Comparison of Vacuum Extraction Delivery Between the Conventional Metal Cup and the New Soft Rubber Cup

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Abstract

To compare the effectiveness and complications of vacuum extraction delivery between the conventional metal cup and the silicone rubber cup.

A prospective randomized clinical trial of 90 pregnant women requiring assisted vaginal delivery who met the predetermined criteria for vacuum extraction were allocated to delivery by the Malstrom metal cup (46 cases) or the silicone rubber cup (44 cases).

The two groups were similar in respect of age, parity gestational age and indications for assisted vaginal delivery. The mean and median numbers of tractions and time from cup application to delivery were not significantly different between the groups. The overall success rate was higher in the metal cup (89.1%) than in the rubber cup (79.5%) but not significantly different. The silicone cup was more likely to fail in cases of occiput posterior position, excessive caput, and severe degree of molding. There were no significant differences between groups in terms of Apgar scores, birth canal injury, and maternal blood loss. Scalp injuries occurred more frequently with the metal than with the rubber cup (P = 0.006).

Vacuum extraction delivery with the silicone rubber cup is associated with reduced scalp injuries but has a greater tendency to fail when the fetus presents in occiput posterior position, has excessive caput or severe degree of molding.

Vacuum extraction is an operative obstetrics for assisting delivery of the fetal head. It has been widely used in Europe and developing countries as the instrument of choice for operative vaginal delivery. The procedure is advocated because it is less traumatic than forceps to the mother and also safely augments the natural process of birth. One of the disadvantages of the vacuum extraction is the time needed to induce the negative pressure before traction can be attempted.

There have been some concerns that the conventional metal cup may be associated with scalp

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injuries including lacerations and hematoma[1,2]. The rigid edges of the metal cup may cause serious trauma to the fetal scalp[3]. Consequently, the soft rubber cup has been devised in an attempt to minimize scalp injuries[4,5]. This cup can shape to the fetal head and has no rigid edge. It was claimed that the soft cup causes less neonatal scalp trauma but is more likely to fail to achieve a vaginal delivery when compared with the conventional metal cup[6-9].

This prospective randomized controlled trial was conducted to compare the effectiveness and complications of vacuum extraction delivery between the conventional metal cup and the new soft rubber cup in pregnant women who met the predetermined criteria for assisted vaginal delivery.

SUBJECTS AND METHOD

The study was carried out between May 1996 and October 1996 at the Department of Obstetrics and Gynecology, Chiang Mai University Hospital and constitutes 90 pregnant women eligible for assisted vaginal delivery. Each patient was more than 37 weeks of gestation, had a single live fetus and met the following criteria : ruptured membranes, fully dilated cervix, vertex presentation, and low or mid station of descent. Once a decision had been made that instrumental vaginal delivery was necessary and the patient was suitable for enrollment in the study, the details of the procedure were explained and informed consent was obtained. Vacuum extraction by means of the metal or soft cup was allocated by blocked randomization. The study was undertaken under the ethical approval of the Research Ethical Committee of the Chiang Mai University Hospital.

After appropriate anesthesia either epidural, pudendal or local lidocaine infiltration, the bladder was emptied before application of the cup. For the conventional metal cup, the original 50 mm Malstrom mushroom- shaped design with central chain and suction pipe was used. For the new soft rubber cup, we chose the Silastic silicone rubber cup with a diameter of 50 mm (Silc Cup, Menox AB, Gothenburg, Sweden)

The rubber cup was introduced by squeezing it together and advanced towards the fetal head and placed near the occipital fontanelle to ensure flexion of the vertex. The maternal soft tissue interposed between the cup and fetal scalp was cleared by digital examination. With the cup gently pressed against the fetal head, the suction pressure was rapidly increased to - 0.8 kg/cm^2 in one step by means of an electric suction pump (Atmoforte 350, Menox AB, Gothenburg, Sweden). With the Malstrom cup, vacuum was created to - 0.8 kg/cm^2 in the same manner as the soft cup. Traction was then applied synchronously with uterine contractions and maternal expulsive efforts.

The time between cup application and delivery of the fetal head was recorded. If the cup separated from the fetal scalp (slip-off) it was replaced once and traction continued with observation of the descent of fetal head at each pull. The time limit of application was 15 minutes and the limit of detachment was two. If delivery was not accomplished within 15 minutes or two or more cup detachments or delivery other than the intended cup occurred, the method was recorded as a failure.

The infant was evaluated immediately after birth and again at 48 hours when a careful inspection was made with particular attention to the fetal scalp i.e., the presence of cup marks, bruising, lacerations, or hematoma. The need for phototherapy or transfer to the neonatal intensive care unit was also recorded.

The baseline data and outcome variables were installed in the microcomputed program Epi Info 6 for analysis. Statistical analyses were conducted by using the Chi-square and the Student's *t* test as appropriate to examine differences between the two groups and were regarded as significant at $P < 0.05$.

RESULTS

A total of 90 pregnant women requiring assisted vaginal delivery were randomly enrolled in the study, 46 for the metal cup and 44 for the silicone rubber cup. There were no significant differences between the two groups in maternal and fetal variables including, the position, station, amount of caput and degree of molding of the fetal head (Table 1).

Table 2 summarizes the details of vacuum extraction deliveries. There were no significant differences between the two types of cup in terms of time from cup application to delivery and number of tractions. Although, detachments occurred more often with the silicone rubber cup (15.9%) than with the metal cup (4.3%), the difference was not statistically significant ($P = 0.06$). Likewise, the overall success rate of the metal cup (89.1%) group did not

Table 1. Characteristics of patients in two study groups.

Variable	Metal cup (n = 46)		Silicone rubber cup (n = 44)	
Maternal age (years)				
Median	27.0		30.0	
Mean (range)	28.8	(18-42)	29.5	(14-42)
Gestational age (weeks)				
Median	39		39	
Mean (range)	39	(37-41)	39.2	(37-43)
Nulliparous	27	(58.7%)	28	(63.6%)
Multiparous	19	(41.3%)	16	(36.4%)
Position of fetal head				
Occiput anterior	29	(63%)	26	(59.1%)
Occiput transverse	7	(15.2%)	11	(25.0%)
Occiput posterior	10	(21.8%)	7	(15.9%)
Station of fetal head				
Mid, station < +2	7	(15.2%)	9	(20.5%)
Low, station ≥ +2	39	(84.8%)	35	(79.5%)
Excessive caput	9	(19.6%)	7	(15.9%)
Molding ++/+++	24	(52.3%)	21	(47.7%)
Indication for assisted delivery				
Delay of second stage	12	(26.1%)	5	(11.4%)
To shorten second stage	11	(23.9%)	8	(18.2%)
Maternal exhaust	22	(47.8%)	29	(65.9%)
Fetal distress	1	(2.2%)	2	(4.5%)

Table 2. Details of delivery in the two groups.

	Metal cup (n = 46)		Silicone rubber cup (n = 44)	
Time from cup application to delivery (minutes)				
Median	6		7	
Mean (range)	6.9	(3-18)	6.6	(3-15)
Number of tractions				
Median	2		2	
Mean (range)	2.4	(1-6)	2.2	(1-4)
Number of detachments*				
One	2	(4.3%)	2	(4.5%)
Two	0		5	(11.4%)
Eventual delivery method**				
Metal cup	41	(89.1%)	5	(11.4%)
Silicone rubber cup	3	(6.5%)	35	(79.5%)
Forceps	1	(2.2%)	1	(2.3%)
Cesarean section	1	(2.2%)	3	(6.8%)
Reasons for failure				
Failure of descent (C.P.D.)	1		3	
Difficult / improper application	1		1	
Cup detachment	0		5	
Duration > 15 minute	1		0	

* P = 0.06, ** P = 0.2, C.P.D. = Cephalopelvic disproportion

Table 3. Maternal injury in the two study groups.

	Metal cup (n = 46)		Silicone rubber cup (n = 44)	
Perineal tear				
None, no episiotomy	1	(2.2%)	3	(6.8%)
First / second	42	(91.3%)	36	(81.8%)
Third	3	(6.5%)	5	(11.4%)
Vaginal tear				
None, no episiotomy	1	(2.2%)	3	(6.8%)
Lower 1/3	24	(52.2%)	25	(56.8%)
Middle 1/3	19	(41.3%)	13	(29.4%)
Upper 1/3	2	(4.3%)	3	(6.8%)
Cervical tear	1	(2.2%)	0	
Postpartum hemorrhage	0		1	(2.3%)

Table 4. Neonatal outcome in the two study groups.

	Metal cup (n = 46)		Silicone rubber cup (n = 44)	
Birthweight (grams)				
Median	2,975		3,100	
Mean (range)	3,021	(2350-3980)	3,057	(2300-3650)
Apgar score < 7				
At 1 minute	4	(8.7%)	6	(13.6%)
At 5 minute	0		0	
Scalp trauma after 48 hours				
No visible injury	24	(52.2%)	35	(79.5%)*
Cup marks	18	(39.1%)	5	(11.4%)**
Swelling / bruising	1	(2.2%)	4	(9.1%)
Lacerations	1	(2.2%)	0	
Cephalhematomas	2	(4.3%)	0	
Jaundice	2	(4.3%)	0	
Phototherapy	2	(4.3%)	0	

* P = 0.006, ** P = 0.002

significantly differ from that of the rubber cup group (79.5%). Delivery with the rubber cup was more likely to fail in occiput posterior position (4 of 7), excessive caput (4 of 7), and severe degree of molding (4 of 4). Among 5 patients of the rubber group with 2 detachments, 4 were later delivered by metal cups and 1 by forceps extraction. Of 4 patients whose fetuses were delivered by cesarean section due to failure of descent, 3 had excessive caput and severe degree of molding, the other one was in occiput posterior position.

There were no significant differences between the two groups in respect of maternal morbidity (Table 3). One patient in the rubber group had postpartum hemorrhage due to uterine atony.

Neonatal outcome is detailed in Table 4. There was no significant difference between the groups with regard to birth weight and Apgar score. Inspection of the fetal scalp at 48 hours after birth showed significantly less visible scalp injuries in the rubber cup group than in the metal cup group. The cup mark originated from the sharp and rigid edge of the metal cup was found significantly more often than that of the rubber cup. Cephalhematomas were observed in 2 babies of the metal group, both presented with occiput posterior, had excessive caput and severe degree of molding. Two babies born by the metal cup required phototherapy for jaundice. There were no neonatal deaths and no baby developed seizure.

DISCUSSION

The failure rate of the silicone rubber cup (20.5%) in this study is higher than that of the metal cup (10.9%). These results are slightly more than those obtained in three larger randomized comparisons between the metal and rubber cups where the Silc Cup represented the rubber cup. Cohn et al reported 21 of 131 (16%) failure,[7] Chenoy and Johanson reported 13 of 98 (13%) failure,[8] and Kuit et al reported 5 of 50 (10%) failure[9] for deliveries with the rubber cups. These may result from the differences in study population, definition of success and failure, technique of vacuum induction and criteria for abandonment of the procedure.

The increased failure rate of the rubber cup in this study is associated with extensive caput formation, excessive molding of the fetal head and occiput posterior position which corresponds with the study of Chenoy and Johanson[8]. The rubber cup tends to slip off during extraction[5]. Slip-offs occur with less traction force than with the metal cups. Cup detachment occurs most often with extensive caput and molding because the rolled edges of the rubber cup do not accommodate well to the hills and valleys of the molded head. A severe degree of molding of the fetal head indicated the possibility of cephalopelvic disproportion, accordingly, cup detachment should not be regarded as a safety mechanism of the vacuum extraction, but as a warning sign of possible cephalopelvic disproportion.

Safe vacuum extraction delivery technique requires progress in descent of the fetal head at each traction. True downward movement of the head, not just elongation of the caput, must occur. Failure of progressive descent may result from improper application, cephalopelvic disproportion, or positional abnormalities. Failure of descent in two traction indicates the need for complete reevaluation of the obstetric situation and delivery method. In the case of occiput posterior presentation which increases the fetal head diameters relative to the occiput anterior presentation, assisted delivery with the metal cup is clearly superior to the rubber cup[6].

This study verifies the previous findings with regard to the differences in fetal scalp injury between the rubber and metal cups[6-10]. Scalp injuries occurred more commonly with the metal cup delivery (47.8%) than with the rubber cup (20.5%). The rubber cup fits over the fetal occiput similar to a skull cap, offering the advantage of less scalp trauma as it better accommodates to the fetal head, requires no chignon, and has no rigid edge. Despite the fact that, detachment with the rubber cups occurred more often than with the metal cups, however, it is much less dangerous. Loss of suction of the metal cup was closely associated with both scalp injuries and instrumental failures[2].

Serious neonatal complications, such as skin ablations or subgaleal hematoma which have been reported to occur with the metal cup but not with the rubber cup[4-7] were not encountered in this study. However, we found 2 infants (4.3%) complicated with cephalhematomas in the metal group which is comparable to the mean incidence of 6 per cent in the literature survey series of metal cup deliveries[2]. The incidence of such a complication with the rubber cup is well below that of the metal cup. Cephalhematomas are rarely detected at the time of delivery, most cases are recognized on re-examination the day after delivery or later[5]. Factors significantly related to cephalhematoma formation included high station of the fetal head, traction of more than 10 minutes, more than one cup detachment and fetal weight more than 3.6 kg[11]. Cephalhematomas usually resolve in 7-10 days.

Generally, perinatal mortality and serious scalp injuries will not occur when the procedure is limited to approximately 15 minutes and / or two cup slip-offs[12]. Decreases in the number and the duration of tractions will reduce the risk for scalp trauma.

In conclusion, the silicone subber cup can be used for assisted vaginal delivery with minimal trauma to the birth canal and fetal scalp. Caution should be taken when used in conditions that are likely to fail especially in cases of excessive caput, occiput posterior position and severe degree of molding.

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การเปรียบเทียบการคลอดด้วยเครื่องดูดสุญญากาศ ระหว่างถ้วยโลหะแบบดั้งเดิมกับถ้วยยางแบบใหม่

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วัตถุประสงค์ : เพื่อเปรียบเทียบประสิทธิภาพและภาวะแทรกซ้อนของการคลอดด้วยเครื่องดูดสุญญากาศระหว่างถ้วยโลหะแบบดั้งเดิมกับถ้วยยางซิลิโคน

รูปแบบการศึกษา : เป็นการศึกษาทางคลินิกแบบสุ่มไปข้างหน้าในสตรีตั้งครรภ์ 90 ราย ที่ต้องช่วยคลอดทางช่องคลอดและมีเกณฑ์ของการใช้เครื่องดูดสุญญากาศ โดยแบ่งออกเป็นการคลอดด้วยถ้วยโลหะมัลสตรอม 46 ราย และถ้วยยางซิลิโคน 44 ราย

ผลการศึกษา : สตรีตั้งครรภ์ทั้ง 2 กลุ่ม มี อายุ จำนวนการคลอด อายุครรภ์ และข้อบ่งชี้ของการช่วยคลอดทางช่องคลอดไม่แตกต่างกัน ค่าเฉลี่ย และค่ามัธยฐานของจำนวนการดึงและระยะเวลาที่ใส่ถ้วยจนกระทั่งคลอดไม่แตกต่างกันอย่างมีนัยสำคัญ อัตราความสำเร็จโดยรวมในกลุ่มที่ใช้ถ้วยโลหะ (89.1%) สูงกว่ากลุ่มที่ใช้ถ้วยยาง (79.5%) แต่ไม่แตกต่างอย่างมีนัยสำคัญทางสถิติ การช่วยคลอดด้วยถ้วยยางมีโอกาสล้มเหลวสูงในกรณีที่ทารกอยู่ในท่าท้ายทอยอยู่ด้านหลัง มีหนังศีรษะบวมมาก และมีกระดูกศีรษะเกยกันมาก คะแนน Apgar การบาดเจ็บต่อช่องทางคลอด และการสูญเสียเลือดของมารดาไม่แตกต่างกันอย่างมีนัยสำคัญในผู้ป่วยทั้ง 2 กลุ่ม กลุ่มที่คลอดด้วยถ้วยโลหะมีการบาดเจ็บต่อหนังศีรษะมากกว่ากลุ่มที่คลอดด้วยถ้วยยางอย่างมีนัยสำคัญทางสถิติ (P = 0.006)

สรุป : การคลอดด้วยเครื่องดูดสุญญากาศโดยใช้ถ้วยยางซิลิโคนมีการบาดเจ็บน้อยต่อหนังศีรษะ ทารก แต่มีโอกาสล้มเหลวได้สูงถ้าทารกอยู่ในท่าท้ายทอยอยู่ด้านหลัง มีหนังศีรษะบวมมาก และมีกระดูกศีรษะเกยกันมาก

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