

**RANDOMISED CONTROLLED-TRIAL COMPARING NO-MESH GATHERING PLICATION REPAIR OF THE POSTERIOR WALL WITH THE REDUNDANT HERNIA SAC WITH MESH HERNIOPLASTY FOR INGUINAL HERNIA.**

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**ABSTRACT**

**Background:** The gold standard for hernia repair has remained a tension free, permanent, simple to perform and safe repair. The absolute achievement of this has remained elusive. For a long time, the Mesh hernioplasty was considered the closest to this standard and was adopted by the European Hernia Society as the procedure of choice. The prosthetic Mesh, mostly polypropylene mesh, has many inherent drawbacks. It is costly, mostly non-available in poor countries, carries the risk of mesh displacement and hernia repair failure, and is associated with high risk of mesh infection that will require subsequent removal. The inguinal hernia fortunately present with a peritoneal sac. The sac is often large, toughened by repeated frictional injury, biological, and can be mobilised to strengthen the posterior wall. This will provide a secure, tension free, safe and simple method of repairing the weak posterior wall of the inguinal canal with a purely biological tissue. This novel repair will solve the problem of early recurrence associated with tension repair and provide a cheap method of repair that is equivalent in its advantages to the prosthetic mesh gold standard. **Aim of the study:** to demonstrate that a gathering plication repair of the weak posterior wall with the redundant sac gives a slightly superior outcome compared to the use of a prosthetic mesh. **Patients and methods:** The study is a prospective, randomised clinical trial. Both elective and acute cases of inguinal hernias admitted for surgery within the period of January 2021 and December 2021 were recruited. All patients 16 years of age and above and consented were recruited. All patients with poor immune status, on cytotoxic chemotherapy, with bleeding diathesis and those with ECOG/WHO stage 4 performance status and those who declined consent for surgery were excluded. **Results:** From our evaluation of the short-term and medium-term outcomes, such as surgery duration, immediate post-operative pain, ability to achieve normal gait, early return to work and early recurrence; peritoneal sac gathering plication technique is effective and safe, with the least post-operative complications compared to Lichtenstein Inginal Hernia repair. **Conclusion:** Peritoneal sac gathering plication repair is simple, faster, and causes less post-operative pain without needing mesh. It is cost-effective and has a similar early recurrence rate to the Lichtenstein method. This technique may be a better option for younger patients due to a potentially lower risk of post-operative sexual dysfunction and subfertility

**Keywords:** Randomised trial, Peritoneal sac gathering plication repair, Lichtenstein repair.

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## INTRODUCTION

The lifetime risk of developing an Inguinal Hernia is 27% for the male and 3% for the female globally.<sup>1</sup> About 800,000 repairs for the inguinal hernia is done in the United States of America annually. Globally, it is estimated that 1 in every 4 Males and 1 in every 50 females will potentially develop an inguinal hernia.<sup>2</sup> Unfortunately, some will present with a giant type of the hernia, which extends down to the level of the mid-thigh when the patient assumes an erect posture.<sup>3</sup>

The repair of a giant inguinal hernia is challenging, fraught with risk of abdominal compartment syndrome because, the content of the hernia has almost lost its right of domain in the abdominal cavity. The repair also fails often, because the weak posterior wall is often brought under tension. Where a prosthetic mesh is deployed for the repair, a larger size of at least 30 inches is required. The average cost is twenty-five to forty thousand naira (25,000-40,000) for a single mesh.

The use of the redundant sac as a biological mesh for the reconstruction of the posterior wall will solve the problem of the exorbitant price of the prosthetic mesh and its notorious non-availability in rural hospitals.

## PATIENTS AND METHODS

The study was a prospective, single-centre, clinical trial. Both elective and acute cases of giant inguinal hernias admitted for surgery during the period of 1<sup>st</sup> January 2021 to 31<sup>st</sup> December 2021 were recruited. All patients 16 years of age and above (15 years and below is the cut off age for Paediatrics for the hospital) who consented/assented to the study were recruited. All patients with poor immune status, on cytotoxic chemotherapy, with bleeding diathesis and those with ECOG/WHO stage 4 performance status and those who declined consent for surgery were excluded. Informed consent was obtained according to the Helsinki guidelines and Ethical clearance was acquired from the Ethics and Research committees of the centre (*Approval reference withheld by the authors*). The study was conducted over a period of one year at the

General surgery unit of the Abubakar Tafawa Balewa University Teaching Hospital Bauchi-Bauchi State. Patients with primary inguinal hernias were randomly allocated intraoperatively to undergo The Peritoneal Sac gathering plication repair or A Lichtenstein mesh Hernioplasty through balloting. The sample size was determined by the duration as this is a cross sectional study. Each patient is allocated to either of the procedures through balloting. The surgeries were conducted by Consultants and Senior registrars in general surgery under regional or general anaesthesia, depending on the presentation and the duration of the hernia. Regional anaesthesia was used for long standing uncomplicated inguinal hernia because, of the possibility of incarceration from adhesions. All complicated cases were treated using general anaesthesia. With patients in supine position, routine cleaning and draping was done, exposing only the operative area. An 8-10 cm oblique groin incision was used for each procedure and surgical steps taken through the subcutaneous tissue and external oblique aponeurosis were done as in standard textbooks. The External Oblique Aponeurosis (EOA) was opened from the upper crux of the superficial ring to expose the arching fibres of the internal oblique muscle, which were retracted laterally to reach the spermatic cord. The cord dissection to separate the sac was done with a non-toothed dissecting forceps and the sac was isolated. The content of the sac was reduced in to the peritoneal cavity. The sac was opened at its fundus and any incarcerated enterocoele or omentocoele released. The sac was twisted, and a transfixing ligature was applied through the twisted segment. The redundant sac was not excised but, a gathering plication was done thrice to produce a thick cord. The lateral part of this thickened peritoneal cord was sutured to the medial shelf of the inguinal ligament from the pubic tubercle to the deep inguinal ring using Polyamide number 1 round body with continuous sutures. The first two sutures were taken from the anterior rectus sheath where the EOA interdigitate with it; the last suture was taken with the aim of narrowing the internal ring without constricting the spermatic cord. Each suture was passed first through the inguinal ligament, then the transversalis fascia and the thickened cord. The index finger of the left hand was used to

protect the femoral vessels and Collingwood Stewart hernia ring was used to retract the cord structures laterally while taking lateral sutures. the conjoined tendon lying close to it with Polyamide number 1 with continuous sutures throughout its length. The aponeurotic portion of the internal oblique muscle was used for suturing to the thick plicated sac to ensure a tension free suturing. The newly created strip was placed behind the cord to form a new posterior wall of the inguinal canal. Each patient was asked to cough to demonstrate the increased tension on the strip exerted by the external oblique muscle, for those given a regional anaesthesia. This increased tension exerted by the external oblique muscle is the bedrock of this repair. The spermatic cord was placed in the inguinal canal and the lateral leaf of the EOA sutured to the medial leaf of the EOA in front of the cord again using Polyamide number 1 sutures. This was followed by closure of the superficial fascia and the skin as usual.

The Lichtenstein Repair was performed as described in standard surgical textbooks.

Pain was measured using the visual analogue scale (VAS), with 0-30 mm signifying mild pain, 31-60 mm moderate pain, 61-90 severe pain and 91-100 excruciating pain.

## RESULTS

A total of fifty (50) subjects were recruited. Males constituted 88%, females 12%, giving a male to female ratio of 7:1. The mean age was 42 years ( $\pm 2.98$ ) and the age range was 18-75 years. A total of 54% presented with right sided inguinal hernia, 42%, had left sided inguinal hernia and the remaining 4% had bilateral inguinal hernia. Sixty percent of the patients had an indirect inguinal hernia with a dilated deep ring, 25% had a direct hernia, 12% had an indirect hernia with an intact deep ring, 3% had a pantaloan hernia and none had a femoral hernia. More than half of the patients (59%) were operated under spinal anaesthesia, 40% via local infiltration and one (1) patient was operated on using general anaesthesia. Twenty-five subjects (50%), had the No-Mesh Peritoneal Sac Plication repair while the remaining 25( 50%) had the Lichtenstein-

The medial border of the plicated sac was sutured -

mesh hernia repair . 95% of the subjects had their surgery in less than 1 hour( 20-45 minutes) while 5% had it for over an hour. Postoperative pain according to VAS (Mean  $\pm$  SD) on day 1 was 31.2 ( $\pm 02.0$ ). Up to 68% of the subjects, experience mild to moderate post - operative pain, only 4% experienced severe pain. The severe pain was associated with the Lichtenstein Repair. There was no intra-operative complications in 94% of the subjects. Only 6% of the patients from each of the study groups had developed Seroma and Haematoma respectively, and only 4% from each developed Surgical Site Infection. Both Seroma and Haematoma formation were more associated with the No-Mesh Plication repair than the Lichtenstein repair. Sixty six percent (66%) of the cases were done as Day Care Surgeries, 36% were discharged within 48 hours and only 6% stayed on admission for more than 48 hours. All the patients that stayed for more than 48 hours had the Lichtenstein hernia repair. Majority of the patients (60%) achieved normal gait within 12 - 24 hours after surgery and returned to work within the first week of the surgery, 28% within 2-3 weeks, only 12% took more than 3 weeks to resume normal work. Up to 83.3% of those who took more than 3 weeks to return to work are the patients with post-operative complications like seroma, haematoma or surgical site infection (SSI). The degree of posterior wall weakness and dilatation of the deep ring increases with age. The weaker the posterior wall, the more dilated the deep ring, also the longer the duration of surgery. Most surgeries that lasted for an hour or above are also those with weaker posterior wall. This relationship also translates into more postoperative complications, irrespective of the type of the procedure done. No recurrence was recorded during the short period of the study.

## DISCUSSION

Inguinal hernia remains a prevalent condition in Africa, with an increasing demand for surgical repair. In many tertiary, secondary, and even primary health centers, hernia repair is now frequently performed as a day-case procedure to

manage this high burden.<sup>4</sup> However, the exact reason for the high prevalence of inguinal hernias among African men remains uncertain. Some studies from East Africa suggest an anatomical predisposition, particularly the low pubic arch, which weakens the pelvic myopectineal fascial system, increasing susceptibility to hernia formation.<sup>5</sup>

The ideal hernia repair should be tension-free, easy to perform, secure, safe, and cost-effective.<sup>6</sup> The Lichtenstein mesh repair, regarded as the gold standard, and has been widely adopted due to its low recurrence rates. However, its use comes with significant drawbacks, including high costs, unavailability in rural settings, mesh migration, infection, and a higher incidence of chronic postoperative pain and mesh-related infertility.<sup>7</sup> Consequently, there has been a growing interest in alternative, no-mesh techniques such as Desarda's repair, which utilizes the external oblique aponeurosis to reinforce the posterior wall. Studies have shown that Desarda repair provides outcomes comparable to Lichtenstein in terms of recurrence rates while reducing complications such as chronic pain and foreign body sensation.<sup>8</sup>

Our study further supports the viability of a no-mesh repair. In a randomized controlled trial comparing peritoneal sac gathering plication repair with Lichtenstein mesh repair, we observed that both techniques had similar short-term outcomes regarding recurrence rates. However, the peritoneal sac plication repair demonstrated several advantages. The operative time was shorter in most cases, with 95% of procedures completed within 45 minutes. Postoperative pain scores were generally lower, with 68% of patients experiencing only mild to moderate pain and severe pain being exclusively associated with Lichtenstein repair. Similar findings have been reported in global studies comparing no-mesh techniques to Lichtenstein, where no-mesh repairs resulted in lower postoperative pain and faster recovery.<sup>9,10</sup>

Additionally, our study found that peritoneal sac plication repair was more commonly associated with seroma and hematoma formation than Lichtenstein repair, although both complications

were minor and self-limiting. Similar trends have been reported in previous studies, where no-mesh repairs occasionally resulted in higher seroma rates due to tissue rearrangement, yet did not translate into increased recurrence risk.<sup>11</sup>

Regarding hospitalization and recovery, 66% of patients in our study underwent day-case surgery, and those requiring admission were primarily Lichtenstein repair recipients. Moreover, 60% of our patients resumed work within a week, and those who took longer than three weeks to return were primarily those with postoperative complications. These findings align with international studies reporting faster recovery and return to daily activities with no-mesh techniques compared to mesh-based repairs.<sup>12</sup>

Another significant finding in this study was the correlation between the degree of posterior wall weakness and operative duration. Patients with a weaker posterior wall tended to have longer surgery times and higher postoperative complication rates, regardless of the technique used. This observation reinforces the importance of selecting an appropriate repair method based on the patient's hernia characteristics.

Although this study was limited by a short follow-up period, the absence of recurrence within the study timeframe is promising. Given the advantages observed, peritoneal sac gathering plication repair presents a viable alternative to mesh repair, particularly in resource-limited settings. With further long-term studies, this biological mesh approach may redefine the gold standard for inguinal hernia repair in African populations.

## CONCLUSION

This study demonstrates that peritoneal sac gathering plication repair is a viable alternative to Lichtenstein mesh repair, offering shorter operative time, reduced postoperative pain, and faster recovery. Although it was associated with slightly higher rates of seroma and hematoma formation, these complications were self-limiting and did not lead to increased recurrence within the study period. The findings suggest that this technique may be particularly beneficial in resource-limited settings where mesh availability

is a challenge. Further long-term studies are needed to establish its durability and effectiveness in reducing recurrence rates.

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