Preventing Maternal and Neonatal Harm during Vacuum-Assisted Vaginal Delivery

Pennsylvania Patient Safety Authority

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Vacuum extractors are used to aid delivery in cases of failure to progress in the second stage of labor.

Their use has increased over the past 10 years, as forceps use has simultaneously decreased.

There are known risks and complications.
Quality Measures

- Hospital-level National Patient Safety Indicator developed by the Agency for Healthcare Research and Quality (AHRQ)
  - Obstetrical trauma associated with instrument-assisted vaginal delivery and birth trauma
  - In June 2009, AHRQ released a statistical brief which revealed that in 2006 nearly 157,700 potentially avoidable injuries to mothers and newborns occurred.
• U.S. Food and Drug Administration (FDA) issued a public health advisory in 1998 highlighting the increased risk of serious fetal intracranial injury or death associated with the use of vacuum devices.

• From 1996 through 2004, the Joint Commission received 47 reports of perinatal death or permanent disability.

• In 2004, the Joint Commission issued a Sentinel Event Alert titled “Preventing Infant Death and Injury During Delivery”
Pennsylvania Patient Safety Authority (Authority) Reports

- From July 2004 through April 2009, 367 reports related to VAVD were received
- 77% of these reports (282) included some form of neonatal or maternal injury
- 14% of these reports (51) were Serious Events including four neonatal deaths
VAVD Injuries

- Of the 282 reports associated with maternal and fetal injury, 51 were Serious Events

<table>
<thead>
<tr>
<th>Type and Number of Maternal Injury</th>
<th>Type and Number of Neonatal Injury</th>
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<tbody>
<tr>
<td>Perineal or cervical tears or lacerations resulting in hemorrhage and blood transfusion</td>
<td>Fractured clavicle or humerus</td>
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<tr>
<td>4th degree perineal tears requiring operative repair</td>
<td>Respiratory distress</td>
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<tr>
<td>Miscellaneous lacerations requiring operative repair</td>
<td>Cephal-, subdural or subgaleal hematoma or skull fracture</td>
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<tr>
<td>Vaginal sulcus tears requiring operative repair</td>
<td>Miscellaneous injuries</td>
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Indications

- Termination of a prolonged second stage of labor
- Suspicion of immediate or potential fetal compromise
- Shortening of the second stage of labor for maternal benefit
Contraindications

• Gestational age of less than 34 weeks
• Fetal bleeding disorders or predisposition to fracture
• Cephalopelvic disproportion
• In cases where:
  – infant head not engaged; incomplete cervical dilatation; intact membranes; there is brow, face or breech presentation
Maternal Complications

- Fewer maternal injuries than forceps
- Injuries include
  - Cervical lacerations
  - Vaginal hematomas
  - Hemorrhage
  - Third and fourth degree perineal tears
  - Anal sphincter injury
• VAVD is associated with higher rates of:
  – Cephalhematoma
  – Neonatal jaundice
  – Retinal hemorrhage
  – Subgaleal hematoma
• Maternal assessment:
  – Full cervical dilatation, ruptured membranes, empty bladder, adequate analgesia
  – Consent and ability to participate in the procedure
• Fetal Assessment
  – General fetal condition (auscultation of the fetal heart rate)
  – Pelvimetry and EFW (>4000 gm is greater potential for fetal injury)
  – Engagement and station
  – Fetal position
Technical Expertise

- A prospective case controlled study (2004) showed that operator technical expertise with vacuum extractors was associated with increased safety for both mother and infant.

- Familiarity with manufacturer guidelines for the device is also very important.
Cup selection and placement

- Flexion Point
- ~ 3 cm
- Posterior Fontanelle
- Anterior Fontanelle
- Parietal Bone
- Frontal Bone
- Occipital Bone
- Mento-Vertical Diameter (from chin to most prominent part of baby’s head)
CORRECT PLACEMENT

POSTERIOR FONTANELLE

ANTERIOR FONTANELLE

FLEXING MEDIAN

INCORRECT PLACEMENTS

FLEXING PARAMEDIAN

DEFLEXING MEDIAN

DEFLEXING PARAMEDIAN
• Per manufacturer’s guidelines:
  – Vacuum pressure
  – Duration
  – Pop-offs
• Traction
• Pulls
Human Factors

- Sequential device use
- Maintaining situational awareness
- Abandoning the procedure
Postoperative Maternal and Neonatal Assessment

• Maternal
  – Injury to the birth canal
    • Bleeding due to cervical tears, perineal tears or lacerations, injury to the anal sphincter
    – Deep vein thrombosis in cases of prolonged labor
    – Urinary, stress and bowel incontinence
Postoperative Maternal and Neonatal Assessment

- Scalp injuries
  - Fractures, hematomas, lacerations
- Retinal hemorrhage
- Subgaleal hematoma
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. Postoperatively, the patient became hypotensive and tachycardic and developed hypovolemic shock/DIC [sic].
• **Physician failed to follow proper procedure during vacuum-assisted delivery.** Attempted 9 pulls with 4 pop-offs. Nurse advised physician of number of pulls without physician stopping. Policy states number of attempts and pop-offs to be limited to 3.

• **Infant delivered via vacuum extraction with cephalohematoma and fracture of right clavicle.** The infant was transferred to a tertiary facility NICU for further evaluation and was found to have a subdural hematoma. . . .
• Term infant attempted to be delivered with vacuum extractor twice and with forceps twice. . . The vacuum extractor was applied the second time, and then [converted to cesarean section]. The baby was born with APGARS1-1-3; required resuscitation/intubation. The baby was transferred to tertiary neonatal intensive care unit and expired there (subdural hematoma/brain death).
Risk Reduction Strategies

• Facility
  – Resident training and credentialing
  – Policy review
  – Implement a VAVD “bundle”
  – Retrospective chart review
Risk Reduction Strategies

- Preoperative strategies
  - Alternative delivery strategies
  - Informed consent
  - Rule out contraindications
  - Have an exit strategy
Risk Reduction Strategies

- Operative strategies
  - Use vacuum extractors only when a specific obstetrical indication is present
  - Use steady traction in line with the birth canal; avoid rocking motions or torque
  - Minimize duration of vacuum application
  - Maintain situational awareness
• Postoperative strategies
  – Notify all members of the maternal and neonatal care teams of use of vacuum
  – Document the procedure carefully
  – Perform thorough maternal and neonatal assessments
  – If neonatal cranial complications occur, intervene quickly and treat aggressively
Making Vacuum-Assisted Vaginal Delivery Safer

- Performing a thorough preoperative maternal and fetal assessment
- Technical proficiency with the vacuum device
- Setting goals and maintaining situational awareness
- Concluding the delivery with a targeted postoperative assessment of both the mother and neonate are all important patient safety concepts