

Shoulder Dystocia Protocol Reduces Injuries

The rate of obstetric brachial plexus injury fell by nearly three-fourths in this study.

BY SUSAN LONDON

FROM THE ANNUAL MEETING OF
THE SOCIETY FOR MATERNAL-FETAL
MEDICINE

SAN FRANCISCO – A simple, standardized protocol for managing shoulder dystocia, called Code D, reduced the incidence of obstetric brachial plexus injury, according to a study reported at the meeting.

Investigators retrospectively assessed the impact of the protocol – which entails mobilization of experienced staff, a hands-off pause for assessment, and varied maneuvers – in a cohort of nearly 12,000 vaginal deliveries.

Study results showed that with use of the protocol, the rate of obstetric brachial plexus injury (Erb's palsy) among cases of shoulder dystocia fell by nearly three-fourths, from 40% before the protocol's implementation to 14% afterward.

"A standardized and simple protocol to manage shoulder dystocia appears to reduce the risk of Erb's palsy," said lead investigator Dr. Steven R. Inglis.

"We were unable to tell which part of the protocol really was helping us," he added, so further research is needed to determine the responsible components and maneuvers.

Rates of both shoulder dystocia and

VITALS **Major Finding:** The rate of obstetric brachial plexus injury in cases of shoulder dystocia fell from 40% before implementation of the Code D protocol to 14% afterward (*P* less than .01).

Data Source: A retrospective cohort study of 11,862 vaginal deliveries of singleton, live born infants.

Disclosures: Dr. Inglis did not report any relevant financial disclosures.

brachial plexus injury appear to be on the rise, in part because of increasing maternal obesity and diabetes, as well as increasing fetal macrosomia, according to Dr. Inglis, chairman of the department of ob.gyn. at the Jamaica (N.Y.) Hospital Medical Center.

These complications not only can be associated with long-term morbidity, but also account for a substantial share of

obstetricians' liability payouts, according to Dr. Inglis.

Many strategies for managing shoulder dystocia have been introduced, but few of them have been studied to assess their impact on important neonatal outcomes, he said.

Dr. Inglis and his colleagues determined the rate of brachial plexus injury at Jamaica Hospital Medical Center before

and after implementation of the Code D shoulder dystocia protocol. The protocol emphasized a stepwise team approach to management, conducted in a calm and relaxed environment.

Code D training was provided to all

labor and delivery staff including attending and resident physicians, midwives, and nurses. "I don't think anybody else has really included nurses," he commented. "I think they were a key part of it."

Training included didactic presentations followed by hands-on practice with a manikin. "Everybody had to go through shoulder dystocia once or twice

and get it done right according to our protocol," Dr. Inglis explained.

When the staff diagnosed dystocia (tight or difficult shoulders, or the so-called turtle sign requiring additional maneuvers to achieve delivery), they activated the Code D protocol, which summoned to the room the most experienced available obstetrician, and also an anesthesiologist, a neonatologist, and a nurse.

Staff were taught, first, to assess – using a hands-off pause during which there was no maternal pushing, application of fundal pressure, or head traction – the orientation of the infant's back and shoulders, and to announce it to the delivery team.

This hands-off period lasted just a few seconds, according to Dr. Inglis. "You basically want to stop, take a deep breath, collect yourself, make sure you are following the protocol, and then go on."

Staff then began one of several maneuvers performed in an order of their choice, including rotating the shoulders to the oblique position, changing maternal position, implementing the corkscrew maneuver, and delivering the posterior arm.

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References: 1. Hollowell JG, Staehling NW, Hannon WH, et al. Iodine nutrition in the United States. Trends and public health implications: iodine excretion data from National Health and Nutrition Examination Surveys I and III (1971-1974 and 1988-1994). *J Clin Endocrinol Metab.* 1998;83(10):3401-3408. 2. Zimmermann MB. Iodine deficiency. *Endocr Rev.* 2009;30(4):376-408. 3. Mock DM. Marginal biotin deficiency is common in normal human pregnancy and is highly teratogenic in mice. *J Nutr.* 2009;139(1):154-157. 4. Horrocks LA, Yeo YK. Health benefits of docosahexaenoic acid (DHA). *Pharmacol Res.* 1999;40(3):211-225. 5. Uauy R, Hoffman DR, Mena P, Llanos A, Birch EE. Term infant studies of DHA and ARA supplementation on neurodevelopment: results of randomized controlled trials. *J Pediatr.* 2003;143(suppl 4):S17-S25. 6. Birch EE, Garfield S, Hoffman DR, Uauy R, Birch DG. A randomized controlled trial of early dietary supply of long-chain polyunsaturated fatty acids and mental development in term infants. *Dev Med Child Neurol.* 2000;42(3):174-181. 7. Agostoni C, Trojan S, Bellù R, Riva E, Giovannini M. Neurodevelopmental quotient of healthy term infants at 4 months and feeding practice: the role of long-chain polyunsaturated fatty acids. *Pediatr Res.* 1995;38(2):262-266. 8. Dietary supplement fact sheet: folate. National Institutes of Health Web site. <http://ods.od.nih.gov/factsheets/folate.asp>. Accessed March 15, 2010. 9. March of Dimes[®] Quick Reference. Folic acid. March of Dimes[®] Web site. http://www.marchofdimes.com/professionals/14332_1151.asp. Accessed March 15, 2010. 10. Metafolin[®]: about Metafolin[®]. Merck KGaA Web site. <http://www.metafolin.com/servlet/PB/menu/1784410/index.html>. Accessed March 15, 2010.

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Unintended Pregnancies Carry Big Price Tag

Taxpayers spend more than \$11 billion each year as a result of unintended pregnancies, according to new data from two separate studies.

The estimates are based on public insurance costs for pregnancies and infant care in the first year. Researchers from the Guttmacher Institute used state-level data from 2006 to come up with a national estimate of \$11.1 billion in public spending on unintended pregnancies. In a separate study, researchers at the Brookings Institution came up with their figures by using 2001 national data on publicly financed unintended pregnancies, resulting in average spending of \$11.3 billion annually. Both studies were published in the June issue of *Perspectives on Sexual and Reproductive Health*.

Researchers from the Guttmacher In-

stitute found that public programs such as Medicaid and the Children's Health Insurance Program bear the brunt of the nation's costs for unintended pregnancies (*Perspect. Sex. Reprod. Health* 2011;43:94-102 [doi:10.1363/4309411]). While 38% of U.S. births result from unintended pregnancies, births from unintended pregnancies make up about half of publicly funded births. But reducing unintended pregnancies also will require

major new public investments, the Guttmacher researchers wrote, including increasing access to family planning services and comprehensive sex education. The Affordable Care Act may help, too, they said, by expanding insurance coverage and giving new authority to states to expand Medicaid eligibility for family planning services.

While preventing unintended pregnancies would require an up-front in-

vestment, the researchers at the Brookings Institution said it would be more than offset by potential savings. They estimated that if unintended pregnancies could be prevented altogether, with some being delayed until the women were ready to be pregnant, it could save taxpayers about \$5.6 billion annually (*Perspect. Sex. Reprod. Health* 2011; 43:88-93 [doi: 10.1363/4308811]).

—Mary Ellen Schneider

Continued from previous page

"Each should last no longer than 30 seconds, and you could go back to a maneuver if it didn't work the first time," Dr. Inglis said. Suprapubic pressure also could be used.

To assess the impact of the Code D protocol, the investigators retrospectively reviewed medical records for mothers and their singleton, live born, nonbreach infants delivered vaginally between August 2003 and December 2009. Analyses were based on 6,269 deliveries in the pretraining period before September 2006, and 5,593 deliveries in the post-training period.

Study results showed that the rate of shoulder dystocia did not differ significantly between periods: This complication occurred in 83 or 1.32% of deliveries in the former period, and in 75 or 1.34% of deliveries in the latter period. However, the percentage of cases of shoulder dystocia that resulted in brachial plexus injury was 40% in the pretraining period, compared with just 14% in the posttraining period.

Among the cases of shoulder dystocia, those in the pretraining period had a higher maternal body mass index (33.4 vs. 30.3 kg/m²) and infant birth weight (3,825 g vs. 3,643 g), both of which are potential confounders, Dr. Inglis noted.

But in a logistic regression analysis, use of the shoulder dystocia protocol was still associated with a reduced risk of obstetric brachial plexus injury.

The interval between delivery of the infant's head and body in cases of shoulder dystocia was longer in the posttraining period than in the pretraining period (2.0 minutes vs. 1.5 minutes).

"We wanted everyone to go slowly, so we were actually happy to see that the head-body interval went up," commented Dr. Inglis. "That certainly didn't seem to worsen the risk of Erb's palsy."

Study results also showed that staff were more likely to use the Rubin maneuver and posterior arm delivery in the posttraining vs. pretraining period, and were less likely to use the McRoberts maneuver. ■

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