

Fetal medicine leaders at CHOP report on 100 prenatal surgeries for spina bifida

August 26 2014

Reporting on 100 recent cases of fetal surgery for spina bifida, specialists at a premier fetal surgery program achieved results similar to those published three years previously in a landmark clinical trial that established a new standard of care for prenatal repair of this birth defect.

Specialists from the Center for Fetal Diagnosis and Treatment at The Children's Hospital of Philadelphia (CHOP) published their findings online August 15 in Fetal Diagnosis and Therapy. The single-center results comprised the largest series reported since 2011 when the National Institutes of Health-sponsored Management of Myelomeningocele Study (MOMS) published its results in the *New England Journal of Medicine* (*NEJM*).

"The MOMS trial presented very encouraging results and helped experts develop guidelines for optimal care, but there were questions about whether the benefits of this procedure could be reproduced outside the setting of a rigorous trial," said Julie S. Moldenhauer, M.D., a Maternal-Fetal Medicine Specialist at CHOP and lead author of the current paper. "This study shows that an experienced program can achieve comparable results, and that we can modify our techniques to improve on the trial outcomes."

Spina bifida is the most common birth defect of the central nervous system, affecting about 1,500 babies born each year in the United States. The most severe form of spina bifida is myelomeningocele, in which part of the spinal column fails to close around the spinal cord, leaving it



vulnerable to devastating neurological injuries during <u>fetal development</u>. Lifelong disabilities may result, such as paralysis, bladder problems and cognitive deficits.

The MOMS trial had shown that <u>fetal surgery</u> led to decreased rates of shunting (implanted tubing to drain excess fluid from the brain) at 12 months of age. Fetal surgery also reversed a life-threatening condition called Arnold Chiari 2 malformation (hindbrain herniation), and improved the children's outcomes, including their ability to walk at 30 months of age.

CHOP's center was one of the three fetal surgery programs that participated in the randomized MOMS trial, and has been performing fetal myelomeningocele (fMMC) repairs since 1998. In total, CHOP has performed over 1,175 fetal surgeries for a range of birth defects, the largest number of any hospital in the world.

The current study draws on a cohort from all patients referred to CHOP for potential fMMC repair between January 2011 and March 2014. Of 587 total referrals, the program designated 139 to be candidates for the fetal surgery, and 100 mothers completed the surgery.

The mothers' average age, race or ethnic group and body mass index were very similar between the MOMS patients and the current cohort. The two groups also had similar rates of preterm labor and membrane separation—two complications of the fetal surgery.

The current cohort had a decreased incidence of preterm premature rupture of membranes (PPROM) compared to the MOMS group: 32 percent compared to 46 percent. The average operative times were also significantly shorter (78.5 minutes vs. 105 minutes), which may reflect the experience and improved efficiency of the operative team. There was also a decreased incidence of pulmonary edema (2 percent vs. 6



percent), which the study team said may be attributable to their practice modifications such as guidelines for fluid intake. One other improved measure in the CHOP cohort was a decrease in the transfusion rate at the time of cesarean delivery (3 percent compared to 9 percent in the MOMS trial), possibly due to modified techniques and the care team's depth of experience.

Early neonatal MRIs showed that 71 percent of the infants had no evidence of hindbrain herniation, in which part of the cerebellum (hindbrain) protrudes through the opening in the base of the skull into the spinal canal and obstructs the flow of cerebrospinal fluid, leading to a progressive hydrocephalus. The authors added that follow-up imaging at age 12 months will be needed to confirm that these very favorable changes persist. In the MOMS trial, 36 percent of the fetal surgery group had no hindbrain herniation at 12 months.

In addition, when compared to prenatal ultrasound evaluations of the anatomic level of the myelomeningocele, 55 percent of the newborns in the study had improved functional motor level, but the authors added that follow-up research will be needed to determine if this benefit persists in longer-term outcome studies.

"Establishing fetal surgery for <u>spina bifida</u> as a standard of care option was one of the most exciting developments in the history of the treatment for birth defects, and one that our CHOP team has spent years helping to pioneer," said N. Scott Adzick, M.D., Surgeon-in-Chief at CHOP and Director of the Center for Fetal Diagnosis and Treatment. Adzick was the lead author of the MOMS trial paper published in the NEJM in 2011. "However, the increased patient acceptance of this procedure, and an increase in centers performing it, underscore the importance of continued collaboration among all centers performing prenatal repair to track long-term results and continue to optimize patient safety and outcomes."



More information: Moldenhauer JS, Soni S, Rintoul NE, Spinner SS, Khalek N, Martinez-Poyer J, Flake AW, Hedrick HL, Peranteau WH, Rendon N, Koh J, Howell LJ, Heuer GG, Sutton LN, Johnson MP, Adzick NS. "Fetal Myelomeningocele Repair: The Post-MOMS Experience at The Children's Hospital of Philadelphia," *Fetal Diagnosis and Therapy*, published online, Aug. 15, 2014.

Provided by Children's Hospital of Philadelphia

Citation: Fetal medicine leaders at CHOP report on 100 prenatal surgeries for spina bifida (2014, August 26) retrieved 1 May 2024 from https://medicalxpress.com/news/2014-08-fetal-medicine-leaders-prenatal-surgeries.html

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