"EVALUATION OF POSTOPERATIVE PAIN FOLLOWING PREEMPTIVE ANALGESIA WITH IV PARACETAMOL IN UNILATERAL LICHTENSTEIN'S INGUINAL HERNIA SURGERY, RANDOMIZED, CONTROL TRIAL."

By

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LIST OF ABBREVIATIONS:

IASP- International Association for the Study of Pain

NHS- National Health Services

CNS- Central Nervous System

PNS- Peripheral Nervous System

NMDA- N-methyl-D-aspartic acid

CABG- Coronary Artery Bypass Graft

LSCS- Lower Section Cesarean Section

GA- General Anaesthesia

SAB- Spinal Anesthesia Block

POD- Postoperative Day

ABG- Arterial Blood Gas

ASA- American Society of Anaesthesiologists

CHEOPS -Children's Hospital of Eastern Ontario Pain Scale.

TEP- Total Extraperitoneal repair

PPI - Present Pain Index

VAS- visual analogue scale

BMI- Body Mass Index

LVHR- Laparoscopic Ventral Hernia Repair

RCT- Randomized Control Trial

MRM- Modified Radical Mastectomy

CWI - continuous wound infiltration

NSAID- Non Steroidal Anti- inflammatory Drugs

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ABSTRACT

Introduction:

Pain from surgical procedures is due to tissue trauma, through activation of nociceptive receptors which causes acute pain and long-term pain (central sensitization), which may cause physical, cognitive and emotional discomfort.

Pre-emptive analgesia refers to the administration of pain-relieving treatments before surgery to prevent the onset of central sensitization caused by the incisional and inflammatory injuries that occur during and after surgery. By intervening before the surgical trauma, pre-emptive analgesia aims to reduce immediate postoperative pain and decrease the likelihood of developing chronic pain by lessening the altered processing of sensory input in the central nervous system.

IV paracetamol is widely used as a first-line analgesic and antipyretic treatment for pain management in both adults and children.

It is the most commonly used drug for postoperative pain management.

In proper dosage it is the safest drug with minimal adverse effects. It can be given in patients with diabetes, hypertension, chronic kidney disease and other comorbidities with minimal to no risk.

IV PARACETAMOL if given as PRE-EMPTIVE ANALGESIA can cover a better range of patients, patients with known comorbidities and can reduce the immediate post surgery pain and therefore the need for administering rescue analgesia along with preventing the possibility of development of chronic pain in patients who are undergoing open inguinal hernia mesh repair surgery(49,56).

Materials and Methods:

Study design= Randomized Control Trial

Inclusion criteria-

- Age 18 and above
- Patients undergoing standard unilateral Lichtenstein Inguinal Hernia Repair.
- Either sex
- ASA grade 1 and 2
- Patients willing to give informed consent.

- Patients given only Spinal Anesthesia.

Exclusion criteria

- Hypersensitivity to Paracetamol
- Patients undergoing a procedure different from the standard unilateral Lichtenstein Inguinal Hernia Repair.
- Patients given Epidural Anesthesia.

Study period- 1 year

Sample size-

Total sample size of 56 cases, 28 in Group-A, 28 in Group-B (alloted by random sampling- SNOSE)

Before 30 minutes of incision, the patients in
Group -A will receive INJ PARACETAMOL 15mg/kg IV in 100ml NS
Group - B will receive plain 100ml NS

Result-

- Group A has marked improvement in pain reduction at 24, 36, 48 hrs.
- By 72 hrs, both groups experienced reduced pain, group A patients with near complete pain relief.
- Group B required higher total dosage of overall standard analgesia (115) than Group A (84)
- Group B required a total of 23 doses of rescue analgesia in 72 hrs as compared to 13 doses in Group A

INTRODUCTION

Pain from Surgical Procedures:

- Surgical pain originates from tissue trauma that activates nociceptive receptors, leading to both acute pain and long-term pain, often referred to as central sensitization.(5,25)
- Central sensitization results in the nervous system becoming more sensitive to stimuli, leading to physical, cognitive, and emotional discomfort, which can persist long after the surgery (64).

Preemptive Analgesia:

- Pre-emptive analgesia involves administering pain-relieving treatments before surgery to prevent central sensitization caused by surgical trauma.
- This method aims to reduce immediate postoperative pain, minimize changes in sensory processing in the cns, and lower its chances of developing chronic pain (24).

IV Paracetamol:

- A common first-line treatment for pain management in both adults and children is intravenous paracetamol, a painkiller and antipyretic.
- Because of its efficacy and generally mild side effect profile when administered in the right dosages, it is frequently utilized in postoperative pain control(65).

Safety and Efficacy:

- When administered at proper dosages, IV paracetamol is considered one of the safest pain management options, with minimal adverse effects.
- It is especially valuable for patients with comorbid conditions like DM, HTN, and CKD, as it poses minimal risks of exacerbating these conditions (66).

Preemptive IV Paracetamol:

- Pre-emptive IV paracetamol can effectively reduce postoperative pain, reduce the need for additional analgesics, and help prevent chronic pain development, particularly in surgeries such as open inguinal hernia mesh repair.
- The preemptive administration of paracetamol ensures immediate postoperative pain relief, while also reducing the risk of long-term pain issues (67).

Impact on Recovery:

- Preemptive IV paracetamol not only reduces pain but also enhances recovery by preventing the alteration of pain pathways during surgery, promoting quicker recovery, and potentially preventing chronic pain syndromes (68).

Conclusion:

- IV paracetamol offers a solution for pain control that is both secure and efficient, especially for patients with multiple health conditions.
- It can alleviate immediate postoperative pain, reduce the need for additional analgesics, and potentially prevent chronic pain after surgery, making it an essential part of preemptive analgesia strategies.

OBJECTIVES OF THE STUDY

- To evaluate the postoperative pain in patients undergoing unilateral hernia mesh repair after giving preemptive analgesia (paracetamol) to group A and placebo (normal saline) to group B.

- To compare the use of standard and rescue analgesia among the two groups.

REVIEW OF LITERATURE

Definition of pain; What is Chronic Pain?

1. **Definition of Pain**: As per the IASP, the Definition of pain is "an unpleasant sensory and emotional experience related to actual or potential tissue damage, or described in terms of such damage."(1) The definition includes both, sensory (physical) and emotional components of pain.
2. **Acute vs. Chronic Pain**: Time is the primary factor that distinguishes acute pain from chronic pain. Acute pain has a positive function by encouraging rest and healing, and it goes away as healing takes place. Chronic pain may not have any biological advantage and lasts longer than the anticipated healing period. It may be brought on by faulty healing mechanisms or circumstances in which healing is impossible.(2)
3. **Classification of Pain**: Pain can be categorized in various ways, including by anatomy, duration, etiology (cause), body system affected, and severity. Portenoy's classification system (4) categorizes pain as nociceptive, neuropathic, or psychogenic:
    - Pain on touch occurs if nociceptors (the pain receptors) are stimulated due to tissue injury or inflammation.It can be separated into two categories:Internal organs can cause visceral pain, while the skin, muscle tissue, and joint can provide external discomfort.
    - Neuropathic pain- Damage or malfunction in the neurological system results in aberrant processing of pain signals, which causes Neuropathic pain. This pain, which is frequently accompanied by feelings like scorching, shooting, or tingling, may be present even after the initial injury is recovered.(3)

- Psychogenic pain is associated with psychological factors, where pain perception is shaped more by emotional or cognitive influences than by actual tissue damage. It can occur without any underlying physical pathology.(2)

4. **Biological Basis of Chronic Pain**: Chronic pain involves changes in cns, including neuronal plasticity (change in nerve function and structure) that contribute to persistent pain signaling.(6) This can occur due to ongoing insult or injury to the peripheral nervous or central nervous system.
5. **Challenges in Pain Classification**: Despite various classification systems, pain classification remains challenging and can be inconsistent.(5) Because painful experiences are complex and unique variations in feeling pain exist, there is no universally accepted classification system.

All things considered, the concept of pain encompasses its physiological underpinnings with its emotional and psychological components. A strategy that considers both physiological and psychological aspects of pain is usually required for effective treatment.

Chronic pain

The complicated phenomena of Chronic pain is impacted with both central and Peripheral sensitization processes:

1. **Peripheral Sensitization:**
   - Chronic pain often begins with peripheral sensitization, where nociceptors (pain receptors) become more sensitive to stimuli. This can be triggered by tissue damage, inflammation, or nerve injury.(6)
   - Bradykinin, prostaglandins, and cytokines are examples of inflammatory mediators that are released at the site of Inflammation or Injury. By

decreasing its stimulation limit, these chemicals sensitize nociceptors and increasing their responsiveness to stimuli..(9)

2. **Central Sensitization:**
    - Central sensitization, in which neurons in the central nervous system (CNS), especially in the brain and spinal cord, become excessively excitable, can be caused by constant nociceptive stimulation from the periphery.
    - This heightened sensitivity amplifies signals of pain, which may raise the reaction to stimuli that are painful (hyperalgesia) or produce pain in response to typically painless stimuli (allodynia).
    - NMDA receptors are vitally involved in the process of Central sensitization. The ongoing stimulation of C-fibers during Inflammation stimulates the release of glutamate, which binds with NMDA receptors, enhancing synaptic transmission and supporting the persistence of chronic pain.(8)

3. **Neuroplastic Changes:**
    - Neuroplasticity is the term for the changes in structure and function in the nervous system brought on by chronic pain. This includes alterations in synaptic connectivity, receptor expression, and neurotransmitter release.
    - Chronic pain is different from acute pain because these alterations might cause pain to persist long after the original damage or illness has healed.(9)

Pathophysiology of chronic pain:

Melzack and Wall's papers, which addressed the neurophysiology of pain, may be their most significant works. In their “Gate Control theory of pain”, they emphasized the CNS acts as a system that filters, where it can modulate the inputs of the PNS. Additionally, it highlighted the dorsal horns as control centers capable of acting as sites of inhibition, excitation, and modulation.(7)

The spinothalamic pathway is the path where temperature and pain travel. Peripheral nerves' non-encapsulated endings are known as nociceptors or pain receptors.

The first sharp and well-localized pain impulse is carried by group alpha-delta fibers, which are small, thin, and myelinated. Rapid 40 m/s transmission of neural impulses occurs.

The second wave of diffuse pain is carried by larger, coarser, unmyelinated Group C fibers at a speed of less than 2 m/s. When group C fibers fire continuously during inflammation, more glutamate is produced, this acts on NMDA receptors to cause central sensitization.

The pain response can be altered by N-methyl-D-aspartic acid antagonists because they reduce central sensitization. An influx of tissue cytokines and mediators occur in response to any stimulus that triggers an inflammatory response. This in turn activates release of “Substance P” and factors such as Bradykinin which kick starts the pain pathway.(6)

Chronic Pain in the Context of Surgery

1. **Postsurgical chronic pain:**
    - Surgery can lead to chronic pain through various mechanisms, including nerve damage, tissue injury, and inflammatory responses.(11)
    - Examples of chronic pain syndromes that can develop after surgery include phantom limb pain (following amputation)(62), post-thoracotomy pain syndrome, persistent abdominal pain after gallbladder surgery, and chronic pain following breast cancer surgery, cardiac surgery, or hernia repair with mesh(58.59,60,61,63)
2. **Risk Factors and Management:**
    - Risk factors for postsurgical chronic pain include preoperative pain, younger age, obesity, and psychological factors.
    - Management strategies may include pharmacological interventions targeting peripheral and central sensitization, physical therapy, psychological interventions, and in some cases, surgical interventions such as nerve blocks or neuromodulation techniques.(12)

Recognizing the central and peripheral processes which cause chronic pain's existence after the anticipated healing period of tissue injury is essential to understanding its pathogenesis. Surgical trauma and the ensuing inflammatory and neuroplastic reactions can cause persistent discomfort in the surgical setting. A comprehensive strategy that takes into consideration of both the causes of pain that is mental and physical, and is tailored to the individual requirements of each patient as well as the underlying pathophysiological variables is necessary for effective management

Inguinal Hernia

Soft tissue, sometimes a section of the colon or omentum, pushes into a weak spot or rupture in the abdominal wall to cause an inguinal hernia, a common ailment.This causes a noticeable groin bulge that could get bigger while standing, coughing, or applying pressure.

Types of Inguinal Hernia

Inguinal hernia can be classified into two categories:

1. Indirect Inguinal Hernia:The most prevalent kind of inguinal hernia is an indirect one, which is frequently congenital and arises from an abnormality in the abdominal wall that exists from birth. The inguinal canal, a tube in the abdomen wall that carries the round ligament in women and the spermatic cord in men, is where it happens when abdominal contents protrude.(13)
2. Direct Inguinal Hernia:This kind usually appears later in life as a result of the abdominal wall muscles being weaker. Contents of abdomen protrude through a weak spot in the lower wall of abdominal, through hesselbach triangle.(14)

Symptoms of Inguinal Hernias

The signs and symptoms of an inguinal hernia can vary, but commonly include:

- Visible bulge: When straining or standing up, a prominent lump or protrusion in the groin area may show up. The bulge can go away upon lying down.
- Pain or discomfort:Pain or discomfort in the groin, particularly when carrying heavy things, bending over, or coughing.

- Heaviness or dragging sensation: A pressure feel, heaviness, or weakness in the inguinal region.
- Occasionally, symptoms can include: Pain or swelling around the testicles in men, especially when the hernia protrudes into the scrotum.(15)

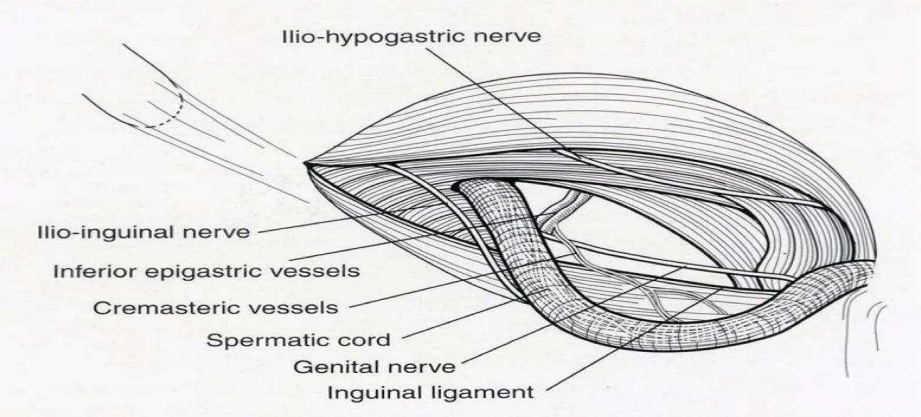


Figure 01- Contents of Inguinal Canal

Causes and Risk Factors

Inguinal hernias are typically caused by a combination of muscle weakness and strain.The following risk factors may accelerate the development of inguinal hernias:

- Gender: Men more likely to develop inguinal hernias than women.
- Age: The risk increases with age due to weakening of muscles and tissues.
- Family history: A family history of hernias may increase the likelihood of developing one.
- Chronic coughing: Conditions that cause chronic coughing, such as smoking or COPD, can increase abdominal pressure and contribute to hernia formation.
- Heavy lifting: Activities that involve heavy lifting or straining can also increase the risk of hernia occurance.

Advancements in Inguinal Hernia Repair

Inguinal hernia repair has changed considerably over past 20 years, from traditional sutured techniques to the widespread adoption of mesh repair (meshplasty).(16) Mesh repair has become the standard due to its lower recurrence rates (around 5%) compared to sutured repairs.

Challenges with Postoperative Pain in Inguinal Hernia Surgery

Despite the benefits of mesh repair, there has been an observed increase in the reporting of postoperative pain and discomfort. This issue is considered one of the drawbacks of mesh repair techniques. Chronic pain following inguinal hernia surgery can be debilitating, impacting a patient's quality of life and work capacity.(17)

There is ongoing debate and research into optimizing pre- and postoperative management strategies to minimize chronic pain following hernia repair. The ideal surgical technique that balances effective hernia repair with reduced postoperative pain has not yet been definitively established.The significance of tailored patient care and collaborative decision-making between patients and healthcare providers is highlighted by this uncertainty..(18)

In conclusion, while mesh repair has improved outcomes in terms of recurrence rates and initial postoperative pain, the issue of chronic pain remains a significant challenge in inguinal hernia management. Continued research and clinical advancements are needed to address this issue and improve outcomes for patients undergoing hernia repair surgery.

Pre- operative factors

Inguinal hernia repair can result in chronic groin pain, but pain may be caused by the hernia which was not recognised initially. Prior unexplained chronic groin pain has been shown to improve by 87% after Lichtenstein's hernia repair.(19)

Intra-op factors

Neuropathic or nociceptive causes of chronic pain are both possible.

Neuropathic pain is typically defined as electric, sharp, and shooting pain and is thought to be caused by nerve damage.(20)

Contrarily, nociceptive pain is usually described as a dragging dull aching type. Three anatomically and physiologically significant nerves in the groin region may contribute to chronic post-inguinal herniorrhaphy pain with neuropathic origin.These are the "genital branch of the genitofemoral nerve", "the ilioinguinal", and the "iliohypogastric nerves". Therefore, it is possible to argue that nerve damage from the initial surgery contributes to chronic postoperative pain.

Chronic postoperative pain can develop when any of the nerves are traumatized as a result of not being recognized. Although clean nerve division does not increase postoperative pain, it does contribute to disorganized sensory changes after repair. However, for severe chronic neuropathic pain, clean nerve division can also be a treatment option. Nerve entrapment in sutures/Tackers may be the cause of the neuropathic pain that may arise.(16)

Post-operative factors

Optimum analgesic drugs in the postoperative phase are of utmost importance in the post-surgical patient. Regardless of the type of anesthesia used to repair the hernia—

local, regional, or general—the patient won't be allowed to leave the hospital until the post-op pain is under control with the appropriate analgesics. Under general, regional, or local anesthesia, inguinal hernias have been repaired.(21)

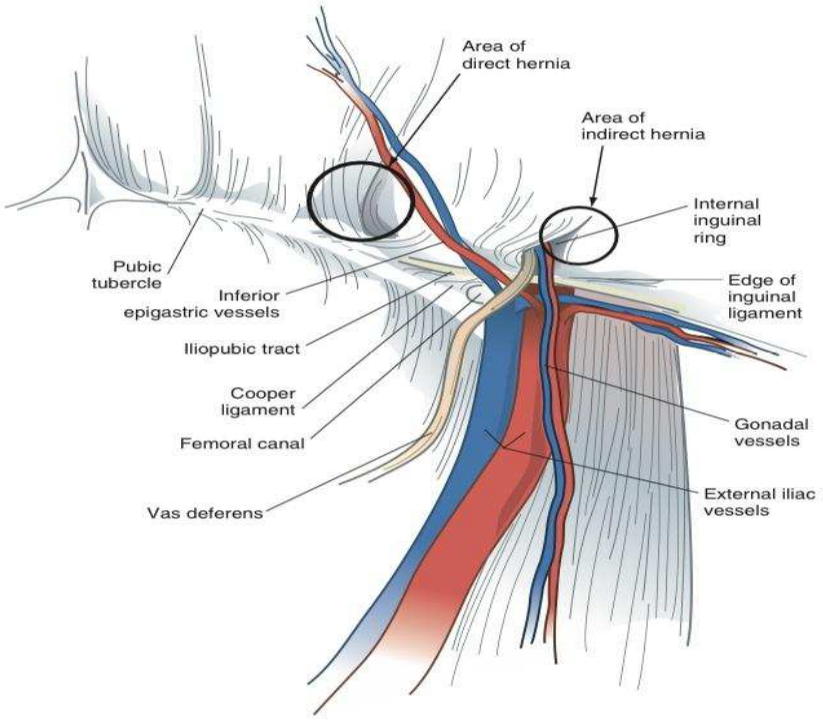


Figure 02- Anatomy of Inguinal Hernia

Management of postoperative pain

In general, pain is regarded as a significant postoperative complication that, if untreated, may have serious morbidities. Different patients have different pain tolerance consequent analgesic needs vary greatly. Use of analgesic drugs are usually restricted due to potential adverse effects.(22) Uncontrolled postoperative pain has a variety of negative effects. According to studies, managing pain in a proactive and preventive manner is much more advantageous than just reacting to pain that has already developed passively(25). But the pursuit of the highest standard continues.

Optimizing surgical site nociception is thought to help prevent postoperative morbidities, speed up early hospital discharge, and lower associated costs.(24)

Preemptive pain management aims to reduce pain by addressing pain signals before a surgical incision is made. NMDA (n-methyl-d-aspartate) receptors, involved in pain transmission, are targeted by antagonists like ketamine and amantadine. However, these NMDA antagonists are not routinely used for long-term analgesia due to associated risks.(23)

Although it is well acknowledged that care of immediate post-operative pain after hernia surgery is crucial. There is not sufficient data to justify giving preemptive analgesia in place of conventional analgesic techniques.(25)

Most research on preemptive analgesia has focused on patients under general anesthesia.A common surgical treatment that can be done under local, spinal, or GA, inguinal hernia repair usually causes moderate to severe pain. Chronic postoperative pain affects 5-35% of patients following hernia repair(26). Preemptive analgesia offers the advantage of quicker recovery and discharge with fewer complications(24). However, some procedures may require general or spinal anesthesia due to patient preference or other factors. Standard pain management for inguinal hernia repair includes narcotics, NSAIDs, local anesthetics, and centrally acting drugs(28). Despite various approaches, only a few studies have directly compared their outcomes, and evidence has yet to demonstrate the superior efficacy of preemptive analgesia as a single method(29). It can be used along with post surgical pain management, so as to decrease the use of narcotics and NSAIDS, which are reported to have multiple side-effects(27).

Paracetamol

Paracetamol, or acetaminophen, is a commonly used medication for alleviating pain and reducing fever. It is frequently utilized in a variety of pain management contexts, including post-surgical recovery(33).

Mode of Action: By preventing the synthesis of prostaglandins, which are molecules linked to pain and inflammation, paracetamol is thought to primarily work in the cns. It has little to no anti-inflammatory action in contrast to NSAIDs (non-steroidal anti-inflammatory medicines).(34).

Paracetamol treats mild to moderate pain, It is recommended in postoperative pain management, including after surgeries like hernia repair(36).

It can be administered orally in tablet, capsule, or liquid form, and can also be given rectally or intravenously in certain settings.(30)

Paracetamol is generally safe and well-tolerated. The recommended maximum dose for adults is typically 4,000 milligrams per day, or 15mg/kg/dose but this can vary based on individual health conditions and the presence of other medications. Overuse or accidental overdose can lead to severe liver damage, so it's crucial to adhere to recommended dosages(35).

Paracetamol is effective in relieving pain and reducing fever, and it generally has fewer side effects compared to NSAIDs or narcotics(31). Unlike NSAIDs, it does not irritate the stomach or increase the risk of bleeding, making it a safer option for certain patients, especially those with gastrointestinal issues or who are at risk of bleeding complications or with comorbidities(37).

It does not have the anti-inflammatory properties of NSAIDs, so it may be less effective for pain involving inflammation. Additionally, its effects are usually less potent compared to stronger analgesics or opioids(35).

This study has been carried out with an aim to evaluate the post-operative pain following preemptive analgesia with paracetamol, and compare with a placebo (normal saline) following unilateral inguinal hernia mesh repair and requirement of analgesia in both groups.

Inguinal hernia surgery continues to evolve, but there remains no universally accepted technique. Postoperative pain is a common and prominent complication for these patients. Considerable research has been dedicated to addressing chronic postoperative pain.

Thenarasu et al 2018(40)

The study compared preemptive analgesic effects of diclofenac and paracetamol in patients requiring tooth extraction using VAS pain score. 20 participants were separated into 2 groups, group 1 was given Tab paracetamol 500mg and group 2 was given Tab diclofenac 100 mg 30 minutes before the procedure and assessment of pain was done usingVAS at 10 min, 1 hour, 3 hrs and. 6 hrs. Patients who were given diclofenac showed a higher and longer analgesic effect compared to paracetamol.

Heiko Neuss et al, 2010(44)

Groups 1 and 2 were randomly assigned to thirty-two patients with stage III/IV melanoma undergoing therapeutic RALND. One group received 40 mg of Parecoxib intravenously, while the second group received a 0.9% normal saline solution, both administered 2 hours before RALND. Patients who received the

preemptive analgesic experienced better outcomes. Pain after mobilization was significantly reduced on the first postoperative morning (P = 0.04). Additionally, these patients reported less fatigue (P = 0.05) and required less pain medication (P = 0.04).

Trichak Sandhu et al, 2011(45)

In a study involving 120 patients scheduled for elective laparoscopic cholecystectomy, participants were randomly divided into two groups. One group received 120 mg of etoricoxib along with diazepam, while the other group received a placebo plus diazepam. The etoricoxib group required significantly fewer oral analgesics (p = 0.006). Furthermore, the postoperative The etoricoxib group had lower Visual Analog Scale (VAS) scores at 10 (p = 0.023), 14 (p = 0.045), and 26 (p = 0.011) hours. Additionally, the etoricoxib group had a significantly lower average VAS score (p = 0.013).

Sh Nesioonpour et al, 2013(47)

In this randomized clinical research, patients having spinal anesthesia for inguinal hernia surgery were evaluated for the efficacy of local bupivacaine infiltration in comparison to a placebo. Two groups of thirty patients each participated in the trial. Prior to the incision, the control group received 10 cc of normal saline at the surgical site, while the case group received 10 cc of 0.5% bupivacaine. In the first 24 hours following surgery, the case group reported considerably lower pain levels and a reduction of 69.6%, 76.5%, 83.2%, and 80%, respectively, in nausea, vomiting, and narcotic use (P < 0.001, P = 0.005, P = 0.001, and P < 0.001).

Pfeiffer U et al (1991)(48)

In their 48-hour, double-blinded study, 72 patients electively undergoing aortic surgery were randomized to be given 40 ml of 0.25 percent bupivacaine vs 40 ml of saline was locally using catheter. In random order, the two catheters were inserted into the rectus sheath or subcutaneously through transverse incisions; one catheter was inserted subcutaneously through vertical incisions. vas and injectable morphine dosages given during the installation phase were used to assess the pain alleviation on POD1 and 2. Peak flow and forced expiratory volume measurements were taken to keep tabs on pulmonary function from POD1 through 5. Monitoring of ABG was done both before surgery and on day two after. NO difference as noted statistically between the two groups. Site of the incision made no difference. The mean VAS on the first POD were 40 and 29, respectively, for vert.(n=21) and trans. (n=49) incisions (p0.05). When compared to saline, bupivacaine wound instillation neither enhances pulmonary function nor lowers the need for morphine. It's possible that transverse incisions hurt less than vertical ones.

Zhe Zhe Peng et al, 2021(50)

Forty patients with solitary cleft palates, ages 9 to 24 months, having palatoplasty were randomly assigned in a 1:1 ratio to receive either normal saline at induction or a single intravenous dosage of 10 mg/kg ibuprofen. As seen in placebo group (n = 20), the group that got IV ibuprofen (n = 20) needed considerably less fentanyl after surgery ($p < 0.001$). Neither the surgical blood loss nor the time to the first rescue analgesia differed significantly between the two groups.

Lior Lowenstein et al, 2008(51)

Twenty milliliters of either 0.9% saline or 1% lidocaine were injected at the site of the incision prior to surgery in a research that involved thirty-two women having hysterectomy. For preemptive analgesia, sixteen women were given lidocaine, while fourteen were given saline as a placebo. All procedures were carried out under general anesthesia, and oral ibuprofen (400 mg) and morphine (10 mg) were used to treat postoperative discomfort. Following surgery, women who received lidocaine reported significantly less pain than those who received a placebo at two, five, and eight hours "(50.1 ± 27.9 vs. 70.6 ± 22.6, p = 0.043, 42.5 ± 25.2 vs. 64.6 ± 28.3, p = 0.043, and 31.2 ± 22.4 vs. 53.3 ± 30.3, p = 0.031)".

Saxena SK et al, 2000(57)

52 found that bupivacaine wound infiltration is a cost-effective, patient-controlled analgesia method that allows patients to manage their pain needs safely. This technique is particularly well-suited for procedures such as herniorrhaphy, herniotomy, appendicectomy, and breast lump excisions. It serves as a valuable adjunct to reduce the need for narcotic analgesics following major surgeries. Given its simplicity and broad applicability, omitting this approach from patient care might be considered a missed opportunity. While the study encompassed a range of surgical procedures, our focus will be on patients undergoing hernia repair surgery.

MATERIALS AND METHODS

Source of Data: Patients aged 18 years and above, of either gender, belonging to ASA grade 1 and 2, undergoing unilateral Lichtenstein inguinal hernia repair surgery under spinal anesthesia at KLE Dr Prabhakar Kore Hospital

Study Design: Randomized control trial

Study Period: 1 year

Sample size:

28 for each group,

Calculations are shown below:

$$n = \frac{(z1-\alpha/2 + z1-\beta)^2 \times [SD1^2 + SD2^2]}{(x1 - x2)^2}$$

Where

- $x1$ is the mean in the first group
- $x2$ is the mean in the second group
- For a 95% confidence level, $Z1\text{-}\alpha/2$ values are 1.96
- For 80% power, $Z1\text{-}\beta$ value is 0.84
- SD = $\sqrt{SD1^2 + SD2^2}$ is the sample standard deviation.

Now, the following are the values of sample means and standard deviations:

- Group 1: $x1$ = 57.1, $SD1$ = 4.68
- Group 2: $x2$ = 58.93, $SD2$ = 6.07

Thus using the above values, at 20% attrition, the sample size for the groups is 28 each.

Sampling technique: After meeting inclusion and exclusion criteria and obtaining informed consent, patients will be randomly allocated into 2 groups using SNOSE technique.

Group A- Patients will receive IV PARACETAMOL 15mg/kg 30 minutes before surgery

Group B- Patients will not receive any analgesia before surgery.

Inclusion Criteria:

- Age 18 years and above
- Patients undergoing standard unilateral lichtenstein inguinal hernia mesh repair surgery under spinal anesthesia.
- Either sex
- ASA grades 1 and 2
- Patients willing to give informed consent.

Exclusion Criteria:

- Hypersensitivity to paracetamol
- Patients undergoing a different procedure of inguinal hernia repair
- Patient given epidural anesthesia.

Study protocol: Consort flow chart for RCTs

After obtaining the approval of the ethical committee and written informed consent, a total of 56 patients undergoing inguinal hernia mesh repair under spinal anesthesia will be included in the study.

After having met inclusion and exclusion criteria and having informed consent, patients will be randomized based on Sequentially numbered, opaque, sealed envelope (SNOSE) technique into one of the two groups.

Before 30 minutes of induction,the patient in

Group A will receive INJ PARACETAMOL 15mg/kg IV

Group B control will receive normal saline

STATISTICAL ANALYSIS:

1. Data will be collected and stored in Microsoft Excel.
2. Data will be analyzed using statistical software R and Microsoft Excel, SPSS.
3. Continuous variables will be given in mean ±sd/median (range).
4. Categorical variables will be represented by frequency.
5. To check the dependency between attributes, a Chi-square test will be used.
6. To check the normality of variables the Quantile-Quantile (QQ) plot/Shapiro-Wilk's test will be used. P-value less than or equal to 0.05 shows statistical significance.
7. To compare mean/distribution over groups t-test/ANOVA/Mann-Whitney test/Kruskal-Wallis test/Freidman test will be used.
8. To compare mean/distributions within time points paired t-test/Wilcoxon's test will be used. To analyze the paired nominal data McNemar's test will be used.

PROCEDURE

After obtaining the approval of the ethical committee and written informed consent, a total of 50 patients undergoing inguinal hernia mesh repair under spinal anesthesia will be included in the study.

After having met inclusion and exclusion criteria and having informed consent, patients will be randomized based on the Sequentially numbered, opaque, sealed envelope (SNOSE) technique into one of the two groups.

Before 30 minutes of induction, the patient in

Group A will receive INJ PARACETAMOL 15mg/kg IV

Group B control will receive normal saline

Post-operative pain will be analyzed with the help of a Visual Analogue Scale (VAS- 1-5) at 6, 12, 24, 36, and 72 hrs, along with requirement of standard and rescue analgesia.

RESULTS

Pain score follow-ups were considered as primary outcome variables. Standard and rescue analgesia (opioids) usage were regarded as secondary outcomes. The study group was regarded as the main explanatory factor.

For quantitative variables, the descriptive analysis utilized the mean and standard deviation, while frequency and proportion were employed for categorical variables. For non-normally distributed quantitative values, the median and interquartile range (IQR) were used. Additionally, data visualization included appropriate diagrams such as box plots, pie charts, and bar charts.

By visually inspecting histograms and normality Q-Q plots, all quantitative variables were examined for normal distribution within each category of the explanatory variable. Additionally, the Shapiro-Wilk test was used to evaluate the normal distribution. When the Shapiro-Wilk test's p-value was >0.05, the distribution was regarded as normal.

The Chi-square test or Fisher's Exact test was employed to evaluate categorical outcomes between study groups when the total sample size was less than 20, or when the anticipated value in any given cell was less than 5.

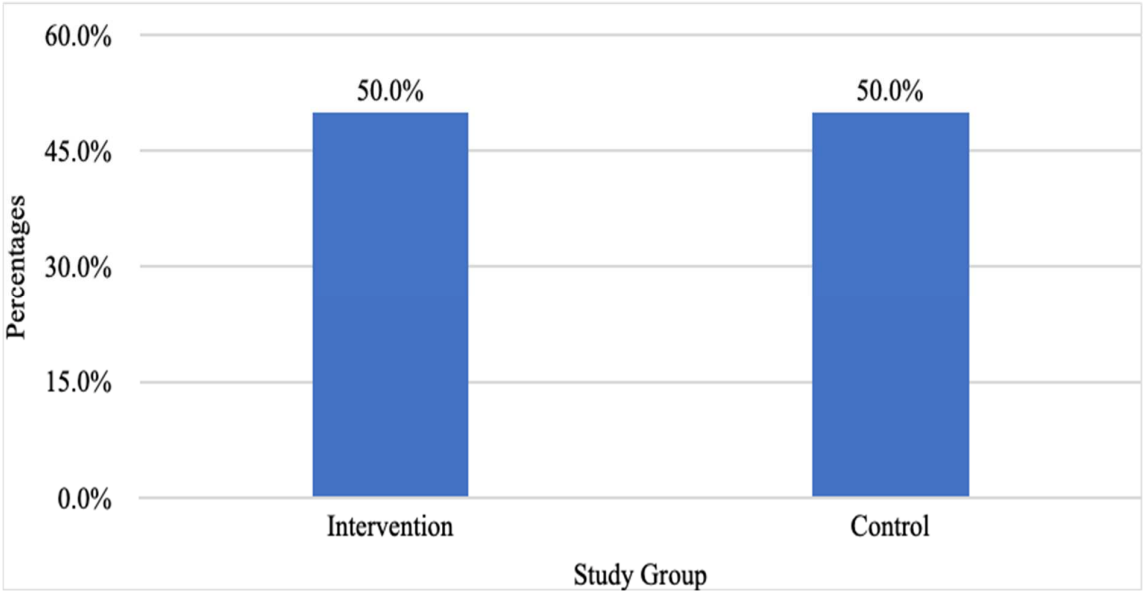
The independent sample t-test was used to compare the mean values of quantitative parameters that were normally distributed amongst study groups (2 groups) Using the Mann Whitney u test, medians and interquartile range (IQR) for quantitative parameters with non-normal distribution were compared between research groups (2 groups).

P value < 0.05 was considered statistically significant. IBM SPSS version 22 was used for statistical analysis.

Table 1: Descriptive analysis of the study group in the study population (N=56)

Study Group	Frequency	Percentages
Intervention	28	50.00%
Control	28	50.00%

Figure 1: Bar chart of the study group in the study population (N=58)



Among the study population, 28 (50%) participants were in the intervention group and the other 28 (50%) were in the control group.

Table 2: Comparison of mean of age between study groups (N=56)

Parameter	Study Group (Mean± SD)		P value
	Intervention (N=28)	Control (N=28)	
Age	60.25 ± 13.52	63.36 ± 16.41	0.45

The mean age (years) was 60.25 ± 13.52 in the study population, ranging between 18 to 70 years.

Table 3: Comparison of gender between study groups (N=56)

Gender	Study Group	
	Intervention (N=56)	Control (N=56)
Male	**28 (100%)**	**28(100%)**

In our study, all our participants were males in both study and control groups.

Table 4: Distribution of diagnosis between study group (N=56)

Diagnosis	Study Group	
	Intervention (N=28)	**Control (N=28)**
Left Direct Inguinal Hernia	3 (10.71%)	4 (14.29%)
Left Indirect Inguinal Hernia	6 (21.43%)	8(28.57%)
Left Pantaloon Inguinal Hernia	0	1 (3.57%)
Right Direct Inguinal Hernia	8(28.57%.)	7 (25%)
Right Indirect Inguinal Hernia	9(32.14%)	7(25%)
Right Pantaloon Inguinal Hernia	2 (7.14%)	1(3.57%)

The study included multiple inguinal hernias like Left Direct Inguinal Hernia 3 (10.71%) in intervention and 4 (14.29%) in control; Left Indirect Inguinal Hernia study group contained 6 (21.43%) and 8(28.57%) in the control; Left Pantaloon Inguinal Hernia 0 in the intervention group and 1 (3.57%) in control; Right Direct Inguinal Hernia 8(28.57%.) included in the control and 7 (25%) in intervention; Right Indirect Inguinal Hernia included 9(32.14%) in the intervention group and 7(25%)in the control; 2 (7.14%) were included in the intervention and in 1(3.57%) control of Right Pantaloon Inguinal Hernia.

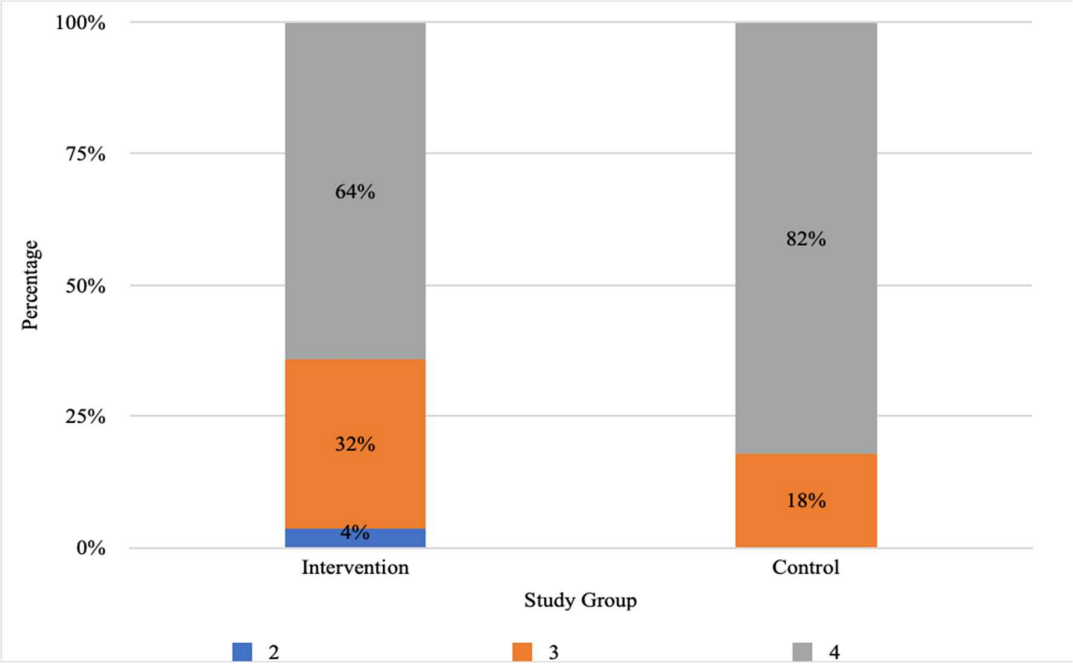
Table 5: Association of pain scores (VAS) at different follow -ups between study group (N=56)

Pain Scores (Vas)	Study Group	
	Intervention (N=28)	Control (N=28)
At 6 Hours		
2	1(3.57%)	0
3	9(32.14%)	5(17.85%)
4	18(64.28)	23(82.14%)
5	0	0
At 12 Hours		
1	1(3.57%)	1(3.57%)
2	10(35.71%)	3(10.71%)
3	13(46.42%0	14(50%)
4	4(14.28%)	10(35.71%)
5	0	0
At 24 Hours		
1	9(32.14%)	4(14.28%)
2	12(42.85%)	10(35.71%)
3	6(21.42%)	13(46.42%)
4	1(3.57%)	1(3.57%)
At 36 Hours		
0		1(3.57%)
1	19(67.85%)	13(46.42%)
2	8(28.57%)	8(28.57%)
3	1(3.57%)	6(21.42%)
4	0	0
At 48 Hours		
0	2(7.14%)	3(10.71%)
1	25(89.28%)	17(60.71%)
2	1(3.57%)	6(21.42%)
3	0	2(7.14%)
At 72 hrs		
0	3(10.71%)	3(10.71%)
1	24(85.71%)	19(67.85%)
2	1(3.57%)	6(21.42%)

Our study includes post-operative pain scoring using VAS scores after 6,12,24,36, 48, and 72 hours of surgery in both control and study groups.

According to the table above, the intervention group seems to show lower pain scores at almost all time points compared to the control group, especially at the later time intervals. The following was observed at specific time points.

Figure 2: Stacked bar chart of comparison of pain scores (VAS) at 6 Hours between study group (N=56)



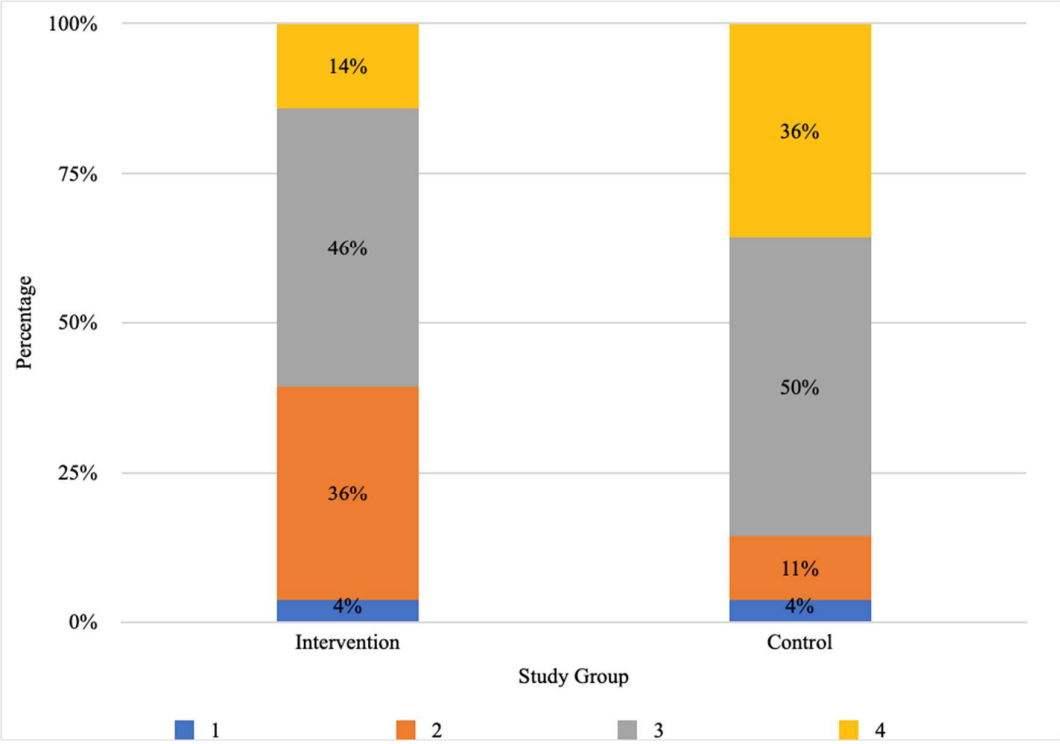
6 Hours:

Intervention Group: Most patients reported scores of 3 (32.14%) and 4 (64.28%).

Control Group: A large portion also reported a score of 4 (82.14%), but fewer participants scored a 3 (17.85%).

Interpretation: At 6 hours, both groups are experiencing relatively high pain, but slightly more patients in the control group are experiencing higher pain (score of 4).

Figure 4: Staked bar chart of comparison of pain scores (VAS) at 12 Hours between study group (N=56)



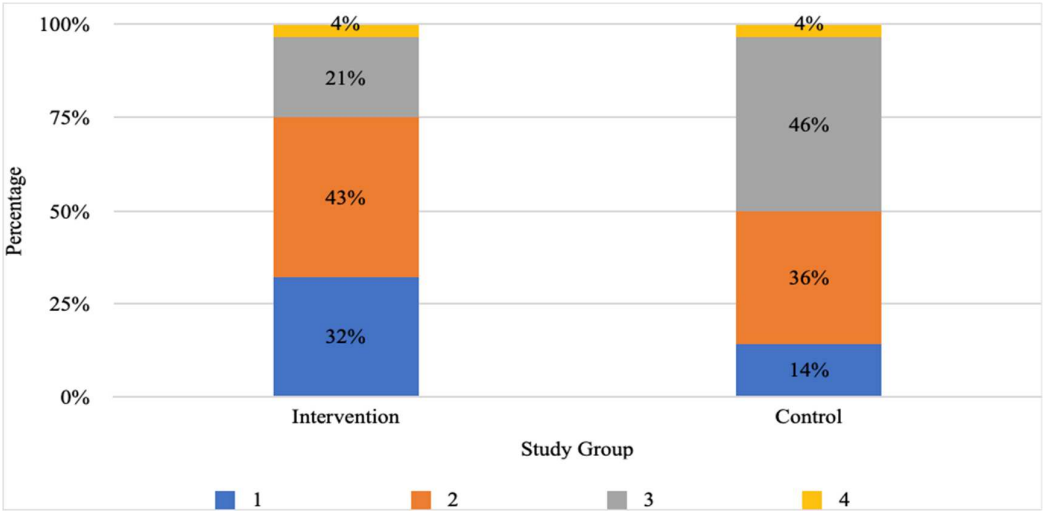
- **12 Hours:**

Intervention Group: A decrease in pain scores, with more patients scoring 2 (35.71%) and 3 (46.42%).

Control Group: A higher proportion of patients still report a score of 3 (50%) or even 4 (35.71%).

Interpretation: Pain decreases more significantly in the intervention group at 12 hours compared to the control group, where a significant portion still reports moderate to high pain.

Figure 4: Staked bar chart of comparison of pain scores (VAS) at 24 Hours between study group (N=56)



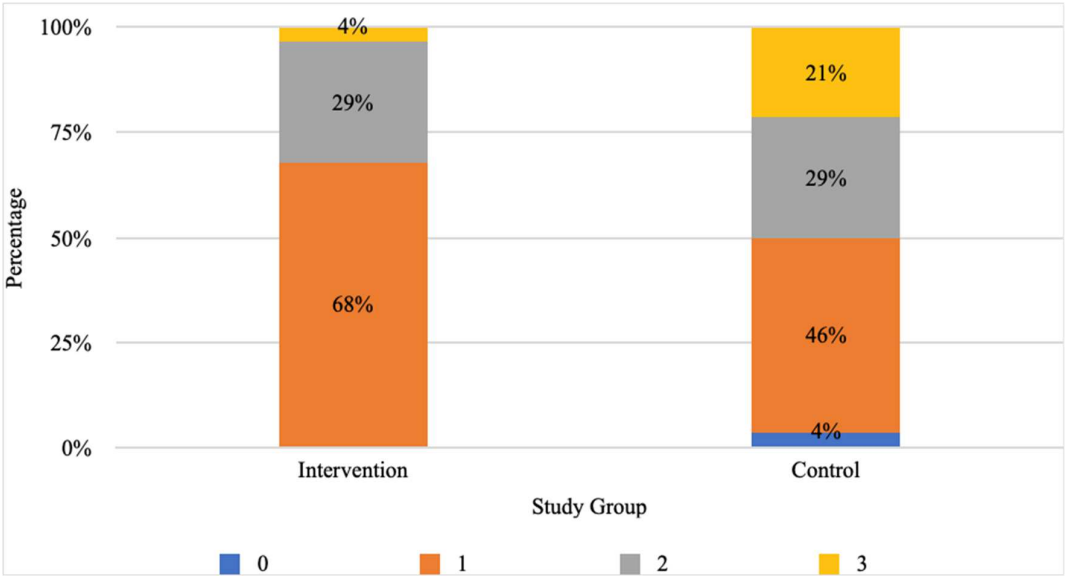
- **24 Hours:**

Intervention Group: Pain continues to decrease, with a large portion reporting scores of 1 (32.14%) and 2 (42.85%).

Control Group: Still more patients reporting scores of 2 (35.71%) and 3 (46.42%).

Interpretation: The intervention group has a marked improvement in pain reduction compared to the control group, where more patients are experiencing moderate pain (scores 3 and above).

Figure 4: Staked bar chart of comparison of pain scores (VAS) at 36 Hours between study group (N=56)



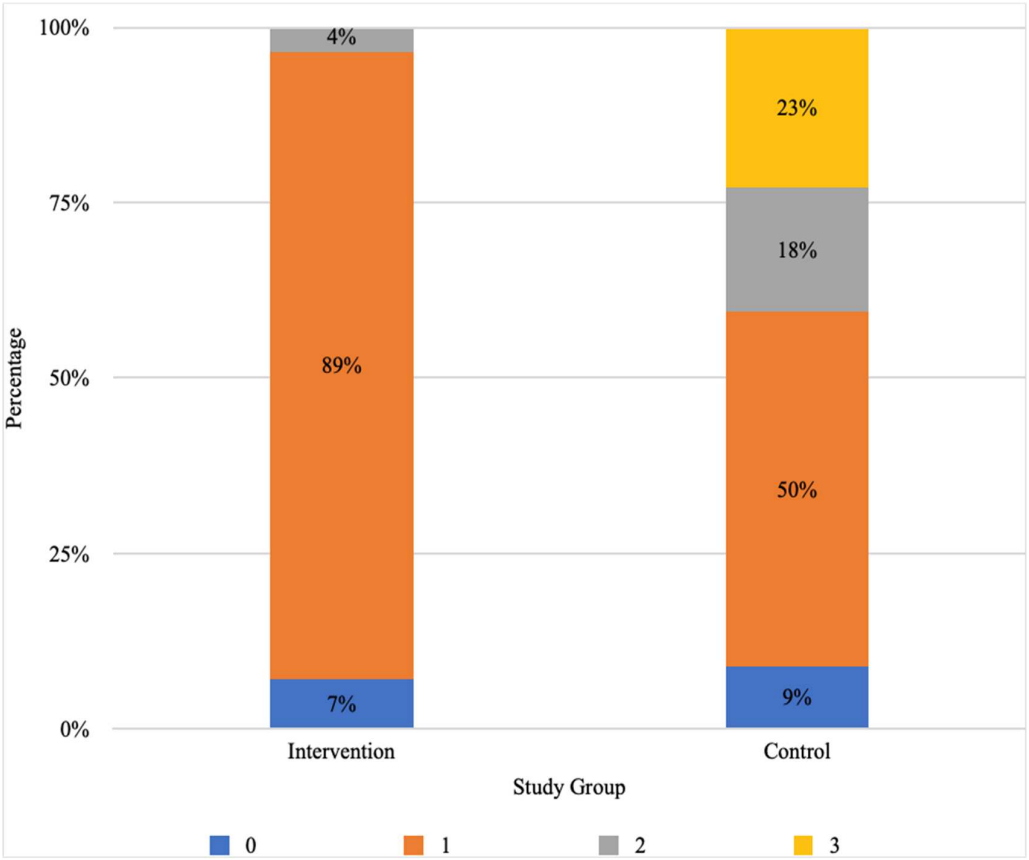
- **36 Hours:**

Intervention Group: The majority report a score of 1 (67.85%) and fewer at a score of 2 (28.57%).

Control Group: More patients report pain scores of 1 (46.42%) and 2 (28.57%), but still a few report higher scores (21.42% at score 3).

Interpretation: Pain reduction continues to be better in the intervention group, with fewer people reporting higher pain scores in the control group.

Figure 5: Staked bar chart of comparison of pain scores (VAS) at 48 Hours between study group (N=56)



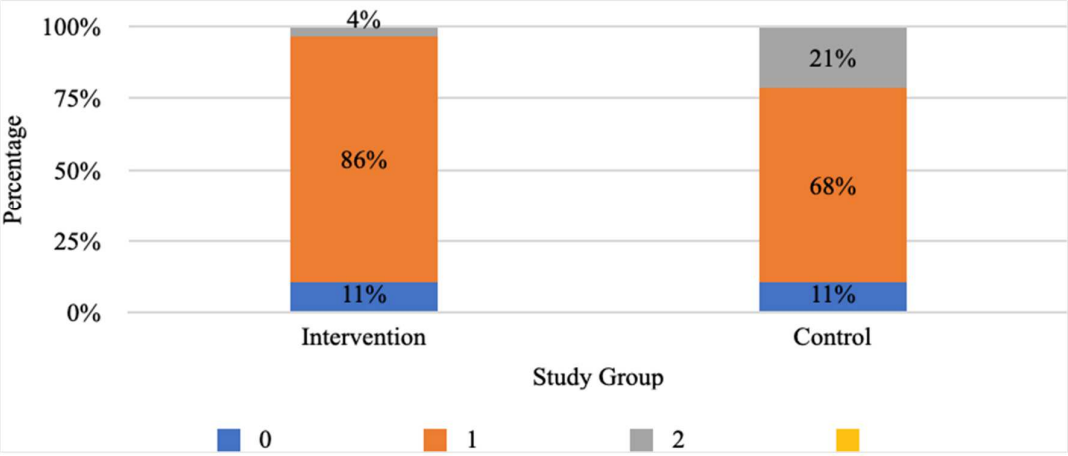
- **48 Hours:**

Intervention Group: 89.28% report minimal pain (score of 1), with a very small proportion scoring 2.

Control Group: Only 60.71% report minimal pain (score of 1), with some patients still scoring 2 (21.42%) and even a few scoring 3 (7.14%).

Interpretation: The intervention group achieves significantly better pain control by 48 hours, with almost all participants experiencing minimal pain, whereas the control group still has some patients with moderate pain.

Figure 6: Staked bar chart of comparison of pain scores (VAS) at 72 Hours between study group (N=56)



- **72 Hours:**

Intervention Group: 85.71% report minimal pain (score of 1), and a small number score of 0 (no pain).

Control Group: 67.85% report minimal pain (score of 1), with some still reporting moderate pain (21.42% score of 2).

Interpretation: By 72 hours, both groups experience reduced pain, but the intervention group has more patients with near-complete pain relief (scores 0 or 1) compared to the control group.

Table 6: Comparison of median pain score (VAS) between the study groups at different follow-up time periods (N= 56)

Pain scores (VAS)	Study Group Median (IQR)				Mann Whitney U test (P value)
	Intervention		Control		
	Shapiro Test for Normality (p-value)	Median	Shapiro Test for Normality (p-value)	Median	
At 6 hours	$9.66 * 10^{-7}$	**4 (4,4)**	$5.39 * 10^{-9}$	**4 (4,4)**	**1**
At 12 hours	**0.0011**	**3 (3,3)**	**0.00013**	**4 (3,4)**	$1.29 * 10^{-13}$
At 24 hours	**0.00085**	**2 (3,2)**	**0.00055**	**3 (3,3)**	$1.29 * 10^{-13}$
At 36 hours	$4.69 * 10^{-7}$	**1 (1,1)**	**0.00039**	**2 (2,2)**	$1.29 * 10^{-13}$
At 48 hours	$1.78 * 10^{-9}$	**1 (1,1)**	**0.00016**	**2 (1,2)**	$1.29 * 10^{-13}$
At 72 hours	$1.62 * 10^{-8}$	**1 (1,1)**	$1.01 * 10^{-5}$	**1 (1,1)**	**1**

The comparison between the intervention and control groups in terms of median pain scores (VAS) and paracetamol dosage usage yields significant findings related to the efficacy of pre-emptive analgesia using IV paracetamol in reducing postoperative pain for patients undergoing inguinal hernia repair surgery.

We assess the normality of the distributions using the Shapiro-Wilk test. Since all p-values are below 0.05, we conclude that none of the distributions follow a normal distribution. Therefore, we calculate the medians for both the control and intervention groups and perform the Mann-Whitney U test.

The results indicate that the intervention had a significant effect on reducing pain between 12 and 48 hours post-surgery compared to the control group. However, at the 6-hour and 72-hour marks, there was no observable difference in pain scores between the two groups. This suggests that the pain-relieving effects of the pre-emptive IV paracetamol may not take full effect until after 6 hours and could diminish or stabilize by 72 hours.

These findings highlight the timing and duration of the intervention's effectiveness. The significant reduction in pain during the critical 12 to 48-hour postoperative period suggests that pre-emptive IV paracetamol is highly beneficial during the early stages of recovery, potentially reducing the need for additional analgesia. By lowering the likelihood of central sensitization during this period, the intervention may also prevent the development of chronic pain, a common concern following surgical procedures.

However, since there was no difference in pain scores at 72 hours, it implies that the long-term pain relief from the intervention plateaus, requiring further management strategies beyond this timeframe if necessary.

This insight underscores the potential for pre-emptive IV paracetamol to enhance postoperative pain management, particularly in the first 48 hours, while ensuring a safer and more comfortable recovery for a wide range of patients, including those with comorbidities.

Table 7: Comparison of doses of paracetamol (standard analgesia) given between the study groups (N=56)

DOSAGE	INTERVENTION GROUP (N=28)	CONTROL GROUP (N=28)
0 DOSE	0	0
1 DOSE	1(3.57%)	2(7.14%)
2 DOSES	12(42.85%)	5(17.85%)
3 DOSES	6(21.42%)	3(10.71%)
4 DOSES	5(17.85%)	8(28.57%)
5 DOSES	3(10.71%)	4(14.28%)
6 DOSES	1(3.57%)	3(10.71%)
7 DOSES	0	0
8 DOSES	0	3(10.71%)
Total doses	84 doses	115 doses

Figure 7: Staked bar chart of comparison of total doses of paracetamol (standard analgesia) given between study group (N=56)

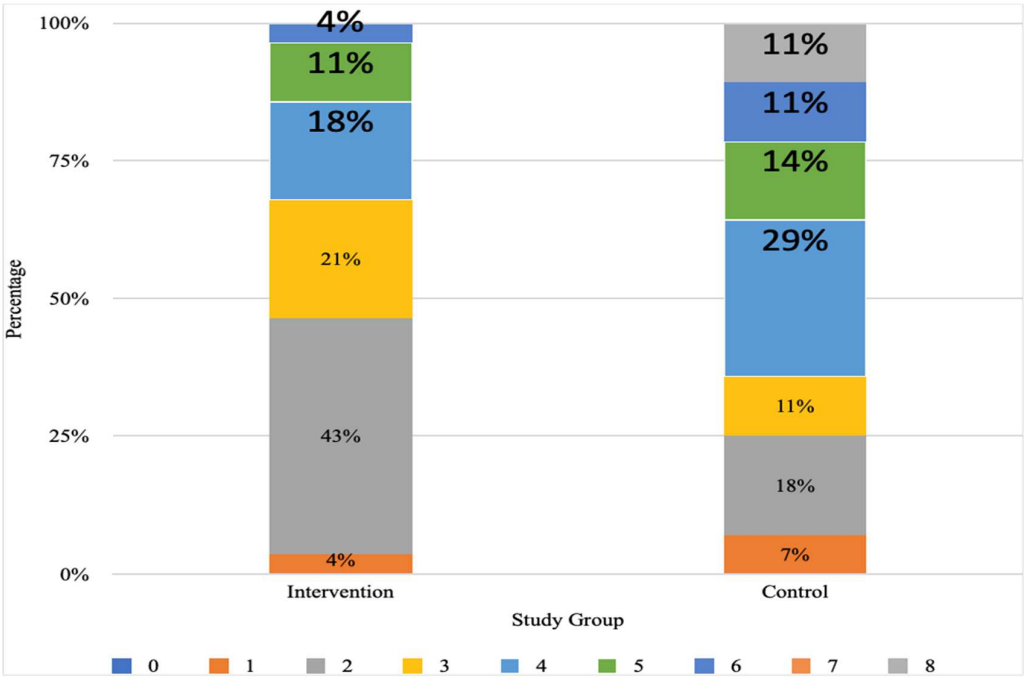
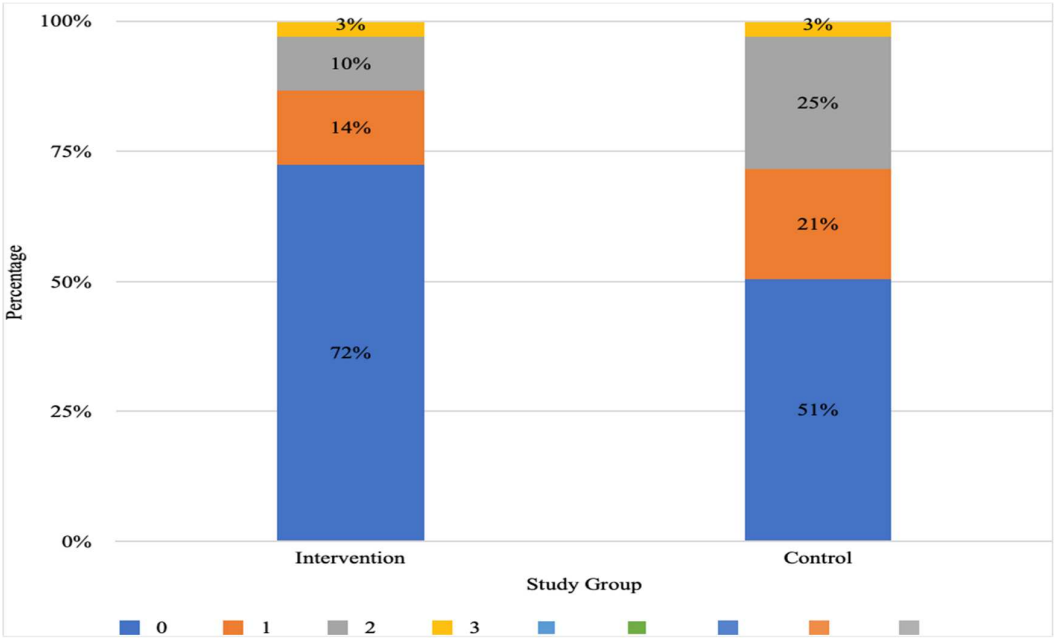


Table 8: Comparison of doses of opioids- Inj Tramadol 50mg iv(rescue analgesia) given between the study groups (N=56)

DOSAGE	INTERVENTION GROUP (N=28)	CONTROL GROUP (N=28)
0 DOSE	20(71.4%)	14(50%)
1 DOSE	4(14.28%)	6(21.4%)
2 DOSES	3(10.71%)	7(25%)
3 DOSES	1(3.57%)	1(3.57%)
Total doses	13 doses	23 doses

Figure 8: Staked bar chart of comparison of total doses of opioids (rescue analgesia) given between study group (N=56)



The above table shows that the participants in the control group required a higher overall dosage of paracetamol, totaling 115 doses compared to 84 doses in the intervention group.

In the intervention group, a majority of patients required only 2 or 3 doses of paracetamol for postoperative pain management, whereas the control group required more frequent dosing, with some patients needing up to 8 doses.

The lower requirement for postoperative analgesia in the intervention group supports the hypothesis that preemptive IV paracetamol reduces the immediate need for additional pain relief, making it an effective strategy for managing postoperative pain.

DISCUSSION

One of the most frequent ailments that general surgeons treat is a hernia. Post-operative pain is the most frequent complication following surgery. Effective pain management is essential for ensuring patient comfort, promoting early discharge, and reducing hospital stays, which in turn helps conserve both hospital and patient resources. Achieving adequate pain relief post-surgery should be a top priority. Proper pain control not only enhances patient comfort but also facilitates a quicker recovery, allowing for a faster discharge. Given that hernia repairs are often performed using systemic, regional, or combined anesthesia techniques, managing analgesic needs becomes increasingly complex.

Use of preemptive analgesia in concordance with other entities have proven to be useful in other studies. It accelerates patient recovery and reduces requirements of post operative analgesics which may otherwise adversely affect recovery. In our study we had two groups with one supplemented with paracetamol and the other with normal saline. We studied the post operative pain in the patients using VAS score in both groups at 6, 12, 24, 36, 48 and 72 hours. The intervention group received IV Paracetamol, 15kg/body weight in 100ml NS while the control group received normal saline.

A total number of 56 patients were included in the study.

All of our patients were males above 18 years of age.

All subtypes of inguinal hernia were included in the study except for complicated cases like obstruction, strangulation etc.

Visual analogue scale as used to assess pain after wearing of spinal anesthesia effect which is after 6 hours of operation.

The comparison of median pain scores (VAS) and paracetamol dosage between the intervention and control groups reveals significant findings regarding the effectiveness of preemptive analgesia with IV paracetamol in reducing postoperative pain following inguinal hernia repair.

The results demonstrate that the intervention significantly reduced pain between 12 and 48 hours post-surgery compared to the control group. However, no notable difference in pain scores was observed at the 6-hour and 72-hour time points. This suggests that the pain-relieving effects of preemptive IV paracetamol may take longer to manifest, possibly not fully taking effect until after 6 hours, and may diminish or stabilize by 72 hours.

These findings emphasize the timing and duration of the intervention's effectiveness. The significant reduction in pain during the critical 12 to 48-hour postoperative window suggests that preemptive IV paracetamol is particularly beneficial in the early stages of recovery, potentially decreasing the need for additional analgesics. Moreover, by reducing the risk of central sensitization during this period, the intervention may help prevent the development of chronic pain, which is a common concern after surgery.

However, as there was no difference in pain scores at 72 hours, it indicates the effects of the intervention plateau in the long term, highlighting the need for additional pain management strategies beyond this timeframe if required. participants in the control group required a significantly higher total dosage of paracetamol, with 115 doses compared to just 84 doses in the intervention group. In the intervention

group, most patients needed only 2 or 3 doses of paracetamol for postoperative pain management, while the control group required more frequent dosing, with some patients needing up to 8 doses of paracetamol. The reduced need for additional analgesia in the intervention group supports the hypothesis that preemptive IV paracetamol effectively decreases the immediate requirement for extra pain relief, making it a valuable strategy for managing postoperative pain.

There were no significant side effects observed in the studies associated with preemptive analgesia. In this study 1 patient complained of nausea not relieving from anti-emetics, and hence analgesics were withheld.

Study done by Mursel Ekinci et al results were comparable to this study where VAS scores in the control group were significantly higher than the intervention group where paracetamol and ibuprofen were administered.

In a study conducted by Aweke et al., the preemptive analgesic effects of paracetamol, paracetamol combined with diclofenac, and paracetamol combined with tramadol were compared. It was observed that the need for rescue analgesia was significantly higher in the paracetamol-only group. Since diclofenac or tramadol were not included, as paracetamol can be administered to a broader range of patients, it is likely that the use of stronger analgesics preemptively could have further reduced the consumption of rescue analgesia.

It's important to note that while the intervention group demonstrated lower pain scores and improved relief, there may be opportunities to achieve even better outcomes with alternative analgesics, such as aceclofenac, diclofenac or tramadol. However, considering the safety profile of the medications and the diverse patient population—including those with diabetes and other comorbidities—IV paracetamol

was chosen as the preferred option in this study. This decision underscores the importance of balancing efficacy with safety, making IV paracetamol a more suitable choice for a broader range of patients.(38,39,45,48)

CONCLUSION

The use of pre-emptive IV paracetamol as part of pain management in inguinal hernia repair surgery significantly reduces postoperative pain, minimizes the need for additional analgesic intervention, and has the potential to prevent chronic pain by inhibiting central sensitization. This study demonstrates that pre-emptive analgesia with IV paracetamol is not only effective but also safe for a wide range of patients, including those with significant comorbidities like Diabetes, CKD and old age. As a first-line treatment with minimal adverse effects, it proves to be an optimal choice for enhancing patient comfort and improving recovery outcomes after surgery.(38,39,45,48)

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ANNEXURE 01-CONSENT

KAHERs JNMC BELAGAVI

INFORMED CONSENT FORM

Title of the study: Evaluation of postoperative pain following preemptive analgesia with IV PARACETAMOL in Unilateral Lichtenstein's Inguinal Hernia Repair surgery, Randomized, control trial.

Name of Student/Principal Investigator: Dr. _____

Name of Guide/Co Investigators: Dr. _____

Introduction: To evaluate postoperative pain in patients undergoing unilateral inguinal hernia mesh repair surgery after giving preemptive analgesia with vi paracetamol. Explanation of procedure: If you agree to enroll in my study, I will ask you about the history of presenting complaints. Clinical examination will be done. You will be allotted into one of the two groups randomly using closed envelope technique.

Group A IV PARACETAMOL 15mg/kg will be added to 10 ml NS, 30 minutes before surgical incision.

Group B 100 ml NS will be given.

Post operative pain will be compared using VAS score after 6,12,24 and 48 hours of the surgery. Duration after which rescue analgesia is needed will also be compared.

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: The study will benefit you by decreasing the postoperative pain after the surgery, and prevent the use of higher analgesics. The data gathered will help the population at large.

Possible risks from participating in the study: There are minimum to no risks involved in participating in this study. However some adverse effects of the drug can be expected like change in breathing patterns, heart rate or hypersensitivity to the drug.

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.

Cost of investigations done during the course of study will be paid by the principal investigator.

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: "Nandini Jain, 883988723 if you have any question or complaints with regard to your right as a study participant.

You may contact Dr Harsha Hegde, Chairperson, Ethical committee of JNMC, 0831-2473777 Extension 4052.

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

Evaluation of postoperative pain following preemptive analgesia with IV PARACETAMOL in Unilateral Lichtenstein's Inguinal Hernia Repair surgery, Randomized, control trial.

My signature below indicates that I have decided to participate and I have read the information provided above or the information provided above has been read to me in the language that I understand best. I was given the opportunity to ask questions and that they have been answered to my satisfaction.

Name of the participant:

Signature or left thumb impression of the participant: Name o f the witness:

Signature or left thumb impression of the witness: Name of the investigator:

Signature of the investigator:

काहेर'स जे एन एम सी बेलागावी

सूचित सहमचत पत्र

"अध्ययनकाशीर्कष:एकतरफाचलिंस्टीनकीवंक्षणहचनयषामरम्मतसजरषी,यादृच्छिक,चनयंत्रण परीक्षणमेंIVपैराचसटामोलके साथप्रीमेच्टटवएनाल्जेचसयाके बादपोस्टऑपरेटटवददषका मूल्यांकन"

प्रधान अन्वेर्क का नाम: डॉ. _____

गाइड/सह अन्वेर्क का नाम:: डॉ. _____

पररिय: IVपेराचसटामोलकेसाथप्रीमेच्टटवएनाल्जेचसयादेनेकेबादएकतरफावंक्षणहचनयषामेशररपेयरसजरषीसेगुजरनेवाले रोचगयों में पोस्टऑपरेटटव ददष का मूल्यांकन करना।

प्रटिया की व्याख्या:
यटद □प मेरे अध्ययन में नामांकन के चलए सहमत हैं, तो मैं □पसे चशकायतों को पेश करने के इचतहास के बारे में पू ूंगा।

क्लीचनकल जां की जाएगी। बंद चलफाफा तकनीक का उपयोग करके □पको यादृच्छिक रूप से दो समूहों में से एक में □वंटटत टकया जाएगा। सच्जकषलीरालगानेसे30चमनटपहलेग्रुपएIVपैराचसटामोल15चमलीग्राम/टकग्रा100चमलीएनएसमेंचमलाया जाएगा।

ग्रुप बी 100 एमएल एनएस टदया जाएगा।
सजरषीके6,12,24और48घंटोंकेबादपोस्टऑपरेटटवददषकीतुलनावीएएसस्कोरकाउपयोगकरके की जाएगी। च्जस अवचध के बाद बिाव एनाल्जेचसया की □वश्यकता होती है, उसकी तुलना भी की जाएगी।

अध्ययन में भाग लेने से पी े हटना: इसअध्ययनमेंभागीदारीस्वैच्छिकहै।□पइसअध्ययनमेंभागलेनेयाएकबारनामांटकतहोनेके बादभागीदारीजारी

रखनेकाचनणयष लेनेकेचलएस्वतंत्रहोंगे।यटद□पअपनीभागीदारीवापसलेनेकाचनणयष लेतेहैं,तो□पऐसाकरनेके चलए स्वतंत्र हैं। हालांटक, कृ पया मुख्य अन्वेर्क को चनणषय बताएं।

अध्ययन में भाग लेने से संभाववत लाभ:
सजरषीकेबादपोस्टऑपरेटटवददषकोकमकरकेऔरउछिएनाल्जेचसककेउपयोगकोरोककरअध्ययन□पको लाभाच्न्वत करेगा। एकत्र टकए गए डेटा से बडे पैमाने पर □बादी को मदद चमलेगी।

अध्ययन में भाग लेने से संभाववत जोच्खम: इसअध्ययनमेंभागलेनेमेंन्यूनतमयाकोईजोच्खमशाचमलनहींहै।हालांटकदवाके कु प्रचतकूलप्रभावोंकीउम्मीद की जा सकती है जैसे सांस लेने के पैटनष में बदलाव, हृदय गचत या दवा के प्रचत अचतसंवेदनशीलता।

गोपनीयता:
टकसी भी व्यवि को □पकी पहिान करने से रोकने के चलए □पसे एकत्र की गई जानकारी को कोटडत टकया जाएगा।

□पकीपहिानकभीउजागरनहींकीजाएगी।□पसेएकत्रटकएगएडेटाकोगोपनीयरखाजाएगाऔरप्रकाशनके चलए के वल संसाचधत या एकवत्रत डेटा का उपयोग टकया जाएगा।

ववत्तीय प्रोत्साहन:
इस अध्ययन में भाग लेने के चलए □पको कोई भुगतान नहीं चमलेगा।
अध्ययन के दौरान टकए गए अन्वेर्णों की लागत का भुगतान प्रधान अन्वेर्क द्वारा टकया जाएगा।

समेटकतडेटाके प्रकाशनके चलएप्राचधकरण:
एकत्र टकए गए डेटा के प्रसंस्करण के बाद प्राप्त पररणाम वैज्ञाचनक उद्देश्यों के चलए प्रकाचशत टकए जाएंगे और या वैज्ञाचनक समूहों को प्रस्तुत टकए जाएंगे। हालांटक, □पकी पहिान कभी उजागर नहीं की जाएगी।

प्रशन:
इस अध्ययन के संबंध में टकसी भी प्रश्न के मामले में, □प संपकष करने के चलए स्वतंत्र हैं: यटद

□पकेपासअध्ययनप्रचतभागीकेरूपमेंअपनेअचधकारके संबंधमेंकोईप्रश्नयाचशकायतहै।
यटद□पके पासकोईप्रश्नयाचशकायतहैअध्ययनप्रचतभागीके रूपमेंअपनेअचधकारके संबंधमें□पडॉहर्ाषहेगडे, अध्यक्ष, जेएनएमसी की नैचतक सचमचत, 0831-2473777 एक्सटेंशन 4052 से संपकष कर सकते हैं।

कानूनी अचधकार:
इस सहमचत फॉमष पर हस्ताक्षर करके , हम □पके टकसी भी कानूनी अचधकार का उल्लंघन नहीं कर रहे हैं।

सहमचत विव्य

मैं अध्ययन में भाग लेने का स्वैच्छिक चनणषय ले रहा/रही हूं "अध्ययन का शीर्कष : एकतरफा चलिंस्टीन की वंक्षण हचनषया मरम्मतसजरषी,यादृच्छिक,चनयंत्रणपरीक्षणमेंIVपैराचसटामोलकेसाथप्रीमेच्टटवएनाल्जेचसयाकेबादपोस्टऑपरेटटव ददष का मूल्यांकन". नीिे टदए गए मेरे हस्ताक्षर इंचगत करते हैं टक मैंने भाग लेने का चनणयष चलया है और मैंने ऊपर दी गई जानकारी को पढ़ चलया है या ऊपर दी गई जानकारी मुझे उस भार्ा में पढ़ ली गई है च्जसे मैं सबसे अछिी तरह समझता हूं।
मुझेप्रश्नपूिनेकाअवसरटदयागयाथाऔरउनकाउत्तरमेरीसंतुविके अनुरूपटदयागयाहै।

प्रचतभागी का नाम:
प्रचतभागी के हस्ताक्षर या बाएं अंगूठे का चनशान: गवाह का नाम:
गवाह के हस्ताक्षर या बाएं अंगूठे का चनशान: अन्वेर्क का नाम:
अन्वेर्क के हस्ताक्षर:

काहेर'स जे एन एम सी बेलागावी

सूचित सहमचत पत्र

"अध्ययनकाशीर्कष:एकतरफाचलिंस्टीनकीवंक्षणहचनयषामरम्मतसजरषी,यादृच्छिक,चनयंत्रण परीक्षणमेंIVपैराचसटामोलके साथप्रीमेच्टटवएनाल्जेचसयाके बादपोस्टऑपरेटटवददषका मूल्यांकन"

प्रधान अन्वेर्क का नाम: डॉ. _____

गाइड/सह अन्वेर्क का नाम:: डॉ. _____

पररय: IVपेराचसटामोलकेसाथप्रीमेच्टटवएनाल्जेचसयादेनेकेबादएकतरफावंक्षणहचनयषामेशररपेयरसजरषीसेगुजरनेवाले रोचगयों में पोस्टऑपरेटटव ददष का मूल्यांकन करना।

प्रटिया की व्याख्या:
यटद □प मेरे अध्ययन में नामांकन के चलए सहमत हैं, तो मैं □पसे चशकायतों को पेश करने के इचतहास के बारे में पू ूंगा।

क्लीचनकल जां की जाएगी। बंद चलफाफा तकनीक का उपयोग करके □पको यादृच्छिक रूप से दो समूहों में से एक में □वंटटत टकया जाएगा। सच्जकषलीरालगानेसे30चमनटपहलेग्रुपएIVपैराचसटामोल15चमलीग्राम/टकग्रा100चमलीएनएसमेंचमलाया जाएगा।

ग्रुप बी 100 एमएल एनएस टदया जाएगा।
सजरषीके6,12,24और48घंटोंकेबादपोस्टऑपरेटटवददषकीतुलनावीएएसस्कोरकाउपयोगकरके की जाएगी। च्जस अवचध के बाद बिाव एनाल्जेचसया की □वश्यकता होती है, उसकी तुलना भी की जाएगी।

अध्ययन में भाग लेने से पी े हटना: इसअध्ययनमेंभागीदारीस्वैच्छिकहै।□पइसअध्ययनमेंभागलेनेयाएकबारनामांटकतहोनेके बादभागीदारीजारी

रखनेकाचनणयष लेनेकेचलएस्वतंत्रहोंगे।यटद□पअपनीभागीदारीवापसलेनेकाचनणयष लेतेहैं,तो□पऐसाकरनेके चलए स्वतंत्र हैं। हालांटक, कृ पया मुख्य अन्वेर्क को चनणषय बताएं।

अध्ययन में भाग लेने से संभाववत लाभ:
सजरषीकेबादपोस्टऑपरेटटवददषकोकमकरकेऔरउछिएनाल्जेचसककेउपयोगकोरोककरअध्ययन□पको लाभाच्न्वत करेगा। एकत्र टकए गए डेटा से बडे पैमाने पर □बादी को मदद चमलेगी।

अध्ययन में भाग लेने से संभाववत जोच्खम: इसअध्ययनमेंभागलेनेमेंन्यूनतमयाकोईजोच्खमशाचमलनहींहै।हालांटकदवाके कु प्रचतकूलप्रभावोंकीउम्मीद की जा सकती है जैसे सांस लेने के पैटनष में बदलाव, हृदय गचत या दवा के प्रचत अचतसंवेदनशीलता।

गोपनीयता:
टकसी भी व्यवि को □पकी पहिान करने से रोकने के चलए □पसे एकत्र की गई जानकारी को कोटडत टकया जाएगा।

□पकीपहिानकभीउजागरनहींकीजाएगी।□पसेएकत्रटकएगएडेटाकोगोपनीयरखाजाएगाऔरप्रकाशनके चलए के वल संसाचधत या एकवत्रत डेटा का उपयोग टकया जाएगा।

ववत्तीय प्रोत्साहन:
इस अध्ययन में भाग लेने के चलए □पको कोई भुगतान नहीं चमलेगा।
अध्ययन के दौरान टकए गए अन्वेर्णों की लागत का भुगतान प्रधान अन्वेर्क द्वारा टकया जाएगा।

समेटकतडेटाके प्रकाशनके चलएप्राचधकरण:
एकत्र टकए गए डेटा के प्रसंस्करण के बाद प्राप्त पररणाम वैज्ञाचनक उद्देश्यों के चलए प्रकाचशत टकए जाएंगे और या वैज्ञाचनक समूहों को प्रस्तुत टकए जाएंगे। हालांटक, □पकी पहिान कभी उजागर नहीं की जाएगी।

प्रशन:
इस अध्ययन के संबंध में टकसी भी प्रश्न के मामले में, □प संपकष करने के चलए स्वतंत्र हैं: यटद

□पकेपासअध्ययनप्रचतभागीकेरूपमेंअपनेअचधकारके संबंधमेंकोईप्रश्नयाचशकायतहै।
यटद□पके पासकोईप्रश्नयाचशकायतहैअध्ययनप्रचतभागीके रूपमेंअपनेअचधकारके संबंधमें□पडॉहर्ाषहेगडे, अध्यक्ष, जेएनएमसी की नैचतक सचमचत, 0831-2473777 एक्सटेंशन 4052 से संपकष कर सकते हैं।

कानूनी अचधकार:
इस सहमचत फॉमष पर हस्ताक्षर करके , हम □पके टकसी भी कानूनी अचधकार का उल्लंघन नहीं कर रहे हैं।

सहमचत विव्य

मैं अध्ययन में भाग लेने का स्वैच्छिक चनणषय ले रहा/रही हूं "अध्ययन का शीर्कष : एकतरफा चलिंस्टीन की वंक्षण हचनषया मरम्मतसजरषी,यादृच्छिक,चनयंत्रणपरीक्षणमेंIVपैराचसटामोलकेसाथप्रीमेच्टटवएनाल्जेचसयाकेबादपोस्टऑपरेटटव ददष का मूल्यांकन". नीिे टदए गए मेरे हस्ताक्षर इंचगत करते हैं टक मैंने भाग लेने का चनणयष चलया है और मैंने ऊपर दी गई जानकारी को पढ़ चलया है या ऊपर दी गई जानकारी मुझे उस भार्ा में पढ़ ली गई है च्जसे मैं सबसे अछी तरह समझता हूं।
मुझेप्रश्नपूिनेकाअवसरटदयागयाथाऔरउनकाउत्तरमेरीसंतुविके अनुरूपटदयागयाहै।

प्रचतभागी का नाम:
प्रचतभागी के हस्ताक्षर या बाएं अंगूठे का चनशान: गवाह का नाम:
गवाह के हस्ताक्षर या बाएं अंगूठे का चनशान: अन्वेर्क का नाम:
अन्वेर्क के हस्ताक्षर:

ಕಾಹೆರ್ಸ್ಟ ಎನ್ಎಂಸಿ ಬ ಳಗಾವಿ

ತಿಳುವಳಿಕೆಯುಳಳ ಒಪ್ಪಿಗೆ ಪತ್ರ

ಅಧ್ಯಯನದ ಶೇಷ್ಕ್ಯ : ಏಕಪಕ್ಷೇಯ ಲಿಚ್ ಿನ್ಸ ಿಂಿಂೃನ್ನ ಇಂಜಿನಲ್ ಅಂಡವಾಯು ದುರಸಿಿ ಶಸ್ತ್ರಚಿಕಿತ್ ಿ, ಯಾದೃಚಿಿಕ, ನಿಯಂತ್ರಣ ಪರಯೇಗದಲಿಿ IV ಪ್ಾಯರಾಸಿಟಮಾಲ್ನ ಂದಿಗ ಪೂರ್ಿಭಾವಿ ನ ಿೇರ್ು ನಿವಾರಕ ನಂತ್ರದ ಶಸ್ತ್ರಚಿಕಿತ್ ಿಯ ನಂತ್ರದ ನ ಿೀವಿನ ಮೌಲ್ಯಮಾಪನ.

ಪರಧಾನ ತ್ನಿಖಾಧಿಕಾರಿಯ ಹ ಸ್ರು: _____

ಮಾಗ್ದರ್ಶ/ಸ್ಹ ತ್ನಿಖಾಧಿಕಾರಿಗಳ ಹ ಸ್ರು: _____

ಪರಿಚಯ:
ಐವಿ ಪ್ಾಯರಸಿಟಮಾಲ ನಂದಿಗ ಪೂರ್ಿಭಾವಿ ನ ಿೇರ್ು ನಿವಾರಕರ್ುನ ನಿಿೀಡಿದ ನಂತ್ರ ಏಕಪಕ್ಷೇಯ ಇಂಜಿನಲ್ ಅಂಡವಾಯು ಜಾಲ್ರಿ

ದುರಸಿಿ ಶಸ್ತ್ರಚಿಕಿತ್ ಿಗ ಒಳಗಾಗುರ್ ರ ಿೇಗಿಗಳಲಿಿ ಶಸ್ತ್ರಚಿಕಿತ್ ಿಯ ನಂತ್ರದ ನ ಿೀರ್ುನ ಮೌಲ್ಯಮಾಪನ ಮಾಡಲ್ು. ಕಾಯ್ವಿಧಾನದ ವಿರ್ರಣ:

ನನನ ಅಧ್ಯಯನಕ ಿ ದಾಖಲಾಗಲ್ು ನಿಿೀರ್ು ಒಪ್ಪಿದರ , ದ ರುಗಳನುನ ಪರಸ್ತುಿತ್ಪಡಿಸ್ತುರ್ ಇತಿಹಾಸ್ತ್ರ ಬಗ ಿ ನಾನು ನಿಮ್ಮನುನ ಕ ಿೀಳುತ್ ಿಿೀನ . ಕಿಿನಿಕಲ್ ಪರಿಿೀಕ್ಷ ಯನುನ ನಡ ಸ್ತ್ಾ ಗುರ್ುದು. ಮ್ುಚಿಿದ ಹ ದಿಕ ತ್ಂತ್ರರ್ುನ ಬಳಸಿಕ ಂಡು ಯಾದೃಚಿಿಕವಾಗಿ ಎರಡು ಗುಂಪುಗಳಲಿಿ ಒಂದಕ ಿ ನಿಮ್ಮನುನ ಹಂಚಲಾಗುತ್ಿದ .
ಗ ರಪ್ ಎ IV ಪ್ಾಯರಾಸಿಟಮಾಲ್ 15 ಮಿಗಾರಂ/ಕ ಜಿ ಅನುನ ಶಸ್ತ್ರಚಿಕಿತ್ಾಿ ಛ ಿೀದನಕ ಿ 30 ನಿಮಿಷಗಳ ಮೊದಲ್ು 100 ಮಿಲಿ ಎನ್.ಎರ್ಸ ಗ ಸ ಿೀರಿಸ್ತ್ಾ ಗುತ್ಿದ .

ಗುಂಪು ಬಿ 100 ಮಿಲಿ ಎನ್ಎರ್ಸ ನಿಿೀಡಲಾಗುರ್ುದು.
ಶಸ್ತ್ರಚಿಕಿತ್ ಿಯ ನಂತ್ರದ ನ ಿೀರ್ುನ ವಿ ಎ ಎರ್ಸ ಸ ಿಿೀರ್ ಬಳಸಿ 6,12,24 ಮ್ುಿ 48 ಗಂಟ ಗಳ ಶಸ್ತ್ರಚಿಕಿತ್ ಿಯ ನಂತ್ರ ಹ ಿೀಲಿಸ್ತ್ಾ ಗುತ್ಿದ . ಪ್ಾರುಗಾಣಿಕಾ ನ ಿೇರ್ು ನಿವಾರಕ ಅಗತ್ಯವಿರುರ್ ಅರ್ಿಯನುನ ಸ್ಹ ಹ ಿೀಲಿಸ್ತ್ಾ ಗುತ್ಿದ .

ಅಧ್ಯಯನದಲಿಿ ಭಾಗರ್ಹಿಸ್ತುವಿಕ ಯಂದ ಹಿಂತ್ ಗ ದುಕ ಳುವಿಕ :

ಈ ಅಧ್ಯಯನದಲಿಿ ಭಾಗರ್ಹಿಸ್ತುವಿಕ ಯು ಸ್ವಯಂಪ್ ರೇರಿತ್ವಾಗಿದ . ಒಮ್ಮಮ ದಾಖಲಾದ ನಂತ್ರ ಈ ಅಧ್ಯಯನದಲಿಿ ಭಾಗರ್ಹಿಸ್ತ್ಬ ಿೇಕ ಅಥವಾ ಭಾಗರ್ಹಿಸ್ತುವಿಕ ಯನುನ ಮ್ುಂದುರ್ರಿಸ್ತ್ಬ ಿೇಕ ಎಂದು ನಿರ್ಿರಿಸ್ತ್ಲ್ು ನಿಿೀರ್ು ಸ್ವತ್ಂತ್ರರಾಗಿರುತಿಿೀರಿ. ನಿಮ್ಮ ಭಾಗರ್ಹಿಸ್ತುವಿಕ ಯನುನ

ಹಿಂತ್ ಗ ದುಕ ಳುಲ್ು ನಿ್ೀರ್ು ನಿಧ್್ರಿಸಿದರ , ಹಾಗ ಮಾಡಲ್ು ನಿ್ೀರ್ು ಸ್ವತ್ಂತ್ರರು. ಆದಾಗ ಯ, ದಯವಿಟು್ ನಿಧಾ್ರರ್ುನ ಪರಧಾನ ತ್ನಿಖಾಧಿಕಾರಿಗ ತಿಳಿಸಿ.

ಅಧ್ಯಯನದಲ್ಿ ಭಾಗರ್ಿಸ್ತ್ುರ್ುದರಿಂದ ಸ್ತ್ಂಭನಿ್ೀಯ ಪರಯೇಜನಗಳು:

ಶಸ್ತ್ರಚಿಕಿತ್ ್ಯ ನಂತ್ರ ಶಸ್ತ್ರಚಿಕಿತ್ ್ಯ ನಂತ್ರದ ನ ್ೀರ್ುನ ಕಡಿಮ್ಮ ಮಾಡುರ್ ಮ್ ಲ್ಕ ಅಧ್ಯಯನರ್ು ನಿಮ್ಗ ಪರಯೇಜನರ್ುನ ನಿ್ೀಡುತ್್ದ ಮ್ತ್ುು ಹ ಚಿ್ನ ನ ್ೀರ್ು ನಿವಾರಕಗಳ ಬಳಕ ಯನುನ ತ್ದ ಯುತ್್ದ . ಸ್ತ್ಂಗರಹಿಸಿದ ಮಾಹಿತಿಯು ಜನಸ್ತ್ಂಖ ಯಗ ದ ಡಡ ಪರಮಾಣದಲ್ಿ ಸ್ತಾ್ಂ ಯ ಮಾಡುತ್್ದ .

ಅಧ್ಯಯನದಲ್ಿ ಭಾಗರ್ಿಸ್ತ್ುರ್ುದರಿಂದ ಸ್ತ್ಂಭನಿ್ೀಯ ಅಪ್ಾಯಗಳು:ಈಅಧ್ಯಯನದಲ್ಿಭಾಗರ್ಿಸ್ತ್ುಲ್ಿಕನಿಷಠಅಪ್ಾಯಗಳಿಲ್ಿ.ಆದಾಗ ಯಔಷಧ್ದಕಲ್ಪುಪರತಿಕ ಲ್ಪರಿಣಾಮ್ಗಳನುನಉಸಿರಾಟದ

ಮಾದರಿಯಲ್ಿ ಬದಲಾರ್ಣ , ಹೃದಯ ಬಡಿತ್ ಅಥವಾ ಔಷಧ್ಕ ್ ಅತಿಸ್ತ್ ಕ್ಷ್ಮತ್ ಎಂದು ನಿರಿ್ೀಕ್ಷಸ್ತ್ಬಹುದು. ಗೌಪ್ಯತೆ

ಯಾರ್ುದ ್ೀ ರ್ಯಕ್ತಿ ನಿಮ್ಮನುನ ಗುರುತಿಸ್ತ್ಂತ್ ತ್ದ ಯಲ್ು ನಿಮಿಮಂದ ಸ್ತ್ಂಗರಹಿಸಿದ ಮಾಹಿತಿಯನುನ ಕ ್ೀಡ್ ಮಾಡಲಾಗುತ್್ದ . ನಿಮ್ಮ ಗುರುತ್ನ ಎಂದಿಗ ಬಹಿರಂಗಪಡಿಸ್ತಾ್ಲ್ ಗುರ್ುದಿಲ್ಿ. ನಿಮಿಮಂದ ಸ್ತ್ಂಗರಹಿಸಿದ ಡ ್ೀಟಾರ್ುನ ಗೌಪಯವಾಗಿ ಇರಿಸ್ತಾ್ಲ್ ಗುತ್್ದ ಮ್ತ್ುು ಪರಕಿರಯೆಗ ಳಿಸಿದ ಅಥವಾ ಒಟುು್ಗ ಡಿದ ಡ ್ೀಟಾರ್ುನ ಮಾತ್ರ ಪರಕಟಣ ಗಾಗಿ ಬಳಸ್ತಾ್ಲ್ ಗುತ್್ದ .

ಆರ್ಥ್ಕ ಪ್ರೇತ್ಾ್ಹಗಳು:
ಈ ಅಧ್ಯಯನದಲ್ಿ ಭಾಗರ್ಿಸಿದದಕಾ್ಗಿ ನಿ್ೀರ್ು ಯಾರ್ುದ ್ೀ ಪ್ಾರ್ತಿಯನುನ ಸಿವೇಕರಿಸ್ತ್ುರ್ುದಿಲ್ಿ.

ಅಧ್ಯಯನದ ಅರ್ಧಿಯಲ್ಿ ಮಾಡಿದ ತ್ನಿಖಗಳ ವಚಿರ್ುನ ಪರಧಾನ ತ್ನಿಖಾಧಿಕಾರಿ ಪ್ಾರ್ತಿಸ್ತ್ುತ್ಾ್ರ. ಒಟುು್ಗ ಡಿದ ಡ ್ೀಟಾದ ಪರಕಟಣ ಗ ಅಧಿಕಾರ:

ಒಟುು್ಗ ಡಿದ ಡ ್ೀಟಾರ್ುನ ಪರಕಿರಯೆಗ ಳಿಸಿದ ನಂತ್ರ ಪಡ ದ ಫಲಿತ್ಾ್ಂಶಗಳನುನ ವ ್ೈಜ್ಞಾನಿಕ ಉದ ದೇಶಗಳಿಗಾಗಿ ಪರಕಟಿಸ್ತಾ್ಲ್ ಗುತ್್ದ ಅಥವಾ ವ ್ೈಜ್ಞಾನಿಕ ಗುಂಪುಗಳಿಗ ಪರಸ್ತ್ುು್ತ್ಪಡಿಸ್ತಾ್ಲ್ ಗುತ್್ದ . ಆದಾಗ ಯ, ನಿಮ್ಮ ಗುರುತ್ನ ಎಂದಿಗ ಬಹಿರಂಗಪಡಿಸ್ತಾ್ಲ್ ಗುರ್ುದಿಲ್ಿ.

ಪ್ರಶ್ನೆಗಳು

ಈ ಅಧ್ಯಯನಕ್ಕೆ ಸ್ಂಬಂಧಿಸಿದಂತ್ ಯಾರ್ುದ್ೇ ಪರಶ್ ನಗಳಿದದಲ್ಲಿ, ನ್ೀವ್ು ಸ್ಂಪಕ್ಿಸ್ಲ್ು ಮ್ುಕಿರಾಗಿರುತ್ತೀರಿ: ಅಧ್ಯಯನದಲ್ಲಿ ಭಾಗರ್ಿಸ್ುರ್ ನಿಮ್ಮ ಹಕ್ಿನ ಕುರಿತ್ು ನ್ೀವ್ು ಯಾರ್ುದ್ೇ ಪರಶ್ ನಗಳನುನ ಹ ಂದಿದದರ ಅಥವಾ ದ ರುಗಳನುನ ಹ ಂದಿದದರ .

ನಿಮ್ಮಲ್ಲಿ ಯಾರ್ುದ್ೇ ಪರಶ್ ನಗಳಿದದರ ಅಥವಾ ದ ರುಗಳಿದದರ ಅಧ್ಯಯನದಲ್ಲಿ ಭಾಗರ್ಿಸ್ುರ್ ನಿಮ್ಮ ಹಕ್ಿಗ ಸ್ಂಬಂಧಿಸಿದಂತ್ ನ್ೀವ್ು
ಡಾ ಹಷ್ ಹ ಗಡ , ಅಧ್ಯಕ್ಷರು, ಜ ಎನ್ ಎಂಸಿ ನ ನ ್ೈತಿಕ ಸ್ಥಿತಿ, 0831-2473777 ವಿಸ್ತ್ೀರಣ 4052 ಅನುನ ಸ್ಂಪಕ್ಿಸ್ಬಹುದು.

ಕಾನ ನುಹಕು್ಗಳು:
ಈ ಸ್ಥತಿಯ ನಮ್ ನ ಗ ಸ್ಹಿ ಮಾಡುರ್ ಮ್ ಲ್ಕ, ನಿಮ್ಮ ಯಾರ್ುದ್ೇ ಕಾನ ನು ಹಕು್ಗಳನುನ ನಾರ್ು ಕ ್ೈ ಬಿ್ೇಸಿ ಕರ ಯುತ್ತಿಲ್ಲ.

ಸ್ಮತಿ ಹ ಿೀಳಿಕ

ನಾನು ಅಧ್ಯಯನದಲಿ ಿ ಭಾಗರ್ಹಿಸ್ಲ್ಲು ಸ್ವಯಂಪ್ ರೇರಿತ್ ನಿಧಾ್ರರ್ನು ಮಾಡುತಿ ಿದ ದೇನ
ಅಧ್ಯಯನದ ಶೇಷ್ಕ್ಯ : ಏಕಪಕ್ಷೇಯ
ಲಿಚ್ ಿನ್ಸ ಿಿಿೃನ್ನ ಇಂಜಿನಲ್ ಅಂಡವಾಯು ದುರಸಿ ಿ ಶಸ್ತ್ರಚಿಕಿತ್ ಿ, ಯಾದೃಚಿ ಿಕ, ನಿಯಂತ್ರಣ
ಪರಯೇಗದಲಿ ಿ IV
ಪ್ಾಯರಾಸಿಟಮಾಲ್ನ ಂದಿಗ ಪೂರ್ ್ಭಾವಿ ನ ಿೀರ್ು ನಿವಾರಕ ನಂತ್ರದ ಶಸ್ತ್ರಚಿಕಿತ್ ಿಯ
ನಂತ್ರದ ನ ಿೀವಿನ ಮೌಲ್ಯಮಾಪನ. ಕ ಳಗಿನ ನನನ ಸ್ಥಿ ನಾನು ಭಾಗರ್ಹಿಸ್ಲ್ಲು ನಿಧ್ ್ರಿಸಿದ ದೇನ
ಮ್ತ್ತು ಿ ನಾನು ಮೈೀಲ ಒದಗಿಸಿದ ಮಾಹಿತಿಯನುನ ಓದಿದ ದೇನ ಅಥವಾ ಮೈೀಲ ಒದಗಿಸಿದ
ಮಾಹಿತಿಯನುನ ನನಗ ಚ್ ನಾನಗಿ ಅರ್ಥ್ವಾಗುರ್ ಭಾಷ ಯಲಿ ಿ ಓದಲಾಗಿದ ಎಂದು ಸ್ಪ್ ಚಿಸ್ತ್ತುತ್ ಿದ .
ಪರಶ್ ನಗಳನುನ ಕ ಿೀಳಲ್ು ನನಗ ಅರ್ಕಾಶರ್ುನ ನಿ ಿೀಡಲಾಯತ್ು ಮ್ತ್ತು ಿ ಅರ್ುಗಳಿಗ
ನನನ ತ್ೃಪ್ತಿಗ ಉತ್ ಿರಿಸ್ಲ್ಲಾಗಿದ .

ಭಾಗರ್ಹಿಸ್ತ್ುರ್ರ್ಹ ಸ್ತ್ರು:
ಭಾಗರ್ಹಿಸ್ತ್ುರ್ರ್ಸ್ಥಿ ಅಥವಾ ಎಡ ಹಬೆರಳಿನ ಗುರುತ್ು: ಸಾಕ್ಷಯ ಹಸ್ತ್ರು:
ಸಾಕ್ಷಯ ಸ್ಥಿ ಅಥವಾ ಎಡ ಹಬೆರಳಿನ ಗುರುತ್ು: ತ್ನಿಖಾಧಿಕಾರಿಯ ಹಸ್ತ್ರು:
ತ್ನಿಖಾಧಿಕಾರಿಯ ಸ್ಥಿ :

ANNEXURE 02- PROFORMA

Personal Information

FULL NAME

ADDRESS

TEL

AGE/SEX

IP NUMBER

WEIGHT

CHIEF COMPLAINS

DOA/DOD

DIAGNOSIS

COMORBIDITIES

PROCEDURE PLANNED- Open Lichtenstein's Hernia Repair Surgery

ANAESTHESIA- Spinal Anaesthesia

ANTIBIOTIC GIVEN- Inj Xone 1gm

STARTING TIME

FINISHING TIME

OTHER MEDICATIONS GIVEN DURING SURGERY

SUBJECT/CONTROL

SERIAL NUMBER

CONSENT

FOR SUBJECT-

PARACETAMOL TIME

DOSE - 15 mg/kg

CALCULATED DOSE

ADVERSE EFFECTS

FOR CONTROL-

PLACEBO- 100ml NS

POSTOPERATIVE PAIN SCORES OF PATIENTS AND NEED FOR RESCUE ANALGESIA-

1. **Total standard analgesia-**

2. **Total rescue analgesia-**

Time	Pain score	Standard analgesia	Rescue analgesia
6hrs			
12hrs			
24 hrs			
36 hrs			
48 hrs			
72 hrs			

EXAMINATION OF SUTURE SITE AFTER 72 HRS-

ADVERSE EVENTS-

DISCUSSION-

ANNEXURE 03- PHOTOGRAPHS

Figure 03- Injection Paracetamol (1amp=325mg)

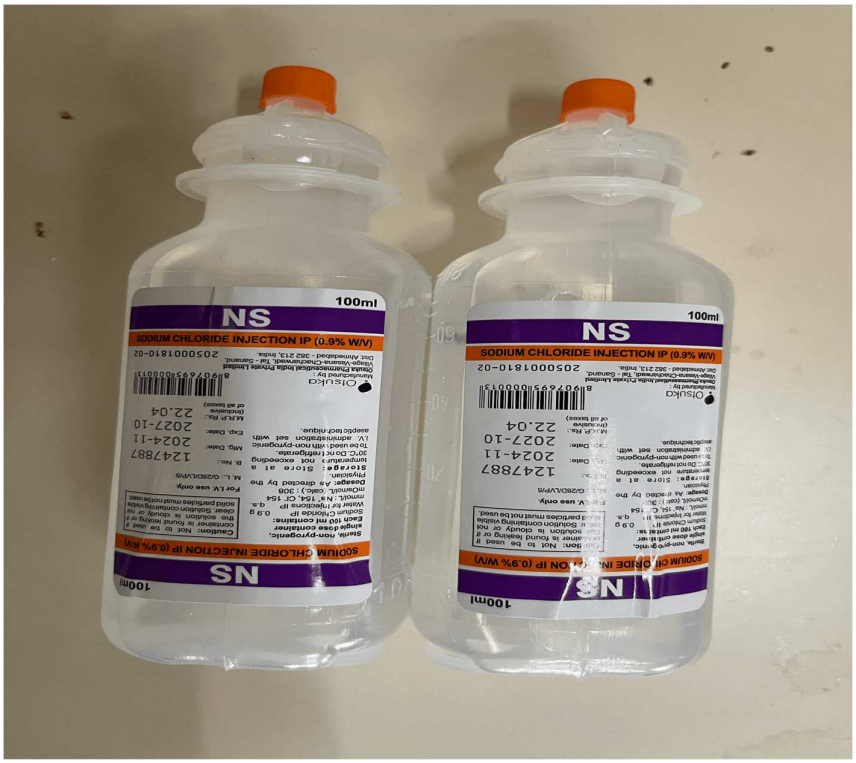

Figure 04- Normal Saline 100ml

Figure 05- patient receiving 100ml NS before 30 minutes

ANNEXURE 04-

MASTER CHART

MASTER CHART Control

Patient Details							Pain Scores						Total PCT doses	Total Tramadol doses
Serial i	IP Number	Age	Sex	Diagnosis	Weight	Comorbid	6 hrs	12 hrs	24 hrs	36 hrs	48 hrs	72 hrs		
1	10034331	26	M	Left indirect inguinal hernia	55kg	-	4	3	2	1	1	1	2 DOSES	
2	10033785	19	M	Left indirect inguinal hernia	50KG	-	4	4	3	3	2	1	6 DOSES	2 DOSES
3	10032811	31	M	Left indirect inguinal hernia	58KG	-	3	1	1	0	0	0	1 DOSE	
4	10032280	40	M	Right indirect inguinal hernia	50KG	-	3	2	1	1	0	0	1 DOSE	
5	10027920	45	M	Left indirect inguinal hernia	60KG	-	4	4	3	2	1	1	4 DOSES	
6	10001708	54	M	right direct inguinal hernia	65KG	-	4	3	2	2	2	1	4 DOSES	
7	10008924	48	M	right pantaloon hernia	65KG	-	4	4	3	3	2	2	5 DOSES	2 DOSES
8	10013137	20	M	Left indirect inguinal hernia	68KG	DM	4	4	4	3	3	2	8 DOSES	2 DOSES
9	10001632	72	M	Right indirect inguinal hernia	48KG	-	4	4	3	3	2	2	5 DOSES	2 DOSES
10	10019520	56	M	left direct inguinal hernia	70KG	DM,HTN	4	4	3	3	2	2	8 DOSES	2 DOSES
11	10014097	59	M	right direct inguinal hernia	62KG	-	4	3	3	2	1	1	5 DOSES	1 DOSE
12	10028521	59	M	Right indirect inguinal hernia	60KG	DM	4	3	3	1	1	1	4 DOSES	
13	10046838	74	M	Left indirect inguinal hernia	60KG	-	4	3	2	1	1	1	2 DOSES	
14	10043813	55	M	right direct inguinal hernia	70KG	HTN	3	3	3	2	2	1	6 DOSES	
15	10043763	67	M	right direct inguinal hernia	55KG	-	4	3	3	2	1	1	3 DOSES	1 DOSE
16	10038905	19	M	left direct inguinal hernia	65KG	-	4	4	3	2	1	1	4 DOSES	
17	10073297	56	M	left direct inguinal hernia	40KG	-	3	2	1	1	0	0	2 DOSES	
18	10071220	60	M	Right indirect inguinal hernia	56KG	HTN	4	3	2	1	1	1	2 DOSES	
19	10062512	50	M	Right indirect inguinal hernia	72KG	DM	4	3	2	1	1	1	3 DOSES	1 DOSE
20	10069403	42	M	right direct inguinal hernia	70KG	HTN	4	4	3	2	1	1	5 DOSES	1 DOSE
21	10067831	70	M	Left indirect inguinal hernia	60KG	-	4	3	2	1	1	1	3 DOSES	
22	10068079	69	M	Right indirect inguinal hernia	58KG	HTN	4	4	3	2	1	1	4 DOSES	2 DOSES
23	10065615	62	M	left pantaloon hernia	50KG	DM,HTN,I	4	3	2	1	1	1	4 DOSES	1 DOSE
24	10065128	50	M	right direct inguinal hernia	45kg	DM,HTN	4	4	3	3	3	2	6 DOSES	2 DOSES
25	10046846	28	M	right direct inguinal hernia	50kg	-	3	2	1	1	1	1	2 DOSES	
26	10055371	50	M	Left indirect inguinal hernia	50kg	-	4	3	2	1	1	1	4 DOSES	
27	10063550	58	M	left direct inguinal hernia	80kg	DM	4	3	2	1	1	2	8 DOSES	3 DOSES
28	10069672	30	M	Right indirect inguinal hernia	58kg	-	4	3	2	1	1	1	4 DOSES	1 DOSE

MASTER CHART Intervention

Patient Details									Pain Scores						Total PCT doses	Total Tramadol doses
Serial number	IP Number	Age	Sex	Diagnosis	Weight	Comorbidities	Paracetamol dose	Duration of Surgery	6 hrs	12 hrs	24 hrs	36 hrs	48 hrs	72 hrs		
1	10026482	59	male	right indirect inguinal hernia	65kg	DM	975mg	60 min	4	3	3	2	1	1	4 doses	0
2	10031247	70	male	right direct inguinal hernia	70kg	HTN	1050mg	60 min	4	3	2	1	1	1	4 doses	0
3	10019680	60	male	left indirect inguinal hernia	50kg	-	750mg	90 min	3	2	1	1	1	1	1 dose	0
4	10026420	70	male	right direct inguinal hernia	55kg	HTN	825mg	60 min	4	3	2	2	1	1	4 doses	0
5	10027201	50	male	right indirect inguinal hernia	60kg	-	900mg	90 min	3	2	2	1	1	1	2 doses	0
6	10031050	62	male	right indirect inguinal hernia	62kg	-	930mg	60 min	3	2	1	1	1	1	2 doses	0
7	10028152	61	male	right direct inguinal hernia	65kg	HTN,DM	975mg	60min	4	4	3	2	1	1	5 doses	1 dose
8	10024325	55	male	right indirect inguinal hernia	60kg	-	900mg	60min	2	1	1	1	1	1	2 doses	0
9	10014077	56	male	right pantaloon inguinal hernia	65kg	DM, HTN	975mg	60min	4	3	3	2	1	1	6 doses	2 doses
10	10011191	46	male	left direct inguinal hernia	62kg	-	930mg	60min	4	3	2	2	1	0	3 doses	0
11	1188109	35	male	left direct inguinal hernia	55kg	-	825mg	90 min	4	4	4	3	3	2	2 doses	2 doses
12	10013158	50	male	right indirect inguinal hernia	70kg	-	1050mg	60min	3	2	2	2	1	1	2 doses	0
13	10014864	50	male	right pantaloon inguinal hernia	72kg	-	1080mg	60min	3	2	1	1	0	0	2 doses	0
14	10039341	43	male	right indirect inguinal hernia	45kg	-	675mg	60min	4	4	3	1	1	1	4 doses	2 doses
15	10068211	20	male	left direct inguinal hernia	70kg	HTN	1050mg	45 min	4	3	2	1	1	1	4 dooses	0
16	10069872	58	male	right indirect inguinal hernia	60kg	-	900mg	60min	3	3	2	1	1	1	3 doses	0
17	10055371	20	male	left indirect inguinal hernia	55kg	-	825mg	60min	4	3	1	1	1	1	2 doses	0
18	10046846	50	male	right direct inguinal hernia	56kg	-	750mg	60min	4	3	3	1	1	1	3 doses	1 dose
19	10040022	65	male	left indirect inguinal hernia	60kg	-	900mg	60min	3	2	1	1	0	0	2 doses	0
20	10045530	60	male	right direct inguinal hernia	60kg	DM	900mg	60min	4	3	2	2	1	1	5 doses	1 dose
21	10051859	67	male	left indirect inguinal hernia	62kg	-	930mg	60min	4	2	2	1	1	1	2 doses	0
22	10050356	55	male	right direct inguinal hernia	65kg	-	975mg	60min	4	3	1	1	1	1	2 doses	0
23	10053794	62	male	right direct inguinal hernia	60kg	HTN	900mg	60min	4	4	3	2	1	1	5 doses	3 doses
24	10053773	60	male	left indirect inguinal hernia	60kg	-	900mg	60min	4	3	2	1	1	1	3 doses	1 dose
25	10055442	70	male	right direct inguinal hernia	70kg	DM,HTN	1050mg	60min	4	3	2	1	1	1	3 doses	0
26	10065968	32	male	left indirect inguinal hernia	62kg	-	930mg	60min	3	2	1	1	1	1	2 doses	0
27	10069999	58	male	right indirect inguinal hernia	60kg	-	900mg		4	2	2	1	1	1	3 dosses	0
28	10045486	23	male	right indirect inguinal hernia	56kg	-	840mg	60min	3	2	1	1	1	1	2 doses	0