VENTRICULO-PERITONEAL SHUNT SURVIVAL AT THE KENYATTA NATIONAL HOSPITAL: A REGISTRY BASED ASSESSMENT

By

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DECLARATION

I hereby confirm that this thesis is my original work and has not been presented for the award of a degree in any other university.

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LIST OF ABBREVIATIONS

Ventriculo-peritoneal ……VP

Kenyatta National Hospital …… KNH

National Association of Children's Hospitals and Related Institutions …… NACHRI

World Health Organization …… WHO

Statistical package for social services ……. SPSS

Analysis of variance ……... ANOVA

Cerebrospinal fluid ……..CSF

Kenyatta National Hospital ……KNH

Kenyatta National Hospital-University of Nairobi Ethics and Research Committee ...KNH/UON- ERC

Nation Hospital Insurance Fund ……NHIF

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ABSTRACT

Background: Hydrocephalus remains one of the common conditions managed by any neurosurgical service. A VP shunt complication is a major obstacle in the management of hydrocephalus. Analysis of data and outcomes in relation to hydrocephalus and shunt procedures would be useful in improving neurosurgical services. Additionally, assessment of risk factors for shunt failure would serve as a platform for the eventual establishment of effective measures to lower procedural variability and improve outcomes.

Objective: This study therefore aimed to assess the etiology of hydrocephalus, shunt outcomes and factors affecting shunt survival at Kenyatta National Hospital.

Study design: A prospective, non-controlled, open-label registry to investigate patients with de novo catheter implantation or catheter replacement of an existing ventriculoperitoneal shunt. The primary outcome was shunt survival.

Materials and methods: Following ethical approval, patients who fit the inclusion criteria were recruited and relevant data was retrieved and input in a preformed data collecting sheet. Assessment of patient biodata, etiology of hydrocephalus, surgical procedure as well as the development of shunt malfunction during a 3-month follow-up period was done. Data was analyzed using SPSS software (Version 19.0, Chicago Illinois) with a p value <0.05 being considered statistically significant.

Results: During the study period, 154 patients met the inclusion criteria and were recruited in the study. There was slight male predominance with 86 (55.8%) male patients and a mean and median age at presentation of 3 years and 3.5 years respectively. Most of the patients (102 patients; 66.2%) were below 5 years of age. Majority of the patients (88 patients; 57.1%) had

post-meningitic hydrocephalus. A total of 35 patients (22.7%) had 39 complications within the study period. Kaplan–Meier shunt survival analysis for adult hydrocephalus showed overall median time to first shunt failure was 69 days ranging from 0 to 362 days and 30 (76.9%; n=39) of these complications occurred within the first 3 months. The most common complications were shunt blockage (n=16, 10.4%) and shunt infection (n=14, 9.1%). The development of shunt failure was significantly influenced by the principal etiology of the hydrocephalus (P = 0.030), principal etiologies (P = 0.003, log-rank test), age (P < 0.001, log-rank test), duration of hospital stay (P < 0.001, log-rank test), patients' pre-operative GCS score of less than 13 and the placement of extra-ventricular drains (P = 0.033, log-rank test) before VP shunt.

Conclusion and Recommendations: Post-meningitic hydrocephalus is the most common encountered aetiology of hydrocephalus among our patient cohort. Though comparable to some other studies, shunt failure remains high among shunted patients at the Kenyatta National hospital with shunt obstruction predominating. Age, primary aetiology, patient's pre-operative neurologic status and the use of an EVD significantly influence VP shunt survival at KNH. Development of a shunt registry capturing all hydrocephalic patients would be beneficial to achieve larger patient numbers with a longer follow-up period to assess the long-term shunt outcomes among our patients.

Key Words: Hydrocephalus, Ventriculoperitoneal shunt, Complications, Survival

CHAPTER ONE

INTRODUCTION AND LITERATURE REVIEW

1.1 Introduction

Hydrocephalus is a condition in which a disturbance in the production, circulation or absorption of cerebrospinal fluid (CSF) causes the accumulation of intraventricular CSF, resulting in progressive ventricular dilation (Mori *et al* 1995). Although hydrocephalus is reported to be more common in developing countries, its prevalence is yet to be determined (Gathura *et al* 2010, Warf 2005).

Shunt registries have been shown in other populations to provide valuable information about the standard of care offered to patients and are amenable to quality control and statistical evaluation, which in turn allow improvements and amendments in the definite care. Over recent years, many databases on hydrocephalic injured patients have been developed. They have demonstrated the possibility to collect comprehensive, credible data through an organisation with strong commitment but only modest resources.

Published local data on hydrocephalus has thus far focused on the rate and causes of ventriculoperitoneal shunt complications. Mwachaka *et al* (2010), Omulo *et al* (1993), Gichuhi *et al* (1989), Noorani *et al* (2003) and Mwang'ombe and Omulo (2000) reported on shunt complications in both prospective and retrospective analyses. An extensive literature search by the principle author did not reveal existence of any shunt registry in Africa. The value of such a data collection and collation method would be immense given the case load of hydrocephalus and the need to assess outcomes for continued improvement of the care provided to our patients.

1.2 Literature review

1.2.1 Preamble

Hydrocephalus is a condition in which a disturbance in the production, circulation or absorption of cerebrospinal fluid (CSF) causes the accumulation of intraventricular CSF, resulting in progressive ventricular dilation (Mori *et al* 1995). This results in increased CSF volume, dilation of the CSF spaces and ultimately, increased intracranial pressure (Rekate 2003).

1.2.2Epidemiology of Hydrocephalus

Heterogeneity in the types of hydrocephalus and affected populations makes a simplistic assessment of its epidemiology problematic. However, mean crude prevalence between 0.47 to 0.60 per 1000 live births have been reported (Persson *et al* 2007; Tully *et al* 2014). The question of the epidemiology of hydrocephalus further compounded when considering congenital and acquired causes. Garne *et al* (2010) using data collected from four European registries of congenital malformations (EUROCAT), reported an overall prevalence of 4.65 per 10,000 births for congenital hydrocephalus. Earlier reports had recorded crude incidence rates ranging from 0.70 per 1,000 births to 66 cases per 100,000 births. Further, Chi *et al* (2005) estimated the incidence of congenital hydrocephalus in developed countries at 0.5 cases per 1000 live births with a male predominance. The incidence distribution is bimodal with most hydrocephalus cases occurring among children (Chi *et al* 2005).

Although hydrocephalus is reported to be more common in developing countries, its prevalence is yet to be determined (Gathura *et al* 2010, Warf 2005). The current incidence of hydrocephalus in sub-Saharan Africa is unknown (Warf 2010). Anecdotal reports have estimated that less than 10% of cases are annually treated using the ventriculoperitoneal shunt (VPS) systems (Salvador *et al* 2014). This may arise from various factors including that many children

with hydrocephalus in sub-Saharan Africa are not taken to health facilities for treatment due to poverty, erroneous cultural interpretations about hydrocephalus in children, and various other reasons and as such many patients are left untreated (Warf 2010, Piquer *et al* 2010).

Warf (2010) estimated the incidence of hydrocephalus in Uganda and extrapolated this to the East African region concluding that the burden of infant hydrocephalus in East Africa is significant, with more than 6000 new cases estimated per year. Salvador *et al* (2014) using Mozambican census demographics and incidence rates from western populations estimated that 480 new cases of congenital hydrocephalus and from 2900 and up to 4800 new cases of neonatal hydrocephalus would be predicted each year in Mozambique. The last official census took place in Kenya was in 2009 showing a crude birth rate of 34.1/1000persons with a projected population of 48,459,811 inhabitants by 2017 (KNBS 2009), which gives an estimate of 1,652,480 births/year. Consequently, using data from developed countries to estimate incidence, 826 new cases of congenital hydrocephalus and between 4900 and 8200 new cases of neonatal hydrocephalus would be predicted each year in Kenya (Salvador *et al* 2014).

1.2.2 Physiology of CSF production, circulation and absorption

CSF is produced by the choroid plexus of the lateral, third and fourth ventricles at 10 ml per hour, corresponding to 200-250 ml/day in a child, with this increasing to 20 ml an hour or 400-500 ml a day in adolescents (Yasuda and Tomita 2002). Milhorat (1982) assessed CSF production after choroid plexectomy and demonstrated that the total amount of produced CSF was reduced by only one-third suggesting that other sites can produce larger amount of CSF. He proposed that CSF is also produced as the result of cellular metabolism of periventricular cortical

gray matter. The total CSF volume depends on the age of the person and is about five ml in a newborn child and reaches the "adult" volume of 80-150 ml at the age of about five years.

CSF flows from the lateral ventricles into the third ventricle via the foramina of Monroe, flowing through the cerebral aqueduct to the fourth ventricle from which it exits through the foramen of Magendie and the lateral foramina of Luschka into the subarachnoid space. CSF flows around the tentorium and is thought to be re-absorbed into the venous system through arachnoid villi into the sagittal sinus. Some flows towards the lumbar subarachnoid space and has been shown to be re-absorbed from the spinal canal (Edsbagge *et al* 2004). Alternative pathways for CSF have been proposed to include lymphatic drainage into the cervical lymphatic chain and paranasal sinuses (Albright *et al* 2007). CSF has an important protective role for the brain and the spinal cord, regulates the intracranial pressure (ICP) within physiological limits and regulates the extracellular environment in the brain (Emerich *et al* 2005).

1.2.4 Aetiology of hydrocephalus

The underlying cause of hydrocephalus may be obstruction of CSF circulation, reduced re-absorption and, in a few cases, CSF overproduction. In infants, hydrocephalus without an obvious extrinsic cause is usually referred to as congenital hydrocephalus. When hydrocephalus occurs as a complication of another condition such as hemorrhage, infection or neoplasm, it is considered acquired or secondary hydrocephalus. One of the earliest classifications for hydrocephalus was the obstructive/communicating dichotomy devised by neurosurgeon Walter Dandy (Dandy 1920). This binary system remains in use, but a more nuanced system that takes advantage of advances in imaging with a classification system that incorporates the exact point of CSF obstruction has been introduced (Oi 2011).

Idowu *et al* (2011) reported in a Nigerian study that in the pediatric population that congenital hydrocephalus (78.8%) was more common than acquired hydrocephalus with Odeku and Adeloye (1970) noting a similar finding (76.8%) in Ibadan. However, the two studies differed on the cause of congenital nontumoral hydrocephalus with Idowu *et al* (2011) reporting 41% associated with myelomeningocele whereas 30.1% and 23.3% secondary to aqueductal stenosis and Dandy-Walker malformation, respectively. On the contrary, Odeku and Adeloye found that congenital hydrocephalus was accounted for by aqueductal stenosis and Dandy-Walker malformation in 23.8% and 4.3% of cases respectively.

This relatively higher frequency of the congenital form of hydrocephalus is strikingly at variance with findings in Uganda where Warf (2005) indicated that hydrocephalus secondary to CNS infection is the single most common cause of hydrocephalus. Further, Handler *et al* (1978) and Peacock *et al* (1984) had earlier reported that post-infectious hydrocephalus was the most common etiology of hydrocephalus in South African populations. The epidemiology of acquired hydrocephalus is less well described attributable to the heterogeneity of etiology, definitions and affected populations making summary statements problematic and possibly inaccurate.

1.2.5 Pathophysiology of Hydrocephalus

The impact of hydrocephalus on the brain is not only macroscopic, with effects on cerebral physiology, biochemistry and ultrastructure. The macroscopic changes lead to the distortion of structures, such as the compression of white and grey matter which are visible on imaging as enlarged ventricles, thinning of the cortical mantle, distortion of structures, and transependymal CSF seepage. The mechanism behind the ventricular enlargement has been a matter of discussion. It has been posited that there exists a transmantle pressure gradient with

higher pressure inside the ventricles than over the convexity. Stephensen *et al* (2002) however, found no such pressure gradient. In a study by Greitz *et al* (1997), the ventricular dilation in communicating hydrocephalus was explained by 3 main disturbances in hemodynamics with reduced compliance of the arteries, such as arteritis and spasm, reduced compliance of the subarachnoid space, as in meningitis and arachnoiditis, and reduced compliance of the intracranial space.

The distortion of the brain tissue that occurs with hydrocephalus also affects the arteries, veins, and capillaries. Deep vessels are affected the most as they may be directly compressed from the increased ventricular size. Blood flow has been shown to be globally decreased to the brain in acute hydrocephalus and to the periventricular white matter in chronic hydrocephalus (Da Silva *et al* 1995). Hypoperfusion may cause damage to neurons and glia and interfere with normal maturation of all brain structures.

Ventricular expansion displaces the surface of the brain and compresses cortical veins, leading to venous congestion and a subsequent increase in ICP. This expansion of the ventricles also affects the surrounding brain structures and the increase in ICP may cause cerebral oedema affecting white matter and eventually grey matter. Periventricular white matter is especially affected by compression and ischemia with additional a thinning of the corpus callosum and of the cerebral cortex which has significant effects on cognition (Fletcher *et al* 1992).

1.2.6 Diagnosis and imaging of Hydrocephalus

The signs and symptoms of hydrocephalus vary depending on the age and degree of hydrocephalus at presentation, the primary etiology, and the time over which the hydrocephalus develops. Because of the plasticity of the infant brain and the ability of the cranium to expand,

ventriculomegaly can progress without obvious signs of increased intracranial pressure. Diagnostic imaging is important for analysis of ventricular size, clarifying the etiology, planning the surgical intervention and following the changes in ventricular size.

1.2.7 Surgical Management of Hydrocephalus

The treatments of hydrocephalus in the early twentieth century with shunts of different kinds, plexus coagulation and ventriculostomies of various kinds were not successful (Shapiro *et al* 1972, Torkildsen 1939, Ziemnovicz 1950). The mortality rate was high and the developmental outcome poor. The results of treatment from the first half of the twentieth century were evaluated by Hagberg (1962) and Laurence and Coates (1962). The mortality rate varied from 45% to 53% in the different studies. During the fifties, the treatment gradually improved, more and better shunts were introduced and there was a therapeutic breakthrough. The mortality rate decreased successively to about five to 15%.

Most patients today are treated with a ventriculo-peritoneal shunt. During the last fifty years, valves of various kinds have been developed, differential pressure valves, followed by adjustable flow-regulated valves, gravitational and antisiphon valves and devices. Most shunt systems consist of a proximal catheter, a reservoir, a valve to regulate pressure and flow and a distal catheter ending most commonly in the peritoneal cavity where the CSF is absorbed. These devices have been shown to extend survival and lead to improved neurological outcome as well structural benefits of improvement in the cortical mantle size and reorganization of the cortical laminae (Glees *et al* 1988).

The most commonly used shunt in our setup is the Chhabra Shunt which is a relatively inexpensive shunt system, retailing at about $65 locally. It has a slit valve which is girdled by a

stainless-steel spring, which protects and supports the slit valve helping it to maintain the opening pressure. Warf (2012) investigated the 1-year outcomes for shunt treatment comparing the inexpensive Chhabra shunt with the Codman-Hakim Micro Precision Valve shunt and found no statistically significant difference in any outcome category for patients receiving the either shunt. Additionally, Lane *et al* (2014) compared the efficacy of an antibiotic-impregnated shunt (Bactiseal shunt system) with Chhabra shunts in a Uganadan population and reported fewer infections (4 vs 11), but the difference was not statistically significant.

1.2.8 Complications

The failure rate for all implanted shunts has been reported to be about 40% by one year and 50% after two years (Kestle *et al* 2000). There are some predictive factors for repeated shunt failure – the age of the patient at the initial operation and the time interval since the prior surgical revision (Tuli *et al* 2000). The risk of shunt infection is 8-10% during the first months in large trials (Enger *et al* 2003**)**. It is highest during the first two months after surgery and 90% of these infections occur during the first six months (Baird *et al* 1999). Infectious complications are responsible for increased morbidity and mortality and lengthy hospitalisation periods. Published rates of CSF shunt infection vary widely from study to study, due in part to differences in study design, definition of shunt infection and duration of surveillance (Vinchon and Dhellemmes 2006, Frykberg and Olden 1983, Kestle *et al* 2000, Cochrane and Kestle 2003).

Non-infectious shunt complications include obstructions, over-drainage, mechanical malfunction, ventricular loculations and abdominal complications. Obstruction can occur at any time after shunt surgery. The most common forms of late shunt failures are fractures of the catheter, over-drainage and abdominal complications such as pseudocysts or perforations.

Locally, there are disparate reports on the rate and causes of ventriculoperitoneal shunt complications. Mwachaka *et al* (2010), in a retrospective study, similarly reported that the most common complication was obstruction, followed by migration and infection. Complementary findings, in unpublished thesis manuscripts, were reported by Omulo *et al* (1993) and Gichuhi *et al* (1989) who reported that the most common reason for shunt revision was shunt blockage, accounting for 52.6% and 38.2% respectively, of indications for shunt revision. However, Noorani *et al* (2003) reported that shunt infection was the most common form of shunt complication (19.8%) with shunt blockage accounting for 9.2% of patients in their series. Additionally, Mwang'ombe and Omulo (2000) reported that shunt infection rates of 24.6% with staphylococcus aureus and coagulase negative staphylococci as the two most commonly isolated micro-organisms

1.2.9 Shunt Registries

Shunt registries have been shown in other populations to provide valuable information about the standard of care offered to patients and are amenable to quality control and statistical evaluation, which in turn allow improvements and amendments in the definite care. Over recent years, many databases on hydrocephalic injured patients have been developed. Some have been designed for data collection during drug clinical trials, others to investigate epidemiology, severity, clinical features and outcome. They have demonstrated the possibility to collect comprehensive, credible data through an organisation with strong commitment but only modest resources.

Steinbok *et al* (2010) established a multi-center multi-national registry for assessing ventriculoperitoneal shunt infections for hydrocephalus. Their reported data accounted for a total

of 440 patients were entered into the registry at 10 sites: 3 in North America, 2 in Singapore, 4 in China and 1 in India. Their principal assessment was for the utility of antibiotic impregnated shunts in an attempt to reduce shunt infection. Their overall shunt infection rate was lower than in previous multi-centered studies. However, given the low rate of AI catheter use, the authors concluded that no meaningful statement regarding the value of AI catheters in reducing the infection rate could be made (Steinbok *et al* 2010). They therefore recommended performing a well-designed, adequately powered, prospective randomized controlled trial to determine whether antibiotic impregnated catheters reduce shunt infection.

Other shunt registries that have been reported include the United Kingdom shunt registry (O'Kane *et al* 1997) and the Australasian shunt registry (Pham *et al* 2013). The Hydrocephalus Clinical Research Network is the North American equivalent aimed at producing research-based evidence to improve the diagnosis, treatment and outcomes of hydrocephalus patients (Kestle *et al* 2009; Pham *at al* 2013;Kulkarni *et al* 2013). Additionally, according to the United Kingdom's NHS specification standards for the children's neuroscience network published December 2011, all units undertaking treatment of paediatric patients with hydrocephalus are required to be involved in national audit. These shunt registries have been designed to collect continuous, standardized, large sets of data for analysis for the purposes of enhancing quality of care, ensuring appropriate resource allocation, and offering evidence of hydrocephalus incidence and care. Moreover, it has been shown that registries are plausible and valuable tools for disease surveillance.

CHAPTER TWO

2.1 Statement of the problem

Hydrocephalus remains one of the common conditions managed by any neurosurgical service. The annual incidence of infant hydrocephalus in sub-Saharan Africa is unknown. Warf (2010) estimated the incidence of hydrocephalus in Uganda and extrapolated this to the East African region concluding that the burden of infant hydrocephalus in East Africa is significant, with more than 6000 new cases estimated per year. Incidence data on hydrocephalus in Kenya is lacking. However, using our population data and rates from developed countries to estimate incidence, 826 new cases of congenital hydrocephalus and between 4900 to 8200 new cases of neonatal hydrocephalus are predicted each year in Kenya (Salvador *et al* 2014). This predicts a large patient number and significant surgical case load and resource strain on the limited neurosurgical services available.

Despite the fact that CSF diversion with ventriculoperitoneal (VP) shunt placement has been the mainstay of management in both pediatric and adult hydrocephalus, VP shunts still have noteworthy complications and failure rate (Lo and Drake 2001; Drake *et al* 2000). A VP shunt complication is a major obstacle in the management of hydrocephalus. The incidence of complications following VP shunt placement is reported to be around 20 to 40% (Al-Tamimi *et al* 2014; Farahmand *et al* 2009; Reddy GK, *et al* 2014). However, over a much longer follow-up period these figures increase dramatically.

2.2 Justification of the Study

An extensive literature search by the principle author did not reveal existence of any shunt registry in Africa. The value of such a data collection and collation method would be immense given the case load of hydrocephalus and the need to assess outcomes for continued improvement of the care provided to our patients. The factors concerning malfunction in a resource limited setting are magnified, and a standard registry for data collection would be essential to assess standard of care and risk factors for shunt failure. The periodic evaluation of patients who are managed with VP shunt placement for hydrocephalus cannot be overlooked. By studying the patterns of shunt survival extensively, one can attempt to predict the behavior of VP shunt functioning from the time of placement to subsequent follow-up. Establishing a protocol has been shown in other population settings to be effective in lowering the risks of shunt malfunction. For this to be achieved in our setup, assessment of associated risk factors would be an important initial step towards achieving this goal. It is envisioned that a protocol for the management of hydrocephalus will be developed in our setup to improve patient care and outcomes.

2.3 Study Question

What are the factors associated with shunt survival at the Kenyatta National Hospital? 2.4 Objectives

2.4.1 Broad Objective:

This study therefore would establish a shunt registry at the Kenyatta National hospital to assess the patient characteristics, etiology of hydrocephalus, and factors associated with shunt survival at the Kenyatta National Hospital.

2.4.2 Specific Objectives:

1. To establish the demographic characteristics of patients with hydrocephalus treated by ventriculoperitoneal shunt placement at the Kenyatta National hospital.
2. To evaluate indications for ventriculo-peritoneal shunt insertion at the Kenyatta National Hospital.
3. To assess the rate of shunt malfunction at the Kenyatta National Hospital.
4. To evaluate the factors associated with shunt survival at the Kenyatta National Hospital.

CHAPTER THREE

3.0 Patients and Methods

3.1 Study area:

The Kenyatta National Teaching and Referral Hospital.

3.2 Study design*:*

A prospective, non-controlled, open-label registry to investigate patients with de novo catheter implantation or catheter replacement of an existing ventriculoperitoneal shunt.

3.3 Ethical Considerations

Ethical approval was sought from the Kenyatta National Hospital-University of Nairobi Ethics and Research Committee (KNH/UON- ERC) before commencement of the study. Permission and requisite authority was obtained from the administration of the KNH medical records archives.

All patients and/or next of kin participating in the prospective arm were requested to give informed consent to participate in the study after a detailed explanation of the study objectives and proposed methodology. It was outlined that participation, or opting out of the study, did not affect the quality of care provided. Participation was on a completely voluntary basis. Information regarding the subjects was held with maximum confidentiality and not disclosed to any unauthorized persons. Data sheet serial numbers, and not names or other identity particulars, were used throughout the study. No copies or photographs of medical records were made or taken out of the confines of the KNH medical records archives. No unnecessary details will be

disclosed during data dissemination either in this thesis manuscript, publications in journals or conference presentations.

3.4 Study Protocol

3.4.1 Study Period

The study was carried out between October 2015 and March 2017.

3.4.2 Sample size determination

Sample size is estimated using the following formula

$N= Z^2 p (1-p)/ d^2$

Where:

N is the sample size

Z is the critical value and using a confidence interval of 95%, this value is 1.96.

P represents prevalence. Al-Tamimi *et al* (2014) reported an early shunt failure rate of 12.9%.

'd' is precision and width of the confidence interval of 10%, this value is set at 0.05.

Thus when substituted into the formula

1.96^2 x 0.129 (1-0.129)/ 0.05^2 = 172.6

Therefore 173 patients were to be recruited for the study.

3.4.3 Sampling procedure

Consecutive sampling technique was employed whereby every subject meeting the criteria of inclusion and who consented to participate was selected.

3.4.4 Inclusion criteria

All patients with a clinical and radiological diagnosis of hydrocephalus who were managed by ventriculoperitoneal shunt placement and who gave informed consent were included in the study. Procedures were classified as shunt insertion (insertion of a shunt in a patient who had not had one previously), shunt revision (surgery in which a patient entered the operating room with all shunt equipment previously implanted and left the operating room with a revised shunt), shunt

insertion after external ventricular drainage, and shunt insertion after a failed endoscopic third ventriculostomy.

3.4.5 Exclusion criteria:

All patients who willingly opted out of the study were excluded from the data collection and collation.

3.5 Data Collection and Analysis

3.5.1 Data collection procedure

Relevant data was retrieved manually from patients' medical records and from interview of the patients or their next of kin by the principal investigator. It was then coded and input in a preformed data collecting sheet (Appendix 3). Patients' names, physical addresses, ethnicity, race or other identifying particulars were not recorded. However, file numbers and contact details were separately collected for the purposes of follow-up but these do not feature in the analyzed or presented data. Information regarding the age, sex, etiology of hydrocephalus, operative procedure performed, existing comorbidities, previous neurosurgery and outcome were recorded. Follow up was made at neurosurgery clinics and outcomes assessed and recorded. The primary outcome of interest of this prospective clinical study was shunt survival. Causes of shunt failure were also determined.

3.5.2 Data management and statistical analysis

Data were recorded on a pre-tested proforma. Statistical procedures included frequency determination, mean and standard deviation, and Pearson's Chi-square test for comparison of proportions. The Student's *t*-test and independent sample *t*-test or the Mann–Whitney U test was

used for comparison of means or medians, respectively. For all comparisons, a $P < 0.05$ was considered statistically significant. Kaplan–Meier curves were used to determine duration from shunt placement to first malfunction. The log-rank (Mantel–Cox) test was used to determine the factors affecting shunt survival. Data entry and statistical analysis were performed on Statistical Package for Social Sciences version 19 (IBM SPSS Statistics 19, IBM Corporation, Chicago, Illinois). Data is presented in prose, tables and charts.

CHAPTER FOUR: FINDINGS

4.1 Results

During the study period, 154 patients met the inclusion criteria and were recruited in the study. Of these, there was slight male predominance, with 86 (55.8%) male and 68 (44.2%) female patients (Figure 1). The age of the patients ranged from 3 days to 61 years with a mean and median age at presentation of 3 years and 3.5 years (SD 8.64) respectively. Majority of the patients (102 patients; 66.2%) were aged less than 5 years (Figure 2).

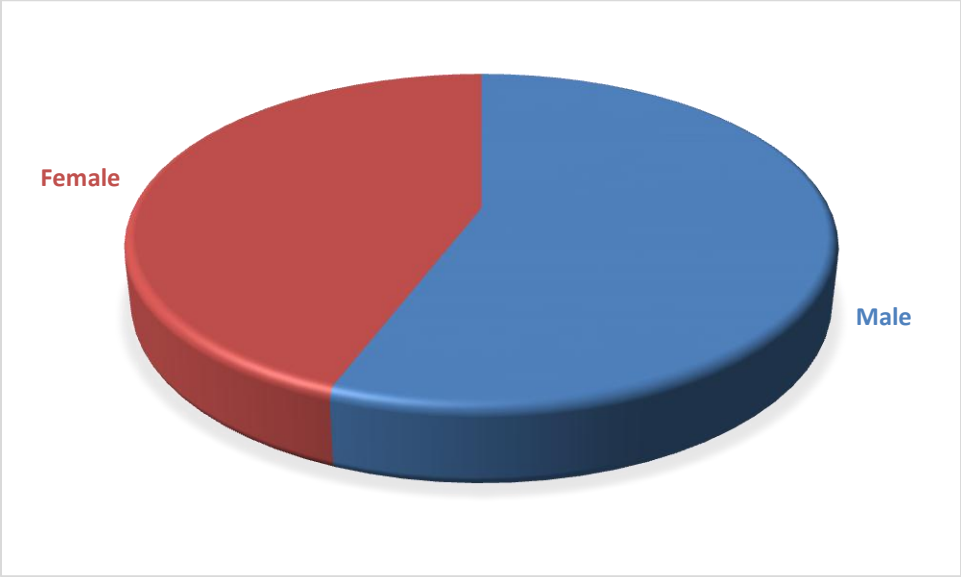

Figure 1: A pie chart illustrating the distribution of patients by age.

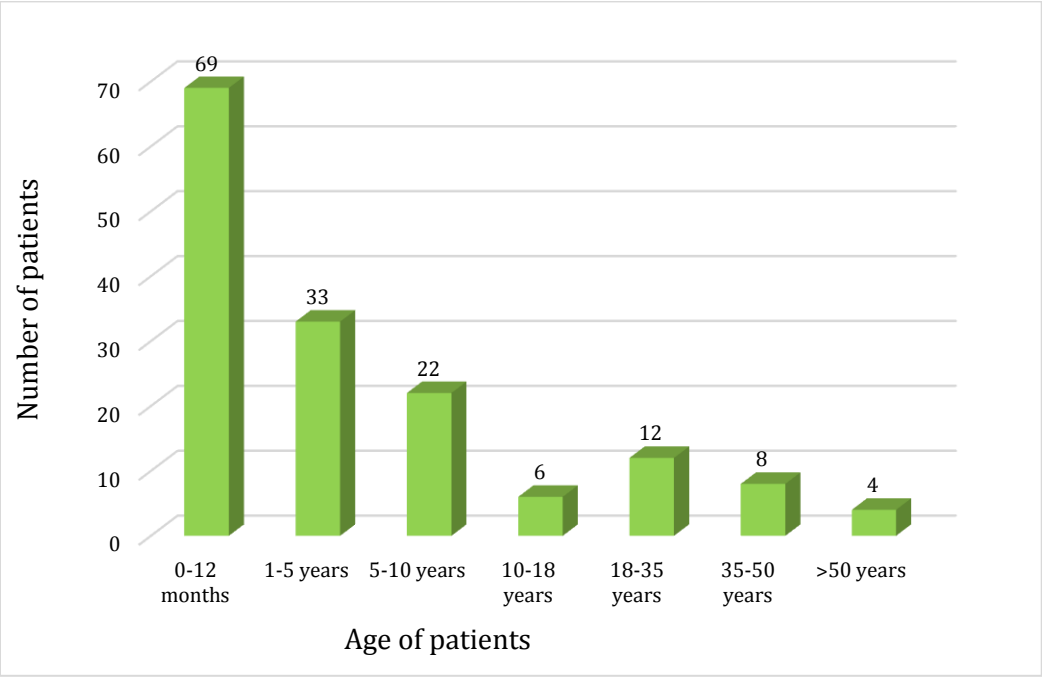

Figure 2: The distribution of patients by age portrayed as a bar graph

Based on pertinent patient history, imaging findings (ultrasonography and CT scanning) and CSF parameters, the etiology of hydrocephalus was determined. The category of post-meningitic hydrocephalus was used in cases in which one of the following criteria were met:

1. There was a clear history of meningitis, which was followed by onset of the hydrocephalus
2. Ultrasonography and CT scans demonstrated post-infectious sequelae such as multi-loculation in the ventricles

Accordingly, majority of the patients (88 patients; 57.1%) had post-meningitic hydrocephalus while posttraumatic hydrocephalus was the least common (Figure 3). Moreover, when analyzed against age at presentation, post-infectious hydrocephalus was more common in younger patients representing 44 patients (63.8%; n=69) aged less than 1 year. Hydrocephalus

associated with tumors accounted for 13% (20 patients) of the patients in this study and was most common in children aged between 5 and 10 years (Table 1).

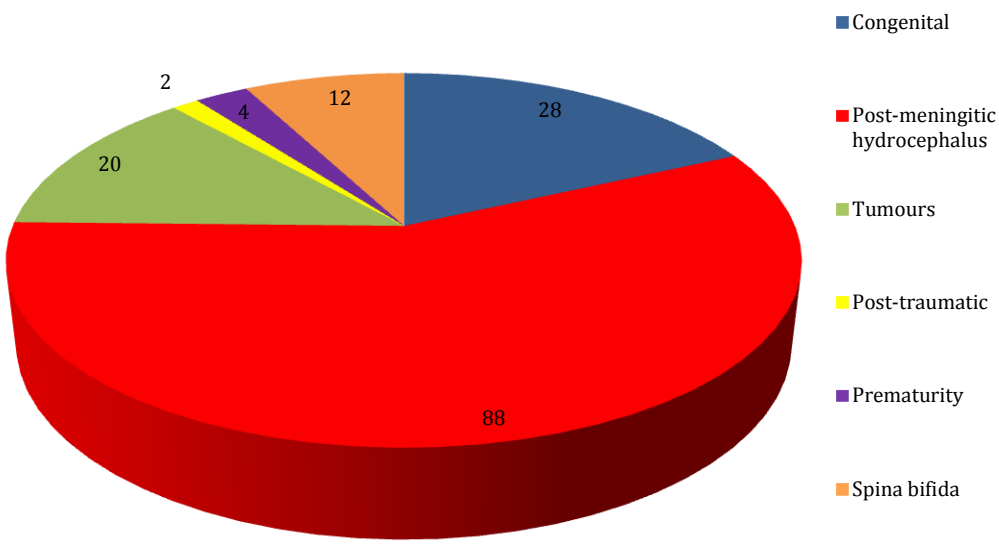

Figure 3: A pie chart demonstrating the various etiologies of hydrocephalus

Age	Congenital	Post-meningitic Hydrocephalus	Tumors	Post-traumatic	Prematurity	Spina bifida	Total
0-12 months	15	44	0	0	4	6	69
1-5 years	10	15	2	0	0	6	33
5-10 years	3	7	12	0	0	0	22
10-18 years	0	4	2	0	0	0	6
18-35 years	0	9	2	1	0	0	12
35-50 years	0	5	2	1	0	0	8
>50 years	0	4	0	0	0	0	4
Total	28	88	20	2	4	12	154

Table 1: The distribution of the etiology of hydrocephalus against age-at-presentation

Of the children with congenital hydrocephalus (28 patients), majority had aqueductal stenosis (12 patients) while Chiari malformation and Dandy Walker malformations accounted for 7 and 6 patients respectively (Figure 4).

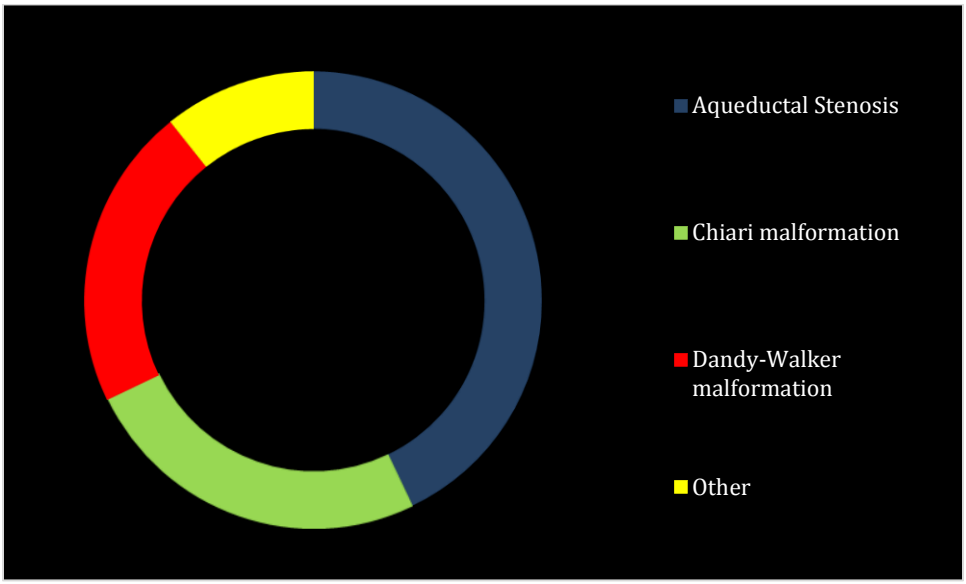

Figure 4: Distribution of the children who presented with congenital hydrocephalus

Computed tomography scans were available for 148 patients while cranial ultrasounds were available for 56 patients.

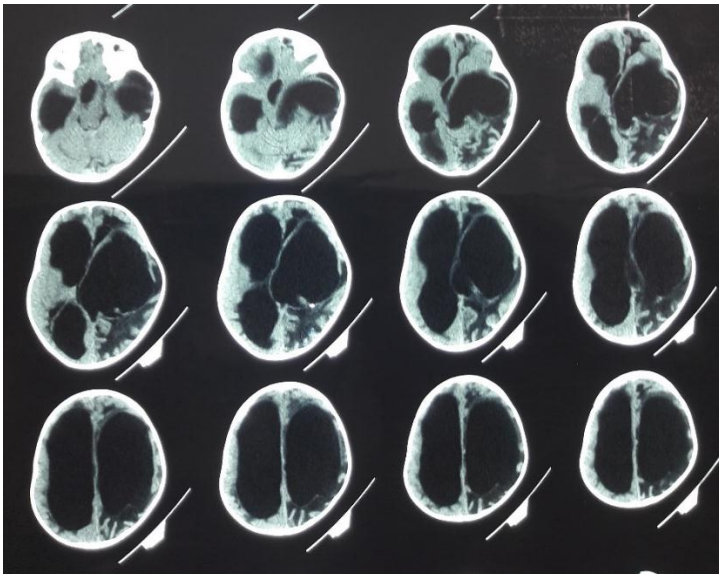

Figure 5: Axial pre-contrast CT scans of a 3-year old with a history of neonatal meningitis at the age of 3 months. Note the lateral and third ventriculomegaly and intraventricular septa isolating the left lateral and posterior horn of the right lateral ventricle. An endoscope-assisted VP shunt was inserted with a good outcome

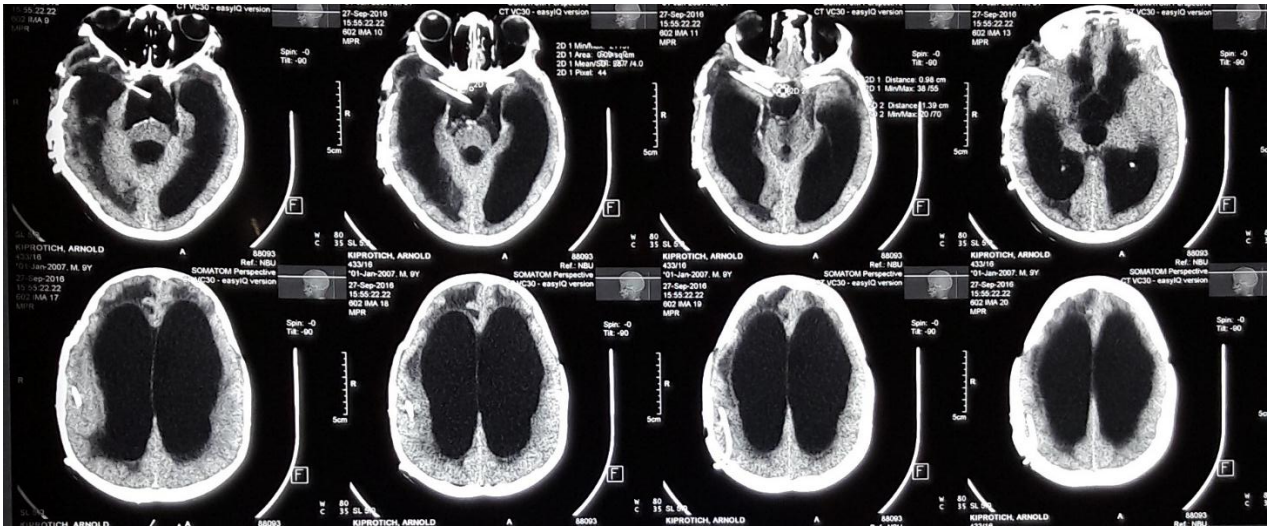

Figure 6: Post-operative axial CT scans of an 11 year old following craniotomy for a craniopharyngioma with an Ommaya reservoir in-situ. Note the marked ventriculomegaly with periventricular CSF seepage. Hydrocephalus was managed by VP shunt insertion and the child started on hormone replacement therapy.

Depending on the clinical condition of the patients, they were managed in general wards, special care units or intensive care units. Of the 154 patients recruited during the study period, 111 (72.1%) had primary VP shunt insertions, 32 (20.7%) had shunt revisions, while 8 and 3 had shunt insertions after EVD and ETV failure respectively. The median time delay from arrival and diagnosis of hydrocephalus to the first VP shunt insertion at KNH was 10 days (mean 11 $\pm$ 16 days). The mean duration of hospital stay was 21.6 $\pm$ 1.1 days. A right-sided shunt was placed in 142 (92.2%) patients, while the remaining 12 (7.8%) patients received a left-sided shunt.

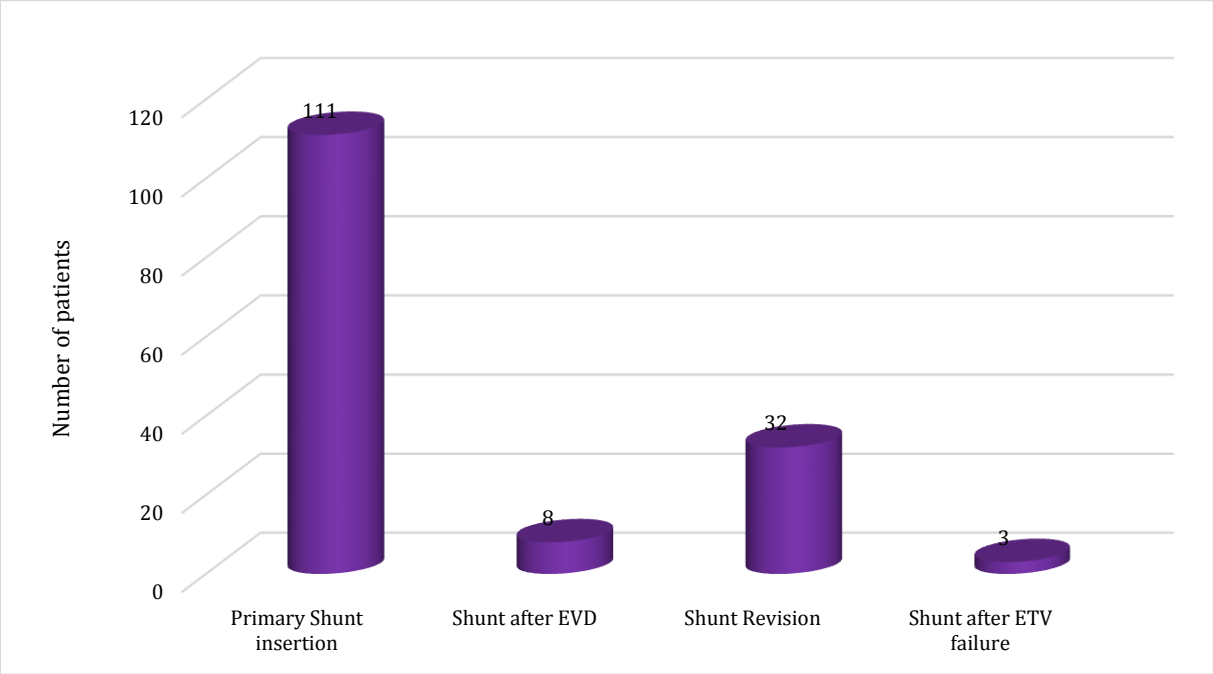

Figure 7: A bar graph showing the distribution of shunting procedures carried out upon recruitment

Eight patients had an EVD inserted due to symptomatic hydrocephalus in the setting of an active infection. Of these, 6 patients had an EVD for a duration between 1 and 2 weeks while one patient each had the EVD for less than 1 week or greater than 2 weeks. Of the 32 patients who were recruited for revision of their shunts, 28 had undergone the original VP shunt insertion at KNH while 4 had been carried out at other facilities. The average time from the first shunt

insertion to presentation for revision was 3.5 months ± 4.1 months (range 0.1-18 months) with majority of the revisions being done in the first 3 months (Figure 8). Majority of these shunts were being revised due to blockage and shunt infection (Figure 9).

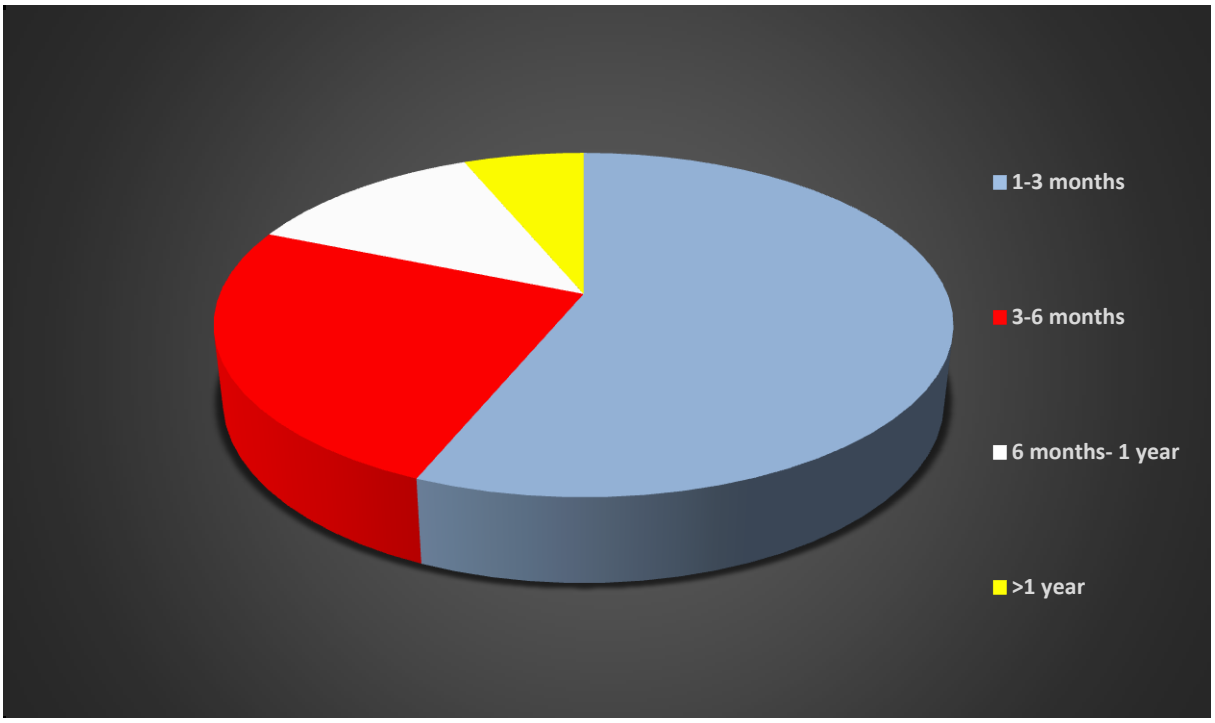

Figure 8: A pictorial representation of the duration of shunt revision after original VP shunt insertion

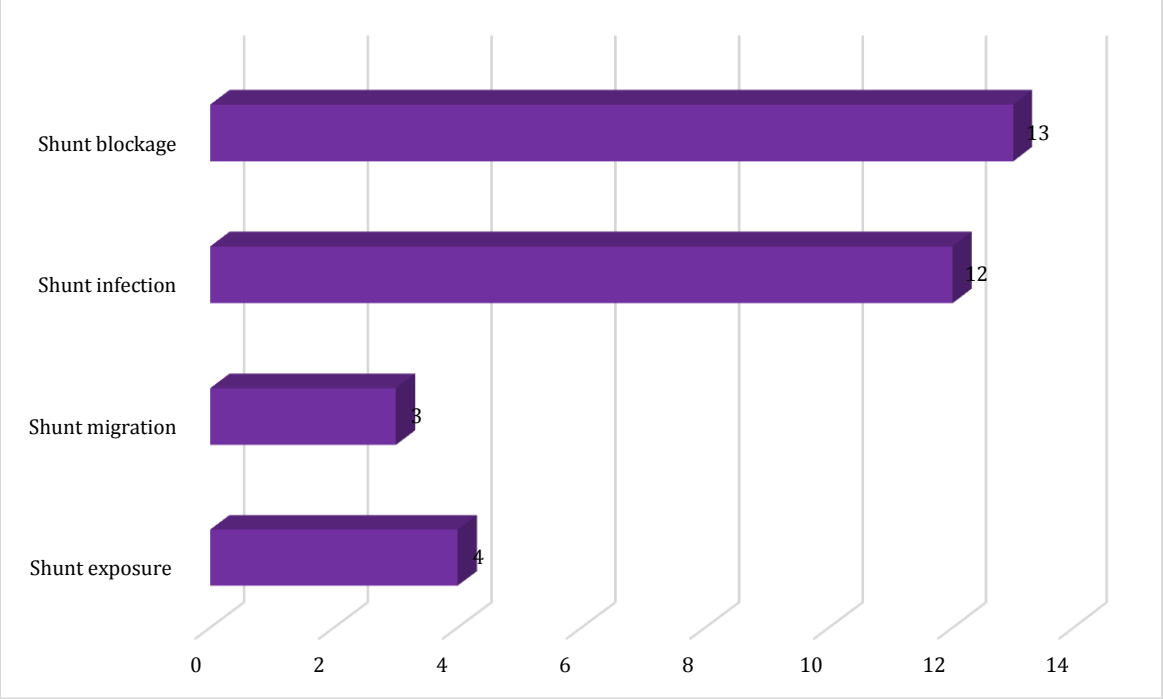

Figure 9: A bar graph showing the indications for VP shunt revision

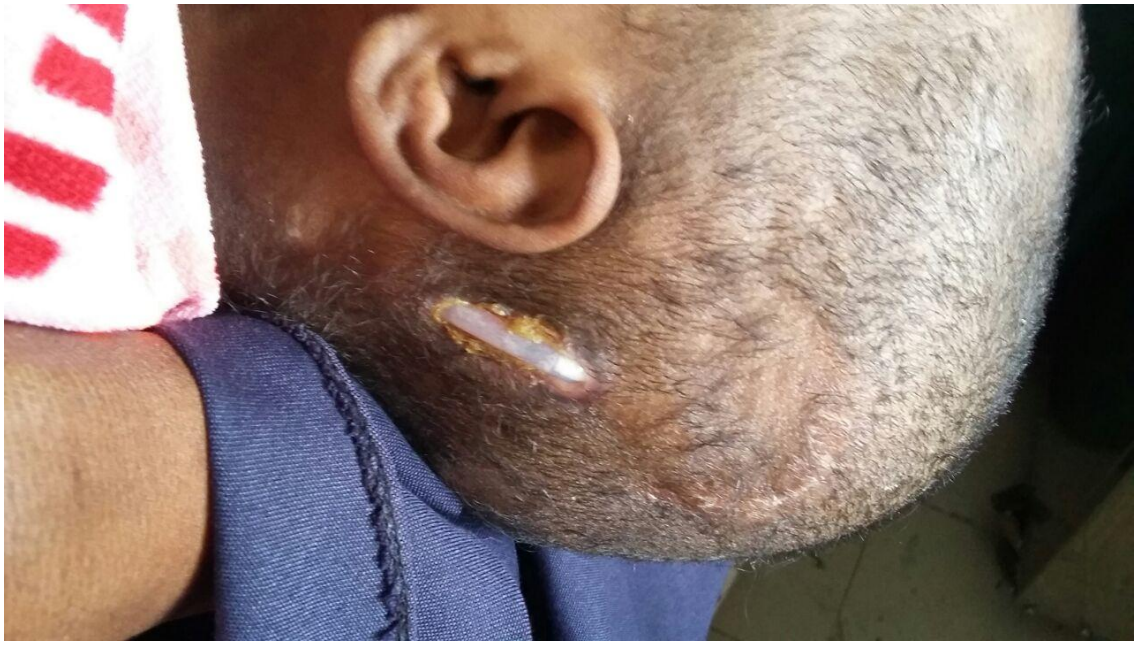

Figure 10: A photograph of a 6 month old child who had been shunted 3 months prior who presented with an exposed VP shunt that had eroded through skin. The child had no systemic features of infection, a no leukocytosis on hemogram and sterile CSF on culture. The exposed shunt was removed and a new shunt placed on the opposite side.

All the VP shunt insertions were performed by residents in their senior 4th to 6th years of residency, majority of whom were in their 5th year as illustrated by Figure 11.

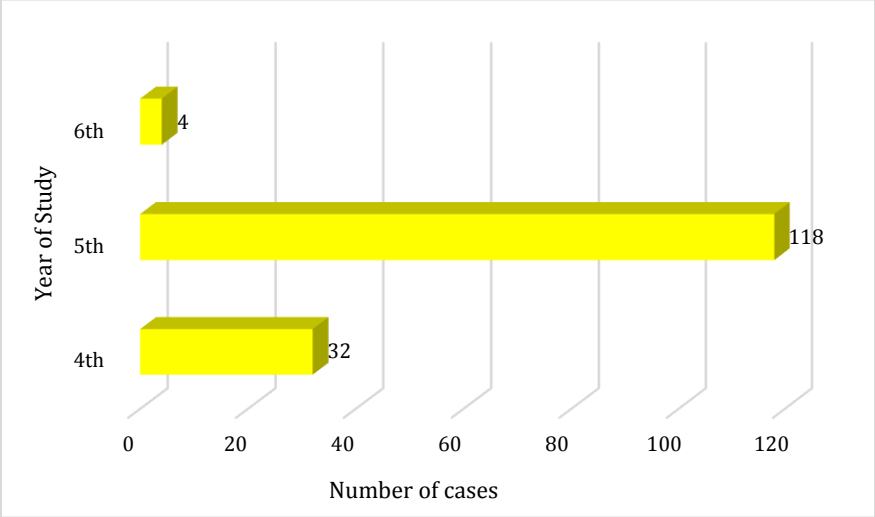

Figure 11: Representation of the year of study of the residents who performed the ventriculoperitoneal shunts

Follow-up was available for all 154 patients with a mean follow-up period of 162 days (90-390 days). A total of 35 patients (22.7%) had 39 complications within the study period, while the incidence of shunt revision was 17.1%. The overall median time from shunt placement to shunt malfunction was 69 days $\pm$ 17 days (range 2-132 days). Notably, no significant intra-operative complications were observed. Early complications were recorded in 3 patients (1.9%); 2 suffered cardiorespiratory arrests and died on post-operative days 2 and 4 after uneventful shunt insertion procedure while another had aspiration pneumonia with a fatal outcome. All of these patients had a Glasgow coma scale (GCS) lower than 5 preoperatively. Four more patients died during the follow-up period bringing the overall mortality to 4.5% (7 patients).

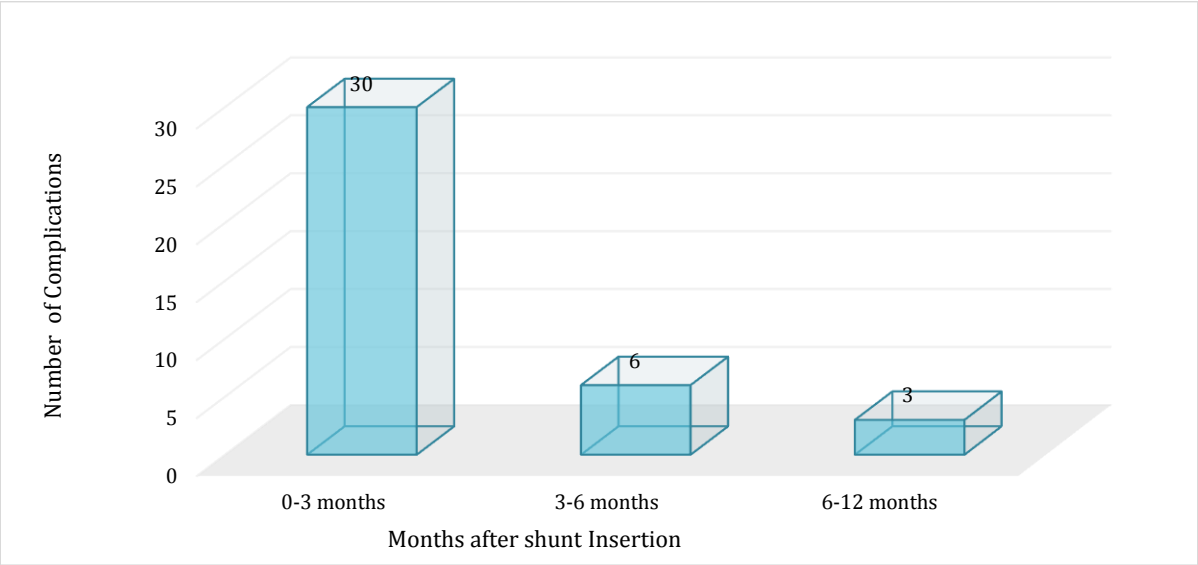

Figure 12: An illustration of the distribution of shunt complications over time after VP shunt insertion.

The most common causes of shunt malfunction were shunt blockage (*n*=16, 10.4%), shunt infection (*n*=14, 9.1%), shunt migration (*n*=3, 2%), CSF leaks (*n*=4, 2.6%) and hollow viscus perforation 2 (1.3%) (Table 2). Of the 35 patients who experienced shunt malfunction, two suffered both shunt blockage and shunt infection while 2 more had CSF leaks and shunt infection.

SHUNT COMPLICATION	NUMBER	PERCENTAGE
Shunt Blockage	16	10.4%
Shunt Infection	14	9.1%
Shunt migration	3	2%
CSF leak	4	2.6%
Hollow viscus perforation	2	1.3%

Table 2: The frequencies of the various types of complications

The development of shunt malfunction was significantly influenced by the principal etiology of the hydrocephalus (P = 0.030). Of 88 patients with post–infectious hydrocephalus, 12 had shunt malfunction (P = 0.580). Nine of these patients underwent shunt revision. Out of the 20 patients with hydrocephalus secondary to tumors- some of which were post-excision and the rest were diagnosed during admission – 10 (50%) developed shunt malfunction (P = 0.0328) and all of them had shunt revision. Of 28 patients with congenital hydrocephalus, 3 developed shunt malfunction (P = 0.248); shunt revision was performed in all of them (Table 3). Descriptive statistics for variables that were collected on the initial procedure performed for each eligible patient are presented in Table 3 for 90- and 180-day failure from the first index procedure. Among the 154 shunt operations there were a total of 39 shunt failures, yielding a shunt failure rate of 19.4% within 90 days and 23.4% within 180 days.

Variable	**90-Day Failure, No. (%)**	**180-Day Failure, No. (%)**	**Overall No. (%)**
Age categories			
Birth–12 mos	8 (11.6%)	10 (14.5%)	69 (44.8%)
1yr–10 yrs	4 (7.3%)	5 (9.1%)	55 (35.7%)
10–18 yrs	2 (33%)	3 (50%)	6 (3.9%)
>18 yrs	16 (66.7%)	20 (83%)	24 (15.6%)
Sex			
Female	12 (17.6%)	14 (20.6%)	68 (44.2%)
Male	18 (20.9%)	22 (25.6%)	86 (55.8%)
Etiology of hydrocephalus			
Congenital	2 (7.1%)	3 (10.7%)	28 (18.2%)
Post-meningitic hydrocephalus	16 (18.2%)	18 (20.5%)	88 (57.1%)
Spina bifida	3 (25%)	4 (33%)	12 (7.8%)
Neoplastic	8 (40%)	10 (50%)	20 (13%)
Prematurity	1 (25%)	1 (25%)	4 (2.6%)
History of shunt or ventricular infection			
Yes	8 (66.7%)	10 (83%)	12 (7.8%)
No	22 (15.5%)	26 (18.3%)	142 (92.2%)
Index surgery due to recently treated shunt blockage			
Yes	8 (61.5%)	10 (76.9%)	13 (8.4%)
No	22 (15.6%)	26 (18.4%)	141 (91.6%)
Index surgery performed after			

elective intradural surgery			
Yes	8 (40%)	10 (50%)	20 (13%)
No	22 (16.4%)	26 (19.4%)	134 (87%)
Type of index surgery			
Shunt revision	8 (25%)	9 (28.1%)	32 (20.8%)
New placement	18 (16.2%)	22 (19.8%)	111 (72.1%)
Shunt after EVD	4 (50%)	5 (62.5%)	8 (5.2%)

Table 3: Descriptive statistics for each variable for 154 patients at the time of the first index shunt surgery and for 90- and 180-day shunt failures from that initial index surgery

Kaplan–Meier shunt survival analysis for adult hydrocephalus shows overall median time to first shunt failure was 69 days. Shunt survival time ranged from 0 to 362 days. Out of 39 shunt malfunctions, 30 occurred before 90 days.

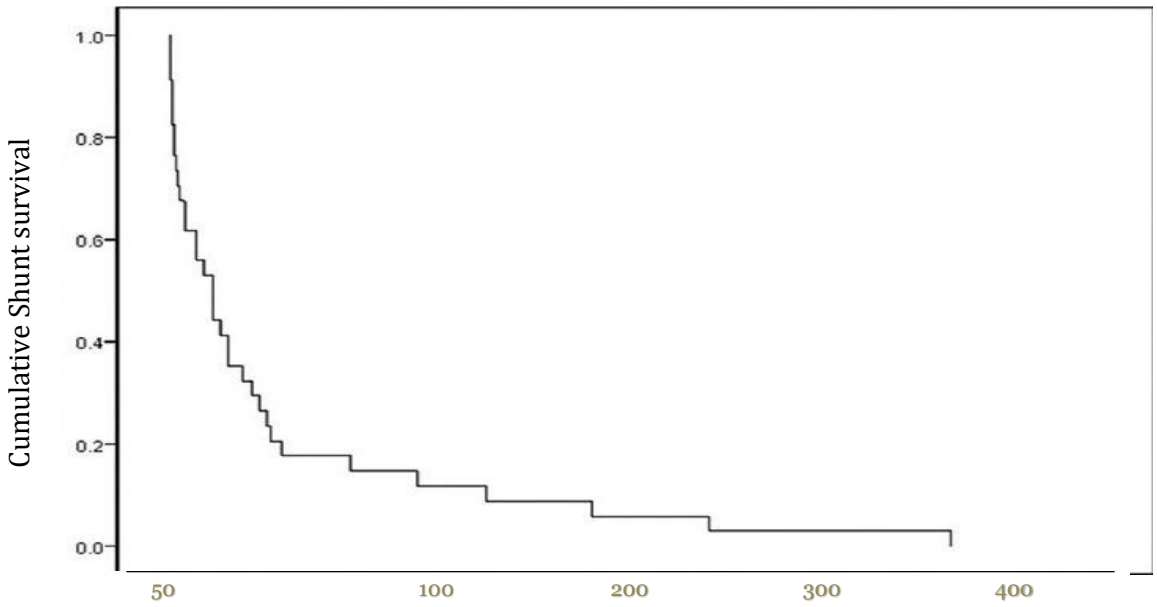

Figure 13: Kaplan–Meier shunt survival analysis for hydrocephalus showing overall median time to first shunt failure of 69 days. Shunt survival time ranged from 0 to 362 days.

Bivariate results of variables with $p < 0.2$ were further examined in the multivariate model to assess the significance of each factor and its effect on 180-day shunt failure (Table 3). Additionally, Kaplan–Meier plots showed that the median time from shunt placement to first shunt failure was significantly different among all individuals in principal etiologies ($P = 0.003$, log-rank test) (Figure 14). Patients' gender did not show significant statistical difference in median time from shunt placement to first shunt failure between male and female individuals ($P = 0.671$, log-rank test) or medical co-morbidities ($P = 0.701$, log-rank test). Time to first shunt failure for adult patients was significantly lower than that for paediatric patients ($P < 0.001$, log-rank test), ranging between 4 and 120 days. Duration of hospital stay was statistically significant for median time to shunt failure ($P < 0.001$, log-rank test). Difference in median time from shunt placement to first shunt failure between the different types of brain tumor ($P = 0.062$, log-rank test) and the different locations of brain tumor ($P = 0.378$, log-rank test) failed to reach statistical significance. Past medical history of the patient did not significantly affect the median time of shunt survival.

Variable	**OR**	**95% CI**	**P Value**
Age in years	1.0107	(0.9769–1.0457)	0.0451
Age categories			
Birth–12 mos	1.1218	(0.6284–2.0023)	0.0675
1yr–10 yrs	1.3187	(0.7285–2.3871)	0.0360
10–18 yrs	1.2243	(0.6757–2.2184)	0.0504
>18 yrs	0.6314	(0.1757–2.2694)	<0.001
Sex (Male vs Female)	0.8611	(0.5680–1.3055)	0.671
Etiology of hydrocephalus			0.003
Congenital	1.1575	(0.6252–2.1430)	0.6417
Post-meningitic hydrocephalus	1.2313	(0.1861–0.9702)	0.580
Spina bifida	1.1663	(0.6074–2.2395)	0.0340
Neoplastic	1.2846	(0.5889–1.6460)	0.0328
Prematurity			
Prior ventricular shunt surgery	1.6712	(0.9202–1.0836)	0.0972
History of shunt or ventricular infection (yes)	1.6060	(0.7584–3.4008)	0.0215
Index surgery due to recently treated shunt blockage (yes)	1.3880	(0.4966–3.8793)	0.0531
Index surgery performed after elective intradural surgery (yes)	1.4447	(0.7611–2.7423)	0.0260
Type of index surgery			0.0335
Shunt revision	1.4256	(0.6507–3.1233)	0.0375
New placement	0.6292	(0.3052–1.2974)	0.0209
Shunt after EVD	1.1184	(0.6564–1.9056)	0.0680
Primary surgeon			0.0642
4th year	0.7384	(0.4086–1.3342)	0.0515
5th year	0.5979	(0.2815–1.2700)	0.0680
6th year	0.5145	(0.2554–1.0365)	0.0629

Table 4: Bivariate results for 180-day shunt failure

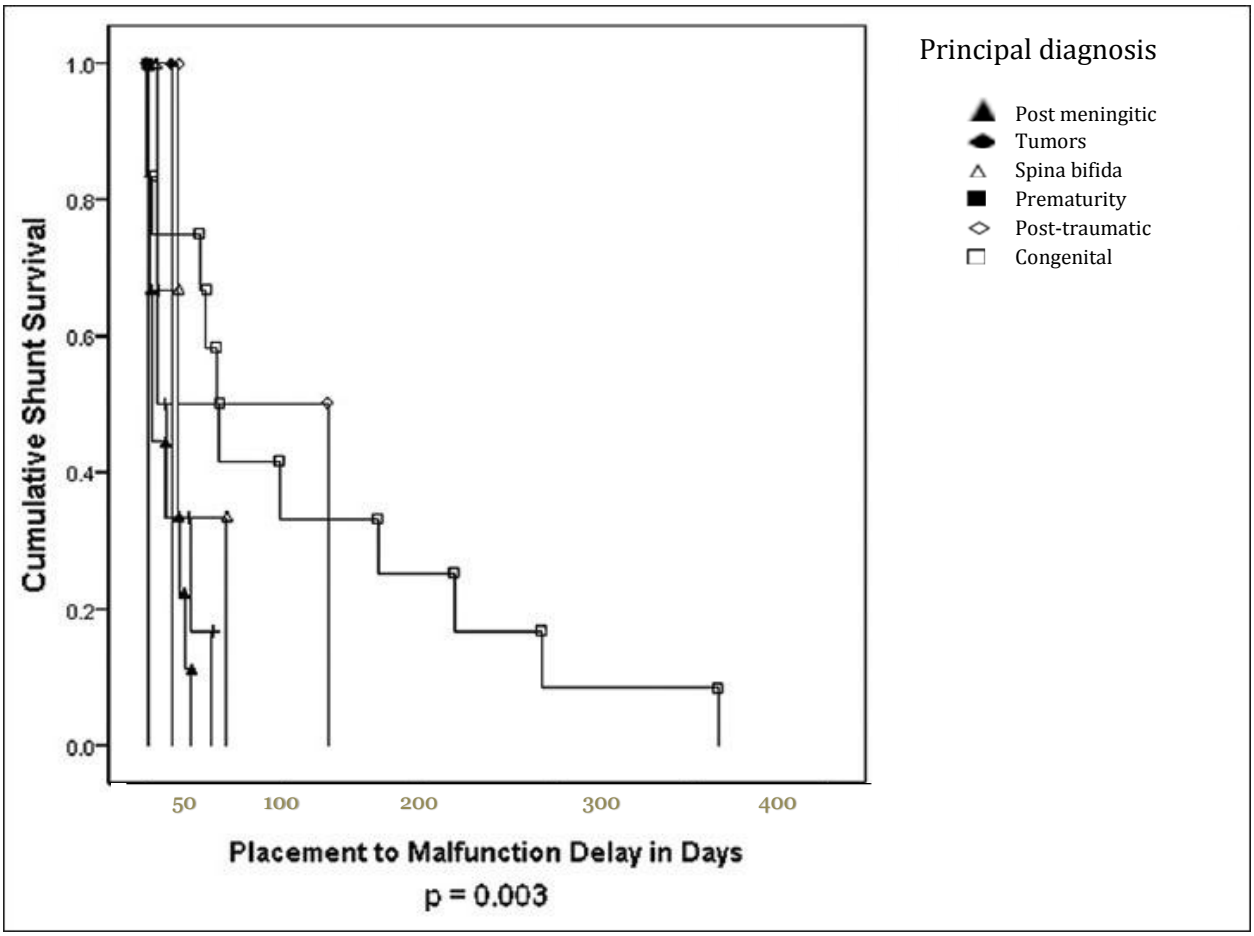

Figure 14: Kaplan–Meier shunt survival analysis for hydrocephalus which showed that etiologies of hydrocephalus significantly differed in median time to first shunt failure (P = 0.003, log-rank test).

Patients who had a GCS score of less than 13 were found to experience early shunt failure (P = 0.010, log-rank test) as shown in Figure 15. Similarly, drowsiness or altered consciousness on presentation was found to have a significant effect on shunt survival (P = 0.010, log-rank test). This adverse impact of drowsiness or altered consciousness on the medial shunt failure time was independent of the etiology of hydrocephalus. Similarly, median shunt survival time was also found to be significantly affected by the placement of extra-ventricular

drains (P = 0.033, log-rank test) before VP shunt Figure16. Side of shunt (P = 0.882, log-rank test), hospital care units (P = 0.171, log-rank test), and level of training of surgeon (P = 0.203, log-rank test) were not found to have any significant effect on median shunt survival time.

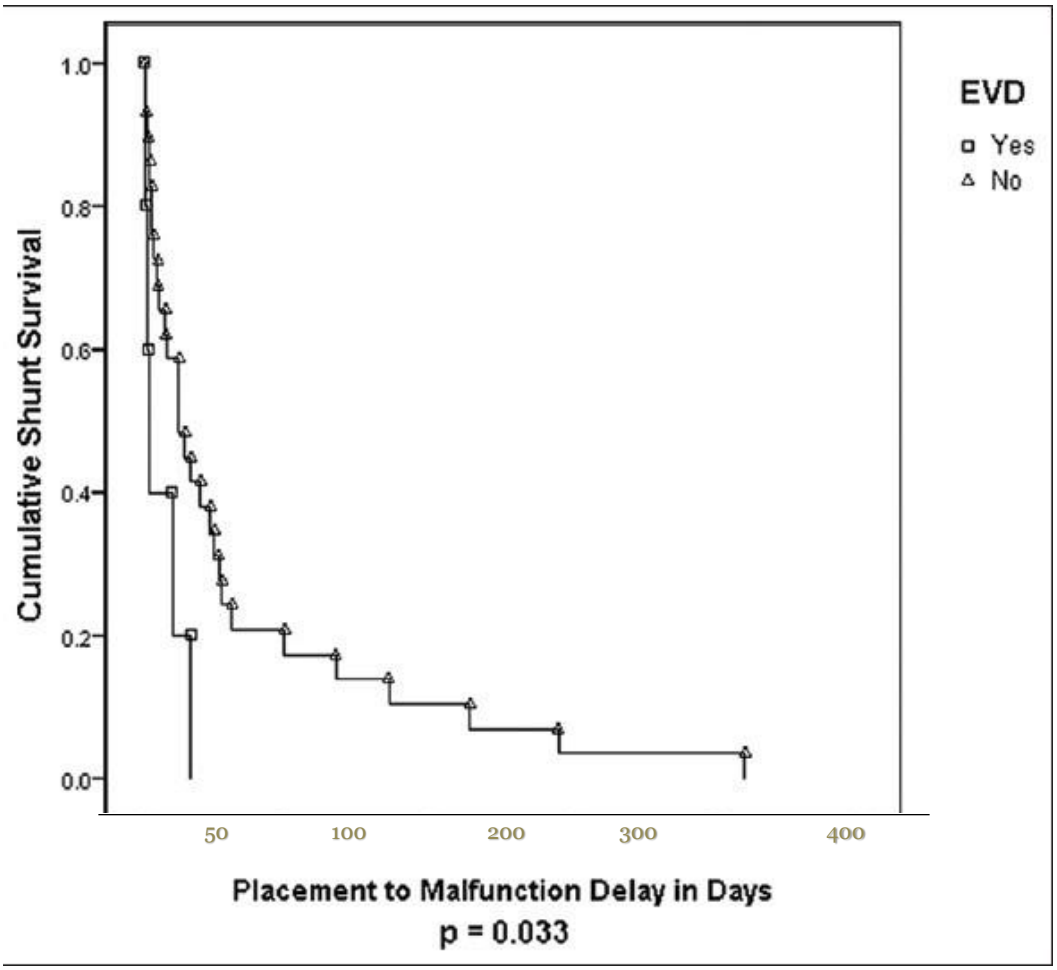

Figure 15: Kaplan–Meier shunt survival analysis for hydrocephalus shows that median time to first shunt failure was significantly different among patients who underwent extra-ventricular drain and those who did not (P = 0.033, log-rank test). EVD: Extra-ventricular drain

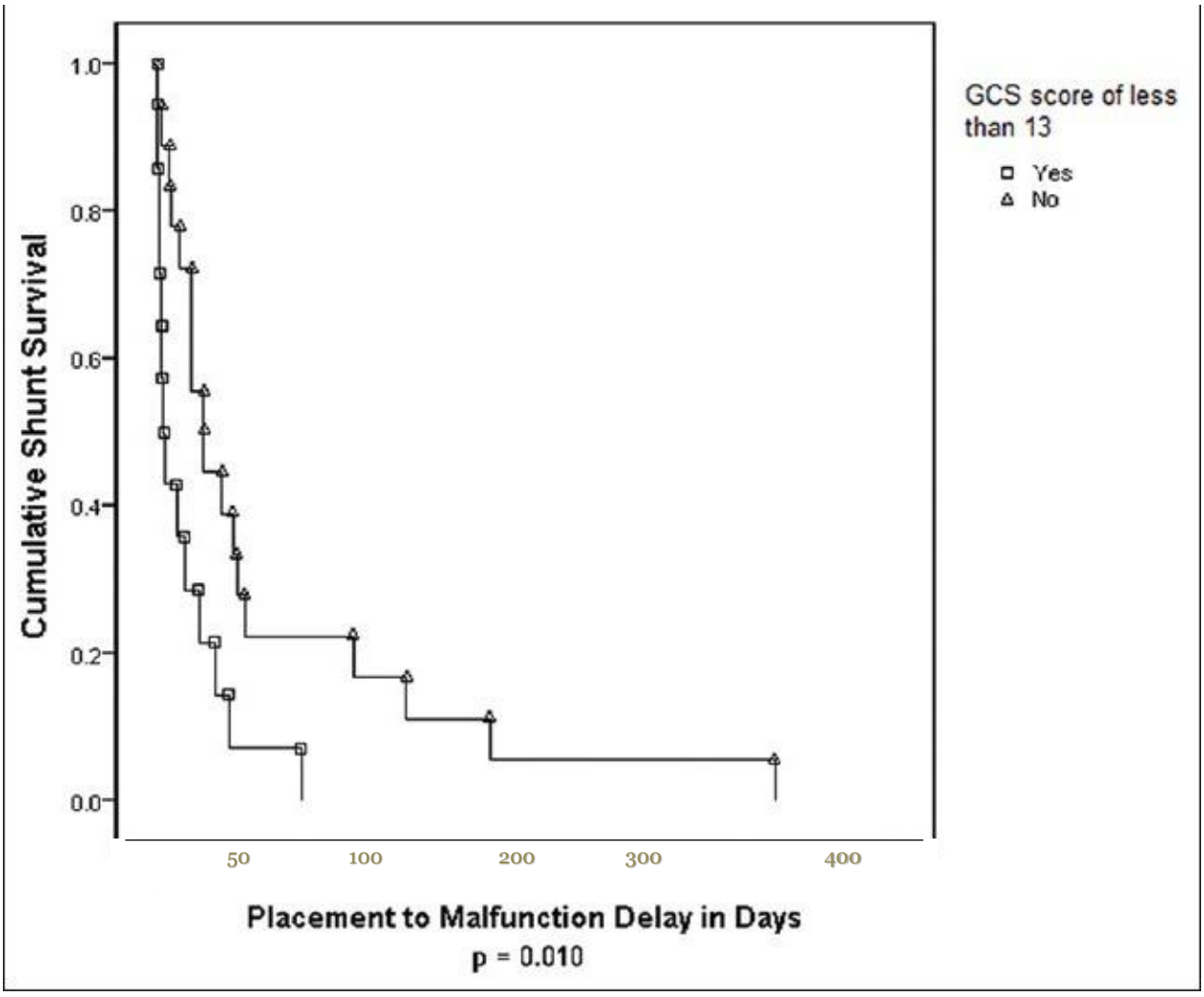

Figure 16: Kaplan–Meier shunt survival analysis for hydrocephalus showing that patients with a GCS score of less than 13 were more likely to experience early shunt failure (*P* = 0.010, log-rank test)

CHAPTER FIVE

5.1 Discussion

Hydrocephalus remains one of the common conditions managed by any neurosurgical service. Heterogeneity in the types of hydrocephalus and affected populations makes a simplistic assessment of its epidemiology problematic. However, in a Swedish epidemiologic study, the mean crude prevalence was 0.60 per 1000 live births in the period 1999-2002 (Persson *et al* 2007). This compares well to a population-based retrospective American cohort from 1991 to 2000 where the prevalence was 0.59 per 1000 and data from 4 European registries which also approximate this, showing a prevalence of 0.47 per 1000 (Tully *et al* 2014). The annual incidence of infant hydrocephalus in sub-Saharan Africa is unknown. Warf (2010) estimated the incidence of hydrocephalus in Uganda and extrapolated this to the East African region concluding that the burden of infant hydrocephalus in East Africa is significant, with more than 6000 new cases estimated per year.

Of the 154 patients recruited in the study, there was slight male predominance, with 86 (55.8%) male and 68 (44.2%) female patients. This is in accord with previous data collected at the same institution in unpublished thesis manuscripts. Noorani *et al* (2003), Omulo *et al* (1993) and Gichuhi *et al* (1989) reported that the proportion of male patients in their series were 60.5%, 56.5% and 62.5% respectively. In a study conducted at Kijabe Mission Hospital, also in Kenya, Gathura *et al* (2010) reported that a slight majority (53%) of the patients were male. Previous reports of male predominance have been alluded to for various anomalies. There are varying reports in literature on differences in the prevalence of hydrocephalus between sexes. Salvador *et al* (2014) in a Mozambican population reported that there were no sex differences with a ratio of 1:1.

An explanation for this difference in literature is elusive. When considered in the general context of congenital anomalies, Hay (1972) reported that males more often than females have been shown to have congenital hydrocephalus as well as other congenital anomalies such as, cleft lip with or without cleft palate, esophageal defects, omphalocele, anorectal defects, syndactyly, and plantar flexion foot defects. Additionally, Sokal *et al* (2014) reported that the prevalence of congenital anomalies, especially of the nervous system, was 26% higher in males compared with females (PR [M:F] 1.26; 95% CI, 1.23–1.30) even after adjusting for some important sociodemographic and maternal risk factors known to be associated with prevalence of congenital anomalies. These results were highly consistent with those from previous studies (Lary and Paulozzi 2001; Shaw *et al* 2003; Lisi *et al* 2005; Tennant *et al* 2011). However, no satisfactory explanations for this disparity have been offered.

The age of the patients in our study, ranged from 3 days to 61 years with a mean and median age at presentation of 3 years and 3.5 years (SD 8.64) with a significant number of patients aged older than 1 year. Previous reports at the same institution by Omulo *et al* (1993) and Noorani *et al* (2003) showed that patients older than 1 year represented 50.4%, and 29.9% respectively. In a Dutch population, Breuning-Broers *et al* (2013) reported that the majority (89%, 95% CI 82–93%) of the patients with hydrocephalus were detected in the first year of life. Similar findings were reported by Zahl *et al (2008) who* concluded that most children with an increased head circumference were detected in the first 10 months of life.

Noting the mean age in our series of 3 years, the reasons for this noted tardiness between the onset of the symptoms and presentation arise and are possibly multiple. With the Kenyatta National Hospital (KNH) serving as a tertiary referral hospital, access in terms of distance, transport and cost may contribute to such delays. Warf (2005) noted that, of 468 Ugandan

children presenting for management of hydrocephalus, the mean time from clinical manifestations of hydrocephalus to presentation for treatment was 7.46 months. Warf (2005) opined that the reasons for such a dramatic delay included misconceptions about the problem (including animistic/spiritualistic interpretations and the early resort to "traditional" practitioners), discouragement from seeking help by members of the local community, hopelessness about accessing help because of lack of funds, and lack of transportation. The author noted that patients tend to present with advanced hydrocephalus and severe ventriculomegaly which had a negative impact on ultimate outcome (Warf 2005). It is evident that much needs to be done in our setting to educate primary caregivers on early identification and referral as well as improving access to the Nation Hospital Insurance Fund (NHIF) for patients and their caregiver to offset the cost of treatment.

With regards to etiology, majority of the patients (88 patients; 57.1%) had post-infectious hydrocephalus while posttraumatic hydrocephalus was the least common. Moreover, when analyzed against age at presentation, post-infectious hydrocephalus was more common in younger patients representing 44 patients (63.8%; n=69) aged less than 1 year. This appears in contradistinction to previous unpublished data collected at the same institution. Noorani *et al* (2003) reported the most common etiology to be congenital (72.4%) while post-meningitic hydrocephalus accounted for 23.7%, while Omulo *et al* (1993) reported congenital causes accounted for 77.6% and post-meningitic accounted for 20%. Additionally, Gichuhi *et al* (1989) reported that congenital hydrocephalus represented for 61.7% and post-meningitic hydrocephalus was 13.3%. These previous studies seem to align with other reports from the region that showed postinfectious hydrocephalus, is not the leading etiology with hydrocephalus secondary to neural tube defects being especially common, along with aqueductal stenosis and hemorrhage, in

Kenya, Nigeria, Cameroon, Zambia, Zimbabwe, Malawi, and Saudi Arabia (Adeleye *et al* 2009; Adeloye 1992; el Awad *et al* 1992; Gathura *et al* 2010; Idowu *et al* 2011).

However, Warf (2005) indicated that hydrocephalus secondary to CNS infection is the single most common cause of hydrocephalus in Uganda. Of their overall experience with the 468 patients with hydrocephalus who presented for treatment between January 2001 and March 2003, the cause of hydrocephalus was determined to be post-infectious in 265 cases (57%), non-postinfectious in 136 cases (29%), associated with myelomeningocele in 61 cases (13%), associated with encephalocele in five cases (1%), and the probable result of neonatal intraventricular hemorrhage in one case (Warf 2005). Further, Handler *et al* (1978) and Peacock *et al* (1984) had earlier reported that post-infectious hydrocephalus was the most common etiology of hydrocephalus in South African populations.

The organisms and mechanisms by which CNS infections cause hydrocephalus have been extensively researched and reported. Meningitis has been previously associated with ventriculitis, aqueductal obstruction, ventricular loculations, and cerebral infarction (Bortolussi *et al* 1978; Kaul *et al* 1978; Ment *et al* 1986). The age at presentation with meningitis would suggest both the probable organisms and their likely mode of acquisition (Heath *et al* 2003). Presentation in the first week of life (early onset) and particularly in the first two days of life, reflects vertical transmission, while late onset infection suggests nosocomial or community acquisition. The corresponding organisms are different; early onset meningitis is more likely to be caused by group B streptococcus (GBS), Escherichia coli, and Listeria monocytogenes, while late onset meningitis may be caused by other Gram negative organisms as well as staphylococcal species (Heath *et al* 2003). A study from Malawi of 61 neonates with meningitis showed the most common causative organisms to include *Streptococcus agalactiae* (23%), *Salmonella*

typhimurium (15%), *Strep. pneumoniae* (11.5%), and other Gram-negative rods (11.5%) (Molyneux *et al* 1998). The cause of the infection preceding onset of hydrocephalus in our patients was not known. However Laving *et al* (2003) in a study of neonatal bacterial meningitis at the newborn unit of Kenyatta National Hospital the most common aetiological agents were *Escherichia coli* (46.7%), Group B *Streptococci* (26.7%) and *Klebsiella pneumonia* (13.3%).

In the current study, a total of 35 patients (22.7%) had 39 complications within the study period. A VP shunt complication is a major obstacle in the management of hydrocephalus. The incidence of complications following VP shunt placement is reported to be around 20 to 40% (Al-Tamimi *et al* 2014; Farahmand *et al* 2009; Reddy GK, *et al* 2014). However, over a much longer follow-up period these figures increase dramatically. Stone *et al* (2013) reported 84.5% of their patients had required shunt revision on 15 year follow up of pediatric shunt surgeries. Stein and Guo (2007) reported the 5-year shunt survival rates in children and adults, estimated using mathematical model, were 49.4 and 60.2%, respectively. Al-Tamimi *et al* 2014, reported a 30-day VP shunt failure rate as a possible barometer of surgical outcome while making comparison with 2 published randomized, controlled trials (RCT). They reported that the overall 30-day and 1-year failure rates for new shunts were 12.9% and 28.8%, respectively and the failure rate of the subsequent revision of those new shunts was 20.7% at 30 days and 40.4% at 1 year (Al-Tamimi *et al* 2014). The results of the current study are comparable to these previous reports considering that the mean duration of follow up in the current study was 162 days (90-390 days).

Of note, all the VP shunt insertions were performed by residents in their senior 4^{th} to 6^{th} years of residency. Per Al-Tamimi et al (2014) in a retrospective international cohort study, reported that shunt survival appeared to be better if performed by a consultant pediatric

neurosurgeon for revision surgery only and not necessarily for *de-novo* shunt insertions. Further, Berry *et al* (2008) reported that higher hospital volume of initial shunt placement was associated with lower revision rates. Cognizant of the few available neurosurgeons locally, and that our shunt outcomes may be comparable to international data, we can recommend all shunt procedures be carried out at high volume referral centres.

The incidence of shunt failure is higher in the first six months following the VP shunt (Reddy *et al* 2014; Park *et al* 2015). Correspondingly, the current study revealed that the vast majority of these complications 30 (76.9%; n=39) occurred within the first 3 months after VP shunt insertion, another 6 (15.4%; n=39) occurred between 3-6 months, and 3 (7.7%) during the last 6 months. Khan *et al* (2015) in a Pakistani cohort reported similar findings with an overall incidence of shunt malfunction of 15.4% and the median time to first shunt failure being 120 days. Lending further support to this assertion is the report by Gathura *et al* (2010) who found that the average time from shunt insertion to the first complication was 3.5 ± 4.1 months (range 0.1–18 months). Park *et al* (2015) in a Korean population over the 10- year period from January 2001 to December 2010 reported a shunt revision rate of 27.7%. In their cohort, 34.9% of their patients were operated on within 1 month after the original surgery. It is thus clear that the incidence of shunt failure is higher in the first six months following the VP shunt. This would inform a more vigilant follow up in patients in our facility soon after a VP shunt insertion to better detect any failure and manage such patients appropriately.

With regards to the type of shunt malfunction, the most common causes were shunt blockage (n=16, 10.4%) and shunt infection (n=14, 9.1%). Mwachaka *et al* (2010), in a retrospective study, similarly reported that the most common complication was obstruction, followed by migration and infection. Complementary findings were reported by Omulo *et al*

(1993) and Gichuhi *et al* (1989) who reported that the most common reason for shunt revision was shunt blockage, accounting for 52.6% and 38.2% respectively, of indications for shunt revision. However Noorani *et al* (2003) reported that shunt infection was the most common form of shunt complication (19.8%) with shunt blockage accounting for 9.2% of patients in their series.

Shunt obstruction has remained a persistent problem in neurosurgical practice. Whereas most early shunt failures are due to infection and technical misadventures, the mechanism of late failure are incompletely understood (Sherize *et al* 2007). Mechanical occlusion of the ventricular end of the catheter has been reported to be the cause of nearly two thirds failures of the shunts (Sherize *et al* 2007). Singh *et al* (2012) in an endoscopic analysis of blocked shunts showed that occlusion of the holes and lumen of the shunt tube can occur due to growth and invasion by the ependymal lining, newly formed vessels, granulation tissue, adhesions and obstruction by the choroid plexus, with the most common cause of block being granulation tissue (41%). Additionally, neovascularisation in the vicinity of the shunt tube was also found to invade via the holes into the lumen of the shunt tube. Surprisingly, the authors found the choroid plexus was to be the cause of the occlusion in only four (7%) patients (Singh *et al* (2012).

Similarly, distal shunt blockage has been proposed to be due to omentum or associated fibrosis. The mechanism for development of fibrosis is still elusive (Bouch *et al* 1998; Aquino *et al* 2006). It may be to be due to biodegradation of shunt system, (Adegbite *et al* 1982) or formation of bacterial biofilm around shunt tube (Aquino *et al* 2006). Sherize *et al* (2007) proposed that the presence of foreign body inside the peritoneal cavity activates macrophages and monocytes, which stimulate mesothelial cells. The mesothelial proliferation sets in fibrosis, a process which is modulated by interleukins and prostaglandins.

Demographics, such as age, gender, and co-morbid conditions, did not upset the shunt function overall, but median time to shunt malfunction was severely affected by extreme of age. This might be accounted for by the fact that very young and elderly patients have fragile and atrophic brain parenchyma, in the case of elderly patients. Surgical intervention in such patients was probably associated with a higher risk of iatrogenic trauma inflicted to the nearby tissues while placing the VP shunt (Reddy 2011). Injury to cells of the choroid plexus within the ventricles could lead to the accumulation of cellular debris within the catheter and clog the tubing of the VP shunt, resulting in shunt blockage (Reddy *et al* 2011). Although this explanation seems plausible theoretically, it cannot be said with certainty that this was the actual reason for early shunt failure in young and elderly patients in our cohort.

Among the etiologies of hydrocephalus, post infectious hydrocephalus was found to have a significantly adverse impact on the functional outcome of patients, which is in line with observation from earlier studies (Khan *et al* 2013). The CSF protein concentration is reported to be higher in patients with bacterial meningitis as well CSF leukocyte count. In the series of Ross *et al* (1988), a mean CSF leukocyte count of 2210/cu mm was noted among cases of Gram-positive meningitis. This may lead to a higher rate of shunt blockage and risk of infection. Additionally, shunts in patients who have experienced intra-parenchymal hemorrhage may become clogged with red blood cells and platelet microthrombi, resulting in shunt blockage (Bhattathiri *et al* 2006). Similarly, some of the etiologies including brain tumor and post-cranial surgery were found to have a shorter time to first malfunction. Development of hydrocephalus following cranial surgery may be attributed to the damage that occurred to cells of the choroid plexus and other nearby tissues during the surgical procedure (Khan *et al* 2014). Likewise, extensive manipulation and injury to tissues occurring during resection of neoplastic disease, as

well as alterations in cerebral blood flow and auto-regulation that occur after the procedure result in early shunt failure in patients with brain tumors (Reddy *et al* 2011).

Albeit previous studies have not found any association between clinical features and shunt survival (Reddy *et al* 2012), we observed in our study that patients with drowsiness and low GCS score on examination had prominently reduced median time to first shunt failure. GCS score is an indirect measure of brain functionality and is often used as a marker of severity of TBI (Vargas *et al* 2013). Patients who had a low GCS score on presentation were more likely to have severe abnormalities and pathologies and, therefore, were at increased risk of experiencing shunt failure. This association between GCS score and early shunt failure has been previously reported. Patients who underwent surgical procedures other than VP shunt placement, particularly craniectomy for excision and extra-ventricular drain placement, had a decreased median time to first shunt failure. This may in turn be related to the induction of inflammation and resultant tissue reaction, resulting in precipitation of hydrocephalus (Lund-Johansen *et al* 1994).

5.2 Conclusions

Hydrocephalus remains a common problem with VP shunt insertion continuing to play a pivotal role in patient management. Post-infectious hydrocephalus is the most common encountered aetiology of hydrocephalus among our patient cohort. Though comparable to some other studies, shunt malfunction remains high among Kenyan shunted patients at the Kenyatta National hospital with shunt obstruction predominating. Age, primary aetiology, patient's pre-operative neurologic status and the use of an EVD significantly influence VP shunt survival at KNH.

5.3 Recommendations

A longer follow-up period would be valuable to assess the long-term shunt outcomes among our patients. This can be achieved by the utilization of this shunt registry capturing all hydrocephalic patients manage by VP shunt procedures. This study has demonstrated the capability of running a shunt registry with great motivation, albeit with modest resources. Additionally, recruitment of patients managed at other facilities within the Republic of Kenya and hopefully within the region would furnish more representative data. Additionally, development of a hydrocephalus management protocol to guide patient identification and selection, procedure guidelines, follow-up, identification and management of complications would reduce management variability and positively impact on patient care and outcomes. With a view of the shunt malfunction rate, making patients shunt independent would be desirable and the widespread adoption of endoscopic third ventriculostomy, where indicated, would help achieve this although great strides have been made in our set-up.

5.4 Limitations and delimitations

The duration of the follow-up could have been longer. However, the nature of the study as a post-graduate thesis had constraints in terms of time of completion. However, a more sustainable model of the registry has already under design which after ethical approval will continuously collect data on management of hydrocephalus. This will have both advantages of greater sample size and longer follow-up period to provide a more robust data pool for analysis. Funding for this model will be sought to ensure that it can be maintained with the collection of high quality data.

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APPENDICES

Appendix 1: Budget

Item	Quantity	Unit cost (Ksh)	Total(Ksh)
Plain paper ream	5	420	2,100
Catridge 48 A	5	5,500	27,500
Binding charges	12	500	6,000
Ethical approval			3,000
Miscellaneous			1000
Total			39,600

Budget Justification: The budget above reflects the cost of the materials and equipment that were required in conducting the study. The unit prices reflect the current market price as per the time of budget preparation. Most of the cost incurred during the study was based on the usual management of the patients and thus there were no additional costs to be borne by the patients, caregivers or investigators.

Appendix 2: Timeline

		Description of Work	Dates	Deliverable Outcome
Milestone One - Conceptualization and Design				
	Proposal writing	Involved the authorship of the proposal and submission to ethical committee for approval of the project	Nov 2014 - Aug 2015	Proposal document
	Protocol development	Protocol development and testing of data entry sheet	Aug-Sep 2015	Data sheet
Milestone Two – Development, Deployment and Implementation				
	Data collation	Duration of data collection	Oct 2015- Mar 2017	
Milestone Three - Audit and Reporting				
	Data analysis	Data entry was continuous and analysis	April 2017	Results and their discussion
	Thesis Writing	Documentation of the findings with recommendations	April-May 2017	Manuscript submitted to department
	Publication and Recommendations	Submit clinical papers to peer reviewed journals	July- October 2017	

Appendix 3: Questionnaire

Study Number **I.P Number**

Age Sex Male ☐ Female ☐

Days Months Years

Admission Date

Month Year

Referral County/Tribe

Aetiology of Hydrocephalus

Congenital ☐ Acquired ☐

If congenital, Specify

Aqueduct stenosis ☐
Dandy-Walker ☐
Chiari ☐
Chiari/spina bifida ☐
Other (specify)

If acquired, specify

Post-meningitic Yes ☐ No ☐

If yes, how long ago

Days Months Years

Tumor Yes ☐ No ☐

If yes, specify

Supratentorial ☐
Infratentorial ☐
Pathology?

Post-traumatic Yes ☐ No ☐

Hemorrhage

Intraventricular ☐
Perinatal ☐
SAH ☐
Aneurysm ☐

Postsurgical Yes ☐ No ☐

Pseudotumour cerebri Yes ☐ No ☐

Idiopathic Normal Pressure Hydrocephalus Yes ☐ No ☐

Any features of concurrent infection

Fever Yes ☐ No ☐

Temperature Highest pre-op

Irritability Yes ☐ No ☐

GI infection Yes ☐ No ☐

Respiratory tract infection Yes ☐ No ☐

Pre-operative work-up

Imaging available? CT ☐ U/S ☐ MRI ☐

TBC

- WBC
- Neutophils
- Lymhocytes
- Eosinophils

CSF sample taken Yes ☐ No ☐

- If yes Vent tap ☐
  Lumbar puncture ☐
  Shunt tap ☐
- Cell count
- Protein
- Glucose
- Culture Yes ☐ No ☐ Organism
  Sensitivity

Operative factors

Type of Shunt procedure

- Primary shunt insertion ☐
- Shunt after EVD ☐
- Shunt revision ☐
- Shunt re-insertion after removal ☐
- External Ventricular Drain ☐
- Endoscopic 3rd Ventriculostomy ☐
- Shunt Externalisation ☐
- Choroid Plexectomy ☐

Shunt details (after insertion/revision)

Indications for shunt revision ☐

- Shunt blockage ☐
- Shunt infection ☐
- Shunt migration ☐
- Shunt exposure ☐

Duration after initial shunt

- <1 month ☐
- 1-3 months ☐
- 3-6 months ☐
- 6 months – 1 year ☐
- >1 year ☐

Surgeon?

- Consultant ☐
- Resident ☐
- If resident, year of study? 4th ☐ 5th ☐ 6th ☐

Proximal catheter

- Right ☐ Left ☐

Frontal ☐
Occipital ☐
Parietal ☐
Fourth ☐
Other

Cyst ☐
Subdural ☐
Cistern ☐
Lumbar ☐

Distal Catheter

Peritoneum ☐ Atrium ☐ Thorax ☐ Externa ☐ Other (specify)_____

Follow up

Duration since shunt

1st visit ———— days
2nd visit ———— days
3rd visit ———— days
4th visit ———— days

Outcome

Duration after procedure

Good ☐

Infection ☐

SSI ☐
Wound infection ☐
Shunt infection ☐
Blockage ☐
Migration ☐
Overdrainage ☐

Subdural collection hygromas ☐ haematomas ☐

Disconnection ☐
Fracture ☐
Other ☐ Specify

Shunt revised ? Yes ☐ No ☐

Appendix 4: CONSENT FORM FOR REPRESENTATIVES AND PATIENTS

Study title	**VENTRICULO-PERITONEAL SHUNT SURVIVAL AT THE KENYATTA NATIONAL HOSPITAL: A RISK FACTORS ASSESSMENT**
Study Site	KENYATTA NATIONAL HOSPITAL

This hospital is taking part in a study to find better treatments for hydrocephalus.
As a patient representative: This leaflet gives information about the study to help you to make a decision on the patient's behalf.

Before you decide, it is important that you know why the study is being done and what it involves. Please read the information below and ask as many questions as you like before deciding. This leaflet explains why we are doing the study and outlines the benefits and risks of taking part. The Doctor will be happy to talk to you about the study and answer any questions.

1) *What is hydrocephalus?*
Hydrocephalus is condition whereby there is reduced absorption or a blockage in the flow of the water that is within the brain. This causes the water to increase causing the head to enlarge and putting pressure on the brain.

2) *What is the purpose of this study?*
In this hospital, patients with hydrocephalus are given the usual emergency treatments. This includes putting a VP shunt which is a pipe that allows the excess water to enter the tummy. The aim of this study is to find out how the patients treated with shunts are fairing with the aim to improve our treatment of this disease.

3) *Why have you/the patient been chosen to take part?*
You (the patient), or your next of kin have been included because of the diagnosis of hydrocephalus and a shunt is to be inserted.

4) *What does taking part in this study involve?*
All the usual treatments for hydrocephalus will be given.

5) *What are the possible risks of being in the study?*
Shunts are not a new treatment. There will be no additional risk to the patient in participating in the study.

6) *What are the possible benefits of being in the study?*
We hope that these findings will help improve how we can manage this condition. The knowledge that we gain from this study will help people with similar conditions in the future.

7) *What if I don't want to be a part of this study anymore?*
You can always withdraw from the study at any time. This will not in any way affect the quality of care you receive at this facility.

8) *Will the information you collect be kept private?*
All information about you/the patient and the disease will be kept private. The only people allowed to look at the information will be the doctors running the study. Personal information will be used in strict confidence by the people working on the study and will not be released under any circumstance. We will publish the results of the study in a medical journal so that other doctors can benefit from the knowledge, but your/the patient's personal information will not be included and there will be no way that you/the patient can be identified.

9) *Who can you/the patient contact about any questions or problems?*
If you have any questions or concerns about any aspect of this study, you should ask to speak with the study doctors who will do their best to answer your questions. The doctor named below is in charge of this study at this hospital. You can contact the doctor as follows:

Name	Dr Peter Kitunguu
Address	P.O. Box 30197, 00100 GPO, University of Nairobi, Nairobi, Kenya
Telephone	0722-881405
Email	pkitunguu@gmail.com

10) *Who has reviewed the study?*
To protect your interests, all studies conducted at this hospital are looked at by an independent group of people called a Research Ethics Committee. This study has been reviewed and has been given a favourable ethical opinion by a Research Ethics Committee.

The Kenyatta National Hospital/University of Nairobi Ethics and Research Review Committee (KNH/UON-ERRC)	**University of Nairobi** College of Health Sciences P.O Box 19676 - 00202 Telegrams: Varsity (254) 020 2726300 Ext 44355 **Kenyatta National Hospital** P.O Box 20723 - 00202 Tel: (254) 020 726300 EXT 44102, 44355 Fax: 725272 Telegrams: MEDSUP, Nairobi uonknh_erc@uonbi.ac.ke

I confirm that I have read and understood the information sheet for the above study and have had the opportunity to ask questions. I agree to me/the patient taking part in the above study:

_____	_____	_____
Name of Patient/Representative	Date	Signature (left thumbprint if unable to sign)
_____	_____	_____
Name of Principal Investigator	Date	Signature

Appendix 5: FOMU YA IDHINI KWA WAWAKILISHI NA WAGONJWA

Utafiti	**KUTATHMINI MATOKEO BAADA YA UWEKAJI SHUNT KWA UBONGO KATIKA HOSPITALI YA KITAIFA YA KENYATTA**
Utafanywa wapi?	HOSPITALI YA KITAIFA YA KENYATTA

Hospitali hii inashiriki katika utafiti wa kupata matibabu bora kwa ugonjwa wa maji ndani ya ubongo. **Kama mwakilishi wa mgonjwa** kipeperushi hiki kinatoa taarifa kuhusu utafiti wa kukusaidia kufanya uamuzi kwa niaba ya mgonjwa.

Kabla ya kuamua, ni muhimu kwamba ujue kwa nini utafiti unafanywa na kile unahusu. Tafadhali soma maelezo hapa chini na uulize maswali yote utakayo kabla ya kuamua. Kipeperushi hiki kinaeleza kwa nini tunafanya utafiti na kinaelezea faida na hatari ya kushiriki. Daktari atafurahia kuzungumza na wewe juu ya utafiti na kujibu maswali yoyote.

1) *Ubongo kuwa na maji zaidi ni nini?*
nI hali ambayo kuna upungufu kuondoa maji au kufungana katika mtiririko wa maji yaliye ndani ya ubongo. Hii husababisha maji kuongezeka na kichwa kupanuka na kuweka shinikizo juu ya ubongo.

2) *Lengo la utafiti huu ni nini?*
Katika hospitali hii, wagonjwa walio na maji zaidi wanapewa matibabu dharura ya kawaida. Hii ni pamoja na kuweka VP shunt ambayo ni bomba ambayo inaruhusu maji ya ziada kuingia katika tumbo. Lengo la utafiti huu ni kupata matibabu bora na kuboresha afueni ya wagonjwa walio na maji kwa ubongo.

3) *Mbona mgonjwa amechaguliwa kushiriki?*
Wewe (mgonjwa) umechaguliwa kwa sababu una maji ya ziada katika ubongo na utafanywa upasuaji wa kuweka shunt.

4) *Kushiriki katika utafiti huu unahusisha nini?*
Matibabu yote ya kawaida ya maji ya ziada katika ubongo ubongo yatapewa.

5) *Je, kuna hatari yeyote ya kuwa katika utafiti huu?*
Mipira ya shunts sio tiba mpya. Hakutakuwa na hatari ya ziada kwa mgonjwa kushiriki katika utafiti huu.

6) *Faida za kuwa katika utafiti ni nini?*

Ni matumaini yetu kwamba matokeo haya yatasaidia kuboresha jinsi ya kutibu hali hii. Maarifa ambayo tutapata kutoka utafiti huu yatasaidia watu walio na hali kama hiyo katika siku zijazo.

7) *Na kama sitaki kuwa katika utafiti huu?*
Unaweza kuondoka kutoka utafiti wakati wowote. Hii haitaathiri ubora wa huduma utakayopokea katika hospitali hii kwa njia yoyote.

8) *Je, habari tutakayokusanya itawekwa binafsi?*
Taarifa zote kuhusu wewe / mgonjwa zitawekwa siri. Taarifa hizi zitatumika kwa imani na watu wanaofanya kazi katika utafiti na hazitatolewa kwa hali yoyote ile. Tutachapisha matokeo ya utafiti katika jarida la matibabu ili madaktari wengine waweze kunufaika na maarifa, lakini taarifa binafsi zako / za mgonjwa hazitatolewa kwa njia ambayo wewe / mgonjwa anaweza kutambuliwa.

9) *Utaweza kuwasiliana na nani kuhusu maswali au matatizo yoyote?*
Kama una maswali yoyote au wasiwasi kuhusu dhana yoyote ya utafiti huu, unapaswa kuuliza kuzungumza na madaktari wa utafiti. Unaweza kuwasiliana na daktari kama ifuatavyo:

Jina	Dr Peter Kitunguu
Anwani	P.O. Box 30197, 00100 GPO, University of Nairobi, Nairobi, Kenya
Simu	0722-881405

10) *Nani ameukagua utafiti huu?*
Kulinda maslahi yako, tafiti zote zinazofanywa katika hospitali hii zinaonekana na kundi huru la watu walioitwa Kamati ya Maadili ya Utafiti.

The Kenyatta National Hospital/University of Nairobi Ethics and Research Review Committee (KNH/UON-ERRC)	**University of Nairobi** College of Health Sciences P.O Box 19676 - 00202 Telegrams: Varsity (254) 020 2726300 Ext 44355 **Kenyatta National Hospital** P.O Box 20723 - 00202 Tel: (254) 020 726300 EXT 44102, 44355 Fax: 725272 Telegrams: MEDSUP, Nairobi uonknh_erc@uonbi.ac.ke

Mimi nathibitisha kwamba nimesoma na kuelewa maelezo ya utafiti juu na nimekuwa na nafasi ya kuuliza maswali. Mimi nakubali kushiriki/ mgonjwa ashiriki katika utafiti huu:

_____	_____	_____
Jina la Mgonjwa / Mwakilishi	Tarehe	Sahihi
_____	_____	_____
Jina la mtafiti mkuu	Tarehe	Sahihi