Clinical Evaluation of a "Hand Pump" Vacuum Delivery Device

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OBJECTIVE: To evaluate the clinical performance of a hand-held vacuum delivery system.

METHODS: Between December 1999 and September 2000, a prospective audit was undertaken of all vacuum deliveries performed at Derby City General Hospital.

RESULTS: In this period, 3296 deliveries occurred, of which 317 (9.6%) were by vacuum. Of these, data were collected on 300 (94.6%), 78 deliveries with the hand-held vacuum and 222 with standard vacuum. There were no differences in the demographic profiles, indication, gestational age at delivery, or birth weights between the two groups (P > .05 in all instances). In all types of delivery, nonrotational and rotational, the hand-held vacuum performed comparably to its contemporaries with no increase in delivery "failures" being noted. There were no differences in the extent or frequency of maternal injuries between the instruments, and other than transient scalp abrasions, there were no significant fetal injuries.

CONCLUSION: The hand-held vacuum delivery system is a functionally effective addition to the practitioners' "armory," providing an alternative to the standard metal and silastic cups. (Obstet Gynecol 2002; 100:1190-5. © 2002 by the American College of Obstetricians and Gynecologists.)

Operative vaginal delivery has been clearly identified as a major risk factor for fetal morbidity and mortality as well as early and late maternal morbidity (including fecal incontinence). The Royal College of Obstetricians and Gynecologists issued clinical guidelines regarding the use of these instruments in assisting vaginal delivery, examining their relative merits, indications for use, and their associated complications. They concluded by stating that: "Obstetricians should be competent, and confident, in the use of both vacuum and forceps,"[1,2] but "in view of the reduction of maternal injuries the vacuum should be considered to be the instrument of first choice."[3]

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Consequent upon this article, interest in the practice of vacuum-assisted vaginal deliveries increased. However, serious neonatal and maternal complications with the incorrect or inappropriate use of a vacuum device reinforced the need for appropriate training in the correct use of this equipment. Attempts have been made to identify and address the predisposing factors associated with the adverse outcomes,[4] and several novel changes have been made to the basic instrument design to facilitate their use and reduce the rate of complications.

The basic premise of any vacuum device is that a suction cup, of silastic or metal construction, is connected, via tubing, to a vacuum source. Either directly, through the tubing, or via a connecting "chain," traction can then be applied to the presenting part, the vertex, to expedite delivery.

For successful use of the vacuum, determination of the flexion point is vital. This is located, in an average term infant, on the sagital suture 3 cm anterior to the posterior fontanelle, and thus 6 cm posterior to the anterior fontanelle. The center of the cup should be placed directly over this, as failure to adequately position the cup can lead to a progressive deflexion of the fetal head during traction, and failure to deliver the baby.[5] However, not all vacuum cup designs allow easy positioning over the flexion point, especially when the fetal head adopts an occipito-posterior or lateral position. This problem is frequently compounded by the presence of asynclitism or deflexion.

The Kiwi OmniCup (Clinical Innovations, Murray, UT) (Figure 1) is a vacuum extraction device that incorporates an integral hand-held pump (PalmPump; Clinical Innovations), making it suitable for single-person use with the addition of a "posterior cup" design that makes it usable for all positions of the vertec.[6] In addition, with the theoretical potential for the transmission of pathogenic organisms between individuals, even with equipment that has undergone surgical standard sterilization, single-use devices should replace the standard reusable equipment.

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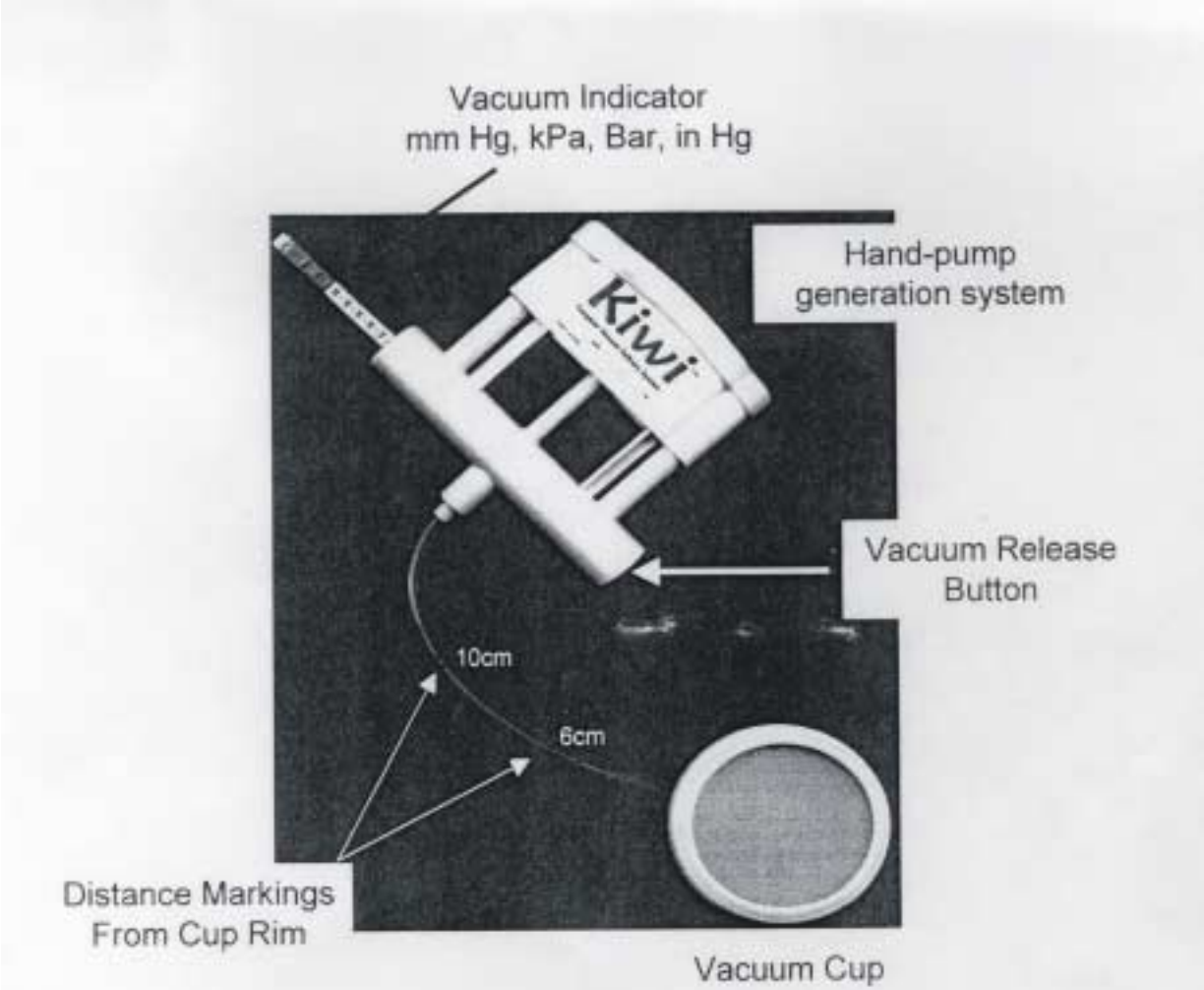

Figure 1. The Kiwi OmniCup vacuum delivery device. Bar = barometric pressure; in = inches.
Hayman, Kiwi Cup Vacuum, Obstet Gynecol 2002

Our hypothesis was that the Kiwi OmniCup delivery device has recently been introduced into the commercial market with little supportive evidence from the literature to suggest that when used by various "grades" of practitioners, it will prove to be an effective alternative to currently available equipment. The only study to date is that performed by an extremely experienced operator,[6] and its findings should be extrapolated to the general labor ward setting with caution. The purpose of this study, therefore, was to see whether the Kiwi OmniCup was an effective instrument in the hands of different grades of practitioners when used in a day-to-day clinical practice.

MATERIALS AND METHODS

Between December 1999 and September 2000, a prospective audit was performed to assess the performance of the Kiwi OmniCup when compared with vacuum deliveries performed with silastic and metal cups (standard vacuum equipment) during the same period by the same operators.

After a brief period of familiarization, the OmniCup was made available to all labor ward practitioners for use alongside the "standard equipment" when a valid indication for vacuum-assisted delivery was present. No specific additional training was given to the practitioners using the Kiwi OmniCup as they had been trained in the use of other types of vacuum cups/devices and were already using them on a daily basis.

The type of cup chosen by the practitioner (Silc, Malmstrom, Bird, or the OmniCup) was based on the obstetric scenario and the clinician's level of experience and training. At no stage was the practitioner instructed to use the OmniCup vacuum in preference to any other, and

Table 1. Information on Patients, Labor Characteristics, and Cup Application

	Standard VDD *n*	OmniCup *n*
Parity		
Nulliparae	179	64
Multiparae	43	14
Age (y) (median and range)	28 (25–31)	28 (26–31)
Gestation at delivery (wk) (median and range)	40 (39–41)	40 (39–41)
Birth weight (g) (median and range)	3505 (3280–3780)	3400 (2982–3717)
Type of labor (%)		
Spontaneous	136 (61.3)	44 (56.4)
Augmented	35 (15.8)	11 (14.1)
Induced	51 (23.0)	23 (29.5)
Analgesia in labor (%)		
None	14 (6.3)	6 (7.7)
Nitrous oxide (Entonox)	25 (11.3)	7 (9.0)
Opiates	45 (20.3)	13 (16.7)
Regional anesthesia	138 (62.2)	52 (66.7)
Indication for delivery (%)		
Presumed fetal jeopardy	63 (28.4)	17 (21.8)
Arrest of descent	108 (48.6)	40 (51.3)
Maternal condition	5 (2.3)	6 (7.7)
Combination of above	46 (20.7)	15 (19.2)
Station of the fetal head compared with ischial spines (%)		
Mid (0 to +1)	138 (62.2)	49 (62.8)
Low (+2 to +4)	84 (37.8)	29 (37.2)
Position at cup application (%)		
OA (<45° rotation)	181 (81.5)	55 (70.5)
OL (>45° rotation)	23 (10.4)	12 (15.4)
OP	18 (8.2)	11 (14.1)

VDD = vacuum delivery device; OA = occipito-anterior; OL = occipito-lateral; OP = occipito-posterior.
$P > .05$ for all comparisons between the groups (see text).

in all cases the procedure was performed according to standard hospital protocol for vacuum extraction.

The ethics committee of Derby City General Hospital determined that as the equipment had previously been shown to be "safe,"[6] special consent to use a specific cup did not have to be obtained from the laboring women for inclusion in this prospective audit.

After the delivery, all the relevant obstetric details were recorded onto a standardized prospective clinical questionnaire. Information regarding the performance of each vacuum, its placement with respect to the vertex, and any complications experienced by the mother and the newborn infants was also collected. Infants were also assessed at 24-48 hours postpartum, and any specific fetal problems noted at that time were reported to the general practitioner/visiting midwife for further monitoring or referral as appropriate.

The primary outcome measures for each instrument used were delivery failure/success rates and fetal and maternal complications.

The successful background rate of vacuum deliveries was observed to be 10% (standard deviation 5%) in the period before the onset of the audit project. It was calculated that a sample size of 130 women (65 in each arm) would be required to observe a difference of 25% between the two cohorts regarding failure of vacuum deliveries with an error of 5% and a power of 80%.

RESULTS

Of the 3296 women who delivered during this period, 317 (9.6%) were delivered by assisted vaginal delivery using a vacuum delivery device. Of these, the audit forms were completed in 300 cases (94.6%).

Deliveries with Silc, Malmstrom, or Bird cups are included in the "standard vacuum" group. Deliveries by the OmniCup vacuum are analyzed separately.

The indications and relevant obstetric circumstances relating to the 300 vacuum deliveries are shown in Table 1. There were no significant differences in the parity, age of the patients, or gestation at delivery ($P > .5$, Mann-Whitney *U* test), in the type of labor ($P = .36$, χ^2 test), analgesic requirements ($P = .59$, χ^2 test), or median birth weights ($P = .54$, Mann-Whitney *U* test).

Arrest of descent of the fetal head was the primary indication for delivery in both groups, presumed fetal jeopardy (suspicious or pathologic findings on the cardio-

Table 2. Operator Status, Who Performed the Deliveries

	Standard VDD *n* (%)	OmniCup *n* (%)
Consultant	1 (0.5)	2 (2.6)
Staff Grade	5 (2.3)	3 (3.8)
Specialist Registrar (trainees y 4–10)	137 (61.7)	57 (72.1)
Senior House Officer (trainees y 1–3)	79 (35.6)	17 (21.8)

VDD = vacuum delivery device.

tocograph[7]), and a combination of fetal compromise and arrest of descent comprising the remainder (Table 1). A total of 62.2% of the procedures performed with the standard vacuum equipment were midcavity deliveries and 37.8% low vacuum deliveries, using the American College of Obstetricians and Gynecologists classification.[8] Corresponding figures for the OmniCup were 62.8% and 37.2%, respectively. These differences were nonsignificant ({ = .99, χ^2 test).

In the majority of cases with both instrument "groups," the position of the fetal head at the time of cup application was occipito-anterior, although there was a slight but not significant increase in the number of rotational deliveries (occipito-lateral and posterior) performed with the OmniCup (P = .105) (Table 1).

The status of the operators who performed the deliveries is shown in Table 2. The majority of deliveries were performed by residents in their fourth to tenth years of training, the remainder being by residents in years 1-3 (Table 2).

The delivery details are shown in Table 3. A total of 90.5% of deliveries were successfully performed with the standard vacuum equipment in comparison with 87.2% with the OmniCup. This difference was nonsignificant (P = .3, χ^2 test). There was a slight, but nonsignificant, increase in the number of deliveries with the OmniCup, which had to be converted to forceps deliveries (P = .12, χ^2 test). Subanalysis of the data revealed that this "failure rate" was similar to that observed for the Bird design of metal cup (P = .13, χ^2 test). However, the number of delivery failures (defined as failure of vaginal delivery with resort to delivery by cesarean) with the standard equipment (2.3%) exceeded those with the OmniCup vacuum (1.3%). This, too, did not reach statistical significance (P = .29, χ^2 test).

With both the standard and OmniCup equipment, all successful vaginal deliveries were completed within 12 minutes of the cup attachment, nearly all deliveries being completed in three pulls or less, with few cup detachments occurring. There were also no significant differences in the extent of perineal trauma between the groups, the number of episiotomies performed, or in the amount of blood lost during delivery. There were no other maternal complications reported.

Table 3. Delivery Outcome Data

	Standard VDD *n* (%)	OmniCup *n* (%)
Successful delivery by a vacuum delivery device (VDD)	202 (90.6)	69 (87.3)
VDD–proceed to forceps delivery	16 (7.2)	9 (11.5)
VDD–proceed to cesarean delivery	4 (2.2)	1 (1.3)
Number of tractions for delivery (median and range)	3 (2–3)	3 (2–3)
Number of cup "detachments" (median and range)	0 (0–1)	0 (0–1)
Perineal trauma		
No trauma–intact	20 (9.0)	9 (11.5)
Tears		
1st degree	26 (11.7)	13 (16.7)
2nd degree	61 (27.5)	20 (25.6)
3rd degree	4 (1.8)	3 (3.8)
4th degree	1 (0.5)	0
Episiotomy	111 (49.7)	33 (42.3)
Blood loss		
<300 mL	105 (47.3)	39 (50.0)
300–500 mL	97 (43.7)	31 (38.6)
500–1000 mL	13 (5.9)	7 (9.0)
>1000 mL	7 (3.2)	2 2.6)

VDD = vacuum delivery device.

Fetal complications were also infrequent and are detailed in Table 4. There were no differences in the Apgar scores at 1 and 5 minutes between the groups (P = .18, χ^2 test). The only significant finding was an increase in the incidence of superficial scalp abrasions (minor graze or linear laceration underling the vacuum cup margins) in the cohort delivered with the OmniCup vacuum (14.1% versus 4.5% in the standard group, P = .006, χ^2 test). All of these abrasions resolved spontaneously with no scarring noticeable at 6 weeks postpartum. It was interesting to observe that incidence of scalp abrasions was the same in the OmniCup cohort as in those infants delivered by rotational metal cup vacuum devices (14.1% versus 11.1%, P = .39, χ^2 test). All the cephalhematomas that developed were transient and were not linked to the development of clinically significant jaundice in any instance.

During the study period, no infants were discharged with any significant delivery-induced complications.

DISCUSSION

This study has shown the OmniCup vacuum system to be an effective alternative to the currently available Silc, Malmstrom, or Bird devices. Our study demonstrates that

Table 4. Delivery Complications

	Standard VDD	OmniCup	
Fetal			
Apgar scores			
1 min (median and range)	9 (8–9)	9 (7–9)	
5 min	10 (9–10)	10 (9–10)	
	Standard VDD *n* (%)	OmniCup *n* (%)	
Resuscitation			
Nil required	193 (86.9)	69 (87.3)	
Bag and mask	26 (11.7)	10 (12.7)	
Intubation	3 (1.4)	0	
	Standard VDD *n* (%)	OmniCup *n* (%)	Rotational metal cup *n* (%)
Superficial scalp abrasions			
Yes	13 (4.5)*	11 (14.1)*†	3 (11.1)†
No	209 (95.5)*	67 (85.9)*	24 (88.9)
Cephalhematoma			
Yes	7 (3.2)	4 (5.1)	
No	215 (96.8)	75 (94.9)	
Jaundice requiring phototherapy			
Yes	3 (1.4)	1 (1.2)	
No	219 (98.6)	78 (98.8)	

VDD = vacuum delivery device.
* $P = .006$.
† $P = .39$.

in the United Kingdom, "junior" medical staff with relatively limited clinical experience carry out the majority of instrumental vaginal deliveries. This may be with or without supervision, and consequently the introduction of any equipment, even if variations on an "old theme," must be made with a degree of circumspection and an appropriate period of training.

It was, therefore, important to observe that in no instance, with any of the equipment used during the course of our audit, did any significant complications occur to either the mother or infant. Although the incidence of scalp abrasions in those infants delivered by the OmniCup was higher than in those delivered by the alternative standard equipment, it was the same as those in the infants delivered by rotational metal cup vacuum devices. This would suggest that it is the process of rotation that is implicated in the generation of the trauma rather than the design of the device itself. However, in all cases, the degree of injury sustained was minor and had resolved completely by 6 weeks postpartum.

The slight increase in the number of forceps deliveries after use of the OmniCup when compared the "standard" vacuum may be explained by examining the indications for delivery. In such cases, it was observed that a significant number of vacuums were being employed to rotate the presenting part to a more favorable position (occipito-anterior) before procuring delivery with forceps. In fact, subanalysis of the data confirms this to be the case, with metal cup vacuum of the Bird design having similar incidence of subsequent forceps deliveries when compared with the OmniCup.

A limitation of this study concerns the nonrandomization of patients to the different delivery device cohorts. This has the potential to introduce a degree of selection bias into data sets, with allocation into each group being on the basis of ease of application/operator confidence. A further randomized study will need to specifically address these issues, as this initial audit cannot exclude this potential problem.

Data from previous studies have shown that procuring a delivery is highly dependent upon the correct placement of a vacuum over the flexion point.[5,6,9] The OmniCup design used in this study facilitates placement over the flexion point akin to the Bird cup currently in use for occipito-posterior positions. Unlike its predecessors,

however, the inclusion of a hand-pump vacuum generation system decreases both the "clumsiness" of the additional equipment required to generate suction and the extra personnel needed to operate the pump. In addition, the flexibility of the traction axis device engendered the OmniCup to the practitioners, enabling its use in all clinical vertex presentations, both "lift out" and rotational.

This study suggests that the Kiwi OmniCup is an effective instrument for assisting a vaginal delivery. As with all instruments used in delivery, however, the device must be used appropriately and correctly, with strict adherence to the recommended safeguard for vacuum-assisted delivery.[6]

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