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ABSTRACT

OBJECTIVES

Evaluation of the influence of difficulty of instrumentation with vacuum on the rate of levator ani muscle (LAM) avulsions.

MATERIAL AND METHOD

Prospective observational study with 86 nulliparous women with at term gestation who required instrumentation with vacuum to complete fetal extraction. After every delivery, each explorer reported the number of vacuum tractions needed to complete fetal extraction, as well as the subjective complexity of the instrumentation. LAM avulsion rate was assessed by 3-4D transperineal ultrasound evaluation 6 months after delivery.

RESULTS

79 cases were evaluated and classified as either 'easy' delivery (<3 vacuum tractions; n:49) or 'difficult' delivery (≥3 vacuum tractions; n:30). No differences in obstetric characteristics were observed between study groups, with the following exceptions: fetal head circumference (34.8±2.7 vs. 35.2±1.1; p= 0.013) and fetal weight at birth (3260 ±421 vs. 3500± 421; p=0.016). No statistically significant differences between study groups were observed in LAM avulsion rate (36.7% vs. 30%) and levator hiatus area (cm2) at rest (18.44 ±3.95 vs 17.75 ±3.90).

CONCLUSIONS

The number of vacuum tractions needed to complete fetal extraction is not associated to a higher LAM avulsion rate nor with differences in levator hiatus area.

INTRODUCTION

Vaginal delivery is associated with levator ani muscle (LAM) and ligament injuries, being LAM avulsion one of the most important factors associated with the appearance of pelvic floor defects[1]. LAM avulsion is the separation of the pubovisceral muscle's insertion into the pubis lower branch, and has been established as the most common injury after vaginal delivery[2,3]. Patients with LAM injuries are 2.3 times more likely to present a significant cystocele and 4 times more likely to have uterine prolapse throughout their lives[4], as well as higher prevalence of voiding dysfunctions[5].

LAM avulsion has been associated with several risk factors, such as: prolonged second stage of labor[6,7], fetal head circumference[8,9], maternal age[10-13], fetal weight at birth[8,14] and instrumental delivery. Among all mentioned, instrumental delivery has been established as the risk factor with a higher association with LAM avulsion[6,15-17]. LAM avulsion is present in 12% of normal vaginal deliveries[14], 34% of vacuum assisted deliveries[15] and 35-64% of forceps assisted deliveries[6,16,17]. It has been observed, that both a difficult or a failed attempt at instrumental delivery is associated with an increased neonatal and maternal morbidity[1,18-20]. However the influence of the difficulty of the instrumentation on the appearance of LAM avulsions has not yet been studied. We propose an evaluation of the relationship between the difficulty of instrumentation with vacuum and the presence of LAM avulsions.

MATERIAL AND METHOD

We performed a prospective observational study with 86 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.

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 who required instrumentation to complete fetal extraction were considered suitable for the study and therefore included therein. Previous written informed consent acceptance was asked

from each participant. Pregnancies with severe maternal or fetal pathology were excluded from the study.

Deliveries were assisted by maternity unit staff, with a minimum of five years' experience in obstetric practice. In terms of analgesia, epidural anesthesia was used for intrapartum analgesia. After every delivery, each explorer reported the number of vacuum tractions needed to complete fetal extraction, as well as the subjective complexity of the instrumentation (simple vs complex). According to the number of vacuum tractions needed to complete the delivery, this was classified as easy vacuum delivery (EVD) (<3 tractions) or difficult vacuum delivery (DVD) (≥3 tractions)[21, 22].

In all cases, a metal vacuum (Bird's cup 50 mm, 80KPa) was used to complete fetal extraction. A suction cup was carefully placed over the flexion point, avoiding caput succedaneum, and rapid negative pressure was applied (over 2 minutes, until 0.6-0.8kg/cm2). 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 minutes, fetal extraction had not been successful.

The following obstetric parameters were recorded: gestational age, labor induction, epidural analgesia, type of instrumentation, second stage of labor duration, fetal head position, episiotomy and presence of perineal tears. Regarding newborn data, sex, head circumference, weight and pH at birth, Apgar test result (at 1 and 5 minutes), presence of neonatal morbidity (cephalohaematoma, brachial plexus palsy, etc.), admission to neonatology department and neonatal mortality were registered.

Ultrasound evaluation was performed 6 months after delivery, by a single examiner with more than five years' experience exclusively in obstetric ultrasound and with specific training in 3 / 4D imaging. Prior and throughout the ultrasound assessment, the examiner was blinded to obstetric data relating to the delivery. A 500® Toshiba Aplio (Toshiba Medical Systems Corp., Tokyo, Japan) ultrasound machine with an abdominal probe PVT-675MV 3D was used for the evaluations. Images were acquired with patients in the dorsal lithotomy position, on the gynecological examination table and with an empty bladder[23]. 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. Analysis of ultrasound volumes was performed offline.

In the multi-view ultrasound, 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 5.0mm slices cranial to this **(Figure 1).** Levator hiatus measurements ie transverse diameter, anteroposterior diameter and area, were also determined in the same plane (PMD), as already described in previous studies[14,15].

In order to compare the proportion of LAM avulsions in EVD and DVD, 30 women from each group were required, assuming an α error of 5%, a power of 80%, for a percentage of expected increase in LAM avulsions of 35% in DVD compared to EVD. Statistical analysis was performed using IBM SPSS Statistics software version 22. 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.

RESULTS

86 pregnants required vacuum instrumentation to complete fetal extraction, out of which 7 were excluded due to lack of assistance to the postpartum ultrasound evaluation

Table 1 presents obstetric and neonatal data regarding the 79 cases evaluated classified by study group (EVD or DVD). Statistically significant differences between study groups were observed exclusively in fetal head circumference (34.8cm vs 35.2cm, p=0.013), fetal weight at birth (3260g vs. 3500g, p=0.016) and fetal head position (p=0.005), being both parameters greater in the group of DVD. Only one case of admission to the neonatal unit was registred because of intrapartum maternal fever. This case belonged to the group of DVD.

Figure 1 shows the association between the subjective assessment of the complexity of instrumentation (simple or complex), reported by the obstetrician carrying out the delivery, and the number of vacuum tractions required to complete fetal extraction. Note that most of the deliveries classified as complex by the obstreticians required more than 3 vacuum tractions.

Table 2 shows the rate of LAM avulsions as well as levator hiatus measurements divided by study groups (EVD or DVD). No statistically significant differences between study groups were observed. LAM avulsion was present in 36.7% (n = 18) of the EVD deliveries and in 30% (n = 9) of the DVD.

Table 3 presents levator hiatus measurements and LAM avulsions according fetal head position (anterior, posterior and transverse). No statistically significant differences between study groups were observed.

DISCUSSION

Instrumental deliveries take place at a rate of 10-13% of total births in the UK. Although the performance of instrumental deliveries is considered a safe practice and present a satisfactory outcome in the majority of cases[24], these kind of deliveries are associated with a slight increase in both maternal and neonatal morbidity (20)

It has been observed, that the increase in neonatal morbidity (asphyxia, intracranial haemorrhage, seizures) that vacuum assisted deliveries present over normal vaginal deliveries[25], is clearly associated with cases of difficult instrumentation[26,27] and failed attempt of instrumental vaginal delivery followed by cesarean section[1,18-20].

In relation to maternal morbidity, the rate of perineal tears is significantly increased in instrumental deliveries[28], rising from a 12% of LAM avulsions described in normal vaginal deliveries[14] to a 34-64%[6,15-17] in instrumental deliveries.

Regarding vacuum assisted deliveries, the rate of LAM avulsions varies according to different study groups, from rates below 20%[6,10,29-33] to 33-41%[15,34,35]. However, none

of these studies has evaluated the influence of the difficulty of the instrumentation on the LAM avulsion rate associated to these kind of deliveries.

Previous studies have evaluated the number of full tractions, both vacuum and forceps, that is associated to what can be considered a 'difficult' delivery, establishing the cut-off in 3 full tractions[22,36,37]. In this study we observe how there is a clear correlation between the obstetrician's subjective evaluation of the instrumentation complexity (simple vs complex) and the definition of 'difficult delivery' previously described in the literature (figure 1).

Attending to the LAM avulsion rate, no differences were observed between study groups (36.7% in EVD vs 30% in DVD, p= NS). In addition, no statistically significant differences were observed in anteroposterior diameter, transverse diameter and levator hiatus area between the study groups, at rest, at maximal contraction or under Valsalva maneuvre.

We observed that DVD (≥3 vacuum tractions) were associated with greater weight at birth and larger head circumference. The association between greater weight at birth and number of tractions needed to complete fetal extraction has been previously described in forceps deliveries[22]. In addition, clinical practice guidelines based on evidence such as the Royal College of Obstetricians and Gynaecologists' have established a relationship between weight at birth and the difficulty of instrumentation[30]. Some authors have relationed fetal weight at birth[8,14] and fetal head circumference[8,9] with the rate of LAM avulsion. However, in our work, although we do have found statistically significant differences between the two study groups in weight at birth and fetal head circumference, we have not found differences in the rate of LAM avulsions between the two groups (group of EVD and DVD). However, the main limitation of our study is the number of patients included. We advise to increase this number for future trials in order to determine the influence of difficulty of instrumentation with vacuum on the rate of LAM avulsions.

In conclusion, we establish that the number of vacuum tractions needed to complete fetal extraction is not associated to a higher LAM avulsion rate nor with differences in anteroposterior diameter, transverse diameter or levator hiatus area.

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Table 1. General obstetric and neonatal characteristics of the 79 nulliparous included in the study and classified by study group.

	Easy vacuum delivery (<3 vacuum tractions) (n=49)	Difficult vacuum delivery (≥3 vacuum tractions) (n=30)	p
Maternal age	29.7 ±5.9	31.7 ±4.4	NS
Gestational age	39.3 ±1.3	39.9 ±0.8	NS
Maternal weight (kg)	63.4 ±8.0	68.5 ±12.1	NS
BMI	24.1 ±2.8	25.1 ±3.6	NS
Induced labor	9 (18.4%)	6 (20%)	NS
Epidural anesthesia	48 (98%)	30 (100%)	NS
Period of epidural anesthesia (min)	417.4 ±250.2	414.5 ±204.7	NS
Second stage of labor duration (min)	122.6 ±89.1	101.6 ±51.1	NS
Fetal head position			
Anterior	31 (63.3%)	9 (30.0%)	
Posterior	7 (14.3%)	6 (20.0%)	0.005
Transverse	11 (22.4%)	15 (50.0%)	
Episiotomy	27 (55.1%)	18 (60%)	NS
Perineal tears	16 (32.7%)	10 (33.3%)	NS
Grade I	8 (16.3%)	3 (10%)	
Grade II	3 (6.1%)	3 (10%)	NS
Grade III	5 (10.2%)	4 (13.3%)	
Grade IV	0	0	
Maternal morbidity	1 (2.0%)	0 (0%)	NS
Uterine atony	1 (2.0%)	0 (0%)	NS
Others	0 (0%)	0 (0%)	NS
Sex of newborn (females)	24 (48.9%)	14 (46.6%)	NS
Fetal weight at birth (g)	3260 ±421	3500 ±421	0.016*
Fetal head circumference(cm)	34.8 ±2.7	35.2 ±1.1	0.013*
APGAR 1 minute	8.8 ±1.0	8.9 ±1.0	NS
APGAR 5 minutes	9.9 ±0.2	10 ±0	NS
Umbilical cord artery pH	7.25 ±0.7	7.26 ±0.6	NS
Perinatal mortality	0 (0%)	0 (0%)	NS
Perinatal morbility	0 (0%)	1 (3.3%)	NS
Admission to the intensive care	0 (0%)	1 (3.3%)	NS
neonatology unit	0 (0%)	0 (0%)	NS
Others			

Not statistically significant values (NS). Statistically significant values (*)

Table 2. LAM rate and levator hiatus measurements (transverse diameters, anteroposterior diameters and area) according to the study group (easy vacuum delivery vs difficult vacuum delivery).

	Easy vacuum delivery (<3 vacuum tractions) (n=49)	Difficult vacuum delivery (≥3 vacuum tractions) (n=30)	p
LAM Avulsion presence	18 (36.7%)	9 (30%)	NS
Levator hiatus antero-posterior diameter (mm) at rest	68.1 (±7.00)	64.74 (±8.03)	NS
Levator hiatus antero-posterior diameter (mm) under Valsalva	70.70 (±8.14)	68.34 (±6.59)	NS
Levator hiatus antero-posterior diameter (mm) with maximum contraction	64.71 (±8.20)	62.64 (±8.74)	NS
Levator hiatus transverse diameter (mm) at rest	41.54 (±9.73)	42.74 (±10.36)	NS
Levator hiatus transverse diameter (mm) under Valsalva	43.92 (±9.54)	44.58 (±10.33)	NS
Levator hiatus transverse diameter (mm) with maximum contraction	41.84 (±8.95)	42.58 (±9.72)	NS
Levator hiatus area (cm2) at rest	18.44 (±3.95)	17.75 (±3.90)	NS
Levator hiatus area (cm2) under Valsalva	20.56 (±4.57)	20.20 (±4.97)	NS
Levator hiatus area (cm2) with maximum contraction	17.91 (±4.35)	17.85 (±4.81)	NS

Not statistically significant values (NS).

Table 3. LAM avulsion rate and levator hiatus measurements (transverse diameters, anteroposterior diameters and area) according fetal head position (anterior, posterior and transverse).

	Anterior (n=40)	Posterior (n=13)	Transverse (n=26)	p
LAM Avulsion presence	12 (30.%)	6 (46.1%)	9 (34.6%)	NS
Levator hiatus antero-posterior diameter (mm) at rest	50.6 (±6.5)	52.8 (±5.6)	47.9 (±7.5)	NS
Levator hiatus antero-posterior diameter (mm) under Valsalva	54.7 (±7.4)	56.1 (±7.2)	52.3 (±11.6)	NS
Levator hiatus antero-posterior diameter (mm) with maximum contraction	45.2 (±6.1)	47.9 (±8.6)	44.8 (±6.6)	NS
Levator hiatus transverse diameter (mm) at rest	41.0 (±8.8)	44.9 (±12.8)	42.2 (±10.5)	NS
Levator hiatus transverse diameter (mm) under Valsalva	45.0 (±9.3)	48.1 (±13.6)	45.8 (±13.3)	NS
Levator hiatus transverse diameter (mm) with maximum contraction	39.3 (±8.8)	44.4 (±17.8)	41.1 (±12.6)	NS
Levator hiatus area (cm2) at rest	14.0 (±3.6)	15.6 (±5.7)	13.1 (±4.9)	NS
Levator hiatus area (cm2) under Valsalva	16.9 (±4.9)	18.5 (±6.8)	16.4 (±8.0)	NS
Levator hiatus area (cm2) with maximum contraction	12.4 (±3.3)	15.4 (±6.5)	12.2 (±5.0)	NS

Not statistically significant values (NS).

Figure 1. Evaluation of the number of vacuum tractions, in relation to the subjective assessment of the complexity of the instrumentation (simple vs complex delivery) reported by the obstetrician performing the delivery. In black, those deliveries classified as 'simple' vs 'complex' deliveries in white.

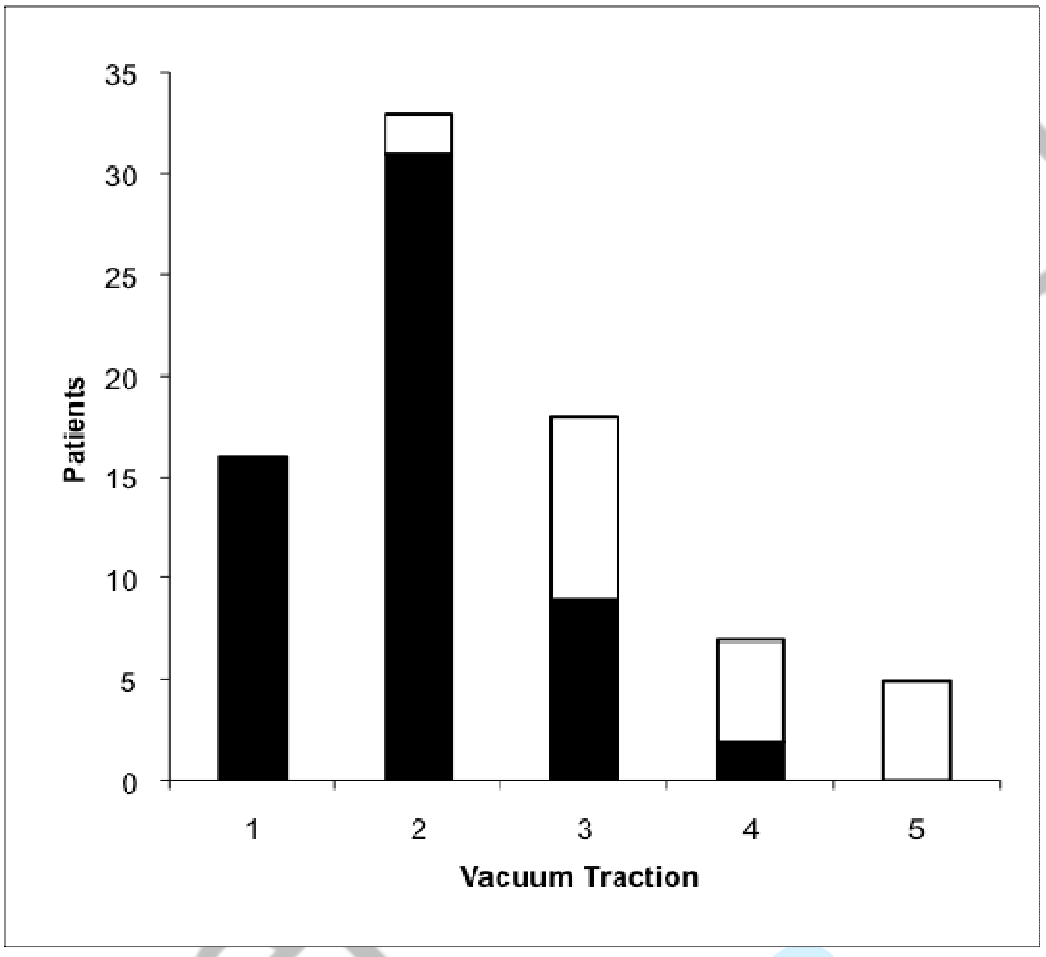

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Table 2. LAM rate and levator hiatus measurements (transverse diameters, anteroposterior diameters and area) according to the study group (easy vacuum delivery vs difficult vacuum delivery).

	Easy vacuum delivery (<3 vacuum tractions) (n=49)	Difficult vacuum delivery (≥3 vacuum tractions) (n=30)	p
LAM Avulsion presence	18 (36.7%)	9 (30%)	NS
Levator hiatus antero-posterior diameter (mm) at rest	68.1 (±7.00)	64.74 (±8.03)	NS
Levator hiatus antero-posterior diameter (mm) under Valsalva	70.70 (±8.14)	68.34 (±6.59)	NS
Levator hiatus antero-posterior diameter (mm) with maximum contraction	64.71 (±8.20)	62.64 (±8.74)	NS
Levator hiatus transverse diameter (mm) at rest	41.54 (±9.73)	42.74 (±10.36)	NS
Levator hiatus transverse diameter (mm) under Valsalva	43.92 (±9.54)	44.58 (±10.33)	NS
Levator hiatus transverse diameter (mm) with maximum contraction	41.84 (±8.95)	42.58 (±9.72)	NS
Levator hiatus area (cm2) at rest	18.44 (±3.95)	17.75 (±3.90)	NS
Levator hiatus area (cm2) under Valsalva	20.56 (±4.57)	20.20 (±4.97)	NS
Levator hiatus area (cm2) with maximum contraction	17.91 (±4.35)	17.85 (±4.81)	NS

Not statistically significant values (NS).

Table 3. LAM avulsion rate and levator hiatus measurements (transverse diameters, anteroposterior diameters and area) according fetal head position (anterior, posterior and transverse).

	Anterior (n=40)	Posterior (n=13)	Transverse (n=26)	p
LAM Avulsion presence	12 (30.%)	6 (46.1%)	9 (34.6%)	NS
Levator hiatus antero-posterior diameter (mm) at rest	50.6 (±6.5)	52.8 (±5.6)	47.9 (±7.5)	NS
Levator hiatus antero-posterior diameter (mm) under Valsalva	54.7 (±7.4)	56.1 (±7.2)	52.3 (±11.6)	NS
Levator hiatus antero-posterior diameter (mm) with maximum contraction	45.2 (±6.1)	47.9 (±8.6)	44.8 (±6.6)	NS
Levator hiatus transverse diameter (mm) at rest	41.0 (±8.8)	44.9 (±12.8)	42.2 (±10.5)	NS
Levator hiatus transverse diameter (mm) under Valsalva	45.0 (±9.3)	48.1 (±13.6)	45.8 (±13.3)	NS
Levator hiatus transverse diameter (mm) with maximum contraction	39.3 (±8.8)	44.4 (±17.8)	41.1 (±12.6)	NS
Levator hiatus area (cm2) at rest	14.0 (±3.6)	15.6 (±5.7)	13.1 (±4.9)	NS
Levator hiatus area (cm2) under Valsalva	16.9 (±4.9)	18.5 (±6.8)	16.4 (±8.0)	NS
Levator hiatus area (cm2) with maximum contraction	12.4 (±3.3)	15.4 (±6.5)	12.2 (±5.0)	NS

Not statistically significant values (NS).

Figure 1. Evaluation of the number of vacuum tractions, in relation to the subjective assessment of the complexity of the instrumentation (simple vs complex delivery) reported by the obstetrician performing the delivery. In black, those deliveries classified as 'simple' vs 'complex' deliveries in white.