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ORIGINAL ARTICLE

Levator ani muscle injuries associated with vaginal vacuum assisted delivery determined by 3/4D transperineal ultrasound

J. A. Garcia-Mejido[1], L. Gutierrez[1], A. Fernandez-Palacín[2], A. Aquise[1], and J. A. Sainz[1,3]

[1]Department of Obstetrics and Gynecology, Valme University Hospital, Seville, Spain, [2]Biostatistics Unit, Department of Preventive Medicine and Public Health, University of Seville, Seville, Spain, and [3]Department of Obstetrics and Gynecology, University of Seville, Seville, Spain

Abstract

Objectives: To determine the rate of pelvic floor trauma, levator ani muscle (LAM) avulsion as well as the mean difference in levator hiatus area, after normal vaginal deliveries (NVD) and vacuum assisted deliveries (VD), assessed with three-dimensional transperineal ultrasound (3D-TpUS).

Materials and methods: Prospective observational study with 151 nulliparous women with NVD or VD at $\geq$37 weeks between 9-2012 and 6-2013. 3D-TpUS was performed six months after every patient's delivery, during which LAM, anteroposterior diameter, transverse diameter and levator hiatus area were assessed.

Results: A total of 146 nulliparous were studied, comprising 73 NVD and 73 VD. No differences in obstetric, intrapartum or neonatal characteristics were observed between study groups, with the following exceptions: maternal age (28.1 ± 5.4 versus 30.4 ± 5.5; $p = 0.008$, OR = 1.1) and episiotomy rate (35.6% versus 97.3%; $p = 0.011$, OR = 4.3). LAM avulsion rate was 9.6% in NVD versus 34.2% in VD ($p = 0.001$, OR 3.99), while levator hiatus area at rest was 16.5 ± 3.2 versus 18.2 ± 3.9 ($p = 0.016$).

Conclusions: Vacuum assisted deliveries present a higher rate of LAM avulsion, as well as a greater increase in levator hiatal area than in NVD.

Keywords

Pelvic floor, levator ani muscle, vacuum, transperineal ultrasound

History

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Introduction

Levator ani muscle (LAM) avulsion is the main pelvic floor lesion associated with vaginal delivery. Current literature emphasizes the role of passing of the fetal head through the maternal perineum as the critical event for LAM avulsion injury [1–3]. In ultrasound evaluation, 'avulsion' is defined as the discontinuity of hyperechogenic puborectalis muscle fibers at their pubic insertion [4], and is present in 13–36% of vaginal deliveries [5]. This kind of injury is significant, as it can result in pelvic organ prolapse [6] involving mainly anterior and middle compartments. After a vaginal delivery, a woman is 2.3–4.0 times more likely to suffer pelvic organ prolapse [7] throughout her life than a nulliparous woman. After a second vaginal delivery, this outcome is 8.4 [7] times more likely.

Multiple risk factors have been associated with LAM injuries during labor: maternal age, prolonged second stage of labor and fetal head circumference [5]. The major risk factor for LAM avulsion is the use of forceps to complete fetal extraction [8], associated with a prevalence of 35–64% [4,9,10] and a RR of 3.4 for this kind of injury [7]. However, there are currently no conclusive studies to determine the significance of the use of vacuum in LAM injuries.

To date, only a few studies, all of them using only a small number of vacuum assisted deliveries (VD), have evaluated LAM avulsion rate [9,11–19]. In this respect, greater work is needed to determine the possible difference in LAM avulsion risk between normal vaginal deliveries (NVD) and VD ones.

Our main target is therefore to determine LAM avulsion rate in VD, comparing it to NVD. As secondary goals, we aim to evaluate the difference in levator hiatus area among our study groups, as well as analyze the impact of obstetric and intrapartum risk factors which have previously been described to be associated with LAM injuries.

Materials and method

A prospective observational study was carried out, with 161 nulliparous women who were recruited for an initial evaluation from our maternity unit, between September 2012 and June 2013. The study was approved by Andalucia's Board of Biomedicine Ethics Committee, with code 3004/2012. During their hospital stay and within the first day after delivery, those women who met inclusion criteria were invited to participate in the study, being consecutively classified according to study group (NVD or VD) until the number of patients needed per study group was reached (72 per study group).

Address for correspondence: José Antonio García Mejido and José Antonio Sainz Bueno, MD, Department of Obstetrics and Gynecology, Valme University Hospital, Seville, Spain. Tel: +34 630132948. E-mail: jagmejido@hotmail.com; joseantoniosainz@hotmail.es

All nulliparous, at term gestation (37–42 weeks), without prior pelvic floor corrective surgery, in active stage of labor, with fetus in cephalic presentation and written informed consent acceptance were considered suitable for the study and therefore included therein. Pregnancies with severe maternal or fetal pathology were excluded.

Deliveries were assisted by maternity unit staff, with a minimum of five years' experience in obstetric practice. In terms of analgesia, epidural analgesia was used for intrapartum analgesia.

Deliveries completed using vacuum instrumentation were performed by obstetricians with a minimum of five years' experience in obstetric practice. In all cases, a metal vacuum (Bird's cup 50 mm, 80 kPa) was used to perform fetal extraction. A suction cup was carefully placed over the flexion point, avoiding caput succedaneum, and rapid negative pressure was applied (over 2 min, until 0.6–0.8 kg/cm^2). Vacuum traction was carried out during contraction, along with maternal push, at a rate of 2–3 vacuum tractions per contraction, and without associating Kristeller maneuver. The procedure was abandoned if, after three cup slides or 15 min, fetal extraction had not been successful. Selective episiotomy was carried out in VD following Valme's University Hospital clinical practice guideline for instrumental deliveries.

Obstetric parameters evaluated were: gestational age, labor induction, epidural analgesia, type of instrumentation, duration of second stage of labor, episiotomy and perineal tears. Fetal parameters studied after birth were: fetal sex, weight, head circumference, umbilical artery pH at birth, Apgar test result (at 1 and 5 min), presence of neonatal morbidity (cephalohaematoma, brachial plexus palsy, etc.), admission to neonatology department and neonatal mortality.

The sonographic evaluation was performed six months after delivery and was carried out by a single examiner, with more than five years experience exclusively in obstetric ultrasound, with specific training in 3/4D imaging and blinded to obstetric data relating to the delivery. A 500® Toshiba Aplio (Toshiba Medical Systems Corp., Tokyo, Japan) ultrasound with an abdominal probe PVT-675MV 3D was used for the assessments. Images were acquired with patients in dorsal lithotomy position, placed on the gynecological examination table and under empty bladder conditions [20,21]. The transducer was carefully placed on each patient's perineum, applying the minimal possible pressure. Three volume measurements were taken for each patient: at rest, with Valsalva maneuver and with maximum contraction. Posteriorly, offline analysis of ultrasound volumes was carried out. Analysis of ultrasound volumes was performed offline.

In the multi-view ultrasound images, complete avulsion was defined as an abnormal insertion of LAM in the lower pubic branch identified in all three central slices, i.e. in the plane of minimal hiatal dimensions (PMD) and the 2.5 and 5.0 mm slices cranial to this one (Figure 1).

Levator hiatus measurements, transverse diameters, anteroposterior diameters and area were also determined in the same plane (PMD), as already described in previous studies [6].

In order to compare the proportion of LAM avulsions in NVD and DV, 72 women from each group were required, assuming an α error of 5%, a power of 80%, a percentage of expected LAM avulsion in NVD of 10% and an expected increase in LAM affection of 20% in VD compared to NVD.

Quantitative variables are expressed in means and standard deviations and assessed by Student's *t*-test or Mann–Whitney *U* test (for non-parametric), depending on the normality of data (Shapiro–Wilk test). Qualitative variables are expressed in percentages and assessed by Chi-square test and Monte Carlo methods (for non-asymptotic). $p < (0).05$ was considered statistically significant. We developed a binary logistic regression model in order to study the influence of obstetric and intrapartum variables on the appearance of avulsions. This model was constructed using a non-automatized method to directly introduce variables. For each variable included in the model, the methods calculate the odds ratio with 95% CI. Univariable logistic regression was used for the calculation of crude odds ratios (cOR) for delivery modes. Multivariable logistic regression analysis was used to correct for possible confounding factors and calculation of adjusted odds ratios (aOR) with 95% CI. ANCOVA was used to test for significant differences between delivery modes for hiatal areas at rest, on maximum contraction and on Valsalva. Both univariable ANCOVA for unadjusted mean difference (MD) with 95% CI among delivery groups, as well as multivariable ANCOVA corrected for possible confounding factors for adjusted MD with 95% CI are reported. Statistical analysis was performed using the IBM SPSS Statistics 23 software (SPSS Inc., Chicago, IL).

Results

One hundred and fifty-one pregnant women in labor with no previous history of vaginal delivery were recruited. Five cases were considered to be lost: in three cases ultrasound evaluation was not performed due to a failure in the researcher's monitoring of the patient; two cases were disregarded owing to poor quality image capture detected while processing volumes offline.

We evaluated 146 patients, comprising 73 cases of NVD and 73 cases of VD. Table 1 presents general obstetric characteristics. We evaluated the effect of obstetric variables on LAM injury rate using two logistic regression models. The first model included the following variables: birth weight, maternal age, epidural period and episiotomy rate. In this model, birth weight and epidural period did not prove to be statistically significant. The final probability model of LAM injury $= 1/1{+}e^{(-(-5.889\,+\,0.116\text{ maternal age}\,+\,1.465\text{ episiotomy}))}$ only included: maternal age ($p = 0.008$, OR 1.1, 95% CI, 1.031–1.224) and episiotomy rate ($p = 0.011$, OR = 4.3, 95% CI, 1.396–13.418) as these were the elements identified as predisposing factors for LAM injury.

Within the NVD with episiotomy group, LAM injury was present in 11.5% (3/26) versus 8.5% (4/47) ($p = 0.69$) detected in the NVD without episiotomy group.

Table 2 presents data concerning the types of LAM and pelvic floor injury associated with each type of delivery. The VD group demonstrated an avulsion rate of 34.2% versus the 9.6% identified in the NVD group ($p = 0.001$) (OR 3.99).

Table 3 shows general data relating to ultrasound measurements of the levator hiatus from the PMD. The mean area of the hiatus at rest in patients with VD was 18.21 cm^2,

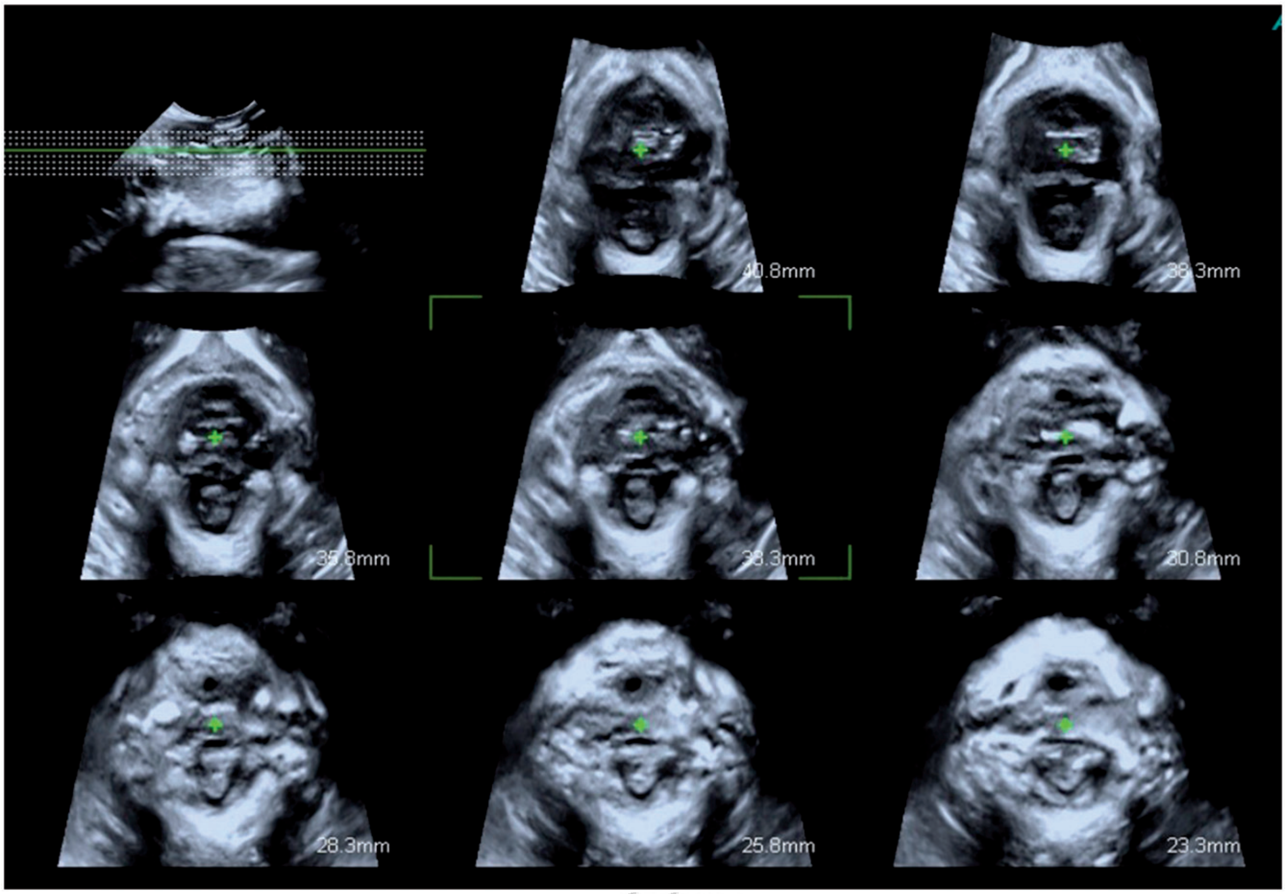

Figure 1. Multiview display of bilateral complete avulsion of levator ani muscle.

Table 1. General obstetric and intrapartum characteristics of the 146 patients studied.

	Mean (±DT) o %		
	Normal (73)	Vacuum (73)	*p*
Mean maternal age	28.10 (±5.47)	30.42 (±5.53)	0.011
Gestational age	39.18 (±1.13)	39.56 (±1.21)	NS
BMI	23.52 (±3.78)	24.46 (±3.15)	NS
Induced labor	13.7	26.0	NS
Epidural anaesthesia	84.9	98.6	0.005
Period of epidural anaesthesia in minutes	352.56 (±161.10)	416.46 (±234.59)	NS
Second stage duration in minutes	95.68 (±65.38)	115.78 (±78.98)	NS
Cephalic circumference (cm)	34.37 (±1.33)	34.97 (±2.36)	NS
Episiotomy	35.6	97.3	<0.0005
Perineal tears	53.4	32.9	0.019
High degree perineal tears	5.5	11	NS
Fetal weight at birth (g)	3248.63 (±363.84)	3339.04 (±403.73)	NS
Sex of newborn (females)	29(39.7%)	31(42.4%)	NS
APGAR 1 min	8.3 ± 1.0	8.8 ± 1.1	NS
APGAR 5 min	9.8 ± 0.4	9.8 ± 0.4	NS
Umbilical cord artery pH	7.25 ± 0.9	7.23 ± 0.9	NS
Perinatal mortality–morbility	0 (0%)	0 (0%)	NS
Control in the neonatology unit	0 (0%)	0 (0%)	NS

Not statistically significant values (NS).

Table 2. Type of levator ani muscle and pelvic floor injury in relation to the type of delivery.

	Normal (73)	Vacuum (73)	Crude odds ratio (IC 95%)	Adjusted odds ratio (IC 95%)
Avulsion presence	7 (9.6%)	25 (34.2%)	4.91 (1.96–12.28) $p=0.001$	3.99 (1.53–10.42) $p=0.005$
Type of avulsion attending to laterality				
Right levator ani muscle avulsion	7 (9.6%)	23 (31.5%)	4.37 (1.72–10.91) $p=0.003$	3.65 (1.39–9.61) $p=0.009$
Left levator ani muscle avulsion	4 (5.5%)	15 (20.6%)	4.46 (1.40–14.19) $p=0.012$	3.56 (1.08–11.73) $p=0.037$
Type of pelvic floor injury				
Unilateral	3 (4.1%)	12 (16.4%)	4.59 (1.24–17.03) $p=0.004$	3.60(0.91–14.21) $p=0.068$
Bilateral	4 (5.5%)	13 (17.8%)	3.74 (1.16–12.08) $p=0.003$	3.14 (0.93–10.55) $p=0.065$

Values in parentheses are 95% CIs. Crude odds ratio (cOR) calculated from univariable logistic regression analysis and adjusted odds ratio (aOR) from multivariable logistic regression. aOR were adjusted for age, body mass index and birth weight of largest infant.

Table 3. General levator hiatus ultrasound measurements.

	Mean (±DT)			
	Normal (73)	Vacuum (73)	uMD	aMD
Antero-posterior levator hiatus diameter (mm)				
Rest	62.33(±7.30)	67.01(±7.48)	4.68 (2.26–7.10) $p=0.001$	4.34 (1.82–6.86) $p=0.001$
Valsalva	65.87(±8.66)	69.92(±7.70)	4.06 (1.37–6.73) $p=0.003$	2.93 (0.21–5.64) $p=0.035$
Maximum contraction	59.12(±7.18)	64.03(±8.38)	4.91 (2.36–7.46) $p=0.001$	4.47 (1.84–7.11) $p=0.001$
Transverse levator hiatus diameter (mm)				
Rest	39.69 (±6.71)	41.94 (±9.88)	2.25 (−0.52 to 5.01) $p=0.111$	1.46 (−1.37 to 4.30) $p=0.310$
Valsalva	42.35 (±8.02)	44.14 (±9.74)	1.79 (−1.13 to 4.71) $p=0.228$	0.84 (−2.16 to 3.83) $p=0.581$
Maximum contraction	39.71 (±7.69)	42.09 (±9.15)	2.38 (−0.39 to 5.14) $p=0.092$	1.57 (−1.28 to 4.42) $p=0.278$
Levator hiatus area (cm^2)				
Rest	16.50 (±3.20)	18.21 (±3.92)	1.71 (0.54–2.89) $p=0.007$	1.50 (0.28–2.71) $p=0.016$
Valsalva	19.01 (±4.36)	20.44 (±4.67)	1.43 (−0.04 to 2.91) $p=0.057$	0.78 (−0.71 to 2.27) $p=0.301$
Maximum contraction	15.88 (±3.46)	17.89 (±4.47)	2.01 (0.69–3.32) $p=0.010$	1.68 (0.32–3.03) $p=0.015$

Values in parentheses are 95% CIs. Unadjusted mean difference (uMD) of hiatal areas between delivery modes calculated from univariable ANCOVA and adjusted mean differences (aMD) from multivariable ANCOVA. aMD were adjusted for age, body mass index and birth weight of largest infant.

as opposed to 16.50 cm^2 ($p=0.016$) for patients with NVD. There were also statistically significant differences between the study groups' anteroposterior diameter measurements for the levator hiatus at rest, under Valsalva maneuver and maximum contraction.

Discussion

The relationship between pelvic floor trauma and VD has not yet been studied in depth. A group of studies with only a small number of cases conclude that the injury rate associated with VD is below 20% [9,11–16]. Regarding this, Shek and Dietz [9] in a series of 34 cases of VD reports a 9% of LAM avulsions. Durnea et al. [16] reports a LAM avulsion rate of 18% after VD. However, Eisenberg et al. [17] and Chan et al. [18], both report a LAM avulsion rate that exceeds the 20% in VD: 41% reported by Eisenberg et al. [17] in a series of 17 cases and 33% reported by Chan et al. [18] after the assessment of 190 cases.

A recent paper comparing LAM avulsion rate according to the different delivery modalities, reported an adjusted OR of 0.96 of LAM avulsions between VD and normal vaginal ones [19]. To date, the vast majority of studies evaluating the LAM avulsion rate associated with VD have used only a limited number of cases. Moreover [9,11,12,15], previous studies were not specifically designed to evaluate the difference in LAM injury rates between VD and spontaneous ones [9,11–19].

After carrying out a study designed specifically to determine the difference between LAM injury rate in NVD and VD, our group established an avulsion rate of 34.2% (OR 3.99) in instrumental deliveries using vacuum. In addition, we performed a standardization of vacuum application. This result differs from conclusions described in previous works, which found the LAM injury rate after VD to not significantly differ from that associated with NVD [22,23]. Previous studies present limited data about the type of vacuum used (soft cup or rigid cup) as well as about the technique carried out. We believe this could explain the difference in the LAM injury rate reported by our group and the previous conclusions in the literature.

We found that the VD group presented a larger levator hiatus area than that measured after NVD (18.2 ± 3.9 versus 16.5 ± 3.2, $p=0.0016$). This can be explained by the higher rate of LAM avulsions after VD. An increase in hiatus area in patients with LAM avulsion has previously been noted in other studies [11,24–26] with level II of evidence [10].

Among obstetric and intrapartum risk factors associated with LAM injuries, the following have been previously described as such: maternal age, birth weight and head circumference.

We found statistically significant differences among study groups regarding maternal age (28.10 ± 5.4 versus 30.4 ± 5.5, $p=0.011$). Although van Delft et al. [12] also observed an association between maternal age and LAM avulsion, other authors, such as Albrich et al. [27] and Valsky et al. [28], did not report this difference. However, this association has recently been described in symptomatic elderly women, reporting an increased risk of major pelvic floor injury rate associated to older maternal age at first delivery [29]. In this way, current literature suggests maternal age at first delivery could influence LAM avulsion rate [30].

Regarding birth weight, our group found no correlation between it and LAM avulsion rate, in line with previous studies results [24].

Epidural anesthesia was found to be a protective factor for the occurrence of LAM avulsion [9], although this finding is not corroborated by previous studies [25,31]. However, we found that patients who required instrumentation to complete fetal extraction typically where those with a longer epidural period. Therefore, we can only state that instrumental deliveries had a longer epidural period than NVD, being unable to prove the protective effect on the pelvic floor previously described by other authors.

Traditionally, fetal head circumference is thought of as a risk factor for LAM injuries [11,32,33] (with a greater risk if the fetal head circumference exceeds 35.5 cm [28]). In addition, the cephalic contour is associated with an increase in the levator hiatus area [24]. In our study, we examined the relationship between head circumference and whether or not instrumentation was required to complete vaginal delivery, finding no differences between groups.

We found that instrumental deliveries where associated to a higher episiotomy rate than NVD, probably due to the fact that instrumental deliveries are technically more difficult, and because of the performance of episiotomy in VD among our working group [34] and following our hospital's clinical practice guideline. However, in line with the conclusions of previous studies [33], we were unable to determine a correlation between episiotomy rate and LAM avulsions. Within the NVD group, episiotomy performance was not identified as a predisposing factor for LAM injuries (11.5% of LAM damage in NVD with episiotomy group versus 8.5% in NVD without episiotomy group $p = 0.69$), consistent with previously reported data [32].

In addition, we found that NVD presented a higher overall rate of perineal tears than instrumental ones, possibly on account of the lower episiotomy rate in this group.

We consider a limitation to our study, the fact that it did not take ''microtrauma'' into account, i.e. assessable injury due to the irreversible overdistension of the urogenital hiatus not associated to LAM avulsion; as well as adequate pelvic floor functionality and presence of pelvic floor prolapse. Furthermore, the absence of randomization could be considered another limitation, meaning we could only determine correlation, and not causality. Nevertheless, we believe our findings to be of interest, as they challenge major conclusions of previous works, which did not find instrumental delivery with vacuum to be a risk factor for pelvic floor muscle injuries [5,14]. We believe it would be interesting to perform more studies designed specifically to evaluate LAM avulsion rate according to the type of vacuum used (soft cup or rigid cup) and the technique applied.

We believe that there is a relationship between instrumental delivery with vacuum and a higher LAM avulsion rate than that associated with NVD. Moreover, there appears to be a relationship between VD and a larger levator hiatus area than that associated with NVD.

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