

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

Kitaw Demissie, George G Rhoads, John C Smulian, Bijal A Balasubramanian, Kishor Gandhi, K S Joseph, Michael Kramer

Division of Epidemiology, University of Medicine and Dentistry of New Jersey, School of Public Health, 683 Hoes Lane West, PO Box 9, Piscataway, NJ 08854, USA
Kitaw Demissie
assistant professor

George G Rhoads
professor
Bijal A Balasubramanian
research associate
Kishor Gandhi
graduate student

Division of Maternal Foetal Medicine, Department of Obstetrics and Gynaecology and Reproductive Sciences, University of Medicine and Dentistry of New Jersey, Robert Wood Johnson Medical School, New Brunswick, NJ 08901, USA
John C Smulian
associate professor

Perinatal Epidemiology Research Unit, Department of Obstetrics and Gynaecology and Paediatrics, Dalhousie University, Halifax, NS, Canada B3H 4N1

K S Joseph
associate professor

Department of Paediatrics, McGill University, Faculty of Medicine, Montreal, QC, Canada H3G 1Y6
Michael Kramer
professor

Correspondence to: K Demissie
demisski@umdnj.edu

BMJ 2004;329:24-6

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 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. 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

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 1990.¹ In 1998, the US Food and Drug Administration released a warning that vacuum assisted deliveries may result in fatal complications, particularly subgaleal haematoma and intracranial haemorrhage.² We undertook a population based study to compare the risk of neonatal morbidities and mortality between vacuum extraction and forceps deliveries.

Materials and methods

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.^{3 4}

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, neonatal seizures, and receipt of assisted ventilation.

Linkage of the hospital discharge summaries to birth certificates in the New Jersey file permitted examination of additional outcomes for neonatal morbidity: cephalohaematoma, intracranial haemorrhage, shoulder dystocia, facial nerve injury, feeding difficulty, and retinal haemorrhage. The file also allowed a detailed comparison of labour complications: obstructed labour; uterine inertia; precipitate labour; abnormal 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 post-partum haemorrhage. Cases were also identified in which vacuum and forceps assistance were used sequentially.

We analysed mother-infant pairs 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.^{5 6} Mode of delivery (unassisted vaginal, vacuum, or forceps) was the independent variable of interest in analyses. Potential determinants or confounders of mortality and morbidity were personal characteristics, risk factors associated with pregnancy, and labour complications.

We compared infant mortality and morbidity and mode of delivery using logistic regression models. Odds ratios and 95% confidence intervals were estimated. Our study had 92% and 81% power to detect 30% and 25% differences in neonatal mortality between forceps and vacuum deliveries, respectively.

Results

Our inclusion criteria were met by 11 639 388 singleton live births in the United States and 375 351 in New Jersey. See bmj.com for proportions of births delivered by vacuum extraction and forceps during 1989-98.

The mothers in New Jersey were more likely to be older than mothers in the United States. Nulliparous women were more likely than parous women to deliver by vacuum or forceps. Fetal distress was more common among instrumental deliveries. The distribution for gestational age was similar between infants delivered by either mode in both cohorts. The proportion of infants born at lower gestational ages was, however, higher for the United States. The frequency of complications among New Jersey births was comparable between both modes of delivery but was more common in the small number of cases when vacuum and forceps were used sequentially.

Table 1 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



This is an abridged version; the full version is on bmj.com

delivered by vacuum or by 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. 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 facial nerve injury was more common among those delivered by forceps (table 2). After adjusting for confounders, the risk of shoulder dystocia was twofold higher among infants delivered by vacuum 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 decreased 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 was associated with an increased risk of need for mechanical ventilation and third and fourth degree perineal tears. In the New Jersey cohort, 523 cases of failed forceps deliveries and 412 cases of 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 attempt with forceps required mechanical ventilation compared with two infants delivered after a failed vacuum extraction.

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.

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 extraction. The higher risk of perineal tears among forceps deliveries was further increased when vacuum and forceps were used sequentially rather than alone. The risks of developing shoulder dystocia and postpartum haemorrhage were higher for infants delivered by vacuum.

The consistency of results from two data sources covering different periods adds credence 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. In the New Jersey cohort, detailed information on labour complications was available from hospital discharge summaries. We believe that the

Table 1 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.

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.

In a meta-analysis summarising outcomes between forceps and vacuum deliveries, the risk of cephalohaematoma was higher among infants delivered by vacuum whereas retinal haemorrhage was lower among infants delivered by forceps.⁷ In this meta-analysis of seven studies, only three perinatal deaths occurred among 901 vacuum deliveries and only four among 899 forceps deliveries.⁷ Thus the results were inconclusive. Our analysis was based on more than 10 million singleton live births. Our results are also population based and generalisable.

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.

Limitations

Our study has limitations that are inherent in the use of birth certificates and administrative data. Indications and complications of operative vaginal deliveries may

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

Table 2 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.

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.⁸⁻⁹ Encouraging operative vaginal deliveries may help to reduce the rates of caesarean section.¹⁰ Emerging evidence suggests an advantage of instrumental vaginal deliveries over caesarean section for subsequent outcomes.¹¹

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: See bmj.com

Funding: None.

Competing interests: None declared.

Ethical approval: The study was approved by the University of Medicine and Dentistry of New Jersey-Robert Wood Johnson Medical School's Institutional Review Board.

- 1 Kozak LJ, Weeks JD. US trends in obstetric procedures, 1990-2000. *Birth* 2002;29:157-61.
- 2 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.
- 3 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.)
- 4 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.
- 5 Cunningham F, MacDonald P, Grant N, Leveno KJ, Gilstrap LL, Hankins G, et al. *William's obstetrics*, 21 ed. New York, NY: McGraw-Hill, 2001.
- 6 Royal College of Obstetricians and Gynaecologists. *Instrumental vaginal delivery*. London: RCOG, 2000. (Clinical Green Top Guideline No 26.)
- 7 Johanson RB, Menon BK. Vacuum extraction versus forceps for assisted vaginal delivery. *Cochrane Database Syst Rev* 2000;(2):CD000224.
- 8 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.
- 9 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.
- 10 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.
- 11 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.

(Accepted 5 March 2004)

One hundred years ago

A museum of security

There is a museum of security at Charlottenburg, near Berlin, which owes its existence to the joint efforts of public authorities and private citizens. The State provides the building and funds necessary for maintenance, while private enterprise has collected the exhibits. The museum grew out of an exposition, held in 1889, of the various devices for the prevention of accidents in manufacture, a subject important in Germany to every manufacturer, as the system of joint State and employers' insurance renders the owner liable to a pension for those who are injured in his works. The general interest in this subject has led to

an appropriation in Germany of £28,400 in 1900, with appropriations of £23,600 in the two following years. The maintenance of the museum costs £1,500 to £2,000 a year. The museum supplies examples, representations, models, drawings, and information in regard to every possible appliance by which life is protected and accident less likely in all forms of manufacture. A museum of security on the same lines is being planned by the Philadelphia Institute of Social Science.

(BMJ 1904;i:389)