BJOG An International Journal of Obstetrics and Gynaecology

Royal College of Obstetricians & Gynaecologists

DOI: 10.1111/1471-0528.16452
www.bjog.org

Randomised Controlled Trial
General obstetrics

Caesarean section in the second delivery to prevent anal incontinence after asymptomatic obstetric anal sphincter injury: the EPIC multicentre randomised trial

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Accepted 8 July 2020. Published Online 6 September 2020.

Objective To determine whether planned caesarean section (CS) for a second delivery protects against anal incontinence in women with obstetric anal sphincter lesions.

Design Randomised trial.

Setting Six maternity units in the Paris area.

Sample Women at high risk of sphincter lesions (first delivery with third-degree laceration and/or forceps) but no symptomatic anal incontinence.

Methods Endoanal ultrasound was performed in the third trimester of the second pregnancy. Women with sphincter lesions were randomised to planned CS or vaginal delivery (VD).

Main outcome measures Anal incontinence at 6 months postpartum. Secondary outcomes were urinary incontinence, sexual morbidity, maternal and neonatal morbidities and worsening of external sphincter lesions.

Results Anal sphincter lesions were detected by ultrasound in 264/434 women enrolled (60.8%); 112 were randomised to planned VD and 110 to planned CS. At 6–8 weeks after delivery, there was no significant difference in anal continence between the two groups. At 6 months after delivery, median Vaizey scores of anal incontinence were 1 (interquartile range 0–4) in the CS group and 1 (interquartile range 0–3) in the VD group ($P = 0.34$). There were no significant differences for urinary continence, sexual functions or for other maternal and neonatal morbidities.

Conclusions In women with asymptomatic obstetric anal sphincter lesions diagnosed by ultrasound, planning a CS had no significant impact on anal continence 6 months after the second delivery. These results do not support advising systematic CS for this indication.

Keywords Anal endosonography, anal incontinence, caesarean section, obstetric anal sphincter lesion.

Tweetable abstract Caesarean section for the second delivery did not protect against anal incontinence in women with asymptomatic obstetric anal sphincter lesions.

Linked article This article is commented on by Tähtinen and Cartwright, pp. 694–695 in this issue. To view this mini commentary visit https://doi.org/10.1111/1471-0528.16486.

Please cite this paper as: Abramowitz L, Mandelbrot L, Bourgeois Moine A, Tohic AL, Carne Carnavalet C, Poujade O, Roy C, Tubach F. Cesarean section in the second delivery to prevent anal incontinence after asymptomatic obstetric anal sphincter injury: the EPIC multicenter randomized trial. BJOG 2021;128: 685–693.

Trial Registration: EPIC trial. ClinicalTrials.gov number NCT00632567.

Introduction

Anal incontinence is a source of distress for individuals, with a major impact on sexual health[1] and quality of life.[2,3] It is a frequent symptom,[4] with a prevalence of 14.8% among women in a population-based study in the USA.[5] Obstetric anal sphincter injuries are visible third- or fourth-degree perineal lacerations, reported in 2–12% of vaginal deliveries,[6,7] and are associated with anal incontinence in up to 38%[1] or even 53%[8] of cases long term. Occult anal sphincter lesions, which are not noticed at the time of delivery, can be detected by systematic endoanal ultrasonography in up to 27% of women after their first vaginal delivery (VD).[9] These undiagnosed anal sphincter lesions may result in anal incontinence in 9% of women.[7,9] Instrumental delivery is the most important risk factor for anal incontinence, with anal sphincter lesions reported in up to 63–82% of forceps deliveries[9] and anal incontinence in 23%.[9] Post-delivery anal incontinence decreases over time, but it contributes to anal incontinence in the long term.[10]

In the case of anal sphincter lesions at the first delivery, caesarean section (CS) is often discussed for subsequent deliveries, with the purpose of protecting anal function, but consensus is lacking.[11–14]. Current Royal College of Obstetricians and Gynaecologists guidelines state that in women who have suffered obstetric anal sphincter injuries, elective CS may be considered in case of symptoms or endoanal ultrasonographic defects.[15] To date there is no high-level evidence from a randomised trial to help make an informed decision.[14] The potential benefit needs to be proven, because CS is a major surgical procedure with risks for the mother and infant,[16] including maternal morbidities and mortality at surgery and during subsequent pregnancies.[17] In recent retrospective cohort studies comparing CS with repeat VD in women with a history of anal sphincter lesions, no significant difference was found in the incidence of anal incontinence.[10,18] However, indication bias could not be ruled out in such observational studies. The potential benefit of prophylactic CS on urinary incontinence, quality of life and sexual functions must also be addressed, as they deeply impact quality of life.[2,19] Our objective was to evaluate whether anal incontinence could be prevented by planned CS for the second delivery, in women with asymptomatic anal sphincter disruption after the first delivery.

Methods

Study design

The multicentre, prospective, randomised, open EPIC (Etude de Prévention de l'Incontinence par Césarienne) trial compared planned CS with planned VD for the second delivery in women with a history of a traumatic first delivery with anal sphincter lesions on endosonography and no self-reported anal incontinence at baseline.

Women were recruited in six maternity units in the Paris area (five academic centres and one general hospital), between 1 March 2008 and 29 December 2014, with their written, informed consent for each of the two steps of the study. Patients were not formally involved in the development of the research and no core outcome was used. The study was approved by an ethics committee (Comité de Protection des Personnes Ile de France V, Paris, France) and funding was provided by a French Ministry of Health National Programme for Clinical Research Grant.

Women with a history of a traumatic first delivery were first assessed for eligibility by the obstetrician at clinic visits in the third trimester of their second pregnancy. They were included if they had a first vaginal instrumental delivery with forceps (vacuum extractions were not considered) and/or with a diagnosis of a third-degree perineal tear, had no self-reported anal incontinence at inclusion (on a questionnaire with yes/no answers), were 18 years old or over, and signed informed consent. The main exclusion criteria were a history of anal surgery, a fourth-degree perineal tear at the first delivery, self-reported anal incontinence, defined as involuntary leakage of gas or stools, and any other indication for planned CS for non-proctological reasons.

After inclusion, women had a proctological evaluation including the Vaizey score[20] and anal endosonography with the same expert operator (LA). The Vaizey score was chosen for its sensitivity by considering 24 components of anal incontinence, including loss of flatus with or without loss of liquid and solid stool, pad use, stool urgency, medication use and quality of life. Endosonography was performed with a 7–10 MHz rotating rectal probe and a hard sonolucent plastic cone (Bruel and Kjaer, Naemm, Denmark). Three anal canal levels (upper, middle and lower) were studied and recorded (video recorder; Sony, Tokyo, Japan). Anal sphincter lesions, were characterised as defined by Law et al.[21] a lesion of internal sphincter was identified as a hyperechoic loss of continuity of the normal internal hypoechoic ring. A lesion of the external anal sphincter was identified as a hypoechoic loss of continuity of the normal external hyperechoic ring (see Supplementary material, Figure S1); the angulation defect was quantified and defined as severe if more than 90°.

Trial procedures

Women with all types of external anal sphincter lesions at ultrasound were asked to participate in the randomised trial, and if they consented were assigned (1:1 ratio) to planned CS at 39 weeks of gestation or VD. Concealment was obtained with a computer-generated randomisation scheme, in various-sized blocks, stratified by centre,

transmitted in separate sealed and opaque envelopes prepared by the sponsor. Blinding was not feasible, but investigators were unaware of aggregate outcomes during the study, as the analysis was performed only after the follow-up period was completed and the database was frozen. In the VD group, the management of the delivery, including episiotomy, forceps or vacuum, was left to the appreciation of the clinician. In case of an emergent indication unrelated to the issue of anal sphincter protection, CS was allowed.

Outcomes

Standard obstetric and perinatal outcomes were recorded after delivery. Study visits were planned with the proctologist and the obstetrician at 6–8 weeks postpartum and 6 months (up to 24 months). The follow-up visits at 6–8 weeks and 6 months included the Vaizey score, Wexner score and also the Female Sexual Function Index (FSFI),[22] physical and mental Short-Form Survey (SF12) and Measurement of Urinary Handicap (MUH) score.[23] In addition, the 6-month visit included an anal ultrasound examination. The primary outcome was anal incontinence at 6 months after delivery (M8), as measured by the Vaizey score.[20] Secondary end points were anal incontinence (Vaizey score) at 6 to 8 weeks after delivery (W6–8); postpartum transient anal incontinence (at least one stool and/or at least two gas leakages after delivery, which has disappeared at W6–8), maternal morbidities (haemorrhage, uterine rupture, placenta accreta, haematomas, cervico-vaginal lacerations, haemoperitoneum, organ wounds, anaesthetic complications, infections, deep vein thrombosis), fetal/neonatal morbidities (respiratory distress, infection, acidosis, trauma, neonatal intensive care), urinary incontinence measured with the MUH score, quality of life with the 12-Item SF12 score,[24] women's sexuality with the FSFI and worsening of external sphincter lesions (defined as increase of angulation from baseline of more than 10°) measured 6 months after delivery.

Statistical analysis

Assuming a mean (standard deviation [SD]) Vaizey score at M8 of 5 (6) in the control group,[9,20] 86 women/group would provide 90% power at a two-sided α-level of 0.05 to detect a clinically meaningful difference of mean Vaizey score of 3 between groups. The target for enrolment was increased to account for potential loss to follow up.

Baseline characteristics are reported by trial group (CS and VD) as numbers (%) for categorical variables and means ($\pm$SD) or medians (interquartile range [IQR]) for continuous variables, as appropriate.

All analyses were performed according to the intention-to-treat principle. Missing data were handled using multiple imputations on principal and secondary end points except maternal and neonatal outcomes. Variables included in the imputation models were body mass index, age, ethnic group, history of constipation, history of diarrhoea, use of forceps, perineal tear, ruptured internal sphincter, components of Vaizey score, MUH score, SF12 score at baseline, W6–8 and M8, and FSFI score at M8. Procedures of multiple imputations used assume that the missing data are missing at random and were adapted for data sets with arbitrary missing patterns. We used fully conditional specification method with linear regression for continuous variables, and with discriminant function for categorical variables. We obtained analyses results by averaging results across five imputed data sets using Rubin's rules. The Vaizey score at M8 postpartum was compared between the CS and VD groups using a permutation test, as this variable was not normally distributed and showed a floor effect. A *post hoc* subgroup analysis of the primary outcome was conducted in the 27 women with Vaizey scores $\geq$5 (a cut-off usually defining anal incontinence[25]) at the prenatal visit, after testing positive for interaction with trial arm. Secondary outcomes were compared between VD and CS groups using chi-square or Fisher exact, Student's, Wilcoxon or permutation tests as appropriate.

All statistical analyses were performed using SAS V.9.4 (SAS Institute Inc., Cary, NC, USA).

Results

A total of 549 women were included, of whom 434 underwent anal endosonography, which showed that 264 (60.8%) had anal sphincter lesions. Of these, 222 (84.1%) accepted to be randomised, 112 were assigned to planned VD and 110 to planned CS (Figure 1). Among the 222 randomised women, 20 (9.0%) had third-degree perineal tears during spontaneous VD and 202 (91.0%) had forceps at the first delivery including 140 (71.1%) without perineal tears and 29 (14.7%) with third-degree perineal lacerations (Table 1). There were no significant differences at baseline between the two trial arms. The only medical history was neurological disease, diabetes and cholecystectomy in two women (0.9%) each. The principal treatments used during the second pregnancy were iron supplements in 133 (61.0%) and laxatives in 8 (3.7%). Although according to the eligibility criteria, none of the women self-reported any anal incontinence symptom at inclusion, the Vaizey score was calculated during the data analysis as being $\geq$5 in 27 women before the second delivery, corresponding to the definition of symptomatic anal incontinence. Women who did not complete the M8 visit did not differ from those who completed this visit except for age (see Supplementary material, Table S1).

For the second delivery, 17 (15.6%) women in the VD arm had CS for obstetric indications, whereas 18 (16.5%) women in the CS arm delivered vaginally (Table 2). In the

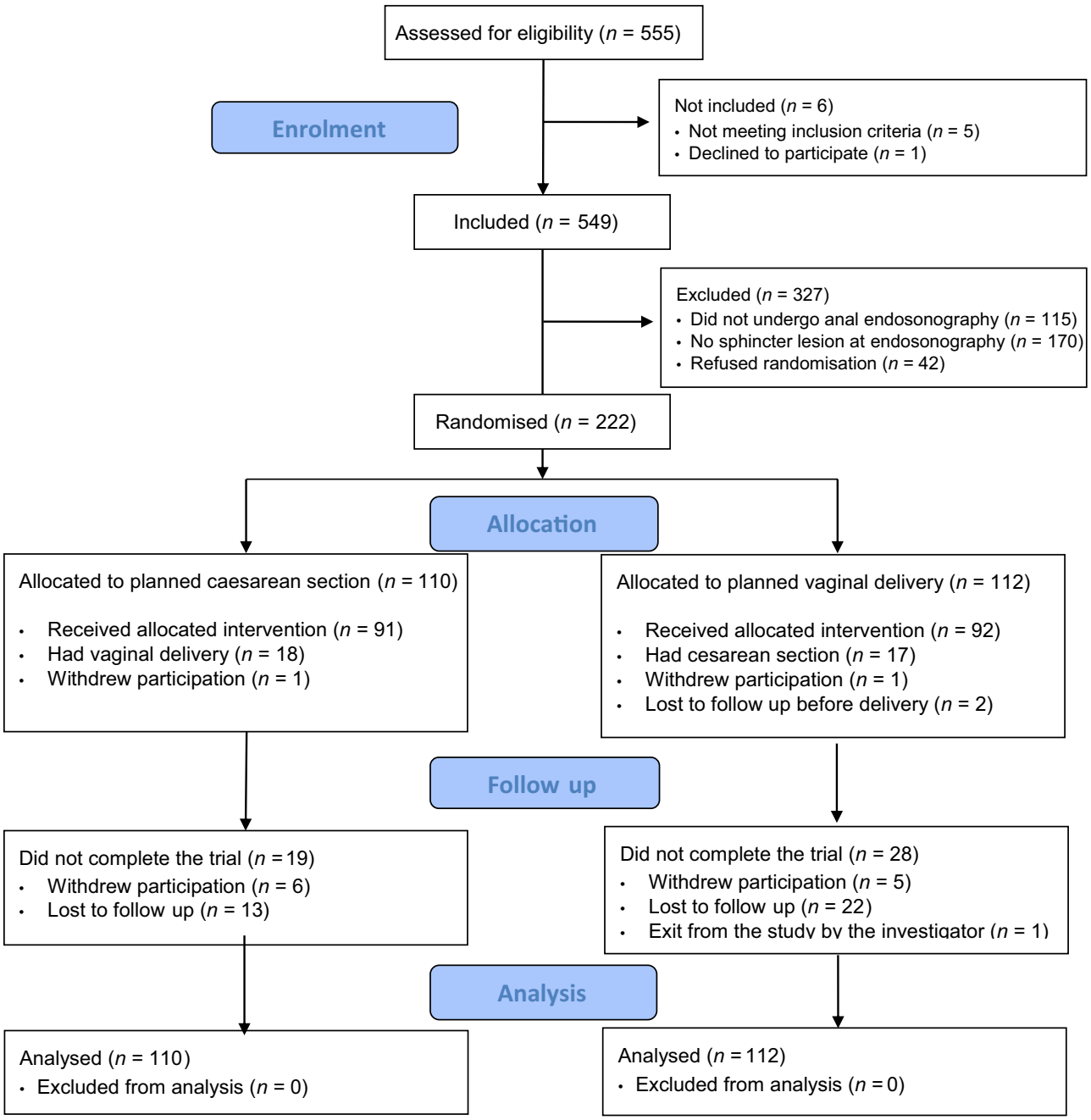

Figure 1. Enrolment, randomisation and follow up of the study participants.

VD arm, five (5.5%) women had a forceps delivery and one (1.9%) developed third-degree lacerations during spontaneous VD.

Outcomes

Primary and secondary outcomes are reported in Table 3. At W6–8 after delivery, anal incontinence was not statistically different between the trial arms, nor was postpartum transient anal incontinence (11.7% in the CS arm versus 25.0% in the VD arm; absolute risk difference −13.3, 95% CI −25.1 to 0.0).

At the M8 end point, the median Vaizey score for anal incontinence was 1/24 (IQR 0–4) in the CS arm versus 1/24 (IQR 0–3) in the VD arm ($P = 0.34$) (Table 3). This primary outcome was measured at a median time of 8.0 (IQR 6.8–11.2) months postpartum (hence M8), as the result of constraints in scheduling and if necessary re-scheduling of appointments. When comparing Vaizey

Table 1. Baseline characteristics of women randomised*

	Total (*n* = 222)	Vaginal delivery group (*n* = 112)	Caesarean section group (*n* = 110)
Age (years), mean ± SD	32.7 ± 4.5	32.8 ± 4.6	32.7 ± 4.5
Body mass index (kg/m^2), mean ± SD	26.6 ± 4.4	26.2 ± 4.2	27.1 ± 4.6
Geographical origin, *n* (%)			
Europe	134 (61.2)	64 (58.2)	70 (64.2)
North Africa	50 (22.8)	26 (23.6)	24 (22.0)
Sub-Saharan Africa	16 (7.3)	11 (10.0)	5 (4.6)
Other	19 (8.7)	9 (8.2)	10 (9.1)
Missing data	3 (1.4)	2 (1.8)	1 (0.9)
First delivery, *n* (%)			
Spontaneous with third-degree perineal laceration	20 (9.0)	11 (9.8)	9 (8.2)
Episiotomy	6 (35.3)	4 (44.4)	2 (25.0)
Missing data	3 (15.0)	2 (18.2)	1 (11.1)
Forceps	202 (91.0)	101 (91.8)	101 (92.7)
No perineal laceration	140 (71.1)	71 (71.7)	69 (70.4)
First-degree perineal laceration	20 (10.2)	12 (12.1)	8 (8.2)
Second-degree perineal laceration	8 (4.1)	1 (1.0)	7 (7.1)
Third-degree perineal laceration	29 (14.7)	15 (15.2)	14 (14.3)
Missing data	5 (2.5)	2 (2.0	3 (3.0)
Episiotomy	180 (90.5)	88 (88.0)	92 (92.9)
Missing data	3 (1.5)	1 (1.0)	2 (2.0)
Birthweight (g), mean ± SD	3388 ± 444	3444 ± 444	3332 ± 438
Care and outcome after first delivery, *n* (%)			
Pelvic floor physical therapy performed	143 (66.5)	75 (69.4)	68 (63.6)
Anal incontinence before 2 months postpartum	27 (12.4)	10 (9.2)	17 (15.7)
Urinary incontinence after first delivery	72 (33.3)	40 (36.7)	32 (29.9)
Continence and health scores during seconnd pregnancy and before second delivery			
Vaizey score, median [IQR]	1.0 [0.0–2.0]	[0.0–2.0]	[0.0–3.0]
Vaizey score ≥5, *n* (%)	27 (12.3)	12 (10.9)	15 (13.8)
Measurement of Urinary Handicap (MUH) score, median [IQR]	4.0 [1.0–8.0]	5.0 [1.0–8.0]	4.0 [1.0–8.0]
Physical Short-Form Health Survey (SF12) score, mean ± SD	42.0 ± 8.6	41.7 ± 8.4	42.3 ± 8.7
Mental SF12 score, mean ± SD	48.8 ± 9.1	48.9 ± 9.1	48.7 ± 9.2

*No significant differences ($P < 0.05$) between the trial arms.

scores at inclusion and at the M8 visit, the results did not differ between the CS and VD groups – median differences 0.0 (IQR −1.5 to 2.0) and 0.0 (IQR 0.0–1.0), respectively, $P = 0.9825$ (see Supplementary material, Figure S2). The effect of trial arm on Vaizey score at M8 differed between women with a Vaizey score at inclusion <5 and women with a Vaizey score at inclusion ≥5 (significant interaction $P = 0.008$). *Post hoc* subgroup analyses showed that in the subgroup of 27 women with a Vaizey score before delivery ≥5, Vaizey score at M8 was significantly lower in the CS than in the VD arm (median 3, IQR 0–7 versus median 6, IQR 3.5–8.5, $P = 0.026$).

At M8, there was no statistically significant difference between groups for urinary incontinence (MUH score), sexual function (FSFI) and physical and mental quality of life (assessed with SF12).

Similarly, we found no difference between the two arms for maternal morbidity. Minor complications occurred in four (4.9%) women in the VD arm and eight (8.8%) in the CS arm, including three (3.3%) anaesthetic complications (headaches) in the CS arm and none in the VD arm. After delivery, 21 (13.8%) received iron supplements and 8 (5.3) took laxatives. For neonatal outcomes, five (6.1%) had at least one complication in the VD arm including four transfers to neonatal care units (two for respiratory distress and two for infection) compared with none in the CS arm.

Among the 222 randomised women, 125 (56.3%) underwent postpartum endosonography at the M8 visit, 61 (54.5%) in the VD arm and 64 (58.2%) in the CS arm. Baseline characteristics of these women did not differ from those without endosonography (see Supplementary material,

Table 2. Description of the second deliveries*

	Total (*n* = 222)	Vaginal delivery group (*n* = 112)	Caesarean section group (*n* = 110)
Lost to follow up	4	3	1
Birthweight (g), mean ± SD	3357 ± 443	3438 ± 443	3234 ± 417
Actual mode of delivery	110 (50.5)		
Vaginal, *n* (%)	108 (49.5)	92 (84.4)	18 (16.5)
Caesarean section, *n* (%)		17 (15.6)	91 (83.5)
In case of vaginal delivery			
Vacuum, *n* (%)	4 (3.7)	3 (3.3)	1 (5.6)
Forceps, *n* (%)	5 (4.6)	5 (5.5)	0 (0.0)
Anterior presentation, *n* (%)	100 (96.2)	84 (95.5)	16 (100.0)
Missing data, *n* (%)	6 (5.5)	4 (4.5)	2 (11.1)
Posterior presentation, *n* (%)	2 (1.9)	2 (2.3)	0 (0.0)
Episiotomy, *n* (%)	34 (31.2)	28 (30.4)	6 (35.3)
Perineal laceration, *n* (%)	57 (52.3)	52 (56.5)	5 (29.4)
First degree	47 (82.5)	42 (80.8)	5 (100.0)
Second degree	9 (15.8)	9 (17.3)	0 (0.0)
Third degree	1 (1.8)	1 (1.9)	0 (0.0)
Shoulder dystocia, *n* (%)	2 (2.5)	2 (2.8)	0 (0.0)
Duration of labour (hours), median [IQR]	4.0 [3.0–5.0]	4.0 [3.0–5.0]	3.0 [1.5–4.5]
Active pushing (min), median [IQR]	11.0 [5.0–15.0]	12.0 [5.0–16.0]	9.5 [7.0–10.0]

Data are mean ± SD or median [interquartile range] or *n* (%).
*There were no significant differences between the trial arms ($P < 0.05$), except for the occurrence of perineal laceration among women who delivered vaginally (absolute difference risk −27.1, 95% CI −49.7 to −1.4).

Table 3. Outcomes following the second delivery in women with anal sphincter lesions randomised to caesarean section versus vaginal delivery

Endpoint	Vaginal delivery arm (*n* = 112)	Caesarean section arm (*n* = 110)	Median or mean difference or Absolute risk difference (95% CI)	*P* value
Primary end point				
Vaizey score at M8, median [IQR]	1.0 [0.0–3.0]	1.0 [0.0–4.0]	0.0 (0.0 to 2.0)	0.34
Secondary end points				
Vaizey score at W6–8, median [IQR]	0.0 [0.0–3.0]	0.0 [0.0–3.0]	0.0 (−2.0 to 1.0)	0.62
Postpartum transient anal incontinence at W6–8, *n* (%)	18 (25.0)	9 (11.7)	−13.3 (−25.1 to 0.0)	0.32
MUH score at M8, median [IQR]	0.0 [0.0–4.0]	1.0 [0.0–4.0]	1.0 (−1.0 to 2.0)	0.72
FSFI score at M8, median [IQR]	28.1 [23.5–31.2]	27.1 [22.1–31.4]	−1.0 (−4.0 to 1.9)	0.61
Physical SF12 score at M8, mean ±SD)	52.1 (6.7)	51.7 (7.0)	−0.4 (−2.5 to 1.6)	0.62
Mental SF12 score at M8, mean (±SD)	46.2 (9.2)	46.6 (9.5)	0.4 (−2.3 to 3.2)	0.39
Maternal morbidities, *n* (%)	4 (4.9)	8 (8.8)	3.9 (−2.7 to 11.2)	0.31
Neonatal morbidities, *n* (%)	5 (6.1)	0 (0.0)	−6.1 (−11.7 to −1.3)	0.023
Worsening of external sphincter lesions at ultrasound, *n* (%)	11 (22.4)	1 (2.2)	−20.2 (−31.7 to −7.6)	0.003

All the analyses were conducted in the intent-to-treat population except maternal and neonatal morbidities (completers), and are superiority analyses. For secondary end points, the confidence intervals have not been adjusted and inferences drawn from the intervals may not be reproducible.

Table S2). External sphincter lesions deteriorated more frequently in the VD arm than in the CS arm – 11 (22.4%) women versus 1 (2.2%), absolute risk difference −20.2 (95% CI −31.7 to −7.6) – but no additional internal sphincter lesions were observed.

Discussion

Main findings

In this randomised trial of women with asymptomatic anal sphincter lesions from a first delivery, planned CS in the

second delivery was not protective against anal incontinence at 8 months postpartum. At 6–8 weeks postpartum, anal incontinence was less frequent in the CS group, but the difference was not statistically significant. In addition, we found no benefit of CS on urinary incontinence, sexual function or quality of life.

Strengths/limitations

To our knowledge, this is the first randomised controlled trial addressing this issue. Anal incontinence was assessed with the standardised and validated Vaizey score, and sphincter lesions were defined by endosonography. External validity was supported by the diversity of trial settings, including teaching hospitals and general hospitals in diverse populations ranging from poor to affluent, with no centre effect.

This trial also has limits. Our study was necessarily unblinded, and the main outcomes were patient-reported, so we cannot exclude reporting bias. However, all investigators were unaware of aggregate outcomes during the study. Also, crossovers were observed (CS in the VD group and vice versa), but the trial was analysed according to the intent-to-treat, as recommended, and so compares the strategy of planned CS versus planned VD. We observed a Vaizey score at M8 of only 1 in the VD group (as well as the CS group), whereas a score of 5 in the VD group was used for sample size calculation because 5 points on the Vaizey score is recognised as reflecting clinically significant anal incontinence,[25] which would justify an indication for CS. This decreased the power to demonstrate a difference between the two trial arms; however, the point estimates are identical in both arms of the trial, which is in favour of an absence of difference rather than a lack of power. Moreover, this does not weaken the main finding because it means that a second VD was not a significant risk factor for developing clinically significant anal incontinence. The main end point planned at M6 after delivery was actually measured at a median of 8 months after delivery, but this longer follow up may strengthen rather than weaken the evaluation. Lastly, one-fifth of the randomised women did not complete the 6 months postpartum follow up, which could lead to attrition bias; however, their characteristics did not differ between the two study groups, and the analysis was performed according to the intent-to-treat principle, with multiple imputations performed for handling missing data.

Interpretation in light of other studies

Our findings are consistent with recent observational studies, including longer follow up.[18,26] In an observational cohort study, CS for women with anal sphincter disruption at the first delivery was associated with no benefit on anal incontinence 5 years after the second delivery.[18] However, most women sustaining obstetric injuries develop anal incontinence later, after their 50s. Nygaard et al.[27] found that anal sphincter disruption following an index delivery was a risk factor for flatus incontinence 30 years later. Some large population-based cohort studies failed to show any difference in the incidence of flatus incontinence in women above 50 years, according to whether they delivered vaginally or by CS,[19] but a recent population-based study from Sweden found that the risk of anal incontinence was lower after CS than after VD.[28] Anal incontinence was also higher among women who delivered by CS compared with nulliparas and higher among nulliparas compared with men. In another study, an association was found between ultrasound diagnosis of anal sphincter lesions and long-term faecal incontinence after a first delivery.[29] Because anal incontinence is multifactorial, including neurological and gastrointestinal causes, this symptom can occur without sphincter lesions and vice versa. Anal sphincter lesions are observed by ultrasound in less than half of women with postpartum anal incontinence.[9] In an unselected primiparous population, anal sphincter disruption was detected by ultrasound screening after delivery in 27% of women, most of whom had no symptoms.[30] Hence, although CS can be protective from anal sphincter lesions,[8,9] ultrasound evidence is one of many factors associated with anal continence. Besides, it has been shown that the severity of the anal sphincter lesion is an important risk factor for subsequent anal incontinence, particularly the depth of the disruption of both the external and internal sphincters.[31] In our trial, we did not observe a protective effect of CS in the subgroup with severe anal sphincter ruptures (defined as >90°) (data not shown). In another study, only fourth-degree tears were associated with an increased risk of anal incontinence at 10 months postpartum,[32] but this was an exclusion criterion in our trial.

One important difference between our trial and most retrospective studies was the inclusion of women whose first delivery was by forceps, even in the absence of a diagnosis of a third-degree perineal laceration. We found 60% with anal sphincter defects at ultrasound in this group. It remains to be shown whether our findings can be replicated in different populations including only obstetric anal sphincter injuries that are diagnosed at delivery.

Some observational studies have shown that a subsequent VD following an obstetric anal sphincter injury may result in additional or recurrent lesions,[33] which may be apparent or occult, but without any significant change in the incontinence score according to the mode of delivery. In our trial, the incidence of repeated clinically apparent obstetric anal sphincter injuries was low, because only one woman had a repeated third-degree tear.

Endosonographic aggravation of external sphincter lesions occurred significantly more often in the VD group

than the CS group. These findings may indicate that CS avoids some occult sphincter disruptions, but on the other hand they signify that ultrasound evidence of anal sphincter lesions is not predictive of symptoms of anal incontinence.

Conclusion

Our findings are not in favour of recommending CS for subsequent deliveries in women with asymptomatic ultrasound anal sphincter lesions resulting from a first delivery. This should be useful for clinicians and women to avoid numerous unnecessary CS.[13] However, we cannot exclude a protective effect of prophylactic CS for women with symptomatic anal sphincter lesions. We did find a significant benefit of CS among women with mild clinical anal incontinence detected before the second delivery at the proctological visit. As this is a *post* hoc subgroup analysis, it must be interpreted with caution.

Because of taboos surrounding anal incontinence, it is difficult to reveal without meticulous questioning. In our trial, 27 women self-reported no anal incontinence at inclusion, but had a Vaizey score ≥5 measured by a proctologist. Comparative to endosonography, clinical-based diagnosis of anal incontinence is less expensive, more accessible and seems more predictive of functional outcome, as has been previously suggested in retrospective studies.[18,26] Hence, our findings do not support performing anal endosonography for women with an overt obstetric anal sphincter injury or forceps instrumentation for their first delivery in order to decide on the mode of delivery.

Further studies are needed to determine whether CS may be useful in the long term among women with mildly symptomatic anal lesions, and if so whether women with third- or fourth-degree perineal tears and/or forceps at their first delivery can benefit from a proctological examination to make a decision regarding their subsequent deliveries.[9]

Disclosure of interests

All the authors report no personal conflict of interests, but this project was funded by a research grant from the Ministry of Health (PHRC). FT was the head of the research unit. Completed disclosure of interests forms are available to view online as supporting information.

Contribution to authorship

LA, FT and ABM contributed to the design of this study. LA, ALT, CCC and OP included most of the patients. CR and FT conducted the analyses and LA, LM, ABM, ALT, CCC, OP, CR and FT contributed to the interpretation of data. LA, LM and FT drafted the manuscript and all the authors critically revised the manuscript and approved the version to published.

Ethics approval

This study (no. ID-RCB 2006-A00518-43) was approved by the Comité de Protection des Personnes (Ethical Human Subjects Protection Review) Paris-Ile-de-France V of Saint Antoine Hospital PARIS 12 on 2 October 2007 (no. 07709) and by the French Health Authority on 22 October 2007 (ref. DGS2007-0188).

Funding

French Ministry of Health National Programme for Clinical Research Grant.

Acknowledgements

We thank Coralie Gernez, Amandine Fauquembergue, Aline Dechanet and Marion Schneider from the Unité de Recherche Clinique of Hôpital Bichat–Claude-Bernard for their efforts in project management, enrolment, data collection, monitoring and data management of the trial, all the staff members of the participating maternity departments and the women who participated. We also thank Drs Anabela Rodrigues, Amélie Benbara and Guillaume Girard for their contributions.

Supporting Information

Additional supporting information may be found online in the Supporting Information section at the end of the article.

Fig S1. External sphincter defect in anterior position (white arrow).

Fig S2. Evolution of Vaizey score between inclusion and M8 visit after the second delivery.

Table S1. Baseline characteristics according to whether M8 visit was completed or not.

Table S2. Baseline characteristics compared between women who received and those who did not receive endoanal sonography at 8 months after the second delivery. ■

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