GYNECOLOGY

Pelvic organ prolapse as a function of levator ani avulsion, hiatus size, and strength

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BACKGROUND: Obstetrical levator ani muscle avulsion is detected after 10%−30% of vaginal deliveries and is associated with pelvic organ prolapse later in life. However, the mechanism by which levator avulsion may contribute to prolapse is unknown.

OBJECTIVES: This study investigated the extent by which size of the levator hiatus and pelvic muscle weakness may explain the association between levator avulsion and pelvic organ prolapse.

STUDY DESIGN: This was a supplementary study of a longitudinal cohort of parous women enrolled 5−10 years after first delivery and assessed annually for prolapse (defined as descent beyond the hymen) for up to 9 annual visits. For this substudy, vaginally parous participants were assessed for levator avulsion using 3-dimensional transperineal ultrasound. Ultrasound was performed at a median interval of 11 years from delivery. Ultrasound volumes also were used to measure levator hiatus area with Valsalva. Pelvic muscle strength was measured with perineometry. Women with and without pelvic organ prolapse were compared for levator avulsion, levator hiatus area, and pelvic muscle strength, using multivariable logistic regression yielding a measure of mediation. Bootstrap methods were used to calculate the confidence interval corresponding to the measure of mediation by hiatus area and pelvic muscle strength.

RESULTS: Prolapse was identified in 109 of 429 (25%) and was significantly associated with levator avulsion (odds ratio, 4.17; 95% confidence interval, 2.28−7.31). Prolapse also was associated with levator hiatus area (odds ratio, 1.52 per 5 cm^2; 95% confidence interval, 1.34−1.73) and inversely with muscle strength (odds ratio, 0.87 per 5 cm H_2O; 95% confidence interval, 0.81−0.94). In a multivariable logistic model including levator avulsion, levator hiatus area, and strength, the association between levator avulsion and prolapse was substantially attenuated and indeed was no longer statistically significant (odds ratio, 1.75; 95% confidence interval, 0.91−3.39). Hiatus area and strength mediated 61% (95% confidence interval, 34%−106%) of the association between avulsion and prolapse. Furthermore, since the 95% confidence interval for this estimate contained 100%, it cannot be ruled out that the 2 markers fully mediate the effect of avulsion on prolapse.

CONCLUSIONS: The strong association between pelvic organ prolapse and levator avulsion can be explained to a large extent by a larger levator hiatus and weaker pelvic muscles after levator avulsion.

Key words: levator ani muscle avulsion, pelvic muscle strength, pelvic organ prolapse

The probability that a woman will develop pelvic organ prolapse is significantly increased by vaginal childbirth.[1] Specifically, previous research suggests a 5-fold increase in the odds of pelvic organ prolapse 5−10 years after vaginal birth vs cesarean delivery.[2]

The reasons for this association are unclear, although one hypothesized mechanism involves obstetrical injury to the levator ani muscles. Recent studies have explored the relationship between obstetrical levator injury, levator hiatus size, levator strength, and prolapse.[3−10] Levator ani muscle avulsion, in which the levator muscle is detached from its origin at the pubis, is observed after 10%−30% of vaginal deliveries[3−5] and is significantly associated with the development of prolapse later in life.[6−8] However, the biological mechanism for this strong association has not been explained. Levator avulsion appears to lead to a significantly larger levator hiatus and significantly poorer muscle strength.[9] It is unknown whether these changes in levator structure and function could explain the development of pelvic organ prolapse after vaginal childbirth.

The objective of this research was to determine the relative contributions of levator avulsion, the size of the levator hiatus, and levator contraction strength to pelvic organ prolapse after vaginal childbirth. Our first hypothesis was that levator hiatus area and pelvic muscle weakness are each independent and significant risk factors for pelvic organ prolapse. Our second hypothesis was that these changes in muscle structure and function explain the association between levator avulsion and prolapse. More specifically, we hypothesized that after controlling for levator weakness and hiatus size, the residual direct effect of levator avulsion on pelvic organ prolapse would be reduced. By addressing these hypotheses in a cohort of vaginally parous women, our goal was to provide insights into the mechanistic relationship between vaginal childbirth and pelvic organ prolapse.

Materials and Methods

Data for this research were acquired in the setting of a longitudinal cohort study of parous women.[2,10] The methods for the parent study have been described previously.[2,10] To summarize, parous women were enrolled 5−10 years from first delivery and followed annually for the incidence of pelvic floor disorders. From May 2015 to April 2017, each vaginally parous study participant was offered participation in this supplementary study.[8,9]

This supplementary study included the measurement of pelvic muscle strength and assessment of the levator

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AJOG at a Glance

Why was the study conducted?

This study was conducted to clarify mechanisms by which obstetrical levator avulsion may lead to pelvic organ prolapse later in life.

Key findings

The key findings are that 2 characteristics associated with levator avulsion, increased levator hiatus area and decreased muscle strength, are strongly associated with prolapse and may explain the association between levator avulsion and prolapse.

What does this add to what is known?

Although it has been shown previously that levator avulsion is strongly associated with prolapse, these results also suggest that this association might be explained, to a large extent (and possibly fully), by the increase in the levator hiatus size and the reduction in pelvic muscle strength seen among women with levator avulsion.

ani muscle using 3-dimensional transperineal ultrasound. Each woman was offered participation at one of her regularly scheduled study visits. Pelvic floor muscle strength (PFMS) was measured during voluntary pelvic muscle contraction with the Peritron perineometer (CardioDesign, Oakleigh, Australia).[11,12] PFMS was defined as the average increase in pressure generated over 2 contraction attempts, both obtained after the participant had been coached in the contraction technique and after an investigator confirmed correct technique via palpation. Women reporting latex allergy did not participate in this aspect of the research.

To assess the levator ani muscle anatomy, ultrasound volumes were captured as cine loops using a GE Voluson s6 system, with a RAB2-6-RS convex transducer (General Electric Healthcare, Chicago, IL), held in the sagittal plane on the perineum. Volumes were obtained for each participant at rest, with maximum Valsalva and with pelvic floor muscle contraction. Levator avulsion was identified on tomographic images,[13] obtained during maximum contraction. A complete levator ani avulsion was diagnosed if volumes demonstrated a complete separation between the levator muscle and the pubis ramus for at least 3 contiguous "slices": at the plane of minimal hiatal dimension and for at least 5 mm above that level.[13] All suspected avulsions were confirmed independently by 2 investigators. We also measured the area of the levator hiatus with maximal Valsalva (in the plane of minimal hiatal dimension[14]), using the area tool provided by GE 4Dview software (General Electric Healthcare, Chicago, IL).

Prolapse was assessed annually in this cohort using the Pelvic Organ Prolapse Quantification examination.[15] Prolapse was defined as descent of the cervix or any vaginal segment beyond the hymen. In addition, participants were asked about previous surgery for pelvic organ prolapse. At the time of the ultrasound assessment, we calculated the cumulative incidence, defined as the proportion of women who had met criteria for prolapse (at any time before or at the time of the study ultrasound), either on physical examination or by a report of surgery for treatment of prolapse.

The database of the parent study provided additional participant data, including primary race, age (at the time of ultrasound), and body mass index (kg/m^2) measured at the time of ultrasound. Obstetrical data included maternal age at first vaginal delivery, any forceps-assisted birth, any deliveries with second stage of labor greater than 120 minutes, any deliveries with birth weight greater than 4 kg, and history of obstetrical anal sphincter laceration. These obstetrical data considered all deliveries for each woman up until the time of the ultrasound. In addition, because pelvic muscle strength was characterized in this study, participants were asked whether they had been in a previous supervised program of pelvic muscle exercises.

The analytic plan for this study was influenced by previous work in this cohort demonstrating that levator avulsion is associated with a significantly larger levator hiatus and significantly poorer muscle strength (as suggested by lower peak perineometry pressures).[9] A logistic regression model was developed to estimate the odds of avulsion as a function of levator hiatus area and PFMS. This model was then used to calculate each woman's propensity of avulsion, based on her hiatus area and PFMS. Specifically, the log odds of avulsion were calculated for each woman and the interquartile range was calculated for the study population. Among women diagnosed with avulsion in the study population, according to criteria established by Tukey,[16] outliers were defined as those with a log odds of avulsion below the first quartile by more than 1.5 times the interquartile range. These participants were considered outliers and were excluded from the primary statistical analyses, as their inclusion would be expected to distort statistical models. However, sensitivity analysis also was performed with the inclusion of the outliers to assess their influence on the study findings.

For the primary statistical analysis, the outcome of interest was pelvic organ prolapse; the exposures of interest were presence of levator avulsion, levator hiatus size, and PFMS. Logistic regression was employed to estimate the odds of pelvic organ prolapse as a function of each of the exposures. Specifically, the logarithm of the odds of pelvic organ prolapse was modeled using the following regression equation:

$$\alpha_0 + \alpha_1 avulsion + \alpha_2(hiatus\ size - 25)/5 + \alpha_3(PFMS - 30)/5$$

Given this regression equation, the crude univariable association of avulsion

TABLE 1
Characteristics of 432 vaginally parous women, by prolapse status[a]

Characteristic[b]	No prolapse (n = 320)	Prolapse (n = 112)	*P* value
Age at ultrasound, y	42.8 [39.5, 46.7]	45.0 [41.0, 48.3]	.008
Years from first vaginal birth to ultrasound visit	10.5 [9.3, 13.3]	12.3 [9.6, 14.6]	.006
Black race (vs nonblack)	12% (37)	8% (9)	.298
Body mass index at ultrasound, kg/m^2	25.6 [22.7, 29.3]	25.9 [22.8, 30.5]	.362
Any[c] vaginal delivery with macrosomia (>4 kg)	14% (45)	17% (19)	.457
Any[c] vaginal delivery with second stage >2 h	28% (89)	32% (36)	.384
Any[c] obstetric anal sphincter laceration	15% (48)	22% (25)	.075
Any[c] vacuum-assisted vaginal delivery	11% (35)	14% (16)	.345
Any[c] forceps-assisted vaginal delivery	10% (33)	25% (28)	<.001

[a] Prolapse was defined as any examination in which Ba, C, or Bp was beyond the hymen or history of surgery for prolapse; [b] Categorical variables reported as percent (n); continuous variables reported as median [interquartile range]; [c] "Any" refers to an occurrence across all deliveries.

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with prolapse is captured by α_1^*, defined as the value of α_1 resulting from imposing $\alpha_2 = 0$ and $\alpha_3 = 0$ (ie, univariate association of avulsion and prolapse).

Our second hypothesis was that these changes in muscle structure and function explain the association between levator avulsion and prolapse. To assess the indirect effect of avulsion on prolapse (ie, mediated by hiatus area and PFMS), we calculated $(\alpha_1^* - \alpha_1)/\alpha_1^*$. This statistic can be read as the percentage of the effect of avulsion on prolapse that is explained by (mediated via) the hiatus area and PFMS. To calculate confidence intervals (CIs) for this statistic, we considered that estimates of α_1 and α_1^* are 2 statistics from regressions on the same data set. Thus, they are subjected to statistical dependencies for which a bootstrap approach offers a way to calculate standard errors. Specifically, to calculate a 95% CI for $(\alpha_1^* - \alpha_1)/\alpha_1^*$, we produced 1000 bootstrap samples (ie, sampling N times with replacement from the N participants of the total study population) and carried out the 2 logistic regressions (with and without the hiatus area and PFMS) to arrive to 1000 estimates of $(\alpha_1^* - \alpha_1)/\alpha_1^*$ so that the 2.5th and 97.5th percentiles define the 95% CI.

In an additional statistical model, the population was stratified by levator avulsion to determine the role of levator hiatus and PFMS on prolapse in women with the same levator avulsion status. In the 2 resultant populations, we carried out 2 logistic regression models, considering prolapse as a function of levator hiatus area and PFMS. Inferences and statistical comparisons were carried out based on maximum likelihood methods using SAS, version 9.4 (SAS Institute, Cary, NC).

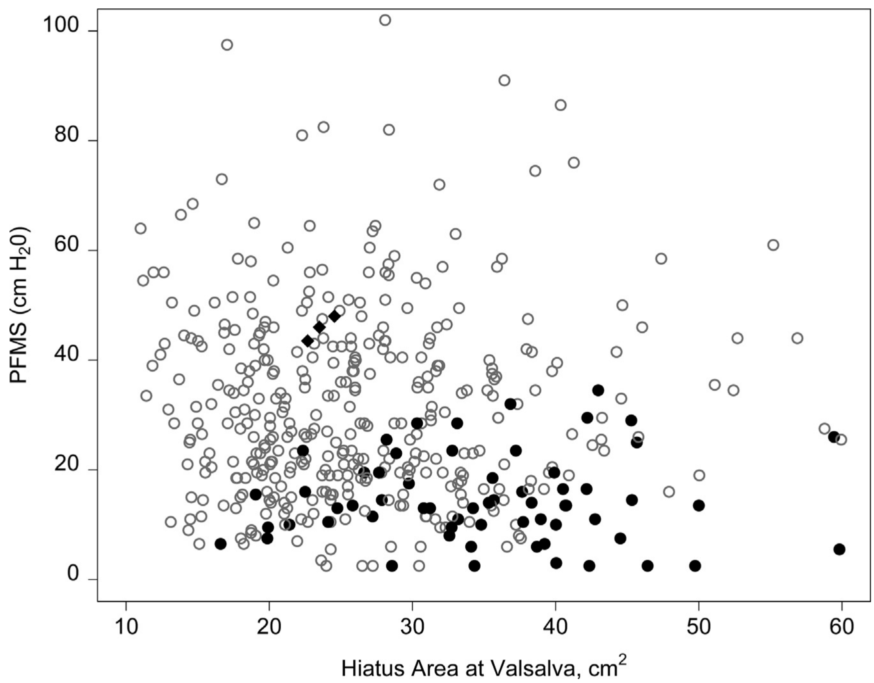
Results

Of 550 eligible women, 10 (2%) declined to participate in this supplemental study, 86 (16%) did not return for a visit during the study interval, 1 had uninterpretable ultrasound volumes, and 21 (4%) did not undergo perineometry (15 due to latex allergy, 6 for other reasons). Thus, 432 vaginally parous women contributed data for this research. At the time of these ultrasound studies, the median age was 43 years. Parity was equal to 1 for 22%, equal to 2 for 57%, and equal to 3 or more for 21% of participants. Only 7 of 432 participants (2%) reported participation in a program of supervised exercises

Of these 432 women, 112 (25%) had prolapse, including 7 with a history of previous surgery for prolapse (but no prolapse on examination) and 105 with prolapse beyond the hymen on physical examination (6 of whom also reported a history of surgery for prolapse). Comparing women with and without prolapse (Table 1), there were no statistically significant differences in race, body mass index, macrosomia or prolonged second stage. However, compared with women without prolapse, those with prolapse were older and were more likely to have experienced forceps delivery.

Levator avulsion was diagnosed among 64 of 432 (15%) women. Comparing women with vs those without levator avulsion (Figure 1), women with avulsion (*black closed circles*) had larger hiatus area (medians: 34.57 cm^2 vs 25.03 cm^2; $P < .001$) and lower perineometry measures (medians: 13.5 cmH_2O vs 28.5 cmH_2O; $P < .001$) when compared with women without levator avulsion (*gray open circles*). The exceptions were the 3 cases shown in *black closed diamonds*. Although these 3 women had ultrasound findings that met diagnostic criteria for avulsion, their hiatus area and PFMS measures were very different from the rest of those with avulsion. This led to the question of whether these 3 cases should be included in further analyses. Using the method for identifying outliers established by Tukey,[16] these 3 participants were confirmed as outliers. More specifically, using their levator hiatus and PFMS

FIGURE 1
Levator hiatus area versus pelvic floor muscle strength



Levator hiatus area (in cm^2) and PFMS (mean peak pressure during voluntary contraction, in cmH_2O), by levator avulsion. Data for women with levator avulsion are shown in *closed black circles*. Three outliers (with levator avulsion) are shown in *closed black diamonds*.

PFMS, pelvic floor muscle strength.

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measures to predict their probability of avulsion, using $\{1 + \exp(3.52 - 0.56(\textit{hiatus area} - 25)/5 + 0.61(\textit{PFMS} - 30)/5)\}^{-1}$, we calculated that the probabilities these 3 women had an avulsion were 0.35%, 0.43%, and 0.31%, respectively. Thus, assuming accurate measurement of hiatus area and PFMS, it was very unlikely these women had levator avulsion. Their data were excluded from further analysis, leaving 429 women for analysis, of whom 61 had levator avulsion and 109 had prolapse.

Among the remaining 429 women, prolapse was significantly associated with levator hiatus size (Figure 2, A). Across 5 ordinal categories of hiatus area size (from $<$20 cm^2 to $\geq$35 cm^2), the odds of prolapse increased more than 7-fold: the relative odds (OR) for prolapse among women with hiatus area $\geq$35 cm^2 vs $<$20 cm^2 was 7.22 (95% CI, 3.40–15.32). Moreover, in an analysis that considered levator hiatus area as a continuous variable, the relative odds for prolapse was found to increase by 50% per 5-cm^2 increase in hiatus size (OR, 1.52; 95% CI, 1.34–1.73).

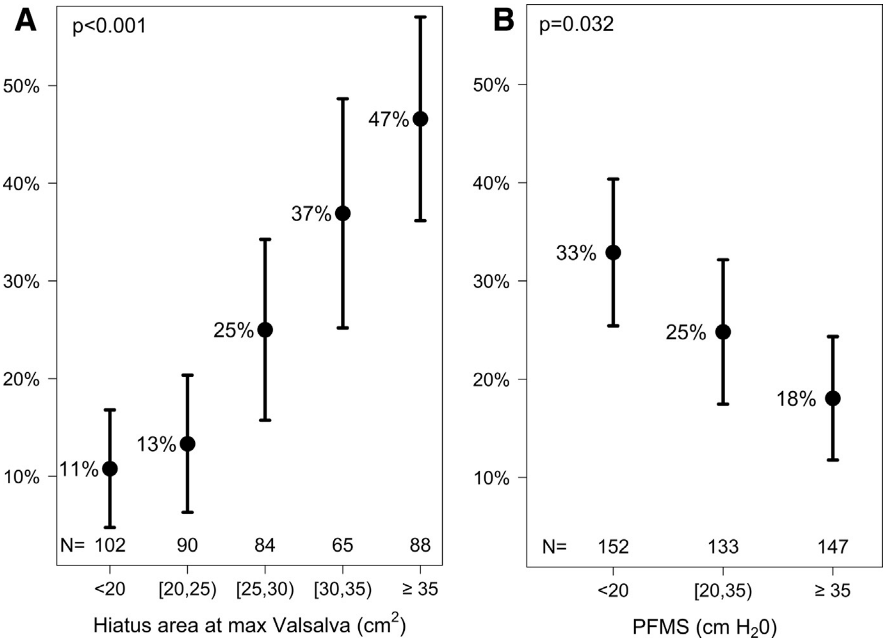
Prolapse also increased as PFMS decreased (Figure 2, B). For women with peak pressure $\geq$35 cm H_2O, the odds of prolapse were halved (OR, 0.45; 95% CI, 0.26–0.77) in comparison with women who had peak pressure $<$20 cmH_2O. Considering PFMS as a continuous variable, for every 5-cmH_2O increase in peak pressure, the odds for prolapse was reduced by 13% (OR, 0.87; 95% CI, 0.81–0.94).

In univariable logistic regression, the relative odds for prolapse associated with levator avulsion was 4.17 (95% CI, 2.28–7.31). Given the association between avulsion, levator hiatus size and PFMS depicted in Figure 1, multivariable logistic regression was next used to investigate whether levator hiatus area and pelvic muscle weakness were each independent and significant risk factors for pelvic organ prolapse (Table 2). In a multivariable model with these 3 variables, the association between levator avulsion and prolapse was substantially attenuated and indeed was no longer statistically significant (OR, 1.75; 95% CI, 0.91–3.39).

For this multivariable logistic regression model, we estimated that the percent of the association between avulsion and prolapse (OR, 4.17) mediated via hiatus area and PFMS was 61% ($= 100 * (\log(4.17) - \log(1.75))/\log(4.17)$). The bootstrap-based 95% CI for this estimate was from 34% to 106%. By the lower bound of the CI being greater than zero, this confirms there is significant mediation. By the upper bound being greater than 100%, the possibility that hiatus area and PFMS fully mediate the avulsion–prolapse association cannot be ruled out. We also considered separate models with hiatus area and PFMS as individual mediators of avulsion, which resulted in partial mediation of 38% (95% CI, 22%–68%) and 19% (95% CI, 2%–40%), respectively. Therefore, although hiatus area and muscle strength separately mediate a portion of the association between prolapse and avulsion, when considered together they may completely mediate the avulsion-prolapse association.

Table 2 also demonstrates the results of stratified multivariable regression models, in which women with and without levator avulsion were considered separately. Among 368 women without levator avulsion, the association between prolapse and both hiatus area and PFMS was statistically significant. Furthermore, the association between levator hiatus area and prolapse was strongest for women with levator avulsion. Specifically, among 61 women with levator avulsion, the odds of prolapse

FIGURE 2
Percentage of women with pelvic organ prolapse



Percentage of women with pelvic organ prolapse as a function of (**A**) levator hiatus area at maximum Valsalva, measured on 3-dimensional transperineal ultrasound; and (**B**) PFMS (mean peak pressure at maximum voluntary contraction), measured via perineometry.

PFMS, pelvic floor muscle strength.

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was more than doubled for each 5-cm^2 increase in levator hiatus area (OR, 2.43; 95% CI, 1.51−3.91).

Finally, in a sensitivity analysis that considered inclusion of the 3 outliers in the multivariable regression model, the impact of these three cases demonstrated their undue influence. When these 3 cases are included in the multivariable model, the OR for avulsion was increased (from 1.75 without them) to 2.27 and was statistically significant (95% CI, 1.21−4.29). In addition, the association between prolapse and PFMS increased toward the null (OR, 0.93), being only marginally significant (95% CI, 0.86−1.00).

Comment

Our results confirm a strong association between prolapse and levator avulsion, previously reported by Dietz and Simpson[7] and DeLancey et al.[6] In addition, the present study extends those findings by demonstrating significant associations between prolapse and 2 characteristics seen among women with levator avulsion[9]: increased levator hiatus area and decreased muscle strength (as measured by the vaginal pressure generated during perineometry). With respect to levator hiatus size, for every 5-cm^2 increase in area, the odds of prolapse was increased by 50% (OR, 1.52; 95% CI, 1.34−1.73). This association is similar to an observation in previous study of care-seeking women, in whom hiatal area was associated with stage ≥2 support.[17] In addition, we found that PFMS was inversely and significantly associated with the odds of prolapse (OR, 0.87; 95% CI, 0.81−0.94).

The results of the present study also suggest that the association between levator avulsion and prolapse might be explained, to a large extent (and possibly fully), by the increase in the levator hiatus size and the reduction in PFMS seen among women with levator avulsion. This is an important finding, which leads us to speculate that levator hiatus size and pelvic muscle weakness may be the mechanism by which levator avulsion is linked to prolapse later in life. This hypothesis would be consistent with biomechanical models that suggest that levator impairment, and more specifically hiatus size, is a critical contributor to anterior vaginal prolapse.[18] This could suggest possible targets for prolapse prevention among vaginally parous women. However, the

TABLE 2
Associations between pelvic organ prolapse and levator avulsion, levator hiatus area, and pelvic muscle strength (n = 429)

			Stratified by avulsion	
	Univariable analyses	Multivariable analysis	No avulsion (n = 368)	Avulsion (n = 61)
Levator avulsion	4.17 (2.38−7.31)[a]	1.75 (0.91−3.39)		
Levator hiatus area (per 5-cm^2)	1.52 (1.34−1.73)[a]	1.46 (1.28−1.67)[a]	1.36 (1.18−1.57)[a]	2.43 (1.51−3.91)[a]
Pelvic muscle strength (per 5-cm H_2O)	0.87 (0.81−0.94)[a]	0.90 (0.83−0.98)[a]	0.91 (0.84−0.99)[a]	0.85 (0.57−1.24)

[a] Statistically significant result.

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residual association between prolapse and levator avulsion in the multivariable model (OR, 1.75), although not statistically significant, cannot be completely discounted. This might suggest some additional mechanism by which levator avulsion may be associated with prolapse.

An additional contribution of this study is the use of each woman's levator hiatus area and PFMS measures to validate her diagnosis of avulsion. Using an established method for identifying avulsion,[13] 64 women initially were diagnosed with avulsion, and this diagnosis was confirmed independently by 2 readers. However, using the levator hiatus area and PFMS, 3 of 64 (5%) women diagnosed with avulsion were considered unlikely to have had avulsion and were excluded from our analysis. This additional validation of the avulsion diagnosis, building on the rigorous use of validated criteria, is a strength of this study. Such validation could improve the diagnostic accuracy of the ultrasound diagnosis of avulsion for further research studies and could provide additional valuable diagnostic criteria for avulsion as the potential clinical value of this diagnosis is established.

Additional strengths of this study were the use of a rigorous definition of prolapse, as well as the masking of observers (reducing the potential for bias). Also, the sample size provided adequate power to address the proposed aims of this study.

Women in this study were relatively young (mid-40s) at the time of this study, and our results might not be generalizable to older women. The focus on relatively young women was intentional, as the impact of childbirth is more likely to be manifested in women with the onset of prolapse at a relatively young age. Indeed, although the peak hazard for prolapse likely occurs more than 20 years after delivery, data from this study cohort suggest that the strong association between childbirth and the incidence of prolapse is sustained over time.[19] Nevertheless, it is possible that different mechanisms might contribute to prolapse that develops later in life.

A potential weakness of this study was perineometry may not accurately reflect pelvic muscle strength. Although perineometry has a strong correlation with more traditional measures of levator strength, such as Brink score, and has demonstrated high inter- and intrarater reliability,[20] this technique may be influenced by a Valsalva effort during pelvic muscle contraction. An additional weakness of this study is that levator hiatus size and PFMS were assessed many years after childbirth. An argument for a causal relationship with prolapse would be stronger if these characteristics had been assessed before the development of prolapse. Although we acknowledge this limitation, there is some reason to believe that PFMS, as assessed with perineometry, is relatively constant over time. For example, research in this population found that PFMS is essentially constant over 4 years of observation.[21] Thus, we believe that PFMS measured 11 years after childbirth is a reasonable approximation of strength a decade before. Less is known about changes in levator hiatus area over time. In one study of 101 vaginally parous women, Chan et al found an increase in mean levator hiatus area between 1 year and 3–5 years postpartum (14.24 cm^2 vs 16.71 cm^2, $P < .005$).[22] Furthermore, they found that the increase in hiatal area was greater among 28 women with levator avulsion vs those without avulsion. These findings, together with the results of the present study, argue for further longitudinal studies of levator biometry and pelvic organ support over time.

The findings of the present study provide important clues about the sequelae of levator avulsion and the pathophysiology of prolapse among parous women. These results suggest that hiatus size and muscle strength may be important markers to identify women at greatest risk to develop prolapse. Further studies are needed to determine whether interventions to reduce hiatus size or increase muscle strength would be effective prevention strategies to reduce the incidence of prolapse later in life. ■

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