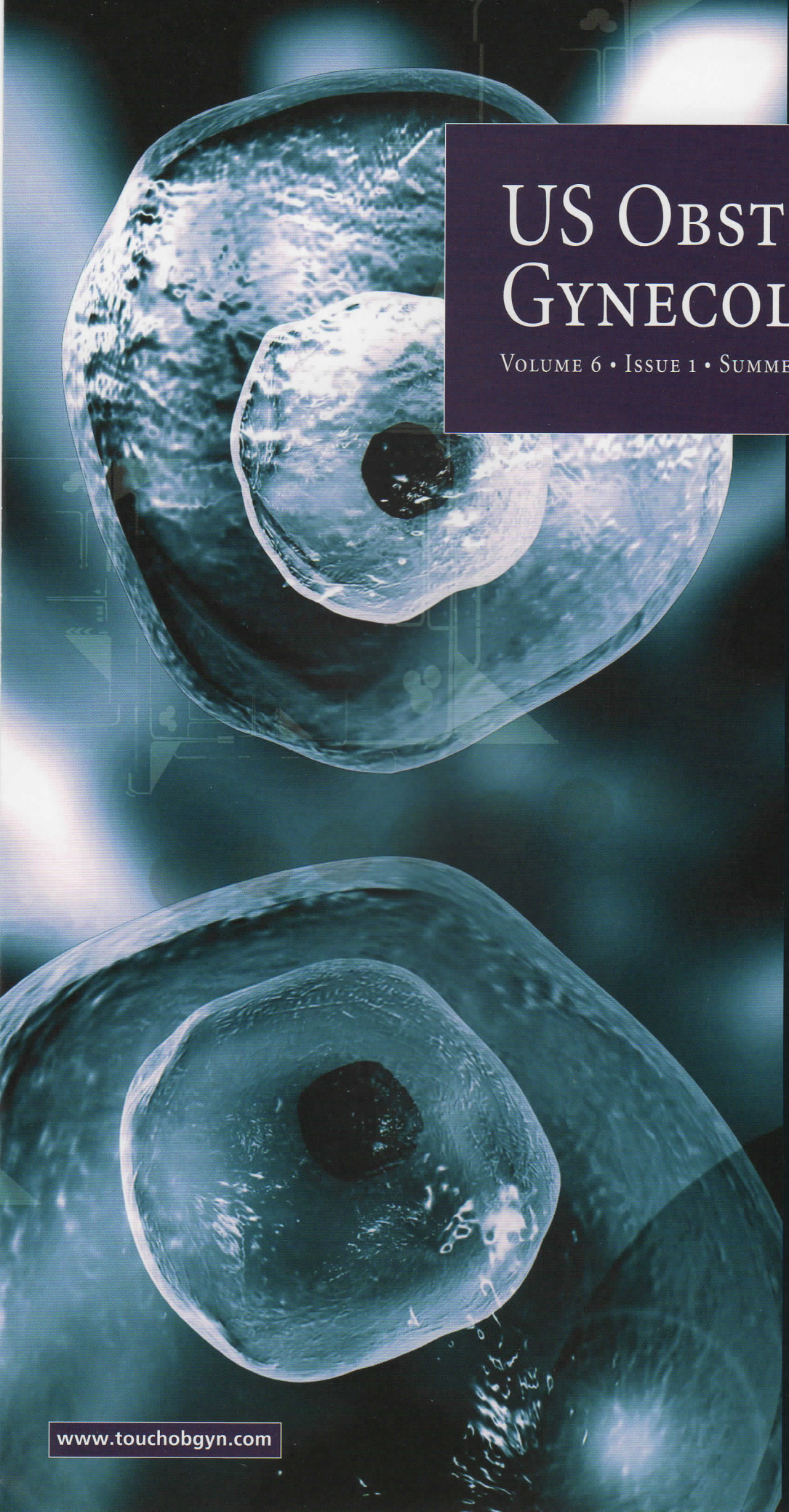

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Results of a Novel Device Designed to Reduce the Occurrence of Hemorrhoids Resulting from Vaginal Deliveries

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Abstract

The purpose of this study was to prospectively assess the effectiveness of the Hem-Avert® Perianal Stabilizer in reducing the occurrence and/or severity of hemorrhoids and/or thrombosed external hemorrhoids attributable to vaginal delivery. Between July 2007 and May 2009 a total of 98 healthy pregnant women were randomized to either the Hem-Avert or control groups at admission for delivery. Success was based upon the absence of either new hemorrhoids and/or progression of pre-existing hemorrhoids postpartum. All investigational patients delivered without any new occurrence of hemorrhoids. Women exhibiting hemorrhoids at admission and randomized to the Hem-Avert group did not encounter hemorrhoid progression. Thirty-three percent of women, hemorrhoid-free at admission and randomized to the control group, developed hemorrhoids. Women diagnosed with hemorrhoids at admission and randomized to the control group encountered hemorrhoid progression. In this limited study, the Hem-Avert Perianal Stabilizer was shown to prevent new occurrences of hemorrhoids and hindered the progression of existing hemorrhoids during vaginal delivery.

Keywords

Postpartum maternal care, delivery-induced hemorrhoids, thrombosed external hemorrhoids

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Background and Objectives

Hemorrhoids and thrombosed external hemorrhoids (TEH) represent common adverse events in vaginal births. Both are produced by blood pooling in a distended vein and forming a clot, or thrombus, in the outer region of the anus. Hemorrhoids are dilated veins in which the valves returning the blood flow are damaged. Damage can occur when these veins become engorged by an increase in abdominal cavity pressure due to pregnancy and childbirth.

While hemorrhoids are a non-life-threatening condition, they generate acute pain, and, in instances of TEH, may require surgical treatment. Currently no preventative treatment exists. Post-outbreak treatments, for example, topical corticosteroid ointments and oral non-steroidal anti-inflammatories, offer non-surgical options to treat the condition, but do not avert the outbreak. Surgical treatment includes excision followed by sitz baths (after each defecation) and continued dexpanthenol ointment treatment. Reappearance of TEH after initial excisions is possible. Post-operative complications include bleeding and development of fistulas and/or abscesses.

Historically, midwives found applying pressure to the perianal region during delivery to support the rectum potentially reduced hemorrhoid occurrence or tearing severity. This method involves placing gauze on the hand and applying pressure on the anus as the head and shoulders breach the birth canal. This maneuver is difficult, given space and time constraints. This procedure also fails to provide consistent pressure, particularly during long deliveries.

The Hem-Avert® Perianal Stabilizer (Plexus Biomedical, Inc., Oakland, TN) was designed to provide consistent counter-pressure to the perianal region, while leaving the physician's hand movements unrestricted. Keeping the veins compressed to prevent overextension or engorgement may reduce or eliminate damage to venous structures. Once the baby is delivered and the device is removed, the veins revert to their natural state.

The Hem-Avert Perianal Stabilizer is a non-invasive device comprising three components:

- a rigid polymer base;
- a centrally located cushioning pad composed of a laminate of polyester non-woven tape and polyethylene foam tape; and
- two lateral fasteners (with liners), which provide the tension required to keep the device firmly in place during delivery.

Based upon a review of the literature and consultation with practitioners, our power analysis reflected an anticipated incidence of delivery-induced hemorrhoids of 30% for untreated control patients. The study's primary objective was to evaluate the safety and efficacy of the Hem-Avert device in reducing the occurrence and/or severity of hemorrhoids and/or TEH. For patients hemorrhoid-free at time of admission, success was defined as the absence of hemorrhoids and/or TEH after normal vaginal delivery. For patients with low-grade hemorrhoids at admission, success was defined as preventing hemorrhoid progression.

Methods and Materials

This prospective study was conducted in a randomized manner with 176 patients divided into two groups. Investigational patients received the Hem-Avert device during vaginal delivery. Control patients underwent the normal birthing process without the study device. Both groups met the same inclusion/exclusion and continuation criteria.

The study involved four obstetrics and gynecology (OBGYN) physician clinics (Women's Care Center, Memphis, TN; Southaven OBGYN, Southaven, MS; Just for Women, Memphis, TN; and Premier Women's Care, Covington, TN), and three delivery sites (Baptist Memorial Hospital for Women, Memphis, TN; Baptist Memorial Hospital-DeSoto, Southaven, MS; and Baptist Memorial Hospital-Tipton, Covington, TN). The study population consisted of women between the ages of 18 and 40, all scheduled for vaginal deliveries. Prenatal examinations indicated all participants anticipated single-birth deliveries.

At the time of the prenatal screenings, none of the prospective patients subsequently enrolled in the study demonstrated signs of hemorrhoids, lacerations, or anal fissures. Patients were automatically excluded if they had a previous rectal surgery, or if a rectal tag was present at the time of the initial physical examination. Presence of a rectal tag suggests previous hemorrhoids that have been reabsorbed.

Subjects were enrolled on a 1:1 (investigational:control) treatment randomization scheme. Eighty-seven subjects were enrolled in the investigational group and 89 subjects were enrolled in the control group. Informed consents were obtained from all study patients.

Upon admission for delivery, a physical examination was performed to document the presence of hemorrhoids, lacerations, and/or anal fissures at the initial stages of cervical dilation. Patients admitted already fully dilated or evidencing crowning were excluded from the study. Investigators measured the perineum to determine if the area was sufficient to properly seat the device. Patients with a perineum length <2 cm were excluded from the study. Physical variables were not significantly different for either group of patients who were hemorrhoid-free at admission as shown in *Table 1*.

Investigational patients had the Hem-Avert device attached when cervical dilation reached 8–10 cm. Application of the device was performed using two hook-and-loop fastener adhesive strips attached to the patient's buttocks and outer thighs. Natural tension created by the straps provided constant pressure to the perianal region and kept the device firmly in place. The device remained attached until the end of the second stage of labor (see *Figure 1*).

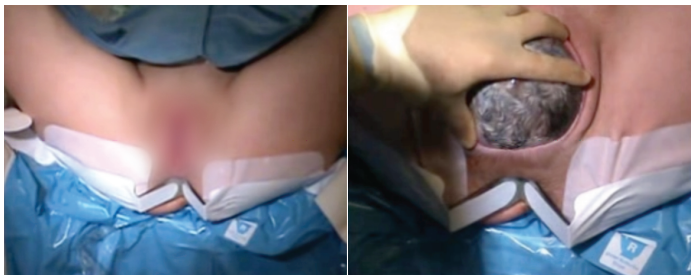
Table 1: Comparison of Patient and Delivery Characteristics

Characteristic Compared	Hem-Avert Group	Control Group
Total patients	34	52
Mean age (years)	25.3	23.6
Mean patient weight (lbs)	186.4	188
Previous pregnancies	25 (73.5 %)	32 (61.5 %)
Mean infant weight (lbs)	7.0	7.1
Minimum–maximum	5.0–9.3	4.1–8.9

Table 2: Study Results

Summary	Hem-Avert	Control	p-value
Efficacy subjects	40	58	
Treatment success for subjects with low-grade hemorrhoids at admission			
Success	6 (100 %)	4 (66.7 %)	
Failure	0	2 (33.3 %)	
Total	6	6	0.0003
Treatment success for subjects with no hemorrhoids at admission			
Success	34 (100 %)	39 (75 %)	
Failure	0	13 (25 %)	
Total	34	52	0.0012

Figure 1: Placement of Hem-Avert Device



Hem-Avert placement prior to delivery

Infant delivered with Hem-Avert in place

Results

Investigators screened 202 subjects for the study between July 31, 2007 and May 26, 2009, with 176 patients meeting the enrollment criteria. Seventy-eight of the 176 randomized subjects were excluded due to protocol restrictions (e.g., perineum <2 cm; baby crowning at admission; delivered at non-investigational facility; converted to Cesarean section; episiotomy required). Biostatistical analysis included Fisher's exact test for categorical variables, Pocock alpha for determining p-values, and the rank-sum test for numeric measures. Ninety-eight patients were evaluated for the final analysis reported in *Table 2*.

Device efficacy was determined through a subject postpartum physical evaluation on the day of discharge. Investigators recorded whether hemorrhoids and/or TEH were observed. If either were present, the investigator graded the severity of the condition observed in each group using a five-point scale developed by the investigator. This scale measured the percentage of anal coverage involvement and was implemented at admission and at 24 hours postpartum.

Fully 100% of the Hem-Avert patients who were hemorrhoid-free at admission remained hemorrhoid-free at discharge and achieved treatment success. Comparatively, 25 % of the control subjects were discharged with delivery-induced hemorrhoids. Also, patients admitted into the center presenting with hemorrhoids and randomized to Hem-Avert saw no progression of hemorrhoids during or after delivery. Conversely, 33 % of control group subjects exhibiting hemorrhoids at admission encountered hemorrhoid progression of at least one grade on the grading scale. Although not a designated outcome measurement, the investigators noted anecdotally that women randomized to the Hem-Avert group did not defecate during delivery. Women assigned to the control group did defecate unintentionally during delivery, which is a common occurrence. Upon removal of the device, normal fecal seepage routinely observed during vaginal delivery resumed.

Adverse Events

Any complication attributable to use of the Hem-Avert device during delivery, as determined by the investigator, was considered as an adverse event. No adverse events or complications involving the investigational device occurred.

Discussion

Postpartum incidence of hemorrhoids is acknowledged as under-reported according to the literature. Brown and Lumley attributed patient embarrassment as an underlying cause.[1] In their retrospective study of 1,336 women, they also found that infant weight plays a role. In their study, 30.6 percent of women who birthed infants greater than 8.8 pounds encountered postpartum hemorrhoids. A study of 2,413 women by Schytt, Lindmark, and Waldenstrom found that 24.6 % of women who delivered vaginally sustained post-delivery hemorrhoids.[2] Schytt et al. suggest that health-related issues such as hemorrhoids go unreported because women consider these 'inconveniences' as natural, temporary byproducts of pregnancy. Yet other studies conclude that hemorrhoids do not resolve quickly, particularly among those who require assisted vaginal delivery.

A study of 1,193 women by Thompson et al. found hemorrhoids affected 37 % of the patients who required assisted vaginal delivery compared with a 30 % incidence rate among unassisted deliveries.[3] During follow–up examination nine to 16 weeks post-delivery, 19 % of the assisted patients continued to suffer from hemorrhoids, as did 17 % of the unassisted patients. When examined during the 17 to 24-week time point, the percentage remained at 19 % for the assisted patients, while for the unassisted patients it dropped to 12 %.

Abramowitz et al. found the appearance of TEH is common among women suffering from dyschezia (5.7 odds ratio), carrying heavier babies, or having superficial perianal tears during childbirth.[4] Initial patient discussions prior to our formal study enrollment found apprehension of developing delivery-induced hemorrhoids was greater than originally considered. Investigators discovered that, since physicians never routinely initiated discussions on hemorrhoids previously, patients rarely brought the issue up. However, from discussions with patients, we are learning that this is an important concern among women. The patients' desire to try this investigational device was surprising. Some patients were forced to be dropped from the study, as they insisted upon receiving the device rather than risk randomization to the control group.

Case Studies

Three case studies viewed as typical of this study's findings are presented here.

Case 1: A 32-year-old woman admitted for induction at 38 weeks. She had two previous vaginal deliveries of infants weighing between six and seven pounds. She reported experiencing severe hemorrhoids after each previous delivery. The second delivery resulted in thrombosed hemorrhoids requiring surgical intervention three months after delivery. Upon admission and subsequent dilation, the Hem-Avert device was attached. She labored for four hours and 45 minutes, during which she pushed for 25 minutes. She delivered a seven pound, two ounce infant (9/9 Apgar). No hemorrhoids were evident after delivery. Six days postpartum the patient had no evidence of hemorrhoids.

Case 2: A 34-year-old control subject induced at 40 weeks. Upon admission the patient had Grade 1 hemorrhoids covering 15 % of the anus. The patient labored for approximately five hours and pushed for approximately 30 minutes. She delivered an eight pound, ten ounce infant (9/9 Apgar). At day one postpartum the patient had Grade 2 hemorrhoids covering 35 % of the anal opening.

Case 3: A 29-year-old investigational patient admitted for induction at 39 weeks gestation. She had a previous vaginal delivery without hemorrhoid occurrence during or after the pregnancy. Complete cervical dilation occurred following four hours of labor after admission. She pushed for 20 minutes before delivering a six pound, 13 ounce infant with an Apgar score of 8/9. She experienced no hemorrhoids postpartum.

Conclusions

In this limited prospective randomized study, none of the patients who used the Hem-Avert Perianal Stabilizer and were hemorrhoid-free at the time of admission developed hemorrhoids. By comparison, 25 % of control patients hemorrhoid-free at admission developed hemorrhoids as a direct result of labor and delivery. Perhaps more telling were the patients who exhibited hemorrhoids at admission. In those cases, patients fitted with the Hem-Avert device demonstrated no hemorrhoid progression, while control patients encountered progression in the severity of hemorrhoids directly attributable to labor and delivery. The Hem-Avert Perianal Stabilizer demonstrated the potential to reduce the possible occurrence of delivery-induced hemorrhoids without risk to the patient. The device provided hands-free perianal pressure and did not obstruct delivery. n

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