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

Authors

Xavier Fritel, MD. 1

Jean-Patrick Schaal, MD, PhD. 2

Arnaud Fauconnier, MD, PhD. 1

Violaine Bertrand, MD. 2

Caroline Levet. 1

Alain Pigné, MD. 1

Institution

1 Service de Gynécologie & Obstétrique, Hôpital Rothschild AP-HP, Université Pierre-et-Marie-Curie, Paris, France. .

2 Service de Gynécologie et Obstétrique, Hôpital saint-Jacques, Université de Franche-Comté, Besançon, France.

Correspondence

Dr Xavier FRITEL

Gynécologie & Obstétrique

CHD Félix-Guyon

F-97405 Saint-Denis cedex, France

tel: +33.262.905.540

fax: +33.262.907.730

e-mail: x-fritel@chd-fguyon.fr (best contact address)

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

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.

Methods

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

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

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

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

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

We used bivariate analysis to examine perineal disorders (urinary incontinence, 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.

Results

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

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

Among women with vaginal deliveries (spontaneous or instrumental), the prevalence 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).

Discussion

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

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

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

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

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

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

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

Conclusion

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

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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

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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	Maternity			Response to questionnaire		
			A	B	p	Yes	No	p
			mean	mean (sd)		mean (sd)	mean (sd)	
			N	n (%)		n (%)	n (%)	
High School Diploma	Yes		191 (61)	220 (74)	0.001	411 (67)	*	
	No		120 (39)	79 (26)		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		17 (6)	16 (5)	0.87	33 (6)	*	
	No		283 (94)	282 (95)		565 (94)		
UI during pregnancy	Yes		65 (21)	68 (23)	0.69	133 (22)	*	
	No		238 (79)	230 (77)		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	654	277 (73)	377 (95)	< 0.0001	526 (84)	128 (87)	0.34
	No	120	102 (27)	18 (5)		101 (16)	19 (13)	
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	435	235 (62)	200 (50)	0.003	368 (59)	67 (46)	0.002
	Operative	266	117 (31)	149 (38)		209 (33)	57 (39)	
	Caesarean	73	27 (7)	46 (12)		50 (8)	23 (16)	
Episiotomy	Yes	534	186 (49)	348 (88)	< 0.0001	433 (69)	101 (69)	0.93
	No	240	193 (51)	47 (12)		194 (31)	46 (31)	
3 rd degree tear	Yes	7	2 (0.5)	5 (1.3)	0.28	6 (1.0)	1 (0.7)	0.75
	No	767	377 (99.5)	395 (98.7)		621 (99.0)	146 (99.3)	
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	627	320 (84)	307 (78)	0.02			
	No	147	59 (16)	88 (22)				
Postpartum pelvic floor exercises	Yes		93 (31)	147 (49)	<0.0001	240 (40)	*	
	No		210 (69)	151 (51)		361 (60)		
Second delivery	Yes		195 (63)	186 (63)	0.93	381 (63)	*	
	No		117 (37)	110 (37)		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, chi² 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)	0.94

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 (%)	Adjusted OR (95% CI)	Crude n (%)	Adjusted OR (95% CI)
Maternity	A restrictive	320	82 (26)	1	33 (11)	1
	B systematic	307	99 (32)	1.35 (0.95-1.91)	49 (16)	1.84 (1.05-3.22)
High school Diploma	No	199	57 (29)	1	26 (13)	1
	Yes	411	118 (29)	0.98 (0.67-1.42)	54 (13)	0.80 (0.47-1.35)
Age at delivery	< 30 years	415	98 (24)	1	48 (12)	1
	≥ 30 years	212	83 (39)	2.07 (1.45-2.97)	34 (16)	1.31 (0.79-2.17)
Gestational age	< 40 weeks	306	82 (27)	1	43 (14)	1
	≥ 40 weeks	321	99 (31)	1.22 (0.86-1.72)	39 (12)	0.98 (0.60-1.61)
Epidural	No	101	28 (28)	1	17 (17)	1
	Yes	526	153 (29)	1.06 (0.66-1.70)	65 (12)	0.47 (0.24-0.91)
Active 2 nd phase	< 20 min	561	161 (29)	1	68 (12)	1
	≥ 20 min	59	19 (32)	1.16 (0.65-2.06)	13 (22)	2.17 (1.07-4.43)
Mode of delivery	Spontaneous	368	102 (28)	1	45 (12)	1
	Operative	209	68 (33)	1.25 (0.86-1.80)	30 (14)	1.13 (0.67-1.92)
	Caesarean	50	11 (22)	0.72 (0.35-1.46)	7 (14)	1.22 (0.49-3.00)
Birth weight	< 4000 g	605	175 (29)	1	81 (13)	1
	≥ 4000 g	22	6 (27)	0.90 (0.35-2.35)	1 (5)	0.34 (0.04-2.74)
Postpartum pelvic floor exercises	No	361	82 (23)	1	40 (11)	1
	Yes	240	95 (40)	2.20 (1.54-3.14)	39 (17)	1.43 (0.86-2.36)