

Trends in urinary incontinence in women between 4 and 24 months postpartum in the EDEN cohort.

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1	<u>Title Page</u>
2	Trends in urinary incontinence in women between 4 and 24 months postpartum in the EDEN
3	cohort
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20	Shortened running title
21	Urinary incontinence between 4 and 24 months postpartum
22	Word count: 2646

23	Trends in urinary incontinence in women between 4 and 24 months postpartum in the EDEN						
24	cohort						
25	Abstract						
26	Objective: Our aim was to study risk factors associated with the prevalence, incidence and						
27	remission of urinary incontinence (UI) between 4 and 24 months postpartum.						
28	Design: Longitudinal study (EDEN cohort).						
29	Setting: Two French university hospitals.						
30	Population: 1643 women completed the questionnaire at 4 months and 1409 at 24 months,						
31	including 1354 who completed it both times.						
32	Methods: Multivariate analyses identified risk factors for UI prevalence at 24 months						
24	postpartum, persistent UI versus remission, de novo UI versus continence, de novo UI versus						
34	persistent UI, and changes in IU severity between 4 and 24 months postpartum.						
35	Main Outcome Measures: Postnatal UI and Sandvik UI severity score.						
36	Results: UI prevalence was 20.7% (340/1643) at 4 months and 19.9% (280/1409) at 24.						
37	Significant factors associated with UI at 24 months were older age (OR = 1.07 /year [95% CI:						
38	1.04-1.11]), BMI (2.35 [1.44-3.85] \geq 30 versus < 25 kg/m ²), higher parity (1.77 [1.14-2.76] \geq						
39	3 versus 1), breast feeding (1.54 [1.08-2.19] \geq 3 versus < 3 months), pregnant at follow-up						
40	(3.44 [2.25-5.26]), and caesarean delivery (0.62 [0.40-0.97] versus vaginal). The likelihood of						
41	UI remission at 24 months was 51.9% (149/287). Caesarean delivery was associated with						
42	increased likelihood of UI remission (0.43 [0.19-0.97]). The risk of de novo UI at 24 months						
43	was 12.5% (135/1067) and was associated with a new pregnancy (3.63 [2.13-6.20]).						
44	Conclusions: Between 4 and 24 months postpartum UI, remission occurred in half of the						
45							

cases. These postnatal UI changes were essentially related to mode of delivery and subsequent

pregnancy.

47

48

Abstract word count: 248.

49

Keywords: female urinary incontinence, postpartum, remission, incidence, pregnancy, cohort

INTRODUCTION

50

51 Urinary incontinence (UI) is defined by complaints of involuntary urinary leakage. This frequent symptom is reported by 10 to 40% of women.¹ It is especially disabling, has an 52 unfavourable effect on women's social and working lives, and is costly from both individual 53 54 (cost of hygiene products and treatment) and societal (health insurance costs and lost work days) perspectives. 55 The natural history of UI remains poorly understood.² Parity, ageing and obesity are the 56 predominant risk factors for women. The prevalence of urinary leakage increases substantially 57 during pregnancy as term approaches.² Different studies report prevalence rates of postpartum 58 UI ranging from 3% to 73%.² The trauma associated with vaginal delivery appears to be the 59 principal risk factor for postnatal UI. The prevalence of UI diminishes in the months after 60 delivery.² However, we still do not know what factors are associated with this postnatal 61 remission of symptoms. Longitudinal data after 12 months postpartum remain sparse,²⁻¹⁰ but 62 those few studies report that the prevalence of UI increases progressively as women age.^{6,8} 63 64 Similarly, we do not know what determinants promote the return of UI long after delivery, and few studies have focused on the remission and incidence of UI in the postpartum period. They 65 can be examined, however, through data from the EDEN mother-child cohort, which describe 66 UI at 4 and 24 months postpartum. The objective of this study was to describe the trends in 67 symptoms between 4 and 24 months postpartum, to estimate remission and incidence rates, 68

69 and to analyse the determinants of these trends.

METHODS

71	The population comes from the EDEN cohort, composed of women recruited during
72	pregnancy between 2003 and 2006 in two French maternity units, Nancy and Poitiers
73	university hospitals (https://eden.vjf.inserm.fr/index.php?lang=en). The inclusion criteria
74	required women to be pregnant with a single fetus, have health insurance, speak and write
75	French, and have no prepregnancy history of diabetes. Women expecting to move away from
76	the region in the 3 years to come were excluded. Among the 3758 women invited to
77	participate, 2002 (53%) agreed (1034 women from Nancy and 968 from Poitiers). Women
78	were included at a mean of 15 weeks of pregnancy (range: 8-26). Their mean age was 29
79	years (range: 18-44) and 30% of them were pregnant for the first time.
80	Postpartum UI was assessed at baseline (4 months postpartum) and at follow-up (24 months
81	postpartum) by self-administered postal questionnaires that asked, among other things, about
82	urinary symptoms during the preceding 4 weeks. Women were classified with UI if they
83	answered yes to the question: "Have you had involuntary urinary leakages?" The UI type was
84	determined with the BFLUTS (British Female Low Urinary Track Symptoms)
85	questionnaire. ¹¹ The question about frequency of leakage had four answer levels (less than
86	once a month, once or several times a month, once or several times a week, every day and/or
87	night), and the question about the amount of leakage three levels (drops, a little amount,
88	more). The severity of UI at 4 and 24 months postpartum was estimated by Sandvik's score,

which has been validated with pad-weighing tests.¹² 89

90	The explanatory variables selected were chosen to reflect different hypotheses of
91	pathophysiologic mechanisms: traumatic factors (parity, characteristics of the index
92	pregnancy and delivery: episiotomy, long second stage of labour, child's gender, child's
93	weight, severe sphincter injury, anal incontinence 4 months postpartum, additional delivery
94	during follow-up); factors affecting tissue modification (pregnant at 24 months postpartum,
95	breast feeding, maternal age), factors affecting pelvic pressure (new pregnancy, body mass
96	index assessed before index pregnancy), constitutional factors (UI history before, during or
97	after the index delivery) and potential protective factors (postpartum pelvic floor muscle
98	training (PFMT)). ² Education level and centre were considered as adjustment variables.
99	Education level may affect women's willingness to report urinary leakage and can thus modify
100	the results. ¹³ We have previously observed that a low education level is associated with both a
101	lower response rate and a lower UI incidence. ^{14,15}
102	The women who responded at 24 months and those who did not were compared with
103	Student's t test for the quantitative variables and a Chi-2 test for the qualitative variables.
104	The analyses of incidence and remission considered four groups of women, defined (Figure
105	S2) according to the presence or absence of postpartum UI at 4 months (baseline) and 24
106	months (follow-up): Group A comprised women who reported no urinary leakage at baseline

107	or at follow-up; group B, women with urinary leakage at baseline and at follow-up; group C
108	the women who reported no leakage at baseline but reported de novo leakage at follow-up;
109	and group D the women with leakage at baseline but not at follow-up.
110	Several multivariate logistic regressions were performed. One was an analysis of UI
111	prevalence at 24 months postpartum, and another an analysis comparing group B (persistent
112	UI) and group D (UI remission) to answer the question: what factors explain UI remission at
113	some period after delivery? An analysis comparing group A (persistent continence) and group
114	C (de novo UI) studied the question: What factors influence the onset of UI at a period after
115	delivery? Each of these models was first studied in a bivariate analysis with each explanatory
116	variable mentioned above; the variables with a <i>P</i> value ≤ 0.20 were included in the
117	multivariate analyses. The variables retained for the final multivariate analyses had P values \leq
118	0.05 and were considered significant. The analyses were adjusted for centre and education
119	level.
120	Finally we applied the same principle to the variation of the UI severity score between 4 and
121	24 months postpartum by a linear regression of the overall population.
122	All statistical analyses were performed with SAS software (version 9.2).
123	The relevant ethics committee (for the protection of people participating in biomedical
124	research at Kremlin-Bicêtre) approved the EDEN cohort study on December 12, 2002. Each

- 125 participating mother provided written consent at inclusion. The required declarations to the
- 126 French data protection authority have been made.

RESULTS



147 the 24-month questionnaire (Table 2).

148	Of the 1067 women who were continent at 4 months and completed the questionnaire at 24					
149	months (groups A and C, Table S1), 135 (12.7%) reported UI at 24 months. The factors					
150	significantly associated with the onset of de novo UI at 24 months were older maternal age,					
151	anal incontinence reported at 4 months, being pregnant at 24 months, and obesity (Table 3).					
152	Among the 273 women incontinent at 24 months who also completed the 4-month					
153	questionnaire (Groups B and C, Table S1), 138 (50.5%) had persistent UI, that is, reported on					
154	both questionnaires, while 135 (49.5%) had developed de novo UI at 24 months. The group of					
155	women with persistent UI, compared with those with de novo UI at 24 months, more					
156	frequently reported moderate or severe UI (49.3% vs. 34.1%) and mixed UI (63.0% vs.					
157	48.9%) at 24 months. Moreover, their parity at inclusion was more often 3 or higher (29.7 vs.					
158	21.5%, Table S1).					
159	PFMT between 4 and 24 months postpartum was not associated with UI remission (group D					
160	compared with group B, P=0.26, bivariate analysis). Only one woman, in group B (persistent					
161	UI), had surgery for this problem.					

162 Trends in UI severity between 4 and 24 months were associated only with new obstetric

- 163 events: an additional delivery during that interval (*P*=0.043) and pregnancy at 24 months
- 164 postpartum (*P*<0.0001). The other variables were not significantly associated with increased

- 165 UI severity. Delivery in the follow-up period was associated with a mean increase of 1.3
- 166 points in the Sandvik score, and a pregnancy at 24 months with an increase of 1.9. When no
- 167 obstetric event occurred during this interval, the mean Sandvik score fell by 0.14 points
- 168 between 4 and 24 months (Figure 1).
- 169

170 DISCUSSION

171 Main findings

172 The prevalence of UI in our population was similar at 4 and 24 months postpartum. The prevalence at 24 months was higher among women with vaginal deliveries and those who 173 174 breastfed. The remission rate between 4 and 24 months was higher in women with caesarean 175 deliveries, and the onset of de novo UI at 24 months more frequent in women who became 176 pregnant again after the index birth. 177 Strengths and limitations 178 The strengths of our study are its longitudinal follow-up and the large number of women 179 included, which enabled us to analyse the risk factors for UI remission and for de novo UI. 180 The women lost to follow-up were more often socioeconomically disadvantaged. This bias 181 could have resulted in an overestimation of UI prevalence because well-off patients report urinary leakages more easily.^{13,15} Nonetheless, our analysis were adjusted for education level, 182 183 and we do not think that this point could have modified the associations observed. Our study 184 of UI changes without considering the UI type (stress, mixed, or urge) may limit the 185 interpretation of the changes we observed. UI may persist but change its nature (e.g., by the 186 disappearance of the stress component and onset of an urge component). The impact of this 187 limitation is nonetheless likely to be low. In clinical practice, changes in the nature of UI 188 during follow-up are rare in the absence of surgery. UI type was not linked to its remission in

189	our analysis. The lack of medical visits (neither clinical assessments nor diagnoses) in our
190	survey prevented any objective confirmation of urinary incontinence or its type.

191 Interpretation

192 At each observation point in our study, some women were no longer incontinent, while others 193 had become so. This dynamic phenomenon has already been examined in some longitudinal studies.^{4,6,10,16} In our study, the chance of remission at 24 months was 51.9% among women 194 195 incontinent at 4 months. Although this remission might have been due to treatment, no 196 significant association was found between postpartum UI remission and PFMT. On the 197 contrary, the women with persistent UI underwent PFMT more often than those whose UI 198 disappeared. We hypothesise that a process of spontaneous recovery of continence during the 199 postnatal period explains our results. Similarly, the longitudinal study by Viktrup⁶ did not find 200 that remission was associated with the different treatments undertaken (physical therapy, surgery) and Hilde's¹⁷ randomised trial reported that postnatal PFMT was not associated with 201 202 a higher probability of urinary continence. 203 In our study, the only factor associated with UI remission was caesarean delivery of the index birth. In other words, vaginal delivery was associated with persistence of UI at 24 months 204 205 postpartum. Gartland et al. found a similar result in a cohort of 1507 Australian nulliparas and

206 observed that persistent UI between 4 and 18 months postpartum was less frequent among

207	women with caesarean deliveries. ¹⁸ DeLancey hypothesised that vaginal delivery affects the
208	pelvic floor in three phases: the first, traumatic phase of delivery, a second phase of repair,
209	and finally a maintenance phase, when other factors influence urinary continence. ¹⁹⁻²¹
210	Continence appears to be restored more often in women with caesarean deliveries, while
211	vaginal delivery appears to expose women to a relapse or a longer recovery.
212	A caesarean delivery alone does not prevent UI in all women. In our study, 14% of the women
213	with only caesarean deliveries reported UI at 24 months postpartum. Gartland et al noted that
214	the nulliparous women with caesareans who had postpartum UI had had their first symptoms
215	during the pregnancy. ¹⁸ Postnatal UI of women with caesareans may therefore result from an
216	effect of the pregnancy itself, rather than the delivery, on continence. This effect of pregnancy
217	on urinary continence may persist after delivery but it is like to be spontaneously reversible
218	more often or more rapidly after a caesarean than a vaginal delivery.
219	In our study, a new pregnancy at 24 months postpartum was associated with the onset of de
220	novo leakage. This association is consistent with Francis's observations. ²² He noted that
221	incontinent women most often reported that their UI began during a pregnancy, not
222	necessarily the first, and that it resolved in the postpartum period, and then recurred at each
223	subsequent pregnancy with increasing severity until it became permanent.
224	Women with de novo UI in the late postnatal period differed from the women whose UI began

225	in the early postpartum and persisted in two ways: parity of the former was lower at inclusion
226	and they were more likely to have had another baby in the interval. The risk of UI persistence
227	at 24 months postpartum is increased among women with UI before the index pregnancy. It is
228	as if on the occasion of this new delivery the women whose UI is recent caught up to the risk
229	level of women with UI that began a longer time ago. McArthur et al. reported that the rate of
230	persistent UI increased with the number of deliveries. ⁴ We hypothesise that women newly
231	incontinent at 24 months postpartum developed the disease later, corresponding to the time
232	required to accumulate the same risk factors (especially obstetric) as the women already
233	incontinent at 4 months.
234	In our study, the Sandvik score deteriorated from 4 to 24 months among the women who had
235	given birth during that interval and those newly pregnant at 24 months, while it fell slightly
236	through 24 months for those with no new obstetric event in the interval. This finding further
237	illustrates the favourable course of continence during the late postnatal period except in cases
238	of new obstetric events and suggests that the repair of obstetric injuries continues during this
239	period unless blocked by a new obstetric event.
240	New obstetrics events, pregnancy and delivery, appear to be central to the development of
241	postpartum UI in mothers. In this population, the natural history of UI is a dynamic and
242	individual phenomenon, combining progressive repair with an accumulation of supplementary
243	risk factors, principally pregnancy and delivery.

245	CONCLUSION
246	Our longitudinal study shows that the prevalence and course of UI in the postpartum period is
247	essentially associated with pregnancies and deliveries. Although the prevalence of UI at 4 and
248	24 months indicates that symptoms are stable over this period, our longitudinal follow-up
249	shows a dynamic process that is a function of intercurrent obstetric events.
250	The remission rate observed in the postpartum period is higher among women with caesarean
251	deliveries. This remission is not complete at 4 months and can continue, absent an intercurrent
252	obstetric event, up to at least 24 months postpartum. Other studies may be necessary over a
253	longer term to know just how long this remission continues and if caesarean delivery remains
254	associated with postnatal remission of UI over a longer period. Among young mothers, the
255	onset of new urinary symptoms at some point after a delivery is principally linked to yet
256	another pregnancy or delivery.
257	

258	Disclosure of interest					
259	None to declare.					
260	Contributions to authorship					
261	EQ and XE performed literature searches, and wrote and edited the article MISC and VE					
262	initiated the project EO and MISC performed data collection and analysis					
263						
264	Details of ethical approval					
265	The study was approved by the CCPPRB (Comité Consultatif de Protection des Personnes					
205	dans la Recherche Biomédicale) of Kremlin-Bicêtre, December 12, 2002.					
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Table 1. Factors associated with prevalence of urinary incontinence 24 months postpartum in the EDEN cohort. Multivariate analysis, logistic regression adjusted for centre and education level (N = 1409).

ur	24 months postpartum inary continence status:	Continent N= 1129	Incontinent N= 280		
Risk factors		n (%), or mean (std)		OR	95 % CI
Maternal age	(mean, years)	31.4 (4.7)	33.3 (4.6)	1.07	1.04-1.11
Parity	1 2 ≥ 3	557 (49.3) 404 (35.8) 167 (14.8)	110 (39.3) 97 (34.6) 72 (25.7)	1 1.07 1.77	- 0.75-1.52 1.14-2.76
Mode of index deliver	y natural instrumental caesarean	815 (72.2) 125 (11.1) 185 (16.4)	218 (77.9) 27 (9.6) 35 (12.5)	1 0.96 0.62	- 0.58-1.57 0.40-0.97
Duration of breast feed	ling none < 3 months + 3 months	319 (28.3) 352 (31.2) 454 (40.2)	61 (21.8) 68 (24.3) 146 (52.1)	1.04 1 1.54	0.69-1.57 - 1.08-2.19
Body mass index	$\begin{array}{l} < 25 \ kg/m^2 \\ 25\text{-}29 \ kg/m^2 \\ \geq 30 \ kg/m^2 \end{array}$	855 (75.7) 192 (17.0) 78 (6.9)	187 (66.8) 55 (19.6) 33 (11.8)	1 1.59 2.35	- 1.09-2.33 1.44-3.85
Pregnant at 24 months postpartum	no yes	1036 (91.8) 89 (7.9)	231 (82.5) 49 (17.5)	1 3.44	- 2.25-5.26

28924 months postpartumyes89 (7.9)49 (17.5)3.442.25-5.26290Factor not found to be significant and excluded from the multivariate analysis: Monthly household income,
additional information about index delivery (episiotomy, long second stage of labour, child's gender, child's
weight, severe sphincter injury), postpartum pelvic floor muscle training, anal incontinence 4 months
postpartum, additional delivery during the follow-up, UI history.

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Table 2. Factors associated with persistent urinary incontinence between 4 and 24 months postpartum in the EDEN cohort. Multivariate analysis, logistic regression for remission (Group D) versus persistence (Group B) of urinary incontinence between 4 and 24 months after delivery index, adjusted for centre and education level (N = 287).

Women incontinent at 4 months, continence status at 24 months		Remission Group D N=149	Persistent incontinence Group B N=138		
Risk factors		n (%)	n (%)	OR	(95% CI)
UI history	before index pregnancy	40 (26.9)	80 (58.0)	3.94	1.91-8.11
(4 months postpartum)	during index pregnancy	64 (42.0)	32 (23.2)	1	-
	after index delivery	34 (22.8)	20 (14.5)	1.03	0.49-2.18
UI severity	mild	91 (61.1)	68 (49.3)	1	-
(4 months postpartum)	moderate to very severe	52 (34.9)	69 (50.0)	2.13	1.20-3.79
Mode of index delivery	vaginal birth	107 (71.8)	108 (78.2)	1	-
,	instrumental delivery	17 (11.4)	15 (10.9)	1.04	0.41-2.60
	caesarean section	25 (16.8)	15 (10.9)	0.43	0.19-0.97
Pregnant at	no	127 (85.2)	111 (80.4)	1	-
24 months postpartum	yes	7 (4.7)	23 (16.7)	3.87	1.39-10.78

30024 months postpartumyes7 (4.7)23 (16.7)3.871.39-10.78301Factor not found to be significant and excluded from the multivariate analysis: Monthly household income,
additional information about index delivery (episiotomy, long second stage of labour, child's gender, child's
weight, severe sphincter injury), postpartum pelvic floor muscle training, duration of breast feeding, anal
incontinence 4 months postpartum, additional delivery during the follow-up, maternal age, parity, body mass
index, UI Type.

305

- 306 Table 3. Factors associated with de novo urinary incontinence at 24 months postpartum in the
- 307 EDEN cohort. Multivariate analysis, logistic regression for persistent continence at 4 and 24
- 308 months postpartum (Group A) versus de novo urinary incontinence at 24 months postpartum
- 309 (Group C) adjusted for centre and education level (N = 1067).
- 310

Women continent at 4 months, continence status at 24 months		Persistent continence Group A N= 932	De novo incontinence Group C N= 135		
Risk factors		n (%), or mean (std)	n (%), or mean (std)	OR	95% CI
Maternal age	(mean, years)	31.9 (4.6)	33.5 (4.6)	1.09	1.04-1.13
Anal incontinence	no	808 (86.7)	100 (74.1)	1	-
(4 months postpartum)	yes	120 (13.1)	32 (24.2)	1.94	1.20-3.14
Pregnant at	no	830 (89.1)	103 (76.3)	1	-
24 months postpartum	yes	73 (8.3)	26 (19.3)	3.63	2.13-6.20
Body mass index	<25 kg/m ²	571 (61.2)	69 (51.1)	1	-
	25-29 kg/m ²	180 (19.3)	35 (25.9)	1.49	0.89-2.49
	$\geq 30 \text{ kg/m}^2$	91 (9.8)	20 (14.8)	2.56	1.37-4.77

312 Factor not found to be significant and excluded from the multivariate analysis: Monthly household income,

313 additional information about index delivery (mode of delivery, episiotomy, long second stage of labour, child's 314 gender, child's weight, severe sphincter injury), postpartum pelvic floor muscle training, duration of breast feeding, additional delivery during the follow-up, parity, UI history.

315

317 318	Figures
319	
320321322	Figure 1. Trends of the mean Sandvik score between 4 and 24 months postpartum according to intercurrent obstetric events (pregnant at 24 months, delivery between 4 and <24 months; $N=1354$).
323	
324	Figure S1. Flow chart
325	
326	Figure S2. Continence status 4-24 months postpartum (N=1354)
327	
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