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Risk of obstetric anal sphincter injury among women who birth vaginally after a prior caesarean section: A state-wide cohort study

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Running title: VBAC and anal sphincter injury risk.

Keywords: vaginal birth, caesarean section, anal sphincter injury, 3rd and 4th degree tear, instrumental birth, relative risk

ABSTRACT

Objective: Vaginal birth after caesarean (VBAC) has been suggested to be associated with an increased risk of obstetric anal sphincter injury (compared with primiparous women who

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1 birth vaginally). However, prior studies have been small, or used outdated methodology. We
2 set out to validate whether the risk of obstetric anal sphincter injury among women having
3 their first VBAC is greater than that among primiparous women having a vaginal birth.

4 **Design:** State-wide retrospective cohort study.

5 **Setting:** Victoria, Australia.

6 **Population:** All births (455,000) between 2009-2014.

7 **Methods:** The risk of severe perineal injury between first vaginal birth and first vaginal birth
8 after previous caesarean section was compared, after adjustment for potential confounding
9 variables. Covariates were examined using logistic regression for categorical data and
10 Wilcoxon rank-sum test for continuous data. Missing data were handled using multiple
11 imputation; the analysis was performed using regression adjustment and Stata v16 multiple
12 imputation and teffects suites.

13 **Results:** Women having a VBAC (n=5,429) were significantly more likely than primiparous
14 women (n=123,353) to sustain a 3rd or 4th degree tear during vaginal birth (7.1 vs 5.7%,
15 p<0.001). After adjustment for mode of birth, body mass index, maternal age, infant
16 birthweight, episiotomy and epidural, there was a 21% increased risk of severe perineal
17 injury (relative risk 1.21 (95%CI 1.07 – 1.38)).

18 **Conclusions:** Women having their first vaginal birth after caesarean section have a
19 significant increased risk of sustaining a 3rd or 4th degree tear, compared with primiparous
20 women having a vaginal birth. Patient counselling and professional guidelines should reflect
21 this increased risk.

22 **Tweetable abstract:** Women having their first vaginal birth after caesarean section have a
23 significantly increased risk of severe perineal injury.

25 INTRODUCTION

26 Obstetric anal sphincter injury reflects significant perineal trauma during childbirth and
27 involves injury of the anal sphincter complex (1). While many heal well after primary repair,
28 the impact of this injury for some can be lifelong with long-term symptoms persisting well
29 beyond the birth (2-4). These symptoms include perineal pain, dyspareunia, defecatory
30 dysfunction and faecal incontinence and they can significantly impact a woman's quality of
31 life and emotional well-being (3, 5).

1 The incidence of obstetric anal sphincter injury amongst primiparous women varies but is
2 reported to be 5.3% in Australia, 6.1% in the UK and between 6 and 16% in the US (1, 6-8).
3 Risk factors include nulliparity, advanced maternal age, and intrapartum factors that might
4 plausibly be associated with pelvic trauma such as infant birthweight >4000g and
5 instrumental vaginal birth (9-12).

6
7 In most Western jurisdictions, up to 30% of primiparous women give birth via caesarean
8 section (6, 13). For women in their second pregnancy, VBAC is an increasingly desired mode
9 of birth, with successful VBAC associated with a quicker post-partum recovery (14, 15).

10
11 However, compared with vaginal birth in primiparous women, there is emerging evidence
12 suggesting successful VBAC is also associated with an increased risk of obstetric anal
13 sphincter injury (10, 11, 16). Past studies in this field have been limited by small cohort sizes,
14 lack of broader generalisability through use of a single hospital cohort only or outdated
15 methodology, such as a reliance on complete case records only, which may lead to
16 ascertainment bias (17).

17
18 Prior studies have consistently suggested that women having a VBAC are up to 1.4-fold
19 more likely to sustain significant perineal injury compared with their primiparous
20 counterparts (9, 10, 16). And yet, the risk of perineal injury is still only peripherally
21 acknowledged in many professional guidelines (18, 19) and is not routinely included in
22 antenatal counselling of women considering a VBAC. Using a large cohort of women who
23 achieved a VBAC for their second birth and employing advanced statistical methodology,
24 our study aimed to rigorously validate a possible association between VBAC and significant
25 perineal injury.

26 27 28 **METHODS**

29 **Study design**

30 We performed a retrospective cohort study including 116,047 women who gave birth in the
31 Australian state of Victoria between 2009 and 2014. Validated data were obtained from the
32 Consultative Council on Obstetric and Paediatric Mortality and Morbidity (CCOPMM) for all
33 births in Victoria. CCOPMM is the central agency that collects and validates data on

1 obstetric and perinatal outcomes within the state (20-22). These data are populated by
2 state-wide hospital documentation of outcomes by midwives caring for the patients at the
3 time of birth.

4
5 Our cohort included all women who gave birth to a live baby at term gestations ($\geq 37^{+0}$
6 weeks) in Victoria from 1st Jan 2009 to 31st Dec 2014. Women were excluded if they had
7 missing or incomplete gestational age data, missing or implausible birthweight ($< 500\text{g}$ or
8 $> 6500\text{g}$), gave birth pre-term (< 37 weeks) or had a stillborn baby (Figure 1). The primary
9 exposure of interest was the first vaginal birth after one previous caesarean section.
10 Women were therefore excluded if they did not fit the inclusion criteria for a) cases:
11 multiparous women having had only one previous caesarean section followed by a vaginal
12 birth, or b) controls: primiparous women having their first vaginal birth. The primary
13 outcome of interest was documented obstetric anal sphincter injury (3rd or 4th degree tear).

14 15 **Statistical analysis**

16 We considered potential confounders between 3rd and 4th degree tear and VBAC status to
17 be: maternal age (recorded to the nearest year at prenatal booking and centred at 30
18 years), mode of birth (normal vaginal birth, forceps vaginal birth and ventouse/vacuum
19 vaginal birth), completed week of term gestational age (37-42 weeks), birthweight (in
20 grams), episiotomy (yes/no), BMI and epidural analgesia (yes/no). Raw data for the
21 outcome and covariates were presented as number (%) or mean (SD) by exposure status.
22 The proportion of missing data was documented for each covariate (Table 1).

23
24 The distribution of covariates between exposure groups was examined using univariable
25 logistic regression for categorical data and Wilcoxon rank-sum test for continuous data,
26 based upon non-missing data. The same tests were repeated as a sub-analysis, looking at
27 the distribution of covariates between women who had a VBAC and had a 3rd or 4th degree
28 tear, and women who had a VBAC but no significant perineal injury.

29
30 The adjusted analysis consisted of two parts: multiple imputation of missing covariate data,
31 followed by regression adjustment analysis based upon potential outcome means (POM).
32 We performed multiple imputation consisting of fully conditional specification (FCS) using a
33 predictive mean model for continuous, logistic model for binary and multinomial model for

1 unordered categorical covariates. The imputation model included outcome, exposure and
2 all covariates used in the analysis model. There were no additional auxiliary variables
3 available for inclusion. The number of imputed datasets (20) was set above the highest
4 percentage of missingness and considered adequate if the Monte Carlo error was less than
5 10% of regression coefficient standard errors. Standard imputation diagnostics included:
6 graphical assessment of convergence; comparison of distributional shape between both
7 imputed (complete) and observed (non-imputed) datasets; and graphical and numerical
8 imputed values and observed values.

9
10 The analysis was then performed on each of the 20 imputed datasets, using Regression
11 Adjustment (RA) to derive a pooled estimate of potential outcome means (POM), Risk
12 difference (RD) and Relative risk (RR) with associated 95% confidence limits adjusted for
13 imputation using Rubin's rules. Regression adjustment estimates the POM separately for
14 both exposure groups and these are then used to derive RD and RR estimates. The model
15 will produce unbiased estimates if both covariate relationships are correctly specified, and
16 no important confounders have been omitted.

17
18 Sensitivity analysis was performed using the same regression adjustment model for two
19 *complete case cohorts* (including and excluding BMI and analgesia in the covariate list).
20 Unadjusted RD and RR are also presented. Analysis was performed using Stata v16,
21 including the multiple imputation and teffects suites. The significance level was two-sided
22 and set at 0.05.

23 24 **Ethics**

25 Ethical approval was obtained from the Mercy Hospital for Women Human Research Ethics
26 Committee (#2019-01). Because this was a retrospective study using archived de-identified
27 data only, obtaining individual patient consent was not considered to be necessary by the
28 ethical review board.

29 30 31 **RESULTS**

32 Our state-wide cohort included 455,455 births. After exclusions, there were 129,964 births
33 for analysis: 123,535 primiparous women who birthed vaginally and 5,429 women who

1 birthed vaginally for the first time after one previous caesarean section (Figure 1). Vaginal
2 birth for both groups included those who birthed with the assistance of ventouse or forceps.

3
4 There were no missing data on VBAC status (exposure); 11.1% of the entire cohort had
5 missing perineal tear data (outcome). There was no difference in distribution of missing
6 outcome data (3rd or 4th degree tears) between exposure groups (10.1% in controls vs 9.3%
7 in cases; $p=0.09$). Imputation of missing outcome data was not performed (as no auxiliary
8 variables) and so all cases with missing outcome data were excluded from final analysis.
9 There were 116,047 births remaining for analysis. The distribution of covariates, including
10 missingness, is presented in Table 1.

11
12 Compared with primiparous women having a vaginal birth, women having a VBAC were
13 more likely to be older (>30 years, $p<0.001$), to have a slightly higher body mass index
14 (mean 25.4 vs 24.7, $p<0.001$), to give birth between 38 and 40 completed weeks ($p<0.001$),
15 to have a ventouse birth (23.6 vs 21.3%, $p<0.001$) and for their baby to have a higher
16 birthweight (mean birthweight 3452.7 vs 3377.3g, $p<0.001$; incidence of birthweight ≥ 4000 g
17 10.8 vs 8.2%, $p<0.001$) (Table 1). The VBAC group were less likely to have a spontaneous
18 (unassisted) vaginal birth (56.7 vs 59.1%, $p<0.001$) and less likely to have an intrapartum
19 epidural (30.2 vs 36.0%, $p<0.001$). There was no difference between the exposure groups in
20 the likelihood of having an episiotomy (45.0 vs 46.2%, $p=0.18$).

21
22 Women having a VBAC were significantly more likely than primiparous women to sustain a
23 3rd or 4th degree tear during vaginal birth (7.1 vs 5.7%, $p<0.001$). A sub-analysis examining
24 only women who had a VBAC demonstrated that those who sustained a 3rd or 4th degree
25 tear were more likely to have had a forceps birth (31.3 vs 18.8%, $p<0.001$) and a baby with a
26 birthweight ≥ 4000 g (15.9 vs 10.4%, $p<0.001$), and less likely to have had an episiotomy (33.6
27 vs 45.9%, $p=0.001$) (Table 2).

28
29 Unadjusted analysis produced a relative risk for women having a VBAC of 3rd or 4th degree
30 tear of 1.24 (95%CI 1.12 to 1.38) and a risk difference of 1.39% (95%CI 0.66 to 2.12). The
31 regression adjustment estimates were pooled over the 20 imputed datasets providing an
32 adjusted relative risk amongst cases of 1.21 (95%CI 1.07 to 1.38) and a risk difference of
33 1.22% (95%CI 0.35 to 2.1). Sensitivity analysis was performed on complete case cohorts,

1 which produced similar adjusted relative risks of 1.19 (95%CI 1.03 to 1.38) when both BMI
2 and analgesia were included, and 1.23 (95%CI 1.09 to 1.39) when BMI and analgesia were
3 both excluded (Table 3).

6 **DISCUSSION**

7 **Main findings**

8 Our study found that women having a vaginal birth after one previous caesarean section
9 were 21% more likely than primiparous women having a vaginal birth to sustain a 3rd or 4th
10 degree tear (RR 1.21, 95%CI 1.07-1.38). Given the baseline risk is not low (6.1% in the UK for
11 instance), this increase may be clinically significant. These findings indicate a level of risk
12 that women should be made aware of during antenatal counselling if a VBAC is being
13 considered. Across the different statistical models, the relative risk estimates were similar,
14 all suggesting a significant increase in the incidence of 3rd or 4th degree tears associated with
15 VBAC.

16
17 Our findings highlight the characteristics of women attempting a VBAC, and of those at
18 increased risk of 3rd and 4th degree tears. These findings are in keeping with studies from
19 comparable settings around the world. Women having a VBAC in our Victorian cohort were
20 more likely to be older, have an instrumental birth and have a baby with higher birthweight.
21 Those that sustained a 3rd or 4th degree tear during VBAC were more likely to have had a
22 forceps birth, a baby of birthweight $\geq 4000\text{g}$ and less likely to have had an episiotomy. These
23 factors are all known to increase the risk of 3rd and 4th degree tears (10, 23, 24), with forceps
24 considered a major risk factor for significant perineal injury (8, 25, 26).

25
26 In 2014, Hehir et al published results of a study from one large tertiary referral hospital in
27 Dublin that concurred with our findings, that women having a VBAC were more likely to be
28 older and have a baby with higher birthweight (consistent with being multiparous), and
29 have an instrumental birth (11). Women who sustained a significant perineal injury during
30 successful VBAC were also more likely to have had a forceps (27). A study conducted in
31 Southampton, UK, between 2004-2014 looked at the maternal, intrapartum and neonatal
32 factors associated with 3rd or 4th degree tear amongst 1,375 secundiparous women having a
33 VBAC (9). They found that advanced maternal age, higher birthweight and an urgent

1 category of first caesarean section were associated with an increased risk of 3rd or 4th
2 degree tear (9). Episiotomy (right mediolateral) was found to be protective, consistent with
3 the findings of ours and other studies (28-31).

4
5 Another UK-based study by Jardine et al examined a cohort of 9,993 secundiparous women
6 having a VBAC and excluded any women with missing data (17). Whilst confirming the
7 above findings, this study also suggested that women having a VBAC were more likely to
8 experience a shoulder dystocia at vaginal birth, and that the increased risk of perineal injury
9 following VBAC was restricted to women who had had an emergency primary caesarean
10 section (17).

11
12 Other studies have hypothesised why women having a VBAC are at increased risk of 3rd and
13 4th degree perineal tears. Proposed mechanisms range from the mismatch between more
14 propulsive uterine contractions in the multigravida VBAC cohort, coupled with a 'nulliparous
15 perineum' (32, 33), through to relative cephalo-pelvic disproportion as the indication for
16 first caesarean section affecting the passage of the fetus and leading to anal sphincter injury
17 in subsequent births for these women (10, 12, 32). In the US, the indication for previous
18 caesarean influences whether a VBAC is recommended, whereas in Australia (and many
19 other countries) women are not excluded from a VBAC because of obstruction in a prior
20 labour. Additionally, US practitioners may use a VBAC risk calculator during antenatal
21 counselling, which is not often employed elsewhere.

22
23 As demonstrated by ours and a number of studies, women attempting a VBAC are more
24 likely to have an operative vaginal birth (11), likely due to concern from the accoucheur
25 about prolonged second stage and the risk of uterine rupture and fetal compromise (9, 34).
26 This lower threshold for operative birth ultimately increases the risk of perineal injury.
27 Irrespective of the mechanism, there is now convincing evidence that VBAC is associated
28 with an increased risk of significant perineal injury, and education and prevention strategies
29 should be directed toward this group.

30 31 **Study strengths and limitations**

32 Our study has several strengths. We used a large, state-wide cohort derived from 5 years of
33 routinely collected data in Australia, to explore the association between VBAC and

1 significant perineal injury. Whilst there is a growing body of published evidence recognising
2 VBAC as a risk factor for 3rd and 4th degree tear, ours is one of the largest, most recently
3 reported studies to explore this association and provides a more rigorous, updated
4 approach to adjusted analyses than the existing published studies.

5
6 The main limitation of our study is the use of retrospective data, which can produce biased
7 estimates of risk due to missing data and limited covariate detail. However, we thoroughly
8 explored the pattern of missing data, specifically for body mass index and epidural for which
9 >10% of data were missing. It was important that data describing these two variables were
10 appropriately accounted for, since high body mass index is thought to be protective against
11 significant perineal injury (35, 36) and epidural increases the likelihood of instrumental birth
12 which is a risk factor for 3rd and 4th degree tear (11, 37, 38).

13
14 In contrast to other studies (17), our study accounted for missing data and our model was
15 carefully planned and scrutinised. We attempted to overcome the limitations of routine
16 data and produce the least biased results by imputing missing data, analysed for bias with
17 appropriate diagnostic techniques, and performing sensitivity analyses with non-missing
18 data. The main limitation for our multiple imputation was the absence of auxiliary variables.
19 However, this is a recognised limitation of using routinely collected population data, and not
20 a limitation of our analysis per se. All adjusted models, including complete case models,
21 produced estimates within close proximity of each other, diminishing the likelihood that our
22 final estimate of risk is misleading.

23 24 **Interpretation**

25 Our study has strong clinical relevance. We set out to validate the association between
26 VBAC and significant perineal injury using a large cohort, and have demonstrated with
27 updated methodology that women having a VBAC are 21% more likely than primiparous
28 women to sustain a 3rd or 4th degree tear during vaginal birth. Current antenatal counselling
29 and patient education for women attempting a VBAC typically focusses on the risk of
30 uterine rupture and subsequent fetal complications (18, 19), often without any reference to
31 the increased risk of obstetric anal sphincter injury. In light of our findings, we feel the
32 evidence now convincingly demonstrates an increased risk of significant perineal injury
33 associated with VBAC. We suggest that this risk should be included in the antenatal

1 counselling of women considering a VBAC and be acknowledged in the guidelines of peak
2 professional bodies such as the Royal Australian and New Zealand College of Obstetricians
3 and Gynaecologists and the Royal College of Obstetricians and Gynaecologists.

4
5 Our study is well-timed with many Western jurisdictions introducing initiatives to prevent
6 and reduce the occurrence of 3rd and 4th degree tears. Through measures such as timely
7 mediolateral episiotomy and Manual Perineal Protection, the OASI Care Bundle, introduced
8 throughout the UK in 2016-2017, was shown to significantly reduce the risk of 3rd and 4th
9 degree tears (aOR 0.80; 95%CI 0.65-0.98) in participating units (39). In Victoria, Australia,
10 there is a current state-wide initiative to reduce the rate of 3rd and 4th degree tears amongst
11 all women having a vaginal birth (the *Better births for women collaborative*), instigated in
12 2019 by the peak safety and quality institution, Safer Care Victoria (40). Neither the OASI
13 Care Bundle in the UK or the Better Births initiative in Australia identified women having
14 VBAC as a high-risk group, however our findings suggest that these women should be
15 prioritised in such initiatives.

16
17 Our intention in pursuing this study was not to dissuade either patients or healthcare
18 providers from supporting women attempting a vaginal birth after caesarean section, but
19 rather to make antenatal counselling more comprehensive, birth management decisions
20 better informed and to help optimise intrapartum care. There are myriad benefits
21 associated with successful, uncomplicated VBAC, some of which include expedited post-
22 birth recovery and improved breastfeeding initiation (41, 42). Vaginal birth after caesarean
23 section also avoids the well-established risks related to repeat caesarean section delivery,
24 such as significant bleeding, development of abdominal adhesions, increased future risk of
25 placenta praevia, disorders of placental adherence and unnecessary iatrogenic preterm
26 birth in the setting of threatened preterm labour (43, 44).

27 28 **Conclusion**

29 There are many social, economic and medical benefits of successful vaginal birth following
30 caesarean section. Our study has confirmed that women considering a vaginal birth after
31 caesarean section should be counselled about the increased risk of 3rd and 4th degree tears,
32 and midwives and obstetricians working in the birthsuite setting should be appropriately
33 educated about this increased risk.

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4 *views or recommendations expressed in this paper are strictly those of the author(s). They do*
5 *not necessarily reflect those of CCOPMM."*

6
7 **Disclosure of interests:** None to declare.

8
9 **Contribution to authorship:** AL, JU and ST devised the study. JU, AL and NP obtained ethical
10 approval and the data used for the study. AL and RJH devised the analysis plan, performed
11 the analyses and wrote the Methods and Results sections of the manuscript. JU and AL
12 wrote the manuscript. ST, RH and SW provided oversight and review of the analysis, results
13 and manuscript on multiple occasions prior to submission for publication.

14
15 **Details of ethical approval:** Ethical approval was obtained from the Mercy Hospital for
16 Women Human Research Ethics Committee (#2019-01). Because this was a retrospective
17 study using archived de-identified data only, obtaining individual patient consent was not
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19
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24
25
26 **Figures and Tables:**

27 Figure 1: Consort diagram of study population

28 Table 1. Participant characteristics by VBAC exposure

29 Table 2. Characteristics of women who had a VBAC, by perineal tear status

30 Table 3. Results of regression adjustment and sensitivity analyses

31
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Table 1. Participant characteristics by VBAC exposure

	Controls* (%) N=111,125	VBAC** (%) N=4,922	P value
Maternal age (years)			
Mean (SD)	28.6 (5.2)	31.7 (4.7)	P<0.001
12-19	5,390 (4.9)	21 (0.4)	
20-24	18,384 (16.5)	365 (7.4)	
25-29	38,656 (34.8)	1,094 (22.2)	
30-34	34,882 (31.4)	2,059 (41.8)	
35-39	11,875 (10.7)	1,211 (24.6)	
40-44	1,827 (1.6)	165 (3.4)	
≥45	46 (0.04)	<5 (0.1)	
Missing	65 (0.1)	<5 (0.1)	
BMI (kg/m²)			
Mean (SD)	24.7 (5.1)	25.4 (5.1)	P<0.001
Missing	14,821 (13.3)	649 (13.2)	
Gestation (weeks)			
37	7,412 (6.7)	330 (6.7)	P<0.001
38	17,415 (15.7)	831 (16.9)	
39	30,067 (27.0)	1,474 (30.0)	
40	34,672 (31.2)	1,631 (33.1)	
41	20,122 (18.1)	602 (12.2)	
≥42	1,437 (1.3)	54 (1.1)	
Missing	Nil	Nil	
Mode of birth			
Spontaneous vaginal	65,653 (59.1)	2,793 (56.7)	P<0.001
Vacuum	23,697 (21.3)	1,160 (23.6)	
Forceps	21,775 (19.6)	969 (19.7)	
Missing	Nil	Nil	
Episiotomy			
No	59,747 (53.8)	2,708 (55.0)	P=0.18
Yes	51,367 (46.2)	2,214 (45.0)	
Missing	11 (<0.1)	Nil	

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Epidural analgesia			
No	61,284 (55.2)	2,829 (57.5)	P<0.001
Yes	39,941 (36.0)	1,486 (30.2)	
<i>Missing</i>	9,900 (8.8)	607 (12.3)	
Birthweight (g)			
Mean (SD)	3377.3 (439.9)	3452.7 (442.7)	P<0.001
Birthweight <4000g	102,053 (91.8)	4,390 (89.2)	
Birthweight ≥4000g	9,072 (8.2)	532 (10.8)	P<0.001
<i>Missing</i>	Nil	Nil	
3rd or 4th degree tear			
No	104,747 (94.3)	4,571 (92.9)	P<0.001
Yes	6,378 (5.7)	351 (7.1)	
<i>Missing</i>	Nil	Nil	

*Controls = primiparous women having a vaginal birth; **VBAC = first vaginal birth after one past caesarean section

Table 2. Characteristics of women who had a VBAC, by perineal tear status

	VBAC without OASIS N=4,571	VBAC with OASIS N=351	p-value
Maternal age			
Mean (SD)	31.7 (4.7)	31.4 (4.5)	P=0.18
12-19	19 (0.4)	<5 (0.6)	P=0.87
20-24	338 (7.4)	27 (7.7)	
25-29	1,013 (22.2)	81 (23.1)	
30-34	1,904 (41.7)	155 (44.2)	
35-39	1,134 (24.8)	77 (21.9)	
40-44	156 (3.4)	9 (2.6)	
≥45	<5 (0.1)	0	
<i>Missing</i>	<5	Nil	
BMI			

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Mean (SD)	25.4 (5.1)	25.7 (5.1)	P=0.32
Missing (%)	1,431 (31.3)	115 (32.8)	
Gestation			
37	314 (6.9)	16 (4.6)	P=0.39
38	770 (16.9)	61 (17.4)	
39	1,371 (30.0)	103 (29.3)	
40	1,515 (33.1)	116 (33.1)	
41	549 (12.0)	53 (15.1)	
≥42	52 (1.1)	<5 (0.6)	
Missing	0	0	
Mode of birth			
Spontaneous vaginal	2,622 (57.3)	171 (48.7)	<0.001
Vacuum	1,090 (23.9)	70 (19.9)	
Forceps	859 (18.8)	110 (31.3)	
Missing	Nil	Nil	
Episiotomy			
No	2,475 (54.2)	233 (66.4)	P<0.001
Yes	2,096 (45.9)	118 (33.6)	
Missing			
Epidural analgesia			
No	2,616 (57.2)	213 (60.7)	P=0.08
Yes	1,398 (30.6)	88 (25.1)	
Missing (%)	557 (12.2)	50 (14.3)	
Birthweight (g)			
Mean (SD)	3443.3 (441.5)	3576.6 (440.2)	P<0.001
Birthweight <4000g	4,095 (89.6)	295 (84.1)	P=0.001
Birthweight ≥4000g	476 (10.4)	56 (15.9)	
Missing	Nil	Nil	

Table 3. Results of regression adjustment and sensitivity analyses

	Exposure		Risk Difference	Relative Risk
	Control	VBAC	(95%CI)	(95%CI)
Unadjusted cohort (N = 116,047) ***				
Logistic regression	0.0574	0.0713	0.0139 (0.0066 to 0.0212, p < 0.001)	1.24 (1.12 to 1.38, p < 0.001)
Multiple imputation cohort (m =20) (N = 116,047)^				
Regression adjustment	0.0575	0.0698	0.0122 (0.0035 to 0.0210, p = 0.006)	1.21 (1.07 to 1.38, p = 0.003)
Complete case cohort excluding analgesia and BMI (N = 115,967)*				
Regression adjustment	0.0575	0.0710	0.0134 (0.0048 to 0.0221, p = 0.002)	1.23 (1.09 to 1.39, p = 0.001)
Complete case cohort including analgesia and BMI (N = 91,491)**				
Regression adjustment	0.0571	0.0680	0.0110 (0.0011 to 0.0208, p = 0.029)	1.19 (1.03 to 1.38, p = 0.018)

^Imputation model: Predictive mean matching based on 5 nearest neighbours for continuous variables (maternal age, height and BMI),; logistic regression for binary (episiotomy, labour analgesia & ATSI), and multinomial logistic model for unordered categorical variables (SEIFA); no missing values included in imputation model (OASIS34, vbac, birthweight, gestational age, mode of birth, episiotomy and BMI and analgesia)

*Model includes OASIS34 ~ vbac + gestation in weeks + maternal age + mode of birth + episiotomy

**Model includes OASIS34 ~ vbac + gestation in weeks + maternal age + mode of birth + episiotomy + BMI + analgesia

***Unadjusted logistic regression model with robust standard errors.

CONSORT 2010 Flow Diagram (modified)

