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

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28

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35

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

44 **ABSTRACT: 250 words**

45

46 **Purpose**

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

50 **Methods**

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

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

60 **Results**

61 In total, 2357 operative deliveries were assessed, including 847 vacuum-, 1350 forceps- and
62 160 spatula-assisted deliveries. Of these, 950 were performed with MLE and 1407 without;
63 37 OASIs (3.9%) occurred in the MLE group, and 137 (9.7%) in the no-MLE group. Between
64 2005 and 2015, MLE use decreased from 78.5% to 16.2% and OASI occurrence increased
65 from 3.1% to 12.7%. The increase in OASI occurrence was significant for forceps deliveries,
66 but not for vacuum or spatula deliveries. Operative delivery with MLE was associated with a
67 3-times lower OASI occurrence than that without MLE (adjusted OR = 0.29, 95% CI [0.20-
68 0.43]).

69 **Conclusions**

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

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76 increase the risk of obstetric anal sphincter injury?

77 **MAIN TEXT: 3.054 words**

78

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.

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

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

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123 MATERIALS AND METHODS

124 This is a retrospective observational study based on French university maternity data
125 (Poitiers University Hospital, France). This study included all the operative deliveries at more
126 than 34 weeks of gestation for singleton births in cephalic presentation between January
127 2005 and December 2015.

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

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

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

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

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

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

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

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195 **RESULTS**

196 During the 11-year period, 22,023 singleton deliveries in cephalic presentation at 34 weeks
197 or over occurred, among which 2357 were operative vaginal deliveries (10.7%) (Figure 1). A
198 total of 1350 operative deliveries were performed with forceps (57.3%), 160 with spatulas
199 (6.8%) and 847 with a vacuum (35.9%). Additionally, 950 of the operative deliveries (40.3%)
200 were performed with MLE (Figure 1). OASI occurred less frequently (3.9%) in operative
201 deliveries with MLE than without MLE (9.7%; $p < 0.005$) (Figure 1).

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

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

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

214 We drastically decreased our rate of MLE during operative delivery from 78.5% in 2005 to
215 16.2% in 2015 ($p < 0.0005$). During the same period, we reported a very significant increase in
216 the OASI rate in operative deliveries from 3.1% to 12.7% ($p < 0.0005$) (Figure 2). If we focus on

217 the first part of this study (2005-2009), we report a significant decrease in MLE use (78.5% to
218 43.5%; $p < 0.05$) without a statistically significant increase in OASI occurrence (3.1% to 9.3%;
219 $p = 0.08$). However, during the second part of the study (2010-2015), the decrease of MLE use
220 was no longer statistically significant (26.9% to 16.2%; $p = 0.35$), and we reported an increase
221 in OASI occurrence from 6.1% to 12.7% ($p < 0.005$).

222 Considering the entire 11-year period, for each instrument, we significantly decreased our
223 rate of MLE (Figure 3). In the forceps group, the rate of OASI significantly increased (3.9% to
224 21%; $p < 0.005$) whereas it remained stable in the vacuum (0 to 6.1%; $p = 0.19$) and spatula
225 (3.2% to 0; $p = 0.87$) groups (Figure 3).

226 In a subgroup univariate analysis, MLE was associated with a lower incidence of OASI with
227 vacuum (1.1% for MLE versus 5.7% without, $OR = 0.19$ [0.02-0.74]) and forceps- (4.1% for MLE
228 versus 13.6% without, $OR = 0.28$ [0.17-0.43]) assisted deliveries. Such an association was not
229 significant for deliveries using spatulas (7% OASI rate for MLE versus 11.7% without, $OR = 0.57$
230 [0.16-2.02]).

231 The univariate analysis results evaluating the effect of several maternal characteristics and
232 delivery characteristics on the risk of OASI occurrence in operative delivery are reported in
233 Table 1. This multivariate analysis reported that the use of MLE during operative delivery
234 was associated with a 3-fold decrease in OASI occurrence (adjusted $OR = 0.29$ [0.20-0.43]).
235 The other outcomes associated with OASI were the use of forceps, the use of spatulas and a
236 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-

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

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

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

275 **Interpretation**

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

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

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

294 The potential protective effect of MLE on OASI occurrence during operative delivery that we
295 reported is consistent with the literature, even if our experience is related to a restrictive
296 use of MLE whereas most of the literature addresses a routine use of MLE. De Leeuw et al.
297 reported a protective effect of MLE with vacuum (OR=0.11 [0.09-0.13]) and forceps-assisted
298 delivery (OR=0.08 [0.07-0.11]) with an episiotomy rate of 82% [9]. De Vogel and al. reported
299 a protective effect of episiotomy with an OR of 0.17 [0.12-0.24] in a population of 2861
300 operative deliveries with an episiotomy rate of 81% [11]. The pilot randomized trial by
301 Murphy et al. did not report any change for the OASI risk during operative delivery between
302 a restrictive versus a routine use of episiotomy [10]. Nevertheless, these results must be
303 interpreted carefully because in the group with a restrictive use of episiotomy, there was an
304 episiotomy rate of 50% [10]. Van Bavel et al. reported a protective effect of MLE during
305 instrumental delivery in both primiparous (OR=0.14 [0.13-0.15]) and multiparous (OR=0.23
306 [0.21-0.27]) women [7].

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

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

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

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

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364 CONCLUSION

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

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393 **Disclosure of interests**

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395 The authors have no conflict of interest to disclose.

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415 **Contribution to authorship**

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

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

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

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

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439 **Details of ethical approval**

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

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460 **Title:** Does the implementation of a restrictive episiotomy policy for operative deliveries

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466 There was no funding for this study

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

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558 **Tables and Figures list**

559

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

562

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

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

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

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