

A Prospective Observational Study of 1000 Vacuum Assisted Deliveries With the OmniCup Device

Thomas F. Baskett, MB, Cora A. Fanning, RN, David C. Young, MD

Department of Obstetrics and Gynaecology, Dalhousie University, Halifax NS

Abstract

Objective: To determine the maternal and perinatal outcomes associated with delivery by the rigid plastic OmniCup vacuum delivery device.

Methods: We conducted a prospective observational study of 1000 consecutive vacuum-assisted deliveries using the OmniCup vacuum device in singleton pregnancies. The relationship of the cup application to the flexion point was independently observed after delivery and related to the neonatal outcome, including scalp trauma.

Results: Of the 1000 women, 70% were nulliparous and 30% parous (\geq para 1). In 87.1% of the women, vacuum-assisted delivery was completed; spontaneous or forceps delivery occurred in 10.9%, and Caesarean section was performed in 2%. The vacuum was applied for ≤ 10 minutes in 97.4% of deliveries, ≤ 3 pulls were required in 95.6%, and ≤ 25 lb traction force was required in 85.7% of cases. There was a statistically significant relationship between unfavourable cup applications (deflexing and paramedian) and scalp trauma in infants born to nulliparous women ($P < 0.01$). Four cases of neonatal intracranial hemorrhage (0.4%) were identified, and three of these infants were subsequently neurodevelopmentally normal. There was one subgaleal hemorrhage.

Conclusions: There is a relationship between unfavourable cup application during vacuum assisted delivery and neonatal scalp trauma in infants born to nulliparous women.

Résumé

Objectif : Déterminer les issues maternelles et périnatales associées à l'accouchement au moyen de la ventouse obstétricale de plastique rigide OmniCup.

Méthodes : Nous avons mené une étude observationnelle prospective portant sur 1 000 accouchements par ventouse obstétricale utilisant le dispositif OmniCup dans le cadre de grossesses monofœtales. La relation entre l'application de la ventouse et le point de flexion a été observée de façon indépendante à la suite de l'accouchement et mise en relation

avec l'issue néonatale, y compris les traumatismes du cuir chevelu.

Résultats : Parmi ces 1 000 femmes, 70 % étaient nullipares et 30 % étaient pares (\geq para 1). Chez 87,1 % de ces femmes, l'accouchement par ventouse obstétricale a été réussi; un accouchement spontané ou par forceps est survenu chez 10,9 % des femmes et 2 % des femmes ont subi une césarienne. La ventouse a été appliquée pendant ≤ 10 minutes dans 97,4 % des accouchements, ≤ 3 tractions ont été nécessaires dans 95,6 % des cas et une force de traction de ≤ 25 lb s'est avérée nécessaire dans 85,7 % des cas. Une relation significative sur le plan statistique a été constatée entre les applications de ventouse non favorables (déflexion et paramédianes) et les traumatismes du cuir chevelu chez les nouveau-nés issus de nullipares ($P < 0,01$). Quatre cas d'hémorragie intracrânienne néonatale (0,4 %) ont été identifiés; trois de ces nouveau-nés ont par la suite connu un développement neurologique normal. Un cas d'hémorragie sous-galéale a été identifié.

Conclusions : Il existe une relation entre l'application non favorable de la ventouse au cours de l'accouchement par ventouse obstétricale et les traumatismes néonataux du cuir chevelu chez les nouveau-nés issus de nullipares.

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INTRODUCTION

Assisted vaginal delivery occurs in 5% to 26% of nulliparous women.¹ In the past 15 years there has been a shift towards using vacuum extraction rather than forceps to assist vaginal delivery.^{2,3} In Canada the vacuum assisted delivery rate has increased from 0.6% in 1980 to 10.6% in 2001, while the forceps delivery rate has decreased from 21.2% in 1980 to 6.8% in 2001.⁴ The main impetus for this change has been evidence suggesting that less maternal perineal trauma occurs with use of the vacuum,⁵ although long-term follow-up suggests no difference in pelvic floor function between women who have undergone vacuum delivery and those who have undergone forceps delivery.⁶ The original metal vacuum cups were associated with a higher rate of fetal scalp trauma than the soft silicone vacuum cups, but the failure-to-deliver rate is higher with the soft cup than with the metal cup design.⁷ Recently a new

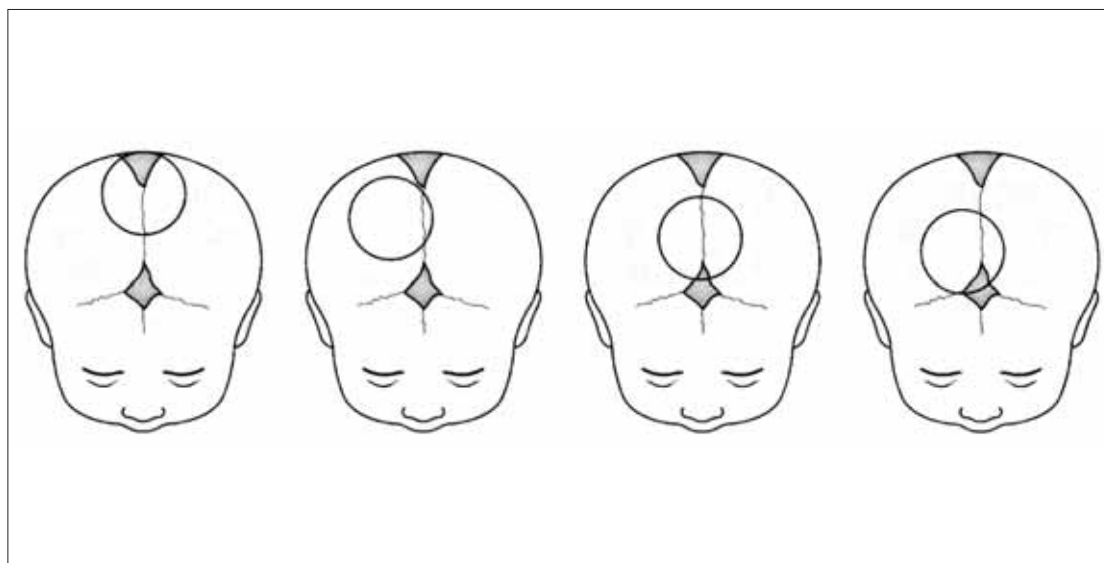
Key Words: Vacuum assisted delivery, fetal scalp trauma, neonatal subgaleal hemorrhage, neonatal intracranial hemorrhage, neonatal brachial plexus injury

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Cup positions on the fetal head: flexing median, flexing paramedian, deflexing median, and deflexing paramedian (left to right)



vacuum delivery device has been developed (Kiwi OmniCup, Clinical Innovations Inc., Murray, Utah). The OmniCup is a rigid plastic cup designed to be similar to the Malmstrom and Bird metal cups.⁸ The vertical profile of the cup is low (2 cm) and the diameter of the cup applied to the fetal scalp is 5 cm. However, the out-curving of the cup from the scalp attachment increases the functional tractional diameter to 6 cm. A thin flexible suction tube, which also incorporates a traction wire, is attached to the centre of the cup, and this tubing can be recessed into a groove on top of the cup. This design improves the manoeuvrability of the cup and allows it to be guided over the flexion point of the fetal head in deflexed occiput-transverse and occiput-posterior positions.⁹ For this reason, the OmniCup can be used for vacuum-assisted delivery in all positions of the occiput. The device incorporates a hand-held vacuum pump (PalmPump, Clinical Innovations, Murray, Utah), which provides suction for the cup attachment to the fetal scalp as well as the handle for traction to assist delivery. The OmniCup model we used also includes a traction force indicator which allows the operator to observe the amount of traction (measured in pounds) used during delivery.¹⁰ These theoretically advantageous design features prompted our observational study of this device for assisted vaginal delivery.

METHODS

The study was conducted at the Women's Hospital, IWK Health Centre, Halifax, Nova Scotia—a teaching hospital with approximately 5000 deliveries annually. All operative vaginal deliveries were conducted by obstetricians or by

residents in training under their direct supervision. The assisted vaginal delivery rate in the year before the study (2001) was 10.4%, of which 5.3% were vacuum-assisted. In the next four years (2002–2005, within which time the study was conducted), the assisted vaginal delivery rate was unchanged at 10.3%; of these deliveries, 5.2% were vacuum-assisted. Until the time of this study, the vacuum device used to assist delivery in this hospital was a soft bell-shaped cup (Mityvac).

In 2002, the OmniCup vacuum device was introduced to our hospital. After education sessions on the clinical application of the OmniCup, its use for assisted vacuum deliveries was adopted. In particular the careful application of the vacuum cup over the flexion point of the fetal head was emphasized.⁹ This point is approximately 3 cm anterior to the posterior fontanel on the sagittal suture. Thus, the cup was to be placed in the midline over the sagittal suture with the posterior aspect of the outcurved cup at the posterior fontanel to achieve the optimum flexing median application.

We undertook a prospective observational study of 1000 consecutive singleton cephalic deliveries using the OmniCup device where an assisted vaginal delivery was indicated at ≥ 35 weeks' gestation, and when the obstetrician chose to use the vacuum. The recorded details of each delivery included parity, position and station of the fetal head at cup application, the number of pulls to delivery (1 pull = traction during one uterine contraction), maximum traction force (in pounds), number of cup detachments during traction ("pop-offs"), duration of cup application (in

Table 1. Details of station and position of the head and cup application

Station at cup application	Para 0 (n = 700)	Para \geq 1 (n = 300)	<i>P</i>	Total (N = 1000)
+ 1 cm	35 (5.0%)	30 (10.0%)		65 (6.5%)
+ 2 cm	258 (36.9%)	103 (34.3%)		362 (36.2%)
+ 3 cm	281 (40.1%)	110 (36.7%)		391 (39.1%)
+ 4 cm	101 (14.4%)	51 (17.0%)		152 (15.2%)
+ 5 cm	25 (3.6%)	6 (2.0%)	0.04	31 (3.1%)
Position of fetal head (at application)				
Occiput anterior	620 (88.6)	251 (83.7)		871 (87.1)
Occiput transverse	27 (3.9)	17 (5.7)		44 (4.4)
Occiput posterior	53 (7.5)	32 (10.6)	0.054	85 (8.5)
Position of fetal head (at delivery)				
Occiput anterior	661 (94.5)	271 (90.3)		932 (93.2)
Occiput transverse	1 (0.1)	2 (0.7)		3 (0.3)
Occiput posterior	38 (5.4)	27 (9.0)	0.03	65 (6.5)
Rate of rotation to occiput anterior (%)				
Occiput transverse	97.3	89.2	0.55	93.2
Occiput posterior	28.4	25.7	0.29	23.6
Type of application				
Flexing median	235 (50.1)	87 (47.8)		322 (49.5)
Flexing paramedian	220 (46.9)	83 (45.6)		303 (46.5)
Deflexing median	6 (1.3)	6 (3.3)		12 (1.8)
Deflexing paramed	8 (1.7)	6 (3.3)	0.19	14 (2.2)

minutes), method of delivery, and perineal lacerations. Within 48 hours of delivery, the position of the cup on the fetal head and any associated trauma was assessed by an independent observer (CAF) and correlated with the outcome. Because of either early postpartum discharge or the absence of any scalp marks, these observations were only recorded in 651 of the 1000 cases. Four cup positions on the fetal head were defined: flexing median, flexing paramedian, deflexing median and deflexing paramedian (Figure). Deflexing and paramedian positions were defined as being >1 cm from the flexion point or sagittal suture respectively. Minor scalp trauma included abrasion, blister, and laceration. Scalp hematoma was defined as cephalhematoma and under-the-cup hematoma. Neonatal morbidity was recorded as follows: brachial plexus injury, fractures, seizures, intracranial hemorrhage, intraventricular hemorrhage, and subgaleal hemorrhage.

Approval for this study was obtained from the Research Ethics Board at the IWK Health Centre in Halifax, Nova Scotia.

Data were analysed using parametric (Student *t* test) and non-parametric (chi-square, Fisher exact, and Mann Whitney *U* tests) statistics as appropriate, using Statistix

8 (Analytical Software, Tallahassee FL) and PEPI Computer Programs for Epidemiologic Analysis (USD Inc., Stone Mountain GA).

RESULTS

Between March 2002 and August 2005 there were 1000 vacuum-assisted deliveries using the OmniCup device. Of these, 700 (70%) were in nulliparous women and 300 (30%) in parous (≥ 1) women. The gestational age at delivery was 33–36 weeks in 59 cases (5.9%) and 37–42 weeks in 941 (94.1%). The results in Tables 1–4 have been compared by parity (para 0 and para ≥ 1).

The details of cup application are shown in Table 1. The position of the fetal head at delivery was more likely to be occipitotransverse or occipitoposterior in the parous group ($P = 0.03$). In those cases with occipitotransverse position, the rotation to anterior position at delivery was 97.3% in nulliparous women and 89.2% in parous women ($P = 0.55$). Where the occiput was posterior, rotation to the anterior position at delivery occurred in 28.4% of nulliparous women and 25.7% of parous women. The type of cup application, as observed after delivery in 651 cases, showed no difference between the parity groups ($P = 0.19$).

Table 2. Technical aspects of delivery

Duration of cup application	Para 0 n = 700	Para ≥ 1 n = 300	<i>P</i>	Total N = 1000
1–10 min	678 (96.9%)	296 (98.7%)		974 (97.4%)
11–20 min	22 (3.0%)	4 (1.3%)		26 (2.6%)
> 20 min	1 (0.1%)	0	0.18	1 (0.1%)
Max traction force (lb) (recorded in 560 cases)	Para 0 (387)	Para ≥ 1 (173)		Total (560)
0–25	326 (84.2%)	154 (89.0%)	0.13	480 (85.7%)
> 25	61 (15.8%)	19 (11.0%)		80 (14.3%)
Number of pulls (recorded in 998 cases)	Para 0 (698)	Para ≥ 1 (300)		Total (998)
0	1 (0.1%)	2 (0.7%)		3 (0.3%)
1	239 (34.3%)	154 (51.4%)		393 (39.3%)
2	294 (42.2%)	105 (35.0%)		399 (39.9%)
3	129 (18.5%)	31 (10.3%)		160 (16.0%)
4	26 (3.7%)	4 (1.3%)		30 (3.0%)
≥ 5	9 (1.2%)	4 (1.3%)	< 0.001*	13 (1.3%)
Pop-offs	Para 0 (700)	Para ≥ 1 (300)		Total (1000)
0	528 (75.4%)	245 (81.7%)		773 (77.3%)
1	118 (16.9%)	40 (13.3%)		158 (15.8%)
2	51 (7.3%)	14 (4.7%)		65 (6.5%)
3	2 (0.3%)	1 (0.3%)		3 (0.3%)
4	1 (0.1%)	0	> 0.5	1 (0.1%)
Method of delivery	Para 0 (700)	Para ≥ 1 (300)		Total (1000)
Vacuum	594 (84.7%)	277 (92.3%)	0.001	871 (87.1%)
Vacuum → forceps	83 (11.8%)	15 (5.0%)		98 (9.8%)
Vacuum → spontaneous	6 (0.9%)	5 (1.7%)		11 (1.1%)
Vacuum → forceps → CS	9 (1.3%)	1 (0.3%)		10 (1.0%)
Vacuum → CS	9 (1.3%)	1 (0.3%)	0.002†	10 (1.0%)

*Comparison of 0–2 pulls with ≥ 3 pulls: $P < 0.001$

†Comparison of vacuum, vacuum → forceps, and vacuum → spontaneous with vacuum → forceps → CS and vacuum → CS.

Some of the technical aspects of delivery are shown in Table 2. There was no difference in the duration of cup application between nulliparous and parous women, and in the great majority of cases (97.4%) the duration of cup application was 1–10 minutes. The cup was applied for longer than 20 minutes only once. There was no difference between nulliparous and parous women in the maximum traction force required for delivery, and in only 14.3% of cases was this greater than 25 lbs. There was, however, a significant relationship between parity and the number of pulls required to effect delivery ($P < 0.001$). In comparing the need for 0–2 pulls with ≥ 3 pulls, parous women

required significantly fewer pulls than nulliparous women ($P = 0.001$). Cup detachment (pop-off) occurred in 24.6% of nulliparous women and in 18.3% of parous women; there was no relationship between parity and the number of pop-offs ($P > 0.5$). Overall, use of the vacuum was successful in achieving vaginal delivery in 87.1% of women; a further 1.1% delivered spontaneously after the vacuum was applied but without traction, and 9.8% had a forceps delivery after a failed attempt at vacuum delivery. In 2% of women, Caesarean section was performed after failed vacuum. Successful vacuum delivery was more likely in multiparous women (92.3%) than in nulliparous women

Table 3. Neonatal and maternal perineal trauma

Neonatal	Para 0 (469) n (%)	Para ≥ 1(182) n (%)	<i>P</i>	Total (651) n (%)
Minor trauma (abrasion / blister)	63 (13.4)	11 (6.0)	0.008	74 (11.4)
Hematoma	61 (13.0)	35 (19.2)	0.049	96 (14.7)
Intracranial hemorrhage	4/700	0/300	0.32	4/1000
Maternal perineal trauma	Para 0 (700)	Para ≥ 1 (300)		Total (1000)
Intact	251 (35.8)	105 (35.0)		356 (35.6)
1st degree tear	95 (13.6)	60 (20.0)		155 (15.5)
2nd degree tear	262 (37.4)	121 (40.3)		383 (38.3)
3rd degree tear	81 (11.6)	11 (3.7)		92 (9.2)
4th degree tear	11 (1.6)	3 (1.0)*	< 0.001	14 (1.4)
Episiotomy	396 (56.6)	84 (28.0)		480 (48.0)
+ 3rd/4th degree tear	68 (17.2)	8 (9.5)		76 (15.8)
No episiotomy	304 (43.4)	216 (72.0)		520 (52.0)
+ 3rd/4th degree tear	24 (7.9)†	6 (2.8)†		30 (5.8)

*Comparison of intact, 1st and 2nd degree with 3rd and 4th degree: $P < 0.001$

†Comparison of 3rd/4th degree tear with episiotomy and without episiotomy: Para 0, $P < 0.001$; Para ≥ 1, $P = 0.02$

(84.7%) ($P = 0.001$). There was a higher rate of delivery by Caesarean section in nulliparous women ($P = 0.002$).

In the 651 cases in which the type of cup application was observed and recorded after delivery, the rate of successful vacuum delivery associated with the three different applications was not significantly different (flexing median 91.6%, flexing paramedian 86.8% and deflexing 92.3%). (Because of small numbers, deflexing median and deflexing paramedian were combined into one group: “deflexing.”)

The incidence of neonatal and maternal perineal trauma related to parity is shown in Table 3. Cup marking, with or without bruising of the scalp, was recorded separately in 651 infants, and these marks resolved without complication within one to four days post partum. Minor trauma (abrasions, blistering, or both) of the scalp was recorded in 13.4% of the infants of nulliparous mothers and 6.0% of the infants of parous women ($P = 0.008$). All abrasions and blisters resolved without complications. There were no scalp lacerations. Cephalhematoma was found in 13.0% of the infants of nulliparous mothers and in 19.2% of the infants of parous women. There was one subgaleal hemorrhage in the infant of a nulliparous woman delivered at 40 weeks' gestation with a flexing median application and an occipitoanterior position. The cup was applied for eight minutes, three pulls were used, and there were no pop-offs. The subgaleal hemorrhage was diagnosed clinically, the neonatal course was uneventful, and no transfusion was

required. In addition, there were four cases of neonatal intracranial hemorrhage; the details are given in Table 4.

There were 56 cases of shoulder dystocia (5.6%). These were clinically described as severe (7), moderate (21), and mild (28). Brachial plexus palsy occurred in three of these 56 cases (all in nullipara): one of these neonates recovered completely, one improved and had no further surgical treatment, and one required surgery. There were two fractures of the clavicle associated with shoulder dystocia, and one case of transient facial nerve palsy. Neonatal seizures occurred in three infants; two of these had intracranial hemorrhage (cases 3 and 4, Table 4). The third involved a baby born to a nulliparous woman using a flexing paramedian application in which the cup was in place for three minutes and delivery of the head occurred with one pull. This was followed by severe shoulder dystocia. The infant weighed 4775 grams with Apgar scores of 4 at one minute and 8 at five minutes. Seizures occurred within 24 hours of delivery, but there were no sequelae and follow-up of the baby at one year showed no abnormality. The single neonatal death was attributed to a hypoplastic left heart syndrome.

Perineal trauma was related to parity, and a statistical comparison showed more third and fourth degree lacerations in nulliparous women than in parous women ($P < 0.001$). Third or fourth degree tears occurred more often in women who had an episiotomy than in those who did not (nulliparous women: $P < 0.001$; parous women: $P = 0.02$).

Table 4. Cases of neonatal intracranial hemorrhage

Case	1	2	3	4
Parity	0	0	0	0
Gestational age (week)	40	41	39	41
Obstetrical complications	Hypertension/induced	Post dates/induced	Ulcerative colitis Prolonged ROM > 24 hrs	Spontaneous labour
Fetal heart rate	Severe variable decelerations	Tachycardia	Tachycardia	Tachycardia
Meconium	no	yes	yes	yes
Chorioamnionitis	no	yes	yes	yes
Duration of 2nd stage (hr)	3 ½	3	2 ½	5
Station (cm)	+4	+4	+3	+3
Presentation	LOA	LOA	LOP	ROA
Duration of cup application (min)	1	5	5	4
Number of pulls	1	2	2	2
Pop-offs	0	0	0	0
Cup application	Flex med	Flex para	Flex para	Flex med
Apgar score (1 and 5 mins)	9/9	4/8	3/7	7/9
Cord pH	7.24	7.16	7.10	7.18
Weight (g)	3960	4775	3460	3116
Neonatal outcome and follow-up	Grade IV IVH Normal at 2 ½ years	Small subdural bleed Normal at 1 year	Small subdural bleed/cerebral edema/laminar necrosis Developmental delay at 1 year	Subarachnoid hemorrhage/ cortical vein thrombosis Normal at 1 year

ROM: rupture of membranes; LOA: left occiput anterior; LOP: left occiput posterior; ROA: right occiput anterior; IVH: intraventricular hemorrhage.

A comparison of the different types of cup application associated with fetal trauma is shown in Table 5. Flexing median application was associated with significantly less minor trauma than deflexing applications and flexing paramedian applications. There was no difference between flexing paramedian and deflexing applications in their association with minor trauma. Hematoma occurred less frequently in association with flexing median than with flexing paramedian applications overall ($P = 0.40$). No other significant differences were found.

DISCUSSION

In this prospective observational study of 1000 assisted vaginal deliveries using a new rigid vacuum cup, 87.1% of babies were successfully delivered by traction with the vacuum, a further 9.8% were delivered by forceps after failed vacuum, and 1.1% were delivered spontaneously. The remaining 2% were delivered by Caesarean section. Nulliparous women had significantly higher rates of failure to deliver by vacuum, more pulls required to achieve delivery, and more perineal trauma than parous women. These findings are in keeping with the assumption that the pelvic floor in multiparous women provides less resistance to

descent of the fetal head.¹⁰ There was no difference related to parity in the duration of cup application, traction force required, or pop-offs. Significantly less fetal scalp trauma was identified with the ideal cup application (flexing median) than with flexing paramedian and deflexing applications, in both nulliparous and parous women. Overall, scalp hematomas were found significantly less often with flexing median applications than with flexing paramedian. The association in this study between fetal scalp trauma and less than ideal cup applications has not been shown previously. However, this does support conventional wisdom and the principle of the optimal (flexing median) application proposed by Bird in 1976.⁹ All of the clinically important neonatal trauma, specifically intracranial hemorrhage, subgaleal hemorrhage, seizures, and brachial plexus injury, occurred in nulliparous women.

This study is the largest prospective trial of use of the OmniCup device reported to date; seven previous reports have included between 50 and 206 cases for a total of 784.^{8,10-15} The failure-to-deliver by vacuum rate in these studies ranged from 2%⁸ to 34.4%,¹² with an average of 17.6%. Our failure-to-deliver rate with vacuum was higher with nulliparous women (15.3%); the only previous study to

Table 5. Comparison of cup applications with fetal scalp trauma*

		<i>P</i>		
		Para 0	Para ≥ 1	Total
Minor trauma	Flexing median vs. deflexing	0.026	0.38	0.006
	Flexing paramedian vs. deflexing	0.481	0.610	0.409
	Flexing median vs. flexing paramedian	0.001	0.016	0.001
Hematoma	Flexing median vs. deflexing	0.639	0.223	0.113
	Flexing paramedian vs. deflexing	1.000	0.458	0.434
	Flexing median vs. flexing paramedian	0.050	0.552	0.040

Minor trauma: abrasion, blister; hematoma: cephalhematoma, under-the-cup hematoma
deflexing: deflexing median and deflexing paramedian.

*Observed in 651 cases

define parity reported a failure-to-deliver rate of 9.2%.¹⁰ The Caesarean section rate is recorded in six of the previous reports,^{8,10-14} and these ranged from 1.2% to 9.3% with an average of 5.0%. Our Caesarean section rate was 2% overall and 2.6% in nulliparous women, compared with 4.2% in Vacca's study of 119 nulliparous women.¹⁰ The two studies with high rates of failure to deliver by vacuum (30.1%¹⁴ and 34.4%¹²) also had the highest Caesarean section rates (8.3%¹⁴ and 9.3%¹²). In our study, the majority (76.0%) of the 129 cases in which the vacuum failed to achieve delivery were subsequently delivered by forceps without any untoward neonatal sequelae.

Our rate of intracranial hemorrhage (4.0/1000) is higher than in some recent reports, which describe rates ranging from 1.2 to 1.6/1000 with vacuum assisted delivery.¹⁶⁻¹⁸ However, in a recently published study from Belgium of 913 successful vacuum-assisted full-term deliveries in which routine cranial ultrasound was performed, intracranial hemorrhage was identified in eight neonates (8.7/1000).¹⁹ Seven of these were asymptomatic, and the eighth infant recovered completely after four days.¹⁹ Nulliparity, cup detachment, a high level of the fetal head, and high fetal weight were factors associated with intracranial hemorrhage. The type of vacuum cup used in the Belgian series was not specified. In the same study, 36 women had Caesarean section after failed vacuum delivery; 22.6% of their babies had asymptomatic cranial fractures, 6.7% had cephalhematomas, and one had intracranial hemorrhage after a difficult attempted vacuum extraction. This is in contrast to the clinical circumstances surrounding the infants in our study who sustained intracranial hemorrhage. Although all the mothers were nulliparous, there were no cup detachments during the procedures and all extractions were completed according to recommended guidelines.²⁰ There was, however, a non-reassuring FHR tracing in each

of the infants, suggesting that vacuum extraction was a coincidental and not a causative factor. In another study in which routine MRI was performed on 111 asymptomatic infants a few days after birth, the incidence of subdural hemorrhage was 6% in 49 infants born spontaneously, 7.7% in 13 infants delivered by successful vacuum extraction, and 28% in infants delivered by forceps after failed vacuum extraction ($P = 0.015$).²¹ Reassuringly, in our study, three of the four infants were neurodevelopmentally normal at one to two and a half years of age.

The prevalence of shoulder dystocia in our study (5.6%) is high but comparable to the rate reported in other series of vacuum-assisted deliveries.²² Two brachial plexus injuries had long-term sequelae, one infant requiring corrective surgery. In our study, clinically important neonatal trauma only occurred in the infants of nulliparous women. The relative ease of vacuum assisted delivery in this series is shown by the fact that in 97.4% of deliveries the vacuum was applied for 10 minutes or less, and in 95.6% there were three or fewer pulls used. In addition, the maximum traction force was 25 pounds or less in 85.7% of deliveries. Although the cup detachment rate was 22.7%, no neonatal morbidity was associated with these cases.

CONCLUSION

The OmniCup is an effective vacuum device for use when assisted vaginal delivery is indicated. Attention to detail in achieving the correct flexing median cup application is warranted. Long-term serious sequelae from the use of the OmniCup or from subsequent vaginal delivery or Caesarean section are rare.

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