Devices for Assisted Vaginal Delivery

Technology Opportunity Assessment

Prepared for the Merck for Mothers Program
Devices for assisted vaginal delivery

Summary

When the stage of labor just before birth is prolonged, the delay can cause life-threatening complications for a mother and her baby. In these situations, health providers can safely expedite vaginal delivery using specialized tools (forceps or vacuum extractors), but the tools can be expensive, carry some risk when used, and require specialized expertise. The Odón Device, a new technology that is easier to use than other tools, may improve the safety and efficacy of assisted vaginal delivery, particularly in low-resource settings.

Statement of need

Obstetric hemorrhage is estimated to cause 25% of all maternal deaths and is the leading direct cause of maternal mortality worldwide. Postpartum hemorrhage (PPH), defined as vaginal bleeding in excess of 500 mL after delivery, accounts for most cases of obstetric hemorrhage. It occurs in more than 10% of all births and is associated with a 1% case fatality rate.

Although active management of the third stage of labor can prevent up to 60% of PPH cases, PPH continues to have a devastating impact on women in low-resource settings, where home births are common and hospitals or health facilities are often inaccessible. Obstetric hemorrhage accounts for 34% of maternal deaths in Africa, 31% in Asia, and 21% in Latin America and the Caribbean. Among women who do survive PPH, approximately 12% will have severe anemia. Also, women who survive severe PPH (greater than 1,000 mL of blood loss) are significantly more likely to die during the following year.

A woman’s second stage of labor is the period between 10 cm dilation and birth of the baby. A prolonged second stage is an important risk factor for PPH and can cause potentially fatal complications for the mother (hemorrhage, infection) and the newborn (birth asphyxia, trauma). After the first hour of expulsive effort, the chances of a spontaneous vaginal birth of a newborn infant without signs of asphyxia decrease significantly every hour. The risk of PPH and intrapartum fever increase significantly after two hours of pushing.

A prolonged second stage of labor may be caused by pushing before spontaneous expulsive efforts or because of abnormalities of the powers (uterine contractility and maternal expulsive efforts), the passenger (the fetus), or the passage (the pelvis). If malpresentation and obvious obstruction have been excluded and there is no descent, even after a woman is given oxytocin to increase uterine contractions, assisted deliveries may be a safe and effective way to prevent perinatal and maternal death and disability. However, as cesarean deliveries become increasingly available worldwide, many providers are opting not to perform assisted deliveries. As a result, assisted delivery instruments are less available; fewer providers
have experience using them, leading to lower confidence in and use of these techniques; and training for assisted deliveries is inadequate, even in settings where cesarean delivery is not an option.

Assisted delivery includes delivery using forceps or a vacuum extractor (VE). All instrumental delivery efforts include an element of uncertainty, so providers should also prepare for a cesarean operation or be ready to transfer the woman to a facility that has operative capacity in case the vaginal procedure does not proceed rapidly and easily. The safety and success of forceps- or VE-assisted deliveries depend on provider skill, case choice,* and instrument design. Although use of forceps or a VE can be lifesaving for pregnant women and their babies, and can prevent a cesarean operation, they are not entirely free of risk.

Risks to the infant include:

- Asphyxia
- Scalp injury
- Head trauma (cephalohematoma or subgaleal hematoma, intracranial hemorrhage)
- Neonatal jaundice
- Intracranial hemorrhage
- Retinal hemorrhage
- Facial/brachial palsy
- Skull fracture
- Death

Risks to the pregnant woman include:

- Genital (perineal, vaginal, cervical) trauma
- PPH
- Sepsis
- Possibility of chronic low backache
- Genital prolapse
- Stress incontinence

There is also a theoretical increase in the risk of mother-to-child transmission of HIV when women infected with HIV are assisted using forceps or a VE.

There is a clear need for research on promising assisted-delivery technologies that address the shortcomings of commercially available tools. In particular, existing tools: (1) are challenging to safely apply to the fetal head, (2) can cause trauma to the woman and her baby, and (3) are complex to use. An

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* General contraindications include the following: operator inexperience; inability to achieve a correct application (midline, over flexion point); an inadequate trial of labor or lack of a standard indication; uncertainty concerning fetal position or station not resolved by examination or real-time ultrasound study; suspicion of fetopelvic disproportion (advanced cranial molding, bone overlap, caput); an inappropriate fetal presentation (e.g., breech, face, brow); a known or suspected fetal bleeding diathesis or demineralizing bone disease. Relative contraindications are as follows: prematurity, prior scalp sampling, prior failed forceps, overlapping cranial bones, heavy caput, known or suspected fetal macrosomia.
A Cochrane review of 32 studies (6,597 women) found that although use of forceps were more likely to achieve vaginal birth than use of VEs, they were also linked to more cesarean operations, more third- or fourth-degree vaginal tears (with or without episiotomy), vaginal trauma, use of general anesthesia, and flatus incontinence or altered continence. Facial injury for the fetus was also more likely, but there was a positive trend toward fewer cases of cephalohematoma. Although there are more than 700 different types of forceps, most of the instruments currently in use were originally designed in the 19th and early 20th centuries. Gei and Pacheco suggest that the factor most likely to improve forceps would be a “scientific redesign.” The cost of a pair of forceps currently falls between US$190 and $250 and varies by brand and shape. Due to the specialized training required for using forceps to assist a delivery and the limited presence of trained specialists, forceps are not widely used in low-resource settings.

Vacuum extractors

VEs have become a preferred alternative because although they have a higher failure rate than forceps, they are associated with fewer complications for women and babies. VEs also require less specialized health worker training and can, therefore, be used more widely by well-trained and qualified midwives and nonspecialist doctors. The first VE was a stainless steel metal cup introduced by Malmström in the 1950s. Over the years, traditional VEs have been modified to increase safety, efficacy, and simplicity. Modifications have included varying the composition, diameter, and depth of the cup, combining the vacuum pump and the handle, using manual instead of electrical pumps, and varying the handle used for traction.

There are two main categories of vacuum cups, as shown in Table 1: rigid, mushroom-shaped cups (M cups) and soft, bell- or trumpet-shaped cups. Although the Cochrane review found that metal cup vacuum extraction was more effective in achieving vaginal birth than the soft cup, it was also associated with a higher frequency of newborn scalp injury and cephalohematoma. A weakness of soft cups is that the combined and centrally located vacuum port and traction stem limit their maneuverability. Because
the effectiveness of the VE depends on correct placement of the cup on the flexion point of the infant’s scalp, limited maneuverability also leads to increased failure rates and increased risk of trauma to the infant and mother.15-17

Table 1. Types of vacuum cup devices for operative vaginal delivery.18

<table>
<thead>
<tr>
<th>Device</th>
<th>Size</th>
<th>Material</th>
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<tbody>
<tr>
<td>Soft cups (bell- or trumpet-shaped cups)</td>
<td></td>
<td></td>
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<tr>
<td>Gentle Vac™ (OB Scientific, Germantown, WI)</td>
<td>60 mm</td>
<td>Soft rubber</td>
</tr>
<tr>
<td>Kiwi ProCup® (Clinical Innovations, Murray, UT)</td>
<td>65 mm</td>
<td>Soft plastic</td>
</tr>
<tr>
<td>Mityvac MitySoft Bell® (CooperSurgical, Trumball, CT)</td>
<td>60 mm</td>
<td>Soft silicone</td>
</tr>
<tr>
<td>Secure Cup™ (Utah Medical, Midvale, UT)</td>
<td>63 mm</td>
<td>Rubber</td>
</tr>
<tr>
<td>Silc Cup (Medela AG, Barr, S2)</td>
<td>50–60 mm</td>
<td>Silicone rubber</td>
</tr>
<tr>
<td>Soft Touch™ (Utah Medical)</td>
<td>60 mm</td>
<td>Soft polyethylene</td>
</tr>
<tr>
<td>Tender Touch® (Utah Medical)</td>
<td>60 mm</td>
<td>Soft silicone</td>
</tr>
<tr>
<td>Vac-U-Nate™ (Utah Medical)</td>
<td>65 mm</td>
<td>Soft silicone</td>
</tr>
<tr>
<td>Rigid anterior cups (M cups)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Flex Cup™ (Utah Medical)</td>
<td>60 mm</td>
<td>Polyurethane</td>
</tr>
<tr>
<td>Kiwi/Vacca Reusable OmniCup® (Clinical Innovations)</td>
<td>50 mm</td>
<td>Rigid plastic</td>
</tr>
<tr>
<td>Malmström (Dickinson Healthcare, Hungerford, UK)</td>
<td>40–60 mm</td>
<td>Metal</td>
</tr>
<tr>
<td>Mityvac M-Style® (CooperSurgical)</td>
<td>50 mm</td>
<td>Rigid polyethylene</td>
</tr>
<tr>
<td>Rigid posterior cups (M cups)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Bird posterior cup (Medela AG)</td>
<td>40–60 mm</td>
<td>Metal</td>
</tr>
<tr>
<td>Kiwi/Vacca Reusable OmniCup® (Clinical Innovations)</td>
<td>50 mm</td>
<td>Rigid plastic</td>
</tr>
<tr>
<td>Mityvac M-Select® (CooperSurgical)</td>
<td>50 mm</td>
<td>Rigid polyethylene</td>
</tr>
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</table>

Alternatively, the Kiwi OmniCup® (Clinical Innovations, Murray, UT) is a plastic cup that can be used in all fetal positions. The Kiwi OmniCup became available in 1999 and is a complete vacuum delivery system with a handheld pump for ease of use by a single operator. Because it is a disposable device, however, its unit cost presents a major obstacle for use in low-resource countries. In 2004, Clinical Innovations produced the Vacca Reusable OmniCup®, a reusable version of the Kiwi OmniCup, specifically for use in low-resource countries.16 The disposable cup devices cost approximately $30 whereas the reusable devices cost around $125.11

These cups reflect advances in technology that increase their versatility for use in low-resource countries. However, none of these variations has improved upon the basic problems associated with VEs. Although one recent study comparing the Vacca Reusable OmniCup to the Bird anterior and posterior metal cups found that there were no significant differences in outcomes between the devices,16 another trial found that the Kiwi Omnicup was less successful at delivery, with a failure rate of 30% compared with 19.2% for the standard vacuum device.19
Odón Device

The Odón Device is an emerging technology in the area of assisted delivery. This device consists of a polyethylene sleeve with a cuff-like fold on the fetal insertion edge which fits the fetal head diameter. This sleeve is introduced using an inserter which allows the care worker to place the device in an adequate final position around the fetus’ head.\textsuperscript{20}

The device decreases the risk of fetal-maternal injury, contributes to the physiologic development of the second stage of labor, and contributes to contraction forces and maternal pushing efforts. The Odón Device could reduce the following:

- Prolonged second stage of labor.
- PPH through a reduction in the second stage of labor.
- The need for operative delivery.
- The incidence of perineal damage.
- Perinatal infections acquired through the birth canal.\textsuperscript{20}

The Odón Device is designed to be used in both high- and low-resource settings. Using the device, health care workers can assist delivery with less specialized training than they would need to use forceps or vacuum extraction. The Odón Device is the first real innovation in the area of assisted vaginal delivery in more than 50 years and may positively impact an area of maternal and neonatal health that has not seen significant improvement in some time. However, the device is still in the early phases of development. As of 2012, a Phase 1 study to evaluate feasibility and safety was under way in Buenos Aires, Argentina, and also in South Africa.\textsuperscript{20} According to Dr. Mario Merialdi with the World Health Organization (WHO) (oral communication, January 2012), future phases of the trial are estimated to be completed in 36 to 48 months.

Although production costs for the device have not yet been estimated, the disposable sleeve is likely to cost less than $1. Even with the added costs of the inserter and hand pump, the Odón Device is projected to be a more affordable option for assisted delivery than VEs or forceps. The Odón Device has received a $250,000 grant as a winner of the Saving Lives at Birth’s Grand Challenges program as well as $50,000 as a first prize winner at the competition for technological innovation, INNOVAR 2011.\textsuperscript{21}

Gap analysis

Forceps or metal cup VEs are the most effective commercialized devices available for assisting vaginal delivery, but their use may carry an increased risk of maternal or neonatal trauma. Both methods also require providers to have access to a surgical theater in case vaginal delivery fails and a cesarean operation is necessary. However, access to cesarean delivery is low in most low-resource settings, and where it is available, it often represents a substantial resource burden. Furthermore, the high level of skill required for forceps delivery effectively precludes it as an option in most low-resource settings.
Of the non-metal VE cups, the Vacca Reusable OmniCup has the most potential for impact in low-resource settings because it is reusable, versatile in almost all fetal positions, can be used by a single operator, and does not require power. However, because this device has a high failure rate and still carries significant risk to the mother and infant, other options should be considered. Table 2 below compares key factors of devices for assisted vaginal delivery.

Table 2. Comparison of devices for assisted vaginal delivery.

<table>
<thead>
<tr>
<th></th>
<th>Forceps</th>
<th>Vacuum Extractors</th>
<th>Odón Device</th>
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</thead>
<tbody>
<tr>
<td><strong>Safety</strong></td>
<td>Risk of significant fetal and maternal morbidity.</td>
<td>Risk of significant fetal and maternal morbidity.</td>
<td>Decreases risk of fetal and maternal morbidity; may protect the baby from intrapartum infection.</td>
</tr>
<tr>
<td><strong>Skill required</strong></td>
<td>Highly trained specialist.</td>
<td>Midwife or skilled birth attendant with adequate training on the device.</td>
<td>Potential for application by midwife, nurse, or physician with short length of training.</td>
</tr>
<tr>
<td><strong>Cost</strong></td>
<td>Between US$190 and $250.</td>
<td>$20 to $30 for disposable; around $125 for reusable.</td>
<td>Unknown; disposable sleeve is estimated at less than $1.</td>
</tr>
<tr>
<td><strong>Level of development</strong></td>
<td>Many commercialized devices.</td>
<td>Many commercialized devices.</td>
<td>Phase 1 testing.</td>
</tr>
</tbody>
</table>

Because the Odón Device has the potential to be safer, easier to use, and less expensive, and because it may decrease PPH, it far exceeds currently available devices in meeting the need for assisted vaginal deliveries. The Odón Device clearly has the most potential to reduce complications and death related to a prolonged expulsive phase and maternal and fetal distress during the second stage of labor.

**Investment opportunity**

Although the Odón Device is an exciting innovation, research and development are needed to determine whether it is feasible, safe, and efficient for delivering babies during a prolonged second stage of labor and to clearly understand how it will affect assisted vaginal delivery. To address this objective, WHO is implementing a three-phased study protocol.20 22

- Phase 1 is under way and involves the testing of the device in Argentina and South Africa for safety and feasibility under normal delivery conditions in both tertiary-care settings and rural facilities.
- During Phase 2, a randomized controlled trial in Argentina and South Africa will test the device for preliminary efficacy in both tertiary-care settings and rural facilities. Preliminary efficacy is the successful delivery of the baby in situations that typically call for use of either forceps or a VE as the next clinical management step prior to cesarean delivery. These are typically deliveries with a prolonged second stage of labor and no fetal distress. Phase 2 trials will enroll women with a prolonged labor who would normally be managed using forceps or a VE. Participants will be randomized to receive these methods or the Odón Device. Phase 2 should be completed by late 2013.
During Phase 3, a large multi-country randomized clinical trial will be conducted to assess the effectiveness of the use of the Odón Device in reducing negative obstetrical outcomes as compared with forceps and VEs as well as in preventing newborn infections acquired intrapartum. It is estimated that Phase 3 will take from 12 to 24 months.

Pending favorable outcomes of the study, production of the device should begin as soon as possible. A manufacturer should be selected and manufacturing plans should be rapidly developed. It will be important to stimulate demand in the short term by investing in medium- to large-scale introductions of the device in two to four early-adopter countries through broad collaborations with ministries of health, nongovernmental organizations, and other key stakeholders. It will be useful to simultaneously lay the foundation for broad, long-term uptake worldwide and to begin cross-cutting activities to achieve quick results in a few targeted countries.

Global regulatory pathways should also be rigorously pursued. Assuming that study results are favorable, this includes seeking a strong recommendation in the WHO guidelines for managing prolonged and obstructed labor and in the organization’s *Managing Complications in Pregnancy and Childbirth: A Guide for Midwives and Doctors*. The device should also be included in the Interagency List of Essential Medical Devices for Reproductive Health.

Regional and national regulatory pathways should also be rigorously pursued. A particular focus should be placed on national regulatory registration and approval in countries where the burden of maternal mortality is high and ministries of health are receptive to the introduction of the Odón Device. Introduction in these countries may be facilitated through existing and future training programs for the active management of the third stage of labor.

Although the Odón Device will require less specialized training than VEs or forceps, investments in adequate training for midwives, nurses, and physicians will be essential to ensure improved treatment outcomes.
References


