Get a Hematocrit in All Vacuum Delivery Cases

BY MICHELE G. SULLIVAN
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RIVIERA MAYA, MEXICO — All babies born by vacuum extraction should have an umbilical cord hematocrit drawn, and be closely monitored for changes that could signify a subgaleal bleed—an unusual injury in these deliveries, but the most devastating one possible, Dr. Michael G. Ross said at a conference on obstetrics, gynecology, perinatal medicine, neonatology, and the law.

"I suggest that all vacuum deliveries have an umbilical cord hematocrit. … It's easy, it's inexpensive and it gives you a benchmark as to where this baby started, so that if it starts behaving abnormally you can easily see what's happening [with regard to bleeding]," said Dr. Ross, chairman of obstetrics and gynecology at the University of California, Los Angeles.

A significant loss of blood may be detected by a decreasing hematocrit, thus increasing the likelihood of catching a potentially fatal bleed.

Intensive monitoring in the first few hours after birth, including noting blood pressure, heart rate, and cephalic swelling, can also help identify these babies, who can easily lose half their blood volume into the subgaleal space before being diagnosed.

All too often, these devastating bleeds escape notice until the baby is in serious danger. "Pediatricians are usually first concerned about anoxia, so they ventilate the baby, and then infection, so they give antibiotics. The initial hematocrit that's drawn in the nursery may come back as 45%, which can be read as a low normal, but which in reality may already be showing a loss of one-third of the baby's blood volume." The umbilical hematocrit provides a true baseline for the baby's red blood cells; a significant neonatal blood loss may be detected by decreasing hematocrit, greatly increasing the likelihood of catching a potentially fatal bleed, he said.

A subgaleal hemorrhage is a large collection of blood in the soft tissue space between the galea aponeurotica and the skull's periosteum. Unlike a cephalohematoma, this bleed crosses suture lines. The space in which it occurs can hold up to 250 cc of blood—equal to a baby's entire blood volume.

Most physicians first became aware of this complication after a 1998 FDA advisory described it in 12 unsolicited deaths and nine serious injuries after vacuum deliveries. After the FDA advisory, which asked physicians and hospitals to report vacuum-related neonatal injuries, 55 injuries came to light in just 6 months; 23 of these were subgaleal hemorrhages.

The American College of Obstetricians and Gynecologists has estimated the incidence as up to 4.5% in vacuum births, though this figure is greater than that of life-threatening subgaleal bleeds, which is likely closer to 1 in 1000 vacuum births. "We do feel that it is vastly, vastly under reported," said Dr. Ross, "The reported cases are probably just the tip of the iceberg."

Babies with this type of bleed usually begin acting abnormally about 1 hour after birth. The swelling on the head is soft to firm, fluctuant, and diffuse. In minor bleeds, the baby may be pale and show anemia. In major bleeds, there can be hypotonia, hypotension, seizures, and permanent brain injury.

Aside from restoring blood volume and administering coagulation factors and vitamin K, the best method of treatment remains unknown, Dr. Ross said. Surgery, drains, and wrapping the head have all been proposed, but there are no good data to support any of these options.

There are no firmly established risk factors for subgaleal bleeds. Preexisting hypoxia or coagulopathy have been proposed, but most proposals focus on vacuum extraction technique: difficult extraction, prolonged vacuum use, incorrect cup placement, rocking motions during extraction, and incorrect direction of traction.

"There are no good data to suggest that any of these factors really cause it, though," Dr. Ross said at the meeting sponsored by Boston University. "I have seen many cases [in legal settings] where there was one pull in the normal direction and the baby came right out, and there was a subgaleal bleed. Nevertheless the liability is such that we have to have good indications for a vacuum delivery and use the right methods, have the right number of pop-offs and the correct duration, because you *will* be held responsible for it if you don't follow the rules."

Attorney commentators at the meeting concurred that defending such cases is "extraordinarily difficult."

"It's almost as if the burden of proof is on the defendant to prove that there was an indication for the delivery and it was done correctly," said Brian McKeen, a plaintiff's attorney from Northville, Mich.

John Scully, a defendant's attorney from Dallas, Texas, agreed. "These are exceptionally difficult cases to defend in a courtroom. They evoke enormous sympathy from a juror. The defendant must walk a fine line by demonstrating that he did everything possible to deliver the baby safely and did it intensely and according to the standards of care, yet still persuade the jury that he did not use excessive force while doing it. And that can be a tough sell," he said. ■

DRUGS, PREGNANCY, AND LACTATION

Vaccines

Vaccines have arguably saved more lives and prevented more diseases than any other class of drug. The American College of Obstetricians and Gynecologists states that vaccination before conception is preferred to vaccination during pregnancy, but the benefits of immunization to the pregnant woman usually outweigh the theoretical risks (Committee Opinion, No. 282, January 2003). Only vaccines recommended for adults of reproductive age are discussed here.

BY GERALD G. BRIGGS, B.PHARM., FCCP

Vaccines are classified as bacterial or viral; whole (killed, inactivated, or live attenuated); or partial microorganisms that can induce antibody formation. Although vaccines can cause infections of the embryo or fetus, and pregnant women should be informed of the presence of live organisms if they are given a live attenuated virus vaccine, there is no convincing evidence that any vaccine, bacterial or viral, has caused fetal or embryonic harm. Theoretically, however, live attenuated bacterial or viral vaccines could cause disseminated infection in pregnant patients with impaired immunity, such as those with HIV or AIDS.

Indications for two bacterial vaccines (both capsular polysaccharide-quadrivalent meningococcal and polyvalent pneumococcal) are not altered by pregnancy. Vaccinating a pregnant woman with the live attenuated BCG vaccine is not recommended, but may be indicated if the woman works in a setting where many patients are infected with resistant strains of TB.

There are two typhoid vaccines available. The oral live attenuated virus vaccine is not advised during pregnancy, except when the mother's in continued, close exposure or travels to typhoid-endemic areas. The capsular polysaccharide intramuscular vaccine should be safer in pregnancy because it does not contain live bacteria.

Live attenuated virus vaccines are normally contraindicated in pregnant women because of the known or potential risks from the wild viruses. These include influenza intranasal, measles, mumps, rubella, smallpox, varicella, and yellow fever. Vaccinating in the postpartum period or avoiding conception for at least 30 days after inoculation are two strategies to avoid exposure during pregnancy.

A live attenuated virus vaccine may be indicated in pregnancy under special circumstances. For example, because the risk of fetal vaccinia is low, smallpox vaccine is recommended for pregnant women exposed to smallpox or monkeypox. Yellow fever vaccine also should be given in pregnancy if exposure is unavoidable.

Rubella infection early in gestation causes congenital rubella syndrome. Over a 10-year period, nearly 700 pregnant women were given rubella vaccine. There was no evidence of embryonic/fetal adverse effects, but subclinical infection was found in 2% of the infants from susceptible mothers. A woman given the vaccine 3 weeks after conception had documented embryonic/fetal infection throughout gestation but still delivered a healthy infant.

Though contraindicated, varicella vaccine may present less risk to the embryo and fetus than from infection with the wild virus. In a pregnancy registry of more than 800 women who had been vaccinated within 3 months of or anytime during pregnancy, there was no evidence of congenital varicella syndrome (CVS) or malformations consistent with it.

Inactivated poliovirus vaccine is not routinely recommended for adults living in the United States; however, it is recommended for unimmunized adults in close contact with a child receiving oral polio vaccine (OPV, which is not available in United States) or who have an increased risk of exposure to OPV or wild poliovirus. Hepatitis A (inactivated) and hepatitis B (recombinant surface antigen) vaccines can be used in pregnancy for pre- and postexposure in women at risk of infection.

The indications for rabies vaccine (killed virus) are not altered by pregnancy. There also seems to be no increased risk to the embryo or fetus from vaccination within 30 days of conception with quadrivalent human papillomavirus (HPV) recombinant vaccine. But if pregnancy is detected, ACOG suggests delaying completion of the three-dose vaccination schedule until after the pregnancy (Committee Opinion, No. 344, September 2006).

The ACOG considers vaccination with inactivated influenza vaccine to be an essential element of prenatal care (Committee Opinion, No. 305, November 2004). The vaccine can be given at any time during pregnancy, but the intranasal influenza vaccine, a live attenuated virus preparation, should not be used in pregnancy.

Excretion of live viruses from vaccines into breast milk may occur. There is a report of tertiary contact vaccinia transmission for smallpox vaccine from a mother to her nursing infant. The effects of the other live virus vaccines on a nursing infant are unknown, but the risk of adverse effects seems to be low. Vaccines that do not contain live viruses probably carry no risk to the infant.

There are pregnancy registries for four vaccines. Health care professionals should report exposures of pregnant women to the appropriate registry: hepatitis B vaccine (800-670-6126); HPV vaccine (800-986-8999); meningococcal vaccine (800-822-2463); and varicella vaccine (800-986-8999).

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