

## Influence of the disengagement of the forceps in levator ani muscle injuries in instrumental delivery: A Multicenter study.

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Page 1 of 18

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# Influence of the disengagement of the forceps in levator ani muscle injuries in instrumental delivery: A Multicenter study

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# **Conflict of interest:**

The authors have stated explicitly that there are no conflicts of interest in connection with this article

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# ABSTRACT

**Introduction:** Forceps use is the main risk factor for levator ani muscle (LAM) injuries. We believe that the disengagement of the forceps branches before delivery of the fetal head could influence LAM injuries, and thus, we aimed to determine the influence of the disengagement of the forceps on the occurrence of LAM avulsion during forceps delivery. **Material and methods:** A prospective, observational, multicenter study was conducted with 261 patients who underwent forceps delivery. The patients were classified according to whether the branches of the forceps had been disengaged before delivery of the fetal head. LAM avulsion was defined using a multislice mode (3 central slices). **Results:** In all, 255 patients completed the study (160 without disengagement and 95 with disengagement). LAM avulsions were observed in 37.9% with and in 41.9% in the group without disengagement. The crude OR (without disengagement vs. with disengagement) for avulsion was 0.90 (95% CI: 0.49 to1.67, p= 0.757) and an adjusted OR of 0.82 (95% CI: 0.40 to1.69, p= 0.603). **Conclusions:** We have not observed a statistically significant reduction in the levator ani muscle avulsion rate with disengagement of the forceps branches before delivery of the fetal head.

# **Key Words**

Levator ani muscle avulsion; forceps; transperineal ultrasound

# Abbreviations

LAM levator ani muscle

- OR odds ratio
- CI confidence intervals
- ACOG American College of Obstetricians and Gynecologists

## Key message

The disengagement of the forceps before delivery of the fetal head does not significantly decrease the rate of levator ani muscle avulsion.

#### **INTRODUCTION**

In recent decades, the rate of cesarean sections has increased in many countries without improvements in neonatal morbidity and mortality. This has led different scientific societies and clinical guidelines to defend and promote the use of rotational forceps in transverse presentations where cesarean section is otherwise frequently performed.

The use of forceps, in some countries, has decreased significantly, so the rate of use in the United States is 0.56% in 2015<sup>1</sup>. This is due to a decrease in the experience of the application technique and the data of some groups that show an increase in maternal morbidity associated with their use<sup>1</sup>.-In this scenario, the American College of Obstetricians and Gynecologists (ACOG) suggests that forceps are an appropriate option in rotational delivery when performed by experienced clinicians<sup>2,3</sup>, although levator ani muscle (LAM) avulsion (disinsertion of the pubic bone) rates between 35-64% have been reported, and using forceps is described as the main risk factor for LAM injuries<sup>4-6</sup>.

Odds ratios for avulsion in forceps assisted delivery relative to normal vaginal delivery are reported as between 3.4 and 32<sup>7</sup>. However, although the association between forceps use and LAM avulsion seems clear<sup>7</sup>, it has not yet been determined if the injury is due to mechanical trauma produced by the instrument or the intrinsic complexity of such deliveries<sup>8</sup>. The most critical time for LAM avulsion is when the fetal head reaches the perineum and the levator hiatus area is largest<sup>9,10</sup>. We believe in the importance of caution at this time and the least trauma possible. Therefore, we hypothesized that the disengagement of the branches of the forceps before delivery of the fetal head can influence LAM injuries. Based on this premise, the aim of our study is to determine the influence of the disengagement of the forceps in LAM avulsion during forceps delivery.

#### **MATERIAL AND METHODS**

A prospective, observational, multicenter study was conducted at 3 participating centers: Virgen de Valme University Hospital of Seville, University Healthcare Complex of Gran Canaria, and University Healthcare Complex of León. In all, 261 nulliparous women were recruited between January 2015 and January 2017. This study included nulliparous women at term gestation with cephalic presentation who underwent instrument-assisted delivery with Kielland's forceps. We

excluded those women with previous disorders of the pelvic floor and those who had a failed instrumental delivery (resulting in cesarean section). Women were recruited after delivery during their hospital stay. disengagement of the forceps branches. Between January 2015 and December 2015, we recruited the cases without disengagement of the forceps branches while between January 2016 and January 2017 we recruited the cases with disengagement of the forceps branches.

Deliveries were performed by qualified obstetricians (over 5 years of experience). Engagement of the forceps and its application followed the method previously described in the literature<sup>9</sup>. Instrumentation was performed during uterine contraction associated with active maternal pushing by applying 2-3 tractions per contraction and without performing the Kristeller maneuver. Fetal head station was assessed [low instrumentation (vertex at +2 station) and mid-cavity instrumentation (head is engaged but leading part above +2 station)] according to the criteria specified by the ACOG<sup>11</sup>. Fetal head position was determined by transabdominal ultrasound (anterior, posterior, and transverse)<sup>12</sup>. In cases of disengagement, forceps branches were disengaged and removed when expulsion is certain but before the widest diameter of the fetal head passes through the introitus<sup>9</sup> (Figures 1 and 2).

We recorded maternal age, gestational age, need for induction of labor, epidural analgesia, duration of epidural analgesia, duration of the second stage of labor, need to perform an episiotomy and occurrence of perineal tears according to Sultan's classification of perineal tears<sup>13</sup>, fetal weight, and head circumference.

Ultrasound assessment was performed 3-6 months after delivery by examiners with experience in 4D pelvic floor ultrasound (JAGM, IOC, EGA). The examiners were blinded to the obstetric data related to the delivery. The ultrasound machines used were the Toshiba® 500 Aplio (Toshiba Medical Systems Corp., Tokyo, Japan) with a PVT-675MV 3D abdominal probe and the Voluson E8 (GE Medical Systems, Zipf, Austria) ultrasound system with a RAB 8 - 4-MHz volume transducer, covered by a sterile glove.

The acquisition and offline analysis of the volumes was performed as previously described<sup>14</sup>. During the examination, dynamic 4D volumes were acquired at rest, during maximum contraction of pelvic muscles, and during Valsalva maneuver. Measurements of the LAM hiatus

were performed in the plane of minimal dimensions<sup>3</sup>. The levator hiatus measurements included the transverse diameter, antero-posterior diameter, and area, which are also described in previous papers<sup>15</sup>. The integrity of the LAM was assessed during maximum contraction using the multislice mode, as previously described<sup>16,17</sup>. Complete avulsion was diagnosed when an abnormal LAM insertion of the public bone was observed in the 3 central slices (Figure 3). In unclear cases, a levator - urethra gap >2.5 cm was used to define an abnormal insertion.

#### Statistical analyses

The statistical analysis was performed using the IBM SPSS Statistics program version 24 (IBM, Armonk, NY, USA). For quantitative variables, the normality of the data was examined (Shapiro-Wilk test) in the groups defined by the type of delivery; analysis of variance (ANOVA) for independent samples or a nonparametric Kruskal-Wallis test was applied, followed by a multiple comparison test if the variance was significant. For the analysis of qualitative variables, either contingency tables and Chi-square tests or the non-asymptotic methods of Monte Carlo and exact tests were performed. We used a univariate binary logistic regression analysis to determine crude odds ratios (ORs) and a multivariate binary logistic regression analysis to control for possible confounding factors. The multivariate model introduces as covariates those variables whose univariate significance was p <0.25. These results were complemented with 95% confidence intervals (CIs) for the ORs. P<0.05 was considered statistically significant.

To detect a 20% difference in the percentage of LAM injuries between the 2 types of instrumental deliveries (50% in forceps without disengagement vs. 30% in forceps with disengagement), we determined that 55 women were needed in each study group to achieve a power of 80% and a significance level of 5%.

#### **Ethical approval**

This study was approved by the Biomedical Ethics Committee of the Junta of Andalusia (1153-N-15). All women provided written informed consent prior to participation in the study.

## RESULTS

We included 261 patients during the recruitment period. Six patients were excluded: 5 did not attend the ultrasound control, and 1 had failed instrumental delivery and required an intrapartum

cesarean section to complete the delivery. Two hundred and fifty-five (255) patients completed the study. One hundred and sixty (160) patients had a forceps delivery without disengagement of the branches during delivery of the fetal head and 95 completed delivery with disengagement of the branches of the forceps before extraction of the fetal head.

Table 1 shows the obstetric characteristics of both groups. We observed that deliveries with disengagement of the forceps showed a higher rate a greater number of perineal tears (18.8% vs. 34.7%; p: 0.007). However, high-grade tears (III and IV degree) were no different in deliveries without disengagement (10.5% v/s 13.6%, p = 0.547).

Both groups showed similar proportions for the different fetal head positions (anterior, posterior, and transverse) and fetal head stations (low and mid) during instrumentation (Table 2).

Table 3 shows the LAM injury rates (avulsion) and measurements of the levator hiatus. Deliveries without disengagement of the forceps showed a greater levator hiatus area both at rest (p<0.0005), during the Valsalva maneuver (p<0.0005), but similar levator hiatus area during maximum contraction (p = 0.632). No statistically significantly difference was seen in the rate of LAM avulsions in the group without disengagement (41.9%) than the group with disengagement (37.9%). The crude OR (without disengagement vs. disengagement) for avulsion, was 0.90 (95% CI: 0.49 to1.67; p= 0.757), and the adjusted (adjusted for maternal age, induced labor, epidural period, second stage of labor, perineal tear and fetal head circumference) OR was 0.82 (95% CI: 0.40 to1.69; p= 0.603).

## DISCUSSION

We observed that deliveries with disengagement of the branches of the forceps before extraction of the fetal head show a similar rate of LAM avulsion with an adjusted OR (without disengagement vs. with disengagement) of 0.82 (95% CI: 0.40 to 1.69; p=0.603). Thus, in deliveries without disengagement, we did not identify any statistically significant increase in the rate of LAM injuries due to the increase in the levator hiatus area because of the association of the fetal head and forceps during the passage of the fetal head at the level of the LAM, during

 which patients are more susceptible to injuries<sup>10</sup>. The increase in the area of the hiatus during the passage of the fetal head in cases of non-disengagement of the forceps may also suggest the hiatal overdistensibility (microtrauma) that we observed in our study in cases of non-disengagement<sup>10</sup>.

Most previously published studies associating LAM avulsion with forceps use do not describe how the instrumentation was used<sup>8,18-21</sup>. This description was also not included in a recent metaanalysis<sup>22</sup> that determined the importance of the risk of forceps use for LAM injuries. We believe that the application of forceps cannot be simplified in this way. In fact, different conditions might influence avulsion in labor, such as the additional space occupied by the branches of the forceps, the increase in the speed of LAM distension, and the greater force required by these deliveries<sup>22,23</sup>. The three- and four-dimensional transperineal ultrasound is an adequate method of evaluation of the pelvic floor musculature because it presents an adequate intra-class correlation coefficient  $(0.97)^{24}$  in relation to the magnetic resonance and also has a very good interobserver correlation  $(0.61-0.93)^{25}$ . In our study of the disengagement of the forceps, we analyzed the space factor added by the forceps during instrumentation, and observed that an increase in this space is not related to a significant increase in the rate of LAM avulsions when forceps are used without disengagement. In vitro studies have concluded that the risk of avulsion from forceps is not completely explained by the increase in space during delivery<sup>22,23</sup>. Additionally, it has been reported that maternal complication rates vary widely and depend on several factors that are not independent. These factors include type of instrument used, head position at application, station, indication for intervention, and operator experience<sup>9</sup>. However, a subsequent study found no differences in the LAM-avulsion rate between rotational forceps and non-rotational forceps in deliveries performed by highly experienced personnel<sup>25</sup>. In this study, we adjusted for the fetal head position and the station at instrumentation to reduce the possible confounding effect associated with the method of forceps application. Similarly, the literature has reported different ways to perform delivery according to different hospital centers<sup>26</sup>, and thus, we have conducted a multicenter study.

Different rates of LAM avulsion have been described in cases of forceps deliveries (50-60%)<sup>4,20</sup> but our group in previous studies described lower rates of LAM avulsion (30-40%)<sup>26</sup>. In our study in cases of non-disengagement of the forceps branches maintains these rates of LAM avulsion. One aspect that must be discussed is the differences in obstetric characteristics found between the groups. Factors that can influence LAM avulsions have been described, such as a prolonged second stage of labor<sup>8</sup>, a greater fetal head circumference<sup>8,28</sup>, and epidural analgesia<sup>4</sup>.

To diminish the possible effect of these factors on LAM injuries, we have adjusted for them to obtain an adjusted OR for LAM avulsion of 0.82 (95% CI: 0.40 to1.69; p=0.60) (with disengagement vs. without disengagement). Although we observed a higher rate of perineal tears in the group with disengagement, possibly due to the manipulation that takes place in the disengagement of the forceps branches. We observed similar rates of severe perineal tears (III and IV) in our study, similar to previous reports<sup>26,27</sup>We believe that the decrease in the area of the hiatus during the passage of the fetal head in cases of disengagement of the forceps may explain this result.

Our study has strengths that are important to highlight. This is the first study that has analyzed LAM injuries associated with the disengagement of the branches of the forceps before delivery of the fetal head. In addition, the multicenter study design allows us to standardize the different ways of applying the forceps among different centers. Likewise, our initial design aimed to not only analyze the disengagement of the forceps but also to avoid the confounding factors related to the instrument characteristics (fetal head position and station at instrumentation). However, this study also has some weaknesses, such as only using Kielland's forceps and not randomizing the patients; also, after analyzing the data, we observed that some obstetric characteristics differed between the two groups. To minimize this, the OR was adjusted for the factors that differed between the groups. Despite this, this study is the first step in the development of future projects to determine the true influence of forceps application on LAM injuries. Considering all these reasons as well as our results, we have not observed statistically significant differences in the LAM avulsion rate between the disengagement or not of the forceps branches.

#### Conclusion

We have not observed that disengagement of the forceps branches prior to head delivery leads to a statistically significant reduction in the LAM avulsion rate.

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# Legends

Table 1. General obstetric and intrapartum characteristics (n: 255).

Table 2: Characteristics of the instrumentation (n: 255).

Table 3: Levator Ani Muscle injury and general levator hiatus ultrasound measurements.

Figure 1: In cases of non-disengagement. Forceps placed in fetal head B. Removal of fetal head without disengaged of the forceps

Figure 2: In cases of disengagement. Forceps placed in fetal head B. Forceps are disengaged and removed when expulsion is certain but before the widest diameter of the fetal head passes through the introitus

Figure 3. A. Three-dimensional transperineal ultrasound evaluation in case of absence of levator ani muscle avulsion. B. Left and right avulsion (white arrows) in the 3 central slices.

	Mean (SD) or N (%)				
	Without disengagement (n=160)	With disengagement (n=95)	р		
Maternal age (years)	33.01±5.38	30.77±5.79	0.011		
Ğestational age (weeks)	39.63±1.50	39.77±1.23	0.691		
Induced labor	77(48.1%)	27(28.4%)	0.003		
Epidural	149(93.1%)	95(100%)	0.022		
Epidural period (min)	537.67±215.74	428.23±196.86	0.001		
2nd stage of labor (min)	145.76±71.01	92.26±64.19	<0.000		
Episiotomy	154(96.3%)	92(96.8%)	1		
Perineal tear	30(18.8%)	33(34.7%)	0.007		
Grade I	3(1.8%)	12(12.6 %)			
Grade II	10(6.2%)	8(8.4%)			
Grade III	15(9.3%)	13(13.6%)			
Grade IV	2(1.2%)	0(0%)			
Newborn weight (kg)	3291.53±451.72	3342.80±434.87	0.347		
Fetal head circumference (cm)	33.88±1.40	34.04±1.37	0.024		

Table 1. General obstetric and intrapartum characteristics (n: 255).

Data are given as mean (Standard deviation) or number (%)

Table 2: Characteristics of the instrumentation (n: 255).

	Mean (SD) or N (%)			
	Without disengagement (n=160)	With disengagement (n=95)	р	
Fetal head				
position Anterior	113(70.6%)	60(63.2%)		
Posterior	32(20.0%)	19(20.0%)	0.2	
Transverse	15(9.4%)	16(16.8%)		
_	,			
Station at instrumentation				
Low	96(60%)	59(62.1%)	0.842	
instrumentation				
Mid instrumentation	64(40%)	36(37.9%)		

Data are given as mean (Standard deviation) or number (%)

Table 3: Levator Ani Muscle injury and general levator hiatus ultrasound measurements.

	Mean (SS) or N(%)						
	Without disengagement (n=160)	With disengagement (n=95)	р	Crude OR	Adjusted OR		
Avulsion	67(41.9%)	36(37.9%)	0.757	0.90 (95%CI: 0.49,	0.82 (95%Cl: 0.40,		
Levator hiatus	area (cm2)			1.67)	1.69)		
Rest	17.34±4.07	14.98±4.00	<0.0005				
Valsalva	27.40±7.85	18.86±5.95	<0.0005				
Maximum contraction	13.56±3.80	13.35±3.97	0.632				

Figure 1: In cases of non-disengagement. Forceps placed in fetal head B. Removal of fetal head without disengaged of the forceps

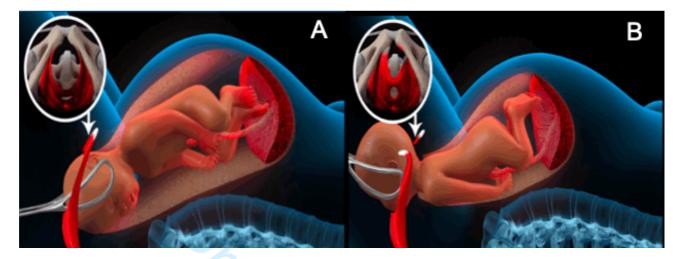


Figure 2: In cases of disengagement. Forceps placed in fetal head B. Forceps are disengaged and removed when expulsion is certain but before the widest diameter of the fetal head passes through the introitus

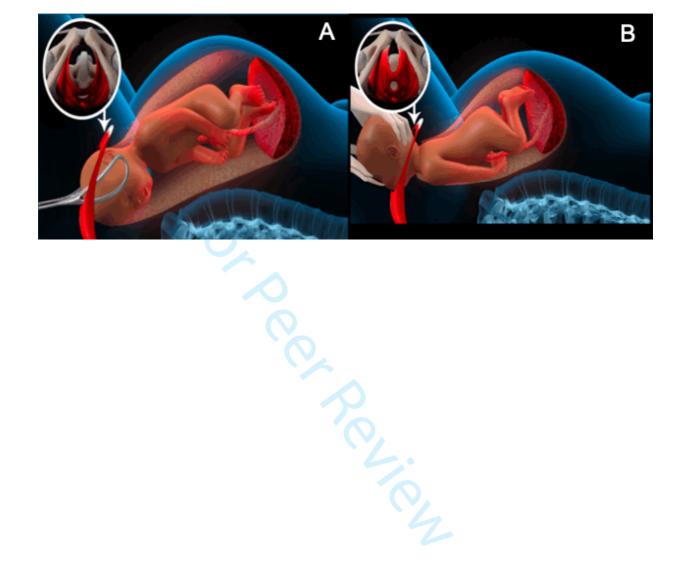


Figure 3.

A. Three-dimensional transperineal ultrasound evaluation in case of absence of levator ani muscle avulsion. B.Left and right avulsion (white arrows) in the 3 central slices.

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