




Open fetal surgery for spina bifida in a tertiary hospital in Argentina: short- and medium-term outcomes

Juliana Moren¹ , Daniel Russo¹, Fernando Palma¹ , Marcelo González-Bernal¹, Ernesto Beruti¹, Rodolfo Fregonese¹, Gabriel Musante¹, Hernán Allegrotti¹, Florencia Contino Storz¹, Ángeles Cibert¹, María F. Jousse¹, Mora Achával¹, Josefina Maquieira¹, Adolfo Etchegaray² 

ABSTRACT

Introduction. Spina bifida, particularly its most common form, myelomeningocele (MMC), is a severe congenital malformation associated with high neonatal morbidity and long-term disability. Since 2015, our center has been performing intrauterine repair of MMC using a modified open surgical technique.

Objective. To describe the obstetric and perinatal outcomes, the need for treatment of hydrocephalus, and the ability to walk in children who underwent open fetal surgery for repair of spinal dysraphism, and to compare these data with those published in the Management of Myelomeningocele Study (MOMS).

Population and methods. Retrospective observational study of 102 consecutive cases operated on between 2015 and 2023. Maternal, neonatal, and neurological variables were analyzed in the medium-term follow-up.

Results. The mean gestational age at the time of surgery was 26.1 weeks. Maternal and neonatal complication rates were similar to or lower than those reported in the MOMS study. The need for ventriculoperitoneal shunting at 12 months was 23.8%. At 30 months, 84.8% of patients were walking with or without orthopedic devices.

Conclusion. Open fetal repair of MMC at our center, performed by a multidisciplinary team using a modified surgical technique, presented a favorable maternal-fetal safety profile. The perinatal and neurological outcomes obtained are comparable to those of international reference centers, with a low rate of ventriculoperitoneal shunting and a high percentage of children able to walk at 30 months of age. These findings support the continuation and optimization of this intervention in experienced centers.

Keywords: spinal dysraphism; myelomeningocele; fetal therapies; neural tube defects; treatment outcomes.

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¹ Hospital Universitario Austral, Pilar, Argentina; ² Nationwide Children's Hospital, Columbus, Ohio, United States.

Correspondence to Juliana Moren: jmoren@cas.austral.edu.ar

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INTRODUCTION

Neural tube defects (NTDs) are a group of severe congenital anomalies associated with high perinatal morbidity and mortality, long-term disability, and significant socioeconomic impact.^{1,2} The most common form is myelomeningocele (MMC) (80%). In Argentina, the prevalence of MMC remains stable following the mandatory fortification of flour with folic acid; it affects approximately 1 in every 2,000 newborns.³ Official data place it among the ten leading causes of neonatal mortality,⁴ with high morbidity, including congenital hydrocephalus (>80%),⁵ varying degrees of lower limb paralysis, and mixed incontinence (50-90%).⁶ Mortality can reach 35% in cases with brainstem dysfunction due to Chiari II malformation.⁷

Ventriculoperitoneal shunting (VPS) remains the primary treatment for symptomatic congenital hydrocephalus despite its complications. Early neurological deficit and history of VPS are key prognostic factors.⁸

The “two-hit hypothesis” proposes that neurological damage occurs in two stages: an initial embryological defect and progressive intrauterine damage.⁹ Based on this hypothesis, prenatal repair was proposed, and the first cases were performed at Vanderbilt¹⁰ and Philadelphia¹¹⁻¹³ in the 1990s. Subsequently, the Management of Myelomeningocele Study (MOMS) demonstrated that this technique reduces the need for VPS (40% vs. 82%) and doubles the rate of independent ambulation at 30 months of age (42% vs. 21%);¹⁴ these results have been replicated by other groups.^{15,16}

The Fetal Surgery Program at Hospital Universitario Austral began performing this procedure in 2015 for selected cases of open spinal dysraphism.

The primary objective of this study is to describe the obstetric, perinatal, and functional outcomes of this experience. The secondary aim is to compare the results obtained with the data published in the MOMS study.

POPULATION AND METHODS

Design

Retrospective observational study of 102 consecutive cases of fetuses with open spinal dysraphism treated at our institution between March 2015 and December 2023. Partial information on 65 of these patients was included in previous publications.^{17,18}

Eligibility criteria

Inclusion: single pregnancy, gestational age between 24+0 and 27+6 weeks, open spinal dysraphism between T1 and S1, hindbrain herniation (HH), normal karyotype, maternal age ≥18 years, and ability to temporarily reside near the center.

Exclusion: multiple pregnancy, unrelated anomalies, high risk of preterm delivery (cervical length <20 mm or history of preterm delivery), previous placental abruption, severe kyphosis (>30°), BMI ≥35, surgical or anesthetic contraindications, maternal risk conditions, alloimmunization, or psychosocial limitations.

Eligible patients were evaluated in a multidisciplinary meeting, where the option of fetal surgery was offered. Advice was provided on risks, benefits, and alternatives, including postnatal repair. Written informed consent was obtained, which was read and signed voluntarily by the parents after they had sufficient time to make a decision. This consent includes a section on the use of non-identifying photographs.

Surgical technique

Open intrauterine MMC repair with uterine opening using bipolar forceps and three-layer hysterorrhaphy.¹⁷

Data collection

With the authorization of the Institutional Ethics Committee, we retrospectively reviewed the electronic medical records, including prenatal fetal magnetic resonance imaging (MRI) and ultrasound (US) images, as well as postnatal follow-up data, for all fetal repairs of spina bifida performed at our center between 2015 and 2023, up to April 2024. When necessary, parents were contacted to complete the information.

Variables analyzed

Maternal/obstetric: gestational age (GA) at the time of surgery, serious complications, surgical time, days of hospitalization, premature rupture of membranes (PROM), chorioamnionitis, uterine dehiscence or rupture, and outcome of subsequent pregnancies.

Perinatal: GA at birth, fetal/neonatal mortality, post-surgical resolution of REH on fetal MRI, need for immediate neonatal skin closure, complications, and evolution of Chiari II.

Others: treatment for hydrocephalus (VPS or endoscopic third ventriculostomy [ETV]), the difference between the functional motor level

assessed prenatally by visualization of fetal lower limb movements and the motor level observed clinically postnatally, and walking at 30 months.

Statistical analysis

The data were analyzed using Wizard version 2.2™ (2013–2020© Evan Miller) and Stata 18.0™ (StataCorp, Texas, USA). Descriptive statistics, including means, standard deviations (SD), medians, and interquartile ranges (IQR), were calculated for all variables. Normality of distribution was assessed using the Shapiro-Wilk test.

Comparisons between groups for continuous variables were performed using Student's t-test or Mann-Whitney U test, depending on the normality of the data. Categorical variables were compared using the chi-square test or Fisher's exact test, as

appropriate. A *p*-value of <0.05 was considered statistically significant.

RESULTS

Between March 2015 and December 2023, 102 open intrauterine surgeries were performed to repair MMC at the Hospital Universitario Austral. The characteristics of the population are detailed in *Table 1*.

Fetal surgery was performed at a mean GA of 26.1 weeks, with 60% of cases operated on after week 26.

The median surgical time was 120 minutes (range 80-187 minutes) with a downward trend over time.

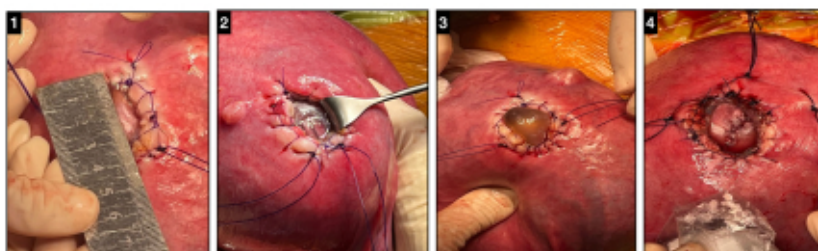
The size of the hysterotomy decreased progressively, from 90 mm initially to an average of 29.8 mm in the last 30 surgeries (range 20-

TABLE 1. Characteristics of the population (n= 102)

Variable	
Maternal age (mean ± SD)	31.5 ± 1.9
Maternal body mass index (mean ± SD)	24.7 ± 0.9
History of previous cesarean section(s), % (n)	25.5 (26)
Nulliparity, % (n)	50 (51)
Spontaneous conception, % (n)	94.1 (96)
Average cervical length, mm (mean ± SD)	36.8 ± 1.1
Gestational age at diagnosis, weeks (mean ± SD)	22.2 ± 0.5
Gestational age at the time of surgery, weeks (mean ± SD)	26.1 ± 0.2
Placental location, % (n)	
-Anterior	55.9 (57)
-Posterior	34.3 (35)
-Lateral	6.9 (7)
-Fundic	2.9 (3)
Characteristics of the lesion, % (n)	
-Myelomeningocele	68.6 (70)
-Myeloschisis	31.4 (32)
Level of lesion, % (n)	
-Lumbosacral	88.1 (90)
-Sacral	11.9 (12)
Number of vertebrae involved (mean ± SD)	5.8 ± 0.2

SD: standard deviation.

FIGURE 1. Surgical technique



1: 30 mm hysterotomy in a case of MMC with L5 level. 2: Lesion exposed through the mini-hysterotomy. 3: Sac protruding through the hysterotomy. 4: Fetal lesion repaired.

90 mm). Of the total, 55% were less than 35 mm (mini-hysterotomy) and 21.6% were 25 mm or less.

Seventy percent of lesions were MMC and 30% were myeloschisis. In 17 cases, skin relaxing incisions were required, and in 11 cases, a dural patch (Duragen™) was used. No cases required a skin patch (Alloderm™).

Maternal outcomes

The median length of hospital stay was 5 days (range 3-30 days). No serious complications such as uterine rupture or maternal deaths were reported; 33.3% (34/102) had premature rupture of membranes (PROM), and 3.1% experienced placental abruption. Two patients required early termination of pregnancy: one due to intrauterine growth restriction (IUGR) and severe

preeclampsia at 30.2 weeks; the other presented with abdominal pain and chronic oligohydramnios in the postoperative period, which led to delivery at 36.2 weeks. During the cesarean section, uterine dehiscence was identified, which explained the symptoms. Feto-maternal complications are summarized in Table 2.

Fetal and neonatal outcomes

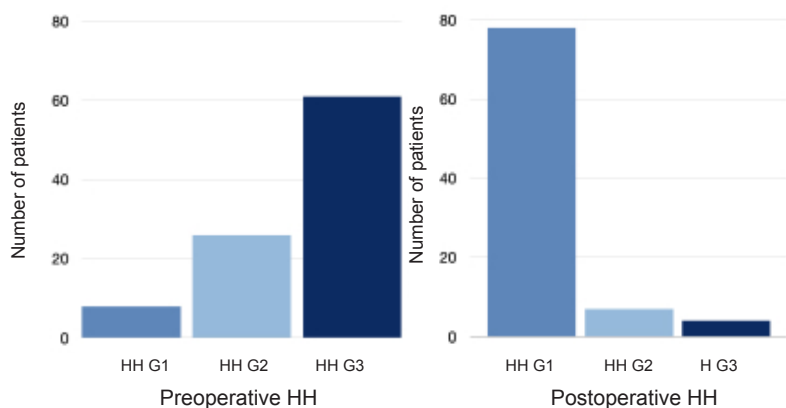
Of the 95 fetuses evaluated with preoperative MRI, 61 (64%) had grade 3 herniation according to Sutton's classification.¹³ Postoperative MRI was performed at 31.5 days (±1.1) in 89 patients. In the MRIs of fetuses in which evolution could be evaluated, improvement or resolution of REH was observed in 94% (80/85), with 87% (78/89) showing grade 1 on postoperative MRI.

The mean GA at birth was 34.9 weeks (±0.5),

TABLE 2. Maternal and obstetric complications (n = 102)

Variable	
Uterine dehiscence, % (n)	0.98 (1)
Chorioamniotic separation, % (n)	10.8 (11)
Oligohydramnios, % (n)	9.8 (10)
Acute pulmonary edema, % (n)	3.9 (4)
Pulmonary thromboembolism, % (n)	1.9 (2)
Placental abruption, % (n)	2.9 (3)
Superficial hematoma, % (n)	0.98 (1)
Adjacent organ injury, % (n)	0.98 (1; intestinal)
Need for transfusion, % (n)	0
Premature rupture of membranes, % (n)	33.3 (34)
Chorioamnionitis, % (n)	3.9 (4)
Premature labor, % (n)	31.4 (32)
Uterine atony, % (n)	0.98 (1)
Amniotic band, % (n)	0.98 (1)

FIGURE 2. Distribution of hindbrain herniation findings in pre- and postoperative fetal MRIs



HH: hindbrain herniation.

7% born before 30 weeks. The median time between surgery and birth was 65.5 days (3-86). Perinatal survival was 98% (100/102). Two fetal deaths were recorded: one due to amniotic band syndrome at 34 weeks (60 days post-surgery) and another due to PDNIP at 27.2 weeks. There were no postnatal deaths.

At birth, 4% (4/100) required skin closure, mainly in cases where dural patches or skin discharge incisions were used (3 cases). Ninety-six percent had normal healing.

Neonatal complications are described in Table 3.

The functional motor level assessed in the neonatal period was equal to or better than the prenatal anatomical level in 78% (73/93) of cases.

Follow-up results (12 and 30 months)

In the medium-term follow-up, 63% (53/84) of patients over one year of age did not require treatment for hydrocephalus. Among those who did require treatment (31/84; 36.9%), 11 were successfully treated with ETV, and 20 required VPS. Most interventions (21/31) were performed before the child reached 6 months of age.

Patients evaluated with MRI between 12 and 30 months of age had a tethered cord; however, only 3.7% (3/82) had a symptomatic tethered cord that underwent detethering.

To date, 67 patients have reached 30 months of age, of whom we have follow-up data for 65 (97%). Of these, 86% (56/65) walk with or without orthopedic assistance.

To date, 13 mothers (12.7%) have had a new pregnancy after cesarean section following intrauterine correction of MMC. Three of them had spontaneous abortions, and the others continued

their pregnancies to term without complications. One patient is currently pregnant without complications at the time of this publication. Among the births recorded, seven were by cesarean section and 1 was vaginal delivery.

Comparison with the MOMS study

The comparison of the 102 cases operated on at our center with the 78 cases in the fetal group of the MOMS study¹⁴ is presented in Table 4.

DISCUSSION

These results support the safety and effectiveness of open fetal repair of MMC, implemented through a multidisciplinary program at a tertiary center in Argentina, with functional outcomes comparable to those reported by international reference centers.

Since the publication of the MOMS trial in 2011, open repair of myelomeningocele has become the standard approach, as it reduces the need for VPS and improves motor function at 30 months.¹⁴ However, the associated maternal morbidity prompted the development of less invasive alternatives, such as fetoscopic surgery. Although the first multicenter reports showed encouraging results, they also reported a higher rate of PROM and preterm delivery. A recent systematic review confirmed that, although fetoscopy can yield comparable neurological outcomes, prematurity remains a key limitation.¹⁹

Critical interpretation of the literature is complex due to the coexistence of two fetoscopic variants with different technical foundations. The multi-port percutaneous approach eliminates the need for maternal laparotomy but requires prolonged insufflation with carbon dioxide.²⁰ In

TABLE 3. Perinatal complications and neonatal treatments

Variable	
Fetal death, % (n)	2 (2/102)
Prematurity, % (n)	64 (64/102)
Respiratory distress syndrome, % (n)	14.3 (14/98)
Necrotizing enterocolitis, % (n)	1 (1/98)
Sepsis, % (n)	2 (2/98)
Bronchopulmonary dysplasia, % (n)	0
Urinary tract infection, % (n)	29 (29/98)
Neurorrhaphy dehiscence, % (n)	4 (4/98)
Cerebrospinal fluid fistula, % (n)	2 (2/98)
Others, %	
-Occipito-cervical sacroradicular release	1
-Perianal fistulas	1
-Surgery for decompression of symptomatic Chiari II malformation	1

TABLE 4. Comparison with the MOMS study ^[14]

Variable	Hospital Universitario Austral (n = 102)	MOMS (fetal group, n= 78)	p-value
Intraoperative bradycardia, % (n)	0 (0/102)	10 (8/78)	<0.01
Perinatal survival, % (n)	98.4 (100/102)	97.4 (76/78)	0.786
Gestational age at birth (weeks)	34.9 (±0.5)	34.1 (±3.1)	0.106
Gestational age at birth % (n)			
<30 weeks	6.9 (7/102)	12.8 (10/78)	0.166
30-34 weeks	34.3 (35/102)	33.3 (26/78)	0.939
35-36 weeks	21.6 (22/102)	33.3 (26/78)	0.068
>37 weeks	37.3 (38/102)	20.5 (16/78)	0.017
Dehiscence of repaired site, % (n)	4 (4/100)	13 (10/77)	0.028
Pneumothorax, % (n)	0	1.3 (1/77)	0.253
RDS, % (n)	14.3 (14/98)	20.8 (16/77)	0.051
Sepsis, % (n)	2 (2/98)	5.2 (4/77)	0.255
NEC, % (n)	1 (1/98)	1.3 (1/77)	0.863
Foot deformity, % (n)	26 (26/100)	50 (39/78)	<0.001
Periventricular leukomalacia, % (n)	1 (1/100)	5.2 (4/77)	0.095
Walking at 30 months with or without orthosis, % (n)	84.8 (56/65)	71 (44/62)	0.058
VPS at 12 months, % (n)	23.8 (20/84)	39.7 (31/78)	0.025

Continuous variables expressed as mean (±SD). Dichotomous variables expressed as % (n/total).

RDS: respiratory distress syndrome; NEC: necrotizing enterocolitis; VPS: ventriculoperitoneal shunt.

contrast, the laparotomy-assisted technique uses a maternal abdominal incision with partial uterine exteriorization and lower insufflation volumes, potentially reducing hemodynamic impact and complication risk.

The main methodological challenge lies in the fact that many studies do not discriminate results by technique, forcing meta-analyses to group them, generating statistical heterogeneity.²²

The most extensive study on the laparotomy-assisted technique, which included a cohort of 100 cases, reported a median GA at delivery of 38.1 weeks, a vaginal delivery rate of 51%, and no cases of uterine dehiscence or rupture.²³ The proportion of patients requiring treatment for hydrocephalus at one year was 35%, while 52% achieved community ambulation at 30 months. These findings suggest that, in experienced centers, this technique could reduce maternal morbidity without compromising neurological functional outcomes.

In our cohort, prematurity was observed in 64% of births, with 34% occurring before 34 weeks and 7% before 30 weeks. These figures are similar to those reported in other series of open fetal surgery. This point is particularly relevant given the complications associated with prematurity.

Maternal morbidity also deserves special attention. In our experience, cases of acute pulmonary edema (APE) and pulmonary

thromboembolism were reported. Although rare, these events underscore the importance of rigorous multidisciplinary follow-up and careful patient selection. APE, for example, has been described as a complication associated with tocolytics and volume overload, and requires prevention strategies and intensive monitoring.

Compared to MOMS, our series demonstrated a lower need for VPS, a higher rate of independent ambulation at 30 months, lower rates of immediate obstetric complications, and higher birth weights. These improvements could be attributed to the technical and anesthetic adaptations introduced in our program, particularly the progressive reduction in the size of uterine incisions. However, it is essential to emphasize that this intervention is not without risks and requires a careful ethical approach. An informed consent process must support the indication, adequate non-directive counseling on risks and benefits, and an individual assessment of each case within a multidisciplinary team.

Strengths and weaknesses

One of the main strengths of this study is that it constitutes the most extensive series of prenatal surgery for MMC published in a tertiary center in Latin America (excluding Brazil), providing evidence from a clinical context that is usually underrepresented. The homogeneous cohort, evaluated and treated by an experienced

multidisciplinary team, allowed for systematic functional follow-up for up to 30 months. In addition, the main results were compared in detail with those of the MOMS trial.

The main limitations include the retrospective design, which may introduce potential selection biases and result in the loss of functional data. The comparison between groups was not randomized, which limits the ability to make causal inferences. Long-term follow-up is ongoing, so some neurological outcomes may be underestimated, as may urological outcomes, which were not evaluated in this study.

CONCLUSION

These results suggest that, under strict eligibility criteria and in the context of a surgical program with adequate training, open fetal surgery significantly reduces neonatal neurological complications and improves motor function in the medium term, without increasing maternal or fetal mortality. Long-term follow-up studies, comparisons with less invasive techniques, and new strategies are needed to reduce associated maternal and neonatal morbidity further. ■

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