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CLINICAL RESEARCH / KLİNİK ARAŞTIRMA

Maternal and Neonatal Outcomes of Patients who Delivered with Kiwi Omnicup Vacuum System: Experience of A Tertiary Care Hospital

Kiwi Omnicup Vakum Sistemi ile Doğum Yapan Hastaların Maternal ve Neonatal Sonuçları: Üçüncü Basamak Bir Sağlık Merkezinin Deneyimi

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Abstract

Objective: Vacuum-assisted delivery is the most preferred operative vaginal delivery method and Kiwi Omnicup is a recently designed system for vacuum-assisted delivery with has a plastic cup, flexible traction wire, and a handheld vacuum pump. The aim of this study was to assess the Kiwi Omnicup application rates in a tertiary care hospital and evaluate the early neonatal and maternal outcomes of Kiwi-assisted deliveries.

Methods: The Kiwi Omnicup Vacuum-assisted deliveries after 37 weeks of gestation between January 2016 and December 2019 at a tertiary care hospital were reviewed in this study. The sociodemographic characteristics of the patients, obstetric data, early postpartum neonatal, and maternal outcomes of the patients were obtained. The vacuum-assisted delivery indications, including the prolonged second stage of labor, maternal exhaustion, and fetal compromise were recorded. Maternal and neonatal complications including, third or fourth-degree perineal lacerations, early postpartum hemorrhagic, shoulder dystocia, fetal death, fetal scalp laceration, and neonatal intensive care unit necessity of newborns were recorded.

Results: During the study period, 58 (1.28%) of the 4525 vaginal deliveries were performed with the Kiwi Omnicup system. The mean age of the patients was 25.3±5.3 years. The mean body mass index of the patients was 28.4±3.2 kg/m^2 and 86.2% of the patients were overweight and obese. The prolonged second stage of labor was the most recorded (48.3%) indication for Kiwi-assisted delivery. Caput succedaneum occurred in 5 neonates (8.6%). Eight newborn babies were observed closely in the Pediatric department. Two newborns were transferred to the intensive care unit. Any other maternal and neonatal complications were observed.

Conclusion: The Kiwi Omnicup Vacuum system is easy to use and has low maternal and neonatal adverse outcomes. Although the feasibility of this system was confirmed by several studies, it has low usage rates. The reasons for avoidance from Kiwi omnicup vacuum usage at delivery should be evaluated.

Keywords: Labor complication, Kiwi Omnicup, maternal and neonatal outcomes, vacuum-assisted delivery

Öz

Amaç: Vakum yardımıyla doğum en çok tercih edilen müdahaleli vajinal doğum yöntemidir ve Kiwi Omnicup, plastik kap, esnek çekiş kablosu ve el tipi vakum pompasına sahip vakum destekli doğum için yakın zamanda tasarlanmış bir sistemdir. Bu çalışmanın amacı, üçüncü basamak bir hastanede Kiwi Omnicup sisteminin uygulanma oranlarını değerlendirmek ve Kiwi Omnicup yardımıyla yapılan doğumların erken neonatal ve maternal sonuçlarını değerlendirmektir.

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Öz

Yöntem: Bu çalışmada, Ocak 2016 ile Aralık 2019 tarihleri arasında üçüncü basamak bir hastanede 37 haftalık gebelik haftasından sonra Kiwi Omnicup Vakum sistemi ile olan doğumlar incelendi. Hastaların sosyo-demografik özellikleri, obstetrik verileri, doğum sonrası erken neonatal ve maternal sonuçları kaydedildi. Uzamış doğumun ikinci evresi, anne yorgunluğu veya tükenmişliği, ve fetal kötülük hali gibi vakum yardımlı doğum endikasyonları kaydedildi. Üçüncü veya dördüncü derece perine yaralanmaları, erken postpartum kanama, omuz distosisi, fetal ölüm, fetal skalp yaralanması, ve yenidoğan yoğun bakım ünitesi ihtiyacını içeren maternal ve neonatal komplikasyonlar kaydedildi.

Bulgular: Çalışma süresi boyunca 4525 vajinal doğumun 58'i (%1,28) Kiwi Omnicup sistemi yardımıyla olmuştur. Hastaların yaş ortalaması 25,3±5,3 idi. Hastaların ortalama vücut kitle indeksi 28,4±3,2 kg/m^2 idi ve hastaların %86,2 si aşırı kilolu ve obez idi. Uzun süren doğum eylemi (%48,3), Kiwi yardımıyla doğum için en fazla kaydedilen endikasyondu. Beş yenidoğanda (%8,6) kaput succedaneum görülmüştür. Sekiz yenidoğan pediatri bölümünde yakın gözlemde kalmıştır. İki bebek yenidoğan yoğun bakım ünitesine transfer edildi. Başka herhangi bir maternal ve neonatal komplikasyon gözlenmemiştir.

Sonuç: Kivi Omnicup Vakum sistemi müdahaleli doğum için kullanımı kolay ve düşük maternal ve neonatal kötü sonuç oranlarına sahiptir. Bu sistemin uygulanabilirliği çeşitli çalışmalarla doğrulanmış olmasına rağmen, klinisyenler tarafından kullanım oranları düşüktür. Doğumda klinisyenlerin Kiwi Omnicup Vakum sistemini kullanmaktan kaçınma nedenleri değerlendirilmelidir.

Anahtar Kelimeler: Doğum komplikasyonu, Kiwi Omnicup, maternal ve neonatal sonuçlar, vakum yardımlı doğum

Introduction

Operative vaginal delivery is defined as the delivery, which obstetricians use devices such as forceps and vacuum to extract the fetus from the vagina for several indications. These indications include the prolonged second stage of the labor, maternal exhaustion, fetal compromise, and shortening the second stage of labor due to maternal medical disorders such as cardiac, neurological, and pulmonary disease. Vacuum-assisted delivery is the most preferred operative vaginal delivery technique that obstetricians often use for several maternal and fetal indications. Although the prevalence rates of operative vaginal delivery vary between countries depending on the development levels of the countries, clinicians' expertise, education and training programs, and accessibility of necessary resources, and overall rates have been decreasing[1,2]. Several vacuum systems differ according to its mechanism, cup material and shape, and disposable or reusable characteristics. A more recent design for the vacuum extractor is the Kiwi vacuum-assisted fetal delivery device (Kiwi Omnicup Vacuum Delivery System; Clinical Innovations, Murray UT, USA)[3]. It is a rigid plastic cup with a central suction catheter, a flexible traction wire, and a small handheld vacuum pump. Disposable characteristics, suitability for occiput anterior-transverse-posterior fetal head positions, easy maneuverability in the vagina due to its flexible traction wire, and do not need a separate electric vacuum device can be counted as the advantages of Kiwi Omnicup compared with conventional vacuum devices[3-5]. Also, in some studies, higher detachment and failure rates than conventional vacuum devices are reported as a disadvantage of this system[4,6,7]. In addition to several advantages of Kiwi Omnicup, the maternal and neonatal adverse outcomes are comparable with conventional vacuum systems[8]. The Kiwi Omnicup system has been used instead of a conventional vacuum system recently when needed. There is a lack of data regarding the prevalence of vacuum-assisted delivery and complication rates of Kiwi Omnicup in Turkey. In this study, we assessed the Kiwi Omnicup application rate at delivery, early postpartum neonatal, and maternal outcomes, and demographic characteristics of the patients who had vacuum-assisted delivery with Kiwi Omnicup at a tertiary care hospital.

Materials and Methods

This retrospective study was conducted at the Obstetrics and Gynecology department of a tertiary care hospital after local ethics approval was obtained from the University of Health Sciences Turkey, Bakırköy Dr. Sadi Konuk Training and Research Hospital Ethics Committee (approval number: 2020/85, date: 17.02.2020). All the patients who were delivered between January 2016 and December 2019 at our hospitals Obstetrics department were retrospectively reviewed from the hospital's written delivery record papers. Of these patients who were recorded as "Kiwi Omnicup (Kiwi Omnicup Vacuum Delivery System; Clinical Innovations, Murray UT, USA) assisted delivery" were included in this study. After obtaining the patients' names and protocol numbers from delivery record papers, the files were requested from the hospital archive. The patients who delivered before 37 weeks of gestation, had in utero ex fetus, and twin pregnancies were excluded from the study. The patients who delivered before 37 weeks of gestation, had in utero ex fetus, and twin pregnancies were excluded from the study. Maternal and neonatal data of

the patients were obtained from both patient files and computer-based hospital database. Socio-demographic characteristics of the patients, including age, Body Mass Index (BMI), gravidity, parity, abortion, and operation history were recorded. The gestational age at delivery was calculated according to the last menstrual date if the patient knows her last menstrual date accurately. If the patient did not know her last menstrual date, gestational age was calculated according to her first trimester ultrasonographic crown-rump length measurements. The cervical dilatation at the admission, the time between admission and delivery, and duration of the second stage of the labor were obtained by evaluating the partogram of the patients. In addition, ultrasonographic measurements of the fetus at the admission including estimated fetal weight (EFW), biparietal diameter, abdominal circumference, and femur length were recorded. The vacuum-assisted delivery indications were obtained from files as a prolonged second stage of labor, maternal exhaustion, and fetal compromise. The prolonged second stage of labor is defined as the longer duration of the second stage than 2 h for nulliparous and one h for multiparous women without epidural anesthesia. Prepartum and postpartum hemoglobin values were recorded. Maternal and neonatal complications including, third or fourth-degree perineal lacerations, early postpartum hemorrhagic, shoulder dystocia, fetal death, fetal scalp lacerations, and neonatal intensive care unit necessity of newborns were recorded. The documented neonatal data including cord blood pH, first and 5th minutes Apgar score, neonatal head circumference, and fetal weight were reviewed. The primary outcome of this study was the evaluation of maternal and neonatal complication rates.

Statistical Analysis

Data analysis was performed using SPSS (IBM SPSS Statistics for Windows, Version 20.0. Armonk, NY: IBM Corp., USA). One sample Kolmogorov-Smirnov test was used to analyze the distribution of the data. The categorical variables are presented as the frequency and percentage values. Also, the meanand standard deviation values of the continuous variables were presented.

Results

During the study period, 8,161 deliveries occurred in our obstetrics and gynecology department. While 3,636 of them were with cesarean section, the remaining 4,525 were vaginal deliveries. After reviewing the delivery records, we detected 58 (1.28%) assisted vaginal delivery and all of them were performed with the Kiwi Omnicup system. The distribution of the deliveries during the study period is shown in Table 1. There were no forceps and conventional vacuum system usage detected during this study period. The results of 58 Kiwi-assisted vaginal deliveries are presented in this study. The mean age and BMI of the patients were 25.3±5.3 years and 28.4±3.2 kg/m^2, respectively. Only 8 patients had normal body weight (BMI <25 kg/m^2), and 50 patients were overweight and obese (BMI >25 kg/m^2). Forty-two patients (72.4%) were nulliparous and 16 patients (27.6%) were multiparous, and the parity of the patients ranged between 0 and 4. Two patients had previous abdominal surgery, one of them had bariatric surgery 2 years ago and the other one had a cesarean section 4 years ago. The mean gestational age was 270±9.5 days and the mean ultrasonographic EFW at admission 3,265±326 gr. The time between admission and delivery ranged between 50 and 1,440 min. The mean second stage duration of labor was 61.1±37.9 minutes. While the labor was initiated with induction in 8 patients, labor initiated spontaneously in 50 patients. The mean cervical dilatation at admission was 4.5 cm. The socio-demographic and clinical characteristics of the patients are presented in Table 2. Kiwi-assisted delivery was performed to shorten the second stage of labor in 3 patients, 2 of them had cardiac valve replacement history and one of them had a previous cesarean section history. The distribution of other common indications is listed in Table 3. Mediolateral episiotomy was performed for 46 patients, and any other birth canal lacerations and 3-4 degree perineal lacerations occurred. Five patients had erythrocyte suspension transfusion after delivery due to symptomatic anemia and these had anemia before labor.

Table 1. The distribution of the deliveries during the study period

	2016	2017	2018	2019	Overall
Normal spontan vaginal delivery n (%)	994 (58.8%)	1033 (52%)	1317 (55.6%)	1123 (53%)	4467 (54.8%)
Cesarean section n (%)	692 (41%)	928 (46.6%)	1036 (43.8%)	980 (46.5%)	3636 (44.5%)
Assisted vaginal delivery n (%)	4 (0.2%)	29 (1.4%)	13 (0.6%)	12 (0.5%)	58 (0.7%)
Overall	1690	1990	2366	2115	8161

No postpartum hemorrhage was encountered. The clinical characteristics of the neonates are shown in Table 4. Caput succedaneum occurred in 5 neonates (8.6%). Eight newborn babies who were observed closely in the Pediatric department had a diagnosis of transient tachypnea of the newborn and treated with nasal oxygen supplementation. The two newborns who were transferred to the intensive care unit were discharged 10 and 12 days later without any problem. There were no data regarding the long -term neurological outcomes of these neonates.

Table 2. Socio-demographic and clinical characteristics of the study population

	Mean ± SD/ median/n	Min-max %
Age (years)	25.3±5.3	17-42
Gravidity	1.6±1.1/1	0-6
Parity	0.5±0.9/0	0-4
Abortion	0.1±0.4/0	0-2
BMI (kg/m^2)	28.4±3.2	21.4-38.2
BMI category		
Normal (18.5-24.9)	8	13.8
Overweight (25-29.9)	29	50
Class 1 obesity (30-34.9)	20	34.5
Class 2 obesity (35-39.9)	1	1.7
Previous surgery		
Bariatric surgery	1	1.7
Cesarean section	1	1.7
Cardiac valve replacement	2	3.4
Number of visits during pregnancy	2.1±1.3/2	1-8
Gestational age (days)	270±9.5	259-295
Estimated fetal weight (gr)	3265±326	2550-4043
Cervical dilatation at admission (cm)	4.6±2.1	1-9
Episiotomy		
Yes	46	79.3
No	12	20.7
Prepartum hemoglobin (g/dL)	11.6±1.8	7.6-14.9
Postpartum hemoglobin (g/dL)	10.4±1.7	6.2-14.1
Hemoglobin difference	1.2±0.8	0-3
Duration of hospital stay (days)	1.2±0.5	1-3
Delivery duration (minutes)	401.3±301	50-1440
Duration of the second stage (minutes)	61.1±37.9	10-140

BMI: Body Mass Index, Min-max: Minimum-maximum, SD: Standard deviation

Discussion

This study demonstrated that although the safety and feasibility of the Kiwi Omnicup system for assisted vaginal delivery were observed in previous studies[1], it has quite low usage rates for assisted vaginal delivery. Low maternal and neonatal complication rates that related to vacuum-assisted delivery support its feasibility when used appropriate indications. There are several reasons for the low usage rates of the vacuum-assisted delivery including, medicolegal problems, insufficient training programs, low number of experienced obstetricians, and historical fear of maternal or neonatal complications[1]. The optimal rate of assisted vaginal delivery, including vacuum-assisted delivery, is not known and varies between countries and regions of a

Table 3. Distribution of vacuum -assisted delivery indications

	n	%
Prolonged second stage	28	48.3
Maternal exhaustion	19	32.8
Abnormal NST	20	34.5
Maternal disease and surgery history	3	5.2
Prolonged second stage and maternal exhaustion	7	12
Prolonged second stage and abnormal NST	3	5.2
Maternal exhaustion, abnormal NST, and prolonged second stage	1	1.7

NST: Non-stress test

Table 4. Clinical characteristics of neonates

	Mean ± SD n (%)
Birth weight (gr)	3380±376
Head circumference (cm)	34.1±1.5
First -minute APGAR score (median; min-max)	8; 6-9
Number of neonates first minute APGAR <7	10 (7.2%)
Number neonates 5th minute APGAR <7	0 (0%)
5th minute APGAR score (median; min-max)	9; 7-10
Cord blood pH	7.24±0.09
Transfer to the neonatal intensive care unit	2 (3.4%)
Transfer to the pediatric department for close follow-up	8 (13.7%)

SD: Standard deviation, Min-max: Minimum-maximum

country[9]. It has been reported that 10% of the deliveries were assisted vaginal delivery and 7% were vacuum-assisted in 1999 in England[10]. Also, in some countries, there has been a decreasing trend in instrumental vaginal delivery recently and the reasons for this decrease could not clearly explain yet[11]. Obesity is a risk factor for the prolonged second stage of labor and emergency cesarean section and cesarean complications[12,13]. However, due to wound infection and wound healing abnormalities, surgery-associated morbidity is also increased in obese women[14]. In our study, 86.2% of the study population were overweight and obese. Considering the risk of assisted delivery at the labor of obese patients Informing obese patients about vacuum-assisted delivery such as the Kiwi Omnicup system during delivery or pregnancy education programs, having the Kiwi system ready during delivery, and performing delivery with experienced specialists in this field can contribute to both reducing cesarean rates and surgery-related complications in obese patients. Also, obesity is associated with neonatal adverse outcomes, including transient tachypnea of neonates[15,16]. In our study, eight babies were diagnosed with transient tachypnea of neonates and this may be associated with maternal obesity because all the mothers of these babies have class 1 obesity. A advantage of Kiwi Omnicup is its flexible traction wire, which aids the correct and easier placement of the cup to the fetal head by improving its maneuverability in the vagina. In obese patients, the excess paravaginal soft tissue may make it difficult to use a conventional vacuum that has a rigid traction wire. At this point, the Kiwi Omnicup system may help us attach the cup on the fetal head easily in obese patients.

In comparison with the conventional vacuum systems, the weaker vacuum strength, and plastic cup material of the Kiwi Omnicup cause an expectation of lower maternal and neonatal adverse outcomes than conventional vacuum systems. Fetal scalp injuries, cephalhematomas, and caput succedaneum were mostly associated with the vacuum strength and cup material. Groom et al.[4] reported lower cephalhematoma rates in the Kiwi group than in the conventional vacuum group. Weissbach et al.[7] showed that Kiwi caused lower fetal scalp laceration rates than the conventional vacuum. In our study population, there were 5 neonates with caput succedaneum and there were no other fetal scalp injuries. In addition, the comparative studies observed that Kiwi has similar maternal and neonatal adverse outcome rates with conventional vacuum systems[4,6,7]. The first and fifth minute Apgar scores and cord blood pH analysis are usually used tools to assess the health status of newborns immediate after delivery, and lower Apgar scores and lower pH values are associated with neonatal morbidity and mortality[17,18]. Ghidini et al.[19] assessed the neonatal complications in vacuum-assisted delivery and reported that neonatal intensive care unit requirement, less than 7 at 5th minute Apgar score, or cord arterial pH <7.10, were independently associated with the duration of vacuum application. Also in this study, it was reported that most of the neonatal complications other than scalp injuries are associated with the unsatisfactory fetal heart traceand meconium-stained amniotic fluid rather than vacuum application[19]. Turkmen[8] reported the mean first and fifth minutes Apgar scores, and cord blood pH of neonates who were delivered with the Kiwi Omnicup system as 9, 10, 7.17; respectively, and they observed no significant difference between the Kiwi system and conventional vacuum in terms of Apgar scores and cord blood pH. In our study, the mean cord blood pH, median first and fifth minutes Apgar scores of newborns were 7.24, 8, and 9; respectively. Although there were 10 neonates with lower than 7 Apgar score at the first minute, there was no neonate with lower than 7 Apgar score at the fifth minute. The improvement in the Apgar scores between the first and fifth minutes may be associated to a good routine neonatal care in the delivery room, including drying the infant, clearing the airway of secretions, and oxygen support and resuscitation when needed. The Kiwi Omnicup system may be helpful for patients and obstetricians for the delivery of patients who want a vaginal birth after cesarean. Li et al.[20] reported their ten-year experience of vaginal delivery after cesarean and they performed a vacuum for 45 of 254 patients (17.7%) who had a previous cesarean section. Son et al.[21] and Krizman et al.[22] demonstrated that assisted vaginal delivery had similar maternal and neonatal outcomes with repeat cesarean section and is a safe option for women who undergo a trial of labor after cesarean section at the second stage of labor. Turkmen[8] reported that 46% of the patients who had vacuum-assisted delivery during the two years had an earlier cesarean section. In our study, there was only one patient who had a previous cesarean section and was delivered via the Kiwi Omnicup system. We think that the widespread usage of Kiwi Omnicup in patients with vaginal delivery after cesarean section will contribute greatly to the reduction in cesarean section ratios. Maternal exhaustion is a cause of assisted vaginal delivery and has not been a standard definition of this term. Maternal insufficient force at the second stage of labor due to loss of energyand

giving up Valsalva to push the baby may be considered maternal exhaustion by the obstetricians. Also, maternal exhaustion is a reason for the prolonged second stage of labor. Siggelkow et al. [6] reported that approximately 4% of patients were performed vacuum-assisted delivery due to maternal exhaustion. Informing the pregnant about the effective use of their powers during delivery at the pregnant training programs and follow-up visits and widespread implementation of these programs can reduce the rate of vacuum application due to maternal exhaustion. The higher maternal exhaustion indication rates of our study population may be due to the low number of prenatal visits and maternal education programs.

Study Limitation

The limitations of this study include retrospective design, a low number of participants, and the lack of comparative maternal and neonatal data of patients who had a normal vaginal delivery, assisted vaginal delivery via the Kiwi Omnicup system, and cesarean delivery. Also, due to the results of this study are from a local hospital's data limits the generalizability of the findings. Future studies that compare maternal and neonatal outcomes between patients who had a normal vaginal delivery, vaginal delivery with the Kiwi Omnicup system, and cesarean delivery may contribute to the literature. A retrospective analysis of deliveries for as long as 4 years and including detailed data about neonates' are the study strengths.

Conclusion

The Kiwi Omnicup vacuum system is easy to use and has low maternal and neonatal adverse outcomes. Although the feasibility of this system confirmed by several studies, it has low usage rates in some countries and regions such as our hospital. The reasons for avoidance from Kiwi Omnicup vacuum usage at delivery should be evaluated. Also, increasing the Kiwi Omnicup usage rates with appropriate indications may reduce the cesarean rates.

Ethics

Ethics Committee Approval: The study was approved by the University of Health Sciences Turkey, Bakırköy Dr. Sadi Konuk Training and Research Hospital Ethics Committee (approval number: 2020/85, date: 17.02.2020).

Informed Consent: Retrospective study.

Peer-review: Externally peer-reviewed.

Authorship Contributions

Surgical and Medical Practices: İ.A., Ş.Y., Concept: İ.A., Design: İ.A., Data Collection or Processing: İ.A., Ş.Y., Analysis or Interpretation: İ.A., Literature Search: İ.A., Ş.Y., Writing: İ.A.

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