

Preventing Maternal and Neonatal Harm during Vacuum-Assisted Vaginal Delivery

ABSTRACT

When women in the second stage of labor fail to progress to a spontaneous delivery, vacuum extractors have been used to successfully aid delivery. Data from the U.S. Department of Health and Human Services' National Center for Health Statistics revealed that vacuum-assisted deliveries accounted for approximately 5% of all deliveries in 2004, based on a seven-state sample of the expanded health data on birth certificates. Additionally, the use of vacuum extraction devices has increased over the last 10 years, while the use of forceps has decreased. Like other operative procedures, vacuum-assisted vaginal delivery has known risk factors and complications. The Pennsylvania Patient Safety Authority received 367 reports of problems involving vacuum-assisted delivery from July 2004 through April 2009. Of these reports, 64 (17%) documented maternal injury and 221 (60%) documented neonatal injury. To maximize the success of vacuum extraction procedures and to minimize complications, clinicians must understand both indications and contraindications for this procedure. Performing a thorough preoperative maternal and fetal assessment, technical proficiency with the vacuum device, setting goals, maintaining situational awareness, and concluding the delivery with a targeted postoperative assessment of both the mother and neonate are all important patient safety concepts associated with vacuum-assisted vaginal delivery procedures. (Pa Patient Saf Advis 2009 Dec 16;6[Suppl 1]:7-17.)

Introduction

Obstetric trauma associated with instrument-assisted vaginal delivery and birth trauma (i.e., injury to the neonate) are hospital-level Patient Safety Indicators developed by the Agency for Healthcare Research and Quality (AHRQ).¹ Vacuum-assisted vaginal delivery (VAVD) is used in specific circumstances during the second stage of labor. An analysis of National Hospital Discharge Survey data in 1992 showed that the vacuum-assisted delivery rate increased from 0.6% in 1980 to 3.3% in 1987.² Furthermore, in 2004, vacuum-assisted deliveries accounted for approximately 5% of all deliveries in the United States, based on a seven-state sampling of expanded health data on birth certificates collected by the U.S. Department of Health and Human Services' National Center for Health Statistics.³ In June 2009, AHRQ released a statistical brief which revealed that in 2006 nearly 157,700 potentially avoidable injuries to mothers and neonates occurred. The highest rates of obstetric trauma for mothers took place during vaginal births

with instruments, occurring in 160.5 deliveries per 1,000 instrument-assisted vaginal births.⁴

While VAVD is viewed as a safe alternative to forceps deliveries, there are known maternal and fetal risks associated with vacuum devices, including maternal perineal injury and fetal cranial hemorrhages, some of which can be fatal. These life-threatening complications led the U.S. Food and Drug Administration to issue a public health advisory in 1998. The advisory highlighted the increased risk of serious fetal intracranial injury or death associated with the use of vacuum devices and discussed a five-fold increase in the reports of fetal death or serious injury from 1994 to 1998.⁵

In 2004, the Joint Commission issued a Sentinel Event Alert titled "Preventing Infant Death and Injury during Delivery." From 1996 through 2004, the Joint Commission received 47 reports of perinatal death or permanent disability (i.e., sentinel events). Of the events, 46% were related to vaginal deliveries, of which 21% were vacuum-assisted. Analysis revealed that communication issues topped the list of identified root causes for these events (72%).⁶ As of June 2009, 197 cumulative cases of perinatal death or loss of function had been reported to the Joint Commission as sentinel events.⁷

Authority Reports

Analysis of reports submitted to the Pennsylvania Patient Safety Authority from July 2004 through April 2009 identified 367 reports of problems related to VAVD. Of the 367 reports, 282 (77%) included some form of maternal or neonatal injury. Sixty-four of the reports (17%) documented maternal injury, including third- and fourth-degree perineal tears, cervical lacerations, vaginal sulcus tears, hematomas, anal sphincter tears, and postpartum hemorrhage. Two hundred twenty-one reports (60%) documented neonatal injury, including scalp lacerations, cephalhematomas, epidural, subdural and subgaleal hematomas (SGHs), fractures, and respiratory distress. Fifty-one reports (14%) were serious injuries, including four neonatal deaths (1%) (see Table 1). One root-cause analysis was reported, and the reported root cause was "communication among staff members." The top three most frequently cited contributing factors in the Authority reports were "procedures not followed," "communication problems between providers," and "issues related to proficiency."

Indications

Indications for VAVD include termination of a prolonged second stage of labor, suspicion of immediate or potential fetal compromise, and shortening of the second stage of labor for maternal benefit.

Table 1. Maternal and Neonatal Serious Injuries by Type

TYPE AND NUMBER OF MATERNAL INJURY		TYPE AND NUMBER OF NEONATAL INJURY	
Perineal or cervical tears or lacerations resulting in hemorrhage and blood transfusion	8	Fractured clavicle or humerus	11
Fourth-degree perineal tears requiring operative repair	4	Respiratory distress	9 (2 deaths)
Miscellaneous lacerations requiring operative repair	3	Cephal, subdural, or subgaleal hematoma or skull fracture	8 (1 death)
Vaginal sulcus tears requiring operative repair	2	Miscellaneous injuries	6 (1 death)

A prolonged second stage of labor is defined by the American College of Obstetrics and Gynecology (ACOG) as the lack of continuing progress in a nulliparous woman for three hours with regional anesthesia or two hours without regional anesthesia, and lack of continuing progress in a multiparous woman for two hours with regional anesthesia and one hour without regional anesthesia.⁸ A retrospective cohort study of 15,759 nulliparous women demonstrated that maternal morbidity increased significantly after 3 hours of the second stage of labor, and increased further after 4 hours. However, there was no indication of neonatal morbidity where increased fetal surveillance and timely obstetric intervention were used.⁹ Therefore, absolute times are not as important as tracking progressive fetal descent during the second stage of labor in conjunction with continuous assessment of both fetal and maternal well-being.

While immediate or suspected fetal compromise is an indication for VAVD, obstetricians must carefully consider whether VAVD, forceps use, or cesarean section is most likely to produce better maternal and fetal outcome. With VAVD, the obstetrician should be prepared to move immediately to an alternative delivery mode if the vacuum-assisted delivery fails.

VAVD is indicated when maternal expulsive effort is medically contraindicated, such as with severe cardiac disease, hypertension, cerebral aneurysm, risk of aortic dissection, proliferative retinopathy, cardiac failure, or in cases of maternal exhaustion.¹⁰

Contraindications

Gestational age of less than 34 weeks is a contraindication to vacuum extraction due to increased risk of intraventricular hemorrhage.^{8,11-14} The procedure is not performed in the presence of fetal bleeding disorders such as alloimmune thrombocytopenia, or with predisposition to fracture such as with osteogenesis imperfecta. Vacuum extraction is also contraindicated if the fetal head is not engaged in the pelvis; with incomplete cervical dilatation; with brow, face, or breech presentations of the fetus; with intact membranes; or when there is suspected cephalopelvic disproportion, which can present as severe or increased molding of the fetal head with a high presenting part failing to descend in the presence of strong uterine contractions. Clinical pelvimetry should be performed to assess the condition of the

maternal pelvis before proceeding with any type of operative vaginal delivery.⁸ If the clinician cannot determine fetal position, lie, presentation, or degree of engagement or asynclitism, vacuum extraction should be avoided.

Complications

Maternal

VAVDs produce fewer maternal perineal injuries than use of forceps.¹⁵ However, complications from VAVD arise in the form of cervical lacerations, vaginal hematomas, hemorrhage, third- and fourth-degree perineal tears, and anal sphincter injury.

Examples of maternal injuries reported to the Authority include the following:

During a VAVD, the patient sustained cervical and vaginal lacerations. She was bleeding heavily . . . the lacerations were repaired but she continued to bleed . . . her hemoglobin dropped to 6. At this point the decision was made to perform a hysterectomy . . .

OR [operating room] team called for repair of fourth-degree vaginal laceration . . . [patient was] returned to the OR for heavy rectal bleeding . . . proctoscope, surgical repair of 6 cm rectal laceration, and diversion . . .

Patient underwent VAVD . . . episiotomy cut, but patient extended to third-degree laceration with a complete transection of the anal sphincter, resulting in extensive repair . . .

[The patient was] admitted at term and underwent VAVD . . . approximately an hour later, [patient was] noted to have large amount of vaginal bleeding. . . . A pelvic exam revealed cervical laceration. . . . [The patient was] taken to OR for repair.

Maternal postoperative bleeding, hypovolemic shock, unplanned hysterectomy, and severe anal sphincter injury are some of the Serious Events reported to the Authority. Anal sphincter injury can lead to maternal fecal incontinence and has been the subject of clinical review. A retrospective cohort study in 2005 showed that vacuum delivery and occipital posterior (OP) position of the fetus were independent risk factors for anal sphincter injury and that the combination of these two factors incrementally increased that risk.¹⁶ A 2008 systematic review of 451 articles and abstracts related to obstetric sphincter damage revealed several

factors that increase the risk of anal sphincter injury including vacuum extraction, midline episiotomy, and OP position of the fetus.¹⁷ There is no conclusive evidence that episiotomy was protective of the anal sphincters, and the role of routine episiotomy for operative vaginal delivery is poorly evaluated.¹¹

Neonatal

Compared to other modes of delivery, vacuum extraction has been associated with higher rates of cephalhematoma, neonatal jaundice, and retinal hemorrhage, all of which are usually transient and self-resolving.^{8,18} Cephalhematomas occur when bridging vessels between the periosteum and bones in the skull are torn and, in up to 5% of the cases, are associated with underlying skull fractures. A Cochrane systematic review comparing vacuum extraction and forceps delivery showed a strong association between vacuum extraction and cephalhematoma, with an average occurrence rate of 10%, compared to a 1% to 2% occurrence with spontaneous vaginal delivery. The accumulation of blood products in the hematoma can lead to secondary jaundice.¹⁸

SGH is a rare but potentially fatal complication of vacuum extraction, with bleeding between the galea aponeurosis of the scalp and the periosteum. This potential space encompasses the area between the orbital ridges anteriorly, the nape of the neck posteriorly, and the ears laterally. Neonates can lose more than 50% of their total blood volume to this space, leading to hypovolemic and/or hemorrhagic shock (characterized by pallor, tachypnea, tachycardia, and hypotension) and secondary coagulopathy.¹⁹ A prospective observational study of 338 infants delivered by vacuum extraction between 2000 and 2002 identified nulliparity, failed vacuum extraction, and improper cup placement as risk factors for SGH.²⁰ SGH presents as a firm to fluctuant mass that crosses suture lines. It is frequently noticed within 4 hours of birth and may progress for 12 to 24 hours. Prompt recognition and treatment is critical to successful outcome, with mortality rates ranging between 2.7% and 22.8%.²¹

Neonatal injuries related to VAVD reported to the Authority include the following:

. . . term infant attempted to be delivered with vacuum extractor twice and with forceps twice. . . [Converted to cesarean section]. . . [The infant] required resuscitation/intubation. The infant was transferred to a tertiary NICU [neonatal intensive care unit] and expired (subdural hematoma/brain death). . .

Infant delivered via vacuum extraction with cephalohematoma and fracture of left clavicle. The infant was transferred to a tertiary facility NICU for further evaluation and was found to have a subdural hematoma. . .

An infant born via VAVD developed seizure one hour after birth. A computed tomography scan [showed] skull fracture and subdural hematomas. . . the infant was transferred to a tertiary facility. . .

Patient [with] term intrauterine pregnancy with arrest of descent, failed vacuum extraction. Infant [was transferred] to NICU [because the infant] sustained subgaleal hemorrhage. . .

Preventing Maternal and Neonatal Injury

The first step in preventing maternal and neonatal injury is to be certain that VAVDs are done only when there are clear indications for vacuum extraction, and when there is a high likelihood of success of the procedure, determined by preoperative maternal and fetal assessment.

Limiting vacuum-assisted procedures through facilitation of spontaneous vaginal deliveries can be accomplished via one-on-one maternal support during labor, by adopting an upright or lateral position to facilitate fetal descent, through judicious use of analgesia, and via administration of oxytocin (endogenous hormone; uterine stimulant), if not contraindicated, to strengthen uterine contractions.¹¹ Delay in pushing for two to three hours during the second stage of labor, or until the urge to push is very strong, may also prevent unnecessary use of the vacuum extraction device. In cases of delayed second stage of labor, cephalopelvic disproportion should be excluded before commencing with the vacuum extraction procedure.

Finally, clinicians sufficiently trained and fully credentialed for VAVD, with the ability to convert the procedure to an immediate cesarean section when indicated, are predictive of successful outcomes.

Once the decision for vacuum extraction has been made, obstetricians can reduce the rate of maternal and neonatal morbidity by performing a thorough preoperative assessment of the mother and fetus, by ensuring technical proficiency with the chosen device, by maintaining vigilant situational awareness during the procedure, and by performing a targeted postoperative assessment of the mother and neonate.

Preoperative Assessment

Maternal Assessment

Consent. Assessment of maternal status includes the mother's willingness and ability to actively participate in the vacuum-assisted delivery; the more effort a mother can contribute during contractions, the less force is required via the vacuum device. Hence, although maternal exhaustion is an indication for VAVD, the mother must be able to participate and facilitate the birth through expulsive effort. Increased traction is not a substitute for absent maternal effort. If the mother is willing and able to participate, informed consent is obtained and documented.²² Maternal understanding of the vacuum extraction procedure and active consent maximizes cooperation and decreases potential anxiety associated with the impending delivery.

Physical assessment. According to ACOG, the cervix is to be fully dilated before attempting VAVD.⁸

Guidelines published by the Canadian Society of Obstetricians and Gynaecologists state that vacuum extraction before full cervical dilatation may be considered in rare cases “only when the benefits significantly outweigh the risks and when there is no viable alternative.”²³ The Royal College of Obstetricians and Gynaecologists cites cord prolapsed at 9 cm in a multiparous woman or a second twin as exceptions to this rule.¹¹ Other maternal prerequisites include ruptured membranes, an empty bladder, and adequate analgesia for the procedure.

Fetal Assessment

General fetal condition. Auscultation of the fetal heart rate or analysis of the electronic fetal monitor strip is documented. Although one indication for vacuum-assisted delivery is fetal compromise, vacuum extraction should not be used as a rescue procedure for a severely compromised fetus, because such neonates may benefit from a rapid cesarean section.¹¹

Size. The fetal weight is estimated and documented. Pelvimetry should indicate a favorable maternal pelvic space relative to fetal size. The vacuum extraction procedure itself, as well as fetal size equal to or greater than 4,000 gm (8 lb, 14 oz), is associated with greater risk of shoulder dystocia and subsequent obstetric brachial plexus palsy, and the obstetrician must be prepared for this complication.²⁴ (For more information about shoulder dystocia, see the article “Neonatal Complications: Recognition and Prompt Treatment of Shoulder Dystocia” in this issue.)

Engagement and station. Vacuum extractors should not be applied unless the fetal head is engaged.^{8,12} Engagement implies that the biparietal diameter of the fetal head has passed through the maternal pelvic inlet and that the leading point of the fetal head is at least at the level of the ischial spines (0-station). (For more information, see the sidebar “Definition of Engagement.”) However, if the head is unusually molded, or if there is a severe caput, as can occur with a prolonged second stage of labor, engagement might not have taken place, even though the head is at 0-station.¹² Severe molding or irreducible overlap of the parietal bones should be taken as a sign of cephalopelvic disproportion, and VAVD should not be attempted.¹¹ To more accurately assess fetal station, obstetricians can palpate the position of the fetal head abdominally, making certain that no more than one-fifth of the head is above the upper level of the pubic symphysis.¹¹

Fetal position. Depending on fetal position, vacuum extraction can be classified as an outlet, low-, or mid-pelvic operation.⁸ For outlet operations, the fetal skull is visible at the introitus without separating the labia; the fetal skull has reached the pelvic floor and the sagittal suture is in the anteroposterior diameter, or right or left occiput anterior or posterior position; the fetal head is at or on the perineum; and rotation does not exceed 45°. For low-pelvis operations, the leading point of the fetal skull is at +2 cm and not on the pelvic floor with two subtypes: (1) a rotation of 45° or

Definition of Engagement

The level of the presenting fetal part in the birth canal is described in relation to the maternal ischial spines, which are halfway between the pelvic inlet and pelvic outlet. When the lower-most presenting part of the fetus is at the level of the ischial spines, it is described as being at “0-station.” The area above and below the ischial spine is divided into fifths. As the presenting fetal part descends from the inlet toward the ischial spine, the station is described as -5, -4, -3, -2, -1 and 0-station at the ischial spine level, proceeding to station +1, +2, +3, +4, and +5, where the fetal presenting part is then visible at the introitus.

Source: Cunningham FG, Gant NF, Leveno KJ, et al. *Williams obstetrics*. New York (NY): McGraw-Hill; 2001: 58-60.

less or (2) a rotation greater than 45°. In mid-pelvic operations, the station is above +2 cm, but the fetal head is engaged.

Recent stratification of VAVDs into low- and moderate-risk categories may help obstetricians more accurately assess both clinical indication and risk of the procedure¹¹ (see Table 2).

Technical Expertise

A prospective case-control study published in 2004 showed that operator technical expertise with vacuum extractors was associated with increased safety for both mother and neonate.²⁵ Obstetric training programs and appropriate credentialing for VAVD procedures can increase safety on the obstetric unit. Hospital credentialing staff will need to understand the type of training area residents receive regarding VAVD, as vacuum extraction is not always a core component of an obstetric training program. If necessary, hospitals can consider supplemental training with instrumental birthing simulator mannequins to improve outcomes.

Familiarity with manufacturer guidelines regarding use of a particular vacuum device is important, including recommendations for placement, maximum time of procedure, maximum vacuum pressure, maximum traction force, number of “pop-offs,” and maximum time on vacuum.

Cup Selection

There are many types of commercial cups available, all of which fall into two main categories: (1) rigid mushroom-shaped cups and (2) soft bell- or trumpet-shaped cups. Generally, soft or rigid anterior cups are used for low or outlet procedures when the fetus is in the occipital anterior (OA) at less than 45° position with little to no asynclitism, and rigid posterior cups are used for rotational (advanced) and mid-pelvic procedures with the fetus at OA greater than 45°, and with OP or occipital transverse (OT) position. Since a number of fetal injuries associated with vacuum

Table 2. Low- and Moderate-Risk VAVD

LOW-RISK VAVD	FETAL CAPUT VISIBLE AND STATION LOW OR OUTLET
	Arrest of descent in second stage of labor Nonreassuring fetal status Maternal exhaustion but satisfactory uterine contractions and some expulsive effort Selective shortening of the second stage of labor
MODERATE-RISK VAVD	FETAL CAPUT NOT VISIBLE AND STATION LOW OR MID
	Arrest of descent in second stage of labor Nonreassuring fetal status Maternal exhaustion, epidural analgesia, and diminished expulsive effort Occiput anterior, greater than 45° rotation; occiput posterior/occiput transverse fetal positions

Source: Vacca A. Reducing the risks of vacuum delivery. *Fetal Matern Medi Rev* 2006;17(4):301-15.
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 Reprinted with permission from Aldo Vacca, MD.

extraction are related to misplacement of the cup,^{12,20} the material of the cup may be less important than correct placement. When the fetus is in the OP or OT position, or when there is a significant amount of asynclitism, then the rigid OP cup should be used, as these are the only type of cups that can be maneuvered easily to the flexion point (see Figure 1). A two-center study in the United Kingdom followed 397 vacuum-assisted vaginal deliveries and found that although an OP or OT position was diagnosed in 11% and 14% of the cases, respectively, there was no use of the specifically designed OP cup. Forty-one percent (n = 56) and 52% (n = 25) of the failed VAVDs in this study were those with the fetus in OP or OT position.²⁶ Special training is required for use of the posterior cup, especially related to maneuvering the cup to achieve correct application, which may explain why obstetricians in the above study failed to utilize this cup even when the fetal position was determined to be OP or OT.

Vacuum Cup Placement

“Flexion point” describes the point on the fetal scalp over which the center of the vacuum should be placed. The flexion point is approximately 3 cm anterior to the posterior fontanelle and centered over the sagittal suture.²⁷ Placing the vacuum accurately on the fetal scalp helps ensure a good seal and promotes synclitism of the fetal head in relationship to the maternal pelvis. Using a 6 cm cup, the practitioner will center the flexion point beneath the cup when the edge lays approximately two finger-widths (approximately 3 cm) posterior to the anterior fontanelle (see Figure 1).

When the vacuum has been accurately placed, it is called a “flexing median” application. Other applications promote extension of the fetal head and asynclitism and either increase or fail to decrease the diameter of the presenting part, making delivery more difficult. A deflexing (suboptimal) application occurs when the cup is placed closer to the anterior fontanelle, and a paramedian application indicates that the cup was placed more than 1 cm to the right or left of the sagittal suture (see Figure 2).

A prospective study of 1,000 consecutive VAVDs in nulliparous women published in 2008 showed a statistically significant relationship between unfavorable cup placement (deflexing or paramedian placement) and neonatal scalp trauma.²⁸ Incorrect placement (off of the sagittal suture, or the edge of the cup less than 3 cm from the anterior fontanelle) was also found to contribute to the development of SGH, according to a prospective, observational study conducted from 2000 to 2002.²⁰ Correct placement of the vacuum cup on the flexion point enhances the natural birthing process and decreases reliance on traction force alone to effect delivery.

Vacuum Pressure

Once the cup has been accurately placed over the flexion point, the operator runs his or her fingers along the edge of the cup to ensure that no maternal tissue is trapped between the cup and the fetal scalp. If tissue is trapped, it will inhibit proper seal of the vacuum device and likely result in maternal tissue tear. Vacuum pressure of 100 to 150 mm Hg is advised, with a reassessment of cup placement and seal. Then, pressure is increased to 500 to 600 mm Hg, according to manufacturer guidelines.

Traction, Pulls, and Duration

Gentle traction force in the axis of the maternal pelvis is introduced in conjunction with uterine contractions. The operator should use both hands: one operating the vacuum device and providing traction force and direction, the other monitoring progress of descent and providing cross pressure to prevent cup detachment (pop-off). The crossbar of the traction device should be held in the fingertips to limit traction force. Steady traction is applied along the axis of the pelvis until the contraction passes or until the mother stops pushing. At this point, traction ceases.

The operator should avoid any intentional rotation of the fetus, or any rocking motion or torque, as this is associated with increased fetal scalp injury.⁵ The ventouse is not a rotating instrument. Attempts at cup rotation may encourage cup displacement, loss of station, or scalp injury. It is important to remember that

Figure 1. Flexion Point

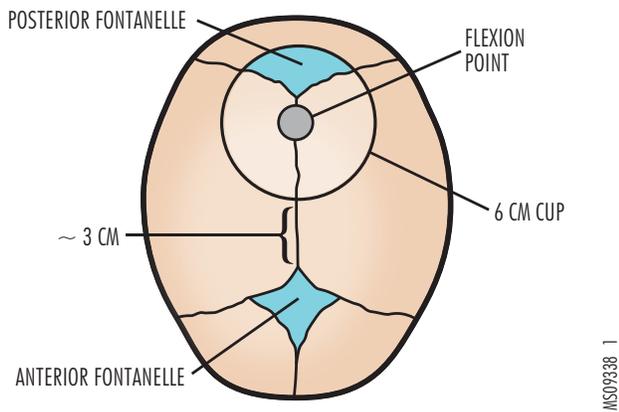
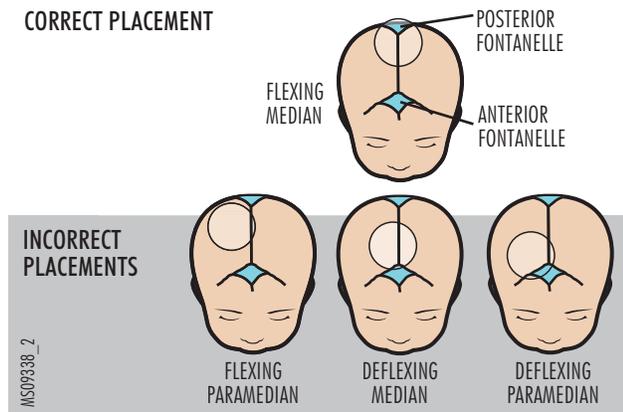


Figure 2. Cup Placement



under traction, the fetal head rotates automatically as descent occurs.

Descent of the fetus should be observed with each traction pull. Recommendations for number of pulls vary by make and model and within the clinical literature. Parameters lie between two and four pulls, with recent recommendations of three pulls during the descent phase and three pulls at the outlet.²⁹ However, some progress should be observed with each and every pull.

Cup detachments or pop-offs are not a safety feature of the device; they may signify incorrect cup placement, incorrect traction technique (pulling too hard, or in an upward direction as opposed to along the axis of the pelvis), a large caput succedaneum, or faulty equipment.¹² Detachment of the cup is associated with increased incidence of cranial fractures, cephalhematomas, and scalp edema.³⁰ Most experts advise halting the procedure if more than two to three pop-offs occur,¹² and manufacturers include information regarding maximum number of pop-offs in their

device literature. All personnel in the room should be aware of these guidelines and attentive to the number of pop-offs that occur.

A prospective observational study of 119 consecutive attempted vacuum deliveries of nulliparous women in 2001 and 2002 demonstrated that at least 80% of the women could be delivered safely by vacuum extraction when the force did not exceed 11.5 kg, the duration of the procedure was limited to 15 minutes, and the number of pulls was limited to three for the descent phase and three for the perineal phase.²⁹

Sequential Device Use

When an obstetrician chooses to perform VAVD and that attempt fails, he or she is left in a precarious situation: continue assisted delivery by attempting to deliver the fetus with forceps or move directly to cesarean section? This decision requires consideration of the details and nuances of each particular delivery. The obstetrician will weigh the potential complications of cesarean section during active labor, especially if performed when the fetus is low in the pelvis, and compare those potential complications to sequential device use. A meta-analysis published in 2000 compared seven studies and showed that sequential device use carried a higher neonatal morbidity than when one instrument was used alone (vacuum or forceps).¹⁸ In the same year, ACOG cautioned against sequential device use.⁸ In summary, if an attempted vacuum delivery fails, the fetus is at increased risk no matter which subsequent mode of delivery is chosen. Hence, the importance of the preoperative maternal and fetal assessment becomes clear: obstetricians perform VAVD only when the chance of success outweighs the possibility of failure.

Abandoning the Procedure

VAVD is abandoned if there is difficulty applying the instrument, if there is no appreciable descent with each pull, if there is no significant descent after three pulls of a correctly applied instrument, or if the fetus has not been delivered within 10 to 20 minutes.¹¹ In a 2005 retrospective population-based study, extended vacuum time of 10 minutes or more was also linked to obstetric brachial plexus palsy injuries in the neonate.²⁴

Conditions associated with difficult VAVD include situations in which the fetus is in the OP position, excessive molding of the fetal head has occurred, fetal macrosomia is present, and dysfunctional or prolonged labor with a maternal body mass index greater than 30 is present.^{11,31} In these cases, a trial of VAVD may be considered, preferably in a room equipped for immediate cesarean section.¹³

Human Factors

Situational awareness is important to prevent maternal and neonatal harm during delivery. In the delivery room, obstetricians can lose track of important information such as the number of pulls, the number of pop-offs, and the total time on vacuum and total

time of procedure when attempting to effect delivery. Some examples of possible loss of situational awareness reported to the Authority include the following:

. . . physician failed to follow proper procedure during vacuum-assisted delivery . . . attempted nine pulls with four pop-offs. . . . The nurse advised physician of number of pulls without physician stopping. . . . Policy states that the number of attempts and pop-offs is to be limited to three. . . .

. . . vacuum extractor applied many times; [nurse] informed physician of limit of applications. . . .

. . . vacuum extractor applied 6 to 7 times by obstetrician; infant born with a large amount of caput. . . .

Strategies to improve and maintain situational awareness include using an obstetric partogram¹¹ and using a checklist or third party to track the important parameters in VAVDs: time on vacuum, total time on procedure, traction, pressure, number of pulls, and number of pop-offs. Teamwork helps the obstetrician provide the best care to the patient. Empowering team members to speak up, acknowledging their feedback when limits are exceeded, and ensuring team agreement of an endpoint to the procedure may all help maintain situational awareness.

Postoperative Maternal and Neonatal Assessment

Maternal

The postpartum maternal patient is assessed for injury to the birth canal; specifically, bleeding due to cervical, perineal tears, lacerations, or injury to the anal sphincter. Lacerations are repaired. Severe tears or lacerations may necessitate repair in the OR. Hemorrhage may necessitate administration of blood products and monitoring in an intensive care unit. There may be risk for deep vein thrombosis in cases of prolonged labor. The extended maternal assessment should include an assessment for urinary, stress and bowel incontinence, especially subsequent to perineal tissue injury, or anal sphincter disruption.

Neonatal

Clinically diagnosed scalp injuries occur largely because of the physics of vacuum extraction. As the vacuum force is applied, the extractor draws the fetal scalp into the body of the cup. This produces the characteristic mound of scalp tissue and edema, the chignon or caput succedaneum, which may be identified after an extraction. While most superficial scalp injuries resolve spontaneously or with minimal treatment, the SGH can be a life-threatening complication of vacuum extraction. Because of the small but significant risk of SGH, the attending personnel should be informed whenever a VAVD has occurred, regardless of the immediate condition of the neonate. SGHs are dangerous because the signs and symptoms may not be clinically apparent until some hours postpartum. Vigilant serial assessment is necessary for 48 hours postvacuum procedure to assess for signs of intra- or extracranial bleeding. Nurses working in

neonatal nurseries fully assess the neonatal scalp by removing the nursery cap and physically inspecting the cranium.

Risk Reduction Strategies

The operative risks of VAVD are a combination of several factors, some of which are modifiable. The following are risk reduction strategies to enhance the success of VAVD.

Facility Strategies

- Become familiar with the training received by residents regarding VAVD. Supplement resident training with formal mentoring programs on-site. Ensure proper credentialing of providers. Consider simulated birthing mannequins as adjuncts to resident and physician training.
- Implement policies that specify parameters such as indications and contraindications for VAVD, total time of procedure, maximum time on vacuum, maximum number of pop-offs, and maximum pressure use. Practice teamwork drills to refine effective communication of the parameters.
- Consider classifying VAVDs into lower and higher risk groups; according to station of outlet, low or mid; and according to rotation of OA less than 45°, OA greater than 45°, OT, or OP.
- Consider bundling VAVD into a set of criteria, all of which must be met in order to proceed with the VAVD. (Visit the Authority's Web site at <http://patientsafetyauthority.org/EducationalTools/PatientSafetyTools/Pages/home.aspx> to view or download accompanying patient safety tools, including a sample VAVD bundle tool and an educational poster.)
- Standardize documentation of vacuum-assisted vaginal deliveries.¹¹ Consider including the indication for the procedure; documentation of the informed consent process, position, and station of the fetal head and how it was assessed (vaginally or abdominally); amount of molding and caput present; assessment of maternal pelvis; assessment of fetal heart rate and contractions; ease of application of vacuum and placement position; duration of traction and force used; and description of any maternal or neonatal injuries.²³
- Implement unit-level auditing of all operative deliveries. Know the rates of VAVD, VAVD failure, sequential device use, neonatal morbidity to composite trauma, APGAR of less than 7 at five minutes, and cord arterial pH of less than 7.1 (or facility-specific parameters). Audit the unit as a whole, and audit individual obstetricians.¹¹

Preoperative Strategies

- Consider alternative delivery strategies, especially those that facilitate normal spontaneous vaginal delivery. These strategies may include labor coaches, maternal upright or lateral positioning, judicious use of epidural analgesia, oxytocin

administration if not contraindicated, and delay of maternal pushing until two hours into the second stage of labor or until the urge to push is very strong.^{11,23}

- Discuss the risks and benefits of VAVD with the mother, preferably in the office setting before the need to proceed with operative delivery occurs. Document informed consent.
- Rule out contraindications to the VAVD, including gestational age less than 34 weeks, fetal osteogenesis imperfecta, fetal alloimmune thrombocytopenia, an unengaged fetal head, or unknown fetal position.⁸
- Have an exit strategy before proceeding with VAVD; be prepared to move to immediate cesarean section if the extraction is unsuccessful, and if sequential device use (forceps) is contraindicated. Remember, the incidence of intracranial hemorrhage is highest in neonates delivered by cesarean section following a failed vacuum or forceps delivery.⁸
- Use vacuum extractors cautiously in cases of neonatal macrosomia or prolonged labor; the risk of shoulder dystocia increases with these conditions.⁸

Operative Strategies

- Use vacuum extractors only when a specific obstetric indication is present. Be sure that the operator is experienced in its use and familiar with indications, contraindications, and manufacturer guidelines regarding use.⁵
- Apply steady traction in the line of the birth canal, which is the supported use for all vacuum devices; avoid rocking or torque type movements, which can lead to cranial injury.⁵
- Minimize the duration of vacuum application, because cephalhematoma is more likely to occur as duration increases.⁸
- Have a designated team member available to track important parameters for VAVD such as time at procedure, total time on vacuum, number of pop-offs, and vacuum pressure. Verbal confirmation of parameters can help team members maintain situational awareness, and avoid the temptation to try “just one more pull” to effect delivery. Empower team members to express concerns, and acknowledge concerns when they are expressed.

Postoperative Strategies

- Notify all members of the maternal and neonatal care team that a VAVD occurred so that they can monitor the neonate for signs of complications.⁵
- Document the procedure carefully, including the indications for procedure, maternal and fetal condition, informed consent process, device use, cup placement, pressure in mm Hg, number of pulls, any pop-offs, and success or failure of the attempt.
- Perform a thorough postoperative maternal assessment to identify any trauma to the perineal tissue, birth canal, or anal sphincters. Repair any injury

carefully. Observe for postpartum bleeding and/or hemorrhage.

- Perform a thorough neonatal assessment focused on the scalp. Assess for signs of cephalhematoma, bruising, bleeding, or lacerations. Perform serial assessments to document signs of intracranial bleeding or SGH.
- If neonatal cranial complications arise, be prepared to intervene quickly and treat aggressively. Neonates may require transfer to a tertiary facility for aggressive management of SGH.

Conclusion

The literature reveals that vacuum extraction devices have an overall low complication rate and can be safely used during the second stage of labor. However, 367 reports of problems with vacuum extractions have been submitted to the Authority since 2004, 282 of which documented either maternal or fetal harm. To maximize both maternal and fetal safety during these procedures, practitioners in obstetrics are encouraged to consider all available delivery modes, and tailor each delivery to their specific patient. If vacuum-assisted delivery is chosen, patient safety can be maximized through comprehensive preoperative assessment of both the mother and fetus; through informed consent; via correctly applied technical expertise related to the chosen device; by maintaining situational awareness; and by performing targeted postoperative maternal and neonatal assessments.

Notes

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(See Self-Assessment Questions on next page.)

Self-Assessment Questions

The following questions about this article may be useful for internal education and assessment. You may use the following examples or come up with your own.

1. All of the following are indications for vacuum-assisted vaginal delivery (VAVD) EXCEPT:
 - a. A multiparous woman with a prolonged second stage of labor, as evidenced by lack of continual progress for more than one hour with regional anesthesia
 - b. Immediate fetal compromise, as indicated by decelerations in fetal heart rate
 - c. Maternal medical conditions that prohibit effective pushing during labor, such as severe cardiac disease, hypertension, or risk of aortic dissection
 - d. Lack of progressive fetal descent during the second stage of labor
2. Which of the following conditions contraindicates VAVD?
 - a. A nulliparous woman with a prolonged second stage of labor, as evidenced by lack of continual progress for three hours with regional anesthesia
 - b. Gestational age of 40 weeks
 - c. Fully dilated cervix and engaged fetal head with occipital anterior (OA) presentation
 - d. A multiparous woman with a prolonged second stage of labor, as evidenced by lack of continual progress for two hours without regional anesthesia with undetermined fetal position and presentation

Case Scenario

A 32-year-old gravid female, G2P1, delivered a 39-week-old male neonate by means of VAVD. The indication for the procedure was a lack of continual progress over a five-hour period, with use of regional anesthesia. Maternal pelvic examination revealed an engaged fetus with OA presentation at less than 45° rotation. The cervix was fully dilated. The fetal size was estimated at 3,800 gm. There were no imminent signs of fetal distress, but the mother displayed signs of exhaustion.

After notifying appropriate team members and ensuring an operating room (OR) for a potential conversion to cesarean section, the obstetrician obtained informed consent from the patient. He chose a 6 cm Kiwi soft-cup vacuum cap for the procedure. The obstetrician applied vacuum three times for approximately 20 seconds each time (force of approximately 450 mm Hg, in conjunction with maternal contractions, and in-line with the pelvic cavity). Between the three pulls, there were two “pop-offs.” One team member stated that in the event of a third pop-off, the obstetrician should move to another mode of delivery. However, during the third pull, with a bit of right rotation of the vacuum, the delivery was successful.

The neonate appeared healthy with pink skin, a robust cry, and full movement of all extremities. There was a chignon on the scalp, just left of the sagittal suture, near the anterior fontanelle. APGAR scores were 7, 7, and 9. The neonate was transferred to the nursery, where nursing staff were unaware

of the vacuum extraction. Within two hours after delivery, the neonate was quiet, listless, and pale.

3. Assess the case study above and choose which of the following statements is true.
 - a. The obstetrician performed VAVD without proper indication for the procedure.
 - b. The obstetrician performed VAVD with proper indication for the procedure.
4. Situational awareness during VAVD is most appropriately illustrated by which of the following case facts?
 - a. The obstetrician applied the vacuum three times for about 20 seconds each time.
 - b. The obstetrician used 450 mm Hg force during the VAVD procedure.
 - c. A team member stated that an alternative delivery mode should be employed if a third pop-off occurred.
 - d. The obstetrician delivered the infant after a bit of right rotation during the third pull.
5. Which of the following statements best illustrates the obstetrician’s lack of technical expertise?
 - a. The obstetrician chose a 6 cm Kiwi soft-cup for the vacuum extraction.
 - b. The neonate developed a chignon just left of the sagittal suture, near the anterior fontanelle.
 - c. The obstetrician used a force of approximately 450 mm Hg in conjunction with maternal contractions.
 - d. There were two pop-offs during the procedure.

Continued Scenario

The nursery staff did not recognize the neonate complication for an additional two hours. By this time, the neonate was gravely ill. When the nurse removed the neonate’s cap, she noticed an enlarged chignon near the anterior fontanelle, as well as diffuse swelling over the entire scalp extending from the brow to the nape of the neck posteriorly. She notified the physician of these findings immediately. The neonate was diagnosed with a subgaleal hemorrhage and transferred to a tertiary facility for continued care.

6. Which technical failures likely contributed to the neonate’s injury?
 - a. The obstetrician’s choice of procedure, choice of cup, and placement of the vacuum cap on the infant’s scalp
 - b. The obstetrician’s inadequate assessment of maternal pelvis and fetal position
 - c. The obstetrician’s placement of cup on the scalp and use of torque during the procedure
 - d. The obstetrician’s failure to notify subsequent caregivers of the vacuum extraction and incorrect APGAR rating

7. Which factors potentially contributed to the delay in the neonate diagnosis of subgaleal hemorrhage?
 - a. Choice of vacuum cup and inaccurate APGAR scores
 - b. Failure to inform subsequent caregivers of the vacuum extraction procedure and lack of serial assessment of the neonate head
 - c. Incorrect APGAR scores and lack of comprehensive documentation of the procedure
 - d. Two pop-offs and use of torque during delivery

8. Which steps, if taken by the obstetrician, have the greatest chance of eliminating or minimizing neonatal injury?
 - a. Use a 5 cm cup instead of a 6 cm cup during the vacuum extraction procedure; use no more than 400 mm Hg of force; apply force during maternal contractions.
 - b. Ensure correct placement of the vacuum cap using well-known fetal scalp landmarks; avoid the use of torque; pull in-line with the vaginal canal during contractions.
 - c. Use the APGAR neonate assessment tool to categorize neonates with high probability of injury.
 - d. Proceed to an alternative mode of delivery after one failed attempt with the vacuum extractor.

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