## นิพนธ์ต้นฉบับ

# Scalp injuries of metal and silastic cups vacuum extraction

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Objective : To compare the incidence of scalp injuries in infants delivered with

metal and silastic vacuum extraction cups

**Design** : Randomized controlled study

Setting : The delivery suite, Chulalongkorn Hospital

Subjects: 200 parturients who received vacuum extraction delivery between

June 1993 and May 1994

**Method**: Subjects were randomized into two groups. Group 1 (n=100)

delivered with metal cup vacuum extraction. Group 2 (n=100) delivered with silastic cup vacuum extraction. Second year obstetric residents performed the deliveries. Fetal scalp injuries

were assessed immediately and 24 hours after birth by pediatrician.

Main outcome

measure : Incidence of scalp injury

Results : Fetal scalp injuries occured in Group 1 (metal cups) was more

than in Group 2 (silastic cups) which was statistically significant

(27% vs14%, p<0.05)

Conclusions : Vacuum extractions with metal cup cause more fetal scalp injuries

than those with silastic cups

Key word : Vacuum extraction.

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วัตถุประสงค์

เปรียบเทียบอัตราการบาดเจ็บต่อหนังศีรษะทารก ซึ่งคลอดโดยเครื่องดึง

สุญญากาศ

รูปแบบการวิจัย

การวิจัยเชิงทดลอง

สถานที่ทำการวิจัย

ห้องคลอด โรงพยาบาลจุฬาลงกรณ์

กลุ่มตัวอย่าง

สตรีตั้งครรภ์ครบกำหนด จำนวน 200 ราย ที่ได้รับการเลือกให้คลอด

โดยเครื่องสุญญากาศ ที่โรงพยาบาลจุฬาลงกรณ์ ในระหว่างเดือน

มิถุนายน พ.ศ. 2536 ถึงเดือนพฤษภาคม พ.ศ. 2537

วิธีการวิจัย

แบ่งกลุ่มตัวอย่างออกเป็นสองกลุ่ม โดยวิธีจับสลาก กลุ่มละ 100 ราย กลุ่มที่ 1 ได้รับการช่วยคลอดโดยเครื่องดึงสุญญากาศชนิดถ้วยโลหะ กลุ่มที่ 2 ได้รับการช่วยคลอดโดยเครื่องดึงสุญญากาศชนิดถ้วยซิลิโคน โดยแพทย์ประจำบ้านปีที่ 2 ตรวจการบาดเจ็บที่หนังศีรษะทารกทันที

หลังคลอด และหลังคลอด 24 ชั่วโมง โดยกุมารแพทย์

ตัววัดที่สำคัญ

ทารกซึ่งคลอดโดยเครื่องดึงสุญญากาศชนิดถ้วยโลหะ มีอัตราการบาดเจ็บ ของหนังศีรษะ 27% ซึ่งแตกต่างอย่างมีนัยสำคัญทางสถิติ (p<0.05) เมื่อเทียบกับ ทารกที่คลอดโดยเครื่องดึงสุญญากาศชนิดถ้วยซิลิโคนซึ่งมี

อัตราการบาดเจ็บของหนังศีรษะเพียง 14%

สรุป

การบาดเจ็บต่อหนังศีรษะทารกคลอดโดยเครื่องดึงสุญญากาศชนิดถ้วย

โลหะมีมากกว่าชนิดถ้วยชิลิโคน

### การบาดเจ็บต่อหนังศีรษะทารกคลอดโดยเครื่องดึงสุญญากาศ ชนิดถ้วยโลหะกับชนิดถ้วยชิลิโคน

Vacuum extraction is a procedure for assisting delivery that is commonly used in European, Scandinavian and developing countries. The advantages of the vacuum extractor over the forceps include the avoidance of insertion of space-occupying steel blades within the vagina and the ability to rotate the fetal head without impinging soft maternal tissues. Therefore, there is less maternal trauma. The technique is easier and there is less increased intracranial pressure than forceps extraction. However, there have been many reports about these injuries following vacuum extraction. However, there have

The soft silastic cup was developed. There are many studies in the literatures comparing metal cup and silastic cup vacuum extractions and they all found significant differences in the incidence of fetal scalp injury between the groups but no difference in the success rate. In Thailand there is no such study so this randomized controlled trial was designed to compare the incidence of scalp injuries and the success of vacuum extraction with the metal cups versus the silastic cups.

#### Material & Methods

This study was performed within the delivery suite of Chulalongkorn hospital between June 1993 and May 1994. Two hundred parturients were selected for delivery with vacuum extraction to shortening the second stage of labor. Vacuum extraction by means of the metal or silastic cup was allocated randomly by drawing the next card of a series containing random numbers ending in 1 (metal cup) or 2 (silastic cup). All deliveries were conducted by second

year residents of the Obstetrics and Gynecology Department.

The criteria required for enrollment in the study included: term pregnancy with single fetus that had occiput presentation, standard criteria for low forceps, and proper informed written consent from the mother. The indication for the procedure was only to shorten the second stage of labour.

Negative pressure was induced by means of an electric suction pump. When the metal cup was applied the vacuum was created gradually by increasing the suction by 0.2 kg/cm² every 2 minutes until a negative pressure of 0.8 kg/cm² was achieved. With the silastic cup, negative pressure was increased to 0.8 kg/cm² immediately. Traction was applied in conjunction with uterine contractions. If a cup slipped off, or if the traction time was more than 30 minutes, the procedure was considered to have failed and the delivery was completed by the physicians' method of choice.

The heads of all infants delivered under this procedure were examined in the delivery room and reexamined 24 hours after birth for any scalp injuries by pediatrician. Mothers and infants were observed until discharge. Complications were recorded.

The sample size was predetermined to have sufficient statistical power to detect a difference in the incidence of fetal scalp injuries with an alpha of 0.05 (two-sided) and a beta of 0.20. Data for each group were compared by the unpaired t-test and Z-test for proportion, P<0.05 indicated significance.

### Results

Table 1. presents maternal and obstetric characteristics of the two groups. There was no difference between the groups. Table 2 shows traction times and success rates of the two groups. The traction time was not different but the success rate with use of the metal cup group

was higher than for the other group. However, if the method of inducing vacuum is the same, the success rate was not different between the groups. In this study, 8 cases failed, 6 of 8 cases had occiput-posterior position, all of them had slipping off of the cup during traction and had normal delivery thereafter.

Table 1. Maternal and Obstetric Characteristics.

	Metal cup	Silastic cup	-	
Age (mean + SD) (year)	25.4 <u>+</u> 4.8	25.6 <u>+</u> 5.9	NS	_
Nulliparous (%)	83	79	NS	
Gestational age (mean + SD) (week)	39.1 <u>+</u> 1.2	39.0 <u>+</u> 1.3	NS	
Oxytocin used (%)	78	73	NS	
Duration of second stage (min)	59 <u>+</u> 31.2	53 <u>+</u> 28.4	NS	
Position of fetal head				
Occiput anterior (%)	73	79	NS	
Occiput posterior/transverse (%)	27	21	NS	

Table 2. Traction time and Success rates.

	Metal cup	Silastic cup	
Traction time (minute)	6.6 <u>+</u> 4.3	5.8 <u>+</u> 4.7	NS
Success rate (%)			
first 50 cases	100*	90**	p<0.01
last 50 cases	98*	96*	NS
total $(n = 100)$	99	93	p<0.05

<sup>\*</sup> Vacuum was created gradually by increasing the suction by 0.2 kg/cm<sup>2</sup> every 2 minutes until pressure of 0.8 kg/cm<sup>2</sup> was reached.

<sup>\*\*</sup> Negative pressure was increased to 0.8 kg/cm<sup>2</sup> immediately

Table 3. showed the infants' data and their neonatal outcome, There were no differences between the groups with regard to birth weight, sex or Apgar scores. The incidence of

fetal scalp injury for the metal cup was significantly higher than with the silastic cup, but other neonatal morbidities were not different.

Table 3. Neonatal Outcome.

	Metal cup	Silastic cup	
	n = 100	n = 100	
Birth weight (g)	3186 <u>+</u> 510.4	3060 <u>+</u> 581.1	
Sex male (%)	53	54	
female (%)	42	46	
Fetal scalp injury			
abrasion	19	11	
laceration	1	0	
ecchymosis	3	1	
cephalhematoma	4	2	
total	27 *	14 *	
<b>Saundice</b>	10	9	
Sepsis	1	-	
Hypoglycemia	-	1	
Aggar score < 7			
at 1 min	6	5	
at 5 min	1	1	

<sup>\*</sup>P<0.05

### **Discussion**

The study found that silastic cup vacuum extractions produced fewer fetal scalp injuries than the metal cup. However, silastic cups had a higher failure rate than the metal cup, especially when negative pressure was immediately induced to 0.8 kg/cm<sup>2</sup>

Most of the scalp injuries found in this study were mild such as abrasions. Severe in-

juries constituted only 8% of injuries in the metal group and 3% in the silastic group. This was much less common than in previous studies, (8-10) but this may be due to the indication only for shortening the second stage of labor which is easier and uses less extraction force than the prolonged second stage. However, this study supports the results of previous studies (8-10) that the fetal scalp injuries caused by metal cup

were more common than the silastic cup. Most of the injuries were found at the rim of the cup, and may be due to most of increased extraction force was applied in this area. The metal cups have harder rims and they adhere to the fetal scalp more firmly than the silastic cups, so they caused more injuries. In this study, there was only one scalp laceration and that was found in a metal group failure case.

Hammarstrom et al found that the silastic cup hads significantly higher failure rates than the metal cup, (8) but Cohn et al found no difference. (9) In our study, we used Compton's suggestion<sup>(3)</sup> to induce negative pressure to 0.8 kg/cm<sup>2</sup> immediately in silastic cup extraction, but a high failure rate (5 in 50 cases) was noted, which was significant higher than the metal cup group. Therefore, in the last 50 cases of the silastic cup group the negative pressure was induced in the same fashion as with the metal cup group. But there was no difference among the last 50 cases of both groups. These reflect that gradually induced negative pressure provided better head-cup contact this than immediate pressure inducing and provided less opportunity for leakage of the system. The other factor that caused failure was the fetal head position. We found occiput posterior position in 6 of 8 failed cases in this study which agree with the Hammarstrom's study. (8) No severe fetal complications occurred in these failed cases except one that had a scalp laceration.

From our results it can be concluded that vacuum extraction with silastic cup is safer than the those with metal cup for shortening the second stage of labor, but it has higher failure rate which can be reduced by gradually inducing the negative pressure. The outcomes of any operative obstetrics depend on the user's knowledge, skill and judgement in selecting the appropriate method for each pateint. This study showed that silastic cup vacuum extraction is most useful for appropriate cases.

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