Thai Journal of Obstetrics and Gynaecology
October 2008, Vol. 16, pp. 206-213

OBSTETRICS

A Randomized Double-Blind Controlled Trial Comparing Rapid Versus Stepwise Negative Pressure Application for Vacuum Extraction Assisted Vaginal Delivery

Suntit Bounyasong MD.

Department of Obstetrics and Gynecology, Health Promotion Region III, Chonburi 20000, Thailand

ABSTRACT

Objective: To compare efficacy and complication of a rapid (one-step) with stepwise application of negative pressure for vacuum extraction.

Materials and Methods: All pregnant women laboring in Health Promotion Hospital, Bangkok between October 1st, 2002 to September 30th, 2007 were simple randomised to be assisted by the rapid vacuum application (study group) or by the stepwise vacuum application technique (control group). Each had the suitable conditions for vacuum assisted delivery. Patients and obstetricians were blinded to the technique used. During the labour, the time for vacuum application, traction, and delivery were recorded. The effectiveness of methods of application, morbidity of mother and infant were evaluated by another doctor.

Results: Three hundred and seventy pregnant women were randomizedly studied. There were no serious complications during or following the procedures in both groups. The both technique were no significant difference in cup detachment rate, procedure failure rate, birth passage injury, fetal injury, hyperbilirubinemia, breastfeeding failure, perineal pain after delivery, perineal wound infection and postpartum haemorrhage. The mean decreasing pressure time and traction time in study group (n=182) were 125.6 and 977.2 seconds respectively. Meanwhile, in the control group (n=188), the mean decreasing pressure time and traction time were 615.2 and 941.4 seconds respectively. The traction times were not different (p=0.29), but the total procedure times in study group were less than in control group (p<0.0001). The Apgar's scores were not different between two groups,both at 1st and 5th minute (p=0.04,0.16 respectively). For the fetus delivering with the indication of fetal distress cases had less birth asphyxia in the study group than in control group (p<0.001) The traction time of two birth asphyxia groups were not different (p=0.23) but the application and total procedure time of both groups were significantly different (p<0.01, 0.01 respectively).

Conclusion: Rapid application of vacuum not only has the same efficiency and safety as stepwise application but also be useful in the fetal distress cases because it has significantly shorter time of a vacuum extraction.

Keywords: vacuum extraction assisted vaginal delivery, rapid, stepwise negative pressure application

Assisted vaginal delivery has become an integral part of obstetric care; the obstetric forceps and vacuum extractor were the primary instrument used in assisting vaginal delivery. Rates of vacuum extraction vary around 4.3% in Thailand[1],10% in Canada and the Middle East[2] and rapidly becomes the method of choice for many assisted vaginal deliveries. When assisted vaginal delivery is required, the vacuum extraction should often be chosen first especially in less difficult cases; principally because it is significantly less likely to injure the mother,[3] though failure of attempted vacuum extraction will occur more often than failed forceps delivery.[4] Indications for vacuum assisted delivery include prolonged second stage of labor, suspicion of actual or potential fetal compromise, deep transverse arrest of fetal head and shortening of second stage of labor for poor maternal effort.[5,6] The vacuum extractor is contraindicated in face, brow or breech presentation and preterm baby because of the high risk of cephalhematoma and intracranial haemorrhage.[7] There is a traditional recommendation that, for vacuum cup application, the operator should gradually increase negative pressure at 0.2 kg/cm^2 every two minutes, to reach 0.8 kg/cm^2 over 8 to 10 minutes. Theoretically, this process would allow the cup to be firmly attached to the fetal head, thus decreasing the chance of vacuum extraction failure.[8] However, some experts suggest that this concept is unnecessary and wastes time,[9] particularly in fetal compromised case. There is no significant difference in the traction force developed between stepwise and rapid applications of the vacuum[10] and an adequate chignon can occur within one to two minutes of creating the vacuum, and traction may also be commenced after one minute without compromising efficiency and safety.[11] It has been proposed that, for the soft cups, negative pressure could be increased to 0.8 kg/cm^2 in as soon as one minute.[12] Theoretically potential adverse effects of rapid application of vacuum extraction include cup detachment, injury of the fetal scalp and blood vessels. The perception that vacuum extraction is too slow to be used when rapid delivery is required (e.g. severe fetal distress) may not therefore be supported. In some countries nowadays most obstetricians still use the stepwise negative pressure application, in the belief that this can prevent cup detachment. The objective of our study is to evaluate whether there are any differences in efficacy (by measuring procedure outcomes) and safety (by measuring mother and neonatal outcomes) of rapid versus stepwise negative pressure applications for vacuum assisted vaginal delivery.

Materials and Methods

All pregnant women laboring in Health Promotion Hospital, Bangkok from October 1st, 2002 to September 30th, 2007 were the studying population. Inclusion criteria were the participants, required vacuum assist with at least one of these following indications: prolonged second stage, suspicion of actual or potential fetal compromise (intrauterine hypoxia),[13] deep transverse arrest of fetal head or shortening of the second stage of labor for poor maternal effort. The prerequisite conditions for the operation were fully dilated cervix, one hundred percent effacement, fetal head at the station at least 3 cm. below the ischial spines, ruptured amniotic membranes and informed consent. Exclusion criteria were multiple pregnancy, gestational age <37 weeks, previous uterine scar, non cephalic presentation or those with contraindications for vaginal delivery from maternal or fetal complications. Patients were randomized by simple randomization for vacuum extraction by either a rapid (one-step) within 120 seconds or conventional stepwise application within 600 seconds of negative pressure. The topics of interest were: success or failure rate (failed traction of vacuum was the traction after using traction time more than 30 minute with subsequent delivery by forceps or caesarean section),[13] detachment rate (the slip of cup during traction after complete application), duration of vacuum application (time from applying the cup to completely lowering the pressure to 0.8 kg/cm^2), traction time (time from starting to pull the

vacuum tractor until birth of fetal head or failure of the procedure), birth passage injury including degree of perineal tears, cervical and uterine tears, actual mode of delivery, postpartum haemorrhage, birth asphyxia,[13] fetal injury including scalp abrasion or laceration, cephalhematoma, subgaleal hemorrhage, intracranial injury, neonatal hyperbilirubinemia, perineal pain after delivery, perineal wound infection, retinal hemorrhage, breastfeeding failure, perinatal death and maternal satisfaction (using 5-point satisfactory rating scale for subjectively self evaluation). The protocol was reviewed and approved by the ethic committee of Health Promotion Hospital Bangkok. To protect the privacy of the patients, their names and unique personal information were not recorded or released.

Statistical analysis

The sample size was calculated by assuming a difference in failure rate between two groups of 13% from the literature review,[11,14] 125 women were required in each group to achieve a power of 0.8 and a type I error of 0.05 with 20% (30 cases of each group) adding in case withdrawn or lost to follow-up so at least of each group were 150 cases.[15] The result were analyzed by SPSS version 9.0. Continuous variables were compared using the T-test. Categorical variables and the quality of each procedure were compared by using Chi-squared analysis. A two –tailed p-value of less than 0.05 was considered statistically significant.

Results

From October 1st, 2002 to September 30th, 2007, total 5,367 deliveries in Health Promotion Hospital, Bangkok were assessed for eligibility. But only 432 were included. Sixty two participants or 14.35% refused to participate. Three hundred and seventy consecutive patients were randomized to be deliveried by vacuum assisted vaginal delivery with either rapid (n=182 cases) or stepwise (n=188 cases) negative pressure application. There were no differences in patient characteristics and also indication of vacuum deliveries between rapid and stepwise methods (Table 1).

Table 1. Demographic data of studying population. (370 cases)

Data	Rapid group (n=182)	Stepwise group (n=188)	p-value
Patient characteristics (mean±SD)			
Average age (yrs)	27.6 (±4.4)	28.3 (±5.4)	0.21
Parity*	1.0	1.0	-
Gestational age (wks)	38.8 (±1.2)	38.8 (±1.1)	0.72
Birth weight (gm.)	3184.0 (±352.4)	3169.0 (±395.1)	0.69
Procedure indications n(%)			0.83
Poor mother effort	144 (79.1)	151 (80.3)	
Prolong second stage	20 (11.0)	18 (9.6)	
Fetal distress	11 (6.0)	9 (4.8)	
Deep transverse arrest	7 (3.8)	10 (5.3)	

*Medium

There were 18 cases of birth passage injuries which were 3rd degree tear of episiotomy wound, tear of lateral vaginal wall, anterior labial minora. The kind and severity of injuries could not be compared between two groups because of limitation of cases. However, overall the maternal outcomes as birth passage injury, perineal wound infection, perineal pain after delivery, postpartum

haemorrhage and maternal satisfaction were not statistically different between two groups (Table 2).

Table 2. The maternal outcomes (370 cases)

Data	Rapid group (n=182)	Stepwise group (n=188)	p-value
Maternal outcome (%)			
Birth passage injury	5.5	4.3	0.58
Perineal wound infection	2.8	3.2	0.80
Perineal pain after delivery	4.4	4.3	0.95
Postpartum haemorrhage	0.6	1.6	0.33
Maternal satisfaction*	91.8	88.3	0.27

* using 5- point satisfactory scales (3 or more were interpreted to be satisfactory)

5 = Superior 4 = Above Satisfactory 3 = Satisfactory 2 = Needs Improvement 1 = Unsatisfactory

The failure rate of rapid group, 8.8% was more than of stepwise groups, 6.9% but they were not statistically significant. The detachment rate of rapid group, 4.4% was nearly the same as of stepwise group, 4.3% (not statistically significant difference). The mean time of rapid negative pressure procedure application was 125.625 seconds, meanwhile it was 615.192 seconds in stepwise application. However, the traction time was not different as in Table 3. Whether the mode of delivery was vacuum extraction or not, the study continually performed on maternal, neonatal and procedure outcome (not to be excluded).

Table 3. The procedure outcomes (370 cases)

Data	Rapid group (n=182)	Stepwise group (n=188)	p-value
- Actual mode of delivery n(%)			0.79
Vacuum extraction	166 (91.2)	175 (93.1)	
Cesarean section	15 (8.2)	12 (6.4)	
Forceps extraction	1 (0.6)	1 (0.5)	
- Failure rate n(%)	16 (8.8)	13 (6.9)	0.50
- Detachment rate n(%)	8 (4.4)	8 (4.3)	0.95
- Procedure time	(seconds means $\pm$ SD)		
Negative pressure application time	125.6 ($\pm$2.6)	615.2 ($\pm$11.9)	0.00*
Traction time	977.2 ($\pm$326.4)	941.4 ($\pm$318.3)	0.29
Total vacuum procedure time	1102.8 ($\pm$326.2)	1556.6 ($\pm$317.9)	0.00*

* Statistical significant $p<0.05$

The percentage of birth asphyxia in stepwise and rapid groups were 9.6 and 3.3 respectively which were statistically different ($p<0.05$). The other overall neonatal outcomes e.g. Apgar score and neonatal injury between two groups were not different (Table 4). There were 3 newborns in rapid group and 2 newborns in stepwise group which were incompletely followed up (less than 7 days), because their mothers were lost to follow-up.

Table 4. The neonatal outcomes (370 cases)

Data	Rapid group (n=182)	Stepwise group (n=188)	p-value
APGAR score (mean ± SD)			
-At 1st minute	8.9 (±0.6)	8.8 (±0.7)	0.04*
-At 5th minute	10.0 (±0.4)	9.9 (±0.4)	0.16
Birth asphyxia** n(%)	6 (3.3)	18 (9.6)	0.01*
Neonatal hyperbilirubinemia n(%)	1 (0.6)	3 (1.6)	0.33
Neonatal Injury n(%)			
-Cephalhematoma	4 (2.2)	9 (4.8)	0.18
-Retinal hemorrhage	0	0	-
-Breast feeding failure	0	0	-
-Perinatal death	0	0	-

* Statistically significant p<0.05 **APGAR score at 1st minute =0-7[15]

Focusing on the birth asphyxia, the birth asphyxia newborns from stepwise group were more statistically significant than those from rapid group (p<0.05) (Table 5).

Table 5. The detailed outcome of fetal distress group (21 cases)

Types of negative pressure application	Birth asphyxia (n=10)	No birth asphyxia (n=11)	p-value
Rapid	1 (9.1%)	10 (90.9%)	
Stepwise	8 (88.9%)	1 (11.1%)	0.00*

* Statistically significant p<0.05

In the Table 6 the newborns who delivered with either failure or detachment of vacuum extraction had the cephalhematoma more often than those who delivered without (p<0.05). The comparison of cephalhematoma rate in the group of failure and detachment could not be done because of the limitation of cases.

Table 6. The cephalhematoma vs failure and detachment of vacuum extraction

Data Vacuum Extraction	Cephalhematoma (n)		p-value
	Yes	No	
Failure			0.00*
-Yes	5	24	
-No	8	333	
Detachment			0.00*
-Yes	4	12	
-No	9	345	

* Statistically significant p<0.05

The means time of application and total procedure time were significantly different, meanwhile the traction time was the same. The shorter time in delivery of fetal distress was, the less birth asphyxia occurred.

Table 7. The effect of vacuum procedure time and fetal outcome in fetal distress group (21 cases).

Data	Birth asphyxia (n=10)	Non birth asphyxia (n=11)	p-value
Application time	564.2	172.3	0.00*
Traction time	1187.0	936.0	0.23
Total procedure time	1751.2	1108.27	0.01*

* Statistically significant p<0.05

Discussion

The present study found no differences in the patient characteristics between the stepwise and rapid application so the chosen samples were from the same population. The maternal outcomes and complications of both groups were the same. None of the case in two groups was discontinued because the design of this study was short and almost was done during hospitalization. The failure and detachment rates of the two groups were not statistically different. A fetal malposition, high station and nulliparity were associated with failure of vacuum-assisted deliveries[16,17] but no supported data in this study. Moreover the contributing factors were the experience and skill of obstetricians in evaluation and diagnosis of cephalo-pelvic disproportion condition before doing vacuum extraction. The procedure times were the same in the traction time while the negative pressure application time were different. Because the traction time were equal, so they were assumed that no difference in the difficulties of the procedure. The mean Apgar score at 1st and 5th minute were not different, but the numbers of birth asphyxia from rapid negative application procedure were significantly less than stepwise one (p<0.05). An incidence of caphalhematoma was about of 6.4 per 1000 vacuum extraction.[18,19] In this study, the incidence in rapid and stepwise groups were 2.198 and 4.787 per 1000 vacuum extraction, respectively. It is widely believed that the vacuum cup will dislodge before causing serious fetal trauma so the shorter time of cup application and traction might be helpful in decreasing the cephalhematoma however the appropriate indication, skills and experience of obstetricians were also importance.[20,21] The slip of the vacuum cup was also a common cause of fetal head injuries. It took place not only from poor artificial caput succedaneum (chignon) forming but also from unsuitable position application of cup and wrong direction of traction, which was not perpendicular to the cup.[22] The best position of vacuum cup is over the point of cranial flexion, or the pivot point. Anatomically, the pivot point is an imaginary spot over the sagittal suture of the fetal skull, 1-2 cm. anterior to the posterior fontanel. Nevertheless their detachment rate and other fetal complications of both groups were not different.[23] So their safety were the same in both groups. The occurrence of birth asphyxia or fetal distress, which was diagnosed before delivery, in the rapid negative pressure application group was lesser than the other group with statistic significance (p<0.05). As shown in the Table 7, the application time of the birth asphyxia group was lesser than non asphyxia group (p<0.05), while the traction time was not different. This means that the shortening of application time may save the fetal distress from birth asphyxia. When the fetuses were quickly deliveried, they had more chance to be out of compromised condition in the uterus and received early resuscitation. So for fetal distress case, the

shorter the time of delivery, the better the neonatal condition. In addition the safety recommendations for vacuum-assisted delivery focus on limiting the number of pulls and the duration of the procedure by sustaining the traction force during traction.[24] The long duration of vacuum extraction may first lead to compromise the fetus first, and then to the mother.[25]

In conclusion, rapid negative pressure application of vacuum not only significantly reduced the duration of a vacuum extraction procedure with the same efficiency and safety as stepwise application but also be useful in the fetal distress condition. However it should be carefully used with correct technique and precise evaluation of cephalopelvic disproportion.

Acknowledgments

The author wish to thank the Health Promotion Hospital, Bangkok to support by grants for this research.

References

1. Bureau of Health Promotion. Health Department Ministry of Public Health Thailand. The Maternal and Perinatal Health Status Report Year 2001-2003.
2. Shihadeh A, Al-Najdawi W. Forceps or vacuum extraction: a comparison of maternal and neonatal morbidity. East Mediterr Health J 2001;7:106-14.
3. Chad CCT. Is the vacuum extractor really the instrument of first choice? Aust NZJ Obstet Gynecol 1999;39:305-9.
4. Johanson RB, Menon V. Vacuum extraction versus forceps extraction for assisted vaginal delivery. Cochrane Database Syst Rev 1999;2:1–25
5. American College of Obstetricians and Gynecologists. Operative vaginal delivery: use of forceps and vacuum extractors for operative vaginal delivery. ACOG Practice Bulletin. Vol. 17, Washington DC: ACOG, 2000.
6. Royal College of Obstetricians and Gynaecologists. Operative vaginal delivery. Clinical Green Top Guidelines (Guideline No. 26). London: RCOG, 2005.
7. Vacca A. The trouble with vacuum extraction. Curr Opin Obstet Gynecol 1999;9:41-5.
8. Malmstrom T, Jansson I. Use of the vacuum extractor. Clin Obstet Gynecol 1965;8:893-913.
9. Wider JA, Erez S, Steer CM. An evaluation of the vacuum extractor in a series of 201 cases. Am J Obstet Gynecol 1967;98:24-31.
10. Svenningsen L. Birth progression and traction forces developed under vacuum extraction after slow or rapid application of suction. Eur J Obstet Gynecol Reprod Biol 1987;26:105-12.
11. Lim FTH, Holm JP, Schuitemaker NW, Jansen FH, Hermans J. Stepwise compared with rapid application of vacuum in ventouse extraction procedures. Br J Obstet Gynaecol 1997;104:33-6.
12. Kuit JA, Eppinga HG, Wallenburge HC, Huikeshoven FJ. A randomized comparison of vacuum extraction delivery with a rigid and a pliable cup. Obstet Gynecol 1993;82:280-4.
13. Groom KM, Jones BA, Miller N, Paterson-Brown S. A prospective randomised controlled trial of the Kiwi Omnicup versus conventional ventouse cups for vacuum-assisted vaginal delivery. BJOG 2006; 113:183-9
14. Meinert CL. Clinical Trial Design, Conduct and Analysis. New York: Oxford University Press; 1986.
15. WHO. O00-P96. International classification disease (ICD-10) version 2007.
16. Ben-Haroush A, Melamed N, Kaplan B, Yogev Y. Predictors of failed operative vaginal delivery: a single-center experience. Am J Obstet Gynecol 2007;3:308-12.
17. Yarrow C, Benoit G, Klein MC. Outcomes after vacuum-assisted deliveries. Births attended by community family practitioners. Can Fam Physician 2004;50:1109-14.
18. Bhide A, Guven M, Prefumo F, Vankalayapati P, Thilaganathan B. Maternal and neonatal outcome after failed ventouse delivery: comparison of forceps versus cesarean section. J Matern Fetal Med 2007; 20:541-5.
19. Kicklighter SD, Wolfe D, Perciaccante JV .Subgaleal hemorrhage with dural tear and parietal-lobe herniation in association with a vacuum extraction. J Perinatol 2007 ;27:797-9.
20. Macleod C, O' Neill C. Vacuum assisted delivery-the need for caution. Br Med J 2003;96:147-8.
21. Uchil D, Arulkumaran S. Neonatal subgaleal hemorrhage and its relationship to delivery by vacuum extraction. Obstet Gynecol Surv 2003;58:687-93.
22. Doumouchtsis SK, Arulkumaran S. Current Opinion in Obstetrics & Gynecology 2006;18:129-34.
23. Cotzias C, Paterson B S. Ventouse: use, cup placement and success. J Obst Gynecol 1998; 18:432-48.
24. Vacca A. Vacuum-assisted delivery: an analysis of traction force and maternal and neonatal outcomes. Aust N Z J Obstet Gynaecol 2006;46:124-7.
25. Salamalekis E, Vitoratos N, Kassanos D, Loghis C, Hintipas E, Salloum I, et al. The influence of vacuum extractor on fetal oxygenation and newborn status. Arch Gynecol Obstet 2005;271:119-22.

การศึกษาแบบสุ่มเปรียบเทียบระหว่างการลดความดันแบบขั้นตอนเดียวกับแบบทีละขั้นสำหรับการใช้เครื่องดึงสุญญากาศช่วยคลอด

สันทิต บุณยะส่ง

วัตถุประสงค์ *: เพื่อศึกษาเปรียบเทียบประสิทธิภาพและภาวะแทรกซ้อนระหว่าง วิธีใช้การลดความดันแบบขั้นตอนเดียวกับแบบทีละขั้นของเครื่องดึงสุญญากาศเพื่อช่วยคลอด*

วัสดุและวิธีการ *: สตรีตั้งครรภ์ทั้งหมดที่มาคลอดที่ รพ.ส่งเสริมสุขภาพ กรุงเทพ ระหว่าง 1 ต.ค. 2545 ถึง 30 ก.ย. 2550 ที่มีสภาพเหมาะสมในการช่วยคลอดด้วยเครื่องดึงสุญญากาศและยินยอมเข้าร่วมการศึกษา ได้รับการเลือกแบบสุ่มเพื่อช่วยคลอดโดยใช้เครื่องดึงสุญญากาศแบบลดความดันลง 0.8 กก./ตร.ซม. ทันทีภายในระยะเวลา 2 นาที (กลุ่มศึกษา) หรือแบบการลดความดันทีละ 0.2 กก./ตร.ซม. ทุก 2 นาทีจนความดันลดลง 0.8 กก./ตร.ซม.(กลุ่มเปรียบเทียบ) สตรีตั้งครรภ์และสูติแพทย์ที่ทำคลอดไม่ทราบว่าใช้เทคนิคใด ทำการบันทึกเวลาที่ใช้ในการใส่ถ้วยสุญญากาศและลดความดัน เวลาในการดึงและช่วยคลอด ประสิทธิภาพของวิธีช่วยคลอดทั้งสองกลุ่ม ภาวะแทรกซ้อนของมารดาและทารกที่เกิดขึ้น โดยถูกประเมินโดยแพทย์อีกท่านหนึ่ง*

ผลการศึกษา *: กลุ่มศึกษามีจำนวน 182 ราย และกลุ่มเปรียบเทียบจำนวน 188 ราย ไม่พบภาวะแทรกซ้อนที่แตกต่างกันอย่างมีนัยสำคัญทางสถิติระหว่างสองกลุ่มในเรื่อง การล้มเหลวของการใช้เครื่องดึงสุญญากาศ การหลุดของถ้วยสุญญากาศ และภาวะแทรกซ้อนในมารดาและทารกแรกเกิด ระยะเวลาเฉลี่ยในการลดความดัน และออกแรงดึงช่วยคลอดในกลุ่มศึกษาเท่ากับ 125.6 วินาที และ 977.2 วินาที ในกลุ่มเปรียบเทียบเท่ากับ 615.2 วินาที และ 941.4 วินาทีตามลำดับ ทั้งสองกลุ่มมีระยะเวลาในการออกแรงดึงเฉลี่ยไม่แตกต่างกันอย่างมีนัยสำคัญ (p=0.29) แต่ทารกที่มีภาวะเครียดระหว่างคลอดมีภาวะขาดอากาศในกลุ่มศึกษาน้อยกว่ากลุ่มควบคุม (p<0.001)*

สรุป *: การช่วยคลอดด้วยเครื่องดึงสุญญากาศที่ใช้วิธีลดความดันของแบบขั้นตอนเดียว นอกจากจะมีความปลอดภัยและมีประสิทธิภาพพอกับการลดความดันแบบทีละขั้นแล้ว ยังได้ผลดีในการช่วยคลอดทารกที่มีภาวะเครียดในระหว่างคลอด เนื่องจากใช้เวลาในการทำคลอดสั้นกว่าการลดความดันแบบทีละขั้น*