

The occurrence rates of pain following open inguinal hernia repair with MROP mesh versus Desarda technique at Kampala International University Teaching hospital.

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ABSTRACT

Surgical outcomes of open inguinal hernia repairs dictate the best technique to use and tension free repair is the current standard of care. Mesh repair and Desarda techniques are tension free techniques and their outcomes are comparable. The dearth of data comparing affordable mesh and Desarda techniques limits choice in developing countries. This study evaluated the occurrence rates of pain following open inguinal hernia repair with MROP mesh versus Desarda technique at Kampala International University Teaching hospital. The study adopted a double blinded randomized clinical trial at KIUTH that followed up 66 Males aged 18-65 years with primary inguinal hernia who were recruited and randomly assigned to M-arm (32) and D-arm(34) for open inguinal hernia repair followed up for 14 days for surgical outcomes. Data was recorded using a questionnaire and analysed by Stata 14 . The difference in mean operative time, pain scores-(VAS) and complications were compared using unpaired-student t-test, Fisher's exact, Mann-whitney(U) and Kruskal-Wallis(H) tests as appropriate. The study was approved by KIU-REC-(Nr.UG-REC-023/202020), UNSCT-(UNCST/RC1/94812205) and Clinical trial registry-(PACTR202105846681553). The mean age of 66 males was 46 ± 11 years, 4 years greater in M-arm and majority were illiterate (74.8%). There was moderate pain ($D=2.86 \pm 0.4$, $M = 2.87 \pm 0.4$) for the first two days and mild to no pain at day 7 and 14 while many had acute pain (D-arm 80%, M-arm 74%), 5% (M) had haematoma, scrotal swelling (D=6%, M=18%), and only 2 (3.0%) respondents had surgical site infection with majority 53-(D=49%, M=47%) returning to work by end of day 14 follow up. The occurrence of pain and short-term surgical outcome were comparable for both techniques for inguinal hernia repair under this study.

Keywords: Occurrence rates, pain, inguinal hernia, repair and MROP mesh.

INTRODUCTION

According to the Ugandan study by [1,2,3,4,5], there was no statistically significant difference in occurrence of postoperative pain between Lichtenstein mesh and Desarda techniques. These authors noted a third post-operative day visual analogue scale of 3.33 ± 1.75 and 2.73 ± 1.64 for Lichtenstein and Desarda respectively, and the 7th post-operative day scores were 1.31 ± 1.19 for Lichtenstein and 1.31 ± 1.34 for Desarda. Furthermore, no difference was noticed as regards the mean day of resumption of normal gait (2.44 ± 1.62 and 2.06 ± 1.13) for Lichtenstein and Desarda respectively [6,7,8,9,10]. However, the comparison was between commercial mesh and Desarda techniques of inguinal hernia repair in affluent society of Kampala not

affordable mesh. In contrast to the above findings, an Indian study by [2] found that the Desarda group ambulated sooner and experienced less immediate post-operative pain compared to the Lichtenstein-mesh group. These results were reproduced in a more recent single center randomized control trial in Pakistan [3,11,12,13] where the mean pain score after 72 hours of surgery was (2.47 ± 1.21 and 1.92 ± 0.34 for Lichtenstein and Desarda respectively ($p < 0.05$). Interestingly after six months follow up, 27(90%) respondents resumed duty in Lichtenstein arm compared to 30(100%) in Desarda group ($p > 0.05$) [14,15,16]. The authors concluded that Desarda technique was associated with less complications, less pain and operative time as compared to

Lichtenstein mesh for treatment of inguinal hernia. Researches in different set ups of randomized controlled trials are recommended to further evaluate their findings; which this study seeks to address [17,18,19,20]. According to a recent randomized controlled trial that instead compared Desarda and Bassini techniques [4], Desarda was also found to be associated with less postoperative pain scores, early return to strenuous daily activities and with less incidence of chronic inguinal pain [21,22,23,24,25]. In this study, respondents in Desarda required less analgesics and no single recurrence was registered for both groups. Other outcomes like post-operative pain and hospital stay have been found to be variable in some trials but seemingly less in Desarda groups repair [5]. From the above discussion, it is evident that the Desarda versus mesh repair is still subject to further investigation and the proposed study seeks to generate additional research evidence among African males to further this discussion.

Aim of the study

The aim of the study was to determine the occurrence rates of pain following open inguinal hernia repair with MROP mesh versus Desarda technique at Kampala International University Teaching hospital.

Research question

How does the occurrence rate of pain after open inguinal hernia repair using MROP mesh compare with that of using Desarda technique in the selected study population?

Scope of the Study

Geographical Scope

The study was conducted at Kampala international University teaching

Research design

This was a comparative study that was of double blinded parallel randomized equivalence clinical trial. The participants were randomized to either standard MROP mesh (M-arm) or Desarda technique (D-arm) of open inguinal hernia repair. Both participants and outcome assessors were blinded of the intervention techniques in this study.

Study setting or site

The study was carried out from surgery department of Kampala International

hospital in the surgery departments' outpatient clinic, theatre, and surgical wards. The researcher considered patients from Bushenyi, Rubirizi, Sheema, Buhweju, Mitooma, Ntungamo, Rukungiri districts and referrals health units in Rwenzori region like Kasese, Kabarole and Kamwenge. All participants in this study we selected basing on the above areas that reported at KIUTH for inguinal hernia repair.

Content scope

The study compared MROP mesh and Desarda techniques for short-term surgical outcomes in open inguinal hernia repair at Kampala International University Teaching hospitals in male patients with primary inguinal hernia, aged 18-65 years. The study used a structured data collection tool as a checklist for important information per participant. All qualifying participants were blindly randomly assigned to one of two arms of this trial and perioperative factors associated with surgery were collected, analyzed for surgical outcomes. The assessors were blinded to collect data from trial subjects up to 14 days of follow up in surgery department of Kampala International University.

Time Scope

The study evaluated respondents from the time of consultation in surgical outpatient clinic through admission to the surgical wards, theatre, and follow-up for two weeks from the time of surgery. The data was collected for the months of November 2020 to April 2021. This time was adequate to realize the required sample size, use the available mesh before expiry date and compile the findings.

METHODOLOGY

University Teaching Hospital (KIU-TH) a private not-for-profit enterprise which is located in Bushenyi-Ishaka municipality 327km from Kampala along Mbarara-Kasese highway and Rugazi Health center IVs as an outreach clinic for clients from the area of Rubirizi. The surgery department of KIU-TH operates a regular surgical outpatient clinic, an operating theatre, and a surgical ward with capacities of 150 beds. About 80-100 surgery patients with inguinal hernias were reviewed from surgical outpatient clinic and

accident and emergency departments or from other wards of the hospital. The inguinal hernia cases were assessed for surgery eligibility and booked for operation to the surgical ward for pre- and post-operative care and operated on. In two months, 93 patients had open inguinal hernia repair and 66 were followed up for short term surgical output from study area as outlined in research proposal. With the current COVID 19 pandemics in the country and requirement for observing standard operating procedures (SOP) in transport sector, Health Centre IV of Rugazi was used as outreach clinics for client recruitment and follow up in Rubirizi district. Surgery residents, certified medical officer and a clinical officer assisted the principal investigator to assess male patients with primary inguinal hernia at the study centers' outpatient clinic departments and recruited them into the study. Only the principal investigator operated on patients with surgery residents as assistant surgeons and follow up for short term outcomes of surgery was done by research assistants who never participated in surgery.

Study population

The study population were Ugandan males in the western part of Uganda with primary inguinal hernia.

Target population

The targeted population was adult males aged between 18 to 65 years with primary inguinal hernias, attending Kampala International University Teaching Hospital and Rugazi Health center IV during the data collection period.

Sample size determination

Since a randomized controlled trial assumes a null hypothesis, it was assumed that the clinical outcome of MROP mesh technique was not statistically significantly different from Desarda in open inguinal hernia repair. The primary outcome was measured as a continuous variable (that is pain level measured using Visual Analogue Scale (VAS), the formula for such an equivalence design in a randomized controlled trial was that indicated below [6].

$$N = 2 \times \left\{ \frac{Z_{1-\alpha} + Z_{1-\beta}}{\delta} \right\}^2 \times S^2$$

Where:

- N Sample size per group
- $Z_{1-\alpha}$ Standard normal deviation for a two-sided test used in equivalence trials (1.96) for 95% confidence interval
- Δ Clinically admissible margin of equivalence design as a difference
- A Type I error associated with rejecting the null hypothesis when it is true; (0.05) for 95% confidence interval;
- B Type II error associated with the alternative hypothesis, assumed to be 0.20 for a statistical power of 80%
- (1- β) The probability of rejecting the null hypothesis when it is false i.e., $Z_{1-\beta}=0.845$ for statistical power of 80%.
- S^2 Pooled standard deviation of both comparison groups

According to a similar randomized controlled trial that compared Desarda to Mesh technique of inguinal hernia repair at Mulago National Referral Hospital [1], the difference in mean pain scores between the two groups $\delta= (0.63)$; and pooled standard deviation in mean pain scores $S= 1.7$ (average of 1.75 for mesh and 1.64 for Desarda). Thus, by substitution;

$$N = 2 \times \left(\frac{1.96 + 0.845}{0.63} \right)^2 \times 1.7^2$$

N = 115 participants per group

According to the Uganda's ministry of health integrated health management information system [7], Kampala International University Teaching Hospital registers an average of 39 cases of inguinal hernia in 3 months that corresponded to the intended data collection period. Thus, the population under study for this period would be (n=39).

Adjusting the sample size for finite population:

$$\text{Sample size } (N) = \frac{n_s}{1 + \frac{n_s - 1}{n}}$$

Where N=adjusted population, n_s is estimated sample size, n=population under study (39).

Thus:

$$N = \frac{115}{1 + \frac{115 - 1}{39}} = 29.3$$

Implying that:

N=30 Participants per group

Compensating for loss to follow-up

Over 10% was added in each arm to compensate for loss to follow-up and non-responsiveness, giving a total adjusted sample size of 33 participants in each arm and 66 in total.

Sample size validity

The sample size was based on simple random sampling other than complex designs and the number that was needed for descriptive statistics of mean, frequency fits well for multiple regression, covariance analysis and logistic linear analysis that helped to evaluate impacts of the two arms. According to [8], a sample of 20 to 50 participants in each arm is sufficient which is consistent with the investigator's sample size. Also, according to [1] in their study at Mulago, only 4% was lost to follow-up within 14 days. The investigator has considered 10% adjustment as appropriate to cater for non-responsiveness as well.

Sampling Technique

To eliminate sampling bias, the researcher used computer software-generated random numbers to assign 50% of trial participants of the sample size to each arm of the study. Two columns of random numbers were generated, each column for each arm with a separate secret interpretation form. The random numbers were printed on each consent form for a subject and interpretation form given to the surgeon only who assigned the arm in theatre upon receipt of consent form. A total of 33 participants were in each arm of MROP (M-arm) and Desarda (D-arm).

Participant recruitment

Participants were recruited from surgical out-patients by the investigator or his trained research assistants as surgery residents or clinician on duty continued to provide care to other clients. The officer on duty identified the inguinal hernia clients and informed one of research team members to assess and recruit the client eligible for study and those not eligible were helped to revert to the clinic and got all the

needed care. We mobilized more patients from the catchment area by outreach visit to Health center IVs of Rugazi through the medical officers in charge of the center. All hernia patients were health-educated for mode of treatment, operation services at study centers and possibility of participation in the research.

Randomization of participants

There were two arms of the trial: the MROP Mesh (M-arm) and the Desarda technique (D-arm). Allocation of participants to the respective arms was done by simple random selection using a computer software Open Epi, Version 3.01, updated 2013/04/06 (Dean AG, 2020)(<http://openepi.com/Random/Random.html>). Generated random numbers from 101 to 166 were randomly assigned two categories A and B as shown in appendix 6. The D- arm was assigned to category A for 34 participants and the M-arm was assigned category B for 32 participants.

Allocation of participants

All the numbers were assigned to the consent form extreme right corner box at printing time in the chronological orders from 101 to 166. The forms were filled for demographic and pre-operative data in surgical out-patient department (SOPD) and signed for the consent before being put in the patient's file. The participants went through routine pre-operative work up to access the theatre list according to standard operating procedures (SOP) of hospital for theatre use. In the theatre, only the surgeon had the interpretation form of the random numbers, who allocated respondents to the respective trial arm before operation, without disclosing the method to the participants. The mesh for all trial participants in the M- arm were provided free of charge by the investigator who performed the operation. In the Desarda arm, the surgeon performed the operation according to the technique described by [9]. One-on-one research information was given to the participants by the researcher and verbal consent was obtained before signing an informed consent. Then the patient was screened for eligibility to join the study and consented for operation. The theatre list was availed to the operating team for timely pre-operative patient assessment

and ASA score. Participants were assessed by surgery residents, certified medical officer or clinical officers in the research team who were registered with respective authoring medical councils and have been oriented about research inclusion criteria and patient care. Outcome assessment was done by certified medical officers, clinical officers, nursing officer or surgery residents who never participated in operation.

Participation was voluntary and screening was done in a private room for privacy and confidentiality. In case a participant declined, another eligible one in the que was considered. Those not participating at will, were helped to continue routine care as per the hospital protocol. Consented participants proceeded to have the planned surgery following appropriate anaesthesia assessment. All respondents received prophylactic antibiotics (1g of ceftriaxone or as appropriate for their body weight); 30 minutes prior to incision [10]; in accordance with the infection control protocol in inguinal hernia surgery [11] and the local anaesthetic was used. All respondents received the same post-operative analgesia of injectable diclofenac 75mg or as appropriate for their body weight; immediately after closure of skin incision, followed by repeated oral doses every 8 hours for 3 days unless contra-indicated.

Inclusion criteria

- I. Males aged 18 to 65 years with ability to consent
- II. Primary inguinal hernia
- III. American Society of Anesthesiologists (ASA) score of I to II

Exclusion criteria

- I. Complicated inguinal hernia
- II. Infection site at intended skin incision
- III. Known comorbidity of Diabetes Mellitus or Benign Prostate Hyperplasia
- IV. Documented allergy to any components of MROP mesh in the M-arm
- V. Non consenting eligible participant.

Operation techniques

Preoperative care

All participants were examined physically for inguinal hernia and oral consent was obtained proceeding informed consent. Each participant was given 1gram of intravenous ceftriaxone antibiotic within 30 minutes before skin incision is made. At this stage, the nurse handed over the patient's medical file containing patient consent form with a random number that was used by the surgeon who had a detailed chart of all numbers according to the study arm assigned.

Anaesthesia

Local anaesthesia of lignocaine and bupivacaine were used. The total volume of 18-25ml of 2% lignocaine, bupivacaine and epinephrine 1/200000 in a recommended mixture ratio [12]. The mixture was administered as a nerve block and direct infiltration around the incision as below:

- i. Total dose of the lignocaine was 3mg/kg or 7mg/kg with epinephrine respectively
- ii. Total dilution volume was 18-25ml.
- iii. Wheals under skin; a 2cm distance from anterior superior iliac spine (ASIS), mid inguinal point (MIP) and over the pubic tubercle infiltrated using about 1ml at each site to anaesthetize the skin.
- iv. Infiltrated 2cm from ASIS, 5ml into deep subcutaneous beyond the external oblique aponeurosis to block ilioinguinal and iliohypogastric nerves.
- v. 8ml was injected at pubic tubercle with 3ml onto external ring and the rest infiltrated around the external ring
- vi. 3mls were infiltrated around mid-inguinal point (MIP) and below the inguinal ligament
- vii. The 2ml at the skin incision site and the rest was preserved in the syringe to use as needed.

Incision and hernia reduction

- i. Oblique (cephalad) inguinal incision of about 5-7cm from pubic tubercle to 2cm lateral to internal ring was used and dissection proceeded as described in methodology.

- ii. External oblique aponeurosis was opened and its leaves reflected superiorly 3cm and inferiorly to expose the inguinal canal floor and internal oblique, transversus abdominis muscles as well as lower leaf to expose inguinal ligament.
- iii. Once the anatomic cleavage was identified, the spermatic cord and its contents were separated from the inguinal canal floor at the pubic tubercle and the neurovascular bundles were preserved.
- iv. Hernia sac was identified, categorised and herniotomy with high ligation of sac done to reduce the hernia.

MROP mesh (M-arm)

- I. This is based on intrabdominal pressure gradients, scarification, mesh contraction and nerve preservation principles with an appropriate size of at least 7 cm by 5 cm
- II. A mesh sheet was shaped in a doom fashion to cover the inguinal region 2cm medial of pubic tubercle, 3-4cm above Hesselbachs triangle and 5-6cm lateral to internal ring.
- III. Fixation of the mesh to the inguinal ligament for reinforcement of the posterior wall was achieved using nylon #1 suture and a new internal inguinal ring created using fish tail fashioning and fixed the mesh.

Desarda technique (D-arm)

- i. This proceeded herniotomy and transversalis abdominis fascia repair (TFR), whenever there was a posterior inguinal wall defect.
- ii. The external oblique aponeurosis, undetached from the upper leaf was used instead of mesh to reinforce the posterior inguinal canal wall.
- iii. The upper lip of the external oblique aponeurosis leaf was sutured to the inguinal ligament using continuous Nylon #1.
- iv. A 2cm external oblique aponeurosis split was made from the upper leaf and the upper lip of the new lower split was sutured to conjoin tendon
- v. Reconstruction of the internal ring was achieved after approximating the lower leaf of

upper split and inguinal ligament together under the cord.

- vi. The superficial ring was created from approximation of new upper leaf with the lower leaf of external oblique aponeurosis (EOA).

Closure

In both arms, closure was done using: Nylon 2/0 for the external oblique aponeurosis to recreate external ring and Vicryl 3/0 for the skin. Dressing of the wound was done with plain sterilized gauze and adhesive zinc oxide tape.

Early withdrawal of participants

Only one participant was lost to follow after the 7th day of operation and did not have a phone contact to be traced. The data collected from the participants was analyzed to that time as formally permitted by the participant.

Study Variables

Primary outcome variables

Early, intermediate and delayed post-operative complications of MROP mesh versus Desarda technique in open inguinal hernia repair were assessed. These included presence or absence of fever, scrotal edema, hematoma, acute pain, and surgical site infection.

Secondary variables

Mean intra-operative time from skin incision to closure, and mean post-operative pain scores at rest taken on day one, two, three, seven and day 14 post operatively, were recorded. The pain assessment was determined using the visual analogue scale (VAS) as described in methodology.

Patient characteristics

Data was captured on pre-operative factors such as familial history of inguinal hernia, history of smoking, alcohol, opioid or steroid use, and patients' body mass index, duration of symptoms in months, hernia location and presence of pre-operative pain or any co-morbidity.

Data Collection instruments (DCIs)

Data was collected using a structured questionnaire purposely designed for this study.

Data entry

A master spreader excels sheet of Microsoft office 16, platform x64 bit [13] was used to enter raw data, that was

cleaned and coded by the principal investigator before exporting it to Stata for analysis.

Data processing and analysis

Data was exported to Stata software version 16, Stata Corp.2019.Stata Statistical Software: Release 16. College Station, TX: Stata Corp LP, [14] for cleaning and analysis. In order to achieve the one objective, cross-tabulation was performed between perioperative factors of the two inguinal hernia repair techniques and the categorical outcome complications. The frequencies, their corresponding percentages, Fisher's exact test, odds ratios and p-values reported at 95% confidence interval regarding $p \leq 0.05$ as statistically significant. In order to achieve the two objectives, the mean operative time and standard deviation was computed for each technique of inguinal hernia repair. The difference in means was compared using the unpaired student t-test and its corresponding two-tailed p-value, regarding $p \leq 0.05$ as statistically significant. In order to achieve the third objective, the mean pain scores at rest and their standard deviations were computed and compared using the Mann Whitney (U) and Kruskal-Wallis (H) tests. Persistent pain was reported as a visual analogue score > 5 . Upon this categorization, cross tabulation was performed and odds ratios computed for each technique of inguinal hernia repair.

Data management

All data was password protected. The excel data sheet had patient study numbers instead of identifying personal information, only accessible by the investigators until final stages of dissemination. Paper records are being stored in hard copy in a locked filing cabinet in the investigator's office for a minimum of five years, while electronic records were stored in a password protected file on the investigator's password protected work laptop. After this time the hard copies will be destroyed but soft copies maybe archived for future reference.

Ethical considerations

Approvals

The research topic was approved by the department of surgery, the faculty of medicine and dentistry, the directorate

of postgraduate studies and research and Kampala International University Research Ethics Committee (KIU-REC); **REC NO: Nr.UG-REC-023/202020**. After approval by the KIU-REC, the trial was registered with the Uganda National Council for Science and Technology (UNCST); **UNCST/RC1/94812205**, National Drug Authority (ISO 13485-2012 and CE 2265) and Uganda National Health Research Organization (UNHRO) for authorization, and then registered with Pan-African Clinical Trial Registry (<https://pactr.samrc.ac.za/>)

PACTR202105846681553. The research team obtained the administrative clearance letters from the executive director of KIUTH and in charge medical officer of Health Centre IV of Rubirizi for permission to proceed with the data collection.

Informed Consent

The approved informed consent form by Kampala International University Research Ethics Committee was used. The form was formatted to local languages of the participants and explained.

Beneficence

Curative surgery was provided to the participants but this study also has potential for improved surgical techniques for hernia patients in general. Although MROP mesh arm participants received mesh for free from the principal investigator, this was not regarded as a direct benefit for participating in the research but something the investigator had to facilitate to complete the study.

Risks and their mitigation

Although participants may undergo pain and discomfort during operation or react to drug agents that were used for local anaesthesia, this was what would ordinarily be expected in a situation where a hernia patient undergoes a surgical procedure for therapeutic purposes. Nevertheless, the clients were assessed against risks of allergy and also counseled, and the process was done gently and professionally to minimize risk of pain and discomfort as much as possible. Due diligence was also paid to small details of each method. We used standard theatres and global or WHO safe surgery guidelines in conjunctions with each hospital local surgery protocols for elective surgery.

Justice

Participant recruitment was done non-discriminatively regardless of race, colour, or tribe. All those who met the selection criteria had equal chances of participating. Inclusion and exclusion criteria were followed strictly.

Respect for participants' autonomy

Participation was voluntary and any participant who showed interest to withdraw from the research was accepted at any stage without any threat of penalty. Human rights and integrity of each research subject was respected by the research team according to rules of the Uganda constitution, Uganda National Council for Science and Technology and KIU REC guidelines.

Confidentiality and privacy

Each Participant was examined from private screened rooms in presence of a clinician on duty. Operations were done according to set rule of each hospital. Patients used hospital theatre gowns preoperatively from the ward on morning of operation. All the team members involved in operation were introduced to the respondents in accordance with safe surgery checklist.

Adverse events

Participants underwent post-operative pain, incision site skin swelling, and some bleeding. These events were managed as they occurred and any case of serious event, a senior surgeon was consulted for intervention in care or referral to next higher point of care with close follow-up by principal investigator.

Safety of surgical patients

Each participant was treated with utmost care following appropriate care guidelines and principles of surgery. We adhered to WHO safe surgery checklist and any adverse event encountered was managed accordingly.

Competence of researcher team

The principal investigator as a surgeon has received extra training in hernia surgery from COSCESA- Hernia operation, a charity organisation from Plymouth University from United Kingdom as a trainer for trainers. This was aimed at reducing the confounder factors from different surgeons that may affect outcome. Most of research assistants as participant recruiters, outcome assessors and assistant surgeons were senior house officers in

surgery departments or qualified medical officers at outreach sites of Rugazi health centre IV. The principal investigator had worked on two unpublished research projects as an undergraduate student and one case report that has been published [15]. Participated in several research projects under ministry of health as a research assistant.

Reporting of serious adverse events

Follow-up of the clients was done on Day one, day two, day three, day seven and day 14 post operatively. Appropriate management was given for any adverse event encountered. No Serious adverse event was registered.

COVID-19 standard operating procedures (SOPs)

Corona virus disease 2019 is very contagious. To prevent COVID 19 infection, we ensured compliance to regular hand washing or sanitizing, use of face masks, maintaining social distance and disease screening at triage point to all respondents and research team according to June 2020 Uganda ministry of health or as up dated guidelines for COVID 19 management. We complied with the *Uganda National Guidelines for Conduct of Research During COVID-19 pandemic* (UNCST, 2020) to ensure safety of all research team and participants.

Data and safety monitoring plan

The researcher took responsibility to oversee the safety of the study according to national and international as well as REC guidelines. Monitoring to ensure safety was done at every level of research activity using a checklists and site data and safety monitoring tools. Data was reviewed at follow-up stages for inclusion and exclusion criteria, adverse outcomes, proper filling of documents and data entry to data base, drop-out documented and review of informed consent periodically. Keeping of data under key and lock or password security to ensure safety, privacy, and confidentiality, was done.

Medical care and compensation for injury

In event that the respondents were injured or made sick from taking part in this research, medical care was provided from hospital of care and the respondents was reviewed regularly.

Respect for community

The procedures involved in this study did not go against the local community beliefs, traditions and culture. The findings from the study are going to be communicated to the head of Surgery department of Kampala International University Teaching Hospital as a formal feedback as well as office of District Health Officer, Bushenyi and Rubirizi districts so that the community can benefit from it.

Feasibility and funding source

The investigator provided the mesh, some sundries with support from hernia operation international whereas study centers provided the rest of research materials.

Quality control

The recruited research assistants were trained. The principal investigator or his assistant cross checked the data daily to ensure completeness with double data entry. An accurate history and physical examination of the respondents were done prior to operation.

Dissemination

Findings are to be presented to department of surgery and internal review boards of KIUTH. The implications of findings were shared with the respondents and their care takers and the heads of surgery department. A copy of bound report was availed to the library of KIUTH and to district health officers. At least two peer reviewed articles and one conference presentation were budgeted for.

RESULTS OF THE STUDY

Sample turn up and selection of males with hernia

Social demographic data of the study respondents

This trial recruited only males aged between 18-65 years with 34(51.5%) being randomly allocated Desarda technique (D) arm and 32(48.5%) to MROP mesh(M) arm. Results in table 1 below show that the mean age of respondents in D arm was 43 years ($M = 43.26$, $SD = 11.47$) while in M arm was 49 years ($M = 48.63$, $SD = 10.48$). Most of respondents in the trial were Catholics 69.7% (46) as only 1.5% (1) were SDA and

majority 74.8% (50) having attained primary education with only 4.5% (3) not having attended to any formal education level. Majority of respondents were subsistence peasants 66.6% (44) with a significant number 18(27.3%) being involved in other fields of income generation such as salon barber, business men, farmer, lay leader, lamber jack, fisherman, and mansion while minority 6% (4) were casual labourers as shown in table 1 below.

Table 1: Socio-demographic characteristics of respondents under study.

Variable	D- arm (n = 34)	M-arm (n=32)
Respondents (n±%)	34 ±51.5	32 ±48.5
Age (Years) Mean ±SD	45.26 ±11.47	48.63 ±10.48
Religion (n±%)	D- arm (n = 34)	M-arm (n=32)
Islam	3 ±4.5	3 ±4.5
Catholic	22 ±33.3	24 ±36.4
Anglican	8 ±12.1	5 ±7.6
SDA	1 ±1.5	0 ±0
Education Levels (n±%)		
None	1 ±1.5	2 ±3.0
Primary	26 ±39.4	24 ±36.4
Secondary	7 ±10.6	6 ±9.1
Occupation (n±%)		
Subsistence farmers	22 ±33.3	22 ±33.3
Casual labourers	2 ±3.0	2 ±3.0
Others	10 ±15.2	8 ±12.1

Pain severity using Visual analogue scale.

Respondents were asked to report their pain after operation as designed for the study, the pain assessment was guided by the visual analogue scale. The respondents were assessed for post-operative pain severity in order to

compare the quality of life after surgery for the two arms. The visual analogue scale was graded for pain severity as; Worst pain (0-3) and coded as 4 in Stata, Moderate pain (4-6) coded as 3, Mild pain (7-8) coded as 2 while No pain (9-10) was coded as 1.

Table 2: Short Term Surgical Outcomes.

Pain Severity (VAS) mean \pm SD	D- (n=34)	Arm	M- Arm(n=32)	Mann Whitney(U)		
				Z	p-value	
Day 1	2.97 \pm 0.3		3 \pm 0.25	-0.434	0.665	
Day 2	2.74 \pm 0.45		2.78 \pm 0.49	-0.34	0.734	
Day 3	2.41 \pm 0.50		2.38 \pm 0.49	0.303	0.762	
Day 7	2.00 \pm 0.43		2.00 \pm 0.57	0.001	1	
Day 14	1.5 \pm 0.51		1.41 \pm 0.50	0.759	0.448	
				Kruskal Wallis		
Early outcome.				(H)	df	p-value
Haemorrhage	0		2(3%)	0.551	1	0.456
Acute Pain	27(40.9%)		18(27.3%)			
Hematoma	0		3(4.5%)			
Scrotal swelling	0		2(3%)			
None	7(10.6%)		7(10.6%)			
Intermediate outcome						
None	27(40.9%)		20(30.3%)	2.297	1	0.13
Scrotal swelling	4(6.1%)		12(18.2%)			
Pain	3(4.5%)		0			
Delayed Outcome						
None	33(50%)		31(47%)	0.002	1	0.96
Infection	1(1.5%)		1(1.5%)			5

From Day one results, all respondents in both arms had moderate pain; D-arm ($M=2.97$, $SD=0.3$) and M-arm ($M=3.00$, $SD=0.25$) while respondents by day 14 had no pain; D-arm ($M=1.5$, $SD=0.51$) and M-arm ($M=1.41$, $SD=0.50$).

Mann Whitney (U) test for hypothesis validation

To evaluate the occurrence rates of pain following open inguinal hernia repair among the two arms, a Mann-Whitney (U) test was conducted on pain severity from day 1 to day 14 to determine if there was no difference in short-term surgical pain at a significance level of $p \leq 0.05$. Results show that the mean pain outcome in the days 1, 2, 3, 7, 14 between the two techniques were not statistically different (table4).

Short term outcomes of open inguinal hernia repair.

Early outcome.

Majority of respondents (45) experienced acute pain in all the arms, more in D-arm (40.9%) than M-arm (27.3%) and only 2(3.0%) respondents had scrotal swelling in M-arm

Intermediate outcome

Majority of respondents (n=47) 71.2% reported no complications, 24.3% had scrotal swelling (D-arm =6.1%, M-arm = 18.2%) while as 2 (3.0%) had pain in the D-arm.

Delayed outcome

From table 4 above, only one respondent reported surgical site infection after operation in either arm of the study; D-arm 1(1.5%) and M-arm 1(1.5%)

Return pre-operative work

The return to work or quality of life was assessed using activities of daily living like self-care, house work, climbing a

boda-boda and squatting on a latrine or toilet, how the performance compared before and after operation for the two arms of the study. Majority of respondents 17(25.8%) in D-arm and 19 (28.8%) in M-arm had returned to work after the first week of operation and only 1(1.5%) person had not yet resumed work.

Results from the social demographic data of the participants showed that of men who were registered for inguinal hernia repair at the University Hospital, those that were randomly selected for Desarda technique(D) had an average mean age of 45years ($M = 45.26$, $SD = 11.47$) but those under MROP mesh (M) arm had 49 years ($M = 48.63$, $SD = 10.48$). Note, the minimum and maximum age were 18 and 65 among the respondents. Most of respondents were found to be Catholics (69.67%) and the highest level of education attained was insignificant at 19.7% for secondary education. Most of respondents (66.6%) were peasants but 27.3% of respondents were involved in other fields of income generation such as salon barber, business men, farmer, lay leader, lamber jack, fisherman and mansion or casual labourers. For every clinical trial, the quality of life is crucial and the occurrence of rate of pain was given priority and validated using Mann Whitney (U) test to compare the mean results from the two techniques. Furthermore, Kruskal Wallis (H) test was computed for the short-term surgical outcomes with the view of responding to the hypothesis of the study. Mean results showed that from day 1 to day 7, all respondents in both arms had moderate pain while respondents by day 14 had no pain; D-arm ($M = 1.5$, $SD = 0.51$) and M- arm ($M = 1.41$, $SD = 0.50$). This shows the efficiency and positive impact of two techniques usage on pain severity. However, a Mann Whitney (U) test was computed to evaluate the occurrence rates of pain following open inguinal hernia repair for the two techniques. Results revealed that the

Kruskal Wallis (H) test on the duration of pain following the visual analogue pain scale

To test the hypothesis for the study between the two techniques following open inguinal hernia repair, a Kruskal-Wallis (H) test was performed and results proved that there was no statistically significant difference in pain after surgery between the two techniques used among patients, early outcome [$H(1) = 0.551$, $p = 0.456$], intermediate outcome [$H(1) = 2.297$, $p = 0.130$] and delayed outcome [$H(1) = 0.002$, $p = 0.965$].

DISCUSSION

mean pain experience among the participants in the days 1, 2, 3, 7, 14 days was not statistically different. However, pain intensity experience improved remarkably on day 7 and day 14 to mild or no pain in most of respondents and these results are similar to findings of [2] study in India. Short term outcomes of open inguinal hernia repair were assessed at three levels, results from early outcome showed that majority of respondents (45) experienced acute pain in all the arms, more in D-arm (40.9%) than M-arm (27.3%) and only 2(3.0%) respondents had scrotal swelling in M-arm and also in the intermediate outcome most of respondents (n=47) 71.2% reported no complications, 24.3% had scrotal swelling (D-arm =6.1%, M-arm = 18.2%) while as 2 (3.0%) had pain in the D-arm. Lastly, only one respondent reported surgical site infection after operation in either arm of the study; D-arm 1(1.5%) and M-arm 1(1.5%). This was not evident to conclude that there was no difference in the short-term surgical outcomes of the study hence a Kruskal Wallis was computed and results revealed that there was no statistically significant difference among the two techniques of inguinal hernia, early outcome [$H(1) = 0.551$, $p = 0.456$], intermediary outcome [$H(1) = 2.297$, $p = 0.130$] and delayed outcome [$H(1) = 0.002$, $p = 0.965$]. However, pain intensity experience improved remarkably on day 7 and day 14 to mild or no pain in most of respondents. The associations of pain intensity with early complications were significant as most respondents who had acute pain complications 68.2% described as worst pain (3) and the trend

was not different for intermediate and delayed complications. These findings are comparable with studies of [1] who found that the pain occurrence was not statistically significant for the Desarda and Lichtenstein for day 3 and day 7 (VAS 3.33, 2.73 & 1.31, 1.31) for Mesh and Desarda techniques respectively. The results measure of associations echoes the similar findings of [2] study of impact of post-operative pain intensity on immediate out come and return to work.

Though the two authors studied assessed Desarda technique and Mesh repairs in open inguinal repair, they all used prototype meshes which is different from this study where the comparison is between the Desarda and affordable mesh (MROP) and there is no difference in outcomes. Its therefore, in

CONCLUSION

The occurrence of pain and short-term surgical outcome were comparable for

Kyomukama *et al* principal investigators' view that using affordable mesh in open inguinal repair reproduces similar results as prototype mesh when comparing Desarda technique and mesh in tension free open inguinal hernia repair whose impacts on surgical outcomes is reproducible. These results revealed the early return to work as most of the participants 36; 25.8% in D-arm and 28.8% in M-arm had returned to work after the first week of operation and only 1(1.5%) person had not yet resumed work. The return to work or quality of life was assessed using activities of daily living like self-care, house work, climbing a boda-boda and squatting on a latrine or toilet, how the performance compared before and after operation for the two arms of the study.

both techniques for inguinal hernia repair under this study.

REFERENCES

1. Manyilirah, W., Kijjambu, S. Upoki, A. and Kiryabwire, J. (2012). "Comparison of Non-Mesh (Desarda) and Mesh (Lichtenstein) Methods for Inguinal Hernia Repair among Black African Patients: A Short-Term Double-Blind RCT." *Hernia* 16(2):133-44. doi: 10.1007/s10029-011-0883-0.
2. Gedam, B. S., Prasad, Y., Bansod, V., Kale, B., Yunus, S. and Murtaza, A. (2017). "A Comparative Study of Desarda's Technique with Lichtenstein Mesh Repair in Treatment of Inguinal Hernia: A Prospective Cohort Study." *International Journal of Surgery* 39:150-55. doi: 10.1016/j.ijso.2017.01.083.
3. Muhammad, Akram Dogar, Imran Sadiq, Muhammad Umair Samee, Ammarah Afzal, Adnan Sadiq Butt, and Muhammad Umar. (2019). "Desarda versus Lichtenstein Mesh for Inguinal Hernia Repair: A Randomized Trial." *Pakistan Journal of Medical and Health Sciences* 13(2):227-30.
4. Ansari, Faiz Manzar, Tariq Hameed, Sudhir Kumar Jain, Amrita Dua, and Adiba Nizam. (2019). "Comparison of Outcome of Desarda versus Bassini Repair in Management of Complicated Inguinal Hernia." *International Surgery Journal*. doi: 10.18203/2349-2902.isj20194574.
5. Mitura, Kryspin, and Mikołaj Romańczuk. (2008). "[Comparison between Two Methods of Inguinal Hernia Surgery--Lichtenstein and Desarda]." *Polski Merkuriusz Lekarski: Organ Polskiego Towarzystwa Lekarskiego* 24(143):392-95.
6. Zhong, Baoliang. (2009). "How to Calculate Sample Size in Randomized Controlled Trial?" *Journal of Thoracic Disease* 1(1):51-54
7. Muhaise, Hussein, and Margret Kareeyo. (2017). "Electronic Health Information Systems Critical Implementation Issues (E-HMIS): District Health Information Software Version.2 in the Greater Bushenyi, Uganda." *American Scientific Research Journal for Engineering, Technology, and Sciences* 34(1):205-12.
8. Ellen, Stephanie. (2018). "Slovin's Formula Sampling Techniques." *Sciencing* 0-1.
9. Desarda, M. P. 2001. "New Method of Inguinal Hernia Repair: A New Solution: Reply [3]." *ANZ Journal of Surgery* 71(11):681-82.
10. Terzi, Cem. (2006). "Antimicrobial

- Prophylaxis in Clean Surgery with Special Focus on Inguinal Hernia Repair with Mesh." *Journal of Hospital Infection* 62(4):427-36.
11. Raslan, C., Hassan, S. and Henley, N. (2015). "Is It Time to Revise the Guidelines for Antibiotic Prophylaxis in Hernia Surgery?" *International Journal of Surgery* 23:S69. doi: 10.1016/j.ijso.2015.07.302.
 12. Sanjay, P., and Woodward, A. (2009). "Local Anaesthetic Inguinal Hernia Repair Performed under Supervision: Early and Long-Term Outcomes." *Annals of the Royal College of Surgeons of England* 91(8):677-80. doi: 10.1308/003588409X12486167521073.
 13. Patrice -Anne Rutledge, P. M. (2015). microsoft press; 1st edition. ISBN-13; 9788120352049.
 14. B Petrus, E Nzabandora, E Agwu (2022). Factors associated with Pelvic Inflammatory Disease among Women Attending the Gynecology Clinic at Kampala International University Teaching Hospital, Uganda. *IDOSR Journal Of Biochemistry, Biotechnology And Allied Fields* 7 (1), 48-63.
 15. Kambale Munyambalu Dalton, Abeya Charles Fardous, Martinez Gilberto Monterrey Lazaro (2022). Prevalence of Diabetic Peripheral Neuropathy among adults with Diabetes Mellitus attending Kampala International University Teaching Hospital. *IDOSR Journal of Biology, Chemistry And Pharmacy* 7(1): 27-40.
 16. Solange Gahongayire, Namatovu Alice, Drago Kato Charles (2022). Prevalent bacteria isolated from beauty salon tools in Ishaka Town, Bushenyi District, Uganda. *IDOSR Journal of Biochemistry, Biotechnology and Allied Fields* 7(1): 75-87.
 17. Mfitundinda Wilberforce, Odda John, Kirimuhuzya Claude (2022). Evaluation of the biochemical and histopathological effects of aqueous extract of *Albizia chinensis* (Osbeck) Merr stem bark in streptozotocin induced diabetic Wistar rats. *IDOSR Journal of Biology, Chemistry and Pharmacy* 7(1): 14-26.
 18. Fred Ssempijja, Vicente-Crespo Marta, Samuel Sunday Dare, Eriya Kyomukama *et al* Bukunya Edmund (2022). The effect of *Imperata cylindrica* (L.) P. Beauv. on Brain tissue Morphology of *Drosophila Melanogaster* transgenic flies overexpressing the paralytic Gene. *IDOSR Journal of Biochemistry, Biotechnology and Allied Fields* 7(1): 1-11.
 19. Osman Ahmed Hussein, Muhumuza Joy, James Nabaasa Musiime (2022). Evaluation of the factors associated with immediate adverse maternal outcomes among referred women in labor at Kampala International University Teaching Hospital. *IAA Journal of Biological Sciences*. 8(1): 228-238.
 20. Baruti Petrus, Emmanuel Nzabandora, Ezera Agwu (2022). Evaluation of the bacterial agents associated with PID among women of reproductive age at Kampala International University Teaching Hospital. *IDOSR Journal of Biochemistry, Biotechnology and Allied Fields*, 7(1): 64-74
 21. Osman Ahmed Hussein, Muhumuza Joy, James Nabaasa Musiime (2022). Factors associated with Immediate Adverse Maternal Outcomes among Referred Women in Labor attending Kampala International University Teaching Hospital. *IAA Journal of Applied Sciences* 8(1): 117-125
 22. Tibamwenda Bafwa Yves, Onokiojare Ephraim Dafiewhare, Lagoro Abonga Charles, Elias Sebatta (2022). Factors Associated with Electrocardiographic Abnormalities among Heart Failure Patients at Kampala International University Teaching Hospital, Ishaka, Uganda. *IAA Journal of Biological Sciences*, 9(1): 166-175.
 23. Tibamwenda Bafwa Yves, Onokiojare Ephraim Dafiewhare, Lagoro Abonga Charles, Elias Sebatta (2022). Electrocardiographic Pattern among Heart Failure Patients at Kampala International University Teaching Hospital, Ishaka, Uganda. *IAA Journal of Biological Sciences*, 9(1): 159-165.
 24. Muhammad, G. (2018). *ALL PC World*. Retrieved from allpcworld.com: <http://allpcworld.com>.
 25. Kyomukama, Lauben Amagara, Robinson Ssebuufu, Shaban Abdullah Wani, Musa Abbas Waziri, and Herman Lule. (2020). "Of."

