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Comparing diagnostic criteria between endoanal ultrasound and transperineal ultrasound for diagnosing anal sphincter defects: secondary analysis of prospective observational study

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Contribution:

What are the novel findings of this work? Transperineal ultrasound (TPUS) had excellent agreement with endoanal ultrasound (EAUS) in diagnosing the presence of a sphincter defect. However, there was poor-to-moderate agreement in the measurement of defect angle, with a standard error of measurement of 16 degrees, and 27 degrees with the external and internal anal sphincter respectively.

What are the clinical implications of this work?

A cut-off angle of 30 degrees should not be used for transperineal ultrasound examination in the diagnosis of a residual anal sphincter defect. Further research is required to determine the cut off-angle for transperineal ultrasound.

Abstract

Objectives

To evaluate the agreement between three-dimensional endoanal ultrasound (3D- EAUS) and four-dimensional transperineal ultrasound (4D-TPUS) in measuring anal sphincter defect angle.

Methods

This was a secondary analysis of the PERINEAL study in women with wound infections. At each review, both 3D EAUS and 4D TPUS (at rest and on maximal pelvic floor muscle contraction (PFMC)) were performed. Kappa coefficient (k), intra-class correlation coefficients (ICC) and standard errors of measurement (SEM) were calculated. The largest angle size of a defect at the same sphincter level was analyzed. A defect was deemed significant if it was >30 degrees.

Results

250 EAUS and 250 TPUS were performed in the same patients at each time point. An external anal sphincter (EAS) defect was found in 55 (22.0%) and 47 (18.8%) images on EAUS and TPUS respectively. An internal anal sphincter (IAS) defect was found in 26 images (10.4%) on both modalities. There was excellent agreement (k=0.87) with diagnosing EAS defects and perfect agreement (k=1.00) with diagnosing IAS defects. With TPUS at rest, there was poor and moderate agreement with EAS defect size and IAS defect size (SEM of $\pm 16.1^\circ$ and $\pm 27.9^\circ$) respectively. With TPUS performed during maximal PFMC, there was poor and moderate agreement with EAS defect size and IAS defect size (SEM of $\pm 16.5^\circ$ and $\pm 26.4^\circ$) respectively. Based on the SEMs, if the diagnostic cut off of 30° was used, incorrect diagnosis of a significant EAS defect could occur in approximately 9-27% of women. Incorrect diagnosis of a significant IAS defect could occur in approximately 7-15% of women.

Conclusions

This is the first study to directly compare EAUS and TPUS angle measurements. A cut-off angle of 30 degrees should not be used for TPUS examination in the diagnosis of a residual anal sphincter defect. Further research is required to determine the cut off-angle for TPUS.

Introduction:

Endoanal ultrasound (EAUS) and transperineal ultrasound (TPUS) are modalities that can be used to evaluate the anal sphincter after obstetric anal sphincter injury (OASI).¹ EAUS has been histologically validated and has been found to correspond with external anal sphincter (EAS) defects, which appear hypoechoic or mixed in echogenicity and also internal anal sphincter (IAS) defects which appear as a hyperechoic disruption within the hypoechoic muscular ring.^{2,3} Therefore EAUS is the agreed gold standard modality to evaluate the anal sphincter.⁴ However, unlike EAUS, TPUS has not been validated histologically.⁵ As EAUS probes measure 17mm in diameter, it is agreed that due to the probe being placed within the anal canal, this may result in stretching and possible distortion of anatomy.^{6,7} In comparison, TPUS allows analysis of the anal sphincter in an undisturbed state as the probe is placed exoanally.⁶

The diagnostic criteria for a significant residual sphincter defect on TPUS was “mathematically validated” taking into account the EAUS criteria used to diagnose a significant sphincter defect.⁵ On EAUS a significant sphincter defect is defined as a discontinuity of greater than 30 degrees in at least two-thirds of the length of the anal sphincter.⁸ This is because with defects less than or equal to 30 degrees it is difficult to decipher whether this is secondary to a scar formed as part of the normal healing process following surgical repair or due to a defect secondary to the sphincter muscles being unopposed.⁸ In addition, the function of the sphincter muscle, which can be demonstrated using anal manometry⁹, has been shown to be significantly worse in women with a sphincter defect greater than 30 degrees in comparison to those less than or equal to 30 degrees.¹⁰ However, defects less than 30 degrees, are considered significant, if anal manometry pressures are substantially reduced, indicating compromised function.⁸

Despite this potential difference in anatomy between EAUS and TPUS, it is assumed that a defect on TPUS should also be greater than 30 degrees.¹ We aimed to establish the agreement between EAUS and TPUS in measuring defect angle, using EAUS as the gold standard.

Methods:

This was a secondary analysis of a previous clinical study completed at Croydon University Hospital which explored the effect of perineal wound infection on anal sphincter integrity. This primary study is registered with the Clinical Trials registry (ClinicalTrials.gov NCT04480684) and was approved by the NHS Health Research Authority, London – Surrey Research Ethics Committee (20/LO/0304).¹¹ All study participants gave written informed consent. To explore the differences between EAUS and TPUS, we used all the data of the primary study population (n=80 women) in our analysis. Women were reviewed once a week until their perineal wound had healed or up to a maximum of 16 weeks. Each ultrasound assessment was performed on the same day. Three-dimensional (3D) EAUS was performed at rest with the patient lying in the left lateral position using the Flex-focus 500 or BK 3000 ultrasound system (BK Medical, Herlev, Denmark). An anal sphincter defect was defined as a discontinuity in the ultrasound appearance of the IAS or the EAS. Figure 1 shows the measurement of an EAS and IAS defect in the same patient taken with EAUS and TPUS at rest. Anal sphincter defect sizes were measured using a three-point angle with images taken at the deep (proximal), superficial (mid) and subcutaneous (distal) levels of the EAS. Four-dimensional (4D) TPUS was performed at rest and on maximal pelvic floor contraction (PFMC) with the patient in a supine position using a 2-8 MHz convex array volume probe (GE Voluson S10, RAB6-RS). The anal sphincter was reviewed on tomographic ultrasound imaging (TUI). On TUI the entire length of the anal sphincter from the puborectalis to the subcutaneous level of the EAS was captured in 8 transverse slices. The anal sphincter was then evaluated in slices 2-7 with the interslice interval adjusted to include the entire length of the anal sphincter. Again, anal sphincter defect sizes were measured using a three-point angle. To allow direct comparison of 3D-EAUS and 4D-TPUS, the largest angle size of any identified defect (including defects < 30 degrees) was taken into account. It was ensured this was measured at the same level of the anal sphincter. A defect of any size, partial or full-thickness was measured for the EAS and IAS. Anal sphincter defects identified on both modalities were also scored using the validated Starck score¹² which accounts for depth, length and size of the defect for both internal and external anal sphincter, with a range from 0 being no defect to 16 being a maximal defect. All image volumes were reviewed offline independently by a single investigator experienced in imaging of the anal sphincter (A.S analysed EAUS, and K.W analysed TPUS). As participants were scanned weekly, ultrasound volumes were analysed with a week interval and each investigator was blinded to the results of the previous scan to avoid bias due to repeated measurements.

Study Outcomes:

The primary study outcome was the agreement between anal sphincter defect three-point radial angle measured on 4D-TPUS and 3D-EAUS (reference standard). The secondary outcomes included the agreement with diagnosing the presence of defect identified on 4D-TPUS and the Stark Score, using 3D-EAUS as the reference standard. The STROBE guidelines were used to ensure the reporting of this observational study.¹³

Statistical Analysis:

Data were analysed using SPSS version 26.0.0.0. Nominal data are expressed as numbers and percentages. The Shapiro-Wilk test was used to check the normality of continuous variables. Continuous data was then reported as median (IQR) or mean (SD). Differences between two measurements were analyzed with the paired-sample t test or the Wilcoxon-signed rank test as appropriate. Intra-class correlation coefficients (ICC) were calculated to assess the inter-instrument agreement between defect angle and Stark Score with 3D EAUS and 4D TPUS. Values of <0.50 indicated poor, 0.50-0.75 moderate, 0.75-0.90 good, and >0.90 excellent reliability.¹⁴ Standard errors of measurement (SEM) were calculated to measure the range of error of each measurement. The SEM were calculated as follows: $SEM = SD \times \sqrt{1 - ICC}$. The defect angle measured at that time point and the relevant SEM was subtracted and added to this value to calculate the number of women that would be incorrectly diagnosed with a significant sphincter defect on TPUS, using a diagnostic cut off of 30 degrees. Kappa coefficient (k) was calculated to assess the agreement between diagnosing a defect with 3D EAUS and 4D TPUS at the end of the wound healing process. Values of ≤ 0 indicated no agreement, 0.01–0.20 as none to slight, 0.21–0.40 as fair, 0.41– 0.60 as moderate, 0.61–0.80 as substantial, and 0.81–1.00 as almost perfect agreement.¹⁵ 3D-EAUS was considered the reference standard.

Results:

Of the 80 women that participated in the primary study, 73 agreed to both 3D EAUS and 4D TPUS. From the 73 women, a total of 500 scans were performed (250 TPUS and 250 EAUS were performed in the same patients at each time point). Table 1 describes the participants' grades of perineal injury diagnosed and their ultrasound findings. Eight (6.8%) women were diagnosed with an OASI and underwent primary OASI repair. However, five women (5.5%) had a missed third-degree tear, identified either on EAUS or TPUS. All these women had an instrumental delivery (ventouse=2, forceps=2, sequential instruments=2) and four (80%) had a mediolateral episiotomy. At the end of the wound healing process, 10 (13.7%) and 8 (10.9%) women were diagnosed with an EAS defect on EAUS and TPUS respectively. An IAS defect was also found in 3 (4.1%) women on both EAUS and TPUS. There was substantial agreement between TPUS and EAUS with diagnosing an EAS defect ($k=0.87$, 95%CI 0.70-1.05) and perfect agreement with diagnosing an IAS defect ($k=1.00$).

The median number of ultrasound scans completed until complete perineal wound healing was 2 (range 1-16). On TPUS, an EAS defect was found in 47 images (18.8%), this was >30 degrees in 42 images (89.4%) at rest and in 34 images (72.3%) on maximal PFMC. On EAUS, an EAS defect was found in 55 images (22.0%) and was >30 degrees in 30 images (54.5%). An IAS defect was found in 26 images (10.4%) on both TPUS and EAUS (Table 2). On TPUS this was >30 degrees in 22 images (84.6%) at rest and on maximum PFMC. On EAUS this was >30 degrees in all images.

Table 3 compares the measurements of EAS and IAS defects and the Starck score on both modalities. EAS defects measured on TPUS in a resting state were significantly larger than those measured with EAUS (51.7° vs 40.5° , $p<0.001$). However, there was no significant difference found with EAS defects measured during maximal PFMC. In comparison to EAUS, IAS defects measured with TPUS in a resting state (86.1° vs 112.4° , $p<0.001$) and on maximal PFMC (78.9° vs 112.4° , $p<0.001$) were significantly smaller. However, there was no significant difference found in the resulting Starck score. Sensitivity analysis was performed using only measurements obtained at the end of the wound healing process ($n=73$ women). No significant difference was found between both modalities (Supplementary Table 1).

In comparison to EAUS, TPUS performed in a resting state had a moderate agreement with EAS defect size (ICC 0.64, 95%CI 0.40-0.80) and poor agreement with IAS defect size (ICC 0.34, 95% CI -0.10-0.67) measurements, with a SEM of ± 16.1 degrees and ± 27.9 degrees respectively. TPUS performed during maximal PFMC had a moderate agreement with EAS defect size (ICC 0.67, 95%CI 0.50-0.80) and poor agreement with IAS defect size (ICC 0.29, 95% CI -0.07-0.60) measurements, with a SEM of ± 16.5 degrees

and ± 26.4 degrees respectively. However, there was excellent reliability with the Starck score on TPUS performed in a resting state and on maximal PFMC, with an SEM of 1 (Table 4).

Based on the SEMs, Figure 2 shows the number of women that would be incorrectly diagnosed with a significant sphincter defect on TPUS in a resting state, if the diagnostic cut off of 30 degrees was used. Underdiagnosis of an EAS defect (n=55 images on EAUS) would occur in 16.3% (n=9) of cases, and overdiagnosis would occur in 20% (n=11). Underdiagnosis of an IAS defect (n=26 images on EAUS) would occur in 7.7% (n=2) of cases, and overdiagnosis would occur in 15.4% (n=4).

For significant sphincter defects diagnosed on TPUS at maximum PFMC, underdiagnosis of an EAS defect would occur in 27.2% (n=15) of cases, and overdiagnosis would occur in 9.1% (n=5). Underdiagnosis of an IAS defect would occur in 15.4% (n=4) of cases, and overdiagnosis would occur in 3.8% (n=1) (Figure 3).

Discussion:

This original study directly compares the defect angle measurements taken using EAUS and TPUS. In this secondary analysis, we showed that TPUS has excellent agreement with EAUS in the detection of a sphincter defect. However, there is a poor to moderate agreement with IAS and EAS defect angle measurements taken using TPUS in a resting state and on maximal PFMC. Moreover, the SEM was approximately ± 16 degrees with the EAS and ± 27 degrees with the IAS. Therefore, if TPUS was performed using the diagnostic cut off of 30 degrees, incorrect diagnosis of a significant EAS defect could occur in approximately 9-27% of women. Also, incorrect diagnosis of a significant IAS defect could occur in approximately 4- 15% of women.

Strengths of this study include that a validated scoring system was used to assess scan findings and all scans were reviewed independently by two reviewers offline, who were blinded to the other scan results and the clinical history, with a weekly interval. Limitations include that with both TPUS and EAUS, that suture material, edema and hematoma may affect the image quality and so assessment of defect angle.^{6,12} This may have affected the defect angles measured at the beginning of the wound infection process. We acknowledge that as this was a secondary analysis, the primary outcome of this study was not powered to assess a difference between EAUS and TPUS measurements. Although our sample size was large (n=500 ultrasound volumes), only 10 women had a defect (10 EAS and 3 IAS) on ultrasound, this equated to 102 ultrasound scans (55 EAUS and 47 TPUS). As the rate of OASI is only approximately 3%¹⁶ and the risk of wound infection in the group has been reported to affect up to 20% of women¹⁷ this small sample size was expected. However, as a difference of 30 degrees is clinically relevant, based on our study findings, for EAS angle, assuming a SD for the differences of 21.52, 5% significance level and 90% power, a future study would need a sample size of 8 women. For IAS angle, assuming a SD for the differences of 28.89, 12 women would be required.

30 degrees is the angle used in the diagnosis of significant defects and is taken into account when making recommendations regarding mode of delivery in subsequent pregnancies after OASI.^{18,19} The Royal College of Obstetricians and Gynaecologists recommend that women who are symptomatic or have abnormal EAUS and/or manometry should be counselled regarding the option of elective caesarean birth.²⁰ We found that if TPUS was used, underdiagnosis of a significant sphincter defect could occur in up to 27%. This would therefore lead to an improper recommendation of vaginal birth, and so, potentially compromise anal sphincter function in a future delivery. Additionally, as

overdiagnosis of a sphincter defect could occur in up to 15%, this could lead to an improper recommendation of caesarean birth, which is not without short or long-term risk.²¹

Taithongchai et al. performed a prospective study comparing the diagnostic accuracy of 3D EAUS and 3D TPUS in 250 women, using EAUS as the reference standard. They found that TPUS had a low positive predictive value of 51% and 37% in diagnosing EAS and IAS defects respectively. However, TPUS had a high negative predictive value of 85% and 93% in diagnosing EAS and IAS defects respectively, meaning that although TPUS could accurately diagnose an intact anal sphincter, it could not accurately diagnose a sphincter defect.²² We found that there was substantial agreement in diagnosing EAS and IAS defects. The difference in our study findings may be due to the difference in TPUS ultrasound systems. We used a newer generation system which may have attributed to better volume acquisition, image quality and so better agreement in the diagnosis of an anal sphincter defect.

As we analyzed EAUS and TPUS at rest, we can suggest the effect distention from the endoanal probe has on the anal sphincter complex, without additional change in anatomy from PFMC. It was unsurprising that in comparison to EAUS, on TPUS, IAS defects were significantly smaller by 26 degrees at rest. However, on TPUS, EAS defects at rest were significantly larger by 11 degrees. A plausible explanation for this is that despite their contractile ability, in comparison to the smooth muscle of the IAS, the striated skeletal muscle of the EAS, has lower elastic capability and therefore is less affected by stretching forces.²³ With TPUS, it is advised that volume acquisition is taken on maximal PFMC, to improve defect visualization.²⁴ However, if sufficient PFMC cannot be achieved, images can be taken at rest and there is no significant difference in diagnostic performance.²⁵ With regards to EAS angle, our study agrees with the recommendation by Dietz et al.²⁴, as no significant difference with EAUS measurements was found. However, with TPUS analyzed at rest, EAS angle was significantly larger by 11 degrees in comparison to EAUS.

The correlation between TPUS and EAUS with defect severity scores such as the Norderval score has been shown to be good.²² With regards to defect angle size, the Norderval score uses 90 degrees as its cut-off.²⁶ We used the Starck score to evaluate the extent of anal sphincter defects, which uses cut-off values of 90 degrees, 91-180 degrees and 180 degrees.¹² We found that with the Starck score there was an excellent correlation between EAUS and TPUS. This is unsurprising as the SEMs were smaller than 90 degrees. This is in keeping with a previous prospective study of 59 women after

primary OASI repair, which found that EAUS and TPUS had a moderate to good correlation in assessing the Starck score.²⁷

In conclusion, we found that 4D TPUS has excellent agreement with 3D EAUS in the detection of a sphincter defect. However, there was poor to moderate agreement between 3D EAUS and 4D TPUS when measuring IAS and EAS defect size. TPUS may therefore incorrectly diagnose significant sphincter defects and lead to inappropriate management. This highlights the need for caution when using TPUS for this purpose in subsequent pregnancy management. Therefore, the diagnostic criteria needs reappraisal. Future studies with larger sample size, powered specifically to assess differences between the two modalities would be required to detect a true difference and to calculate a new cut-off for TPUS.

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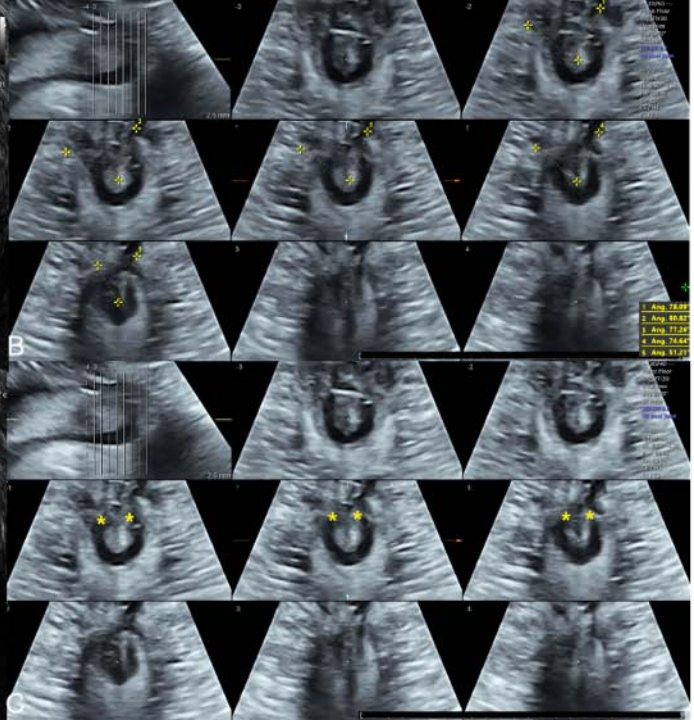
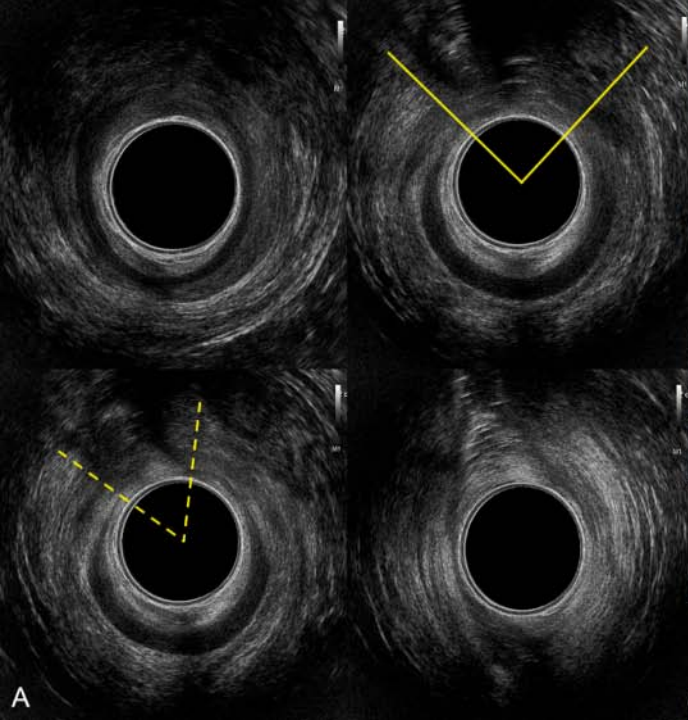
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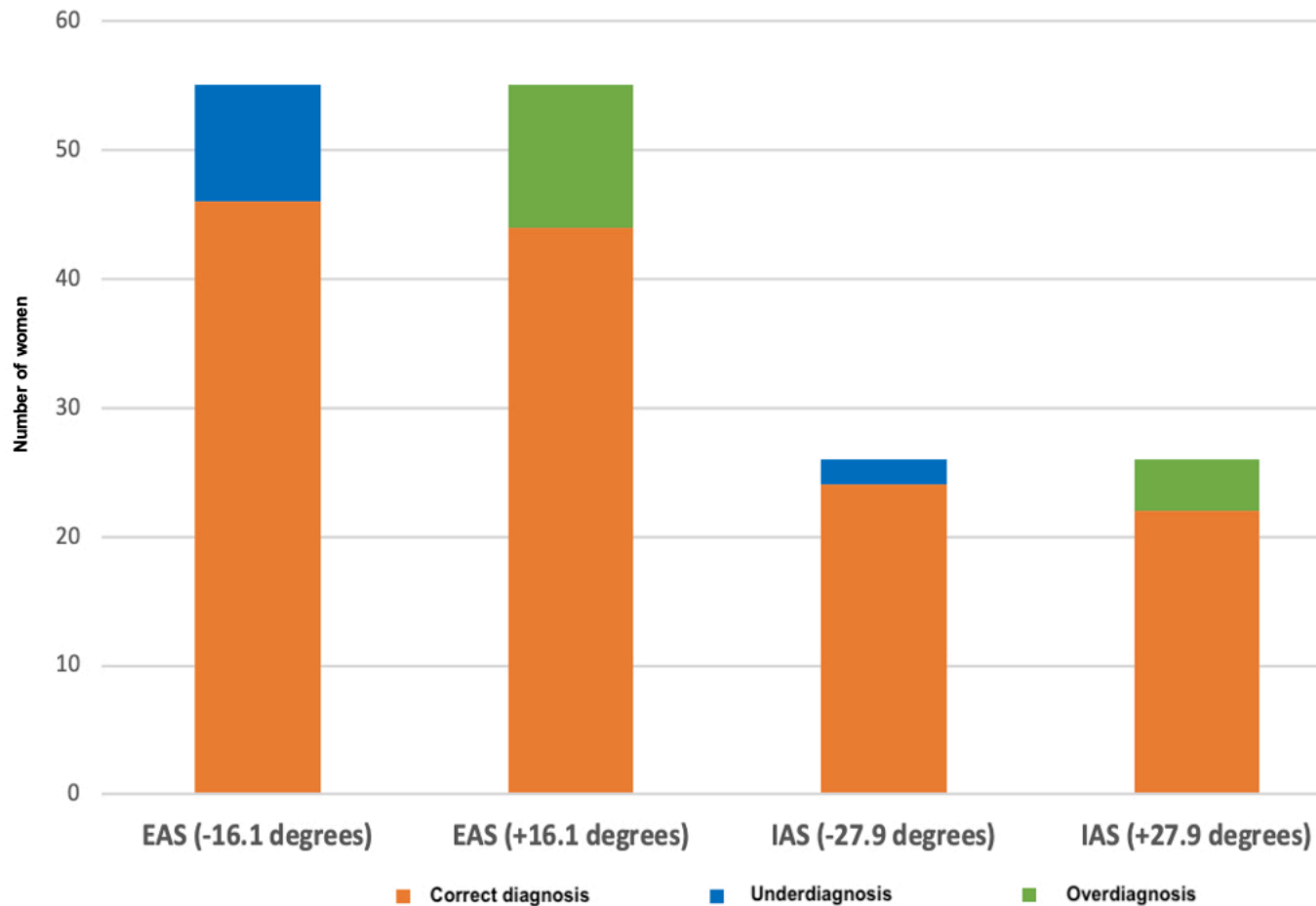
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Figure 1: Images of an external anal sphincter (EAS) and internal sphincter (IAS) defect from the same patient on endoanal ultrasound (A) (EAS defect=solid line, IAS defect= dashed line) and transperineal ultrasound (B, C) measured using a three-point angle

Figure 2: Number of women incorrectly diagnosed with a significant anal sphincter defect on TPUS taken at rest if 30 degrees diagnostic cut off used

Figure 3: Number of women incorrectly diagnosed with a significant anal sphincter defect on TPUS taken on maximum contraction, if 30 degrees diagnostic cut off used





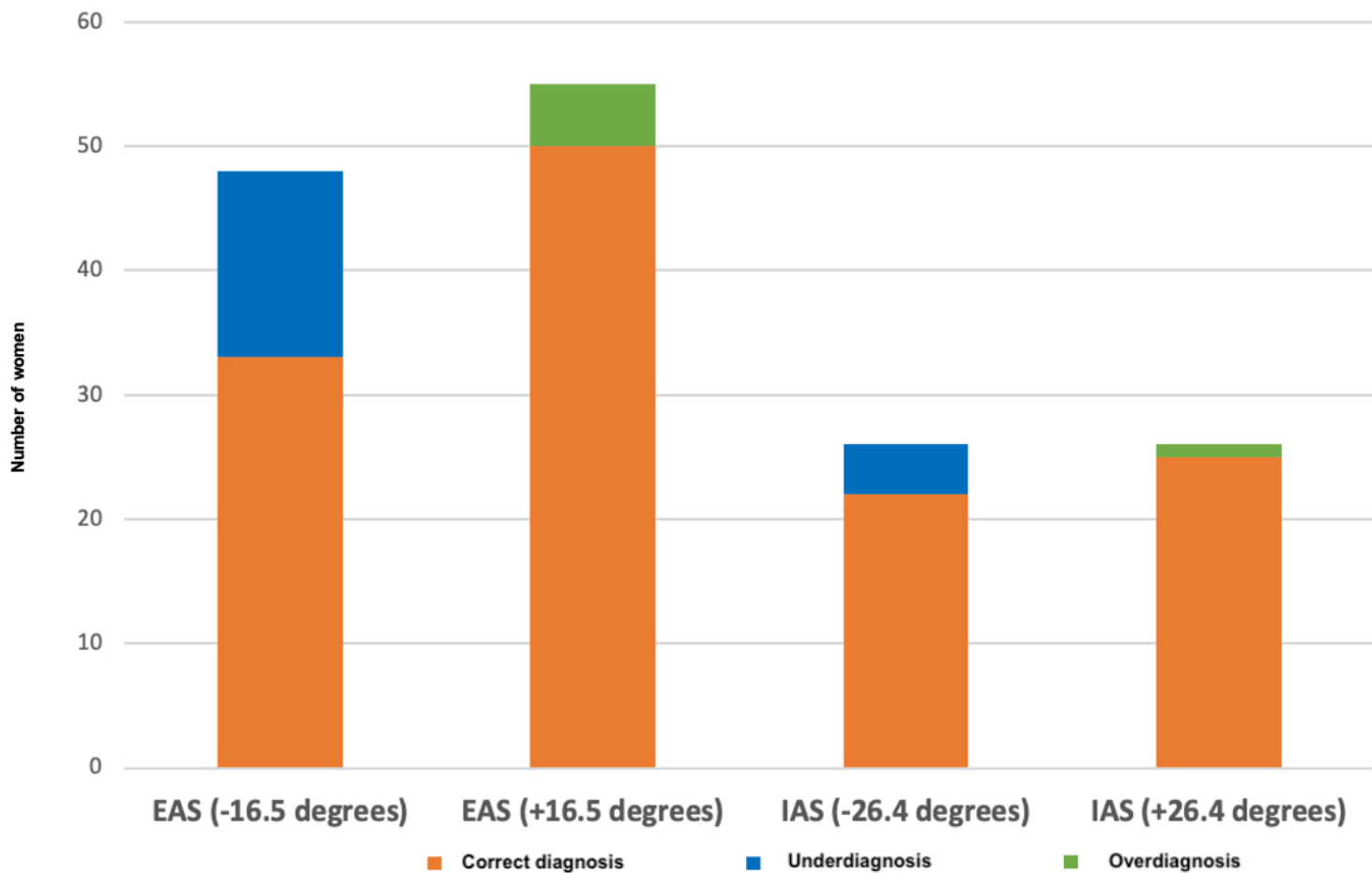


Table 1: Participant's grade of perineal injury diagnosed at delivery and on 3D EAUS and 4D TPUS:

n=73	n (%)
1st degree	1 (1.4)
2nd degree	13 (17.8)
Episiotomy	46 (64.4)
Episiotomy and additional tear	
2nd degree	7 (9.6)
OASI	3 (4.1)
OASI	
3a	3 (4.1)
3b	1 (1.4)
3c	0 (0)
4th	1 (1.4)
EAUS	
EAS defect	10 (13.7)
IAS defect	3 (4.1)
TPUS	
EAS defect	8 (10.9)
IAS defect	3 (4.1)

OASI- Obstetric anal sphincter injury

EAS- External anal sphincter

IAS- Internal anal sphincter

EAUS- Endoanal Ultrasound scan

TPUS- Transperineal Ultrasound scan

Table 2: Anal sphincter defects diagnosed on 3D EAUS and 4D TPUS during wound healing

n=250	n (%) / Median (IQR)
Number of scans/Weeks to wound healing	2 (1-4)
EAUS	
EAS defect	55 (22.0)
>30 degrees	30 (54.5)
IAS defect	26 (10.4)
>30 degrees	26 (100.0)
TPUS (rest)	
EAS defect	47 (18.8)
>30 degrees	42 (89.4)
IAS defect	26 (10.4)
>30 degrees	22 (84.6)
TPUS (maximal PFMC)	
EAS defect	47 (18.8)
>30 degrees	34 (72.3)
IAS defect	26 (10.4)
>30 degrees	22 (84.6)

EAS- External anal sphincter

IAS- Internal anal sphincter

EAUS- Endoanal Ultrasound scan

TPUS- Transperineal Ultrasound scan

PFMC- Pelvic floor muscle contraction

IQR- Interquartile range

Table 3: Difference in defect angle size and Starck Score on 3D EAUS and 4D TPUS at rest and during maximal contraction

n=250	3D EAUS	4D TPUS (rest)	p-value	4D TPUS (maximal PFMC)	p-value
	Mean (SD)/Median (IQR)	Mean (SD)/Median (IQR)		Mean (SD)/Median (IQR)	
EAS angle	40.5 (18.6)	51.7 (35.6)	<0.001*	45.6 (33.3)	0.09*
IAS angle	112.4 (19.5)	86.1 (35.4)	<0.001*	78.9 (38.0)	<0.001*
Starck Score	5 (4.0-12.0)	5 (4.0-12.0)	0.70**	5 (4.0-12.0)	0.45**

*Paired t-test

**Wilcoxon Signed Rank Test

SD- Standard deviation

IQR- Interquartile range

EAUS- Endoanal Ultrasound Scan

TPUS- Transperineal Ultrasound Scan

PFMC- Pelvic floor muscle contraction

EAS- External anal sphincter

IAS- Internal anal sphincter

Table 4: Comparison of defect angle size and Starck Score measured using 4D TPUS at rest or during maximal contraction using 3D EAUS as the reference standard:

3D EAUS (n=250)	4D TPUS (rest) (n=250)				4D TPUS (maximal PFMC) (n=250)			
	ICC	95% CI	SEM (degrees)/(score)	p-value	ICC	95% CI	SEM (degrees)/(score)	p-value
EAS angle	0.64	0.40-0.80	±16.1	<0.001	0.67	0.50-0.80	±16.5	0.02
IAS angle	0.34	-0.10-0.67	±27.9	0.02	0.29	-0.07-0.60	±26.4	0.02
Starck Score	0.95	0.92-0.97	±1.0	<0.001	0.95	0.91-0.97	±1.0	<0.001

SEM- Standard Error of Measurement

ICC-Intraclass Correlation

EAUS- Endoanal Ultrasound Scan

TPUS- Transperineal Ultrasound Scan

PFMC- Pelvic floor muscle contraction

EAS- External anal sphincter

IAS- Internal anal sphincter