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Original Research Article

Randomized control trial to find the safety and efficacy of the Kiwi OmniCup system in comparison with the conventional vacuum delivery

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ABSTRACT

Background: Ventouse delivery, also known as vacuum extraction, is a medical procedure employed during childbirth to assist in the safe delivery of a baby when conditions necessitate a quicker or controlled delivery to safeguard the health and well-being of both the baby and the mother.
Methods: The research was conducted in the labour room of the Department of Obstetrics and Gynaecology at Baba Raghav das Medical College in Gorakhpur, Uttar Pradesh during September 2019 to August 2020 involve all pregnant women undergoing the process of normal delivery. Thorough maternal histories, physical examinations, and diagnostic tests were conducted and documented. Group A undergoing conventional vacuum extraction and group B utilizing the Kiwi OmniCup. The outcomes of the procedures were meticulously recorded.
Results: Instrumental deliveries in both the Ventouse and Kiwi OmniCup groups were primarily conducted due to fetal distress, with 16 cases (40%) and 23 cases (57.5%), respectively. Other medical conditions also contributed to instrumental deliveries, accounting for 16 cases (40%) in the Ventouse group and 9 cases (22.5%) in the Kiwi OmniCup group. Maternal exhaustion led to instrumental deliveries in 8 cases (20%) in both groups.
Conclusions: Instrumental deliveries, primarily ventouse and Kiwi OmniCup, were mainly performed due to fetal distress, with ventouse often requiring longer cup application and resulting in more significant blood loss, while Kiwi OmniCup led to neonatal intensive care unit (NICU) admissions primarily due to respiratory distress; however, both methods showed comparable APGAR scores and low rates of severe neonatal complications.

Keywords: Kiwi OmniCup, Conventional vacuum delivery, Ventouse, Parturient women, Fetal distress, APGAR scores, Labour, Caesarean sections

INTRODUCTION

Childbirth, particularly the method of delivery, poses substantial stress for both the mother and the newborn. Assisted or operative vaginal delivery denotes the vaginal birth of a baby aided by forceps or a vacuum device. Research findings indicate that the prevalence of operative vaginal delivery varies from 3 to 11% across different healthcare settings.[1,2] Furthermore, a shift from using forceps to ventouse deliveries has been observed in recent decades. To address the utilization of these instruments for assisting vaginal delivery, their indications, instrument selection, an assessment of their respective advantages, and associated complications, guidelines were issued by "The Royal College of Obstetricians and Gynaecology". In summary, these guidelines emphasize that obstetricians

should possess proficiency and confidence in employing both vacuum and forceps techniques.[3,4] Operative intervention aims to shorten the second stage of labour, which should be discussed for specific medical conditions whenever feasible during the antenatal period. Technical challenges arise in cases of emergency caesarean sections when the cervix is fully dilated, and the fetal head is deeply engaged in the maternal pelvis. This situation carries significant risks for both the mother and the fetus. Compared to caesarean sections performed during the first stage of labour, those conducted during the second stage exhibit a notably increased risk of maternal morbidity, encompassing uterine incision tears, haemorrhage, blood transfusion, bladder trauma, and the need for intensive care. Additionally, there is potential for complications in subsequent pregnancies related to uterine scar rupture during labor and heightened risks associated with repeated caesarean sections, which escalate with each successive caesarean delivery required. Addressing these issues, the college statement on vaginal birth after previous caesarean section seeks to provide guidance and mitigate potential complications.[5,6]

The vacuum extractor has become the preferred choice for assisted vaginal delivery since its development, primarily due to its lower risk of causing maternal complications when compared to forceps. However, when considering long-term outcomes, there appears to be no discernible difference in pelvic floor function between women who have undergone vacuum-assisted delivery and those who have been subjected to forceps-assisted delivery. In contemporary obstetrics, the utilization of the vacuum cup for operative vaginal delivery has become exceedingly commonplace. Over time, various adaptations and improvements have been introduced to vacuum cups since their initial introduction by Malmstrom in 1950.[7-10]

Ventouse cups can be categorized into two main types.

Ventouse cups with a central port

These central port ventouse cups come in both rigid and soft varieties and are employed for occipitoanterior deliveries.

Ventouse cups with a lateral port for suction catheter attachment

These lateral port ventouse cups are always rigid and are specifically used for rotational deliveries.

The design distinction facilitates accurate cup placement over the flexion point, even in cases of fetal head malposition. The successful outcome of these deliveries greatly hinges on the correct placement of the cup. The choice between a hard or soft vacuum cup also plays a significant role in determining the success of the procedure. Notably, soft cups tend to exhibit higher failure rates when compared to their hard counterparts.[10-15]

Recent advancements in vacuum-assisted deliveries have introduced several innovative instruments, including the Bird cup designed for posterior position applications, the soft cup (such as the mystic pump or mushroom cup), and the latest addition, the Kiwi OmniCup. Notably, the Kiwi OmniCup represents a single integrated tool equipped with a hand-held vacuum pump. This cup possesses a rigid structure with a central connection for the suction catheter. When lateral traction is applied, a specially designed groove in the flat outer part of the cup allows the traction element to slide, thereby enhancing the ease of head rotation compared to conventional vacuum suction cups. It's important to note that the Kiwi OmniCup can be utilized in various positions of the occiput. However, it does have a drawback in that its slightly longer and more flexible traction mechanism can make it somewhat challenging to precisely and consistently apply traction force while maintaining an optimal direction of traction.[7,9,16,17] In the broader context, instrumental vaginal birth, while not without its considerations, remains a safe and effective option when appropriately selected for specific cases. Additionally, it's worth mentioning that a vaginal birth during a woman's first pregnancy is associated with a significantly high likelihood (ranging from 78% to 91%) of experiencing a spontaneous vaginal birth in subsequent pregnancies.

Aim

To find the Kiwi OmniCup system's efficacy compared to the conventional vacuum delivery and the safety of the Kiwi OmniCup system in comparison with the conventional vacuum delivery in terms of parturient women and their fetuses.

METHODS

The study was conducted at the labor room of BRD Medical College in Gorakhpur and It was designed as a randomized controlled trial and took place over a one-year period, running from 01 September 2019 to 31 August 2020 focusing all women admitted to the labor room were enrolled as participants in the study. Prior to any procedures, informed consent was obtained from each participant and their respective family members. The research involved a total of 80 participants, with an equal distribution into two study groups. Subsequently, comprehensive maternal histories, physical examinations, and diagnostic tests were conducted and meticulously documented.

Inclusion criteria

Inclusion criteria encompassed women with prolonged second stage of labor (arrest of descent of presenting part, protracted labor), poor maternal bearing down efforts (maternal exhaustion), heart disease, hypertensive disorder of pregnancy, occipito-posterior position of head of the baby, CTG abnormality/auscultatory abnormality and

informed consent (verbal or written) with a prior clear explanation.

Exclusion criteria

Exclusion criteria involved the exclusion of women in labour with presentation of cephalopelvic disproportion, non-vertex, fetal prematurity, placenta previa, fetal hypoxia, suspected or confirmed - fetal bleeding diathesis - demineralizing bone disease and mother disagreement.

A randomization process was employed, resulting in the formation of two distinct groups: group A and group B. In group A, conventional vacuum extraction was employed for the delivery procedure, while in group B, the Kiwi OmniCup was utilized. Following the completion of the respective procedures, the outcomes were meticulously recorded. It is important to note that neither blinding nor allocation concealment was implemented in this study.

Statistical analysis

Data collection was conducted utilizing a pre-structured data collection form, with meticulous attention to detail. The collected data were then entered into Microsoft excel for subsequent analysis. The data were presented in the form of frequency and percentage distributions. Statistical analysis involved the utilization of the chi-square test and the Z test to compare the two sets of grouped data. The calculated p value was utilized to determine the significance of the observed differences.

RESULTS

In this study, the highest number of patients in the Ventouse and Kiwi OmniCup groups fell within the age bracket of 21 to 25 years, constituting 26 individuals (65%) and 22 individuals (55%), respectively. Following closely were the age groups of 26 to 30 years, with 10 individuals (25%) in the Ventouse group and 14 individuals (35%) in the Kiwi OmniCup group. The majority of patients in both the Ventouse and Kiwi OmniCup groups were primigravida, accounting for 23 individuals (57.5%) and 27 individuals (67.5%), respectively. Gravida 2 patients numbered 11 individuals (27.5%) in the Ventouse group and 9 individuals (22.5%) in the Kiwi OmniCup group, while gravida 3 patients were fewer, with 4 individuals (10%) in the Ventouse group and 3 individuals (7.5%) in the Kiwi OmniCup group. In terms of gestational age, most patients in both the Ventouse and Kiwi OmniCup groups were full-term, comprising 19 individuals (47.5%) in each group. Early-term pregnancies were the next most common, with 17 individuals (42.5%) in the Ventouse group and 18 individuals (45%) in the Kiwi OmniCup group, followed by late-term pregnancies, which accounted for 4 individuals (10%) in the Ventouse group and 1 individual (2.5%) in the Kiwi OmniCup group. The majority of patients in both the Ventouse and Kiwi OmniCup groups belonged to the lower socioeconomic status, with 19 individuals (47.5%) and 18 individuals (45%), respectively. The next most common socioeconomic status was upper lower, with 11 individuals (27.5%) in the Ventouse group and 15 individuals (37.5%) in the Kiwi OmniCup group, followed by lower middle, with 8 individuals (20%) in the Ventouse group and 5 individuals (12.5%) in the Kiwi OmniCup group. Regarding body mass index (BMI), the highest number of patients in both the Ventouse and Kiwi OmniCup groups had a BMI of 25-30, accounting for 17 individuals (42.5%) and 18 individuals (45%), respectively. The next most common BMI category was less than 25, with 16 individuals (40%) in the Ventouse group and 11 individuals (27.5%) in the Kiwi OmniCup group. The majority of patients in both the Ventouse and Kiwi OmniCup groups had a history of previous vaginal delivery, with 35 individuals (87.5%) in the Ventouse group and 38 individuals (95%) in the Kiwi OmniCup group (Table 1).

Table 1: Distribution and comparison of the sociodemographic profile and clinical profile of the participants according to the application of the assistance provided for the delivery (n=80).

Variables	Ventouse cup applied (%)	Kiwi OmniCup applied (%)	Total	P value
Maternal age (years)				
16-20	02 (5)	01 (2.5)	03	0.472
21-25	26 (65)	22 (55)	48	
26-30	10 (25)	14 (35)	24	
31-35	02 (5)	03 (7.5)	05	
Gravida				
Primigravida	23 (57.5)	27 (67.5)	50	0.723
Gravida 2	11 (27.5)	9 (22.5)	20	
Gravida 3	04 (10)	3 (7.5)	07	
Gravida 4	02 (5)	00	02	
Gravida ≥5	00	1 (2.5)	01	
Gestational age at delivery				
Early term (37-0/7 to 38-6/7) weeks	17 (42.5)	18 (45)	35	0. 411

Continued.

Variables	Ventouse cup applied (%)	Kiwi OmniCup applied (%)	Total	P value
Full term (39-0/7 to 40-6/7 weeks)	19 (47.5)	19 (47.5)	38	
Late-term (41-0/7 to 41-6/7 weeks)	04 (10)	01 (2.5)	05	
Post-term (42-0/7 weeks and beyond)	00	02 (5)	02	
Socioeconomic status				
Upper	00	00	00	
Upper middle	02 (5)	02 (5)	04	
Lower middle	08 (20)	05 (12.5)	13	0.7209
Upper lower	11 (27.5)	15 (37.5)	26	
Lower	19 (47.5)	18 (45)	37	
Obstetric history				
Previous C section	5 (12.5)	2 (5)	07	0.235
Previous VD	35 (87.5)	38 (95)	73	

Table 2: Distribution and comparison of operative procedures applied to the patients (n=80).

Variables	Ventouse cup applied	Kiwi OmniCup applied	Total	P value
Indication for instrumental delivery				
Fetal distress	16 (40)	23 (57.5)	39	0.56
Maternal exhaustion	08 (20)	08 (20)	16	00
Other medical condition	16 (40)	09 (22.5)	25	0.54
Station of fetal head during cup application				
+1	13 (32.5)	21 (52.5)	34	0.070
+2	27 (67.5)	19 (47.5)	46	
Position of fetal head				
Left occipitoanterior	33 (82.5)	31 (77.5)	64	
Right occipitoanterior	04 (10)	08 (20)	12	0.424
Left occipitoposterior	02 (5)	01 (2.5)	03	
Right occipitoposterior	01 (2.5)	00	01	
Number of pulls				
1	05 (12.5)	28 (70)	33	
2	21 (52.5)	11 (27.5)	32	<0.001
3	14 (35)	01 (2.5)	15	
Maximum tractional force applied for delivery (mmHg)				
400-500	6 (15)	5 (12.5)	11	0.745
501-600	34 (85)	35 (87.5)	69	
Maximum duration of cup application (min)				
<2	01 (2.5)	28 (70)	29	
2-4	23 (57.5)	11 (27.5)	34	<0.001
>4-6	16 (40)	01 (2.5)	17	
Successful instrumental delivery	38	40	78	4.16
Failure to deliver				
Failure to deliver in OA position	01 (2.5)	00	01	
Failure to deliver in OP position	01 (2.5)	00	01	

Table 3: Distribution and comparison of operative procedures applied to the patients and maternal complications (n=80).

Variables	Ventouse cup applied	Kiwi OmniCup applied	Total	P value
Episiotomy				
Indicated	34 (85)	32 (80)	66	0.556
Not indicated	06 (15)	08 (20)	14	
Perineal tear				

Continued.

Variables	Ventouse cup applied	Kiwi OmniCup applied	Total	P value
No tear	32 (80)	39 (97.5)	71	0.040
First degree	06 (15)	01 (2.5)	07	
Second degree	02 (5)	00	02	
Third degree	00	00	00	
CPT	00	00	00	
Blood loss (ml)				
<500	31 (77.5)	39 (97.5)	70	0.007
>500	09 (22.5)	01 (2.5)	10	

Table 4: Distribution and comparison of operative procedures applied to the patients and fetal outcome (n=80).

Variables	Ventouse cup applied	Kiwi OmniCup applied	Total	P value
Baby birth weight (kg)				
1.5-1.9	03 (7.5)	01 (2.5)	04	0.234
2.0-2.4	13 (32.5)	07 (17.5)	20	
2.5-2.9	14 (35)	15 (37.5)	29	
3.0-3.4	09 (22.5)	09 (22.5)	28	
3.5-3.9	01 (2.5)	07 (17.5)	08	
≥4.0	00	01 (2.5)	01	
APGAR score (at 1 min)				
<7	13 (32.5)	8 (20)		0.204
≥7	27 (67.5)	32 (80)		
APGAR score (at 5 min)				
<7	13 (32.5)	8 (20)		0.204
≥7	27 (67.5)	32 (80)		
Resuscitation to baby				
Required	14 (35)	10 (25)	24	0.292
Not required	25 (62.5)	30 (75)	55	
IUD	01 (2.5)	00	01	
Indication for NICU admission				
Respiratory distress	10 (25)	7 (17.5)		0.793
LBW	1 (2.5)	1 (2.5)		
Respiratory distress + LBW	3 (7.5)	1 (2.5)		
Moulding				
0	35 (87.5)	35 (87.5)	70	
+1	05 (12.5)	05 (12.5)	10	
≥+2	00	00	00	
Neonatal morbidity				
Caput succadeneum	09 (22.5)	01 (2.5)		
cephalhematoma	00	00		
Liquor				
Clear	25 (62.5)	20 (50)	45	0.260
Meconium stained	15 (37.5)	20 (50)	35	

Instrumental deliveries in both the Ventouse and Kiwi OmniCup groups were primarily conducted due to fetal distress, with 16 cases (40%) and 23 cases (57.5%), respectively. Other medical conditions also contributed to instrumental deliveries, accounting for 16 cases (40%) in the Ventouse group and 9 cases (22.5%) in the Kiwi OmniCup group. Maternal exhaustion led to instrumental deliveries in 8 cases (20%) in both groups. In the Ventouse group, the majority of deliveries were performed with the cup applied to the fetal head at station +2, comprising 27 cases (67.5%), followed by station +1, with 13 cases (32.5%). In the Kiwi OmniCup group, most deliveries were successfully conducted with the instrument's application at station +1, accounting for 21 cases (52.5%), followed by station +2, with 19 cases (47.5%). In both the Ventouse and Kiwi OmniCup groups, the cup was predominantly applied in the left occipitoanterior position, with 33 cases (82.5%) in the Ventouse group and 31 cases

(77.5%) in the Kiwi OmniCup group. The right occiput anterior position was less common, with 4 cases (10%) in the Ventouse group and 8 cases (20%) in the Kiwi OmniCup group. The left occiput posterior position accounted for 2 cases (5%) in the Ventouse group and 1 case (2.5%) in the Kiwi OmniCup group, and the right occipital-posterior position was rare, with 1 case (2.5%) in the Ventouse group and none in the Kiwi OmniCup group. In the Ventouse group, the majority of deliveries were achieved with 2 pulls, accounting for 21 cases (52.5%), followed by 3 pulls, with 14 cases (35%). In the Kiwi OmniCup group, most deliveries were completed with 1 pull, comprising 28 cases (70%), and 2 pulls in 11 cases (27.5%). Both the Ventouse and Kiwi OmniCup groups applied the maximum tractional force for delivery between 501-600 mmHg, with 34 cases (85%) and 35 cases (87.5%), respectively. The longest duration of cup application for the Ventouse was between 2-4 minutes in 23 cases (57.5%) and over 4-6 minutes in 16 cases (40%). For the KiwiOmni Cup, the application duration was less than 2 minutes in 28 cases (70%) and 2-4 minutes in 11 cases (27.5%). In cases where Ventouse delivery failed and necessitated cesarean section, both occiput anterior and occiput posterior positions were equally involved, each accounting for 1 case (2.5%). Episiotomy was administered to the majority of patients in both the Ventouse and Kiwi OmniCup groups, with 34 cases (85%) and 32 cases (80%), respectively. Most patients in both groups did not experience tears during instrumental delivery, with 32 cases (80%) in the Ventouse group and 39 cases (97.5%) in the Kiwi OmniCup group. First-degree tears were reported in 6 cases (15%) in the Ventouse group, and no second-degree tears were observed in the Kiwi OmniCup group. Notably, blood loss exceeding 500 ml was significantly higher in the Ventouse group, with 9 cases (22.5%), compared to only 1 case (2.5%) in the Kiwi OmniCup group (Tables 2 and 3).

The APGAR score at 1 minute for both the Ventouse and Kiwi OmniCup groups predominantly fell into the category of ≥7, with 27 cases (67.5%) and 32 cases (80%), respectively. Similarly, at 5 minutes, the majority of cases in both groups had an APGAR score of ≥7, with 27 cases (67.5%) in the Ventouse group and 32 cases (80%) in the Kiwi OmniCup group. In the Ventouse group, 14 cases (35%) required post-delivery resuscitation for the baby, while in the Kiwi OmniCup group, this need was present in 10 cases (25%).

Respiratory distress emerged as the primary indication for NICU admission in both the Ventouse and Kiwi OmniCup groups, with 10 cases (25%) and 7 cases (17.5%), respectively (Table 4).

DISCUSSION

The demographic profile of patients in both the ventouse group and the Kiwi OmniCup group was compared. The age distribution of the patients showed that the majority of the women belonged to the age group 21-25 years. A similar observation was seen in the study of Groom, et al, they reported the mean maternal age to be 30.8 versus 31.4 years whereas Aapkes et al reported the mean maternal age to be 31.8 in both groups.[17,18]

Siggelkow et al noted that there was no difference in patient age between both groups. the gravidity of the participants ranged from 0-5. maximum patients of ventouse and Kiwi OmniCup groups belong to primigravida (57.5% and 67.5% respectively) with a p value of 0.723.[19] It means both the groups are behaving similarly with respect to gravidity, which was comparable to the study of Ismail et al (58.8% versus 57%, p value >0.05) and in Aapkes et al (89.6% versus 80%, p value >0.05) primigravida respectively. the mean gestational age at the time of delivery in ventouse group verses Kiwi OmniCup group is 39.175±1.258 weeks versus 38.875±1.362 weeks with a p value 0.411.[18,20] It means both the groups are behaving similarly with respect to gestational age. which is comparable to the study of Groom et al, Aapkes et al, and Siggelkow et al.[17-19]

In our study, we found that the indication for maximum instrumental delivery by ventouse and Kiwi OmniCup conducted was due to fetal distress (40%). Similarly, in the study by Ismail et al fetal distress was the primary indication, whereas Edgar et al reported that the most common indication for assisted vaginal delivery was dystocia (45.1%), followed by abnormal fetal heart rate (38.9%) followed by poor maternal effort and exhaustion (7.6%). maximum successful deliveries were carried out in ventouse versus kiwi group via one pull (12.5% versus 70%), 2 pulls (52.5% versus 27.5%), 3 pulls (35% versus 2.5%), with p value <0.001.[20,21] The number of successful deliveries in ≤2 pulls were (65% versus 97.5%, p value <0.001) which was comparable to Aapkes, et al who observed that maximum successful delivery occur in ≤2 pulls were (63.8% versus 73.5%, p value (0.01).[19] In our study, the mean duration of cup application in both the groups were 4.06±1.19 versus 2.25±0.751 minutes with p value <0.05).

Limitations

The relatively small study group, consisting of only 40 patients/mothers in each group, may have influenced the results and could explain any deviations from findings in studies with larger participant numbers. Larger sample sizes are often preferred to enhance the statistical power and generalizability of study results. Second, the study did not assess long-term fetal and maternal morbidity, focusing primarily on immediate outcomes. Long-term follow-up could provide valuable insights into potential complications or benefits associated with the use of these instrumental delivery methods. Another noteworthy limitation is the non-reusability of the Kiwi OmniCup, which presents a significant drawback in terms of cost-effectiveness. This disposable nature of the instrument may result in higher healthcare expenses compared to

reusable alternatives, impacting healthcare resource allocation.

Additionally, the study highlights that proper training and expertise are required for the application of the Kiwi OmniCup. This underscores the importance of healthcare professionals receiving comprehensive training in the correct use of the instrument to ensure its safe and effective application in clinical practice. Inadequate training or experience may lead to suboptimal outcomes and safety concerns for both the mother and the neonate. Thus, future research and clinical practice should consider these limitations when evaluating the use of the Kiwi OmniCup and its implications for patient care.

CONCLUSION

The maximum utilization of instrumental delivery methods, such as ventouse and Kiwi OmniCup, was primarily necessitated by fetal distress, followed by other medical conditions, and maternal exhaustion. In the ventouse group, the majority of deliveries were successfully accomplished in either two or three pulls, while in the Kiwi OmniCup group, one or two pulls sufficed. Notably, the mean duration of cup application was longer in the ventouse group compared to the Kiwi OmniCup group. Episiotomies were administered to a significant portion of patients in both the ventouse and Kiwi OmniCup groups. When evaluating perineal trauma, first-degree tears were observed in both groups, whereas second-degree tears were limited to a few patients in the ventouse group alone. It is noteworthy that blood loss exceeding 500 ml was notably more prevalent in the ventouse group than in the Kiwi OmniCup group. The mean APGAR scores at 1 minute and 5 minutes post-delivery exhibited no significant differences between the two groups. However, in the ventouse group, a subset of newborns required resuscitation immediately after delivery. Conversely, the Kiwi OmniCup group necessitated admission to the neonatal intensive care unit (NICU), with respiratory distress being the predominant reason for NICU admission in both groups. Upon scrutinizing intrapartum injuries to the fetal head in both groups, cases of caput succedaneum were reported in some instances within both the ventouse and Kiwi OmniCup groups. Importantly, no cases of cephalhematoma were reported in either group, and there were no other instances of neonatal morbidity or mortality observed.

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