Precision of Ultrasound During Peripartum for Predicting and Diagnosing Obstetric Anal Sphincter injuries

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Abstract

Background: Early detection of obstetric anal sphincter injuries (OASIs) following vaginal delivery is essential for effective care and management.Obstetric anal sphincter injury (OASI) is the most common cause of anal incontinence in women and can have a devastating effect on a woman's mental and physical health as well as their social wellbeing. Other long-term effects after OASIS are perineal pain, dyspareuniaand more unusual abscess formation and anovaginal fistulas. This study aimed to assess the accuracy of transperineal ultrasound (TPUS) in diagnosing OASIs in primiparous women between 37 and 41 weeks of gestation.

Methods: A cohort observational study was performed on 697 nulliparous women with singleton pregnancies at 37-41 weeks' gestation. The study involved prenatal ultrasound measurement of ano-vaginal distance (AVD) and postnatal evaluation of anal sphincter contraction.

Results: Significant differences were observed between women with and without OASIs in terms of BMI, fetal parameters (BPD, HC, gestational age by US), and AVD. The area under the receiver operating characteristic curve (AUC) for AVD was 0.659 (95% CI: 0.583-0.735), indicating moderate predictive ability for OASIs. Multivariate analysis revealed significant correlations among BMI, AVD, duration of the second stage of labor, and fetal occiput position at delivery. The strongest correlation was between AVD and the duration of the second stage, while the weakest was between BMI and fetal occiput position.

Conclusion: TPUS could serve as a valuable complement to clinical examination for identifying women at risk of OASIs, potentially lowering the incidence of undiagnosed or occult injuries. Enhanced training and competency assessment are crucial for improving OASIs detection by healthcare professionals.

Keywords: Ano-Vaginal Distance (AVD), Obstetric Anal Sphincter Injuries (OASIs), Primiparous Women, Transperineal Ultrasound (TPUS), Vaginal Delivery.

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Introduction

Injury of anal sphincter during delivery (OASI) is a significant cause of anal incontinence in women, impacting their physical, mental, and social well-being. In the UK, the incidence of OASI among firsttime mothers is 6.1%, with a threefold increase from 2000 to 2012.¹ Overall, studies looking at the incidence of OASIS based on the WHO's International Classification of Diseases (WH0,2015). Report an incidence of 4% to 6.6% of all vaginal birth, with higher rates in assisted deliveries (6%) than in spontaneous vaginal deliveries (5.7%), However, the prevalence is dependent on variations in obstetric practice, including rates and type of episiotomy, which vary not only between one country and the next but also at a national level between delivery units and individual practitioners .OASI can range from minor tears to severe injuries involving the perineal body, pelvic floor muscles, and anal sphincters. These injuries can lead to short-term issues like hemorrhage and perineal pain, as well as long-term complications, including rectovaginal fistulae and anal incontinence.² Prompt diagnosis of OASI after vaginal delivery is critical for appropriate care. Perineal lacerations should be examined immediately postpartum, with diagnosis established before primary suturing.³. The examination typically involves inspecting and palpating the vagina and perineum, often under adequate anesthesia, to determine sphincter involvement. Accurate differentiation between isolated lacerations and sphincter injuries is essential to prevent long-term consequences. Research indicates that undiagnosed sphincter injuries may result from misidentification or inadequate repair.⁴ Enhancing clinical awareness and documentation of anal sphincter injuries is

vital for improving diagnostic accuracy. Endoanal ultrasonography (EAUS) has advanced the evaluation of the anal sphincter complex but is limited by cost, the need for specialized training, and discomfort compared to other imaging modalities like transperineal ultrasound (TPUS). TPUS, increasingly used over the past decade, is widely accessible, allows multiplanar imaging, and supports 3D volume storage for offline review.^{5,6} This study aims to assess the accuracy and diagnostic value of peripartum ultrasound in detecting obstetric anal sphincter injuries in primiparous women between 37 and 41 weeks + 6 days of gestation.

Methods

This cohort observational study was carried out at the Kasr Alainy Hospital for and Gynecology, Obstetrics Cairo University, from January 2021 to May 2023. A total of 697 nulliparous women who presented to the Labor and Delivery Unit with a singleton, living fetus at a gestational age between 37 weeks and 41 weeks + 6 days were included. All participants were fully informed about the study's purpose and procedures and written consent provided before participating. The study received approval from the Ethical Committee. The study included nulliparous women at term with a singleton, vertex presentation, and aged between 18 and 40 years. All participants were in labor, and none had a history of medical conditions. Women with the following conditions were excluded: congenital fetal anomalies, maternal age below 18 or above 40 years, non-vertex presentation, multifetal pregnancies, and those with medical disorders such as diabetes mellitus or hypertensive

conditions. Comprehensive patient history was obtained, including age, confirmed gestational age (based on the first day of the first trimester), gravidity, parity, and medical history. A thorough physical examination was performed. which included vital signs, weight, height, and a full obstetric examination. All ultrasound assessments were conducted using the SONOACE R3 (Samsung Medison Company Ltd, Seoul, South Korea) ultrasound machine, equipped with a convex 3.5-5 MHz transducer for transabdominal scans. To minimize interobserver variability, a single examiner (Dr. Niven) performed all ultrasounds. Routine ultrasonography was performed to confirm fetal viability, gestational age, and to rule out multiple and maior pregnancies congenital anomalies. Detailed ultrasound examinations were carried out in the emergency room and during labor, measuring parameters such as head circumference, biparietal diameter, and estimated fetal weight. Additionally, transperineal ultrasound was employed to assess anal sphincter contraction and anovaginal distance (AVD)using the standard convex 5-9 MHz probe of the same ultrasound machine used for trans abdominal probe. Fetal biometry followed established guidelines, and the fetal occiput position was determined using a clock-face method. The transperineal ultrasound was conducted by placing a sterile, glove-covered transducer between the labia majora and moving it cranially along the anal canal to measure the internal anal sphincter distance in millimeters. The AVD was measured using the standardized procedure.7 (Figure 1a,b).



Figure (1): (A)Anovaginal distance in women with OASIs, (B): Anovaginal distance in women without OASIs. Postpartum ultrasound EAS assessment (C): An intact external anal sphincter, (D): A torn external anal sphincter (site of tear shown at the cursor).

The examination was done with the woman in the lithotomy position. The probe was placed at a right angle to the posterior vaginal distal wall and in a transverse scanning plane. The probe was then moved cranially in the vagina from the distal to middle level anal canal until the internal anal sphincter could be seen as a low-echogenic ring. The distance between the anal edge of the internal sphincter and the probe was measured in millimeters (Figure 2). Standard obstetric care was provided by the labor ward team, independently of the specialist conducting the ultrasounds. After delivery, obstetric anal sphincter injuries (OASIs) were initially identified by the attending birth assistant and then confirmed by the study specialist. The specialist assessed the

thickness of the anal sphincter without sharing the diagnosis with the labor ward team, and the birth assistant repaired the independently, sphincter without interference from the study group.Postnatally, the women underwent a perineal examination in the lithotomy position to check for OASIs. A "pill-rolling" technique was used for palpation, with the dominant index finger placed in the anus and the thumb in the vagina. A cavity was palpated along the sphincter muscle if the external sphincter was torn. Following delivery, a dynamic 2D transperineal ultrasound was conducted in a supine position with an empty bladder to assess the anal sphincters at rest and during contraction.⁸ Patients were instructed to voluntarily contract their anal sphincter prior to the examination. The ultrasound probe was positioned between the vaginal fourchette and the perineal body to visualize the sphincters (Figure 1-b, c). The primary outcome was the prediction of the risk of OASIs, as determined by clinical examination and supported by transperineal ultrasound findings. Secondary outcomes included other degrees of perineal trauma and the duration of the second stage of labor.



Figure (2):

A Transperineal ultrasound image of the anovaginal distance measured from the anal mucosa to the posterior vaginal wall.

B Transperineal ultrasound method to determine the anovaginal distance.

Sample Size

Given that we have five candidate predictors, our cohort will require at least 50 women who experience the primary outcome of interest, which is obstetric anal sphincter injuries (OASIs). Based on the reported OASIs rate of 4% in primiparous women,⁹ we estimate the need to recruit 1,250 women to observe the required number of OASIs cases. Consequently, we plan to continue enrollment until we either achieve 50 confirmed cases of thirdor fourth-degree tears or reach a total of 1,250 participants, whichever occurs first. For candidate predictors that do not normal distribution. follow а log transformation will be applied to enhance model fit. Missing data will be handled using multiple imputation methods to address any absent predictor values. The backward selection method will be employed to determine which predictors should be included in the final models. The model's performance will be assessed by its capacity to differentiate between those who do and do not develop the outcome. Prior to conducting any analysis, a detailed Statistical Analysis Plan will be developed and reviewed by an independent Data Monitoring Committee (DMC).

Statistical Analysis

Data were analyzed using IBM SPSS Statistics version 25. Descriptive statistics, including mean and standard deviation (SD), were used for quantitative variables, while frequency and percentages were employed for qualitative variables. Comparisons between qualitative variables were made using the chisquared or Fisher's exact tests, and the Mann-Whitney test was applied to skewed quantitative variables. The discriminatory power of AVD for OASIs was assessed using Receiver Operating Characteristics (ROC) curve analysis. Multivariate logistic regression was used to identify predictors of clinical OASIs, employing the ENTER method, with significance set at $p \le 0.05$.

Results

This cohort study included 697 pregnant women who presented to the emergency department, all of whom underwent antenatal ultrasound evaluations, except for the assessment of external anal sphincter (EAS) contraction, which was performed postpartum. Out of these participants, obstetric anal sphincter injuries (OASIs) were identified in 50 women.

Table 1 outlines the baselinecharacteristics of the study population,revealing that the participants wererelatively young, with a mean age of 23.6years and an age range of 18-40 years.

The majority of pregnancies were at term, with gestational ages ranging from 37 to 42 weeks and a mean of 38.9 weeks. A significant finding was the high *Values for continuous quantitative data are given as mean \pm SD.

******Values for categorical data are presented as numbers (percentage).

Kolmogorov–Smirnov test was used to examine the normal data distributional characteristics of all study cases.

***The t-test was used for normally distributed continuous quantitative data.

#The chi-square test was used for categorical data. A P-value of <0.05 is considered significant

prevalence of obesity, with 58.2% of participants classified as obese, which could potentially influence the study's outcomes, particularly concerning BMIrelated pregnancy complications.

Table 1 also highlights a significant association between BMI and the occurrence of OASIs, where women with OASIs had a significantly higher mean BMI (33.8±5.2) compared to those without OASIs (31.2±4.5), with a highly significant p-value of 0.000. Notably, 84% of women who sustained OASIs were categorized as obese, suggesting that obesity may be a critical risk factor for these injuries during childbirth.

	Description (n=697)	OASIs Clinically	OASIs Clinically	P-value
		Y es (n=50)	No (n=647)	
Age [∗]		-	-	-
Range	18-40			
Mean± SD	23.6±4.6			
Gestational age*		-	-	-
Range	37-42			
Mean± SD	38.9±1.2			
BMI*				
Range	20.3-46	20.5-44.9	20.3-46	
Mean± SD	31.4±4.6	33.8 ± 5.2	31.2 ± 4.5	<0.001***
BMI**				
Normal weight	50(7.2%)	3 (6%)	47 (7.3%)	<0.001#
Overweight	241(34.6%)	5 (10%)	236 (36.5%)	
Obese	406(58.2%)	42 (84%)	364(56.2%)	

Table (1) Demographic and baseline characteristics of the participants, with a comparison of BMI between women with and without obstetric anal sphincter injuries (OASIs):

	0ASIs clinically					
	Yes($n=50$) No($n=647$)		P value			
conventional US						
Occinut nosition*						
Antorior	10(2606)	225(51.00%)	0.097##			
Antenior	10(30%) 22(4.4%)	210(22 50%)	0.077			
Transvorso	22(44%) 10(20%)	210(32.370) 102(15.90%)				
GA**	10(20%)	102(13.070)				
Range	36.7-40.7	36-41				
Mean± SD	38.5±1.1	37.9±1	0.000#			
BPD**						
Range	85-103	67-101	0.000#			
Mean± SD	94.5±3.7	92.4±3.4				
HC**						
Range	312-355	290-357	0.000#			
Mean± SD	331.1±10.8	324±9.1				
Fetal weight**						
Range	3033-4390	2013-4340	0.000#			
Mean± SD	3539.6±319.3	3200.4±294.9				
AVD(mm)**						
Range	10-26	11-35	0.000#			
Mean± SD	19.4±4.2	22.1±4.2				
External anal sphincter contraction*						
Yes	12(24%)	457(70.6%)	0.000##			
No	38(76%)	190(29.4%)				
Postpartum Data	00(/0/0)	190(291170)				
Occiput Position [*]			0.000##			
- Anterior	33 (66%)	560 (86.6%)				
- Posterior	17 (34%)	87 (13.4%)				
Duration of Second Stage (mins) **			0.000#			
- Range	25-120	15-120				
- Mean ± SD	87.9 ± 25.0	57 ± 27.5				
Episiotomy**			0.713##			
- Yes	49 (98%)	620 (95.8%)				
- No	1 (2%)	27 (4.2%)				
Fetal Weight (Postpartum) (g) **			0.000#			
- Range	2800-4000	1900-4000				
- Mean ± SD	3415.6 ± 272.4	3110.9 ± 251.2				
Spontaneous Perineal Tears*			0.092##			
- 1st Degree	0 (0%)	11 (40.7%)				
- 2nd Degree	1 (100%)	4 (14.8%)				
- No Tears	0 (0%)	12 (44.4%)				

Table (2): Comparison Between Women With and Without OASIs Regarding Ultrasound (US) and Postpartum Data:

*Values Qualitative (categorical) data are given as numbers (percentage). **Values (continuous quantitative data) are given as mean± SD and range while Kolmogorov–Smirnov test was used to examine the normal data distributional characteristics of all study cases. #t-test was used for normally distributed continuous quantitative data ##Chi-square test was used for qualitative (categorical) data P value <0.05 significant

Table 2 compares various obstetric ultrasound parameters between women with and without OASIs. The data shows that women with OASIs had significantly higher mean gestational ages (38.5 weeks vs. 37.9 weeks, p=0.000) and larger fetal head measurements, including biparietal diameter (BPD) and head circumference (HC), both with p-values of 0.000. Additionally, the mean fetal weight was significantly higher in the OASIs group (3539.6 g vs. 3200.4 g, p=0.000). Interestingly, the mean Ano-vaginal diameter (AVD) was notably smaller in women with OASIs (19.4 mm vs. 22.1 mm, p=0.000), and the absence of EAS contraction was significantly more common in women with OASIs (24% vs. 70.6%, p=0.000). These findings suggest that larger fetal size and the absence of EAS contraction are associated with an increased risk of OASIs.

 Table 2 also presents postpartum data,
showing significant differences in several key areas between women with and without OASIs. Women with OASIs were more likely to have a posterior occiput position at delivery (34% vs. 13.4%, p=0.000) and a longer second stage of labor (87.9 minutes vs. 57 minutes, p=0.000). They also had significantly higher mean fetal birth weights (3415.6 g 3110.9 p=0.000). vs. g, Although episiotomy rates were high in both groups, no significant difference was found (p=0.713), but there was a trend towards fewer spontaneous perineal tears in the OASIs group, although not statistically significant (p=0.092).

Table (3): Multivariate analysis to explore the independent predictors of OASIS.

	P-value OR		95% CI for OR		
Age	0.537	0.972	0.887	-	1.065
Gestational age by date	0.940	1.019	0.625	-	1.660
BMI	0.042	1.086	1.003	-	1.175
Occiput position by US (posterior or	0.553	1.277	0.569	-	2.862
Transverses VS Anterior)					
Gestational age by US	0.708	1.115	0.631	-	1.969
BPD	0.429	0.953	0.846	-	1.074
НС	0.209	1.030	0.984	-	1.077
Fetal weight	0.709	1.001	0.998	-	1.003
AVD(mm)	0.000	0.785	0.713	-	0.864
Occiput position by at delivery	0.032	2.627	1.087	-	6.353
(posterior VS Anterior)					
Duration of the 2 nd stage in mins	0.000	1.027	1.013	-	1.041
Episiotomy	0.995	0.992	0.079	-	12.469
Fetal weight (PP)	0.085	1.003	1.000	-	1.006
					15

Table 3 identifies independent predictors of OASIs through multivariate analysis. Significant predictors included BMI (p=0.042, OR=1.086), AVD (p=0.000, OR=0.785), occiput position at delivery (p=0.032, OR=2.627), and the duration of the second stage of labor (p=0.000, OR=1.027). These findings emphasize the importance of monitoring these factors to reduce the risk of OASIs during childbirth.



Figure (3): ROC curve for AVD values

Finally, **Figure 3** provides ROC curve analysis for AVD in predicting OASIs, with an AUC of 0.659, indicating moderate discriminatory power. The cut-off point of ≤21.5 mm yielded a sensitivity of 68.0% and a specificity of 52.6%, highlighting a balance between sensitivity and specificity but also suggesting a relatively higher rate of false positives. This indicates that while AVD measurements can be a useful predictor of OASIs, their application in clinical practice should be carefully considered to ensure reliability in prediction (Figure 3).

Discussion

Injury of anal sphincter during delivery (OASI) is a leading cause of anal leakage in women, adversely affecting their mental, physical, and social well-being. In the UK, the incidence of OASI in primiparous women is 6.1%, with a threefold increase from 2000 to 2012.1 Women with undiagnosed OASIs are more likely to develop anal incontinence.¹⁰ To enhance the detection of OASIs during delivery, endoanal ultrasound (EAUS) has been evaluated. A previous study revealed that 58% of OASIs were missed by doctors and midwives but were identified using EAUS, though it had a 2% false-positive rate.¹¹ Endoanal ultrasound is considered the golden standard when diagnosing issues with the anatomy of the perineum and anal sphincters when examining women with anal incontinence. The use of endoanal ultrasound before or immediately after primary repair postpartum improved the diagnosis of anal sphincter tears and reduced the risk of severe fecal incontinence postpartum. It has been suggested to routinely use endoanal ultrasound of the perineal tissues and anal sphincters immediately after childbirth. However, EAUS is costly, requires specialized training, and is not widely available. Moreover, it causes more discomfort compared to other imaging methods like transperineal ultrasound (TPUS).⁵ In recent years, TPUS has gained attention for imaging the anal sphincter, as it is less invasive, widely accessible, and allows for visualization without disrupting the anatomy.⁵ Given the poor outcomes associated with injury of anal sphincter during delivery and repair,¹² identifying antepartum clinical risk factors is crucial. This study evaluated anovaginal distance

(AVD) as a predictor of anal sphincter tears during the first vaginal delivery, finding it to be a safe, non-invasive, and cost-effective assessment tool.In this prospective cohort study, primiparous women with confirmed external sphincter injury had a shorter AVD compared to those with perineal lacerations without sphincter injury. The palpatory thickness of the anal sphincter, as measured by the specialist, correlated well with the AVD measured using TPUS. Previous research has not explored antenatal anovaginal distance or perineal tissue assessment in pregnancies full-term using TPUS. Typically, the perineal area is evaluated during pregnancy or postpartum, with EAUS considered the gold standard for assessing perineal tissues, including the anal sphincter complex.¹³ Our findings align with another researcher, who reported a higher incidence of third- and fourth-degree perineal lacerations when the perineal body was ≤ 2.5 cm.¹⁴ Another research suggested a 20 mm AVD threshold for predicting external sphincter injury,¹⁵ with our study identifying an AVD of 21.5 mm as a cutoff for EAS injuries. However, comparing these findings to another study., who assessed the perineal body and anal sphincter complex antenatally using EAUS, is challenging due to differences in techniques. EAUS impacts perineal tissues differently than TPUS, and no comparative studies between TPUS and EAUS during term pregnancy are available.¹⁶ Transperineal ultrasound (TPUS), in both two-dimensional and three-dimensional formats. has been utilized in the postpartum period to evaluate anal sphincter injuries and their repairs.¹⁷ Applied TPUS using a vaginal ultrasound probe prior to hospital discharge following vaginal birth, observing a notable difference in the average perineal body distance among mothers, with thinner perineums linked to cases involving obstetric anal sphincter injuries (OASIs).¹⁷ Additionally, a strong correlation was reported between the bidigital assessment of external sphincter thickness and TPUS measurements of perineal length immediately following the primary repair of an external anal sphincter tear. These findings align with our own study, conducted shortly after childbirth.¹⁸

In our study, the gold standard was the inspection and palpation of perineal lacerations, with TPUS compared to these methods. However, as TPUS is not vet widely used in clinical practice, standard served examination as а logical comparison. To our knowledge, this is the first study to evaluate the anal sphincter immediately after delivery in а postpartum ward using 2D TPUS and anal sphincter contraction. We found that 76% of clinically visible anal sphincter defects were confirmed on ultrasound by the absence of anal sphincter contractions, and 70.6% of clinically intact sphincters exhibited good contractions on 2D TPUS. TPUS demonstrated a low positive predictive value (16.7%) for diagnosing sphincter defects, a high negative predictive value (97.4%) for detecting intact sphincters, and an overall accuracy of 71%. While most patients showed no contraction effect on ultrasound three days postpartum, contractions were observed in all patients after six months, likely due to healing.¹⁹ The most robust study to date comparing TPUS. TVUS, and EAUS noted that their training standards were exceptionally high, potentially limiting generalizability. TPUS has additionally been applied in the early postpartum period to assess the anal sphincter complex.⁵ In another study

among 146 women who had TPUS within 48 hours postpartum, 12 clinically detected OASIs were confirmed through TPUS.⁶ However, due to the small sample size and insufficient power, these results should be interpreted with caution.

In our study, two anal sphincter defects (4%) observed on ultrasound were classified as third-degree tears clinically but were missed during the clinical examination. These might represent occult sphincter injuries, which are defects visible only on ultrasound and not clinically detectable. Previously thought to be "occult," these injuries are now recognized as clinically missed OASIs. Our findings align with an observational study, where 1% of OASIs were visible on ultrasound but not detected clinically.¹¹ In a similar study, it was reported that three sphincter defects (2%) anal went during undetected the clinical examination but were identified in later ultrasound imaging.⁶ However, findings studies contradictory. across are Numerous extensive population-based have pinpointed cohort studies independent risk factors for both primary and recurrent OASIs, which include factors such as nulliparity, higher birth weight, vaginal deliverv. and a operative persistent occipito-posterior fetal position.²⁰⁻²² In our study, maternal BMI was a significant factor, consistent with recent UK data indicating that higher BMI is protective against minor perineal trauma but not OASIs.23 However, other studies suggest that higher BMI is protective against OASIs.24,25 Consistent with other studies, we found that high birth weight is a significant risk factor for OASIs. Although the risk was higher when birth weight exceeded 4000 g, the use of episiotomy did not significantly reduce the risk.²⁶ In contrast to our findings, another mediolateral study reported that

episiotomy strongly protects against third-degree perineal ruptures and may serve as a primary method for preventing incontinence.27 fecal А thorough knowledge of perineal and anal sphincter accurately anatomv is crucial for diagnosing sphincter obstetric anal injuries (OASIS). Reconstructive surgery aims to reestablish continuity of both the internal and external anal sphincters, ideally performed promptly after the injury occurs. Key factors in reducing complications following chronic perineal rupture repair include accurate anatomical identification of the anal sphincter complex. careful surgical technique, and attentive postoperative care.28,29 Our study did not observe a significant difference in the performance of mediolateral episiotomy between women with and without OASIs, with pvalues >0.05.

Conclusion

This study concludes that transperineal ultrasound (TPUS) is a valuable tool for diagnosing pelvic floor injuries and dysfunction, offering significant potential for improving women's health through early detection of risk factors and encouraging timelv pelvic floor rehabilitation. The anovaginal distance (AVD) measured via ultrasound is closely associated with perineal laceration outcomes, with a shorter AVD indicating a higher risk of external sphincter injury. An AVD cutoff of 21.5 mm could be used as a clinical warning sign in the delivery room, prompting careful examination of perineal lacerations before suturing but it is not a perfect tool alone for detection of OASIs as it had low sensitivity and specificity.

Strength and limitation of the study Strengths:

- **1. Novelty:** The study explores the accuracy of transperineal ultrasound (TPUS) in diagnosing obstetric anal sphincter injuries (OASIs), a relatively underexplored area.
- **2. Large Sample Size:** Involving 697 participants, the study ensures robust statistical analysis.
- **3. Comprehensive Analysis:** The study evaluates multiple variables, including BMI, gestational age, fetal parameters, and AVD, providing a thorough understanding of risk factors.
- 4. **Real-world Application:** The findings suggest TPUS can complement clinical examinations, potentially improving OASI diagnosis and management.

Limitations:

- **1. Moderate Predictive Power:** The AVD's area under the curve (AUC) was 0.659, indicating only moderate accuracy in predicting OASIs.
- 2. Single-Center Study: Conducted at one hospital, the results may not be generalizable to other settings.
- **3. Observer Bias:** A single examiner performed all ultrasounds, which could introduce observer bias.
- 4. Limited Follow-Up: The study focuses on immediate postpartum outcomes, lacking long-term follow-up data on the effectiveness of TPUS in preventing complications from OASIs.

Ethical approval statement

This research has received ethical approval from faculty of medicine of Cairo University's Ethical Research Committee approved the study protocol. under protocol number (MD-21-2021). The study adheres to all ethical principles, ensuring the protection, rights, and wellbeing of participants. Consent has been obtained, and confidentiality measures are in place to safeguard sensitive information. The research design aligns with established ethical guidelines, and any potential risks have been minimized to ensure the ethical integrity of the study.

Patient and public involvement

This study was conducted at Kasr Alainy Hospital, Cairo University, with 697 nulliparous women. Although patients were fully informed and provided consent, they were not involved in the study's design, conduct, selection of outcome measures, or dissemination planning. The research questions and methods were formulated by the clinical team based on existing knowledge, with the goal of improving maternal health outcomes. The study's findings will be disseminated through academic channels to advance clinical practice, indirectly benefiting the patient community. Future research could be strengthened by incorporating more direct involvement from patients and the public.

Consent to Participate:

Informed consent was obtained from all participants. They were provided with detailed information about the study objectives, procedures, potential risks and benefits, confidentiality measures, and their right to withdraw at any time without consequences. Written consent was obtained from each participant before their inclusion. Participants' confidentiality was strictly maintained throughout the research process, and all data were anonymized.

Authors Contributions

The authors contributed to the study as follows: Dalia Samir ZoElfakar contributed to the conception and design of the study,

data collection, and interpretation of the results. Niven Abu Al-Foutouh Shaban was involved in the acquisition of data, drafting the manuscript, and critical revision for important intellectual content. Ahmed Nagy Shaker wrote and edited the manuscript, revised the statistical plan and analysis, and contributed to the interpretation of the results. Sherif Mohamed Negm contributed to data analysis, interpretation, and assisted in drafting and revising the manuscript. Mohamed Fikry Kasem participated in the study design, data collection, and provided critical revisions to the manuscript.

Guarantor Statement

Dr. Ahmed Nagy Shaker, is the guarantor for this manuscript. As the corresponding author, Dr. Shaker takes full responsibility for the integrity of the research, including the data. analysis. and conclusions presented. Dr. Shaker is accountable for ensuring that all aspects of the study, including its design, execution, and reporting, adhere to ethical standards and journal guidelines. Any potential conflicts of interest have been disclosed, and all authors have contributed significantly to the research and manuscript preparation. Dr. Shaker is also responsible for addressing any queries or concerns that arise during the review process.

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Conflict of interest

The authors have no conflicts of interest.

Data Availability Statemen

The data supporting this research is available upon request. Please contact corresponding Author at ahmedafifi38527@postgrad.kasralainy.ed

<u>u.eg</u> for access to the relevant datasets. We are committed to transparency and facilitating the reproducibility of our findings, and we welcome inquiries regarding the data used in this study.

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Consent for publication.

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