

ORIGINAL RESEARCH

Impact of levator ani muscle avulsions on Manchester procedure outcomes: A 5-year follow-up study

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Abstract

Introduction: Levator ani muscle avulsion is a risk factor for inferior outcomes after native tissue pelvic organ prolapse repair. In a previously published study, we found no such association 1 year after the Manchester procedure (anterior repair combined with cardinal and uterosacral ligament suspension and perineal repair). The aim of the present study was to compare women with and without levator ani muscle avulsions in terms of patient-reported and anatomical outcomes, and failure rates in the same cohort after 5 years.

Material and Methods: Five-year prospective cohort study of 143 women operated on for anterior and/or mid-compartment pelvic organ prolapse with the Manchester procedure between October 2014 and January 2017, Clinical Trial study number NCT02246387. Levator ani muscle avulsions (uni- or bilateral) were diagnosed at inclusion by transperineal ultrasound. Primary outcome at 5-year follow-up was subjective bulge symptoms (question 3, Pelvic Floor Distress Inventory-20). Secondary outcomes were total score from the same questionnaire, sexual distress (Pelvic Organ Prolapse/Urinary Incontinence Sexual Questionnaire-12), subjective cure, Pelvic Organ Prolapse Quantification scale measurements, defining optimal outcomes as anterior compartment stage <0–1 and mid-compartment point C ≤–5, and new surgical or conservative prolapse treatment.

Results: Among 143 women followed up after 5 years, the avulsion rate was 52.4%. Both groups showed similar reductions in bulge symptoms, pelvic floor symptoms, and anatomical anterior- and mid-compartment measurements. Sexual distress improvement was significantly greater for women with avulsion (Mean change difference: –3.4 (–6.4 to –0.5)). Multivariate regression revealed no significant effect of avulsion on symptom scores, cure rates, or need for new prolapse treatment. Women with avulsion had half the odds of obtaining an optimal anterior compartment outcome compared to those without avulsion (adjusted odds ratio: 0.5 (0.2–0.9)).

Abbreviations: LAM, levator ani muscle; MP, Manchester procedure; PFDI-20, Pelvic Floor Distress Inventory Short Form 20; PISQ-12, POP/Urinary Incontinence Sexual Questionnaire; POP, pelvic organ prolapse; POP-Q, Pelvic Organ Prolapse Quantification scale.

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Conclusions: Although women with levator ani muscle avulsion had lower odds of achieving an optimal anterior compartment outcome, the overall anatomical changes from preoperative to 5 years were similar in both groups. Importantly, avulsion did not impact symptom improvement, patient-reported outcomes, or the need for further treatment. These findings support the Manchester procedure as an effective and durable surgical option for women with POP, regardless of avulsion status.

KEYWORDS

gynecologic surgical procedures, pelvic organ prolapse, physiological, recurrence, sexual dysfunction, treatment outcome

INTRODUCTION

Major levator ani muscle (LAM) injuries, also called LAM avulsions, occur in 15% of spontaneous vaginal childbirths, with a threefold increased risk in forceps-assisted deliveries.¹ Such delivery-related injuries are known to increase the risk of symptomatic pelvic floor dysfunction, in particular pelvic organ prolapse (POP).^{2,3} Most previous studies indicate that women with LAM avulsions have inferior outcomes after POP surgery, but a recent review concluded that further studies are needed to evaluate the association between avulsions and the risk of subjective recurrence and reoperation.⁴ The prevalence of LAM avulsions among women undergoing POP surgery is high, about 50%.^{5,6} The choice of POP surgical treatment that compensates for the lack of pelvic floor support from the LAM could therefore be of importance to obtain long-lasting results.⁵⁻⁷

Surgical traditions and treatment options vary considerably, ranging from vaginal repair with native tissue to laparoscopic procedures with the use of synthetic mesh. During the last decade, various publications from the Netherlands and the Nordic countries have presented promising results after the native tissue Manchester procedure (MP) combining anterior wall repair with uterosacral ligament suspension and perineal body repair.⁸⁻¹⁰ In a previous study on the 1-year outcome after MP for primary anterior- and mid-compartment POP, we found neither difference in anatomical or patient-reported outcomes nor need for new treatment when comparing women with and without LAM avulsions.¹¹ However, recurrent symptoms or anatomical POP among women with avulsions may potentially become more evident with time.

In the present study, we aimed to compare women with and without LAM avulsions in terms of patient-reported and anatomical outcomes and failure rates in the same cohort 5 years after MP. We hypothesized that there would be no significant differences between the groups (null hypothesis).

MATERIAL AND METHODS

This 5-year prospective cohort study included women with intact uteruses and symptomatic anterior and mid-compartment POP who were scheduled for primary surgery with the MP at Oslo University

Key message

Despite an inferior anatomical anterior compartment outcome 5 years after the Manchester procedure in women with levator ani muscle avulsions, the avulsions had no negative impact on patient-reported outcomes or the need for additional treatment.

Hospital between October 2014 and January 2017. The Department serves as a local center for Oslo residents and a tertiary referral center for other Norwegian regions. The standard surgical technique for anterior- and mid-compartment prolapse at the department is the MP, representing about 60% of POP surgeries performed.¹² Inclusion criteria were symptomatic anterior and mid-compartment POP requiring surgery, age 18 years or older, and fluency in a Scandinavian language or English. Exclusion criteria included uterine descent beyond the hymen (present in less than 10%¹²), prior POP surgery, hysterectomy, or conditions requiring hysterectomy. One-year results from the cohort were previously published. For the 5-year follow-up, participants were invited back for clinical assessment. Participants who underwent new POP treatment after the initial surgery were classified as treatment failures, while those with hysterectomy between the 1- and 5-year follow-ups were excluded.

Preoperative evaluation included POP-Q measurements and transperineal ultrasound to assess LAM integrity, focusing on complete avulsions, as incomplete LAM defects have been found to be of minor clinical importance.¹³ The methodology for ultrasound image evaluation and validation was detailed in the 2019 publication on 1-year results.¹¹ Preoperative questionnaires included the Pelvic Floor Distress Inventory (PFDI-20) and the POP/Urinary Incontinence Sexual Questionnaire (PISQ-12) for sexually active participants, using translations from linguistically similar Swedish versions due to the lack of Norwegian validations.^{14,15} The PFDI-20 can be divided into three subscales assessing pelvic floor, urinary, and colorectal-anal symptoms. It includes 20 items, each with response options ranging from 0 (symptom not present) to 4 (symptom bothers quite a bit). The PISQ-12 consists of 12 questions, each with response options ranging from 0 (always) to 4 (never). Missing data were handled

per original protocols.^{14,15} Surgical procedures followed a standardized MP technique incorporating anterior colporrhaphy, uterosacral/cardinal ligament shortening with cervical fixation, and perineal body reconstruction. Surgeons were blinded to preoperative ultrasound results.¹¹

At 5 years, blinded clinicians conducted standardized interviews and POP-Q measurements. Participants completed the PFDI-20 and PISQ-12 and answered a question about subjective cure of POP symptoms, with the four response options "cured," "improved," "unchanged," and "worse." This subjective cure question is part of the department's routine follow-up. Participants who missed follow-ups were contacted up to three times and then by phone to encourage attendance.

In this study, the null hypothesis was that patient-reported outcomes, anatomical outcomes, and failure rates were similar between women with and without LAM avulsions 5 years after the MP.

The primary outcome at the 5-year follow-up was the difference in mean scores for question 3 of the PFDI-20: "Do you usually have a bulge or something falling out that you can see or feel in your vaginal area?," comparing women with and without LAM avulsions.

Secondary outcomes included:

- I Patient-reported outcomes:
 - o Differences in mean scores for pelvic floor (PFDI-20) and sexual symptoms (PISQ-12).
 - o Subjective cure, defined as responding "cured" to the question about being cured of POP symptoms.
- II Anatomical outcomes:
 - o Optimal anatomical outcomes in the anterior and mid-compartments are defined as POP-Q stages 0–1 in the anterior compartment and point C <–5 in the mid-compartment.
 - o Mean anatomical changes from preoperative to 5-year postoperative POP-Q measurements of points Ba and C.
- III Other comparison:
 - o Rates of new treatment for POP (surgery, pessary use, or pelvic floor muscle training) after the initial surgery.

Statistical analyses

Statistical analyses were performed using SPSS version 29 (IBM Corp., Armonk, NY, USA) and STATA SE version 18 (Stata Corp., College Station, TX, USA).

Means were compared using independent student's t-test for normally distributed data and Mann-Whitney U test when normality assumption was not met. Proportions were compared using chi-square test or Fisher's exact test when appropriate.

The associations between LAM and the symptom of bulge (q.3, PFDI-20), pelvic floor symptoms (PFDI-20), and sexual distress scores (PISQ-12) were tested using multivariate linear regression. Associations between LAM and poor anatomical outcomes in the anterior (POP-Q point Ba) or mid-compartment (POP-Q point C) were analyzed with multivariate logistic regression, while subjective

cure was evaluated using ordered logistic regression. A separate model was created for each outcome.

Univariate analyses identified potential confounders to adjust for in the multivariate models. Dichotomous variables included preoperative anterior compartment POP-Q stage \geq III, use of local estrogen, and chronic disease (e.g., chronic pain, fatigue, or increased intra-abdominal pressure). Continuous variables included age at surgery, BMI, and preoperative PFDI-20 and PISQ-12 scores.

Log-transformation was applied to the right-skewed postoperative PFDI-20 scores to meet linear regression assumptions. Variables with $p < 0.2$ in univariate analyses were included in multivariate models and retained if $p < 0.2$ was maintained. Logistic models were tested for goodness-of-fit using the Hosmer–Lemeshow test, with statistical significance set at $p < 0.05$.

Since the evaluation of new POP treatment had to account for the entire initial study population, not just those followed up at 5 years, the comparison was performed exclusively using the chi-square test.

The pre-study sample size estimation was performed in 2013 based on an assumed 20% recurrence risk in women with LAM avulsions, derived from best clinical practice in the absence of specific data on LAM avulsions and MP outcomes. For women without avulsions, a 3% recurrence risk was assumed, based on findings from a previously published internal quality control study at our department, which did not include information on LAM avulsions.¹¹ With a 1:3 group ratio (reflecting an estimated 25% prevalence of LAM avulsions), a 17% effect size, 80% power, and a significance level of 0.05, the estimated total sample size was 189: 142 without LAM avulsions and 47 with avulsions.⁶ After ultrasound diagnosis of LAM avulsion in the study population, it was found that the prevalence of avulsions was much higher than anticipated, resulting in nearly equal group sizes for avulsion versus non-avulsion. Post hoc sample size estimations were not performed as they do not provide a reliable assessment of necessary study changes.

RESULTS

Between September 2014 and January 2017, 195 women were preoperatively included in the study, of whom 143 met for 5-year follow-up: 75 with LAM avulsion and 68 without (Figure 1). Median follow-up time from the MP was 69 months (Range: 62–92 months). Baseline data were similar between groups for preoperative bulge symptoms (q.3, PFDI-20) PFDI-20, PISQ-12 scores, and POP-Q measurements, but women with LAM avulsions were younger and had lower BMI (Table 1). The reduction in bulging (q.3, PFDI-20) and pelvic floor symptom scores (PFDI-20) was similar between the groups, while sexual distress (PISQ-12) showed a significantly greater reduction among women with avulsions. On multivariate linear regression analysis, LAM avulsion had no significant impact on 5-year PFDI-20 q.3 scores, total PFDI-20 scores, or PISQ-12 scores. Subjective cure at 5 years was also similar between the groups based on multivariate ordered regression (Table 2).

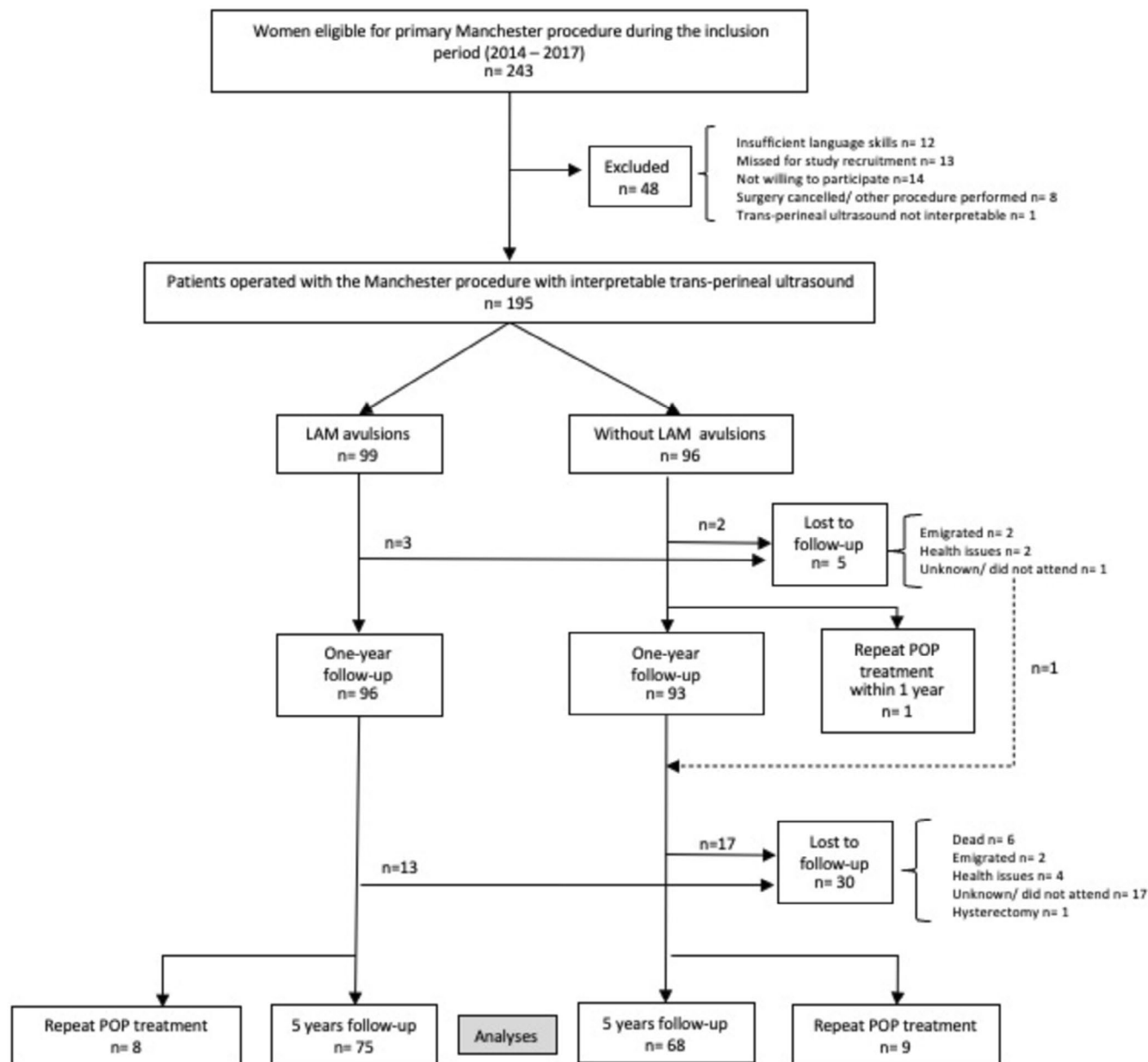


FIGURE 1 Flowchart: Study population at 5-year follow-up after the Manchester procedure.

Reductions in anatomical measurements of the anterior and mid-compartments (Ba and C) were comparable between the groups (Table 1). These findings remained consistent after adjustments in multivariate regression analyses.

Multivariate logistic regression revealed a significant association between LAM avulsion and a less likely achievement of an optimal anatomical outcome in the anterior compartment 5 years after MP, although the wide 95% confidence interval (CI) indicated some uncertainty. Additionally, fewer women with LAM avulsion obtained optimal anatomical outcomes in the mid-compartment, but these differences were not statistically significant, again with wide 95% CIs (Table 2).

The need for new POP treatment was similar between women with and without avulsions. Among the 96 women without LAM

avulsions who underwent the MP, 9.4% required additional prolapse treatment, compared to 8.0% of the 99 women with LAM avulsions ($p=0.75$).

DISCUSSION

In this study, we found that women with preoperatively diagnosed LAM avulsion more seldom obtained an optimal anatomical outcome in the anterior compartment 5 years after surgery. However, they had similar pelvic floor symptom and sexual function scores compared to women without avulsions 5 years after the MP.

A Dutch cohort study including a heterogeneous group of POP surgeries finds that the hazards ratio for recurrence flattened after

TABLE 1 Comparison of preoperative and 5-year postoperative data after the Manchester procedure for women with and without levator ani muscle (LAM) avulsions ($n = 143$).

Independent variables	LAM avulsion ($n = 75$)		Intact LAM ($n = 68$)		Mean difference (95% CI)
	PREOP	5YR	PREOP	5YR	
Age, mean years (SD)	57.2 (12.0)		63.7 (10.4)		-6.5 (-10.2 to -2.7)
BMI, mean kg/m ² (SD)	24.2 (3.0)		25.6 (3.8)		-1.4 (-2.6 to -0.3)
					Mean difference of change (95% CI)
Symptom of bulge (q.3, PFDI-20), mean score (SD)	3.0 (1.3)	0.5 (1.1)	3.1 (1.2)	0.7 (1.4)	-0.0 (0.6 to -0.6)
Pelvic floor symptoms (PFDI-20), mean score (SD)	96.2 (46.2)	54.8 (60.0)	105.5 (51.9)	58.8 (56.5)	4.8 (-12.5 to 22.1)
Sexual Distress (PISQ-12), mean score (SD)	13.7 (6.5)	11.4 (4.8)	13.9 (6.2)	13.6 (5.4)	-3.4 (-6.4 to -0.5)
Anterior compartment (Ba), median cm (range)	2.0 (-1.0 to 6.0)	-1.0 (-3.0 to 2.0)	2.0 (-2.0 to 7.0)	-1.5 (-3.0 to 3.0)	0.0 (-0.6 to 0.6)
Mid-compartment (C), median cm (range)	-1.0 (-7.0 to 6.0)	-6.5 (-11.0 to -4.0)	-2.0 (-7.5 to 5.0)	-7.0 (-10.0 to 0.0)	-0.2 (-1.1 to 0.8)
Posterior compartment (Bp), median cm (range)	-1.5 (-3.0 to 3.0)	-3.0 (-3.0 to -1.0)	-1.0 (-3.0 to 4.0)	-3.0 (-3.0 to 0.0)	0.0 (-0.5 to 0.5)

Abbreviations: MP, Manchester procedure; PFDI-20, Pelvic Floor Distress Inventory Short Form 20; PISQ-12, POP/Urinary Incontinence Sexual Questionnaire.

2 years.¹⁶ Some studies show inferior outcomes in women with avulsions also at short-term follow-up.⁴ In contrast, the association between LAM avulsions and inferior anatomical outcomes in the anterior compartment was not evident for this cohort at 1-year follow-up.¹¹ Our findings suggest that avulsions may primarily impact long-term surgical outcomes after the MP. We have not found other studies that focus on Manchester and LAM avulsions. Neither have we found studies on the long-term impact of LAM avulsions after other types of native tissue repairs.

In our cohort, between-group differences in new treatment were not seen at 5 years. Unlike the studies describing inferior symptomatic outcomes in women with LAM avulsions after various POP procedures, we could not find such an impact of LAM avulsions after the MP neither at the 1- nor at the 5-year follow-up.^{17,18} The latter may seem illogical given the inferior anatomical outcomes described above. However, the association between POP symptoms and anatomical findings is known to be weak.¹⁹ Another possible explanation is that the thorough pelvic floor support provided by the MP, including the apical lift by the shortening and repositioning of the ligaments and the reconstruction of the perineal body, protects the anterior prolapse from becoming symptomatic. This has also been suggested by other authors such as Tolstrup et al. in a matched historical cohort study comparing MP to vaginal hysterectomy.²⁰ However, in contrast to other studies, the failure rate was around 8%–9% regardless of LAM avulsion. Recurrence risk differs according to procedures and populations but has in some studies been described as quadrupled in women with LAM avulsions.²¹

The strengths of this study include its prospective design and the homogeneity of the surgical procedure performed. The study also used validated questionnaires that are well established for pelvic floor research (PFDI-20 and PISQ-12) and an intra- and inter-rater

validation of the diagnosis of LAM avulsions was performed as part of the study inclusion process.¹¹ All 5-year clinical follow-ups were performed by a clinician not involved in the patient's surgical treatment to reduce the risk of cognitive bias on behalf of the examiner.

Accomplishing any long-term follow-up study is demanding, especially when the cohort consists of aging individuals. This resulted in the number of study participants being fewer than originally planned for by the power calculations at study start, which is a weakness. The significant findings also have wide confidence intervals, implying some level of uncertainty.

We believe that our previous finding of women with avulsions being significantly younger when seeking surgical POP treatment is clinically relevant.¹¹ This association has also previously been shown.²² It is well established that younger women have an increased risk of dyspareunia following POP surgery.²³ Therefore, it is particularly interesting that, in our population, we observed a greater reduction in sexual dysfunction in the younger group of women with LAM avulsions compared to those without such injury. This may be related to the fact that the MP includes reconstruction of the perineal body, and a well-reconstructed perineal body likely improves sexual function for many women.

Young age at the time of surgery in itself is identified as a risk factor for POP recurrence.²² One explanation could be that younger women have a longer life span to potentially develop recurrent POP. Another explanation is that better blood circulation and more intact innervation in younger women negatively impact the threshold for symptomatic recurrence.²² In our study, we saw that adjusting for the fact that women with avulsions were younger at the time of surgery unveiled the association between avulsions and an inferior anatomical outcome in the anterior vaginal compartment. A tendency toward poorer outcomes also in the mid-compartment was seen,

TABLE 2 Adjusted 5-year patient-reported and anatomical outcomes after the Manchester procedure comparing women with and without levator ani muscle (LAM) avulsions ($n = 143$).

Outcome variables	LAM avulsion ($n = 75$) Mean (SD)	Intact LAM ($n = 68$) Mean (SD)	Regression analysis		
			Univariate		Multivariate
			Coeff. B (95% CI)		Coeff. B (95% CI) R ²
Bulge symptoms (Q3, PFDI-20) ^a	0.5 (1.1)	0.7 (1.4)	−0.1 (−0.6–0.3)		—
Sexual distress (PISQ-12)	11.4 (4.8)	13.6 (5.4)	−2.2 (−4.6–0.2)		−2.1 (−4.3–0.1) 0.41
Pelvic floor symptoms (PFDI-20)	54.8 (60.0)	58.8 (56.5)	Coeff. (β)	Exp (β) (95% CI)	Exp (β) (95% CI) 0.33
			−4.0	−0.1 (−0.4–0.3)	0.1 (−0.2–0.3)
Subjective cure	n (%)	n (%)	Ordered Coeff. (95% CI)		Ordered Coeff. (95% CI)
Cured	51 (68.0)	51 (75.0)	−0.4 (−1.1–0.4)		−0.1 (−0.9–0.7)
Improved	20 (26.7)	15 (22.1)			
Unchanged	2 (2.7)	2 (2.9)			
Worsened	2 (2.7)	0 (0.0)			
Optimal anatomical outcome	n (%)	n (%)	Crude OR		Adjust. OR (95% CI)
Anterior compartment	30/72 (41.7)	36/66 (54.5)	0.6 (0.3–1.2)		0.5 (0.2–0.9)
Mid-compartment	64/72 (89.9)	64/66 (97.0)	0.3 (0.1–1.2)		0.2 (0.0–1.0)

Abbreviations: PFDI-20, Pelvic Floor Distress Inventory Short Form 20; PISQ-12, POP/Urinary Incontinence Sexual Questionnaire.

^aThe analysis for Bulge symptoms is unadjusted as no relevant confounding factors were identified.

though not significant. Several other publications describe such an impact of LAM avulsions on anterior compartment outcomes after vaginal native tissue repair procedures. However, also in accordance with our findings, no such clear association between LAM avulsions and mid-compartment outcomes has been seen.^{17,24,25}

CONCLUSION

Although anatomical outcomes in the anterior compartment were inferior among women with LAM avulsions 5 years after the MP, no differences in patient-reported pelvic floor or sexual symptoms were found when compared to women without avulsions. Neither were there any differences in the need for a new POP treatment. We conclude that the MP may therefore be considered an excellent treatment for women with intact uterus and primary anterior- or mid-compartment prolapses regardless of LAM avulsions.

AUTHOR CONTRIBUTIONS

Sissel Hegdahl Oversand: Study planning, data collection and analysis, and manuscript writing. Anne Cathrine Staff: Study planning, discussion of results, manuscript writing, and proofreading. Ingrid Volløyhaug: Study planning, discussion of results, and manuscript writing. Rune Svenningsen: Study planning, data collection and analysis, manuscript writing, and editing.

CONFLICT OF INTEREST STATEMENT

Rune Svenningsen: Has received speaker fees from Astellas. The rest of the authors declare no conflicts of interest.

ETHICS STATEMENT

Ethical approval was obtained by the Regional Committee for Medical and Health Research Ethics of South-Eastern Norway (2013/2093) on December 10, 2013, and reviewed by the Oslo University Hospital personal data officer. Written, informed consent, including the future 5-year follow-up, was obtained from all study participants at the initial inclusion. The study was registered on [ClinicalTrials.gov](https://clinicaltrials.gov) in 2014 with registry number NCT02246387.

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