1	Management of Fetal Malposition in the Second Stage of Labor: A Propensity
2	Score Analysis
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19	Disclosure Statement: The authors report no conflict of interest.
20	Sources of Financial Support: During data analysis, A.R.A. was supported by an
21	NICHD Predoctoral Fellowship under grant number F31HD079182 and by grant
22	R24HD042849, awarded to the Population Research Center at The University of
23	Texas at Austin. She is currently supported by grant R24HD047879 for Population
24	Research at Princeton University. J.G.S. is partially funded by a CAREER grant from
25	the National Science Foundation (DMS-1255187).

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27	Reprints: Reprints will not be available.
28	Word Count: Abstract 268 Main Text 2992
29	Condensation: After stratifying cases of persistent malposition on variables
30	determining decision to attempt rotation, rotational instrumental delivery was not
31	associated with worse outcomes than cesarean delivery.
32	
33	Short Version of Article Title: Managing fetal malposition in second stage

34	Abstract

35	Objective: To determine the factors associated with selection of rotational
36	instrumental versus cesarean delivery to manage persistent fetal malposition, and to
37	assess differences in adverse neonatal and maternal outcomes following delivery by
38	rotational instruments versus cesarean section.
39	Study Design: We conducted a retrospective cohort study over a 5-year period in a
40	tertiary UK obstetrics center. 868 women with vertex-presenting, single, live-born
41	infants at term with persistent malposition in the second stage of labor were included.
42	Propensity-score stratification was used to control for selection bias: the possibility
43	that obstetricians may systematically select more difficult cases for cesarean section.
44	Linear and logistic regression models were used to compare maternal and neonatal
45	outcomes for delivery by rotational forceps or ventouse versus cesarean section,
46	adjusting for propensity scores.
47	Results: Increased likelihood of rotational instrumental delivery was associated with
48	lower maternal age (OR= 0.95 p<0.01), lower BMI (OR=0.94 p<0.001), lower birth-
49	weight (OR=0.95 p<0.01), no evidence of fetal compromise at the time of delivery
50	(OR=0.31 p<0.001), delivery during the daytime (OR= 1.45, P<0.05), and delivery by
51	a more experienced obstetrician (OR=7.21 p<0.001). Following propensity score
52	stratification, there was no difference by delivery method in the rates of delayed
53	neonatal respiration, reported critical incidents, or low fetal arterial pH. Maternal
54	blood loss was higher in the cesarean group (295.8± 48ml p<0.001).
55	Conclusions: Rotational instrumental delivery is often regarded as unsafe. However,
56	we find that neonatal outcomes are no worse once selection bias is accounted for, and
57	that the likelihood of severe obstetric hemorrhage is reduced. More widespread

training of obstetricians in rotational instrumental delivery should be considered,
particularly in light of rising cesarean section rates. **Key Words:** cesarean section; operative vaginal delivery; fetal malposition; delivery;
intra-partum care

Introduction

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Fetal head malposition in the second stage of labor is a significant risk factor for adverse maternal and neonatal outcomes, and is associated with high rates of both instrumental delivery and cesarean section [1]. While some women will spontaneously deliver a malpositioned fetus, most require obstetric intervention [2]. In cases of persistent malposition, the obstetrician must choose between a potentially difficult rotational instrumental delivery and a second-stage cesarean section. Instrumental rotation of the fetal head has fallen out of favor in modern obstetric practice in much of the world, despite data showing low complication rates [3, 4]. It has recently been demonstrated that, while the majority of obstetricians considered rotation of the fetal head to be an acceptable intervention (97%), less than half (41%) had performed it within the previous year [5]. Second-stage cesarean section is an increasingly common alternative [6], but carries a significant burden of maternal morbidity [7, 8]. A small number of studies have compared the morbidity associated with different instruments used to effect rotational delivery, and have found low prevalence of adverse maternal and neonatal outcomes, as well as increased risk of some adverse events with emergency cesarean section [9-11]. However, any comparison of delivery outcomes by rotational instruments versus second-stage cesarean section must confront the possibility that obstetricians systematically select more difficult cases for cesarean section, thereby introducing a selection bias. This study has two main objectives: first, to illuminate the factors that make an attempt at rotational

instrumental delivery more likely, by modeling the obstetrician's decision-making

process; and second, to use propensity-score stratification to create comparable groups that allow differences in maternal and fetal outcomes by delivery type to be tested reliably.

Materials and Methods

A cohort of 25,886 women with vertex-presenting, single, live-born infants at term (37 – 42 completed weeks of gestation), aiming for vaginal delivery was identified over a 5-year period (Jan 2008- Oct 2013) in a single tertiary obstetrics center in the UK. A sub-cohort of 868 women was identified with a confirmed cephalic fetal malposition in the second stage of labor. Of these, 833 underwent either cesarean section (n=534) or successful instrumental delivery (n=299), and 35 underwent failed instrumental delivery, followed by second-stage cesarean section.

Fetal malposition was defined as any cephalic position greater than 45 degrees from direct occipito-anterior [12], and was diagnosed by digital examination. The rate of malpositions delivered by each method did not vary significantly across the study years. Deliveries where the obstetrician performed manual rotation of the fetal head followed by direct instrumental delivery were not considered to be cases of persistent fetal malposition, and were not included in the analysis. The indications and procedures for instrumental delivery in our center are defined in the operative vaginal delivery guidance from the Royal College of Obstetricians and Gynaecologists (RCOG, UK) [12]. The classification of and indications for operative vaginal delivery are materially identical to the American College of Obstetricians and Gynecologists (ACOG) Practice Bulletin Number 17 on operative vaginal delivery [13].

Rotational instrumental delivery was carried out with either Kielland's forceps or ventouse. Ventouse devices available in the unit include posterior and rotational metal cups, silastic cups, and Kiwi Omnicups. Of the 334 successful instrumental deliveries, 62.0% (n=207) were conducted with Kielland's forceps and 38.0% (n=127) using ventouse.

Data regarding each woman's pregnancy, labor, and delivery were recorded by midwives shortly after birth, and were subsequently obtained from the hospital's Protos data-recording system. The database is regularly validated by a rolling program of audits where the original case notes are checked against the information recorded in the database. No patient-identifiable data were accessed during this research, which was performed as part of a provision-of-service study for the obstetrics center. Individual medical records were not accessed at any stage.

Institutional Review Board approval was therefore not required.

Characteristics of the materno-fetal dyad were extracted from the database, including maternal age (at time of delivery), BMI (at first-trimester prenatal booking), parity (prior to delivery), ethnicity, and birth-weight to the nearest gram. Also recorded were the time between diagnosis of second stage and delivery (time fully dilated), and the instrument selected. Gestational age (measured by crown-rump length at first-trimester ultrasound) was recorded to the nearest week. Only cases where birth occurred within the interval 37-42 weeks' completed gestation were included. No adjustment was made for infants found to be small or large for gestational age. The indication for delivery was also classified into those where there was evidence of fetal compromise (including pathological fetal-heart tracing, abnormal fetal-blood

sampling result, evidence of sepsis) and those where delivery was undertaken on other grounds (including failure to progress in second stage and maternal exhaustion).

Deliveries were conducted under regional anesthesia (epidural or spinal), excepting a small number who required general anesthetic because of time constraints or failure of regional anesthesia during the procedure.

The level of experience of the obstetrician attempting delivery and the time at which the delivery took place were also recorded. Obstetricians were classified into three types using years of training as a proxy for experience. Type-1 and Type-2 obstetricians have 3-5 years and 5-10 years of obstetric training, respectively. Type 3 obstetricians typically have >10 years of clinical obstetric experience. Our study was conducted in a unit where 2 obstetricians are available to perform instrumental deliveries or cesarean sections at any time. The first is typically a type-1 obstetrician, and is always supported by an immediately available doctor with >5 years obstetric training: a type-3 obstetrician during the day, or type-2 overnight. All obstetricians had training in at least one method of rotational instrumental delivery, in line with RCOG training requirements.

Delay in neonatal respiration was recorded where spontaneous respiration was not achieved within 1 minute of delivery. Umbilical cord blood was obtained immediately following delivery, and the arterial pH recorded. Correlation between arterial and venous pH was checked to confirm accuracy of the measurements. Arterial pH was categorized as >=7.1 or <7.1 [14]. A critical-incident form was generated at delivery in the case of any obstetric or neonatal emergency, including neonatal resuscitation, post-partum hemorrhage, shoulder dystocia, severe perineal trauma, maternal visceral

injury, or any other event generating an obstetric emergency call. Maternal blood loss was measured by operating-room staff immediately after delivery, using suction blood collection and weighing of swabs and other pads. Blood loss was treated as a numerical variable to the nearest milliliter, and also categorized as minor (<1500ml) or major (>=1500ml). Severe perineal trauma was defined as any disruption to the anal sphincter complex. Simple groupwise comparisons of these outcomes for women undergoing rotational instrumental versus cesarean delivery were carried out using either Student's t-test or the Mann-Whitney test for numerical data, and Pearson's chi-squared test for categorical data.

Any rigorous attempt to compare outcomes for the rotational-instrumental and cesarean-section groups is complicated by the fact that obstetricians may systematically select more difficult cases for cesarean section. This selection bias may involve physicians' own training and experience, their immediate concern for fetal well-being, and anticipated fetal weight. An extensive set of these assignment-related variables are available in our data set, allowing us to explicitly model the obstetrician's decision-making process. This allows us to use propensity-score stratification to adjust for factors that influence the decision to move towards cesarean section. Propensity-score stratification involves two stages. First, we build a statistical model for the treatment assignment (instrumental versus cesarean delivery), given a suitable set of predictors. The propensity score is the predicted probability of receiving the treatment derived from this first model. We then build a second set of models to estimate the effect of the treatment on each clinical outcome of interest, conditional on subjects' propensity scores. This approach generates a balanced cohort of subjects whose baseline characteristics will be statistically similar, regardless of

treatment status. For the purpose of estimating treatment effects, it is typically more robust than standard regression modeling, and may be formally justified under the potential-outcomes framework for causal inference [15]. The effect of the covariates themselves on the clinical outcome is captured by the propensity score, and is never explicitly modeled.

For the purpose of estimating propensity scores, the 35 failed instrumental deliveries were included in the instrumental group, as the goal of this first-stage analysis was to model the physician's initial treatment decision. For the purpose of estimating treatment effects, we ran two sets of second-stage analyses: one set with the 35 failed instrumental deliveries included, and one with them excluded.

Propensity scores were generated using a logistic-regression model predicting assignment to the instrumental-delivery group (the "treatment"). The regression model included seven covariates found to be significantly different between women undergoing rotational instrumental and cesarean section, and which were thought to be clinically relevant: maternal age, maternal BMI, parity, birth-weight, evidence of fetal compromise, time of delivery, and degree of experience of the delivering obstetrician. Although birth-weight is unknown before delivery, it has been included because it plausibly may be anticipated by the physician and it strongly predicts the decision to move to cesarean delivery.

The resulting propensity scores were then stratified by quintile [16], and the balance of covariates between cases of rotational instrumental delivery and cesarean section delivery checked within each quintile to verify that no significant differences

remained. Adverse maternal and fetal outcomes were then modeled using linear and binary logistic regression, including the type of delivery and dummy variables for the propensity score quintiles as predictors. Findings were considered statistically significant at an alpha level of 0.05. Power calculations were performed by Monte Carlo simulation. All data analysis was conducted using the R statistical software package version 2.14.1.

Results

868 women with confirmed fetal malpositions in the second stage of labor were identified. 534 (61.5%) were delivered directly by second-stage cesarean section; and 334 (38.5%) had an attempted rotational instrumental delivery, 299 of which resulted in successful delivery, and 35 of which were converted to second-stage cesarean section. Characteristics of the maternal-fetal dyad were compared between the instrumental-delivery and cesarean-section groups (Table 1). Women in the cesarean-section group were more likely to be older (p<0.01), to have higher BMI (p<0.001), and to have babies with higher birth-weights (p<0.01). In terms of events surrounding delivery, women in the cesarean-section group were more likely to have had a delivery involving evidence of fetal compromise (p<0.001), to have been delivered during the night (p<0.01), and to have been delivered by a less experienced obstetrician (p<0.001).

Table 2 shows the results of the logistic regression predicting assignment to rotational instrumental delivery (the "treatment"). Lower birth-weight (p<0.01), lower maternal age (p<0.01), lower maternal BMI, (p<0.001), higher parity (p<0.1), absence of evidence of fetal compromise (p<0.001), delivery during the daytime (p<0.05), and

increased experience of obstetrician (p<0.001) are all significant predictors of assignment to rotational instrumental delivery.

The balance of covariates between the two groups was then checked within each propensity-score quintile. There were no significant differences between the groups on any covariates in any of the quintiles. The results for the fourth quintile are shown as an example (Table 3); note that the propensity score quintiles are based on the combined groups. The characteristics of the materno-fetal dyad are now much more similar across the two groups than they were before stratification (c.f. Table 1).

Unadjusted comparison of delivery outcomes (Table 4) showed that a higher percentage of deliveries in the cesarean-section group was associated with a critical incident at the time of delivery (p<0.01) and increased estimated blood loss (491.6ml v. 792.5ml, p<0.001). As expected, there were a number of infants with shoulder dystocia (2.7%) and severe maternal perineal trauma (3-4th degree tears; 6%) in the rotational-instrumental group. In the cesarean-section group, 9.4% required administration of general anesthesia.

Table 5 shows the associations between mode of delivery and adverse maternal and neonatal outcomes following propensity-score adjustment. As a robustness check, results are shown both with and without the failed instrumental deliveries included in the rotational-instrumental cohort, and are very similar in both cases. There were no differences between deliveries preformed by rotational instruments versus cesarean section in the time to neonatal respiration, reported critical incidents associated with the delivery, or likelihood of fetal umbilical arterial pH of <= 7.1. The estimated

blood loss was higher in the cesarean group by 295.8 ± 48 ml (p<0.001). In addition, the likelihood of sustaining >1500ml estimated blood loss was lower in the instrumental group (OR 0.24, p<0.01). Power calculations showed that, at a Type-I error rate of 5%, we have at least 80% power to detect odds ratios outside the interval (0.54, 1.85) for binary outcomes, and to detect blood-loss effect sizes of at least 135 milliliters.

Comment

After propensity-score adjustment, instrumental delivery does not appear to be associated with worse maternal and neonatal outcomes. If anything, it offers a significantly lower risk than cesarean section of postpartum hemorrhage. We found no difference in delay to neonatal respiration following instrumental delivery, and no clinically significant difference in the risk of a low fetal arterial pH. We also demonstrate systematic differences between women who are assigned by obstetricians to rotational instrumental delivery versus second-stage cesarean section. These differences include lower birth-weight, lower maternal age, lower BMI and higher parity. Obstetricians are also more likely to undertake rotational instrumental delivery when they have more experience and when working during daylight hours (which may reflect the availability of immediate back-up from more experienced colleagues).

Our results are in general agreement with previous studies examining the maternal and neonatal risks of rotational instrumental delivery [9-11]. In addition to the outcomes reported here, these studies are reassuring regarding maternal outcomes, including duration of hospital stay [17] and obstetric anal sphincter injury [11]; and neonatal outcomes, including fetal injury [9, 10, 18]. Although we did not specifically

examine it here, even in cases where instrumental deliveries are not successful, the outcomes of such attempts do not appear to be worse outcomes than proceeding directly to cesarean section [19].

The main strength of our study is its methodological robustness in addressing selection bias. Systematic differences between delivery groups are likely to affect any observational study, complicating any attempt to compare maternal and neonatal outcomes using standard regression analysis. The use of propensity-score stratification, a technique that is becoming more widely used in obstetrics [20, 21], offers major advantages in this context. In particular, as long as the covariates can be shown to be properly balanced after stratification, the subsequent estimate of the treatment effect does not rely upon the precise mathematical relationship between the outcome and the covariates. This stands in strong contrast to standard regression analysis: when the covariates are heavily imbalanced between the groups, as they are in our data set, all treatment effects estimated by regression depend upon the specific form of the model, and are not robust to violations of standard assumptions, such as linearity, separability of covariate effects, and homoscedasticity [22, 23].

The main limitations of our study include the inability to distinguish between different fetal malpositions (occipito-posterior, occipito-transverse etc.), and the lack of sub-division of the cohort to distinguish between deliveries conducted using rotational forceps and ventouse. While these data are available, a further sub-cohort analysis has not been performed, as sample sizes would be insufficiently large to allow adequate propensity-score stratification between groups. Additionally, we did not have information about attempts at manual rotation, as these are not routinely

recorded in our database. Another limitation is the lack of information about caput, molding, and station. We were thus unable to account for the influence of these subjective but important variables in the decision-making process. We were also unable to control for the presence of maternal diabetes. Our study documents adverse maternal and neonatal outcomes at birth; however, we lack the follow-up data to ensure that there is no excess of late adverse outcomes in either group. Existing data suggest that there is no evidence of increased adverse neurodevelopmental outcomes in neonates following instrumental delivery [24]. Additionally, data are collected shortly after delivery, and therefore do not include information on length of stay in hospital, either for the mother or the neonate.

The association we demonstrate between obstetrician experience and likelihood of proceeding to instrumental delivery likely reflects the difficulty of such deliveries and the experience required to undertake them with confidence. Indeed, others have noted the importance of operator experience in the safe use of Kielland's forceps [25] and that junior obstetricians are relatively more likely to use rotational ventouse rather than forceps [26]. We have shown elsewhere that obstetricians in their first 5 years of training are more likely to have unsuccessful instrumental deliveries than more experienced obstetricians [27]. Our findings imply that increased training and experience for trainee obstetricians is important, especially in light of rising cesarean section rates. Other studies have also recognized a need for improved training in instrumental delivery techniques [28]. While 'real-life' experience is desirable, simulator-based training has been developed and may help fulfill some learning needs [29].

The obstetrician's perception of the safety of the mother and fetus plays a major role in the decision to perform rotational instrumental delivery in the face of persistent malposition. Our analysis shows that higher maternal weight and age, the expectation that the fetus is large, and the presence of fetal distress all make the choice of cesarean section more likely. However, once we adjust for these factors, it does not appear that rotational instrumental delivery is associated with a higher rate of adverse outcomes. A risk of shoulder dystocia is inherent in vaginal deliveries, as is the risk of severe perineal trauma. The obstetrician must carefully weigh these risks against the increased risk of maternal hemorrhage and of requiring general anesthesia with second-stage cesarean section. Rotational instrumental delivery, particularly by Kielland's forceps, has been all but abandoned in many obstetric practices. Yet the findings presented here suggest that there is room for further debate about the inclusion of rotational instruments in the clinical toolkit of modern obstetricians, especially in settings where cesarean section has become the default mode of delivery.

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Table 1—Characteristics of the Maternal-Fetal Dyad for the Full Sample and
 Stratified by Decision to Rotate

Characteristic	All Patients (N=868)	Rotational Instrumental Delivery (n=334)	Second Stage Cesarean (n=534)
Maternal age (yrs)	30.5	29.8	31.0**
Maternal BMI (kg/m²)	25.5	24.4	26.2***
Gestation (wks)	39.9	39.9	39.8
Parity			
0	454 (52.3)	166 (49.7)	288 (53.9)
1+	414 (47.7)	168 (50.3)	246 (46.1)
Time fully dilated (min)	159.1	159.8	161.2
Epidural			_
Yes	601 (69.2)	229 (68.6)	372 (69.7)
No	267 (30.8)	105 (31.4)	162 (30.3)
Obstetrician type			
1	405 (46.7)	104 (31.1)	301 (56.4)***
2	366 (42.2)	159 (47.6)	207 (38.8)
3	97 (11.2)	71 (21.3)	26 (4.9)
Birth weight (g)	3592	3532	3630**
Fetal Indication			steate at
Yes	439 (50.6)	116 (34.7)	313 (58.6)***
No	429 (49.4)	218 (65.3)	221 (41.4)
Ethnicity			
White	784 (90.3)	303 (90.7)	481 (90.1)
Southeast Asian	53 (6.1)	21 (6.3)	32 (6.0)
Black	9 (1.0)	5 (1.5)	4 (0.7)
Chinese	8 (1.0)	1 (0.3)	7 (1.3)
Other	14 (1.6)	4 (1.2)	10 (1.9)
Time of Delivery			
Day	467 (53.8)	206 (61.7)	261 (48.9)
Night	401 (46.2)	128 (38.3)	273 (51.1)**

Figures are means or n, percentages in parentheses

449 **p<0.01, ***p<0.001

Table 2—Factors Associated with Decision to Perform Rotational Instrumental

452 Delivery (N=868)

Variable	Odds Ratio (95% CI)
Maternal Age (yrs)	0.95** (0.93-0.98)
Maternal BMI (kg/m²)	0.94*** (0.91-0.97)
Parity	
0	ref
1+	1.36^{\dagger} (1.00-1.85)
Obstetrician Type	
1	ref
2	2.49*** (1.79-3.48)
3	7.21*** (4.22-12.64)
Birth Weight (per 100g)	0.95** (0.92-0.98)
Fetal Indication	0.31*** (0.23-0.43)
Time of Delivery	
Night	ref
Day	1.45^* (1.05-2.01)

Model coefficients are expressed as odds ratios and 95% confidence intervals (CI).

 † p<0.1, *p<0.05, **p<0.01, ***p<0.001

 Table 3—Balance of Matched Covariates after Propensity Score Stratification

(Fourth Quintile)

Characteristic	Rotational	Second Stage	P
	Instrumental	Cesarean	
	Delivery (n=81)	(n=92)	
Maternal age (yrs)	29.4	29.8	0.60
Maternal BMI (kg/m²)	23.8	24.0	0.69
Parity			
0	42 (51.9)	46 (50.0)	0.81
1+	39 (48.1)	46 (50.0)	
Obstetrician type			
1	27 (33.3)	31 (33.7)	0.96
2	45 (55.6)	58 (63.0)	
3	9 (11.1)	3 (3.3)	
Birth weight (g)	3531.7	3592.4	0.10
Fetal Indication			
Yes	58 (71.6)	68 (73.9)	0.73
No	23 (28.4)	24 (26.1)	
Time of Delivery			
Day	48 (59.3)	52 (56.5)	0.72
Night	33 (40.7)	40 (43.5)	

Figures are means or n, percentages in parentheses

Table 4—Maternal and Neonatal Outcomes for the Full Sample and Stratified by

485 Decision to Rotate

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Characteristic	All Patients (N=868)	Rotational Instrumental Delivery (n=334)	Second Stage Cesarean (n=534)
Estimated Blood Loss	677.2	491.6	792.5***
(ml)			
Delayed Neonatal	86 (9.9)	27 (8.1)	59 (11.0)
Respiration			
Critical Incident	89 (10.3)	23 (6.9)	66 (12.4)**
Reported			
Umbilical Arterial pH	43 (5.0)	14 (4.2)	29 (5.4)
<7.1			
Shoulder Dystocia	9 (1.0)	9 (2.7)	-
Severe Perineal Trauma	20 (2.3)	20 (6.0)	-
General Anesthesia	50 (5.8)	-	50 (9.4)

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Figures are means or n, percentages in parentheses

Failed Instrumentals included in rotational instrumental delivery group

490 **p<0.01, ***p<0.001

 Table 5
 Associations Between Mode of Delivery and Adverse Maternal and

Neonatal Outcomes for the Propensity Score Adjusted Sample

	Failed Instrumental Deliveries Not		Failed Instrumental Deliveries Included	
	Included (N=833)		(N=868)	
Outcome	OR (95% C.I.)	P	OR (95% C.I.)	P
Time to Neonatal				
Respiration				
Cesarean Section	ref		ref	
Rotational Instrumental	0.77 (0.43-1.31)	0.35	0.77 (0.44-1.29)	0.31
Incidence of Critical				
Incident				
Cesarean Section	ref		ref	
Rotational Instrumental	1.52 (0.77-3.09)	0.24	1.66 (0.86-3.31)	0.14
Fetal Umbilical Arterial				
pH<7.1				
Cesarean Section	ref		ref	
Rotational Instrumental	0.63 (0.26-1.40)	0.27	0.77 (0.36-1.60)	0.49
Estimated Blood Loss				
>1.5L				
Cesarean Section	ref		ref	
Rotational Instrumental	$0.20 \ (0.10 - 0.38)$	<0.01	0.24 (0.13-0.43)	<0.01
	Coefficient (S.E.)		Coefficient (S.E.)	
Estimated Blood Loss (ml)				
Cesarean Section	ref		ref	
Rotational Instrumental	-333.4 (50.09)	<0.001	-295.8 (47.98)	<0.001

496 ** p<0.01, ***p<0.001