MIDWEST FETAL CARE CENTER OVERVIEW

The Midwest Fetal Care Center (MWFCC), a collaboration between Allina Health and Children’s Minnesota, brings together a multidisciplinary team of highly trained maternal-fetal medicine experts from Allina Health and pediatric and neonatal specialists from Children’s Minnesota. Open since 2008, the MWFCC is a national referral center and national leader in fetal diagnosis, fetal intervention and comprehensive fetal care for unborn babies with abnormalities.

The center was started to meet regional fetal care needs and has quickly grown into a national center with world-class outcomes. Between 2016 and September 10, 2021, the MWFCC has evaluated 7,074 fetal cases and performed 322 total fetal procedures.

SPINA BIFIDA + MWFCC

In 2016, our center performed our first fetal repair of myelomeningocele (MMC), the most severe form of spina bifida. Led by a team of medical experts in the field of fetal diagnosis and therapy, our program has grown to become a high volume MMC fetal surgery center. As of September 2021, the Midwest Fetal Care Center has evaluated more than 81 women for maternal-fetal surgery for spina bifida; 54 chose to undergo surgery.

THE MOMS AND MOMS2 TRAILS

The Management of Myelomeningocele Study (MOMS Trial) was a 7-year, multi-center, randomized clinical research trial that comprehensively studied the outcomes of open fetal surgery for repair of spina bifida compared to a traditional postnatal repair. The MOMS Trial included 183 surgically eligible patients, who were randomized to either fetal or postnatal MMC repair. Of those, 80 patients underwent post-birth surgical repair and 78 underwent open fetal surgery for spina bifida. Overall, the MOMS Trial concluded that prenatal surgery for myelomeningocele reduced the need for hydrocephalus-related neurosurgical interventions, including cerebrospinal shunt placement, and improved motor outcomes at 30 months versus postnatal repair, but was also associated with maternal and fetal risks. The MOMS Trial is seen as the industry benchmark for this treatment, and here we describe how our outcomes compare to those from this seminal study.

In addition, to study the long-term impact of maternal-fetal surgical closure of spina bifida versus post-natal management, more than 150 patients from the original MOMS trial were enrolled into follow-up studies to compare childhood outcomes (MOMS2). In a secondary analysis, 51.3% of children who underwent prenatal repair could independently walk community distances compared with 23.1% of children who underwent standard postnatal repair. Additional long-term benefits of prenatal surgery included improved independent functioning as well as fewer surgeries for shunt placement and revision. Overall, these secondary analyses found that the benefits of prenatal repair reported at age 30 months persisted into school age.

Our goal is to provide our patients and community the latest patient outcomes data to support informed decision making. We encourage you to reach out to other health care systems to request and review their outcomes data in order to utilize the information available when evaluating your health care options.
OPEN VS. FETOSCOPIC MATERNAL-FETAL SURGERY

For patients that are eligible for maternal-fetal surgery for spina bifida, the MWFCC offers two different surgical access strategies, open and fetoscopic. Open maternal-fetal surgery for spina bifida requires a maternal surgery technique known as a hysterotomy, which is the making of an approximately 6 cm incision in the uterus, to access the unborn baby. After an open maternal-fetal surgery, the baby and all future pregnancies have increased risk and must be delivered by cesarean section.6

For certain patients a minimally invasive fetoscopic approach is offered at our center to reduce the risks associated with a hysterotomy and allow for the potential of a vaginal birth. In a fetoscopic repair, the surgery is completed through three small 5 mm incisions in the uterus using a small camera known as a fetoscope and laparoscopic instruments. The fetal repair technique is the same for both the open and fetoscopic surgical access methods.

We discuss all available medical options including open vs. fetoscopic prenatal surgery or post-birth management with our patients to create a care plan that works best for each individual family.

Here we present composite outcomes for both our open and fetoscopic surgeries compared to the open surgery outcomes reported by the MOMS trial.

MATERNAL OUTCOMES AND DELIVERY

To date, 54 mothers have elected to undergo open fetal repair of MMC at our center. The average post-surgery length of stay was four days for the last 15 patients. Mothers are typically discharged home and further post-surgery care is co-managed with the mother’s referring maternal-fetal medicine specialist. For the open fetal repair patients cesarean section deliveries are scheduled for approximately 36 weeks gestation at our center, while fetoscopic repair patients may carry until the onset of labor or otherwise medically indicated.

To date, our center has completed 13 fetoscopic maternal-fetal spina bifida closures, of which eight of 11 or 72% of delivered patients gave birth vaginally. On average, our delivered fetoscopic repair patients also continued their pregnancies a week longer than our open maternal-fetal surgery patients, averaging an estimated gestational age at birth of 35.2 weeks for fetoscopic surgeries versus 34.2 weeks for our 41 open surgeries. Six of the 11 (58%) of delivered mothers carried longer than 36 weeks.

The majority of patients spent less than a week in the hospital before delivery, and around three days in the hospital after delivery. Our team makes every effort to minimize any potential maternal complications related to the fetal repair.

ANTENATAL AND NEONATAL OUTCOMES

Currently, pediatric outcomes data is available for a subset of our patients through 24 months.

Hydrocephalus, or brain swelling, can occur in babies with spina bifida and is typically treated by diverting cerebrospinal fluid using a surgical procedure (endoscopic third ventriculostomy, ETV) or by permanently placed brain shunt. For more information on hydrocephalus, ETV and shunt procedures, please refer to childrensMN.org/neurosurgery.

The MOMS Trial showed important benefits to infants that underwent fetal repairs, including a reduction in the need for shunt/ETV from 82% (postnatal repair) to 40% during the first 12 months of life.7 Overall, the patient data from our center is similar to the outcomes reported in the MOMS Trial, with a 35% rate of surgical management of hydrocephalus.

In addition, more than 61% of our fetal MMC repair patients showed an improvement in motor function at their 24 month follow-up, compared to the function predicted by their prenatal imaging (prior to MMC repair). These findings are consistent with the MOMS trial, and the impact of the prenatal repair was also seen into childhood (MOMS2).8,9

Urinary, bladder and bowel dysfunction may occur in babies with spina bifida due to the nerve damage caused to be the spine defect. A MOMS Trial companion paper found that at 30 months, the fetal MMC repair group had a clean intermittent catheterization (CIC) rate of 38%.1 Long-term, the MOMS2 childhood data showed CIC rates of 62% vs 87% for the prenatal and postnatal groups respectively defined as requiring catheterization three or more times per day.1 Data the currently available for our center shows a 15% CIC rate at 12 months (5/34 patients). Reoccurring urinary tract infections (UTIs) occurred in 3% (1/34) of our fetal repair patients, and constipation in 41% (14/34).

OUTCOMES AFTER FETAL MMC REPAIR

<table>
<thead>
<tr>
<th>Surgical mgmt of hydrocephalus, 12 mo</th>
<th>MWFCC</th>
<th>MOMS Trial</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age at pediatric function assessment</td>
<td>24 mos</td>
<td>30 mos</td>
</tr>
<tr>
<td>≥Two levels better</td>
<td>11 of 26</td>
<td>42%</td>
</tr>
<tr>
<td>One level better</td>
<td>5 of 26</td>
<td>19%</td>
</tr>
<tr>
<td>No difference</td>
<td>6 of 26</td>
<td>23%</td>
</tr>
<tr>
<td>One level worse</td>
<td>4 of 26</td>
<td>15%</td>
</tr>
<tr>
<td>≥Two levels worse</td>
<td>0 of 26</td>
<td>0%</td>
</tr>
</tbody>
</table>

Data for 2/1/2016–9/16/2021
5 Surgical management included shunt (n=9) or ETV (n=3)
6 For the difference between the pediatric motor function level (24 months post-birth neurosurgery clinic assessment, average adjusted age at the time of the assessments=23±2.0 months) and the anatomical level (pre-birth ultrasound), “better” indicates function that is better than expected on the basis of the anatomical level.

Neonatal Outcomes after Fetal MMC Repair

<table>
<thead>
<tr>
<th>Neonatal survival to delivery</th>
<th>MWFCC</th>
<th>MOMS Trial</th>
</tr>
</thead>
<tbody>
<tr>
<td>Neonatal survival post-delivery</td>
<td>51 of 52</td>
<td>97%</td>
</tr>
<tr>
<td>Average GA at delivery (weeks)</td>
<td>33.4 ± 2.9</td>
<td>34.1 ± 3.1</td>
</tr>
<tr>
<td>Average Birthweight, g</td>
<td>2336 ± 596</td>
<td>2383 ± 688</td>
</tr>
<tr>
<td>Apnea‡</td>
<td>17 of 50</td>
<td>34%</td>
</tr>
<tr>
<td>Respiratory Distress Syndrome</td>
<td>11 of 50</td>
<td>22%</td>
</tr>
<tr>
<td>Foot deformity</td>
<td>14 of 50</td>
<td>28%</td>
</tr>
</tbody>
</table>

Data for 2/1/2016–9/16/2021
‡ One spontaneous intratuberal fetal demise (IUFD) occurred 28 days after surgery with no identifiable cause.
‡ Definition: true cessation of breathing during rest that results in the need for caffeine due to apnea-based symptoms (not given prophylactically) or home-monitor at NICU discharge.
‡ 50 of 51 neonates had NICU data available.

References