

## Global neurosurgery: Reflections on myelomeningocele in the Zanzibar archipelago (Tanzania)

Luis Moreno-Oliveras<sup>a,\*</sup>, Ruben Rodriguez-Mena<sup>a</sup>, Hadia Nahoda<sup>b</sup>, Pilar Chisbert-Genoves<sup>a</sup>, Mohamed Ali Haji<sup>b</sup>, Jose L. Llacer-Ortega<sup>a</sup>, Jose Piquer-Belloch<sup>a,b</sup>

<sup>a</sup> *Cátedra Neurociencia Global y Cambio Social NED VIU. Calle Pintor Sorolla 21, 46002, Valencia, Spain*

<sup>b</sup> *Neurosurgery Education and Development (NED) Institute, Mnazi Mmoja Hospital, Zanzibar, Tanzania*

### ARTICLE INFO

#### Keywords:

East Africa  
Global neurosurgery  
Hydrocephalus  
Myelomeningocele  
NED Institute  
Neurosurgical care

### ABSTRACT

**Objective:** Our main goal was to describe the general characteristics and demographic data of myelomeningocele (MMC) patients at Mnazi Mmoja Surgical NED Institute (MMSNI) in Zanzibar and to assess the clinical characteristics and medium-term result-impact of the implemented health care measures.

**Methods:** This is a retrospective study on 41 MMC patients treated at the MMSNI in Zanzibar (Tanzania) from September 2016 to September 2018. Patient demographics, prenatal care, clinical and radiographic characteristics, surgical management and nursing care, and clinical outcomes were abstracted.

**Results:** The mean age of the patients was  $6.1 \pm 4.6$  days, and 53.7% were males. A total of 51.2% came from Zanzibar, 39% to Pemba, and 9.8% from mainland Tanzania. Maternal ultrasound checkups revealed hydrocephalus in 18.7% of the cases. 85.4% of the newborns were operated on. Surgical wound infection was the most frequent complication (28.6%). A significantly higher risk of complications was observed in children from Pemba Island ( $p = 0.046$ ) and those born by vaginal delivery ( $p = 0.694$ ), particularly infections. During follow-up, 48.57% of the patients presented with infantile hydrocephalus and in the majority of them, a ventriculoperitoneal shunt was inserted.

**Conclusions:** Proper prenatal care with early diagnosis, together with the neurosurgical and nursing standard of care in a specialized institution, are all essential to increase the chances of successful treatment of newborns harboring MMC and is one of the main goals pursued in the MMSNI, as the only referral public health center with locally trained health personnel in Zanzibar archipelago.

### 1. Introduction

Open spina bifida or myelomeningocele (MMC) is a closure defect of the spinal neural tube with exposure to its contents: the spinal cord and nerve roots. The treatment of this pathology represents a great challenge in the public health system of East African countries given the lack of adequate framework for epidemiological research, the excessive socio-economic impact, and limited progress on health care quality in these underdeveloped countries. Early access to prenatal care is crucial, but there is no functioning clinical or educational infrastructure in sub-Saharan Africa for the prevention and/or early detection of neural tube defects (NTDs). This is likely to contribute to the higher incidence, and, although published data are still scarce,<sup>1-4</sup> an estimated 37,000

children are born with spina bifida each year in sub-Saharan Africa.<sup>4</sup>

The Valencia-based Neurosurgery, Education and Development (NED) foundation has developed a new and evolving model to address this problem: the establishment of an exclusively humanitarian and public neurosurgical institution in Zanzibar, Tanzania, supporting the expansion and consolidation of neurosurgical care in the country.<sup>5-9</sup> The Mnazi Mmoja Surgical NED Institute (MMSNI) is located on the outskirts of Stone Town (the capital of the island), the historic center of the city of Zanzibar (Tanzania). The hospital is managed by the NED Foundation and the Government of Zanzibar, serving a population of approximately 1.8 million people. It has Computerized Axial Tomography (CAT), three hospitalization rooms with five beds each, two operative rooms, a sterilization center, a post-operative recovery area with six beds, an

**Abbreviations:** CAT, computerized axial tomography; CSF, cerebrospinal fluid; LMIC, low and middle-income countries; MMC, myelomeningocele; MMSNI, Mnazi Mmoja surgical NED Institute; NED, neurosurgery education and development; NTDs, Neural tube defects; VPS, ventriculoperitoneal shunt.

\* Corresponding author. Cátedra Neurociencia Global y Cambio Social NED VIU, Valencian International University, Spain.

E-mail address: [moreno\\_luioli@gva.es](mailto:moreno_luioli@gva.es) (L. Moreno-Oliveras).

<https://doi.org/10.1016/j.wnsx.2023.100222>

Received 6 September 2022; Received in revised form 16 May 2023; Accepted 12 June 2023

Available online 30 June 2023

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office, and a minor surgery room (Fig. 1). A comprehensive electronic database is regularly updated with all relevant clinical information from patients' medical records. In addition to neurosurgical practice, continuing education and training have been provided to healthcare personnel since 2008. Our purpose is to describe the clinical and epidemiological characteristics of the patients with MMC treated at the MMSNI and to assess the medium-term results of the implemented nursing and neurosurgical care measures.

## 2. Material and methods

This is a retrospective, descriptive study on MMC patients operated from September 2016 to September 2018 at the MMSNI in Zanzibar, including those that were born at Mnazi Mmoja Hospital, as well as the ones referred from any medical center or hospital in the Zanzibar archipelago (Unguja and Pemba islands). Patients with other forms of NTDs (i.e., spina bifida occulta, encephalocele, and anencephaly), and with known genetic syndromes or other serious comorbidities that could represent a significant immediate threat to their lives were excluded. Local institutional review board approval was obtained and all the patients' families signed an informed consent agreeing to participate in this study. Demographic data, maternal and neonatal history (e.g., folate supplement intake during early pregnancy, prenatal ultrasound checkups, gestational age at birth) together with physical examination, having special attention to any neurological deficits and the presence of cerebrospinal fluid (CSF) leak and/or purulent discharge from the dysraphism, were collected.

Personal hygiene was applied to patients before surgery and the cleaning and sterilization of the operating room and surgical instruments were monitored. Furthermore, complementary preoperative tests were completed, fasting protocol and antibiotic prophylaxis were insisted upon, and the surgical site was shaved moments before the surgical incision. The cleaning and disinfection of the surgical instruments were carried out with enzymatic detergents, sterilizing the heat-resistant surgical instruments and textiles using the steam sterilization method at 134 °C. The endoscopes used for ventriculostomies were sterilized by chemical sterilization with peracetic acid (Perasafe®), immersing the optics and their components for 10 min as recommended by the manufacturer. After surgery, antiseptic cleaning of the wound was performed. All surgical procedures were performed based on cleaning, disinfection, and sterilization techniques following international recommendations.<sup>10-14</sup>

All MMC surgical repairs were performed under general anesthesia. Antibiotic prophylaxis was administered 30 min before surgery and during the following 10 days (covering gram-negative bacteria). Patients were daily monitored in the ward for around 2 weeks after the surgical intervention, during which the cranial perimeter was measured and their neurological status was evaluated, having special consideration for any improvement or worsening of their neurological function.



Fig. 1. The NED Institute within the grounds of Mnazi Mmoja Hospital.

If postoperative hydrocephalus was suspected, a transfontanelar ultrasound was performed to confirm and plan the correct treatment. Proper cleaning and dressing of the wound were performed every two days. At discharge, all mothers received nursing advice about daily bathing and basic hygiene measures including frequent diaper changes, wound dressing check-ups, temperature control, as well as early detection of warning signs.

Patients were followed-up for at least one year after discharge. In each appointment at the outpatient clinic, patient evaluation combined: Head circumference measurement, general physical and neurological examination, and surgical wound care (if necessary). Infants from the island of Pemba or remote villages were followed-up by their local primary care doctor while maintaining consecutive telephone contact with the MMSNI head nurse. Detection of late hydrocephalus and signs of wound infection were some of the main goals during check-ups. In the event of hydrocephalus being diagnosed, readmission for surgical placement of a ventriculoperitoneal shunt (VPS) was scheduled accordingly.

Statistical analysis was conducted with Microsoft Office Excel 2011 and SPSS version 22.0 (IBN Corp., Armonk, New York, USA). Bivariate analysis with Chi-square was conducted to compare the place of origin (birth), prenatal care, vaginal delivery, early antibiotic therapy, presence of CSF leak and/or purulent discharge from the dysraphism, and the development of perinatal and postsurgical infections as well as mortality, during hospitalization and follow-ups. Student *t*-tests were conducted to compare the meantime to receiving the first neurosurgical consultation, the defect area, cranial perimeter, the mean hospital stay, and the presence of surgical and non-surgical complications and mortality, also during hospitalization and follow-ups.

## 3. Results

In total, there were 41 patients diagnosed with MMC at the MMSNI. 53.7% ( $n = 22$ ) were male, with a mean age of  $6.1 \pm 4.6$  days. 51.2% ( $n = 21$ ) of the patients came from Zanzibar, 39% ( $n = 16$ ) from Pemba, and 9.8% ( $n = 4$ ) from the mainland. Concerning maternal data, prenatal care by a doctor was given to most of the pregnant women (97.6%). Ultrasound checkups were made in 78% of them ( $n = 32$ ), and open spina bifida was detected in 5 patients (15.6%). Other common findings such as ventriculomegaly in 6 cases (18.7%) and breech position fetuses in other 6 cases (18.7%) were revealed, with normal ultrasound reports in the rest of the mothers (46.9%,  $n = 15$ ). Only 3 women (7.3%) received prophylactic treatment with folic acid. Almost all our cases (97.6%) were full-term pregnancies, and no one tested positive for HIV. A total of 90.2% ( $n = 37$ ) of the children were born by vaginal delivery and only 4 cesarean sections were performed. 89% ( $n = 33$ ) of the former were eutocic and happened inside a hospital, while the other 8 children (21.6%) were born at home (Fig. 2). The average head circumference at birth was  $34 \pm 3.4$  cm. Antibiotic prophylaxis was administered to 70.7% ( $n = 29$ ) of the study sample just following delivery, with the use of amoxicillin in 44.8% and gentamicin in 55.3% of the cases.

In the first 24 h after birth, merely 41.5% of newborns were seen by a doctor at the MMSNI. The meantime to receive the first neurosurgical consultation was 6 days, ranging from around 2.8 days, when patients were born in Zanzibar, up to 11.2 days, if they were coming from Pemba. Spina bifida was characterized by having an open defect, with incomplete epithelialization in 70.7% of the cases. Upon arrival at the MMSNI, 34.1% ( $n = 14$ ) had CSF fistula associated with the defect, and purulent discharge was observed in 29.3% of them ( $n = 12$ ), with 3 patients presenting with fever. The mean surface area of the defect was  $25.2 \pm 16.2$  cm. Lumbosacral (L3-S1) was the most common location of the MMC (70.7%). In relation to motor function, 46.3% presented with a motor level of L2 or higher, 41.5% with a level of L3-L4, and 36.6% with a level of L5 or lower. A cranial CAT scan was requested only for 21.9% of the neonates ( $n = 9$ ), in situations when transfontanelar ultrasound

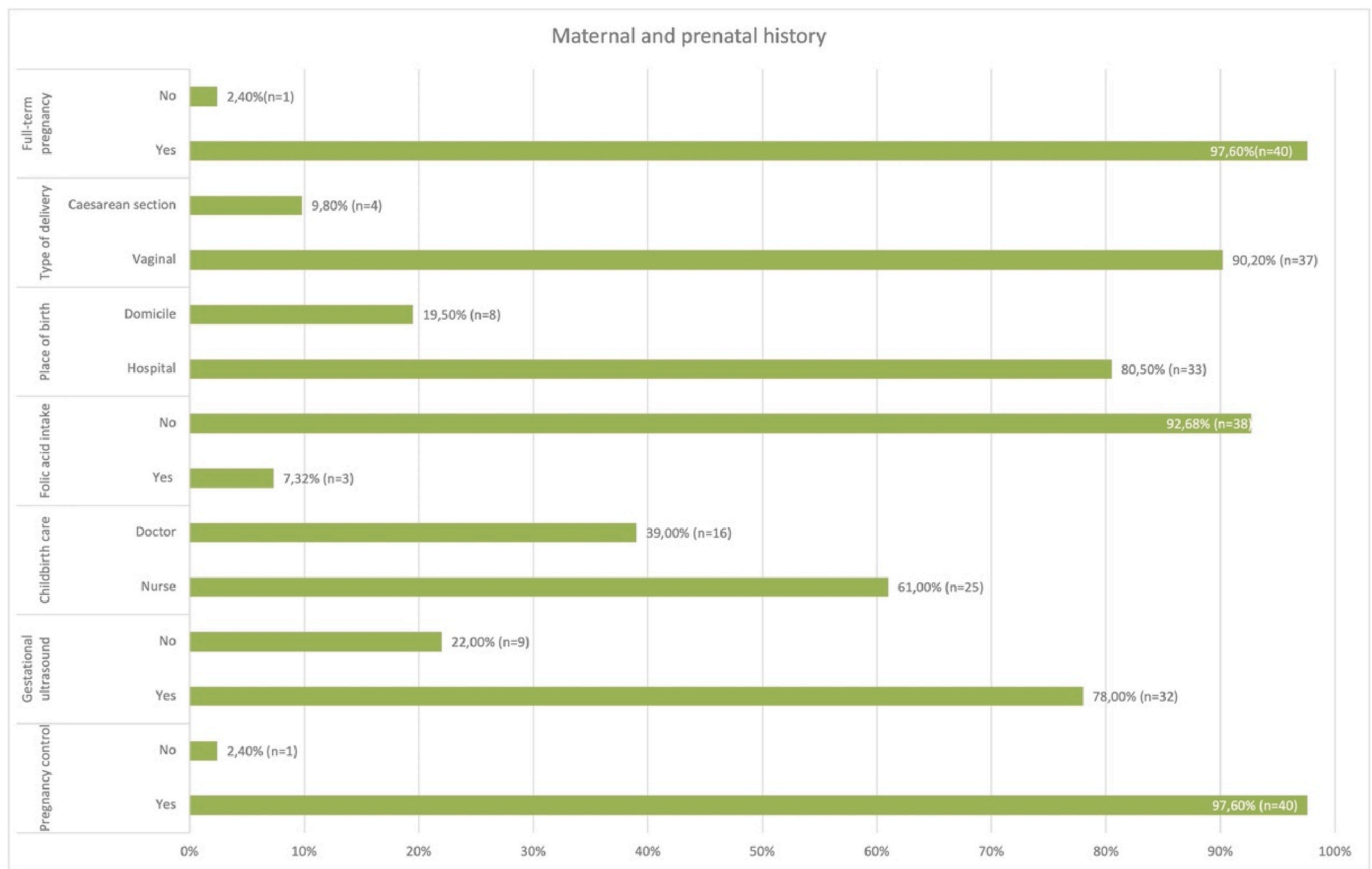


Fig. 2. Maternal and prenatal history.

diagnosis of hydrocephalus was uncertain. Mean hemoglobin was  $13.6 \pm 4.0$  mg/dL, noticing a lower hemoglobin count in neonates derived from Pemba than in those coming from Zanzibar, 11.4 mg/dL and 14.7 mg/dL, respectively.

85.4% of the patients ( $n = 35$ ) were operated on. Superficial surgical wound infection occurred in 28.6% ( $n = 10$ ) of the patients and was the most frequent postoperative complication; followed by CSF leak in 2 cases, severe bronchospasm in 2 patients, and finally, 1 patient with sepsis and progressive deterioration who died during hospital admission (Table 1). Postoperative CSF leak management included surgical revision and repair with subsequent new closure of the defect back again. Superficial wound infections were solved conservatively with a period of intravenous antibiotic treatment and daily local wound care. The mean stay was about 25 days.

Among the 6 remaining patients who were not operated on (14.6%), it's worth mentioning 4 newborns arriving from Pemba in critical condition: one (9 days old) who presented purulent discharge in the region of the defect and septic shock, and other 3 with respiratory distress, stridor, malnutrition and hemodynamically unstable. All of them died in

Table 1  
Complications and secondary hydrocephalus.

Complications	n = 35 (100%)
<b>Early postoperative complications:</b>	15 (42,87%)
• Surgical site infection	10 (28,57%)
• CSF fistula	2 (5,72%)
• Severe bronchospasm	2 (5,72%)
• Bloating	1 (2,86%)
<b>Complications after hospital discharge:</b>	4 (11,42%)
Secondary hydrocephalus:	17 (48,57%)
• Mean time from diagnosis and CMM repair (days)	44,85
• Mean time from MMC repair and DVP placement (days)	21,37

the hospital. Babies born from vaginal delivery had statistically significantly greater chances of suffering perinatal infections ( $p = 0.044$ ) and CSF leak from the dysraphism, and there was a significant association between being derived from Pemba and developing any type of complication during their hospital stay ( $p = 0.046$ ). Overall, during postoperative admission and after discharge, 48.6% of the infants with MMC ( $n = 17$ ) were diagnosed with infantile hydrocephalus, confirmed with transfontanelar ultrasound and/or CAT scan, and in the majority of them ( $n = 15$ ), a ventriculoperitoneal shunt was placed in a mean period of  $21.4 \pm 8.5$  days, with a mean age of  $60 \pm 6$  days old at the time of the surgery. In the other 2 cases, endoscopic III ventriculostomy was the procedure of choice (performed in a mean period of  $54.5 \pm 14.8$  days). The mean time between MMC repair and the diagnosis and consecutive treatment of hydrocephalus was  $44.9 \pm 7.5$  days.

Follow-up visits at the Institute took place after an average of 7 days from discharge. During one year of follow-up, any improvement of baseline neurologic function (including sensory and/or motor response in lower limbs) was evident in 16 cases; nevertheless, no apparent bladder and bowel function recovery was confirmed. 4 patients presented late complications after discharge: surgical site infection in 3 cases, resolved with conservative management (as described previously), and sepsis in a newborn with malnutrition and severe dehydration. A few days after hospital discharge, one of the operated patients died at home due to a severe respiratory infection. Hence, the total mortality rate in the current series was 19.5% ( $n = 8$ ), including 2 surgical patients and 6 nonsurgical patients. Although not statistically significant, a higher risk of death was seen in newborns coming from Pemba, and those with greater size of the neural defect; also, a lower risk was noticed in newborns managed with early antibiotic therapy.

#### 4. Discussion

Demographic and epidemiological data related to NTDs in low- and middle-income countries (LMIC) are scarce and uncertain; however, they are necessary to understand their incidence and risk factors, in addition to design strategies for their prevention and treatment. A recent report from Ethiopia<sup>15</sup> estimated that NTDs comprise an annual birth incidence of 63.4 per 10,000 births.<sup>16</sup> Likewise, in Tanzania, the numbers were 13.0 per 10,000 births with no precise information on the Zanzibar archipelago. Generally, much of the clinical and epidemiological information available from patients with open spina bifida is obtained from studies carried out in tertiary hospitals; thus, there is significant bias on this topic in sub-Saharan African countries.<sup>17</sup>

There are still ongoing difficulties in Sub-Saharan Africa regarding the prevention, diagnosis, and management of patients with NTDs. Lack of resources and substantial differences in health policies make it difficult the existence of a standardized healthcare program that could reduce mortality and disability and improve quality of life.<sup>1</sup> On numerous occasions, diagnosis of MMC is not made by prenatal ultrasound checkups, but it's rather a clinical finding at the time of delivery, a situation supported by this investigation, where an indirect prenatal diagnosis was only registered in 6 cases (18.7%). Therefore, the main health leaders in charge must take action to implement proper prenatal care programs that grant pregnant women the opportunity to have access to ultrasound checkups done by well-trained health workers. This would allow gynecologists and midwives to recognize obstetric risks and make informed decisions, and ultimately schedule elective cesarean sections or judiciously monitor vaginal deliveries for these patients. Furthermore, in our sample, no patients with CSF leak were observed after cesarean delivery, but there was a risk of suffering interruptions of lumbar dysraphism defects and the resulting CSF leak, due to trauma during the passage through the birth canal, principally in instrumented deliveries. Likewise, vaginal delivery was demonstrated to be a significant risk factor to develop perinatal infections, given that early contact with the bacterial flora of the birth canal could be responsible for neonatal sepsis in NTDs.

Many sub-Saharan countries have implemented programs to provide folates to women of childbearing age, such as grain fortification projects. Some researchers have stated that when the intake is started on time, the appearance of NTDs can be reduced by up to 70%.<sup>1,18–20</sup> In the Zanzibar archipelago, Plotkin et al<sup>21</sup> concluded that 52% of all pregnant women in Zanzibar had received folic acid supplements in their diet. This information is in great contrast to our current research since only 7.32% had taken folate supplements, consistent with a previous publication from our group on patients with infantile hydrocephalus (8.30% of folate supplement intake).<sup>22</sup>

MMC patients are born in primary health centers, without anticipating needs such as neonatal intensive care or early neurosurgical treatment. Among perinatal risks, we must acknowledge that, on many occasions, traumatic, instrumented, and/or prolonged deliveries can damage the integrity of the lumbar defect. Moreover, in LMIC countries the lack of access to an intensive care unit requires the newborn to be transferred to a different institution. In that event, long-distance transportation often takes place to offer treatment in more specialized referral centers, which entails high costs and delayed management. All these factors imply there are higher risks of presenting CSF leaks, meningitis, and severe sepsis, secondary to the open and infected lumbar defect.<sup>1,4</sup>

On the other hand, in high-income countries, patients with MMC are operated on in the first 24 h, and opportunities for intrauterine surgeries are rising in specific centers. Sims et al<sup>4</sup> warned that between 24 and 48 h, early neonatal surgery reduces complications and mortality. The setbacks that sub-Saharan countries face to accomplish the mission of early MMC repair combine the shortage of specialized and trained personnel, inadequate facilities with the absence of neonatal intensive care units, long distances to a hospital, poor road conditions,

deficiencies in transportation, insufficiency of local resources, surgical care costs, and finally the general fear for surgery and anesthesia.<sup>4,23–25</sup> It could be possible for African general surgeons with appropriate training to perform this type of surgery, with a few studies considering that throughout the time neurosurgery is being developed in LMIC the training and education of general surgeons could be an alternative for treating patients with NTDs and effectively carrying out MMC surgical repairs,<sup>1,26</sup> particularly since the technique is not excessively complicated, and even though microsurgical instruments of certain precision are required, they don't need to be very expensive or unique.

MMC is associated with very high morbidity and mortality and poor quality of life once they overcome surgical treatment without major complications, making it imperative to address programs and strategies for prevention, early diagnosis, and treatment.<sup>1,4,17,27</sup> In this regard, transferring these pregnant women to a referral center once a prenatal NTD has been diagnosed would be yet another measure to implement and promote. In that event, in the Zanzibar archipelago, patients should be sent to Mnazi Mmoja Hospital where newborns could be managed at its intensive care unit, apart from having access to surgery at the MMSNI on short notice. Our results showed that it took an average of 11 days for the patients from Pemba (a very poor and remote island within the Zanzibar archipelago) to arrive at the Institute, while it took 3 days for those from Zanzibar. This difference resulted in an increased risk of developing an infection or purulent discharge through the dysraphism, primarily in patients who had not received intravenous antibiotic therapy on time.

Some authors have pointed out that preoperative levels of serum hemoglobin below 11.9 g/dL may be unfavorable to face surgery due to hemodynamic complications, in addition to increasing the risk for postoperative infections.<sup>1,28–30</sup> We observed lower levels of serum hemoglobin in patients from Pemba (11.4 mg/dL) than in those from Zanzibar (12.7 mg/dL), which could influence the worse clinical course that was noticed in the former.

According to Álvarez CA et al,<sup>31</sup> when preparing the surgical site for neurosurgical procedures it is possible to apply chlorhexidine 2% plus alcohol 70%, if the protocol is strictly followed, including the need of letting it dry to reduce the risk of neurotoxicity, with a preferable application of the antiseptic using a swab. Povidone-iodine plus alcohol also represents an alternative. In our study, however, on nearly all occasions, povidone-iodine was the antiseptic of choice. Most surgical wounds in MMC repairs can suffer micro-abrasions and can be in contact with diapers and fecal matter, resulting in skin infections and meningitis. For these reasons, aseptic technique, antiseptic wound cleaning, frequent diaper changes, and health education for the family should be rigorous and was thoroughly carried out during hospitalization, as recommended in the literature.<sup>27,28,32</sup> Conjointly, early initiation of intravenous antibiotic therapy has been advocated with the intent to reduce infection rates.<sup>1,33–35</sup> In our institution, antibiotic treatment was administered to all children for surgical prophylaxis and 10 days after surgery, except for two patients who presented postoperative CSF leak that required revision surgery, where this prophylaxis was prolonged for another 10 more days, having an uneventful recovery afterward.

The presence of hydrocephalus in patients with NTDs is well known,<sup>4,27,35</sup> and its multifactorial pathophysiology, with the coexistence of both obstructive and nonobstructive forms, has somehow contributed to the controversy regarding surgical options in these distinct subpopulation of patients and healthcare scenario. Additionally, surgical repair of the MMC can accelerate the appearance and/or course of hydrocephalus, whose treatment should be urged promptly to decrease the impact on future sequels on executive function and dependence, occurring from 50% to 90% of the cases.<sup>1,4,36</sup> In our series, 17 patients (48.6%) were diagnosed with infantile hydrocephalus and in 15 of them, a ventriculoperitoneal shunt was inserted, while in the remaining two an endoscopic III ventriculostomy was performed. In our study, indications for CSF diversion included an increase in head circumference, signs and symptoms of intracranial hypertension, and

imaging findings of enlarged lateral ventricles. It is true, though, current data support that ETV is associated with acceptable success rates in the treatment of MMC-associated hydrocephalus, especially when performed in conjunction with choroid plexus coagulation<sup>37–42</sup>; and, in fact, under the NED foundation, our group had initially developed a mobile neuroendoscopy training program aimed at training local neurosurgeons and nurses in different hospitals and countries in sub-Saharan Africa to perform ETV for the management of infantile hydrocephalus, but favorable outcomes were mostly obtained in patients older than 1-year-old, with stenosis of the aqueduct of Sylvius, and absence of infection.<sup>43</sup> In the Zanzibar setting as an LMIC, the NED foundation started neurosurgical practice from the ground, with an initial paucity of infrastructure, equipment, and high dependency on short-term surgical missions carried out by volunteers, as well as external mentorship, having notable challenges with the proper maintenance and sterilization of endoscopic tools. The use of a standard rigid endoscope (we have had no continuous access to flexible endoscopes) and the presence of variations in ventricular anatomy in MMC patients have also added technical difficulties.<sup>44</sup> Altogether have prompted our team to encourage the treatment of MMC-associated hydrocephalus mainly with ventriculoperitoneal shunts. In this context, the recommendation for implanting a low-profile shunt device to prevent shunt-related ulcers is of paramount importance and has been a regular practice in our institution.<sup>45,46</sup> In general, the rate and type of surgical complications in the present investigation resemble those reported in other centers in East African countries, and we highlight that the MMSNI healthcare measures are aimed at preventing and reducing the postoperative risk of complications.<sup>1,17,34,43,47,48</sup>

Over the past few years, our group has dedicated significant effort to training nurses in the neurosurgical field, particularly in East Africa.<sup>49</sup> We believe implementing perioperative standardized nursing care had a positive influence on our results. Health education concerning cleaning and general body hygiene, general preoperative patient preparation, surgical site cleaning, and shaving before surgery, high-level disinfection techniques of surgical material with sterilization of endoscopes, postoperative surgical wound care, cranial perimeter measurement control, care of peripheral venous accesses and drains, and identifying warning signs in post-surgical patients, together with collaborating in outpatient follow-up, have been crucial tasks led by the nurse staff of the MMSNI becoming an important part of its successful functioning over the past few years.

Today, the MMSNI is a pioneer health center to offer continuing neurosurgical education for nurses in the public practice and is one of the few public centers in East Africa with a comprehensive registry of healthcare activity whose database includes medical records of all patients, methodically updated, and controlled by local health staff, that makes possible to study a series of factors related to the neurosurgical care provided to patients harboring NTDs. This research indicates that MMC in Zanzibar has a similar etiology, course, and complication rate to those described to date in sub-Saharan Africa.

## 5. Conclusions

NTDs are neurosurgical conditions considered essential within the scope of global neurosurgery based on their high morbidity, disability, and mortality. Proper prenatal care with early diagnosis based on serial detailed ultrasound checkups, combined with neurosurgical and nursing standard of care in a specialized institution, are all essential to increase the chances of successful treatment that improves the quality of life of these newborns. As the referral public health center for patients harboring NTDs, the MMSNI's commitment to the population of the Zanzibar Archipelago entails a constant effort to provide high-quality health care with locally trained health personnel, in an intent to tackle some key factors such as aseptic patient preparation and meticulous surgical technique, wound care, and patient follow-up, to avoid major complications (principally infections) during pre and postoperative care

in this subset of patients.

## CRediT authorship contribution statement

**Luis Moreno-Oliveras:** Conceptualization, Formal analysis, Investigation, Methodology, Validation, Writing – original draft, Writing – review & editing, Resources. **Ruben Rodríguez-Mena:** Conceptualization, Formal analysis, Investigation, Methodology, Resources, Writing – original draft, Writing – review & editing. **Hadia Nahoda:** Investigation, Methodology, Writing – original draft. **Pilar Chisbert-Genovés:** Formal analysis, Investigation, Methodology, Visualization, Writing – original draft. **Mohamed Ali Haji:** Investigation, Methodology, Resources, Writing – original draft. **José L. Llácer-Ortega:** Conceptualization, Formal analysis, Investigation, Methodology, Resources, Writing – original draft. **José Piquer-Belloch:** Conceptualization, Formal analysis, Investigation, Methodology, Project administration, Resources, Supervision, Validation, Writing – original draft, Writing – review & editing.

## Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper

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