

**OUTCOMES OF HYDROCELE SURGERY AT SURGICAL CAMPS  
CONDUCTED ALONG THE COASTAL REGIONS OF TANZANIA**

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**Master of Medicine in Surgery  
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ALONG THE COASTAL REGIONS OF TANZANIA**

**By**

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**A Dissertation Submitted in (Partial) Fulfillment of the Requirements for the  
Degree of Master of Medicine in Surgery of the  
Muhimbili University of Health and Allied Sciences  
October, 2019.**

## **CERTIFICATION**

The under signed certifies that he has read and hereby recommend for acceptance by Muhimbili University of Health and Allied sciences a dissertation entitled: *“Outcomes of hydrocele surgery at surgical camps conducted along the coastal regions of Tanzania.”*In (partial) fulfillment of the requirements for the degree of Master of Medicine (General surgery) of Muhimbili University of Health and Allied Sciences.

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**Dr. Larry O. Akoko**  
**Senior Lecturer Department of Surgery**  
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Date

## **DECLARATION AND COPYRIGHT**

I, Hussein MohsinKhanbhai, declare that this is my original work and that it has neither been presented nor will it be presented to any other University or learning Institutes for a similar or any other degree award.

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## **DEDICATION**

This work is dedicated to my Family,

Mom and Dad: Mohsin and Durriyah,

To my Wife and Siblings: Fatema, Samina and Mustafa

To my Baby boy, Burhanuddin

## ABSTRACT

**Background:** Hydrocele is a known endemic disease, a common chronic manifestation of Lymphatic Filariasis. Hydrocele being endemic in Tanzania especially along its coastal regions causes physical disability and embarrassment in the most productive stage of life, affecting one's work capacity, social life, married life and frustrations due to inability to perform during sexual intercourse. Hydrocelectomy is the treatment of choice of which partial sac excision technique becoming a technique of choice for most hydroceles especially for huge hydrocele which seem to be common among patients at hydrocele surgical camps held along Tanzanian coastal regions. Despite several hydrocelectomies done over the years at these surgical camps, with partial sac excision technique mostly used, a follow up on its outcomes, especially long-term, hasn't been done.

**Objective:** To assess the outcome of hydrocelectomy on patients who attend hydrocele surgical camps in Tanzania.

**Methodology:** a descriptive cross-sectional study design was used, conducted over a one-year period involving all patients who underwent hydrocelectomy at hydrocele camps conducted along the Tanzanian coastal regions from January 2016 to December 2017. A sample size of 393 was calculated. Data was extracted from the prefilled questionnaires used at the camps and this data was part of the information needed for the questionnaire designed for this study. The remaining information was gathered via telephone interview. A pre-tested and coded Swahili version questionnaire was used with confidentiality adhered, and data was analyzed using the SPSS version 24 program. Ethical clearance was attained from MUHAS research and publication committee.

**Results:** A total of 393 patients were selected, who underwent hydrocelectomy and were called and interviewed, of which 390 responded (response rate of 98.5%). The mean age of the respondents was  $49.15 \pm 13.3$  (20 – 101) years. Large sized hydrocele were among the majority, 235 (62.3%), followed by medium sized that accounted for 112 (29.7%) patients. Most patients before surgery had issues with work engagement, being stigmatized and sexual

performance as was reported by 343 (87.9%), 323 (82.8%) and 300 (76.9%) patients respectively. Pain and micturition difficulties was reported by a few, in 16 (4.1%) and 7 (1.8%) respectively. Overall complication rate was observed to be 27%, SSI being the leading by 19%, followed by persistent scrotal swelling (7.4%) and scrotal oedema (1.3%). Haematoma formation (0.6%), chronic pain and recurrence (0.5% each) were least reported complications. A statistically significant association was noted between persistence of scrotal swelling and having small to medium sized hydrocele. Also, statistically significant changes in the marital status of the patients who underwent hydrocelectomy was noted before and after the procedure, such that, more patients got married or were cohabiting and less remained single, separated or divorced after hydrocelectomy. Majority of the study participants felt that surgery had brought positive changes in their sex lives, in performing their routine and occupational activities and were satisfied with the appearance of their genitals. They strongly agreed at recommending their peers and relatives suffering from a similar condition to seek for such a treatment.

**Conclusion:** The hydrocele surgical camps are a great contribution towards the fight and elimination of this neglected tropical disease. Some post procedural complications have been highlighted in this study, but these are to a minimal extent. Partial sac excision technique as practiced in our camps is safe, with minimal complications. Any reduction in scrotal size has a positive impact on the patients' quality of life.

**Recommendation:** Partial sac excision technique of hydrocelectomy to be advocated more among surgeons with patient follow-up to be given more emphasis.



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## **LIST OF ABBREVIATIONS**

CDD- Community Drug Distributor

DM- Diabetes Mellitus

HOD- Head of Department

HTN- Hypertension

MMed- Masters of Medicine

MNH- Muhimbili National Hospital

MUHAS- Muhimbili University of Health and Allied Sciences

NCD- Non-Communicable Disease

NIMR- National Institute for Medical Research

NTD- Neglected Tropical Disease

NTDCP- Neglected Tropical Diseases Control Program

QOL- Quality of Life

SPSS- Statistical Package for Social Sciences

WHO- World Health Organization

## **DEFINITION OF TERMS**

1. Hydrocele- is a fluid filled sac inside the scrotum; an abnormal collection of fluid within the tunica vaginalis (between its parietal and visceral layer).
2. Lymphatic Filariasis- is a human disease caused by parasitic worms known as filarial worms. It is transmitted to human via mosquitoes (Culex mosquito).
3. Hydrocelectomy- is surgical procedure to repair a hydrocele.
4. Spermatocelectomy- is an operation to remove a spermatocele from the epididymis of a testicle.
5. Orchiectomy- is a surgical procedure in which one or both testicles are removed.
6. Scrotoplasty/reduction scrotoplasty- is a reparative or plastic surgery of the scrotum
7. Vaginallectomy- refers to excision of the tunica vaginalis upon performing a hydrocelectomy.
8. Penoscrotallymphoedema- swelling of the penis and scrotum due to lymphatic blockage.
9. Scrotal oedema- swelling of the scrotal skin causing enlargement of the scrotal sac.
10. Hematoma- an abnormal collection of blood outside of a blood vessel.
11. Surgical Site Infection (SSI)- is an infection that occurs after surgery in the part of the body where the surgery took place. It could be superficial involving the skin where the incision took place, Deep incisional affecting the muscles and surrounding tissues, or, affecting the underlying organs or space between organs.
12. Persistent scrotal swelling- is any scrotal swelling of considerable size that persists for more than 6months post scrotal surgery.
13. Recurrence of hydrocele post hydrocelectomy refers to hydrocele recurrence within months (>6months) post-surgery.
14. Seroma- an accumulation of clear serous fluid, confined in a space created within tissues post-surgery.
15. Chronic pain- post hydrocelectomy refers to scrotal pain that persists beyond 6 months of surgery.
16. Change in QOL- refers mostly to change in sexual performance, work capacity and self-esteem.

## CHAPTER ONE

### 1. INTRODUCTION

#### 1.1. Background

Hydrocele is a known endemic disease in over 80 countries, and is the most common chronic manifestation of Lymphatic Filariasis(1). Globally, almost 25 million men are affected by hydrocele (2). In the endemic communities, 7% of the adult population suffer from lymphoedema out of which 30–50% develop hydrocele. The prevalence of Hydrocele in Dar es Salaam as obtained from three major Districts; Ilala, Kinondoni and Temeke was 80.9 per 100,000 total population and 185.7 per 100,000 male population (3).

A Hydrocele is an abnormal collection of fluid within the tunica vaginalis (between its parietal and visceral layer). Hydroceles can be primary or idiopathic, or secondary due to testicular or epididymal disease. It can be produced in four different ways; by excessive secretion of fluid within the sac; by defective absorption of fluid; by lymphatic obstruction or by communication with the peritoneum via a patent processus vaginalis (congenital). Filarial hydrocele results from recurrent episodes of filarial epididymo-orchitis. It is a parasitic disease, largely caused by the nematode (roundworm) *Wuchereria bancrofti*. The Adult worms cause mechanical blockage of lymphatic vessels which, in turn, triggers an immune response that leads to dilation of scrotal lymphatics and accumulation of fluid into the tunica vaginalis of the scrotum(4).

Though the scrotal swelling is painless and causes most patients to seek treatment when it has become tremendously huge, it causes considerable physical disfigurement with patients burdened with social stigma and poverty. A noted decline in socio-economic growth is evident that leads to a very poor quality of life for most of those suffering (5)

Classification of hydroceles clinically aid in the decision making of appropriate management needed. It may be classified based on the type of hydrocele (unilateral vs bilateral), side of hydrocele (right or left) and size of the hydrocele(6). Hydrocele fluid volume is also used by several authors in grading depicting disease severity. Less than 200mls of fluid labelled as

small hydrocele, 200-500mls as medium hydrocele, >500mls to 2 L as large hydroceles and >2L as extra-large hydroceles (7).

Small acquired hydrocele may be managed conservatively. It includes observation, aspiration and sclerotherapy (8). Sclerotherapy has shown some success in treating hydrocele, being useful in older men whom fertility need not be maintained. Sclerosants such as tetracycline derivatives and 95% alcohol are instilled for some time after which it may be drained or allowed to be reabsorbed. Significant postoperative pain and recurrence is reported as compared to the commonly used surgical techniques (9).

Surgical treatment is offered to hydroceles that are sizeable and bothersome for the patient. Currently, the treatment of choice for filarial hydrocele is hydrocelectomy and has been proven the gold standard technique (10)(11). The use of pre and post-operative antibiotics helps yield good postoperative results as evidenced in most surgical interventions (2). Commonly used techniques in performing hydrocelectomy are using Jaboulay's procedure, Lord's procedure and excision technique depending on the size of the hydrocele (sac), thickness of the sac and the surgeon's preference (9).

Jaboulay's procedure involves making a 6-10 cm scrotal incision along the anterior surface through which the hydrocele sac is dissected and delivered. Great care is taken not to damage the testicle which usually lies postero-inferiorly. The sac is drained of fluid and is everted behind the testis so that the serous lining of the tunica vaginalis lines outward. It is then sutured using uninterrupted suture technique (4,9,12). Lord described a bloodless operation for the radical cure of idiopathic hydrocele in which the hydrocele sac is opened and the testicle is brought out with some eversion of the parietal vaginalis. The tunica then is plicated by taking radial sutures 1 cm. apart, forming a collar around the junction of the testis and epididymis. No dissection or excision of the vaginalis is done (4,9,11,12). These two widely adopted techniques for years have a setback when it comes to huge hydroceles as the culprit which is the secretory sac and its altered lymphatic drainage isn't excised but rather everted (Jaboulay's) or plicated (Lord's). The sac left within still has the potential to cause re-accumulation of fluid and lead towards recurrent or persistent scrotal swelling.

A more recently developed technique that excise's the tunical sac is advocated especially for huge hydroceles which have huge sacs. The technique of total tunical resection (excision technique) has been found to yield good post-operative results with fewer complications as compared to other traditional techniques (Jaboulay's and Lord's). This modified filarial hydrocelectomy technique was advocated in West African countries and subsequently is adopted in the hydrocele camps conducted in Tanzania (13). The technique was described in Sri Lanka in 1948 and was modified and perfected in Brazil by Noroes and Dreyer (1,14). It aids in minimizing complications such as haematoma, infection and recurrence. A fibrosed, thickened and sometimes calcified tunica vaginalis encountered in most filarial hydroceles necessitates its total resection in order to minimize postoperative complications. Meticulous hemostasis and close follow up is mandatory to avoid serious complications (7). In the excision technique, the tunica vaginalis is excised extensively leaving 1-2cm of the sac from the adjacent testis and epididymis. This technique reduces the size of the remaining contents to near normal postoperatively and the risk of spermatic cord strangulation as may be seen upon using Jaboulay's technique(13).

Hematoma is a common complication of hydrocelectomy. Upon employing the excision technique, the incidence of hematoma can be reduced by careful over sewing of raw edges of the sac and keeping a drainage in place when needed. Other complications include surgical site infection, persistent scrotal swelling and recurrence being the least reported as most patients have a successful outcome with a minimal incidence of recurrence(15).

For large and extra-large hydroceles with or without penoscrotallymphoedemalabelledascomplicated hydrocele, some authors advocate tertiary level of health facility with hydrocelectomy by complete vaginalectomy and reduction scrotoplasty to be done to attain the required outcome and patient satisfaction. Hydroceles that are small to moderate in size regarded as simple hydrocele suffice to only hydrocelectomy by complete vaginalectomy and simple closure of scrotum (6).

Most hydroceles encountered in Tanzania including those in the hydrocele camps conducted are huge with hydrocele fluid volume >500mls. But the technique used is that of simple

hydrocelectomy (without reduction scrotoplasty). It is of much interest to know the outcome of these patients in terms of short, long term complications and patient satisfaction. Indeed, this will highlight the efficacy of the hydrocele camp program and pave the way for further research on the appropriate technique that gives the best possible outcome regarding this neglected tropical disease in our locality.



## **1.2 Literature review**

Hydrocele causes physical disability and embarrassment in the most productive stage of life. Financial problems are a great cause of stress and anxiety mainly due to reduced patient's work capacity, lowered employment opportunity and impaired mobility. It causes frustration due to inability to perform during sexual intercourse, this was noted in 93.7% of patients in a study done in Orissa, India. Severe pain was reported during intercourse which ultimately led to avoidance of sex. Married life was also seen to be affected in several instances(2,5,16). People with hydrocele also faced emotional distress due to the social stigma associated with deformed genitals; they tend to isolate themselves from the society contributing towards delay in diagnosis and treatment(17).

A study done in Washington on complications of scrotal surgery for benign conditions (of which 74 procedures out of 110 were hydrocelectomies) described indications for surgery being isolated pain or discomfort in 50% of cases, sensation of scrotal mass (heaviness) alone in 18% and combination of pain and scrotal mass in 14%(18). A report by the World Health organization on Surgical approaches to the urogenital manifestations of lymphatic filariasis described several indications for hydrocele surgery such as interference with work, with sexual function, with urination due to burial of penis in the scrotal sac, dragging pain, increased likelihood to trauma upon carrying out daily activities and negative perception towards patient's family (social stigma) (2).

According to the WHO 2002 report, preoperative assessment of co-morbidities is necessary such as hypertension, Diabetes mellitus, asthma, drug allergies and anemia as such conditions increase the risk of surgery and would be wise to manage at a higher health facility (level III). Also, post-operative complications are influenced by such comorbidities. A suggested cut-off of haemoglobin of 10g/dL was advised below which patients should be referred to level III centers such as district hospitals (2).

Currently, the treatment of choice for filarial hydrocele is hydrocelectomy and has been proven the gold standard technique (10,11). The consequences of this procedure regardless of the technique used are both in the positive, and some on the negative side. A comparison study

done in Korea, comparing 3 techniques (excisional, plication and internal drainage) in treating hydrocelectomy surgically in terms of their outcomes reported an overall complication rate (both early and late) to be 53.8% with scrotal oedema being the leading one(8).A population-based study done in Alberta, Canada on the assessment of complications following outpatient hydrocelectomy and spermatocelectomy reported a total complication rate of 19.2% (31 of 161 cases) with an overall cure rate of 90% for hydrocelectomy (81 of 90 cases)(15). Likewise, another study on complications of scrotal surgery for benign conditions (of which 74 procedures out of 110 were hydrocelectomies), noted an overall complication rate of 20%, of which majority (95%) occurred after procedures that included hydrocelectomy. Overall the most common complications noted in this study were recurrences and scrotal hematomas(18). A comparison study done in Egypt reported an overall complication rate of 37% with eversion technique used in the group that underwent conventional hydrocelectomy(10).

Upon looking at each individual complication following hydrocelectomy, several studies report different complication rates more or less over the years. Scrotal oedema being one of the leading complication in a study done in Puerto Rico comparing four basic techniques in operative treatment of hydrocele showed that 50.5% of patients who underwent hydrocelectomy using Jaboulay's and Lord's technique developed scrotal wall swelling immediately after the procedure (19).A study that was done to compare Jaboulay's technique with a new minimally access technique noted that 24.2% of patients that underwent Hydrocelectomy using the Jaboulay's procedure had edema(10).A comparison study done in Korea comparing 3 techniques (excisional, plication and internal drainage) in treating hydrocelectomy surgically in terms of their outcomes reported an overall complication rate of 46.2% (61 out of 132) in developing scrotal oedema post hydrocelectomy with excisional technique leading (74%), plication technique (Lord's) having 2 patients with scrotal oedema out of 8 operated (contributing by 8% ) and internal drainage technique not encountering scrotal oedema as a complication(8). Whereas another study noted persistent scrotal swelling in 7.4% of cases who underwent hydrocelectomywith/without spermatocelectomy(15).

Haematoma defined as any visible or palpable collection of blood was shown to be only 11% immediately after surgery(15). Another similar study showed a haematoma rate of 4.8%(19). A study done in Korea reported hematoma to be one among the complications post hydrocelectomy accounting for 1.5% of all patients operated regardless of the technique used and Excision technique alone encountered hematoma in 2.5% of all patients on whom excision technique was used (8).The study done in Washington reported hematoma to be one among the complications (5%)of scrotal surgery for benign condition(18). A pilot program done in Nigeria which used eversion technique for most cases reported hematoma in 3.7% of cases (20).

Surgical site infection being a complication following all surgical procedures is also documented to be a complication following hydrocelectomy. It can be described as any evidence of inflammation of the scrotal wound with induration, erythema, increased temperature and exudation. The study done in Puerto Rico noted such infection in 7% of patients that underwent hydrocelectomy using the Jaboulay's and Lord's procedure (19). the comparison study in Korea noted wound infection to be encountered in 6.1% of the patients who underwent hydrocelectomy regardless of the technique used but lacked statistical significance over this finding (8). The Canadian population-based study noted a post-operative infection occurring in 15 of the 161 patients (9.3%). The diagnosis was established mostly clinically by looking for erythema, induration and pain, and by aspirating purulent material from the surgical site. Hydrocelectomy alone accounted for 6.2% of the surgical site infection (15). The study done in Washington on scrotal surgery for benign conditions (hydrocelectomies being the leading procedure) also encountered SSIs among 3.6% cases (18). A Nigerian pilot program encountered infection in 3% of their cases of which one succumbed death due to being an elderly with previously unrecognized diabetic additionally (20).

Recurrence of hydrocele is reported to be an uncommon complication in several studies especially following hydrocelectomy. Other less favorable treatment options such as needle aspiration and sclerotherapy encounter more recurrence. A Puerto Rican study noted

norecurrences(19). A 1.6% recurrence rate was reported in a similar study (15). Swartz and colleagues from Washington reported a 6% recurrence rate though their study included other benign scrotal conditions, hydrocele being the majority (18). As mentioned earlier, other techniques such as the internal drainage technique for hydrocele repair have a less favorable outcome in terms of recurrence, Ku and colleagues in their study done in Korea noted an overall recurrence rate of 18.9%. Majority seen in the internal drainage technique (85%, 23 out of 27) until the author recommended abandoning the use of the internal drainage technique (8). In a Nigerian study where eversion technique was used in majority of cases, a 7% recurrence rate was noted after a follow-up period ranging 1-3 years (20).

Chronic pain though being reported less frequently as a complication in several studies was noted in the study done in Alberta, Canada, 0.6% of patients reported chronic pain (pain present at 22weeks of follow-up) (15). The study done in Washington reported a case of chronic scrotal pain (1%) in a study that involved 110 procedures of which 74 were hydrocelectomies(18).

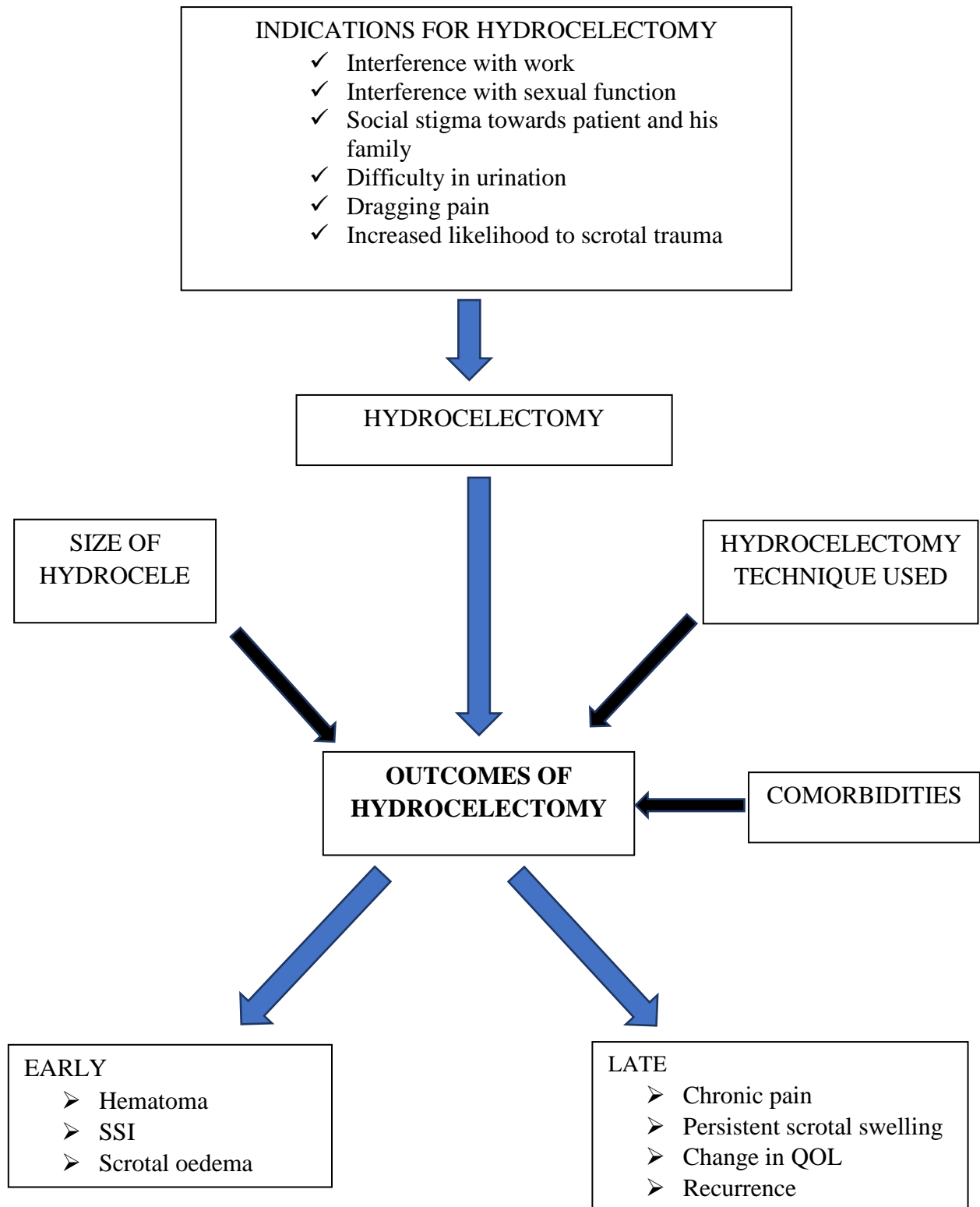
Regarding simple hydrocelectomy techniques, a current systematic review done by Lim and colleagues report that for the resource-limited (developing countries) settings to the least, no significant benefit was noted among the techniques (i.e. excision or eversion) regarding the early and late outcomes following simple hydrocelectomy(21). Mchembe et al, in a study done in three hospitals in Dar es Salaam, Tanzania, advocated the use of the tunical excision technique and concluded to have provided excellent outcomes in the treatment of idiopathic hydrocele (13). Though for complicated hydrocelectomies requiring penoscrotal reconstructive techniques a conclusion on its superiority in terms of its outcome in comparison to simple hydrocelectomy techniques wasn't possible as the authors (West African, Brazilian) encountered extra huge hydroceles with or without significant penoscrotallymphoedemarelyand more studies and follow ups are needed (21). Another study done in the Fiji Islands that included most patients with huge hydroceles (77% of 83 hydrocelectomies)requiringmore complicated procedures (penoscrotal reconstruction), made

these cases more prone to complications such as hematoma and SSIs. Emphasis on recognition of cases at an earlier stage was put forward(6).

Therefore, the existing practice of using simple hydrocelectomy on most cases (including huge hydroceles) especially in the hydrocele camps needs assessment as making use and implementation of research evidences from existing studies on this topic seems to be far fetched and the need for reconstructive surgery may have been undermined.

Several studies report the misery patients with hydroceles face in their respective societies. The quality of life of such patient is quite poor with stigmatization, psychosocial burden, sexual incompetence and economic setbacks (5,22,23). This misery is not only suffered by the patient but also by their family members. A qualitative study done in Ghana looked into the patients' perspective on the consequences of hydrocele and the benefits of hydrocelectomy. It concluded that hydrocelectomy not only corrected the hydrocele but also improved the physical and social status of the patient, his household (in terms of increased capacity to work and improved sexual function) and the community (in terms of active participation in communal activities)(22). People in the community started abandoning their old beliefs and fear of losing their manhood and becoming sexually incompetent following hydrocele surgery and realized the fact that sexual performance improves significantly in most men following surgery (16). Also, a case report that was done on three patients showed to have improved sexual function 6 weeks after surgery which before surgery was difficult due to the dragging effect of the mass on the phallus (16).

### 1.3. CONCEPTUAL FRAMEWORK



#### **1.4. PROBLEM STATEMENT**

Various surgical procedures have been developed to treat patients with hydrocele. Surgical camps are commonly performed in Tanzanian coastal regions to treat the condition. However, post-surgery assessment is rarely done to check on the patients' improvement and condition.

In every surgical procedure, including hydrocelectomy, post-operative care and follow up is one of the most crucial phases that determine the outcome. Outcomes of recovery are defined from the perspective of different stakeholders and time frames. No single definition of recovery exists. There are overlapping phases of recovery which are of particular interest to different stakeholders (surgeons, nurses, patients and their family members). The primary outcome of interest may vary depending on the phase and the perspective. In the earliest phase (at the recovery), biologic and physiologic outcomes are emphasized. In the intermediate phase (from theatre recovery room to discharge from the hospital), symptoms related to pain and bleeding as well as basic activities are important. Patients define recovery as return to normal functioning, a process that occurs over weeks to months (late phase)(24).

To the surgeon, an important finding in post hydrocelectomy patients is complication rates and types. From the patient's point of view, however, adverse effects such as pain, reduced work capacity, poor sexual performance, and social stigma carry more relevance. One of the most important areas, which is rarely investigated is the patient's perspective.

## **1.5. RATIONALE**

A follow up is always crucial to ascertain whether or not the intended outcome is realized and a change is brought about by offering treatment to individuals suffering from this neglected tropical disease. Assessment on the changes in the quality of life of these patients will influence patient participation and improvement in their health seeking behaviour. Also, determining complications and their magnitude post operatively will help medical personnel to identify areas where more emphasis needs to be kept to improve outcome.

As mentioned earlier; the hydroceles mostly encountered during camps held are huge. The efficacy of the hydrocele camps program and its use of partial sac excision (most cases) without scrotoplasty needs an assessment of outcome as this technique favoured by other tropical countries might not be giving a similar outcome in our setting.

The results from this study will be helpful in ensuring better morbidity management and enlighten on better prevention of post-operative complications and their management.

## **1.6. RESEARCH QUESTIONS**

1. What reasons make patients with hydrocele seek medical attention?
2. What are the early and late complications of hydrocelectomy in surgical camps?
3. Is there a change in the quality of life among patients who undergo hydrocelectomy in surgical camps?



## **CHAPTER TWO**

### **2. OBJECTIVES**

#### **2.1. Broad Objective:**

To assess the outcome of hydrocelectomy on patients who attend hydrocele surgical camps in Tanzania.

#### **2.2. Specific Objectives:**

1. To determine the WHO indications for hydrocelectomy among hydrocele patients in Tanzania.
2. To describe the prevalence of co-morbidities among patients with hydrocele.
3. To determine the proportion of hydrocelectomy patients developing post-operative complications.
4. To ascertain the association between post hydrocelectomy complications and its associated factors.
5. To describe the self-reported quality of life of post hydrocelectomy.

## **CHAPTER THREE**

### **3. METHODOLOGY**

#### **3.1. Study Design**

A descriptive cross-sectional study to determine the outcomes among patients who underwent hydrocelectomy at hydrocele surgical camps in Tanzania.

#### **3.2. Study Duration**

The study was conducted over a period of one year starting May 2018 to April 2019.

#### **3.3. Study Area**

Study area included the Tanzanian coastal regions where the hydrocele camps get conducted. Over the 2-year duration from January 2016 to December 2017, hydrocele surgical camps have been conducted at Mtwara, Lindi, Tanga, and Dar es Salaam regions at various level II health facilities.

#### **3.4. Study Population**

All patients who underwent hydrocelectomy at the Hydrocele surgical camps that took place along the Tanzanian coastal regions from January 2016 to December 2017.

#### **3.5. Study Sample**

Using a Random cluster sampling (Multistage), patients were recruited with sample size being realized. Total number of hydrocele surgical camps held between January 2016 to December 2017 were listed and each group (camp) numbered with a unique number and a small sample of relevant discrete groups was selected (by lottery method). Then, participants from those relevant groups were listed and selected at random (systematic sampling) until 393 participants were attained.

### **3.6. Sample Size Estimation**

The sample size was calculated using an electronic calculator(25).

Where  $p= 37\%$  (10)

N was calculated to be 357.

Taking 10% non-response rate into account makes the sample size to be 393.

This calculator used the following formula for the sample size n:

$$n = N * X / (X + N - 1),$$

where,

$$X = Z_{\alpha/2}^2 * p * (1-p) / MOE^2,$$

And  $Z_{\alpha/2}$  is the critical value of the Normal distribution at  $\alpha/2$  (e.g. for a confidence level of 95%,  $\alpha$  is 0.05 and the critical value is 1.96), MOE being the margin of error, p being the sample proportion, and N, the population size. Note that a Finite Population Correction has been applied to the sample size formula.

### **3.7. Inclusion Criteria**

All patients who underwent hydrocelectomy in the hydrocele camps conducted along Tanzanian coastal regions from January 2016 to December 2017 and have given consent to participate in this study over the telephone.

### **3.8. Exclusion Criteria**

Patients having filarial scrotum (lymphoedema) requiring scrotoplasty.

Those who underwent additional procedures such as concomitant hernia repair surgery.

### **3.9. Procedure Description**

At the camps, patients were recruited and screened at the respective health facilities for their scrotal conditions. Those with pure hydroceles and those with mixed hydroceles and hernias were selected and screened further, in preparation for the procedure. A thorough history and physical examination would then be conducted, checking patients vital signs, random blood

glucose, haemoglobin level, HIV testing and an anaesthetic review. The patient would then proceed for the procedure after being explained thoroughly and signing a consent.

Preoperatively, patients were given IV Ceftriaxone 1g stat and IM Diclofenac 75mg stat. Patient lying supine on the operating table with lower limbs adducted and scrotum lifted, resting on the patients thighs. Patients were told to shave and make the area clean prior from home. Spirit solution (96% Alcohol) was sprayed along the procedure site while the surgeon prepared and scrubbed with soap and water, sterile gowning and sterile gloves worn. The procedure site thereafter prepped with 10% povidone iodine solution and draped with sterile drapes. Local anaesthesia was used (1% Lignocaine), infiltrated along the cord of the hydrocele side, pudendal block and along the median raphe where the surgical incision was made.

Upon making the incision along the median raphe, the scrotal wall was sharp dissected layer by layer until reaching the tunica vaginalis. Using the scalpel, a stab incision was made being careful not to stab the testis. The contents (hydrocele fluid) was drained and its volume measured using a measuring cylinder. The Excision technique was commonly used, with a few small hydroceles operated using the eversion technique. The use of diathermy was less common, with surgeons being quick and meticulous with haemostasis. Testis, epididymis and the tunica vaginalis were thoroughly inspected and their state documented. Unusual findings were seldom encountered warranting a biopsy specimen to be taken. A layered closure of the scrotal wall then followed ensuring haemostasis with vicryl 2-0 being the suture commonly used throughout the procedure. The surgical wound was then dressed using compression dressing (scrotal support) and kept elevated to hasten the resolution of resulting scrotal oedema and maintain hygiene of the surgical site. Oral antibiotics (Amoxicillin capsules 500mg and Metronidazole tablets 400mg both thrice a day for 5 days) with Acetaminophen tablets for analgesia were prescribed and given to all patients post operatively.

Day 1 post operatively, patients' wounds were assessed and re-dressed and health education provided on their condition and adherence to medical advice. Those patients fit for discharge

would then be discharged home with follow up visit scheduled after a week and alternate days wound dressing emphasized.

### **3.10. Recruitment and Data Collection Procedure**

Hydrocele camps conducted along the Tanzanian coastal regions under the MoHSW have a questionnaire designed and being used to collect patient particulars, relevant perioperative and follow up visits data at days 7,14, and 28of those who attended the camps and underwent hydrocelectomy.

A written informed consent gets attained at the camps from patients for the hydrocelectomy to be performed including consent for any additional surgery that may be seen to be necessary such as hernia repair and orchiectomy. Further consent was taken the patients to extract and record further details regarding their condition by filling a structured questionnaire of research purposes that was used at the camps under the blanket of MoHSW, subcommittee of NTDCP. The questionnaires were kept confidential in the patient's files. The Department of Surgery, MUHAS has access to this data base. Patients mobile phone numbers and of their chosen relative's mobile phone numberswere recorded to keep track of them upon follow up clinic visits and for research purposes.

This study intends to extract data of patients from the questionnaires prefilled during the camps conducted in the 2-year time frame (January 2016 - December 2017). Using a Random cluster sampling (Multistage), patients were recruited with sample size being realized. Total number of hydrocele surgical camps held between January 2016 to December 2017 were listed and each group (camp) numbered with a unique number and a small sample of relevant discrete groups was selected (by lottery method). Then, participants from those relevant groups were listed and selected at random (systematic sampling) until sample size needed was attained. So, the first sampling frame was all camps (groups) numbered and listed, out of which 4 camps were selected at random from a lottery bowl. A second sampling frame was made listing all participants (patients) from the 4 camps who underwent hydrocelectomy and by using systematic sampling 393 participants were sampled for the study.

The data attained was part of the information needed in the questionnaire designed for this study. Case notes and the questionnaires of the study participants were retrieved as are stored by NIMR and are available at the MUHAS Department of Surgery and can be accessed through the head of Department of Surgery. Telephone interview by the researcher and his research assistant of the participants on long-term complications and quality of life gave further information. If a patient raised concerns on phone interview that warrants a clinical examination, a meeting with him was arranged. The NCD coordinator and the CDD (community drug distributor) who know and have details of their respective patients from their district were requested for assistance in tracing patients the researcher wanted to meet and further assess. The research questionnaire tool was tested before the start of the study which was translated to Swahili.

### 3.11. Study Variables

The study had the following variables:

<b>Independent variables</b>	<b>Dependent variables</b>
Demographic characteristics	Post-hydrocelectomy complications such as hematoma, scrotal oedema, SSIs, recurrence etc.
Co-morbidities such as DM, HTN, Asthma, Anaemia	Presence of persistent scrotal swelling
Size of the hydrocele	Improvement in quality of life in terms of sexual, economic and social life
Use of peri-operative antibiotics	
Surgical technique used	

### **3.12. Data Management and Analysis**

Part of the data to be analyzed was already collected with some additional data attained by telephone interview and meeting some patients physically. A secondary data analysis was intended. The researcher had access to the surgical camps data base and was permitted by the MUHAS HOD Surgery who too hosts the data base. A sample of the structured data base has been provided (see appendices). Remaining data was collected on a daily basis over telephone interview, coded, sorted and entered to the SPSS program. An SPSS version24 was used and data analyzed. Chi square test and students t-test was used to determine association between different variables. P value <0.05 represented statistical significance among tested variables.

### **3.13. Ethical Clearance**

MUHAS research and publication committee was asked to provide the ethical clearance for the commencement of the study, MUHAS IRB, Ref. No. DA.287/298/01A. Confidentiality of patient's data and information was strictly observed and kept with the department of surgery MUHAS, including research questionnaires and consent forms. Patients had the right to participate or not to participate in the study, and right to withdrawal from the study at any point in time if the participant wasn't willing to be interviewed or be part of the study.

Consent for the use of the prefilled questionnaires used in the camps was already sought, for various research purposes and even for secondary data analysis, so to extract data from this data pool required no additional consent. Only that, upon calling participants for further information, a verbal consent was taken before further commencement of the interview and those participants who did not consent were not further interviewed. Confidentiality was adhered to on the interviewed information. For the few participants who needed to be seen physically, a written informed consent was provided for them to sign so as to further inquire and examine them.

### **3.14. Dissemination of Data**

Scientific research report has been presented to the department of surgery at MUHAS for MMed Surgery degree award that will thereafter be submitted to The Dean, School of

Medicine and Director of Postgraduate office. Also results will be used for teaching and further research purposes at MNH and MUHAS.

**3.15. Study Limitations**

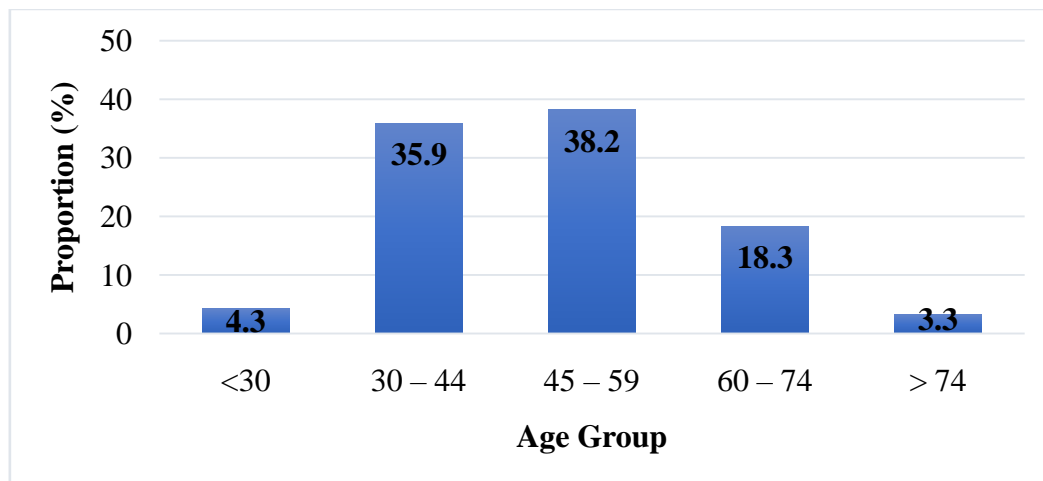
- i. Recall bias - as the study involved interviewing patients' months after surgery.
- ii. Incomplete (missing) data- Some of the data that was attained from the surgical camp data base was unclear and documentation was incomplete.
- iii. Non-response bias- Very few participants upon calling were less willing and some unable to participate in this study.



## CHAPTER FOUR

### 4. RESULTS

A total of 393 patients who underwent hydrocelectomy at the Hydrocele surgical camps that took place along the Tanzanian coastal regions from January 2016 to December 2017 were called and interviewed, of which **390 responded** (response rate of 98.5%): of those that did not respond, 3 were reported by relatives to have passed away, with their cause of death not related to the hydrocelectomy done. The mean age of the respondents was  $49.15 \pm 13.3$  (20 – 101) years with majority in the age group of 45 – 59 years accounting for 150 (38.2%), followed by those in age group 30 – 44 years having 141 (35.9%), 60 – 74 years with 72 (18.3%) as shown in **Figure 1 below**.



**Fig. 1: Age group distribution of 393 hydrocelectomy patients in Dar es Salaam region, Tanzania**

As seen below in **Table 1**, majority of patients, 283 (72 %) had a primary level of education followed by 66 (16.8%) patients with no formal education at all and 11.2% who had secondary education or higher. It can also be noted that majority of the participants were living in a relationship, where 277 (70.5%) and 52 (13.2%) were either married or cohabiting respectively, while 64 (16.4%) were living alone with no partners. Most of the hydroceles occurred unilaterally as was seen in 263 (66.9%) of the patients, with large sized hydrocele being the majority as witnessed among 235 (62.3%), followed by medium sized accounting

for 112 (29.7%). The existence of chronic health comorbidities was observed in only 46 (11.7%) of the participants, hypertension being the most common of all, affected 47.87%.

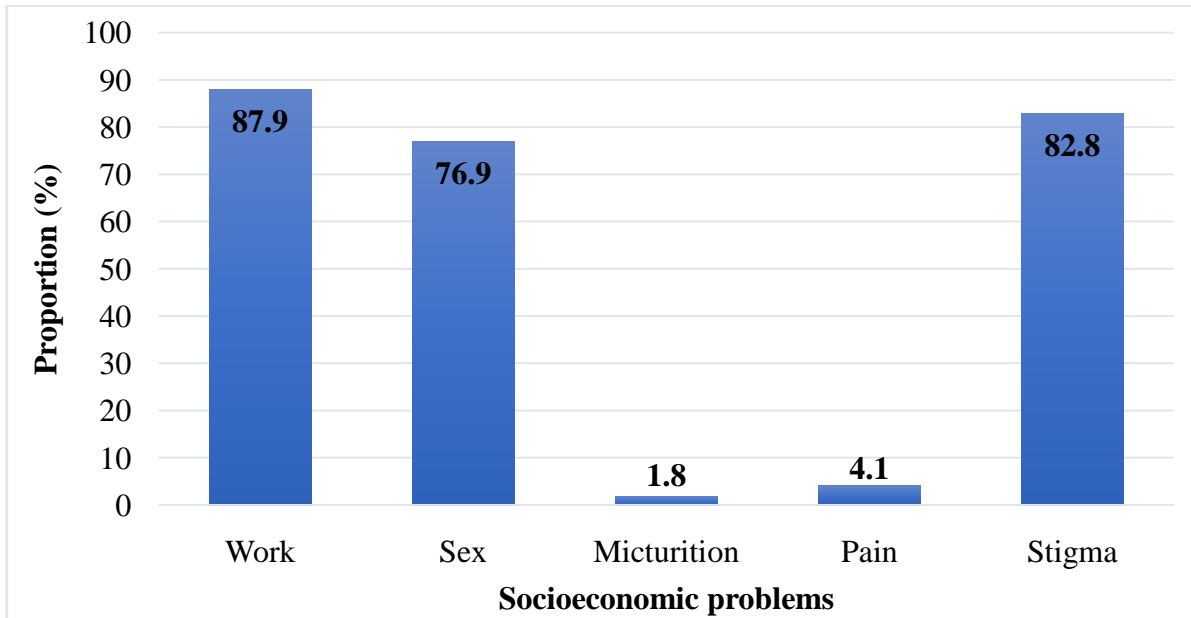
**Table 1: Overall Characteristics of patients in Dar es Salaam region who underwent hydrocelectomy.**

<b>Patient Characteristic</b>		<b>Frequency (%)</b>
<b>Level of Education</b>	No formal education	66 (16.8)
	Primary	283 (72.0)
	Secondary	41 (10.4)
	Higher education	3 (0.8)
<b>Marital Status</b>	Married	277 (70.5)
	Co-habiting	52 (13.2)
	Separated/Divorced	14 (3.6)
	Single	50 (12.7)
<b>Hydrocele Side</b>	Unilateral	263 (66.9)
	Bilateral	130 (33.1)
<b>Size of the Hydrocele*</b>	Small (<200mls)	15 (4.0)
	Medium (200 – 500mls)	112 (29.7)
	Large (>500 – 2000mls)	235 (62.3)
	Extra-large (>2000mls)	15 (4.0)
<b>Co-morbidities</b>	Hypertension	22 (47.83)
	Diabetes Mellitus	8 (17.39)
	Asthma	5 (10.87)
	Heart Disease	4 (8.70)
	Epilepsy	2 (4.35)
	Others**	5 (10.87)

Key: \*size was based on volume of fluid drained and was measure in 377 patients; \*\* included Heroin addicts, Tuberculosis, Stroke and HIV/AIDS.

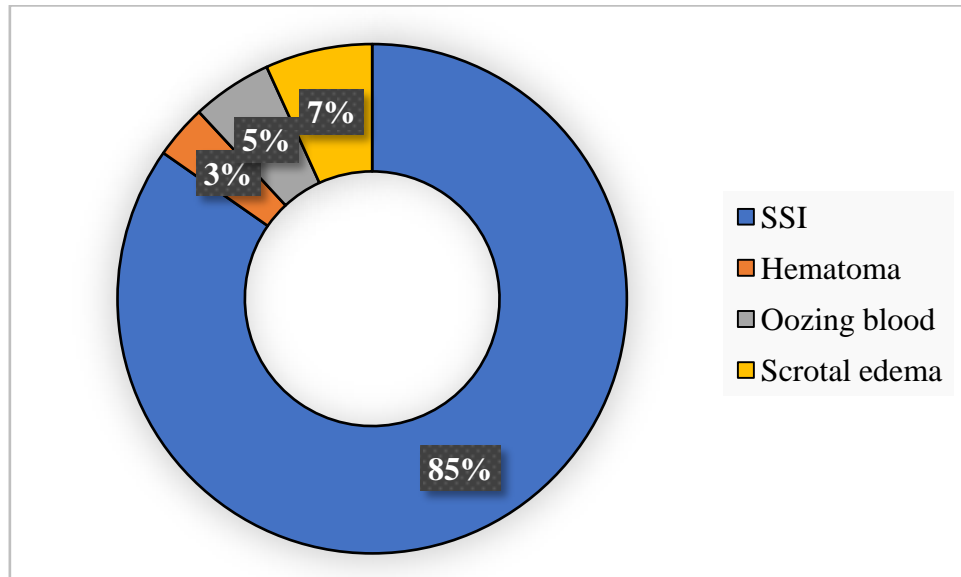
We assessed for socio-economic problems faced by the patients before surgery, and these could be mentioned multiply by the patients, hence, values represent frequency of mentioning and not number of patients affected per se. These are summarized in the bar chart represented

in **Figure 2** below whereby it can be noted that most patients had issues with work engagement, being stigmatized and sexual performance as was reported by 343 (87.9%), 323 (82.8%) and 300 (76.9%) patients respectively. Few patients had reported pain and difficulties with passing urine as was seen in 16 (4.1%) and 7 (1.8%) respectively.



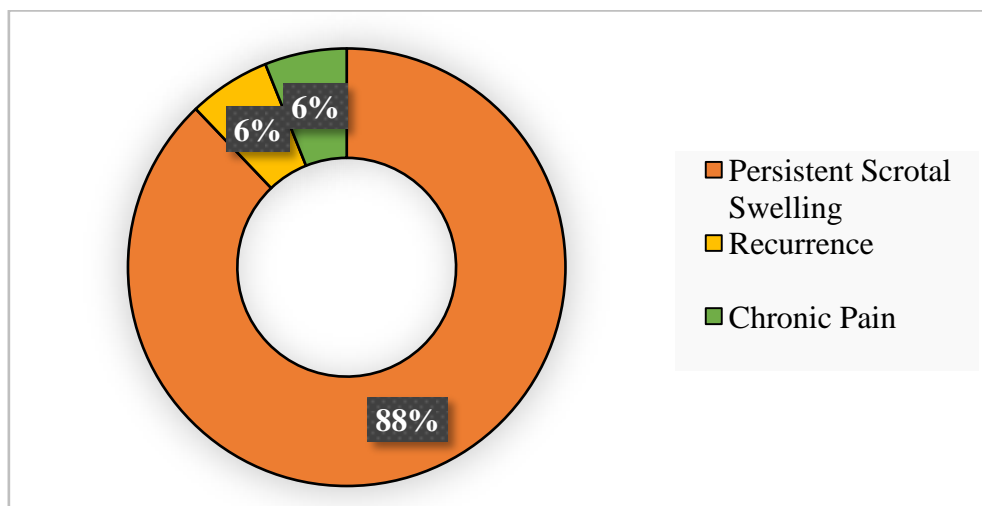
**Fig 2: Socioeconomic problems among hydrocele patients who underwent hydrocelectomy**

Referring to **Figure 3** below, out of 393 patients sampled, 82 patients had missing data regarding early post-operative complications. Of the 311 patients, 59 (19%) patients developed early post-operative complications. The leading complication among the 59 patients was SSI, accounting to 50 (85%) followed by scrotal edema, oozing of blood and hematoma, 4 (7%), 3 (5%) and 2 (3%) respectively.



**Fig 3: Early post-operative complications among patients who underwent hydrocelectomy**

From **Figure 4** seen below, of the 390 patients who underwent hydrocelectomy, 33 (8.4%) patients reported late post-operative complications of which 29 (88%) reported persistent scrotal swelling which was noted to be redundancy in the scrotum, and 2 (6%) patients each reported a recurrence and existence of chronic pain.



**Fig 4: Late post-operative complications among patients who underwent hydrocelectomy**

As depicted in **Table 2** below, association between persistent scrotal swelling and the size of the hydrocele, was such that, majority of patients 29 (7.75%) with persistent scrotal swelling were patients who had a small to medium sized hydrocele with their volumes ranging from 50 – 480 mls as compared to the patients who had resolved scrotal swelling who had large to extra-large hydroceles with volumes ranging from 500 – 3600 mls. The mean hydrocele volume was 168.28±80.80 mls among patients with persistent scrotal swelling and 804.36±511.80 mls among patients with resolved scrotal swelling, a finding that was statistically significant with p-value of <0.001.

**Table 2: Association between Hydrocele size and the presence of Persistent Scrotal swelling (N=374)**

<b>Scrotal swelling</b>	<b>Frequency (%)</b>	<b>Mean Hydrocele size (in mls)</b>	<b>Standard deviation</b>
<b>Persistent</b>	29 (7.75)	168.28	80.803
<b>Resolved</b>	345 (92.25)	804.36	511.798

16 patients had missing data on the volume of hydrocele fluid evacuated.

As shown in **Table 3** below, statistically significant changes in the marital status of the patients who underwent hydrocelectomy was noted before and after the procedure. After hydrocelectomy, more patients got married or were cohabiting and less remained single, separated or divorced.

**Table 3: Comparison between Marital status of patients before and after hydrocelectomy as a measure of Change in QOL (N=390)**

<b>Marital Status</b>	<b>Before N (%)</b>	<b>After N (%)</b>	<b>p-value</b>
<b>Married/Co-habiting</b>	327 (83.8)	375 (96.2)	<0.001
<b>Separated/Divorced</b>	13 (3.3)	4 (1.0)	<0.001
<b>Single</b>	50 (12.8)	11 (2.8)	<0.001

On a global rating scale, questions on how participants felt the surgery had brought changes in their lives specifically economic life, sexual life and overall satisfaction with surgery were asked and changes in QOL assessed. In **Table 4** below, the results are presented showing improvement in all parameters. Majority, 356 (91.3%) participants reported a satisfactory sex life with 299 (76.7 %) of the patients partners being happy with their sex life. Likewise most reported an improvement in performing their routine and occupational activities 376 (96.4%) and 371 (95.1%) respectively. Most patients also reported to be satisfied with the appearance of their genitals and 377 (96.7%) of the patients strongly agreed at recommending their peers and relatives suffering from a similar condition to seek for such a treatment.

**Table 4: Description of the Overall Changes in the Quality of Life of patients who underwent Hydrocelectomy (N=390)**

<b>Improvement in sex life and partner perception</b>		<b>Frequency (%)</b>
Sex Life	Yes	356 (91.3)
	Undecided	34 (8.7)
Partner Perception	Happy	299 (76.7)
	Not Happy	42 (10.8)*
<b>Improvement in quality of life</b>		
Daily activities	Yes	376 (96.4)
	No	14 (3.6)
Occupational activities	Yes	371 (95.1)
	No	19 (4.9)
<b>Satisfaction with surgery</b>		
Satisfaction	Yes	371 (95.1)
	No	19 (4.9)
Recommendation	Yes	377 (96.7)
	No	13 (3.3)

**Key: \*Some, 49 (12.6%) had no partner**

## CHAPTER FIVE

### 5. DISCUSSION

Surgery for hydrocele conditions is a very common procedure among surgeons in countries where the disease is endemic. In spite of this, long term follow up results of such surgery is scarce and available data comes from patients who self-report with recurrence. While in Tanzania several surgical camps have been organized in the past with the introduction of sac excision technique, these patients have never been offered beyond 30 days follow up hence the satisfaction of outcome and patients perception have never been covered. This study therefore becomes the first one in the region to address long-term results following partial sac excision hydrocelectomy on many patients. The results from this study could be generalized as a reflection of the true outcome of the technique in real clinical practice given its design and the number of cases reviewed.

Patients affected by hydrocele were largely young in their early fifties, hence suffering inflicted by hydrocele can be huge and devastating. This age group resembles that observed in many more other countries where hydrocele is endemic (15, 18, 10, 26). This might imply that mass drug chemoadministration is being effective in terminating the spread of filariasis as the young are less affected and the current patients might have been inflicted before the program begun, 2004 in Tanzania (27). Similarly, it calls for aggressiveness in eradicating filarial hydrocele as part of filariasis campaign in endemic countries and regions around the globe.

Filarial hydrocele in Tanzania was noted to be relatively large when measured based on amount of fluid and compared to another similar study from Nigeria (20). This has implication that simple drainage and eversion would result in an unsightly scrotum and even recurrence. For this reason, partial sac excision seemed a better option for our patients. The technique of partial sac excision was described in detail by a Srilankan Surgeon in 1971 and was popularized by Noroes and Colleagues while working on filarial hydrocele patients in



Brazil (1, 14). This technique was first tried in Tanzania by Mchembe et al and it was noted to be a very useful technique with satisfactory results (13).

Socio-economic problems stated as indications in the 2002 WHO report were faced by majority of our patients before surgery. Majority reported problems with work engagement, being stigmatized and sexual performance whereas a few stated pain and micturition difficulties. These were comparable to other studies on the socio-economic problems and were of a similar magnitude: further emphasizing on the physical disability, embarrassment and economic problems faced by patients with hydrocele, not to forget the affection towards sexual health and relationships (2, 5, 16, 22, 29, 30). Topics regarding sex life and partner satisfaction are usually sensitive, and participants may not express their views openly especially upon being telephone interviewed. But in this study most participants were quite open at discussing and the researcher and his assistant tried their level best to extract as much information possible regarding this aspect.

Both early and late complications were reported as seen in other studies. During the camps, all patients were given preoperatively intravenous ceftriaxone 1 gram stat, and post operatively kept on broad spectrum oral antibiotics. The overall complication rate (both early and late) in this study was found to be 27% of which SSI was the leading complication followed by persistent scrotal swelling. The least common complication was found to be chronic pain and recurrence (0.5% each). Similar studies elsewhere reported varying but comparable overall complication rates ranging from 19% to 53.8% (8, 15, 18, 10).

Surgical site infection was found to be the most prevailing complication among patients (19%), whereas most similar studies have their SSI rates lower ranging from 1.5% to 9.3% (8, 15, 18, 19, 20). For clean urological procedures, Cruse and Ford reported a wound infection rate of 1.5% based on a 10 year prospective evaluation (28). Despite of the higher SSI rate reported, no drainage or any more invasive surgical intervention was needed among the patients. Sterility of surgical preparations and congestion within theatre rooms may be a contributing factor as many patients were operated on a daily basis with operating rooms

being overcrowded at times. Poor compliance to post-operative antibiotics may also play a role in contributing towards a comparably high SSI rate seen in this study. Also, fluid re-accumulation which acts as a medium of infection may be a cause of the high SSI rate, as post-operative surgical drains were not placed. Postoperative dressings done improperly and poor scrotal hygiene could also be contributing factors. The fact that the current study shows such a high infection rate justifies further studies.

Scrotal edema being the top most complication reported in most studies was noted at a much lower rate in our study (1.3%). Studies done most endemic countries report much prevalence rates of more than 20% reaching 50% in other studies (8, 10, 19). Such low prevalence rate in our study could be an underestimate because majority of patients were discharged the next morning after the procedure and the next follow up visit was after 7 days. So most scrotal edemas, if occurred, may have gone unnoticed and resolved spontaneously.

Likewise, haematoma formation was also encountered to a much lower extent among our patients as compared to similar studies. Most studies had reported haematoma to be a common early post-operative complication with prevalence rates ranging between 1.5% to 11% amongst studies (8, 15, 19, 20). The lower rate of haematoma noted in this study could be explained by meticulous haemostasis that was achieved during surgery despite of the use of excision technique on most patients. Thorough attention was paid during both sharp and blunt dissection to minimize bleeding and the excised sac edges were plicated using running interlocking Vicryl suture. Post-operatively, patients were given clear instructions on scrotal care and to avoid strenuous activities at least for a week such as riding a bicycle. Further studies would help confirm and clarify more on such an observation.

Upon calling patients and interviewing, several late complications were brought to attention. Persistent scrotal swelling noted as scrotal sac redundancy and not having an expected scrotal size (still being large) was complained by several patients (7.4%). Further follow up and studies need to be done incorporating physical examination of such patients to establish whether such patients have true recurrence, or have a seroma, or have scrotal skin redundancy such that incorporating scrotoplasty during hydrocelectomy to such patients would bring about

a better outcome. Both recurrence and chronic pain weren't commonly reported, noted among 2 patients (0.5% each). Chronic pain though being reported less frequently as a complication in this study also seems to be the case in several other similar studies (15, 18). Hence, chronic pain is also a less frequent complication in our settings. Among the few studies done, comparable recurrence rates have been reported and a similar study done in Nigeria reported a 7% recurrence (8, 15, 19, 20). Recurrence is anticipated more in patients who undergo internal drainage, and thus open hydrocelectomy is gold standard for treating hydroceles with partial sac excision technique more suitable in our settings, a technique implemented on most patients with hydroceles coming to the hydrocele camps. Recurrence as a complication being noted to be very minimal in this study, adds to the success of the hydrocele camp program.

Persistent scrotal swelling as one of the late complication noted in this study was also of much interest, and an association with size of hydrocele if any was sought. A statistically significant finding was noted that, as majority of patients with persistent scrotal swelling were patients with small to medium sized hydroceles. No scrotal skin redundancy was complained by patients who had large to extra-large hydroceles upon follow up. This finding needs further studies, as one would expect, patients with large and extra-large hydroceles to be presenting more with scrotal swelling persistence as well as recurrence. Another explanation for the above finding would be that some patients who at the time of surgery presented with small to medium sized hydroceles noted less of a difference months after surgery in their scrotal size as compared to patients who had large and extra-large hydroceles. An underlying seroma could also be a possibility as mentioned earlier. Limited studies are available regarding this matter of which none have compared outcome in such manner (1, 20).

Marital status of the patients who underwent hydrocelectomy in this study was noted before and after the procedure. After hydrocelectomy, more patients got married or were cohabiting and less remained single, separated or divorced. Likewise, majority reported a satisfactory sex life with their partners also being happy with their sex life. Also marked improvement was reported by majority in performing their routine and occupational activities. Most patients also reported to be satisfied with the appearance of their genitals and strongly agreed at

recommending their peers and relatives suffering from a similar condition to seek such a treatment. Other similar studies likewise reported similar outcomes and concluded hydrocele surgery to have a positive impact in the quality of life of the patients and their families (22, 16).

## **CHAPTER SIX**

### **6. CONCLUSION AND RECOMMENDATIONS**

#### **6.1. Conclusion**

The hydrocele surgical camps being conducted in Tanzania since 2008 are a great contribution towards the fight and elimination of this neglected tropical disease. Some post procedural complications have been highlighted in this study, but these are to a minimal extent. Partial sac excision technique as practiced in our camps is safe, with minimal complications. Any reduction in scrotal size has a positive impact on the patients' quality of life.

#### **6.2. Recommendations**

- i. The partial sac excision technique of hydrocelectomy to be advocated more among surgeons.
- ii. The hydrocele surgical camps to increase aseptic precautions so as to reduce the rate of SSIs encountered.
- iii. Keeping more efforts at long term follow up of patients and doing their physical assessment to enable more identification of any recurrence, seroma development, scrotal skin redundancy and eventually assessing the need of incorporating scrotoplasty to selected cases.

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## APPENDICES

### A. APPENDIX I: CONSENTFORM (ENGLISH VERSION)

FORM FOR PATIENTS WHO UNDERWENT HYDROCELECTOMY AT HYDROCELE SURGICAL CAMPS TO INQUIRE FURTHER ON THEIR PROGRESS: (ENGLISH)

#### INTRODUCTION

My name is ....., I am doing research on outcomes of hydrocele surgery at surgical camps conducted along coastal regions of Tanzania. I am going to give you some information and invite you to be part of this research, I will conduct an interview session with you and fill up my questionnaire.

**Purpose of the research;** the aim of this research is to identify the outcome of hydrocelectomies that are performed at the surgical camps. The program has been carried out for years (since 2008) and an assessment of its outcome and patient satisfaction is necessary to ascertain its efficiency and efficacy.

**What participation involves;** this research involves some few randomly selected patients who underwent hydrocelectomy at hydrocele surgical camps conducted along the Tanzanian coastal regions between January 2016 and December 2017.

**Voluntary participation;** your participation is entirely voluntary and if you agree to join the study, you will be interviewed to answer questions from the questionnaires and some of your information will be extracted from the data base that is hosted by the MoHSW under NTDCP. Whether you choose to join the study or not you will have no implications what so ever on the further health care that you may need and are free to choose to/not to participate in this study.

**Confidentiality;** Confidentiality will be observed and unauthorized persons will have no access to the data collected.

**Costs:** No payment will be requested from you as a fee to participate in the study.

**Benefits;** The information you provide will enable us to assess the impact of this program on patients treated and the society as a whole. It will enable us to know the setbacks and the way to improve further the camp undertakings. This will ensure better service to be delivered to the patients that get treated at the hydrocele surgical camps.

**Risks;** We do not expect that any harm will happen to you upon participating in this study.

**Right to withdraw:** You can stop participating in this study at any time, even if you have already given your consent and refusal to participate or withdrawal from the study will involve no penalty.

**Who to Contact:** If you have questions about this study, you should contact the

In case of any information about your rights as a participant in this study, please contact:

Dr. Joyce R Masalu  
Director of Research and Publications,  
Muhimbili University of Health and Allied sciences (MUHAS)  
P. O. Box 65001, Dar es Salaam.  
Tel: +255 22 2152489/0302-6  
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Dr Larry O Akoko  
Consultant surgeon and senior lecturer at surgery department  
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Telephone: +255 692107359  
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Dr. Hussein M Khanbhai  
Principal investigator  
P.O.BOX 65001, Dar es salaam  
Tel: +255714409972  
Email address: drhuseinshakir@gmail.com

I .....have read and understood the contents in this form and my questions have been answered.

I agree /do not agree to participate in this research.

Signature/thumb print of the participant.....

Signature of the Investigator .....

Date of signed Consent .....

## **B. APPENDIX II: CONSENT FORM (SWAHILI VERSION)**

FOMU YA RIDHAA KWA MGONJWA ALIYEFANYIWA UPASUAJI WA MABUSHA KATIKA KAMBI LA UPASUAJI WA MABUSHA ZILIZOFANYIKA MIKOANI TANGA, DARES SALAAM, LINDI NA MTWARA JANUARI 2016 HADI DESEMBA 2017

### **UTANGULIZI**

Mimi.....

ninafanyautafiti juuyamotokeayaupasujiamabushayaliyofanyikakatikamakambizaupasujiyamabushamikoayapwanitoka Januari 2016 hadi Desemba 2017. Matokeohayayanajumuishamatatizoyaliyokumbwamarabaadayaupasujimatatizosuguyanayowakumbawagonjwahadisasayanayohusikanaupasujiuilofanyikanapiauborawamaishayawagonjwawaliofanyiwaupasujiamabusha (kijamii, kiuchuminakisaikolojia). Nakualikakuwasehemuyautafitihuubaadayakukufafanulia, halafunitafanyamahojianonawewekishanitajazadosolangu.

**Dhumuni la utafiti; lengo la**  
utafitihuunikugunduamotokeayaupasujiamabushailiofanyikakatikamakambiyaupasujiamabusha. Hudumahiinatolewakuanziamwaka 2008 nakutathminimatokeoyakenauridhikajiyawagonjwawaliopokeamatibabuhayanimuhimu ilikuim arishaprogramuhiinakuwezakutoahuduma bora zaidikwawenginewafuatao.

### **Ushiriki unahusisha;**

utafitihuunahusishabaadhiyawagonjwawaliofanyiwaupasujiamabushakatikamakambiyaupasujiamabushayaliyofanyikamikoayapwani, Tanzania toka Januari 2016 hadi Desemba 2017.

### **Ushiriki wahiri;**

ushiriki wakokatika utafitihuuni wahiri bilakushurutishwa, utahoji wailikupata arifa muhimu, taarifa yingine zitapatikanakwenye jaladalakonakutokwa Wizaraya Afya, Maendeleo ya Jamii, Jinsia, Wazeena Watoto pamojama Mpangowa Taifa wa Kudhibiti Magonjwa Yaliyokuwa Hayapevi Kipao mbele (NTDCP). Endapo utakata kutokuhojiwa au kutokuendelea mahojianounaruhusiwa.

### **Faidana athari;**

Utafitihuuna athari yoyote kwamshiriki. Mshirikiataelimishwakuhusu ugonjwahusika.

### **Usiri wataarifa;**

Taarifa tutakazochukuazitatunzwakwasiri. Taarifa hizo zitatumikakwaajiliyautafitihuutu.

**Gharamayakushirikikatikautafitihuu;**

Mshirikihataingiagharamayoyoteilikushirikikatikautafitihuu.

**Ukiwanamaswali au shidawakatiwowotekuhusiananautafitihuuwasiliana  
nawafuatao:**

Iwapoutakuwanaswalilolotekuhusuhakizakokamamshirikikatikautafitihuuwasilianana:

Dr. Joyce R Masalu  
MkurugenziwaUtafitinaMachapisho  
Chuo Kikuu cha afyanaSayansishirikishi Muhimbili,  
S.L.P. 65001, Dar es Salaam.  
Simuyaofisi: +255 22 2152489/0302-6  
Baruapepe: drp@muhas.ac.tz

Dr Larry O Akoko  
Mshauriwaupasujinamuhadhiriwaupasujaji  
Chuo kikuu cha afya Muhimbili MUHAS  
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MkuuwaUchunguzi  
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Simu +255714409972  
Baruapepe: drhuseinshakir@gmail.com

Mimi ..... nimeelezwa/nimesomayaliyomokatika  
fomuhiinanimeelewamaanayake. Nakubalikushirikikatikautafitihuu.

Sahihi..... (Mshiriki) Tarehe.....

Sahihi ..... (Mtafiti) Tarehe .....

**C. APPENDIX III: QUESTIONNAIRE (ENGLISH VERSION)**

**BROAD OBJECTIVE:** To assess the outcome of hydrocelectomy on patients who attend hydrocele surgical camps in Tanzania.

Questionnaire number.....

Participant contact.....

Date of surgery .....

**PRE-SURGICAL QUESTIONNAIRE**

**Socio-demographic characteristics of the study population**

1. Age ..... (in years)
  - a. 0-14
  - b. 15-29
  - c. 30-44
  - d. 45-59
  - e. 60-74
  - f. >74
2. Residence ..... (Region)
3. Level of education
  - a. No formal education
  - b. Primary education
  - c. Secondary education
  - d. Higher education
4. Occupation
  - a. Peasant
  - b. Employed
  - c. Unemployed
  - d. Retired
5. Marital status
  - a. Married
  - b. Co-habiting
  - c. Separated
  - d. Divorced
  - e. Single

**Specific Objective:** To assess co-morbidities that may affect outcome

6. Any co-morbidities present pre-operatively?
  - a. Heart Disease YES  NO
  - b. Diabetes Mellitus YES  NO
  - c. Sickle cell Disease YES  NO
  - d. Asthma YES  NO
7. What was the Haemoglobin level (in g/dL) pre-operatively?
  - a. > 12.9
  - b. 10 -12.9
  - c. 7 – 9.9
  - d. < 7
  - e. Not recorded
8. What was the Random blood glucose (in mmol/L) pre-operatively?
  - a. < 7.8
  - b. 7.8 – 11
  - c. > 11.1
  - d. Not recorded
9. What was the Blood pressure (in mmHg) pre-operatively?
  - a. < 90/60
  - b. Between 90/60 and 140/90
  - c. > 140/90
  - d. Not recorded

## POST-SURGICAL QUESTIONNAIRE

**Specific objective:** To evaluate the association between the size of the scrotum (hydrocele) and the susceptibility towards developing persistent scrotal swelling.

10. What was the size of the hydrocele? (ascertained from the amount of fluid drained in mls)
  - a. Small (<200mls)
  - b. Medium (200-500mls)
  - c. Large (500- <2L)
  - d. Extra-large (>2L)

**Specific Objective:** To describe early post-operative complications of hydrocelectomy.

11. Where pre-operative antibiotics prescribed? YES  NO

12. Duration of Hospital stay post operatively ..... (in Days)

13. Any complication noted?

a. Hematoma YES  NO

b. Surgical site infection YES  NO

c. Oozing of fluids at surgical site YES  NO

14. What was the wound status at first follow up visit (7<sup>th</sup> Day post op)?

.....

### INTERVIEW (OVER THE PHONE)

The participant who underwent hydrocelectomy being the interviewee

NB: for those participants whose interview over the phone yields unclear responses, a meeting has to be arranged with the participant and the researcher has to further inquire and if need be, examine the participant to attain clear and correct data. A written consent is needed from such participants.

**Specific objective:** To determine the WHO indications for hydrocelectomy.

15. What are the reason(s) that made you seek medical attention?

a. It interfered with my work YES  NO

b. It interfered with my sexual life YES  NO

c. It brought difficulty in passing urine YES  NO

d. It was painful YES  NO

e. It brought humility and disgrace to me and my family YES  NO

f. Others.....

**Specific Objective:** To describe late post-operative complications of hydrocelectomy.

16. Is there reduction in the size of your scrotum after you underwent surgery to the moment?

YES  NO

17. If yes, how satisfied are you with the size of your scrotum that you have at the moment?

a. Very much

b. Somewhat



- c. Undecided
  - d. Not really
  - e. Not at all
18. If No, is your scrotum
- a. The same as it was before surgery
  - b. Bigger than what it was before surgery
19. How do you grade your scrotal pain at the moment, if any?
- a. No pain
  - b. Mild pain
  - c. Moderate pain
  - d. Severe pain
20. Have you noted any recurrence of the scrotal swelling (that resembles the previous one that underwent surgery)?
- YES  NO

NB: Participants who respond YES to Qn.22 will be asked to meet with the researcher where by the researcher has to confirm this finding further by examining the participant.

**Specific Objective:** To assess quality of life of patients that have undergone hydrocelectomy(Sexual, economic and psychosocial)

21. Marital status after undergoing hydrocelectomy
- a. Married
  - b. Co-habiting
  - c. Separated
  - d. Divorced
  - e. Single
22. Is there any improvement in your sex life?
- a. Very much
  - b. Somewhat
  - c. Undecided
  - d. Not really
  - e. Not at all
23. How does your life(sex) partner perceive you now?  
 .....
24. Is there any improvement in ambulation?
- a. Very much
  - b. Somewhat
  - c. Undecided

- d. Not really
  - e. Not at all
25. Is there any improvement in performing your daily chores?
- a. Very much
  - b. Somewhat
  - c. Undecided
  - d. Not really
  - e. Not at all
26. Is there any improvement in performing your occupational activities?
- a. Very much
  - b. Somewhat
  - c. Undecided
  - d. Not really
  - e. Not at all
27. Are you satisfied the way your penis and scrotum look?
- a. Very much
  - b. Somewhat
  - c. Undecided
  - d. Not really
  - e. Not at all
28. Would you recommend someone else suffering from a similar problem like the one you had to seek medical attention?
- a. Very much
  - b. Somewhat
  - c. Undecided
  - d. Not really
  - e. Not at all

..... **END** .....

**D. APPENDIX IV: QUESTIONNAIRE (SWAHILI VERSION)**

NB: Swahili translation is only seen necessary for the set of questions that will be asked to the patient (over the phone or in person), as other questions will be answered from the structured data base of the hydrocele surgical camps.

**BROAD OBJECTIVE:** To assess the outcome of hydrocelectomy on patients who attend hydrocele surgical camps in Tanzania.

Questionnaire number .....

Participant contact .....

Date of surgery .....

**PRE-SURGICAL QUESTIONNAIRE**

**Socio-demographic characteristics of the study population**

1. Age ..... (in years)
  - a. 0-14
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  - c. 30-44
  - d. 45-59
  - e. 60-74
  - f. >74
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  - b. Primary education
  - c. Secondary education
  - d. Higher education
4. Occupation
  - a. Peasant
  - b. Employed
  - c. Unemployed
  - d. Retired
5. Marital status
  - a. Married
  - b. Co-habiting
  - c. Separated
  - d. Divorced

- e. Single

**Specific Objective:** To assess co-morbidities that may affect outcome

6. Any co-morbidities present pre-operatively?
  - a. Heart Disease YES  NO
  - b. Diabetes Mellitus YES  NO
  - c. Sickle cell Disease YES  NO
  - d. Asthma YES  NO
7. What was the Haemoglobin level (in g/dL) pre-operatively?
  - a. > 12.9
  - b. 10 -12.9
  - c. 7 – 9.9
  - d. < 7
  - e. Not recorded
8. What was the Random blood glucose (in mmol/L) pre-operatively?
  - a. < 7.8
  - b. 7.8 – 11
  - c. > 11.1
  - d. Not recorded
9. What was the Blood pressure (in mmHg) pre-operatively?
  - a. < 90/60
  - b. Between 90/60 and 140/90
  - c. > 140/90
  - d. Not recorded

## POST-SURGICAL QUESTIONNAIRE

**Specific objective:** To evaluate the association between the size of the scrotum (hydrocele) and the susceptibility towards developing persistent scrotal swelling.

10. What was the size of the hydrocele? (ascertained from the amount of fluid drained in mls)
  - e. Small (<200mls)
  - f. Medium (200-500mls)
  - g. Large (500- <2L)
  - h. Extra-large (>2L)

**Specific Objective:** To describe early post-operative complications of hydrocelectomy.

11. Where pre-operative antibiotics prescribed? YES  NO

12. Duration of Hospital stay post operatively ..... (in Days)

13. Any complication noted?

a. Hematoma YES  NO

b. Surgical site infection YES  NO

c. Oozing of fluids at surgical site YES  NO

14. What was the wound status at first follow up visit (7<sup>th</sup> Day post op)?

.....

### INTERVIEW (OVER THE PHONE)

The participant who underwent hydrocelectomy being the interviewee

NB: for those participants whose interview over the phone yields unclear responses, a meeting has to be arranged with the participant and the researcher has to further inquire and if need be, examine the participant to attain clear and correct data. A written consent is needed from such participants.

**LengoMaalum:** Kujuasababuzilizompelekeamgonjwaafanyiweupusuajiwamabusha.

15. Je, nisababuzipizilizokufanyautafutematibabu?

a. Iiingiliananautekelezajewanguwakazi NDIYO  APANA

b. Iiingiliananamaishayanguyakimapezi NDIYO  HAPANA

c. Iiletashidakatikakujisaidiahajandogo NDIYO  APANA

d. Iiletamaumivu NDIYO  HAPANA

e. IiletaUnyenyekevunaabukwanguwakwafamilyangu  
NDIYO  HAPANA

f. Mengineo .....

**LengoMaalum:** Kutathminimatatizosuguyanayowezakutokeabaadayaupusuajiwamabusha

16. Je, kunaupungufukatikaukubwawapumbubaadayakufanyiwaupasuji?

NDIYO  HAPANA

18. Kama Ndiyo, Je, umeridhikakiasiganinaukubwaulionaowapumbu?

a. Sana

b. Kiasi

c. Sijui

- d. Sijaridhika
- e. Sijiridhikakabisa

19. Kama Hapana, Je, pumbulako
- a. Ni sawanailivyokuwakablayaupasuji
  - b. Ni kubwaukilinganishanayakablayaupasuji

20. Je, unamaumivuyoyoteyapumbu?
- a. Hapana
  - b. Maumivumadogo
  - c. Maumivuwastani
  - d. Maumivumakali

21. Je, umebainikurudiakwailehaliyaawaliyamapumbu (busha)?

NDIYO  HAPANA

NB: Participants who respond YES to Qn.22 will be asked to meet with the researcher where by the researcher has to confirm this finding further by examining the participant.

**LengoMaalum:** KutathminiuborawaMaishayawagonjwawaliofanyiwaupasujiwamabusha (kijamii, kiuchuminakisaikolojia)

22. HaliyaNdoabaadayaupasujiwabusha
- a. Nimeoa
  - b. Naishinampenzi
  - c. Tumeachana
  - d. Talaka
  - e. Sijaoawalasinampenzi
23. Je, maishayakoyakimapenziyameboreshwakwakiasigani?
- a. Yameboreshwasana
  - b. Yameboreshwakiasi
  - c. Sijui
  - d. Yamekuwamabayakiasi
  - e. Yamekuwamabayasana.
24. Mpenzi/mkewakoanamtazamoupijuuyakokwasasakimapenzi?  
.....
25. Je, harakatizakozimeboreshwa?
- a. Yameboreshwasana
  - b. Yameboreshwakiasi
  - c. Sijui

- d. Yamekuwamabayakiasi
  - e. Yamekuwamabayasana.
26. Je, kunaunafuukatikautekelezajiwakazizakozakilasiku?
- a. Mwingi
  - b. Kiasi
  - c. Sijui
  - d. Hamna
  - e. Hamnaunafuukabisa
  - f.
27. Je, kunaunafuukatikautekelezajiwashughulizakozakimapato?
- a. Mwingi
  - b. Kiasi
  - c. Sijui
  - d. Hamna
  - e. Hamnaunafuukabisa
28. Je, umeridhikanamnaumenapumbuyakoinavyoonekana?
- a. Nimeridhikasana
  - b. Nimeridhikakiasi
  - c. Sijui
  - d. Sijaridhika
  - e. Sijaridhikakabisa
29. Je, ungependekezamtuwakowakaribu au mtuyeyotemwenyeshidainayolingananauliyokuwanayokutafutamababu?
- a. Ningependekezasana
  - b. Ningependekezakwakusita
  - c. Sijui
  - d. Nisingependekeza
  - e. Nisingependekezakabisa

..... **MWISHO** .....