

## **Levator ani morphology and function in women who have sustained obstetric anal sphincter injuries**

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**Abstract**

*Objectives:* To estimate the prevalence and explore risk factors of levator ani muscle injury in women with clinically diagnosed obstetric anal sphincter injuries (OASIs). Secondly, we aimed to assess the association between levator injury and pelvic floor muscle contraction, anal incontinence (AI) and urinary incontinence (UI) in women with OASIs.

*Methods:* Cross-sectional study of 250 women with OASIs, recruited from 2013 until 2015 in a tertiary referral centre at Croydon University Hospital, UK. AI symptoms were assessed using the modified St Mark's Incontinence Score and UI using the International Consultation on Incontinence modular Questionnaire for Urinary Incontinence - Short Form. All women underwent 3D/4D transperineal ultrasound at rest and at maximum pelvic floor contraction. Major levator injury was defined as a uni- or bilateral defect in all three central slices using tomographic ultrasound imaging. Muscle contraction was assessed using the Modified Oxford Scale (MOS) and measured on ultrasound as the proportional change of the anteroposterior (AP) levator hiatal diameter between rest and contraction. We used multivariable logistic regression to study risk factors for levator injury. Multivariable ANCOVA and Mann-Whitney U test were used to study difference in contraction and symptoms between women with intact and injured levator.

*Results:* 29.4% of women who previously sustained OASIs were found to have major levator injury. This was 23.6% after normal vaginal delivery, and 40.2% after operative vaginal delivery; adjusted odds ratio 4.1 (95% CI 1.4-11.9),  $p=0.01$ . Levator injury was associated with weaker pelvic floor muscle contraction; adjusted mean difference for proportional change in AP difference 4.2 (95% CI 1.7 - 6.7) and MOS 0.5 (95% CI 0.2-0.9),  $p < 0.01$ . Symptoms were similar for women with intact and injured levator muscle.

*Conclusions:* Operative vaginal delivery was a risk factor for levator injury in women with OASIs, and levator injury was associated with a weaker pelvic floor muscle contraction. Special attention is recommended for women with OASI and levator injury as they would be at high risk of future pelvic floor disorders. The benefits of implementation of an intensive, focused and structured pelvic floor rehabilitation program needs to be evaluated in these women.

## Introduction

The pelvic floor provides functional support to the urinary tract, vagina, uterus and rectum. The muscular resting tone and contraction are important to maintain continence and prevent pelvic organ prolapse.<sup>1</sup> Injury of the most medial part of the levator muscle at its insertion to the pubic bone, identifiable by palpation, ultrasound or magnetic resonance imaging (MRI), is a risk factor for pelvic organ prolapse,<sup>2-4</sup> but whether levator trauma is also a risk factor for anal (AI) and urinary incontinence (UI) is controversial.<sup>4-7</sup>

Pelvic floor muscle exercise is recommended as first-line treatment for women with prolapse and incontinence symptoms.<sup>8,9</sup> The effects of exercise for prevention and treatment of incontinence in antenatal and postnatal women is less clear, and it is possible that subgroups of women may benefit more from training.<sup>10</sup> Some previous studies have found that levator injury can lead to reduced pelvic floor muscle contraction and strength.<sup>3,5,11</sup> Weaker contraction could impair women's potential to restore pelvic floor function and prevent or control incontinence and prolapse symptoms.

Obstetric anal sphincter injury (OASI) is clinically identified by inspection and palpation immediately after delivery.<sup>12</sup> In contrast, levator trauma is often occult.<sup>13</sup> Previous studies have shown that OASIs and levator trauma share common risk factors, such as primiparity, high infant birth weight and forceps delivery.<sup>3,14-18</sup> If OASI is associated with a high prevalence of levator injuries, the identification of OASI at

delivery could be a marker for occult levator trauma.<sup>13</sup> Few studies have explored the prevalence of levator trauma among women with OASIs,<sup>4,19,20</sup> and we found no study evaluating a possible effect of levator injury on pelvic floor muscle contraction, AI and UI among women with OASIs.

The primary aim of our study was to estimate the prevalence of major levator injury in women with a clinically diagnosed OASI and to explore risk factors associated with levator injury. Secondly, we aimed to study the association between levator injury, pelvic floor muscle contraction, AI and UI in women who sustained OASI.

## Methods

This was a cross-sectional study of 250 consecutive women who had sustained OASIs at delivery and were routinely referred to the perineal clinic at Croydon University Hospital (CUH), UK from October 2013 to August 2015. This is a tertiary referral centre where women delivering at CUH and surrounding hospitals are assessed 6 to 12 weeks post-partum and given advice regarding future mode of delivery. Women are also re-assessed in any subsequent pregnancy. Women 18 years or older who could read and understand English were eligible. The study was approved by the National Research Ethics Service South East London Committee (REC number 13/LO/0232) and was registered in clinicaltrials.gov (NCT 02655900). All study participants gave written informed consent.

As part of routine care, a clinical history was obtained. Symptoms of AI were assessed with the validated modified St Mark's Incontinence Score ranging from 0 (no symptoms) to 24 (severe incontinence),<sup>21</sup> and UI was assessed with the validated International Consultation on Incontinence modular Questionnaire for Urinary Incontinence - Short Form (ICIQ -UI-SF) ranging from 0 (no symptoms) to 21 (severe incontinence).<sup>22</sup> Women were examined clinically by vaginal palpation and pelvic floor muscle contraction was quantified with the Modified Oxford Scale (MOS), where 0 =

no contraction and 5 = maximum pelvic floor muscle contraction.<sup>23</sup> The mean value of the left and right side was used for analysis.

In addition, women were examined with transperineal ultrasound using the GE Voluson i system with a 3D/4D 4-8.5 MHz curved array abdominal probe with an acquisition angle of 85°. The women were placed in the supine position with the knees and hips semi flexed. The probe was placed on the perineum in the vertical position. Each woman had three 4D volumes acquired during maximum pelvic floor muscle contraction by an experienced ultrasonographer (IvG). The ultrasound volumes were stored and analysed off-line by two independent investigators (IV and AT), both blinded to demographic and clinical background data and symptom scores. Analyses were performed using the GE 4D view software and the best contraction was used for analysis. A major levator injury was diagnosed at pelvic floor muscle contraction when an abnormal insertion of the levator muscle to the pubic bone was found in all three central slices (at the level of the plane of minimal dimensions and at 2.5 and 5 mm above this plane) on tomographic ultrasound imaging, either uni- or bilaterally (Figure 1).<sup>24</sup> In the case of discordant diagnosis between the two investigators, volumes were re-examined together and the diagnosis verified. In addition, the change from rest to contraction in levator hiatal anteroposterior (AP) diameter measured from the distal border of the symphysis pubis to the puborectalis muscle in the midsagittal plane (2D) was used as a measure of pelvic floor muscle contraction (Figure 2).<sup>25</sup> The proportional change between rest and contraction ( $((\text{measurement}_{\text{rest}} - \text{measurement}_{\text{contraction}}) / \text{measurement}_{\text{rest}}) \times 100$ ) was measured by both investigators independently.

The current study is a sub-analysis of a study assessing test accuracy of ultrasound for OASIs for which a power calculation showed that 250 women were needed.<sup>26</sup>

### *Statistical analyses*

Statistical analysis was performed with IBM SPSS statistics version 23 software (IBM SPSS, Armonk, NY, USA). The proportion of women with any (uni- or bilateral) major levator injury was calculated. Then, prevalence and mean values of demographic and obstetric variables were calculated and compared between women with major levator injury and intact (including minor defects) levator muscles using chi-squared test and independent samples *t*-test after testing for normal distribution. Variables that were different between the groups at a significance level of  $p < 0.1$  were entered in a multivariable logistic regression model to test their association with levator injury. Because of small group sizes, subgroup analyses for women with forceps and ventouse deliveries were performed with Fisher's exact test (<http://astatsa.com/FisherTest/>).

Inter class correlation analysis (absolute agreement between mean of two raters, 2-way random-effects model) between the two investigators was performed for the proportional change from rest to contraction in levator hiatal AP diameter. The measurements assessed by the more experienced examiner (IV) were used for subsequent analyses. Then, univariable and multivariable (adjusting for ongoing pregnancy) ANCOVA were used to study any difference in muscle contraction between women with intact and injured levator. The symptom scores were not normally distributed, and Mann-Whitney U test was used to study any difference between the



groups. We also tested the effect of an ongoing pregnancy on the symptom scores. Subgroup analyses of women with bilateral levator injury were performed. We used Spearman's rank correlation to explore any correlation between measures of muscle contraction and symptom scores. A  $p$ -value  $<0.05$  was considered statistically significant for all analyses.

## Results

The 250 women included were examined at a median of 5 (range 1-137) months after the index (OASI) delivery. In total 88 were pregnant at examination. Ethnicity was white British 98 (39%), other white 18 (7%), Indian 55 (22%), other Asian 35 (14%), black 27 (11%) and 17 (7%) of mixed or unknown ethnicity. The levator muscle was assessed in 248 ultrasound volumes, after exclusion of two volumes where the insertion point of the muscle was obscured by an artefact. We found major levator injury in 73 women (29.4%) of which 49 (19.8%) were unilateral and 24 (9.7%) were bilateral.

Demographic background variables and obstetrical data for the whole study population and for women with intact and injured levator with comparison between the groups are presented in Table 1. Body mass index (BMI), birth weight, episiotomy and mode of delivery were different between the groups at a significance level of  $p < 0.1$  and

were entered in the multivariable logistic regression model. Only lower BMI and operative delivery remained significant risk factors for levator injury. The prevalence of levator injury was 23.6% after normal vaginal delivery, and 40.2% after operative vaginal delivery, giving an adjusted odds ratio 4.1 (95% CI 1.4-11.9),  $p=0.01$ . At subgroup analyses forceps was associated with increased risk of levator injury but not ventouse; crude odds ratio 2.4 (95% CI 1.0-5.5),  $p=0.03$  and 1.6 (95% CI 0.6-3.8),  $p=0.27$  respectively.

The intra-class correlation coefficient (ICC) for proportional change in levator hiatal AP diameter between rest and contraction for the two investigators was 0.77, 95% CI 0.70-0.82,  $p< 0.01$ . Significant weaker pelvic floor muscle contraction was found for women with major levator injury compared to women with intact muscle, and bilateral injury was associated with even weaker contraction, Table 2. We found that pregnant women had stronger contraction than non-pregnant women on ultrasound [mean proportional AP change 15.6 (SD 8.3) versus 12.9 (SD 6.9),  $p= 0.01$ ], but not on MOS [mean 2.1 (SD 1.3) versus 1.9 (SD 1.1),  $p= 0.22$ ]. Since the proportion of pregnant women at examination was similar in both groups (Table 1), this had no impact on the results. Most women were asymptomatic for AI and UI (151/250). In total 61 women had St. Mark's score  $>0$  and 60 had ICIQ-UI-SF score  $>0$ , of whom 21 had symptoms from both domains. Pregnant women had significantly higher ICIQ-UI-SF scores than non-pregnant women; mean 3.4 (SD 4.6) versus 1.3 (SD 3.7),  $p< 0.01$ , but no significant difference was found for the St. Mark's score. Symptom scores for women with intact and injured levator are presented in Table 2. Comparison of scores between

the groups, even after eliminating pregnant women showed no significant difference. No correlations between pelvic floor muscle contraction and symptoms were found (ultrasound and St. Mark's score:  $r_s$  -0.03,  $p=0.64$ , ultrasound and ICIQ-UI-SF:  $r_s$  0.04,  $p=0.53$  MOS and St. Mark's score:  $r_s$  -0.03,  $p=0.66$ , MOS and ICIQ-UI-SF:  $r_s$  -0.03,  $p=0.67$ ).

## Discussion

The prevalence of major levator injuries among women who have sustained OASIs was 29%. Operative vaginal delivery was associated with a four-fold higher risk of levator injury than normal vaginal delivery. Women with major levator injury had weaker pelvic floor muscle contraction assessed by palpation and ultrasound. We found no association between levator injury, AI or UI, and no association between muscle contraction and incontinence.

In previous studies, odds ratios ranging from 3.5 to 8.1 have been found for OASIs as a risk factor for levator injury.<sup>13, 18, 20, 27</sup> In a study using MRI, the prevalence of levator injuries among women with OASIs was 19% and much lower in women without sphincter tears (3.5%).<sup>4</sup> Valsky et al used transperineal ultrasound and found a prevalence of 40%, which was significantly higher than among women without OASI (16%).<sup>20</sup> Another recent study found levator trauma in 34% of women with sphincter injuries, which was not significantly higher than in women without injury (24%).<sup>19</sup> The prevalence of 29% for major levator injuries found in the present study corresponds with these other studies. This study had no direct comparison group of women without OASI, but a lower prevalence of 16% was found in a population including women after vaginal delivery with and without OASI recruited at CUH.<sup>5, 27</sup>

Operative vaginal delivery was a risk factor for levator trauma, and this is supported by previous studies.<sup>14, 15, 18, 27</sup> In particular, the use of forceps but not ventouse, has been identified as a risk factor, also found in the present study. A small number of women with ventouse and forceps delivery were included, and we acknowledge that adjusting for confounders was not possible for the subgroup analyses. Episiotomy was a risk factor for levator injury in one previous study,<sup>18</sup> but most studies, including a large recent study controlling for other obstetric factors, found no association between episiotomy and levator trauma.<sup>15, 20, 28</sup> In our study, episiotomy seemed to be a risk factor at univariate analysis, but the multiple regression model showed no significant effect of episiotomy. A likely explanation is that episiotomy is more often used for operative vaginal delivery, which is the main risk factor for levator

trauma. We also found a slight protective effect of higher BMI on levator injury, consistent with a recent study by Caudwell-hall et al,<sup>29</sup> but acknowledge that we had BMI data only for 146 women.

Guzman-Rojas et al found weaker muscle contraction in women with levator injury measured with ultrasound, but no difference using MOS.<sup>11</sup> The MOS is a more subjective measure of contraction, and the examiner's experience as well as the number of examiners involved may influence the results. Another study found weaker muscle contraction at palpation in women with levator injury examined 10-26 weeks postpartum and a higher prevalence of UI among women with levator injuries.<sup>5</sup> Dietz et al examined urogynaecological patients with a mean age of 55 years, and found no relationship between levator injuries and UI.<sup>6</sup> Heilbrun et al examined women 6-12 months postpartum and found a non-significant trend towards more faecal incontinence in women with levator injuries,<sup>4</sup> whereas a study of urogynaecological patients showed no such correlation.<sup>7</sup> We found no association between levator trauma and incontinence at a median follow up of 5 months after sustaining OASI.

To our knowledge this is, hitherto, the largest study of prevalence and risk factors of levator injuries among women who have sustained OASIs. Women with different ethnicities were included, increasing the external validity of our results. Levator injuries were assessed by two independent raters, providing quality assurance for the diagnosis of levator injury. Pelvic floor muscle contraction was measured objectively by palpation using the MOS and ultrasound, and similar results were obtained using both methods.

Women were examined at a median of 5 (range 1-137) months after the index delivery. This could be a limitation, as some pelvic floor disorders could appear later in life. The low prevalence and severity of symptoms makes the comparison between women with intact and injured levator difficult. As some women were referred to CUH from other hospitals, we have no information regarding advice on pelvic floor exercises such as information leaflets or referral to a physiotherapist for pelvic floor training.

We know that pelvic floor muscle contraction plays an important role in the continence mechanism.<sup>1,30</sup> In this population of women with OASIs, muscle contraction was weaker compared to women examined sooner (3 months) and later (15-20 years) after delivery in previous studies.<sup>25,31</sup> This suggests that special attention is needed for women who have sustained OASI to initiate and maintain pelvic floor muscle exercises. Women with levator injury had an even weaker muscle contraction implicating that more vigorous follow-up is indicated for women with double injuries. We postulate that transperineal ultrasound screening of all women who have sustained OASI could be beneficial, as detection of complex pelvic floor injury may allow for early referral to secondary preventative strategies for pelvic floor disorders.

Anal continence depends upon many factors in addition to anal sphincter function, such as cognitive function, nutrients, stool consistency, colonic transit, rectal compliance, anorectal sensation, and anorectal reflexes.<sup>30</sup> Lewicky-Gaupp et al found that levator defects were common among older women with faecal incontinence.<sup>32</sup> As symptoms of UI and AI are likely to increase as women get older, we intend to perform

a longer-term follow-up study to establish the natural history of these injuries in our study population.

In conclusion, we found that 29% of women sustaining OASI had a major injury of the levator muscle, and operative vaginal delivery was associated with a four-fold higher risk of levator injury than normal delivery. Levator injury was associated with a weaker pelvic floor muscle contraction but not with incontinence symptoms. As the prevalence of incontinence is likely to increase over time, special attention should be given to these women with OASI and levator injury. The benefits of implementing an intensive, focused and structured pelvic floor rehabilitation program needs to be evaluated in these women.

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**Figure legends****Figure 1**

Woman with intact levator (A) and major right sided levator injury (B) indicated with arrows in all three central slices on tomographic ultrasound imaging.

**Figure 2**

Levator hiatal antero-posterior diameter measured from the distal border of the symphysis pubis to the Puborectalis muscle in the midsagittal plane for women with an intact levator at rest (A), contraction (B), and with major levator trauma at rest (C) and contraction (D).

**Table 1**

Demographic and obstetric variables for the total study population and for women with an intact and injured levator. Comparison of women with an intact and injured levator with *t*-test and chi-squared test. Adjusted odds ratios with 95% confidence intervals (CI) for variables that were different between the groups at significance level  $p < 0.1$ .

	<b>Total</b>	<b>Intact levator</b>	<b>Injured levator</b>			
	<i>Mean (SD)</i>	<i>Mean (SD)</i>	<i>Mean (SD)</i>	<i>t-test, p</i>	<i>Adjusted odds ratio, 95% CI</i>	<i>p</i>
<i>Age, years</i> (n= 248)	31.5 (4.5)	31.3 (4.5)	31.8 (4.5)	0.43		
<b>BMI</b> , kg/m <sup>2</sup> (n= 146)	25.3 (4.7)	25.8 (4.9)	24.2 (4.0)	0.06	0.9 (0.8-1.0)	0.03
<i>Birthweight</i> , g (n= 239)	3418 (506)	3385 (499)	3514 (516)	0.08	1.0 (1.0-1.0)	0.34
	<i>n/N (%)</i>	<i>n/N (%)</i>	<i>n/N (%)</i>	<i>Chi-squared test, p</i>	<i>Adjusted odds ratio, 95% CI</i>	<i>p</i>
<b>Epidural</b>	61/222 (27.5)	48/160 (30.0)	12/60 (20.0)	0.14		
<b>Episiotomy</b>	91/218 (41.7)	59/158 (37.3)	31/58 (53.4)	0.03	0.8 (0.3-2.4)	0.75

<b>Parity e2</b>	65/248 (26.2)	45/175 (25.7)	20/73 (27.4)	0.78		
<b>Mode of delivery</b>						
Normal delivery	165/247 (66.8)	126/175 (72.0)	39/72 (54.2)	reference		
Operative delivery	82/247 (33.2)	49/175 (28.0)	33/72 (45.8)	0.01	4.1 (1.4-11.9)	0.01
Ventouse	33/247 (13.4)	22/175 (12.6)	11/72 (6.4)			
Forceps	35/247 (14.2)	20/175 (11.4)	15/72 (20.8)			
Ventouse + forceps	14/247 (5.7)	7/175 (4.0)	7/72 (9.7)			
<b>Grade of tear</b>						
Grade 3a + 3b	194/223 (87)	141/158 (89.2)	53/65 (81.5)	reference		
Grade 3c + 4	29/223 (13)	17/158 (10.8)	12/65 (18.5)	0.12		
<b>Pregnant at examination</b>	88/248 (35.5)	61/175 (43.9)	27/73 (37.0)	0.75		

**Table 2**

Mean (SD) values for measures of pelvic floor muscle contraction for women with intact (including minor defects) and any levator injury (uni- or bilateral), with unadjusted and adjusted mean differences between the groups. Mean (SD) and Median (range) values for symptoms of urinary and anal incontinence for women with intact and injured levator with comparison between the groups. Subgroup analyses for women with bilateral injury.

	<b>Total</b>	<b>Intact levator</b>	<b>Levator injury, any</b>	<b>Levator injury, bilateral</b>	<b>Any levator injury vs intact levator</b>	<b>Bilateral levator injury vs intact levator</b>
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<b>Measure of pelvic floor muscle contraction</b>	<i>Mean (SD)</i>	<i>Mean (SD)</i>	<i>Mean (SD)</i>	<i>Mean (SD)</i>	<i>Unadjusted mean difference (95% CI), p</i>	<i>Adjusted* mean difference (95% CI), p</i>	<i>Unadjusted mean difference (95% CI), p</i>	<i>Adjusted* mean difference (95% CI), p</i>
Palpation <i>Mean Modified Oxford Scale</i>	2.0 (1.1)	2.2 (1.2)	1.6 (1.0)	1.3 (0.9)	0.6 (0.3 - 0.9), <0.001	0.6 (0.3 - 1.0), <0.001	0.8 (0.4 - 1.3), 0.001	1.0 (0.5 - 1.5), <0.001
Ultrasound <i>% change AP diameter</i>	13.8 (7.6)	15.3 (7.7)	10.4 (6.0)	7.8 (5.8)	4.9 (2.9 - 6.9), <0.001	5.2 (3.2 - 7.3), <0.001	7.5 (4.3 - 10.7), <0.001	8.8 (5.4 - 12.2), <sup>†</sup> <0.001
<b>Symptoms</b>	<i>Mean (SD)</i> <i>Median</i> <i>(Range)</i>	<i>Mean (SD)</i> <i>Median</i> <i>(Range)</i>	<i>Mean (SD)</i> <i>Median</i> <i>(Range)</i>	<i>Mean (SD)</i> <i>Median</i> <i>(Range)</i>	<i>Mann-Whitney U-test, p</i>		<i>Mann-Whitney U-test, p</i>	
Anal incontinence <i>St Mark's score</i>	1.4 (3.0) 0 (0-16)	1.3 (2.9) 0 (0-16)	1.5 (3.3) 0 (0-15)	1.0 (2.6) 0 (0-11)	0.33		0.81	
Urinary incontinence <i>ICIQ-UI-SF</i>	2.1 (4.1) 0.0 (0-18)	2.2 (4.3) 0 (0-16)	1.6 (3.4) 0 (0-16)	1.8 (3.6) 0 (0-14)	0.83		0.96	



\*Adjusted for ongoing pregnancy. †Ongoing pregnancy was a significant confounder for % change AP diameter: Pregnant women had stronger contraction, adjusted mean difference 2.3 (95% CI 0.3 – 4.4),  $p=0.03$ .

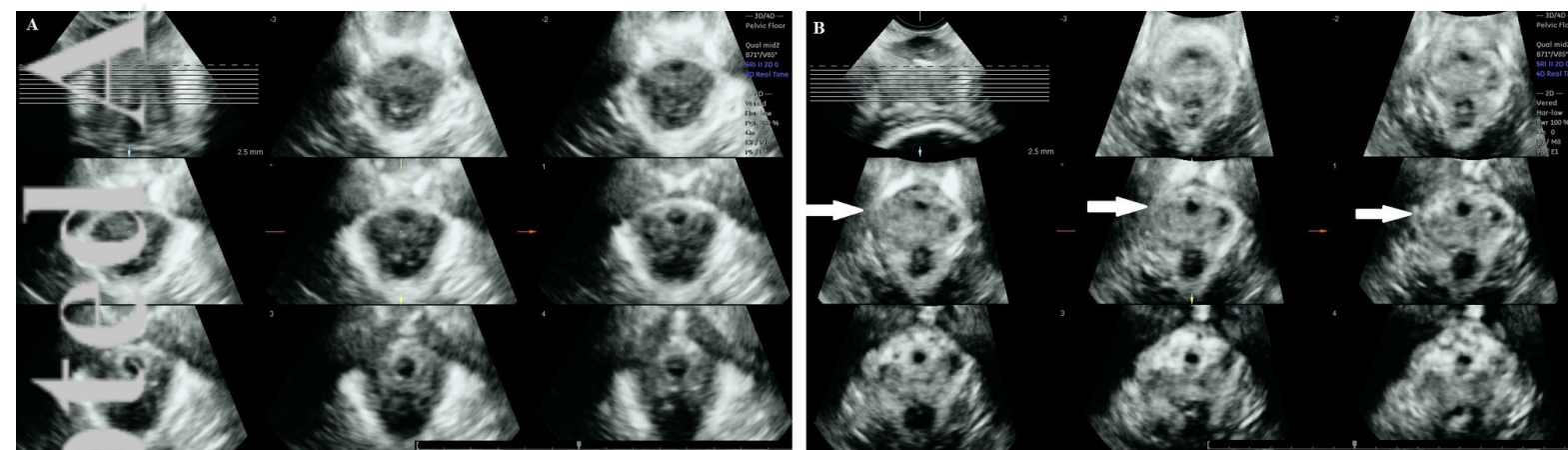


Figure 1.jpg

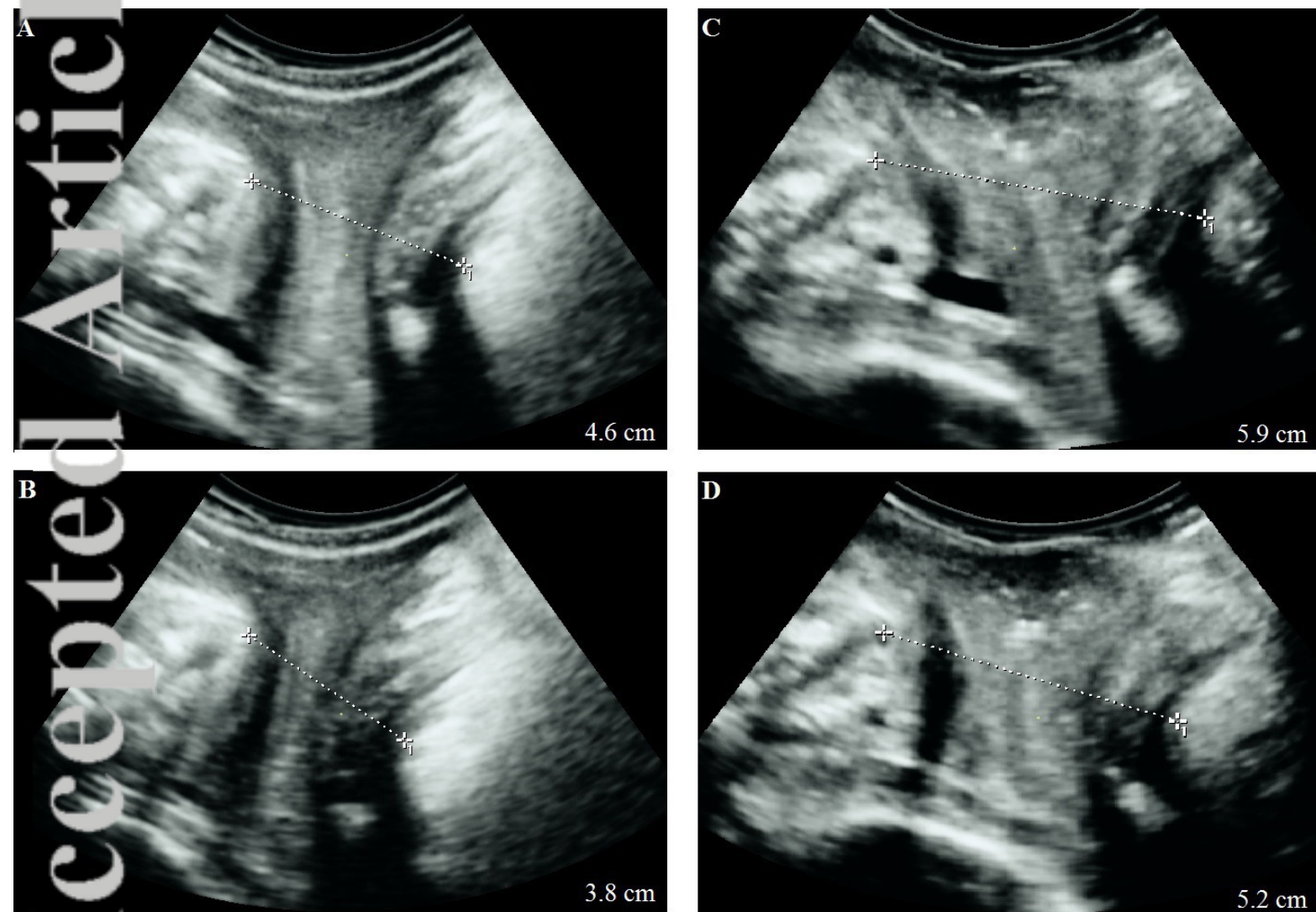


Figure 2.jpg