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1 Evaluating pelvic floor muscle contractility using two-dimensional transperineal  
2 ultrasonography in patients with pelvic organ prolapse

3

#### 4 **Abstract**

##### 5 **Aims:**

6 The hiatal anterior-posterior distance (APD), as measured by two-dimensional (2D)  
7 transperineal ultrasonography, is an indicator of pelvic floor muscle (PFM) contractility.  
8 The function of the pelvic floor is independently related to pelvic organ prolapse (POP)  
9 severity. However, little evidence concerning the APD for patients with POP before and  
10 after PFM training (PFMT) has been published. Therefore, we analyzed 2D transperineal  
11 ultrasonography in women with POP.

##### 12 **Methods:**

13 Twenty-eight women with POP completed a physiotherapist-led PFMT regimen that  
14 consisted of 4 months of one-on-one PFMT and lifestyle advice. The APD was measured  
15 using 2D transperineal ultrasonography immediately before and after the PFMT period  
16 and used to calculate  $\Delta$ APD (APD at rest – APD during contraction). Vaginal squeeze  
17 pressure during maximum voluntary contractions was also assessed using a manometer.  
18 We then analyzed the reliability and the correlation between  $\Delta$ APD as measured using 2D

19 transperineal ultrasonography and vaginal squeeze pressure before and after PFMT.

20 Results:

21 The APD at rest and during PFM contractions demonstrated intraclass correlation  
22 coefficients (ICCs) of 0.89 and 0.88, respectively. The ICC of maximal vaginal squeeze  
23 pressure was 0.97 during PFM contractions. Both  $\Delta$ APD ( $p < 0.01$ ) and PFM strength ( $p <$   
24  $0.05$ ) increased significantly after PFMT. PFM strength and  $\Delta$ APD were correlated before  
25 ( $R = 0.53$ ) and after ( $R = 0.68$ ) PFM training ( $p < 0.01$ ).

26 Conclusions:

27 We demonstrated that dynamic 2D transperineal ultrasonography could be used for  
28 studying functional changes in patients with POP. The  $\Delta$ APD of the levator hiatus has  
29 potential as an anatomical surrogate marker for evaluating PFM function in hospitals.

30

## 31 **1 | INTRODUCTION**

32 According to epidemiological studies, the prevalence of symptomatic pelvic organ  
33 prolapse (POP) is 3–6% among women, and up to 50% based on POP quantification stage  
34 0, I, II, and III as follows: 6.4%, 43.3%, 47.7%, and 2.6%, respectively.<sup>1,2</sup> Pelvic floor  
35 muscle (PFM) training (PFMT) is widely prescribed for women with POP and is the  
36 first-line treatment for POP; recommended by the International Continence Society as  
37 Grade A.<sup>3</sup> PFM function is thought to play a significant role in the pathogenesis of POP.<sup>4</sup>  
38 PFM kinesio logic function is assessed using relatively reliable measurements, such as  
39 digital examination, manometry, and electromyography using a vaginal probe.<sup>5–7</sup> However,  
40 there are some patients, for example those immediately after transvaginal surgery or  
41 vaginal delivery, who feel discomfort and pain. We also had patients who declined to take  
42 part in studies because of cultural factors in Asian countries. Ultrasonography has been  
43 developed as an alternative method and a more practical approach for both anatomical and  
44 functional assessments. Ultrasonography is considered to be more reproducible and  
45 objective, with imaging of deep pelvic floor structures, which are difficult to access by  
46 palpation.<sup>8</sup> A ultrasonography transducer placed on the perineum can be used to visualize  
47 whole structures, such as the bladder, urethra, rectum, anal canal, and vagina in the  
48 midsagittal plane. Braekken et al.<sup>9</sup> found that there were negative correlations between the

49 hiatus area based on three-dimensional (3D) ultrasonography and PFM strength compared  
50 with manometer measurements in women with POP. A previous study showed that 2D  
51 transperineal ultrasonography measurements of the anterior–posterior distance (APD) of  
52 the levator hiatus on ultrasonography during voluntary contraction of the PFM can be used  
53 to assess both the supporting function and the contractile function of the pelvic floor in  
54 postpartum women.<sup>10</sup> Nevertheless, to date, few reports on APD for patients with POP  
55 have described the reliability of 2D transperineal ultrasonography before and after PFMT.  
56 We hypothesized that 2D transperineal ultrasonography is reliable to assess PFM functions,  
57 and there is correlation between vaginal squeeze pressure and anterior–posterior distance  
58 of the levator hiatus in patients with POP.

59

## 60 **2 | METHODS**

61 Thirty-one patients with POP participated in this study. The sample size was  
62 calculated based on the significant change in PFM strength that occurs after PFMT, and on  
63 a previous before and after trial with an effect size of 0.69, a power of 0.8, and a  
64 significance level of 0.05.<sup>11</sup> Thus, the sample size was set as 22. We determined that a  
65 final sample size of 27, including dropouts, would be appropriate<sup>12</sup>. Only patients who  
66 were diagnosed with POP (stage II or III) evaluated using the Pelvic Organ Prolapse

67 Quantification System<sup>13</sup> by a urologist were included in the present study. Women with  
68 POP included in this study visited a urology department from 2013 to 2014. Exclusion  
69 criteria were as follows: serious psychiatric or neurological disease, pregnancy, less than 1  
70 year after giving birth, urinary tract infection, gynecology or obstetric surgery, concurrent  
71 therapy for incontinence or POP, or hormonal replacement therapy. The ethical approval  
72 for this study was obtained from the Research Ethics Committee of our institution  
73 (13-502). All participants provided written consent.

74 One physiotherapist performed the manometry and ultrasonography examinations of  
75 PFM function. The physiotherapist checked if each woman could contract their PFM  
76 properly. If not, they were taught how to do correct PFM contractions with normal  
77 breathing without contracting the abdominal muscles and muscles surrounding the right  
78 and left hip joints. We assessed the perineal movement with palpation and inspection to  
79 check if PFM contraction occurred properly in this study. We confirmed that all  
80 participants could perform correct PFM contractions before starting the examination. The  
81 maximum voluntary contraction (MVC) of the PFM was assessed using a manometer  
82 (Peritoron<sup>®</sup>; Cardio-Design Pty, Oakleigh, VIC, Australia), which consisted of an air-filled  
83 sensor through the vaginal tube attached to a manometer with a pressure transducer. The  
84 manometer was inflated up to 100 cmH<sub>2</sub>O in the vagina and reset to zero. Three MVCs

85 were measured for each participant, and the average value was recorded.

86 The APD was defined as the minimum distance between the hyperechogenic posterior  
87 aspect of the pubic symphysis and the anterior border of the hyperechogenic pubovisceral  
88 muscle in the mid-sagittal plane by 2D transperineal ultrasonography (Aplio 300®,  
89 Toshiba, Tokyo) (Figure 1).<sup>14</sup> A curved array ultrasound transducer (7.5 MHz, PLT-704AT,  
90 Toshiba, Japan) was used to image pelvic structures. Images from which the APD  
91 measurements were made were obtained by placing a curved array ultrasonography  
92 transducer on the perineum in the mid-sagittal plane between the pubic symphysis and the  
93 anus. The APD was measured at rest (APD at rest) and during PFM contraction (APD  
94 during contraction) (Figure 2). Women were placed in the supine position on a bed with  
95 hip joints flexed and slightly abducted. The participants were instructed to contract the  
96 PFM as strongly as possible for 10 seconds and to relax their PFM for 10 seconds after  
97 each contraction. Dynamic images were obtained during PFM contractions and at rest. At  
98 least three cycles of PFM contraction and relaxation were recorded for each individual. We  
99 observed the inward movement of the perineum to confirm patients contracted the PFM  
100 only without intra-abdominal pressure.<sup>15</sup> The formula used to calculate the difference in  
101 terms of distance (in millimeters) between the maximum contraction and rest was as  
102 follows:  $\Delta\text{APD} = (\text{APD at rest} - \text{APD during contraction})$ . The average value was used.

103 Reliability tests for vaginal squeeze pressure and  $\Delta$ APD were conducted before the  
104 commencement of 4 months of PFMT. We conducted tests between 2 different days. The  
105 patients were asked not to perform PFMT during reliability tests.

106 During the PFMT period, all participants attended physiotherapy sessions six times (at  
107 0, 2, 4, 8, 12, and 16 weeks). They received physiotherapist-led one-on-one PFMT and  
108 received lifestyle advice from the physiotherapist. In addition, they were instructed to  
109 perform three sets of PFMT per day at home and to keep a report of their home exercise  
110 adherence using an exercise calendar. The present study was one component of a previous  
111 clinical trial that investigated changes in physical activities due to PFMT in patients with  
112 POP.<sup>12</sup>

113 Statistical analysis was conducted using the Statistical Package for the Social Sciences  
114 (SPSS) 23.0J, Mac version. In the data analysis, 28 of the 31 original participants  
115 completed PFMT and were included. Data distribution was assessed with the  
116 Shapiro–Wilk test. Paired-t test was conducted for POP-Q Ba and gh between before and  
117 after PFMT. Wilcoxon signed-rank test was conducted for POP-Q other parameters  
118 between before and after PFMT. Because the vaginal squeeze pressure and  $\Delta$ APD were  
119 not normally distributed, we utilized non-parametric statistical methods. Wilcoxon  
120 signed-rank test was conducted to analyze changes in pelvic floor function before and after



121 PFMT. Spearman's rank correlation coefficient was performed to compare vaginal squeeze  
122 pressure during MVC and  $\Delta$ APD. Data were interpreted as follows: +1 indicates a perfect  
123 association between vaginal squeeze pressure and  $\Delta$ APD. An alpha of 0.05 was set for the  
124 significance level.

125

### 126 **3 | RESULTS**

127 Thirty-one outpatients who visited the female urology department between November  
128 2013 and May 2014 were assessed. Twenty-eight women with POP (Stage II or III) were  
129 included in the study (age:  $65.8 \pm 7.5$  years, mean  $\pm$  SD; Table 1). POP-Q Aa and Ba were  
130 significantly improved (Table 2). ICC values of the length of the APD at rest and during  
131 voluntary PFM contractions were 0.89 and 0.88, respectively. The ICC value of maximal  
132 vaginal squeeze pressure, as measured using a manometer, was 0.97 during voluntary  
133 PFM contractions (Table 3). The PFM strength increased significantly after 4 months of  
134 PFMT relative to before PFMT ( $p = 0.0001$ ).  $\Delta$ APD also increased significantly ( $p <$   
135  $0.0001$ ), as shown in Table 4. Moreover, the current study showed that there was a  
136 moderate correlation between MVC and  $\Delta$ APD both before ( $R = 0.53$ ) and after ( $R = 0.68$ )  
137 PFM training ( $p < 0.01$ ) (Figure 3).

138

139 **4 | DISCUSSION**

140 This was a prospective study that demonstrated a significant correlation between  
141 vaginal squeeze pressure and  $\Delta$ APD both before and after 4 months of PFMT in patients  
142 with POP. APD, as measured using 2D, 3D, and 4D ultrasonography, has been analyzed in  
143 nulliparous, primiparous, and patients with POP.<sup>10,14,16</sup> A previous study demonstrated that  
144 ultrasonography could be used to visualize the displacement of the anorectal junction  
145 during PFM contraction, which produces a decline in the anterior–posterior levator hiatus  
146 distance in women.<sup>17</sup> Patients with POP stage II or above were more likely to have weak  
147 PFM strength and endurance compared with those with POP stages 0 and I.<sup>4</sup> PFM  
148 contractility was significantly associated with POP, and, in addition, PFMT improved  
149 PFM strength and prolapse symptoms compared with a control group.<sup>4,18</sup> Braekken et al.<sup>9</sup>  
150 provided robust evidence that as vaginal squeeze pressure increased in the PFMT group,  
151 pubovisceral muscle thickness increased by 15.6%, and the area of levator hiatus narrowed  
152 by 6.3%. Additionally, PFM strength had a positive association with decreased hiatal area  
153 ( $\rho = 0.25$ ,  $p = 0.028$ ).<sup>18</sup> In our study,  $\Delta$ APD and vaginal squeeze pressure increased  
154 significantly after PFMT relative to measurements in individual participants before PFMT.  
155 These results also confirmed that 2D ultrasonography can successfully detect changes in  
156 PFM contractility. Thus, 2D ultrasonography can be used for patients with POP in hospital

157 or clinic settings. This method is additionally advantageous because it does not require  
158 additional investment in equipment.  $\Delta$ APD as measured by 2D ultrasonography may thus  
159 serve as an acceptable surrogate marker for PFM strength in patients with POP, as an  
160 alternative to measuring vaginal squeeze pressure.

161 The acquisition of measurements by ultrasonography is considered to be easy, but  
162 their accuracy depends on the skill of the operator. Transperineal assessment results in  
163 visualization of the pubic symphysis as a bony landmark, which may help in identifying  
164 the precise location of anatomical structures in the pelvic floor. We chose this landmark, as  
165 reported previously (Figure 1).<sup>10,14,19</sup> In addition, the puborectalis muscle whose fibers  
166 form a sling (U) shape arising from the posterior aspect of the pubic symphysis to the  
167 rectum in the urogenital diaphragm can be clearly seen with this method. During  
168 assessment of  $\Delta$ APD, the hyperechoic site of the puborectalis muscle was displaced in the  
169 cranial–ventral direction. We also confirmed that the patients were correctly generating  
170 PFM contractions, based on observation of the cranially directed displacement without  
171 increased abdominal pressure. Using this feedback, the patients were taught the correct  
172 method for generating PFM contractions. The Modified Oxford Scale is commonly used  
173 for assessing PFM contractions. Dietz et al.<sup>20</sup> showed that the Modified Oxford Scale is a  
174 more sensitive predictor of maximum urethral closure pressure compared with hiatal

175 diameters, because the results from digital assessment are positively correlated with the  
176 augmentation of urethral closure pressure during PFM contractions ( $r = 0.24$ ,  $p = 0.001$ ).  
177 In contrast, no correlation was found between hiatal diameters and digital assessment.<sup>20</sup>  
178 Digital assessment, however, requires that trained health professionals digitally assess  
179 PFM function. With the transperineal measurements described here, numeric data are  
180 acquired easily, and clinicians can easily introduce this method into their clinics for PFM  
181 functional assessment without additional training. In this study, a manometer was used to  
182 assess vaginal squeeze pressure, which is considered to be a relative not absolute  
183 measurement. It can be impacted by vaginal capacitance and/or voluntary controlled PFM  
184 contractions, etc. However, a previous study for reliability testing demonstrated that the  
185 correlation coefficient between manometry and the digital examination was found to be  
186 moderate.<sup>21</sup> We thought that the manometer was reliable enough to measure the vaginal  
187 squeeze pressure.

188 Our results showed a high reliability of measurements of both  $\Delta$ APD and vaginal  
189 squeeze pressure. A previous study<sup>14,22</sup> and our findings here indicate an good to perfect  
190 ICC for APD, suggesting a high degree of reproducibility in this study. Measuring  
191 increases in vaginal squeeze pressure during contraction of the PFM with a manometer  
192 shows acceptable reliability<sup>5,7,21</sup>. It is widely performed in test-retest and re-evaluations

193 used by different examiners. The present study achieved almost perfect agreement, with  
194 ICC values of 0.96 (for same-day measurements) and 0.97 (for different-day  
195 measurements) for vaginal squeeze pressure with maximal PFM contraction.

196 2D transperineal ultrasonography allows visualization from the pubic symphysis to  
197 the anorectal junction with a depth of 8 cm. We measured the distance between the  
198 posterior aspect of the pubic symphysis and the anorectal junction and could thus quantify  
199 displacement of the anorectal junction during PFM contraction compared with its position  
200 at rest, which is considered indicative of the movement of the levator ani muscle.  
201 Although the puborectalis muscles cannot be separately distinguished from the  
202 pubococcygeus muscle,<sup>23</sup> imaging of the perineum in the sagittal plane detects the highly  
203 echogenic part of the anorectal junction due to the posterior attachment of the pubovisceral  
204 muscle. The  $\Delta$ APD indicates the ventral displacement of the pubovisceral muscle during  
205 voluntary PFM contraction, and cranial movement between the PFM at rest and during  
206 contraction. This could suggest that the voluntarily augmented urethral closure pressure  
207 can be represented by measuring  $\Delta$ APD and is positively associated with PFM  
208 contractility.<sup>20</sup>

209 We provided supervised PFMT for all patients with POP for 4 months.<sup>12</sup> The results  
210 showed significant improvement in vaginal squeeze pressure and  $\Delta$ APD after PFMT

211 compared with before PFMT. Additionally, PFMT improves POP-related symptoms, such  
212 as frequently going to the bathroom to urinate, stress urinary incontinence,  
213 post-micturition dribble, and feeling vaginal bulge interfering with emptying of the bowels  
214 in our previous study. A previous study that analyzed risk factors for POP demonstrated  
215 that PFM strength is an independent factor for POP.<sup>4</sup> PFMT is recommended as Grade A for  
216 pelvic floor symptoms on POP.<sup>3</sup> Additionally, a meta-analysis concluded that PFMT is  
217 effective for increasing PFM strength and improving POP symptoms and stage, compared  
218 with controls.<sup>24</sup> The significant increase in  $\Delta$ APD can be interpreted to represent increased  
219 PFM function, and by extension the potential to improve some POP-related symptoms.

220 This study had the following limitations. The small sample size of this study is a  
221 reflection of the small number of individuals who seek treatment for lower urinary tract  
222 symptoms in Japan.<sup>25</sup> We found difficulty in including patients with mild to moderate POP  
223 in the present conditions. Because physiotherapy has yet to be fully covered by public  
224 insurance in women's health, very few physiotherapists treat patients with POP in a  
225 clinical setting. The present study involved a quasi-experimental design without a control  
226 group. Because of the study design, it was not possible to determine the cause and effect  
227 relationship. Larger randomized control trials will be needed to overcome this limitation in  
228 the future.

229 **5 | CONCLUSIONS**

230 We propose that  $\Delta$ APD of the levator hiatus could represent an anatomical  
231 measurement for assessing PFM function in clinic and hospital settings. Moreover,  
232 dynamic 2D transperineal ultrasonography could be a method for studying functional  
233 changes in individuals with POP.

234

235

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308

309 **Financial Disclaimers/Conflict of Interest statement**

310 None

311 **LEGENDS**

312 Table 1.

313 BMI: body mass index ( $\text{kg}/\text{m}^2$ ), POP-Q: Pelvic Organ Prolapse Quantification System

314 Data are indicated as follows; body mass index: mean  $\pm$  SD, age and parity: median

315 (minimum – maximum), POP-Q Stage, type of POP, and numbers of women who had an

316 occupation, regular exercise, or sexual intercourse: n (%).

317

318 Table 2.

319 The data are presented as medians (minimum – maximum). Ns are not shown because they

320 were not significant. Aa: 3 cm proximal to or above the hymenal ring anteriorly, Ap: 3 cm

321 proximal to or above the hymenal ring posteriorly, C: the anterior apex (cervix), D: the

322 posterior apex (pouch of Douglas), gh: the genital hiatus, pb: the perineal body, tvl: the

323 total vaginal length

324

325 Table 3.

326 The data from day 1 and 2 are shown as means  $\pm$  SD

327 ICC are presented as medians (minimum – maximum) (n=6)

328

329 Table 4.

330 The data are shown as means  $\pm$  SD. The significance level was set at 0.05. n.s: not

331 significant

332

333 Figure 1.

334 The APD corresponds to the length of the black double-headed arrow between the

335 posterior aspect of the pubic symphysis and the anorectal junction.  $\Delta$ APD was defined as  
336 APD at rest – APD during contraction. This drawing represents the pelvic floor of a patient  
337 with POP and shows the dislocation of the posterior bladder into the vagina.

338

339 Figure 2.

340 Measurement of APD at rest and during contraction. (a, b) Images from 2D transperineal  
341 ultrasonography in the mid-sagittal plane show the minimal hiatal diameter (white  
342 double-headed arrow) between the posterior aspect of the pubic symphysis and the  
343 anorectal junction at rest (a) and during contraction (b). The pubovisceral muscle is  
344 determined based on the hyperechogenic region posterior to the anorectal junction<sup>14</sup>. P,  
345 pubic symphysis; B, bladder; R, rectum; A, anus.

346

347 Figure 3.

348 Correlation between  $\Delta$ APD and vaginal squeeze pressure before and after PFMT. Data are  
349 shown for all participants (n = 28).

Table 1. Demographic characteristics of all participants (n=28)

| Characteristic                     | Value <sup>a</sup> |
|------------------------------------|--------------------|
| Age (years)                        | 67 (49–76)         |
| BMI                                | 23.1 ± 3.3         |
| Parity                             | 2 (2–3)            |
| POP-Q Stage II                     | 16 (57.1)          |
| POP-Q Stage III                    | 12 (42.9)          |
| Type of POP: Anterior vaginal wall | 27 (96.5)          |
| Posterior vaginal wall             | 0 (0.0)            |
| Apical prolapse                    | 1 (3.5)            |

Table2. POP-Q data before and after PFMT in patients with POP (n=28)

|     | Before PFMT |      |      | After PFMT |      |      | p value |
|-----|-------------|------|------|------------|------|------|---------|
|     | Median      | Min  | Max  | Median     | Min  | Max  |         |
| Aa  | 1.0         | -2.0 | 2.5  | 0.5        | -2.5 | 2.5  | 0.0024  |
| Ba  | 1.0         | -1.5 | 4.0  | 0.5        | -2.5 | 3.5  | 0.0005  |
| C   | -4.0        | -6.0 | 2.5  | -5.0       | -6.5 | 2.0  | Ns      |
| gh  | 3.8         | 2.0  | 5.5  | 3.5        | 1.0  | 5.0  | 0.0080  |
| pb  | 3.0         | 2.0  | 3.5  | 3.0        | 2.0  | 4.0  | Ns      |
| tvI | 7.5         | 6.0  | 8.5  | 7.5        | 7.0  | 9.0  | Ns      |
| Ap  | -2.5        | -3.0 | 1.5  | -3.0       | -3.0 | 1.0  | Ns      |
| Bp  | -2.5        | -3.0 | 1.5  | -3.0       | -3.0 | 1.0  | Ns      |
| D   | -6.0        | -7.0 | -2.0 | -6.5       | -8.0 | -3.0 | Ns      |

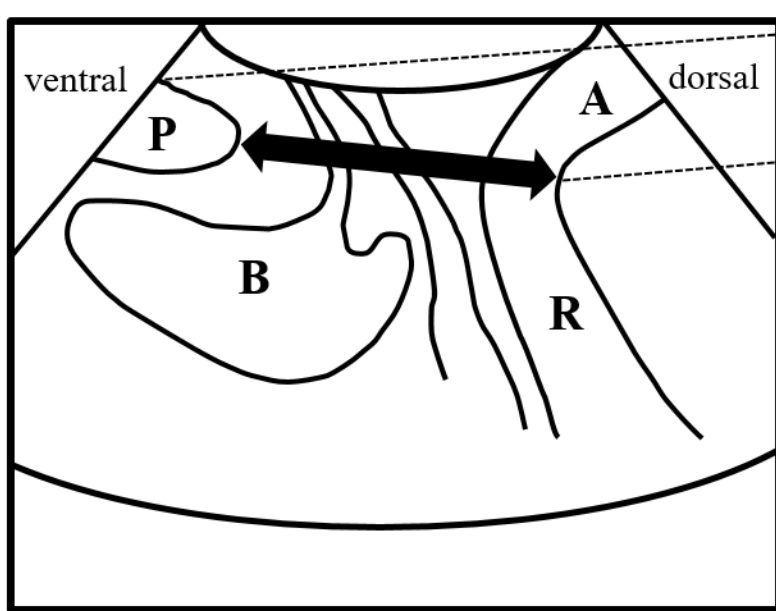


Table 3. Reliability indexes of each PFM function (n=5)

| Characteristic                                | Day 1       | Day 2      | ICC                 |
|---|-------------|------------|---------------------|
| APD at rest (mm)                              | 59.3 ± 4.7  | 58.6 ± 5.1 | 0.89<br>(0.39–0.99) |
| APD during PFM contraction (mm)               | 47.9 ± 3.2  | 49.3 ± 2.8 | 0.88<br>(0.37–0.99) |
| Vaginal squeeze pressure (cmH <sub>2</sub> O) | 20.8 ± 10.6 | 21.6 ± 9.3 | 0.97<br>(0.80–0.99) |

Table 4. Changes in PFM functions before and after PFMT (n=28)

| Characteristic                                | Before PFMT | After PFMT  | p-value |
|---|-------------|-------------|---------|
| APD at rest (mm)                              | 50.7 ± 6.4  | 51.3 ± 4.3  | n.s.    |
| APD during PFM contraction (mm)               | 42.5 ± 6.0  | 39.1 ± 5.3  | <0.0001 |
| ΔAPD (mm)                                     | 8.9 ± 5.1   | 12.1 ± 4.4  | <0.0001 |
| Vaginal squeeze pressure (cmH <sub>2</sub> O) | 24.0 ± 13.9 | 31.2 ± 14.5 | 0.0001  |



Posterior aspect of pubic synphysis

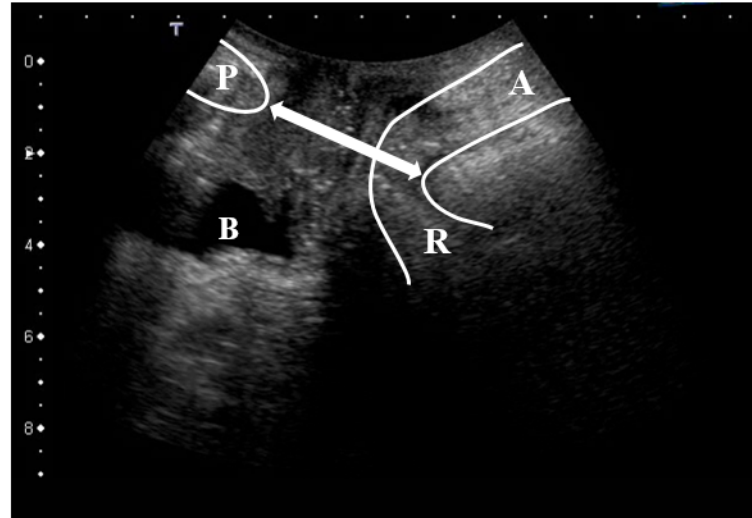
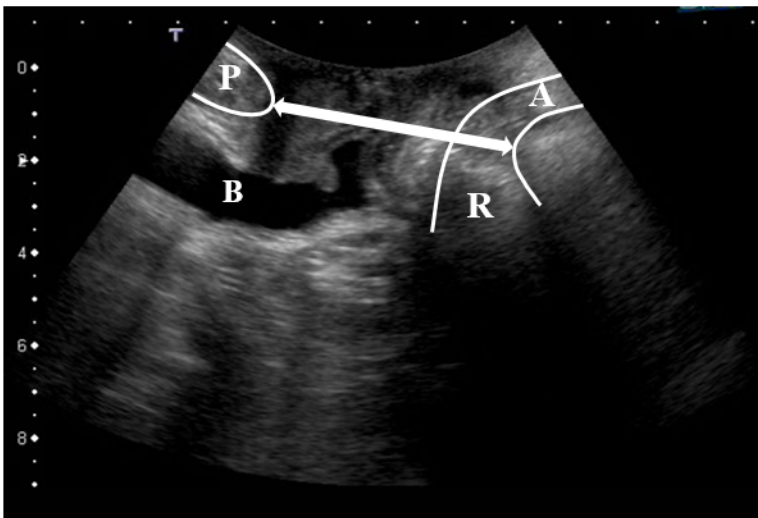
Anorectal junction

P: pubic synphysis

B: bladder

R: rectum

A: anus



P: pubic synphysis

B: bladder

R: rectum

A: anus

