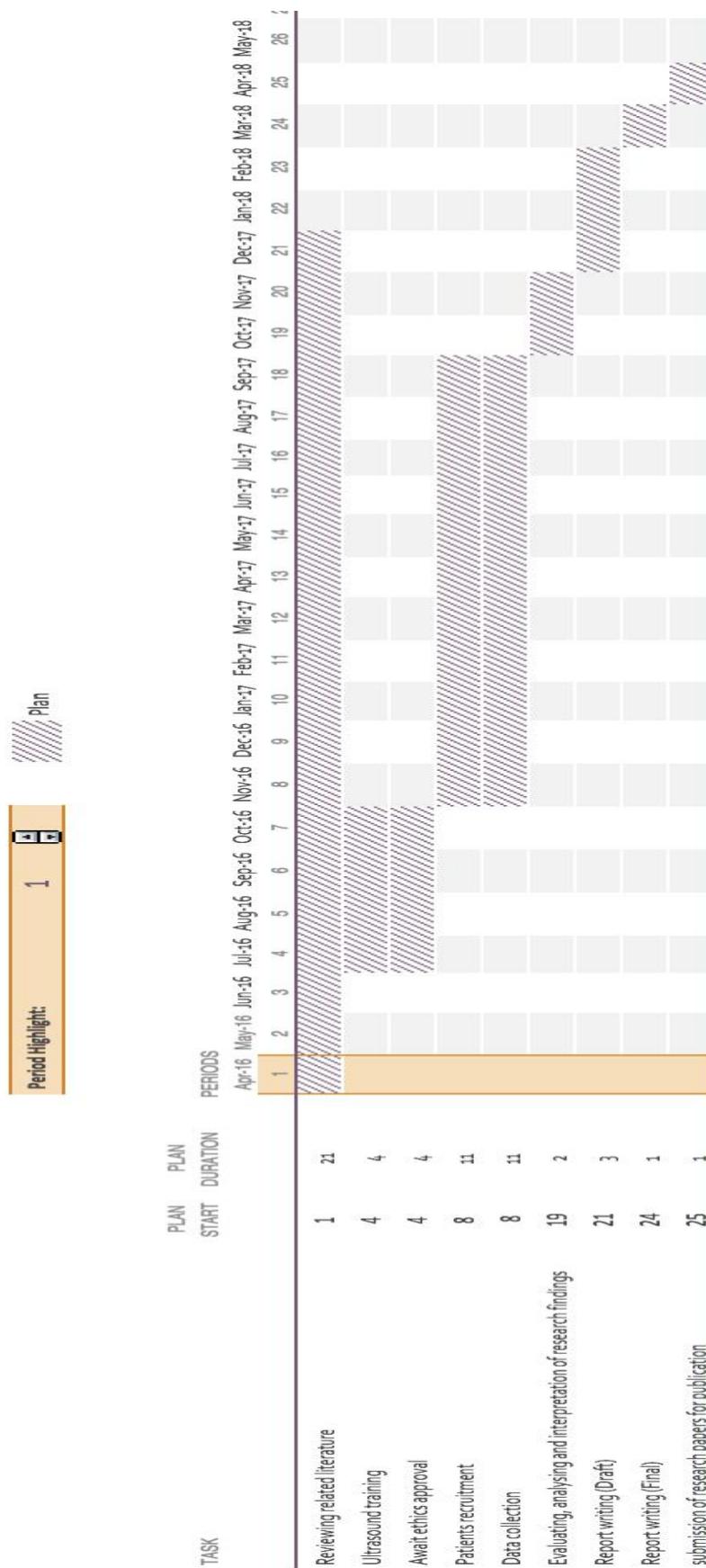
PROTOCOL COMPLIANCE

Any accidental protocol deviations will be documented on the relevant forms and reported to the chief investigator.

DATA PROTECTION AND PATIENT CONFIDENTIALITY

All investigators will comply with the requirements of the Data Protection Act 1998 with regards to the collection, storage, processing and disclosure of personal information and will uphold the Act's core principles.

STUDY FLOW CHART



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