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Kiwi OmniCup versus Malmström's Metal Cup: Comparing Maternal and Neonatal Outcomes

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Abstract. With the introduction of the Kiwi OmniCup vacuum extractor at our institute, we aimed to evaluate and compare maternal and neonatal outcomes between the Kiwi OmniCup and the Malmström's metal cup in vacuum-assisted deliveries. A retrospective study on all women who delivered by vacuum extraction between November 2010 and April 2012 was conducted. We compared neonatal and maternal morbidity as well as the outcomes in the Kiwi and metal cup group by using chi-square tests. 202 women who had assisted-vaginal delivery (112 by Kiwi OmniCup and 90 by Malmström's metal cup) were included in this study. The mean Apgar scores at one and five minutes were lower in the metal cup group (P-value = 0.07 and 0.08, respectively). Thirty-nine newborns were admitted to the neonatal intensive care unit, of which 38 were discharged within one week. Eight of the 39 neonates were delivered by consultants versus 31 delivered by registrars (P-value = 0.039). There were no intrapartum or neonatal deaths. In conclusion, the Kiwi OmniCup is a safe alternative to the currently available Malmström's metal cup for vacuum assisted delivery.

Keywords: Kiwi OmniCup, Malmström's metal cup, Perinatal outcome, Maternal outcome.

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Introduction

The vacuum extractor, initially in the form of a cupping-glass, was invented in 1705 by an English surgeon called James Yonge. However, it did not gain popularity until a Swedish obstetrician named Dr. Tage Malmström developed a metal cup in 1953 and published a series of studies over a period of almost 20 years[1]. Vacuum extractors gradually replaced forceps for assisted vaginal deliveries in Europe and eventually the world.

In the United States, the average rate of operative deliveries is 5% out of which 70% are vacuum extractor deliveries[2,3]. In Saudi Arabia, there was an overall significant 29% drop in the rate of operative vaginal deliveries from 3.1% in 1997 to 2.2% in 2006 ($P < 0.0001$)[4]. Maternity data from 19 reporting units showed a decrease in the operative vaginal delivery rate, with the highest decrease at King Abdulaziz University Hospital (KAUH) in Jeddah (68.8%) and the lowest in the northern region (3%). Four reporting units showed an increase in operative vaginal delivery rates as follows: King Khalid University Hospital in Riyadh by 17.8%, the eastern region by 12.3%, National Guard Hospital by 8.1%, and Security Forces Hospital in Riyadh by 1.5%[4].

Vacuum extractors were invented to save the lives of women in obstructed labor. Subsequently, the safety of the neonate became a major concern as serious neonatal complications were observed. As a result, different types of vacuum extractors were invented in order to minimize neonatal morbidity. However, there are controversial reports regarding the efficacy of one extractor over the other[5,6].

Recently, the Kiwi OmniCup extractor was introduced at KAUH. Thus, we aimed to compare maternal and neonatal outcomes when using the Kiwi OmniCup and the Malmström's metal cup in vacuum-assisted deliveries.

Materials and Methods

A retrospective study on women who delivered at KAUH, a tertiary referral medical center in Jeddah, between November 2010

and April 2012 was performed. All women who underwent vacuum-assisted deliveries for various indications were included.

For all participating female patients: Basic demographic data, details of parity, maternal age and gestation at delivery, duration of each stage of labor, and fetal position and station at the time of vacuum application were collected. The indications for intervention were prolonged second stage of labor with documented uterine activity, maternal exhaustion (maternal inability to deliver due to physical exhaustion), non-reassuring fetal status and shortening of the second stage of labor due to maternal disease (cardiac, vascular, pulmonary, *etc*.). Data regarding details of the procedure and delivery outcome, including success, failure, mode of delivery, perineal trauma, birth weight, and low Apgar scores following birth (≤ 4 and < 7, at 1 and 5 min, respectively) were also collected. In addition, neonatal intensive care unit (NICU) admission rates, duration of NICU stay, the need for intubation, and neonatal complications in the form of major brain injury, defined as intracranial ventricular hemorrhage (IVH) grade 3 or higher according to Papile's classification[7]. We documented other neonatal complications due to trauma, including cephalohematomas, Subgaleal hematomas, clavicle fractures, and brachial plexus injury.

All vacuum-assisted deliveries were conducted according to the hospital protocol and performed by obstetric registrars or consultants. The level of qualification of the obstetricians and neonatologists who were in charge of the parturient were also documented.

Statistical Analysis

Data were collected and analyzed using the IBM Statistical Package for the Social Sciences (IBM SPSS Statistics), Version 20 (IBM Inc., Armonk, New York USA). Chi-square (χ^2) test was used to compare the variables between the two groups. Statistical significance was set at $P < 0.05$.

Permission to conduct the study was granted by the local Ethics Committee of KAU.

Results

Between November 2010 and April 2012 the total number of deliveries was 3,974, out of which 960 (24.15%) delivered by cesarean section, of those 437 (45.5%) were emergency cesarean section, only 3 (0.07%) women delivered by forceps, and 54 (1.35%) delivered by assisted breech vaginal delivery, while 202 (5.1%) were by ventose (112 by Kiwi OmniCup and 90 by Malmström's metal cup). The two groups were similar in terms of maternal characteristics. The mean age of the study group was 27.7 ± 5.5 years (range, 14-52 years). The mean age of the women in the Kiwi group was 27.4 ± 5.2 years and 27.5 ± 5.8 years for those in the metal cup group. The study population consisted of 100 (49%) nulliparous and 102 (51%) multiparous women. The mean parity was 2.3 ± 2.1 for women in the Kiwi group and 2.2 ± 2.3 for those in the metal cup group. The mean gestational age was 40 ± 1.3 weeks for the Kiwi group and 40 ± 2.0 weeks for the metal cup group.

The main indication for the use of ventouse was non-reassuring cardiotocography in 40 (44.4%) women in the metal cup versus 41 (36.6%) in the Kiwi group. Ventouse delivery was indicated for shortening of the second stage of labor due maternal disease in six women (five (5.6%) in the metal cup group versus one (0.9%) in the Kiwi group). The failure rate was higher in the metal cup group (eight (8.9%) versus six (5.4%) cases in the Kiwi group).

The first stage of labor was shorter in the Kiwi group (558.2 ± 745.7 min versus 434.8 ± 194.7 min for the metal cup group; P = 0.1). Similarly, the second stage of labor was shorter in the Kiwi group (70.7 ± 49.6 min versus 85.2 ± 64.3 min for the metal cup group; P = 0.08). In most cases, vacuum extraction was done with the baby's head at station -1 (in 49 (43.8%) women in the Kiwi group versus 33 (36.6%) in the metal cup group). Vacuum delivery was done with the fetal head at station 0 in 19 (17.0%) women in the Kiwi group versus 13 (14.4%) in the metal group. At station +1, delivery was done in 27 (24.1%) women in the Kiwi group versus 25 (27.7%) in the metal cup group, and at station +2, it was done in 16 (14.3%) women in the

Kiwi group versus and 18 (20.0%) in the metal cup group. The station was not documented in two cases (one in each group).

The mean Apgar scores were higher in the Kiwi group. The mean Apgar score at one minute in the Kiwi group was 8.1 ± 1.6 versus 7.7 ± 1.7 for the metal cup group (P value = 0.07), and at five min, it was 9.6 ± 0.9 versus 9.3 ± 1.5 for the metal cup group (P value = 0.08). The average birth weight was higher in the metal cup group (3.6 ± 3.9 kg versus 3.1 ± 0.4 kg for the Kiwi group; P = 0.17).

The rate of episiotomies was 75.7% for the Kiwi group versus 71.3% for the metal cup group (P = 0.49). The rate of intact perineum was 8.9% for Kiwi versus 10.0% for metal cup (P = 0.67). First and second degree perineal tears were more frequent in the Kiwi group. The frequency of first degree perineal tears in the Kiwi group was 4.5% versus 8.9% for the metal cup group (P = 1.6). Second degree perineal tears occurred in 8.0% of the cases in the Kiwi group versus 4.4% in the metal group (P = 0.3). On the contrary, third degree perineal tears were more frequent in the metal group (11.1% *vs*. 5.4% for the Kiwi group (P = 0.13)). One case of fourth degree tear and two cases of cervical tear were documented with the Kiwi vacuum extractor.

The following fetal complications were documented: intubation (three in the Kiwi group and two in the metal cup group), scalp laceration (two cases in the Kiwi group and three in the metal cup group), cephalohematoma (11 cases in the Kiwi group and three in the metal cup group), Subgaleal hematoma (two cases in the Kiwi group), and facial nerve palsy in one neonate in the metal cup group. There were three cases of shoulder dystocia in the metal cup group and none in the Kiwi group. Hyperbilirubinemia was documented in 11 neonates in the Kiwi group and in seven infants in the metal cup group.

Out of 202 ventouse deliveries, 39 newborns were admitted to the Neonatal-ICU. Eight of the 39 neonates were delivered by consultants versus 31 delivered by registrars (P value = 0.039). There were no intrapartum or neonatal deaths. All the babies who were admitted to the NICU were discharged within one week.

Discussion

The objective of this retrospective analysis was to compare maternal and neonatal outcomes of the Kiwi OmniCup and the Malmström's metal cup at our hospital. Importantly, all vacuum-assisted deliveries were conducted according to the hospital protocol and performed by obstetric registrars or consultants. Additionally, maternal characteristics were similar in both groups, thus allowing more accurate comparisons between the study groups.

Our results demonstrate that the rate of maternal complications was comparable in both groups, which is in line with the results of other authors[8,9], including those of a randomized comparative trial that showed that in terms of maternal morbidity, 100% success was achieved with both the Kiwi OmniCup and Malmström's vacuum extractors[10]. In the current study, we did not document any case of serious maternal trauma or neonatal deaths, and all the neonates who were admitted to the NICU were discharged within one week. The most common neonatal complications included cephalohematoma, and Subgaleal hematoma, which were more frequent in the Kiwi group. Scalp lacerations were documented in two cases in the Kiwi group and in three neonates in the metal cup group. Results from the Cochrane Systematic Review of trials that compared soft and rigid vacuum cups demonstrated that soft cups caused less scalp injury, similar to our finding[11]. However, there are insufficient data to underpin the relative merits of different vacuum cups regarding potentially life-threatening outcomes such as Subgaleal hematoma and intracranial hemorrhage. Presently, there are a few reports that suggest that soft cups are not advantageous over rigid cups for the prevention of these injuries[12,13].

Amongst the cases admitted to the NICU, a significantly lower number of infants were delivered by consultants in comparison to those delivered by registrars. However, it is not clear whether this is directly related to physician expertise, the type of vacuum extractor used, or the number of deliveries individually performed by registrars and consultants. Although most obstetricians would agree that the success of vacuum delivery depends on the knowledge, experience,

and skill of the operator, system analyses of adverse outcomes often demonstrate inadequate experience to be a major contributing factor[14,15]. Furthermore, some deliveries (mid-cavity and rotational), independent of the type of instrument used, demand a high level of clinical and technical skill, and adequate training on the part of the operator[16].

There is evidence that the routine use of episiotomy with vacuum extraction is associated with an increased, rather than a decreased risk of perineal trauma and rectal injuries[17,18]. However, findings from a recent population-based observational study, concluded that because of the occurrence of anal sphincter injury during operative vaginal delivery, mediolateral episiotomies should be used routinely during these interventions to protect the anal sphincters[19]. According to our hospital protocol, episiotomies are not routinely performed during operative vaginal delivery and are only indicated to avoid severe maternal lacerations or to facilitate or expedite the second stage of labor.

The second stage of labor in our patients was on the average longer in the metal cup group (85.2 ± 64.3 min versus 70.7 ± 49.6 min for the Kiwi group) and infants delivered by Malmström's metal cup weighed, on average, 500 g more than infants born by Kiwi. This may explain why shoulder dystocia was more common in the metal cup group, as there is an increased risk of shoulder dystocia in fetuses with macrosomia[20], especially in cases of prolonged labor[21]. Although deliveries requiring instrumental assistance have a higher risk of shoulder dystocia[22,23], there are no randomized trials that compare the frequency of dystocias in babies delivered with the Kiwi OmniCup and those delivered with the Malmström's metal cup extractor.

Contrary to the findings of other authors[8,24], the extraction failure rate in our study was higher in the metal cup group. Reports from three randomized trials that compared the standard vacuum cup to the Kiwi OmniCup device[8,10,24], showed that failure rates for the Kiwi OmniCup were generally higher at 30-34% compared with 19-21% for the standard vacuum device[8,24], albeit this association was not

confirmed by all studies[10]. The reason for the higher failure rate was explained by the more frequent detachments associated with the Kiwi OmniCup.

There are two main shortcomings in this study. First, is it limited by its retrospective nature. Second, it is limited by the small sample size. We, therefore, recommend a prospective study with a larger sample size to further assess maternal and neonatal outcomes when using the Kiwi and Malmström's vacuum extractors.

Conclusion

Maternal and neonatal outcomes were comparable with the Kiwi OmniCup and Malmström's metal cup extractor. Although complications such as cephalohematoma, and Subgaleal hematoma were more frequent with the Kiwi OmniCup, the outcome was in general favorable for neonates in both groups. Hence, the Kiwi OmniCup is a safe alternative to the currently available Malmström's metal cup for vacuum assisted delivery.

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مقارنة ناتح الحمل لدى الأمهات وحديثي الولادة عبر إستخدام جهاز الشفط كيوي مقارنة بالمالمستروم

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المستخلص. نظراً لإدخال جهاز سحب الجنين OmniCup الى قسم النساء والولادة عملنا على التقييم والمقارنة بين جهازي ال Kiwi OmniCup و Malmström's ذا الرأس المعدني وذلك في تأثيرهم على ناتج الحمل لحديثي الولادة وعلى الحامل. تم إجراء دراسة بأثر رجعي على جميع السيدات اللواتي ولدن ما بين تشرين الثاني ٢٠١٠ ونيسان ٢٠١٢م. تم مقارنة الاختلاطات لحديثي الولادة وللأمهات كذلك. تم المقارنة بين أداء الجهازين Kiwi and metal cup وذلك باستعمال فحص كاي سكوير. تم إدراج ٢٠٢ سيدة من اللواتي خضعن للولادة بالجهازين (Kiwi OmniCup ١١٢ و Malmström's metal cup ٩٠)، فوجد أن وسطي تقييم أبغار في الدقيقة الأولى والخامسة كان أقل في حالة الولادة بالجهازالمعدني (بالتسلسل ٠،٠٨ و٠،٠٧ = P–value) تسعة وثلاثون حديث ولادة تم ادخالهم الى قسم عناية الأطفال الفائقة، منهم ٣٨ خرجوا من المستشفى خلال اسبوع من تاريخ دخولهم، ٨ من ال ٣٩ تمت ولادتهم عن طريق أطباء استشاريين مقابل ٣١ تم ولادتهم من قبل أخصائيين (P–value = ٠،٠٣٩). لم يتم تسجيل أية حالة وفاة للأم أو الجنين

في هذه الدراسة. تم استنتاج أن الجهاز الجديد Kiwi OmniCup هو خيار آمن مقارنة بالجهاز السابق Malmström's metal cup.