Neonatal Subgaleal Hemorrhage Following Vacuum Extraction Delivery
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Citation

Abstract
A rare complication of vacuum extraction delivery is subgaleal hemorrhage which may be associated with significant morbidities such as anemia, hypotension, persistent metabolic acidosis and hyperbilirubinemia.

Background: Instruments such as vacuum extractors and forceps are used in ten percent of all vaginal deliveries. Currently, in the United States, the use of vacuum extractors is twice as frequent as that of forceps. A rare, but potentially lethal complication of vacuum extraction deliveries is subgaleal hemorrhage (SGH). This potentially lethal complication of vacuum extraction vaginal delivery is frequently unrecognized or incorrectly diagnosed. More importantly, the pediatric literature in the United States is devoid of a systematic reports and review of this not very infrequent neonatal problem.

Methods: Fifteen cases of SGH following vacuum extraction deliveries are presented with detailed descriptions of two cases, one resulting in death and another resulting in long-term morbidity. With this case reports, current literature was reviewed and a detailed description of the instrumentation, frequency of its use, traumatic complications, predisposing risk factors, clinical features of SGH, its recognition, and its differential diagnosis is provided.

Results: SGH was frequently associated with intracranial hemorrhage and/or cephalohematoma making its diagnosis more difficult by the healthcare providers. Moderate to massive size SGH was associated with anemia, metabolic acidosis, hyperbilirubinemia, intracranial hemorrhage, respiratory distress, seizures, shock, and death. In most cases, SGH following vacuum extraction vaginal delivery was not recognized or there were significant delays in correct diagnosis. The delay in correct diagnosis and the institution of early and appropriate treatment may have resulted in significant morbidity and even mortality.

Conclusions: It is recommended that the neonatal healthcare providers should be made aware when vacuum extractors are used, and be familiar with possible complications associated with its use. If vacuum extractor is used, neonates should be frequently evaluated for early diagnosis of SGH, and the institution of early treatment should be implemented with the hope of minimizing neonatal morbidity and mortality.

INTRODUCTION
Operative pelvic delivery is an important component of obstetrical care (1). Instrumented vaginal delivery, with the use of forceps and vacuum extraction, is fairly common in the United States and Europe as well as in developing countries (2,3,4,5,6). In the United States, vacuum extraction has replaced forceps as the preferred method of instrumented delivery (7,8,9). Reporting their experiences, over a five year period (1979-84) for instrumented deliveries, Broekhuizen et al. (9) noted that the use of vacuum extraction has increased from 0.3 to 3.1%, while forceps use declined from 10.1 to 4.9%. In 1999, report by the National Center for Health Statistics (10) notes that between 1989 and 1997, the use of forceps declined 49% (5.5% to 2.8% of all births) and the use of the vacuum extraction increased 77% (3.5% to 6.2%). By 1992, in the Netherlands, vacuum extraction was used twice as often as forceps for instrumental vaginal delivery (11). By the same year, the number of vacuum deliveries in the U.S. surpassed the number of forceps deliveries, and by 1997, the ratio of vacuum to forceps deliveries was more than 2:1 (10).

Instrument-assisted deliveries are associated with an increased risk of significant birth trauma (12,13). In randomized clinical studies, vacuum extraction deliveries, when used judiciously, were associated with minimal rates...
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of significant intracranial injuries ($\text{i}_\text{d}$). Rigid vacuum extractors are more effective than pliable instruments but are associated with more fetal scalp trauma ($\text{i}_\text{f}$). A rare, but serious and, at times, fatal complication of vacuum extraction delivery is subgaleal (subaponeurotic) hemorrhage (SGH) ($\text{i}_{16,17}$). Hemorrhage in subaponeurotic space of the scalp occurs gradually and may progress to massive hemorrhage and disseminated intravascular coagulation, hypovolemic shock and death. The lesion may not be apparent soon after birth and is commonly incorrectly diagnosed as a large caput succedaneum or cephalohematoma. As it was noted previously, this potentially fatal entity has not received the necessary attention in the pediatric literature ($\text{i}_{18,19}$). Based on our experience, pediatric residents, pediatricians and neonatologists very frequently fail to diagnose SGH. Our experience with SGH is reported with emphasis on its occurrence, neonatal morbidity/mortality and the early recognition of SGH and possible treatment.

**CASE PRESENTATIONS**

During a period of several years in our practice, we cared for or consulted on, 15 cases of neonatal scalp injuries involving SGH. Table 1, is a summary of these cases related to vacuum extraction deliveries with their birth weight, gestational age, associated injuries, and infants' morbidity and mortality. Two representative cases are reported in detail to emphasize diagnostic difficulties and significant morbidity and mortality associated with SGH.

**CASE 1**

A 2200 g birth weight, female infant delivered vaginally post vacuum application at 34-35 weeks gestation. The infant's mother was a 24 year old, gravida 2, para 1. Her antenatal laboratory tests were normal but her vaginal culture was positive for group B Beta-hemolytic streptococcus. Her previous child was delivered at term gestation by vaginal breech presentation without any complications. Her antenatal laboratory tests were normal but her vaginal culture was positive for group B Beta-hemolytic streptococcus. Her previous child was delivered at term gestation by vaginal breech presentation without any complications. During the two weeks prior to this delivery she was admitted twice to the hospital, and observed for several hours only for vaginal spotting and premature labor. She was given subcutaneous and oral terbutaline. She received two doses of ampicillin, one on admission and another 3 hours prior to delivery. The delivery was vaginal vertex with vacuum extraction. The obstetrician noted that there was shoulder dystocia with severe molding of the infant's head. At birth, the attending neonatologist described the infant to be pale, flaccid with no audible heart sound and no respiratory effort. The delivery was vaginal vertex with vacuum extraction. The obstetrician noted that there was shoulder dystocia with severe molding of the infant's head. At birth, the attending neonatologist described the infant to be pale, flaccid with no audible heart sound and no respiratory effort. The infant was resuscitated with endotracheal intubation, external cardiac massage and positive pressure ventilation with 100% oxygen. The first gasp was noted at about one minute of life. The Apgar scores were assigned as 2 at one, 4 at 5 and 6 at 10 minutes of life. Upon admission to the NICU the infant was described to be grossly pale with poor perfusion, lethargic, decreased muscle tone and shocky in appearance with blood pressure of 32/21 and mean of 25 mmHg. The infant was described by the attending neonatologist as having a large caput and “mushy” scalp. At 16 hours of life
the attending nurse described the infant as having a large left parietal cephalohematoma with “a very heavy and boggy” head. The infant’s initial capillary HCT was 27%. For the first 24 hours of life the infant received multiple boluses of albumin, FFP, and packed RBC’s, together with broad spectrum antibiotics, dopamine and dobutamine. The infant remained hypotensive with a bleeding tendency, a persistent metabolic acidosis, and no urine output. Septic shock and disseminated intravascular coagulation were diagnosed prior to the transport of the infant to a regional tertiary NICU. The admission diagnoses at the receiving hospital were: 1) 34-35 weeks gestation, AGA, female infant; 2) respiratory failure; 3) septic shock; 4) hypotension secondary to septic shock; and 5) DIC secondary to septic shock. About 24 hours post admission a neurosurgical consultation was obtained. The diagnosis of massive subgaleal hemorrhage (Figure 1) due to vacuum application was made by the neurosurgeon as the principal reason for this infant’s problems. The infant remained anuric for several days and developed anasarca. Peritoneal dialysis was done. Despite intensive therapy, the infant developed systemic fungal infection at 2 weeks of life and expired.

Figure 2
Figure 2: Photograph of Case 1. Note the elongated head with massive subgaleal hemorrhage. The blood collection in subgaleal space was gravity dependent. Elevation of the right ear is also noticeable. This infant expired secondary to renal failure and subsequent systemic fungal infection. Written parental consent was obtained for the publication of this photograph.

CASE 2
A 3100 g birth weight male infant delivered vaginally at 37 6/7 weeks gestation to a 25 year old caucasian woman, gravida 2, para 0 with one therapeutic abortion. The mother's blood type was 0, Rh negative with antibody screen negative. She received Rhogam at 28 weeks gestation. She was admitted for elective induction. There was prolonged second stage of labor. The obstetrician recorded that at 2+ station with occiput anterior, the vacuum was applied to the infant’s scalp to expedite delivery. After several attempts, it did not result in the descent of the fetal head therefore forceps was applied to effect delivery with midline episiotomy. The attending pediatrician described the infant to be limp, cyanotic with no respiratory effort. Airway suction, positive pressure ventilation with bag and mask and 100% oxygen was carried out for 2 minutes. The assigned Apgar scores were 6 at one, 8 at 5 and 9 at 10 minutes of life. The infant was admitted to the regular nursery with the recommendation of close observation and monitoring with pulse oximetry. At about 2 hours of life a capillary hematocrit was 54%. At 6 hour of life a second year pediatric resident evaluated the infant and reported the infant to be stable, not in acute distress, but having a large caput. Pulse oximetry was discontinued. A repeat HCT at this time was noted to be 41.7%. The attending pediatrician re-evaluated the infant at 11 hours of life. He recorded the head circumference of 34 cm. He noted that “the infant had cranial molding with cephalohematoma or subgaleal hematoma (not subperiostal) of about 20 cc volume”. He also described “waves can be seen when handled”. The infant’s blood type was O, Rh positive with negative direct Coombs test result. At 35 hours of life the infant’s serum total bilirubin was 8.3 mg%. The infant was discharged home soon after a second physical examination by the pediatrician. At the time of discharge, the nursery attending nurse noted: “Molding of head: Elongated or misshapen head. Head shapes according to birth canal for easier birth. It will round out in a few days. Puffy eyes may be due to trauma of delivery or the eye ointment”. The infant was taken to the pediatrician’s office 4 days post discharge or at the 6th day of life. His weight was 3140 g (birth weight 3100 g). He was noted to be markedly jaundiced. Serum total bilirubin was 30.6 mg%. With the diagnosis of “severe hyperbilirubinemia due to the resolution of hematoma which was the result of vacuum application”, the infant was immediately admitted to the hospital. He underwent a double volume blood exchange transfusion. Post-exchange serum total bilirubin was 17.1 mg%. Soon after admission for exchange transfusion, the infant was noted to be jittery and having seizure-like activities. An EEG showed multiple seizure foci arising from both temporal regions, right greater than left. Prior to discharge a hearing test revealed bilateral
neurosensorial hearing loss. Follow-up neurological evaluations showed persistence of abnormal EEG with seizure disorder and bilateral neurosensorial hearing loss.

DISCUSSION

Instrumentation. Current vacuum instruments used in obstetrical practice are based on the original design by Malmstrom in 1950’s (20, 21). Subsequently, the use of vacuum extraction-assisted delivery has become widespread in Europe (22). Malmstrom's metal cup is a hollow hemisphere with incurved margins, designed to be filled with artificial caput succedaneum. A traction chain is passed through suction tubing, which is attached to a short metal pipe at the dome of the cup, and a hand-pump is connected through a suction bottle. The suction induces an artificial caput succedaneum or chignon within the cup to which a traction force is applied in concert with uterine contractions. In the early 1970's, a soft vacuum cup was introduced with several modifications. Currently available soft vacuums are made of soft rubber, rigid plastic, soft silicone, and rigid or soft polyethylene. These are manually or electronically operated (7). These soft vacuum extractors have become the predominant instrument used for operative vaginal delivery in the United States (10). Significant scalp injuries, hematomas, and resulting hyperbilirubinemia are more common with the metal cup instrument compared with the soft cup devise (9).

Indications for Use of Vacuum Extractor. The American College of Obstetricians and Gynecologists has published guidelines for the indications of vacuum use for maternal and fetal reasons (23, 24). Maternal reasons include failure to deliver vaginally following the appropriate management of the second stage of labor. Fetal indications are fetal distress in the second stage of labor, with clinical evidence of increasing risk for fetal hypoxia requiring prompt delivery of the infant. Other indications are fetal compromise defined as, or related to intrauterine growth restriction/oligohydramnios preceding labor, placenta abruption and cord entanglement. Relative contraindications for its use are fetal malpresentation, prematurity with gestational age less than 37 weeks (absolute contraindication for gestational age less than 34 weeks), prior fetal scalp sampling and mid-pelvic delivery. Additionally, further recommendations were made regarding the application of cup pressure, traction, pressure release and discontinuation of its application based on cup dislodgements, lack of progress and the duration of its use. In Table 2, predisposing risk factors associated with complications associated with vacuum extraction deliveries are described.

Figure 3
Table 2: Predisposing Risk Factors for Complications Associated with Vacuum Extraction Deliveries.

Complications Associated With Vacuum-Assisted Deliveries. Compared to obstetric forceps, the vacuum extractor is easier to apply and has less maternal injuries. However, the vacuum extractor is associated with significantly more fetal injuries (9, 25, 26, 27, 28, 29). Fetal/neonatal injuries include scalp lacerations and bruising, SGH, cephalohematoma, intracranial hemorrhage, neonatal jaundice, subconjunctival and retinal hemorrhage, shoulder dystocia, clavicular fracture, skull fracture, and fetal death (9). Following 12 reports of deaths and nine serious injuries in 4 years, in May 1998, the FDA released a public health advisory based on a need for caution when using vacuum assisted delivery devices citing the occurrence of subgaleal hematoma and intracranial hemorrhage (30). It encouraged the reporting of adverse events to the FDA citing The Safe Medical Devices Act of 1990 which requires hospitals and other user facilities to report deaths, serious illnesses, and injuries associated with the use of medical devices. In September of the same year, the American College of Obstetricians and Gynecologists, Committee on Obstetric Practice published a Committee Opinion stating that, as with any other obstetric procedure, obstetric care clinicians using vacuum-assisted delivery devices to effect operative vaginal deliveries should be appropriately trained and familiar with the indications and contraindications for the use of the device, as well as with its proper application and traction procedure. The Committee on Obstetric Practice strongly recommended the continued use of vacuum-assisted delivery devices in appropriate clinical settings (31). During the 6 months following the FDA advisory, there were 10 neonatal deaths, 30 life-threatening events, 12 none life-threatening events, and three equipment-related reports. Infant deaths were due to intracranial or subgaleal hematomas. Other injuries included skull fracture, scalp abrasions, and
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In February 1999, Health Canada, Health Products and Food Branch, published its advisory entitled: “The Use of Vacuum Assisted Delivery Devices and Fetal SGH” (16). Table 3, depicts fetal/neonatal complications that can be associated with vacuum extraction deliveries.

Figure 4
Table 3: Potential Complications Associated with Vacuum Extraction deliveries.

<table>
<thead>
<tr>
<th>Complication</th>
<th>Description</th>
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</thead>
<tbody>
<tr>
<td>Scalp edema, i.e. bruising, hematoma</td>
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<tr>
<td>Large caput succedaneum</td>
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<tr>
<td>Subgaleal hemorrhage</td>
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<tr>
<td>Cephalohematoma</td>
<td></td>
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<tr>
<td>Intracranial hemorrhage (subdural, subarachnoid, intraventricular and cerebral)</td>
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<tr>
<td>Skull fracture</td>
<td></td>
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<tr>
<td>Gastrointestinal</td>
<td></td>
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<tr>
<td>Anemia, metabolic acidosis, hypotension, shock and disseminated intravascular coagulation</td>
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<tr>
<td>Hyperbilirubinemia</td>
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<tr>
<td>Shoulder dystocia</td>
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<tr>
<td>Clavicular fracture</td>
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<tr>
<td>Fracture of clavicle (\times) (\times) (\times) (\times)</td>
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<tr>
<td>Subconjunctival hemorrhage</td>
<td></td>
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<tr>
<td>Retinal hemorrhage</td>
<td></td>
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<tr>
<td>Fetal/neonatal death</td>
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</table>

Sequential use of forceps and vacuum. The vast majority of deliveries can be accomplished with only one instrument. On occasion, both forceps application and vacuum extraction are utilized to effect vaginal delivery. Broekhuizen et al. (9), an early advocate of the use of vacuum, discouraged the sequential use of vacuum extraction and forceps. In a prospective, randomized study, Williams et al. reported on patients delivered by sequential use of forceps after vacuum or by vacuum after failed forceps application did not suffer significantly increased morbidity relative to those delivered by forceps or vacuum alone (16). Similarly, Ezenagu et al. (32), reviewing the sequential use of vacuum and forceps, concluded that the prudent use of sequential instruments at operative vaginal delivery did not engender higher rates of maternal or neonatal morbidity. Other reports (1, 4, 13, 33, 34, 35) found increased fetal/neonatal complications associated with the sequential use of vacuum and forceps.

Subgaleal Hemorrhage. Subgaleal hemorrhage occurs when emissary veins bridging the subgaleal space are damaged and blood accumulates in the potential space between the galea aponeurotica (epicranial aponeurosis) and the periosteum of the skull bones (pericranium). Since the subaponeurotic space has no containing membranes or boundaries, the SGH may extend from the orbital ridges to the nape of the neck. This condition is dangerous because of the large potential space for blood accumulation with a volume of several hundred milliliters (7). This blood loss can produce profound hypovolemic shock, disseminated intravascular coagulation (DIC), unresponsive metabolic acidosis and death. The hemorrhage in the subgaleal space is not instantaneous but is gradual and it may not be apparent or diagnosed at the time of delivery or at the initial neonatal examination during the first few hours of life. It may not become clinically apparent until several hours or up to a few days following delivery. Based on our experience, SGH may be initially confused with large caput succedaneum or cephalohematoma. Although a caput succedaneum, which is made of edema and transudation into the dermis, is commonly present with a SGH, it should regress by the first 24 hours of life. Cephalohematoma, on the other hand, is a subperiostial hemorrhage, which may not be apparent at the time of delivery. Initially it is tense in consistency and is limited to the individual skull bone with which it is associated and does not cross the midline. A persistent fluctuating and boggy scalp lesion persisting after 24 hours of life should suggest the diagnosis of SGH. The head will appear elongated (Figures 1 and 2) with considerable molding of the skull bones. The lesion is fluctuating and gives the sensation of an old leather pouch filled with fluid. The fluid will be gravity dependent and accumulates on the dependent aspects of the head. In severe cases of massive SGH, there can be elevation and displacement of the ear lobes and puffiness of the eyelids without superficial ecchymosis of the overlying skin. Massive SGH is frequently associated with hypovolemic shock, DIC, persistent metabolic acidosis and death despite treatment with transfusions of blood and blood products. Associated findings are low Apgar scores, pallor, tachycardia, increased respiratory rate, hypotension and neonatal anemia.
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Figure 5
Figure 2: Photograph of the head of case #3 in the table taken by the 4th day of life. The scalp shows ecchymosis and gravity dependent subgaleal blood collection. Because of anemia, persistent hypotension and metabolic acidosis, in addition of vasoactive drugs, this infant received 90cc/Kg of FFP and packed RBC’s during the first few hours of life. He was also treated with phototherapy for hyperbilirubinemia. Written parental consent was obtained for the publication of this photograph.

LITERATURE REVIEW
Except for a few case reports, the pediatric literature in the United States is devoid of systematic reports on the problem of neonatal SGH (35, 36, 37, 38, 39). Conversely, European and world literature have more published systematic reports on vacuum-assisted delivery and SGH (40, 41, 42, 43, 44, 45, 46). Several prospective and retrospective studies examined the association between vacuum-assisted deliveries and the incidence of SGH (13, 14, 46, 53, 54, 55, 56). In a retrospective review of 583,340 live-born singleton infants born to nulliparous women in California between 1992 and 1994, and weighing between 2500 and 4000 g, 59,354 infants were delivered by vacuum extraction and 2,817 were delivered by combined use of forceps and vacuum extraction (13). Intracranial hemorrhage was diagnosed in 1 of 860 infants delivered by vacuum extraction. This complication was significantly less than previously reported by Plauche (13) who reviewed 15 studies involving a total of 7,124 deliveries with the use of the metal Malmstrom vacuum extractor, and found an incidence of 1 in 286 infants. A recent population-based historical cohort study in the Canadian province of Quebec to assess the maternal and infant outcomes associated with vacuum extraction and forceps deliveries was reported by Wen et al. (50). The study involved singleton live births with a non-breech presentation at the gestational age of 37 or more completed weeks and a birth weight between 2,500 and 4,000 g during fiscal years 1991/1992 to 1995/1996. Of the births, 31,015 were delivered by vacuum extraction, and 18,727 were delivered by forceps. This study results were different from the California study reported by Towner et al. (13), regarding the incidence of maternal and neonatal morbidity and mortality. Buekens (57), commenting on Wen et al. (50) study, noted that in the California study, subarachnoid hemorrhages were not more frequent among vacuum extractions compared with forceps. He further noted that the differences in results between the California and Quebec studies are puzzling. Frequencies of subarachnoid hemorrhages among babies who delivered spontaneously were similar in the two studies, suggesting that differences in measurement were limited. Towner et al. (13) noted that the occurrence of intracranial hemorrhage was similar with vacuum extractors alone, vacuum extractors combined with forceps application and delivery by cesarean section during labor, but it was significantly higher than those infants spontaneously delivered vaginally. The clinical information in the database, reported by Towner et al. (13) was limited to data entered on birth certificates, death certificates, and International Classification of Diseases, 9th Revision Diagnostic Codes and Current Procedural Terminology Procedural Codes abstracted from the mother’s and infant’s discharge summaries. While reporting the incidence of subdural, subarachnoid, cerebral and intraventricular hemorrhage, both studies by Towner et al. (13) and Wen et al. (50) did not report the incidence of SGH. We suspect that the information regarding subgaleal hemorrhage was not part of the database or the presence of the SGH was not recognized. It is this author’s opinion that with the application of vacuum extractor in 59,354 and by combined use of forces and vacuum extraction in 2,817 deliveries, there were a substantial number of occurrences of SGH alone or in association with the intracranial hemorrhage which was not recorded or recognized. The incidence of subgaleal hemorrhage is estimated to occur in 4 of 10,000 spontaneous vaginal deliveries and in 59 of 10,000 vacuum-assisted deliveries (58). In a prospective study Gebremariam (59) examined data over 5 years on 69 newborns with SGH from a cohort of 23,353 live and term deliveries. That study demonstrated an incidence of SGH of 3.0 per 1000 live and term births. In a 30-month prospective study involving 64,424 Malaysian neonates, 101 cases were found to have subaponeurotic hemorrhage shortly after delivery (60). In a
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Retrospective analysis of data on vacuum-assisted deliveries, during a two time periods 1983-85 and 1993-95, involving 17,110 and 18,599 deliveries respectively, there were 4.85% and 2.65% vacuum-assisted deliveries. The respective perinatal morbidities were 10.82 and 8.93 and mortalities were 15.13 and 11.12 per 1000 deliveries. In a review of 278 consecutive vacuum extraction cases occurring in an 18-month period in a community hospital setting, Plauche reported significant trauma to the fetal scalp in 18.7% of cases.

Diagnosis and Management. Early recognition of SGH and the institution of supportive care such as blood transfusion, volume support, and coagulation factors, in the presence of DIC, may be useful. Palliative treatment such as head wrapping has limited value. We believe that SGH occurs more frequently than is reported in the obstetrics and pediatric literature. This is most likely due to failure of diagnosis, partly because of its association with intracranial hemorrhage. Lack of experience of the pediatricians due to their limited time in neonatal care during their training may be another reason for failure to diagnose SGH. Subgaleal hemorrhage is associated with significant neonatal morbidity and mortality. Early recognition and treatment of SGH is critical. Serial observations for neonatal scalp changes, as described above, signs of pallor, anemia, metabolic acidosis and hypovolemia are recommended after vacuum-assisted deliveries. In table 4, the clinical feature of SGH is described in order to help the reader to be vigilant about the rare occurrence of this serious complication with the application of vacuum extractor. We understand the limitations of this report which is based on personal clinical experiences and it is not intended to be repudiation for the proper and the judicious use of vacuum in the practice of obstetrics. The obstetrician should inform the neonatal healthcare providers that a vacuum extractor was used to effect delivery. Neonatal staff should be educated about the specific complications associated with vacuum devices. Neonatal healthcare personnel should evaluate the infant frequently in order to timely diagnose and institute appropriate therapy in order to avoid serious morbidity and/or neonatal death.

Table 4: Features of Clinically Significant Subgaleal Hemorrhage.

- Vacuum extraction with or without forceps application delivery.
- Diffuse scalp swelling associated with neonatal distress, i.e. Pallor, tachycardia, tachypnea.
- Neonatal anemia with persistent metabolic acidosis, hypotension and/or disseminated intravascular coagulation.
- Occipital scalp swelling increasing in size after birth.
- Occipital scalp swelling persisting after 34 hours of birth.
- Persistent scalp swelling not confined to one skull bone.
- Scalp swelling which is gravity dependent. It shifts dependently when the infant’s head is repositioned.
- Scalp swelling developing fluctuance giving the sensation of a filled leather pouch.
- Scalp swelling extending to the neck, eyelids and ears.
- Persistent scalp swelling not confined to parietal bone.

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