Hem-Avert® Perianal Stabilizer for the Prevention of Cesarean Delivery: A Cost-Effectiveness Analysis

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Abstract

Background: Cesarean delivery is the most common operating room procedure in the United States with approximately one in three babies being born through surgical means. The rate of cesarean delivery is 70% higher today in the US than it was twenty years ago. Yet despite the fact that for several decades many editorials in leading obstetric journals and childbirth advocates have called for urgent action to reverse this trend, cesarean delivery rates have continued to rise. A novel device, the Hem-Avert Perianal Stabilizer has been shown to reduce both the rate of cesarean births and the duration of second-stage labor. This study demonstrates the cost-effectiveness of the Hem-Avert device.

Methods: Data from peer-reviewed journal articles, systematic review organizations, data collection agencies, society statements and cost information from the manufacturer were assembled to provide a health economic analysis of the Hem-Avert Perianal Stabilizer. Information from a previous randomized, controlled, prospective study where Hem-Avert was employed served as the reference for the cost assessment.

Results: Due to the reduction in cesarean births obtained with the device, the average gross cost savings to Commercial insurers would be $2,487 less per scheduled vaginal birth for patients who received the Hem-Avert device and $1,193 less for Medicaid patients. With a previously determined number needed to treat of four, the Hem-Avert device was shown to produce a net savings of $1,999 and $825 per birth for Commercial and Medicaid payers respectively.

Conclusions: Based upon the effectiveness of the device during the most recent clinical study illustrating improvement in maternal and newborn outcomes, decreasing progression to cesarean delivery and duration of second-stage labor the Hem-Avert Perianal Stabilizer maintains the ability to substantially decrease the cost of care for child birth.

Keywords: Hem-avert; Hem-avert perianal stabilizer; Cesarean delivery; Vaginal delivery; Cost-effectiveness analysis; Health economics; Commercial and medicaid insurers

Description of the Related Condition

The condition in the clinical setting

Cesarean delivery is the most common operating room procedure in the United States, with approximately one in three babies being born through surgical means. The rate of cesarean delivery is 70% higher today in the US than it was twenty years ago, with an estimated 50% of this increase occurring between 1998 and 2008. This is more than twice the target rate recommended by the World Health Organization (WHO). The rate of cesarean deliveries has also grown in practically every demographic and epidemiological cohort-among women with and without prior cesarean births; in both preterm and term pregnancies; in women at low and high risk of complications; and among women of all ages, races and ethnicities. This is despite evidence that currently suggests cesarean deliveries do not improve patient outcomes in many instances and carry substantial costs and potential risks to both the mother and child. These include life-threatening complications that occur more frequently with accumulating surgeries, as well as other downstream effects, including some chronic childhood illnesses and placental complications in subsequent pregnancies [1-6].

In many contexts, cesarean delivery has come to be regarded as the safer option, when in fact it has greater risks and complications than vaginal birth. Higher cesarean delivery rates have brought higher economic costs and greater health complications for mother and child, with little demonstrable benefit for the large majority of cases. With the marked decline in vaginal births after cesarean, cesarean deliveries have become self-perpetuating; and every subsequent cesarean brings even higher risks. Yet despite the fact that for several decades many editorials in leading obstetric journals and childbirth advocates have called for urgent action to reverse this trend, cesarean delivery rates have continued to rise [6].

Rates of cesarean deliveries vary considerably across providers, facilities and states. A research team from the University of Minnesota’s School of Public Health examined hospital discharge data from a representative sample of 593 hospitals with at least 100 births in 2009 and published their results in March 2013. They found that cesarean delivery rates varied nearly tenfold across U.S. hospitals, from 7.1% to 69.9%. The variations uncovered were not explained by hospital size, geographic location or hospital teaching status. These trends suggest that cesarean rates are influenced by clinician practice preferences, institutional and system factors and women's preferences more than being influenced by evidence-based principles (Figure 1) [5-16].

One possible reason for the rapid rise in the cesarean delivery rate over the past decade is a combination of decreasing downward pressures and increasing upward drivers. Most of the pressures on providers and hospitals that kept cesarean delivery rates stable in the past have all but disappeared, including physician pride in a low cesarean rate,
As cesarean delivery is the most common surgical procedure performed in America today, it is well worth the time and effort of the medical community at large to examine the costs and benefits of this procedure. There are, of course, times when cesarean delivery is medically necessary and when its utilization is in the best interest of the mother and/or child. However, new evidence suggests that cesarean deliveries are being performed with no clear medical benefit and potentially to the detriment of the mother or child. Finally, there is no consensus as to why cesarean has increased 70% during the last twenty years.

The Literature

Description of the related condition

In 2012, Goer et al. performed a systematic review of the literature concerning the use of cesarean in the US healthcare system. Table 1 summarizes the research and the findings of the report [5].

As there are no randomized controlled trials of planned vaginal birth versus planned primary cesarean delivery (other than breech presentation), systematic reviews have been limited to observational or descriptive studies, which in most cases do not allow for meta-analysis. Despite intra-study methodological weaknesses, the sheer volume of academic works on the benefits of vaginal birth as compared to cesarean delivery is compelling.

This year, the American College of Obstetricians and Gynecologists (ACOG), the nation’s largest ob-gyn organization, recommended that pregnant women plan for vaginal birth unless there is a medical reason for a cesarean. In new guidelines, the ACOG Committee on Obstetric Practice says maternal-request cesareans are especially not recommended for women planning to have several children, nor should they be performed before thirty-nine completed weeks of pregnancy [18].

A Hayes review published in January 2009 based on an article by Tita et al. published in the New England Journal of Medicine, examined the relationship between elective cesarean delivery at term (after thirty-seven weeks of gestation or longer) but before thirty-nine weeks of gestation and neonatal outcomes. The group found that early deliveries are associated with a significant increase in risk of a complicated outcome that included neonatal mortality and morbidity. While there may be many motivations for scheduling elective cesarean deliveries, including a woman’s desire to give birth once term is attained and an obstetrician’s desire to schedule the procedure at a convenient time, this study and others indicate that this trend may not be in the best interest of the newborn or in the best interest of society which must bear the burden of the increased healthcare costs to care for infants who have these outcomes [17,19].

Findings from the National Quality Forum, Hayes Review, the California Maternal Quality Care Collaborative and other authors overwhelmingly support vaginal birth- and spontaneous vaginal birth in particular-in the absence of a compelling reason to do otherwise. Clinicians, policy makers and other stakeholders should prioritize identifying and promulgating practices that promote safe, spontaneous vaginal birth and reduce the use of cesarean delivery to improve both the quality and value of maternity care in the United States and promote the optimal health of women and infants [1,2,5,6,16,17,20-23].

The device

The Hem-Avert® Perianal Stabilizer (Plexus Biomedical, Oakland, TN) comes in a single-use, gamma-sterilized peel pouch. The externally applied device is put on the patient when she has reached between 8-10 cm. of cervical dilation. The device consists of three components: (Figure 2) [24]

• A rigid polymer base manufactured from a medical grade polycarbonate;

• A centrally located cushioning pad which is composed of a laminate of medical grade polyester non-woven tape and medical grade polyethylene foam tape;

• Two lateral hook and loop fastener adhesive strips (with liners) - “loop” strips that attach to the mating “hook” which are used to provide the tension needed to keep the device firmly in place during delivery. The cushioning pad and adhesive strips are manufactured using materials commonly found in medical instruments and used in medical procedures.

Proposed indications for the device/procedure

The Hem-Avert Perianal Stabilizer is FDA-cleared and indicated for the prevention of external hemorrhoids during vaginal childbirth.
Evidence

Data conflict but suggest that a limited evidence suggests that a large excess number of healthy women having cesarean delivery may experience complications with anesthesia.

Cardiac arrest

Limited evidence suggests that a moderate excess number of healthy women may experience cardiac arrest in association with cesarean delivery.

Cesarean scar endometriosis

Limited evidence suggests that a small to large excess number of women having cesarean delivery develop cesarean scar endometriosis.

Dense intra-abdominal adhesions

Limited evidence suggests that a very large number of women develop dense adhesions after cesarean delivery.

Hematoma

Limited evidence suggests that a large excess number of healthy women having cesarean delivery have wound hematomas.

Hospital readmission

A moderate to large excess number of healthy women having cesarean delivery require readmission to the hospital compared to women with prior vaginal births.

Hysterectomy

A moderate excess number of women with prior cesarean delivery require an urgent hysterectomy during the next delivery admission compared with women with only prior vaginal birth. Limited evidence suggests that the excess increases with subsequent pregnancies.

ICU admission

Limited Evidence Suggests that a large excess number of women with prior cesarean are admitted to ICU at the next delivery.

Longer hospital stay

Planned cesarean delivery increases length of hospital stay for mothers by at least 0.5 to 2 days. Limited evidence suggests that a large excess number of babies whose mothers had prior cesarean delivery have hospital stays of more than 7 days compared with babies whose mothers had prior vaginal birth.

Major infection

Evidence suggests that a moderate to large excess number of healthy women having planned cesarean delivery experience major puerperal infection.

Obesity

Limited evidence suggests that a large excess number of children delivered by cesarean may be obese at age three.

Operative maternal injury

Among women having a first delivery via cesarean delivery, a moderate number of women experience bladder puncture and a small number experience bowel injury to a ureter.

Persistent pain at the site of the cesarean incision

Limited evidence suggests that a large to very large number of women still experience pain at the incision site 6-10 months or more after cesarean delivery.

Physical recovery

With the exception of the presence of hemorrhoids, which are more common with vaginal birth, a large to very large excess number of women having cesarean delivery experience problems with physical recovery, including general health, bodily pain, extreme tiredness, sleep problem, bowel problems, ability to carry out daily activities and ability to perform strenuous activities.

Placenta abruption

A moderate excess number of women with first delivery via cesarean have placental abruption in subsequent pregnancies.

Placenta accreta

A small excess number of women with first delivery via cesarean delivery develop placenta accreta in the next pregnancy. A large excess number of women develop placenta accrete after multiple prior cesareans.

Placenta previa

A small excess number of women with first delivery by cesarean delivery develop placenta previa in the next pregnancy. A large excess number of women develop placenta previa after two or more prior cesareans.

Pulmonary hypertension

Limited evidence suggests that a moderate excess number of babies delivered by elective cesarean delivery may develop pulmonary hypertension.

Re-operation

Limited evidence suggests that a moderate number of women having cesarean delivery require re-operation.

Stillbirth

Data conflict but suggest that a small to moderate excess number of babies developing in a uterus with a cesarean scar are stillborn.

Surgical cuts to the baby

Limited evidence suggests that a moderate number of babies are cut during cesarean delivery.

Thromboembolic events

A small to moderate excess number of healthy women having cesarean delivery experience a blood clot.

Urgent hysterectomy

A small to moderate excess number of women having initial cesarean delivery undergo unplanned hysterectomy.

Uterine rupture

A moderate excess number of women will experience uterine rupture with prior cesarean delivery.

Ventilation at birth

Limited evidence suggests that a large excess number of babies whose mothers had prior cesarean may require ventilation at birth.

Voluntary infertility

A large to very large excess number of women choose to not conceive again after cesarean delivery.

Wound disruption

Limited evidence suggests that a small excess number of healthy women having cesarean delivery have wound disruption.

Wound infection

A large excess number of healthy women having cesarean delivery have wound infections.

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Table 1: Evidence-based Review of Cesarean vs. Vaginal Delivery (for magnitude of absolute risk, see Table 1A).

The Hem-Avert applies perianal pressure and provides patients with a tactile target to push against during the second stage of labor [25].

Cost and Economics

New technology

The Hem-Avert device (Plexus Biomedical, Oakland, TN) has an average selling price of $256.

Current costs

A 2013 report published by Truven Health Analytics (Ann Arbor, MI) examined the costs of labor and delivery in the U.S. and illustrated the differences between Commercial and government payers amounts issued. These numbers are shown in Figure 3 [14].

It is important to note from the Figure 3 that, for Commercial patients, facility fees for cesarean deliveries are 54.1% ($3,058) more,
Intrapartum Costs Associated with Labor and Delivery by Either

<table>
<thead>
<tr>
<th>Type of Birth</th>
<th>No. of Patients</th>
<th>Average Insurer Payment ($)</th>
<th>Total Payment for Group ($)</th>
</tr>
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<tbody>
<tr>
<td>Cesarean</td>
<td>6</td>
<td>24,949</td>
<td>149,694</td>
</tr>
<tr>
<td>Vaginal</td>
<td>44</td>
<td>15,931</td>
<td>700,964</td>
</tr>
<tr>
<td>Total Commercial Insurer Payment for Investigational Group: $850,858</td>
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<tr>
<td>Average Commercial Insurer Payment per Patient: $17,013</td>
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<tr>
<td>Cesarean</td>
<td>19</td>
<td>24,949</td>
<td>474,031</td>
</tr>
<tr>
<td>Vaginal</td>
<td>29</td>
<td>15,931</td>
<td>461,999</td>
</tr>
<tr>
<td>Total Commercial Insurer Payment for Control Group: $936,030</td>
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<tr>
<td>Average Commercial Insurer Payment per Patient: $19,500</td>
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Table 2: National Average Costs for Vaginal and Cesarean Intrapartum Care for Commercial Payers.

Similar cost savings could potentially be realized for Medicaid, as

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<tr>
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<td>79,962</td>
</tr>
<tr>
<td>Vaginal</td>
<td>44</td>
<td>9,002</td>
<td>396,038</td>
</tr>
<tr>
<td>Total Medicaid Payment for Investigational Group: $476,050</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Average Medicaid Payment per Patient: $9,521</td>
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</tbody>
</table>

Table 4: Potential Cost Offsets from Use of the Hem-Avert Device–Medicaid.

professional service fees are 16.6% ($401) more and professional anesthesia fees are 21.4% ($203) more expensive than for vaginal births.

For Medicaid patients, facility fees for cesarean deliveries are 51.4% ($1,115) more, professional service fees are 16.7% ($168) more and professional anesthesia fees are 13.8% ($22) more expensive than for vaginal births. In particular, professional service fees and professional anesthesia fees increase from vaginal births to cesarean births and the hospital (facility) captures most of the difference.

Nationally weighted averages for vaginal and cesarean childbirth for the year 2010 based on Commercial payer values obtained from Truven Healthcare Analytics are listed in Table 2 [14].

Potential Cost Offsets

A prospective, randomized trial of women using the Hem-Avert device to reduce the incidence of cesarean delivery was recently conducted. All ninety-eight patients in the study were originally scheduled for vaginal delivery. Fifty patients used the Hem-Avert device, while forty-eight patients gave birth without the device. Six women assigned to the investigational group required cesarean delivery compared to nineteen patients in the control group. The chi-square test result indicated that this difference was statistically significant and showed that patients using the Hem-Avert device had a lower cesarean rate (12.0% for Hem-Avert patients versus 39.6% for control patients, P=0.0017). The difference between the two groups was 27.6%, with a corresponding relative reduction of 69.7%. The results were further analyzed to determine whether the reduction in cesarean births could be attributed to other factors, such as history of previous cesarean births, epidural usage or newborn weight. No differences were found between the two study groups, leading to a conclusion that cesarean reduction was due also to the result of the prophylactic application of perineal utilization of the Hem-Avert device. Inclusion criteria consisted of scheduled singleton vaginal delivery. Exclusion criteria included: the patient was scheduled for an elective cesarean delivery; the patient was scheduled for vaginal delivery with anticipated complications (i.e., breech presentation) and patient’s prenatal information indicated that it would not be a singleton birth [25].

The previously cited report by Truven Health Analytics found that, on average, employer-provided Commercial insurers paid $15,931 for maternal and newborn care for vaginal births. By comparison, each cesarean delivery resulted in Commercial insurer payments of $24,949. These amounts excluded payments made by secondary insurers and out-of-pocket costs to patients of $2,244 for vaginal births and $2,669 for cesarean deliveries. Prevention of each cesarean birth therefore provides a potential savings to the average Commercial insurer of $9,018 [14].

In order to obtain a total assessment of the potential cost savings for primary payers if the Hem-Avert device were used during labor, maternal and newborn payments should not only include intrapartum care but also the result of the prophylactic application payments as well. These total care childbirth payments include facility, maternity care providers, and anesthesia, radiology/imaging, pharmacy and laboratory services. If the same study was conducted again and the data from the Truven Health Analytics report were applied, the cost savings could be significant as shown in Table 3. Due to the reduction in cesarean births obtained with the device, the average cost difference of Commercial insurer payments would be $2,487 less per scheduled vaginal birth for patients who received the Hem-Avert device [14].

Similar cost savings could potentially be realized for Medicaid, as
shown in Table 4. The average Medicaid payment would be $1,193 less per vaginally scheduled birth for patients who received the Hem-Avert device.

For determining cost savings outside the study it is necessary to utilize the number needed to treat (NNT) for the device. The NNT for the study was determined to be four which means that for every four patients that give birth with the device, one patient avoids cesarean delivery that would otherwise have a cesarean delivery.

After subtracting the cost of the device, the net cost savings in payments for primary Commercial insurers for maternal and newborn delivery is $1,999 each time the device is used. Correspondingly, the net cost savings for Medicaid insurers is $825 per birth (Table 5).

### Conclusion

It is believed that the Hem-Avert device plays a role in labor progression by increasing the patient's ability to push effectively. Effective pushing is achieved by the application of perianal pressure exhibited by the device.

Analysis from a prospective, randomized trial demonstrated that the device is associated with a decrease in cesarean delivery rates. This was true even among patients who received epidural analgesia during delivery. Based upon the effectiveness of the Hem-Avert device during the clinical study, better patient outcomes and avoidance of cesarean delivery were obtained by 27.6% of patients. Net utilization costs during delivery were obtained by 27.6% of patients. Net utilization costs during delivery. Based upon the effectiveness of the Hem-Avert device during the second stage of labor to the length of the second stage. Obstet Gynecol 122: 27-32.

### References


