DeviceSafety

Problems after vacuum-assisted childbirth

BY DIANE DWYEX. RN, BSN, AND SONIA SWAYZE, RN,C, MS
Nurse-Consultants • Center for Devices and Radiological Health
Food and Drug Administration • Rockville, Md.

TWO HOURS AFTER DELIVERY assisted by a vacuum extractor, an infant developed shortness of breath, poor perfusion, hypotension, and head swelling. The infant later died of subgaleal hemorrhage.

A vacuum extractor applies suction to the fetal scalp during childbirth. Infants delivered with this device commonly develop caput succedaneum (a fluid collection in the scalp) or cephalohematoma (a limited subperiosteal hemorrhage) — injuriesthat typically resolve without complications. However, the FDA has received reports of two much more serious complications:

• Subgaleal (subaponeurotic) **hematoma** can occur when emissary veins in the skull are damaged during extraction, causing blood to accumulate between the galea aponeurotica and the skull. Diffuse swelling may extend from the orbital ridges to the nape of the neck. The swelling shifts dependently with head position and indents easily on palpation. Occasionally, the infant develops hypotension and pallor without significant cranial findings. Subgaleal hematoma can trigger life-threatening subgaleal hemorrhage and hypovolemic shock at delivery or within a few days.

• Intracranial hemorrhage may be subdural, subarachnoid, intraventricular, or intraparenchymal. Signs and symptoms, which may not appear for several hours, include convulsions, lethargy, obtundation, tachypnea, a bulging fontanel, poor feeding, increasing irritability, tachycardia, and shock.

If you care for neonates, be aware of the possible complications of vacuum extraction. If an infant has undergone this procedure, closely monitor her for several days. Teach the parents how to monitor her and what signs and symptoms to report — specially if subgaleal hematoma or intracranial hemorrhage has already been identified. And be sure to report any adverse reactions to vacuum extraction to the FDA. N

See the FDA Public Health Advisory "Need for Caution When Using Vacuum Assisted Delivery Devices" at http://www.fda.gov/cdrh/safety.html from 5-21-98.

Although you need to support the adverse event-reporting process of your health care facility, you may voluntarily report a medical device that doesn't perform as intended by calling MedWatch at 1-800-FDA-1088 (fax: 1-800-FDA-0178). The opinions and statements in this report are those of the author and may not reflect the views of the Department of Health and Human Services. Device Safety is coordinated by Beverly Albrecht Gallauresi, RN, MPH, BS.