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The mean operative time used for 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 compares the mean operative time used for 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%).The mean operative time (minutes) was longer for M-(*M*=60.78, *SD*=22.93) than D (*M*=51.44, *SD* =30.36) with a variance of 9.3 and p = 0.16 indicating no statistical significance between the two arms. Relatively more sundries were needed in M-arm than Desarda arm for inguinal hernia repair and use of more than three sterile gauze pieces is a predictor of intraoperative events. The mean operative time was high for mesh than Desarda techniques but statistically insignificant.

Keywords: Mean operative, time, inguinal hernia, repair and MROP mesh

INTRODUCTION

There are many factors that influence uptake of a new surgical technique like its simplicity and scalability amongst junior surgeons and surgery residents but the learning curve is crucial. Techniques with shorter learning curves gain more popularity than those that require vast experience for one to perform. A case in point is the delayed uptake of laparoscopic inguinal hernia repair in some parts of the world as it required a minimum of 13 cases before one could work independently [1,2,3,4] while for Shouldice repair, a surgeon is deemed competent after observing 500 operations, performing 500 and 1000 audited operations. In such cases, the operative time decreases with the surgeon's experience [2,5,6,7,8] and so does the complication and conversion rates [3,9,10,11,12]. In a study by [13,14,15], it was found that despite the post-operative pain and duration of hospital stay being lessened in the laparoscopic inguinal hernia repair group, it took twice more time compared to open inguinal hernia repair [16,17,18]. Thus to- date, despite a new era for minimally invasive surgery; open repair of primary inguinal hernia still has a place in low-income countries and in developed countries for recurrent, complicated hernias or when there is need for conversion from laparo-endoscopic surgery [5,19,20,21]. Well knowing that safety takes precedence in surgery, longer than usual surgery can increase intra-operative risks such as toxicity due to larger doses of anaesthesia or pain when the local

anaesthesia wears off during the operation. In an England study by [6], it was noted that as a result of differing operative times, the volume of local anaesthesia used for inguinal hernia repair differed significantly between surgery trainees and consultants (42 ml versus 69 ml; P = 0.03). Furthermore, the day-case rate was much higher for the surgeons than residents (84% versus 69%; P = 0.02) and that these patients operated by surgeons in training required conversion to a general anesthetic repair [21,22,23,24,25]. These findings deduce that even though intra-operative time might be variable between two qualified surgeons, its impact cannot be underscored in lieu of patient safety. The present study will thus compare the operative times between MROP mesh and Desarda techniques in primary inguinal hernia repair [26,27,28].

In an Indian study by [7], there was no statistically significant difference in the operative time between the two techniques. However patients are unique in a way that they present late with giant inguinal-scrotal hernias [8,29,30,31] which might have a bearing on the intra-operative time especially for MROP mesh technique that requires extensive dissection. In a local Ugandan study by [9,32,33,34,35], Desarda technique took significantly a shorter operative time than mesh-repair (10.02 ± 2.93 min versus 15.9 ± 3.52 min) respectively, (P = 0.0001). A similar randomized controlled trial in Pakistan found comparable results; with the mean duration of surgery being (44.57±3.95 and 35.96±2.76) minutes for Lichtenstein and with Desarda respectively [10,36,37,38,39,40]. These findings are in congruity with those of [11], when they compared Desarda and Bassinis and found the former associated with shorter operative time. However, all these findings are based on studies that used prototype mesh which needs to be validated with the affordable MROP mesh. Although some authors think Desarda method has potential to become the gold standard of inguinal hernia repair, its cooperative competitor (mesh repair) need to be equally evaluated in African populations to be certain of the clinical outcome experience of both techniques. Moreover, some randomized controlled trials have not documented any significant difference in the operative time [12]. Although some authors believe the available evidence is adequate to recommend Desarda technique as gold standard even in complicated strangulated hernias without risk of infection [13], majority believe in the international guidelines that recommends mesh repair [14]. Long-term randomized control trials are still recommended [15] based on difficulties in choosing Desarda for patients with thinner weaker external oblique aponeurosis [16]. There is a knowledge gap on effectiveness in terms of surgical outcome for both affordable mesh and Desarda technique comparing time of operation for the two techniques. This study compared the operative time in inguinal hernia repair using the two techniques.

Aim of the study

The aim of this study was to compare the mean operative time used for open inguinal hernia repair with MROP mesh versus Desarda technique at Kampala International University Teaching Hospital.

Research question

How does the operative time for open inguinal hernia repair using MROP mesh compare with that of Desarda technique among respondents at Kampala International Teaching Hospital?

Scope of the Study

Geographical Scope

The study was conducted at Kampala international University teaching 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 out-patient 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

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 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 [17].

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

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 [9],the difference in mean pain scores between the two groups δ= (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 [18], 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 [19], a sample of 20 to 50 participants in each arm is sufficient which is consistent with the investigator's sample size. Also, according to [9] 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 [20]. 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 [21]; in accordance with the infection control protocol in inguinal hernia surgery [22] 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 [6]. 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 ilio-hypogastric 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 [23] 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, [24] 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 rations 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 [25]. 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 DuringCOVID-19 pandemic* [26]) 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

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

There was a history of familial risk of inguinal hernia reported by 20(30.3%) of respondents as having one or more family member with inguinal hernia with D (n=8, 12.1%) and M (n=12, 18.2%). As shown in table 2 below, majority of the respondents 34.8% (D-arm) and 27.3% (M-arm) had not used any substance of habit forming. However, alcohol was commonly used by 24.3% of respondents and 5(7.8%) of respondents used both alcohol and smoking. The respondents in M arm (m = 84.94, SD 89.23) had stayed with inguinal swelling longer than those in D arm (m = 82.32, SD 65.49) by two months as shown in table 2 and with majority of inguinal hernias found in right inguinal canal; M arm- 21 (31.8%) and D arm - 21 (31.8%) while only 2 (3.0%) for M-Arm had the swelling on both sides of the body. For inguinal mass reducibility and tenderness, only 1 (1.5%) of respondents in M arm had irreducible inguinal hernia and majority had non tender inguinal masses. Most respondents had a mean body mass index (BMI) of 22 kg/m^2 (*M* = 22.08, *SD* = 3.04) in M arm while those in D arm had BMI of 20kg/m^2 (M = 20.31, *SD* = 2.88). All respondents were euthermic; D-arm (*M* = 36.46, *SD* = 0.47) and M-arm (*M* = 36.40, *SD* = 0.40) with majority having normal blood pressure of 128/82mmHg; D (M = 127.7/82.26, SD = 13.19/9.56) and 131/82mmHg for M (*M* = 130.7/81.59, *SD* = 18.37/8.57). From table 2, majority of respondents in D-arm (*M* = 3.03, *SD* = 0.52) had moderate pain (3) pain as well as M-arm subjects (*M* = 3.16, *SD* = 0.45) before operation when asked to describe pain severity using Visual analogue (VAS).

Type of inguinal hernia using Gilbert-Modified Robbins Rutkow classification systems

In this study, inguinal hernia was classified using Gilbert-Modified Robbins Rutkow classification systems among respondents recruited for inguinal hernia repair show that majority 22.7% and 15.2% of the men under the D-arm and M-arm respectively were diagnosed with type 4 of the inguinal hernia (direct hernia with

destroyed wall of the inguinal canal as only one respondent had type 1 inguinal hernia in D-arm (1.5%).

American Society of Anesthesiologists (ASA) physical status classification system.

Results reveal that majority of the respondents recruited for inguinal hernia repair during the study period, 50.0% and 37.9% who were selected for Desarda technique and MROP mesh techniques respectively were rated to class I of the American Society of Anesthesiologists (ASA).

Prophylactic antibiotic

All trial subjects in either arm received ceftriaxone 2grams within 30 minutes prior to skin incision as prophylactic antibiotics.

Table 2: Frequencies for preoperative clinical factors of trial respondents

Variable	D - Arm (n=34)	M - Arm (n= 32)	
Family Members with Hernia n (%)			
Parent with inguinal hernia	0(0)	5(7.6)	
Siblings with inguinal hernia	4(6.1)	2(3.0)	
Relative with inguinal hernia	1(1.5)	4(6.1)	
Son with inguinal hernia	3(4.5)	1(1.5)	
No family member with inguinal hernia	26(39.4)	20(30.3)	
Substances used	**D - Arm (n=34)**	**M - Arm (n= 32)**	**Fisher's test p. value**
Alcohol	6(9.1)	10(15.2)	0.377
Smoking	2(3.0)	2(3.0)	
Both Alcohol/Smoking	3(4.5)	2(3.0)	
Non	23(34.8)	18(27.3)	
Duration	**mean ± SD**	**mean ± SD**	
Duration of groin swelling (months)	82.32±65.49	84.94±89.23	
Location of swelling on the body; n (%)	**D - Arm (n=34)**	**M - Arm (n= 32)**	
Swelling On Right Side	21(31.8)	21(31.8)	
Swelling On Left Side	13(19.7)	9(13.6)	
Both Sides	0	2(3.0)	
Pain Severity (VAS) Mean ± SD	3.03±0.52	3.16±0.45	
BMI(Kg/M^2) Mean ± SD	22.08±3.04	20.31±2.88	
Blood Pressure(mmHg) Mean± SD	127.7/82.26±13.19/9.56	130.7/81.59	
Temperature(0^C) Mean ± SD	36.44±0.48	36.43±0.40	
Mass Tenderness n (%)	D - Arm (n=34)	M - Arm (n= 32)	
Yes	2(3.0)	2(3.0)	
No	32(48.5)	30(45.6)	
Reducibility; n (%)			
Yes	32(48.5)	31(47.0)	
No	2(3.0)	1(1.5)	
Gilbert-Modified Robbins Rutkow Classification Systems; n (%)			
Type 1	1(1.5)	0	

Type 2	7(10.6)	8(12.1)
Type 3	6(9.1)	8(12.1)
Type 4	15(22.7)	10(15.2)
Type 5	2(3.0)	5(7.6)
Type 6	3(4.5)	1(1.5)
ASA Classification of Respondents; n (%)		
Asa I	33(50.0)	25(37.7)
Asa II	1(1.5)	7(10.6)

Effects of risk factor on early surgical outcome during open inguinal hernia

The results show that 5(7.6%) alcoholic respondents suffered pain while smokers 1(1.5%) had scrotal swelling during the open inguinal hernia repair. The difference was not statistically significant (t = 0.377) (table 2 above)

The intra operative events for open inguinal hernia repair.

The duration of operation, the quantity of Local Anaesthesia used, number of sundries, the inguinal posterior wall defect size and intra operative complications were assessed and reported the mean operative time and standard deviation computed for each technique of inguinal hernia repair. The difference in means for operative time was compared using the unpaired student t-test and its corresponding two-tailed p-value, regarding p≤ 0.05 for statistical significance.

Table 3: Mean results for intra operative events for study participants

Variable	D- Arm (n= 34)	M -Arm (n = 32)	*t-test*	*p- valve*
Mean operative time mean ± SD	51.44±30.36	60.78±22.93	-1.403	0.165[a]
local anaesthesia (ml) mean ± SD	20.21±3.52	21.56±4.83		
Type of Hernia (%)				
Medial	16(24.3)	16(24.3)		
Lateral	15(22.7)	`14(21.2)		
Both	3(4.5)	2(3.0)		
Inguinal canal posterior wall defect size (cm) mean ± SD	4.65±1.65	5.44±1.83		
Sundries used mean ± SD				
Nylon	0.85±0.62	1.81±1.46		
Absorbable suture Vicryl	1.74±0.67	2.13±0.66		
Surgical gloves	4.12±0.95	4.97±1.43		
Disposable gloves	1.24±1.89	2.19±1.67		
Sterile gauze	3.29±1.27	4.88±2.72		
Complications n (%)				
No complication	21 (31.8%)	15(22.7%)		
Bleeding	1(1.5%)	1(1.5%)		
Injured nerve	5(7.6%)	5(7.6%)		
Pain	7(10.6%)	8(12.1%)		
Urine retention	0(0%)	2(3.0%)		

a = 95% CI 49.28-62.66

Comparison of Mean operative time.

After observing sterility procedure to positioning of patient, draping, and administering the local anaesthesia, a stop clock was used to record the time of operation from making skin incision

to the last stitch of closing the skin incision in minutes. Descriptive statistics of mean operation time and standard deviation is reported. Results show that the mean operative time was longer for M-arm (61) minutes (*M* = 60.78, *SD* = 22.93) compared to Desarda arm (51) minutes (*M* = 51.44, *SD* = 30.36) with a variance of 9.3minutes. When an independent t-test was performed at a statistical significance of p≤0.05 and 95% confidence interval. Results show that respondents who were randomly selected for Desarda technique for inguinal hernia repair had a slightly low average operative mean time of the open inguinal hernia repair compared to MROP mesh technique. The mean difference of 9.34, 95%CI [49.3, 62.66] showed that there was no statistically significant difference between the mean operative time for surgery between Desarda technique and MROP mesh technique, t (64) = -1.403, p = 0.165.

Volume of Local anaesthesia

More volume (22ml) of Local anaesthesia (Lignocaine, Bupivacaine, Adrenaline) was used in M-arm (*M* = 21.56, *SD* = 4.83) than D-arm; 20ml (*M* = 20.21, *SD* = 3.52).

Types of inguinal hernia in relation to inferior epigastria vessels

Majority 32(48.6%) of respondents had medial hernia sac, (M-arm=16(24.3%), D-arm=16(24.3%), 29(43.9%) had lateral hernia sac (M-arm=15(22.7%), D-arm=14(21.2%) and minority 5(7.5%) had both medial and lateral(M-arm=3(4.5%), D-arm=2(3.0%).

The inguinal canal/ posterior wall defect size.

The average mean size of the posterior wall defect of the inguinal canal among the respondents (66) was 4.65 (*M* = 4.65, *SD* = 1.65) for D-arm and 5.44; M-arm (*M* = 5.44, *SD* = 1.83) as shown in table 3 above.

Number of sundries used during operation.

From table 3 above, generally more sundries were used in M-arm (nylon2[*M*=1.81, *SD*=1.46], absorbable suture vicryl 2[*M*=2.13, *SD*=0.66], surgical gloves 5[*M*=4.97, *SD*=1.43], disposable gloves 2[*M*=2.12, *SD*=1.67], sterile gauze 5[*M*=4.88, *SD*=2.72]) than D-arm(nylon1[*M*=0.85, *SD*=0.62], absorbable suture vicryl 2[*M*=1.74, *SD*=0.67], surgical gloves 4[*M*=4.12, *SD*=.095], disposable gloves 1[*M*=1.24, *SD*=1.89], sterile gauze 3[*M*=3.29, *SD*=1.27]).

Intra Operative Complications.

Results reveal that majority of respondents (36) experienced no complications; D-arm (*n*=21, *%*=31.8) and M-arm (*n*=15, *%*=22.7) while only 2 (3.0%) respondents bled during the operation in the two arms.

Fishers exact test for early outcome for inguinal hernia repair techniques.

To validate the hypothesis on the two techniques (Desarda and MROP mesh), fishers exact t test was performed on the early outcome among the men recruited with primary hernia. The follow up of assessment shows 16 of 20 (80%) faced acute pain among men in D-arm and 14 of 19 (74%) as well suffered acute pain among men who were subject to M-arm for inguinal hernia repair. The *Fishers exact test* revealed no statistically significant difference between the two arms (p = 0.196)

DISCUSSION AND CONCLUSION

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.

Comparison of perioperative factors.

The research team with the principal investigator focused on the perioperative factor that had an impact on the surgical outcomes. Cross tabulation was conducted and their corresponding frequencies were recorded by fisher's exact test at

significant level p< 0.05 to find out the effect of risk factors on the early complications during the surgery. Results revealed a connection of current inguinal hernia with familial history of inguinal hernia in 20 (30.3%) respondents, 25 (37.9%) of respondents either smoked or consumed alcohol and results from a cross tabulation showed that 5(7.6%) alcoholic respondents experienced pain while smokers 1(1.5%) had scrotal swelling during operation. For this study there was equal effect of the risk factor such as alcohol and smoking to experience of pain in both arms with Fisher's exact test 0.377. Factors like alcohol and nicotine from tobacco are novel risk factors for complications during or after open inguinal hernia surgery.

Furthermore, it was observed that most inguinal swelling existed in the right inguinal canal (64%) and for mean duration of 82 months D- arm and 85 months in M-arm with moderate pain of 3 when graded using VAS. These factors affected the duration of operation, post-operative pain experience but there was no observable preferential effect to the technique of open inguinal hernia in either arm of Desarda or MROP mesh. This is similar to study by [27] where most participants had most indirect hernias in right inguinal canal and had stayed with inguinal hernia for over 60 month before operation.

Most respondents had normal physical vital signs of temperatures, Blood pressure, and the average mean BMI for both techniques was at 21kg/m^2. These factors are associated with good surgical outcomes. Patients who were found with tender irreducible inguinal hernia experienced moderately severe postoperative pain than their counterparts who had none. There was no effect on mean operative time in either arm of the study by the physical vital signs above. All respondents received 2grams of ceftriaxone as a prophylactic antibiotic because of use of mesh implant and level two operative theatre sterility. This affected the outcome positively as only 2% of postoperative infection were reported in all clinical trial participants under this study which is in relation to [9]

Comparison of the intraoperative events.

It is crucial to understand the intraoperative events that were studied during operation in the use of both techniques for the study. Results revealed that disposable gloves, surgical gloves, the sutures for both absorbable and non-absorbable and standard pieces of sterile gauze were used. No specific scientific tool was used to assess the uniformity of these sundries and the choice of sutures size and surgical gloves depended on hospital stocking protocols. Over all nylon number one and Vicryl one was used just as surgical gloves size 7.5 during the study.

On average one pieces of nylon #1 and 2 absorbable vicryl #1 sutures was used for D-arm (M = 0.85, SD = 0.62, M = 1.74, SD = 0.67) while two pieces of nylon and vicryl were used in M-arm (M = 1.81, SD = 0.68, M = 2.13, SD = 0.65) per patient. The mean of 4 and 5 pairs surgical gloves were used in D-arm (M = 4.12, SD=0.95) and M-arm (M = 4.97, SD = 1.43) while only two pairs of disposable gloves were used in either arm of inguinal hernia repair (M = 1.24, SD = 1.89) and M-arm (M = 2.19, SD = 1.67) respectively. The mean number of standard sterile gauze used was 3 pieces for D-arm (M=3.29, SD=1.27) and 5 for M-arm (M=4.88, SD=2.72). The above sundries were used in uncomplicated open inguinal hernia repair for either arm and whenever more than four or six pieces of gauze were used for D-arm and M-arm respectively, there was more complications observed intra operatively.

The mean volume of local anaesthesia used was 20ml and 22ml for D – arm (M= 20.21, SD 3.52) and M- arm (M=21.56, SD 4.83) respectively as in proposal. The process of administering the local anaesthesia was as planned though we use less than the planned 45-60ml volume and it was sufficient for successful hernioplasty in either arm. Furthermore, most respondents (22.7% for Desarda and 15.2% for mesh) had type 4 inguinal hernia according to Gilbert-Modified Robbins Rutkow classification systems with medial sacs and posterior wall defect of about 6cm; "direct hernia with destroyed posterior wall of the inguinal canal". Although

there seem to be no relationship between the type of inguinal hernia and ASA classification, the impact of the two factors on surgical outcome was not well assessed and further studies are recommended. During operation, any complication experienced by the respondent was recorded randomly and many respondents never experienced any post-operative complications (36); D-arm (n=21, 31.8%) and M- arm (n=15, 22.7%). The rest of 30 respondents experience bleeding, nerve injury, pain, or urine retention in no specific pattern. Pain was the most complication experienced; D-arm (n = 7, %= 10.6) and M-arm (n=8, %=12.1) that could be attributed to nerve injury, alcohol or smoking, non-response to used volume of local anaesthesia or previous experiences of lump pain and duration of the mass. To eliminate pain, patients received more local anaesthetic volume infiltrated or had prophylactic neurectomy of either ilioinguinal or illiohypogastric nerves as described in the study by [28]. A few of respondents (2); D-arm (n=1, 1.5%) and M-arm (n=1, 1.5%) had intra operative bleeding. This was attributable to use of adrenaline mixture (juggle juice) in local anaesthesia that besides increasing anaesthetic effect of lignocaine, it causes vasoconstrictions which reduces bleeding from operative field and there are undisputable studies available in this regard describing effect of juggle juice use in surgery.

The operative time was measured from time of making skin incision to closing it. The average mean operative time was 51minutes (M = 51.44, SD = 30.36) in D-arm and 61minutes for M-arm (M = 60.78, SD = 22.93) with a difference of 9.34 minutes with shortest being 28 minutes and longest as 115 minutes of operation. The independent sample t-test revealed that there was no statistically significant difference in the two techniques t (64) = -1.403, p = 0.165 The results are in contrast with [7] study in India and [9] study in Uganda though reported operative time to be shorter for Desarda technique than mesh repair but in keeping with Pakistan study of [10] who measured operative time from skin incision to closing and found an average mean time of 44.57±3.95 and 35.96±2.76 minutes for Mesh repair and Desarda techniques. The longer operative time in mesh repair could be attributed to gentle traction in fixing the mesh to inguinal ligament, care at the pubic tubercle and inferior epigastric vessels and the time required to fashion the mesh around the cord. These observations are consistent with [29] who recorded 45-47 vs 49-93 minutes for Desarda and Mesh repairs respectively.

More than 60 minutes of operation was needed when the assistant surgeon was a surgery resident due to need to transfer skills which is in agreement with [30] study. Other factors like age above 50 years in 3(4.5%) respondents, Alcohol 5(7.6%) where Fisher's exact test ($p=0.743$) for smoking and alcohol use revealed no statistically significant increase in the duration of operation. The respondents who had inguinal hernia in the right inguinal canal needed more than 60 minutes of operation than those whose lump was in left inguinal canal just as the defect of more than 6cm; 12(18%) in posterior inguinal canal wall and respondents who were found with lateral hernia sac 11(16.7%) than medial sac 8(12.1%) with Fisher's exact test of 0.457. More than 60 minutes was used while operating on 19(28.8%) respondents who reported moderate severe pain of VAS <5 and M-arm 14(21.2%) than D-arm 8(12%).

When more than 60 minutes was spent during operation, the impact on surgical outcome was not good as evidenced by rate of complications in 14(21%), moderate pain in 21(31.8%) respondents with VAS < 5. Therefore, more than 4 pairs of surgical gloves and 4 standard pieces of sterile gauze in 9(13.6%) and 21 (31.8%) respondents respectively were used. No observable impact was recorded significantly; 0.812 Fisher's test of association on return to work. In the investigators view therefore, it takes shorter time of operation to perform Desarda technique than Mesh repair however, it was revealed to be statistically insignificant and when the duration of operation exceeds 60 minutes, there was always a negative impact on the cost of operation to hospital and patient as evidenced by amount of sundries used and it

increases the rate of complications experienced post operatively.

CONCLUSION

Relatively more sundries were needed in M-arm than Desarda arm for inguinal hernia repair and use of more than three sterile gauze pieces is a predictor of intraoperative events. The mean operative time was high for mesh than Desarda techniques but statistically insignificant.

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