UNIVERSITY OF NAIROBI

Incidence of impaired renal function and clinical characteristics of children 1 to 5 years after repair of myelomeningocele at the Kenyatta National Hospital.

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STUDENT'S DECLARATION

I, **Dr. Samuel Oluka,** do declare that this dissertation, is purely my original work and has not been presented, to the best of my knowledge, for a degree in any other University.

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This research proposal was presented at the department of surgery meeting held on the 31st/March/2022 at the university of Nairobi. It was subsequently approved by the Kenyatta National Hospital and University of Nairobi Ethics and research committee (KNH/UON ERC) on 12th /October/2022 the dissertation is therefore submitted for examination with my approval as the chairman of the department of surgery

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DEDICATION

This is dedicated to children with myelomeningocele whose parents have been supportive through the study and volunteered information.

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ABBREVIATIONS

KNH- Kenyatta National Hospital

MMC- Myelomeningocele

KUB- Kidney Bladder and Ureter

IC- Intermittent Catheterization

CIC- Clean Intermittent Catheterization

CSF- Cerebral Spinal Fluid

VCUG- Voiding Cystourethrogram

CMG - Cystometrography

EMG- Electromyogram

UTI – Urinary Tract Infection

EBC- Expected Bladder Capacity

SPSS- Statistical Package for Social Sciences

CNS- Central Nervous System

PGN- Preganglionic Neurons

Ach- Acetylcholine

CKiDSCr-Chronic Kidney Disease in Children Serum creatinine

KDIGO- Kidney Disease: Improving Global Outcomes

CKD-EPI-Chronic Kidney Disease Epidemiology Collaboration

MDRD-Modification of Diet in Renal Disease

eGFR-estimate glomerular filtration rate

ABSTRACT

Background: Myelomeningocele (MMC) is a defect of primary neurulation that manifests at birth as a cleft in the vertebral column and the overlying skin resulting in exposure of spinal neural tissues, a persistent neural placode, and exposed surrounding meninges with resultant neurological impairment. It results in impaired bladder function, resulting in both storage and voiding complications. These complications are primarily treated by the practice of intermittent catheterization (IC). This practice should be started early in life to prevent or slow down the development of chronic kidney disease which will manifest as impaired renal function.

Objective: To determine the incidence of impaired renal function and clinical characteristics of children at 1 to 5 years after repair of myelomeningocele in children at the Kenyatta National Hospital (KNH).

Materials and Methods:

This was 3-months long descriptive cross-sectional study on the incidence of impaired renal function and clinical characteristics of children at one to five years after undergoing myelomeningocele at the Kenyatta National Hospital (KNH). A consecutive sampling technique was employed to recruit subjects, whereby, every subject meeting the inclusion criteria and consent to the study was included. The data was collected using a data abstraction tool, that included demographic, clinical characteristics of the children, and serum creatinine for estimation of the glomerular filtration rate.

Data management and results: Data was collected using predesigned data collection forms, then

entered Stata version 24.0

Results: Seventy-seven (77) children underwent myelomeningocele repair within our study category from 1st January 2016 to 1st January 2021. Fourteen patients were reported dead by the relatives when contacted, and thirty-three (33) patients were lost to follow-up, due to either having no records of contacts or being unreachable by telephone contact found in the records. Thirty (30) children with myelomeningocele repaired within the last one to five years were recruited into the study and the results were analyzed. The mean age of the patients was 2.6 years (SD 0.9), whereas the median age was 2.6 years (Inter Quartile Range (IQR) 2.0 – 3.1). The youngest patient was 1.0 years while the oldest was 4.3 years. The male-to-female ratio was 1:1.31, with males 13 (43.3%), and females 17 (56.7%).

All the children presented with urinary incontinence. Twenty-six (86.7%) had associated Hydrocephalus and had undergone ventriculoperitoneal shunting (VPS). Parents of 5 (16.7%) had Knowledge of Clean Intermittent Catheterization (CIC) and 25 (83.3%) parents did not know about CIC. No patient had urodynamic studies 30 (100.0%). Twenty-eight (93.3%) children had normal kidney function, Kidney Disease: Improving Global Outcomes (KDIGO) stage 1, whereas 2 (6.7%) had impaired renal function, KDIGO stage II

Conclusion: This study shows that more female patients presented with myelomeningocele in this population. The incidence of renal impairment in the first 5 years was significant. with a majority neither having prior knowledge nor elementary education on the practice of Clean Intermittent Catherization (CIC) and its benefits. Hydrocephalus is a predominant associated presentation in patients with MMC all of whom had benefited from Cerebral Spinal Fluid (CSF) diversion.

1.0 CHAPTER ONE: INTRODUCTION

The most frequent form of spina bifida is myelomeningocele, which is defined by a fissure in the vertebral column and a corresponding gap in the skin that exposes the meninges and spinal cord/neuro placode. Depending on the level of the defect on the vertebral column, patients with myelomeningocele (MMC) may present with motor deficits, sensory deficits, and autonomic deficits in the areas distal to the lesion

At least 95% of patients with myelomeningocele have bladder dysfunction (neurogenic bladder) [1] and about 30% to 40% develop some degree of renal dysfunction [2]. Treatment plans are designed to mitigate high bladder pressures or minimize stasis of urine in the bladder which can either prevent or attenuate these renal dysfunctions.

Baseline blood work for kidney function (blood urea nitrogen and creatinine) should be performed in infancy and every year thereafter [3]. If there are recurrent urinary tract infections (UTIs) or significant bilateral hydronephrosis, it should be done more often. It is also recommended for all patients with myelomeningoceles to have an early kidney, ureters, and bladder (KUB) ultrasound scan done shortly after birth, for early diagnosis of urinary tract complications [4,5]. It also serves as a baseline for clinical follow-up and may detect deterioration after repair

A study by Houle AM, Gilmour RF, Churchill BM, et al reported that over 95% of normal children have bladder storage pressures of <30 cm H_2O at full capacity [6].

Another study also shows that urinary bladder storage pressures of >40 cm H_2O are associated with chronic kidney injuries [7] Patients with myelomeningocele with neurogenic bladders tend to have altered bladder storage pressures given the associated storage and voiding complications.

Intermittent catheterization (IC) is the first-line treatment for children with neurogenic bladder. Self-catheterization, also known as intermittent self-catheterization, is a method of draining the bladder at predetermined intervals. It is widely used to treat individuals who have incomplete bladder emptying due to detrusor underactivity or urethral sphincter overactivity, resulting in urine retention. The fixed intervals are typically between 4 and 6 hours, and it relieves patients of indwelling catheter issues. When taken early after delivery in patients with myelomeningocele (MMC), it has been reported to reduce the risk of upper urinary tract infection, bladder calculi, cystitis, and bladder compliance [8, 9].

In this study, we intend to assess the clinical characteristics of the patients who have undergone repair of myelomeningocele which include the continuous practice of Clean Intermittent catheterization (CIC) as required, use of anticholinergic medication to reduce bladder storage pressures, and frequency of occurrence of urinary tract infections. Certain actions such as frequent bladder emptying through performing CIC, use of anticholinergic medication to reduce bladder storage pressures, and early treatment of frequently occurring urinary tract infections have been known to prevent chronic and progressive kidney failure caused by high bladder storage pressure, upper urinary tract infections and urine retention due to a poorly innervated urinary bladder as a result of myelomeningocele (MMC). It's upon the above findings that we will develop local KNH bladder care protocols for children with MMC and possibly establish a dedicated clinic that will keep records and provide a lifelong follow-up for patients born with myelomeningocele.

2.0 CHAPTER TWO: LITERATURE REVIEW

2.1 Myelomeningocele - Definition, Epidemiology, Evaluation & Management

Myelomeningoceles (MMC) is a defect of primary neurulation that manifests at birth as a cleft in the vertebral column and the overlying skin resulting in exposure of spinal neural tissues, with a persistent neural placode and exposed surrounding meninges, resulting in neurological impairment in the areas distal to the defect

The general worldwide incidence is highly variable ranging from <1 to 7 per 1000 live births, [10, 11] depending on population, race, and geographical location. The prevalence is, therefore, also widely variable. The highest prevalence is found in China, Ireland, Great Britain, Pakistan, India, and Egypt [10]. Generally, females tend to be more affected than males.

The incidence of MMC in the developed world is about 1:1000 births. Based on this data, in sub-Saharan Africa with a population of approximately 961,500,000, and a crude birth rate of 38:1000 population, it is estimated that there are about 37,000 children born with Myelomeningocele each year in sub-Saharan Africa [12].

Between 2005-2010, a study done in Kenya showed the overall average prevalence of spina bifida and encephaloceles at 3 cases per 10,000 live births [13]. In the same study, there was variable regional distribution, the Rift Valley province had the highest prevalence at about 6.9 cases per 10,000 live births. Western and Coast provinces stood lowest at 1.3 and 1.3 cases per 10,000 live births, respectively [13].

A local study done at Kijabe AIC hospital had shown that about 8.2% of the 110 patients followed up in clinics after repair of myelomeningocele had an abnormality in serum creatinine signifying impaired renal function [14]. This finding was consistent with other global studies that averaged about 8% [15]

The diagnosis is obvious during the initial examination of the neonate. If not ruptured, it is a cystic mass located anywhere along the spinal column with a neural placode seen at its tip. The cystic mass is usually fluctuant on palpation and comprises a sac containing cerebrospinal fluid (CSF), neural tissue, and part of the meninges.

A study of 352 patients by Attila Rab et al shows that in approximately 73% of cases, the vertebral defect involves the lumbar and sacral region; lumbar 16.8%, lumbosacral 22.3%, and sacral 34.5% [16]. This is because the lumbosacral segment of the spine is the last part of the neural tube to close during embryonal development, which occurs around day 27 of pregnancy. Any portion of the spinal column, however, could be affected.

The level of the lesion along the spine determines the presenting neurological deficits with urinary incontinence occurring in 85.5% of patients with myelomeningocele by the age of 5 years [17]. This is because nerves for bladder control originate in the sacral segments (S2-S4). Lesions at this level or higher up tend to be more severe and may result in paresis or paralysis, sensory deficits, and autonomic dysfunction

2.2 Innervation of the bladder

To voluntarily control the lower urinary tract, a complex interaction between autonomic, sensory afferent innervation, and somatic efferent pathways are required [18, 19].

The autonomic system is composed of sympathetic and parasympathetic nerves and the somatic efferent pathways carried by the pudendal nerves. The sensation of the lower urinary tract is mediated by afferent axons that travel in these same nerves

2.2.1 Parasympathetic Pathways

Preganglionic neurons (PGN) of the parasympathetic type that innervate the lower urinary tract originate at the level of S2 to S4 in the lateral section of the sacral intermediate gray matter in an area called the sacral parasympathetic nucleus [20].

These parasympathetic PGN axons migrate to the peripheral ganglia via the ventral nerve roots, where they synapse with postganglionic nerve dendrites and produce the excitatory transmitter acetylcholine (ACh), which stimulates the postganglionic nerves. The release of ACh by the postganglionic nerve terminals promotes stimulation of different muscarinic receptors inside bladder smooth muscles, resulting in bladder contractions and hence voiding

2.2.2 Sympathetic Pathways

The sympathetic innervations to the bladder originate from the caudal thoracic to the rostral lumbar spinal cord, at a level of T12-L2 and serve the noradrenergic excitatory and inhibitory function to the bladder wall and internal urethral sphincter respectively [21].

After passing through the sympathetic chain without synapsing, the sympathetic preganglionic axons will synapse at the inferior mesenteric ganglia. The inferior hypogastric plexus receives postganglionic fibers from the inferior mesenteric ganglion, which severely innervates the bladder neck (internal urethral sphincter) and trigone.

Innervation of the bladder neck is by alpha-1 adrenergic receptors whose stimulation will result in bladder neck closure resulting in bladder filling during the storage phase of the bladder. Simultaneously, the beta-3 adrenergic receptor in detrusor smooth muscle upon stimulation will lead to bladder relaxation [22].

During the micturition phase, there's inhibition of internal sphincter stimulation. The internal sphincter will relax during the micturition phase

2.2.3 Somatic Pathways

On the ventral horn lateral border of the sacral spinal cord level S2-S4, usually referred to as Onuf's nucleus, are somatic efferent motor neurons that innervate the striated external urethral sphincter muscle and the muscles of the pelvic floor [23].

At the neuromuscular junction nerve terminal releases acetylcholine (Ach), to the nicotinic receptors which induce skeletal muscle contraction. This mechanism is under cortical control and brings about voluntary control of micturition allowing an individual to consciously void at an appropriate place. However, this effect can be overridden by the pontine micturition center responsible for the involuntary micturition reflex should the individual hold urine for long to exceed the critical capacity for voluntary control.

2.2.4 Afferent Pathways

The afferent nerve axons that transmit sensory information from the lower urinary tract to the lumbosacral spinal cord are carried in the pelvic, hypogastric, and pudendal nerves [24, 21].

The sacral dorsal root ganglia include both pelvic and pudendal primary afferent neurons, whereas the rostral lumbar dorsal root ganglia contain the afferent innervation of the hypogastric nerves.

The synapse locations between first-order and second-order neurons, whose axons transport sensory information centrally in the spinal cord, are known as the dorsal root ganglia.

The pelvic and pudendal nerves' visceral afferent fibers enter the spinal cord and move rostro-caudally along Lissauer's tract.

Pelvic nerve afferents are primarily responsible for monitoring bladder volume and contraction amplitude. Small myelinated A-fibers and unmyelinated C-fibers are the nerve fiber types discussed here [25].

2.3 Initial post-natal evaluation

The diagnosis of myelomeningocele is clinically made at birth. However, with the advent of obstetric high-resolution fetal ultrasonography, an abnormality check study done in the second trimester may reveal the abnormality.

Initial evaluation among other parameters should include an ultrasound of the kidneys, ureter, and bladder (KUB) [26, 27] which may detect the presence of hydronephrosis or hydroureter, and also assesses bladder wall thickness and distension. The study may be diagnostic of associated early urinary tract abnormalities as well as form a basis for future reference.

2.4 Monitoring

After the initial evaluation with kidney function tests, renal and bladder ultrasounds along with other urologic studies: Voiding Cystourethrogram (VCUG), Cystometrography (CMG), and Electromyogram (EMG), periodic evaluation is thereafter recommended throughout life [28]. Some of the changes may occur in the first few months of life after the repair of the

myelomeningocele and is attributable to manipulation of the nervous tissue and changes attributable to the healing process [3]. The development of a tethered spinal cord may also contribute to changes in the lower urinary tract function [29], which may be alleviated by surgical release and this may lead to improvement of the urologic function and thereafter prevent any further neurologic sequelae [30].

2.5 Evaluation of renal function

Renal function is best measured using glomerular filtration rate (GFR) [31]. This, under ideal circumstances, is achieved using inulin clearance [32]. An invasive process that constantly requires inulin intravenous infusions with a serial sampling of urine from an indwelling catheter in children who may not void on instruction or voluntarily, for this reason, endogenous biomarkers such as **creatinine** and **cystatin C** serum levels have been used to estimate Glomerular Filtration Rate [GFR] [33], with the most common being serum creatinine concentration. The challenge with its use is that its metabolism is largely affected by various factors such as sex, age, race, muscle mass, dietary protein intake, and corticosteroid interference [34, 35]. Also, altered muscle mass to total body weight ratio due to nutrition may grossly affect serum creatinine accuracy in GFR estimation [36]

On the other hand, Cystatin-C is now the novel bio-marker widely advocated for the estimation of the Glomerular filtration rate (GFR). It has been shown with high-level evidence to have high diagnostic sensitivity for the detection of mildly impaired GFR [37]

It is free from the interference of height, gender, age, and muscle mass. It is, therefore, a preferred biomarker for groups with reduced muscle mass such as children, the elderly, and those with

conditions like spina bifida who have reduced muscle mass [38]. Despite these advantages of using cystatin C, it is not widely available in sub-Saharan Africa and remains expensive in the few laboratories it is done. This restricts most clinicians from using widely available and cost-effective biomarkers like serum creatinine despite its shortcomings.

There are several equations used to estimate glomerular filtration rate (eGFR), but about five Serum creatinine equations are used in children and these include: the original Schwartz equation; Chronic Kidney Disease in Children Serum creatinine (CKiDSCr) equation; Pottel equation; Modification of Diet in Renal Disease (MDRD) equation; and Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) equation.

Of these, 2 are more accurate in children when compared with the inulin clearance test, that is, Pottel and CKiDSCr equations with accuracy as high as 80% and low bias (< 5 ml/min/1.73 m^2) [39]. However, the most commonly used is the CKiDSCr equation for children as recommended by the Kidney Disease: Improving Global Outcomes (KDIGO) guidelines [40]

The CKiDSCr equation was first published in 2009 by the Chronic Kidney Disease in Children Cohort Study (CKiD). Its bedside applicability makes it easy to apply and it eliminates most other parameters, utilizing only the height and serum creatinine [41]

$$\text{CKiDSCr} = 0.413 \times \frac{height(cm)}{serum\ creatinine(mg/dl)}$$

Where CKiDSCr is the Estimated Glomerular Filtration Rate (eGFR)

The estimated Glomerular Filtration Rate (eGFR) value obtained can be used to grade the degree of chronic kidney disease.

Kidney Disease: Improving Global Outcomes **(KDIGO)** defines chronic kidney disease as changes in renal structure or function that last longer than three months. Albuminuria, abnormal urine sediment, electrolyte, and other abnormalities related to tubular diseases, abnormalities discovered by histology, structural abnormalities detected by imaging, or a history of kidney transplantation are among the anomalies [42]

KDIGO further classifies chronic kidney disease as per **table 1** below:

Table 1: KDIGO classification of the stages of chronic kidney disease

Stage	GFR (ml/min/1.7m^2)	Terms
1	≥90	Normal or high
2	60-89	Mildly decreased
3a	45-59	Mild-moderately decreased
3b	30-44	Moderately –severely decreased
4	15-29	Severely decreased
5	<15	Kidney failure

2.6 Chronic kidney disease in spina bifida

By the age of 20 years, 15% of patients with spina bifida acquired end-stage chronic kidney disease (CKD), according to a Taiwanese study based on the National Health Insurance database released in 2010 [43]

About 1.5% of both pediatric and adults as per a study on Scottish dialysis patients, had the end-stage renal disease (ESRD) due to spina bifida and spinal cord injury with the median age of renal transplantation being 27 years [44].

So, even if clean intermittent catheterization (CIC) is started early, with or without anticholinergic medication [45], there is a risk of increased renal injury in these individuals due to abnormal bladder dynamics [46].

2.7 Ultrasound/Sonography

A kidney and bladder sonography is a noninvasive investigation most commonly used in the assessment of situations of bladder dysfunction in children. It should be performed whenever there's a suspected functional neurologic or anatomical lesion, UTI, or features of an obstructive process such as a weak urinary stream.

Soon after the baseline sonographic evaluation of the kidney and bladder is done post-natal, it should be repeated at three to four months of age or after complete recovery from myelomeningocele repair with the resolution of post-surgical swelling [28].

In the event of clinical symptoms suggestive of UTI or the patient undergoes other neurosurgical or spinal surgery such as detethering of the cord or spinal fusion, the kidney and bladder ultrasound

can be used repeatedly for evaluation of urinary tract changes. The study can also be used if there is a suspicion of non-compliance with sterile interval catheterization or in the case of a high-risk bladder [28].

The normal bladder wall thickness when assessed sonographically should be less than 3mm thick when full, and less than 5mm when relatively empty [47].

Bladder outlet obstruction may cause increased bladder wall thickness. The likely cause of this may be an anatomical or functional abnormality. Overactive bladder is the most common cause of thickened bladder as seen in 92% of patients in a case series by Yeung CK, Sreedhar B, et al [46]. The following sonographic findings suggest abnormal voiding mechanics and a risk of chronic kidney disease: Excessive post-void residual volume, hydronephrosis, hydroureter, improper bladder wall thickness, or hydronephrosis.

Baseline blood work-up for kidney function (blood urea nitrogen, electrolytes, and creatinine) is recommended during infancy and every few years thereafter [3]. It may be done more often if there are recurrent UTIs or significant bilateral hydronephrosis.

2.8 Bladder capacity

The expected bladder capacity (EBC) is the volume of urine that can be stored by the urinary bladder under normal physiological and anatomical conditions before micturition can be automatically triggered. It is dependent on the age of the patient.

For children aged 2 years to 16 years, it can be calculated using the following formula [49]

EBC (mL) = (age of the patient in years + 2) x (30 mL)

The bladder capacity increases with age as seen in infants and young children (**Table 2**). However, there is observed minimal post-void residual urine volume [50, 51, 52]

Table 2: Estimated bladder capacity and post-void urine volume for infants and young children up to 36 months of age

Age	**Bladder capacity**	**Post-void residual volume**
Newborns up to 1 week of age	25 ± 10 cc	PVR: 1.4 ± 1.1 cc
1 week to 3 months of age	BC: 53 ± 13 cc	PVR: 5.7 ± 4.5 cc
3 to 12 months of age	BC: 70 ± 30 cc	PVR: 7.1 ± 6.3
12 to 24 months of age	BC: 76 ± 31 cc	PVR: 6.6 ± 7 cc
24 to 36 months of age	BC: 128 ± 72 cc	PVR: 3.3 ± 5.3 cc

2.9 Management of neurogenic bladder

In patients with myelomeningocele, neurogenic bladder treatment is tailored to preserving kidney function and achieving social continence of both bowel and bladder that is appropriate for age [53] A combination of clinical symptoms and signs, sonographic findings, urodynamic studies, as well as psychological readiness should all be taken into consideration when designing a treatment plan When there's evidence of neurogenic bladder, Clean Intermittent Catheterization (CIC) is recommended for this category of patients. Other medical therapies may often be added such as anticholinergic agents if there's evidence of high bladder storage pressures or hyper-reflexic

bladder. Anticholinergics may also be added in situations of vesicoureteral reflux (VUR) as well as prophylactic antibiotics [54, 55]

2.10 Clean intermittent catheterization:

Recommended practice is early initiation of CIC (i.e. shortly after birth) for all infants with neurogenic bladder [3] to reduce the risk of urinary tract infection (UTI) and bladder overdistension, which can lead to hydronephrosis, vesicoureteral reflux (VUR), and chronic kidney disease.

There is the benefit of early initiation of CIC in comparison with delayed initiation. When initiated at less than 1 year of age, there is less deterioration of urinary tract function when compared with initiation after the age of 3 years as seen in patients followed in a study for at least 11 years [56]. Initiation in the first three months of life has been shown to have additional benefits [57, 58]. When the CIC regimen is used consistently, there is a benefit of reduced need for bladder augmentation surgery later in life [3]

Individuals with MMC and neurogenic bladder will at some point in life require CIC to attain social continence that also serves to protect the kidneys. It is, therefore, best adopted when initiated in infancy.

Most children can be able to perform CIC by the age of five if it is initiated in infancy. Children initiated at infancy are also seen to be more tolerant and compliant with the CIC regimen when compared to counterparts who are initiated later [57, 58]. There are very few complications of CIC as seen in a study of 31 females followed from 10 to 19 years of practicing CIC with or without anticholinergic agents with only minor complications reported and were linked to urethral catheter

sizes of 12 French or larger and assisted catheterization rather than self-catheterizations [59]. Low rates of complication have also been observed in male counterparts [60].

When there is continuing deterioration of urinary tract function despite optimal CIC practice, it may be helpful to carry out continuous bladder emptying during the night by either placing a continuously draining catheter during the night or scheduling night-time CIC sessions to relieve bladder pressure. One of the studies recruited 19 children for a night-time bladder drainage regimen, 15 of whom clinically benefitted from subsiding hydronephrosis, fewer UTIs and increasing bladder capacity, and improved continence [61, 62].

2.11 Anticholinergic medication

Patients with myelomeningocele who exhibit high urinary bladder storage pressures, bladder hyperreflexia, and/or features of vesicoureteral reflux (VUR) are treated using the anticholinergic medication, which includes Oxybutynin, hyoscyamine, imipramine, etc. the VUR occurs secondarily as a result of high bladder storage pressure which if untreated will result in impairment of renal function. When combined with CIC this treatment regimen is superior for the treatment of VUR [55]. A similar study involving a large case series showed that only 3 percent of the children initiated early on anticholinergic and CIC programs showed features of renal deterioration [63]

2.12 Study justification

Following myelomeningocele repair, these children require multi-disciplinary care from neurosurgeons, orthopedic surgeons, pediatricians, nephrologists, and social workers to cater to their lifelong health needs. However, at KNH, we do not have a dedicated clinic where these patients can access these services at a one-stop point. KNH does not have local bladder care

guidelines and protocols for the management of these patients who are known to generally have high urinary bladder storage pressures which if not treated may lead to progressive kidney failure. From the current neurosurgical clinic records, most of these patients are getting lost in follow-up and are, therefore, not getting adequately assessed for their renal function, and little is known about their knowledge of various urinary bladder care protocols. This study seeks to assess the incidence of impaired renal function and clinical characteristics of children at 1 to 5 years after repair of myelomeningocele at the Kenyatta National Hospital.

2.13 Study Question

What is the incidence of impaired renal function and clinical characteristics of children at 1 to 5 years after repair of myelomeningocele at the Kenyatta National Hospital?

2.14 Objectives

2.14.1 Broad Objective

To determine the incidence of impaired renal function and clinical characteristics of children at 1 to 5 years after repair of myelomeningocele at the Kenyatta National Hospital

2.14.2 Specific Objective

- To determine the incidence of impaired renal function in children with myelomeningocele
- To describe the demographic and clinical characteristics of children at 1 to 5 years after repair of myelomeningocele

- To determine the association between renal impairment with the demographic and clinical characteristics of children at 1 to 5 years after repair of myelomeningocele (MMC).

3.0 CHAPTER THREE: METHODOLOGY

3.1 Study design

This was a descriptive cross-sectional study.

3.2 Study area description

This study was conducted at the Kenyatta National hospital neurosurgical surgical wards and pediatric neurosurgical clinic. KNH is currently the largest referral and teaching hospital in the country and it is the seat of medical and surgical training in Kenya. Kenyatta National Hospital has a capacity of 1800 beds. The hospital has 50 wards, 22 out-patient clinics, and Accident & Emergency Department. The department of surgery comprises 24 theatres,16 of which are specialized theatres including neurosurgery.

3.3 Study population

The study population included all patients who underwent repair of myelomeningocele one to five years earlier at KNH and were later scheduled for follow-up in the neurosurgical clinic or were lost to follow but still had existing records at the registry.

3.3.1 Inclusion criteria

- All patients falling within one to five years from the time of repair MMC at KNH

3.3.2 Exclusion criteria

- Children born with myelomeningocele with concurrent presence of other urogenital anomalies like bladder exstrophy, agenesis of the ureters, or both kidneys which are known to cause abnormal renal function.
- More than 5 years from the time of repair of MMC

- Less than 1 year from the time of MMC repair
- Patients who opt out of the study

3.4 Sample size

The sample size was calculated using Cochrane's formula

$$\boldsymbol{N = \frac{Z^2 P(1-P)}{d^2}}$$

N=sample size

Z= statistic value for a desired level of confidence=1.96

P=expected prevalence or proportion. From a study done at the Kijabe AIC hospital about 8.2% of the patients after the repair of myelomeningocele had impaired renal function [14]

d=Precision, set at 0.05

$$\boldsymbol{N = \frac{1.96^2 X\ 0.082(1-0.082)}{0.05^2}}$$

substituting in the formula gives a sample size of 116 participants.

Records from the KNH operating theatre surgical register indicated that there had been 77 pediatric MMC patients operated on between January 2016 to January 2021. For finite populations of less than 10,000 people, the sample size was adjusted as follows;

$$nf = \frac{n_0}{1+\frac{n_0-1}{N}} = \frac{116}{1+\frac{116-1}{77}} = 46.$$

Hence, the study required 46 patients.

However, out of the 77 patients in the surgical register 14 had been reported dead by relatives, and 34 participants were lost to follow-up either due to absent contacts or unreachable by telephone. Thirty (30) patients were contacted and were available for the study.

3.5 Sampling procedure

A consecutive sampling technique was employed whereby every patient meeting the inclusion criteria and consenting to the study was included.

3.6 Recruitment and consenting procedures

Upon first contact with participants, the clinical interviewer comprehensively introduced himself, then fully explained the components of the study to the next of kin of the patient (parent/guardian) in detail, and he/she was allowed to seek clarification or ask questions. Informed consent was sought and only those who consented to participate were recruited.

3.7 Independent variables

Input variables were data such as demographic information like age, gender, serum creatinine, number of CIC sessions per day, recovery data, and frequency of urinary tract infections (UTIs).

3.8 Dependent variable

The main output variable was the normal or abnormal renal function tests based on the KDIGO staging system

3.9 Data collection procedure

The structured questionnaire (Appendix 1) for data collection, was administered to parents/guardians of children who met the inclusion criteria. Demographic information, relevant clinical history, and a physical examination were conducted and documented in parts I and part II of the data collection tool. Part III of the data collection tool was only completed after the laboratory analysis of the kidney function test (urea, Electrolyte, and Creatinine).

3.9.1 Sample collection and transport to the laboratory and analysis of the sample

Upon taking consent, a trained medical practitioner (principal investigator of the study) collected a venous blood sample. The identified blood collection site was swabbed 3 times using an alcohol swab to disinfect the site. A 22-gauge vacutainer needle connected to a vacutainer holder was used for blood collection into a plane red-top vacutainer (vacutainer with no additives) labeled with the patient's details. The sample containing the vacutainer was packaged according to the standard laboratory safety procedure. The sample was then transported using the cool box to the clinical chemistry laboratory 16 at KNH as routinely done. The sample was processed and analyzed immediately using the same machine. Reagents with the same batch number were used to analyze

blood from all the patients in the study. The results were availed within 24 hours. We ensured no interference with the routine flow of patients at Kenyatta national hospital. The appointments of patients to the clinic were spaced to a maximum of 4 per clinic visit to ensure no overcrowding.

All parameters were carefully analyzed and serum creatine levels were used to calculate the estimated Glomerular filtration rate (eGFR) according to using the $CKiD_{SCr}$ equation for children shown below.

$$\text{CKiDSCr} = 0.413 \times \frac{height\ (cm)}{serum\ creatinine(mg/dl)}$$

Where CKiDSCr is the eGFR (mL/min/1.73 m^2)

Serum creatinine laboratory results in S.I units were obtained in µmol/L and converted into mg/dl and fed into the equation together with the height in S.I units - centimeters (cm)

The results were recorded in a tabular format for statistical analysis.

The estimated Glomerular Filtration (eGFR) rate was used to grade the degree of renal function according to the Kidney Disease: Improving Global Outcomes (**KDIGO**) grading system as per t**able 1** above.

3.10 Ethical Consideration

Approval of this study was sought from the Kenyatta National Hospital-University of Nairobi Ethics and Research Committee (KNH-UoN Ethics and Research Committee)

The cost of the sample analysis was borne by the principal investigator.

3.11 Data management and analysis

The questionnaire forms were thoroughly crosschecked for completeness and free of errors before entry into the Microsoft Excel spreadsheet 2019. The data was later exported to the Statistical Package for Social Sciences (SPSS) version 24.0 for analysis. Demographics and clinical characteristics that were categorical were analyzed and presented as frequencies and percentages, while those that were continuous were analyzed and presented as means with standard deviations or as medians with interquartile range. The incidence of renal impairment was calculated as a proportion of those children with renal impairment and presented as a percentage. The association between demographic and clinical characteristics with renal impairment was assessed with the use of the Pearson Chi-square test, Fisher's Exact test, and Independent t-test. All tests were considered significant where the p-value < 0.05

3.11.1 Confidentiality

The participant research number was assigned and used to track the clients in the study, no names or hospital numbers were used in the data collection tool.

An inventory of the participant's tracking system was kept in a password-protected system only known to the principal investigator. Confidentiality of the clinical information of the participants was ensured at all stages of the research.

3.11.2 Quality Assurance

Clinical principles ensuring quality assurance included the use of a trained clinical practitioner familiar with laboratory procedures throughout the sample collection procedure. The patient interview was staggered at different time intervals to prevent any mislabeling or interchange of

the blood sample containers. A red vacutainer bottle was strictly used for the sample collection, this contains no additives and is used for serum-based laboratory tests, and ensures the accuracy of the results. The sample was then packaged in a cooler box used for the transportation of the samples. Lastly, the sample upon reaching the laboratory was processed and analyzed within two hours of collection of the blood sample

3.12 Study limitations and how to minimize them.

1. Failure of the participants/parents/guardians to raise funds for the laboratory investigations

The principal investigator provided funds for the laboratory investigation.

2. Missing contact information or lost documents containing contact information.

These patients were left out of the study.

3. Patients/guardians/parents of patients willing to participate in the study, but unable to afford the transport costs to KNH

The principal investigator met the transport cost of the participants.

4.0 CHAPTER FOUR: RESULTS

Seventy-seven patients had myelomeningocele repair in the study period between January 2016 to January 2021. Fourteen of these patients were reported dead by relatives when contacted by telephone call. Thirty-three participants either had incomplete records in the files or had their telephone contacts out of service and were therefore unavailable for the study. Thirty patients were successfully contacted by telephone, and all of them consented to participate in the study.

4.1 PATIENTS' DEMOGRAPHICS

A. PATIENT DETAILS

Age

The mean age of the patients was 2.6 (SD 0.9) years, whereas the median age was 2.6 (IQR 2.0 – 3.1) years. The youngest patient was 1.0 years while the oldest was 4.3 years. A majority of the patients (36.7%) were between 3.0-3.9 years of age, and a few patients (6.7%) were above 4 years of age, as shown in table 3 and figure 1 below.

Table 3: Shows the age distribution of the participants

Age (years)	Frequency, *n=30*	Percent
1.0 – 1.9	7	23.3
2.0 – 2.9	10	33.3
3.0 – 3.9	11	36.7
4.0 – 4.9	2	6.7

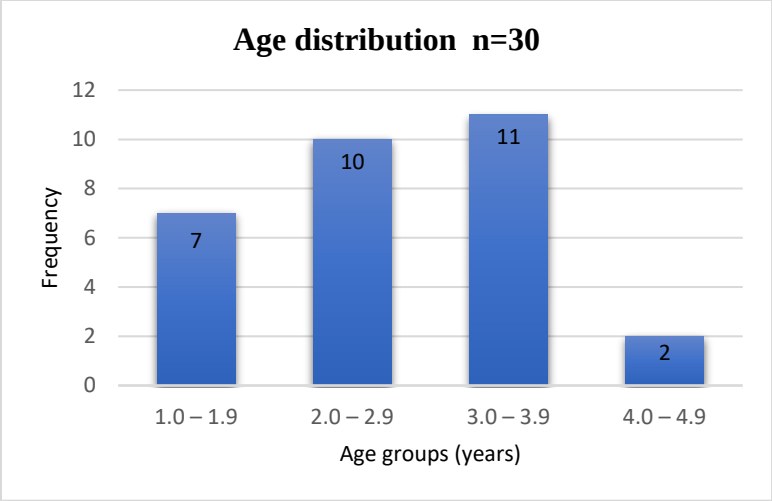

Figure 1: Histogram showing the age distribution

Sex

There were more female patients 17 (57%) with myelomeningocele than males who were 13 (43%) as shown in figure 2 below

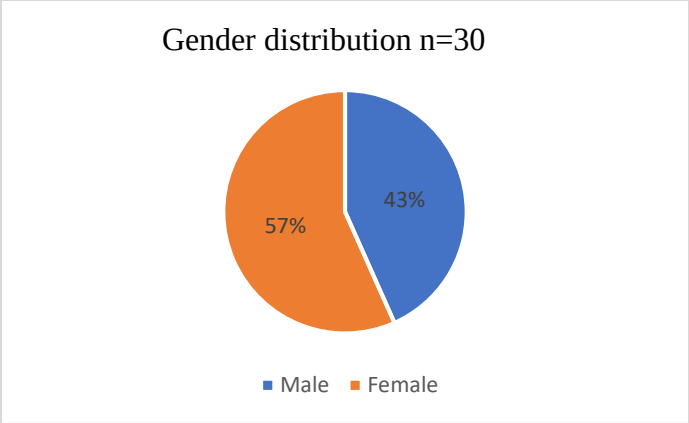

Figure 2: Pie chart showing sex distribution among patients

4.2 Distribution of Body Mass Index (BMI)

Eleven (36.7%) participants were underweight with a BMI <5th percentile according to the CDC 2000 classification. Those with normal weight were 12 (40%), with BMI ≥5th – 85th percentile; Six (20%) patients were overweight with a BMI of ≥85th – <95th percentile. one patient (3.3%) was obese with a BMI of ≥95th percentile as shown in table 4 and figure 3 below.

Table 4: Showing BMI distribution of participants

BMI Classification	CDC Percentile score For children & teens	Frequency	Percentage
Underweight	<5th percentile	11	36.7
Normal weight	≥5th – 85th percentile	12	40.0
Overweight	≥85th – <95th percentile	6	20.0
Obese	≥95th percentile	1	3.3

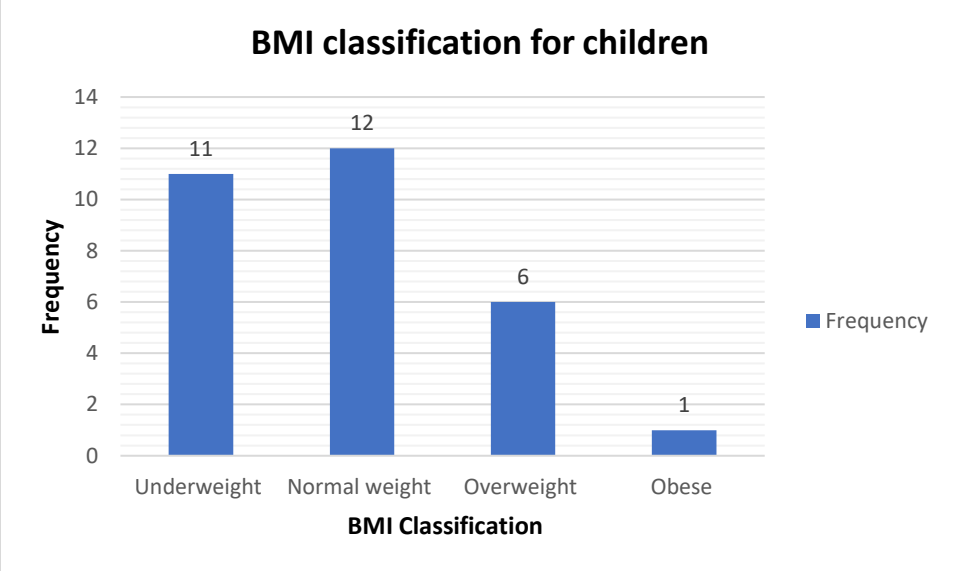

Figure 3: Histogram showing BMI classification

4.2 Patient characteristics

4.2.1Presence of hydrocephalus:

The majority of participants 26 (87%) had associated hydrocephalus, all had been treated by CSF diversion through ventriculoperitoneal shunting. Few patients 4 (13%) did not have associated hydrocephalus as shown in figure 4 below

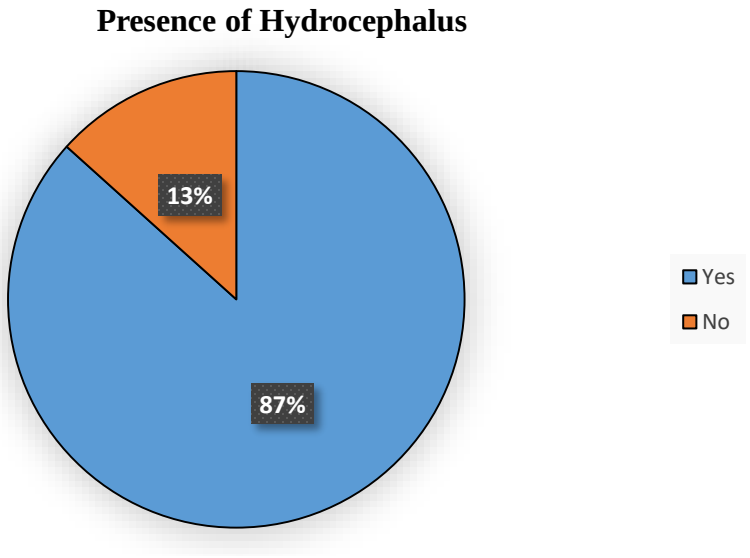

Figure 4: Pie chart showing hydrocephalus distribution

4.2.1 Anatomic location of MMC

The most common anatomical location for the myelomeningoceles (MMC) was the lumbosacral region 11 (36.6%) followed by sacral location 9 (30%) then the lumbar region 5 (16.6). Participants with MMC in the thoracolumbar region was 4 (13.3%) and the least common location was thoracic 1 (30%) as shown in table 5 and figure 5 below.

Table 5shows the anatomical location of MMC and its frequency

MMC location	Frequency	percentage
Lumbar	5	16.6
Lumbosacral	11	36.6
Thoracic	1	3.3
Thoracolumbar	4	13.3
Sacral	9	30

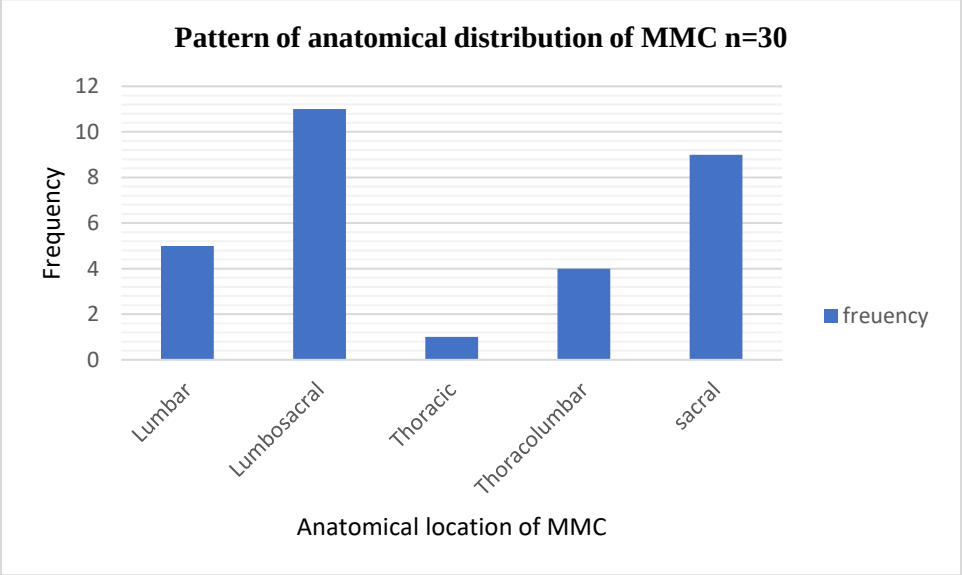

Figure 5: Histogram showing frequency anatomical location MMC:

4.2.3 Motor/Sensory level distribution:

Most patients 8 (26.6%) had the best Motor/sensory level in L5, followed by S1 level with 6 (20%) participants. The distribution of participants with motor/sensory levels of L1, L3, and L4 tied with 3 (10%) participants respectively. Similarly, the distribution with the motor/sensory levels of T10, L2, and S3 tied with 1 (3.3) participant in each category. Levels T12 and S2 levels 2 participants (6.6) in either category as represented in table 6 and figure 6 below

Table 6: Shows the motor/sensory level distribution

Best motor/sensory level	Frequency	Percentage
T10	1	3.3
T12	2	6.6
L1	3	10.0
L2	1	3.3
L3	3	10
L4	3	10
L5	8	26.6
S1	6	20
S2	2	6.6
S3	1	3.3

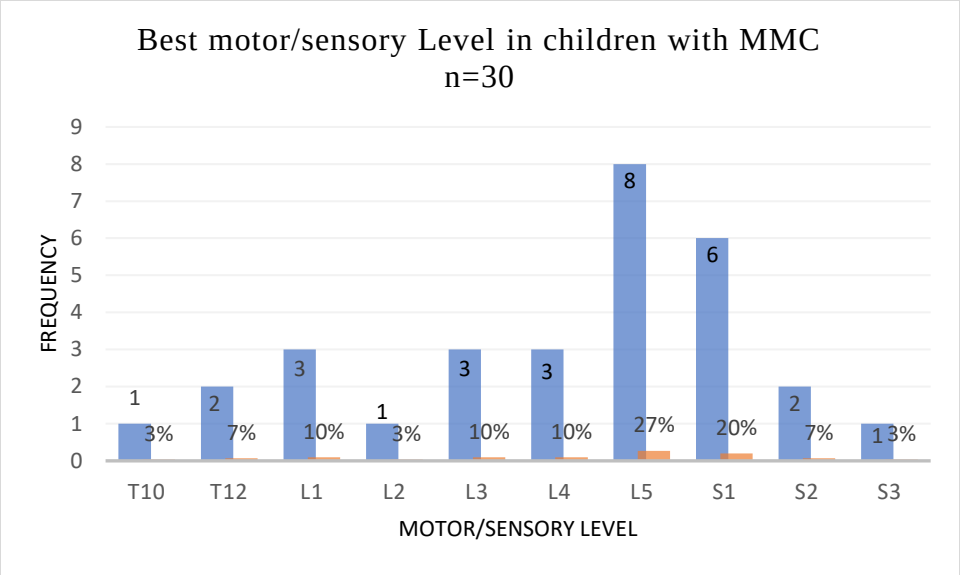

Figure 6: Histogram showing the best motor/sensory Level in children with MMC

4.2.4 Control of micturition and Previous diagnosis of UTI

All of the 30 (100%) participants in this study had reported an inability to control urine outflow, and mostly reported continuous dribbling of urine. Similarly, no participant had previously suffered a urinary tract infection.

4.2.5 Urodynamic investigations:

No participant had undertaken baseline urodynamic studies such as; Voiding Cystourethrogram (VCUG), Cystometrography (CMG), and Electromyogram (EMG)

4.2.6 Clean Intermittent catheterization (CIC)

4.2.6.1 Knowledge of CIC

A majority of patients 25 (83.3%) did not have any prior knowledge or education practice and benefits of Clean intermittent catheterization (CIC). Five (16.7%) participants had prior knowledge about CIC as shown in table 7 and figure 7 below.

Table 7: shows knowledge of CIC among study participants

Knowledge	Frequency, *n=30*	Percent
Yes	5	16.7
No	25	83.3

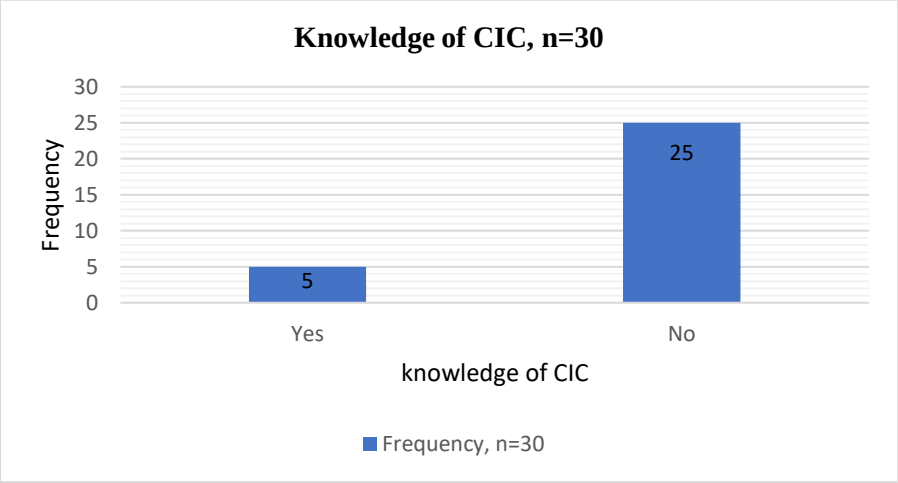

Figure 7: Histogram showing knowledge of CIC

4.2.6.2 Practice of CIC

Four (13.3%) participants reported practicing CIC daily. These patients had received training from a patients' association within Nairobi, they also reported being able to obtain catheterization equipment and other support through donations in the same association. One (3.3%) participant despite having knowledge of CIC was not able to practice CIC, she reported having no access to catheterization equipment. A majority of participants 25 (83.3%) had no prior knowledge of CIC and therefore did not practice CIC as represented in table 8 and figure 8 below

Table 8: Shows the Place of prior CIC education

First, hear of CIC	Frequency	Percentage
KNH	1	3.3
Patient association	4	13.3
Never	25	83.3

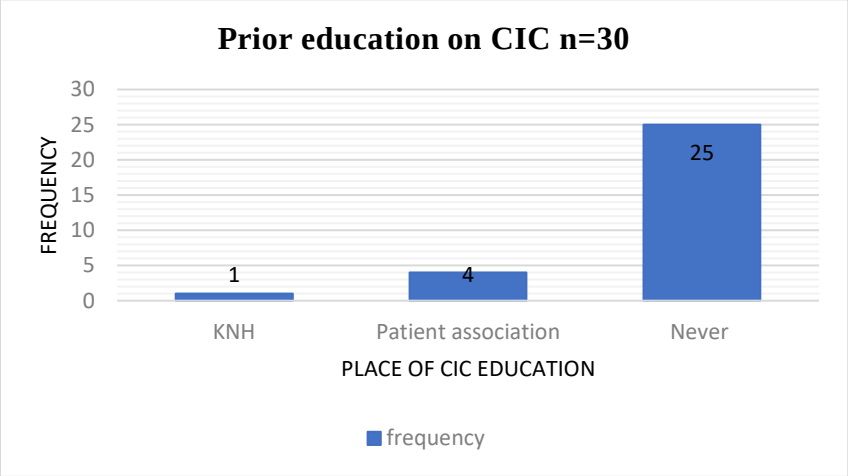

Figure 8: Histogram showing the place of Prior education on CIC

Self-catheterization

No participant had started training on self-catheterization

4.2.6.3 Age of initiation of CIC

The earliest age CIC was initiated was 1.5 years (1 participant) followed by 1.7 years (1 participant) and lastly 2 years (2 participants). Twenty-six participants were not practicing CIC as represented in table 9 and figure 9 below

Table 9: Shows the age of initiation of CIC

Age of CIC initiation	Frequency	Percentage
1.5	1	3.3
1.7	1	3.3
2.0	2	6.7
No	26	86.7

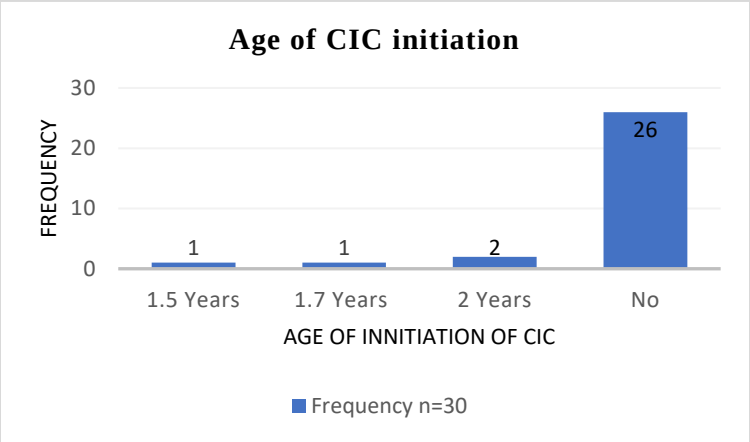

Figure 9: Histogram showing the Age of CIC initiation

4.2.6.4 Frequency of CIC sessions per day

The majority of those practicing CIC were only doing 2 sessions per day 3 (10%), one patient had 3 sessions per day 1 (3.3%), and all did not practice the recommended 4 to 6 hourly sessions [6] [64]. The majority of patients did not practice CIC 26 (86.7%) as shown in figure 10 below

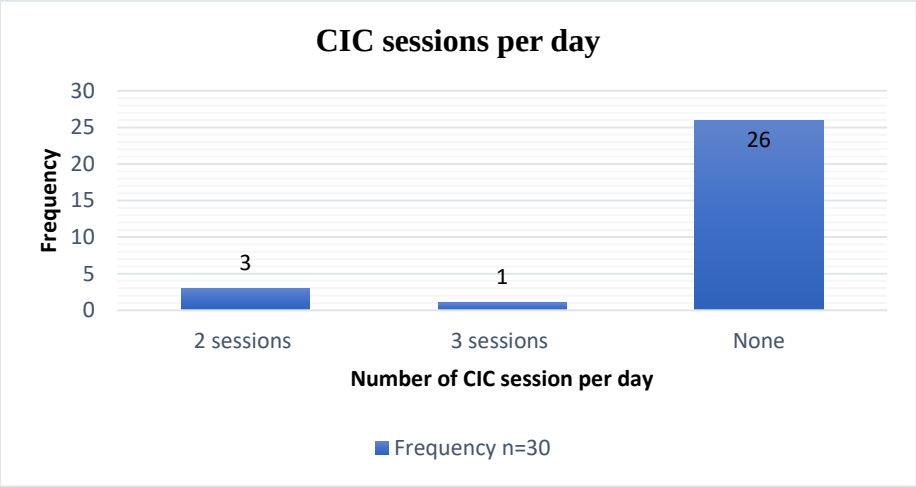

Figure 10: Histogram showing CIC sessions per day

4.3 Staging of kidney function according to KDIGO

Staging of kidney function is per KDIGO. The majority of participants 28 (93.3%) had normal kidney function, KDIGO stage 1. A few participants 2 (6.7%) had a reduced renal function, with KDIGO stage 2 as shown in figure 11 below.

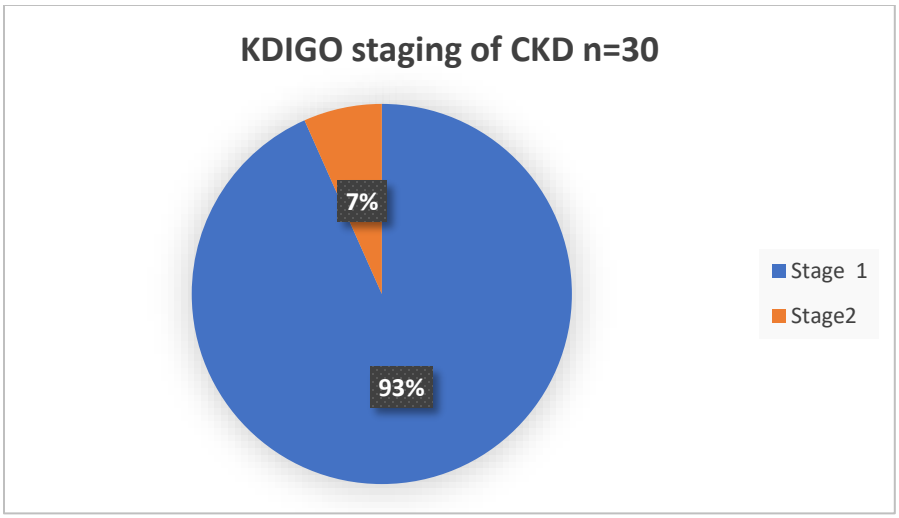

Figure 11: Pie chart showing proportions of KDIGO staging of CKD

4.4 Association between renal impairment and demographic characteristics

This study did not find any association between renal impairment and the demographic characteristics of the study participants. This is shown by the p-value of 1.00 for age, a p-value of 0.492 for sex, and a p-value of 1.00 for BMI as indicated in table 10 below.

Table 10: Association between renal impairment and demographic characteristics:

	Impaired	Not impaired	p-value
Age			
1.0 – 2.9	16 (57.1)	1 (50.0)	1.000
3.0 – 4.9	12 (42.9)	1 (50.0)	
Gender			
Male	13 (46/4)	0 (0.0)	0.492
Female	17 (53.6)	2 (100.0)	
BMI			
<5th percentile	10 (35.7)	1 (50.0)	1.000
≥5th- 85th percentile	18 (64.3)	1 (50.0)	
≥85th-<95th percentile			
≥95th percentile	1		

4.5 Association between clinical characteristics and renal impairment

There is an association between the anatomical location of the myelomeningocele and renal impairment (p-value 0.009). There is also an association between the motor/sensory level and renal impairment (p-value of 0.055) as shown in the table below.

Table 11: Association between clinical characteristics and renal impairment

	Impaired	Not impaired	p-value
Hydrocephalus			
Yes	24 (85.7)	2 (100.0)	1.000
No	4 (14.3)	0 (0.0)	
MMC location			
Lumbar	5 (17.9)	0 (0.0)	
Lumbosacral	11 (39.3)	0 (0.0)	
Sacral	9 (32.1)	0 (0.0)	**0.009**
Thoracic	0 (0.0)	1 (50.0)	
Thoracolumbar	3 (10.7)	1 (50.0)	
Best Motor/sensory level			
L1	3 (10.7)	0 (0.0)	
L2	1 (3.6)	0 (0.0)	
L3	3 (10.7)	0 (0.0)	
L4	2 (7.1)	0 (0.0)	
L5	9 (32.1)	0 (0.0)	0.055
S1	6 (21.4)	0 (0.0)	
S2	2 (7.1)	0 (0.0)	
S3	1 (3.6)	0 (0.0)	
T10	0 (0.0)	1 (50)	
T12	1 (3.6)	1 (50)	

5.0 CHAPTER FIVE: DISCUSSION OF RESULTS

During the study period, a review of the study register revealed that a total of 77 patients with myelomeningocele (MMC) were operated on. However, fourteen (18%) of the 77 children operated on in the study period (January 2016 to January 2021) were reported dead by the next of kin when contacted by telephone. No information confirming the cause of death was available, but the likely causes of early childhood deaths in these children could be related to acute hydrocephalus which we found to be the most predominant associated complication in our study (86.7%). Similar studies report 24% mortality when patients with MMC were followed up in adulthood and the predominant associated complication was hydrocephalus in 86% of patients [65]. Other cohort studies report an even higher mortality rate with only 56% of the patients surviving to the adulthood age of 20 years [66, 67]. During adulthood, however, renal failure is a common cause of mortality. Nonetheless, a majority of deaths have been reported within infancy and preschool period [65, 68, 69, 70]. other possible causes of early mortality could be malnutrition-related illnesses since 36% of children were underweight with a BMI <18 likely due to malnutrition, or deaths related to febrile illness such as urinary tract infections known to be common in this category of patients.

Thirty-three (43%) patients from the record were unreachable by telephone, either due to no contact information in the record or the contacts they had provided in the admission records were no longer available. However, thirty (39%) patients were successfully contacted by telephone, were able to come, and consented to participate in the study.

Of the thirty participants, the males 13(43.3%) and females were 17 (56.7%) with a male-to-female ratio of 1:1.3. This is consistent with a study earlier done by Ndegwa D et al. [71] at KNH on the

Pattern of presentation of spina bifida as seen and managed in Kenyatta National Hospital (2004). They reported a male-to-female ratio of 1:1.2, with more females who accounted for 54.7% of the study population. There have been many other published studies that similarly have shown a slightly predominant female population; In A study by Robin M. Bowman et al 71 patients were recruited in their study, the females were 38 (53.5%) and the males were 33 (46.5%) males [65]. McPherson et al. in a study of 180 participants similarly reported slightly higher female patient numbers of 94 (52.2%) and male 86 (47.2%) [72]. However, there have been some publications from India found a higher male population with spina bifida, Singh et al [73] reported Male: female ratio of 1.23:1, while Raj Kumar [74] reported 58 (56.9%) males and 44 (43.1%) females.

Underweight children with a BMI $<5^{th}$ percentile was 11 (36.7%), this could be due to malnutrition these children since they were mostly born to parents with low socio-economic status and young mothers with less experience in childcare [71]. Children with normal body weight, with a BMI of $\geq5^{th}$ – $<85^{th}$ percentile were 12 (40.0%). Children who were overweight as indicated by a BMI of 85^{th} -$<95^{th}$ percentile was 6 (20.0%), and obese children with BMI $\geq95^{th}$ percentile was 1 (3.3%). Overweight/obesity is usually caused by excessive calories in children with MMC who are mostly immobile owing to the lower limb weakness a majority suffer and this can lead to accumulated weight gain that will in turn lead to metabolic problems in these patients. A study by Amy C. McPherson et al. in a report of 67 patients found that 15 (23.8%) of the patients were overweight, while 11 (17.5%) were obese, 6 (9.5%) were underweight and 31 (49.2%) children had a normal BMI. They noted dietary intake and immobility as the main contributing factors to overweight/obese presentation [72]. Children similarly tend to have obesity rates as high as18% [74]

Twenty-six (86.7%) of the children had associated hydrocephalus all of whom had been treated with ventriculoperitoneal shunting (VPS) as the preferred modality of CSF diversion. Only four (13.7%) children did not have associated hydrocephalus. Our report is similar to other published data which has reported generally high rates of associated hydrocephalus from 80% [75] to as high as 86% all of whom had been treated by cerebrospinal fluid (CSF) diversion [65].

The anatomical location of the myelomeningocele along the vertebral column in our study was distributed such that the Lumbar spine was 7 (23.3%) participants, the Lumbosacral spine was 17 (56.7%) participants, the sacral spine 5 (16.7%) participants, Thoracic spine 1 (3.3%) participant and Thoracolumbar 5 (16.7%). This appears to be the common phenotypic presentation of these lesions [16] since the lumbosacral segment of the spine is the last part of the neural tube to close during primary and secondary neurulation, which occurs around day 27 of pregnancy. However, any portion of the spinal column could be affected [16]. This phenotypic presentation does not cut across all populations studied, with some reporting large numbers in thoracic or higher spine up to 15% [76].

All children seen in our study were reported to be urine incontinent, continuously dribbling urine without episodes of an urge to void a significant volume. These children were mostly managed with diapers throughout the day which are known to be costly. Those on CIC 4 (13.3%), who were mostly performing 2 sessions or more per day required fewer diapers, which indicates the benefits of CIC in achieving social continence as well as reducing daily costs of care. However, incontinence is often not diagnosed until the child is 5 years old following which if control is not present, may not develop subsequently [77]. To voluntarily control the lower urinary tract, a complex interaction between autonomic, sensory afferent innervation, and somatic efferent pathways are required [18,

19]. The parasympathetic supply to the bladder is derived from the sacral segment S2-S4 [20] which is almost always affected in patients with MMC of all anatomical locations which explain this high prevalence of incontinence. Regardless of the bladder and bowel management used, urinary and fecal incontinence may persist even in young adults with spina bifida (60.9 and 34.1%, respectively) [78]. Kurt A. some reports show significant numbers up to 39.4% being continent of urine [79]. Associated hydrocephalus in some studies has been found to increase the risk of urinary incontinence more than those without hydrocephalus (70.6 and 41.7%, respectively); P-value= 0.000 [80].

Bladder disturbances may present in various ways such as urinary tract infections and range from 24% and 94% of children and adults with spina bifida [81]. However, in our study, no child had ever been clinically diagnosed with a urinary tract infection, although previous Urinary Tract infections (UTI) could not be firmly excluded since some children had previously been treated for febrile illnesses. Fever, cultures, and symptoms of UTI such as flank/abdominal pain, change in continence pattern, change in urine odor, and dysuria is used to define UTI [82]. Recurrent UTIs are well documented as a significant factor in the development of reduced renal function in individuals with MMC [83] and should therefore be actively sought out whenever these patients present with suggestive symptoms

The best Motor/sensory were distributed such that, T10 motor/sensory was 1 (3.3%), T12 was 2 (6.6%), L1 was 3 (10.0%), L2 was 1 (3.3%), L3 was 3 (10.0%), L4 was 3 (10%), L5 was 8 (26.6%), S1 was 6 (20.0%), S2 was 2 (6.6%), and S3 was 1 (3.3%). Participants with the best motor/sensory level closer to the sacral segment had better power and ability to walk independently compared to those with lesions high up in the thoracic with motor/sensory levels in the lower thoracic and upper

lumber levels T10-L4 who had difficulty standing without support. Patients with a level of lesion of L5 or above are more likely to be incontinent for urine than patients with a lesion S1 or below (68.8 and 31.6% respectively) [80]

In principle, all newborn patients should be put on clean intermittent catheterization (CIC), oxybutynin, and chemoprophylaxis (trimethoprim 2 mg/kg once daily) immediately after closure of the back [3]. A few participants reported knowing CIC 5 (16.7%) and a majority 25 (83.3%) denied knowing CIC. Of the 5 participants with knowledge of CIC 4 participants reported first hearing about CIC in patients' managed spina bifida and hydrocephalus association and were actively practicing CIC, with catheters and other equipment obtained from donations from the same association, 1 of the 5 patients with knowledge of CIC had been educated on CIC during a clinic visit at KNH but, was comfortable performing the procedure on her daughter since she had no prior training, and besides also had no access to catheterization equipment. We thereafter noticed we had no staff dedicated to training these participants on performing CIC procedures which often is a multidisciplinary program. We noticed a need for a one-stop clinic to cover these gaps.

None of the 4 patients had been introduced to self-catheterization and most parents thought the children were too young to understand the procedure, although self-catheterization programs can be initiated as early as 3 years of age. The earliest age of initiation of CIC in our study was 1.5years 1 (3.3%) followed by 1.7years 1 (3.3%) and the oldest children were initiated at 2.0 years of age 2 (6.7%), however, as noted above children can be initiated as earlier as 6 months of age.

The majority of children 26 (86.7%) had not been initiated or even educated on CIC. Of note is that children initiated on a CIC program at infancy are seen to be more tolerant and compliant with the CIC regimen when compared to counterparts who are initiated later [57, 58].

Recommended frequency of carrying out CIC per day is 4 to 6 hourly intervals and may be increased when needed, and when unresponsive with persistent hydronephrosis continuous bladder drainage may be used in the night by the placement of a catheter [61, 62]. Three of the 4 children on CIC performed only 2 times a day and 1 child performed 3 times a day, and we, therefore, found these to be below the recommended routine of renal protection and social continence.

None of the children had even undertaken urodynamic studies as a baseline test to assess bladder function. These include the evaluation of bladder leak point pressure (LPP) that helps reveal bladder pressures and may be the basis for the needed frequency of CIC sessions. We further emphasize the importance of clean intermittent catheterization (CIC) as a method used to achieve social continence that will in turn prevent skin irritation from urine. The wetness from urine also causes rashes, maceration, ulceration, or hypertrophic changes involving the already insensitive skin of the anesthetic perineum [77]

A majority of upper tract changes occur within the first 4 years of life; regular radiological evaluation is therefore mandatory during this period [77]. These include techniques such as kidney, ureter, and bladder ultrasound (KUB) that detect reflux and upper tract dilatation as well as reduce the radiation dose to these young children. In this study, KUB ultrasounds had only been conducted in 13.3% of children. The majority 86.7% had not been investigated for upper urinary tract disease caused by a neurogenic bladder. Any detected upper urinary tract features such as hydro ureters and hydronephrosis may be managed through CIC as soon as it is detected.

Bladder dynamics of children put them at risk of developing renal damage despite being born with normal upper urinary tract function. Proactive and early institution of therapy is the key to preventing this renal damage [84].

Two children in this study exhibited features of early renal failure with KDIGO grade 2. They may potentially have high bladder storage pressures with vesicoureteric reflux and hydroureters/hydronephrosis and will necessitate a clinical intervention such as CIC. Although these children were asymptomatic, they risk clinical progression if the underlying disease process is not mitigated, we recommended urodynamic studies, and KUB ultrasound and referred them to the pediatric nephrology team for further care. They will also commence the CIC program as indicated with immediate effect.

There was an association between renal failure and the anatomical location of the MMC, with thoracic and upper lumber location patients appearing to be at a higher risk of developing renal impairment (P-Value = **0.009).** There was also a correlation between the motor/sensory level with the risk of developing renal impairment (P-value 0.055) with the higher motor/sensory level more associated with the development of renal impairment. Renal failure is still the leading cause of death in older patients with spina bifida, with renal insufficiency responsible for 30% of all deaths [85]

We did not find any association between impaired renal function the demographic characteristics such as age, sex, and BMI.

5.1 Conclusion:

Seventy-seven patients had been operated on between January 2016 to January 2021, fourteen were reported dead, 33 were lost to follow-up, and only 30 participated in the study

The youngest participant in the study population was 1 year of age and the oldest was 4.3 years mean age of 2.6 years. The study shows that more female patients presented with myelomeningocele in the study period of January 2016 to January 2021.

Most participants had associated hydrocephalus all of whom had undergone CSF diversion and were clinically stable. The study reveals that a significant number 36.7% were underweight with a BMI $<5^{th}$ percentile, this was explained by a study earlier in 2004 done by Ndegwa et al that had found that most of these children were born to young mothers of low socio-economic status. However, a majority (40%) of the study participants were of normal BMI, with the remainder being overweight or obese.

Sixteen percent of the participants had prior been educated on the practice and benefits of clean intermittent catheterization, and of those practicing CIC, 13% obtain their equipment from donations in the patient association. No participants had been subjected to urodynamic studies as a baseline before the initiation of CIC.

Two of the thirty participants exhibited reduced renal function at KDIGO Grade 2. These participants were clinically asymptomatic but were linked to the care of a pediatric nephrologist and the upper urinary tract evaluation was immediately recommended. The study also revealed that renal impairment was largely associated with a higher lumber or thoracic anatomical location of the myelomeningocele.

5.2 Recommendations:

1. Early education of patient relatives on the benefits of Clean intermittent catheterization.
2. Introduce the use of urodynamic studies in the early evaluation of patients with myelomeningocele
3. Routine surveillance for early renal impairment for all children with myelomeningocele.
4. To establish a one-stop clinic that covers all the needs of patients with myelomeningocele
5. To train medical staff who will eventually train patient attendants on a day to day care of children with myelomeningocele
6. To regularly update the contact records of patients attending the clinics to mitigate issues of missing or unavailable phone contacts

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APPENDICES

Appendix 1

DATA COLLECTION TOOL

Questionnaire number

PART 1

Demographic information

Age: Gender: Male Female

Weight (Kg) Height(Length) (cm) Arm span (cm)

Date of surgery / /

Clinical information

Best sensory level Best motor level

Anatomic location of MMC: 1. cervical 2. Thoracic 3. Thoracolumbar

4. Lumber 5. Lumbosacral 6. Sacral

Does the child have control of micturition? Yes No

Frequency of micturition /day

Presence of Hydrocephalus: yes No

Continence after surgery: Improved Remain the same Got worse

Do not know

PART 2

Urinary tract infection (UTI)

Previous diagnosis of UTI? Yes ☐ No ☐

Number of UTIs since surgery ☐ None ☐ Unknown: ☐ Countless ☐

Prior hospitalization due to UTI Yes ☐ No ☐

Clean Intermittent Catheterization

Have you heard about CIC? **Yes** ☐ **No** ☐

Do you practice CIC? Daily ☐ Sometimes ☐ No ☐

From where did you first hear about CIC?

KNH ☐ Another Hospital ☐ A friend ☐ internet ☐ Patient associations ☐

Age of initiation of CIC ☐ s Unknown ☐

Have you started initiating the child to Self-catheterization

Yes ☐ No ☐

If yes at what age did you first initiate self-CIC ☐ years/months

How many CIC sessions per day ☐ Unkno ☐

Where do you get catheters? Buy ☐ Donation ☐

If buy what's the average cost of catheter ☐ KSH

How do you store the catheter in between CIC sessions?

Clean container ☐ in an open place ☐ I do not reuse catheters ☐

Do you wash the catheters before re-using: yes ☐ No ☐

How do you Lubricate the catheter: plain water ☐ Medically provided lubricant ☐

I do not use lubrication ☐

Do you wash your hands before and after every CIC session?

Yes ☐ No ☐ Only after but not before ☐ Only before but not after ☐

Anticholinergic Medication Use

Prior use of anticholinergic medication: yes ☐ No ☐

Reason for not using: Never been prescribed ☐, unable to afford ☐,

suffered adverse effects from the drug ☐ and did not see any benefit from using the drug ☐

Part 3

Urodynamic Studies

Has the child undergone urodynamic studies: Yes ☐ No ☐

If yes above EMG ☐ VCUG ☐ CMG ☐

Renal function tests

Serum creatinine ☐

Urea ☐

Serum potassium ☐

Sodium ☐

Chloride ☐

APPENDIX 2

PARTICIPANT INFORMATION AND CONSENT FORM

Title of Study: Incidence of impaired renal function and clinical characteristics of children 1 to 5 years after repair of myelomeningocele at the Kenyatta National Hospital.

Principal investigator

Dr. Samuel Oluka

M.Med Neurosurgery, Department of Surgery

School of Medicine, University of Nairobi

P.O. Box 19676 KNH, Nairobi 00202.

Mobile no. 0750910363

Introduction:

This Informed Consent form is intended for patients/parents/guardians in the wards and those attending the neurosurgery Outpatient Clinic at KNH eligible for the study.

It serves to request those eligible patients to participate in this research project whose title is:

Incidence of impaired renal function and clinical characteristics of children 1 to 5 years after repair of myelomeningocele at the Kenyatta National Hospital.

Principal Investigator: Dr. Samuel Oluka

Institution: Department of Surgery, School of Medicine, University of Nairobi.

This Informed Consent Form has three parts:

1) Information Sheet (to share information about the research with you).

2) Certificate of Consent (for signatures if you agree to take part).

3) Statement by the researcher/person taking consent.

You will be given a copy of the full informed consent form.

PART I: Information Sheet

Introduction

I Dr. Samuel Oluka, I'm a postgraduate student in Neurosurgery, department of surgery at the University of Nairobi, in Kenyatta National Hospital KNH

I'm researching **the Incidence of impaired renal function and clinical characteristics of children 1 to 5 years after repair of myelomeningocele at the Kenyatta National Hospital.**

Purpose of the research

I will sufficiently give you information concerning the study as I invite you to participate in this research. In cases of my lack of clarity in the wording or explanation please feel free to ask me to clarify for you.

If you agree to participate in this study, the following things will happen:

You will be interviewed by a trained interviewer in a private area where you feel comfortable answering questions. The interview will last approximately 30 minutes. The interview will cover topics such as the history of the disease and surgery, the investigations that have been done to this day, the practice of bladder care, and a physical examination. After the interview is finished, you will be required to have a venous blood sample taken by a trained phlebotomist who will label the sample bottle appropriately and take it to the laboratory.

We will ask for a telephone number where we can contact you if necessary. If you agree to provide your contact information, it will be used only by people working for this study and will never be shared with others.

The reasons why we may need to contact you include: the patient may need a medical intervention especially after seeing the laboratory findings

What is this study about?

The study seeks to assess the Incidence of impaired renal function and clinical characteristics of children 1 to 5 years after repair of myelomeningocele at the Kenyatta National Hospital. It will further seek to correlate between clinicodemographic and the clinical characteristics of these children with impaired renal function

Type of Research Intervention

This research will involve finding a routine anthropometric assessment, and to further assess your practice of clean intermittent catheterization, previous urinary tract infections, use of anticholinergic medications on the day-to-day basis, and thereafter Urea, electrolyte, and Creatinine tests will be requested to be done in the KNH laboratory, as a routine test done on the follow up of the child.

Voluntary participation/right to refuse or withdraw

Participating in the study is optional and you have a right to opt out of the study at any stage. You will also continue to receive all the services at the hospital with minimal delays. There will be no victimization whatsoever should you refuse to participate in the study. I further extend that you should feel free to report to the hospital authorities any breach of your rights as a patient on matters involving this study.

I will lastly remind you of your right to withdraw or refuse to participate in this study at any stage.

Confidentiality

The information obtained henceforth will be treated with utmost confidentiality only to be used by the principal investigator and the study team. No names shall be used throughout the study. A study number is all that will be assigned to you the participant. We will further record your hospital number should there be a need to trace you for an intervention following the investigations done

Sharing the results

The result of this study will be shared with the hospital management for the possible creation of protocols for the management of this category of patients. It will further be extended to the ministry of health for making policies regarding patient care. Be notified that no personal information will be shared about you as an individual.

Benefits

What are the benefits of joining this study?

i. To contribute to the improvement of healthcare provision for the current patients and those to come.
ii. Patients found needing any immediate medical intervention shall be recalled and provided as required.

Risks

There will be no risks involved

Cost and Compensation

This research proposal is fully reviewed and approved by the UoN/KNH Ethics Committee, whose mandate is to ensure the safety of participants recruited in the study. The Urea, Electrolyte, and Creatinine (UEC) will be the required test and will be part of your clinical follow-up. Should you

be for whatsoever reason unable to meet the bill of the laboratory test, it will be borne by the principal investigator

NB: No inducements/incentives shall be given to participants in the study

Whom to Contact

For any queries or further inquiries please feel free to contact the following:

Principal Researcher:

Dr. Samuel Oluka,

Neurosurgery resident, Department of Surgery, School of Medicine, University of Nairobi

P.O. Box 19676 KNH, Nairobi 00202.

Mobile no. 0750910363

University of Nairobi Supervisors:

DR. Julius Githinji Kiboi

MBChB, M.MED (Surgery) (UoN), Neurosurgery

Consultant Neurosurgeon

Chairman Department of Surgery, University of Nairobi.

Dr. Patrick Okoth Akuku

MBChB, M.Med Surgery (UoN), Neurosurgery

Senior Lecturer and Consultant Neurosurgeon

Department of Surgery, University of Nairobi.

DR. PETER GICHURU MWANGI

Senior Consultant Neurosurgeon,

MB ChB, MMed (UoN), Neurosurgery

Kenyatta national hospital/ university of Nairobi

If you have any ethical concerns, you may contact:

Secretary, UON/KNH-ERC,

P.O. Box 20723- 00202,

KNH, Nairobi.

Tel: 020-726300-9 EXT 44355

Email: uonknh_erc@uonbi.ac.ke

PART II: CERTIFICATE OF CONSENT

I have read and comprehended the prior information, or it has been translated and interpreted into the best language I understand. The interaction was cordial and I had the opportunity to ask questions that have been answered to my satisfaction. No incentives or inducements or coercion has been used.

I, therefore, consent to participate in this research.

Name of participant…….

In-patient/out-patient number of participants……

Date…….

For patient/parent/guardian unable to read or write:

I have witnessed the accurate reading of the consent form to the potential participant, and the individual has had the opportunity to ask questions. I confirm that the individual has given consent freely.

Name of parent/Guardian……...

Name of participant/patient……

The thumbprint of the parent/guardian

Signature of parent/guardian …….

Date ……

PART III: Statement by the researcher

I have correctly given information written here forth in the consent form to the participant in the simplest language they understand and crosschecked to confirm they understand the phrases inscribed in the document:

- Their objection to participating in the study will not in any way compromise their right to get treatment.
- Confidentiality will be maintained at all levels of the study
- I confirm that the participant was allowed to ask questions about the study, and all the questions asked by the participant have been answered correctly and to the best of my ability.
- I confirm that the individual has not been coerced into giving consent, and the consent has been given freely and voluntarily.
- A copy of this Informed Consent Form has been provided to the participant.

Name of researcher/person taking consent ……

Signature of researcher/person taking consent ……

Date……. Contact information …….

KIAMBATISHO 2

FOMU YA TAARIFA NA RIDHAA YA MSHIRIKI

Kichwa cha Utafiti: Matukio ya kuharibika kwa utendakazi wa figo na sifa za kiafya za watoto mwaka 1 hadi 5 baada ya ukarabati wa myelomeningocele katika Hospitali ya Kitaifa ya Kenyatta.

Mkuu wa shulempelelezi

Dkt Samuel Oluka

M.MedUpasuaji wa neva,Idara ya Upasuaji

Shule ya Tiba, Chuo Kikuu cha Nairobi

PO Box 19676 KNH, Nairobi 00202.

Nambari ya simu ya rununu. 0750910363

Utangulizi:

Fomu hii ya Idhini ya Kuarifiwa inakusudiwa wagonjwa/wazazi/walezi katika wadi na wale wanaohudhuria Kliniki ya Wagonjwa wa Upasuaji wa Mishipa katika KNH wanaostahiki utafiti. Inatumika kuwaomba wale wagonjwa wanaostahiki kushiriki katika mradi huu wa utafiti ambao jina lake ni:

Matukio ya kuharibika kwa utendakazi wa figo na sifa za kiafya za watoto mwaka 1 hadi 5 baada ya ukarabati wa myelomeningocele katika Hospitali ya Kitaifa ya Kenyatta.

Mpelelezi Mkuu:Dkt Samuel Oluka

Taasisi: Idara ya Upasuaji, Shule ya Tiba, Chuo Kikuu cha Nairobi.

Fomu hii ya Idhini iliyo na Taarifa ina sehemu tatu:

1) Karatasi ya Taarifa (kushiriki nawe habari kuhusu utafiti).

2) Cheti cha Idhini (kwa saini ikiwa unakubali kushiriki).

3) Taarifa ya mtafiti/mtu anayekubali.

Utapewa nakala ya fomu ya idhini iliyo na taarifa kamili.

SEHEMU YA I: Karatasi ya Taarifa

Utangulizi

Mimi Dkt. Samuel Oluka, mimi ni mwanafunzi wa shahada ya uzamili katika Neurosurgery, idara ya upasuaji katika Chuo Kikuu cha Nairobi, katika Hospitali ya Kitaifa ya Kenyatta KNH

Ninatafiti**Matukio ya kuharibika kwa figo na sifa za kiafya za watoto mwaka 1 hadi 5 baada ya ukarabati wa myelomeningocele katika Hospitali ya Kitaifa ya Kenyatta.**

Madhubani ya utafiti

Nitakupa taarifa za kutosha kuhusu utafiti ninapokualika kushiriki katika utafiti huu. Katika hali ya ukosefu wangu wa uwazi katika maneno au maelezo tafadhali jisikie huru kuniuliza nikufafanulie.

Ukikubali kushiriki katika utafiti huu, mambo yafuatayo yatafanyika:

Utahojiwa na mhojiwa aliyefunzwa katika eneo la faragha ambapo unajisikia vizuri

kujibu maswali. Mahojiano yatadumu takriban dakika 30. Mahojiano hayo yatashughulikia mada kama vile historia ya ugonjwa na upasuaji, uchunguzi ambao umefanywa hadi leo, mazoezi ya utunzaji wa kibofu cha mkojo, na uchunguzi wa mwili. Baada ya mahojiano kukamilika, utahitajika kuwa na sampuli ya damu ya vena iliyochukuliwa na mtaalamu wa phlebotomist ambaye ataweka alama kwenye chupa ya sampuli ipasavyo na kuipeleka kwenye maabara.

Tutaomba nambari ya simu ambapo tunaweza kuwasiliana nawe ikibidi. Ukikubali kutoa maelezo yako ya mawasiliano, yatatumiwa na watu wanaofanya kazi katika utafiti huu pekee na kamwe hayatashirikiwa na wengine.

Sababu ambazo tunaweza kuhitaji kuwasiliana nawe ni pamoja na: mgonjwa anaweza kuhitaji uingiliaji wa matibabu hasa baada ya kuona matokeo ya maabara.

Utafiti huu unahusu nini?

Utafiti unalenga kutathminiMatukio ya kuharibika kwa figo na sifa za kiafya za watoto mwaka 1 hadi 5 baada ya ukarabati wa myelomeningocele katika Hospitali ya Kitaifa ya Kenyatta. Itatafuta zaidi kuunganisha kati ya klinikidemografia na sifa za kliniki za watoto hawa walio na kazi ya figo iliyoharibika.

Aina ya Uingiliaji kati wa Utafiti

Utafiti huu utahusisha kutafuta tathmini ya kawaida ya kianthropometriki, na kutathmini zaidi mazoezi yako ya uwekaji damu wa mara kwa mara wa katheta, baada ya hapo vipimo vya Urea, electrolyte, na Creatinine vitaombwa kufanywa katika maabara ya KNH, kama jaribio la kawaida linalofanywa katika ufuatiliaji wa mtoto.

Kushiriki kwa hiari/haki ya kukataa au kujiondoa

Kushiriki katika utafiti ni hiari na una haki ya kuondoka kwenye utafiti katika hatua yoyote. Pia utaendelea kupata huduma zote hospitalini kwa ucheleweshaji mdogo. Hakutakuwa na uonevu wowote ukikataa kushiriki katika utafiti. Ninaongeza zaidi kwamba unapaswa kujisikia huru kuripoti kwa mamlaka ya hospitali ukiukaji wowote wa haki zako kama mgonjwa kuhusu masuala yanayohusu utafiti huu.

Nitakukumbusha mwisho kuhusu haki yako ya kujiondoa au kukataa kushiriki katika utafiti huu katika hatua yoyote ile.

Usiri

Taarifa zitakazopatikana kuanzia sasa zitashughulikiwa kwa usiri wa hali ya juu ili tu zitumike na mpelelezi mkuu na timu ya utafiti. Hakuna majina yatatumika katika kipindi chote cha utafiti. Nambari ya somo ndiyo yote ambayo utapewa wewe mshiriki. Tutarekodi zaidi nambari yako ya hospitali iwapo kutakuwa na haja ya kukutafuta kwa ajili ya uingiliaji kati kufuatia uchunguzi uliofanywa

Kushiriki matokeo

Matokeo ya utafiti huu yatashirikiwa na wasimamizi wa hospitali kwa ajili ya kuunda itifaki za usimamizi wa aina hii ya wagonjwa. Itapanuliwa zaidi kwa wizara ya afya kwa kuunda sera kuhusu utunzaji wa wagonjwa. Arifiwa kuwa hakuna maelezo ya kibinafsi yatashirikiwa kukuhusu kama mtu binafsi.

Faida

Je, ni faida gani za kujiunga na utafiti huu?

iii. Kuchangia katika uboreshaji wa utoaji wa huduma za afya kwa wagonjwa wa sasa na wale watakaokuja.

iv. Wagonjwa wanaopatikana wanahitaji uingiliaji wa haraka wa matibabu watakumbushwa na kutolewa kama inavyohitajika.

Hatari

Hakutakuwa na hatari zinazohusika

Gharama na fidia

Pendekezo hili la utafiti linakaguliwa kikamilifu na kuidhinishwa na Kamati ya Maadili ya UoN/KNH, ambayo jukumu lake ni kuhakikisha usalama wa washiriki walioajiriwa katika utafiti. Urea, Electrolyte, na Creatinine (UEC) ndicho kitakuwa kipimo kinachohitajika na kitakuwa sehemu ya ufuatiliaji wako wa kimatibabu. Iwapo kwa sababu yoyote ile huwezi kufikia muswada wa uchunguzi wa kimaabara, itachukuliwa na mpelelezi mkuu.

NB: Hakuna vishawishi/vishawishi vitatolewa kwa washiriki katika utafiti

Nani wa Kuwasiliana

Kwa maswali yoyote au maswali zaidi tafadhali jisikie huru kuwasiliana na wafuatao:

Mtafiti Mkuu:

Dkt Samuel Oluka,

Mkazi wa Upasuaji wa Ubongo, Idara ya Upasuaji, Shule ya Tiba, Chuo Kikuu cha Nairobi

PO Box 19676 KNH, Nairobi 00202.

Nambari ya simu ya rununu. 0750910363

Wasimamizi wa Chuo Kikuu cha Nairobi:

DR. Julius GithinjiKiboi

MBChB, M.MED (Upasuaji) (UoN), Upasuaji wa Mishipa ya Fahamu

Mshauri wa Neurosurgeon

Mwenyekiti Idara ya Upasuaji, Chuo Kikuu cha Nairobi.

Dkt Patrick Okoth Akuku

MBChB, Upasuaji wa M.Med (UoN), Upasuaji wa Mishipa ya Fahamu

Mhadhiri Mwandamizi na Daktari Bingwa wa Upasuaji wa Neuro

Idara ya Upasuaji, Chuo Kikuu cha Nairobi.

DR. PETER GICHURU MWANGI

Mshauri Mwandamizi Daktari wa upasuaji wa neva,

MB ChB, MMed (UoN), Upasuaji wa Mishipa ya Fahamu

Hospitali ya kitaifa ya Kenyatta/ chuo kikuu cha Nairobi

Ikiwa una matatizo yoyote ya kimaadili, unaweza kuwasiliana na:

Katibu, UON/KNH-ERC,

PO Box 20723- 00202,

KNH, Nairobi.

Simu: 020-726300-9 EXT 44355

Barua pepe: uonknh_erc@uonbi.ac.ke

SEHEMU YA II: CHETI CHA RIDHAA

Nimesoma na kuelewa maelezo ya awali, au yametafsiriwa na kufasiriwa kwa lugha bora ninayoelewa. Mwingiliano ulikuwa wa kupendeza na nimepata fursa ya kuuliza maswali ambayo yamejibiwa kwa kuridhika kwangu. Hakuna motisha au vishawishi au shuruti imetumika.

Kwa hivyo, nakubali kushiriki katika utafiti huu.

Jina la mshiriki …….

Nambari ya mgonjwa aliyelazwa/nje ya Mshiriki ……

Tarehe…….

Kwa mgonjwa/mzazi/mlezi asiyeweza kusoma wala kuandika:

Nimeshuhudia usomaji sahihi wa fomu ya idhini kwa mshiriki anayetarajiwa, na mtu binafsi amepata nafasi ya kuuliza maswali. Ninathibitisha kuwa mtu huyo ametoa kibali kwa uhuru.

Jina la mzazi/Mlezi……

Jina la mshiriki/mgonjwa……

Alama ya kidole gumba chamzazi/mlezi

Sahihi yamzazi/mlezi …….

Tarehe ……

SEHEMU YA TATU: Taarifa ya mtafiti

Nimetoa maelezo yaliyoandikwa hapa katika fomu ya idhini kwa mshiriki kwa lugha rahisi zaidi anayoelewa na kuchaguliwa ili kuthibitisha kuwa anaelewa vifungu vilivyoandikwa kwenye hati:

- Upinzani wao wa kushiriki katika utafiti hautahatarisha kwa vyovyote vile haki yao ya kupata matibabu.
- Siri itadumishwa katika viwango vyote vya utafiti
- Ninathibitisha kuwa mshiriki aliruhusiwa kuuliza maswali kuhusu utafiti, na maswali yote yaliyoulizwa na mshiriki yamejibiwa kwa usahihi na kwa uwezo wangu wote.
- Ninathibitisha kuwa mtu huyo hajalazimishwa kutoa idhini, na idhini imetolewa kwa hiari na kwa hiari.
- Nakala ya Fomu hii ya Idhini iliyoarifiwa imetolewa kwa mshiriki.

Jina la mtafiti/mtu anayepokea kibali ……

Saini ya mtafiti/mtu anayechukua kibali ……

Tarehe……Maelezo ya mawasiliano …….

UNIVERSITY OF NAIROBI
FACULTY OF HEALTH SCIENCES
P O BOX 19676 Code 00202
Telegrams: varsity
Tel:(254-020) 2726300 Ext 44355

KNH-UON ERC
Email: uonknh_erc@uonbi.ac.ke
Website: http://www.erc.uonbi.ac.ke
Facebook: https://www.facebook.com/uonknh.erc
Twitter: @UONKNH_ERC https://twitter.com/UONKNH_ERC

KENYATTA NATIONAL HOSPITAL
P O BOX 20723 Code 00202
Tel: 726300-9
Fax: 725272
Telegrams: MEDSUP, Nairobi

Ref: KNH-ERC/A/404

12th October, 2022

Dr. Samuel Oluka
Reg No. H58/88595/2016
Dept of Surgery
Faculty of Health Sciences
University of Nairobi

KENYATTA NATIONAL HOSPITAL APPROVED 12 OCT 2022 QUALITY HEALTH CARE KNH/UoN-ERC P.O. Box 20723 - 00202, NAIROBI

Dear Dr. Oluka,

RESEARCH PROPOSAL: INCIDENCE OF IMPAIRED RENAL FUNCTION AND CLINICAL CHARACTERISTICS OF CHILDREN 1 TO 5 YEARS AFTER REPAIR OF MYCLOMENINGOCELE AT THE KENYATTA NATIONAL HOSPITAL (P293/04/2022)

This is to inform you that KNH-UoN ERC has reviewed and approved your above research proposal. Your application approval number is **P293/04/2022.** The approval period is 12th October 2022 – 11th October 2023.

This approval is subject to compliance with the following requirements;

i. Only approved documents including (informed consents, study instruments, MTA) will be used.
ii. All changes including (amendments, deviations, and violations) are submitted for review and approval by KNH-UoN ERC.
iii. Death and life threatening problems and serious adverse events or unexpected adverse events whether related or unrelated to the study must be reported to KNH-UoN ERC 72 hours of notification.
iv. Any changes, anticipated or otherwise that may increase the risks or affected safety or welfare of study participants and others or affect the integrity of the research must be reported to KNH-UoN ERC within 72 hours.
v. Clearance for export of biological specimens must be obtained from relevant institutions.
vi. Submission of a request for renewal of approval at least 60 days prior to expiry of the approval period. Attach a comprehensive progress report to support the renewal.
vii. Submission of an executive summary report within 90 days upon completion of the study to KNH-UoN ERC.

Prior to commencing your study, you will be expected to obtain a research license from National Commission for Science, Technology and Innovation (NACOSTI) https://research-portal.nacosti.go.ke and also obtain other clearances needed.

Yours sincerely,

DR. BEATRICE K.M. AMUGUNE
SECRETARY, KNH-UoN ERC

c.c. The Dean, Faculty of Health Sciences, UoN
The Senior Director, CS, KNH
The Assistant Director, Health Information Dept., KNH
The Chairperson, KNH- UoN ERC
The Chair, Dept, of Surgery, UoN
Supervisors: Dr. Julius G Kiboi, Dept, of Surgery, UoN
Dr. Patrick O Akuku Dept. of Surgery, UoN
Dr. Peter G Mwangi, Senior Consultant Neurosurgeon, KNH

24/3/2023 Confirmed

DR. SAMUEL OLUKA
NEUROSURGERY
H58/88595/2016

DEPARTMENT OF SURGERY
FACULTY OF HEALTH SCIENCES
P O Box 19676 - 00202 KNH
NAIROBI
Tel: 020 491 5043

Incidence Of Impaired Renal Function And Clinical Characteristics Of Children 1 To 5 Years After Repair Of Myelomeningocele At The Kenyatta National Hospital.

ORIGINALITY REPORT

13%	9%	8%	5%
SIMILARITY INDEX	INTERNET SOURCES	PUBLICATIONS	STUDENT PAPERS

PRIMARY SOURCES

1	Kwanchai Pirojsakul, Nisha Mathews, Mouin G. Seikaly. "Chronic Kidney Disease in Children: Recent Update", The Open Urology & Nephrology Journal, 2015 Publication	1%
2	erepository.uonbi.ac.ke Internet Source	1%
3	Submitted to Excelsior College Student Paper	1%
4	Raja Dandamudi, Neil Vyas, Stanley P. Hmiel, Vikas R. Dharnidharka. "Performance of the various serum creatinine-based GFR estimating equations in pediatric kidney transplant recipients, stratified by age and CKD staging", Pediatric Nephrology, 2021 Publication	1%
5	acikerisim.pau.edu.tr Internet Source	1%