

**COMPARATIVE STUDY OF SCLEROTHERAPY  
WITH PHENOL AND SURGICAL  
TREATMENT FOR HYDROCOELE AT THE  
UNIVERSITY TEACHING HOSPITAL**

BY

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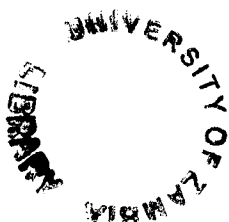
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University of Zambia  
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## APPROVAL FOR EXAMINATION

This Dissertation is ready for examination

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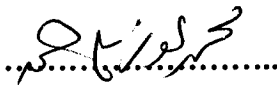
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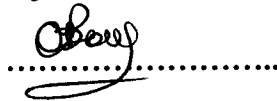
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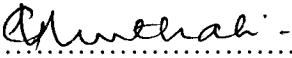
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## Declaration

I hereby declare that this dissertation herein presented for the degree of Master of Medicine Surgery has not been previously submitted wholly or in part for any other degree at this or any other University, nor is it being currently submitted for any other degree.

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## ABBREVIATION

### Abbreviations

<b>FIG</b>	-	<b>Figure</b>
<b>UTH</b>	-	<b>University Teaching Hospital</b>
<b>Pt</b>	-	<b>Patient</b>
<b>No.</b>	-	<b>Number</b>
<b>Pos</b>	-	<b>Post operative stay</b>

## **TERMINOLOGIES**

### **Terminologies**

1. Hydrocele - Fluid collection in the tunica vaginalis
2. Sclerotherapy - Treatment of hydrocele using sclerosant
3. Hydrocelectomy - Operative treatment of hydrocele
4. Recurrence rate - Rate of recollection of fluid in the tunica vaginalis
5. Idiopathic - of not known cause.
6. Haematoma - collection of extravasated blood in the tissues.
7. Multiloculated - Many pockets of fluid collection.

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## **ABSTRACT**

This study was carried out to study the efficacy and short term outcome of sclerotherapy with phenol, to study its complications and compare it to hydrocelectomy for the treatment of hydroceles at the UTH. The study was carried out over a period of 12 months starting in August 2003.

The details of the technique used and patient selection are described. Fifty patients with hydrocele were recruited into the study. Thirty-five patients had undergone sclerotherapy and fifteen hydrocelectomy. The age range was 24 – 84 years (mean 65 years). The cause was not known in all of them and cytology and ultrasound of the testes were normal. The average duration of the hydrocele was 30 months ranging from 1 – 264 months. The most frequent was 24 months. The right side was affected 47.1% of cases and the left 52.9%. Complications were infection in 12.5% of cases and recurrence 87.5%. There was no recurrence in 19 patients, which accounted for 59.4%. Fifteen patients underwent hydrocelectomy and in the short term (8 months) there were no recurrences.

## **OBJECTIVES**

- a. To study the efficacy and short-term outcome of sclerotherapy with phenol.
- b. To study the complications of sclerotherapy with phenol.
- c. To compare sclerotherapy to hydrocelectomy for the treatment of hydrocele.
- d. To provide guidelines for the use of sclerotherapy as a method of treatment for hydrocele

## **RATIONALE**

Hydrocele is a common problem in Zambia affecting males of different age groups. The current method of treatment, hydrocelectomy, involves long waiting lists, complications like infections, haematomas and is expensive in terms of loss of many working hours, hospital admissions, anaesthesia and other surgical consumables.

Any method of treatment, which is safer, painless and cheaper, will improve patient care. The little information available on sclerotherapy for hydrocele makes it necessary to study its feasibility, safety and efficacy as an option of treatment of hydrocele in Zambia.

Sclerotherapy as a method of treatment of hydrocele is technically simple, painless, minimally invasive, safe, cheap, efficient, gives lasting results and is an outpatient procedure. In other countries it has proved to be an efficient and safe procedure, which allows the patient to return to normal activities on the same day. However, opinions on the procedure have not yet achieved unanimities

## LITERATURE REVIEW

A Hydrocele has been defined as an abnormal collection of serous fluid in some part of the processus vaginalis, usually the tunica<sup>1</sup>. The anatomical classification of hydrocele is:-

- a. Communicating
  - Congenital hydrocele
  - Communicating hydrocele of the cord (funicular)
  - Communicating complete hydrocele
  - Hydrocele of hernial sac
- b. Non-communicating types
  - Infantile hydrocele
  - Non-communicating funicular (encysted hydrocele of the cord)
  - Hydrocele of tunica vaginalis testis
  - Hydrocele-en-bisac (Dupuytren's)

The clinical classification is:-

1. Congenital hydrocele
2. Acquired which can be
  - Idiopathic
  - Secondary
    - Acute/chronic epididymoorchitis
    - Filarial epididymitis
    - Syphilitic orchitis
    - Post Operation complication

- Malignant tumours
- Lymphatic stasis of different aetiology

## **ETIOLOGY & PATHOPHYSIOLOGY**

A hydrocele can be produced in four ways <sup>(1,8)</sup>;

- By excessive production of fluid within the sac e.g. secondary

hydrocele

- By defective absorption of fluid. This appears to be the explanation for most primary hydroceles, though the reason why the fluid is not absorbed is obscure.

- By interference with lymphatic drainage of scrotal structures.

- By connection with a hernia of the peritoneal cavity in the congenital variety

Hydrocele fluid is amber coloured, sterile and contains albumin and fibrinogen.

Hydroceles are almost invariably translucent and it is possible to “get above the swelling” on examination of the scrotum.

## **FREQUENCY**

Patent processus vaginalis are found in 80-90% of term male infants at birth.

This frequency rate decreases steadily until age 2 years, when it appears to plateau at approximately 25 – 40%.

However, clinically apparent scrotal hydroceles are evident in only 6% of term males beyond the new born period.

## TREATMENT

The treatment of hydrocele is aspiration, hydrocelectomy and sclerotherapy.

Sclerotherapy, performed on an out-patient basis involves aspiration of the hydrocele fluid and injection of 2.5% phenol in aqueous medium (10% volume of aspirated fluid <sup>7,21</sup>).

## METHODS OF REPAIR

### a. Excisional techniques

These are most certain to result in permanent elimination of the hydrocele. Excision is performed for long-standing hydroceles with thick walled sacs and multiloculated hydroceles.

### b. Plication techniques

Plication operations (Lord, 1964)<sup>9</sup> can be employed for thin sacs but are not suitable for multiloculated hydroceles or long standing thick walled hydroceles because plication will leave a large bundle of residual tissue within the scrotum.

### c. Window operations

These offer a quick, bloodless method of repair but are associated with a high recurrence rate if they are used for large hydroceles.

### d. Dartos Pouch technique

This is suitable for thin walled sacs. As in plication and window techniques, sac dissection is not required and bleeding is minimal.

### e. Sclerotherapy

Sclerotherapy has been used with some success in the treatment of hydrocele. Sclerotherapy with tetracycline derivatives may result in epididymal obstruction

and sometimes is associated substantial post operative pain and recurrence <sup>10</sup>. Sclerotherapy with phenol is performed on an out-patient basis with the patient in normal clothing and without shaving. The puncture site is identified and prepared with iodine. The skin and subcutaneous tissues are infiltrated with 1% Lignocaine. Scrotal puncture is done with a size 16G cannula and the hydrocele is drained completely. A maximum of 5mls of 1% Lignocaine is injected into the tunica. After 1 minute, 2.5% phenol in aqueous medium with PH between 4 & 6 is injected. The volume of phenol injected is calculated to correspond to 10% of the volume of the drained hydrocele when less than 400mls, to 5% of drained volume when it exceeds 400mls. Neither analgesics, nor antibiotics are used.

## **COMPLICATIONS**

Haematoma is the most common complication of hydrocele. When excision techniques are employed, the incidence of haematoma can be minimised by meticulously oversewing all raw edges of the sac and draining the scrotum. In men desiring to maintain fertility for the future, the primary dangers associated with hydrocelectomy operations are injury to the epididymis or the vas deferens <sup>11</sup>. Recurrence, wound infection and injury to the genitofemoral and ilioinguinal nerves are other complications.

## **ETHICAL CONSIDERATIONS**

Well informed consent will be obtained and confidentiality will be observed throughout the study. Psychological care will be given continuously from the fist visit. Ethical approval will be sought from the Research Ethics Committee.

## **PATIENTS AND METHODS**

- Study site:** The study will be conducted at the University Teaching Hospital Dept. of Surgery.
- Study design:** A descriptive and longitudinal randomised study of patients diagnosed with idiopathic hydrocele
- Setting:** Urology clinic at the UTH. A “hydrocele clinic” will be started in clinic 7 and patients will be reviewed there.
- Sample size:** Fifty patients will be recruited – 35 for sclerotherapy and 15 for hydrocelectomy.
- Follow-up:** Patients will comeback to the clinic at 1,3, & 6 months to look for complications of the procedure done.
- Results:** Objective and subjective results will be used to determine the benefits to the patients.

### **Inclusion Criteria**

This will include patients clinically diagnosed with idiopathic hydrocele and referred from general surgical units to the urology unit. Their ages should be above 15 years. Patients with mild to moderate hydroceles shall be included in the study. Informed consent shall be sought from these patients.

### **Exclusion Criteria**

Patients with hydroceles, who will not meet the above mentioned criteria will be excluded from the study.

## **Clinical Methods**

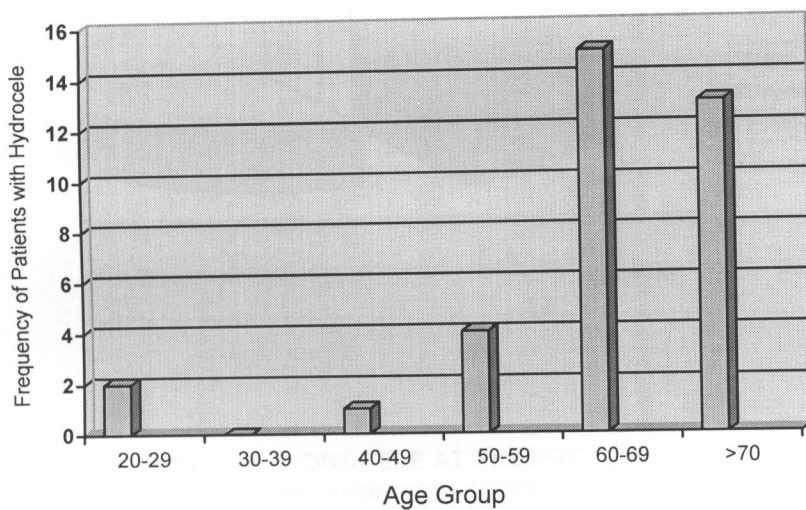
All patients in the study will undergo thorough clinical evaluation. This will include a detailed medical history focusing on the urinary tract, previous urological procedures, general health issues and fitness for possible surgical procedures. Examination of the external genitalia shall be carried out and a fluctuant translucent swelling shall be sought for. In hydroceles it is possible to “get above the swelling” as opposed to hernias on examination of the scrotum. A scrotal tap will be done to collect the hydrocele fluid for cytology.

## **Laboratory Methods**

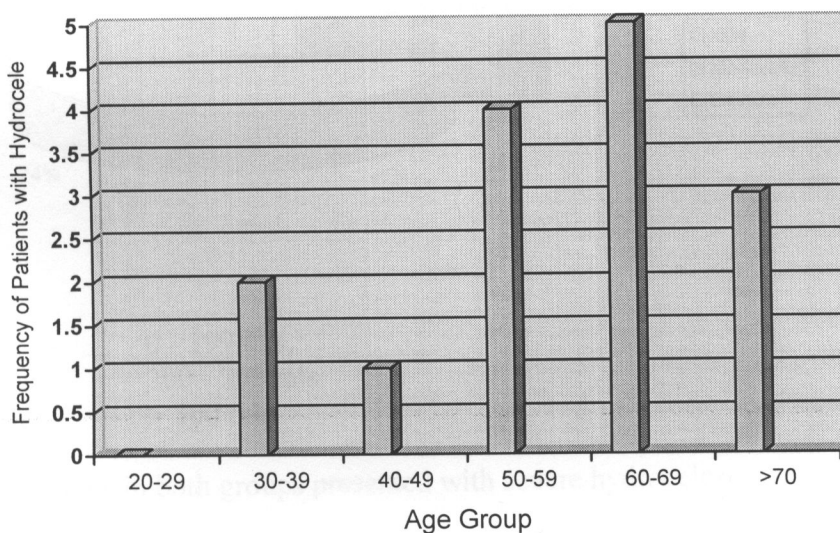
1. **Cytology** of the hydrocele fluid will be done for neoplastic cells and filariasis.
2. **Ultra sonography** will be routinely used to determine the state of the testis and possibly the size of the hydrocele.

## RESULTS

**Fig. 1 AGE DISTRIBUTION OF THE PATIENTS FOR SCLEROTHERAPY**

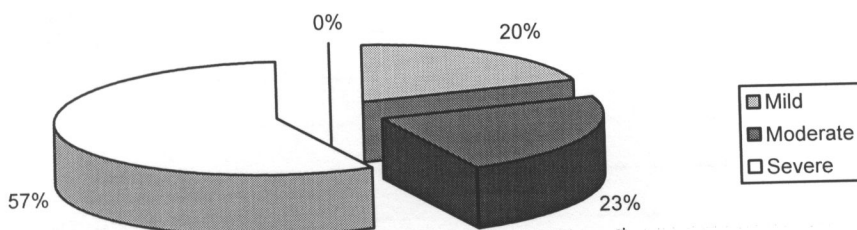


**Fig. 1 AGE DISTRIBUTION OF THE PATIENTS FOR HYDROCELECTOMY**

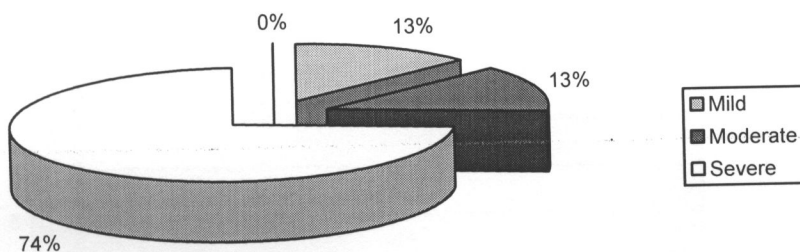


Most of the patients in both study groups were aged between 40 and 70 years.

**Fig. 2 SEVERITY OF HYDROCELE AT PRESENTATION IN PATIENTS FOR SCLEROTHERAPY**



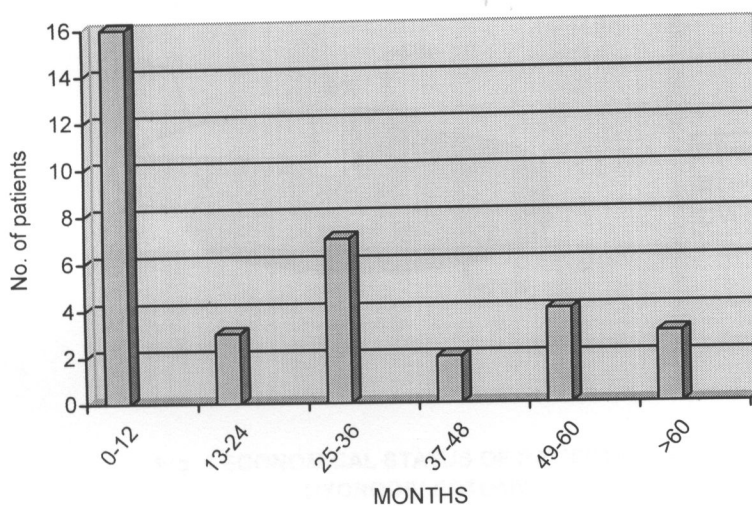
**Fig. 2 SEVERITY OF HYDROCELE AT PRESENTATION IN PATIENTS FOR HYDROCELECTOMY**



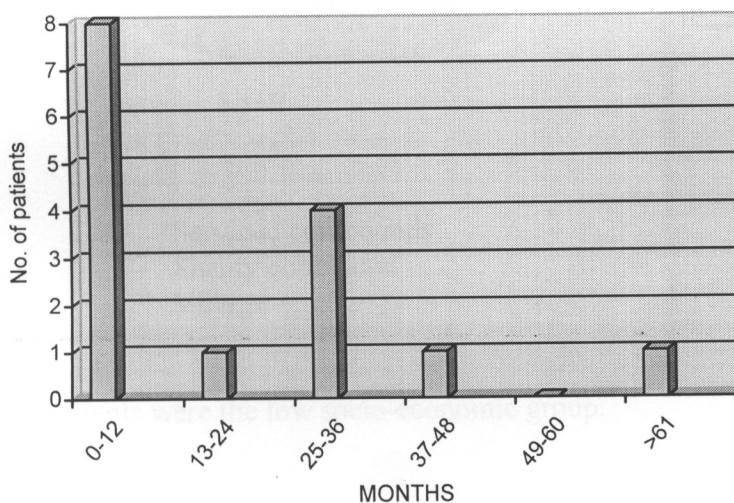
Mild	-	0 - 199 mls,
Moderate	-	200 - 299 mls
Severe	-	> 300 mls

Majority of patients in both groups presented with severe hydroceles

**Fig 3 DISEASE DURATION OF ALL THE PATIENTS IN THE STUDY FOR SCLEROTHERAPY**

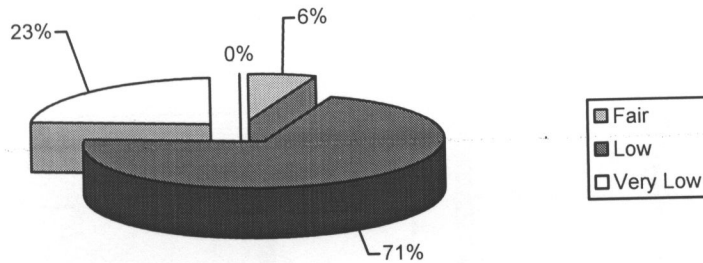


**Fig 3 DISEASE DURATION OF ALL THE PATIENTS IN THE STUDY FOR HYDROCELECTOMY**

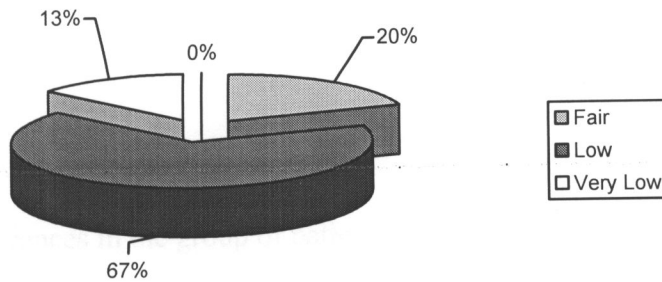


In both groups the disease duration of most patient was year.

**Fig. 4 ECONOMICAL STATUS OF PATIENTS FOR SCLEROTHERAPY**



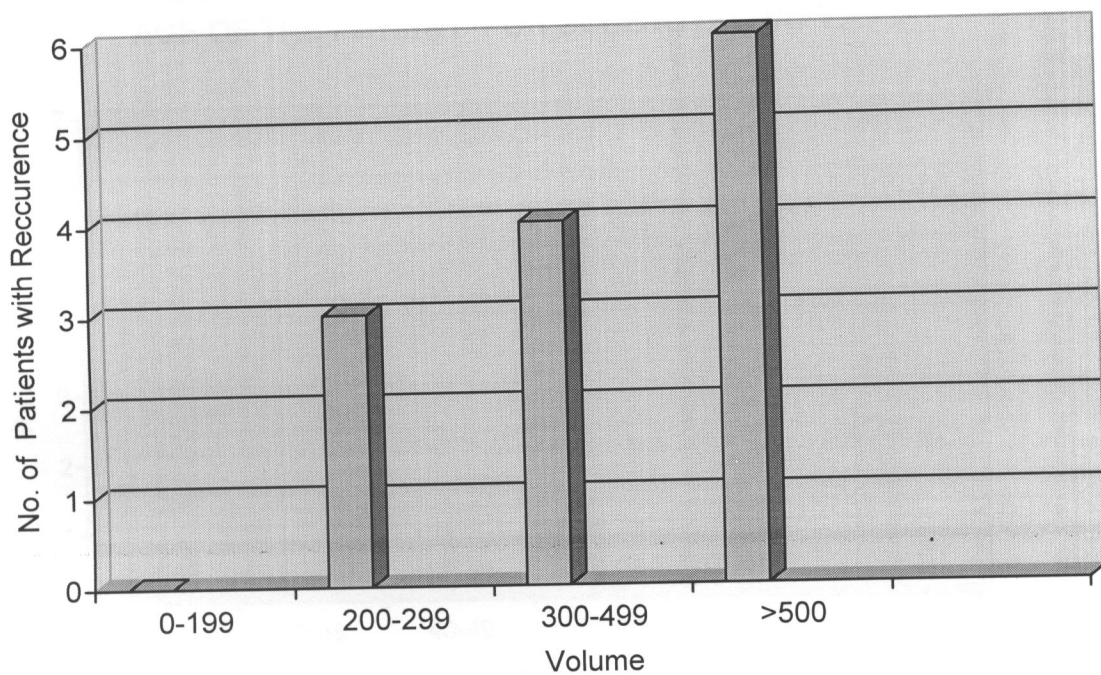
**Fig. 4 ECONOMICAL STATUS OF PATIENTS FOR HYDROCELECTOMY**



- Fair - Serviced compounds
- Low - Shanty compound
- Very low - Village

Most of the patients were the low socio-economic group.

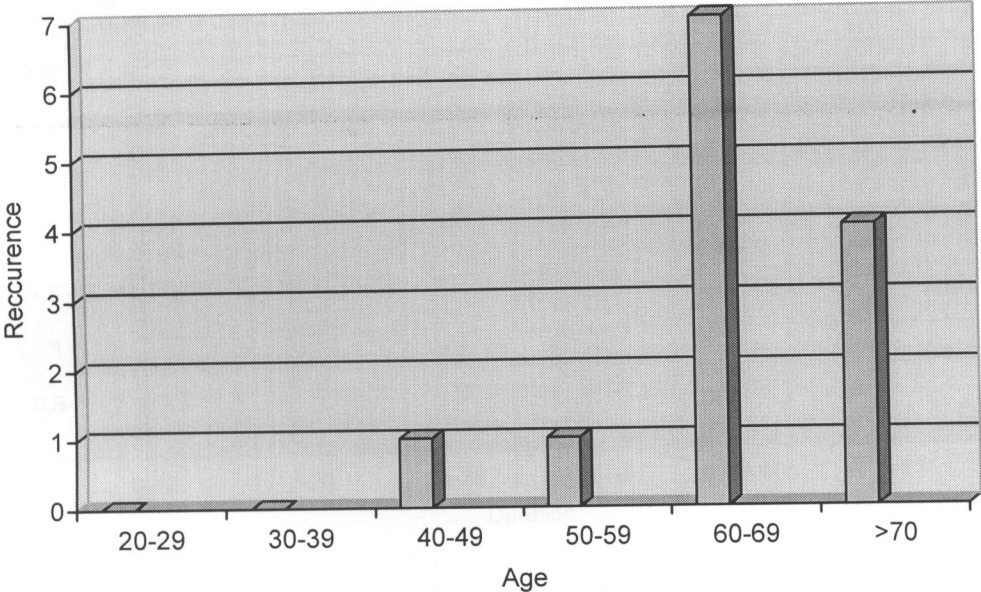
**Fig. 5 RECCURENCE RATE AT THE FIRST REVIEW**



There were no recurrences in the group of patients post hydrocelectomy.

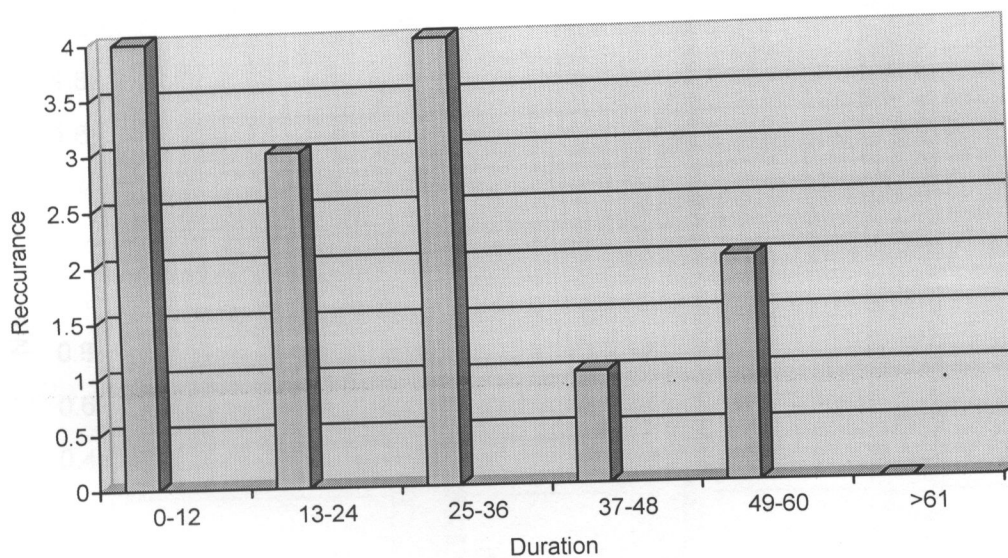
There were more recurrence in the patients with severe hydrocele after sclerotherapy.

**Fig. 6 COMPARISON OF THE RECCURENCE RATE TO THE AGE OF THE PATIENT FOR SCLEROTHERAPY.**



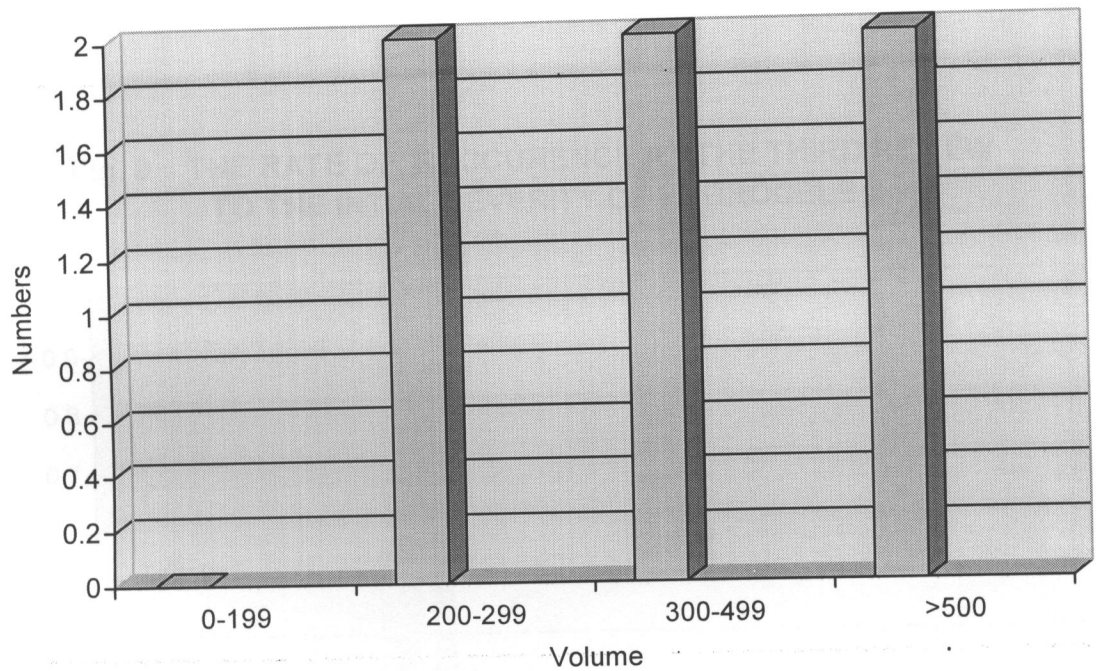
The age group 60-69 years had the most number of recurrences. There were none in the age group below 40 years.

**Fig. 7 COMPARISON OF RECCURANCE WITH DISEASE DURATION AT FIRST REVIEW IN THE PATIENTS FOR SCLEROTHERAPY**



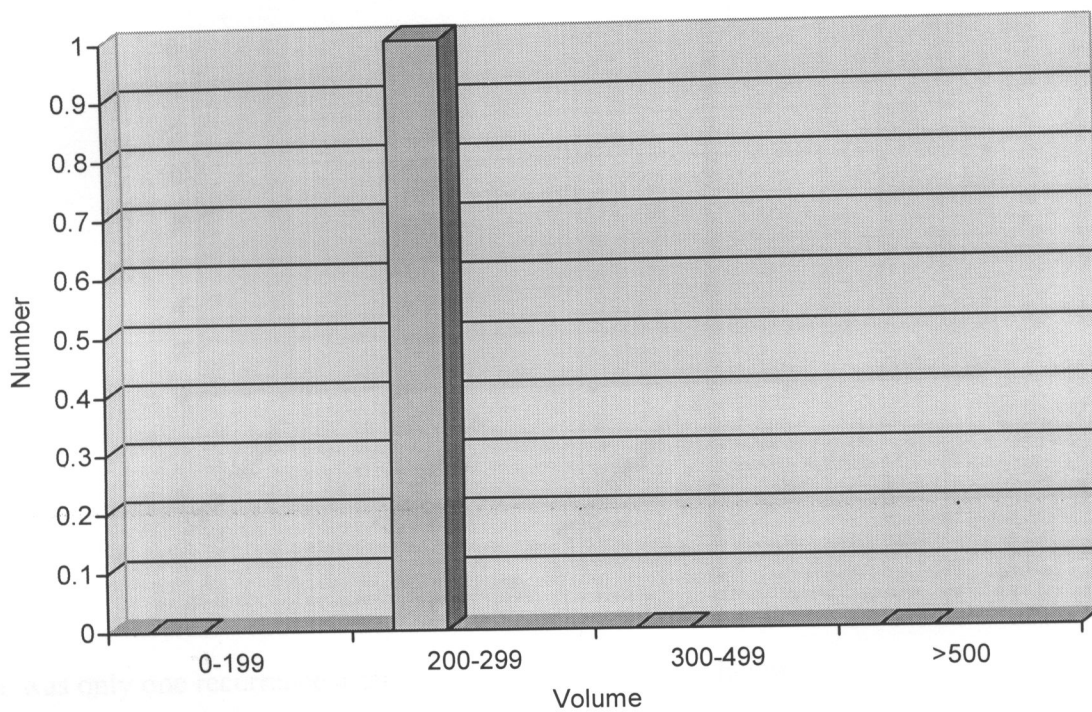
The shorter the disease duration the more recurrences were noted.

**Fig. 8 COMPARING THE RECCURENCE AT SECOND REVIEW TO THE INTIAL SEVERITY**



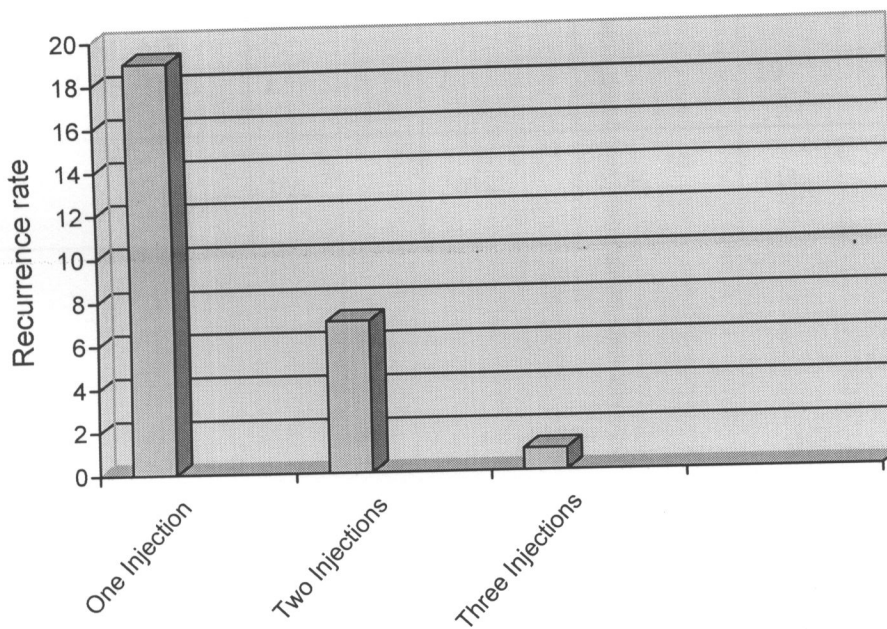
At the second review the recurrence rate did not depend on the initial severity of the disease.

**Fig. 9 THE RATE OF RECCURENCE AT THE THIRD REVIEW TO THE INTIAL SEVERITY OF HYDROCELE**



The recurrence at the third review was in the cases with moderate hydrocele.

**Fig 10 COMPARING RATE OF RECCURRENCE AND NUMBER OF INJECTIONS**



There was only one recurrence after three injections of sclerotherapy.

**TABLE 1. FINAL OUT COME**

	<b>POOR</b>	<b>BETTER</b>	<b>SAME</b>	<b>VERY GOOD</b>
<b>PATIENTS ASSESSMENT DURING AND AFTER THE STUDY</b>	1	7	8	19
<b>%</b>	3%	20%	23%	54%

## RESULTS

The study looked at the comparison of sclerotherapy and surgical treatment hydrocele at the University Teaching Hospital, Lusaka.

There were 35 patients in the study treated with phenol.

There was a wide range in terms of age distribution. The youngest was 24 years old and the oldest was 84 years old in this study group, The mean age was 65 years. The majority of the patients were in the age range of 60-69 (42.9%) See figure 1.

These results are similar to the findings by other investigators (<sup>2</sup>). This means that idiopathic hydrocele is a disease of the elderly.

The severity of the hydroceles was classified as mild, moderate and severe depending on the amount of fluid aspirated. 20 patients (57.1%) had severe hydroceles, 08 (22.9%) had moderate and 07 (20%) had mild hydrocele. See figure 2

The socio-economic status of the patients was described according to where they came from as fair, low or very low Most of them 33 (94.3%) came from low economic group. See figure 4

The duration of hydroceles from the patients in the study group ranged from 0-22 years. The mean duration was 2.7 years. The majority of patients had duration of hydrocele between 0-1 year (45.7%) See figure 3

The duration of the disease did not depend on the age distribution of the patients and the severity did not depend on the age. See figure 7

Complications encountered were recurrence and infection.

thirteen patients (40.6%) had at least one recurrence while 2 (6.3%) had infection after the procedure.

*The majority of patients 19 (56.4%) had no recurrences.* This was observed by other investigations as well, who found similar results (<sup>6</sup>)See figure No. 5

Among the recurrences at the first review the majority (46.2%) had hydroceles with more than 500mls fluids. Those with fluids in the range of 0-199mls had no recurrences. This shows that the efficacy of phenol as treatment for hydrocele depends on the initial severity of the disease. See figure No.5.

At the second review there was no correlation between recurrence and the initial volume of the fluid. Recurrence was also not age dependant. See figure No.8.

There was one-third recurrence on 84-year-old man with a moderate hydrocele (figure No. 9). This could have been due to the advanced age of the patient. The overall outcome was that 7 patients felt they were better, 8 patients thought they were the same and 1 thought that they were worse than before. Nineteen patients described their outcome as very good. See table No. 1. The maximum number of injections that each patient had was 3, a rate comparable to 6<sup>6</sup> to and 7<sup>7</sup> by other investigators. The overall cure rate after 3 injections was 97.1% similar to the 90%<sup>6</sup>, 95.5%<sup>21</sup> and 98%<sup>7</sup> reported by others who also used phenol. This is close to the cure rate of hydrocelectomy which comes to near a 100%<sup>16</sup> in the short term.

All the 15 patients, who underwent hydrocelectomy were cured with one operation. No patient was reoperated in the eight month follow up period. Ten patients complained of pain one week post operatively. A total of twelve patients rested for 4, 5, 8 days

respectively. (average 6.8 days)<sup>3</sup>. Three patients (20%) had signs of infection and were treated with doxycycline<sup>3</sup>. One week post operatively all patients who underwent hydrocelectomy had different degrees of oedema with hardening of and pain in the testicular sac.



## DISCUSSION

The progressive historical tendency in the types of treatment advocated shows the quest for greater patient comfort and less aggressive procedures.

Sclerotherapy for hydrocele was perhaps one of the first attempts to adopt a less invasive procedure. However, opinions on the procedure have not yet achieved unanimity.

Scrotal puncture and aspiration of the fluid is comfortable for the physician and the patient. Phenol or carbolic acid, which is a chemical product much used in the past as an antiseptic, is easily obtained, efficient for hydroceles and has a low complication rate.

Immediately after the sclerotherapy new liquid accumulated within the tunica vaginalis, attaining a maximum volume between week 3 and 4. Thus new injection of phenol was done one month later.

In our study of sclerotherapy with 2,5% phenol the results were good with a 97.1% cure rate, similar to other studies, who also used phenol. The largest number of injections in a single patient was 3.

A number of surgical techniques for hydrocelectomy have been developed<sup>3,5</sup>. We chose the technique of partial excision and eversion of the tunica vaginalis with fixation behind the epididymis, because the technique is classically accepted as a standard method for the cure of hydroceles<sup>1</sup>.

Rodriguez et al showed that in operations requiring greater manipulation, such as dissection and ample removal of the tunica vaginalis, the incidence of oedema was 91%, while without dissection or removal, oedema developed only in 10% to 20% of all operations<sup>3</sup>.

As for the efficacy of a single procedure hydrocelectomy was superior and it avoided the need for several follow up visits. Thus, when follow up is difficult, hydrocelectomy is the intervention of choice.

## CONCLUSION AND RECOMMENDATIONS

From the mean age of the patients in the study, we can see that idiopathic hydrocele is a disease of the elderly. Most of them are from a low social class with limited access to medical facilities. This may be the reason why most of them came with severe hydroceles of long duration. This study has shown that sclerotherapy for hydrocele (97.1% cure rate) is an efficient cure for hydrocele<sup>5,6</sup>. The risk of complications which include recurrence and infection is quite minimal. In Zambia, sclerotherapy is feasible in the rural areas where there are no trained surgeons to carry out hydrocelectomies.

Phenol, which is supplied in powder form, can be reconstituted to the required concentration (2.5% in aqueous solution). The medical officers and clinical officers working here can be trained in how to carry out sclerotherapy.

Phenol is always in good supply and affordable by all health institutions in the country. After this study we recommend sclerotherapy with phenol for patients with mild to moderate hydrocele in areas where there are no trained surgeons.

The sclerotherapy for hydrocele can be used as a method of treatment in place of hydrocelectomy to minimise long waiting lists<sup>13</sup>.

From this study, we recommend sclerotherapy with phenol when there are long waiting lists or the general condition of the patient cannot allow surgery. For the patients who are difficult to be followed-up, we recommend hydrocelectomy. Hydrocelectomy should also be reserved for patients with severe hydroceles

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## Appendix 1

### RESEARCH CONSENT FORM

#### COMPARATIVE STUDY OF SCLEROTHERAPY WITH PHENOL AND SURGICAL TREATMENT FOR HYDROCELE

**1. Why are we giving you this form?**

We are giving you this form telling you what it means and giving you the chance to ask questions about the study. Then you can decide if you want to take part in this study that is trying to compare sclerotherapy (injection of phenol into the scrotal sac) to surgical treatment for hydrocele (collection of fluid in the scrotal sac).

**2. Who is carrying out this study?**

Dr. Gloria Munthali is the principal investigator in this study. She is being supervised by Dr. Mohammed Labib and Mr. Kasonde Bowa who will help her monitor the progress of patients.

The study is being done in the Urology section of the department of surgery at the University Teaching Hospital in Lusaka, Zambia.

The Official name of the study is "comparative study of sclerotherapy with phenol and surgical treatment for hydrocele at the University Teaching Hospital.

**3. Background information**

You are being asked to take part in the research study because you have a hydrocele of unknown cause. We are trying to see if sclerotherapy will cure you of the hydrocele without undergoing surgery. Some medical studies suggest that sclerotherapy is as effective as surgical treatment for the treatment of hydrocele. We hope this study will show such a benefit in patients being treated similarly in the UTH, Lusaka.

**4. What happens in this research?**

- a) A form will be used to enter your personal details and results of your investigation.
- b) You will have a tests performed on you prior to the sclerotherapy.
- c) An ultrasound of the testis will be performed prior to surgery.
- d) You will be seen at regular times.

**5. Possible problems:**

Other studies which have been done have shown that sclerotherapy is not harmful. However, there maybe a risk of infection, some scaring and it may come back. Once you are in the study, we will tell you of anything that we think might make you change your mind about being part of the study.

**6. Benefits**

You may not benefit from participating in the study.

**7. Your rights to participate, not participate, or to withdraw from the study.**

Taking part in this study is voluntary. You do not need to take part in this study – it is up to you.

You may choose to either participate or not. If you choose to take part in the study, you can later change your mind and withdraw from the study. You will still receive the standard management for hydrocele.

You will suffer no penalty if you do not take part in the study and you will not loose any benefits to which you are entitled as a patient of this hospital. Your present and future medical care at the UTH, Lusaka will be the same whether or not you take part in this study.

If there are any new findings in this study during the study that may affect whether you want to continue to take part in this study you will be told about them as soon as possible.

The investigators may decide to discontinue your participation without your permission because they may decide that staying in the study will be bad for you.

**8. Confidentiality**

Your name will never be made public by the investigators. The medical record of your care will be treated the same as all medical records at the University Teaching Hospital, Lusaka.

Information from this study and from your medical record may be reviewed and copied by the study investigators and examiners that may be appointed by the University of Zambia. A code number that makes it very difficult for anyone to identify you will identify the research information gathered by the study. All information will be stored in a secure place. Information from this study and from your medical record may be used for research purposes and may be published; however, your name will not be made public by the investigators. It is possible that after the study is over, we may want to look again at the laboratory

and medical record data collected during the study to help us answer another question. If this happens, your name will not be made public by the investigators.

I..... have been informed about the study of the comparison of sclerotherapy with phenol and surgical treatment for hydrocele. I will undergo sclerotherapy. A copy of this form signed by me and one of the study investigators is being given to me.

Signature;..... Date:.....

I have explained this research study to the subject. I am available to answer any questions now or in the future regarding the study and the subject's rights.

The principal investigators Dr. Gloria Munthali and her supervisors can be reached at the Department of Surgery, University Teaching Hospital, Lusaka, Zambia.

.....  
**Signature of Investigator and Printed Name**

## Appendix 2

### DATA COLLECTION FORM

- A. Study number:.....  
File number:.....  
Age:.....  
Sex:.....  
Address:.....
- B. CLINIC FEATURES**
1. Disease duration:.....
  2. Volume of fluid withdrawn:.....
- C. PREOPERATIVE INVESTIGATIONS**
1. Cytology:.....
  2. Ultrasound of testis:.....
- D. PROCEDURE**
- a. Injection
    - i. Number of injection:.....
    - ii. Volume of phenol injected:.....
  - b. Hydrocelectomy
  - c. POS
  - d. Side

**REVIEW**

- 1. Number of review.
- 2. Post op complications
  - Recurrence by ultrasound:.....
  - Infection:.....

**QUESTIONNAIRE**

	Score	1	2	3	4	5
1	Size of scrotum					
2	Sexual activity					
3	Discomfort					
4	Psychological effect					

**Key to Scoring**

- 1. Very bad
- 2. Worse
- 3. Same
- 4. Better
- 5. Excellent