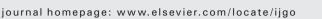
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# CLINICAL ARTICLE

# Vaginal support as determined by levator ani defect status 6 weeks after primary surgery for pelvic organ prolapse

Daniel M. Morgan <sup>a,\*</sup>, Kindra Larson <sup>b</sup>, Christina Lewicky-Gaupp <sup>c</sup>, Dee E. Fenner <sup>a</sup>, John O.L. DeLancey <sup>a</sup>

<sup>a</sup> Department of Obstetrics and Gynecology, Division of Gynecology, Pelvic Floor Research Group, University of Michigan Medical School, Ann Arbor, USA

<sup>b</sup> Department of Obstetrics and Gynecology, Eastern Virginia Medical School, Norfolk, USA

<sup>c</sup> Department of Obstetrics and Gynecology, Northwestern University, Chicago, USA

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#### ABSTRACT

*Objective:* To evaluate whether major levator ani muscle defects were associated with differences in postoperative vaginal support after primary surgery for pelvic organ prolapse (POP). *Methods:* A retrospective chart review of a subgroup of patients in the Organ Prolapse and Levator (OPAL) study. Of the 247 women recruited into OPAL, 107 underwent surgery for prolapse and were the cohort for the present analysis. Major levator ani defects were diagnosed when more than 50% of the pubovisceral muscle was missing on MRI. Postoperative vaginal support was assessed via POP-quantification system. Postoperative anatomic outcome was analyzed according to levator ani defect status, as determined by MRI. *Results:* Support of the anterior vaginal wall 2 cm above the hymen occurred among 62% of women with normal levator ani muscles/minor defects and 35% of those with major defects. Support of the anterior wall 1 cm above the hymen occurred among 32% women with normal muscles /minor defects and 59% of those with major defects. Levator ani defects were not associated with differences in postoperative apical/posterior vaginal support. *Conclusion:* Six weeks after primary surgery for prolapse, women with normal levator ani muscles/minor defects had better anterior vaginal support than those with major levator defects.

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# 1. Introduction

Approximately 200000 operations are performed each year for pelvic organ prolapse [1]. The most frequent site of operative failure is, by far, the anterior vaginal wall [2,3]. Being involved in 72% of recurrences [4], it is the "Achilles heel" of prolapse surgery. These facts highlight the need to develop our understanding of the anatomical factors underlying loss of anterior vaginal wall support.

The levator ani muscles are an important element of anterior vaginal wall structural support. Several studies have identified levator ani injury as an important factor in the pathophysiology of prolapse and anterior wall prolapse in particular [3,5–7]. The medial portions of the levator ani attach to the vaginal wall and endopelvic fascia to provide an elevating force for the anterior vaginal wall [8], and to close the genital hiatus [9,10]. Empirical evidence regarding the importance of levator ani function has been provided by a study in which women who demonstrated better pelvic floor muscle strength had a lower likelihood of needing another operation [11].

There are 2 ways in which levator injury might influence support. First, detachment of the anteriorly directed levator ani muscle fibers from the pubic bone seen with levator injury [12] might mean that

*E-mail address:* morgand@umich.edu (D.M. Morgan).

operations are not able to achieve as much anterior wall elevation at the time of surgery as compared with women with more normal muscles. Second, loss of levator support might result, over time, in a greater load sharing by connective tissue supports in the anterior wall.

The presence of major defects in the levator ani muscle may make it less likely that surgery for pelvic organ prolapse will result in optimal anterior vaginal wall position. Thus, the aim of the present study was to address whether operations in women with major levator damage can achieve as good elevation of the anterior vaginal wall as operations in women with normal muscles or only minor injuries.

## 2. Materials and methods

Between November 2, 2000, and November 24, 2008, 247 women with primary pelvic organ prolapse were recruited into the Organ Prolapse and Levator (OPAL) study, an institutional review boardapproved, case-control study with a primary aim of elucidating the role of levator ani muscle injury in the pathophysiology of pelvic organ prolapse [6]. The study was carried out at a single tertiary center: the University of Michigan, Ann Arbor, Michigan, USA. The present secondary analysis involved 107 participants from OPAL who had primary pelvic organ prolapse (i.e. no previous surgery for pelvic floor dysfunction) and who decided to have surgery for their condition.

The methods and findings of patients recruited to OPAL in the first 5 years of enrollment have been published [6]. The participants

<sup>\*</sup> Corresponding author at: 1500 East Medical Center Drive, Women's Hospital L4000, Ann Arbor MI 48109, USA. Tel.: +1 734 647 5866; fax: +1 734 647 9727.

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were almost exclusively recruited from female pelvic medicine and reconstructive surgery clinics at a tertiary medical center. Inclusion criteria for OPAL included descent of anterior, apical, or posterior support at least 1 cm below the hymen, willingness to undergo a pelvic examination and magnetic resonance imaging (MRI), ability to understand and complete questionnaires in English, and age at least 18 years. Women who had undergone hysterectomy were eligible if the surgery had been done at least 2 years before enrollment and the indication did not include pelvic floor dysfunction. Exclusion criteria included vaginal prolapse less than 1 cm beyond the hymenal ring, history of prolapse surgery, history of radiation therapy, inability to read or understand English, age younger than 18 years, and contraindications to pelvic floor testing or MRI. All women provided full informed consent.

Details of the protocol have previously been published [6]. In brief, a personal health questionnaire was the source of demographic and medical information. The pelvic organ prolapse-quantification system (POP-Q) was used to describe vaginal support [13]. Strength of levator ani contraction by palpation was graded as "good," "fair," "poor," or "absent." Vaginal closure force at rest and with maximum contraction was assessed with an instrumented vaginal speculum (US Patent: 6,468,232 B1). Augmentation of vaginal closure force was calculated as the mean difference between the measure at rest and the measure at maximum contraction in 3 trials. Urethral pressure profiles with an 8-French dual-tip microtransducer were performed. The maximum urethral closure pressure was calculated as the mean difference between the maximum urethral pressure and the resting bladder pressure in 3 trials. The participants' height and weight were also measured.

After completing the symptom questionnaire and examination, participants underwent a MRI scan. Axial, sagittal, and coronal 2-dimensional fast-spin proton density MRI scans (echo time, 15 ms; repetition time, 4000 ms) were obtained in the supine position. Initially scans were performed on a 1.5-Tesla Signa superconducting magnet (General Electric Medical Systems, Milwaukee, WI, USA). In the second phase of recruitment, a 3-Tesla Achieva System (Philips, Amsterdam, The Netherlands) was used. The slice thickness was 4 mm with a slice gap of 1 mm, yielding an image spacing of 5 mm. A  $160 \times 160$  mm field of view and an imaging matrix of  $256 \times 256$  were used.

Two examiners, blind to participant prolapse status, independently graded the MRI scans of the levator ani via a system previously described for evaluating birth-associated damage [14,15]. The left and right pubovisceral levator ani muscles were scored separately. Examples of different degrees of muscle defect and the scoring methods have been published [6,14,15]. A score of "0" was assigned if no damage was visible, "1" if less than half of the muscle was missing, "2" if more than half was missing, and "3" if the complete muscle bulk was lost. The scores for the left and right sides were added to give a total score ranging from 0 to 6. When the scores of the 2 examiners differed, the scans were reviewed jointly by both individuals to assign a final score. Because lesser degrees of injury are not associated with an increased occurrence of prolapse [6], in the present study women were classified as having a major defect when at least 50% of the muscle was missing.

Clinical care was not part of the OPAL study design. Surgeons knew when a patient was participating in OPAL. Because of the potential impact on clinical care, urodynamic data (e.g. post-void residual, bladder capacity, and presence or absence of stress incontinence), and gynecologic pathology (e.g. ovarian tumors or fibroids on MRI) were communicated to surgeons. Information regarding levator injury was neither available to surgeons nor used in surgical decision-making. The decision to proceed with surgery and the choice of surgical repair were based on symptoms and the findings of clinical and surgical examination.

For the present secondary analysis, chart review of the 247 women who completed OPAL was undertaken to identify individuals who underwent surgery at the University of Michigan for symptoms of pelvic floor dysfunction. The surgical procedures performed and postoperative POP-Q data from the 6-week postoperative visit were abstracted for 107 women. If the clinical documentation did not include POP-Q data (as was the case for 24 women), patients were not included in the study to avoid interpretation of what a clinician meant by terms such as "normal" or "good." Subjective postoperative symptoms regarding bladder and bowel function were not described or were elicited in a standardized fashion to facilitate analysis.

The 83 women in OPAL who underwent surgery for prolapse and had postoperative POP-Q data in their clinical charts were divided into 2 groups: those with a major levator ani defect, and those with normal levator ani muscles or minor defects. Student *t* test (for continuous variables) and  $\chi^2$  analysis (for categoric values) were used to compare demographics; personal health information from a questionnaire; "good" or "fair" levator ani contraction by palpation; vaginal closure force measures, preoperative severity of prolapse by POP-Q staging criteria using points Ba, C, or Bp; surgical procedures performed; and postoperative outcomes by POP-Q points Ba, C, and Bp. STATA version 9 (StataCorp, College Station, TX, USA) was used for all analyses. *P*<0.05 was considered to be statistically significant.

# 3. Results

In total, 247 women with primary pelvic organ prolapse were recruited into OPAL, and surgery was undertaken for 107 (43.3%) of the OPAL case cohort. Quantitative POP-Q data describing anterior, apical, and posterior compartment support approximately 6 weeks after surgery was available for 77.6% (83/107) women. Data regarding the 24 women who did not have POP-Q data are provided below, but the qualitative description of their outcomes was not sufficient for analysis.

The demographics and health information of women with sufficient postoperative anatomic data for inclusion in this analysis (n=83) were grouped according to those with and those without major levator ani defects (Table 1). Evaluation of MRI revealed major levator ani defects in 46 women (55.4%) and normal levator ani muscles or minor defects in 37 women (44.6%). Women who had 3 or more vaginal births were more likely to have normal levator ani muscles. The groups did not differ with respect to age, body mass index (BMI, calculated as weight in kilograms divided by the square of height in meters), history of hysterectomy, menopausal status, or mean follow-up time.

Preoperative findings with respect to vaginal support, levator ani function, and urodynamics are reported in Table 2. Preoperative prolapse severity according to anterior, apical, and posterior compartment POP-Q data was similar between those with and those without a major levator ani defect. The genital hiatus measures, vaginal closure force by an instrumented speculum, strength of pelvic

Table 1
Demographic data according to levator ani defect status.

Data	Normal levator ani or minor defect (n=37)	Major levator ani defect (n=46)	P value
Follow up, days	$43.5\pm12.0$	$42.3 \pm 12.0$	0.642
Age, years	$58.5 \pm 10.1$	$58.5 \pm 11.2$	0.995
BMI	$27.6 \pm 5.3$	$26.9 \pm 5.3$	0.529
Total parity			0.010
1	5.4	17.4	
2	27.0	47.8	
≥3	67.6	34.8	
History of forceps	57.1	52.6	0.204
Menopausal	70.6	71.1	0.992
History of hysterectomy	21.6	39.1	0.087
History of both ovaries removed	18.8	17.1	0.236

Abbreviation: BMI, body mass index (calculated as weight in kilograms divided by the square of height in meters).

<sup>a</sup> Values are given as mean  $\pm$  SD or percentage of participants.

#### Table 2

Preoperative vaginal support, urethral function, and pelvic floor function.

	Normal levator ani or minor defect (n=37)	Major levator ani defect (n=46)	P value
Anterior prolapse			0.520
Stage 0 and 1	1 (2.7)	0(0)	
Stage 2	11 (29.7)	13 (28.3)	
Stage 3 and 4	25 (67.6)	33 (71.7)	
Apical prolapse			0.396
Stage 0 and 1	20 (54.1)	18 (39.1)	
Stage 2	4 (10.8)	7 (15.2)	
Stage 3 and 4	13 (35.1)	21 (45.6)	
Posterior prolapse			0.776
Stage 0 and 1	14 (37.8)	14 (30.4)	
Stage 2	12 (32.4)	17 (37.0)	
Stage 3 and 4	11 (29.7)	15 (32.6)	
Point Ba	$3.3 \pm 3.2$	$2.9 \pm 2.4$	0.558
Point C	$-0.4 \pm 5.5$	$0.2 \pm 4.2$	0.543
Point Bp	$0.4 \pm 3.3$	$0.6 \pm 3.1$	0.721
Genital hiatus, resting	$5.2 \pm 1.6$	$5.3 \pm 1.4$	0.984
Genital hiatus, straining	$6.5 \pm 2.0$	$6.2 \pm 1.6$	0.455
Genital hiatus, Kegel	$4.7 \pm 1.7$	$4.8 \pm 1.4$	0.830
Maximum urethral closure pressure	$61.9 \pm 38.6$	$53.0 \pm 21.1$	0.192
LA "strength"			0.352
Good/fair, %	57.1	46.7	
Poor/absent, %	42.9	53.3	
Speculum (vaginal closure force)			
Resting	$4.0 \pm 1.3$	$4.0\pm1.4$	0.971
Maximum	$1.6 \pm 1.1$	$1.3\pm1.0$	0.178

<sup>a</sup> Values are given as mean  $\pm$  SD or number (percentage) unless stated otherwise.

floor contraction by palpation, and maximum urethral closure pressure also did not differ between the groups.

Vaginal surgery was performed in 79 (95.1%) women. Mesh was used only in 4 women in whom a sacrocolpopexy was performed. The presence of a major levator ani defect was not associated with choice of surgical procedure for apical vaginal suspension (Table 3). A posterior colporrhaphy was performed more often for women with defects as compared with those with normal muscles or minor defects. The percentage of anterior colporrhaphy and mid-urethral sling surgeries did not differ between the groups.

Postoperative support in the anterior, apical, and posterior vaginal compartments is analyzed according to levator ani defect status in Fig. 1. The main difference observed in the anterior compartment was that women with major levator ani defects were less likely than women with minor defects or normal muscles to have support at least 2 cm above the hymen (P=0.042). Anterior vaginal support at the level of the hymen did not differ between the groups. Apical and

#### Table 3

Surgical procedures performed.

Procedure	Normal levator ani or minor defect (n=37)	Major levator ani defect (n=46)	P value
Apical prolapse procedure <sup>a</sup>			0.451
Vaginal	32 (86.5)	42 (91.3)	
Abdominal	3 (8.1)	1 (2.2)	
No apical suspension required	2 (5.4)	3 (6.5)	
Anterior colporrhaphy	28 (75.7)	40 (87.0)	0.184
Mid-urethral sling (i.e. TVT)	9 (24.3)	6 (13.0)	0.184
Kelly placation	16 (43.3)	21 (45.6)	0.826
Posterior colporrhaphy	27 (73.0)	43 (93.5)	0.011

Abbreviation: TVT, transvaginal tape.

<sup>a</sup> "Vaginal" includes vaginal hysterectomy, uterosacral ligament suspension and/or sacrospinous ligament suspension. "Abdominal" includes sacrocolpopexy with or without total abdominal hysterectomy. Among participants in this group in whom neither vaginal nor abdominal repair was required, 3 patients had anterior and posterior colporrhaphy and a mid-urethral sling, 1 patient had only an anterior colporrhaphy, and 1 patient had an abdominal paravaginal repair and posterior colporrhaphy.

#### Postoperative support at 6 weeks

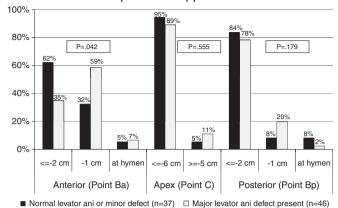


Fig. 1. Support of the anterior, apical, and posterior vaginal compartments 6 weeks after surgery according to levator ani muscle defect status.

posterior vaginal support did not differ significantly as a function of levator ani defect status (P = 0.555 and P = 0.179, respectively).

Twenty-four women were not included in the analysis because their documentation was inadequate with respect to vaginal support. "Normal" support without quantitative information about anterior, apical, and posterior vaginal support was reported for 17 (70.8%) of these participants. Two women (8.3%) were seen but did not have any documented description of vaginal support. Five women (20.8%) did not return for scheduled follow up.

A comparison of those who were "included" (i.e. they had POP-Q data at postoperative follow up; n = 83) and "not included" (n = 24) was performed. Women who were included were older than those who were not included (58 years versus 53 years, P = 0.035), but did not differ in parity; BMI; history of hysterectomy; distribution of preoperative prolapse severity by staging in the anterior, apical, or posterior compartments; or likelihood that they had a major levator ani defect. They were more likely to have had a posterior colporrhaphy (84.3% versus 62.5%, P = 0.02) and a sacrospinous ligament suspension (44.6% versus 20.8%, P = 0.036), but showed no differences among the other surgical procedures—anterior colporrhaphy, hysterectomy, mid-urethral sling, or uterosacral ligament suspension.

# 4. Discussion

Six weeks after surgery, anterior vaginal wall support is not as optimal in women with major pubovisceral levator ani defects as in women with normal muscles or minor defects. This anatomic difference may reflect the extent to which vaginal support can be restored. We recognize that both groups of women in the present study had relatively normal support after surgery (i.e. the vast majority of both groups had support above the hymen) and that the follow-up period of 6 weeks is not sufficient to determine the clinical significance, if any, of this difference. However, it seems reasonable to propose that major levator ani defects may account, in part, for the high and unexplained rates of recurrent anterior vaginal wall prolapse. The effect of levator ani defects on the durability of repairs remains unknown, but the present data provide preliminary evidence that clinical trials evaluating recurrence rates with longer-term follow up are warranted.

It seems logical that major damage to the medial portion of the levator ani muscle would make it more difficult to achieve excellent support in the anterior vaginal wall because this portion of the levator ani muscle attaches the anterior vaginal wall to the pubic bone. Both the mechanism by which a levator defect compromises anterior vaginal support and operative success are probably related to this fact, as is the muscles' ability to close the genital hiatus. Among young, nulliparous women without any history of pelvic floor dysfunction, the width of the levator hiatus, as determined by ultrasound, affects pelvic organ mobility [16]. This effect is more pronounced among individuals with symptomatic prolapse. A biomechanical model based on the use of dynamic MRI scans during Valsalva maneuvers has shown that the genital hiatus opens when there is an impairment in the pubovisceral muscle, and that the change in the size of the anterior prolapse is dependent on the degree of levator ani impairment [9]. In addition, 2 clinical studies have found that a wider genital hiatus is associated with surgical failure of the anterior wall [11,17].

The present finding of a lower anterior vaginal wall among women with levator defects is consistent with published data. The most common site of primary and recurrent failure of support is the anterior compartment [3,4,18]. Levator ani defects also seem to be more strongly associated with failure of anterior than failure of posterior support [6,19]. The present finding that women with levator defects are more likely to undergo a posterior colporrhaphy is likely to be a reflection of the effect that the levator ani defect has on the genital hiatus.

The present study has strengths and limitations. The study population consisted of patients whose operations were performed by surgeons with extensive experience in treating prolapse, and whose vaginal support and levator ani muscles were well-characterized preoperatively. The surgical approach used was predominantly vaginal. Some patients were excluded from the study owing to incomplete data because postoperative follow up was not planned as part of the original OPAL project. This partially accounts for why a group of patients were noted to have "normal" support but did not have quantitative information regarding vaginal support. The utility of MRI in evaluation and management of women with prolapse remains to be determined, and recommendations cannot be made on the basis of the data of the present analysis. In the future, evaluation and treatment in the context of clinical research protocols, especially in combination with imaging studies, may address these limitations and promote a better understanding of how levator ani defects affect surgical outcome.

The study of how levator ani injury affects the pathophysiology and treatment of pelvic organ prolapse is in its infancy. Prolapse is a condition that often recurs after surgical management. Characterization of levator ani defect status with imaging studies and long-term follow up has the potential to explain why recurrence rates might be high among subgroups of patients. How the small but detectable difference in vaginal support 6 weeks after surgery is related to long-term follow up warrants further study.

# **Conflict of interest**

The authors have no conflicts of interest.

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