

## **ABSTRACT**

**Background and Objective:** There is paucity of data on the outcome of combined VPS insertion and myelomeningocele repair, and whether this will reduce morbidity and mortality. This study was designed to address this research question.

**Method:** Prospective descriptive interventional study was used and patients were recruited between January and October 2009, giving a total of 22. Information on sociodemographic, referral status, preoperative and postoperative outcome was documented and analysed.

**Result:** Males constituted 54.7% and females 45.2% of cases. The youngest age at presentation was 1 week, the oldest was 32 weeks. The majority (90%) were referred from clinics and hospitals outside Lusaka, and most hail from poor socioeconomic backgrounds (64%). The malformation occurred in the lumbar and sacral regions in 77.4%. Most of the patients presented with normal and mild forms of neurological impairment. Ultrasound examination showed that 90% had mild findings and 9% had moderate form of hydrocephalus. All patients were shunted and had surgical closure of the sac. Postoperative complications were seen in patients who had oedematous (59%) and infected wounds (9%). One patient had CSF leakage and later died of meningitis. Average hospital stay for all patients was 25days.

**Conclusion:** Being the only referral hospital and the only centre with neurosurgical unit for all public institutions, children born with such defects outside Lusaka will continue being seen late.

Although the sample size was small, it could show that even when they come late, a combined surgical approach can still be recommended in such patients. Most of the patients operated on recovered well postoperatively, but period of hospital stay was too short to be assessed neurologically.

## **INTRODUCTION**

### **1. Background**

Spinal dysraphism encompasses a group of congenital malformations that include pseudo tails, notomelia, lipoma, spinal bifida and anterior sacral meningocele. Of these, spina bifida and its variations are the commonest, (1, 2, and 5).

Myelomeningocele results from a teratogenic process causing failed closure and abnormal differentiation of the embryonic neural tube during the first 28 days of gestation. Abnormal development of the posterior caudal neural tube produces spinal cord lesion roughly correlating with the patient's neurological, motor and sensory deficits. The Arnold Chiari II malformation impedes the flow and absorption of cerebrospinal fluid and causes hydrocephalus, which occurs in more than 90% infants with myelomeningocele. (2, 5).

In a significant proportion of patients with Spina bifida Aperta, hydrocephalus is absent at birth but develops in the first few weeks or months of life. Hydrocephalus occurs 15 – 25% of children with open myelomeningocele at birth; however, in most surgical series, the proportion of patients with the lesion who require shunting reaches 80 -90% (4,8).

Myelomeningocele is the commonest form in many African countries, while meningocele is the simplest form with no associated limb paralysis or sphincter disturbance (1, 2).

### **2. Prevalence**

Available data from the developed countries show that outcome of patients with spinal dysraphism has improved. In one cohort study, of the patients treated in the 1970s, 52% were alive 20 years after treatment. Most deaths observed occurred in the first year of life, mostly due to renal and respiratory problems associated with spina bifida. A few deaths were related to hydrocephalus (3, 5).

In a similar but recent study, review of children treated in the 1980s, only 27% died, most of them in the first year of life from causes related to spina bifida than hydrocephalus. (5)

The incidence of myelomeningocele, the commonest form of spinal dysraphism, ranges from 0.2 to 2 per 1000 live births in most developed countries. Overall incidence has significantly declined in the last 2 decades because of improved maternal nutrition during pregnancy, including folic acid addition, a wider availability of prenatal diagnostic wakeup and therapeutic termination of pregnancy. (6, 8, 9).

For the United States, spina bifida occurs in 7 out of 10,000 live births. In Arkansas, the Centre for Birth Defects Prevention (ACBDP) calculated a rate of 5.1 per 10,000 live births for the years 1998 – 2000. For this time period, ACBDP indicated that 57 persons were born with spina bifida in Arkansas. (10)

Most cases of myelomeningocele are managed prenatally with surgical correction, or within 48 hours of delivery to prevent infection and protect exposed neural tissue from trauma and drying. Neurological deficit depends on the level of lesion and initial condition of spinal cord/nerves. Possible outcomes range from normal development to various losses of muscle function and or bladder control. Deterioration is faster in the absence of surgery. (7, 8).

Mutuszczan et al showed that a higher spinal cord lesion, hydrocephalus and complications due to its surgical management had a negative influence on the development of children with myelomeningocele. In the absence of treatment, mortality was estimated at 50%. (10).

In recent retrospective case reviews, shunt placement has been shown to vary based on the level of lesion, with a greater number of patients with thoracic lesions requiring shunts than those with lumbar or sacral lesions. Lesions at levels of T12 and above have also been associated with increased incidence of brain abnormalities and lower scores on psychometric testing than lesions at L1 or below. (2, 4, 13).

### **3. Outcome of surgery**

Surgery is commonly staged, with shunt placement for hydrocephalus followed by definitive surgery a few weeks later to repair the lesion. A few cases had shunt placement and repair of lesion in one setting. (9, 11, 13).

Miller et al reviewed results obtained in the study to compare simultaneous and delayed ventriculoperitoneal shunt insertion in children undergoing myelomeningocele repair at the University Of Pittsburgh School Of Medicine. Sixty-nine patients were followed up between 1987 and 1993, were they found that neither the overall frequency of complications nor the frequency of CSF infection, shunt malfunction, or symptomatic Chiari malformation differed significantly between the two groups. In contrast, there was a significant higher rate of myelomeningocele wound leak (eight versus zero;  $P= .05$ ) and longer mean hospital stay in the sequential group versus the simultaneous group (22 days versus 13 days;  $P= .05$ ). (17).

Hubballah and Hoffman followed up patients between 1975 and 1985 at the Hospital of the Sick children in Toronto, Canada. In the 10 patients who underwent simultaneous myelomeningocele repair and VPS insertion, none developed shunt infections or wound repair breakdown in the follow-up period of 1 to 9 years. (18).

In Brazil, Machado and Santos de Oliveira followed 28 patients between 1998 and 2001 that underwent closure of neural tube defects at Paediatric Neurosurgical division of University of Sao Paulo. Of the 11 patients that had concomitant surgery performed after birth, they concluded that simultaneous VPS insertion and correction of myelomeningocele did not pose an additional risk to the child and do have some advantages, facilitating healing of the back without CSF leakage and protecting the brain from effects of progressive ventricular dilatation. (19).

Studies done in Africa show that management is selective due to difficulties with multidisciplinary care and rehabilitation. Furthermore, late presentation, preoperative infection and poor care of patients with functional handicap remain a challenge. (1, 12, 15, 16).

Default rate was found to be high in cases where parents failed to get expected hospital treatment. The type of surgery performed also depended on the extent and size of lesion and age of the baby. (14).

#### **4. The problem**

In Zambia, the incidence of spinal dysraphism has not been documented, but epidemiological survey showed most patients came from outside Lusaka, most affected the sacral region with a female preponderance and characteristically low socioeconomic status. Folic acid consumption was less in more than 50% study subjects. (20)

Furthermore, no intervention measures have been outlined to properly manage such patients. Lack of proper anaesthetic equipment means surgery cannot be done in newborn babies. Being the only public referral hospital for such cases, late patient presentation is inevitable.

#### **5. The question**

Would combined ventriculoperitoneal shunting and myelomeningocele repair improve the postoperative outcome and reduce morbidity in paediatric neurosurgical patients presenting to UTH?

## **II STUDY JUSTIFICATION**

Since early closure of the sac is said to decrease morbidity/mortality and prevent deteriorating neurological symptoms, late presentation and poor patient follow up will necessitate a combined surgical approach.

This will reduce on total hospital stay and reduce theatre time for the patients.

Early and appropriate intervention is likely to prevent recurrent infections, facilitate nursing care and handling of these patients. In addition and depending on surgical outcome, multidisciplinary management will be instituted with referral to specific subspecialty when need arises.

## **Hypothesis**

H1 combined ventriculoperitoneal shunting and repair of meningomyelocele reduces risks of meningitis, has less hospital stay and contributes to significant neurological outcome.

## **III OBJECTIVES**

### **1. General**

To determine the short-term outcome of simultaneous VPS insertion and repair of myelomeningocele in paediatric neurosurgical patients at UTH.

### **2. Secondary**

- a. To find out the socio-demographic factors associated hydrocephalus/myelomeningocele
- b. To determine the age at presentation, size and site of lesion
- c. To document and evaluate the post operative outcome

## **IV METHODOLOGY AND RESULTS**

### **Study site and setting**

The study was conducted at university teaching hospital in Lusaka, in the paediatric neurosurgical wards

### **Study Population**

All paediatric patients admitted with spinal dysraphism and hydrocephalus meeting inclusion criteria were recruited.

### **Study design**

Prospective descriptive interventional study was used and patient recruitment between January and October 2009. A total of 22 patients were enrolled.

A case control study would not be done due to late patient presentation, poor patient compliance and small sample size.

### **Case Definition**

A case was defined as a patient with spinal dysraphism complicated by hydrocephalus.

### **Inclusion criteria**

All patients with meningomyelocele complicated by hydrocephalus and who had given consent were included.

## **Exclusion criteria**

Infected and/or ulcerated sac

Severe hydrocephalus

Severe neurological and/or kyphoscoliosis

Prematurity

Refusal of consent

## **Entry and analysis**

Entry was done on epi data sheet and analysis based on descriptions and possible associations.

## **Ethical Considerations**

- The University of Zambia Biomedical Research Ethics Committee approved the study, and consent for inclusion into the study was obtained from the parents/guardians.



## V. RESULTS:

A total of 22 patients were studied and the following tables summarise the findings.

**Table 1: sex ratio of myelomeningocele patients**

	Frequency	percentage
Male	12	54.5
Female	10	45.5
Total	22	100

Of the total seen, the majority were males

**Table 2: socioeconomic status of parents/guardians**

	Frequency	percentage
Employed	8	36.4
Unemployed	14	63.6
Total	22	100

The majority of the guardians were in informal employment

**Table 3: referral system**

	Frequency	percentage
Referral outside Lusaka	20	90.9
Referral within Lusaka	2	9.1
Total	22	100

The majority of referred patients were from hospitals outside Lusaka

**Figure 4:**

pie chart showing percentage of referrals

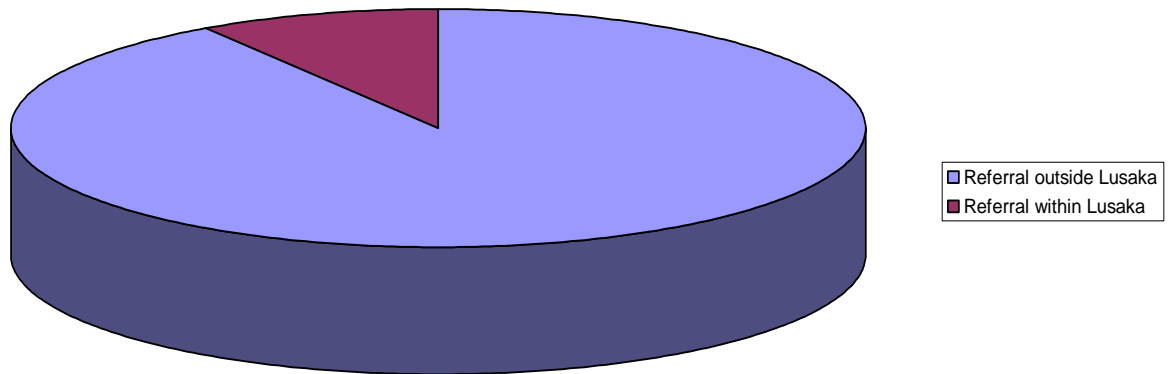
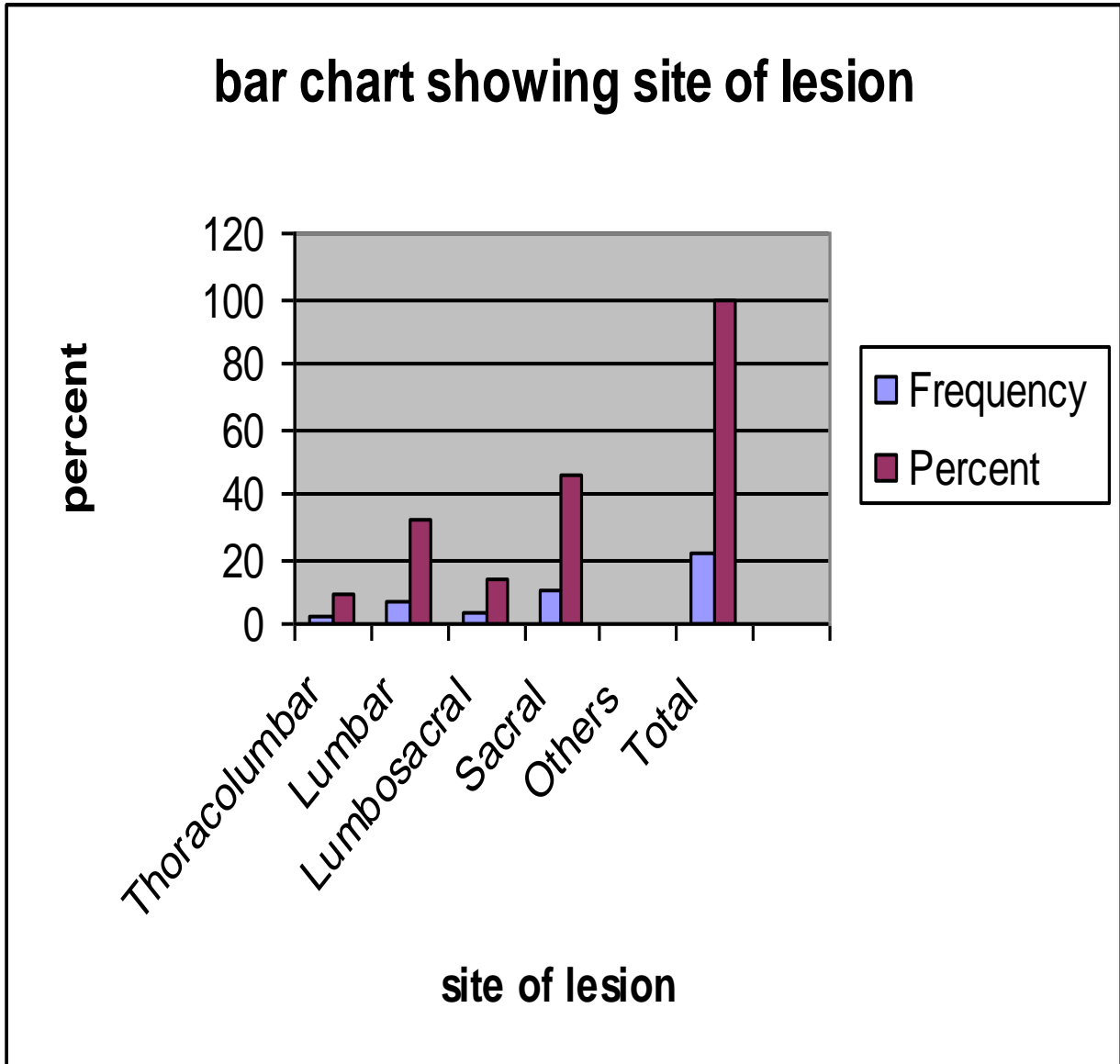
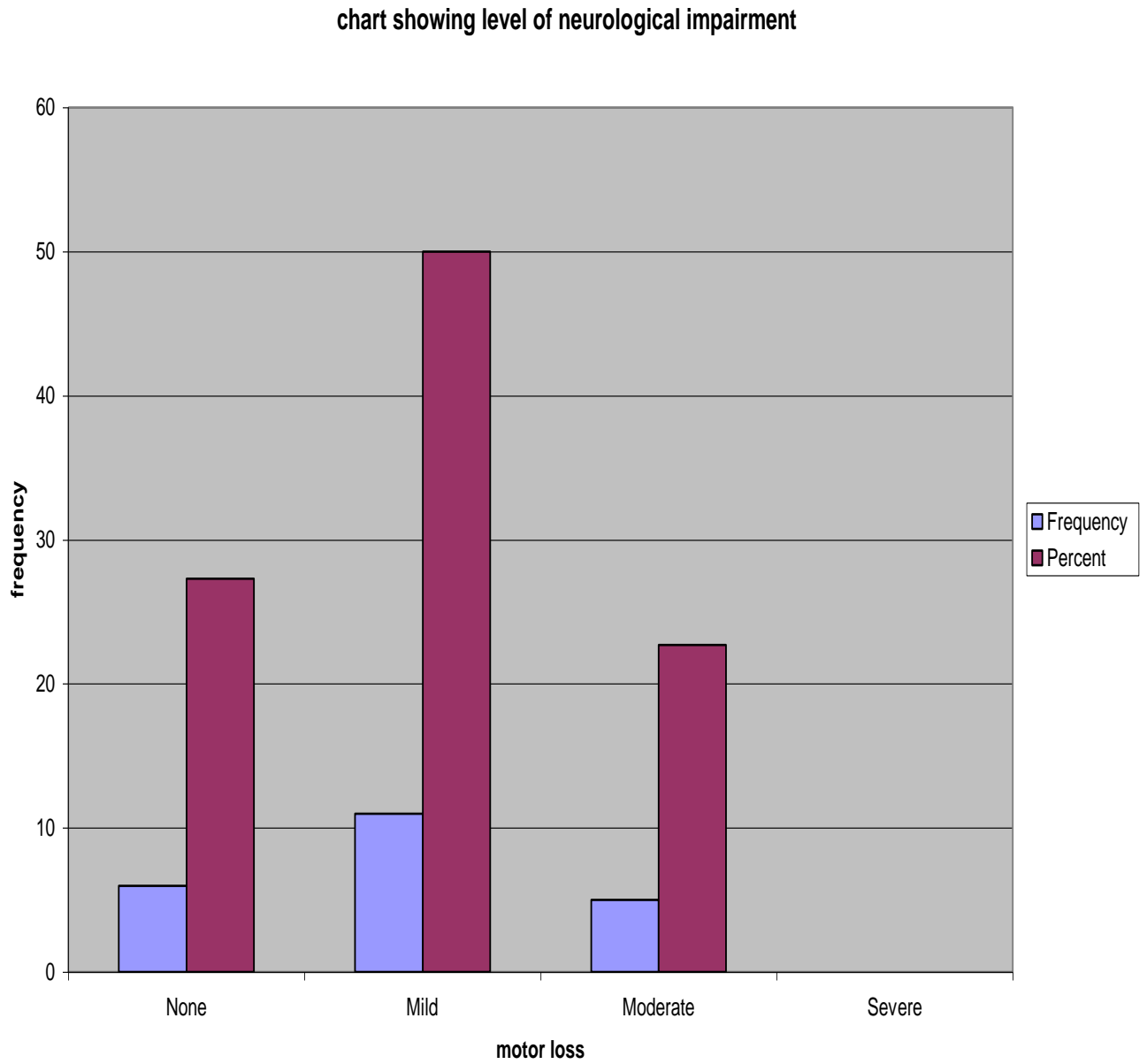


Figure 5: site of lesion



**Figure 6: nature of neurological impairment**



11 patients (50%) had mild form of neurological impairment, 8 patients had none while 3 had moderate motor loss.

**Table 7: degree of hydrocephalus**

	Frequency	Percent
None	2	9.1
Mild	0	0
Moderate	20	90.9
Severe	0	0
Total	22	100

The above findings were determined at ultrasound evaluation as a preoperative assessment. 90.9% had moderate findings, 2 had none. Those with severe hydrocephalus were not recruited for the study.

**Table 8: postoperative wound appearance**

	Frequency	Percent
Clean and healing	6	27.3
Oedematous	13	59.1
infected	2	9.1
CSF leakage	1	4.5
Total	22	100

The figure shows that 6 (27%) patients had clean and healing wounds, about 60% oedematous wounds while 2 patients got infected wounds. One patient developed CSF leakage.

**Table 9: general health of patient**

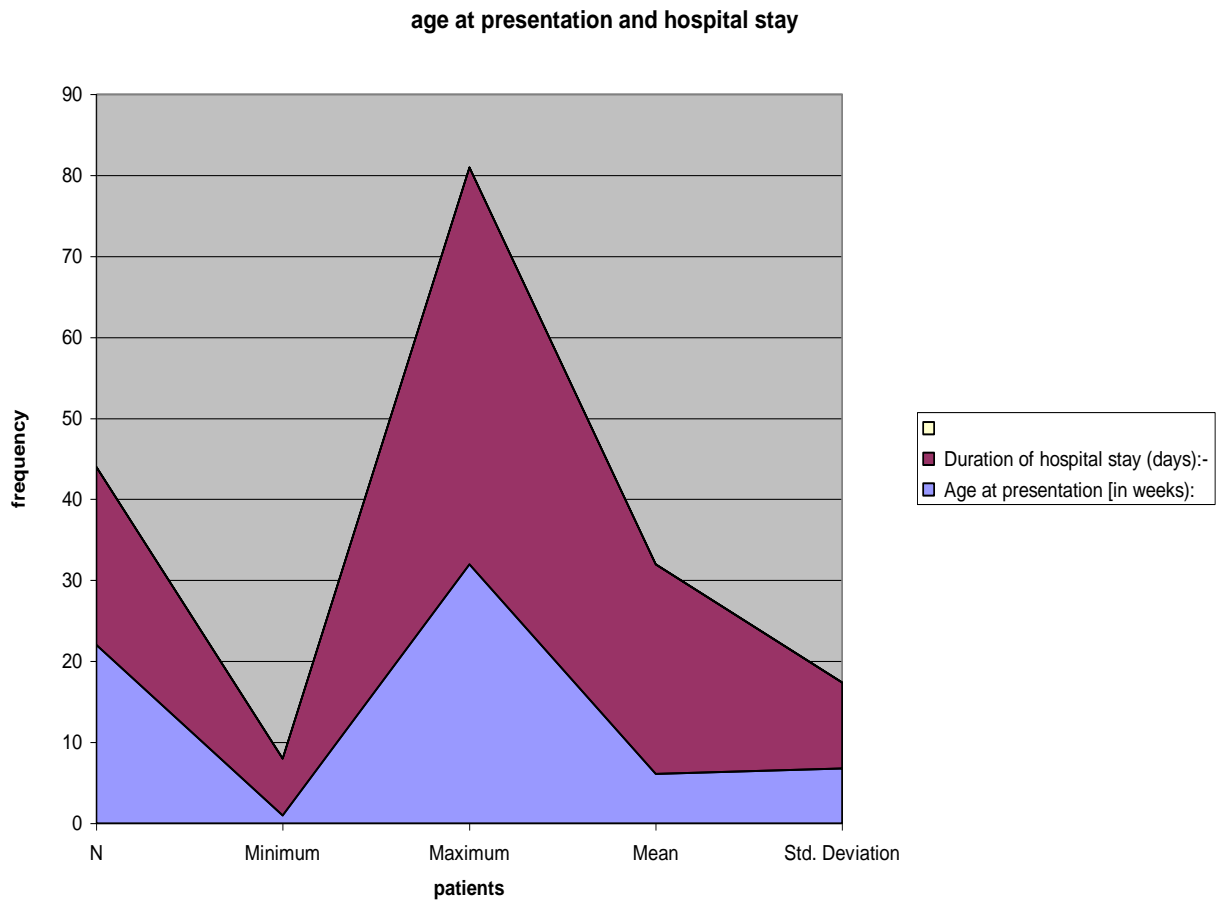
	Frequency	Percent
Improving	11	50.0
febrile	8	36.4
Deteriorating	2	9.1
Death	1	4.5
Total	22	100

From the table, 50% patients showed remarkable improvement, while 36% spiked temperatures. One death occurred while on the ward.

**Table 10: age at presentation and duration of hospital stay**

	N	Minimum	Maximum	Mean	Std. Deviation
Age at presentation [in weeks):	22	1	32	6.09	6.796
Duration of hospital stay (days):-	22	7	49	25.91	10.583

**Figure 11: graphical representation of age and duration of hospital stay**





## VI. DISCUSSION

### Demographic characteristics

From the study, both sexes were equally represented, albeit a small sample size. Available data shows a female preponderance, and that the majority of patients are a referral from hospitals outside Lusaka. The study reveals that about 90% patients are referrals and most were from economically disadvantaged parents/guardians. This has a bearing on total patient care and hospital stay.

### Preoperative assessment

Table 4 shows that about 46% had myelomeningocele occurring in the sacral region, followed by lumbar area. This conforms to studies done elsewhere, which show that the higher the lesion, the more likelihood of finding severe cranial malformation {2, 4, 13, 20).

The actual sizes of the lesions were not measured but their appearance assessed for leakage and /or rupture. Over 90% of the patients had intact sac, though the older ones showed varied degrees of bruising.

Figure 5 summarises the degree of motor dysfunction at presentation. The majority of those less than 4 weeks presented with normal or mild form of dysfunction (27 and 50% respectively). The rest had moderate degree of neurological impairment, and none had any bladder or anal sphincter dysfunction.

For the purpose of this survey, the degree of paralysis has been divided into three grades:

**Mild**-The muscle weakness was slight and confined to muscles below the knee, *denoting paralysis below the fifth lumbar or first sacral neural segments.*

**Moderate**-There was severe or complete paralysis of muscles below the knee, but sufficient action in hip flexors, quadriceps, hamstrings and glutei so that control of the hip and knee might be expected: paralysis *below the fourth lumbar neural segment*.

**Severe**-All muscles of the limb except possibly the iliopsoas and hip adductors were paralysed so that control of the hip and knee were poor-*paralysis proximal to the fourth lumbar neural segment*.

The parents/guardians were counselled on possible unfavourable postoperative outcome, in view of late presentation and the nature of neurological impairment. The duration of postoperative review was too short to document notable changes neurologically.

Ultrasound evaluation revealed that over 90% had moderate findings and only 9% had none. These were recruited for study and shunted routinely as previous hospital reviews showed that such presented with hydrocephalus following repair of myelomeningocele alone. In the quoted literature, hydrocephalus was seen in 15 to 25% of patients with open MMC, of which 80 to 90% required shunting. (4, 8) Those with severe hydrocephalus were shunted as an emergency for immediate relief and repair was rescheduled for later date.

### **Postoperative assessment**

The postoperative period was centred mainly on wound appearance and general health of the patient, as the recovery from any neurological impairment was considered too short a time.

From figure 8 on postoperative wound appearance, 27% were clean and healing well. 59% had oedematous wounds mostly in the younger population, but recovered well too. Only 2 patients had wound infection and were noted to have bruised sac preoperatively. They recovered after antibiotics treatment and wound care. In the initial postoperative days, the sterile dressings were kept for 5 days and change of dressing done by attending doctor. The parents/guardians were not allowed to touch the wounds till they were comfortable with nursing care. No special dressings were applied as cost was a factor in the management. In more advanced setups, no postoperative complications were recorded between 1 to 9 year follow-up. (18)

One patient died following wound dehiscence complicating into meningitis. CSF culture revealed gram positive diplococcal.

Table 9 shows results on general health of patients while on the ward. All patients did well except for the mortality and the 2 who had fever but responded to treatment. The babies were nursed prone till the wounds were dry and less oedematous.

Some studies done does show that the combined approach pose no additional risk to the child, but facilitate wound healing and protect the brain from ventricular dilatation. (19)

The rationale of shunting patients with no hydrocephalus is prophylactic, as they tend to develop the condition late on.

As most of the patients were referrals from peri-urban and hospitals outside Lusaka, the period of hospital stay was extended so as to remove stitches and adequately teach guardians how to care for their patients. This was also preventing poor patient compliance and follow up due to low socioeconomic status. Being a small sample size, extended hospital stay ensured that a good number were retained at the end of the study period. Most western centres discharge patients after 14 days of hospital stay in the absence of complications.

The average hospital stay for this study was 25 days, due to different healing times and presence of oedema on the surgical wounds.

## **CONCLUSION AND RECOMMENDATIONS**

Most literature quoted show that the number of patients with myelomeningocele is declining in the west due to various interventions being put in place to prevent occurrence. However, countries like Zambia still lag behind in folic acid fortification, improving peoples living conditions and expanding tertiary level hospitals.

Being the only referral hospital and the only centre with neurosurgical unit for all public institutions, children born with such defects outside Lusaka will continue being seen late. Although the sample size was small, it could show that even when they come late, a combined surgical approach can still be recommended in such patients. The duration of hospital stay may not compare with what most literature show, but given the low socioeconomic status and distant referral centres, patients can be kept in till wounds heal completely.

The postoperative review for the study needs to be extended so that neurological recovery and /or deterioration can be documented.

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**PATIENT INFORMATION SHEET**  
**(To be handed to patient/parent/guardian)**

**1. PURPOSE OF THE STUDY AND EXPLANATION OF PROCEDURES**

We are asking you and your child to be in a research study because you want him/her to be operated on. This study is about inserting a tube in head to drain excess water and at the same time remove and close the growth at the back of child. This is done separately within the first two days of birth. In this study we are trying to learn whether combining putting a tube and removing the growth will reduce time spent in hospital and number of operating times in an older child. We also want to see if the wounds would heal fast especially that the child is older. This will reduce chances of the child harming him/herself with the growth on the back, which maybe infected.

The operation will be done by a doctor at University Teaching Hospital's children's surgical ward.

Before you decide if you want your child to be in the study, you need to know its purpose, the possible risks and benefits, and what is expected of you. Then, you can decide whether or not you want him/her to be in the study. This process is called informed consent. This consent form gives you information about the study. If you agree for your son to take part in the study, you will be asked to sign this consent form. You will be offered a copy to keep. You may choose to read this consent or have the consent read to you.

It is important that you know certain things:

- Taking part in the study is entirely voluntary. It is up to you to decide whether or not you and your son will be in the study.
- You may decide not to take part or to leave the study at any time.

***Inserting the tube and removing the growth Procedures***

After you agree to the procedure, your child will have the operation done. It usually takes about 2hours 30minutes. Your child will be made to sleep while being operated, so there



will be no pain. After the procedure, your child will remain on the ward to check on the wounds and size of the head. Any problems arising will be addressed and the child will continue receiving treatment. Before you go home, we will advise you on how to care for your child and the wound.

### ***Follow-up Visits***

We will ask you to return with your child for at least two follow-up visits. As your child will be on the ward for at least a week, the first follow up visit at one month is to check that the tube is working well and there are no problems. The next visits will not be part of the study but to continue looking after the child as he/she will require regular checkups. At each visit your child will have a physical exam. We will also ask you some questions about your experiences with the procedure and the results.

If you and your child miss a follow up visit, we would like to be able to contact you. If you agree, we will ask you to provide contact information for you and a family member or friend who could help us find you in case you move or change your phone number. If you decide at any time that you do not want to be contacted by the study, we will no longer contact you.

If you have questions or concerns at any time during the study please let us know.

## **2. RISKS OR DISCOMFORTS**

- Risks of the operation include bleeding and infection. When the operation is done under sterile conditions in a hospital, these risks are small. Bleeding is usually stopped with a small amount of pressure or other safe methods available in theatre. When an infection occurs, it may involve just the skin or the brain when severe. The infection can be treated with antibiotic medicines, if needed.
- Very rarely, more than normal fluid can be drained from the head causing it to shrink. However this is prevented because the tubes inserted have a valve that allows a little fluid at a time.

- Your child will be given an injection of numbing medicine to decrease any pain he/she may feel after the operation. This will cause the child to appear sleepy once injected.
- Your child will have a tube put in theatre for passing urine, and may cause some discomfort. It should not be removed as nurses will want to record the amount of urine he/she is passing in a day.
- There may be other risks and discomforts that are not known at this time.

### **3. POTENTIAL BENEFITS**

Your child may benefit from taking part in this study if he is operated. However, we cannot guarantee that this will happen. It is possible that your son may not benefit from being in this study. Information learned from this study may help other parents with such children to have a combined operation of putting a tube and removing the growth on the back.

### **4. ALTERNATIVES TO PARTICIPATION**

This study is entirely voluntary. Your decision about whether or not you and your child will be in the study will not affect the care that you or your child receives. If you do not choose to take part in this study, your child will still be operated.

### **5. CONFIDENTIALITY**

If you agree for you and your child to be in the study, you agree to allow the information we collect to be used for scientific purposes. We will not use any names of participants when we publish or share results of the study. Your records and your child's records will be kept confidential. You and your child will be identified in our records by a code. However, your doctor and their staff, and study personnel will be able to look at your medical records and have access to confidential information that identifies you by name.

## **6. WITHDRAWAL FROM THE STUDY / REASONS WHY YOU MAY BE WITHDRAWN FROM THE STUDY WITHOUT YOUR CONSENT**

At any time during the study, you are free to withdraw your son without any discrimination against you. You may be removed from the study without your consent if the study doctor decides that remaining in the study would be harmful to your son.

## **7. PERSONS TO CONTACT FOR PROBLEMS OR QUESTIONS**

If you ever have questions about this study or in case you are injured because of participation in this study, you should contact:

Dr. Daniel Makawa  
University Teaching Hospital  
Department of Surgery  
P/B RW IX  
Nationalist Road  
Lusaka, Zambia  
260-977100044, 0955765000

If you ever have questions about your rights as a research subject you may call:

Dr. E.M. Nkandu  
Chair, Research and Ethics Committee  
Department of Physiotherapy  
Lusaka, Zambia

## **EVALUATION FORM**

### **1. Demographic Data**

- a) Date..... b). File No:.....
- b) Age: ..... c). Sex:.....
- c) Age at presentation:.....
- d) Prematurity:.....
- Yes [    ]            No [    ]
- e) Tribe .....
- f) Education level of parent/guardian.....
- g) Occupation of parent/guardian.....
- h) Referral patient.....

### **2. Preoperative assessment**

#### **2.1 Physical signs**

- a) Sun setting eyes            Yes [    ]            No [    ]
- b) Patent anterior fontanelle    Yes [    ]            No [    ]
- c) Head circumference in cm    Yes [    ]            No [    ]

**3. Ultrasound cranial ventricular dimensions in mm**

- a) Bifrontal diameter.....
- b) Bicaudate diameter.....
- c) Maximum transverse diameter of lateral ventricle-----

**4. Level of Lesion:**

- a) Thoracolumbar.....
- b) Lumbar.....
- c) Lumbosacral.....
- d) Sacral.....
- e) Others.....

**5. Size of Lesion**

**5.1 Appearance of sac:**

Yes = [ 1 ]      No = [ 2 ]

- a) Intact      {    }
- b) Ruptured    {    }
- c) Infected    {    }

**6. Type of neurological impairment:**

**6.1 Loss of motor function**

Yes = [ 1 ]      No = [ 2 ]

- |                                   |     |     |
|-----------------------------------|-----|-----|
| a) None                           | { } | { } |
| b) Mild                           | { } | { } |
| c) Moderate                       | { } | { } |
| d) Severe                         | { } | { } |
| e) Loss of bladder control        | { } | { } |
| f) Loss of anal sphincter control | { } | { } |

**7. Ultra findings of hydrocephalus:**

Yes = [ 1 ]      No = [ 2 ]

- |             |     |     |
|-------------|-----|-----|
| a) None     | { } | { } |
| b) Mild     | { } | { } |
| b) Moderate | { } | { } |
| c) Severe   | { } | { } |

**8. Post operative assessment:**

Yes = [ 1 ]      No = [ 2 ]

- |                    |     |     |
|--------------------|-----|-----|
| a) CSF Leakage     | { } | { } |
| b) Wound infection | { } | { } |
| c) Meningitis      | { } | { } |
| d) Blocked Shunt   | { } | { } |

**9. Wound appearance:**

Yes = [ 1 ]      No = [ 2 ]

- |                           |     |     |
|---------------------------|-----|-----|
| a) Clean and healing well | { } | { } |
| b) Oedematous             | { } | { } |
| c) Infected               | { } | { } |
| d) CSF Leakage            | { } | { } |

**10. General Health of Patient:**

Yes = [ 1 ]      No = [ 2 ]

- |                  |     |     |
|------------------|-----|-----|
| a) Improving     | { } | { } |
| b) Febrile       | { } | { } |
| c) Deteriorating | { } | { } |

**11. Duration of hospital stay:-**

.....