ORIGINAL RESEARCH

DOI: 10.5336/jcog.2021-82080

Comparison of Maternal-Fetal Outcome Following Operative Delivery: Omnicup Versus Malmstrom Metal Cup: Clinical Research

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ABSTRACT Objective: To compare the success, clinical outcomes, maternal and neonatal complication rates following Kiwi Omnicup or the Malmstrom metal cup in vacuum assisted delivery. **Material and Methods:** One hundred eighty eight vaginal deliveries which were achieved by the use of Kiwi Omnicup or the Malmstrom metal cup in Zeynep Kamil Women's Health Training and Research Hospital between January 2008 to March 2015 were screened from prospectively collected database. All cases were singleton, viable pregnancies with cephalic presentation. Groups were compared in terms of some maternal and fetal complications and morbidities including cephal hematoma, caput succadanum, hemorrhagic ischemic encephalopathy, molding, acidosis, hypothonia, shoulder distocia, meconium passage, maternal vaginal lacerations, blood hematoma, rib fracture, cervical laceration, 3rd and 4th degree lacerations and the uterine atonia. **Results:** Fetal complications were significantly different between groups. The rate of cephal hematoma was significantly higher in Malmstrom metal cup whereas the rate of fetal acidosis was significantly higher in group with Kiwi Omnicup ($p<0.05$). Also the rate of unsuccessful cases was significantly higher in Malmstrom metal cup group. There were 2 cases of fetal death in Kiwi Omnicup group, however no case of fetal death in other group. **Conclusion:** In our study, we have shown that there are some specific fetal complications for each tool and the rate of unsuccessful cases was significantly higher in Malmstrom metal cup group. We concluded that selection of vacuum extraction tool should be based on the knowledge of maternal fetal conditions, specific complications and the success rates of the tools.

Keywords: Operative vajinal delivery; vacuum; Malmstrom metal cup; Kiwi Omnicup

Operative vaginal delivery refers to the application of forceps or a vacuum device to assist the mother in performing a vaginal delivery of a fetus. In the United States, the incidence of operative vaginal birth is estimated to be 5%, although there are large geographical differences in operative vaginal delivery rates throughout the country.[1-4] In the Northeast, instrumental vaginal delivery rates (5%) and the highest rates (20%-25%) are in the South.[2] Although overall operative vaginal delivery rates have declined, the number of vacuum-assisted deliveries is increasing and is now about 4 times the forceps-assisted vaginal delivery rate.[2] Vacuum systems vary according to the vacuum mechanism (traditional vs. hand type), cup material and hardness (metal, plastic or silicone), cup shape (cork or bell) and whether they are disposable or reusable. These characteristics are thought to have an impact on the profile of efficacy and adverse outcomes as reflected in various studies.[5-11] There is significant evidence that instrumental deliveries increase perineal pain during labor, early postpartum pain, perineal lacerations, hematomas, blood loss and anemia, urinary retention, and urinary and fecal incontinence and several other maternal morbidities on the other hand vacuum-assisted vaginal deliveries can cause significant fetal morbidity, including scalp lacerations, cephalohematomas, subgaleal hematomas, intracranial hemorrhage, facial

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Peer review under responsibility of Journal of Clinical Obstetrics & Gynecology.

Received: 08 Feb 2021 ***Received in revised form:*** 02 May 2021 ***Accepted:*** 04 May 2021 ***Available online:*** 05 May 2021

nerve palsies, hyperbilirubinemia, and retinal hemorrhage.[10]

The aim of this study was to compare the success, clinical outcomes, maternal and neonatal complication rates following Kiwi Omnicup or the Malmstrom metal cup in vacuum assisted delivery.

MATERIAL AND METHODS

One hundred eighty eight vaginal deliveries which were achieved by the use of Kiwi Omnicup (Figure 1, n=62) or the Malmstrom metal cup (Figure 2, n=126) in Zeynep Kamil Women's Health Training and Research Hospital between January 2008 to March 2015 were screened from prospectively collected database. Study protocol was approved by institutional clinical researches ethics committee of University of Health Sciences Zeynep Kamil Women and Children's Health Training Hospital (2015/10) and informed consent was obtained from each participant. The study was conducted in accordance with the Declaration of Helsinki ethical principles and good clinical practices and was approved at each site by an independent local ethics committee and informed consent was obtained from each participant.

All cases were singleton, viable pregnancies with cephalic presentation. Groups were compared in terms of some maternal and fetal complications and morbidities including cephal hematoma, caput succadanum, hemorrhagic ischemic encephalopathy, molding, acidosis, hypothonia, shoulder distocia, meconium passage, maternal vaginal lacerations, blood transfusion, hematoma, rib fracture, cervical laceration, 3rd and 4th degree lacerations and uterine atonia. Operative delivery by the vacuum extraction was indicated in cases of fetal distress, where the second stage of labor was prolonged, requiring rapid delivery. The patients were placed in the lithotomy position on the delivery table who had full cervical opening. The amniotic sac was opened. There was no suspicion of cephalopelvic pelvic disproportion in the examination of the fetus. Following confirmation of the fetal head engagement, adequate anesthesia was provided and episiotomy was performed. Maternal bladder was emptied. The procedures were carried out by experienced physicians with the help of an expert instructor and assistant and the conditions for emergency cesarean section were kept ready. In cases with face or breech presentation, cephalopelvic disproportion, congenital fetal head anomalies, gestational age <34 weeks, estimated fetal weight less than 2,000 g or more than 4,000 g, vacuum extraction procedure was not used. Omnicup vacuum (Kiwi) with elastic body or Malmstrom metal cup were used for fetal head extraction. In both instruments; pressures of approximately 0.8 kg/cm^2 (600 mmHg) were applied for fetal head extraction.

FIGURE 1: Soft cup vacuum we used in our delivery room.

FIGURE 2: Metal cup vacuum we used in our delivery room.

The center of the cups were applied on the sagittal suture and 3 cm in front of the posterior fontanelle. The mother's soft tissue did not remain between the cup and the fetal head. Both cups were manually controlled all around after the vacuum was formed. Like-

wise, it was checked that the maternal tissues were not squeezed between the cup and fetal head before traction was applied. When using metal cups, vacuum was applied until the negative pressure of 0.8 kg/cm^2 was reached by increasing the suction power in a controlled manner of 0.2 kg/cm^2 every 2 minutes. Likewise, when Kiwi Omnicup was used, negative pressure of 0.8 kg/cm^2 was reached in 1 minute. Traction was intermittent and performed simultaneously with the mother's pushing effort. Age, body mass index [calculated by dividing body weight (kg), height in square meters] gestational age (weeks), fetal biparietal diameter, fetal abdominal circumference and estimated fetal weight values, labor induction, total induction duration, newborn sex, birth weight, APGAR score, necessity of neonatal intensive care admission, neonatal morbidity, maternal prenatal and postnatal complete blood count values, presence of maternal complications were noted. Urethral and bladder injuries, cervical, vaginal, perianal lacerations and vaginal hematomas were evaluated as maternal complications after vacuum application. Fetal complications include caput succadenum (between skin and epicranial aponeurrosis, edema that can exceed sutures, which can be sutured outside the periosteum), cephal hematoma (subperiostal hemorrhage not exceeding sutures), subgaleal hematoma, intracranial hemorrhage, subconjunctival and retinal hemorrhage. APGAR scores were evaluated by pediatricians twice at the first and fifth minutes. In APGAR scoring, neonatal muscle tension, heart rate, response to painful stimuli, skin color and respiratory rate were scored between 0 and 2. Accordingly, scores 8-10 were determined to be normal. Neonates with 4-6 score were directed to the neonatal intensive care unit with respiratory support and supportive treatment was applied. While neonates with a score of 0-3 received newborn intensive care support after urgent intervention and resuscitation.

STATISTICAL ANALYSIS

When evaluating the findings obtained in the study, IBM SPSS Statistics 15 for statistical analysis (SPSS IBM, Turkey) programs were used. Descriptive statistical methods (mean, standard deviation, frequency) were used for the evaluation of the study data. Student t-test was used for comparison of quantitative data between 2 groups and Mann-Whitney U test was used for comparison of non-normally distributed parameters between 2 groups. The chi-square test was used to compare the qualitative data. Significance was evaluated at $p<0.05$.

RESULTS

The number of vaginal deliveries during the 5-years period (2008-2013) was 31,497 and the incidence of operative deliveries using vacuum was 0.4% (n=126). The incidence of operative delivery was 0.8% (n=62) in 7,564 normal spontaneous vaginal deliveries after the supply of Kiwi Omnicup vacuum (2013-2015), a soft-cup device, over a 3-year period. Comparison of some demographic and clinical characteristics of study groups was summarized in Table 1. A significant difference was observed between the 2 groups in terms of mean estimated fetal weight ($p<0.05$, Figure 3), on the other hand no difference was determined in terms of age, gravidity, parity, APGAR 1. minute, APGAR 5. minute, birth weight (kg), body mass index, hematocrit level before delivery, hematocrit level after delivery ($p>0.05$). In 59 (95.1%) cases of Kiwi Omnicup group, no medical chronic disease was reported whereas 3 (4%) patients had hypothyroidism. There was no chronic disease in 106 (84%) patients who underwent vacuum extraction with metal cup, and preeclampsia was defined in 12 (9.5%) patients in this group. Induction was applied to 48.3% (n=30) of patients who had Kiwi Omnicup and 46% (n=58) of patients who had vacuum extraction by metal cup. Induction rates were similar between the 2 groups ($p>0.05$). Among cases who underwent metal vacuum extraction, 2 (1.58%) patients had previous cesarean section, the rates of some other systemic disorders were; chronic hypertention 0.79% (n=1), cardiac disorder 0.79% (n=1), previous multiple cesarean section 0.79% (n=1), twin pregnancy 0.79% (n=1) and familial Mediterranean fever 0.79% (n=1). Neonatal complications were not observed in 70.96% (n=44) of the babies who were extracted by Omnicup. Frequency of some neonatal complications were as follows; cephal hematoma in 2.38% (n=3), caput succadenum 2.38% (n=3) of the cases, and 8.73% (n=11) showed acidosis, and no in-

TABLE 1: Comparison of some demographic and clinical characteristics of 2 different intervention groups.

	Kiwi Omnicup		Metal cup vacuum		
	Mean	SD	Mean	SD	p value
Age (years)	27.4	5.3	26.8	5.7	NS
Gravidity	1.6	1.2	1.7	1.2	NS
Parity	1.3	0.7	1.4	0.8	NS
Estimated fetal weight	3,444.03	376.3	3,319.2	320.08	0.02
APGAR 1. min	6.9	2.09	6.9	1.4	NS
APGAR 5. min	8.2	1.8	8.5	1.1	NS
Fetal birth weight	3,345	398.3	3,335.9	391.2	NS
Body mass index	29.9	4.01	33.2	2.5	NS
Hematocrit level before delivery (%)	35.4	3.3	35.3	3.8	NS
Hemoglobin level before delivery	10.4	1.7	10.4	1.4	NS
Hematocrit level after delivery (%)	31.9	4.7	30.9	4.1	NS

SD: Standard deviation.

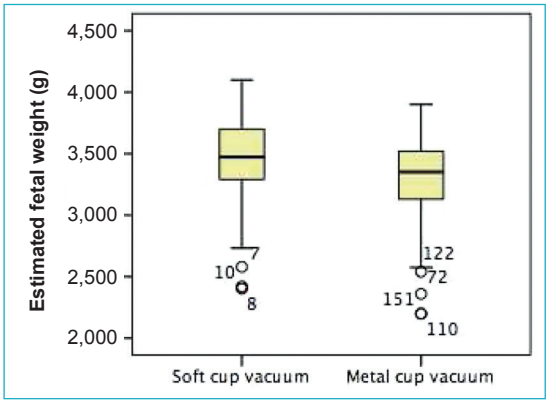

FIGURE 3: Estimated fetal weight comparison of groups with soft versus metal cup vacuum extraction.

fant had molding, shoulder dystocia and meconium passage. Neonatal complications were not observed in 80.15% (n=101) of infants who underwent vacuum extraction with metal cup, while the rates of complications were cephal hematoma in 11.90% (n=15), caput succadenum in 5.55% (n=7), and molding in 0.79%, (n=1), shoulder dytocia in 0.79% (n=1), meconium passage in 0.79% (n=1) of the cases. No infant had acidosis in this group. Fetal complications were significantly different between the 2 groups, the cephalic hematoma was significantly higher in the metal-cup vacuum group, while the acidosis rate was higher in the Kiwi Omnicup group (Table 2). There was no maternal complication in 42% (n=53) of pregnant women in omnicup group, while blood transfusion in 3.96% (n=5), levator hematoma in 1.58% (n=2), and 1.58% (n=2) of cases showed cervical laceration. Rib fracture, 3rd and 4th degree lacerations, deep vaginal laceration were not observed. While 81.74% (n=103) of the patients who underwent vacuum with metal cups had no maternal complications, blood transfusion requirement was observed in 3.96% (n=5), deep vaginal laceration in 1.58% (n=2), levator hematoma in 0.79% (n=1), 3rd degree laceration in 3.96% (n=5), 4th degree laceration in 2.38% (n=3), rib fracture in 0.79% (n=1), cervical laceration in 4.76% (n=6) of the cases were observed. Maternal complication rates were similar in both groups (p>0.05).

DISCUSSION

Vaginal delivery by applying a vacuum device is a decreasing practice. Salamalekis et al. showed that the average annual vaginal birth vacuum decreased from 4.24% to 1.09%, from 1976 to 1995.[12] Fear of malpractice, lack of self-confidence and education may be one of the important reasons for this decrease. The incidence of operative delivery in 7,564 normal spontaneous vaginal births by vacuum extraction was 0.8% (n=62) in our series. On the other hand following introduction of omnicup vacuum device, the incidence of operative deliveries increased in 2013.

Due to its elasticity and ease of use, it is thought that the learning and applications are easier than the

TABLE 2: Kiwi Omnicup and Metal bell vacuum neonatal complication rates.

		Kiwi Omnicup	Metal cup vacuum	
Newborn complications	No complication	44 (71%)	101 (80%)	145 (77%)
	Cephal hematoma	3 (4.8%)	15 (12%)	18 (9.5%)
	Caput succadenum	4 (6.4%)	7 (5.5%)	11 (5.8%)
	Molding	0 (0%)	1 (0.7%)	1 (0.5%)
	Acidosis	11 (17.7%)	0 (0%)	11 (5.8%)
	Meconium passage	0 (0%)	1 (0.7%)	1 (0.5%)
	Shoulder dystocia	0 (0%)	1 (0.7%)	1 (0.5%)
Total		62 (100%)	126 (100%)	188 (100%)

p<0.001; There was a significant difference between the 2 groups in terms of neonatal complications rates.

metal cup vacuum and that it is subjectively less traumatic and that the omnicup (Kiwi) is used twice as often as the metal cup vacuum. We aimed to present the differences at an objective level by comparing the use of Kiwi Omnicup vacuum and metal cup vacuum in terms of fetal and maternal outcome.

It has been reported in the literature that, soft cup instruments have less scalp trauma but higher failure rates than hard metal vacuum cups.[5,13] In the meta-analysis of nine randomized controlled trials comparing soft and hard vacuum extractor cups; average failure rates were 16% for soft cups and 9% for hard cups. The separation rates were 22% for soft cups and 10% for metal cups.[13,14] In our study, the rate of patients requiring cesarean delivery after unsuccessful application was 8% (n=5) in patients who had Kiwi Omnicup vacuum extraction. No failure was observed following metal cup vacuum application. As a result, failure of Kiwi Omnicup vacuum was significantly higher than that of steel cup vacuum (p=0.003). In a study, although soft cups cause scalp injury to a lesser extent, it was observed that subgaleal hemorrhage rates did not decrease compared to metal cups.[13]

In our study, fetal complications were significantly different between the 2 groups. Cephal hematoma was significantly higher in the metal-bladed vacuum group (11.90%) and was approximately 5 times less in the soft-bladed group (2.38%). In another study in which 85 patients with Kiwi Omnicup and 79 patients with Malmstrom cups were examined, no difference was observed in terms of maternal morbidity (p=0.66, p>0.05). In the same study, acidosis was detected in 3 infants in both soft-bladed vacuum and metal-bladed vacuum groups.[15] In our study, the rate of acidosis was significantly higher in the soft bladed vacuum group. This may be related to the high rate of failure of the soft-bladed vacuum and the prolongation of the fetus during bradycardic period.

In the same study, intrapartum and neonatal deaths were not observed in both groups. In our study, fetal deaths were observed in 2 babies who had Kiwi Omnicup vacuum, and no fetal death was observed in any of the babies with metal cup vacuum. Angioli et al. reported that 3rd and 4th degree perianal lacerations were more frequent in cases using vacuum tools (10%-2% respectively) than spontaneous vagnal births.[16] In our study, no third and fourth degree laceration was observed in Kiwi Omnicup treated patients, while the third and fourth degree laceration was observed in 8 patients who underwent vacuum with metal cup (6.3%). Although there was no statistically significant difference, less 3rd and 4th degree laceration was observed in patients who received Kiwi Omnicup vacuum compared to patients with metal cup vacuum.

The need for blood transfusion due to maternal hemorrhage was observed in 8% (n=5) of patients who had Kiwi Omnicup vacuum and 3.9% (n=5) of patients with metal cup vacuum, but no statistically significant difference was observed. A study was carried out at a tertiary medical center with approximately 7,000 deliveries per year. It was found that the handheld system has more malfunctions than the traditional system. The rate of postpartum hemor-

rhage was higher in the conventional group. Both systems had similar 3rd/4th grade perineal tears, shoulder dystocia, and adverse neonatal outcomes. The authors showed greater failure with Kiwi compared to Mityvac in general and at any fetal position/station, with no significant difference in adverse outcome profile.[17]

In a previous study, levator muscle avulsion rates (LAM) were evaluated between deliveries with Malmstrom's vacuum and Kiwi vacuum. Among 199 primiparous women, all patients underwent vaginal delivery by vacuum extraction (Malmstrom's or Kiwi). Avulsion was defined as abnormal LAM placement in the lower groin branch in multichannel mode as described in three central sections by transperineal 3/4D echography 6 months after birth. LAM was found in 33.1% of cases using Malmstrom vacuum and 29.4% of cases using Kiwi vacuum (the difference was not statistically significant). The study showed that the vacuum of Malmstrom was not associated with a higher risk of LAM compared with the Omnicup of Kiwi.[18]

Maternal or neonatal outcomes and failure rates did not differ between the 2 groups, but procedure time and fundal pressure maneuver were more frequent in the Malmstrom group. The authors of this study suggested that Kiwi Omnicup and Malmstrom metal cup vacuum aspirators were safe and functionally effective for vacuum assisted delivery.[19]

Vacuum application has been decreasing day by day and its practical training has not been taught routinely. Fear of malpractice, lack of self-confidence, and lack of education are seen as one of the important reasons for this decrease.

When applied under appropriate conditions, although it causes various perinatal complications, it continues to be an effective application and the rate of serious fetal maternal complications is very low. Practical training should be provided in appropriate cases as the vacuum tool, which is easy to implement and obtain, may be required under mandatory conditions. Ensure that the necessary fetal and maternal indications are available.

CONCLUSION

In conclusion, there are some specific fetal complications for each tool and the rate of unsuccessful cases was significantly higher in group with Malmstrom metal cup. We concluded that selection of vacuum extraction tool should be based on the knowledge of maternal fetal conditions, specific complications and the success rates of the tools.

Source of Finance

During this study, no financial or spiritual support was received neither from any pharmaceutical company that has a direct connection with the research subject, nor from a company that provides or produces medical instruments and materials which may negatively affect the evaluation process of this study.

Conflict of Interest

No conflicts of interest between the authors and / or family members of the scientific and medical committee members or members of the potential conflicts of interest, counseling, expertise, working conditions, share holding and similar situations in any firm.

Authorship Contributions

Idea/Concept: *Resul Karakuş;* ***Design:*** *Resul Karakuş;* ***Control/Supervision:*** *Enis Özkaya;* ***Data Collection and/or Processing:*** *Resul Karakuş, Sultan Seren Karakuş, Gökhan Ünver, Zafer Bütün;* ***Analysis and/or Interpretation:*** *Enis Özkaya;* ***Literature Review:*** *Enis Özkaya;* ***Writing the Article:*** *Enis Özkaya;* ***Critical Review:*** *Enis Özkaya;* ***Materials:*** *Gökhan Ünver.*

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