



Does the implementation of a restrictive episiotomy policy for operative deliveries increase the risk of obstetric anal sphincter injury?

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Title: Does the implementation of a restrictive episiotomy policy for operative deliveries increase the risk of obstetric anal sphincter injury?

ABSTRACT: 250 words

Purpose

Our main objective was to investigate whether the implementation of a restrictive episiotomy policy in operative deliveries changes the incidence of obstetric anal sphincter injury (OASI).

Methods

This is an observational study over an 11-year period in Poitiers University Maternity, France.

We included women with vaginal operative deliveries after 34 gestational weeks for singleton births in cephalic presentation. We collected data on the mother and operative delivery characteristics: indication, instrument, epidural analgesia, labor length, episiotomy, OASI, and birthweight. We investigated the changes in the mediolateral episiotomy (MLE) and OASI rates and the association between MLE and OASI. The primary outcome was the evolution of the OASI and MLE rates. The secondary outcome was the occurrence of OASI during operative delivery with or without MLE.

Results

In total, 2357 operative deliveries were assessed, including 847 vacuum-, 1350 forceps- and 160 spatula-assisted deliveries. Of these, 950 were performed with MLE and 1407 without; 37 OASIs (3.9%) occurred in the MLE group, and 137 (9.7%) in the no-MLE group. Between 2005 and 2015, MLE use decreased from 78.5% to 16.2% and OASI occurrence increased from 3.1% to 12.7%. The increase in OASI occurrence was significant for forceps deliveries, but not for vacuum or spatula deliveries. Operative delivery with MLE was associated with a 3-times lower OASI occurrence than that without MLE (adjusted OR = 0.29, 95% CI [0.20-0.43]).

Conclusions

Implementation of a restrictive MLE policy for operative delivery seem associated with an increase in OASI incidence with forceps, but not with vacuum.

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79 INTRODUCTION

80 Obstetric anal sphincter injuries (OASIs) occur in 0.4-5% of deliveries and can strongly affect
81 women's health and quality of life [1-3]. OASIs are associated with a high prevalence of
82 postnatal fecal incontinence, pain and sexual complaints [1-3]. Several risk factors are well
83 described in the literature for OASI occurrence: nulliparity, short perineal body, prolonged
84 second stage of labor, fetal macrosomia, posterior presentation, and operative delivery,
85 particularly with forceps delivery [1, 4, 5]. The literature clearly reports that a routine use of
86 episiotomy to prevent OASI in spontaneous vaginal delivery has no benefit and is even
87 reported as a risk factor, particularly for midline episiotomy [6]. Nevertheless, the potential
88 protective effect of mediolateral episiotomy (MLE) during operative vaginal delivery remains
89 unclear. Operative delivery is a high-risk situation for OASI occurrence, particularly when
90 other risk factors coexist [1, 4, 5]. The literature in this thematic is contradictory, but there
91 are several studies reporting an increase in OASI occurrence when there is an operative
92 delivery without MLE [7-13]. These studies are difficult to interpret since they often evaluate
93 teams that routinely use MLE for operative deliveries, and OASI occurs in the few cases
94 without MLE. Thus, it remains unclear whether a restrictive use of MLE during an operative
95 delivery is associated with a higher risk of OASI.

Since 2005, according to the French guidelines [14], our institution introduced a restrictive use of MLE for all vaginal deliveries including operative deliveries. This considered, our local guidelines recommend since 2005, a restrictive use of MLE in case of operative delivery. It was requested to each obstetrician in our labor ward to reduce its use of episiotomy in case of operative delivery and to consider individually its use only for specific cases for which they think the intervention is beneficial for the woman and / or her baby. We hypothesize that this change in our practices may have affected our OASI incidence in operative deliveries, which is a high-risk situation for this outcome.

The primary endpoint was to investigate the effect of a restrictive policy of MLE during operative deliveries by measuring the evolution of OASI and MLE rates across an 11-year period. The secondary outcome was to assess the risk of OASI during an operative delivery with or without MLE.

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MATERIALS AND METHODS

This is a retrospective observational study based on French university maternity data (Poitiers University Hospital, France). This study included all the operative deliveries at more than 34 weeks of gestation for singleton births in cephalic presentation between January 2005 and December 2015.

We systematically collected data from the patient's medical records, information about the women's characteristics (age, body mass index, parity) and the mode of delivery: epidural analgesia, term, second stage of labor length, expulsive phase length, MLE use, type of instrument used for the delivery, perineal tears occurrence and classification, and birthweight. The second stage of labor length was defined as the delay between full cervical dilatation and birth. The expulsive phase length was defined as the delay between the onset of pushing and birth. When using different instruments for the same delivery, the instrument used to finish the delivery was the instrument considered in the analysis. When an episiotomy was performed, it was always classified as MLE, in accordance with our institutional guidelines.

An OASI was defined as a stage 3 or 4 perineal tear according to the Royal College of Obstetricians and Gynaecologists (RCOG) guidelines [3]. During the first period (2005-2009), no distinction was made between stage 3 subtypes (3a, 3b and 3C) according the International Classification of Diseases. During the second period (2010-2015), our obstetrical teams (obstetricians, midwives, students) were made aware of the diagnosis of OASI, and our local guidelines recommended a standardized report of OASI including all subtypes of stage 3. In our institution, all operative deliveries are performed by or under direct supervision of a senior obstetrician. Therefore, every perineal tear that occurred

during an operative delivery was examined by a senior obstetrician and thus every diagnosis of OASI was made by a senior obstetrician.

We first described our population characteristics in terms of the mean (standard deviation (SD)) for continuous variables and effectives (percentage) for categorical variables. We then assessed the evolution of both MLE and OASI rates and our obstetrical practices (cesarean rate, operative delivery rate, type of instrument used) across the period of interest. We described the cross evolution of OASI and MLE rates during the studied period according to the type of instrument. Finally, we investigated the effect of MLE during operative delivery on OASI incidence.

To investigate any increase/decrease in the rate of MLE and the rate of OASI across the period of interest, we used a non-parametric test for continuous data (Spearman test). This methodology has been previously used in previous works investigating changes in OASI occurrence and MLE rates across time [15]. The same type of analysis was used to investigate any change in our obstetrical practices during the period (operative delivery rate, cesarean section rate, forceps delivery rate, spatulas delivery rate, vacuum delivery rate, OASI and MLE rates according the type of instrument). We conducted a subgroup univariate analysis to investigate the effect of MLE for each instrument (a multivariate analysis was not performed because of the low number of cases expected in each group). Finally, we performed a multivariate analysis using a logistic regression to investigate the effect of MLE during an operative delivery (regardless of instrument type) for OASI occurrence. For this analysis, continuous data were converted into categorical data corresponding to the thresholds described in the literature as associated with OASI: age (< 25 years, 25 to 34 years, 35 years or more), maternal BMI (< 25 kg.m⁻², 25 to 30 kg.m⁻², 30 kg.m⁻² or more), second stage of labor length greater than 120 minutes, pushing phase length greater than 30

minutes, and birthweight (< 3500 g, 3500 to 4000 g, 4000 g or more) [1]. Outcomes with a level of significance greater than $p < 0.15$ in the univariate analysis were included in the multivariate analysis using logistic regression. Analyses were performed with Stata software (version V14IC; Stata Corporation, College Station, TX, USA). For all analyses, significance was considered for $p < 0.05$, and we calculated odd ratios (OR) with 95% confidence intervals when appropriate.

Upon admission, each patient at our institution receives a document that specifically mentions the possibility that anonymized medical data collected during hospitalization could be utilized for medical research. Data have been collected in accordance with our typical practices, and the women underwent no supplementary procedures for this research. Considering French regulations (loi Jardé), ethical committee approval was not required for this non-interventional retrospective study.

RESULTS

During the 11-year period, 22,023 singleton deliveries in cephalic presentation at 34 weeks or over occurred, among which 2357 were operative vaginal deliveries (10.7%) (Figure 1). A total of 1350 operative deliveries were performed with forceps (57.3%), 160 with spatulas (6.8%) and 847 with a vacuum (35.9%). Additionally, 950 of the operative deliveries (40.3%) were performed with MLE (Figure 1). OASI occurred less frequently (3.9%) in operative deliveries with MLE than without MLE (9.7%; $p < 0.005$) (Figure 1).

The mean age of the women who delivered by operative vaginal delivery was 29 (SD=5) years, and the mean BMI was 23 (SD=4.6) Kg.m^{-2} . The mean term at birth was 40 (SD=1.3) weeks, the mean second stage of labor length was 119 (SD=68) minutes, the mean expulsive phase length was 23 (SD=12) minutes and the mean birthweight was 3337 g (SD=465).

The other characteristics of the mothers who delivered via operative delivery are reported in table 1, as are the characteristics of the operative deliveries.

From 2005 to 2015, in all cephalic presentation deliveries above 34 weeks, our rate of operative delivery did not significantly change (10.1% in 2005 to 10.5% in 2015; $p = 0.47$). We significantly increased our cesarean section rate from 9.2% in 2005 to 12.6% in 2015 ($p < 0.005$). From 2005 to 2015, we decreased our forceps utilization rate from 66% to 45% ($p < 0.005$), we increased our vacuum-assisted delivery rate from 17.5% to 50% ($p < 0.005$) and our annual rate of spatula-assisted delivery remained stable (16 to 4.6%; $p = 0.12$).

We drastically decreased our rate of MLE during operative delivery from 78.5% in 2005 to 16.2% in 2015 ($p < 0.0005$). During the same period, we reported a very significant increase in the OASI rate in operative deliveries from 3.1% to 12.7% ($p < 0.0005$) (Figure 2). If we focus on

the first part of this study (2005-2009), we report a significant decrease in MLE use (78.5% to 43.5%; $p<0.05$) without a statistically significant increase in OASI occurrence (3.1% to 9.3%; $p=0.08$). However, during the second part of the study (2010-2015), the decrease of MLE use was no longer statistically significant (26.9% to 16.2%; $p=0.35$), and we reported an increase in OASI occurrence from 6.1% to 12.7% ($p<0.005$).

Considering the entire 11-year period, for each instrument, we significantly decreased our rate of MLE (Figure 3). In the forceps group, the rate of OASI significantly increased (3.9% to 21%; $p<0.005$) whereas it remained stable in the vacuum (0 to 6.1%; $p=0.19$) and spatula (3.2% to 0; $p=0.87$) groups (Figure 3).

In a subgroup univariate analysis, MLE was associated with a lower incidence of OASI with vacuum (1.1% for MLE versus 5.7% without, $OR=0.19$ [0.02-0.74]) and forceps- (4.1% for MLE versus 13.6% without, $OR=0.28$ [0.17-0.43]) assisted deliveries. Such an association was not significant for deliveries using spatulas (7% OASI rate for MLE versus 11.7% without, $OR=0.57$ [0.16-2.02]).

The univariate analysis results evaluating the effect of several maternal characteristics and delivery characteristics on the risk of OASI occurrence in operative delivery are reported in Table 1. This multivariate analysis reported that the use of MLE during operative delivery was associated with a 3-fold decrease in OASI occurrence (adjusted $OR = 0.29$ [0.20-0.43]). The other outcomes associated with OASI were the use of forceps, the use of spatulas and a birthweight higher than 4 Kg (Table 1).

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243 **DISCUSSION**

244 **Main findings**

245 During an 11-year observational period, among 2357 vaginal operative deliveries, we
246 reported a 4-fold decrease in MLE use and a 4-fold increase in OASI occurrence. The
247 utilization of MLE during operative delivery was associated with a 3-fold lower OASI
248 occurrence (adjusted OR = 0.29, 95% CI [0.20-0.43]). A restrictive policy of MLE during an
249 operative delivery appears to be associated with an increased risk of OASI whereas there
250 was no increased risk with vacuum delivery.

251 **Strengths and limitations**

252 The main strength of this study is that it provides data about the experience of an obstetrical
253 team implementing a restrictive use of MLE. Indeed, most of the papers available in the
254 literature report the experience of obstetrical teams with a routine use of MLE [7-13]. In
255 these studies, most of the operative deliveries were performed with MLE, and OASI occurred
256 in the few cases without MLE.

257 The main limitation of this study is its historical design; thus, the association between the
258 restrictive use of MLE and the increase of OASI occurrence should be cautiously interpreted.

259 There might be other factors that could contribute to the increase of OASI. However, our
260 rate of operative delivery did not significantly change during the 11 years considered. Even if
261 we reported an increase in our cesarean section rate and a decrease in our forceps-assisted
262 delivery rate associated with an increase in our vacuum utilization, the expected effect of
263 these changes would be a decrease in our OASI rate and not an increase of OASI occurrence.

264 It is possible that after 2010, the use of the RCOG classification, with a description of all sub-

types of OASIs, particularly 3a, may have induced a more frequent diagnosis of OASI in the second part of the studied period compared to the first part in which these tears may have been considered stage 2. Even if it did not reach statistical significance, we reported an increase in OASI occurrence before 2010 (from 3.1% in 2005 to 9.3% in 2009), which seems clinically significant.

Another limitation is the low number of cases in the spatulas group, which should lead to a careful interpretation of our results in this group; therefore, most of our conclusions and our discussion are focused on vacuum and forceps use.

The last limitation is that some data are missing. In most cases, the proportion of missing data was low (less than 4%), so we do not believe that this limitation biased our analysis.

Interpretation

The decrease of MLE rate that we report for operative delivery (from 78.5% to 16.2%) is consistent with other work for a comparable period in France. Indeed, Goueslard et al. reported that in France from 2007 to 2014, the French rate of MLE in case of operative delivery decrease from 60% to 50% ($p<0.05$) [16]. This decrease is more important in our experience than for the national rate. This might be explained by the fact that the national data contains rates of different teams with a variable application of the national guidelines (some with an important decrease of MLE, some other without any changes). In our experience, a restrictive use of MLE in case of operative delivery was clearly requested from all of our practitioners.

Our rate of OASI (3.9% with episiotomy, 9.7% without episiotomy) is comparable to rates reported in the literature. De Leeuw et al. reported an OASI rate of 3.5% during operative delivery with an episiotomy rate of 82.3% [9]. In their pilot study for a randomized trial about routine versus restrictive episiotomy, Murphy et al. reported an OASI rate of 8.1% in

the routine group and 10.9% in the restrictive group [10]. De Vogel et al. reported an OASI rate of 5.7% (3.3% with episiotomy and 15.6% without episiotomy) in 2861 operative deliveries with an episiotomy rate of 81% [11]. Van Bavel et al. reported an OASI rate of 2.5% with episiotomy and 14% without episiotomy for 170,969 operative deliveries with an episiotomy rate of 84.5% [7].

The potential protective effect of MLE on OASI occurrence during operative delivery that we reported is consistent with the literature, even if our experience is related to a restrictive use of MLE whereas most of the literature addresses a routine use of MLE. De Leeuw et al. reported a protective effect of MLE with vacuum (OR=0.11 [0.09-0.13]) and forceps-assisted delivery (OR=0.08 [0.07-0.11]) with an episiotomy rate of 82% [9]. De Vogel and al. reported a protective effect of episiotomy with an OR of 0.17 [0.12-0.24] in a population of 2861 operative deliveries with an episiotomy rate of 81% [11]. The pilot randomized trial by Murphy et al. did not report any change for the OASI risk during operative delivery between a restrictive versus a routine use of episiotomy [10]. Nevertheless, these results must be interpreted carefully because in the group with a restrictive use of episiotomy, there was an episiotomy rate of 50% [10]. Van Bavel et al. reported a protective effect of MLE during instrumental delivery in both primiparous (OR=0.14 [0.13-0.15]) and multiparous (OR=0.23 [0.21-0.27]) women [7].

Our results suggest that the implementation of a restrictive use of MLE is associated with an increased risk of OASI during operative deliveries. This result is significant for forceps-assisted deliveries, but not for vacuum-assisted deliveries, and is consistent with the results of our multivariate analysis, in which we reported 2-fold more OASIs with forceps delivery compared to vacuum delivery. This result is also consistent with the literature in which it is widely reported that the use of forceps for operative delivery is associated with an increased

risk of OASI [17-19]. Finally, this result is consistent with the clinical conclusion that forceps (or spatulas) placed on the fetal head increase the fetal cephalic perimeter and particularly its transverse diameter, which induces more important stress to the perineum. In our team, obstetricians were free to use the instrument of their choice. There were no guidelines that recommend a type of instrument according to the indication of operative delivery. The proportion of vacuum assisted deliveries increased from 2005 to 2015 which is consistent with the national French data which indicates that vacuum became the most commonly used instrument for operative delivery (50% of operative deliveries) [20]. Furthermore, the French 2018 guidelines recommend using preferentially a vacuum when an operative delivery is necessary and that several instrument can be used [21].

Because of its historical design, this study cannot conclude whether there is a protective effect of MLE for OASI occurrence during operative delivery and particularly for forceps- or spatula-assisted delivery. Nevertheless, considering that our rate of operative delivery remains stable whereas we reported an increase of cesarean section and vacuum assisted deliveries (two outcomes expected to reduce the incidence of OASI) the hypothesis of the MLE's role is admissible. Only prospective studies and ideally a randomized trial (restrictive versus routine use of MLE during operative deliveries) could report such an association. The fact that most operative deliveries are performed within an emergency context leads to the necessity of including a very high number of women before the indication of procedure delivery to give information to women and obtain their free written consent [22]. Prenatal information about the possibility of an operative delivery, the risk of OASI and the question of the episiotomy delivered to a high number of women could be difficult to justify based on ethical considerations. Indeed, this information may be considered unnecessarily disturbing and inappropriate. In 2008, Murphy et al. published a pilot study for a randomized trial that

reported these ethical difficulties and the fact that a complete randomized trial about this intervention would have to include a very high number of women [10]. Considering these difficulties of implementing a randomized trial to investigate the effect of MLE on the risk of OASI during operative delivery, one option leading to an analysis with a high level of evidence (level 2) may be a large prospective multicentric cohort analysis including practices of different centers with restrictive and liberal MLE use during operative delivery.

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CONCLUSION

The implementation of a restrictive policy of MLE appears associated with an increase in OASI occurrence during operative delivery. The increase of OASI occurrence is significant in forceps-assisted delivery, but not vacuum- or spatula-assisted delivery. These results on a 11 years retrospective experience must be confirmed in prospective studies. The use of MLE to protect from OASI might be considered during instrumental delivery when other risk factors exist, particularly with forceps delivery.

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Title: Does the implementation of a restrictive episiotomy policy for operative deliveries
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Disclosure of interests

The authors have no conflict of interest to disclose.

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Contribution to authorship

Bertrand GACHON: wrote the main text of this manuscript, contribution to the study design, contribution to data analysis and interpretation, contribution to statistical analysis. He wrote the revised version of the manuscript.

Carine FRADET MENARD: data collection, data analysis, statistical analysis, review of each version of the manuscript. She reviewed the revised version of the manuscript.

Fabrice PIERRE: contribution to the study design, contribution to data analysis and interpretation and review of each version of the manuscript. She reviewed the revised version of the manuscript.

Xavier FRITEL: contribution to the study design, contribution to data analysis and interpretation, contribution to statistical analysis, draft the work. She reviewed the revised version of the manuscript.

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Details of ethical approval

Ethical committee approval was not required for this study because we solely reported on anonymized data from patient's medical records. These data have been collected in accordance with our usual practices and patients underwent no supplementary procedures for this investigation. Upon admission, each patient at our institution receives an institutional chart that specifically mention the possibility that anonymized medical data collected during hospitalization could be used for medical research.

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Title: Does the implementation of a restrictive episiotomy policy for operative deliveries increase the risk of obstetric anal sphincter injury?

Tables and Figures list

Table 1: Univariate and multivariate analysis for OASIS occurrence according to maternal and delivery characteristics (N=2357 instrumental deliveries).

Figure 1: Flow chart for deliveries of cephalic singleton above 34 weeks

Figure 2: Cross evolution of mediolateral episiotomy annual and OASI annual rates in case of operative delivery from 2005 to 2015

Figure 3: Cross evolution of mediolateral episiotomy and OASI annual rates according to the type of instrument from 2005 to 2015

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