# Implementation of in utero laparotomy-assisted fetoscopic spina bifida repair in two centers in **Latin America: rationale for this approach** in this region



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**BACKGROUND:** Spina bifida (SB) is a severe congenital malformation that affects approximately 150,000 infants annually, predominantly in low- and middle-income countries, leading to significant morbidity and lifelong disabilities. In Latin America, the birth prevalence of SB is notably high, often exacerbated by limited healthcare resources and poor access to advanced medical care. The implementation of laparotomy-assisted fetoscopic in-utero SB repair programs in Latin America targets reducing prematurity rates and enabling vaginal births while preserving the benefits of decreased need for hydrocephalus treatment and improved mobility in children.

**OBJECTIVE:** This study evaluated the safety, efficacy, and outcomes of laparotomy-assisted fetoscopic in-utero SB repair in Latin America compared to traditional open-hysterotomy methods.

STUDY DESIGN: This retrospective cohort study included 39 cases of laparotomy-assisted fetoscopic in-utero SB repair, with 14 cases from Mexico (2017-2021) and 25 cases from Colombia (2019-2024). These cases were compared to 78 cases from the MOMs trial and 314 from other Latin American centers using traditional open-hysterotomy methods. Statistical analyses included the Student's t-test, Kruskal-Wallis test, and Pearson's chi-square test.

**RESULTS:** The gestational age (GA) at the time of surgery was significantly higher in fetoscopic centers (26±1.27 weeks) compared to the MOMs trial (23.6±1.42 weeks) and traditional hysterotomy methods (25.4±1 weeks) (P<.001). Mean GA at delivery was significantly earlier in the hysterotomy-based groups than in our fetoscopic group (MOMs: 34.1 [± 3.1] vs open-repair centers in LATAM: 34 [±3002] vs Fetoscopic: 35.3 [± 3.79] weeks; P values=.14 and 0004, respectively). Moreover, and the fetoscopic repair group exhibited a significantly lower rate of spontaneous preterm births (<34 weeks) at 15.8%, compared to 46.2% in the MOMs trial group and 49% in the other Latin American centers using traditional open-hysterotomy methods (P=.004 and .001, respectively). Additionally, the fetoscopic group had higher birthweights (2618 $\pm$ 738g) and a lower cesarean delivery rate (65.8%) compared to the other groups (P<.001). Hydrocephalus treatment requirements at 12 months were similar across all groups. No maternal deaths or other outcomes such as pulmonary edema or need for maternal transfusion were noted in the fetoscopic SB repair group.

CONCLUSION: The laparotomy-assisted fetoscopic SB repair offers a feasible and safer alternative to traditional hysterotomy-based techniques in Latin America. This approach significantly reduces the rates of prematurity and cesarean deliveries, facilitating vaginal births and

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minimizing maternal morbidity. These findings support the broader adoption of fetoscopic SB repair in regions with a high prevalence of SB and suboptimal perinatal outcomes, underscoring its advantages over hysterotomy-based approaches.

**Key words:** congenital malformations, fetal neural tube defects, fetal surgery, minimally invasive surgery, myelomeningocele, pediatric neurosurgery, prematurity, safety, spina bifida

### Introduction

Spina bifida (SB), the most prevalent nonlethal congenital malformation of the nervous system, remains a significant public health concern due to its considerable morbidity, mortality, and lifelong disabilities to the affected individuals and their families. 1-3 The prevalence of SB varies globally and is primarily influenced by prenatal diagnosis, elective termination policies, and folic acid fortification policies. This is notably higher in low- and middleincome countries, where nearly 150,000 infants are born with the defect annually.<sup>1,3</sup> While in the United States, the birth prevalence of SB is 7 cases per 10,000 live births,<sup>3</sup> in some countries in Latin America, such as Guatemala or Brazil, it can be as high as 96/10,000 or  $142/10,000,^{4-7}$  respectively. Moreover, prevalence and outcomes related to SB exhibit distinct ethnic and racial disparities; for instance, SB is more common

among Hispanics in the United States when compared to other racial groups.8,9

Mortality associated with spina bifida is higher in countries with fewer resources and poorer access to healthcare compared with their counterparts in high-income countries.<sup>3,10</sup> While highincome countries report first-week mortality around 6.9% and 5-year survival between 86%–96%,<sup>10</sup> rates resource settings report first-day mortality as high as 15% and 5-year survival rates at only 50%. 10,11 Moreover, Latin America endures 1 of the world's highest rates of neonatal mortality (9.6 deaths x 1000 livebirths), often due to insufficient neonatal intensive care resources. 12-14

With the development of fetal centers in the region and teams able to deliver less complex in-utero interventions with adequate outcomes, 15 there has been a growing interest and

pressing need to perform in-utero SB repair surgeries in LatAm. This interest arises from a combination of regional challenges, including limited healthcare infrastructures, economic conand barriers straints, legal pregnancy termination.<sup>16</sup> The Management of Myelomeningocele Study (MOMs),<sup>17</sup> a multicenter randomized trial performed in the United States, established the benefits of prenatal hysterotomy-based repair in reducing the need for ventriculoperitoneal shunting alongside improved motor skills at 30 months, compared to traditional postnatal surgery, 17-19 Nonetheless, this technique is inherently associated with increased maternal and fetal risks, including preterm birth, prematurityrelated neonatal complications, preterm premature rupture of membranes (PPROM), potential for uterine rupture and the need for cesarean delivery in future pregnancies. 17,20 In a region where a higher number of subsequent births can be expected more than in others, having the option of a vaginal birth seems of critical relevance.

Since 2019, the introduction of laparotomy-assisted fetoscopic repair in 2 Latin American centers adapting the technique proposed by Belfort et al.<sup>21</sup> has marked a pivotal point, following comprehensive training and detailed prospective outcomes follow-up. This study aimed to report obstetrical, perinatal, and neurosurgical outcomes in cases of fetoscopic repair in 2 centers in Latin America, comparing them with the hysterotomy-based repair fetal surgery results from the MOMs trial<sup>17</sup> and other Latin American centers<sup>15</sup> over the past decade.

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### Why was this study conducted?

Spina bifida affects approximately 150,000 infants each year, with a particularly high prevalence in low- and middle-income countries. In Latin America, where spina bifida rates are notably elevated, traditional hysterotomy-based repairs carry significant risks for both mother and child. However, there is a scarcity of data on the outcomes of intrauterine repair for myelomeningocele in the region, highlighting the need for further investigation. This study aimed to address this gap by evaluating the safety and efficacy of laparotomy-assisted fetoscopic repair as a less invasive alternative.

### **Key findings**

Compared to the hysterotomy-based repair in the MOMs trial and other Latin American centers, laparotomy-assisted fetoscopic approach results in significantly lower rates of spontaneous preterm birth, higher birthweights, and a lower cesarean delivery rate, thereby improving maternal care and obstetric outcomes.

# What does this study add to what is already known?

This study introduces laparotomy-assisted fetoscopic repair as a viable, safer alternative in Latin America, decreasing spontaneous preterm birth and cesarean delivery needs, enabling vaginal births, and potentially improving obstetric outcomes, highlighting its benefits over traditional methods.

# Materials and methods Study area, design, and period

This was a retrospective analysis of prospectively collected data in both centers. We included a total of 39 cases in which pregnant women, carrying fetuses diagnosed with open neural tube defects, underwent in-utero repair using a laparotomy-assisted fetoscopic technique. These procedures were conducted from 2017 to 2021 in Monterrey, Mexico, and from 2019 to 2024 in Barranquilla, Colombia, across two fetal surgery centers. The outcomes from this cohort were compared against the hysterotomy-based fetal repair group from the MOMs, comprising 78 cases, 17 and 314 cases from Latin America centers over the past decades who also underwent a hysterotomy-based SB repair. 15 Both participating centers adhered to a standardized protocol for the surgical procedures, which has been detailed previously.<sup>22–24</sup> Before surgery, each fetus underwent a detailed anatomy scan to rule out potential associated anomalies and fetal growth. Assessment of key features related to the open neural tube defect, such as degree of ventriculomegaly, hindbrain herniation. anatomical level of the lesion, fetal movements and position of lower extremities were assessed in all cases. A fetal echocardiogram was also part of the preoperative assessment, together with karyotype analysis, to exclude chromosomal anomalies. A transvaginal ultrasound was performed to assess cervical length at least one week prior to surgery. All cases met all the inclusion criteria from the MOMs trial and none of the exclusion criteria, except for gestational age at surgery, allowing for surgery up until 27 weeks, and maternal pre-pregnancy body mass index (BMI), extending this criterion up to 40 kg/m<sup>2</sup>. All patients were extensively counseled about the risks and benefits of this surgical approach. They were given the option to choose between fetoscopic or prenatal hysterotomy-based repair, or to opt for postnatal repair. To receive fetoscopic repair, patients would have to remain near the fetal surgery center for about one week before returning to their referring center of care. Delivery was offered in our center or at a center close to the patient's home, where appropriate neurosurgery and NICU services were available. If in agreement with surgery, patients provided their signed informed consent for surgery and prospective follow-up.

### Surgical technique

All patients were managed per a standard protocol as detailed by others<sup>21,23–25</sup> (see Supplementary Appendix) for full details. The protocol involved steroid administration (12 mg of Betamethasone IM daily, 2 doses), prophylactic tocolysis (A 4g Magnesium bolus administered over 20-30 minutes, followed by a 1-2g/h infusion prior to transfering the patient to the operating room, continued for the first 24 hours after surgery), and preoperative prophylactic antibiotics (cefazolin, metronidazole, and azithromycin or, if allergic, clindamycin and gentamicin). Informed consent was obtained from the patient, and the study protocol was approved by the ethics committees from the University of Cartagena School of Medicine (DB-FM-CERT 28 4-08-2023), and the Comité de Ética en Investigación of Christus Muguerza, Sistemas Hospitalarios S.A. de C.V (CONBIOETICA 19CEI00420170601).

Myelomeningocele repair was performed using standardized operative techniques (Supplementary Appendix). This laparotomy-assisted procedure involves the exteriorization of the uterus to facilitate trocar placements at both centers. However, the Colombian group, with more than four years of continuous refinement of the technique, demonstrated a few noteworthy differences that merit highlighting. The Colombian team placed two parallel 2/0 polydioxanone stitches in the exteriorized uterus under ultrasound guidance to attach the membranes to the uterine wall. Meanwhile, the Mexican team completed four stitches, with the additional two placed directly in the uterus under visual guidance. Fetal position is achieved after ultrasound-guided intramuscular injection of analgesia (fentanyl [10 mcg/kg], atropine [20 mcg/kg], and vecuronium [0.2 mg/kg]) into the buttock or extremity using a long 22gauge needle, and the fetus is fixed with a temporary stitch to the uterine wall to allow surgical repair. The Colombian

team opted for all three 12 French trocars, while the Mexican team used a 12 French trocar with two additional 10 French trocars. Dural patch was placed directly on top of the placode (Dura-Gen by the Colombian team and Durepair by the Mexican team), patches were covered with a myofascial flap that was sutured with interrupted 4-0 Vycril stitches, and over that layer, fetal skin was closed with interrupted 4-0 Vycril stitches. While adhering to the overarching framework, there were some small differences between both surgical centers related to tocolytic postoperative care: Instead of the magnesium sulfate intravenously (2g/h for 24 hours) infusion and oral tocolytics such as Nifedipine 30mg q8h po used by the Colombian team, the team from Mexico opted for a combination of nifedipine 10mg q6h and indomethacin. Pain control was managed by the administration of epidural analgesia during the first 24 hours after surgery followed by paracetamol with oxycodone 5mg po q4h PRN during admission stay and paracetamol (1g q8h po) after hospital discharge. Patients stayed hospitalized on average for four days until they met all postoperative milestones and were discharged. After one week after surgery and if no complications were noted, patients were cleared to return to their referring provider's care. They were instructed to continue with nifedipine 30 mg q8 hours po, by the Colombian team, and the team from Mexico opted for a nifedipine 10mg q6h.

## **Statistical analysis**

Continuous variables were reported as means or medians with interquartile ranges (IQRs) or standard deviations (SDs) according to their distribution. Categorical variables were reported in percentages. To determine the normality of continuous data, we utilized the Kolmogorov—Smirnov test alongside visual assessment of distribution plots. Comparisons within the fetoscopic cohort were referenced against the open fetal surgery group from MOMS trial and the Latin America post-MOMS cohort of 314 cases who underwent open fetal surgery. For comparative

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analysis, the student's t-test, or Mann-Whitney U-test, was applied to quantitative data, and the Pearson Chi-square test, or Fisher's exact test, to categorical data, as appropriate. Due to the unavailability of individual data from the MOMs and Latin America cohorts, continuous data comparisons were restricted to cases where mean and SD were provided. Statistical significance was set at *P*<.05. All analyses were performed using R software.

# Results Clinical characteristics of study participants

Upon analysis, 39 patients had undergone laparotomy-assisted fetoscopic repair for spina bifida, with 25 procedures conducted in Barranquilla, Colombia, and 14 in Monterrey, Mexico. Table 1 describes the maternal sociodemographic characteristics by country. The mean maternal age at surgery was 29.7  $\pm$  6.2 years, with a homogeneous ethnic distribution, predominantly Hispanic, and a median pre-pregnancy BMI of 27.6 (IQR: 24.9-30.1) kg/m<sup>2</sup>. Ten patients underwent surgery with a BMI above 30 kg/m<sup>2</sup>. Nulliparity was noted in 48.7% of the cohort.

Table 1 displays clinical characteristics among the two centers performing fetoscopic SB repair surgeries. Presurgical evaluations revealed a median gestational age (GA) at referral of 23.3 (21.8 -24.7) weeks, with earlier GA referral in the Colombian group (22.1 [ $\pm 2$ ] compared to the Mexican group: 24.7  $[\pm 1.9]$  weeks; P=.001). The level of the lesion was similar among the centers, being below L2 in 83.3% of cases in Colombia and in all cases from Mexico. Surgery was performed at a median GA of 26 (25.2-26.5) weeks with a median surgical duration of 301 (244 - 351) minutes, achieving complete skin closure in 92.1% of the cases. The median hospital stay postsurgery was 5.68  $[\pm 2.7]$  days. There were no maternal deaths, and the most common obstetric complications postsurgery included PPROM (<37 weeks) (27%), threatened preterm labor (onset of symptomatic contractions before 37 weeks, 18.9%), chorioamnionitis (5.41%), and fetal demise (2.7%). No significant differences were observed between the two centers in obstetric outcomes, including gestational age at delivery, prematurity, and birthweight. However, it is noteworthy that the Colombian group achieved a greater gestational age and a significantly lower shunt placement rate than the fetoscopic repair group from Mexico (30.4% vs 76.9%; P=.019) (Table 1).

# Comparative analysis with MOMs and Latin America open repair reported experience

Table 2 describes the comparative data between our cohort, the hysterotomybased repair from the MOMs trial, <sup>17</sup> and open hysterotomy-based repair in Latin American centers. 15 Across these groups, maternal age, nulliparity, anatomical level of the lesion, and placenta location were comparable. However, maternal BMI was significantly higher in the fetoscopic repair group than in patients from MOMS trial (28.8  $[\pm 4.83]$  vs 26.2  $[\pm 3.3]$ , kg/m<sup>2</sup> P=.001). Surgery occurred at a later GA in the fetoscopic repair group (26±1.27) when compared to the MOMS (23.6±1.4 weeks) or the hysterotomy-based repair centers in LATAM (mean, 25.4±1 weeks; all P-values <.01)

Mean GA at delivery was significantly earlier in the hysterotomy-based groups than in our fetoscopic group (MOMS: 34.1  $[\pm 3.1]$  vs open-repair centers in LATAM: 34 [ $\pm 3.02$ ] vs Fetoscopic: 35.3 [ $\pm 3.79$ ] weeks; P values=.14 and .04, respectively), with a higher rate of spontaneous preterm births (<37 weeks) in the MOMs trial compared to our fetoscopic group (79.5% vs 47.4%; P=.001). When assessing spontaneous preterm births before 34 weeks, the rate was significantly lower in our cohort (15.8%) compared to the hysterotomy-based repair centers (MOMs: 46.2% and centers from LATAM 49%; P-values .004 and .001, respectively). Consequently, birthweights were significantly higher in the fetoscopic repair group (Fetoscopic: 2618 [ $\pm$ 738] vs MOMS: 2383 [ $\pm$ 688] vs open-repair centers in LATAM: 2236 [ $\pm 651$ ] grams; P=.17 and 0.003) (Table 2).

Cesarean delivery rate was significantly lower in the fetoscopic group (65.8%) than in the open repair groups (MOMS [100%] and open repair centers in LATAM [98.4%]; All *P* values <.001). Perinatal morbidity and neonatal complications showed no significant differences between the datasets at birth. With 9 of the 34 live births under 12 months, 1-year outcomes were assessed for 28 infants (82.3%), revealing no significant difference in hydrocephalus treatment between the fetoscopic and open fetal surgery groups (Table 2). No maternal deaths or other outcomes such as pulmonary edema or need for maternal transfusion were noted in the fetoscopic SB repair group.

# Discussion Principal findings of the study

Herein, we report the largest reported experience of laparotomy-assisted fetoscopic repair in Latin America. The principal finding of this study is the viability of laparotomy-assisted fetoscopic repair programs in middle-income settings, potentially conferring advantages such as reduction in prematurity and allowing for a vaginal birth over conventional open fetal repair. This could be of critical relevance, especially in middle-income countries. This innovative approach signifies a crucial advancement in obstetric outcomes in Latin America, demonstrating the region's potential to lead in adopting new surgical techniques.

# Results - in the context of what is known

Training and skill development for local healthcare professionals is key for implementing medical advances in low- and middle-income countries. Before the MOMs trial,<sup>17</sup> fetal surgery for myelomeningocele was a specialized expertise limited to a few global institutions. Hysterotomy-based fetal surgery, described in the MOMs trial, is still considered the gold standard for fetal SB repair. It involves a maternal laparotomy, a hysterotomy, dissection of the neural placode, watertight closure of the dura, and closure of the fetal skin.26 Other innovative techniques for intrauterine SB

**TABLE 1** Maternal demographics and clinical characteristics of patients that underwent laparotomy-assisted fetoscopic repair of fetal spina bifida in the 2 centers

Colombia (N=25)

Mexico (N=14)

Pvalue

	Colombia (N=25)	Mexico (N=14)	<i>P</i> value
Age, y	29.7 (6.17)	29.6 (6.37)	.971
Body mass index, kg/m <sup>2</sup>	28.2 (25.9-30)	26.4 (24.7—30.2)	.333
Weight classification:			.246
BMI below 25	5 (20.8)	6 (42.9)	
Overweight (BMI >25 kg/m <sup>2</sup> )	13 (54.2)	4 (28.6)	
Obesity (BMI >30 kg/m <sup>2</sup> )	6 (25)	4 (28.6)	
Highest maternal level of education			.002
Basic primary	1 (4.35)	2 (14.3)	
High School	8 (34.8)	11 (78.6)	
University	11 (47.8)	0	
Master's degree	3 (13)	1 (7.14)	
Nulliparity	10 (40)	9 (64.3)	.262
Gestational age at diagnosis, weeks	22.2 (±2)	24.7 (±1.9)	.001
Estimated fetal weight, grams	600 (±177)	726 (±171)	.064
Largest atrial width, mm	10.2 (8.8—12)	12.2 (9.22-16)	.659
Ventricle size >15 mm	2 (18.2)	7 (50)	.208
Type of lesion			.203
Myelomeningocele	22 (88)	9 (69.2)	
Myelocele	3 (12)	4 (30.8)	
Level of the lesion			.276
At or above L2	4 (16.7)	0	
Below L2	20 (83.3)	14 (100)	
Gestational age at surgery, weeks	25.8 (1.32)	26.5 (1.07)	.070
Gestational age at delivery, weeks	37 (35.3-38)	35 (34-37.3)	.206
Spontaneous preterm birth			
<37 weeks	9 (37.5%)	9 (64.3%)	.262
<34 weeks	3 (12.5%)	3 (21.4%)	.686
<30 weeks	1 (4.35%)	3 (21.4%)	.329
Birthweight, grams	2772 [2386;3208]	2430 [2040;2910]	.173
Cesarean section	16 (66.7%)	9 (64.3%)	.344
Neonatal death before discharge	2 (8.00%)	2 (14.3%)	.609

Values are expressed as mean  $\pm$  standard deviation, if data were normally distributed), as median (interquartile range), if nonnormally distributed, or as proportions (%), as appropriate.

BMI, body mass index; IQR, interquartile range; NICU, neonatal intensive care unit; VP, Ventriculoperitoneal.

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repair include an approach with a markedly smaller uterine incision (15 -20 mm), which has shown a 19%

PPROM rate and a mean gestational age at birth of 35 weeks, on par with our data but without allowing for a vaginal birth.<sup>27</sup>

Our technique, adapted from Belfort et al, involves accessing the uterus through a maternal laparotomy, using three uterine ports after securing the membranes against the uterine wall with sutures. 23,24 Another fetoscopic approach that has been described by different groups involves percutaneous access into the uterus; however, reported results from that approach include higher PPROM rates, earlier gestational age at birth, and a similar need for ventriculo-peritoneal shunting. 28,29

From our experience, an important lesson has been the significance of multidisciplinary robust teams, focusing on their learning curves at specialized centers. The necessity for ongoing research into fetal intervention programs in middle and low-income countries remains urgent. Such research is essential for customizing solutions to overcome global medical challenges and address the intricate healthcare needs unique to specific populations, including Latin America. Our findings, along with those reported by Sepulveda et al., 15 indicate that accumulating experience in managing myelomeningocele across Latin American countries is feasible.<sup>15</sup> However, while the hysterotomy-based approach detailed in the MOMs trial yielded positive results in primary outcomes -namely reducing fetal or neonatal death and the necessity for ventriculoperitoneal shunt placement by 12 months of age- also had concerning outcomes related to morbidity for the pregnant patient and the prematurity observed in the

All patients who undergo an open fetal SB repair need to be aware that all their subsequent pregnancies must have cesarean delivery before the onset of labor to prevent uterine rupture and potential fetal and maternal death.<sup>30</sup> By avoiding a large hysterotomy during fetoscopic SB repair, the risk of uterine rupture and the need for cesarean delivery decreases drastically, as shown in our cohort. This is particularly advantageous in Latin America, where cesarean-related morbidity is substantial.<sup>31</sup>

	Laparotomy-assisted fetoscopic repair in LATAM (N=39)	Hysterotomy-based repair in the MOMs trial (N=78) <sup>17</sup>	<i>P</i> value	Hysterotomy-based repair in centers from LATAM (N=314) <sup>15</sup>	<i>P</i> value
Maternal characteristics					
Maternal age, y	29.7 (± 6.2)	29.3 (± 5.3)	.94	29.2 (± 6.2)	.90
Maternal BMI, kg/m <sup>2</sup>	28.8 (± 4.83)	26.2 (± 3.3)	.001	NI	-
Nulliparity	19 (47.4)	33 (42.3)	.65	121 (38.5)	.64
Characteristics of the lesion					
Level of the lesion			.08		<.001
At or above L2	4 (10.5)	21 (26.9)		12 (3.82)	
Below L2	33 (89.2)	57 (73.1)		302 (96.2)	
Placenta location, anterior	16 (53.3)	36 (46.2)	.20	NI	-
Gestational age at surgery, weeks	26 (± 1.27)	23.6 (± 1.42)	<.001	25.4 (± 1.0)	<.001
Perinatal outcomes					
Gestational age at delivery, weeks	35.3 (± 3.79)	34.1 (± 3.1)	.14	34 (± 3.02)	.04
Preterm birth					
<37 weeks	18 (47.4)	62 (79.5)	.001	NI	-
<34 weeks	6 (15.8)	36 (46.2)	.004	154 (49)	.001
<30 weeks	4 (10.8)	10 (12.8)	1	36 (11.5)	1
Birthweight, grams	$2618~(\pm~738)$	2383 ( $\pm$ 688)	.17	2236 (± 651)	.003
Cesarean section	25 (65.8)	78 (100)	<.001	309 (98.4)	<.001
Neonatal death before discharge	4 (10.3)	2 (2.56)	.28	17 (5.41)	.39
Bronchopulmonary dysplasia	2 (5.41)	4 (5.13)	1.0	NI	-
Respiratory distress syndrome	9 (25)	16 (20.5)	.77	NI	-
Retinopathy	2 (5.56)	0	.23	NI	-
Necrotizing enterocolitis	2 (5.56)	1 (1.28)	.32	NI	-
Patent ductus arteriosus	2 (5.71)	3 (3.85)	.65	NI	-
Periventricular leukomalacia	0	4 (5.13)	.31	NI	-
Treatment of hydrocephalus at 12 months (VP Shunt)	17 (44.7)	31 (39.7)	.65	63 (37.7)	.65

Values are expressed as mean±standard deviation, if data were normally distributed), as median (interquartile range), if nonnormally distributed, or as proportions (%), as appropriate.

LATAM, Latin America; MOMs, management of myelomeningocele study; NI, no information; VP, Ventriculoperitoneal.

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Another advantage of the laparotomy-assisted fetoscopic repair approach is that delivery does not need to be scheduled by 37 weeks, <sup>32</sup> as recommended after open fetal SB repair surgery, and can be scheduled at full-term (39–40 weeks). We believe this could also represent a strength for developing countries with limited resources, minimizing the effects of spontaneous preterm birth or early-term delivery. <sup>32</sup>

# **Clinical implications**

Healthcare equity for disadvantaged populations is a very important matter to consider. Prenatal SB repair surgery shows improved quality of life of the family members and reduces parental stress. Maternal-fetal surgery demands considerable commitment from expectant mothers and families. Our surgical approach offers advantages, including the promotion of

vaginal delivery and the potential to reduce neonatal morbidity associated with prematurity, benefiting mothers and children. Moreover, our postoperative strategy of allowing the patient to return to their referring center suits Latin America's economic context, providing less financial burden. We hope our initiative can stimulate equitable access to advanced SB care in middle-income countries.

Long-term follow-up and community support for SB patients are vital. The MOMs trial indicates that fetal repair offers marginal urological benefits.35 Regular physical therapy and early intervention programs are crucial for these families. However, we acknowledge the limitations of our sample size in drawing definitive conclusions about long-term outcomes. To date, our data suggests no adverse neurological effects from delayed surgeries, consistent with findings from other studies in Latin America, where diagnostic delays have led to extended timelines for surgical interventions.<sup>15</sup> It is possible that in countries where termination of pregnancy is not an option, these surgeries, performed later in gestation, can still be beneficial. Emphasizing the importance of comprehensive care and community support for spina bifida patients in resource-constrained environments is essential. It is also important to emphasize that folate supplementation plays a crucial role in preventing spina bifida, particularly in low-income countries where access to adequate prenatal care and early diagnostic services may be limited. Public health initiatives to improve folate intake through supplementation or food fortification could significantly reduce the incidence of neural tube defects in these resourceconstrained settings.

# Strengths and limitations of the

Our study's strengths lie in the prospective data collection. While minor differences in trocar placement membrane plication exist between the two centers, the principles of the surgical procedure were uniformly applied. Moreover, since patients returned to their referring centers, the management plan for complications, such as the onset of preterm labor, PPROM, etc., may be exposed to some variability after being managed by different providers. Same as neurosurgical evaluation and care. This was attempted to be minimized since cases were discussed with referral centers to assure optimal clinical care. The comparison between our cohort and the hysterotomy-based cohorts (MoMs trial and LATAM) provides a valuable perspective on scenarios with differing resource availability. However, variability in the inclusion criteria between the cohorts exists, such as gestational age limits (up to 28 weeks) and maternal BMI thresholds (above 35 kg/ m<sup>2</sup>). These differences highlight the heterogeneity in patient selection but do not detract from the overall conclusions of this study. In addition, future studies with a larger sample size will be necessary to demonstrate statistically significant differences, as type II errors may occur with our limited cohort. These studies should aim to assess the persistence of early benefits and explore longterm cognitive, behavioral, and functional outcomes, including continence and sexual function.

### **Conclusions**

Laparotomy-assisted fetoscopic spina bifida repair represents a viable surgical option for middle-income countries, achieving obstetric outcomes comparable to those reported for hysterotomybased intrauterine spina bifida repair. Based on the results of this study, our approach reduces prematurity and facilitates vaginal deliveries. Future research should focus on collecting postnatal data to comprehensively assess neurological and long-term outcomes.

Ethical approval and informed consent were obtained for this study. The study protocol was approved by the ethics committees of the University of Cartagena School of Medicine (DB-FM-CERT 28 4-08-2023) and the Comité de Ética en Investigación of Christus Muguerza, Sistemas Hospitalarios S.A. de C.V. (CON-BIOETICA 19CEI00420170601). Written informed consent was obtained from all participants. The information collected from each study participant was kept confidential.

The dataset used in this study is available from the corresponding author upon reasonable request.

## Credit authorship contribution statement

Jezid Miranda: Writing - review & editing, Writing - original draft,

Supervision, Methodology, Investigation, Formal analysis, Data curation, Conceptualization. Miguel A. Parra-Saavedra: Writing - review & editing, Writing - original draft, Validation, Supervision, Methodology, Investigation, Conceptualization. William O. **Contreras-Lopez:** Writing – review & editing, Writing - original draft, Supervision, Formal analysis, Conceptualization. Cristóbal Abello: Writing review & editing, Writing - original draft, Supervision, Conceptualization. Guido Parra: Writing - review & editing, Writing - original draft, Conceptualization. Juan Hernandez: Writing review & editing, Writing - original draft, Validation, Conceptualization. **Amanda Barrero:** Writing – review & editing, Writing - original draft. Isabela Leones: Writing - original draft, Supervision, Conceptualization. Adriana Nieto-Sanjuanero: Writing review & editing, Writing - original draft, Data curation, Conceptualization. Gerardo Sepúlveda-Gonzalez: Writing - review & editing, Writing - original draft, Data curation, Conceptualization. Magdalena Sanz-Cortes: Writing review & editing, Writing - original draft, Supervision, Formal analysis, Conceptualization.

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## Supplementary materials

Supplementary material associated with this article can be found, in the online version, at doi:10.1016/j.xagr.2025. 100442.

#### REFERENCES

- 1. Ssentongo P, Heilbrunn ES, Ssentongo AE, Ssenyonga LVN, Lekoubou A. Birth prevalence of neural tube defects in eastern Africa: a systematic review and meta-analysis. BMC Neurol 2022;22(1):202.
- 2. Copp AJ, Adzick NS, Chitty LS, Fletcher JM, Holmbeck GN, Shaw GM. Spina bifida. Nature Reviews Disease Primers 2015;1:1-18.
- 3. Blencowe H, Kancherla V, Moorthie S, Darlison MW, Modell B. Estimates of global and regional prevalence of neural tube defects for

- 2015: a systematic analysis. Ann N Y Acad Sci 2018;1414(1):31-46.
- 4. López-Camelo JS, Castilla EE, Orioli IM. Folic acid flour fortification: impact on the frequencies of 52 congenital anomaly types in three South American countries. Am J Med Genet A 2010;152A(10):2444-58.
- 5. Acevedo CR, Anzueto ER, Mendez AG, Ramirez FM. Prevalencia de anomalías congénitas mayores externas, en recién nacidos atendidos en hospitales nacionales y regionales de Guatemala 2001-2003. Undergrad Thesis, Sch Med, Universidad de San Carlos de Guatemala 2004. Published online https://biblioteca. medicina.usac.edu.qt/tesis/pre/2004/001.pdf.
- 6. Atta CAM, Fiest KM, Frolkis AD, et al. Global birth prevalence of spina bifida by folic acid fortification status: a systematic review and meta-analysis. Am J Public Health 2016;106(1):e24-34.
- 7. Zaganjor I, Sekkarie A, Tsang BL, et al. Describing the prevalence of neural tube defects worldwide: a systematic literature review. Cruz-Martinez R, ed. PLoS ONE 2016;11(4):e0151586.
- 8. Castillo J. Social determinants of health and spina bifida care: immigrant and minority health in an era of quality of life and multicenter comparative analysis. Castillo J, ed. PRM 2018;11 (4):213-6.
- 9. Mai CT, Isenburg JL, Canfield MA, et al. National population-based estimates for major birth defects, 2010-2014. Birth Defects Res 2019;111(18):1420-35.
- 10. Bakker MK, Kancherla V, Canfield MA, et al. Analysis of mortality among neonates and children with spina bifida: an international registry-based study, 2001-2012. Paediatr Perinat Epidemiol 2019;33(6):436-48.
- 11. Oakeshott P, Hunt GM, Poulton A, Reid F. Expectation of life and unexpected death in open spina bifida: a 40-year complete, nonselective, longitudinal cohort study. Dev Med Child Neurol 2010;52(8):749-53.
- 12. Hug L, Alexander M, You D, Alkema L. National, regional, and global levels and trends in neonatal mortality between 1990 and 2017, with scenario-based projections to 2030: a systematic analysis. Lancet Glob Health 2019;7(6): e710-20.
- 13. Burstein R, Henry NJ, Collison ML, et al. Mapping 123 million neonatal, infant and child deaths between 2000 and 2017. Nature 2019;574(7778):353-8.

- 14. Campos-Miño S, Sasbón JS, von Dessauer B. [Pediatric intensive care in Latin Americal. Med Intensiva 2012:36(1):3-10.
- 15. Sepulveda W. Cruz-Martinez R. Etchegaray A, et al. Open intrauterine repair of spina bifida aperta: historical aspects, current availability, and clinical outcomes from the Latin American Spina Bifida Consortium. Prenat Diagn 2021;41(8):933-41.
- 16. Zarante I. Hurtado-Villa P. Walani SR. et al. A consensus statement on birth defects surveillance, prevention, and care in Latin America and the Caribbean. Rev Panam Salud Publica 2019;43:e2.
- 17. Adzick NS, Thom EA, Spong CY, et al. A randomized trial of prenatal versus postnatal repair of myelomeningocele. N Engl J Med 2011;364(11):993-1004.
- 18. Farmer DL, Thom EA, Brock JW, et al. The management of myelomeningocele study: full cohort 30-month pediatric outcomes. Am J Obstet Gynecol 2018;218(2):256.e1-256.e13.
- 19. Tulipan N, Wellons 3rd JC, Thom EA, et al. Prenatal surgery for myelomeningocele and the need for cerebrospinal fluid shunt placement. J Neurosurg Pediatr 2015;16(6):613-20.
- 20. Danzer E, Joyeux L, Flake AW, Deprest J. Fetal surgical intervention for myelomeningocele: lessons learned, outcomes, and future implications. Dev Med Child Neurol 2020;62 (4):417-25
- 21. Sanz Cortes M, Lapa DA, Acacio GL, et al. Proceedings of the first annual meeting of the international fetoscopic myelomeningocele repair consortium. Ultrasound Obstet Gynecol 2019;53(6):855-63.
- 22. Sanz-Cortés M, Chmait RH, Lapa D, Belfort MA, Carreras E, Miller JL. Experince of 300 cases of prenatal fetoscopic open spina bifida repair: report of the international fetoscopic neural tube defect repair consortium. Am J Obstet Gynecol 2021;225(6):678.
- 23. Belfort MA, Whitehead WE, Shamshirsaz AA, et al. Fetoscopic open neural tube defect repair: development and refinement of a twoport, carbon dioxide insufflation technique. Obstetr Gynecol 2017;129(4):734-43.
- 24. Belfort MA, Whitehead WE, Shamshirsaz AA, et al. Comparison of two fetoscopic open neural tube defect repair techniques: single- vs three-layer closure. Ultrasound Obstetr Gynecol 2020;56(4):532-40.

- 25. Belfort MA, Whitehead WE, Shamshirsaz AA, Ruano R, Cass DL, Olutoye OO. Fetoscopic repair of meningomyelocele. Obstetr Gynecol 2015;126(4):881-4.
- 26. Bennett KA, Carroll MA, Shannon CN, et al. Reducing perinatal complications and preterm delivery for patients undergoing in utero closure of fetal myelomeningocele: further modifications to the multidisciplinary surgical technique. J Neurosurg Pediatr 2014;14(1):108-14.
- 27. Cruz-Martínez R. Chavelas-Ochoa F. Martínez-Rodríguez M, et al. Open fetal microneurosurgery for intrauterine spina bifida repair. Fetal Diagno Ther 2021;48(3):163-73.
- 28. Lapa Pedreira DA, Acacio GL, Gonçalves RT, et al. Percutaneous fetoscopic closure of large open spina bifida using a bilaminar skin substitute. Ultrasound Obstetr Gynecol 2018;52(4):458-66.
- 29. Graf K, Kohl T, Neubauer BA, et al. Percutaneous minimally invasive fetoscopic surgery for spina bifida aperta. Part III: Neurosurgical intervention in the first postnatal year. Ultrasound Obstetr Gynecol 2016;47(2):
- 30. Goodnight WH, Bahtiyar O, Bennett KA, et al. Subsequent pregnancy outcomes after open maternal-fetal surgery for myelomeningocele. Am J Obstet Gynecol 2019;220(5):494.
- 31. Sosa C, de Mucio B, Colomar M, et al. The impact of maternal morbidity on cesarean section rates: exploring a Latin American network of sentinel facilities using the robson's ten group classification system. BMC Pregnancy Childbirth 2023;23(1):605.
- 32. Carreras E, Maroto A, Illescas T, et al. Prenatal ultrasound evaluation of segmental level of neurological lesion in fetuses with myelomeningocele: development of a new technique: Functional ultrasound in MMC. Ultrasound Obstet Gynecol 2016;47(2):162-7.
- 33. Antiel RM, Adzick NS, Thom EA, et al. Impact on family and parental stress of prenatal vs postnatal repair of myelomeningocele. Am J Obstet Gynecol 2016;215(4):522.e1-6.
- 34. Houtrow AJ, Thom EA, Fletcher JM, et al. Prenatal repair of myelomeningocele and school-age functional outcomes. Pediatrics 2020;145:e20191544.
- 35. Brock 3rd JW, Carr MC, Adzick NS, et al. Bladder function after fetal surgery for myelomeningocele. Pediatrics 2015;136(4):e906-13.