EFFECT ON SHUNT SURVIVAL OF THE BIOCHEMICAL AND CELLULAR PROPERTIES OF CEREBROSPINAL FLUID AMONG PATIENTS FOLLOWING VENTRICULOPERITONEAL SHUNTING

DR. BENJAMIN KASYOKA MUTISO

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STUDENT'S DECLARATION

I, **Dr. Benjamin Kasyoka Mutiso,** do hereby declare that this dissertation is my original work and has not been presented for the award of a degree at any other university

Dr. Benjamin Kasyoka Mutiso, MBCHB (UON)

H58/81098/2015

Signature: ………… Date: …

SUPERVISORS' APPROVAL

This dissertation is submitted with our approval as supervisors

Dr. Michael Magoha
MBChB (U.O.N), MMED Neurosurgery (U.O.N)
Consultant Neurosurgeon and Lecturer,
Department of Surgery, Division of Neurosurgery

Signature: ..... Date: 4/6/21

Dr. Kiboi Julius Githinji
MBChB (U.O.N), MMED SURGERY (U.O.N), Supernumerary neurosurgery training Pretoria academic hospital, University of Pretoria, South Africa.
Consultant neurosurgeon and senior lecturer
Department of Surgery, Division of neurosurgery
University of Nairobi

Signature: ..... Date: 4/6/2021

Prof. Angela Atieno Amayo
MBChB (U.O.N), MMED PATHOLOGY (U.O.N)
Fellow of the College of Pathologists East, Central and Southern Africa (FCPath ECSA)
Senior lecturer, Department of Pathology
University of Nairobi

Signature: ..... Date: 4/6/2021

Dr. John Boore
MBChB (U.O.N), MMED SURGERY (U.O.N), Fellow of the College of Surgeons of East Central and Southern Africa (Neurosurgery)
Consultant Neurosurgeon
Kenyatta National Hospital

Signature: ..... Date: 03/06/2021

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DEPARTMENTAL APPROVAL

This dissertation has been submitted for examination with the approval of the Department of Surgery

Dr. Kiboi Julius Githinji

Senior lecturer and consultant neurosurgeon

Chairman department of surgery, school of medicine

University of Nairobi

Signature: ..... Date: 4/6/2024

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LIST OF ABBREVIATIONS

VPS - Ventriculoperitoneal shunt

KNH- Kenyatta National Hospital

CSF- Cerebrospinal fluid

SPSS- Statistical package for social sciences

TB- Tuberculosis

TBM- Tuberculous meningitis

PPV- Positive predictive value

LOC- Loss of consciousness

WBCs- White blood cells

OPERATIONAL DEFINITIONS

Ventriculoperitoneal Shunt survival – Time (in days) from insertion of VPS to the diagnosis of shunt failure

ABSTRACT

Study background: The burden of hydrocephalus in our region is huge. It is estimated that 6000 new cases are diagnosed in Kenya, most of which undergo ventriculoperitoneal shunting. These shunts frequently malfunction, with shunt blockage being the commonest cause of shunt failure. The biochemical and cellular properties of CSF are hypothesized to contribute to shunt blockage. This study aimed to demonstrate the impact of these CSF properties on shunt survival.

Broad objective: To assess the biochemical and cellular properties of cerebrospinal fluid among patients undergoing ventriculoperitoneal shunting and their effect on shunt survival

Study design and site: Prospective cohort study. This study was carried out in Kenyatta national hospital within the neurosurgical (ward 4C and the neurosurgical outpatient clinic), pediatric units (wards 3A, 3B, 3C and 3D)and the medical wards (wards 7A, 7B, 7D, 8A,8B and 8D).

Participants and Methods: Patients were recruited into the study following VP shunt surgery for hydrocephalus. Data collected at recruitment included study identification, age, sex, residence and etiology of hydrocephalus. Additionally, data regarding the CSF biochemistry including proteins and glucose and cellularity was also abstracted from the patient files. Based on their baseline CSF biochemical and cellular properties, the patients were divided into two groups; those with normal and those with abnormal CSF biochemistry and cellularity. Patients were then be followed up in the neurosurgical clinics for a period of 3months during which shunt function was assessed clinically.

Data management: This data was then entered to the statistical package for social sciences (IBM SPSS statistics 25.0) for data analysis. Descriptive statistics including means and medians, and proportions were run to establish characteristics of the study participants.For hypothesis testing, students' T test of independence will be used for Continuous variables such as age and time to shunt failure (in days). Chi square was used for continuous variables. P values of <0.05 was considered statistically significant. Features significant in the univariate analysis will be advanced to a binary logistic regression model to assess for risk factors of shunt failure. Results of the regression model were reported in Odds ratios and corresponding 95% confidence intervals. Survival analysis using Kaplan Meir was used to assess for time to shunt failure. Categorical variables like marital status, gender, occupation is presented as proportions, bar charts, pie charts, and frequency tables while continuous variables was presented in histograms.

Expected main outcome measure: Shunt survival in days

Results: During the study period, a total of 82 patients met the inclusion criteria and were recruited into the study. Forty-six (56.1%) were male while 36(43.9%) of them were female. The mean age was 15.5 months (SD 23.4 months). Majority (82.9%) of the patients had congenital hydrocephalus with Dandy walker malformation being the most common congenital anomaly seen. Most patients (52.44%) had normal CSF proteins while the remainder had elevated CSF proteins. Majority of the patients had reduced levels of CSF glucose at 65.9%. The CSF cell count was normal for most of the patients at 86.6%. Elevated CSF protein concentration was associated with an increased likelihood of ventriculoperitoneal shunt failure by 8.7 times compared to the patients with normal CSF protein concentration. Reduced CSF glucose concentration was associated was also found to increase the likelihood of shunt failure in this study. There was no correlation between the CSF cell count and the likelihood of shunt failure.

Conclusion: Congenital anomalies were the commonest cause of hydrocephalus in this study. Almost half of the patients treated with hydrocephalus during the study period had elevated CSF proteins. Elevated CSF proteins increased the probability of shunt failure at 3 months of follow up. A positive correlation was also seen with reduced CSF glucose and the likelihood of shunt failure. CSF cell count did not affect shunt function in this study.

Utility of the study: This study establishes evidence upon which the practice of shunt surgery in patients with abnormal CSF biochemical and cellular properties will be based on by showing the effects of this parameters on shunt survival.

Key words: Hydrocephalus, CSF biochemistry and cellularity, ventriculoperitoneal shunt survival

1.0 CHAPTER ONE: INTRODUCTION AND LITERATURE REVIEW

1.1 Introduction

Hydrocephalus is a condition characterized by abnormalities in production, flow, or absorption of cerebrospinal fluid which results in ventricular dilatation and raised intracranial pressure. The burden of this disorder in our east Africa is huge. Crude estimates of the prevalence of hydrocephalus in the East African region are between 0.47 to 0.60 per 100 live births with an estimated incidence of between 4900 and 8200 new cases per year in Kenya.[9]

The treatment of hydrocephalus involves surgical diversion of cerebrospinal fluid by use of shunting devices or endoscopic third ventriculostomy. Various shunt devices have been used to divert CSF from the ventricles to the pleura, peritoneum, atrium, or rarely the gallbladder. [25]Majority of the patients who suffer from this disease undergo ventriculoperitoneal shunting, owing to the ease of access, fewer associated complications, and high absorptive capacity of the peritoneum.[9]

Shunt systems comprise a proximal ventricular catheter, a valve to regulate flow, a CSF reservoir, and a distal peritoneal catheter.[25] Since their invention, shunts have undergone various modifications to improve their efficacy and minimize the complications associated with their use. First-generation shunts employed the use of differential pressure valves. These were followed by flow adjustable valves, then valves with antisiphon properties, and lately the programmable valves.[9] The commonly used shunt type in KNH is the Chhabra shunt. This shunt type has a differential pressure valve with antisiphon properties.[26] This relatively inexpensive shunt type has similar outcomes with costly programmable shunt designs and comparable infection rates with antibiotic-impregnated shunts. [27]

VP shunts frequently malfunction with recent studies finding that up to 30-40% of VP shunts fail in the first one year after insertion.[12] The commonest cause of shunt failure is shunt blockage.[9] Our setting has reported one of the highest rates of shunt blockage.[6, 9] The causes of this relatively high failure rates in our setting compared to the western world have not been elucidated. Shunts can be blocked by the ependymal lining, choroid plexus or gliotic brain matter in the proximal ventricular end. Kinking or disconnection of the shunt tubing can also obstruct the catheters along the tract. proteinaceous debris can also obstruct the lumen of the catheters. Blockage of the abdominal end is caused by omentum, adhesions or pseudocysts,

High CSF protein concentrations have commonly been thought to impair shunt function through various mechanisms. [2] In clinical practice, placement of VP shunts is avoided in patients with elevated CSF proteins with alternative CSF diversion means used, despite the lack of compelling evidence to support this practice.[7] These include placement of external ventricular drains or frequent ventricular taps both of which have high risk of infection with its attendant morbidity and mortality. This study aimed to assess the biochemical and cellular characteristics of CSF among hydrocephalic patients undergoing ventriculoperitoneal shunting and the impact of this CSF parameters on the shunt survival.

1.2. Literature Review

1.2.1 Epidemiology of Shunt Failure

Shunt tubings used for CSF diversion in hydrocephalic patients frequently malfunction.[15] Only 15% of shunts placed will be functional at 10 years without having needed revision.[11] Several factors affect flow of CSF within a shunt. This includes the intraventricular pressure, pressure in the draining cavity, and the resistance to flow within the shunt tubing. [2]Sterile shunt blockage is common and represents up to 30% of all shunt malfunctions.[2] Studies have found some of these shunts to have proteinaceous or cellular debris within the lumen that obstructs CSF flow.[2] Kitunguu et al, in a prospective study conducted in KNH, found that post meningitic hydrocephalus to be the most common disease entity seen our set up accounting for 51.7% of the patients with hydrocephalus. A majority of the shunts in this cohort failed and required revision surgery in the first 1 -3 months following insertion. The commonest cause of shunt failure in this cohort was shunt blockage occurring in 10% of the patients on 3 months follow up[11]. Meningitis is an established cause of elevated CSF proteins however the link between this etiology and shunt failure is not well defined.[9]

Mwachaka et al, in a 3-year retrospective study in KNH, found shunt blockage to be the commonest cause of shunt malfunction occurring in 53.8% of the patients in this study. This is the highest rate of shunt blockage reported in the literature. [8]

1.2.2 Physiology of CSF Proteins and Glucose

The normal CSF protein is 0.2 to 0.4g/L.[10] Several disease states can lead to an increase in this protein concentration. CSF protein levels may rise either due to an increase in the permeability of the blood brain barrier, proteins may be synthesized by inflammatory cells within the CSF spaces, or due to impaired absorption by the arachnoid villi.[16] Viral meningitis causes a mild protein elevation while bacterial and tuberculous meningitis causing more pronounced elevation. In the normal physiological state, albumin constitutes 35 to 80% of CSF proteins with globulins accounting for the remainder.[16] In disease states, this balance is shifted with globulins dominating to various degrees depending on etiology.[10, 16]

CSF glucose level is dependent on serum glucose level. The normal CSF to plasma glucose ratio is 0.5-0.8. Bacterial meningitis causes a decline in CSF glucose level with a value of 0.44 or less being suggestive of a bacterial rather than a viral cause of meningitis.[17] CSF glucose has not been shown to affect shunt survival in following tuberculous meningitis.[5] It has also

been shown not to affect shunt survival in low-birth-weight neonates with post hemorrhagic hydrocephalus.[1] Its impact on the other subtypes of hydrocephalus has not been studied.

1.2.3 CSF Proteins and Shunt Failure

There are conflicting reports as to whether elevated proteins affect shunt function. Sudheer et al found that a high CSF concentration of proteins (>200 mg/dL) predisposed patients with TBM undergoing VP shunt for hydrocephalus to develop shunt block leading to shunt malfunction.[5] Kamat et al, in a 30-year retrospective study, found that post-TBM patients with elevated protein levels in CSF are at a high risk of shunt blockage. In this study, he concluded that alternative means should be used in these patients until CSF protein concentrations decrease.[7]

In an in vitro model, Thomas et al, found that a CSF protein concentration of 5g/L was the threshold level to adversely affect shunt function. In this study, the average incubation period to shunt blockage attributed to high CSF proteins was 46 days. [2]

Howard et al, however, found no correlation between CSF protein concentration and shunt malfunction adding that protein deposition does not occur in sufficient levels to cause shunt blockage. [8]

Cheatle et al, in an experimental laboratory study, demonstrated decreasing resistance to flow along shunt tubings with increasing CSF protein concentrations. They concluded that placement of shunts in hyperproteinorhachic patients is unlikely to contribute to the risk of shunt malfunction. [14]

Table 1: Findings of various studies on the impact of CSF proteins on VP shunt function

Study topic	Author	Year	Remarks
Does CSF composition predict shunt malfunction in tuberculous meningitis?	Sudheer et al	2011	CSF protein concentration >200 mg/dL predisposed to shunt blockage
CSF Protein Concentration Associated with Ventriculoperitoneal Shunt Obstruction in Tuberculous Meningitis	Kamat et al	2018	Post-TBM patients with elevated protein levels in CSF are at a high risk of shunt blockage. Temporary means of CSF diversion should be used
Effect of Protein Concentration on the Flow of Cerebrospinal Fluid Through Shunt Tubing	Cheattle et al	2015	CSF protein concentration of 5g/L was the threshold level to adversely affect shunt function thus are unlikely to affect shunt function
The Effect of Protein and Blood Cells on the Flow-pressure Characteristics of Shunts	Howard et al	1996	No correlation between CSF protein concentration and shunt malfunction. Protein deposition does not occur in sufficient levels to cause shunt blockage
Analysis of the risk of shunt failure or infection related to cerebrospinal fluid cell count, protein level, and glucose levels in low-birth-weight premature infants with post-hemorrhagic hydrocephalus	Fulkerson et al	2011	No association between shunt function and CSF proteins or cellularity. Timing of shunt insertion should not be based on these parameters.

Fulkerson et al, in a study on post-hemorrhagic hydrocephalus in low birth weight premature infants, found no correlation between shunt failure and CSF protein concentration, red and white cell count, or glucose level. They recommended that the timing of shunt insertion should not be based on these CSF biochemical parameters.[1]

1.2.4 Elevated CSF Proteins and Risk of Shunt Infection

Elevated CSF proteins at insertion of a VP shunt have also been associated a higher incidence of shunt related infections and thus contributing to an increase in morbidity and mortality among hydrocephalic patients undergoing this surgical procedure [13]

Nurhayat et al in a retrospective multicenter study noted that a persistently elevated CSF protein level above 100mg/dl was associated with shunt reinfection following treatment for shunt infection. Shunt infection among these patients occurred at a median of 2 months following shunt insertion.[13]

Fulkerson et al, in his 10year retrospective cohort study on the risk factors for shunt failure in low-birth-weight preterm infants, found no correlation between CSF protein levels and the risk of shunt infection.[1]

1.2.5 CSF Cellularity and Ventriculoperitoneal Shunt Blockage

Normal CSF contains up to 5 WBCs per microliter in adults and 20 WBCs per microliter in newborns. Seventy percent of these white cells are lymphocytes and 30% are monocytes. It usually has no erythrocytes.[10]

Elevated CSF cell count occurs in meningitis and intraventricular hemorrhage both of which are established causes of hydrocephalus.[10]Fulkerson et al, in a retrospective cohort study, found no association between elevated CSF cell count and shunt failure. This study was conducted on neonates with low birth weight who had posthemorrhagic hydrocephalus.[1] A similar observation has also been made in post TB hydrocephalus [5]Other authors have had differing findings in different patient cohorts, establishing an association between increased CSF cellularity and shunt blockage.[12]

1.2.6 Clinical Diagnosis of Ventriculoperitoneal Shunt Failure

Patients with ventriculoperitoneal shunt failure present with various clinical and radiological features. History and physical examination findings have been found to be reliable in detection of shunt failure in several studies. Common signs and symptoms that suggest shunt blockage in children according to Piatt et al in a prospective study among children with shunt failure include bulging fontanelle, fluid collection along the shunt, depressed level of consciousness, irritability, abdominal pain, nausea, and vomiting.[19] In a randomized controlled trial by Hugh J in 2001, different clinical features had varying predictive value for shunt failure. In the early post-operative period following shunt surgery (within 5 months), Nausea and vomiting (PPV 79%), irritability (PPV 78%), reduced level of consciousness (PPV 100%), and a bulging, tense fontanelle (PPV 92%) were the most reliable clinical features. Between 9 months and 2 years following shunt insertion only loss of developmental milestones (PPV 83%) and reduced LOC (PPV 100%) were strong predictors of shunt failure.[18]

Head CT scan alone has a sensitivity and specificity of 77.8% and 87% respectively for shunt failure.[20] The addition of radioisotope shunt grams in the assessment of children with shunt blockage improves the sensitivity to 96.3%. [21]

Table 2: Comparison of the sensitivity and specificity of various clinical features in the diagnosis of shunt failure

	Hug et al, 2001		Piatt et al, 2008	
Clinical features	Sensitivity	Specificity	Sensitivity	specificity
Nausea and vomiting	37	96	39	96
Decreased level of consciousness	15	97	22	95
Irritability	10	100	20	99
Abdominal pain	7	100	7	100
Papilledema	3	100	NS	NS
Fluid tracking along the shunt	21	98	ND	ND
Fever	23	99	16	99

Shunt infection occurs in up to 9.1% of children undergoing VP shunting in KNH. [11] Shunt infection is defined as the demonstration of bacteria from the CSF both by gram stain and culture, together with CSF pleocytosis, fever, neurologic symptoms, in a patient with signs of shunt malfunction.[23] Fever at presentation is present in 16 – 42% of patients. Fever in the presence of CSF pleocytosis has a sensitivity of 82% and a specificity of 99%. [22] Other features such as CSF eosinophilia, elevated C reactive protein, lactate and procalcitonin are nonspecific.

2.0 CHAPTER TWO

2.1 Statement of the Problem

Hydrocephalus is a common disorder in Kenya. It has an estimated incidence of about 6000 new cases per year.[12] It also constitutes the commonest disorder managed in pediatric neurosurgery units in our country. The leading cause of hydrocephalus among patients seen in KNH is meningitis. The majority of the patients with this disorder are managed by insertion of ventriculoperitoneal shunts.[34]

These shunts frequently fail requiring revision surgery. The leading causes of shunt failure in KNH are shunt blockage and shunt infection. Kenya has reported one of the highest rates of shunt blockage in literature. Shunt failure is commonest in the first 3 months following insertion.[6]

Biochemical and cellular properties of CSF among patients undergoing VP shunting and the impact of these properties on shunt survival is not well known and has not been studied in Kenya. These parameters have been shown to affect shunt function in studies in other parts of the world.

2.2 Study Justification

Ventriculoperitoneal shunting is common in our neurosurgical practice in the management of hydrocephalic patients. Shunt malfunction requiring revision surgery is equally common owing to the high rates of shunt malfunction. Shunt blockage is the commonest cause of shunt failure in our setup. Shunt failure and subsequent revision are associated with an increase in mortality. The predictors of shunt failure have not been well studied with conflicting reports on the effect of CSF proteins, cellularity, and glucose level on shunt function. In our setup, patients with elevated CSF proteins requiring shunt surgery are oftentimes offered temporary alternative means of CSF diversion such as external ventricular drains that are expensive and risk ventriculitis. This study aimed to assess the impact of CSF proteins, glucose, and cellularity on early shunt outcomes and therefore establish evidence upon which the practice of shunt surgery in patients with abnormal CSF biochemical and cellular properties was based on.

2.3 Broad Objective

To assess the biochemical and cellular properties of cerebrospinal fluid among patients undergoing ventriculoperitoneal shunting and their effect on shunt survival

2.4 Specific Objectives

a) To describe the pattern of CSF protein concentration, glucose level and cellularity among patients undergoing ventriculoperitoneal shunting in KNH

b) To establish the effect of elevated CSF proteins, abnormal CSF glucose and abnormal CSF cellularity on shunt survival

3.0 CHAPTER THREE: PARTICIPANTS AND METHODOLOGY

3.1 Study Design

Prospective cohort study

3.2 Study Location

This study was carried out in Kenyatta national hospital within the neurosurgical (ward 4C and the neurosurgical outpatient clinic), pediatric units (wards 3A, 3B, 3C and 3D) and the medical wards (wards 7A, 7B, 7D, 8A,8B and 8D). These units manage about 40 to 50 patients with hydrocephalus every month according to the shunt register in KNH main theater.

3.3 Study Population

Patients with hydrocephalus who had a ventriculoperitoneal shunt surgery.

3.4 Inclusion Criteria

All patients undergoing VP shunt placement for treatment of hydrocephalus
Patients of all age groups were included

3.5 Exclusion Criteria

All patients with tumor related hydrocephalus
Patients who underwent cranial surgical procedures during the follow up period
Patients who developed mechanical causes of shunt failure, that is, kinking, migration and disconnection or fracture of shunt components

3.6 Sample Size Estimation

Sample size was estimated using the formula for prospective cohort studies with two groups as shown below

$$N_1 = \left\{ z_{1-\alpha/2} * \sqrt{\bar{p} * \bar{q} * (1 + \frac{1}{k})} + z_{1-\beta} * \sqrt{p_1 * q_1 + (\frac{p_2 * q_2}{k})} \right\}^2 / \Delta^2$$

$$q_1 = 1 - p_1$$

$$q_2 = 1 - p_2$$

$$\bar{p} = \frac{p_1 + kp_2}{1 + K}$$

$$\bar{q} = 1 - \bar{p}$$

$$N_1 = \left\{ 1.96 * \sqrt{0.25 * 0.75 * (1 + \frac{1}{1})} + 0.84 * \sqrt{0.1 * 0.9 + (\frac{0.4 * 0.6}{1})} \right\}^2 / 0.3^2$$

$$N_1 = 31$$

$$N_2 = K * N_1 = 31$$

p_1, p_2 = proportion (incidence) of groups #1 and #2
$\Delta = |p_2 - p_1|$ = absolute difference between two proportions
n_1 = sample size for group #1
n_2 = sample size for group #2
α = probability of type I error (usually 0.05)
β = probability of type II error (usually 0.2)
z = critical Z value for a given α or β
K = ratio of sample size for group #2 to group #1

Dichotomous Endpoint, Two Independent Sample Study

Sample Size	
Group 1	31
Group 2	31
Total	**62**

Study Parameters	
Incidence, group 1	10%
Incidence, group 2	40%
Alpha	0.05
Beta	0.2
Power	0.8

Group 1 prevalence is based on the established incidence of VP shunt blockage in KNH three months after insertion.[12]

Group 2 prevalence is based on the estimated incidence of shunt failure among patients with abnormal CSF biochemistry [5]

3.7 Sampling Method

Random sampling technique were applied for all cases that meet the inclusion criteria.

3.8 Study Procedure

Patients were recruited into the study following VP shunt surgery for hydrocephalus. Data collected at recruitment included study identification, age, sex, residence and etiology of hydrocephalus. Additionally, data regarding the CSF biochemistry including proteins and glucose and cellularity was also abstracted from the patient files. This result was for a sterile CSF sample taken upon insertion of the ventricular catheter during shunt surgery for biochemical analysis for proteins and glucose level and microscopic examination for cellularity. This is part of the standard management of hydrocephalus patients in the hospital. Based on their baseline CSF biochemical and cellular properties, the patients were divided into two groups; those with normal and those with abnormal CSF biochemistry and cellularity.

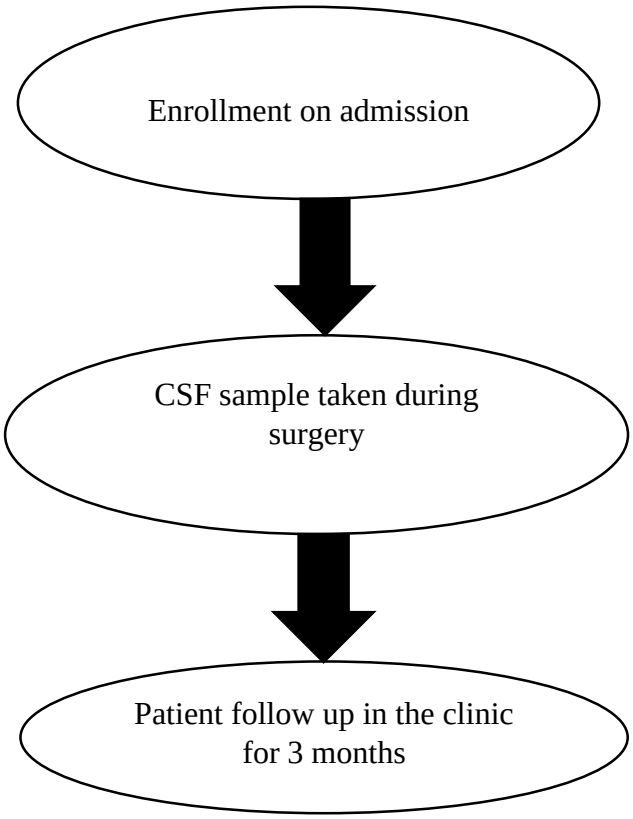
Patients were then followed up in the neurosurgical clinics for a period of 3months during which shunt function was assessed. Screening for shunt failure used clinical signs and symptoms and imaging findings as outlined in the data collection tool. Clinical signs of shunt blockage included, bulging fontanelle, fluid collection along the shunt tract, depressed level of consciousness, irritability, abdominal pain, nausea, and vomiting. Clinical features that were used to establish a diagnosis of shunt infection included CSF pleocytosis in the presence of fever. Patients with clinical features of shunt failure had a CT scan imaging of the head to affirm the diagnosis. The primary outcome of interest in this follow up period was duration of shunt survival, defined as the duration in days since insertion of the ventriculoperitoneal shunt to the diagnosis of shunt failure, and etiology of shunt failure resulting either from shunt blockage or shunt infection. Mechanical causes of failure such as breakage, kinking, disconnection, or migration of shunt components were excluded.

3.8.1 Laboratory Methods

CSF samples were collected in a sterile manner from the lateral ventricle through the ventricular catheter during shunt surgery. The samples were put in a plain sterile container and transported to the lab within 30mins of collection. In the lab, biochemical tests were carried out in the KNH lab 16 using the BioLis 50i superior machines. Both internal and external quality control measures were applied to ensure results were accurate and reproducible.

CSF cellularity was established by light microscopy by a qualified laboratory technologist in the KNH microbiology laboratory. The CSF sample was placed in a Neubauer counting chamber then examined under a light microscope. All standard operating procedures for running above stated laboratory tests were strictly adhered to.

3.8.2 Flow Chart Indicating Flow of Patients during the Study Period



3.8.3 COVID- 19 Precautions

Containment measures to reduce the spread of the corona virus disease recommended by the ministry of health were adhered to as the study was being carried out. This included the use of face masks by the researcher, frequent hand washing or disinfection and maintaining a social distance of at least 1.5 meters**.**

3.8.4 Quality Assurance and Control Measures

The principal investigator carried out all the interviews and physical examinations. The data collection tools were cross-checked for completeness and any missing entries corrected. The quantitative and qualitative data collected was cross-checked for any inconsistencies and outliers rectified. For the laboratory test, daily internal quality control checks were done every morning to ensure that the results were valid. The Biolis 50i Superior Chemistry Analyser machine comes with its own internal quality control reagents. These were used for the study. In addition, external quality control checks were done through the Randox International Quality Assessment Scheme (RIQAS). KNH Clinical Chemistry laboratory was already enrolled into the RIQAS scheme and sends monthly reports for external quality control. RIQAS is the world's largest global External Quality Assessment (EQA / Proficiency Testing (PT) schemes serving over 45,000 participating laboratories in more than 133 countries.

3.8.5 Ethical Considerations

The study was undertaken after approval by the Department of surgery, University of Nairobi and the Kenyatta National Hospital/University of Nairobi Ethics and Review Committee. The aims and intention of the study was distinctly explained to eligible participants in a suitable language prior to recruitment into the study. Only patients who gave informed consent were enrolled. It was emphasized that participating or opting out of the study did not affect the quality of care provided. Patients were free to withdraw from the study anytime during the study period without discrimination. Information gathered from the study participants was kept confidential. Data sheet serial numbers and not patient names were used.

3.8.6 Data Management

Data collected was entered into a questionnaire (appendix 1). The data entry and cleaning was done using Microsoft Excel.

3.8.7 Data Analysis

This data was then transferred to the statistical package for social sciences (IBM SPSS statistics 25.0) for data analysis. Descriptive statistics including means and medians, and proportions were run to establish characteristics of the study participants. For hypothesis testing, students' T test of independence was used for Continuous variables such as age and time to shunt failure

(in days). Chi square was used for continuous variables. P values of <0.05 were considered statistically significant.

Features significant in the univariate analysis were advanced to a binary logistic regression model to assess for risk factors of shunt failure. Results of the regression model were reported in Odds ratios and corresponding 95% confidence intervals. Survival analysis using Kaplan Meir was used to assess for time to shunt failure. Categorical variables like marital status, gender, occupation were presented as proportions, bar charts, pie charts and frequency tables while continuous variables will be presented in histograms.

3.8.9 Study Results Dissemination Plan

The findings of this study were submitted to the KNH/UoN ethics and research committee and to the board of post-graduate studies in the university of Nairobi for publication on its online platform. Further to this, copies of the findings were sent to the unit of neurosurgery in Kenyatta national hospital. The final manuscript was sent to an international journal for publication.

3.8.10 Study Limitations

a) Due to a relatively short period of follow-up, this study was not able to establish the long-term effects of abnormal CSF biochemistry or cellularity on shunt function beyond 3 months.

b) A direct causal relationship between CSF biochemistry and cellularity could not be established based on this study due to its design.

3.8.11 Study Closure plan

This study was terminated once all the data was analysed, manuscript written and the results presented in the department of Neurosurgery, university of Nairobi.

4.0 CHAPTER FOUR: RESULTS

4.1 Demographic Data

During the study period, a total of 82 patients met the inclusion criteria and were recruited into the study. Fourty six(56.1%) were male while 36(43.9%) of them were female (Figure 1). The age of these patients ranged between 3weeks of age to 10years of age, with a mean age of 15.5 months (SD 23.4 months). Majority (78.04%) of the patients were less than one year of age (Figure 2)

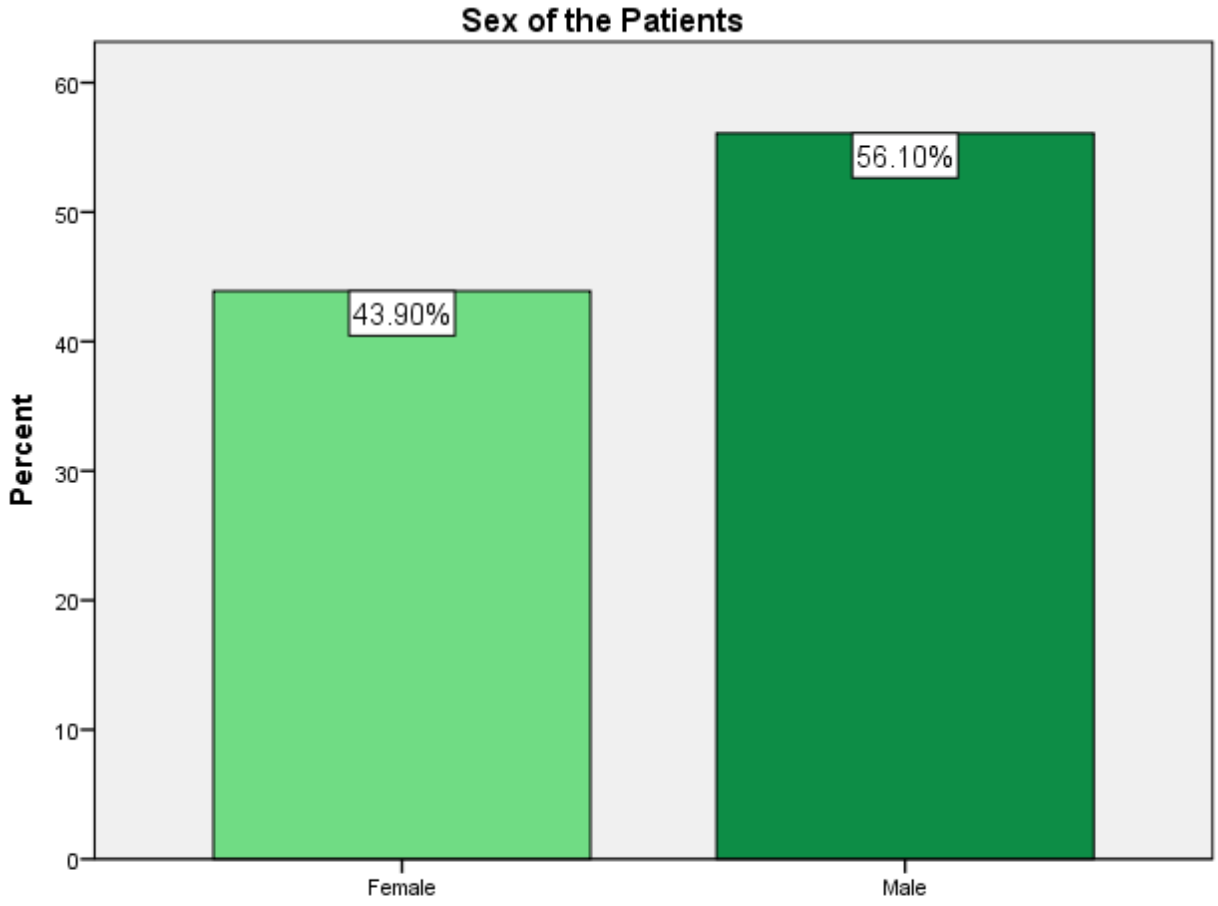


Figure 1: A bar chart illustrating the patient distribution by gender

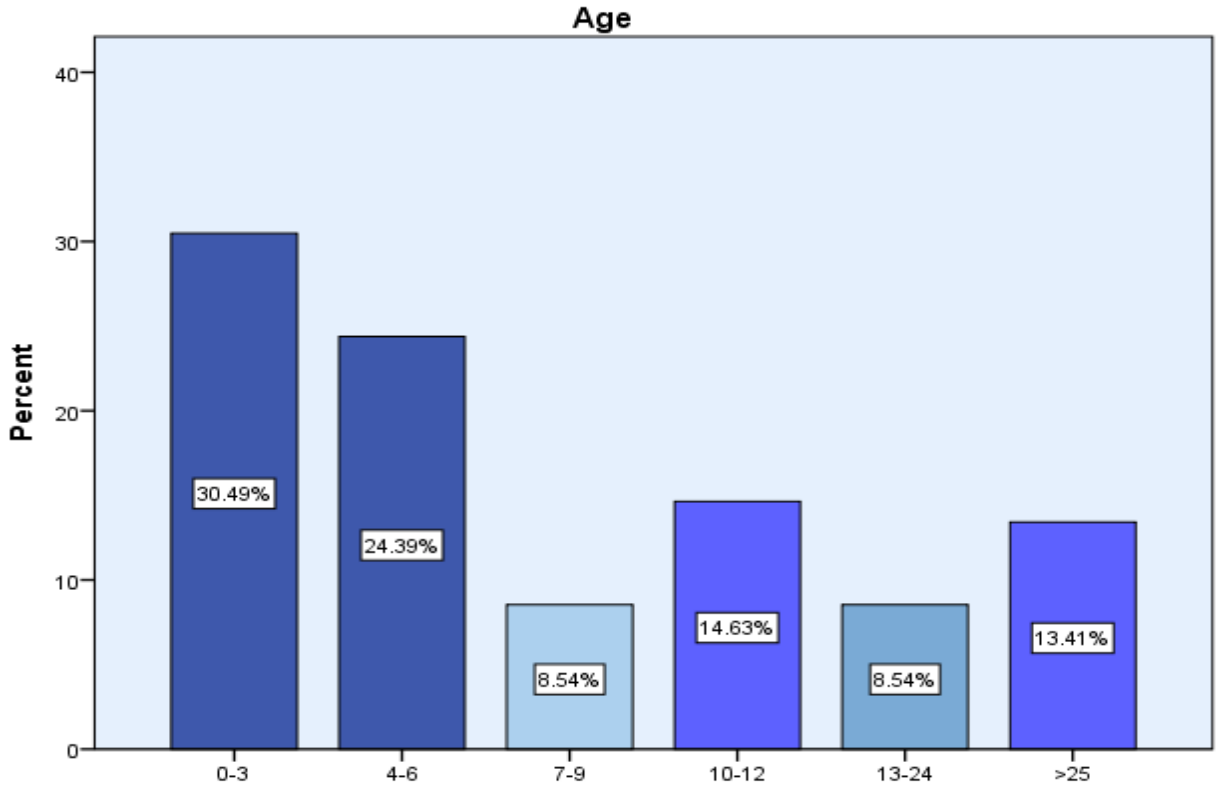


Figure 2:A bar chart illustrating the patient distribution by age

4.2 Etiology of Hydrocephalus

The etiology of hydrocephalus was determined by clinical history, laboratory tests and radiologic tests performed. Majority (91.46%) of patients had cranial CT scan as the diagnostic imaging work up performed. Only 4.8% of the patients had magnetic resonance imaging performed in the initial work up for hydrocephalus (Table 1). Congenital hydrocephalus was diagnosed in children with hydrocephalus resulting from congenital intracranial malformations demonstrated on imaging. Post meningitic hydrocephalus was diagnosed based on a clinical history of meningitis preceding the onset of hydrocephalus or imaging findings consistent with post meningitic hydrocephalus such as multiple loculations within the ventricles.

Table 3:Table showing initial diagnostic work up for patients with hydrocephalus

Diagnostic Imaging Done	Frequency	Percent	Cumulative Frequency
CT	75	91.46	91.46
MRI	4	4.88	96.34
Ultrasound	3	3.66	100
Total	82	100	

Most of the patients in this patient group had congenital hydrocephalus (82.9%). The commonest congenital intracranial malformation leading to hydrocephalus was Dandy walker malformation accounting for about 36.76% of all patients with congenital hydrocephalus.

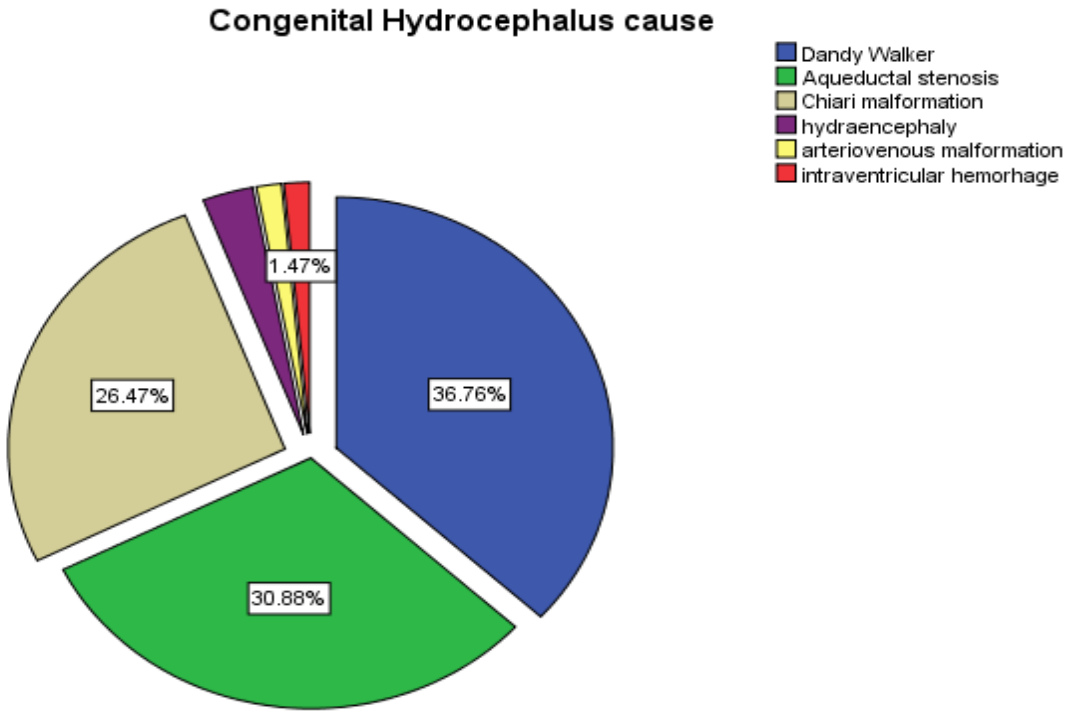


Figure 3: A pie chart showing the frequency of various causes of congenital hydrocephalus in the study population

Eighteen(21.9%) of the patients had spina bifida as well. The rest (78.1%) had hydrocephalus with no associated spinal neural tube defects.

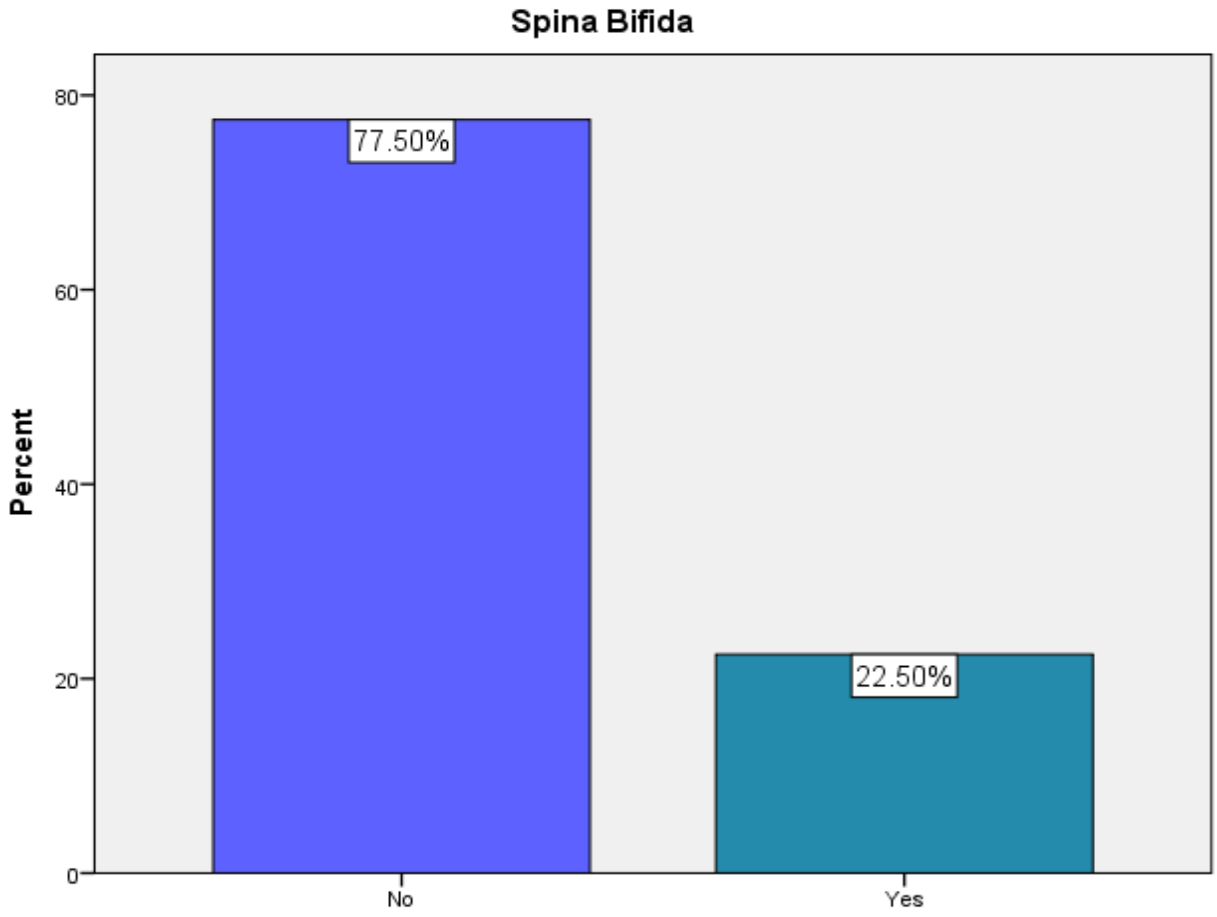


Figure 4:A bar chart illustrating the prevalence of spina bifida in the study population

For the majority (92.7%) of the patients, it was the primary shunt insertion while for 6(7.3%) it was shunt revision.

Table 4:Table illustrating the type of shunt surgery performed in the study population

Type of Shunt Surgery	Frequency	Percent	Cumulative Frequency
Primary	76	92.7	100
Revision	6	7.3	100
Total	82	100	

Most (96.3%) shunt surgeries in this study group were performed by residents, mostly in their sixth year of residency (62.2%) with only 3.6% of these procedures performed by consultant neurosurgeons.

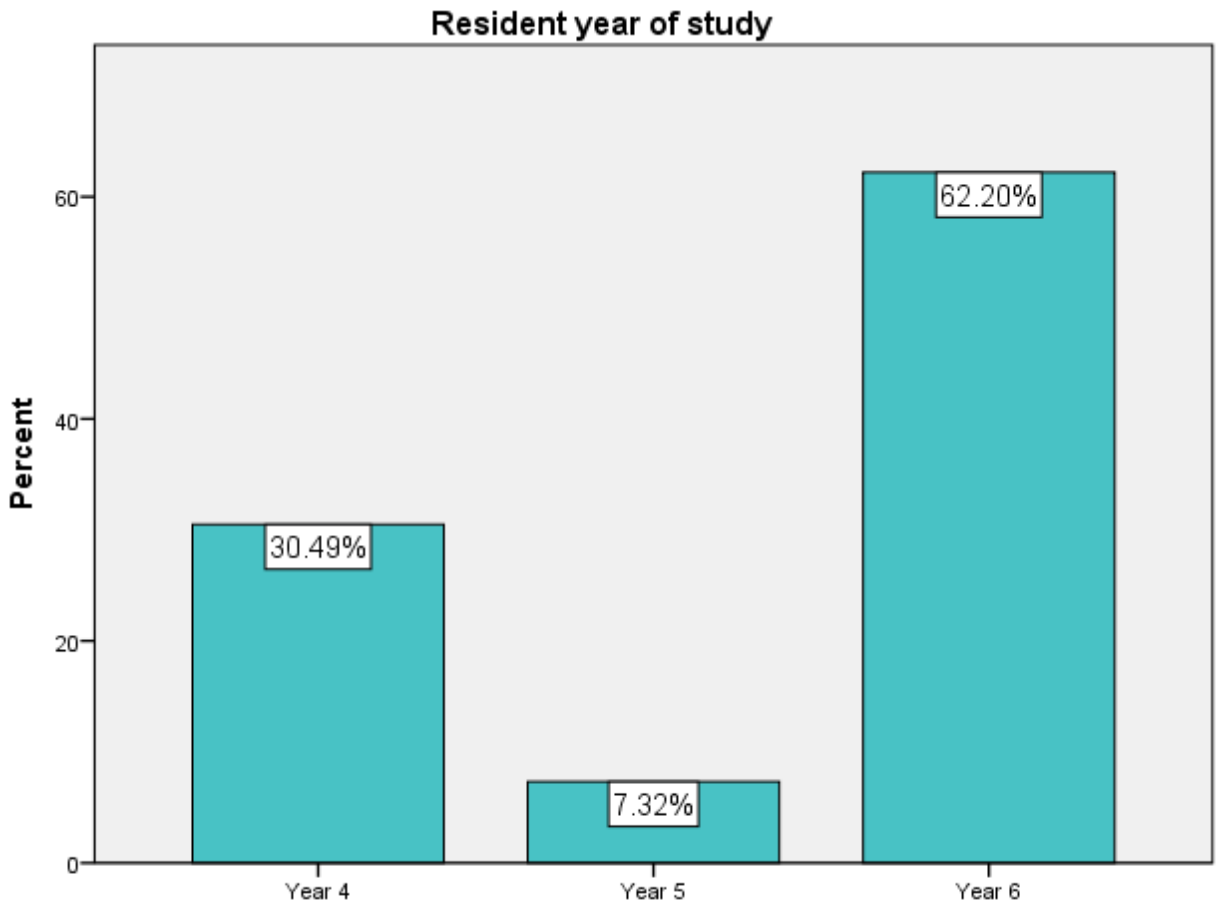


Figure 5:Bar graph illustrating the level of study of residents performing shunt surgery

During shunt insertion, the most commonly utilized ventricular access point was the Keen's point in 98.7% of the cases.

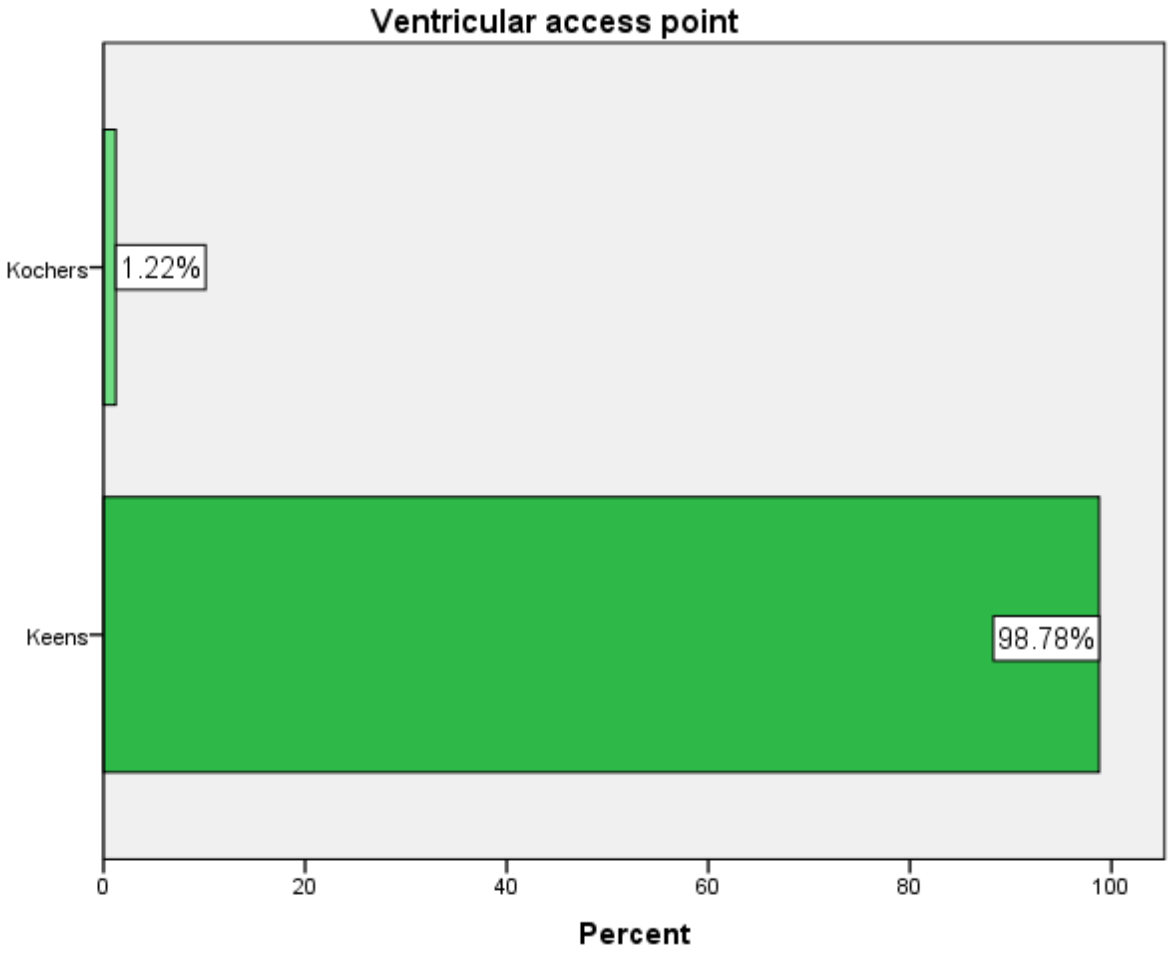


Figure 6:A bar chart showing the ventricular access point used during shunt insertion for patients in this study

In all the patients in the study population, a medium pressure Chhabra shunt was used with the distal shunt catheter placed in the peritoneum.

4.3 Laboratory Findings in the Study Group

Most patients (52.44%) had normal CSF proteins while the remainder had elevated CSF proteins. The reference range used was 150-400mMol/L.

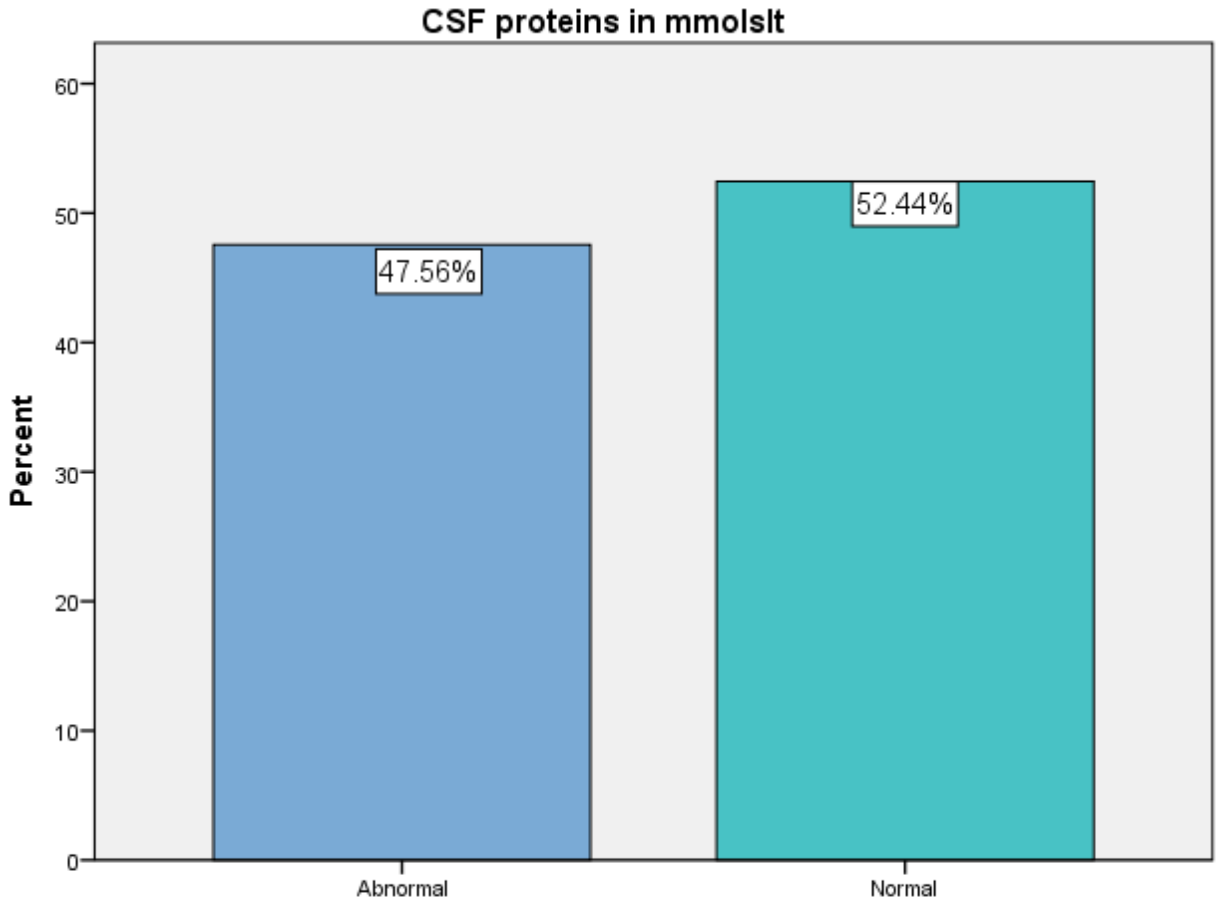


Figure 7:Bar graph illustrating the distribution of CSF proteins among patients in the study group

The mean CSF protein concentration in the entire patient group was 588.3mMol/L. The protein concentration ranged between 5 and 2045mMol/L.

Majority of the patients had reduced levels of CSF glucose at 65.9%. The mean CSF glucose concentration in the study group was 2.42mMol/L.

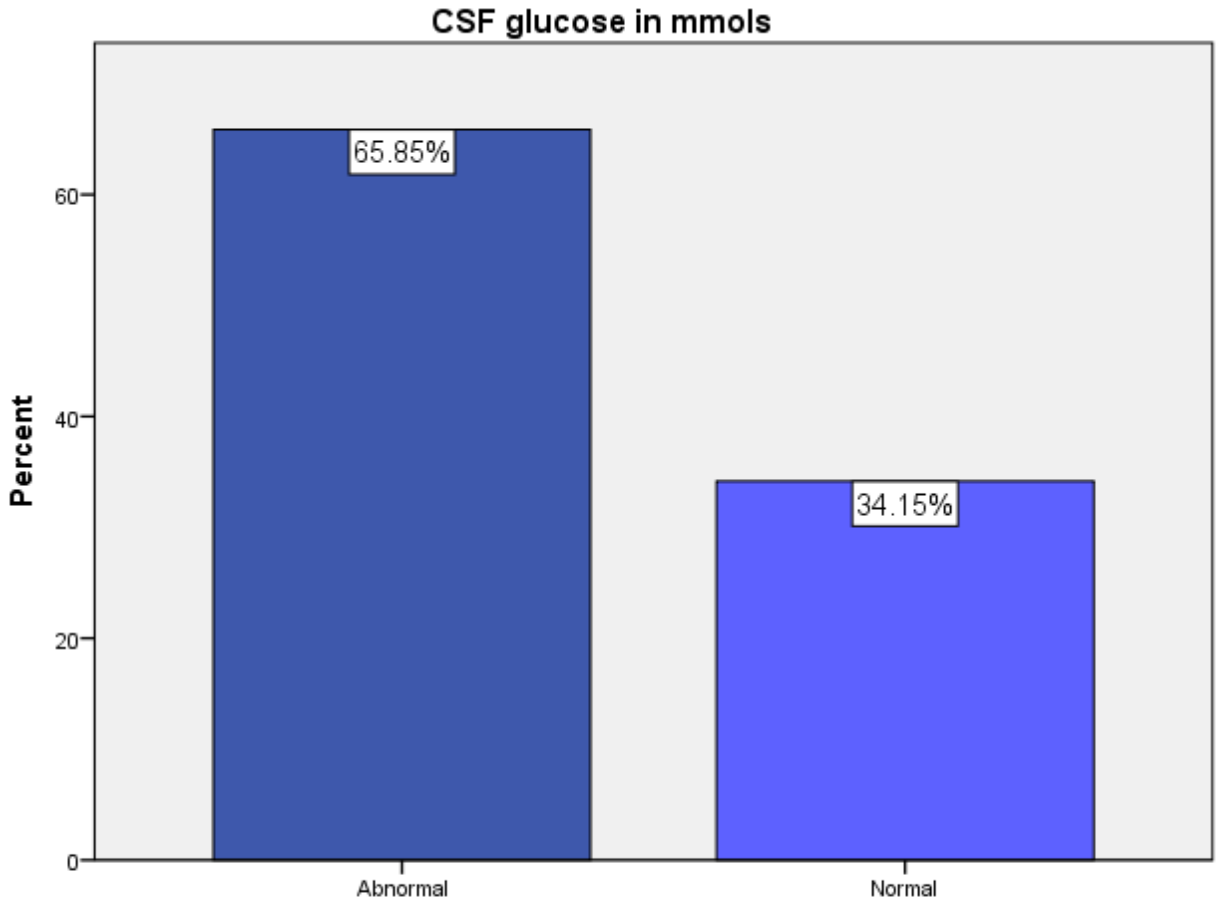


Figure 8 :Bar graph illustrating the distribution of CSF glucose levels in the study population

The CSF cell count was normal for most of the patients at 86.6%. A cell count of greater than 5 cells per high power field was considered elevated.

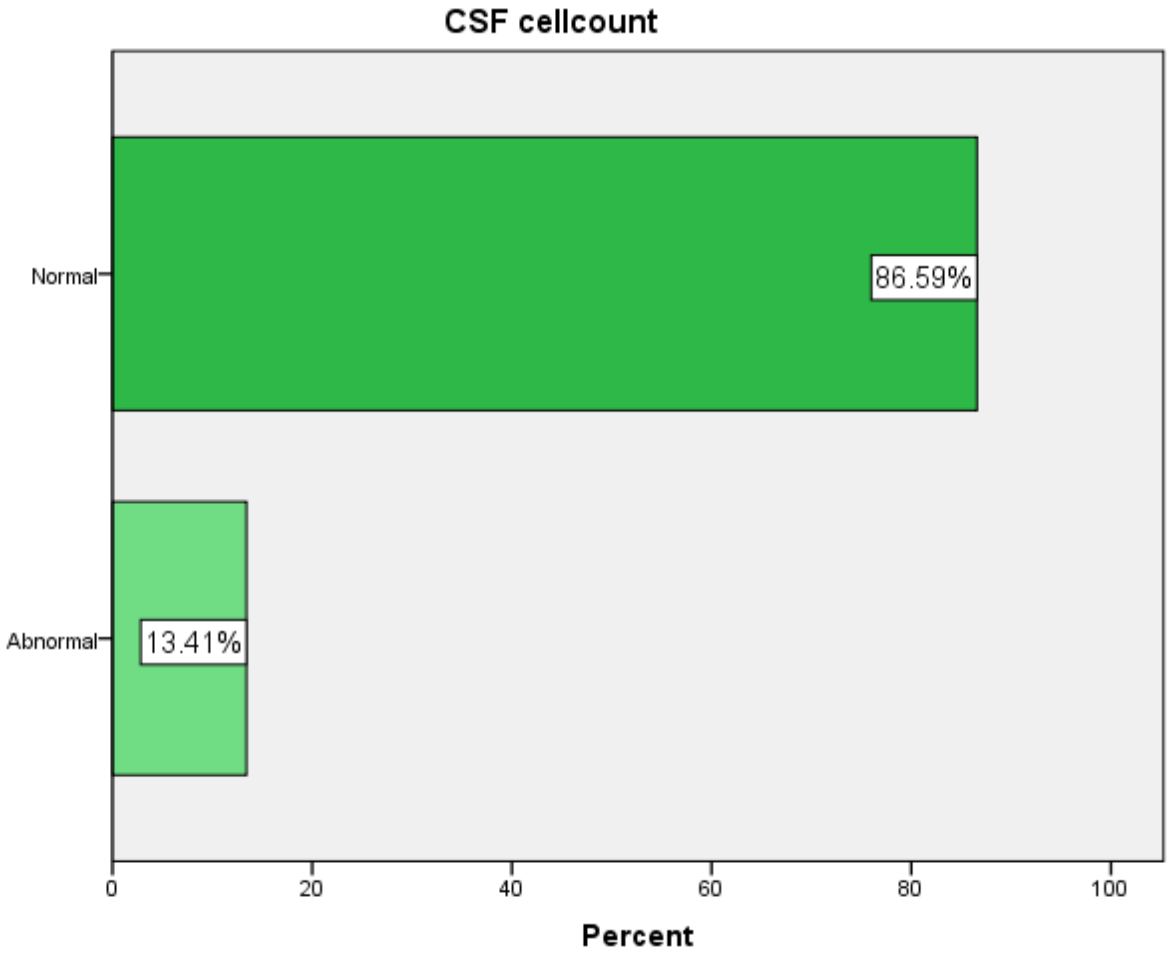


Figure 9: A bar chart illustrating the pattern of CSF cellularity in the study group

4.4 Patient Follow Up Parameters

The shunt failure rate at 3 months for this patient cohort was 9.8%. The average shunt survival for the shunts that failed was 60 days. Failure of all these shunts was attributed to shunt blockage**.**

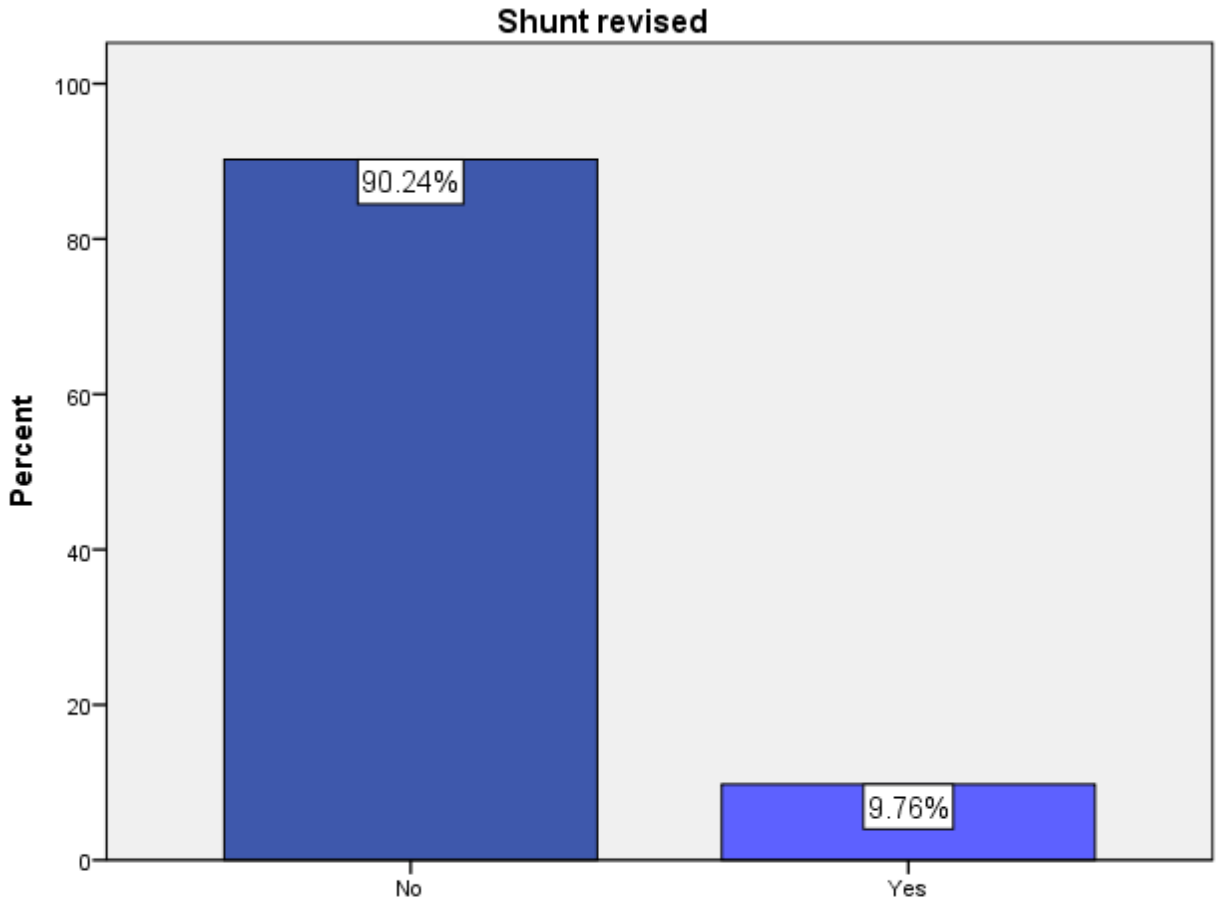


Figure 10:A bar chart showing the shunt outcomes at 3 months of follow up

4.5 Patients Gender and Risk of Shunt Failure

There was no correlation between the patient's gender and shunt failure as shown in the table below

Table 5: Table showing the relationship of patient's gender and shunt failure at 3 months of follow up

Sex	**Shunt Failed**		
	Yes	No	Total
Female	30	6	36
Male	44	2	46
Total	74	8	82
Pearson Chi square	**3.4809**	Probability	**0.062**

4.6 Etiology of Hydrocephalus and Shunt Failure

There was no correlation between shunt failure and the underlying etiology as shown in the table below.

Table 6:Table showing the relationship between the etiology of hydrocephalus and the likelihood of shunt failure

Hydrocephalus	Shunt Revised		
	Yes	No	Total
Acquired	13	1	14
Congenital	61	7	68
Total	74	8	82
Pearson Chi square	0.1309	Probability	0.717

4.7 Spina Bifida and Shunt Failure

There was no correlation between the presence of spina bifida and the incidence of shunt failure in this patient group as shown below

Table 7:Table showing the relationship between the presence of spina bifida and shunt failure

Spina bifida	Shunt Failed		
	No	Yes	total
No	57	5	62
Yes	15	3	18
Total	72	8	80
Pearson Chi square	1.1470	Probability	0.284

4.8 Nature of Shunt Surgery and Shunt Failure

The nature of shunt surgery as to whether it was a primary shunt insertion or a shunt revision did not affect the rate of shunt failure at 3 months,

Table 8:A table showing the relationship between the nature of surgery done and shunt failure in 3 months

Type of Shunt Surgery	Shunt Failed		
	No	Yes	total
First	68	8	76
Revision	6	0	6
Total	74	8	82
Pearson Chi square	0.6999	Probability	0.403

4.9 Resident's Level of Training and Shunt Failure

The year of training of the resident performing shunt surgery did not affect the shunt failure rate at 3 months of follow-up.

Table 9: A table showing the relationship between the year of training of a resident performing shunt surgery and the shunt failure at 3 months

The resident Year of Study	Shunt Failed		
	No	Yes	total
Year 4	24	1	25
Year 5	5	1	6
Year 6	45	6	51
Total	74	8	82
Pearson Chi square	1.5000	Probability	0.472

4.10 CSF Protein Level and Shunt Failure

There is a significant correlation between CSF protein levels and shunt failure in this study. All shunt failures occurring in this study were seen in patients with elevated CSF proteins.

Table 10;A table showing the relationship between CSF protein concentration and shunt failure at 3 months

CSF proteins	Shunt Failed		
	No	Yes	Total
Elevated	31	8	39
Normal	43	0	43
Total	74	8	82
		Fisher's Exact P-value	0.002

Shunt failure in patients with elevated proteins occurred at an average of day 60 after shunt insertion. The incidence of shunt failure in the patient group with elevated CSF proteins at 3 months post-insertion was 20%, while the incidence of shunt failure in the normal protein group was 2.3%. From the findings of this study, elevated CSF proteins increase the likelihood of shunt failure in the first 3 months after insertion by 8.7 times. It was further observed that the protein concentration among the patients that developed shunt failure was 1250mMols/L compared to a mean protein concentration of 545mmol/L in the patients whose shunts were functional at 3 months.

The presence of spina bifida did not affect the CSF protein concentration as there was no correlation between these variables as shown below.

Table 11:: A table showing the relationship between the presence of spina bifida and elevated CSF proteins

	CSF Protein concentration		
Spina bifida	elevated proteins	normal proteins	Total
No	29	33	62
Yes	10	8	18
Total	39	41	80
	Pearson chi2(1) = 0.4306 P value= 0.512		

4.11 CSF Glucose and Shunt Failure

There is a positive correlation between reduced glucose CSF levels and the incidence of shunt failure at 3 months. All the shunt failures recorded in this study group occurred in patients with reduced CSF glucose levels.

Table 12;A table showing the relationship between CSF glucose level and shunt failure at 3 months

CSF Glucose	Shunt Failed		
	No	Yes	total
Abnormal	46	8	54
Normal	28	0	28
Total	74	8	82
		Fischer's exact P-value	0.046

Patients with reduced CSF glucose therefore may be at an increased risk of shunt blockage at 3 months. This finding could however be confounded by the fact that all these patients with low CSF glucose at shunt insertion who developed shunt failure in the follow-up period also had elevated CSF protein levels.

4.12 CSF Cellularity and Shunt Failure

There was no association between CSF cell count and the incidence of shunt failure as shown below.

Table 13:A table showing the relationship between CSF cell count and shunt failure at 3 months

CSF cell count	Shunt Failed		
	No	Yes	total
Abnormal	9	2	11
Normal	65	6	71
Total	74	8	82
Pearson Chi square	1.0244	Probability	0.311

Table 14:Summary of the Patient Variables and Correlation with Shunt Failure at 3 Months

Variable		**Percentages**	**P-value**
Sex	Female Male	36(43.9%) 46(56.1%)	0.062
Type of hydrocephalus	Acquired Congenital	14(17.07%) 68(82.93%)	0.717
spina bifida	Yes No	18(22.50%) 62(77.50%)	0.284
Type of shunt surgery	First Revision	76(92.7%) 6(7.3%)	0.403
Year of Study	Year4 Year5 Year6	25(305.5%) 6(7.3%) 51(62.2%)	0.472
CSF Proteins	Normal Abnormal	43(52.4%) 39(47.6%)	0.002
CSFGlucose	Normal Abnormal	28(34.1%) 54(65.9%)	0.032
CSFCell count	Normal Abnormal	71(86.6%) 11(13.4%)	0.311

5.0 CHAPTER FIVE : DISCUSSION

5.1 Discussion

Hydrocephalus remains a prevalent neurosurgical disorder in Kenya with more than 80 children treated in KNH in 2 months. Crude estimates of the prevalence of hydrocephalus in the East African region are between 0.47 to 0.60 per 100 live births with an estimated incidence of between 4900 and 8200 new cases per year in Kenya. This incidence is higher than that of sub-Saharan Africa which is estimated at 0.14 per 100 live births. From a global perspective, this is the highest incident rate reported with Latin America and North America reporting rates of 0.32 and 0.07 per 100 live births respectively. [29]

There is an observed male predominance in the patients included in this study, with 46(56.1%) being male while 36(43.9%) of them were female. Kitunguu et al in 2017 reported a similar pattern of male predominance with 55.8% of the patients in his study being male. Previous studies in KNH by Noorani et al in 2003 and Omulo et al in 1993 have had similar findings as well.[12] Worldwide, a similar observation has been made in most parts of the world except in Mozambique where the male to female ratio is 1:1.

The largest gender gap has been observed in Pakistan, with males affected at more than twice the rate of females.[30]The lowest gender differences were reported by studies from Taiwan and Papua New Guinea (1.04:1 and 1.03:1, respectively), while most reported a ratio around 1.05:1–1.41:1 (M/F).

The age of the patients in this current study ranged from 3weeks to 10years with a mean and median age of 15.5months and 6months respectively. 78.05% of the patients in this study were below the age of 1 year. A study conducted by Kitunguu et al (2017) in the same institution found a mean and a median age of presentation of children with hydrocephalus of 3years and 3.5years respectively.[12]

Our study however selectively included children as opposed to the latter study that included patients of all age groups. The findings of these studies show that hydrocephalus, though affects all age groups, in this country is more common in the pediatric population. Global systemic meta-analyses investigating the epidemiology of hydrocephalus have had similar findings of higher prevalence in children compared to adults with 89% of patients diagnosed before one year of age. [31]

Benjamin Warf in 2010 opined that the delay in diagnosis evidenced in the East African region may be attributed to misconceptions about the illness, lack of transport, lack of funds, and tendencies of this population to seek traditional remedies before finally seeking healthcare.[32]

As regards the radiologic investigation of children presenting with features of hydrocephalus, the majority (91.46%) of patients had cranial CT scan as the diagnostic imaging work up performed with only 4.8% of the patients having magnetic resonance imaging performed in the initial work up for hydrocephalus. Imaging tools available to the clinician in the initial assessment of hydrocephalic children include ultrasound, CT scans, and magnetic resonance imaging.

The modality of choice in imaging pediatric hydrocephalus is MRI, as it provides detailed anatomical and functional information important in managing these patients.[33] The reason most patients in this study underwent CT scan, which is not the gold standard imaging modality, is likely due to its wide availability, its relatively lower cost, and ease of performing in children without requiring sedation, compared to MRI.

Congenital hydrocephalus was the most common entity, diagnosed in 89.2% of the patients in this study with Dandy walker spectrum of malformations being the most identifiable congenital anomalies in 36.76% of those with congenital hydrocephalus. A similar finding was recorded by Omulo et al in the year 2000 in a study conducted in KNH with 74.4% of the patients he had studied having congenital hydrocephalus. [34]

Kitunguu et al in 2017 however had a different observation in a study conducted in the same institution, with a majority (57.1%) of the patients in his study having post-infectious hydrocephalus. This difference in etiology of hydrocephalus among patients managed in the same institution can be attributed partly to the different patient populations in each of the studies with the later study having included patients of all age groups while the former only studied pediatric hydrocephalus. Additionally, an earlier study in 1989 by Gichuhi et al on pediatric hydrocephalus in KNH found congenital hydrocephalus to be the commonest entity. [35]

The findings of this study are in contrast to what was recorded in Uganda by Warf in 2010, where he observed that a majority (57%) of the pediatric hydrocephalus was post-infectious. [36]

The observation in the current study is somewhat similar to what is seen in developed countries where the leading causes of pediatric hydrocephalus are congenital causes and intraventricular hemorrhage. [37]

In the current study, 18(21.9%) of the patients had spina bifida. Of the these, 10 (55.5%) had elevated CSF protein while 8 (44.5%) had normal CSF proteins. There was no correlation

between elevated CSF protein and the presence of spina bifida in this study. (P-value 0.512). This variable could not be found in existing literature both locally and internationally. The presence of spina bifida did not affect shunt survival at 3 months in the present study.

For the large majority of patients in this study,76(92.7%) shunt surgery performed during the study period was the first-ever shunt insertion. This finding is in keeping with the findings of previous studies in the same institutions where primary shunt insertions account for 75-95% of children undergoing shunt surgery. [12,13,34,35.]

Most (96.3%) shunt surgeries in this study were performed by residents in their 4th, 5th, and 6th years of study. Among the shunt surgeries performed by residents, most of them were performed by finalist residents in their last year of training (66.2%). D. Cochrane et al in 2005 reported that there is a relationship between the surgeon's operative experience and the shunt surgery outcomes with higher shunt failure rates at 6 months after surgery in less experienced surgeons. [38.] Anderson et al in 2021, in a prospective study, reported that the presence of a pediatric neurosurgeon during shunt surgery had better 30-day outcomes than surgeries performed by residents alone.[39.] In the current study, there was no statistically significant difference in 90-day outcomes between shunt outcomes performed by residents in different stages of their training. This finding is in keeping with that of a previous study conducted in the same institution in 2010 by the principal investigator in this study. [13]

With regards to the CSF protein content, 52.4% of the patients had normal CSF proteins while 47.6% had elevated CSF proteins. This variable could not be found in literature both locally and internationally for comparison. This is an important finding that highlights that nearly half of the patients undergoing shunt insertion for non-tumor hydrocephalus in our hospital have elevated CSF protein. This study further shows the impact that elevated CSF proteins have on shunt survival in the first 3 months after shunt insertion.

This study established a positive correlation between elevated CSF proteins and early shunt failure due to shunt blockage at 3 months post-insertion. (P-value 0.002). The incidence of shunt failure in the patient group with elevated CSF proteins at 3 months post-insertion was 20%, while the incidence of shunt failure in the normal protein group was 2.3%. From the findings of this study, elevated CSF proteins increase the likelihood of shunt failure in the first 3 months after insertion by 8.7 times. It was further observed that the protein concentration among the patients that developed shunt failure was 1250mMols/L compared to a mean protein concentration of 545mmol/L in the patients whose shunts were functional at 3 months.

This finding that elevated CSF proteins increase the likelihood of shunt failure due to shunt blockage has been observed by Sudheer et al 5 and Kamat et al 7 in patients with tuberculous

meningitis. In an in vitro study by Thomas [2], he established that the average incubation period to shunt blockage attributed to high CSF proteins was 46days. In this current study, the average incubation period was 60days. A study by Kitunguu et al in the same institution showed that among the shunts that failed, the average incubation period was 67 days.

The overall shunt failure rate in this study was 9.8% at 3 months of follow-up. All shunt failures were attributed to shunt blockage. A previous prospective study in the same institution reported a shunt blockage rate of 10%. [12] A retrospective study by Mwachaka et al in 2010 in the same institution reported that shunt blockage accounted for a majority (53.8%) of the shunt complications seen in KNH.

Nurhayat et al in a retrospective multicenter study noted that a persistently elevated CSF protein level above 100mg/dl was associated with shunt infection.[13] No case of shunt infection was noted in this current study among the patients with elevated CSF proteins. Fulkerson et al, in his 10year retrospective cohort study on the risk factors for shunt failure in low-birth-weight preterm infants, observed a similar finding that there was no correlation between CSF protein levels and the risk of shunt infection.[1]

With regards to CSF cellularity and shunt blockage, this study finds no correlation between elevated CSF cell count at shunt insertion and the likelihood of shunt failure at 3 months. (P-value 0.311). A similar observation was made in neonates undergoing VP shunting after intraventricular hemorrhage 1 and also in patients with tuberculous meningitis undergoing VP shunting.[5]

There was a positive correlation between reduced CSF glucose and the risk of shunt failure at 3 months. (P-value - 0.003). studies in neonates with post hemorrhagic hydrocephalus[1] and with post tuberculous hydrocephalus[5] have had a contrary finding with both concluding that there was no link between CSF glucose level and shunt failure. It is also important to note that all patients with shunt failure at 3 months and low CSF glucose at shunt insertion also had elevated CSF proteins. The author here hypothesizes that partial treatment of preceding meningitis could explain this finding of reduced CSF glucose with elevated proteins. Further studies to validate this finding are therefore warranted.

5.2 Conclusion

Shunt blockage remains the leading cause of early shunt failure in KNH.

About half of the pediatric patients undergoing ventriculoperitoneal shunting in KNH have elevated CSF proteins. Elevated CSF proteins at the time of surgery for shunt insertion have been shown in this current study to increase the likelihood of shunt failure due to shunt blockage by 3 months of follow-up. Patients with elevated CSF proteins have been shown in this current study to have a 8.7 times higher incidence of shunt failure at 3 months of follow up compared to their counterparts with normal CSF protein concentration.

Majority(58.5%) of the patients in this study had reduced CSF glucose levels. Reduced CSF glucose may also contribute to shunt blockage. All the patients who developed shunt failure in this study had reduced CSF glucose level. This finding may however be compounded by the fact that these same patients had elevated CSF proteins.

Majority(86.6%) of the study participants had a normal CSF cell count. CSF cellularity however did not affect the incidence of shunt failure at 3 months of follow-up.

5.3 Recommendations

In this study, 80% of patients with elevated CSF proteins had functional shunts at 3 months of follow-up, thus, the use of Ventriculoperitoneal shunts remains a viable option in patients with elevated CSF proteins. It is however recommended that a closer follow-up of this patient is done to screen for features of shunt blockage as its incidence is significantly higher in this patient group. It is thus recommended that patients with elevated CSF proteins at the time of shunt insertion should have a shorter clinic interval that does not exceed a month in the initial 3 months of follow up. An institutional based hydrocephalus follow up protocol that is based on the CSF protein levels would be ideal to achieve this.

Seeing that a large number of children with hydrocephalus have elevated CSF proteins, a study to investigate the long term effects of this finding on shunt survival is adviced.

Further studies on the chemical interaction between shunt tubings and CSF proteins that leads to shunt blockage are also recommended. The findings of such a study can later inform the materials used to manufacture shunts that will have less interactions with CSF proteins.

Further studies are also recommended to investigate the relationship between decreased CSF glucose levels and shunt survival as a strong conclusion cannot be made from the findings of this study as mentioned before.

5.3 Limitations and delimitations

This study provides the first ever description of common biochemical parameters in children with hydrocephalus, not only in Kenya but in the East African region. It has further provided evidence upon which the practice of shunt surgery and the follow up of patients thereafter will be based on depending on various laboratory CSF findings.

A longer duration of follow-up would have been better to screen for the effects of the CSF biochemical and cellular characteristics over many years of follow-up. A larger patient group would have also yielded higher-quality data about this important neurosurgical disorder.

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STUDY TIMELINE

Study activity	May – December 2020	Jan – April 2020	May 2021	June 2021
Proposal development				
Data collection				
Data entry and analysis				
Writing the final manuscript				

BUDGET

Item	Quantity	Unit cost (Kshs)	Total (Kshs)
Plain paper ream	5	530	2650
Cartridge 48 A	5	6000	30000
Binding	12	500	6000
Ethical approval			3000
Contingencies			5000
Statistician			30000
Total			76,650

The budget will be catered for by the principal investigator. No extra costs will be incurred by the patient following enrollment in to the study**.**

APPENDICES

Appendix I: Questionnaire

BIODATA

Study number:

Age : Sex :

Date of admission : Residence/county :

Occupation : Marital status:

ETIOLOGY OF HYDROCEPHALUS

Congenital ☐ Acquired ☐

If congenital, specify the cause

- Aqueductal stenosis ☐
- Dandy Walker malformation ☐
- Chiari Malformation ☐
- Others (specify) _____

If acquired, specify the cause

- Bacterial meningitis ☐
- Tuberculous meningitis ☐
- Meningitis not specified ☐
- Subarachnoid hemorrhage (specify cause) ☐
- Post traumatic ☐
- Intraventricular hemorrhage ☐
- Tumor ☐
- Others(specify) _____

Does the patient have spina bifida Yes ☐ No ☐

If yes specify type _____

Has the patient had previous neurosurgical procedures

Yes ☐ NO ☐

If yes, specify type: _____

Date of surgery: _____

Diagnostic cranial imaging done

MRI ☐ CT scan ☐ ultrasound ☐

OPERATIVE FACTORS

Date of surgery: _____

Shunt details First surgery ☐ Revision surgery ☐

Reason for revision: _____

Surgeon Consultant ☐

Resident ☐ specify year of study: _____

Ventricular access point for the proximal catheter

Keens point ☐

Kochers point ☐

Other (specify) ☐

Location of distal catheter

Peritoneum ☐

Atrium ☐

Pleura ☐

Others (specify) ☐

Type of shunt valve

Low pressure ☐

Medium pressure ☐

High pressure ☐

Laboratory Parameters of CSF Sample Obtained

Proteins: _____ (mMol/L)

Glucose:_____(mMol)

Cell count:_____ per microliter

Follow Up Parameters

	Duration since shunt surgery	Complication, if any
1st visit		
2nd visit		
3rd visit		
4th visit		

Shunt revised Yes ☐ No ☐

Days since insertion of shunt that revision is done _____

Outcome, at discharge after shunt revision

Patient is well, no new neurologic deficits ☐

Patient has deteriorated with new neurologic deficits ☐

Dead ☐

Length of hospital stay during shunt revision: _____

Appendix II: Consent Form for Study Participants or Their Representatives (English Version)

Study topic: Biochemical and cellular properties of cerebrospinal fluid among patients undergoing ventriculoperitoneal shunting in Kenyatta national hospital and its impact on shunt survival.

Principle investigator: Dr. Benjamin Kasyoka Mutiso

Study site: Kenyatta national hospital

Introduction

I, Dr. Benjamin Kasyoka Mutiso , am a post graduate student in the university of Nairobi, department of neurosurgery. I am conducting a study on the above stated topic in the Kenyatta national hospital. This section gives you information concerning this study to help you make a decision as to whether to participate or not. Feel free to seek any clarification in any areas that you may not understand.

Purpose of the research

This study is on a common disease in this part of the world called hydrocephalus. This is a condition that results from blockage of the normal pathways or reduced absorption of the water inside the brain. To treat this disease, a special type of a tube is used to divert the water from the head to the abdomen from where it is absorbed. This tubings to divert this fluid frequently block requiring surgery to change the tubings. This study aims to investigate some of the factors that contribute to blockage of this tubes and hence help us manage this condition better.

What does participating in this study entail

Once you are recruited in to this study, about 2mls of the water in the brain will be taken during surgery and subjected to laboratory tests. The investigator will also follow you up in the clinic to check on the function of the tubing placed during surgery. Participating in this study does not in any means change the way in which the surgery is performed neither does it require additional surgical procedures.

Voluntary participation

Your participation is voluntary. Choosing to participate in this study or not does not in any way affect the way that you will be treated.

Risks

There no additional risks to the patient by participating in this study.

Benefits of participation

The results of this study will be used to improve on how we treat patients with hydrocephalus. It will help us understand how the various components of the water within the brain affect the tubings we use to treat this disease.

Reimbursement

There will be no incentives from participating on this study.

Confidentiality

All the information obtained during this study will be kept private. It shall only be accessible to the doctors carrying out the study. The results of the study will be published in a medical journal for improvement of medical practice in hydrocephalus but will not include any information that can identify the you the patient

Right to withdraw from the study

You have the right to withdraw from this study at any point. This will by no means affect the quality of care provided to you in the hospital.

Who to contact?

If you have any questions about this study, feel free to contact the persons below at any time.

Principal investigator

Dr Benjamin Kasyoka Mutiso
Phone contact - 0722527257
P O BOX 914,
Machakos, Kenya.

Lead supervisor

Dr Michael Magoha
Phone contact – 0710388279
P.O BOX 19868 – 00202
Nairobi, Kenya.

KNH/UoN ethics and research committee

Telephone : 020-726300 EXT 44102.
P O BOX 20723 – 00202
KNH, Nairobi.

Participants declaration

I confirm that I have read and understood the information regarding this study and hereby agree to participate.

Name of the patient: ……
Relationship to the patient: …….

Signature: …… Date: ……

Name of the doctor taking consent:……..

Signature: …… Date: ……

Appendix III: Consent Form for Study Participants or Their Representatives (Swahili Version)

FOMU YA IDHINI YA WAGONJWA AU WAWAKILISHI WAO

Utangulizi

Mimi, Dr Benjamin Kasyoka Mutiso, ni mwanafunzi wa kuhitimu katika chuo kikuu cha Nairobi, idara ya magonjwa ya akili. Ninafanya utafiti juu ya mada iliyosemwa hapo juu katika hospitali ya kitaifa ya Kenyatta. Sehemu hii inakupa habari kuhusu utafiti huu ili kukusaidia kufanya uamuzi wa kushiriki au la. Jisikie huru kutafuta ufafanuzi wowote katika maeneo yoyote ambayo labda hayaeleweki.

Kusudi la utafiti

Utafiti huu ni juu ya ugonjwa uliokita katika sehemu hii ya ulimwengu unayoitwa hydrocephalus. Hii ni hali ambayo hutokana na kuziba kwa njia za kawaida kwa maji ndani ya ubongo. Ili kutibu ugonjwa huu, aina maalum ya bomba hutumika kupotosha maji kutoka kichwani kwenda kwenye tumbo kutoka mahali ambapo huingizwa.mipira hii inayotumika kutibu huu ugonjwa mara nyingi hushikwa na hitilafu. Utafiti huu unakusudia kuchunguza baadhi ya sababu zinazochangia mipira hii kuwa na hitilafu na kwa hivyo kutusaidia kutibu hali hii vyema.

Je! Kushiriki katika utafiti huu kunamaanisha nini?

Mara tu unapoandikishwa kwenye utafiti huu, karibu 2mls za maji kwenye ubongo zitachukuliwa wakati wa upasuaji na kufanyishwa vipimo vya maabara. Mpelelezi pia atakufuata katika kliniki ili kuangalia juu ya kazi ya mipira iliyowekwa wakati wa upasuaji. Kushiriki katika utafiti huu haibadilishi kwa njia yoyote upasuaji ambao hufanywa wala hauitaji taratibu za upasuaji zaidi.

Kushiriki kwa hiari

Ushiriki wako ni wa hiari. Kuamua kushiriki katika utafiti huu au sio kwa njia yoyote hakuathiri njia ambayo utatibiwa.

Hatari

Hakuna hatari zaidi kwa mgonjwa kwa kushiriki katika utafiti huu.

Faida za kushiriki

Matokeo ya utafiti huu yatatumika kuboresha jinsi tunavyowatibu wagonjwa na hydrocephalus. Itatusaidia kuelewa jinsi sehemu mbali mbali za maji ndani ya ubongo zinaathiri viini tunavyotumia kutibu ugonjwa huu.

Kulipia

Hakutakuwa na motisha kutoka kwa kushiriki kwenye utafiti huu.

Usiri

Habari zote zilizopatikana wakati wa utafiti huu zitahifadhiwa. Itapatikana tu kwa madaktari wanaofanya uchunguzi. Matokeo ya utafiti huo yatachapishwa katika jarida la matibabu kwa uboreshaji wa mazoezi ya matibabu katika hydrocephalus lakini haitajumuisha habari yoyote ambayo inaweza kumtambulisha mgonjwa

Haki ya kujiondoa kwenye masomo

Una haki ya kujiondoa kutoka kwa utafiti huu wakati wowote. Hii haitaathiri ubora wa huduma uliyopewa hospitalini.

Nani kuwasiliana?

Ikiwa inahitajika ufafanuzi zaidi, mchunguzi wa kanuni yuko tayari na inapatikana kushughulikia maswali yoyote au maswali. Mpelelezi mkuu anaweza kufikiwa kwa simu yake ya rununu kwa namba 0722527257. Utafiti huu pia umepitiwa na kupitishwa na kamati ya maadili ya hospitali ya Kenyatta na kamati ya utafiti ili kuhakikisha haikudhuru. Ofisi yao inaweza kupatikana kwa namba hii 0799495829.

Ninathibitisha kwamba nimesoma na nimeelewa habari inayohusu utafiti huu na kwa hivyo nakubali kushiriki.

Jina la mgonjwa:.....

uhusiano na mgonjwa:.....

Sahihi: …… Tarehe: …….……

Jina la daktari anayechukua idhini:.....

Sahihi: …… Tarehe: …….……

Appendix IV: Minor Assent Document For Those Aged 6 To 17 Years

Project Title: Impact on shunt survival of the biochemical and cellular properties of cerebrospinal fluid among patients following ventriculoperitoneal shunting

Principal Investigator: Dr Benjamin Kasyoka Mutiso

We are doing a research study about on how the components of the water in the brain affect the function of the shunt we use to treat hydrocephalus. Permission has been granted to undertake this study by the Kenyatta National Hospital-University of Nairobi Ethics and Research Committee (KNH-UoN ERC Protocol No. P432/08/2020)

This research study is a way to learn more about people with hydrocephalus. At least other 60 children will be participating in this research study with you. If you decide that you want to be part of this study, you will be asked to take some time to provide some information to the researcher, who will also keep track of your status for the next three months.

When we are finished with this study, we will write a report about what was learned. This report will not include your name or that you were in the study. There will be no additional procedures or costs by agreeing to participate in this study. By you agreeing to be part of this study, you will help us treat patients with hydrocephalus better.

If you do not wish to be part of it, you are free to tell us so, and this will by no means affect the quality of care we provide you.

If you decide you want to be in this study, please sign your name.

I, _____, want to be in this research study.

(Signature/Thumb stamp)_____ (Date) _____

Appendix V: Swahili Version

Idhini ya wale wenye umri wa miaka 6 hadi 17

Kichwa cha Mradi: Impact on shunt survival of the biochemical and cellular properties of cerebrospinal fluid among patients following ventriculoperitoneal shunting

Mchunguzi Mkuu: Dk Benjamin Kasyoka Mutiso

Tunafanya utafiti kuhusu jinsi vifaa vya maji kwenye ubongo vinavyoathiri kazi ya shunt tunayotumia kutibu hydrocephalus.

Ruhusa imepewa kufanya utafiti huu na Hospitali ya Kitaifa ya Kenyatta-Chuo Kikuu

cha Kamati ya Maadili na Utafiti ya Nairobi (Itifaki ya KNH-UoN ERC Namba P432 / 08/2020)

Utafiti huu ni njia ya kujifunza zaidi juu ya watu walio na ugonjwa wa hydrocephalus. Angalau watoto wengine 60 watashiriki katika utafiti huu na wewe.

Ukiamua kuwa unataka kuwa sehemu ya utafiti huu, utaulizwa kuchukua muda kutoa habari kwa mtafiti, ambaye pia atafuatilia hali yako kwa miezi mitatu ijayo.

Tutakapomaliza na utafiti huu, tutaandika ripoti juu ya kile kilichojifunza. Ripoti hii haitajumuisha jina lako au kwamba ulikuwa kwenye utafiti. Hakutakuwa na taratibu za ziada au gharama kwa kukubali kushiriki katika utafiti huu. Kwa kukubali kuwa sehemu ya utafiti huu, utatusaidia kutibu wagonjwa walio na hydrocephalus vizuri. Ikiwa hutaki kuwa sehemu yake, uko huru kutuambia hivyo, na hii haitaathiri ubora wa huduma tunayokupa.

Ikiwa unaamua unataka kuwa katika utafiti huu, tafadhali saini jina lako.

Mimi, _____, ninataka kuwa katika utafiti huu.

(Saini / stempu ya kidole gumba)_____ (Tarehe) _____

Appendix VI: Parental Consent For Their Children

Title of Study: The impact on shunt survival of cerebrospinal fluid biochemistry and cellularity following ventriculoperitoneal shunting

Principal Investigator: Dr Benjamin Kasyoka Mutiso, a neurosurgery resident in the university of Nairobi

Co-Investigators: Dr Magoha, a lecturer in the university of Nairobi

Introduction:

I would like to tell you about a study being conducted by the above listed researchers. The purpose of this consent form is to give you the information you will need to help you decide whether or not your child should participate in the study. Feel free to ask any questions about the purpose of the research, what happens if your child participates in the study, the possible risks and benefits, the rights of your child as a volunteer, and anything else about the research or this form that is not clear.

When we have answered all your questions to your satisfaction, you may decide if you want your child to be in the study or not. This process is called 'informed consent'. Once you understand and agree for your child to be in the study, I will request you to sign your name on this form. You should understand the general principles which apply to all participants in a medical research: i) Your child decision to participate is entirely voluntary ii) You child may withdraw from the study at any time without necessarily giving a reason for his/her withdrawal iii) Refusal to participate in the research will not affect the services your child is entitled to in this health facility or other facilities.

May I continue? YES / NO (circle appropriately)

For children below 18 years of age we give information about the study to parents or guardians. We will go over this information with you and you need to give permission in order for your child to participate in this study. We will give you a copy of this form for your records. Add comment on ascent (e.g If the child is at an age that he/she can appreciate what is being done the he/she will also be required to agree to participate in the study after being fully informed).

What Is The Purpose Of The Study?

The researchers listed above are interviewing individuals who are suffering from hydrocephalus and have undergone a surgical procedure to place a ventriculoperitoneal shunt. The purpose of the interview is to find out various characteristics of your child's illness which are of interest in this study. Participants in this research study will be asked questions regarding the cause and treatment of the hydrocephalus. We shall also obtain details on lab parameters of

cerebrospinal fluid obtained during surgery for your child. There will be approximately 70 participants in this study randomly chosen. We are asking for your consent to consider your child to participate in this study.

What Will Happen if you Decide you Want Your Child to be in this Research Study?

If you agree for your child 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 5 minutes. The interview will cover topics such as the cause of hydrocephalus and treatment history of your child. After the interview has finished, the interviewer will obtain details of laboratory results of the cerebrospinal fluid for your child from the file. We will ask for a telephone number where we can contact you if necessary. We shall review your child again after 3 months during your routine follow up clinic visits to see the treatment progress. 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.

Are There Any Risks, Harms, Discomforts Associated With This Study?

Medical research has the potential to introduce psychological, social, emotional and physical risks. Effort should always be put in place to minimize the risks. One potential risk of being in the study is loss of privacy. We will keep everything you tell us as confidential as possible. We will use a code number to identify your child in a password-protected computer database and will keep all of our paper records in a locked file cabinet. However, no system of protecting confidentiality can be absolutely secure so it is still possible that someone could find out your child was in this study and could find out information about your child. Also, answering questions in the interview may be uncomfortable for you. If there are any questions you do not want to answer, you can skip them. You have the right to refuse the interview or any questions asked during the interview. Furthermore, all study staff and interviewers are professionals with special training in these interviews.

Are There Any Benefits Being In This Study?

The information you provide will help us better understand hydrocephalus better and how to best treat it in different case scenarios. This information is a major contribution to science and will go a long way in improving the quality of care we offer to patients.

Will Being in this Study Cost You Anything?

There will be no additional costs to you by choosing to participate in this study. The laboratory tests being studied here are routinely done to all patients with hydrocephalus.

Is There Reimbursement For Participating in this Study?

There will be no reimbursements for participating in this study.

What If You Have Questions In Future?

If you have further questions or concerns about your child participating in this study, please call or send a text message to the study staff at the number provided at the bottom of this page. For more information about your child's rights as a research participant you may contact the Secretary/Chairperson, Kenyatta National Hospital-University of Nairobi Ethics and Research Committee Telephone No. 2726300 Ext. 44102 email uonknh_erc@uonbi.ac.ke. The study staff will pay you back for your charges to these numbers if the call is for study-related communication.

What Are Your Other Choices?

Your decision to have your child participate in this research is voluntary. You are free to decline or withdraw participation of your child in the study at any time without injustice or loss of benefits. Just inform the study staff and the participation of your child in the study will be stopped. You do not have to give reasons for withdrawing your child if you do not wish to do so. Withdrawal of your child from the study will not affect the services your child is otherwise entitled to in this health facility or other health facilities. For more information contact _Dr Benjamin Kasyoka Mutiso at the department of neurosurgery in KNH from 8AM to 5PM

Statement of Consent

The person being considered for this study is unable to consent for him/herself because he or she is a minor (a person less than 18 years of age). You are being asked to give your permission to include your child in this study. Parent/guardian statement I have read this consent form or had the information read to me. I have had the chance to discuss this research study with a study counselor. I have had my questions answered by him or her in a language that I understand. The risks and benefits have been explained to me. I understand that I will be given a copy of this consent form after signing it.

I understand that my participation and that of my child in this study is voluntary and that I may choose to withdraw it any time. I understand that all efforts will be made to keep information

regarding me and my child's personal identity confidential. By signing this consent form, I have not given up my child's legal rights as a participant in this research study.

I voluntarily agree to my child's participation in this research study: Yes / No (circle your response)

I agree to provide contact information for follow-up: Yes/ No (circle your response)

Parent/Guardian signature /Thumb stamp: _____ Date _____
Parent/Guardian printed name: _____

Researcher's statement

I, the undersigned, have fully explained the relevant details of this research study to the participant named above and believe that the participant has understood and has knowingly given his/her consent.

Printed Name: _____ Date: _____

Signature: _____

Role in the study: _____ [i.e. study staff who explained informed consent form.]

Appendix VII: Idhini Ya Wazazi Kwa Watoto Wao

Kichwa cha Utafiti: The impact on shunt survival of cerebrospinal fluid biochemistry and cellularity following ventriculoperitoneal shunting

Mchunguzi Mkuu: Dk Benjamin Kasyoka Mutiso, mwanafunzi wa upasuaji wa ubongo katika chuo kikuu cha Nairobi

Wachunguzi-pamoja: Dk Magoha, mhadhiri katika chuo kikuu cha Nairobi

Utangulizi:

Ningependa kukuambia juu ya utafiti unaofanywa na watafiti walioorodheshwa hapo juu. Madhumuni ya fomu hii ya idhini ni kukupa habari utakayohitaji kukusaidia kuamua ikiwa mtoto wako anapaswa kushiriki katika utafiti huo au la. Jisikie huru kuuliza maswali yoyote juu ya kusudi la utafiti, ni nini kitatokea ikiwa mtoto wako atashiriki katika utafiti, hatari na faida zinazowezekana, haki za mtoto wako kama kujitolea, na chochote kingine juu ya utafiti au fomu hii ambayo sio wazi. Wakati tumejibu maswali yako yote kwa kuridhika kwako, unaweza kuamua ikiwa unataka mtoto wako awepo kwenye somo au la. Utaratibu huu unaitwa 'ridhaa inayofahamishwa'. Mara tu utakapoelewa na kukubali mtoto wako awepo kwenye utafiti, nitakuomba utie sahihi jina lako kwenye fomu hii. Unapaswa kuelewa kanuni za jumla ambazo zinatumika kwa washiriki wote katika utafiti wa matibabu:

i) Uamuzi wa mtoto wako kushiriki ni wa hiari kabisa

ii) Mtoto wako anaweza kujiondoa kwenye utafiti wakati wowote bila kutoa sababu ya kujiondoa kwake

iii) Kukataa kushiriki katika utafiti hakuwezi kuathiri huduma ambazo mtoto wako anastahili katika kituo hiki cha afya au vituo vingine.

Naweza kuendelea? NDIYO / HAPANA (duara ipasavyo)

Kwa watoto walio chini ya umri wa miaka 18 tunatoa habari kuhusu utafiti huo kwa wazazi au walezi. Tutapita habari hii na wewe na unahitaji kutoa ruhusa ili mtoto wako ashiriki katika utafiti huu. Tutakupa nakala ya fomu hii kwa kumbukumbu zako. Ongeza maoni juu ya kupaa (k.v. Ikiwa mtoto ana umri ambao anaweza kufahamu kile kinachofanyika yeye pia atahitajika kukubali kushiriki katika utafiti baada ya kupata habari kamili).

Kusudi La Utafiti Ni Nini?

Watafiti walioorodheshwa hapo juu wanawahoji watu ambao wanaugua hydrocephalus na wamepata utaratibu wa upasuaji kuweka shunti ya ventriculoperitoneal shunt. Kusudi la mahojiano ni kujua tabia anuwai ya ugonjwa wa mtoto wako ambayo ni ya kupendeza katika utafiti huu. Washiriki katika utafiti huu wataulizwa maswali kuhusu sababu na matibabu ya

hydrocephalus. Tutapata pia maelezo juu ya vigezo vya maabara ya giligili ya ubongo inayopatikana wakati wa upasuaji kwa mtoto wako. Kutakuwa na takriban washiriki 70 katika utafiti huu waliochaguliwa bila mpangilio. Tunaomba idhini yako ya kuzingatia mtoto wako kushiriki katika utafiti huu.

Nini Kitatokea Ukiamua Unataka Mtoto Wako Awe Kwenye Utafiti Huu?

Ikiwa unakubali mtoto wako kushiriki katika utafiti huu, mambo yafuatayo yatatokea: Utahojiwa na mhojiwa aliyefundishwa katika eneo la faragha ambapo unahisi raha kujibu maswali. Mahojiano yatachukua takriban dakika tano. Mahojiano yataangazia mada kama vile sababu ya hydrocephalus na historia ya matibabu ya mtoto wako. Baada ya mahojiano kumaliza, mhojiwa atapata maelezo ya maabara ya giligili ya ubongo kwa mtoto wako kutoka kwa faili. Tutauliza nambari ya simu ambapo tunaweza kuwasiliana nawe ikiwa ni lazima. Tutamkagua mtoto wako tena baada ya miezi 3 wakati wa ziara yako ya kawaida ya kliniki ili kuona maendeleo ya matibabu. Ikiwa unakubali kutoa anwani yako ya mawasiliano, itatumika tu na watu wanaofanya kazi kwa utafiti huu na hawatashirikiwa na wengine kamwe.

Kuna Athari Zozote, Madhara, Hasara Zinazohusiana na Utafiti Huu?

Utafiti wa kimatibabu una uwezo wa kuanzisha hatari za kisaikolojia, kijamii, kihemko na kiafya. Jitihada inapaswa kuwekwa kila wakati ili kupunguza hatari. Hatari moja ya kuwa katika utafiti ni kupoteza faragha. Tutaweka kila kitu unatuambia kama siri iwezekanavyo. Tutatumia nambari ya nambari kutambua mtoto wako katika hifadhidata ya kompyuta inayolindwa na nywila na tutaweka rekodi zetu zote za karatasi kwenye kabati la faili lililofungwa. Walakini, hakuna mfumo wa kulinda usiri ambao unaweza kuwa salama kabisa kwa hivyo bado inawezekana mtu anaweza kujua mtoto wako alikuwa kwenye utafiti huu na angeweza kupata habari juu ya mtoto wako. Pia, kujibu maswali kwenye mahojiano inaweza kuwa mbaya kwako. Ikiwa kuna maswali ambayo hautaki kujibu, unaweza kuyaruka. Una haki ya kukataa mahojiano au maswali yoyote yatakayoulizwa wakati wa mahojiano. Kwa kuongezea, wafanyikazi wote wa utafiti na wahojiwa ni wataalamu wenye mafunzo maalum katika mahojiano haya.

Kuna Faida Zozote Zinakuwa Katika Utafiti Huu?

Habari unayotoa itatusaidia kuelewa vizuri hydrocephalus vizuri na jinsi ya kuitibu vizuri katika hali tofauti. Habari hii ni mchango mkubwa kwa sayansi na itasaidia sana katika kuboresha ubora wa huduma tunayotoa kwa wagonjwa.

Je, Kuwa Kwenye Utafiti Huu Kutakugharimu Chochote?

Hakutakuwa na gharama za ziada kwako kwa kuchagua kushiriki katika utafiti huu. Uchunguzi wa maabara unaosomwa hapa hufanywa mara kwa mara kwa wagonjwa wote wenye hydrocephalus.

Kuna Kulipwa Kwa Kushiriki Katika Utafiti Huu?

Haitakuwa malipo yoyote kwa kushiriki katika utafiti huu.

Je, Kama Una Maswali Baadaye?

Ikiwa una maswali zaidi au wasiwasi juu ya mtoto wako kushiriki katika utafiti huu, tafadhali piga simu au tuma ujumbe wa maandishi kwa wafanyikazi wa utafiti kwa nambari iliyotolewa chini ya ukurasa huu. Kwa habari zaidi juu ya haki za mtoto wako kama mshiriki wa utafiti unaweza kuwasiliana na Katibu / Mwenyekiti, Hospitali ya Kitaifa ya Kenyatta-Kamati ya Maadili na Utafiti ya Chuo Kikuu cha Nairobi Nambari ya simu 2726300 Ext. Barua pepe 44102 uonknh_erc@uonbi.ac.ke. Wafanyakazi wa utafiti watakulipa malipo yako kwa nambari hizi ikiwa simu ni ya mawasiliano yanayohusiana na utafiti. CHAGUO ZAKO ZINGINE NI NINI? Uamuzi wako wa kumfanya mtoto wako ashiriki katika utafiti huu ni wa hiari. Uko huru kukataa au kuondoa ushiriki wa mtoto wako katika utafiti wakati wowote bila udhalimu au kupoteza faida. Wajulishe tu wafanyikazi wa utafiti na ushiriki wa mtoto wako katika utafiti utasimamishwa. Sio lazima utoe sababu za kumtoa mtoto wako ikiwa hutaki kufanya hivyo. Kuondolewa kwa mtoto wako kwenye utafiti hakutaathiri huduma ambazo mtoto wako anastahiki vinginevyo katika kituo hiki cha afya au vituo vingine vya afya. Kwa habari zaidi wasiliana na _Dkt Benjamin Kasyoka Mutiso katika idara ya upasuaji wa neva katika KNH kutoka 8AM hadi 5PM

Taarifa Ya Ukubali

Mtu anayezingatiwa kwa utafiti huu hawezi kukubali kwake kwa sababu yeye ni mdogo (mtu chini ya umri wa miaka 18). Unaulizwa kutoa ruhusa yako kumjumuisha mtoto wako katika utafiti huu. Taarifa ya mzazi / mlezi Nimesoma fomu hii ya idhini au nikasomewa habari. Nimekuwa na nafasi ya kujadili utafiti huu wa utafiti na mshauri wa utafiti. Nimejibiwa maswali yangu na yeye katika lugha ambayo ninaelewa. Hatari na faida zimeelezewa kwangu. Ninaelewa kuwa nitapewa nakala ya fomu hii ya idhini baada ya kutia saini. Ninaelewa kuwa ushiriki wangu na wa mtoto wangu katika utafiti huu ni wa hiari na kwamba ninaweza kuchagua kuiondoa wakati wowote.

Ninaelewa kuwa juhudi zote zitafanywa kutunza siri kunihusu mimi na utambulisho wa kibinafsi wa mtoto wangu. Kwa kusaini fomu hii ya idhini, sijatoa haki za kisheria za mtoto wangu kama mshiriki katika utafiti huu.

Ninakubali kwa hiari kushiriki kwa mtoto wangu katika utafiti huu: Ndio / Hapana (zungusha jibu lako)

Ninakubali kutoa habari ya mawasiliano kwa ufuatiliaji: Ndio / Hapana (zungusha jibu lako)
Saini ya Mzazi / Mlezi / Muhuri wa kidole gumba: _____
Tarehe _____
Mzazi / Mlinzi jina lililochapishwa: _____

Kauli ya mtafiti

Mimi, aliyesainiwa chini, nimeelezea kabisa maelezo yanayofaa ya utafiti huu kwa mshiriki aliyetajwa hapo juu na ninaamini kwamba mshiriki ameelewa na ametoa idhini yake kwa kujua.
Jina Lililochapishwa: _____ Tarehe: _____
Saini: _____
Jukumu katika utafiti: _____ [i.e. wafanyikazi wa utafiti ambao walielezea fomu ya idhini ya habari.]

Appendix VIII: KNH/UoN-ERC Letter of Approval