

Original Research

A prospective observational study on the influence of the difficulty of forceps application and the avulsion of the levator ani muscle

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Abstract

Background: To compare the rate of levator ani muscle (LAM) avulsion between normal deliveries (ND) and forceps deliveries (FD) and to determine whether the difficulty of forceps application in FD is related to the occurrence of LAM avulsion. **Methods:** This prospective observational study included 240 primiparous patients (125 ND and 115 FD). FD were classified according to the difficulty of forceps application. The application was considered difficult if the fetal head was in a transverse position or if it was midforceps (head engaged by the leading part was above +2 stations) with the fetal head in the occipito-posterior position; otherwise, the application was considered easy. Ultrasound evaluation was performed 6 months after delivery, and complete avulsion was diagnosed when there was abnormal insertion of the LAM in all three central slices. **Results:** There were statistically significant differences between the ND and FD groups in the presence of LAM avulsion (15.6% vs. 38.3%; $p < 0.0005$), with a crude Odds Ratio (OR) of 3.36 and an adjusted OR of 4.219. However, there were no statistically significant differences in the LAM avulsion rates between the easy and difficult application groups (34.2% vs. 45.2%; $p: 0.244$). **Conclusions:** FD have higher rates of LAM avulsion than ND, although the difficulty of forceps application does not have an influence on the rates of LAM avulsion.

Keywords: 3D transperineal ultrasound; Pelvic floor; Delivery; Levator ani muscle; Forceps delivery

Impact statement

What is already known on this subject?

Although the association between the use of forceps and LAM avulsion seems to be clear, whether the injury is caused by the mechanical trauma caused by the instrument or by the intrinsic difficulty of these type of deliveries remains to be determined.

What do the results of this study add?

FD have higher rates of LAM avulsion than ND, although the difficulty of forceps application does not have an influence on the rates of LAM avulsion.

What are the implications of these findings for clinical practice and/or further research?

The difficulty of forceps application should not be an influencing factor for its use due to its relationship with LAM avulsion.

1. Introduction

Vaginal delivery is the main risk factor for the appearance of levator ani muscle (LAM) injury [1] and is associated with an increase in its hiatus area [2,3], especially in cases of LAM avulsion [4]. The appearance of a LAM

injury most likely occurs when the fetal head is at Hodge plane IV (vertex at +3 or +4 station) and when the LAM hiatus area is at its peak [5]; thus, this is the time when LAM avulsion is most likely to occur [6,7].

Many risk factors for the occurrence of LAM avulsion have been described, and forceps deliveries (FD) are the most important risk factor, with a risk ratio (RR) of 3.4 [8]. A recent meta-analysis comparing FD with normal deliveries (ND) described an Odds Ratio (OR) of 7.02 (5.04–9.78) [9] in favor of FD. Indeed, LAM injuries after FD are between 4 and 32 times more likely to occur than after ND [10], with diagnosis rates ranging from 35% to 89% [11–17].

Reported maternal and fetal lesions after FD have contributed to a progressive decrease in the use of forceps in delivery rooms. This is associated with less experience in the application of the instrument, which affects the data from some groups and increases maternal morbidity due to its use. In this scenario, the American Colleges of Obstetricians and Gynecologists (ACOG) indicate that forceps are a valid choice in cases where there is a need to rotate the fetal head during birth [18], when used by experienced obstetricians [19]. These recommendations contrast with the opinion that rotational forceps should be used infrequently and intrapartum cesarean delivery should be the preferred



option in cases of difficult operative vaginal deliveries [11]. However, although the association between the use of forceps and LAM avulsion seems to be clear [10], whether the injury is caused by the mechanical trauma from the instrument, or by the intrinsic difficulty of these types of deliveries, remains to be determined [20]. In previous studies, our group did not observe a difference in the rate of LAM avulsion, including the mode of instrument application, between FD and vacuum deliveries [21]. Now, our objective was to compare the rate of avulsion between ND and FD, as well as to determine whether the difficulty of FD is related to the occurrence of LAM avulsion.

2. Methods

A prospective observational study was conducted between April 1, 2019, and January 31, 2020 (Fig. 1) before delivery, and those who met the inclusion criteria were invited to participate in the study.

The inclusion criteria were as follows: women who were primiparous with at-term gestation (37–42 weeks), had a normal or Kielland's forceps delivery in cases of cephalic presentation, had no prior pelvic floor corrective surgery and completed written informed consent. Women who met these criteria were considered suitable for the study and therefore included.

Deliveries were assisted by our maternity unit staff. FD were performed by obstetricians with more than 5 years of experience. The fetal head station was assessed by transvaginal digital examination for low or outlet instrumental deliveries, as defined by the ACOG guidelines [22]. Subsequently, a transabdominal ultrasound was performed to monitor fetal head position [23]: suprapubic transabdominal real-time ultrasound assessment enhances the correct identification of fetal head position during assisted vaginal delivery [23]. All deliveries were performed without the Kristeller maneuver and with the protection of the maternal perineum at the moment of exit of the fetal head. In FD, the two branches of the forceps were disassembled before the exit of the fetal head. Selective episiotomy (mediolateral) was carried out following Valme's University Hospital clinical practice guidelines for operative vaginal deliveries.

The obstetric parameters evaluated were maternal age, gestational age, labor induction, epidural analgesia, duration of the second stage of labor, episiotomy and perineal tears according to Sultan's classification of perineal tears [24]. The fetal parameters studied after birth were fetal weight and head circumference. Forceps were used during uterine contraction associated with active maternal pushing by applying 2–3 tractions per contraction and without performing the Kristeller maneuver. Forceps branches were disengaged and removed when fetal expulsion was certain, but before the widest diameter of the fetal head had passed through the introitus. FD were classified according to the difficulty of forceps application. The application was considered difficult if the fetal head was in a transverse position

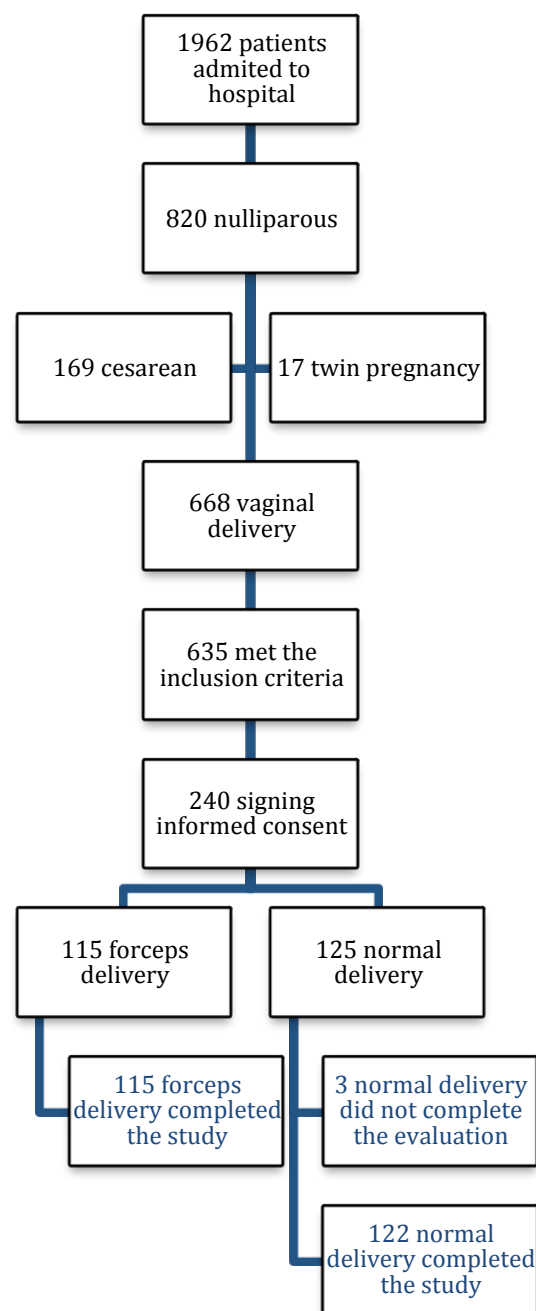


Fig. 1. The process of recruiting patients.

or if it was midforceps (station was 0 to +1/5 cm of the bone of the head) with the fetal head in the occipito-posterior position [22–25]; otherwise, the application was considered easy (Fig. 2).

An ultrasound evaluation was performed 6 months after delivery by a single examiner with specific training in 3D pelvic floor ultrasound. Prior to and throughout the ultrasound assessment, the examiner was blinded to the obstetric data relating to the delivery and clinical manifestations. A 500® Toshiba Aplio (Toshiba Medical Systems Corp., Tokyo, Japan) ultrasound with a PVT-675 MV 3D

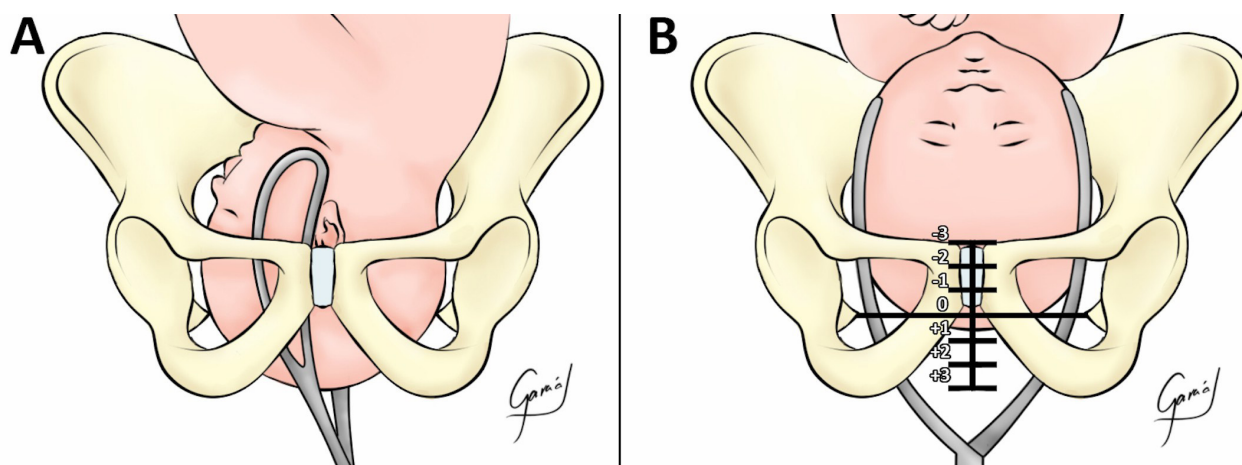


Fig. 2. The classification of difficult forceps. (A) Fetal head in a transverse position. (B) Midforceps (head is engaged but leading part is above +2 station) with the fetal head in the occipito-posterior position.



Fig. 3. Complete avulsion was diagnosed when there was abnormal insertion of the LAM in 3 central slices.

abdominal probe (Toshiba Medical Systems Corp., Tokyo, Japan) was used.

The technique of image acquisition and offline analysis of the volumes captured was carried out as described in previous studies [26]. Three volumes were captured for each patient: at rest, during Valsalva maneuver and at maximum contraction. The LAM hiatus area, transverse diameters and antero-posterior diameters were also measured in the plane of minimal hiatal dimensions (PMD) [26]. Avulsion was defined in the multiscreen mode at maximum contraction as described above [27,28]. Complete avulsion was diagnosed when there was an abnormal insertion of the LAM in all three central slices. In unclear cases, abnormal insertion was defined by a levator-urethral gap greater than 2.5 cm [29] (Fig. 3).

2.1 Statistical analyses

Quantitative variables were described as the means and standard deviations, while qualitative variables were described as percentages. For quantitative variables, the normality of the data was contrasted by using the Shapiro-Wilk test. Comparisons of quantitative variables between study groups were performed using Student's *t*-test for independent samples if the data were normally distributed, and

the nonparametric Mann-Whitney U-test was performed for nonnormally distributed data. For qualitative variables, comparisons between study groups were made with either contingency tables and Chi-square tests or nonasymptotic methods of the Monte Carlo and exact tests. We used univariate binary logistic regression analysis to determine crude odds ratios (ORs) and multivariate binary logistic regression analysis to control for possible confounding factors. The significance level was set at 95% ($p < 0.05$).

2.2 Power analysis

Presuming that the LAM avulsion rate was 35% in FD versus 15% in ND, to detect statistically significant differences, we needed a sample of 97 women per study group (alpha error of 5% and power of 90%). Regarding the type of forceps application (difficult vs. easy), to detect a difference of 35% in the rate of LAM injury (55% vs. 20%), 42 women would be needed per study group (alpha error of 5% and power of 90%).

3. Results

All eligible women who were admitted to our delivery room within the study period were invited to participate. A total of 240 patients were recruited: 115 women with FD

Table 1. Maternal and labor characteristics in the women with normal deliveries (ND) and those with easy and difficult forceps applications.

	Normal delivery (n = 122)	Forceps delivery			p^a	p^b
		All forceps (n = 115)	Easy application (n = 73)	Difficult application (n = 42)		
Maternal age in years, mean (SD)	28.9 ± 5.2	29.3 ± 5.7	29.7 ± 5.6	28.6 ± 6.0	0.423	0.520
Gestational age in weeks, mean (SD)	39.3 ± 1.1	39.7 ± 1.3	39.7 ± 1.5	39.8 ± 0.9	0.002	0.646
Induction of labor, n (%)	25 (20.5%)	27 (23.5%)	17 (23.3%)	10 (23.8%)	0.639	1.000
Epidural analgesia, n (%)	109 (89.3%)	114 (99.1%)	73 (100%)	41 (97.6%)	0.001	0.365
Epidural onset to delivery in minutes, mean (SD)	378.6 ± 177.4	446.4 ± 206.6	457.7 ± 211.3	426.7 ± 199.1	0.008	0.440
Second stage of labor in minutes, mean (SD)	95.7 ± 62.4	98.9 ± 70.2	96.6 ± 69.6	103.1 ± 71.9	0.870	0.688
Episiotomy, n (%)	54 (44.3%)	107 (93%)	69 (94.5%)	38 (90.5%)	<0.0005	0.461
Perineal tear, n (%)	71 (58.2%)	45 (39.1%)	29 (39.7%)	16 (38.1%)	0.004	1.000
Grade III	9 (12.9%)	15 (33.3%)	10 (34.5%)	5 (31.3%)	0.002	0.452
Grade IV	0 (0%)	3 (6.7%)	1 (3.4%)	2 (12.5%)		
Birth weight in grams, mean (SD)	3482.4 ± 419.1	3417.3 ± 414.9	3407.1 ± 431.9	3434.9 ± 387.9	0.150	0.731
Fetal head circumference in cm, mean (SD)	34.8 ± 1.4	34.5 ± 1.3	34.5 ± 1.3	34.5 ± 1.3	0.062	0.664

p^a = comparison between normal deliveries (ND) and forceps deliveries (FD).

p^b = comparison between the easy and difficult forceps application groups.

Table 2. Characteristics of the ultrasound evaluation between normal deliveries (ND) and forceps deliveries (FD).

	Normal delivery	All forceps deliveries	p^a	Crude OR ^a	95% CI	Adjusted OR ^a	95% CI
	(n = 122)	(n = 115)					
Avulsion, n (%)	19 (15.6%)	44 (38.3%)	<0.0005	3.360	1.812–6.227	4.219	2.162–8.311
Antero-posterior levator hiatus diameter (mm)							
Rest, mean (SD)	59.8 ± 7.9	53.6 ± 7.3	<0.0005	0.898			
Valsalva maneuver, mean (SD)	64.4 ± 9.3	59.1 ± 8.9	<0.0005	0.937			
Maximum contraction, mean (SD)	55.0 ± 9.2	49.1 ± 8.1	<0.0005	0.925			
Transverse levator hiatus diameter (mm)							
Rest, mean (SD)	40.4 ± 7.8	43.4 ± 10.4	0.099	1.037			
Valsalva maneuver, mean (SD)	43.8 ± 8.5	47.6 ± 10.5	0.009	1.044			
Maximum contraction, mean (SD)	38.8 ± 8.1	41.2 ± 10.8	0.185	1.027			
Levator hiatus area (cm ²)							
Rest, mean (SD)	16.8 ± 6.1	16.6 ± 8.6	0.032	0.996	0.962–1.031	1.000	0.966–1.036
Valsalva maneuver, mean (SD)	19.4 ± 4.8	19.3 ± 5.2	0.647	0.997	0.947–1.049	1.005	0.953–1.060
Maximum contraction, mean (SD)	15.3 ± 4.4	14.1 ± 4.7	0.025	0.946	0.893–1.003	0.960	0.904–1.020

p^a = comparison between ND and FD.

Crude OR^a = comparison between ND and FD.

Adjusted OR^a = comparison between ND and FD.

CI, Confidence interval.

Table 3. Characteristics of the ultrasound evaluation among Forceps deliveries (FD) with easy application and difficult application.

	Easy application (n = 73)	Difficult application (n = 42)	p^b	Crude OR ^b	95% CI	Adjusted OR ^b	95% CI
Avulsion, n (%)	25 (34.2%)	19 (45.2%)	0.244	1.586	0.730–3.448	1.499	0.684–3.287
Antero-posterior levator hiatus diameter (mm)							
Rest, mean (SD)	52.9 ± 7.2	54.8 ± 7.6	0.189	1.036			
Valsalva maneuver, mean (SD)	57.8 ± 8.8	61.3 ± 8.8	0.046	1.046			
Maximum contraction, mean (SD)	47.9 ± 8.1	51.0 ± 7.8	0.055	1.049			
Transverse levator hiatus diameter (mm)							
Rest, mean (SD)	42.6 ± 10.3	44.8 ± 10.4	0.274	1.020			
Valsalva maneuver, mean (SD)	45.9 ± 10.0	50.6 ± 10.8	0.024	1.043			
Maximum contraction, mean (SD)	40.5 ± 11.2	42.4 ± 10.0	0.355	1.017			
Levator hiatus area (cm ²)							
Rest, mean (SD)	15.8 ± 7.3	17.9 ± 10.5	0.238	1.027	0.982–1.074	1.026	0.980–1.074
Valsalva maneuver, mean (SD)	18.4 ± 4.9	20.9 ± 5.4	0.014	1.100	1.019–1.188	1.105	1.022–1.194
Maximum contraction, mean (SD)	13.6 ± 4.5	15.1 ± 4.9	0.087	1.075	0.990–1.167	1.078	0.991–1.173

p^b = comparison between the easy and difficult forceps application groups.

Crude OR^b = comparison between the easy and difficult forceps application groups.

Adjusted OR^b = comparison between the easy and difficult forceps application groups.

and 125 women with ND. A total of 237 women completed the study; 3 patients with a ND did not complete the postpartum ultrasound evaluation.

The maternal and labor parameters in women with ND and FD, including those with easy and difficult forceps applications, are shown and compared in Table 1. The FD group had a higher gestational age in weeks (39.3 ± 1.1 vs. 39.7 ± 1.3 ; p : 0.002), rate of epidural anesthesia (89.3% vs. 99.1%; p : 0.001), epidural onset to delivery in minutes (378.6 ± 177.4 vs. 446.4 ± 206.6 p : 0.008), and rate of episiotomy (44.3% vs. 93%; p : 0.0005) and perineal tears (58.2% vs. 39.1%; p : 0.004). These data were expected since instrumental delivery is associated with a longer time of epidural analgesia, and higher rates of episiotomy and perineal tears; however, no statistically significant differences were detected between easy application and difficult application, and both groups were comparable.

As seen in Table 2, there were statistically significant differences between the ND and FD groups in the presence of LAM avulsion (15.6% vs. 38.3%; p : 0.0005), with a crude OR of 3.36 and an adjusted OR of 4.219 (adjusted by epidural analgesia, second stage of labor and fetal head circumference). This OR adjustment was made based on the parameters that could potentially influence the avulsion rate and act as possible biases. Furthermore, we observed statistically significant differences between the ND and FD groups in the following LAM hiatus measurements: antero-posterior diameter (at rest, during Valsalva maneuver and at maximum contraction), transverse diameter (during Valsalva maneuver) and area (at rest and at maximum

contraction); however, there were no statistically significant differences in the LAM avulsion rates between the easy and difficult application groups (34.2% vs. 45.2%; p : 0.244) (Table 3). Only the LAM hiatus area measurement at rest showed statistically significant differences between the easy and difficult forceps application groups (p : 0.014), with an adjusted OR of 1.105 (95% Confidence interval (CI): 1.022–1.194). Therefore, the difficulty of forceps application did not influence the LAM avulsion rates or the LAM hiatus area measurement during Valsalva maneuver or in maximum contraction.

4. Discussion

We observed that FD had a higher rate of LAM avulsion than ND, with an adjusted OR (epidural analgesia, second stage of labor and fetal head circumference) of 4.219 (2.162–8.311). Nonetheless, there were no statistically significant differences in the LAM avulsion rates between the easy and difficult application groups.

The literature has shown that FD have a higher risk of LAM avulsion than ND [9]. Nonetheless, most of the studies that claim that LAM avulsion is related to FD do not describe the mode of the instrumentation application [8,15,21,30,31]. The use of forceps has numerous factors that can influence the increase in avulsion in this type of delivery, such as the additional space required by the forceps branches, the increase in the LAM distension velocity and the higher force exerted by the obstetrician required in this type of delivery [31]. Previously, our group considered these factors with the aim of showing which FD parameter

causes the most LAM injuries the most. We did not observe differences in the LAM avulsion rates between the rotational and nonrotational FD. We did not observe that the disassembly of the forceps branches before the exit of the fetal head [32,33] helped decrease the rate of avulsion. Moreover, if we consider the mode of instrument application, avulsion rates are similar in FD and vacuum deliveries [21,34]. However, it has been described that maternal complication rates vary widely and depend on a number of factors that are not independent. These factors include the type of instrument used, head position at instrument application, fetal head station, indication of the intervention and operator experience [35]; thus, the application of forceps in the transverse fetal position as a rotational instrument is infrequent in some clinics, and intrapartum cesarean delivery is the preferred option in cases of difficult operative vaginal deliveries [11]. Transverse positions (rotational forceps) and higher presentations (midforceps) have been described as the major risk factors for maternal trauma during operative vaginal deliveries [35]. This is why these as criteria were used to classify FD as difficult applications, with no statistically significant difference observed in avulsion rates when compared to the easy application group. We believe that our results might be influenced by our application technique consisting of gentle disassembly of the forceps branches before the exit of the fetal head. We believe that this is the most critical time for the occurrence of LAM injuries given that it is the moment when the LAM hiatus area is at its highest point, which suggests the importance of taking extreme care at that moment.

This is the first study to compare the avulsion rates of FD classified as easy or difficult applications, which is its greatest strength. Moreover, all instrumental deliveries were performed by highly experienced obstetricians; thus, possible damage due to inexperience of the doctor performing the delivery was avoided. We also adjusted the OR by factors described in the literature that may influence LAM avulsion, such as epidural analgesia, the second stage of labor and fetal head circumference. This allowed us to avoid possible confounding factors that may have affected our final results. One limitation is that we did not report whether the participants had complaints and/or symptoms related to avulsion LAM. Nevertheless, our study has limitations, not all the parameters associated with LAM avulsion during delivery have been evaluated in this study, we can consider that the classification of the difficulty of the application of the forceps is a subjective classification and given that the ultrasound evaluation was performed 6 months after delivery, and we did not record whether the LAM avulsion was type I or II. A recent study concluded that the type of LAM avulsion observed 6 months after delivery predicted the persistence of avulsion 1 year postpartum; thus, by not recording the type of avulsion, we did not know which of these lesions would be permanent and irreversible. Furthermore, only one kind of forceps (Kielland forceps) was used, al-

though future studies should determine if the kind of forceps used has an influence on the rates of LAM avulsion.

5. Conclusions

FD has higher rates of LAM avulsion than ND, although the difficulty of forceps application does not have an influence on the rates of LAM avulsion.

Abbreviations

LAM, Levator ani muscle; ND, Normal deliveries; FD, Forceps deliveries.

Author contributions

JAGM and JASB designed the research study. RGJ performed the research. AFP analyzed the data. RGJ, AA, LCP, JAGM and JASB wrote the manuscript. All authors contributed to editorial changes in the manuscript. All authors read and approved the final manuscript.

Ethics approval and consent to participate

All subjects gave their informed consent for inclusion before they participated in the study. The study was conducted in accordance with the Declaration of Helsinki, and the protocol was approved by Andalusia's Board of Biomedicine Ethics Committee (0153-N-15). Approval date: April 14, 2015.

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Conflict of interest

The authors declare no conflict of interest.

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