Operative vaginal delivery and neonatal and infant adverse outcomes: population based retrospective analysis

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Abstract

Objective To compare the risk of neonatal and infant adverse outcomes between vacuum and forceps assisted deliveries.

Design Population based study.

Setting US linked natality and mortality birth cohort file and the New Jersey linked natality, mortality, and hospital discharge summary birth cohort file.

Participants Singleton live births in the United States (n = 11 639 388) and New Jersey (n = 375 351).

Main outcome measures Neonatal morbidity and mortality.

Results Neonatal mortality was comparable between vacuum and forceps deliveries in US births (odds ratio 0.94, 95% confidence interval 0.79 to 1.12). Vacuum delivery was associated with a lower risk of birth injuries (0.69, 0.66 to 0.72), neonatal seizures (0.78, 0.68 to 0.90), and need for assisted ventilation (< 30 minutes 0.94, 0.92 to 0.97; ≥ 30 minutes 0.92, 0.88 to 0.98). Among births in New Jersey, vacuum extraction was more likely than forceps to be complicated by postpartum haemorrhage (1.22, 1.07 to 1.39) and shoulder dystocia (2.00, 1.62 to 2.48). The risks of intracranial haemorrhage, difficulty with feeding, and retinal haemorrhage were comparable between both modes of delivery. The sequential use of vacuum and forceps was associated with an increased risk of need for mechanical ventilation in the infant and third and fourth degree perineal tears.

Conclusion Although vacuum extraction does have risks, it remains a safe alternative to forceps delivery.

Introduction

Vacuum extraction and obstetric forceps are operative procedures used during complicated vaginal deliveries. They are indicated for cord prolapse, a non-reassuring fetal heart rate, prolonged second stage labour, intrapartum haemorrhage, exhaustion, and heart disease, pulmonary injury, and certain neurological conditions in the mother.^{1 2} The use of vacuum extraction relative to forceps has increased in the United States, accounting for 68% of all operative vaginal deliveries in 2000—an increase from 41% in 1990.³ This increase, however, has been accompanied by reports to the US Food and Drug Administration of fetal deaths and serious injuries.⁴

In 1998, the FDA released a warning that vacuum assisted deliveries may result in fatal complications, particularly subgaleal haematoma and intracranial haemorrhage (including subdural, subarachnoid, intraventricular, and intraparenchymal haemorrhage).⁴ We undertook a population based study to compare the risk of neonatal morbidities and mortality between deliveries by vacuum extraction and forceps.

Materials and methods

Birth cohorts

Our data were derived from two sources: the Center for Disease Control's linked natality and mortality birth cohort file for the United States, 1995-8; and the linked natality, mortality, and hospital discharge summary birth cohort file for New Jersey, 1989-93.^{5 6} The linked cohort file for New Jersey was not available for recent years.

United States file

The Center for Disease Control's linked file is produced annually and includes data from birth and death certificates provided by individual states under the Vital Statistics Cooperative Program. Because a large study size is needed to study mortality as an end point, we used data from the US file to examine neonatal deaths (0-27 days) and infant deaths (0-364 days). Neonatal morbidities were also examined, including birth injuries (facial nerve injury, intracranial haemorrhage, haematoma of internal organs, and bone fractures), seizures, and receipt of assisted ventilation (< 30 minutes and ≥ 30 minutes). The reporting of operative vaginal deliveries from birth certificates has shown a moderate to high sensitivity compared with hospital records.^{7 8}

New Jersey file

The New Jersey file contains linked information on birth certificates, infant death certificates, and maternal and newborn hospital discharge summaries. Linkage of the hospital discharge summaries to birth certificates permitted examination of additional outcomes for neonatal morbidity, including cephalohaematoma, intracranial haemorrhage (subdural or cerebral haemorrhage, intraventricular haemorrhage, and subarachnoid haemorrhage), shoulder dystocia,

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Table 1 Maternal and infant risk factors by mode of delivery. Values are numbers (percentages)

Risk factors	Deliveries in United States (1995-8)			Deliveries in New Jersey (1989-93)			
	Unassisted (n=10137144)	Forceps (n=435 339)	Vacuum (n=891 340)	Unassisted (n=327 373)	Forceps (n=26 491)	Vacuum (n=19 120)	Vacuum plus forceps (n=1889)
Maternal factors							
Age*:							
<20	1 372 658 (13.5)	63 640 (14.6)	129 062 (14.5)	32 563 (10.0)	1659 (6.3)	1 842 (9.6)	133 (7.1)
20-24	2 613 107 (25.8)	104 528 (24.0)	208 926 (23.4)	68 674 (21.0)	4160 (15.7)	3792 (19.8)	347 (18.4)
25-29	2 793 585 (27.6)	126 264 (29.0)	253 795 (28.5)	101 331 (31.0)	9489 (35.8)	6250 (32.7)	661 (35.0)
30-34	2 236 445 (22.1)	95 513 (21.9)	201 388 (22.6)	89 059 (27.2)	8098 (30.6)	5118 (26.8)	543 (28.8)
≥35	1 121 349 (11.1)	45 394 (10.4)	98 169 (11.0)	35 509 (10.9)	3073 (11.6)	2110 (11.0)	203 (10.8)
Race:							
White	8 062 451 (79.5)	365 418 (83.9)	747 107 (83.8)	194 971 (59.6)	20 793 (78.5)	12 928 (67.6)	1446 (76.6)
Black	1 540 533 (15.2)	49 328 (11.3)	86 516 (9.7)	63 049 (19.3)	2332 (8.8)	2551 (13.3)	188 (10.0)
Other	534 160 (5.3)	20 593 (4.7)	57 717 (6.5)	69 353 (21.2)	3366 (12.7)	3641 (19.0)	255 (13.5)
Parity*:							
Nulliparous	3 744 621 (36.9)	307 533 (70.6)	566 200 (63.5)	125 828 (38.4)	18 370 (69.3)	12 313 (64.4)	1439 (76.1)
Multiparous	6 340 340 (62.6)	125 690 (29.0)	320 345 (35.9)	195 263 (59.7)	7590 (28.7)	6404 (33.5)	424 (22.5)
Disorders:							
Diabetes mellitus	206 951 (2.0)	11 113 (2.6)	20 319 (2.3)	6159 (1.9)	470 (1.8)	359 (1.9)	42 (2.2)
Prepregnancy hypertension	49 845 (0.5)	2742 (0.6)	4953 (0.6)	2641 (0.8)	211 (0.8)	163 (0.9)	10 (0.5)
Pregnancy induced hypertension	265 632 (2.6)	19 414 (4.5)	35 576 (4.0)	11 506 (3.5)	1111 (4.2)	995 (5.2)	100 (5.3)
Neonatal factors							
Gestational age (weeks):							
35-36	607 120 (6.0)	21 624 (5.0)	42 828 (4.8)	13 298 (4.1)	737 (2.8)	527 (2.8)	41 (2.2)
37-38	2 362 731 (23.3)	89 011 (20.5)	188 664 (21.2)	57 444 (17.6)	3472 (13.1)	2797 (14.6)	276 (14.6)
39-40	4 991 664 (49.2)	217 312 (49.9)	448 030 (50.3)	203 460 (62.2)	16 685 (63.0)	11 781 (61.6)	1152 (61.0)
41-42	1 739 305 (17.2)	88 329 (20.3)	173 243 (19.4)	52 384 (16.0)	5507 (20.8)	3974 (20.8)	418 (22.1)
>42	436 324 (4.3)	19 063 (4.4)	38 575 (4.3)	787 (0.2)	90 (0.3)	41 (0.2)	2 (0.1)
Birth weight (g)*:							
<1500	4314 (0)	105 (0)	135 (0)	173 (0.1)	5 (0)	5 (0)	0 (0)
1500-2499	349 550 (3.5)	11 295 (2.6)	21 056 (2.4)	11 449 (3.5)	644 (2.4)	411 (2.2)	30 (1.6)
2500-3999	8 815 485 (87.0)	347 627 (86.1)	774 612 (86.9)	283 075 (86.6)	22 612 (85.4)	16 593 (86.8)	1608 (85.1)
>4000	967 795 (9.6)	49 312 (11.3)	95 537 (10.7)	32 032 (9.8)	3 179 (12.0)	2 079 (10.8)	246 (13.0)

*Results may not add to 100% because of missing values.

facial nerve injury, feeding difficulty, and retinal haemorrhage. The file also allowed a detailed comparison of labour complications that are likely to influence outcomes of deliveries by forceps or vacuum extraction. These complications included disproportion, malposition at onset of labour, obstruction by bony pelvis, deep transverse arrest and persistent occipitoposterior position, and other causes of obstructed labour; primary, secondary, and other uterine inertia; precipitate labour; hypertonic, incoordinate, or prolonged uterine contraction; long labour; and complications due to the umbilical cord. We were also able to examine selected maternal outcomes, including third and fourth degree perineal tears and postpartum haemorrhage. Cases concerning sequential use of vacuum and forceps were also identified. Information from hospital discharge summaries and birth certificates were used to define complications, obstetric procedures, and outcomes. Linked data were more complete for mode of delivery and maternal and fetal complications than for birth certificates alone.⁷⁻⁹

Participants

We analysed mother-infant pairs from the US and New Jersey files if they concerned singleton live births. Exclusions were caesarean or breech deliveries, infants with congenital malformations, or infants born at less than 35 weeks' gestation (at this age delivery is a relative contraindication for vacuum extraction).^{1 10}

Mode of delivery (unassisted vaginal, vacuum, or forceps) was the independent variable of interest in

both analyses. Potential determinants or confounders of mortality and morbidity were personal characteristics (maternal age, race, and education), risk factors associated with pregnancy (gestational age, parity, birth weight, diabetes mellitus, gestational diabetes, chronic hypertension, pregnancy induced hypertension), and labour complications (premature rupture of membranes, induction of labour, fetal distress, placental abruption, and intrapartum bleeding).

Statistical analysis

We examined the association between infant mortality and morbidity and mode of delivery using logistic regression models. Odds ratios and 95% confidence intervals were estimated before and after adjusting for confounders. We performed a post hoc power calculation¹¹ based on an α of 0.05, sample size of 435 339 for the forceps group and 891 340 for the vacuum group, and a neonatal mortality of 5 per 10 000 deliveries for the forceps group. Our study had 92% and 81% power to detect 30% and 25% differences in neonatal mortality between forceps and vacuum deliveries, respectively. All analyses were performed using SAS.

Results

Overall, there were 15 189 537 singleton live births in the United States during 1995-8 and 556 597 in New Jersey during 1989-93. Vacuum extraction and forceps accounted for 7.4% and 4.4%, respectively, of all US deliveries in 1995, 7.8% and 4.0% in 1996, 7.8% and

Table 2 Complications of labour among deliveries in New Jersey, 1989-93. Values are numbers (percentages)

Complication	Unassisted (n=327 373)	Forceps (n=26 491)	Vacuum (n=19 120)	Vacuum plus forceps (n=1889)
Premature rupture of membranes	19 330 (5.9)	1927 (7.3)	1251 (6.5)	160 (8.5)
Disproportion	253 (0.1)	100 (0.4)	33 (0.2)	7 (0.4)
Obstructed labour:				
Malposition at onset of labour	49 (0.0)	30 (0.1)	14 (0.1)	1 (0.1)
Obstruction by bony pelvis	6 (0.0)	22 (0.1)	7 (0.0)	2 (0.1)
Deep transverse arrest and persistent occipitoposterior position	532 (0.2)	585 (2.2)	247 (1.3)	63 (3.3)
Other causes	10 (0.0)	40 (0.2)	5 (0.0)	3 (0.2)
Abnormal forces of labour:				
Primary uterine inertia	2987 (0.9)	387 (1.5)	349 (1.8)	49 (2.6)
Secondary uterine inertia	1810 (0.6)	640 (2.4)	335 (1.8)	52 (2.8)
Other uterine inertia	7897 (2.4)	926 (3.5)	679 (3.6)	66 (3.5)
Precipitate labour	8763 (2.7)	117 (0.4)	141 (0.7)	8 (0.4)
Hypertonic labour, incoordinate or prolonged uterine contraction	298 (0.1)	50 (0.2)	43 (0.2)	10 (0.5)
Long labour	3 342 (1.0)	1320 (5.0)	870 (4.6)	141 (7.5)
Umbilical cord:				
Prolapse	1129 (0.3)	173 (0.7)	90 (0.5)	19 (1.0)
Tight around neck*	10 290 (3.1)	791 (3.0)	736 (3.8)	67 (3.5)
Entanglement with and without compression*	53 352 (16.3)	5327 (20.1)	3413 (17.9)	357 (18.9)
Other*	946 (0.3)	88 (0.3)	71 (0.4)	9 (0.5)
Induction of labour	33 509 (10.2)	2940 (11.1)	2820 (14.7)	311 (16.5)
Placental abruption	1175 (0.4)	217 (0.8)	109 (0.6)	17 (0.9)
Intrapartum bleeding	927 (0.3)	89 (0.3)	80 (0.4)	8 (0.4)
Fetal distress	4974 (1.5)	1508 (5.7)	1118 (5.8)	166 (8.8)

*Diagnoses after birth.

3.6% in 1997, and 7.6% and 3.2% in 1998. The values for New Jersey were 2.5% and 6.4% in 1989, 3.2% and 5.7% in 1990, 3.8% and 5.0% in 1991, 4.4% and 4.6% in 1992, and 4.9% and 4.1% in 1993. This represents a 96% relative increase in the use of vacuum assisted deliveries from 1989 to 1993.

Our inclusion criteria were met by 11 639 388 births in the United States and 375 351 births in New Jersey. Table 1 shows the distribution of maternal and infant risk factors by mode of delivery. The mothers in New Jersey were more likely to be older than US mothers. Nulliparous women were more likely to deliver by either vacuum or forceps than parous women. The frequency of diabetes mellitus and intrapartum bleeding was slightly higher among the US mothers, whereas hypertensive disorders of pregnancy and placental abruption were slightly higher among the New Jersey mothers. These rates were similar for both modes of delivery. Fetal distress was more common among instrumental deliveries. The distribution for gestational age was similar between infants delivered by forceps and those delivered by vacuum in both cohorts. The proportion of infants born at lower gestational ages was, however, higher for the United States. This is likely due to the increasing trend of preterm birth during the past few years; data for US births are more recent than those for New Jersey births.

Table 2 shows the rates of labour complications by mode of delivery among New Jersey births. The frequency of complications was comparable between vacuum and forceps deliveries but was more common in the small number of cases when vacuum and forceps were used sequentially.

Table 3 shows the risks of neonatal mortality and morbidity associated with mode of delivery for US births. After adjusting for important confounders, the risk of neonatal mortality was similar between infants delivered by vacuum or forceps. Because of the strong association between parity and mode of delivery, we

carried out separate analyses for nulliparous and parous mothers. The results of these analyses were similar to the overall (unstratified) results. For instance, among nulliparous women the risk of neonatal mortality for vacuum deliveries compared with forceps deliveries was similar to the risk among parous women (odds ratio 0.95, 95% confidence interval 0.76 to 1.18 and 0.93, 0.69 to 1.27, respectively). The risk of infant mortality was also similar between these two groups (0.91, 0.81 to 1.04 and 0.83, 0.71 to 0.97, respectively). The risks of birth injuries and neonatal seizures were lower for vacuum deliveries.

In New Jersey births, cephalohaematoma was more common among infants delivered by vacuum, and

Table 3 Neonatal and infant mortality and morbidity by mode of delivery in United States, 1995-8. Values are number (incidence) unless stated otherwise

	Unassisted (n=10 137 144)	Forceps (n=435 339)	Vacuum (n=891 340)
Mortality			
Neonatal death*†:	3741 (3.7)	218 (5.0)	416 (4.7)
Adjusted odds ratio (95% CI)‡	0.75 (0.64 to 0.87)	1.00	0.94 (0.79 to 1.12)
Infant death§	18 303 (18.1)	714 (16.4)	1316 (15.8)
Adjusted odds ratio (95% CI)	0.87 (0.80 to 0.94)	1.00	0.88 (0.79 to 0.96)
Morbidity			
Birth injuries:	21 729 (21.4)	4751 (109.1)	6783 (76.1)
Adjusted odds ratio (95% CI)	0.25 (0.24 to 0.26)	1.00	0.69 (0.66 to 0.72)
Neonatal seizures:	5119 (5.0)	380 (8.7)	581 (6.5)
Adjusted odds ratio (95% CI)	0.75 (0.67 to 0.84)	1.00	0.78 (0.68 to 0.90)
Assisted ventilation			
<30 minutes:	148 478 (146.5)	12 753 (292.9)	22 298 (250.2)
Adjusted odds ratio (95% CI)	0.66 (0.65 to 0.67)	1.00	0.94 (0.92 to 0.97)
≥30 minutes:	26 286 (25.9)	2405 (55.2)	4246 (47.6)
Adjusted odds ratio (95% CI)	0.61 (0.58 to 0.64)	1.00	0.92 (0.88 to 0.98)

*Death within 0-27 days.

†Number per 10 000 deliveries.

‡Adjusted for maternal age, race, parity, education, gestational age, birth weight, diabetes, pre-existing hypertension, pregnancy induced hypertension, premature rupture of membranes, induction of labour, fetal distress, placental abruption, and intrapartum bleeding.

§Death within 0-364 days.

Table 4 Neonatal and maternal morbidity by mode of delivery in New Jersey, 1989-93. Values are number (incidence) unless stated otherwise

	Unassisted (n=327 373)	Forceps (n=26 491)	Vacuum (n=19 120)	Vacuum plus forceps (n=1889)
Neonatal morbidity				
Cephalohaematoma*	5457 (166.7)	1681 (634.6)	2135 (1116.6)	257 (1360.5)
Facial nerve injury	78 (2.4)	98 (37.0)	10 (5.2)	10 (52.9)
Intracranial haemorrhage	122 (3.7)	45 (17.0)	31 (16.2)	5 (26.5)
Adjusted odds ratio (95% CI)†	0.29 (0.20 to 0.41)	1.00	0.96 (0.62 to 1.52)	1.35 (0.53 to 3.42)
Shoulder dystocia	1464 (44.7)	145 (54.7)	216 (113.0)	12 (63.5)
Adjusted odds ratio (95% CI)	0.71 (0.59 to 0.85)	1.00	2.00 (1.62 to 2.48)	1.10 (0.59 to 2.03)
Feeding difficulty	763 (23.3)	68 (25.7)	57 (29.8)	6 (31.8)
Adjusted odds ratio (95% CI)	0.89 (0.69 to 1.15)	1.00	1.15 (0.80 to 1.64)	1.23 (0.53 to 2.84)
Mechanical ventilation	768 (23.5)	83 (31.3)	77 (40.3)	14 (74.1)
Adjusted odds ratio (95% CI)	0.84 (0.66 to 1.06)	1.00	1.27 (0.92 to 1.74)	2.22 (1.24 to 3.97)
Retinal haemorrhage	597 (18.2)	51 (19.3)	30 (15.7)	6 (31.8)
Adjusted odds ratio (95% CI)	0.87 (0.65 to 1.18)	1.00	0.78 (0.50 to 1.24)	1.65 (0.71 to 3.86)
Maternal morbidity				
Third degree perineal tear	12 359 (377.5)	3316 (1251.7)	1840 (962.3)	295 (1561.7)
Adjusted odds ratio (95% CI)	0.39 (0.38 to 0.41)	1.00	0.78 (0.73 to 0.83)	1.21 (1.06 to 1.38)
Fourth degree perineal tear	6626 (202.4)	2584 (975.4)	1199 (627.1)	251 (1328.7)
Adjusted odds ratio (95% CI)	0.28 (0.27 to 0.30)	1.00	0.64 (0.60 to 0.69)	1.33 (1.15 to 1.53)
Postpartum haemorrhage	4734 (144.6)	517 (195.1)	458 (239.5)	43 (227.6)
Adjusted odds ratio (95% CI)	0.79 (0.72 to 0.87)	1.00	1.22 (1.07 to 1.39)	1.12 (0.81 to 1.55)

*Number of cases per 10 000 deliveries

†Adjusted for birth weight, gestational age, deep transverse arrest, persistent occipitoposterior position, long labour, fetal distress, cord prolapse, placental abruption, and intrapartum bleeding.

facial nerve injury was more common among those delivered by forceps (table 4). After adjusting for confounders, the risk of shoulder dystocia among infants delivered by vacuum was twofold higher than those delivered by forceps. The risks of intracranial haemorrhage or retinal haemorrhage, feeding difficulties, or need for mechanical ventilation were similar between both modes of delivery. Vacuum extraction carried a slightly lower risk of third and fourth degree perineal tears. The results of stratified analyses by parity did not differ meaningfully from the unstratified analyses (data not shown).

After adjusting for confounders, sequential use of vacuum and forceps compared with forceps alone was associated with an increased risk of need for mechanical ventilation and third and fourth degree perineal tears. In the New Jersey cohort, 523 failed forceps deliveries and 412 failed vacuum deliveries resulted in caesarean section. Of the failed forceps deliveries, two infants each had intracranial haemorrhage and feeding difficulties compared with three cases each for failed vacuum deliveries. Seven infants who were delivered by caesarean section after a failed forceps delivery required mechanical ventilation compared with two infants after a failed vacuum delivery.

Our study included preterm infants (35-36 weeks' gestation) and those at term (>34 weeks). As severe morbidities such as intracranial haemorrhage are more common among preterm infants, we reanalysed the data after their exclusion. The results for term infants were similar to the main analyses for both populations—for example, the odds of mortality during the neonatal period for US infants delivered by vacuum compared with forceps was 0.95 (0.78 to 1.14). In New Jersey, the odds of intracranial haemorrhage for infants delivered by vacuum compared with forceps was 0.96 (0.59 to 1.55).

Discussion

Delivery by vacuum extraction is at least as safe as delivery by forceps. Fatal complications and outcomes (neonatal death and intracranial haemorrhage) were similar between neonates and infants from two large birth cohorts in the United States after delivery by forceps or vacuum extraction. The risk of birth injuries, neonatal seizures, and third and fourth degree perineal tears were lower for vacuum deliveries. The higher risk of such tears among forceps deliveries was further increased when vacuum and forceps were used sequentially. The risks of developing shoulder dystocia and postpartum haemorrhage were higher for vacuum deliveries.

Vacuum extraction versus forceps assisted delivery

The consistency of results from two data sources covering different periods adds credibility to our conclusion that vacuum extraction is at least as safe as forceps. Although delayed second stage of labour is the general indication for use of either procedure, there may be differences in selection of cases affecting comparability. A randomised controlled design would have avoided this problem; however, a study large enough to examine neonatal mortality would be costly, and the results might not reflect the manner in which assisted deliveries are done in the community. In the New Jersey cohort, detailed information on labour complications was available from hospital discharge summaries. We believe that the extensive control of these variables minimised the problem of confounding by indication. Overall, the relatively low rates of fatal complications observed among vacuum deliveries argue against the warning provided by the FDA.

Studies have compared several neonatal outcomes between forceps and vacuum deliveries.¹²⁻²³ A meta-analysis that summarised the results of seven studies found that the risk of cephalohaematoma was higher

with vacuum deliveries whereas retinal haemorrhage was lower with forceps deliveries.² Because of the requirement for a large sample size, infant mortality, particularly in neonates, has not been compared between the two modes of delivery. In Johanson's meta-analysis of seven studies, only three perinatal deaths occurred among 901 vacuum deliveries and four among 899 forceps deliveries.² Thus the results were inconclusive. Our analysis was based on more than 10 million singleton live births. Our study had sufficient power to detect important differences in deaths among the two modes of delivery, and our results are population based and generalisable.

Studies from California and Quebec have examined the rates of intracranial haemorrhage by mode of delivery.^{12 14} The California study was restricted to singleton live born infants to nulliparous women; both forceps and vacuum extraction were associated with an increased risk of intracranial haemorrhage.¹⁴ In the Canadian study only vacuum extraction was associated with subarachnoid haemorrhage.¹² (This finding was based on a small number of cases, and the increased risk had a wide confidence interval.)

Assisted vaginal deliveries using multiple instruments

Difficult deliveries in which vacuum was followed by forceps, or either procedure was followed by caesarean section, had worse outcomes than procedures that were successful on the first attempt. Although difficult labour rather than mode of delivery may have been responsible for this, an excessive number of pulls during attempted instrumental deliveries or use of multiple instruments cannot be excluded. In a cohort of over 10 000 deliveries in the United Kingdom, the use of multiple instruments and more than three pulls at attempted instrumental delivery were associated with increased neonatal trauma.²⁴

Limitations

Our study has limitations that are inherent in the use of birth certificates and administrative data. Indications and complications of operative vaginal deliveries (defined by codes from the international classification of disease, ninth revision) may not have been captured accurately on hospital discharge summaries, resulting in residual confounding. Also, the occurrence of birth injuries and some other neonatal morbidities are likely to be underestimated. Consequently, our findings on morbidity are likely to be conservative. Nonetheless, our results agree with previous reports on the association between neonatal morbidity and mode of delivery.^{12 14} The experience of the operator may also determine the outcome of delivery.^{24 25} The data do not, however, capture such information. Encouraging operative vaginal deliveries may help to reduce the rates of caesarean section.²⁶ Emerging evidence suggests an advantage of instrumental vaginal deliveries over caesarean section for subsequent outcomes.²⁷

Although delivery by vacuum extraction does have risks, it remains a safe alternative to forceps delivery. Our results underscore the need for obstetric standards in performing instrumental deliveries.

Contributors: KD designed the study, contributed to the analysis, interpreted the results, and wrote the manuscript. KG analysed the US file as part of his fieldwork project for MPH degree. BAB reanalysed the data after combining information

What is already known on this topic

A meta-analysis was too small to provide conclusive evidence of the risk of neonatal morbidity between forceps and vacuum deliveries

What this study adds

Evidence from two large birth cohorts shows that infants delivered by forceps or vacuum are at similar risk of mortality

from both the US and New Jersey files and addressed reviewer's comments. JCS, GGR, KSJ, and MK contributed to the design and write up of the manuscript. KD will act as guarantor for the paper.

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- Cunningham F, MacDonald P, Grant N, Leveno KJ, Gilstrap LI, Hankins G, et al. *Williams's obstetrics*, 21 ed. New York, NY: McGraw-Hill, 2001.
- Johanson RB, Menon BK. Vacuum extraction versus forceps for assisted vaginal delivery. *Cochrane Database Syst Rev* 2000;(2):CD000224.
- Kozak LJ, Weeks JD. US trends in obstetric procedures, 1990-2000. *Birth* 2002;29:157-61.
- US Food and Drug Administration. *Public Health Advisory: need for caution when using vacuum assisted delivery devices*. Rockville, MD: FDA Center for Devices and Radiological Health, 1998.
- National Center for Health Statistics. *1995-1999 Linked birth/infant death dataset*. Hyattsville, MD: US Department of Health and Human Services, Centers for Disease Control and Prevention. (NCHS CD-Rom Series 20, Nos 12-14.)
- Demissie K, Breckenridge MB, Rhoads GG. Infant and maternal outcomes in the pregnancies of asthmatic women. *Am J Respir Crit Care Med* 1998;158:1091-5.
- Parrish KM, Holt VL, Connell FA, Williams B, LoGerfo JP. Variations in the accuracy of obstetric procedures and diagnoses on birth records in Washington State, 1989. *Am J Epidemiol* 1993;138:119-27.
- Piper JM, Mitchell EF Jr, Snowden M, Hall C, Adams M, Taylor P. Validation of 1989 Tennessee birth certificates using maternal and newborn hospital records. *Am J Epidemiol* 1993;137:758-68.
- Green DC, Moore JM, Adams MM, Berg CJ, Wilcox LS, McCarthy BJ. Are we underestimating rates of vaginal birth after previous cesarean birth? The validity of delivery methods from birth certificates. *Am J Epidemiol* 1998;147:581-6.
- Royal College of Obstetricians and Gynaecologists. *Instrumental vaginal delivery*. London: RCOG, 2000. (Clinical Green Top Guideline No 26.)
- Schlesselman JJ. Sample size requirements in cohort and case-control studies of disease. *Am J Epidemiol* 1974;99:381-4.
- Wen SW, Liu S, Kramer MS, Marcoux S, Ohlsson A, Sauve R, et al. Comparison of maternal and infant outcomes between vacuum extraction and forceps deliveries. *Am J Epidemiol* 2001;153:103-7.
- Vacca A, Grant A, Wyatt G, Chalmers I. Portsmouth operative delivery trial: a comparison between vacuum extraction and forceps delivery. *Br J Obstet Gynaecol* 1983;90:1107-12.
- Towner D, Castro MA, Eby-Wilkens E, Gilbert WM. Effect of mode of delivery in nulliparous women on neonatal intracranial injury. *N Engl J Med* 1999;341:1709-14.
- Punnonen R, Aro P, Kuukankorpi A, Pystynen P. Fetal and maternal effects of forceps and vacuum extraction. *Br J Obstet Gynaecol* 1986;93:1132-5.
- Johanson R, Pusey J, Livera N, Jones P. North Staffordshire/Wigan assisted delivery trial. *Br J Obstet Gynaecol* 1989;96:537-44.
- Herabutya Y, O-Prasertsawat P, Boonrangsamant P. Kielland's forceps or ventouse—a comparison. *Br J Obstet Gynaecol* 1988;95:483-7.
- Hankins GD, Rowe TF. Operative vaginal delivery—year 2000. *Am J Obstet Gynecol* 1996;175:275-82.
- Ehlers N, Jensen IK, Hansen KB. Retinal haemorrhages in the newborn. Comparison of delivery by forceps and by vacuum extractor. *Acta Ophthalmol (Copenh)* 1974;52:73-82.
- Broekhuizen FF, Washington JM, Johnson F, Hamilton PR. Vacuum extraction versus forceps delivery: indications and complications, 1979 to 1984. *Obstet Gynecol* 1987;69:338-42.
- Bofill JA, Rust OA, Schorr SJ, Brown RC, Martin RW, Martin JN Jr, et al. A randomized prospective trial of the obstetric forceps versus the M-cup vacuum extractor. *Am J Obstet Gynecol* 1996;175:1325-30.
- Greis JB, Bieniarz J, Scommegna A. Comparison of maternal and fetal effects of vacuum extraction with forceps or cesarean deliveries. *Obstet Gynecol* 1981;57:571-7.
- Johanson RB, Rice C, Doyle M, Arthur J, Anyanwu L, Ibrahim J, et al. A randomised prospective study comparing the new vacuum extractor policy with forceps delivery. *Br J Obstet Gynaecol* 1993;100:524-30.
- Murphy DJ, Liebling RE, Patel R, Verity L, Swingler R. Cohort study of operative delivery in the second stage of labour and standard of obstetric care. *Br J Obstet Gynaecol* 2003;110:610-5.

- 25 Murphy DJ, Liebling RE, Verity L, Swingler R, Patel R. Early maternal and neonatal morbidity associated with operative delivery in second stage of labour: a cohort study. *Lancet* 2001;358:1203-7.
- 26 US Department of Health and Human Services. Understanding and improving health and objectives for improving health. *Healthy people 2010*. 2nd ed. Washington, DC: US Government Printing Office, 2000.
- 27 Bahl R, Strachan B, Murphy DJ. Outcome of subsequent pregnancy three years after previous operative delivery in the second stage of labour: cohort study. *BMJ* 2004;328:311.
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