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► To cite this version:

Xavier * Fritel, Jean-Patrick Schaal, Arnaud Fauconnier, Violaine Bertrand, Caroline Levet, et al.. Pelvic floor disorders 4 years after first delivery: a comparative study of restrictive versus systematic episiotomy.. *BJOG An International Journal of Obstetrics and Gynaecology*, 2008, 115 (2), pp.247-52. 10.1111/j.1471-0528.2007.01540.x . inserm-00356856v2

HAL Id: inserm-00356856

<https://www.hal.inserm.fr/inserm-00356856v2>

Submitted on 26 Feb 2009

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1 **Pelvic floor disorders 4 years after first delivery, a comparative**
2 **study of restrictive versus systematic episiotomy**

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23 Key words: Episiotomy, Delivery, Perineal pain, Urinary incontinence, Anal incontinence.

24 Short title: Restrictive vs. routine episiotomy and incontinence.

25 **Abstract**

26 **Objective:** To compare two policies for episiotomy: restrictive and systematic.

27 **Design:** Quasi-randomised comparative study.

28 **Setting:** Two French university hospitals with contrasting policies for episiotomy: one using it
29 restrictively and the second routinely.

30 **Population:** 774 nulliparous women delivered during 1996 of a singleton in cephalic
31 presentation at a term of 37-41 weeks.

32 **Methods:** A questionnaire was mailed 4 years after delivery. Sample size was calculated to
33 allow us to show a 10% difference in the prevalence of urinary incontinence with 80% power.

34 **Main outcome measures:** Urinary incontinence, anal incontinence, perineal pain, and pain
35 during intercourse.

36 **Results:** We received 627 responses (81%), 320 from women delivered under the restrictive
37 policy, 307 from women delivered under the routine policy. In the restrictive group, 186
38 (49%) deliveries included mediolateral episiotomies and in the routine group, 348 (88%).

39 Four years after the first delivery, the groups did not differ in the prevalence of urinary
40 incontinence (26 versus 32%), perineal pain (6 versus 8%), or pain during intercourse (18
41 versus 21%). Anal incontinence was less prevalent in the restrictive group (11 versus 16%).

42 The difference was significant for flatus (8 versus 13%) but not for faecal incontinence (3%
43 for both groups). Logistic regression confirmed that a policy of routine episiotomy was
44 associated with a risk of anal incontinence nearly twice as high as the risk associated with a
45 restrictive policy (OR=1.84, 95% CI:1.05-3.22).

46 **Conclusions:** A policy of routine episiotomy does not protect against urinary or anal
47 incontinence 4 years after first delivery.

48 Introduction

49 Episiotomy has long been recommended to avoid perineal sequelae after delivery.
50 Despite the absence of evidence of its efficacy, it is still very widely used.¹ Nonetheless its
51 frequency varies greatly between hospitals and in different European countries. For example,
52 rates are reported to be 10% in Upssala (Sweden) compared with 58% in Perugia (Italy).^{2, 3}
53 Little is known about its long-term sequelae or benefits. Our objective was to compare results
54 for pelvic floor disorders several years after first delivery at hospitals with two different
55 policies for episiotomy: one with a policy of routine episiotomy and the other with a policy of
56 avoiding episiotomy as much as possible.

57 Methods

58 The study included nulliparous women who gave birth in 1996 at a term of 37-41
59 weeks to a liveborn singleton child in cephalic presentation and who had an up-to-date mail
60 address in 2000. Examination of delivery registries allowed us to identify the mothers who
61 met these criteria. Data about the mothers (age, height, weight before conception), pregnancy
62 (presentation), and delivery (epidural, mode of delivery, duration of the active-pushing second
63 stage of labour, child's weight) were collected at delivery. Information about pelvic floor
64 disorders was obtained from a questionnaire mailed 4 years after delivery. A second and even
65 a third mailing went to the women from whom we received no response. The questionnaire
66 asked about educational level, postpartum pelvic floor exercises, subsequent deliveries, and
67 urinary symptoms during the preceding 4 weeks. Those women who answered *yes* to the entry
68 question "*Do you have involuntary loss of urine?*" were considered to have urinary
69 incontinence and were then asked further questions from a validated questionnaire,⁴ about the
70 frequency, amount, and circumstances of leakage, and if incontinence was a problem for her.
71 Stress incontinence was defined by any positive response (*occasionally, sometimes, most of*
72 *the time, or all of the time*) to "*Does urine leak when you are physically active, exert yourself,*
73 *cough or sneeze?*", urge incontinence by any positive response to "*Does urine leak before*
74 *you can get to the toilet?*", and mixed incontinence by a positive response to both of previous
75 questions.⁴ Severity of urinary incontinence was measured with Sandvik's score, which has
76 been validated with pad-weighing tests.⁵ Additional items asked about urinary urgency,
77 voiding difficulty, pain, and anal incontinence. Urinary urgency was assessed by "*Do you*
78 *have to rush to the toilet to urinate?*".⁴ Voiding difficulty was assessed by "*Do you have*
79 *difficulties in emptying your bladder?*". Perineal pain was defined as a "yes" (versus *no*)
80 response to "*Do you have chronic perineal pain (perineum designates the skin and muscle*
81 *around the vaginal and anal outlets)?*". Pain during intercourse was defined as a *yes* (versus

82 *no* response or *no intercourse at present*) response to “*Do you experience pain during sexual*
83 *intercourse?*”. Anal incontinence was defined by *yes* (versus *no*) response to “*Do you have*
84 *involuntary loss of flatus or stool?*”. The severity of anal incontinence was assessed as a
85 function of the type of incontinence (gas only, liquid stool or solid stool) and its frequency,
86 according to Pescatori’s score.⁶ The questionnaire used for the study is available from the
87 authors upon request.

88 The questionnaire was initially tested on a small sample (50 women in each maternity
89 ward). This pilot test allowed us to estimate the prevalence of urinary incontinence (20%)
90 among women with vaginal deliveries, the percentage of caesarean sections (10%), and the
91 risk of non-response (20%) overall and in each facility. We determined that it would require
92 248 responses from each group to show a 10% difference in urinary incontinence (15% versus
93 25%, $\alpha=0.05$ and $\beta=0.20$, bilateral test) among women with vaginal deliveries. Given the
94 rates of caesarean delivery and non-response, we needed at least 345 women in each group.
95 This number is approximately the number of nulliparous women meeting the inclusion criteria
96 delivered in one year in each hospital.

97 Policies and protocols at the first hospital (A) recommended strongly against
98 episiotomy, while in the second (B), it was strongly recommended for first deliveries. All
99 episiotomies were mediolateral. In both cases, residents repaired episiotomies. Technical
100 guidelines for episiotomy and its repair were similar in each hospital.^{7,8} Each obstetric
101 department had previously published its arguments in favour of or against episiotomy.^{9,10}

102 We first analysed the differences between Hospitals A and B and between responders
103 and non-responders (Table 1). We also examined the variables associated with episiotomies in
104 the restrictive-policy maternity ward (A).

105 We used bivariate analysis to examine perineal disorders (urinary incontinence,
106 urinary urgency, voiding difficulty, perineal pain, pain during intercourse, and anal

107 incontinence) as a function of maternity ward episiotomy policy (routine versus restrictive).
108 Analysis was performed on an intention-to-treat basis, as if patients had been randomised
109 before delivery. In particular, women with caesareans were not excluded because each
110 nulliparous woman included had a singleton term pregnancy in cephalic presentation, with no
111 indication at inclusion for elective caesarean section, and each woman was exposed to the
112 hospital episiotomy policy. The factors retained for the multivariable analysis were those that
113 differed significantly between the two hospitals, even if they were not significantly associated
114 with incontinence. Each statistical test was considered significant if $p < 0.05$. All analyses
115 were performed with Statview (SAS Institute Inc., Cary, NC, USA).

116 Our study complied with French law about biomedical research. The department head
117 of each department approved the study. Each respondent provided informed consent.

118 Results

119 Of the women who gave birth in 1996, 774 met the inclusion criteria. We had 627
120 (81%) responses to the questionnaire. Table 1 reports the differences between those who gave
121 birth in hospital A and hospital B and between respondents and non-respondents. The women
122 who gave birth in hospital B were significantly older and had a higher educational level, more
123 epidurals and more instrumental or caesarean deliveries. Respondents were significantly
124 older, had more spontaneous deliveries and came more often from hospital A. In the maternity
125 ward with a restrictive policy (A), episiotomy in women with vaginal delivery was associated
126 with epidural anaesthesia (53% episiotomies compared with 38% without epidural, $p = 0.01$),
127 with instrumental intervention (71% episiotomy versus 39% for spontaneous delivery, $p <$
128 0.0001), and with active second stage pushing for longer than 20 minutes (78% episiotomies
129 versus 45% for less than 20 minutes, $p < 0.0001$). The other variables (age, BMI, infant birth
130 weight) were not associated with episiotomy.

131 The bivariate comparison between the two institutions showed no differences for
132 urinary disorders, perineal pain or pain during intercourse. Flatus incontinence, on the other
133 hand, was more frequent in women who gave birth at the maternity ward with a routine
134 episiotomy policy (Table 2). Anal incontinence was reported by 33 women in the restrictive
135 group and 50 in the routine group. Its severity, measured by Pescatori's score, was similar in
136 both groups with a median score of 3 in both. Among women reporting only flatus
137 incontinence, 21 (33%) considered it *a serious problem*, 10 (16%) *quite a problem*, and 31
138 (48%) *a bit of a problem*; these results did not differ significantly between the 2 hospitals ($p =$
139 0.79).

140 Among women with vaginal deliveries (spontaneous or instrumental), the prevalence
141 of urinary incontinence was 27% (78/294) in the restrictive episiotomy group versus 33%

142 (92/275) in the routine group ($p=0.07$), and the prevalence of anal incontinence was 10%
143 (29/291) in the restrictive and 17% (46/269) in the routine group ($p=0.01$).

144 The comparison between the hospitals for urinary incontinence and anal incontinence
145 was adjusted according to the known differences between the populations of each hospital. In
146 the multivariable analysis, the episiotomy policy did not affect the risk of urinary
147 incontinence 4 years after the first delivery. On the other hand, a routine episiotomy policy
148 nearly doubled the risk of anal incontinence (Table 3).

149 Discussion

150 Our study found no benefits to routine mediolateral episiotomy during first deliveries.
151 This result is consistent with the few studies that have compared restrictive to routine
152 episiotomy.¹¹ The West Berkshire perineal management trial is the only comparative trial that
153 focused on late consequences of mediolateral episiotomy. It found no differences in urinary
154 incontinence, perineal pain, or dyspareunia 3 years after delivery in the 2 groups, randomised
155 to restrictive (11%) or liberal (52%) use of mediolateral episiotomy.¹² Our work confirms that
156 liberal use of episiotomy does not diminish the prevalence of urinary incontinence. It also
157 confirms that episiotomy is not associated with an increased risk of perineal pain or
158 dyspareunia.

159 Our questionnaire response rate (81%) 4 years after first delivery was similar to the
160 rate observed 3 years after the West Berkshire trial (76% among 885 women with known
161 addresses).¹² The questionnaires were in French. While it is unlikely that any women who did
162 not speak French responded, we do not think that there is any reason that language should
163 have a differential effect on the prevalence of perineal sequelae between the 2 institutions.

164 The restrictive episiotomy rate may appear quite high, but it must be borne in mind
165 that episiotomy rates are higher in France than elsewhere in Europe. In 1996, the date of first
166 delivery for the women in our study, the episiotomy rate in France was 79% for nulliparous
167 women; in 2002 it was still 68%.¹³

168 In our study flatus incontinence was more frequent in the women in the routine-
169 episiotomy group. The association between episiotomy and perineal trauma (3rd degree
170 lacerations) is complex. On the one hand, mediolateral episiotomy is associated with a lower
171 risk of anal sphincter rupture at delivery.¹⁴⁻¹⁵ On the other hand, it has also been shown that
172 the number of mediolateral episiotomies can be reduced without an increase in perineal
173 trauma.^{9, 16} Thus the protective effect of mediolateral episiotomy may be limited to situations

174 in which its use is inevitable, while its routine performance may increase the risk of anal
175 incontinence. It is possible that performing an episiotomy when the anal sphincter is not in
176 danger increases risk of direct scissors injury to the sphincter. Unfortunately we do not know
177 what episiotomy rate offers the best balance between benefits and risks for the anal sphincter.
178 Similarly, we do not know at what moment of perineal dilatation during delivery or according
179 to what clinical signs it is best to perform an episiotomy to protect the external anal sphincter.

180 The interest of our work is that we looked at late consequences of episiotomy, a
181 subject for which data are sparse. We decided not to attempt a randomised trial, such as the
182 West Berkshire perineal management trial, because it appears very difficult to us to ask each
183 team trained according to particular practice to develop a different practice for the trial.
184 Deliveries without episiotomy are practised differently than those with routine episiotomies.
185 The method of comparison used in our study is called "quasi-randomised" because the
186 exposure (episiotomy policy) is controlled. If the populations are similar and adjustment is
187 planned for the possible differences, this type of study produces robust findings.

188 Despite the adjustment for known differences between institutions (women's age,
189 educational level, gestational age, epidural, time of pushing, mode of delivery, birth weight,
190 postpartum pelvic floor exercises), it remains possible that our results are due to other
191 differences in the populations or in medical practices between the 2 institutions. We did not
192 take into account such risk factors for postpartum incontinence as smoking, bladder neck
193 mobility or prenatal pelvic floor exercises.¹⁷⁻¹⁹ However, it is very unlikely that taking these
194 possible differences between the 2 institutions into account would lead to the conclusion that
195 routine episiotomy has a protective effect.

196 Conclusion

197 A policy of routine episiotomy does not protect against urinary or anal incontinence 4
198 years after first delivery.

199 Acknowledgements

200 We thank Jo Ann Cahn and Liliane Cotte for editorial assistance.

201

202 Contribution to authorship

203 XF contributed to the conception, design, analysis, interpretation of data and article writing,

204 JPS and AP contributed to the conception, design, data interpretation and revision of the

205 manuscript, VB and CL contributed to data management, AF contributed to analysis, data

206 interpretation and revision of the manuscript.

207

208 Disclosure of interests

209 We have no direct or indirect commercial financial incentive associated with publishing the

210 article.

211

212 Details of ethics approval

213 Our work complied with French statutes and regulations, which authorise epidemiological

214 surveys without advance approval of an ethics committee. Our survey involved no

215 intervention and is thus excluded from the French statute on biomedical research (Loi Huriet-

216 Sérusclat, dated 20 December 1998). We complied with all French statutes concerning data

217 about the subjects, confidentiality and restrictions (e.g., no religious or racial data). Informed

218 consent was obtained from each responding woman.

219

220 Funding

221 We had no exterior funding for this work.

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223 Table 1

224 Women's characteristics according to maternity unit (A: restrictive episiotomy, B: routine
 225 episiotomy) and response to questionnaire. Chi² test for nominal variables [n (%)], t-test for
 226 continuous variables [mean (sd)].

Characteristics		Total mean N	Maternity			Response to questionnaire		
			A	B	p	Yes	No	p
			mean (sd) n (%)	mean (sd) n (%)		mean (sd) n (%)	mean (sd) n (%)	
High School Diploma	Yes No		191 (61) 120 (39)	220 (74) 79 (26)	0.001	411 (67) 199 (33)	*	
Age at delivery	(years)	28.2	27.1 (4.7)	29.3 (4.5)	< 0.0001	28.4 (4.5)	27.4 (5.2)	0.03
	< 30	522	288 (76)	234 (59)	< 0.0001	415 (66)	107 (73)	0.12
	≥ 30	252	91 (24)	161 (41)		212 (34)	40 (27)	
Body Mass Index	(kg/m ²)	21.4	21.5 (3.1)	21.4 (3.0)	0.52	21.4 (3.0)	21.7 (3.3)	0.31
	< 25	690	340 (90)	350 (89)	0.53	564 (90)	126 (87)	0.21
	≥ 25	79	36 (10)	43 (11)		60 (10)	19 (13)	
UI before pregnancy	Yes No		17 (6) 283 (94)	16 (5) 282 (95)	0.87	33 (6) 565 (94)	*	
UI during pregnancy	Yes No		65 (21) 238 (79)	68 (23) 230 (77)	0.69	133 (22) 468 (78)	*	
Gestational age	(weeks)	39.9	40.2 (1.2)	39.6 (0.9)	< 0.0001	39.9 (1.1)	39.7 (1.0)	0.06
	< 40	385	147 (39)	238 (60)	< 0.0001	306 (49)	79 (54)	0.28
	≥ 40	389	232 (61)	157 (40)		321 (51)	68 (46)	
Epidural	Yes No	654 120	277 (73) 102 (27)	377 (95) 18 (5)	< 0.0001	526 (84) 101 (16)	128 (87) 19 (13)	0.34
Active 2 nd phase	(min)	12.0	13.1 (7.7)	11.0 (7.6)	0.0002	12.1 (7.7)	11.5 (7.7)	0.41
	< 20	694	330 (89)	364 (92)	0.13	561 (90)	133 (91)	0.82
	≥ 20	72	41 (11)	31 (8)		59 (10)	13 (9)	
Mode of delivery	Spontaneous Operative Caesarean	435 266 73	235 (62) 117 (31) 27 (7)	200 (50) 149 (38) 46 (12)	0.003	368 (59) 209 (33) 50 (8)	67 (46) 57 (39) 23 (16)	0.002
Episiotomy	Yes No	534 240	186 (49) 193 (51)	348 (88) 47 (12)	< 0.0001	433 (69) 194 (31)	101 (69) 46 (31)	0.93
3 rd degree tear	Yes No	7 767	2 (0.5) 377 (99.5)	5 (1.3) 395 (98.7)	0.28	6 (1.0) 621 (99.0)	1 (0.7) 146 (99.3)	0.75
Birth weight	(g)	3266	3293 (430)	3240 (394)	0.08	3273 (413)	3239 (413)	0.37
	< 4000	754	362 (96)	388 (98)	0.03	605 (96)	145 (99)	0.18
	≥ 4000	24	17 (4)	7 (2)		22 (4)	2 (1)	
Response to questionnaire	Yes No	627 147	320 (84) 59 (16)	307 (78) 88 (22)	0.02			
Postpartum pelvic floor exercises	Yes No		93 (31) 210 (69)	147 (49) 151 (51)	<0.0001	240 (40) 361 (60)	*	
Second delivery	Yes No		195 (63) 117 (37)	186 (63) 110 (37)	0.93	381 (63) 227 (37)	*	

227 * data available only for responders.

228 Table 2

229 Pelvic floor disorders in 627 women 4 years after delivery according to episiotomy policy
 230 (bivariate analysis, χ^2 test).

231

Pelvic floor disorders 4 years after first delivery		Maternity A restrictive episiotomy n (%)	Maternity B routine episiotomy n (%)	p
Urinary incontinence (UI)	No	231 (74)	207 (68)	0.09
	Yes	82 (26)	99 (32)	
UI type (% among women with UI)	Stress	24 (29)	31 (31)	0.67
	Urge	6 (7)	6 (6)	
	Mixed	51 (62)	58 (59)	
UI severity (Sandvik score)	Dry	231 (74)	207 (68)	0.45
	Slight	48 (15)	62 (20)	
	Moderate	21 (7)	21 (7)	
	Severe	8 (3)	8 (3)	
UI bothersome (% among women with UI)	<i>Not a problem</i>	7 (9)	17 (18)	0.33
	<i>A bit of a problem</i>	53 (67)	54 (56)	
	<i>Quite a problem</i>	12 (15)	15 (16)	
	<i>A serious problem</i>	7 (9)	10 (10)	
Urgency	<i>Never</i>	133 (43)	114 (38)	0.22
	<i>Occasionally</i>	102 (33)	116 (39)	
	<i>Sometimes</i>	54 (17)	57 (19)	
	<i>Often or all of the time</i>	23 (7)	14 (5)	
Difficult voiding	<i>Never</i>	224 (71)	217 (72)	0.32
	<i>Occasionally</i>	44 (14)	52 (17)	
	<i>Sometimes</i>	37 (12)	24 (8)	
	<i>Often or all of the time</i>	9 (3)	7 (2)	
Perineal pain	No	291 (94)	272 (92)	0.26
	Yes	17 (6)	23 (8)	
Pain during intercourse	No intercourse	7 (2)	9 (3)	0.45
	No pain	247 (80)	225 (76)	
	Yes	54 (18)	62 (21)	
Anal incontinence (AI)	No	276 (89)	249 (84)	0.04
	Yes	33 (11)	49 (16)	
AI bothersome (% among women with AI)	<i>Not a problem</i>	0 (0)	1 (2)	0.65
	<i>A bit of a problem</i>	14 (42)	22 (45)	
	<i>Quite a problem</i>	7 (21)	6 (12)	
	<i>A serious problem</i>	12 (36)	18 (37)	
AI type	Flatus only	24 (8)	40 (13)	0.02
	Stool	9 (3)	9 (3)	

232 Table 3

233 Risk of urinary and anal incontinence 4 years after first delivery according to episiotomy
 234 policy (routine versus restrictive) adjusted for variables associated with maternity hospital
 235 (logistic regression).

Characters	N	Urinary Incontinence		Anal Incontinence		
		Crude n (%) OR (95% CI)	Adjusted OR (95% CI)	Crude n (%) OR (95% CI)	Adjusted OR (95% CI)	
Maternity	A restrictive	320	82 (26) 1	1	33 (11) 1	1
	B systematic	307	99 (32) 1.35 (0.95-1.91)	1.21 (0.80-1.83)	49 (16) 1.65 (1.03-2.64)	1.84 (1.05-3.22)
High school Diploma	No	199	57 (29) 1	1	26 (13) 1	1
	Yes	411	118 (29) 0.98 (0.67-1.42)	0.74 (0.49-1.10)	54 (13) 0.95 (0.58-1.58)	0.80 (0.47-1.35)
Age at delivery	< 30 years	415	98 (24) 1	1	48 (12) 1	1
	≥ 30 years	212	83 (39) 2.07 (1.45-2.97)	2.13 (1.46-3.13)	34 (16) 1.45 (0.90-2.34)	1.31 (0.79-2.17)
Gestational age	< 40 weeks	306	82 (27) 1	1	43 (14) 1	1
	≥ 40 weeks	321	99 (31) 1.22 (0.86-1.72)	1.51 (1.03-2.22)	39 (12) 0.84 (0.53-1.33)	0.98 (0.60-1.61)
Epidural	No	101	28 (28) 1	1	17 (17) 1	1
	Yes	526	153 (29) 1.06 (0.66-1.70)	0.88 (0.52-1.49)	65 (12) 0.69 (0.38-1.23)	0.47 (0.24-0.91)
Active 2 nd phase	< 20 min	561	161 (29) 1	1	68 (12) 1	1
	≥ 20 min	59	19 (32) 1.16 (0.65-2.06)	1.00 (0.54-1.85)	13 (22) 1.97 (1.01-3.83)	2.17 (1.07-4.43)
Mode of delivery	Spontaneous	368	102 (28) 1	1	45 (12) 1	1
	Operative	209	68 (33) 1.25 (0.86-1.80)	1.08 (0.73-1.61)	30 (14) 1.19 (0.72-1.96)	1.13 (0.67-1.92)
	Caesarean	50	11 (22) 0.72 (0.35-1.46)	0.63 (0.29-1.34)	7 (14) 1.21 (0.51-2.86)	1.22 (0.49-3.00)
Birth weight	< 4000 g	605	175 (29) 1	1	81 (13) 1	1
	≥ 4000 g	22	6 (27) 0.90 (0.35-2.35)	0.74 (0.26-2.07)	1 (5) 0.66 (0.15-2.88)	0.34 (0.04-2.74)
Postpartum pelvic floor exercises	No	361	82 (23) 1	1	40 (11) 1	1
	Yes	240	95 (40) 2.20 (1.54-3.14)	2.12 (1.45-3.10)	39 (17) 1.54 (0.96-2.48)	1.43 (0.86-2.36)