"A RANDOMISED CONTROL TRIAL TO EVALUATE THE ROLE/EFFICACY OF SINGLE DOSE INTRAVENOUS TRANEXAMIC ACID AT THE TIME OF INDUCTION OF ANAESTHESIA FOR POSTOPERATIVE SEROMA FORMATION IN PARAUMBILICAL HERNIOPLASTY AT A TERTIARY CARE CENTRE FROM 1ST SEPTEMBER 2023 TO 31ST AUGUST 2024"

BY

REG. NO.: BH0122013

Dissertation

Submitted to

KLE Academy of Higher Education & Research (Deemed-to-be University),

Belagavi, Karnataka

In Partial fulfilment of the requirements for the degree of

MASTER OF SURGERY (M.S.)

in

GENERAL SURGERY

JAWAHARLAL NEHRU MEDICAL COLLEGE,

BELAGAVI, KARNATAKA

September/October 2025

KLE ACADEMY OF HIGHER EDUCATION AND RESEARCH,
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Sub: Institutional Ethical Clearance for the study.

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LIST OF ABBREVIATIONS

TXA	:	Tranexamic acid
POD	:	Post-Operative Day
SSI	:	Surgical Site Infection
HTN	:	Hypertension
T2DM	:	Type 2 Diabetes Mellitus
USG	:	Ultrasonography
BP	:	Blood pressure
CBC	:	Complete blood count
HB	:	Haemoglobin (g/dl)
G/DL	:	gram per decilitre
MG/DL	:	milligram per decilitre
CM	:	Centimetre
CNS	:	Central nervous system
CVS	:	Cardiovascular system
E.G.	:	For example
I.E.	:	That is
VS.	:	Versus
EHS	:	European hernia system
PTFE	:	polytetrafloroethylene

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ABSTRACT

Title:

A randomised control trial to evaluate the role/efficacy of single dose intravenous tranexamic acid at the time of induction of anaesthesia for postoperative seroma formation in paraumbilical hernioplasty at a tertiary care centre from 1st September 2023 to 31st August 2024

Background:

Paraumbilical hernia is a prevalent surgical procedure, and advancement in using newer pharmacologic agents such as Tranexamic acid (TXA) aim to optimize patient outcomes by reducing seroma formation, surgical site infections and related complications. This study aims to compare the outcomes of two groups one of which received intravenous tranexamic acid and its effect on drain output.

Aim:

To evaluate the efficacy of intravenous Tranexamic acid (TXA) at the time of induction of anaesthesia in reducing post-operative seroma formation after para-umbilical hernioplasty

Settings:

Kle's Dr. Prabhakar Kore hospital and Medical Research Centre, Belagavi, Karnataka

Methodology:

A randomized controlled study was conducted over one year, involving 70 patients who were divided into two groups. Group A / Test group (n=35) who received intravenous Tranexamic acid during induction of anaesthesia and underwent on-lay paraumbilical hernioplasty, while group B / Control group (n=35) who underwent conventional on-lay paraumbilical hernioplasty. The primary endpoint included, post

operative reduction in drain output as monitored on POD1,3 and 5 and hospital stay. Complications such as seroma formation, surgical site infection rates were monitored.

Results:

The study found a significant reduction in the drain output on postoperative day 1, 3 and 5 in the test group with p value <0.05. These results are suggestive that tranexamic acid significantly reduces drain output leading to earlier resolution of the fluid accumulated.

Our study observed that seroma formation was lower in TRANEXAMIC ACID treated patients. It was 8.57% in test group while 25.71% in the control group.

It was seen that 0% of the patients in test group developed surgical site infection as compared to control group which was 20%. P value <0.05

This study also found that that in 60% of the patients in the test group drain removal was done on POD-5 and 31.4% on POD-6. However, in the control group, only in 35% of the patients drain was removed on POD-5. P value was 0.004 which is significant. The study reveals that 60% of the patients in the test group were discharged on POD-5 as compared to control group in which only 31.5% of the patients were discharged on POD-5. P value <0.05 which is statistically significant. This shows that usage of tranexamic acid can decrease hospitalization significantly.

Conclusion:

Intravenous tranexamic acid during induction of anaesthesia offers significant reduction in the drain output on postoperative days. This reduction in seroma benefits in reducing seroma formation, surgical site infection and thus reduced hospital stay. These findings suggests that intravenous tranexamic acid can be used as an upcoming modality in reducing seroma formation in para-umbilical hernioplasty procedure,

though further long-term studies are recommended to confirm these benefits over extended follow-up periods.

Keywords: Paraumbilical hernia, tranexamic acid, seroma, surgical site infection.

INTRODUCTION

Para-umbilical hernia is a considerable burden on healthcare system in India and worldwide too and is one of the most commonly performed surgery.

According to epidemiological data, para-umbilical hernia constitutes about 10% of all abdominal wall hernias encountered in clinical practice[1]. The incidence varies in different age groups with notable increase in older adults. Umbilical hernia in the infants is congenital and is not uncommon. They usually close spontaneously by the age of 2 years[1,2].

Para-umbilical hernia in the adults is mostly acquired. They are common in women between ages 31-40 years and in patients with predisposing factors such as obesity, ascites, pregnancy, chronic distention of abdomen[1,2]. The economic burden of para-umbilical hernia includes direct costs related to hospitalization and surgical procedure and indirect costs from lost productivity and disability. Complications includes incarceration, strangulation and bowel obstruction need effective management strategies[3]. It can rupture and can cause generalized peritonitis and death.[3]

In earlier days repair was done using the vest over pants technique proposed by MAYO, which used imbrication of the superior and inferior fascial edges. The problem faced with this repair was recurrence rates of nearly 30% after long term follow up[2]. For the defects larger than 3cm prosthetic mesh is preferred and there are many techniques where mesh placement can be done. Options of mesh placement include bridging the defect, placing an on-lay or sub-lay or preperitoneal mesh reinforced with suture repair. On the other hand, laparoscopic repair, a minimally invasive approach which uses small abdominal incisions and a laparoscope to visualize the defect and repair the hernia with mesh[4]. Laparoscopic repairs include

IPOM (intra-peritoneal on-lay mesh repair) and IPOM plus in which the defect is sutured.[4]

Complications in Para-umbilical hernioplasty are not uncommon. Post-op complications includes surgical site infection, hematoma formation and early recurrence are quite common. Diabetes, chronic alcohol intake, tobacco chewers and morbidly obese patients are at more risk of developing these complications as compared to others.[1,2] Complications specific to mesh placement includes SEROMA formation, mesh infection and migration.[3]

Different methods evolved to prevent these complications such as usage of compression dressings, drain placement over the mesh to prevent seroma formation which further prevents mesh infection and surgical site infections. Once seroma persists it can form in pseudo-bursa which is more challenging to manage and requires invasive procedures[3]. These post-operative complications put a major impact on the patient both mentally and physically as well as financially as in increases the overall cost of stay in hospital.

Eliminating the post-operative impact of seroma formation is the need of the hour. One such pharmacological agent that has drawn attention is the

Tranexamic acid (TXA), a synthetic lysine derivative known for its anti-fibrinolytic activity and is widely used to control bleeding in various surgical specialties.[5] Though Tranexamic acid has been used in some studies regarding incisional hernias and ventral hernias, there is still a relative paucity of robust data specific to its use in para-umbilical hernioplasty.

There are many previous studies in the literature which were conducted evaluating the efficacy of tranexamic acid but many fallacies were noted such as small sample size, lack of randomization, single center study and improper data analysis.

The rationale is to compare the role of TXA in on-lay paraumbilical hernioplasty and its effect on decrease in seroma formations as depicted by post-operative drain output. However, despite the theoretical advantages of tranexamic acid, there is limited clinical evidence comparing the outcomes and complications.

Therefore, the rationale for conducting a detailed randomized control study lies in the need to systematically evaluate and compare the operative time, clinical outcome including complication rates and decrease in seroma formation by using tranexamic acid during induction of anesthesia during para-umbilical hernioplasty. By minimizing seroma formation, surgeons may lower the risk of subsequent mesh infection, thereby preserving the integrity of the hernia repair and improving overall patient outcomes

Furthermore, given the prevalence and impact of para-umbilical hernias on patient morbidity and healthcare costs, identifying the most effective way of reducing seroma formation is of paramount importance. The findings from this study have the capability to aid in contributing to advancements in hernia surgery practices, improve patient outcome and reduce overall healthcare burden associated with para-umbilical hernia repair.

AIMS AND OBJECTIVES

Primary Objective: To evaluate the efficacy of intravenous Tranexamic acid (TXA) at the time of induction of anaesthesia in reducing post-operative seroma formation after para-umbilical hernioplasty

REVIEW OF LITERATURE

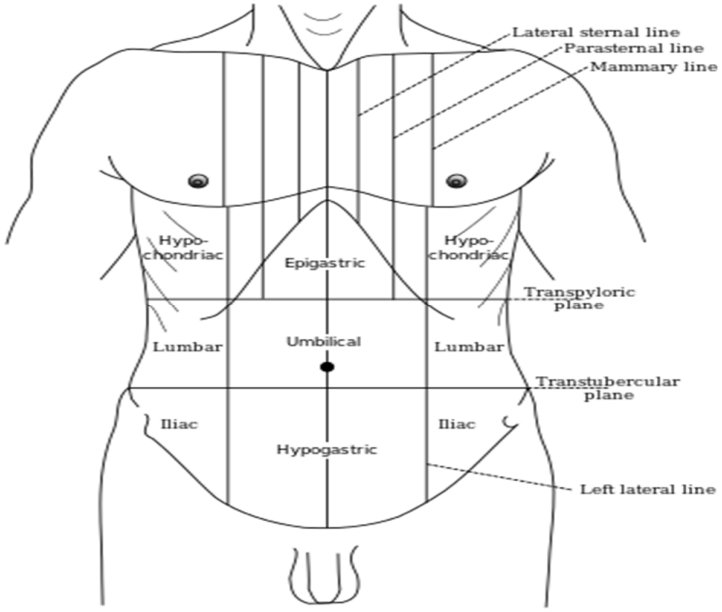
General surgeons execute about 5 lakh para-umbilical hernia repair each year, making it one of the most often done surgery[6]. A para-umbilical hernia is a condition characterized by the protrusion of abdominal contents via a weak area in linea alba which is located in the umbilical region[7].

RELEVANT SURGICAL ANATOMY OF UMBILICAL REGION[7]

Extent of the Anterior Abdominal wall[7]

- **Superiorly:** The Xiphoid process as well as the costal margins.
- **Inferiorly:** Extends to the pubis, pubic symphysis, and bilateral iliac crests.
- **Groin Region:** Situated below the ASIS level.

FIGURE 1. SHOWS DIFFERENT REGIONS OF ANTERIOR ABDOMINAL WALL[7]



Umbilicus[8]:

- The umbilicus is a scar which is formed: umbilical ring in the Linea alba and is made up of dense fibrous tissue
- It is attached to fetal end of umbilical cord, through which the fetus is attached to the placenta
- Intraabdominally, superiorly it is formed by ligamentum teres and paraumbilical veins
- The median umbilcal ligament (uracus) inferiorly.
- Level: L4 and L5
- Umbilical skin supplied by T10 spinal cord.
- Drains venous blood and lymphatics.
- Drainage is via axillary vein superiorly.
- Inferiorly drainage is into inguinal region

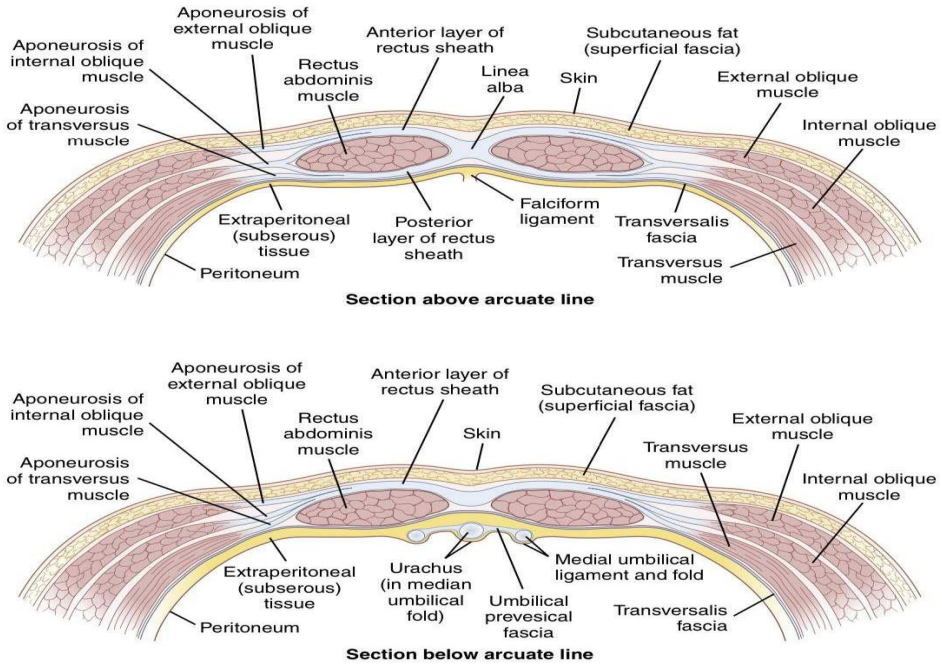


FIGURE 2 Shows the cross section of the rectus abdominis muscle below and above arcuate line[1]

Pathophysiology of para-umbilical hernia[2,3]

- Umbilical hernias in infants are congenital and common, typically closing on their own by the age of two.
- If the hernia persists beyond the age of five, surgical repair is often performed, although complications in children are rare.
- In adults, paraumbilical hernias are usually acquired.
- Paraumbilical hernias are more prevalent in individuals with a single midline aponeurotic decussation, as opposed to the normal decussation of fibres from 3 layers of abdominal wall.

Etiology and predisposing factors for of para-umbilical hernia[1,2,3]

The majority of para-umbilical hernias are acquired.

Predisposing factors[2]

- Increased intra-abdominal pressure (obesity, persistent coughing, excessive physical exertion caused by constipation, pregnancy ascites or chronic abdominal distention).
- Additional factors for adult paraumbilical hernia include connective tissue disorders, ethnic background, Beckwith-Wiedemann syndrome and poor nutrition

Epidemiology of the occurrence of para-umbilical hernia[2,3]

- Demographically, paraumbilical hernias exhibit a female predominance.
- The overall incidence is 23% and 50%
- The prevalence of paraumbilical hernia peaks between ages 31-40 years in women and between 61 to 70 years in men.

- The female to male ratio of its occurrence is 3:1.
- Despite the higher incidence in women, 70% of repair procedures are performed in men.
- The risk rises with advancing age, reaching its highest point around 5 years old and beyond 70-75years.
- Geographically, the prevalence of umbilical hernia demonstrates variability across regions and populations. While umbilical is prevalent globally, their incidence tends to be higher in certain geographic regions, including parts of Africa, Asia, and Latin America.

Classification of para-umbilical hernias[9]:

1. European hernia society (EHS) classification:

EHS Primary Abdominal Wall Hernia Classification		**Diameter cm**	**Small** <2cm	**Medium** ≥2-4cm	**Large** ≥4cm
Midline	Epigastric				
	Umbilical				
Lateral	Spigelian				
	Lumbar				

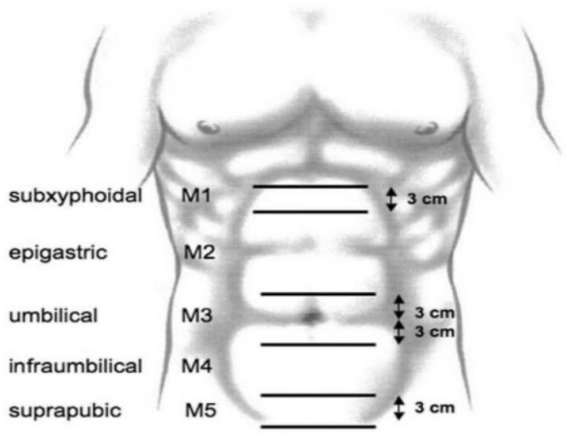


FIGURE 3. Different zones for midline abdominal wall hernias[9]

Indications for hernia repair[2,3]

Surgical intervention is often necessary for hernias that result in persistent pain, discomfort, or the potential for exacerbation of symptoms.

- Symptomatic hernias. Symptoms such as pain, discomfort.
- Complicated hernias (obstructed hernias, incarcerated hernias, and strangulation).
- Patient preference.
- Recurrent hernias.

Although not all hernias need urgent surgical intervention, the majority will ultimately necessitate treatment due to their tendency to increase in size over time.

Evolution of hernia repair and historical perspective[10]:

Hippocrates in (400BC) described umbilical hernia.

Hernia repair has undergone a process of evolution, shifting from conventional open procedures to minimally invasive treatments using the use of mesh.

Traditional Techniques[11]:

Historically, hernia repair relied on conventional methods such as primary tissue approximation or herniorrhaphy. These techniques, dating back centuries, involved the closure of hernia defects using sutures without the use of prosthetic mesh reinforcement. While effective in some cases, traditional hernia repairs were linked to high instances of recurrence and complications as a consequence

the reliance on tension-bearing sutures and the inability to address underlying weaknesses in the abdominal wall

1. **Primary closure of the defect[10,11]:**

Infraumbilical transverse incision was made, sac was dissected circumferential manner and released from subcutaneous tissue and the umbilicus. Sac was opened and contents were reduced. defect was approximated with interrupted nonabsorbable polypropylene sutures, umbilicoplasty was done by creating umbilical dimpling.

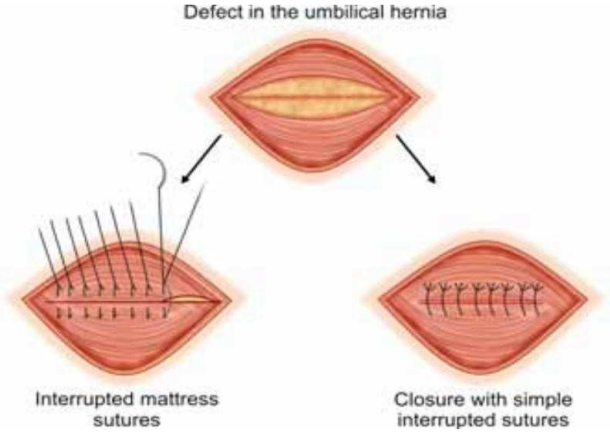


Figure 4. Primary closure of the defect with interrupted sutures[11]

2. **Mayo's operation[10,11]:**

In this procedure, rectus is opened in horizontal fashion and is approximated using a double-breasting technique, with the upper flap overlapping the lower flap anteriorly. Interrupted non-absorbable polypropylene 2-0 sutures were used for closure. A suction drain was placed beneath the main suture line. This technique is also referred to as the "vest-over-pants" autogenous repair.

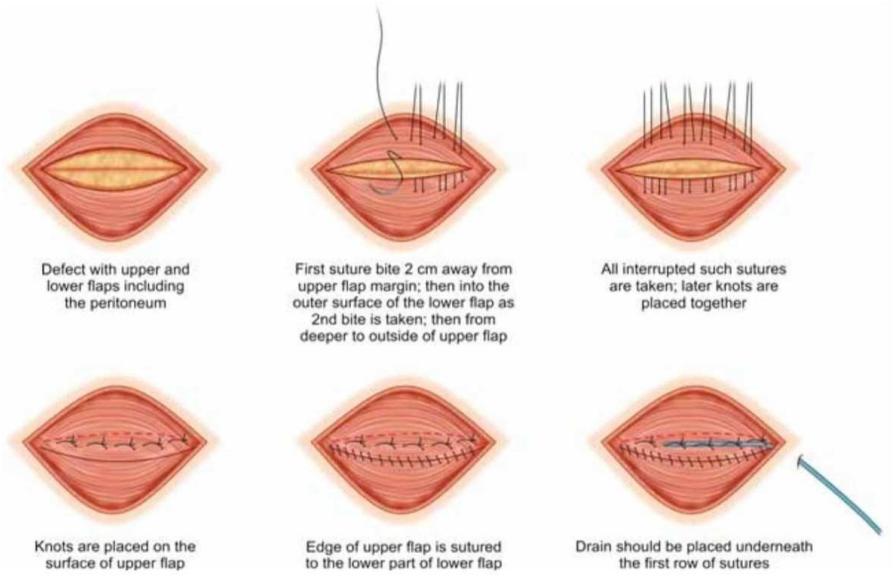


FIGURE 5. Mayo's repair for paraumbilical hernia steps[11]

3. **Umbilectomy[10,11]:**

Fragile, skin above a large umbilical hernia poses a significant challenge. In such cases, excision of the umbilical cicatrix (umbilectomy) is the preferred approach. Negative suction drain is kept and rectus closure is done.

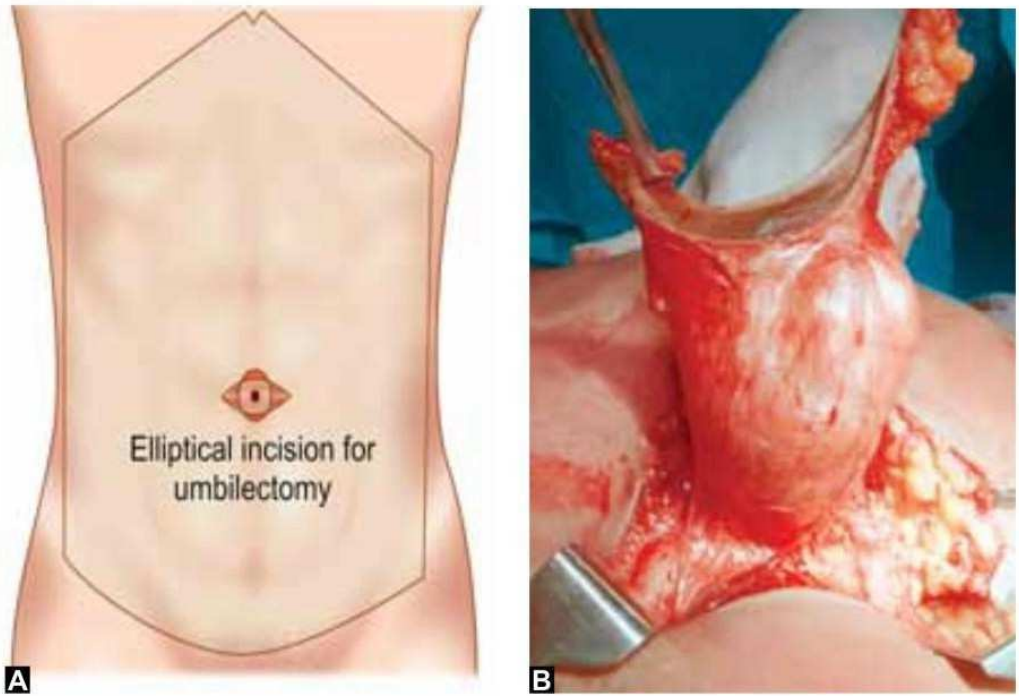


FIGURE 6A AND 6B – Shows the incision for umbilectomy and the excision of large hernia[11].

4. **Open dual PTFE and polypropylene mesh placement[11].**

A specialized composite mesh, featuring a PTFE layer on inner side and a polypropylne mesh on outer side, is used. This design has demonstrated excellent outcomes with a lower recurrence rate.

5. **On-lay mesh repair[11,12]**.

Infra-umbilical incision is taken and subcutaneous plane is created. Sac identification done and is separated from umbilicus circumferentially. Contents are reduced and rectus sheath is approximated with continuous polypropylene suture. Suction drain is kept over the mesh in subcutaneous plane.

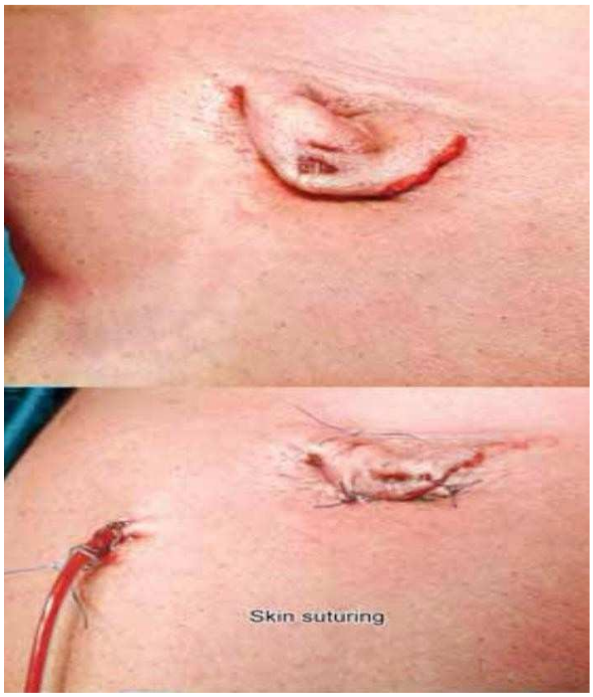
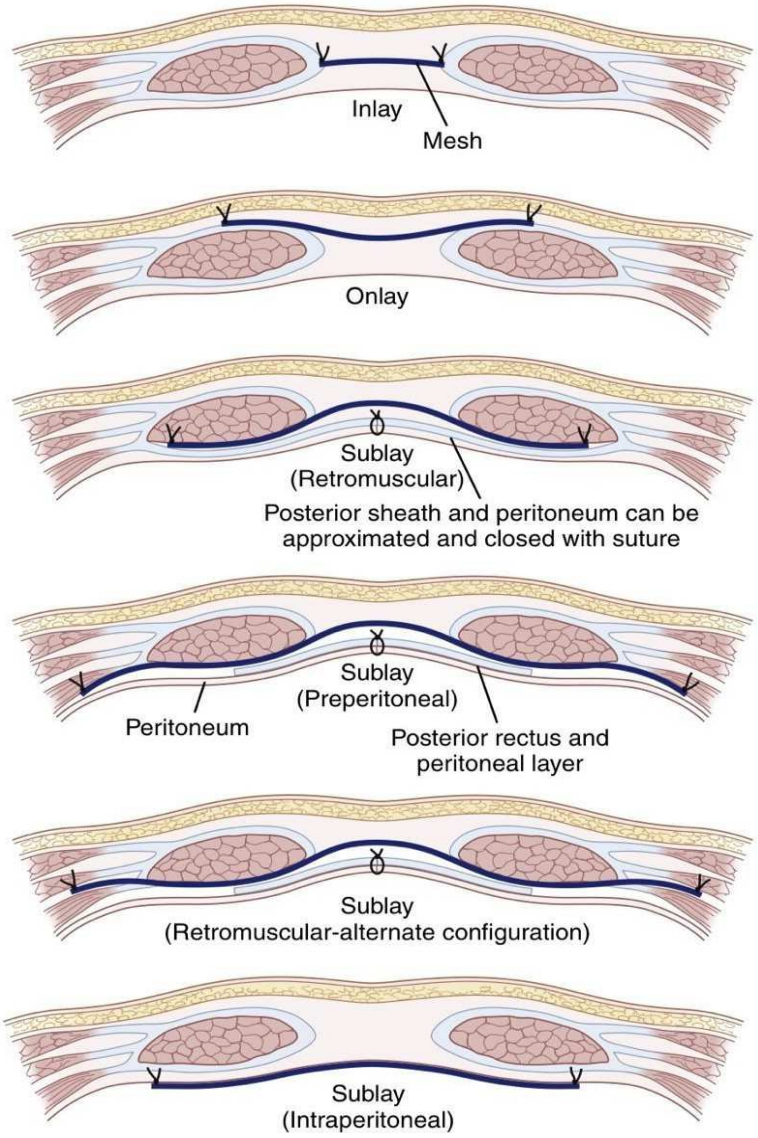


FIGURE 7 Shows infraumbilical incision and drain placement in on- lay paraumbilical hernioplasty[11]

FIGURE 8. Different mesh placement options in para-umbilical hernia surgery[2,11]



6 Minimally invasive procedures[13]:

In the 1990s, laparoscopic techniques came up as minimally invasive option to open hernia repair, offering many perks such as lesser postoperative pain, lesser hospital stays, and speedy recovery. Early studies demonstrated comparable outcomes between laparoscopic and open approaches, prompting increased utilization of laparoscopy in hernia surgery[13]

IPOM[13] (Intraperitoneal On lay Mesh) is a procedure in which a mesh is positioned within the abdominal cavity and placed internally over the hernia defect. Using a special instrument, the double threads are guided out and knotted via small skin punctures over abdominal wall fascia. Mesh is secured from inside using with special tacks with titanium spirals or absorbable screws.

IPOM PLUS[13]: It is a minimally invasive procedure which includes intraperitoneal on-lay mesh repair with defect closure.

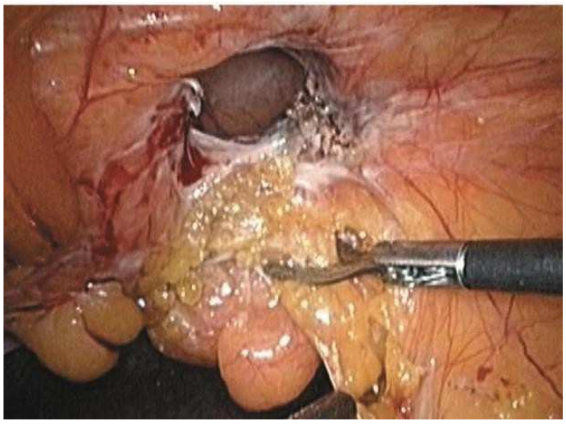


FIGURE 9 show laparoscopic view of paraumbilical hernia repair[2]

Outpatient hernia repair/ Day care hernia repair: Recent advancements in minimally invasive methods and recovery regimens have made it possible to do hernia repairs on an outpatient basis. This can save expenses, speed up the healing process, return to the everyday activities more quickly.

POST OPERATIVE COMPLICATIONS OF ON-LAY PARAUMBILICAL HERNIA REPAIR[2,3]

Similar to any surgical intervention, hernia repair includes problems/complications. Below are a few possible issues that may arise with hernia repair[2,3]:

- Hematoma
- Seroma
- Surgical site infection
- Mesh migration and erosion
- Hernia Recurrence

As an increased population of patients are undergoing para-umbilical hernioplasty, they are exposed to longer period of indwelling mesh and they present with long term mesh related complications.

1. Surgical Site Infection (SSI)[3,4]

Definition: infection occurring at the site within 30days of surgical procedure if no implant is left or within 1 year if implant is in the place.

Incidence: Surgical site infections occur in 1% to 5% of open paraumbilical hernia repairs.

Risk Factors[2]:

- **Patient-related:** Advanced age, diabetes, obesity, immune suppression, and smoking.
- **Surgery-related:** Extended operative time, suboptimal surgical techniques, and absence of prophylactic antibiotics.
- **Postoperative care:** Poor wound management.

Prevention Strategies[3,4]:

- **Preoperative:** Timely administration of antibiotics, patient health optimization, and management of co morbidities.
- **Intraoperative:** Strict aseptic techniques, appropriate mesh utilization, reduced surgery duration.
- **Postoperative:** Proper wound care, vigilant monitoring, and patient education on infection indicators.

Type of SSI[2]:

- **Superficial incisional SSI:** occurs in 30 days after the procedure and involves skin and subcutaneous tissue.
- **Deep incisional SSI:** deep soft tissue (fascia/muscle)

- **Organ or space SSI:** infection in any body part excluding the skin, fascia or muscle layers.

Treatment Strategies[2,3]:

- Identification of the pathogen
- Empiric antibiotic coverage
- Source control by opening the incision or Image guided drainage can be done. Organ space – open drainage
- Local wound care.

Surgical site infections Severity Assessment[3]:

The Southampton Grading System offers a structured approach to categorizing the severity of surgical site infections (SSI) following surgery. This system assigns grades ranging from Grade 0 to Grade 5 based on clinical parameters indicative of infection severity. The following scoring method is typically used:

Grade	Definition
0	Normal healing
I	Normal healing with mild bruising or haematoma
II	Erythema plus other signs of inflammation
III	Clear or haemoserous discharge
IV	Pus
V	Deep or severe wound infection with or without tissue breakdown; haematoma requiring aspiration

FIGURE 10. Southampton scoring system[3]

2. SEROMA FORMATION IN PARA-UMBILICAL HERNIA[1,14]:

Definition: Seroma formation the most common seen complications following para-umbilical hernioplasty, with incidence rates varying significantly based on surgical technique, patient characteristics, and postoperative management. A seroma is defined: Accumulation of fluid mainly serous in the dead space created by dissection, occurring as a result of the inflammatory response triggered by tissue trauma[3,4]. The condition, though often self-limiting, can lead to patient discomfort, prolonged hospital stays, and potential infection risks, making its prevention a crucial aspect of surgical management.

Incidence rates of seroma formation post-para-umbilical hernioplasty range from 2% to 38%, depending on factors - the use of synthetic mesh, surgical technique, and the presence of comorbidities[2,3].

Pathophysiology of seroma formation[2,15]:

Current hypotheses from various studies suggest that the source of the fluid accumulation is likely multifactorial. Surgical techniques involving massive soft tissue dissection can lead to damage to blood vessels and lymphatic, which can lead to collection of transudate. In cases where significant tissue resection has occurred, a large potential dead space is created, which complicates flap adherence and introduces forces between tissue surfaces. This triggers an inflammatory response, with fluid from the tissues contributing to seroma formation.

Causes of seroma formation[2,3]:

- Diabetes Mellitus
- Immunocompromised patients
- Chronic smoking
- Alcohol consumption
- Obesity
- Malnutrition
- Non administration of pre-operative antibiotics
- Improper surgical technique
- Non compressive dressings
- Non usage of abdominal binders' post-surgery

Prevention strategies[16]:

Pre-operative strategies:

- Pre-operative weight optimization
- Proper glycaemic control
- Smoking cessation
- Alcohol cessation
- Appropriate antibiotic prophylaxis

Intra-operative strategies[16]:

- Meticulous surgical technique
- Avoid excessive use of energy devices
- Proper closure techniques
- Maintaining aseptic precautions throughout the procedure.
- Negative pressure Drain placement over the mesh

Post-operative strategies[16]:

- Adequate compression by the dressing
- Usage of compression garments or abdominal binders
- Early mobilization

Treatment of seroma[17]:

- Less volume seromas which not cause much pain can be managed conservatively with observation
- Large volume seromas cause pain, surgical site infection, decreased function of affected region. Aspiration can be carried out in these patients Sometimes multiple aspirations are needed.
- Usg guided aspiration done in patients with periprosthetic seroma e.g., Breast implants
- Open surgery and debridement are seldom necessary and are typically done for cases with encapsulated pseudocyst formation or in re- infection.

Technique[16,17]:

- Under aseptic precautions, with proper patient positioning, seroma should be examined and plan site for aspiration
- Entered via the scar to reduce the pain
- The sample should be sent for microscopy and culture.
- Once the seroma has resolved, gentle pressure should be applied with help of a gauze and compression dressing is done.
- Ultrasound guided aspiration will give better outcomes.

Latest advances in seroma management[17,18]:

- **Sclerotherapy**: it involves filling the seroma cavity with an irritant that triggers a fibrotic response, which helps seal the dead space.
- **Talc**: commonly used for pleural effusion and pleurodesis, has also been applied to seromas in various anatomical areas, including the abdominal wall
- **Tetracycline and Erythromycin** have been used as primary sclerosants for seromas in the trunk and lower limbs.
- **Ethanol**
- **Polidocanol**
- **Fibrin glue**

Therefore, to decrease seroma formation and its impact on healthcare system. The aim of this study is to make the use of I/V **Tranexamic acid**, modality which has shown to decrease seroma formation and reducing drain output and thus offloading its impact on the overall morbidity to the patient.

TRANEXAMIC ACID(TXA):

Pharmacology[5]:

- Tranexamic acid (TXA), synthetic derivative of lysine which works as an antifibrinolytic agent by inhibiting plasminogen activation
- TXA is similar to aminocaproic acid and works by reversibly binding to lysine-binding sites on plasminogen and plasmin, thereby preventing fibrinolysis

Bioavailability[5]:

30-50% when administered intravenously and reaches peak plasma concentrations within 3 hours.

Dosage[5]: 10mg/kg body weight.

Half-life[5]: 2 hours

Clearance[5]: Renal being the primary route of elimination.

FIG 11. Shows structure of tranexamic acid[19]

Advantages[5,19]:

- Trauma causing significant blood loss
- Heavy menstrual bleeding
- Epistaxis
- Tooth extraction surgeries
- Cardio pulmonary bypass surgery
- Hyphema due to ocular trauma
- Bleeding Peptic ulcer
- Cosmetic use in various skin care products
- Bleeding disorders such as VON WILLEBRAND'S disease
- Post-partum haemorrhage

Disadvantages[5,19]:

- Nausea
- Diarrhoea
- Thromboembolic events
- Disturbed colour vision
- Thrombophlebitis of the vein
- Seizures

Contraindications[5,19]:

- Allergy
- Seizure history
- venous or arterial thromboembolism history
- Chronic kidney disease (CKD). Dose adjustments are required

Historical review with respect to Tranexamic Acid

Lashari et al. (2020)[20]:

Lashari et al. (2020) investigated the efficacy of TXA in preventing post-op seroma in the ventral hernioplasty. In this single enter randomized trial, 90 patients with ventral hernias (umbilical or paraumbilical) were allocated equally into a tranexamic acid group (receiving a standardized IV dose) and a placebo group. Incidence of clinically significant seroma—defined as fluid collections >20 mL on ultrasound—emerged as the primary outcome. The study reported that 12% of patients in the tranexamic acid arm developed seromas, versus 28% in the placebo arm, indicating a 57% relative risk reduction. While the authors acknowledged that larger multicentre studies could reinforce these findings, they concluded that tranexamic acid is a promising adjunct in lowering postoperative seroma in ventral hernioplasties

Ahmed et al. (2020)[21]:

Ahmed et al. also investigated the efficacy of I/V tranexamic acid in seroma reduction in ventral hernia repair. He conducted a cross sectional study which included 80 patients. 25% were males and 75% were females. He concluded that in 81% of the patients, seroma resolved in 5 days wherein 19% of the patients took more than 5 days

for seroma resolution. However, because of short sample size and single centre study, further studies are required.

Junaid et al. (2023)[22]:

This study was aimed to evaluate the role of TXA in reduction of post- op seroma formation in ventral hernia repair. The study included 70 patients. The study showed that 35.7% of the patients were male, while 64.3% female.

Among the patients, seroma formation resolved within six days in 53 individuals (75.71%), whereas in 17 patients (24.28%), it persisted for more than six days (P = 0.0001). In conclusion, the findings indicate that tranexamic acid significantly reduced post-op seroma in patients being operated for ventral hernioplasty. The study did not mention about surgical site infections, operative time and hospital stay.

Oertli et al. (1994)[23]:

Oertli et al. (1994) investigated the role of peri-op and post-op TXA in reducing wound complication rates in breast cancer surgery. In this prospective study, they enrolled a cohort of female patients undergoing various breast cancer procedures, including lumpectomies and mastectomies, and randomly assigned them to receive tranexamic acid or standard care without antifibrinolytic therapy. Numerical outcomes highlighted that the incidence of localized complications eg. seroma, hematoma, and dehiscence of wound , dropped from roughly 15–20% in the control group to about 5–10% in those who received tranexamic acid. Though promising, the authors recommended larger multicentre trials to validate the findings.

Patel et al. (2014)[24]:

Patel et al. in 2014 presented a randomized study comparing I/V vs topical TXA in total knee arthroplasty (TKA). The trial enrolled around 180 patients undergoing primary TKA, randomly assigning them into three groups: I/V TXA, topical TXA, and control (no tranexamic acid). The authors monitored perioperative blood loss, transfusion requirements, and postoperative haemoglobin drops. Numerically, patients receiving intravenous tranexamic acid exhibited the greatest reduction in total blood loss (by nearly 40% relative to controls). But the sample size was not adequate.

Ausen et al. (2015)[25]:

Ausen et al. (2015) did a randomized clinical trial investigating the role of topical TXA in patients having reduction mammoplasty. The study involved approximately 90 female patients divided evenly into a treatment group (topical tranexamic acid) and a control group (saline solution). The primary outcomes included quantitative blood loss, incidence of postoperative hematoma, and wound complications. Results indicated that the topical tranexamic acid group experienced a roughly 30% decrease in intraoperative bleeding, measured via standardized gravimetric methods, compared to controls.

As the above-mentioned studies have various limitations as described, and there is limited literature available on this topic, hence this study was conducted in an effort to fill in those gaps from previous studies and hence deduce a structured, statistically relevant result.

MATERIALS AND METHOD

Study Design: This study adopted a randomized controlled study design to compare the role of I/V TXA in reducing seroma formation during induction of anaesthesia in the patients undergoing on-lay paraumbilical hernioplasty.

Randomization allocated patients into 2 groups: GROUP-A (control) and GROUP-B (test) ensuring unbiased assignment

Source of data collection: The study was conducted at: KLE'S Dr. Prabhakar kore charitable hospital and MRC, located in Nehru Nagar, Belagavi, and KLES Dr. Prabhakar kore hospital and MRC.

Study duration: 1 year

Sample size: 70. The sample size was decided on the minimum sample size formula for two proportions. With the desired power of 80% and 95% confidence, the sample size is determined to be 35 for each group, considering an expected sample loss during follow up.

The minimum sample size formula calculation based on-

$$n = \frac{(Z_{1-\alpha/2} + Z_{1-\beta})^2 \times (SD_1^2 + SD_2^2)}{(X_1 - X_2)^2}$$

$$n = \frac{(1.96 + 0.84)^2 \times [(52)^2 + (40.2)^2]}{(98 - 67.6)^2} = 35$$

- Values: Z1−α/2=1.96Z = 1.96
- Z1−β =0.84
- SD1=52
- SD2=40.2
- X1=98

- X2=67.6
- **REF:** Albatanony et al [30]

Study participants: In this prospective study, 70 patients were studied. Control- 35 patients and test-35 patients

Inclusion Criteria:

- Patients with uncomplicated para-umbilical hernia
- Patient aged between 18-70 years
- All elective cases

Exclusion Criteria:

- Patients <18 years and >70 years
- Patients presenting with complicated hernias such as obstruction, strangulation or incarceration.
- Patients with medical disorders affecting coagulation profile, chronic renal insufficiency, vision disorder and color blindness.
- Pregnant/ lactating women.

Sampling technique: Simple random sampling using the computerized SPSS software was utilized.

Group allocation: Group allocation was performed using simple random sampling, making sure that each patient had a same chance of being assigned to either Group A or Group B. This randomization process helped to minimize selection bias and ensure that the groups were comparable at baseline.

Group-A (Control Group): Consisted of patients undergoing open on-lay paraumbilical hernioplasty.

Group-B (Test Group): Consisted of patients receiving of tranexamic acid 10mg/kg body weight during induction of anaesthesia and undergoing open on-lay paraumbilical hernioplasty.

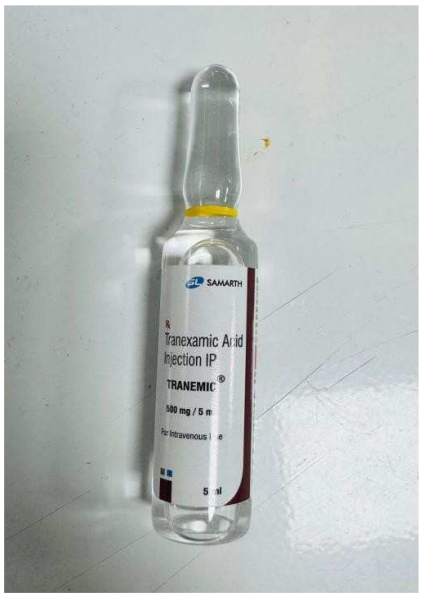


Image 1. Ampule of tranexamic acid, 500mg/5ml

Study protocol:

The study protocol involved the enrolment of 70 patients with para-umbilical hernia. Informed consent taken from all participants before their inclusion in study and before undergoing the operative procedure.

Data Collection:

Data collection for this study involved several steps to ensure comprehensive and accurate gathering of information related to para-umbilical hernioplasty and drain output measurement at post-operative day 1,3, and 5.

- **Preoperative Data Collection:** Detailed patient histories and physical examinations were recorded, including demographic information, and medical co morbidities, etc. in the predefined proforma after taking consent from the participants to take part in the study.

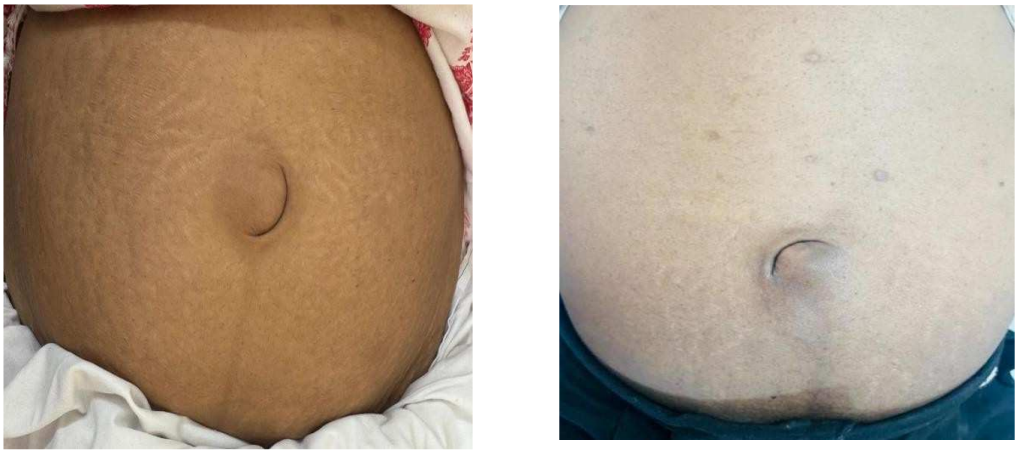


IMAGE 2. Showing patients with para-umbilical hernia

Investigations: Patients underwent preoperative imaging studies – Ultrasound of abdomen and pelvis to know the defect size and routine blood investigations such as Hb, creatinine, HBA1c with 2d ECHO as and when necessary.

Physician fitness was obtained and pre-operative assessment (PAE) was done by the anaesthesiologists. The patient was then taken up for on-lay para-umbilical hernioplasty under Spinal anaesthesia.

Intraoperative data: All the patients underwent on-lay paraumbilical hernioplasty with a transverse incision and 6X11 cm polypropylene mesh was kept in subcutaneous plane. Operative time was documented for each patient during the procedure and a negative suction drain was kept for all the patients.

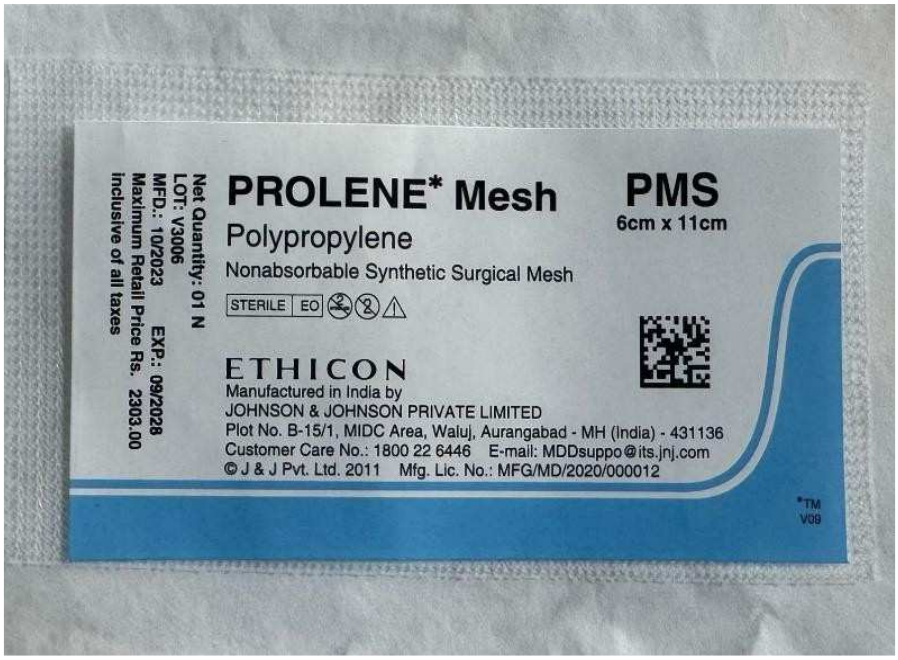


Image 3. 6X11cm polypropylene mesh

IMAGE 4. OT Setup showing administration of intravenous tranexamic acid.

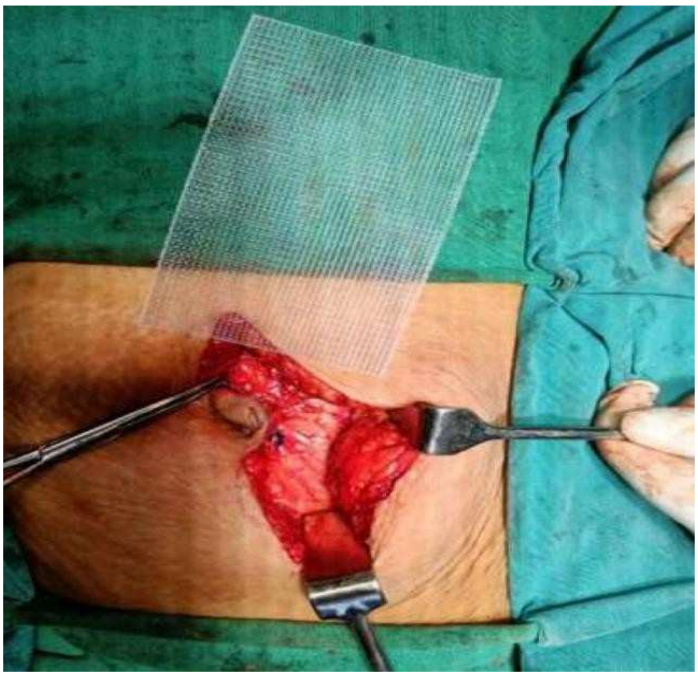


Image 5. 6X11 cm polypropylene mesh being placed in on lay repair.

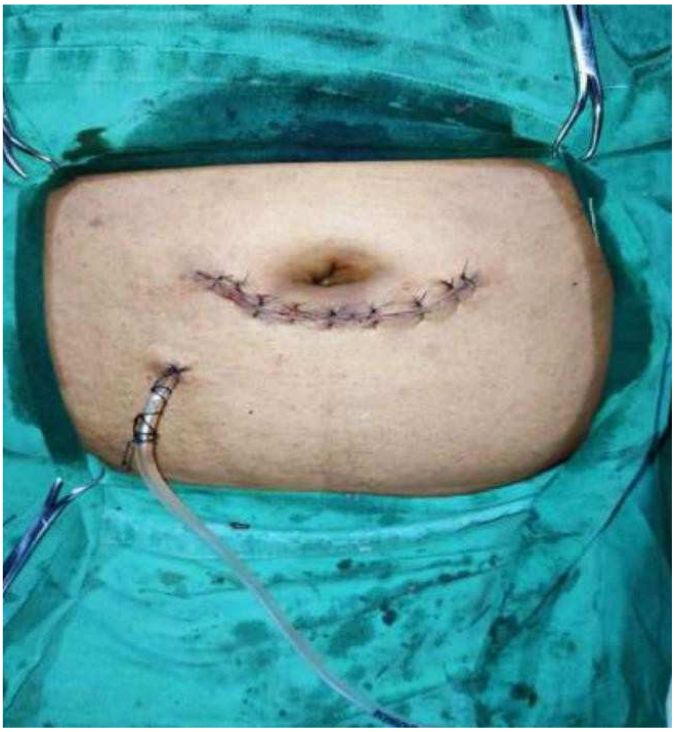


Image 6. Skin suturing and negative drain placement after procedure.

Postoperative Follow-up: Patients were followed up at specified intervals postoperatively and drain output was measured and documented on POD 1, 3 and 5.

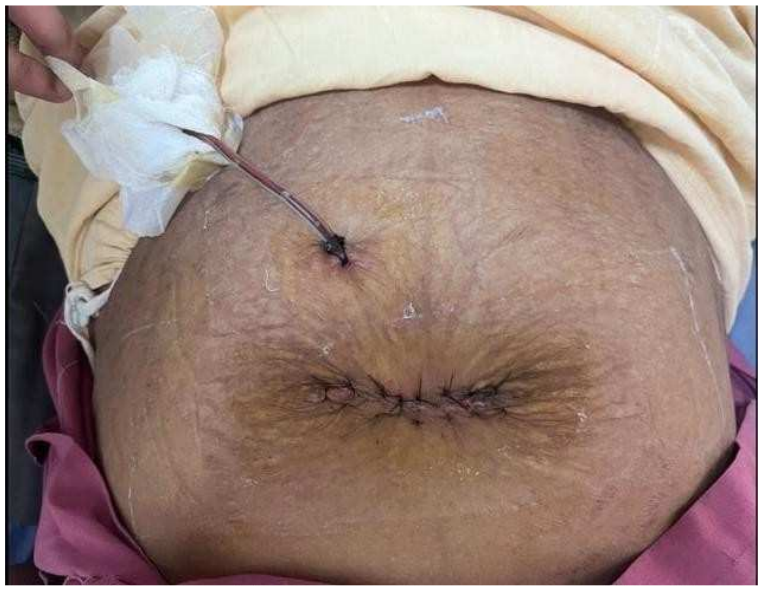


Image 7. Post procedure wound with drain in-situ.

Outcome Measures:

- the primary outcome is drain output as measured on post-operative day 1, 3 and 5
- Secondary outcomes include intraoperative time and postoperative complications – Seroma and surgical site infection

Data Entry: Collected data entered into a secure database system Microsoft Excel sheet, ensuring confidentiality and accuracy.

❖ **Quality Control:** Quality checks were performed regularly to validate data accuracy and completeness.

❖ **Data Analysis:** After completing data collection, statistical analysis was done using the SPSS software 26th version, to compare outcomes bw Group A and Group B.

Data processing and Statistical Analysis:

Data processed and statistically analyzed. For continuous data, such as the duration of surgery, the average and standard deviation were calculated for each group. Differences were compared using an unpaired Student's t-test. Comparisons within each group were conducted using a paired Student's t-test.

Categorical data, including postoperative complications and drain output, were presented as percentages. The relationship between outcomes and clinical or demographic characteristics was assessed utilizing either the Fisher's exact test or Chi-square test, based on the data size and distribution. Medians represented discrete variables, with nonparametric tests used for comparisons.

Bar charts and line graphs depicted group comparisons. p-value of lesser than 0.05-statistically significant.

RESULTS

A 1-year RANDOMISED CONTROL STUDY was conducted, and the results analyzed as required.

A total of 70 subjects admitted with para-umbilical hernia requiring mesh repair were a part of the study. These patients were further randomized and divided into two groups of 35 each, categorized as follows:

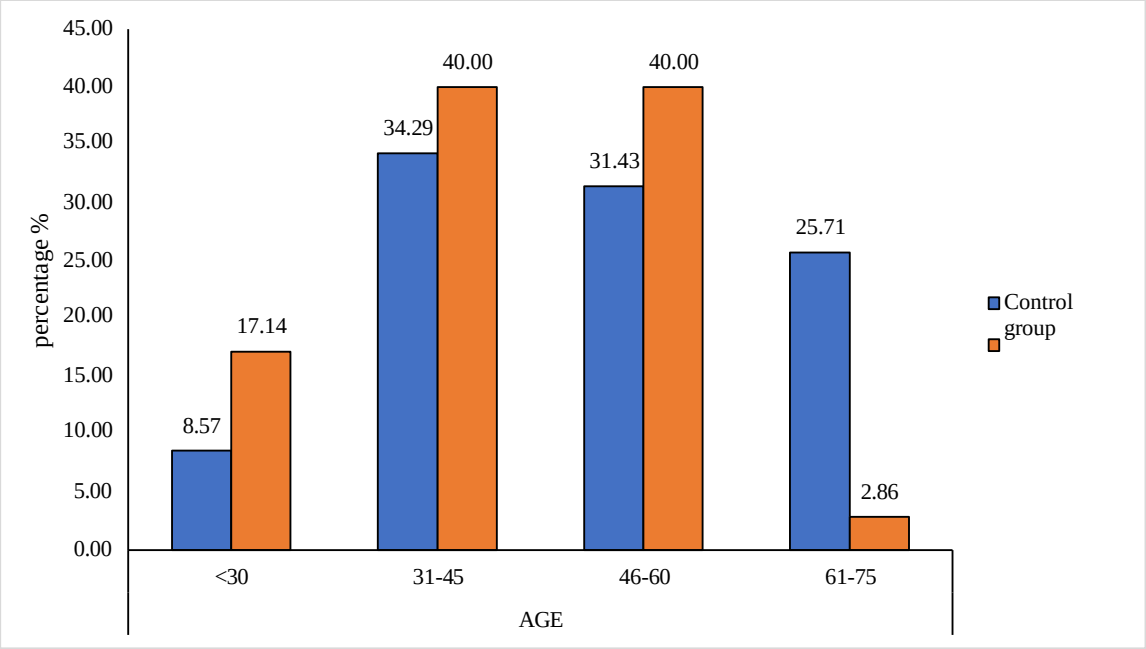
- **Group-A (Control Group):** Consisted of patients undergoing open on-lay paraumbilical hernioplasty.
- **Group-B (Test Group):** Consisted of patients receiving 1gm of tranexamic acid during induction of anaesthesia and undergoing open on-lay paraumbilical hernioplasty.

The details and all the relevant data were noted in predefined proforma. The collected data was then put in the Microsoft Excel spreadsheets, divided into two sheets as control group and test groups, and compared with each other for further analysis of the results.

1. AGE DISTRIBUTION

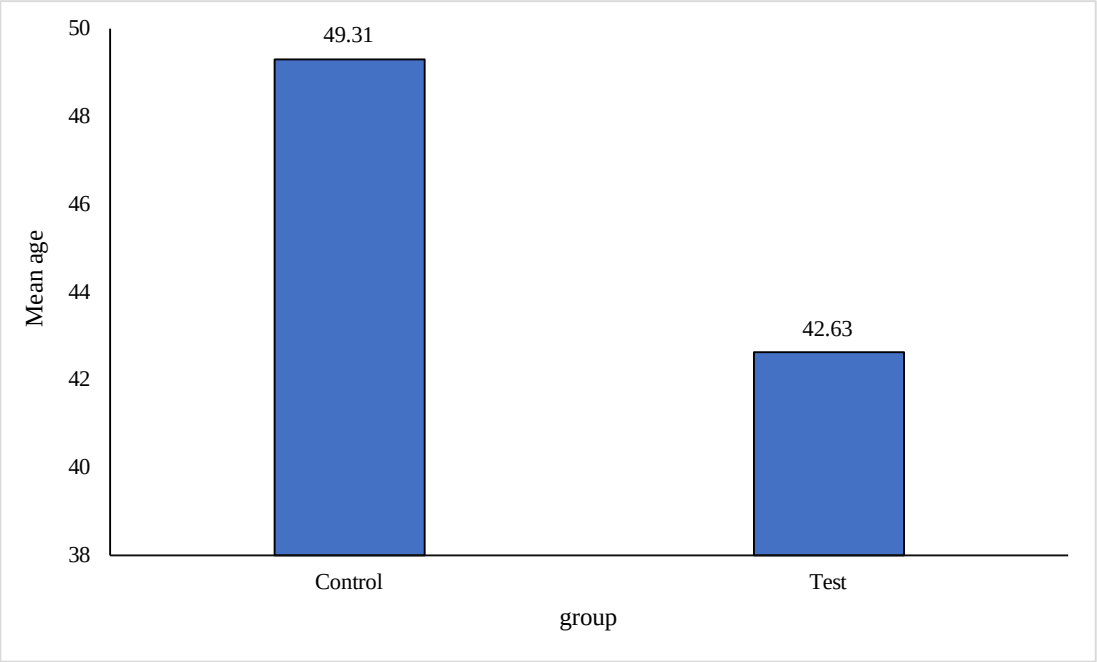
TABLE 1. showing categorization of age into various age groups

		Control group(n=35)		Test group(n=35)		Total n	Chi-square	p value	Significance
		n	%	n	%				
AGE	<30	3	8.57	6	17.14	9	7.99	(0.472)	Non-Significant
	31-45	12	34.29	14	40.00	26			
	46-60	11	31.43	14	40.00	25			
	61-75	9	25.71	1	2.86	10			
Mean ± *SD*		49.31 ± 13.79		42.63 ± 11.10					



GRAPH 1a. showing categorization of age into various age groups

The above table and graph show the age distribution among control and test groups. The mean age in test group is 42.63 ± 11.10 years and in control group is 49.31 ± 13.79 years



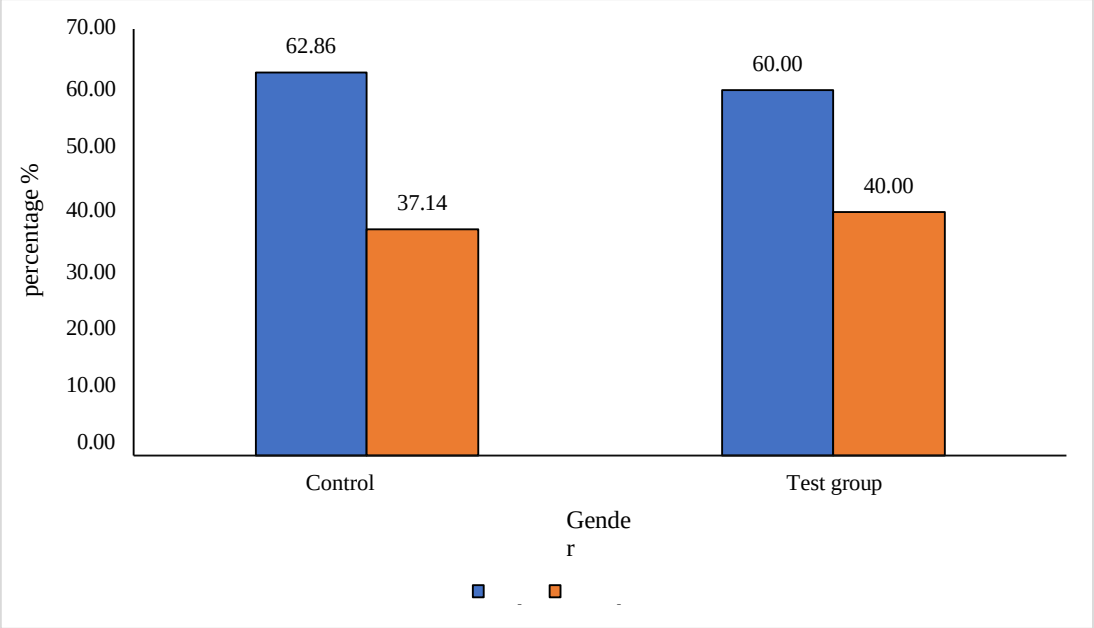
GRAPH 1b: Mean age in years between the study groups

The above table and graph suggest that mean age in control group is 49.31 years and 42.63 years in test group, though slightly more in control group, the age distribution among the groups seems consistent

2. GENDER DISTRIBUTION

TABLE 2 Gender distribution of control and test group

		control group(n=35)		Test group(n=35)		Total	Chi-square	p value	Significance
		n	%	n	%				
SEX	Male	22	62.86	21	60.00	43	0.060	(0.806)	Non-significant
	Female	13	37.14	14	40.00	27			



GRAPH 2. Gender distribution between control and test group

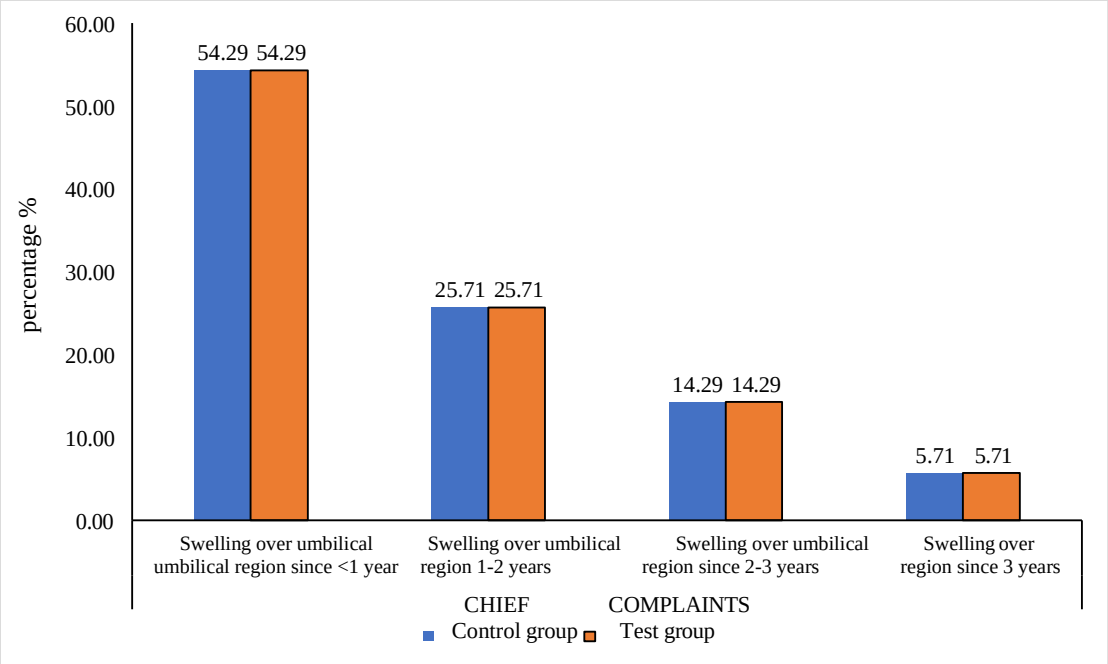
The above table and graph suggest that both groups the participants were males and females distributed equally. Control group 62.86% - males and 37.14%- females. Test group, 60%-males and 40%- females. This shows para-umbilcal hernia is more seen in male. P value- 0.806

3. COMPLAINTS AND DURATION

TABLE 3 Distributions of complaints and duration

		Control group(n=35)		Test group(n=35)		Total	Chi-square	p value	Significance
		n	%	n	%	n			
CHIEF COMPLAINTS	Swelling over umbilical region since <1 year	19	54.29	19	54.29	38	0	(1.000)	Non-significant
	Swelling over umbilical region 1-2 years	9	25.71	9	25.71	18			
	Swelling over umbilical region since 2-3 years	5	14.29	5	14.29	10			
	Swelling over umbilical region since 3 years	2	5.71	2	5.71	4			

The table shows that majority of patients had para-umbilical swelling since <1 year (54.29%). Followed by 1-2 years (25.71%) with p value of 1.00

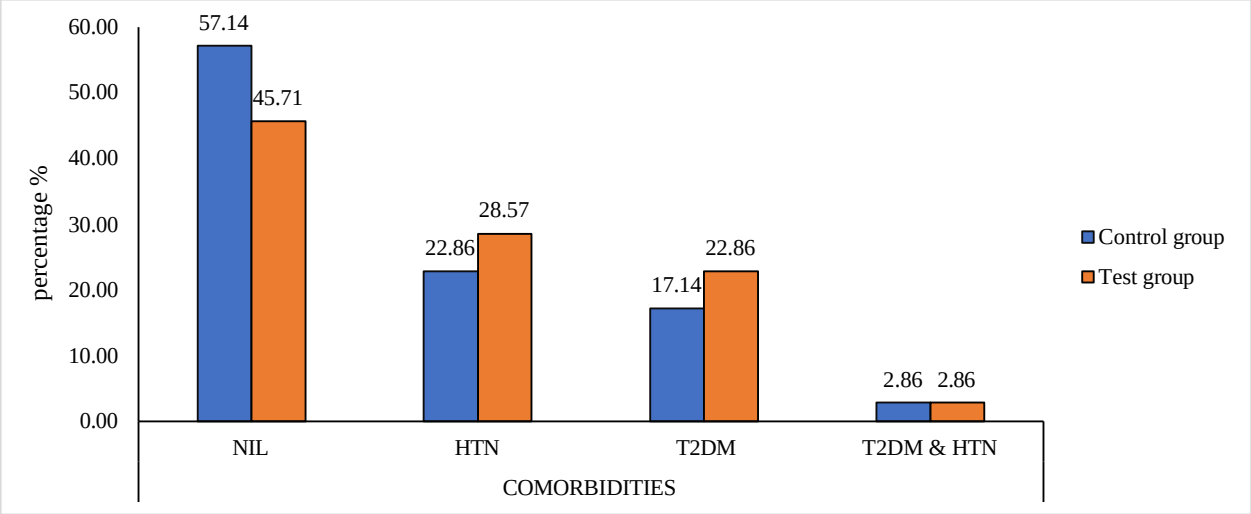


GRAPH 3. Distribution between complaints and duration.

4 CO-MORBIDITIES

TABLE 4. Showing the various comorbidities between groups

		Control group (n=35)		Test group (n=35)		Total	Chi-square	p value	Significance
		n	%	n	%	n			
COMORBIDITIES	NIL	20	57.14	16	45.71	36	0.999	0.813	Non-significant
	HTN	8	22.86	10	28.57	18			
	T2DM	6	17.14	8	22.86	14			
	T2DM & HTN	1	2.86	1	2.86	2			



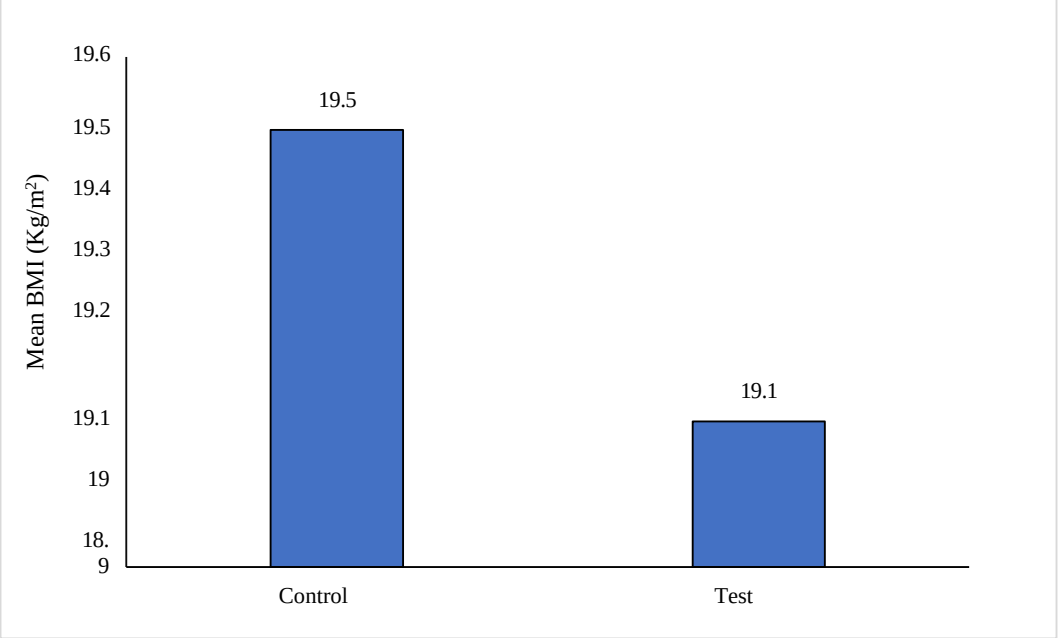
GRAPH 4. Showing the comorbidities in test and control groups

Patients with hypertension were 8(22.86%) in control group and 10(28.57%) in test group, type 2 diabetes mellitus 6(17.14%) in control and 8(22.86%) in test group. And one patient in each group had both hypertension and T2DM

5. **BODY MASS INDEX (BMI)**

Table 5 Comparison of BMI (Kg/m^2) control & test group

	Control group Mean	Test group Mean	p value	Significance
BMI	19.50 ± 1.80	19.10 ± 2.20	0.192	Not significant



Graph 5 Comparison of BMI in control and test group.

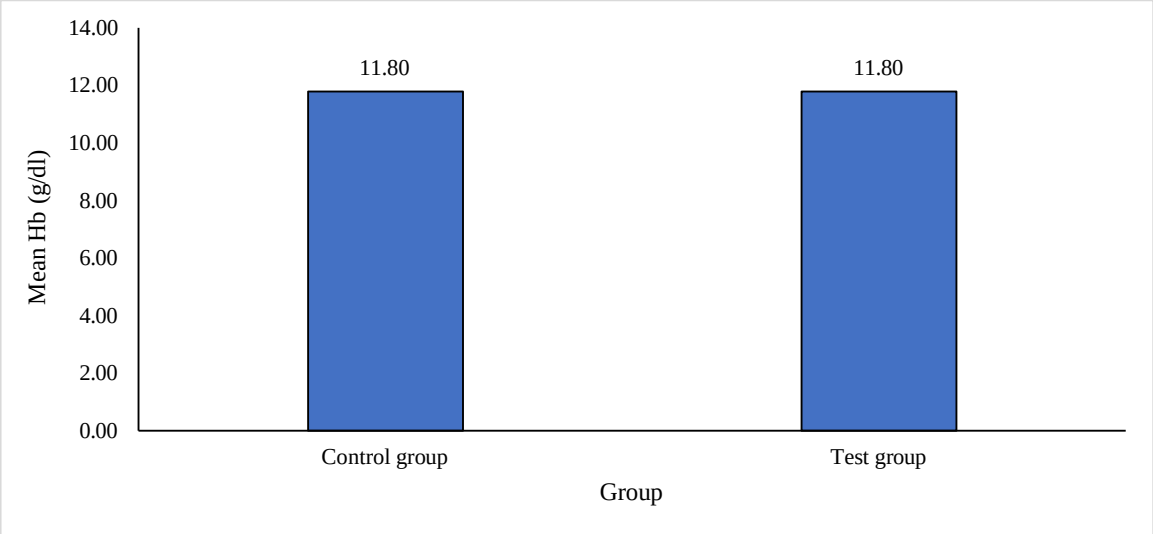
The table and graph show that the mean BMI in control group is 19.50 ± 1.80 (Kg/m^2) and in the test group is 19.10 ± 2.20 (Kg/m^2). p value is 0.192 which is non-significant.

6. BLOOD INVESTIGATIONS

6a- Haemoglobin(g/dl)

Table 6a Comparison of Haemoglobin(g/dl) Levels Between Control and Test Groups

Hb(g/dl)	Mean ± SD	Minimum	Maximum	U	p value
Control group	11.8 ± 2.0	9.5	14.1	612.500	1.000
Test group	11.8 ± 2.0	9.5	14.1		



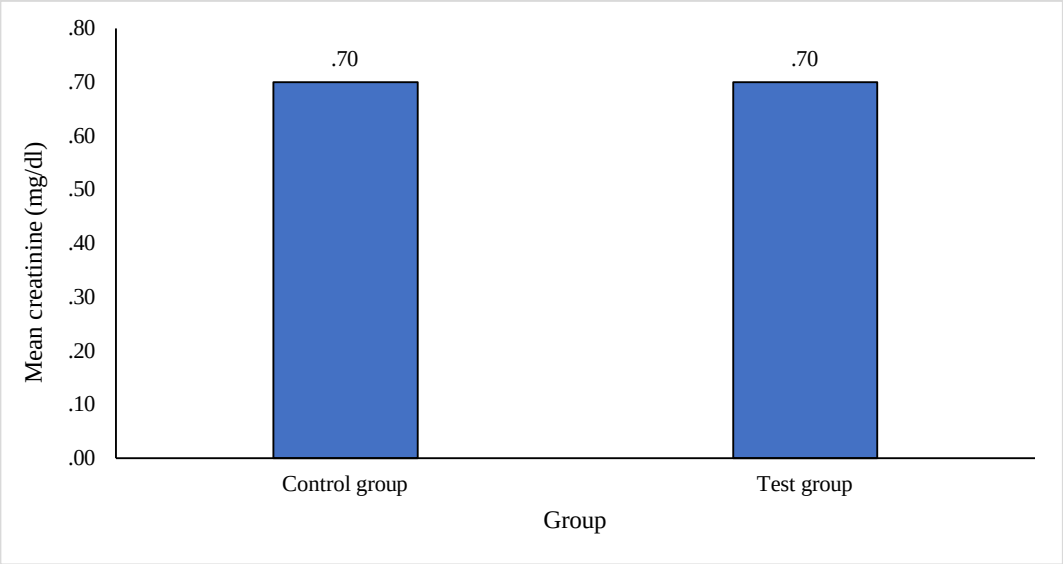
GRAPH 6a showing Haemoglobin (g/dl) levels in control and test group

The table and graph show that haemoglobin levels almost similar in both the groups with mean value 11.8 g/dl with p value of 1.00

6b – Creatinine(mg/dl)

Table 6b Comparison of creatinine(mg/dl) Levels Between Control and Test Groups

Creatine(mg/dl)	Mean ± SD	Minimum	Maximum	U	p value
Control group	0.70 ± 0.36	0.25	1.20	612.500	1.000
Test group	0.70 ± 0.36	0.25	1.20		



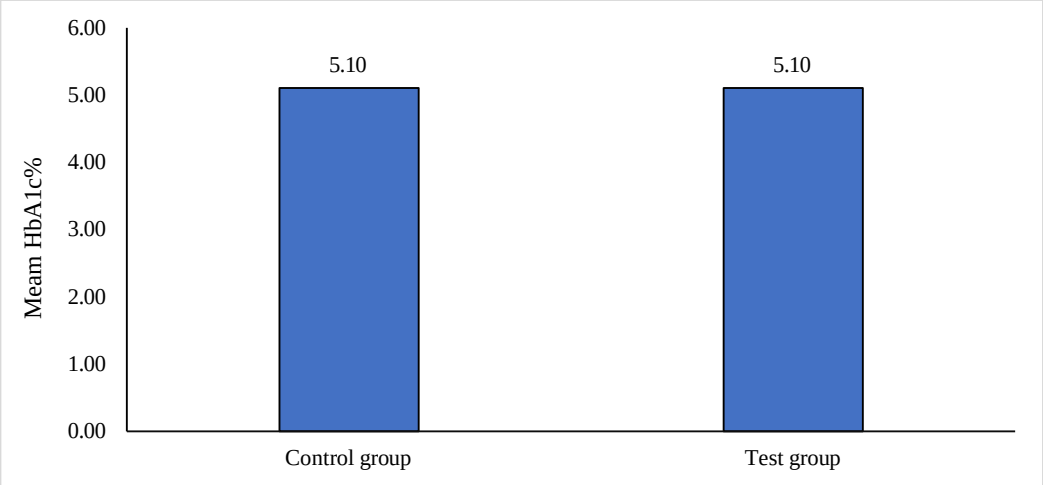
GRAPH 6b Showing creatinine(mg/dl) levels in control and test group

Table and graph show mean creatinine value as 0.70 mg/dl in both control and test group with p value of 1.00

6c- HbA1c

Table 6c Comparison of HbA1c % Levels in Control and Test Groups

HbA1c %	Mean ± SD	Minimum	Maximum	U	p value
Control group	5.10 ± 1.20	3.80	7.20	578.000	0.684
Test group	5.10 ±1.80	3.80	7.20		



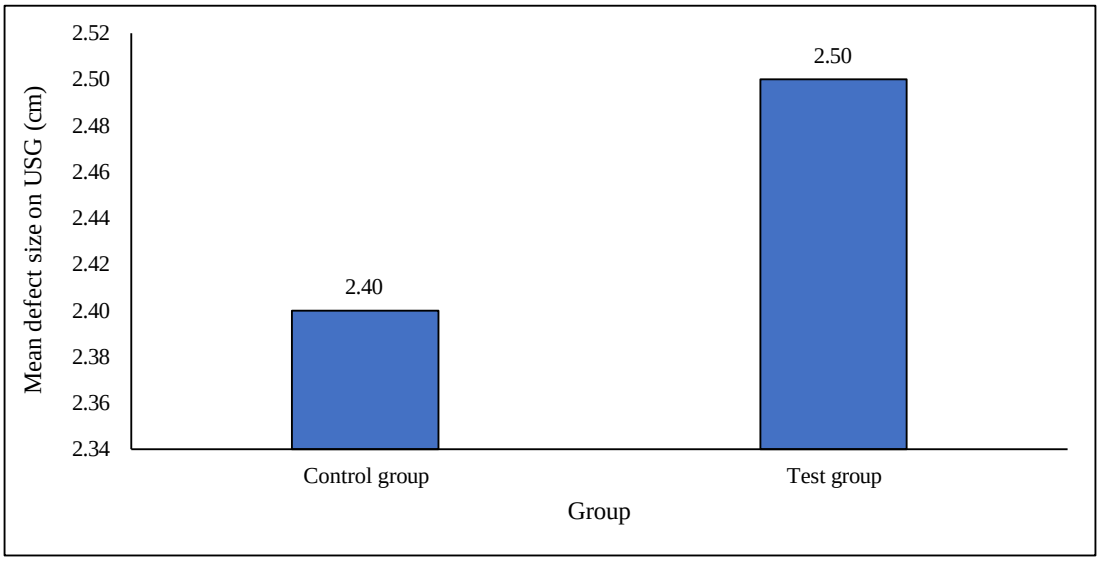
GRAPH 6c Showing HbA1c levels in control and test group

Table and graph show mean HbA1c value as 5.10% in both control and test group.

7. DEFECT SIZE IN ULTRASONOGRAPHY:

TABLE 7 Showing comparison of mean defect sizes (Cm)in test and control group

Defect size on USG in cm	Mean ± SD	Minimum	Maximum	U	p value
Control group	2.40 ± 1.70	1.1	4.3	546.500	0.437
Test group	2.50 ± 1.40	1.2	5		



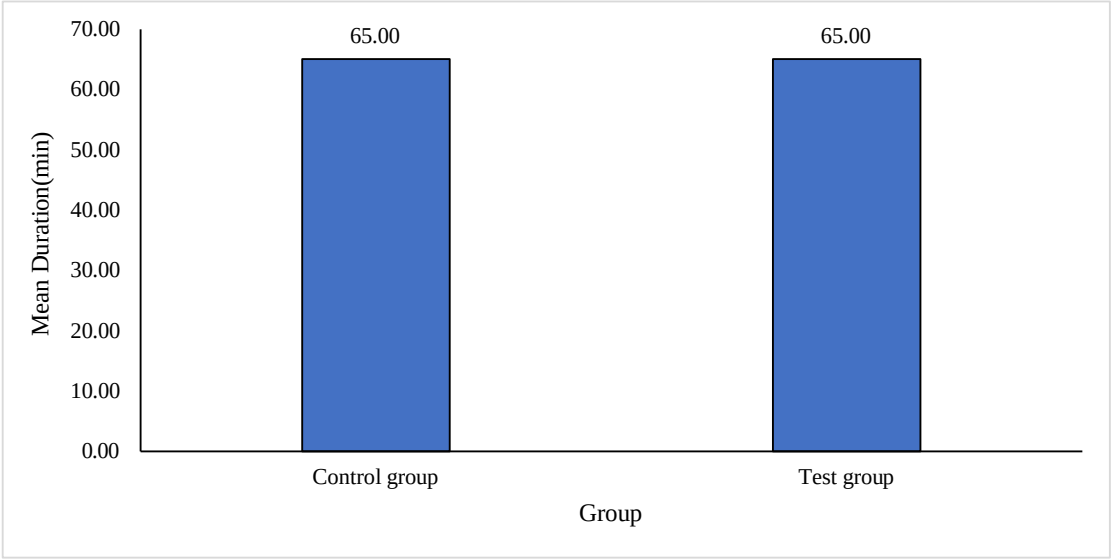
GRAPH 7 Show mean defect size (Cm)

Defect size based on ultrasound in control group: 2.40±1.70 cm and in test group: 2.50±1.40 cm which was not significant (p value: 0.437) but slightly larger in test group.

8. OPERATIVE TIME

TABLE 8 Distribution of operative time in minutes in control group and test group

Duration in min	Mean ± SD	Minimum	Maximum	U	p value
Control group	65.0 ±15.0	50	95	612.500	1.00
Test group	65.0 ±15.0	50	95		



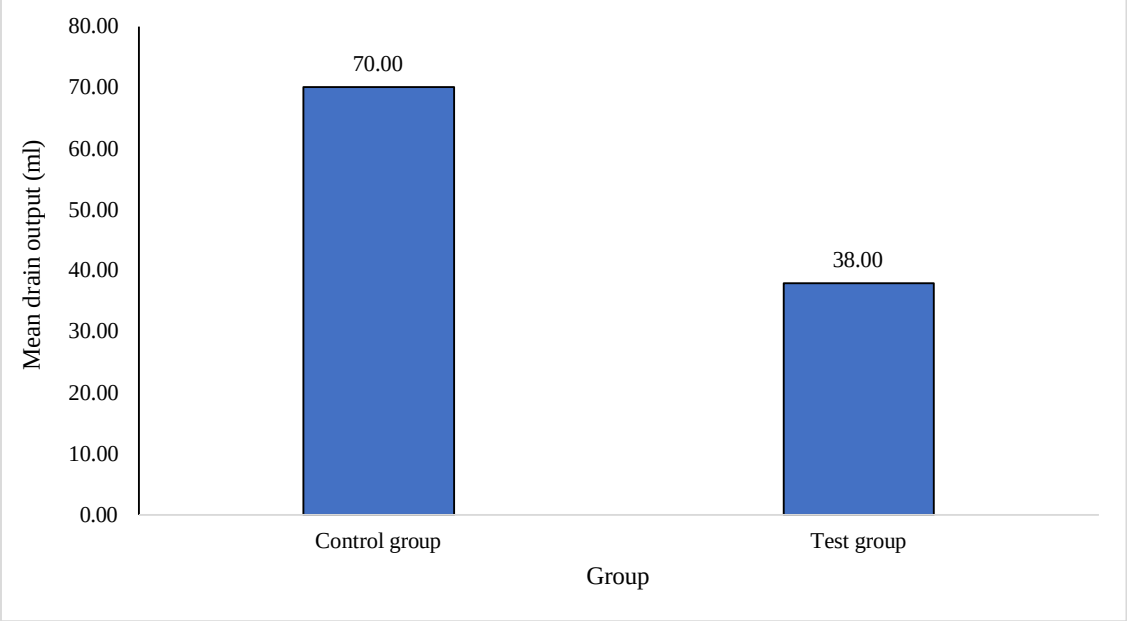
GRAPH 8 Distribution of operative time in minutes in control group and test group

The above table and graph depict operative time (in minutes) which is around 65 minutes in both the groups with p value of 1.00

9. POST-OPERATIVE DRAIN OUTPUT

Table 9a Comparison of Drain output POD-1 Between Control and Test Group

Drain output POD-1	Mean ± SD	Minimum	Maximum	U	p value
Control group	70 ±20.0	46	100	31.500	<0.05* (sig)
Test group	38 ±15.0	28	60		

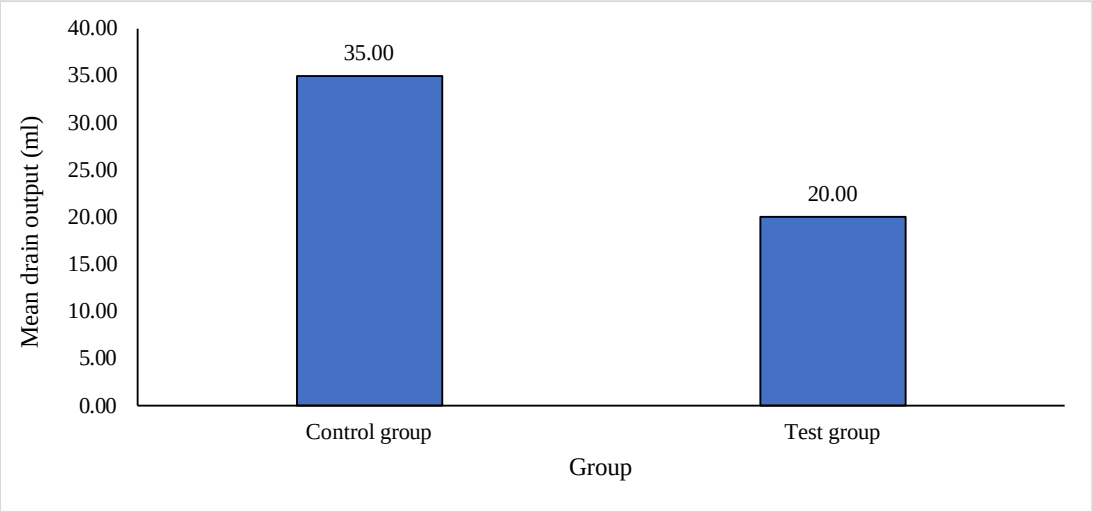


Graph 9a Comparison of Drain output POD-1 Between Control and Test Group

Table and graph show the mean drain output of 70 ±20.0 ml in control group and 38 ±15.0 ml in test group. P value is <0.05 which is significant

Table 9b Comparison of Drain output POD-3 Between Control and Test Group

Drain output POD-3	Mean ± SD	Minimum	Maximum	U	p value
Control group	35 ±17.0	20	55	88.000	<0.05*
Test group	20 ±12.0	5	30		

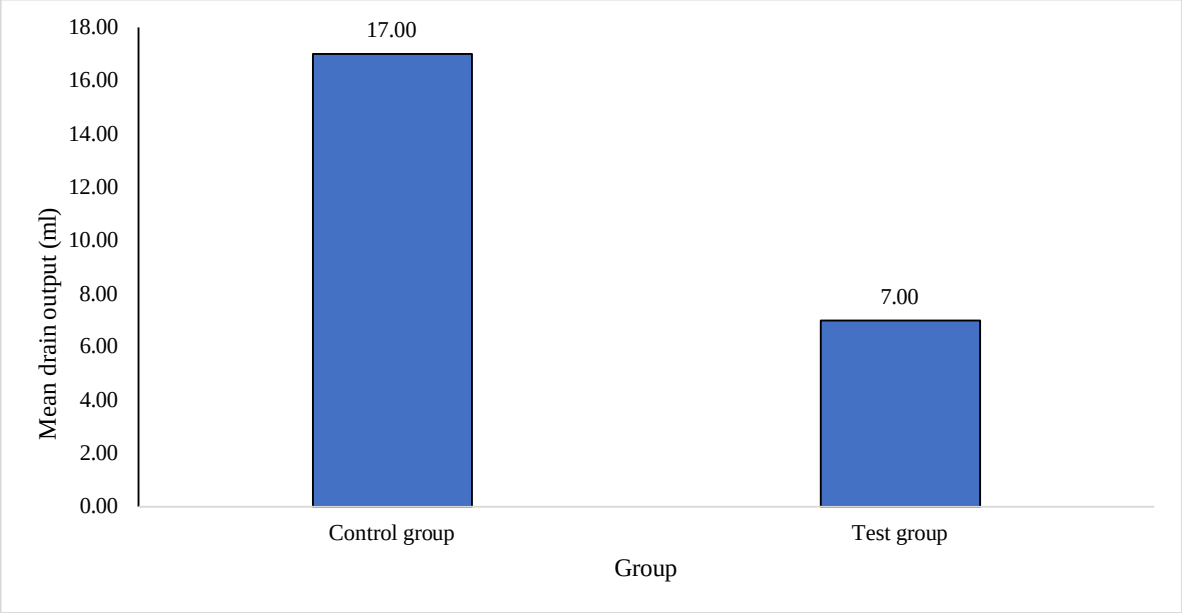


Graph 9b Comparison of Drain output POD-3 Between Control and Test Group

Table and graph show the mean drain output of 35 ±17.0 ml in control group and 20 ±12.0 ml in test group. P value <0.05 (significant)

Table 9c Comparison of Drain output POD-5 Between Control and Test Group

Drain output POD-5	Mean±SD	Minimum	Maximum	U	p value
Control group	17 ±11.0	5	30	87.500	<0.05*
Test group	7 ±7.0	2	16		



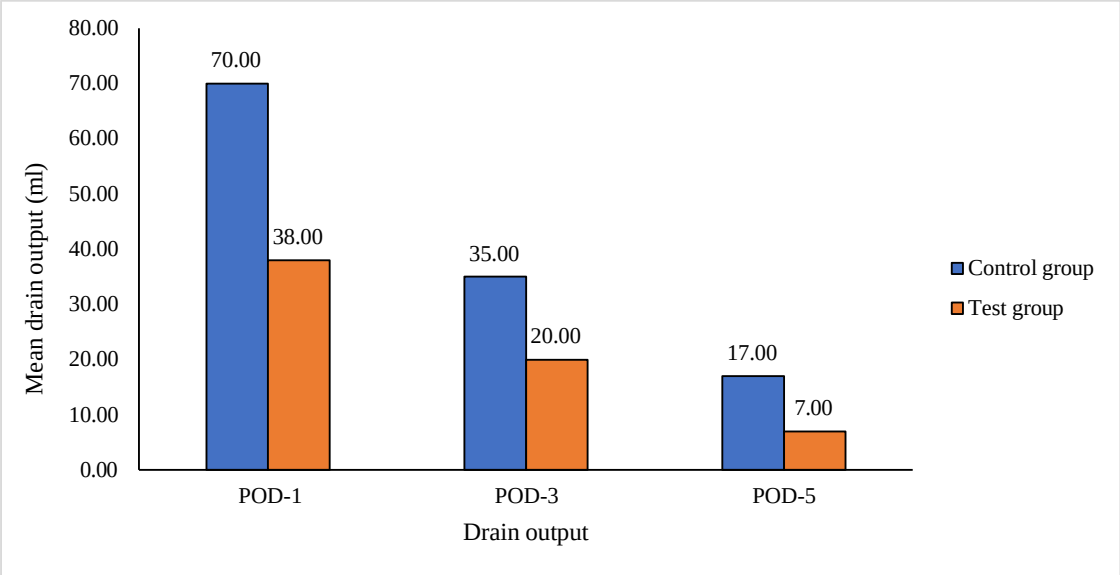
Graph 9c Comparison of Drain output POD-5 Between Control and Test Group

Table and graph show the mean drain output of 17 ±11.0 ml in control group and 7 ±7.0 ml in test group. P value is <0.05 (significant)

10. COMPARISON OF THE DRAIN OUTPUT ON POD 1, 3 AND 5

Table 10 Drain output post op day 1, 3 &5 in control and test group

Drain output	Control group Mean	Test group Mean	p-value
POD-1	70.00	38.00	<0.05*
POD-3	35.00	20.00	<0.05*
POD-5	17.00	7.00	<0.05*



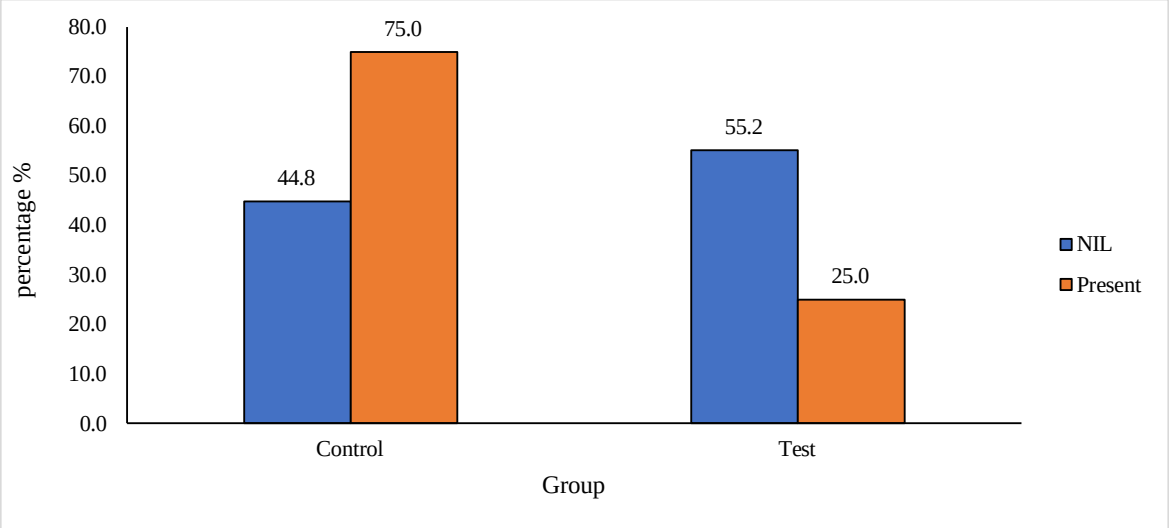
Graph 10 Drain output post op day 1, 3 &5 in control and test group

The graph and table show the drain output on POD 1, 3 and 5 in the test and control groups with p value of <0.05 which is significant.

11. ASSESSMENT OF SEROMA FORMATION:

Table 11 Seroma formation in control and test groups:

		Group					Chi-square	p value	Significance
		control group		Test group		Total			
		n	%	n	%	n			
SEROMA	NIL	26	74.3	32	91.4	58.0	3.621	(0.057)	Non-significant
	Present	9	25.7	3	8.6	12.0			



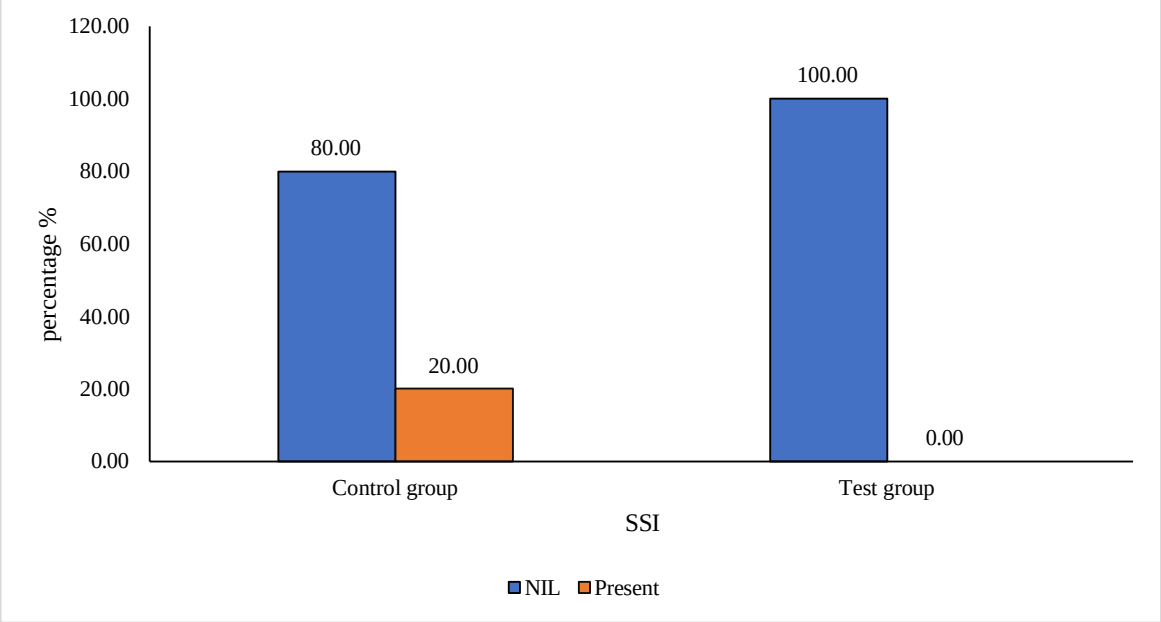
Graph 11 seroma formation in control and test groups

The table and graph show that seroma formation was present in 9(25.7%) control cases and only 3(8.6%) test cases. Seroma was absent in 32 (91.4%) test cases.

12. SURGICAL SITE INFECTION (SSI)

Table 12 Comparison of SSI in Control and Test Groups

		Control group (n=35)		Test Group (n=35)		Total	Chi-square	p value	Significance
		n	%	n	%	n			
SSI	NIL	28	80.00	35	100.00	63	7.78	0.005	Significant
	Present	7	20.00	0	0.00	7			



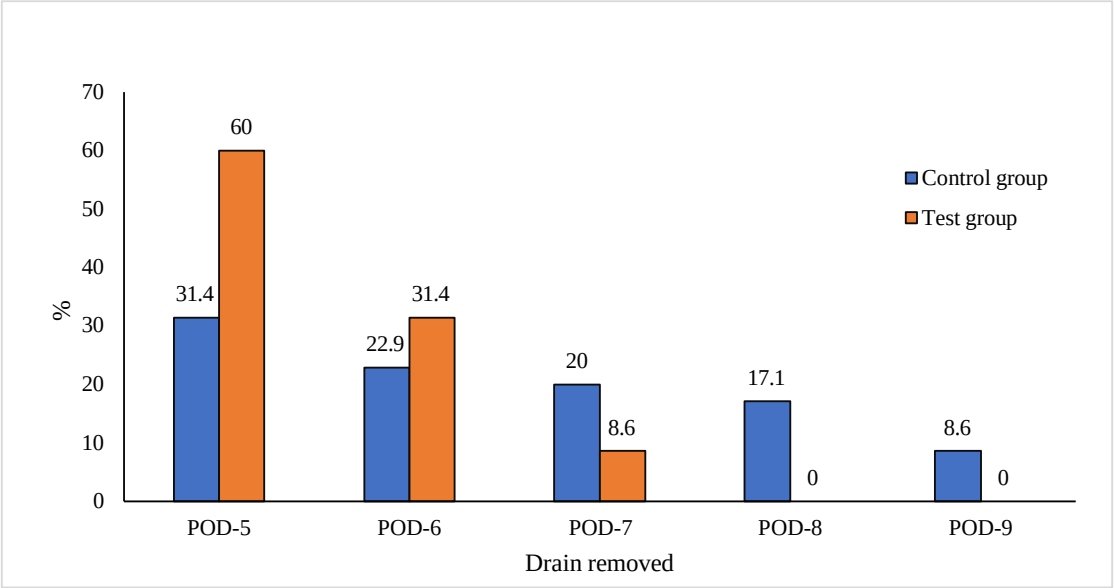
Graph 12 Comparison of SSI in Control and Test Groups

The table and graph show that SSI in the form of Erythema with signs of inflammation was present in 7(20%) cases in control group and was absent in all test group cases (100%). P value is <0.05 which is significant

13. DRAIN REMOVAL

		Control group		Test group		Chi-square	p-value	Significance
		n	%	n	%			
Drained removed	POD- 5	11	31.4	21	60	13.780	0.004	Significant
	POD- 6	8	22.9	11	31.4			
	POD- 7	7	20.0	3	8.6			
	POD- 8	6	17.1	0	.0			
	POD- 9	3	8.6	0	.0			

Table 13 drain removal in control and test group



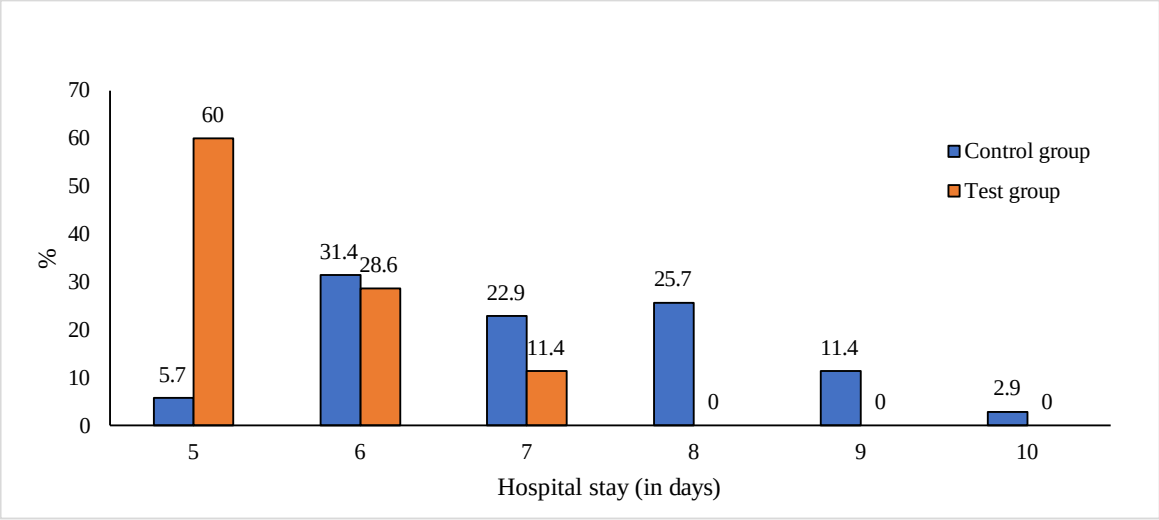
Graph 13 drain removal in control and test group

The table and the graph show that in 60% of the test group patients drain removed on POD-5 and 31.4% on POD-6. However, in the control group, 31.4% drain was removed on POD-5, 22.9% On POD-6, 20% on POD-7. P value is 0.004 which is significant.

14. **HOSPITAL STAY (IN DAYS):**

		Control group		Test group		Chi-square	p-value	Significance
		n	%	n	%			
Hospital stays	5	2	5.7	21	60.0	33.053	<0.05	Significant
	6	11	31.4	10	28.6			
	7	8	22.9	4	11.4			
	8	9	25.7	0	.0			
	9	4	11.4	0	.0			
	10	1	2.9	0	.0			

Table 14 hospital stay (in days) in control and test group.



Graph 14 hospital stay (in days) in control and test group.

The table and graph show that 60% of the patients in the test group were discharged on POD-5, 28.6% on POD-6, and 11.4% on POD-7. However, 31.4% of the patients in the control group were discharged on POD-6, 22.9% on POD- 7 and 25.7% on POD-7. P value is <0.05 which is significant.

DISCUSSION

Surgical intervention for para-umbilical hernias is a frequently conducted procedure, utilizing a range of techniques to achieve the best possible result.

This study examines the effectiveness of intravenous tranexamic acid at the time of induction of anaesthesia on reducing post-operative seroma formation in cases of para-umbilical hernioplasty[22-25]. A transversee incision was made and a negative suction drain was kept in all patients

Our randomized controlled study focussed on assessing the postoperative reduction in seroma formation, operative time, and postoperative surgical site infection between these two groups over one year. This study is significant because it thoroughly examines different factors that can affect the results of hernia repair surgeries. It takes into account pre-existing conditions, other health issues, surgical techniques and potential complications. This study offers important insights into the influence of various factors on surgical outcomes in hernia repair. The findings have the potential to facilitate in treatment decision- making and improve the patient care protocols, leading to more effective treatments and increased patient satisfaction.

This study involved 70 cases of paraumbilical hernia and aimed to compare the effectiveness of I/V TXAduring induction of anaesthesia and results of two different groups. Control group underwent conventional on-lay paraumbilical hernioplasty while test group received 1 gram of tranexamic acid during induction of anaesthesia.

The age in the control group was ranging from 23 to 76 years, mean age of 49.31 years, while in the test group, the ages were ranging from 20 to 78 years, mean age of 42.63 years. The age distribution did not vary significantly between control and test groups.

The gender distribution in our study shows that both males and females were distributed equally in both the groups. In control group, 62.86% males and 37.14% females. In test group, 60% males and 40% females. This shows that para-umbilical hernia is more prevalent in male population. Patel et al[24] in 2014 tells the comparison of I/V versus topical tranexamic acid in TKA (p value was 0.342). other study done by Yan-ping et[26] al told the chances for seroma formation in Chinese Ca breast patients. Both these studies showed significant relation between age and gender and occurrence of seroma

In our study the duration of chief complaints was studied, however no significant differences were seen in between control and test groups.

In, our study the (BMI) of all the patients taken. The mean BMI in control group was 19.50±1.80 and in test group was 19.10±2.20. p value was 0.192 which was non-significant. Albatanony A et al[30] also compared BMI in control and test groups and found it non-significant.

In our study, the occurrence of other health conditions like high blood pressure, diabetes mellitus did not vary significantly between the control and test groups. p value was 1.00.

The preoperative blood investigations were done in our study which included haemoglobin levels, creatinine levels and Hba1C levels. The mean haemoglobin 11.8 ± 2.0 in both the groups with p value of 1.000. the mean creatinine value in both the groups were 0.70 ± 0.36 with p value of 1.000 which is statistically in significant. Similarly, the mean HBA1c level in control group was 5.10 ± 1.20 while in the test group was 5.10 ± 1.80 with p value of 0.684. This confirms that TXA administration did not negatively impact renal function, glycaemic control, or surgical efficiency, consistent with findings from Khan et al[27]. (2022) and Saeed et al[28]. (2024)**.**

Our study found that the defect sizes observed in both the control and test groups were same and no significant difference in the average defect size. The mean defect size in control group was 2.40 ± 1.70 cm while in the test group was 2.50 ± 1.40 cm. p value- 0.437 which is statistically in significant.

In terms of management, cases receiving intravenous tranexamic acid were evenly distributed, highlighting the fair allocation of treatment options.

However, no difference in the operative time bw control and test groups with the mean operative time of 65.0 ±15.0 minutes. P value of 1 which shows that administration of intravenous tranexamic acid has no effect on the operative time of the surgery performed.

The key finding in our study was the significant reduction in the postoperative drain output in the cases in which intravenous tranexamic acid was given.

POD-1: 70.0 ml (control) vs. **38.0 ml** (test group) ($p < 0.05$) **POD-3:** 35.0 ml (control) vs. **20.0 ml** (test group) ($p < 0.05$) **POD-5:** 17.0 ml (control) vs. **7.0 ml** (test group) ($p < 0.05$)

These results suggests that tranexamic acid significantly reduces the drain output as seen in POD1, 3 and 5 leading to earlier resolution of the fluid which was accumulated. Rahman et al[29]. (2024) similarly reported that TXA reduced mean seroma volume from 32 ml to 18 ml**,** and Saeed et al[28]. (2024) found a 40% reduction in total drain output in TXA-treated patients. This supports the hypothesis that tranexamic acid due to its antifibrinolytic activity, limits the fluid collection thus reducing chances of seroma formation.

Our study also observed that that seroma formation was lower in the TXA-treated group (8.57%) compared to control group (25.71%), though statistical significance was borderline (*p = 0.057*). This trend aligns with findings from Albatanony et al[30]. (2019)**,** who reported a reduction in seroma incidence from 27% to 10% in patients receiving perioperative TXA for para-umbilical hernioplasty. Similarly, Lashari et al[20]. (2020) observed a 57% relative risk reduction in seroma formation in TXA-treated patients undergoing ventral hernioplasty.

While some studies, such as Yao et al[31]. (2024) in breast reduction surgery, failed to demonstrate a significant reduction in seroma formation with TXA, differences in surgical techniques, tissue handling, and patient populations may explain the variation in outcomes. Large trails are required to confirm its usage in abdominal hernioplasties.

The study found that no patient (0%) in the test group developed surgical site infection compared to control group in which 20% patients developed SSI. p value of <0.05(significant). This suggests that tranexamic acid has potential protective effect against wound infection possible due to limiting seroma formation which is a known risk factor in forming surgical site infection. Ahmed et al[21]. (2020) and Nawaz et al[32]. (2021) also reported lower infection rates in TXA-treated patients undergoing hernia repair.

This study also found that that in 60% of the patients in the test group drain removal was done on POD-5 and 31.4% on POD-6. However, in the control group, only in 35% of the patients drain was removed on POD-5. P value was 0.004 which is significant as shown by Ahmed et al[21]

The study reveals that 60% of the patients in the test group were discharged on POD-5 as compared to control group in which only 31.5% of the patients were discharged on POD-5. P value <0.05 which is significant. This shows that usage of tranexamic acid can decrease hospitalization significantly.

In our study 70 patients underwent on lay mesh repair and none of the patients had major complications such as mesh infection, migration etc. No recurrence was reported in long term follow up. However, minor ward related complications such as superficial surgical site infection, seroma formation etc were seen.

While concerns have been raised about TXA increasing thromboembolic risk**,** large trials such as CRASH-2 and Ker et al[33]. (2012) have found no significant increase in thrombotic events when TXA is used within recommended dosages.

TABLE 15. COMPARATIVE ANALYSIS OF PRESENT STUDY WITH PREVIOUS SIMILAR STUDIES

	Present study N= 70	Albatanony A et al [30] N= 70	Ahmed et al [25] N=80	Junaid et al [27] N=70	Lashari et al [20] N=90	R Zubair et al [34] N=70
Post operative drain output	Drain output was low in the test group on POD1, 3 And 5 P value < 0.05	Significant reduction on POD-1 and POD-5 p value- 0.001	Not mentioned	Not mentioned	Significant reduction in drain output p value <0.05	52.4% reduction in drain output On POD-1
Seroma formation	8.57% in test, 25.71% control group in	No effect	81% reduction in seroma formation in the test group.	75.71% patient's seroma subsided in 6 days.	8.89% in Test and 15.56% in control had seroma	Only 14.2% had seroma formation. 65.7% in control group formed seroma
Surgical site infection (SSI)	0% SSI in the test group, 20% in control.	No effect	Not mentioned.	Not mentioned	Not mentioned	Not mentioned.

LIMITATIONS:

Though our study was conducted in rigorous and meticulous manner and is a randomised control study, small sample size, heterogeneity of surgical expertise of surgeons, less follow-up done and single centre study to be noted.

FUTURE SCOPE:

A multicentric study with comparatively larger sample size and long-term follow- up will be useful for this study

CONCLUSION

In conclusion, this study examined the efficacy of intravenous tranexamic acid administered in the cases of para-umbilical hernioplasty procedure.

There was notable reduction in the drain output on post-operative days 1, 3 and 5 in the patients receiving intravenous tranexamic acid during induction of anaesthesia thus reducing the chances of seroma formation significantly and reducing patient morbidity.

There was a significant decrease in seroma formation in the test group as compared to control group.

Also, there was notable reduction in surgical site infection in the test group patients.

There was significant difference in the test and control group in view of timing of the drain removal.

Also, the hospital stay in the test group was much lower as compared to control group.

Additional follow-up studies could provide more insight into the impacts of intravenous tranexamic acid on reduction of seroma formation in the future.

SUMMARY

The study conducted a thorough comparison between two group of patients in which test group received intravenous tranexamic acid during induction of anaesthesia and its effect on postoperative reduction of seroma formation was studied. This comparison involved 70 patients, divided equally into two groups. The control group underwent conventional on-lay paraumbilical hernioplasty, while the test group received intravenous tranexamic acid during the procedure. Several metrics were evaluated to find out the efficacy and benefits of tranexamic acid including operative time, post-operative drain output, and complications such as seroma and infections.

The ages in the control group ranged from 23 to 76 years, mean age of 49.31 years, while in the test group, the ages ranged from 20 to 78 years, mean age of 42.63 years.

The gender distribution shows that both males and females were distributed equally in both the groups. In control group, 62.86% males and 37.14% females. In test group, 60% males and 40% females. This shows that para-umbilical hernia is more prevalent in male population.

No difference was there in the operative time between control and test groups with the mean operative time of 65.0 ±15.0 minutes. Thus, administration of intravenous tranexamic acid has no effect on the operative time of the surgery performed.

The key finding was that significant reduction in the postoperative drain output in the cases in which intravenous tranexamic acid was given. These results suggests that tranexamic acid significantly reduces the drain output as seen in

POD1, 3 and 5 leading to earlier resolution of the fluid which was accumulated p value <0.05.

It was seen that seroma formation was lower in the TXA-treated group (8.57%) when compared to the control group (25.71%), though statistical significance was borderline (*p = 0.057*).

The study found that no patient 0% in the test group developed surgical site infection compared to control group in which 20% patients developed SSI. This was significant with p value of <0.05.

It was also observed that the hospital stay in the test group was much lower than the control group. 60% of the patients were discharged on POD-5 in the test group whereas only 35% patients got discharged on POD-5 on the control group. p value <0.05. This is a significant finding as it can decrease overall cost and can prevent excessive usage of hospital resources.

Intravenous tranexamic acid offers significant advantage during on-lay paraumbilical hernioplasty. These benefits include, decreased drain output and thus decrease the chances of seroma formation. The surgical site infection (SSI) was (0%) in the test group while its was (20%) in the control group.

All the 70 patients underwent on-lay mesh repair which was less time consuming with minimal complications.

These findings suggests that intravenous tranexamic acid can be used as an upcoming modality in reducing seroma formation in para-umbilical hernioplasty procedure, though further long-term studies are recommended to confirm these benefits over extended follow-up periods.

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KAHERs JNMC BELAGAVI

INFORMED CONSENT FORM

"To evaluate the efficacy of intravenous tranexamic acid during induction of anaesthesia in reducing post-operative seroma formation after para-umbilical hernioplasty"

Name of the student/Principal investigator: _____ Name of the guide/Co- Investigator: _____

Introduction

Para-umbilical hernia is one of the most common performed surgeries in the world. According to epidemiological data, para-umbilical hernia constitutes about 10% of all abdominal wall hernias encountered in clinical practice. Para- umbilical hernia in the adults is mostly acquired. They are common in women between ages 31-40 years and in patients with predisposing factors such as obesity, ascites, pregnancy, chronic distention of abdomen. The economic burden of para-umbilical hernia includes direct costs related to hospitalization and surgical procedure and indirect costs from lost productivity and disability. Complications such as incarceration, strangulation and bowel obstruction need effective management strategies.

Complications in Para-umbilical hernioplasty are not uncommon. Postoperative complications such as surgical site infection, hematoma formation and early recurrence are quite common. Diabetes, chronic alcohol intake, tobacco chewers and morbidly obese patients are at more risk of developing these complications as compared to others. Complications specific to mesh

placement includes SEROMA formation, mesh infection and migration. These post-operative complications put a major impact on the patient both mentally and physically as well as financially as in increases the overall cost of stay in hospital.

The usage of tranexamic acid in on-lay paraumbilical hernioplasty and its effect on decrease in seroma formations as depicted by post-operative drain output. However, despite the theoretical advantages of tranexamic acid, there is limited clinical evidence comparing the outcomes and complications. It can decrease operative time; clinical outcome including complication rates and decrease in seroma formation by using tranexamic acid during induction of anesthesia during para-umbilical hernioplasty. By minimizing seroma formation, surgeons may lower the risk of subsequent mesh infection, thereby preserving the integrity of the hernia repair and improving overall patient outcomes

Objective: To evaluate the efficacy of intravenous tranexamic acid during induction of anaesthesia in reducing post-operative seroma formation after para-umbilical hernioplasty.

Explanation of the procedure: This prospective randomized control study comprised of 70 cases of para-umbilical hernia which will be randomly divided into two groups of 35 each named group A and group B. Group A includes patients which receive intravenous tranexamic acid and Group B who will undergo convectional on-lay para-umbilical hernioplasty. Written and Informed Consent will be obtained for taking part in study and for operative procedure.

Patient's history and examination will be recorded in detail. Time period for surgery in each patient will be noted for comparison. Each group will be compared postoperatively for drain output and seroma formation.

Withdrawal from participation in the study: Participation in this study is voluntary. You will be free to decide whether to participate in this study or continue participation once enrolled. In case you decide to withdraw your participation, you are free to do so. However, please convey the decision to the principal investigator.

Possible benefits from participating in the study: You will/will not have nor get any benefits by participating in this study. The data gathered will help the population at large.

Possible risks from participating in the study: There are no risks involved in participating in this study.

Privacy and confidentiality: The information collected from you will be coded, to prevent any person from identifying you. Your identity will never be revealed. The data collected from you will be kept confidential and only processed or aggregated data will be used for publication.

Financial incentives: You will not receive any payment for participating in this study.

Authorization for publication of aggregated data: Results obtained after processing of the aggregated data will be published for scientific purposes and or presented to scientific groups. However, your identity will never be revealed.

Questions: In case of any questions with regard to this study, you are free to contact:" _____" If you have any question or complaints with regard to your right as study participant you may contact

Legal rights: By signing this consent form, we are not waving any of your legal rights.

CONSENT STATEMENT

I am making a voluntary decision to participate in the study **"A randomised control trial to evaluate the role/efficacy of single dose intravenous tranexamic acid at the time of induction of anaesthesia for postoperative seroma formation in paraumbilical hernioplasty at a tertiary care centre from 1st September 2023 to 31st August 2024"**

1. I confirm that I have read and understood the information sheet for the above study and have had the opportunity to ask questions.
2. I understood that my participation in the study is voluntary and that I am free to withdraw any time, without giving any reason, without my medical care or legal rights being affected.
3. I understood that sponsor and others working on the sponsor's behalf, The Ethics Committee and the regulatory authorities will not need my permission to look at my health records both in respect of current study and at any further research that may be conducted in relation to it, even if I withdraw from the study. I agree to this. However, I understood that my identity will not be revealed in any information released to third parties or published.
4. I agree to restrict the use of any data or results that arise from this study provided such a use for scientific purposes.
5. I agree to take part in the above study.

Signature or left thumb impression of the participant

Name of the participant:

Signature or left thumb impression of witness:

Name of the witness:

Signature of the investigator

Name of the investigator

PROFORMA

Screening

- Case number:
- I.P Number
- Date of screening:
- First Name:
- Middle Name:
- Last Name:
- Age (Years):

Address

- House number:
- Street:
- Taluka:
- District:
- Phone number 1:
- Phone number 2:

Patient with uncomplicated para-umbilical hernia:

- Yes ☐
- No ☐

Patient age above 18:

- Yes ☐
- No ☐

Applicant is willing to give consent:

- Yes ☐
- No ☐

Patient undergoing open on-lay paraumbilical hernia repair:

- Yes ☐
- No ☐

Patient has no associated illness or complications:

- Yes ☐
- No ☐

FINAL RESULT

- Ineligible ☐
- Eligible but refused ☐
- Eligible and participating ☐

PROFORMA

• Case no:	
• Name:	
• Age:	
• Sex:	
• Informant:	
• Address:	
• Ip no:	
• Unit/ward:	
• Date of admission:	
• Date of surgery:	
• Which surgical procedure?	
• Date of discharge:	
• Chief complaints:	

• Past history:	
• Personal history:	
• Treatment history:	
• Clinical diagnosis with ultrasonography defect size:	
• General physical conditions and BMI (Body mass index)	
Investigations: **1.** Hb: **2.** Creatinine: **3.** HBA1c:	

Intervention: intravenous tranexamic acid at the induction of anesthesia		Given	Not given
Operation details: • Procedure:			
• Type of surgery:			
• Duration			
• Operative findings			
• Intra-op complications:			

Post operative: • Drain output:	pod 1:	pod 3:	pod 5:
• Drain removed:			
• Seroma formation:			
• Surgical site infection			
• Hospital stays			

PHOTOGRAPHS

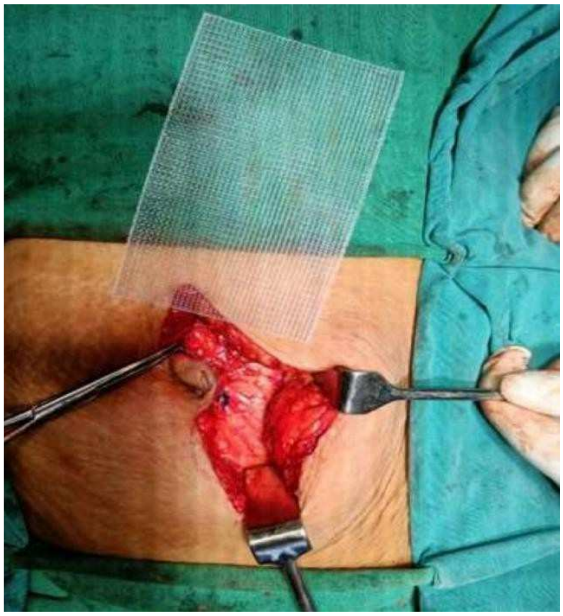

IMAGE 8a. 6X11 Polypropylene mesh being placed in test group.

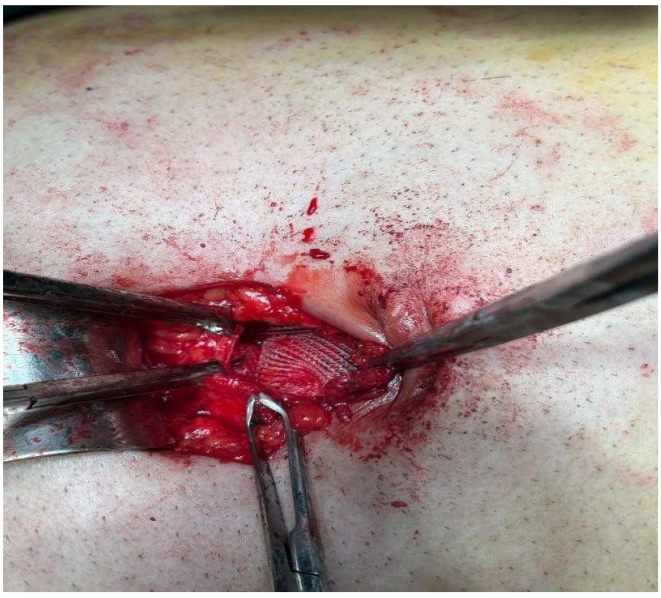

IMAGE 8b. 6X11 Polypropylene mesh being placed in control group

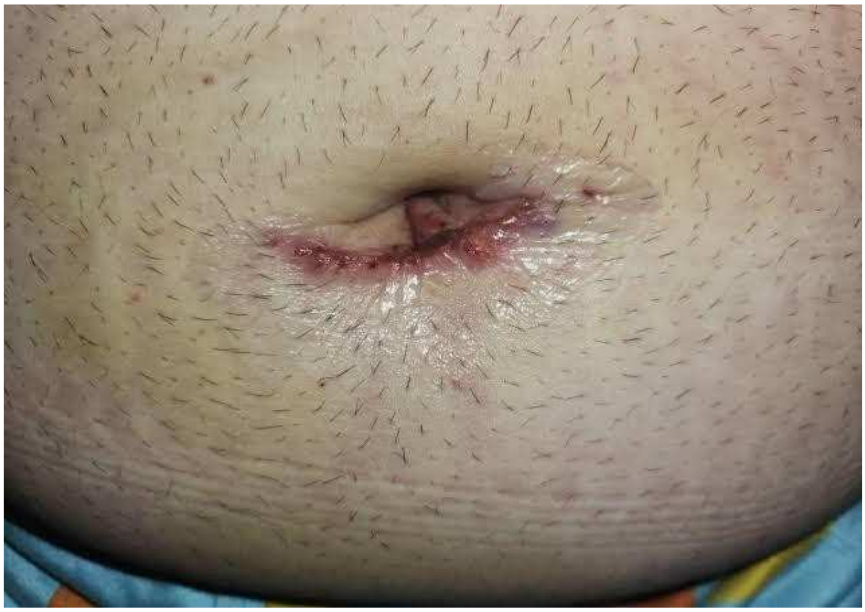

IMAGE 9. Post-operative Seroma formation

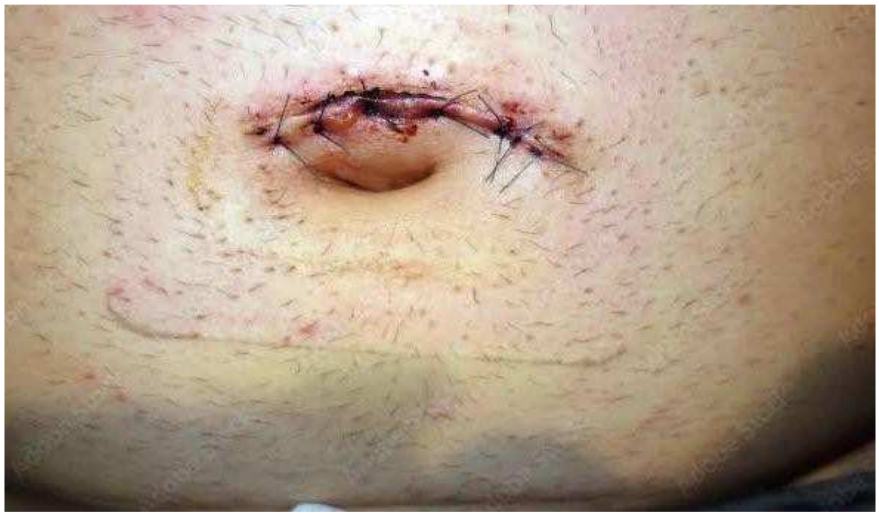

IMAGE 10. Post-operative Superficial Surgical site infection (SSI)

KEY TO MASTER CHART

- S.NO. – Serial number
- Age
- Sex
- I.P Number
- DOA: Date of admission
- DOS: Date of surgery
- DOD: Date of discharge
- Chief complaints
- Comorbidities
- BMI (Body Mass Index)
- Hb (g/dl)
- Creatinine (mg/dl)
- HbA1c (%)
- Defect size on Ultrasonography in centimeters (cm)
- Intra-op complications
- Duration
- Drain output on POD 1,3 and 5
- Drain removed
- Seroma
- SSI (Surgical site infection)
- Hospital stay in days.

S. NO.	AGE	SEX	LP NO	DOA	DOS	DOD	CHIEF COMPLAINTS	COMORBIDITIES	BMI	Hb(g/dl)	Creatinine	HbA1C	Defect sixe on USG	Intra-op complications	Duration	Drain Output POD-1	POD-3	POD-5	Drain removed	Seroma	SSI	Hosp Stay
1	52	F	1066930	02-09-2023	03-09-2023	07-09-2023	Swelling over umbilical region since 1 year	T2DM	20.8	10.2	1.1	6.4	1.4cm	NIL	60 Min	30ml	12ml	5ml	POD-5	NIL	NIL	5 days
2	56	M	1170747	04-09-2023	05-09-2023	09-09-2023	Swelling over umbilical region since 2 months	HTN	19.8	12.1	0.98	5.2	2.5cm	NIL	50 min	35ml	13ml	3ml	POD-6	NIL	NIL	6 days
3	45	M	1178497	13-09-2023	14-09-2023	18-09-2023	Swelling over umbilical region since 2 year	NIL	22.8	14.1	0.7	5.4	3cm	NIL	55 min	30ml	15ml	6ml	POD-5	NIL	NIL	5 days
4	28	M	1182914	16-09-2023	17-09-2023	21-09-2023	Swelling over umbilical region since 8 months	HTN	18.9	12.4	0.65	6	5cm	NIL	70min	38ml	5ml	2ml	POD-6	NIL	NIL	6 days
5	56	M	1181916	17-09-2023	18-09-2023	22-09-2023	Swelling over umbilical region since 3 months	NIL	19.4	9.8	0.45	4.8	2.6cm	NIL	50min	40ml	12ml	10ml	POD-6	NIL	NIL	6 days
6	41	M	1191107	19-09-2023	20-09-2023	24-09-2023	Swelling over umbilical region since 2 years	T2DM	18.2	12.6	0.52	7.1	2.4cm	NIL	65min	55ml	15ml	9ml	POD-5	PRESENT	NIL	5 days
7	46	F	1166930	22-09-2023	23-09-2023	27-09-2023	Swelling over umbilical region since 1 year	NIL	17.9	13.4	1	5	3.2cm	NIL	70min	30ml	20ml	12ml	POD-7	NIL	NIL	7 days
8	55	F	1002528	25-09-2023	26-09-2023	30-09-2023	Swelling over umbilical region since 6 months	HTN	19.7	14	0.25	5.1	2.3cm	NIL	50min	35ml	25ml	13ml	POD-5	NIL	NIL	5 days
9	44	M	1203312	29-09-2023	30-09-2023	04-09-2023	Swelling over umbilical region since 9 months	NIL	18.2	12	0.54	4.8	2.4cm	NIL	58min	40ml	20ml	15ml	POD-5	NIL	NIL	5 days
10	61	F	1003840	02-10-2023	03-10-2023	07-10-2023	Swelling over umbilical region since 3 years	HTN	20.5	11.3	0.56	4.2	1.8cm	NIL	90min	36ml	15ml	5ml	POD-6	PRESENT	NIL	7 days
11	52	M	1001610	10-10-2023	11-10-2023	15-10-2023	Swelling over umbilical region since 2 months	NIL	18.6	11.2	1.2	5	1.9cm	NIL	60min	38ml	14ml	5ml	POD-6	NIL	NIL	6 days
12	24	F	1001662	15-10-2023	16-10-2023	20-10-2023	Swelling over umbilical region since 2.5 years	T2DM	21.6	10.3	1.12	6.9	2.6cm	NIL	65min	45ml	19ml	4ml	POD-5	NIL	NIL	5 days
13	41	M	1005442	19-10-2023	20-10-2023	24-10-2023	Swelling over umbilical region since 1 year	NIL	18.1	9.8	0.54	5.5	2.3cm	NIL	70min	55ml	30ml	8ml	POD-5	NIL	NIL	5 days
14	46	M	1025282	28-10-2023	29-10-2023	02-10-2023	Swelling over umbilical region since 4.5 months	NIL	19.2	9.9	0.31	5.1	3.8cm	NIL	80min	50ml	23ml	8ml	POD-5	NIL	NIL	5 days
15	54	M	1005530	02-11-2023	03-11-2023	07-11-2023	Swelling over umbilical region since 2 months	T2DM	20.8	13	0.65	6.8	4cm	NIL	85min	30ml	25ml	13ml	POD-6	NIL	NIL	6 days
16	53	M	1004251	13-11-2023	14-11-2023	18-11-2023	Swelling over umbilical region since 11 months	T2DM	19.3	12.5	0.85	7.2	2.1cm	NIL	90min	36ml	20ml	14ml	POD-5	NIL	NIL	5 days
17	35	F	1006699	23-11-2023	24-11-2023	28-11-2023	Swelling over umbilical region since 2 years	HTN	19.9	14	0.86	4	2.2cm	NIL	65min	50ml	25ml	3ml	POD-7	NIL	NIL	7 days
18	38	F	1003123	30-11-2023	31-11-2023	05-11-2023	Swelling over umbilical region since 5 months	NIL	17.4	12.6	0.74	4.5	1.5cm	NIL	50min	60ml	30ml	6ml	POD-5	NIL	NIL	5 days
19	36	M	1006622	02-12-2023	03-12-2023	07-12-2023	Swelling over umbilical region since 3 years	HTN	21.2	12.4	0.75	4.3	3.4cm	NIL	70min	55ml	23ml	7ml	POD-5	NIL	NIL	5 days
20	56	M	1008613	09-12-2023	10-12-2023	14-12-2023	Swelling over umbilical region since 6 months	NIL	19.4	12.9	0.65	5.1	2.8cm	NIL	60min	38ml	15ml	12ml	POD-6	NIL	NIL	6 days
21	54	F	1002474	10-12-2023	11-12-2023	15-12-2023	Swelling over umbilical region since 1 year	HTN	18.1	11	0.62	3.8	4.9cm	NIL	70min	45ml	20ml	5ml	POD-5	NIL	NIL	5 days
22	45	M	1189541	28-12-2023	29-12-2023	02-01-2024	Swelling over umbilical region since 4 months	HTN	17.8	11.5	0.85	4.6	1.4cm	NIL	55min	48ml	28ml	12ml	POD-6	NIL	NIL	6 days
23	42	M	1008929	02-01-2024	03-01-2024	07-01-2024	Swelling over umbilical region since 5 months	NIL	19.4	9.5	0.54	6.9	2.2cm	NIL	60min	55ml	30ml	5ml	POD-5	NIL	NIL	5 days
24	36	F	1189298	02-01-2024	03-01-2024	07-01-2024	Swelling over umbilical region since 1 year	NIL	17.5	11.6	0.56	4.2	2.4cm	NIL	70min	30ml	12ml	5ml	POD-5	NIL	NIL	5 days
25	34	M	1187196	04-01-2024	05-01-2024	09-01-2024	Swelling over umbilical region since 2 years	T2DM	21.1	9.9	0.98	7.1	3.2cm	NIL	75min	35ml	13ml	10ml	POD-6	NIL	NIL	6 days
26	28	F	1186498	15-01-2024	16-01-2024	20-01-2024	Swelling over umbilical region since 3 months	NIL	22.4	9.5	0.92	5.1	3.8cm	NIL	80min	55ml	20ml	6ml	POD-5	NIL	NIL	5 days
27	30	F	1177198	05-03-2024	06-03-2024	10-03-2024	Swelling over umbilical region since 9 months	NIL	18.6	12.4	0.45	4.8	5cm	NIL	85min	30ml	13ml	10ml	POD-5	PRESENT	NIL	5 days
28	29	M	1183471	06-03-2024	07-03-2024	11-03-2024	Swelling over umbilical region since 1.5 years	T2DM	18.5	11.9	0.88	6.8	4.5cm	NIL	60min	45ml	29ml	9ml	POD-6	NIL	NIL	6 days
29	22	F	1007734	07-03-2024	08-03-2024	12-03-2024	Swelling over umbilical region since 1 year	HTN	19.1	11.5	0.99	6	3.5cm	NIL	65min	35ml	13ml	12ml	POD-5	NIL	NIL	5 days
30	55	F	1075262	08-03-2024	09-03-2024	13-03-2024	Swelling over umbilical region since 8 months	T2DM HTN	20.4	13.6	0.57	7	2.4cm	NIL	75min	28ml	16ml	16ml	POD-5	NIL	NIL	5 days
31	58	M	1075529	09-04-2024	10-04-2024	14-04-2024	Swelling over umbilical region since 4 months	NIL	18.5	14	0.65	5.1	2.5cm	NIL	60min	30ml	10ml	5ml	POD-7	NIL	NIL	7 days
32	38	M	1012134	10-05-2024	11-05-2024	15-05-2024	Swelling over umbilical region since 1.2 years	NIL	19.1	11.8	0.89	4.8	1.6cm	NIL	80min	35ml	10ml	3ml	POD-5	NIL	NIL	5 days
33	45	M	1011221	11-05-2024	12-05-2024	16-05-2024	Swelling over umbilical region since 11 months	HTN	18.5	11.4	1.1	5	1.2cm	NIL	95min	43ml	23ml	8ml	POD-5	NIL	NIL	5 days
34	41	F	1012498	12-06-2024	13-06-2024	17-06-2024	Swelling over umbilical region since 1 year	T2DM	17.8	10.8	0.84	6.6	3.5cm	NIL	55min	45ml	20ml	5ml	POD-6	NIL	NIL	6 days
35	52	M	1155413	13-06-2024	14-06-2024	18-06-2024	Swelling over umbilical region since 7 months	NIL	18.9	10.6	0.58	6.1	1.2cm	NIL	75min	60ml	30ml	5ml	POD-5	NIL	NIL	5 days

S. NO.	AGE	SEX	I.P NO	DOA	DOS	DOD	CHIEF COMPLAINTS	COMORBIDITIES	BMI	Hb(g/dl)	Creatinine	HbA1C	Defect size on USG	Intra-op complications	Duration	Drain output POD-1	POD-3	POD-5	Drain removed	SEROMA	SSI	HOSP STAY
1	71	M	1066930	02-09-2023	03-09-2023	07-09-2023	Swelling over umbilical region since 1 year	T2DM	20.4	10.2	1.1	6.4	1.4cm	NIL	60 Min	80ml	30ml	25ml	POD-5	NIL	NIL	6 days
2	64	M	1170747	04-09-2023	05-09-2023	09-09-2023	Swelling over umbilical region since 2 months	HTN	19.8	12.1	0.98	5.2	2.5cm	NIL	50 min	70ml	35ml	20ml	POD-6	NIL	NIL	6 days
3	41	M	1178497	13-09-2023	14-09-2023	18-09-2023	Swelling over umbilical region since 2 year	NIL	22.8	14.1	0.7	5.4	3cm	NIL	55 min	55ml	45ml	15ml	POD-7	NIL	NIL	7days
4	63	M	1182914	16-09-2023	17-09-2023	21-09-2023	Swelling over umbilical region since 8 months	NIL	17.6	12.4	0.65	6	1.2cm	NIL	70min	52ml	25ml	16ml	POD-5	PRESENT	PRESENT	6days
5	37	F	1181916	17-09-2023	18-09-2023	22-09-2023	Swelling over umbilical region since 3 months	NIL	19.2	9.8	0.45	4.8	1.1cm	NIL	50min	90ml	45ml	28ml	POD-8	NIL	NIL	8days
6	38	M	1191107	19-09-2023	20-09-2023	24-09-2023	Swelling over umbilical region since 2 years	T2DM	18.9	12.6	0.52	7.1	2.4cm	NIL	65min	70ml	25ml	14ml	POD-5	NIL	NIL	6days
7	46	F	1166930	22-09-2023	23-09-2023	27-09-2023	Swelling over umbilical region since 1 year	NIL	21.4	13.4	1	5	3.8cm	NIL	70min	60ml	22ml	16ml	POD-6	NIL	NIL	6days
8	56	F	1002528	25-09-2023	26-09-2023	30-09-2023	Swelling over umbilical region since 6 months	HTN	19.8	14	0.25	5.1	2.3cm	NIL	50min	65ml	40ml	25ml	POD-8	NIL	NIL	9days
9	25	M	1203312	29-09-2023	30-09-2023	04-09-2023	Swelling over umbilical region since 9 months	NIL	18.2	12	0.54	4.8	2.4cm	NIL	58min	64ml	35ml	22ml	POD-5	NIL	NIL	6days
10	53	M	1003840	02-10-2023	03-10-2023	07-10-2023	Swelling over umbilical region since 3 years	HTN	20.5	11.3	0.56	4.2	1.8cm	NIL	90min	46ml	28ml	17ml	POD-9	PRESENT	PRESENT	9days
11	73	F	1001610	10-10-2023	11-10-2023	15-10-2023	Swelling over umbilical region since 2 months	NIL	19.4	11.2	1.2	5	1.9cm	NIL	60min	65ml	30ml	18ml	POD-5	NIL	NIL	6days
12	67	M	1001662	15-10-2023	16-10-2023	20-10-2023	Swelling over umbilical region since 2.5 years	NIL	21.2	10.3	1.12	5.4	2.6cm	NIL	65min	55ml	28ml	14ml	POD-6	NIL	NIL	7days
13	52	F	1005442	19-10-2023	20-10-2023	24-10-2023	Swelling over umbilical region since 1 year	NIL	18.3	9.8	0.54	5.5	2.3cm	NIL	70min	80ml	40ml	25ml	POD-8	NIL	NIL	8days
14	35	M	1025282	28-10-2023	29-10-2023	02-10-2023	Swelling over umbilical region since 4.5 months	NIL	19.6	9.9	0.31	5.1	3.8cm	NIL	80min	85ml	45ml	25ml	POD-7	NIL	NIL	8days
15	38	F	1005530	02-11-2023	03-11-2023	07-11-2023	Swelling over umbilical region since 2 months	T2DM	20.8	13	0.65	6.8	4cm	NIL	85min	90ml	50ml	30ml	POD-6	NIL	NIL	6days
16	72	M	1004251	13-11-2023	14-11-2023	18-11-2023	Swelling over umbilical region since 11 months	T2DM	18.7	12.5	0.85	7.2	2.1cm	NIL	90min	80ml	55ml	25ml	POD-7	PRESENT	PRESENT	8days
17	35	F	1006699	23-11-2023	24-11-2023	28-11-2023	Swelling over umbilical region since 2 years	HTN	19.9	14	0.86	4	2.2cm	NIL	65min	68ml	45ml	15ml	POD-5	NIL	NIL	7days
18	68	M	1003123	30-11-2023	31-11-2023	05-11-2023	Swelling over umbilical region since 5 months	NIL	17.4	12.6	0.74	4.5	1.5cm	NIL	50min	95ml	50ml	24ml	POD-8	NIL	NIL	9days
19	35	M	1006622	02-12-2023	03-12-2023	07-12-2023	Swelling over umbilical region since 3 years	NIL	21.3	12.4	0.75	4.3	3.4cm	NIL	70min	100ml	55ml	25ml	POD-9	PRESENT	PRESENT	10days
20	34	F	1008613	09-12-2023	10-12-2023	14-12-2023	Swelling over umbilical region since 6 months	NIL	19.4	12.9	0.65	5.1	2.8cm	NIL	60min	85ml	28ml	14ml	POD-6	NIL	NIL	7days
21	67	M	1002474	10-12-2023	11-12-2023	15-12-2023	Swelling over umbilical region since 1 year	HTN	18.9	11	0.62	3.8	4.3cm	NIL	70min	65ml	30ml	12ml	POD-5	PRESENT	PRESENT	5days
22	52	M	1189541	28-12-2023	29-12-2023	02-01-2024	Swelling over umbilical region since 4 months	HTN	20.4	11.5	0.85	4.6	1.4cm	NIL	55min	68ml	30ml	13ml	POD-7	NIL	NIL	7days
23	38	M	1008929	02-01-2024	03-01-2024	07-01-2024	Swelling over umbilical region since 5 months	T2DM	19.4	9.5	0.54	6.9	2.2cm	NIL	60min	55ml	28ml	10ml	POD-6	NIL	NIL	8days
24	40	M	1189298	02-01-2024	03-01-2024	07-01-2024	Swelling over umbilical region since 1 year	NIL	19.5	11.6	0.56	4.2	2.4cm	NIL	70min	67ml	32ml	25ml	POD-5	NIL	NIL	6days
25	29	M	1187196	04-01-2024	05-01-2024	09-01-2024	Swelling over umbilical region since 2 years	NIL	21.2	9.9	0.98	5.2	3.5cm	NIL	75min	66ml	30ml	15ml	POD-8	NIL	NIL	8days
26	56	F	1186498	15-01-2024	16-01-2024	20-01-2024	Swelling over umbilical region since 3 months	NIL	22.4	9.5	0.92	5.1	3.8cm	NIL	80min	90ml	45ml	20ml	POD-5	PRESENT	NIL	6days
27	32	M	1177198	05-03-2024	06-03-2024	10-03-2024	Swelling over umbilical region since 9 months	NIL	18.6	12.4	0.45	4.8	2.4cm	NIL	85min	95ml	50ml	25ml	POD-9	PRESENT	PRESENT	9days
28	49	F	1183471	06-03-2024	07-03-2024	11-03-2024	Swelling over umbilical region since 1.5 years	NIL	18.5	11.9	0.88	5.1	4.1cm	NIL	60min	100ml	55ml	28ml	POD-6	NIL	NIL	7days
29	70	M	1007734	07-03-2024	08-03-2024	12-03-2024	Swelling over umbilical region since 1 year	HTN	19.1	11.5	0.99	6	3.5cm	NIL	65min	85ml	42ml	24ml	POD-5	NIL	NIL	6days
30	60	M	1075262	08-03-2024	09-03-2024	13-03-2024	Swelling over umbilical region since 8 months	T2DM HTN	20.4	13.6	0.57	7	2.4cm	NIL	75min	64ml	30ml	14ml	POD-7	NIL	NIL	7days
31	56	F	1075529	09-04-2024	10-04-2024	14-04-2024	Swelling over umbilical region since 4 months	NIL	21	14	0.65	5.1	2.5cm	NIL	60min	65ml	35ml	14ml	POD-6	NIL	NIL	7days
32	43	M	1012134	10-05-2024	11-05-2024	15-05-2024	Swelling over umbilical region since 1.2 years	NIL	19.1	11.8	0.89	4.8	1.6cm	NIL	80min	75ml	22ml	5ml	POD-5	PRESENT	PRESENT	5days
33	48	F	1011221	11-05-2024	12-05-2024	16-05-2024	Swelling over umbilical region since 11 months	HTN	18.5	11.4	1.1	5	1.2cm	NIL	95min	70ml	40ml	14ml	POD-7	NIL	NIL	8days
34	58	F	1012498	12-06-2024	13-06-2024	17-06-2024	Swelling over umbilical region since 1 year	T2DM	17.8	10.8	0.84	6.6	3.5cm	NIL	55min	65ml	20ml	6ml	POD-7	NIL	NIL	8days
35	28	M	1155413	13-06-2024	14-06-2024	18-06-2024	Swelling over umbilical region since 7 months	NIL	19.8	10.6	0.58	6.1	1.2cm	NIL	75min	85ml	45ml	16ml	POD-8	PRESENT	NIL	8days