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A comparison of the MOMS trial results to a contemporaneous, single-institution, post-natal closure cohort

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Abstract

Purpose—We evaluate a single-institution cohort of mothers contemporaneous with the Management of Myelomeningocele (MOMS) trial to determine the generalizability of MOMS results and compare shunt rates.

Methods—A retrospective chart review identified patients with myelomeningocele born between 2003 and 2009. We applied MOMS eligibility criteria, and compared sociodemographic variables between patients at our institution who would have been eligible or ineligible and MOMS participants. Finally, we applied the original MOMS primary outcome and the revised primary outcome to our cohort.

Results—Of the 78 patients, 55 (70.5%) were eligible for the MOMS trial. Mean maternal age, race, and marital status were different from both MOMS groups. Comparing our series to MOMS postnatal shows fewer female infants (44.9% vs. 63.8%, p=0.017) and more thoracic lesions (12.8% vs. 3.8%, p=0.038). Shunt rates in our cohort (84.6%) were higher than MOMS prenatal and similar to MOMS postnatal (44.0% and 83.7% respectively). Fewer children met the original primary outcome than the postnatal group (84.6% vs. 97.8%, p=0.002). There was no significant difference between our cohort and the prenatal group (84.6% vs. 72.5%, p=0.058). When applying the revised criteria, we find the opposite: a significant difference between local and MOMS prenatal (84.6% vs. 49.5%, p<0.001) but no difference between the local group and MOMS postnatal (84.6% vs. 87.0%, p=0.662).

Conclusions—Mothers in our cohort differ from mothers enrolled in MOMS via several sociodemographic factors. Baseline fetal characteristics show a significantly higher functional lesion level in between our cohort and MOMS. Treatment of hydrocephalus in our series tracks almost identically with original MOMS shunt criteria. Revision of the criteria led to greater

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Conflict of Interest:

The authors declare that they have no conflict of interest.

concordance between meeting criteria and receiving a shunt in MOMS patients, but changes the results in our series.

Keywords

myelomeningocele; hydrocephalus; shunt; Chiari II malformation; Management of Myelomeningocele Study

Introduction

Myelomeningocele (MMC) is the most complex congenital neurologic defect that is compatible with life [Bowman 2009]. Children are often left with lifelong morbidity that affects their quality of life, including hydrocephalus, Chiari II malformation (CM-II), bladder and bowel dysfunction and some degree of paralysis of the lower extremities. Concomitant hydrocephalus is also common [1–8], but there is some variability in the literature regarding the frequency that MMC-related hydrocephalus requires surgical treatment. Rates vary in the literature between 57 and 86% [9–14].

The Management of Myelomeningocele Study (MOMS) was a randomized, controlled trial published in 2011 [15]. In this study, patients at three maternal-fetal surgery centers were randomized to receive *in utero* closure of myelomeningocele versus standard, postnatal closure. The primary endpoint for the trial was a composite of neonate death, and either cerebrospinal fluid (CSF) shunt placement or meeting the pre-specified criteria for CSF shunt placement (regardless of whether a shunt was placed). The trial was terminated early because of the demonstrated effectiveness of prenatal repair. Only 158 of 183 pregnancies were originally reported. Prenatal closure showed a lower rate of reaching the composite endpoint (68% versus 98%, $p<0.001$).

Inclusion criteria for MOMS enrollment were: 1) MMC at level T1 through S1 confirmed by ultrasound, 2) evidence of hindbrain herniation confirmed by MRI, 3) maternal age of at least 18 years, 3) gestational age at randomization of 19 to 25 weeks, and 4) normal karyotype. There were also several specific exclusion criteria, including: non-US residency, obesity (BMI ≥ 35), lack of a “support person” (e.g. husband, partner, mother), inability to comply with travel and follow-up requirements, and failure to meet psychosocial criteria for the trial (as determined by a psychosocial interviewer). See Table 1. These exclusion criteria have been a point of discussion, as it is argued that many expectant mothers carrying a child with MMC may not meet these criteria. Therefore, it is possible that the results of MOMS are not broadly applicable to a diverse patient population.

The MOMS trial also reported a large discrepancy between the number of children who received CSF shunts and those who met the pre-specified criteria for shunting. (See Table 2 with criteria). The initial article stated that there was a successful decrease in shunting rates when comparing the postnatal surgical group to the prenatal surgical group from 82% to 40%. However, substantially more patients in each group met the pre-specified criteria than actually underwent shunt placement (92% vs. 65%) [15]. A follow up publication in 2015 reported the 1-year outcomes for the entire 183-patient trial, and suggested a revision to the

CSF shunting criteria [16]. Using the revised criteria, the authors report much closer correlation between meeting revised criteria and actually receiving a CSF shunt.

The purposes of the present study are twofold. First, we intend to compare the mothers and children who participated in MOMS to those at a single, high volume institution over the same time period. We hypothesize that there are significant differences in sociodemographic variables between our population and the patients included in the MOMS trial. Second, we compare the rate of shunt placement among MOMS patients with our contemporaneous single-institution series. We compare the proportion of patients who met both primary MOMS criteria and revised MOMS criteria amongst our population. We hypothesize that the MOMS postnatal closure cohort is substantially similar to our series.

Methods

After institutional review board approval, we conducted a retrospective chart review of all myelomeningocele patients born, initially diagnosed, treated and followed at Children's of Alabama (COA) between February 2003 and July 2009 (concurrent with MOMS trial enrollment). Applicable MOMS inclusion criteria included a singleton pregnancy, maternal age of at least 18 years, a fetus with T1–S1 lesions by ultrasound, and evidence of hindbrain herniation (determined in our population using the first post-natal cerebral imaging study, as fetal MRI was not routinely available). Normal karyotype, U.S. residency, and gestational age at randomization (19–25 weeks) were not applied due to insufficient available data. Infant data including demographic, clinical, and birth information were captured. Maternal demographics including marriage status and past neural tube defect history were obtained from medical records.

We compared our institutional cohort to the MOMS inclusion criteria, characterizing the specific differences between our patients and those included in the MOMS trial. We then compared maternal and fetal characteristics of three groups: our patients who would have been MOMS eligible, our patients who would not have been MOMS eligible, and the MOMS postnatal closure group. Finally, we applied both the original MOMS shunting criteria and the revised 2015 MOMS shunting criteria to our series of patients and compared shunting rates to the full MOMS trial results.

Statistical tests (IBM SPSS Statistics for Windows, Version 21.0), including student T-test, Chi-square test, and Fisher's exact test were applied as appropriate (statistical significance defined as $p<0.05$).

Results

Patient Characteristics

We initially identified 80 patients. Two patients were excluded due to myelomeningocele closure elsewhere and birth place outside of the US, leaving a final cohort of 78 patients. After applying MOMS eligibility criteria for inclusion in the trial, 55 out of 78 patients in our institution would have been eligible.

The mean maternal age, race, and marital status in our population were significantly different from both MOMS surgical groups (Table 3). Notable distinctions include younger mean age (25.8±5.5; p<.0001 and p<.0004) and fewer white (70.5%) but more African-American (20.5%) mothers in the COA cohort compared to both MOMS groups (p<.001 for both comparisons). Additionally, fewer of the COA cohort (66.7%) were married or living with partner compared to both MOMS groups (93.6% and 92.5%, respectively; p<.001 for both comparisons). BMI was similar across groups.

Of our overall cohort, 23 (29%) patients would have been ineligible to participate in the MOMS trial. The most frequently encountered criteria that resulted in exclusion in our cohort was the absence of hindbrain herniation (33.3%). Additional exclusion criteria for our population can be seen in Table 4.

When compared to the MOMS postnatal closure group, the COA cohort had significantly fewer female fetuses (p=0.017) and fewer lesions at L3 or lower (70.5% vs. 83.8%, p=0.047), and more frequent thoracic lesions (12.8% vs. 3.8%, p=0.038). There were no other statistically significant differences between the COA cohort and the MOMS postnatal arm (Table 5). There were significant differences between the COA cohort and the MOMS prenatal group, with COA having a higher mean gestational age at birth (37.4 vs. 34.1 weeks, p<0.001) and higher mean birth weight (3.07±0.68 kg vs. 2.38±0.69 kg), as expected.

Characteristics of both the eligible (N=55) and the ineligible (N=23) COA groups were compared with each other and with the MOMS postnatal closure arm (Table 6). There were no significant differences in maternal characteristics between the COA cohort of MOMS eligible patients and MOMS ineligible patients. However, there were noteworthy fetal distinctions, which included lesion level on ultrasonography (p=0.001) and a greater proportion of female fetuses in the ineligible group (65.2% vs. 35.4%, p=0.019). Interestingly, despite the significant difference in lesion levels, lesions at or below the level of L3 were similar (69.1% vs. 73.9%). All other fetal characteristics analyzed between the two COA groups lacked significant variation.

Mothers in both the eligible and ineligible COA group were significantly different from mothers in the MOMS postnatal arm in mean age, race, and marital status. Compared with the MOMS postnatal cohort, the concomitant COA mothers were more likely to be younger (eligible 26.04±4.6 and ineligible 25.2±7.4 vs. MOMS 28.8±4.9; p=0.0013 and p=0.0071 respectively), African-American (eligible 20% and ineligible 21.7% vs. MOMS 1.3%; p<0.001 and p=0.002 respectively) and less likely to be living with a spouse or partner (eligible 67.3% and ineligible 65.2% vs. MOMS 92.5%; p<0.001 and p=0.002 respectively) (Table 6). The fetal characteristics of the eligible COA group demonstrated fewer female fetuses (36.4% vs. 63.4%, p=0.002) and fewer lesions at the level of L3 or lower (69.1% vs. 83.8%, p=0.044) when compared to the fetal characteristics of the MOMS postnatal group,

Evaluation of shunt criteria and related outcomes

The primary outcome for the MOMS trial was defined as a composite of fetal loss, infant death, CSF shunt placement or meeting the criteria for shunt placement before 1 year of age.

The 2015 revised composite outcome incorporates slightly different criteria for shunt placement (Table 2). Significantly fewer children from the COA cohort met the original composite outcome than those from the MOMS postnatal group (84.6% vs. 97.8%, p=0.002). There was no significant difference in primary outcome between our cohort and the MOMS prenatal group (84.6% vs. 72.5%, p=0.058).

However, when we consider the revised composite outcome, the results are exactly the opposite. There is no significant difference between the COA cohort and MOMS postnatal (84.6% vs. 87.0%, p=0.662), whereas significantly more COA patients met the revised criteria compared to MOMS prenatal (84.6% vs. 49.5%, p<0.001) (Table 7).

Actual CSF shunting rates in patients with MMC in our cohort (84.6 %) were higher than prenatal and similar to postnatal MOMS patients (44.0% and 83.7% respectively). Nearly all of our patients who received a shunt (82.1%) met MOMS criteria, and no patient who met criteria did not receive a shunt. This stands in contrast to the MOMS trial where 26.4% of the MOMS prenatal group and 14.1% of the MOMS postnatal group did not receive a shunt, despite meeting criteria for placement.

With regard to the revised 2015 criteria, there is a decrease in patients who met criteria and had a shunt placed in all three groups. Similarly, there is an increase in patients who did not meet criteria yet had a shunt placed. In the COA group, there is no change in the proportion of patients who met criteria and did not have a shunt (0), or those who did not meet criteria and did not have a shunt (15.4%). In contrast, in both MOMS groups, revision of the criteria led to a decrease in those who met criteria, but had no shunt; and an increase in those who did not meet criteria and had no shunt. To summarize, the 2015 change in criteria for shunt candidacy led to a higher rate of concordance between meeting shunt eligibility criteria and receiving a shunt in the both MOMS groups, and a lower rate of concordance between meeting shunt eligibility and having a shunt placed in our institutional cohort.

Discussion

MOMS Trial Eligibility

One of the limitations of the MOMS trial is the strict set of inclusion/exclusion criteria. Mothers who did not have adequate psychosocial support, including a partner or designated support person, were not eligible. Furthermore, participants were required to comply with the travel and follow up requirements, which in some cases amounted to several weeks or months away from home. While the necessity of these criteria is understandable from a research standpoint, it potentially impacts the study population and thereby may limit the applicability of the findings found within this tightly defined group. Since the MOMS intervention was fetal surgery, these strict inclusion criteria are necessary and appropriate to assure that mothers understand and are prepared to handle the many challenges attendant to fetal surgery. While we have only limited sociodemographic variables to use in comparison, in the present study, we have shown that mothers from our cohort were younger, and more often of minority race than those participating in MOMS. They were also substantially less likely to be married or living with their partner.

However, despite the differences in the mothers, there were fewer differences between the children from our cohort and the MOMS postnatal group. There were more female infants in the MOMS postnatal group (64% vs 45%), and fewer thoracic level MMCs (4% vs. 13%). Given the number of comparisons undertaken in this retrospective study, these two would fail to maintain statistical significance if a correction for multiple measures were applied. One might cautiously interpret this as a validation of MOMS results. In spite of the differences in the populations of mothers, the infants treated with postnatal closure were relatively similar between the MOMS cohort and our own. Conversely, the larger component of cephalad lesions within our own cohort may have been a factor affecting our shunt rates, as higher lesion level is associated with higher rates of hydrocephalus [16].

Interestingly, our own cohort of postnatal closure patients exhibited seemingly high rates of absent hindbrain herniation (33.3%) compared to the postnatal closure group within MOMS (4%), but was similar to the rate the MOMS group saw in their prenatal closure group (36%) [15]. It is unclear why such a contrast was seen in our own patients and may simply be attributable to population differences, but further study is likely required to elicit the cause.

Furthermore, when we compare those mothers from our cohort who would have met MOMS inclusion criteria to those who would not, we see no significant differences save the percentage of patients with L3–4 and L5–S1 lesions. This would suggest that the MOMS results might, to some extent, be more generalizable to the larger population, despite the aforementioned limitations.

Shunt Placement Criteria

Another point of discussion surrounding the MOMS trial relates to the discrepancy between patients meeting criteria for shunt placement and those who actually received a shunt. In the prenatal MOMS group, 70.4% of patients met criteria and only 44.0% actually received a shunt. The difference between meeting criteria and receiving a shunt is smaller in the MOMS postnatal group (93.4% vs. 83.6%). In our institutional series, 100% patients who met criteria received a shunt. One possible explanation for this is that MOMS shunting criteria guided COA practice during the years of the MOMS trial, which explains the congruence between MOMS postnatal cohort and our own. Another is that the discrepancy seen between the prenatal MOMS patients who met criteria and received a shunt represents a treatment bias. This is plausible, given that the treating outside neurosurgeons may not have been aware of which arm their patients fell into directly, but the mothers certainly would have been.

Interestingly, in our own cohort, the percentage of patients who met criteria for the primary outcome (84.6%) was not significantly different from the amount that met criteria in the prenatal MOMS group (72%). This would suggest that rates of hydrocephalus may not in fact be decreased in those patients that have undergone prenatal myelomeningocele repair, as has been previously described [15–17].

The stated intention of the MOMS shunting criteria is to provide a standardized, blinded assessment. The investigators realized that, given that neither the treating neurosurgeon nor the family could be blinded to the closure method, there was real potential for different

thresholds for shunting in prenatal versus postnatal closure patients. The discrepancy between the proportion of patients meeting criteria and those receiving shunts supports the notion that this concern was valid.

The 2015 revision to MOMS shunting criteria was performed to address a perceived evolution in management of the treatment of hydrocephalus during the 8-year duration of the MOMS trial [16]. The impact of applying the revised criteria to our series is that there is better correlation between meeting criteria for shunt placement and actually receiving a shunt in the MOMS patients while it demonstrated a lower correlation in our patients. It also changes the results of the present comparison between the local cohort and the two MOMS groups in interesting ways. In our institutional cohort, the proportion of patients reaching the original composite outcome was not significantly different from the MOMS prenatal cohort (84.6% vs. 72.5%, $p=0.058$). It becomes significantly different with the revised criteria (84.6% vs. 49.5%, $p<0.001$). The exact opposite is seen with the MOMS postnatal cohort (84.6% vs. 97.8%, $p=0.002$ original criteria; 84.6% vs. 87.0%, $p=0.662$ revised criteria).

The revision of shunt placement criteria has identified criteria more reflective of overall shunt placement practice in the setting of the MOMS trial. However, the new criteria less accurately reflect practice at our institution. It is important to note that while these revised criteria reflect past practice, they have not been validated or vetted as criteria to prospectively guide shunt placement in children with spina bifida.

Limitations

When applying the MOMS inclusion criteria to our own population of patients, we were limited by what variables were available for consideration. For example, we do not routinely obtain karyotype, so we have no basis for evaluating that eligibility criterion. In addition, fetal MRI was not typically performed, so we used the initial post-natal imaging study to determine the degree of fetal hindbrain herniation. Gestational parameters, such as gestational age and placental abruption were also not considered. Gestational age at diagnosis of MMC was removed from our own evaluation due to incomplete data and few diagnoses identified prior to 25 weeks gestational age.

When making comparisons between mothers from the COA series and those included in MOMS, we utilized only the original 158 patients from the first report of the MOMS trial [15]. Many maternal variables were not reported in the follow up study that included all 183 patients. Furthermore, there were some variables reported in the MOMS trial that we were unable to extract accurately from our medical record, such as years of schooling and maternal smoking status.

We elected to use the complete MOMS trial enrollment of 183 patients for the comparisons of shunting and shunt placement criteria. These results are largely similar to the original report, but give a more complete view of the trial results. Furthermore, using this complete group allows comparison between the original and the revised shunting criteria.

Conclusion

We have performed a retrospective review of our institutional series of children with myelomeningocele and their mothers born during the years of enrollment of the MOMS trial. We have shown that racial, socio-economic, and physiologic disparities exist in the maternal cohorts. The mothers from our cohort are significantly younger, more likely to be of an ethnic minority background, and less likely to be married. However despite these differences, the children from our cohort are remarkably similar in their baseline characteristics to those from the MOMS postnatal group.

Our institutional series shows rates of shunt placement that are almost exactly what would be predicted by the original MOMS criteria for shunt placement. Evolution of the criteria for shunt placement within the trial led to higher concordance between meeting criteria and receiving a shunt in the MOMS patients, but lower concordance in our institutional series. If the goal of the revised criteria is to better describe the shunting practices of the neurosurgeons who treated the MOMS patients, then this makes sense. However, if the goal of revised shunting criteria is to guide placement of shunts in children with myelomeningocele, prospective validation of these criteria is needed.

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TABLE 1

MOMS eligibility criteria

Inclusion Criteria	Select Exclusion Criteria
• Myelomeningocele (including myeloschisis) at level T1 through S1 with hindbrain herniation • Maternal age ≥18 years • Gestational age at randomization of 19–25 weeks • Normal Karyotype	• Non-resident of the United States • Multifetal Pregnancy • Obesity defined as BMI ≥35 • Lack of support person (e.g., husband, partner, mother) • Inability to comply with the travel and follow-up requirements • Failure to meet psychosocial criteria for the trial (as determined by a psychosocial interviewer)

* Detailed Inclusion and Exclusion Criteria can be found in MOMS Supplementary Appendix

TABLE 2

MOMS Primary and Revised Shunting Criteria

Primary Criteria	Revised Criteria
1) Meeting at least two: • (a) an increase in the circumference/crossing percentiles • (b) a bulging fontanelle or split sutures or sunsetting sign • (c) an increasing hydrocephalus on consecutive imaging studies • (d) head circumference >95th percentile	**1)** Bulging fontanelle or split sutures or sunsetting sign AND one of the following: • (a) an increase in the circumference/crossing percentiles • (b) an increasing hydrocephalus on consecutive imaging studies • (c) head circumference >95th percentile
2) Syringomyelia with ventriculomegaly	**2)** Syringomyelia with ventriculomegaly
3) Ventriculomegaly and symptoms of Chiari II Malformation	**3)** Ventriculomegaly and symptoms of Chiari II Malformation
4) Persistent CSF leakage from the myelomeningocele wound or bulging at the repair site	**4)** Persistent CSF leakage from the myelomeningocele wound or bulging at the repair site

TABLE 3

Baseline characteristics of the mothers in the overall study population *

Characteristic	COA (N=78)	MOMS prenatal (N=78)‡	MOMS postnatal (N=80)‡	p-value	p-value
	1	2	3	1–2	1–3
Age – yrs †	25.8±5.5; M 26	29.3±5.3	28.8±4.9	**<.0001**	**<.0004**
Race or ethnicity, no. (%)					
white	55 (70.5)	73 (93.6)	74 (92.5)	**<.001**	**<.001**
black	16 (20.5)	1 (1.3)	1 (1.3)	**<.001**	**<.001**
hispanic	7 (9.0)	2 (2.6)	4 (5.0)	0.167	0.326
other	0 (0.0)	2 (2.6)	1 (1.3)	0.497	1.000
Married or living with partner, no. (%)	52 (66.7)	73 (93.6)	74 (92.5)	**<.001**	**<.001**
BMI †	25.3±5.5; M 23.5; (N=54)	26.2±3.7	25.9±3.9	0.232	0.429

BMI = Body Mass Index; M = Median

* Statistical analysis was performed using student T-Test, Fisher's exact test, and chi-square test, as appropriate.

† Values are reported as mean ± SD

‡ The initial patients reported by MOMS[1]

TABLE 4

Frequency of exclusion criteria met by ineligible COA cohort *

Exclusion Criteria	No. (%)
Absent Hindbrain Herniation	7/21 (33.3)
Maternal age <18 years	6/22 (27.3)
Multifetal pregnancy	6/23 (26.1)
MMC at level other than T1–S1	4/23 (17.4)
BMI ≥ 35	1/12 (8.3)

MMC = Myelomeningocele; BMI = Body Mass Index

* Data for Hindbrain Herniation, Maternal Age, and BMI of the entire ineligible COA cohort were not available for consideration.

TABLE 5

Fetal characteristics of the overall study population [*]

Characteristic	COA (N=78)	MOMS prenatal (N=78)[‡]	MOMS postnatal (N=80)[‡]	p-value	p-value
	1	2	3	1–2	1–3
Fetal sex female, no. (%)	35 (44.9)	35 (44.8)	51 (63.8)	1.000	**0.017**
Lesion level on ultrasonography, no. (%)				**0.025**	0.051
Thoracic	10 (12.8)	4 (5.1)	3 (3.8)	0.093	**0.038**
L1–L2	11 (14.1)	21 (26.9)	10 (12.5)	**0.047**	0.767
L3–L4	36 (46.2)	30 (38.5)	45 (56.3)	0.331	0.204
L5–S1	17 (21.8)	23 (29.5)	22 (27.5)	0.271	0.406
Other	4 (5.1)	0 (0.0)	0 (0.0)	0.120	0.057
Lesion level L3 or lower, no. (%)	55 (70.5)	53 (67.9)	67 (83.8)	0.729	**0.047**
Gestational age at birth – wks [†]	37.4±2.37; M 38.0	34.1±3.1	37.3±1.1	**<.0001**	0.7331
Gestational age at birth, no. (%)				**<.001**	0.442
<30 wks	2 (2.6)	10 (12.8)	0 (0.0)	**0.016**	0.242
30–34 wks	5 (6.4)	26 (33.3)	4 (5.0)	**<.001**	0.744
35–36 wks	10 (12.8)	26 (33.3)	8 (10.0)	**0.002**	0.577
≥37 wks	61 (78.2)	16 (20.5)	68 (85.0)	**<.001**	0.27
Birth weight					
Mean – kg [†]	3.07±0.68; M 3.12	2.38±0.69	3.04±0.47	**<.0001**	0.7469

M = Median

[*] Statistical analysis was performed using student T-Test, Fisher's exact test, and chi-square test, as appropriate.

[†] Values are reported as mean ± SD.

[‡] The initial patients reported by MOMS.[1]

TABLE 6

Characteristics of eligible and ineligible COA cohort*

Characteristic	Eligible COA (N=55)	Ineligible COA (N=23)	MOMS Postnatal (N=80)‡	p-value	p-value	p-value
	1	2	3	1–2	1–3	2–3
Mother						
Age – yrs†	26.04±4.6	25.2±7.4	28.8±4.9	0.5455	**0.0013**	**0.0071**
Race or ethnicity, no. (%)				0.685	**0.002**	**0.001**
white	40 (72.7)	15 (65.2)	74 (92.5)	0.507	**0.002**	**0.002**
black	11 (20.0)	5 (21.7)	1 (1.3)	1.000	**<.001**	**0.002**
hispanic	4 (7.3)	3 (13.0)	4 (5.0)	0.687	0.485	0.184
other	0 (0.0)	0 (0.0)	1 (1.3)	NA	1.000	1.000
Married or living with partner, no. (%)	37 (67.3)	15 (65.2)	74 (92.5)	0.861	**<.001**	**0.002**
BMI†	25.36±5.75; N=42	25.05±5.07; N=12	25.9±3.9	0.8667	0.5404	0.5007
Fetus						
Fetal sex female, no. (%)	20 (36.4)	15 (65.2)	51 (63.4)	**0.019**	**0.002**	0.897
Lesion level on ultrasonography, no. (%)				**0.001**	0.081	**<.001**
Thoracic	7 (12.7)	3 (13.0)	3 (3.4)	1.000	0.090	0.123
L1–L2	10 (18.2)	1 (4.3)	10 (12.5)	0.745	0.361	1.000
L3–L4	30 (54.5)	6 (26.1)	45 (56.3)	**0.022**	0.845	**0.011**
L5–S1	8 (14.5)	9 (39.1)	22 (27.5)	**0.016**	0.075	0.284
Other	0 (0.0)	4 (17.4)	0 (0.0)	**0.006**	NA	**0.002**
Lesion level L3 or lower, no. (%)	38 (69.1)	17 (73.9)	67 (83.8)	0.670	**0.044**	0.36
Gestational age at birth – wks†	37.6±2.1	37.0±2.9	37.3±1.1	0.3091	0.2816	0.4486
Birth weight - kg†	3.11±0.59	2.99±0.88	3.04±0.47	0.4837	0.4453	0.7184

BMI = Body Mass Index

*Statistical analysis was performed using student T-Test, Fisher's exact test, and chi-square test, as appropriate.

†Values are reported as mean ± SD.

‡The initial patients reported by MOMS.[1]

TABLE 7

Primary and Revised composite outcomes*

Outcome	No. (%)			p-value	p-value
	COA (N=78)	MOMS Prenatal (N=91) †	MOMS Postnatal (N=92) †		
	1	2	3	1–2	1–3
Primary Outcome	66 (84.6)	66 (72.5)	90 (97.8)	0.058	**0.002**
Death before shunt criteria could be evaluated	0 (0.0)	2 (2.2)	0 (0.0)	0.500	NA
Met criteria, shunt placed	64 (82.1)	40 (44.0)	73 (79.3)	**<.001**	0.929
Did not meet criteria, shunt placed	2 (2.6)	0 (0.0)	4 (4.3)	0.212	0.688
Met criteria, no shunt placed	0 (0.0)	24 (26.4)	13 (14.1)	**<.001**	**0.001**
Did not meet criteria, no shunt placed	12 (15.4)	25 (27.5)	2 (2.2)	0.058	**0.002**
Revised composite outcome	66 (84.6)	45 (49.5)	80 (87.0)	**<.001**	0.662
Death before shunt criteria could be evaluated	0 (0.0)	2 (2.2)	0 (0.0)	0.500	NA
Met criteria, shunt placed	43 (55.1)	25 (27.5)	63 (68.5)	**<.001**	0.073
Did not meet criteria, shunt placed	23 (29.5)	15 (16.5)	14 (15.2)	**0.044**	**0.025**
Met criteria, no shunt placed	0 (0.0)	3 (3.3)	3 (3.3)	0.250	0.251
Did not meet criteria, no shunt placed	12 (15.4)	46 (50.5)	12 (13.0)	**<.001**	0.662

*Statistical analysis was performed using Fisher's exact test and chi-square test, as appropriate.

†The complete number of enrollees for MOMS.[13]