Vacuum-assisted vaginal delivery (VAVD)—Basics for the risk manager

By Larry Veltman, MD, FACOG

The neonatal intensive care unit (NICU) manager calls you about a baby delivered last night now with brain trauma. She understands that it was a difficult delivery with a vacuum. There were “multiple pop-offs” and, after the baby was delivered, the NICU resuscitation team was called. The Apgar scores were 3 and 5. They are requesting risk management to lead a debriefing today. What to ask? How many pop-offs are allowed? What was the interaction between the nurses and physician? Why wasn’t the resuscitation team in attendance before the delivery? Was the vacuum placed properly? How many pulls? How long was the vacuum in place? What should be documented, and was the documentation adequate? All of these are appropriate questions for an adequate analysis of an adverse outcome resulting from a vacuum-assisted vaginal delivery (VAVD). This article focuses on the risk management issues of VAVD in order to give the risk manager a better understanding of appropriate use, data-gathering tools, educational opportunities, and assistance in establishing a culture of safety for the entire perinatal team regarding the use of the vacuum device.

Attaining expertise and safety with operative vaginal delivery (OVD) is an important component of obstetrical care. While the use of forceps to perform operative vaginal deliveries has dramatically declined in the past several decades, the vacuum extractor continues to be used with regularity to assist with vaginal delivery when labor arrests in the second stage. In 1998, the FDA issued a warning to obstetricians, birthing centers, nurse midwives, pediatricians, ultrasonographers, OB/GYN nurses, family practitioners, radiologists, hospital risk managers, and hospital OB/GYN departments regarding the “Need for CAUTION When Using Vacuum Assisted Delivery Devices.” This warning described a range of neonatal injuries that were reported using vacuum delivery devices. It is through this document and efforts by organizations such as the Institute of Healthcare Improvement (IHI) that attention has recently been focused on safety and injury protection for infants and mothers when VAVD is indicated.

THE RISKS OF VAVD

There are both maternal and neonatal risks associated with VAVD. They comprise:
• Maternal risks. Primarily injury to the birth canal including cervical and vaginal tears, third- and fourth-degree lacerations, and injuries to the bladder and urethra.

• Neonatal risks. Injuries include primarily injuries to the scalp and underlining vascular structures, skull fractures, retinal tears, and brain injury.

Most of these injuries can be prevented by utilizing proper indications and patient selection for VAVD and by adherence to appropriate safety protocols. These safety protocols involve utilizing the cognitive process of choosing when to attempt VAVD, teamwork and communication among members of the delivery room team, and individual expertise in the use of the particular instruments to assist the delivery.

Such a protocol is exemplified in the incorporation of a vacuum “bundle,” as recommended by the Institute of Healthcare Improvement (IHI).

1. Consider alternative labor strategies. This bundle element addresses strategies applicable to the second stage of labor and should be considered once the patient is fully dilated. Alternatives may include resting the patient when she has no urge to push (passive descent/laboring down); specific considerations for the patient with an epidural; and pushing and breathing techniques (such as pushing with every other contraction) that may facilitate descent and delivery.

2. Prepared patient. This element represents both a discussion and documentation of informed consent and the physical preparation of the patient for a VAVD. Overall, the incidence of serious complications with the use of the vacuum extractor is approximately 5%.

Therefore, it is important that the patient is aware of the possible outcomes with the use of this intervention. During a prenatal care office visit, it is prudent for the provider and the patient to have a discussion about the risks and benefits of vacuum use, and the provider should, of course, document this discussion. In addition, at the time of delivery, the patient’s bladder should be emptied, the presenting part and station has been determined, and adequate anesthesia is assured.

3. Predict a high probability of success by estimating the fetal weight (EFW), knowing the fetal position, and determining the station of the fetal head. The American College of Obstetricians and Gynecologists (ACOG), in their Practice Bulletin devoted to operative vaginal delivery, reports that a randomized study identified 3 factors associated with the development of shoulder dystocia: use of a vacuum device, the time required for delivery, and the infant’s birth weight. They also report that data from a California study identified the highest risk of fetal injury occurred when both the vacuum and forceps were used during a delivery or when a vaginal operative attempt is followed by cesarean delivery. In light of this data, knowing the EFW, fetal position, and station will help to predict a high probability of success.

4. Determine maximum vacuum device application time and pop-offs. A multidisciplinary team in each hospital’s obstetrical department should establish parameters for maximum vacuum application time and the number of acceptable pop-offs based on the type of equipment used and the corresponding manufacturer recommendations. The ability to communicate effectively for all members of the delivery team with regard to these parameters is critical.

5. Have an effective contingency strategy if the vacuum attempt is not successful (an exit strategy). This includes having a resuscitation team at the delivery and preparing for the potential of a cesarean delivery. It is recommended that a prebriefing huddle be part of the strategy for using the vacuum device to ensure that the operating room and nursery staff is immediately available should the use of the vacuum fail, thereby avoiding delay in care or rescue.

Another protocol developed by the author is that of the 7 “Ts”:

1. Timing—when and under what conditions to consider VAVD.

2. Talking with the patient regarding risks, benefits, and alternatives.

3. Technical expertise in the operator—instrumentation, correct application, pressures, axis of traction.

4. Teamwork—the ability to have ongoing communications between team members in the delivery room with regard to fetal status, safety concerns, and notification and requests for additional resources.

5. Termination—when to stop: limits to the number of pop-offs, total time of vacuum application, lack of decent of the fetal head with appropriate traction, having situational awareness and an exit policy (to proceed to cesarean delivery).

6. The newborn—the resuscitation team is present for the delivery and there is an observation protocol for the newborn after delivery.

7. Template—developed for complete and appropriate documentation of the operative delivery (see Exhibit 1 for documentation guidelines).

All guidelines and protocols have various iterations of similar principles that apply to VAVD. They are:

• Determination that certain clinical prerequisites are met such as ensuring vertex presentation, appropriate fetal station, ruptured membranes, appropriate gestational
age (usually > 34 weeks), empty maternal bladder, and adequate pain relief.

• Determination that alternatives have been considered and that the timing is appropriate for VAVD. The ACOG Practice Bulletin on OVD uses the following definitions for a prolonged second stage:
  
  • Nulliparous women (first delivery). Lack of continuing progress for 3 hours with regional anesthesia, or 2 hours without regional anesthesia.
  
  • Multiparous women (second delivery or greater). Lack of continuing progress for 2 hours with regional anesthesia, or 1 hour without regional anesthesia. 4

• Employing a cognitive process that estimates a high probability of success for the vacuum trial. This includes consideration of the estimated fetal weight (EFW), a station (the position of the head in relationship to the maternal pelvis) that is low enough and a determined vertex position that will allow assurance of a proper application. A large EFW, high station (+2 station), and an undetermined or fetal position other than occiput anterior, while not necessarily contraindicated, reduce the probability of success. (There may be times when a vacuum is indicated at a higher station than +2, such as with a second twin or in a multiparous patient with a significantly abnormal fetal heart tracing.)

• Addressing consent issues with the mother and their documentation. Since the decision to use a vacuum or forceps most often occurs late in the second stage (full dilation to delivery), having discussions about the potential for OVD, including the risks, benefits, and alternatives (cesarean delivery) during prenatal care is prudent. Practitioners should have these types of evolving consent discussions with their patients during the third trimester.

  Establishing expectations in the parents regarding the potential swelling of the newborn’s head (the chignon) and its normality is also an important point to include in any conversation regarding a vacuum delivery.

• Consideration of manual rotation of the vertex in cases where the position of the vertex is not occiput anterior (OA). 5

• Assuring that there is appropriate knowledge and skill with respect to the technical expertise of the operator. This includes selection of the appropriate instrument, ability to determine the position of the presenting part and the flexion point on the vertex, appropriate application technique to the vertex with protection of maternal tissues, using the appropriate inflation pressures, and using the appropriate amount of traction required to achieve the delivery.

• Ensuring that policies, procedures, and practices that are in place that standardize the amount of time of

### Exhibit 1: Documentation Guidelines

**Indications for use:**
- Prolonged second stage
- Suspicion of potential/immediate fetal compromise
- Maternal exhaustion
- Other
- Describe fetal status using accepted NICHD terminology

**Examination Findings:**
- EFW
- Station
- Position of vertex
- Cervix completely dilated and effaced
- Maternal/fetal size appropriate for application
- Maternal bladder empty
- Patient counseling/consent
- Indications discussed
- Questions answered
- Patient consented to operative delivery

**Vacuum Procedure Note:**
- Type of vacuum used
- Cup placement for vacuum extraction
- Flexion point identified
- Cup choice appropriate for application site
- Maternal tissue excluded from vacuum cup
- Complete and check all categories:
  - Total time of vacuum application minutes 1st application to delivery
  - Maximum vacuum achieved at mm Hg
  - Number of pulls (number of assisted maternal contractions)
  - Number of involuntary releases (“pop offs”)
  - Vacuum reduced between contractions
  - Advancement in station (descent) with each pull
- Station at application
- Position (OA, LOA, etc)
- Anesthesia – Local, Epidural, Spinal, General, Sedation
- Episiotomy
  - No Yes, Median, Mediolateral
  - Degree: 1, 2, 3, 4
- Repair Suture
- Laceration No Yes
  - Degree: 1, 2, 3, 4
- The newborn
  - Inspection of scalp and location of chignon
  - Apgar scores
  - Resuscitation team in attendance
  - Additional information
application, define and determine the number of “pop-offs” and the number of “pulls” permitted, and the requirement that descent occur with each contraction (pull). There are times when there is confusion between a contraction and a “pull.” Most define a single pull as the traction applied during a single contraction. That is, the number of maternal pushes does not define pulls during a given contraction. These policies should also strongly caution against the sequential use of forceps and vacuum or vice versa.4

- Vacuum delivery at cesarean section should not be a routine practice and should occur only after manual attempts for delivery have failed.6

- Determination of communication “codes” among the team that signals safety concerns, if limits on time or pop-offs have been exceeded, and signals readiness to abandon attempts at OVD and proceed to cesarean delivery. A departmental “escalation” policy and “chain of command” policy should be available. Some organizations have used acronyms such as “Dr. EDNA” (Emergency Developing, Needs Assistance) that signals a need for safety discussions without alarming the patient.

- Determination of an appropriate exit strategy for the procedure. This requires the judgment to know when to stop trying for an operative delivery (usually lack of descent, exceeding the department’s allowed number of pop-offs, or exceeding the department’s total recommended length of time for the application). In addition, the exit strategy requires situational awareness of what else is occurring on the unit, whether or not a cesarean section room is available, and whether or not there is an anesthesia team and an operating room team that has been notified and is available if the VAVD trial fails. Finally, a failed OVD should not result in additional active management of the second stage. It is illogical to think that additional maternal expulsive forces will result in a vaginal delivery if these expulsive forces were previously assisted with vacuum that failed to accomplish the delivery.

- Because of the potential for a compromised newborn, many organizations require the attendance of a resuscitation team at every delivery involving the vacuum.

- Attention to the newborn with respect to having a resuscitation team present at each OVD and having a protocol for observation of any newborn for several hours after any OVD trial, successful or not.7

  - Inform infant care providers of vacuum delivery.
  - Recommend that all infants delivered with VAVD be observed for a minimum 4 hours:
    - Monitor infant vital signs, color, and behavior.
  - Measure head circumference at birth, and at hourly intervals for 4 hours.

  - Examine newborn for scalp swelling, which may be indicative of an underlying scalp or brain injury.

  - Should physical signs demonstrate possible newborn compromise, notify physician.

  - Check newborn hematocrit if there is a change in head circumference of 1 cm or greater.

**SUMMARY**

Vacuum-assisted vaginal delivery is an important obstetrical intervention that can assist in accomplishing a safe vaginal birth. Knowledge of the principles needed to achieve a safe VAVD is important for all practitioners. The risk manager should also have an understanding of these principles if he or she is to be able to intelligently approach and analyze any maternal or fetal adverse outcomes that may occur. It is hoped that this article will help the risk manager ask the right questions, gather the appropriate data (see Appendix), and design appropriate risk management educational activities to make VAVD a safe procedure in their labor suite.

**SEE ALSO**


**REFERENCES**


ABOUT THE AUTHOR

Larry Veltman, MD, FACOG, practiced obstetrics and gynecology in Portland, Oregon, for 30 years. He was the chairman of the Department of Obstetrics and Gynecology at Providence St. Vincent Medical Center in Portland. He served as chair of the Professional Liability Committee of the American College of Obstetricians and Gynecologists and vice chair of ACOG’s Committee on Patient Safety and Quality Improvement. He has published articles and given presentations regarding multiple areas of patient safety in obstetrics and the patient safety aspects of disruptive professional behavior.
### Appendix: Vacuum Extraction Audit Form

<table>
<thead>
<tr>
<th>Vacuum Extraction</th>
<th>Med Record 1</th>
<th>Med Record 2</th>
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<tbody>
<tr>
<td>1. Patient consent on record (or progress note reflects discussion); includes discussion of alternative of cesarean delivery</td>
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<tr>
<td>2. Delivery prerequisites documented</td>
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<tr>
<td>• Position (OA, OP, etc)</td>
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<tr>
<td>• Presentation (vertex only)</td>
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<tr>
<td>• Station of vertex</td>
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<td>• Asynclitism? Y or N</td>
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<tr>
<td>• Clinical pelvimetry</td>
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<td>• Adequate analgesia</td>
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<tr>
<td>• Neonatal resuscitation expertise available and in delivery room at the time of delivery</td>
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<tr>
<td>• Complete cervical dilatation</td>
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<tr>
<td>• Membranes ruptured</td>
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<tr>
<td>• Estimated fetal weight (EFW)</td>
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<tr>
<td>3. Descriptive delivery note includes:</td>
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<tr>
<td>• Indications for use</td>
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<td>• Station of presenting part</td>
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<tr>
<td>• Steps taken to confirm proper placement of the cup on flexion point</td>
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<td>• Duration and time the cup was applied to the vertex</td>
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<td>• Number of pop-offs, if any, documented</td>
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<tr>
<td>• Number of contractions vacuum used (number of pulls)</td>
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<tr>
<td>• Reduction of pressure between contractions? Y or N</td>
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<td>• Delivery accomplished within 20 minutes of start of procedure</td>
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<td>• Fetal assessment is on-going during procedure</td>
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<tr>
<td>• Neonatal resuscitation team is in attendance</td>
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<tr>
<td>• Appearance of fetal head on delivery</td>
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<tr>
<td>• Location of chignon documented for vacuum</td>
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<td>• Dictated physician note operative deliveries</td>
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<tr>
<td>• Evidence that sequential instruments were not used (either vacuum or forceps in either order)</td>
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<tr>
<td>• Type of vacuum used</td>
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<tr>
<td>• There is an established protocol for postdelivery observation of the newborn in every neonate who has undergone a vacuum delivery</td>
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