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Does it matter whether levator avulsion is diagnosed pre- or postoperatively?

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KEYWORDS: avulsion; pelvic floor; prolapse; recurrence; translabial ultrasound

ABSTRACT

Objective *Levator ani muscle avulsion is found in 15–30% of parturients and is associated with recurrence of pelvic organ prolapse (POP) following surgery, although most published evidence on recurrence relates to postoperative diagnosis. We performed a study to determine whether a diagnosis of avulsion after pelvic floor surgery can be used as a proxy for preoperative diagnosis.*

Methods *This was a retrospective study of 207 patients who were seen before and after surgery for POP between February 2007 and May 2013. All assessments included a three/four-dimensional transperineal tomographic ultrasound examination. Volume data were stored and analyzed at a later date by an operator who was blinded against all clinical data. The primary outcome measure was agreement between preoperative and postoperative diagnoses of avulsion, as evaluated by Cohen's kappa. Secondary outcome measures were the associations of pre- and postoperative diagnoses of levator avulsion with prolapse recurrence, defined as International Continence Society POP-Q Stage ≥ 2 in any compartment.*

Results *Mean follow-up after surgery was 1.3 (range, 0.3–5.5) years. Levator avulsion was found preoperatively in 111 (53.6%) patients and postoperatively in 109 (52.7%). The kappa value for the association between pre- and postoperative avulsion was 0.864 (95% CI, 0.796–0.933), signifying high agreement. The odds ratio of prolapse recurrence in women with a preoperative diagnosis of avulsion was 2.5 (95% CI, 1.3–4.5) and in those with a postoperative diagnosis it was 2.3 (95% CI, 1.3–4.2).*

Conclusions *The diagnosis of levator avulsion by tomographic pelvic floor ultrasound is equally valid before and after pelvic reconstructive surgery for POP, and both diagnoses show excellent agreement. This implies that a postoperative diagnosis of avulsion can be used as a proxy for preoperative diagnosis. Hence, avulsion can be identified postoperatively and used for subgroup analysis in prospective surgical intervention trials to define high-risk patients. Copyright © 2015 ISUOG. Published by John Wiley & Sons Ltd.*

INTRODUCTION

Levator ani muscle avulsion seems to occur in 15–30% of women after a first vaginal birth[1,2], with the main risk factors being a higher maternal age[3], use of forceps[4–6], a long second stage of labor[7], occipitoposterior position[8] and a larger baby[9]. Levator avulsion has substantial effects on the static and dynamic properties of the levator hiatus, an opening that constitutes the largest potential hernial portal in the human body. In the case of avulsion, the hiatus is enlarged[10] and may show marked asymmetry[11], and contractile properties are impaired[12,13].

Avulsion seems to be associated with the recurrence of pelvic organ prolapse (POP) following surgery[14–19]. It seems probable that avulsion is the single most powerful predictor of prolapse recurrence and is potentially of great clinical utility, especially as it seems that its effects may be mitigated by anterior compartment anchored mesh[20].

Several studies have used avulsion diagnosed years after the index surgery as a proxy for preoperative diagnosis. It is conceivable that surgical interventions for prolapse, especially when including transobturator mesh placement, may alter the sonographic appearance to such a degree as to result in false-positive or false-negative diagnoses. The authors of a recent study that showed a non-significantly increased risk of recurrence of POP in women with

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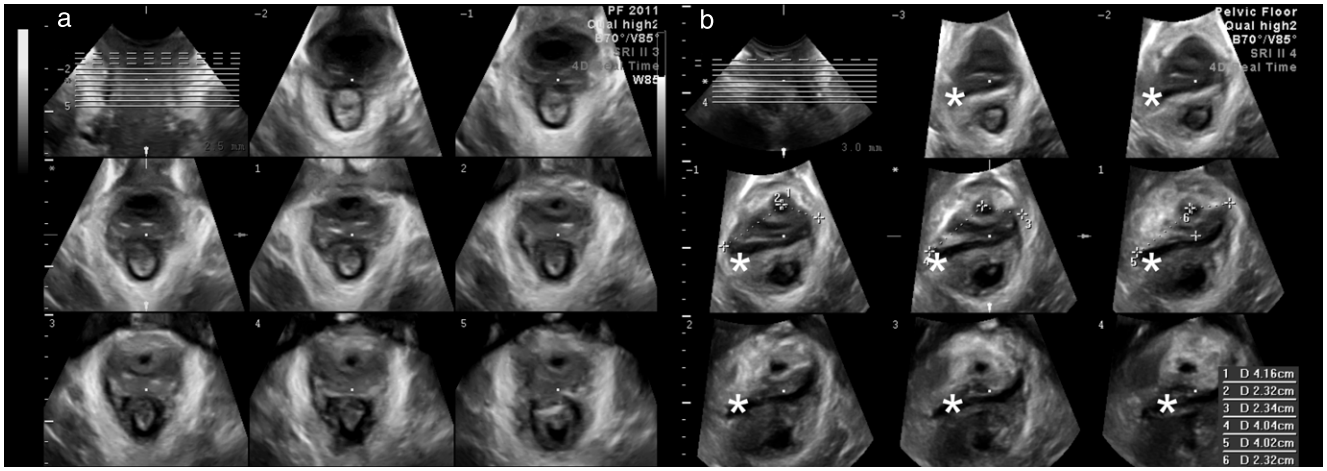

Figure 1 Normal pelvic floor (a) and unilateral right-sided levator avulsion (✱) (b) identified on tomographic translabial three/four-dimensional ultrasound. Measurements of distances in (b) represent the levator–urethra gap[23].

avulsion suggested that a postoperative diagnosis of avulsion may be invalid. Hence, it seems timely to compare pre- and postoperative diagnoses of avulsion for their relative predictive ability. For this purpose we performed a study utilizing saved volume datasets of women seen before and after prolapse surgery at a single tertiary unit, in order to determine whether diagnosis of avulsion after pelvic floor surgery is equally as valid as is a preoperative diagnosis.

PATIENTS AND METHODS

This was a retrospective study involving patients seen at a tertiary urogynecological unit between February 2007 and May 2013 who had undergone prolapse surgery and had been seen for follow-up at least once ≥ 3 months after their operation. The women had presented originally with symptoms of prolapse and a variety of other symptoms of pelvic floor dysfunction. All women underwent a standardized, non-validated in-house interview administered by a senior clinician, clinical prolapse assessment (International Continence Society pelvic organ prolapse quantification system (ICS POP-Q)) and a three/four-dimensional (3D/4D) transperineal ultrasound examination (GE Voluson 730 Expert and Voluson I systems with RAB 8–4-MHz transducers, GE Medical Systems, Zipf, Austria), as described previously[21]. After failed attempts at conservative management the women underwent prolapse surgery. Patients were seen at 3, 6, 12 and 24 months after the surgery as part of a surgical audit which included a 3D/4D ultrasound examination. At least 3 months after the clinical audit appointments, one author (S.S.A.J.) performed offline analysis of the stored volume datasets, using proprietary software (4DView 10.0, GE Medical Systems), for the diagnosis of levator avulsion. Avulsion was diagnosed using tomographic ultrasound as described previously (Figure 1)[22], incorporating measurement of the levator–urethra gap in doubtful cases[23]. For this postprocessing analysis, we used volumes obtained on maximum pelvic floor muscle contraction or volumes obtained at rest in those unable to perform the contraction[24]. A test–retest series of 20 ultrasound volume datasets was undertaken by S.S.A.J. prior to commencement of the study, with a kappa of 0.69 (95% CI, 0.58–0.81) for single-slice assessment and a kappa of 0.91 (95% CI, 0.73–1.09) for the diagnosis of avulsion after 3 days of training. The operator was blinded to the order of the assessments and, for the second assessment, to the diagnosis obtained from the first assessment.

The primary outcome measure was agreement between preoperative and postoperative diagnoses of avulsion, as defined by Cohen's kappa. Secondary outcome measures were the associations of pre- and postoperative diagnoses of avulsion with prolapse recurrence, as defined by odds ratios (ORs). The study was approved by the Nepean Blue Mountains Local Health District Human Research Ethics Committee (NBMLHD HREC reference no. 09–03). Statistical analysis was carried out using SPSS v12 (SPSS Inc., Chicago, IL, USA) and Minitab v 10 (Minitab Inc., State College, PA, USA). $P < 0.05$ was considered to be statistically significant.

RESULTS

Two hundred and forty patients who had been assessed between February 2007 and May 2013 met the inclusion criteria of the study. For postoperative appointments, the minimum time between surgery and follow-up was 3 months. In 32 cases, ultrasound volumes were missing, and one patient was lost to follow-up, so the final analysis was performed on the remaining 207 patients. Table 1 provides the demographic characteristics of these 207 women. Operations performed for POP included either one or a combination of the following: vaginal hysterectomy; anterior native tissue repair without mesh; Perigee® anterior mesh; defect-specific posterior repair; sacrospinous fixation; Anterior Elevate® mesh; Uphold® mesh. Table 2 shows data on the prolapse procedures

Table 1 Demographic characteristics of 207 women with levator avulsion diagnosed before or after surgery for pelvic organ prolapse

Characteristic	*Value*
Age (years)	59 ± 11.8
Body mass index (kg/m^2)	29.7 ± 5.8
Vaginal parity	3 ± 1.4
Vaginally parous	205 (99.0)
One or more forceps delivery	56 (27.1)
Symptoms of prolapse	174 (84.1)
Stress urinary incontinence	146 (70.5)
Urge urinary incontinence	140 (67.6)
ICS POP-Q Stage ≥ 2	207 (100.0)
Stage ≥ 2 in anterior compartment	155 (74.9)
Stage ≥ 2 in central compartment	73 (35.3)
Stage ≥ 2 in posterior compartment	156 (75.4)

Data are given as mean ± SD or *n* (%). ICS POP-Q, International Continence Society pelvic organ prolapse quantification system.

Table 2 Operative procedures for pelvic organ prolapse performed in 207 women with levator avulsion diagnosed before or after surgery

Procedure	n *(%)*
Anterior compartment	
Anterior native tissue repair	95 (45.9)
Perigee® anterior mesh	52 (25.1)
Anterior Elevate® mesh	5 (2.4)
Uphold® mesh	4 (1.9)
Central compartment	
Vaginal hysterectomy	56 (27.1)
Hysteropexy	2 (1.0)
Sacrospinous fixation	94 (45.4)
Posterior compartment	
Defect specific posterior repair	149 (72.0)
Levatorplasty	9 (4.3)

performed in the study cohort. In addition, 107 women had a Monarc® suburethral sling, and seven a tension-free vaginal tape (TVT®). The mean interval between the index surgery and follow-up appointment was 1.3 (range, 0.3–5.5) years. Postoperatively, 82% of patients were satisfied with the outcome of their prolapse surgery and 88% felt that their prolapse symptoms were improved or cured.

On postprocessing analysis of the tomographic ultrasound images obtained before and after surgery, full levator avulsion was diagnosed preoperatively in 111 (53.6%) patients and postoperatively in 109 (52.7%) patients, with the operator blinded to the results of both assessments. Kappa for the association between preoperative and postoperative diagnoses of avulsion was 0.864 (95% CI, 0.796–0.933). The kappa value for single-slice agreement was 0.646. In order to validate both pre- and postoperative diagnoses, we ascertained the association with prolapse recurrence. The OR for prolapse recurrence in women with avulsion was 2.5 (95% CI, 1.3–4.5) for those with a preoperative diagnosis and 2.3 (95% CI, 1.3–4.2) for those with a postoperative diagnosis.

DISCUSSION

The use of imaging in the investigation of pelvic floor disorders has increased substantially over the last 20 years. One of the consequences of this development is an increasing interest in the state of the pelvic floor, in particular the puborectalis muscle, which constitutes the largest potential hernial portal in the human body, the 'levator hiatus'. It is becoming generally accepted that childbirth can cause considerable damage to this muscle, presenting as over-distension and as frank muscle tears that affect the attachment of the puborectalis to the inferior pubic ramus, usually referred to as 'avulsion'[1]. This damage is probably the single most important etiological factor in the pathogenesis of female POP, especially in cases of cystocele and uterine prolapse.

Since 2010, several groups have shown that such trauma is associated with prolapse recurrence after pelvic reconstructive surgery[14–19]. All but one study[25] have shown a significant association between avulsion and recurrence, but definitions of avulsion and recurrence vary, as do the imaging methodologies used. One explanation for the differing results is that some studies used preoperative imaging, and others considered postoperative imaging a valid proxy for preoperative imaging. This concept seems entirely logical from an anatomical point of view, as routine surgical prolapse repair never approaches closer than 2–3 cm to the site of avulsion. However, we felt that it was necessary to compare the predictive value of pre- and postoperative imaging in order to validate the use of postoperative diagnoses. This is important for subgroup analysis of surgical trials and will probably be of particular value for major investigative efforts such as the PROSPECT Trial (PROlapse Surgery: Pragmatic Evaluation and randomised Controlled Trial), a large prospective trial on prolapse surgery outcomes that did not include the preoperative diagnosis of levator avulsion. Our results suggest that diagnosis of avulsion at a later date is feasible and valid.

Our study shows that pelvic floor surgery does not affect the validity of a diagnosis of avulsion using tomographic ultrasound imaging. There is excellent agreement between the pre- and postoperative diagnoses, an agreement that is within the 95% CIs for interobserver repeatability. Both diagnoses appear equally valid, given that their associations with prolapse recurrence after pelvic reconstructive surgery were of virtually equal strength. This implies that previous studies that used postoperative assessment to determine the association between avulsion and prolapse recurrence are as valid as those that used preoperative diagnoses of avulsion.

There are several limitations of this study that should be mentioned. The need for the availability of both pre- and postoperative assessments limited the number of patients we were able to include in this retrospective study; a prospective design would have been better. The dataset includes a large number of different procedures, and technical changes over time cannot be overlooked. In

addition, most procedures were carried out by junior staff in a teaching situation, and the range of follow-up was wide (0.3–5.5 years). Mesh use may partly compensate for avulsion, especially in the anterior compartment[19], which could have resulted in reduced ORs and reduced power. However, most of these potential confounders affect both pre- and postoperative diagnoses of avulsion and therefore should not affect the validity of our conclusions.

It should be mentioned that a recent study using cadaver imaging and dissection has claimed that the term 'avulsion' is misrepresentative and should not be used to describe this imaging finding[26]. We disagree, maintaining that, in our own experience of ultrasound imaging of formalin-fixed cadavers, it is virtually impossible to identify avulsion owing to tissue dehydration, autolysis, altered tissue biomechanics and distortional effects (e.g. perimortem stool impaction)[27]. Therefore, to compare results obtained in two fundamentally different types of situation is likely to mislead rather than inform.

In conclusion, diagnoses of levator avulsion by tomographic pelvic floor ultrasound before and after pelvic reconstructive surgery are both valid, and both diagnoses show excellent agreement. This implies that a postoperative diagnosis of avulsion can be used as a proxy for preoperative avulsion. Hence, avulsion can be identified postoperatively and used for subgroup analysis in prospective surgical intervention trials to define a high-risk group of patients. This may become important in the near future as the utility of existing prospective surgical trials may be enhanced substantially if subgroup analysis of women with avulsion were to become possible. To date, there has been only one prospective surgical trial that used avulsion as an entry criterion[28], showing a very high effect size for the use of mesh on prolapse recurrence in women with avulsion. This implies that any assessment of the effect of mesh use on clinical outcomes in prolapse surgery would benefit from the identification of women with avulsion, either prospectively as a means of selecting women at high risk of recurrence, or retrospectively for subgroup analysis. Our study shows that such retrospective identification of high-risk women is valid and likely to add substantial value to existing and future intervention trials in pelvic reconstructive surgery.

DISCLOSURE

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