"COMPARISION OF INTRA INCISIONAL INSTILLATION OF BUPIVACAINE WITH NORMAL SALINE INTO THE WOUND FOR POST OPERATIVE ANALGESIA. A 1 YEAR HOSPITAL BASED RCT STUDY AT KLES DR. PRABHAKAR KORE HOSPITAL AND MRC."

By

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LIST OF ABBREVIATIONS:

IASP	-	International Association for the Study of Pain
NHS	-	National Heath Services
CNS	-	Central Nervous System
PNS	-	Peripheral Nervous System
NMDA	-	N-methyl-D-aspartic acid
CABG	-	Coronary Artery Bypass Graft
LSCS	-	Lower Section Caesarian Section
GA	-	General Anaesthesia
SAB	-	Spinal Anesthesia Block
POD	-	Post Operative 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

ABSTRACT

Introduction: A hernia is defined as protrusion of whole or a part of a viscus through the wall that contains it. Pain is described by the International Association for the Study of Pain as "an unpleasant sensory and emotional experience related to actual or potential tissue damage or described in terms of such damage. [25]The reporting of post-operative pain and discomfort seems to be on the rise, which is one of the perceived drawbacks of this kind of repair. Inguinal hernia pain that persists after surgery can be very painful and incapacitating. It affects the person negatively in terms of quality of life and work. The present study has been carried out with an aim to compare the efficacy of bupivacaine with normal saline (placebo) instillation into the incisional wound following hernia surgery and requirement of analgesia in the two groups as a part of multi modal analgesia.

Materials and Methods:

Study design = Randomized control Trial

Inclusion criteria-

- All cases of elective uncomplicated inguinal hernia.

Exclusion criteria-

- Complicated inguinal hernia.
- Pediatric age group (less than 18 years) and geriatric age group (more than 65 years).

Study period: 1 year

Sample size – total sample size of 58 cases, 29 in group A and the other 29 in group B (allotted by random sampling: SNOSE)

Continuous infusion pumps are a quick and efficient way of postoperative wound infiltration. Continuous infusion pumps specially designed for postoperative patient-controlled analgesia (PCA). PCA pumps enable the delivery of continuous medication dosages that offer adequate analgesia during periods of rest and an additional dose during periods of daily activity.

All the patients undergoing operations for inguinal hernia after the closure of external oblique aponeurosis an infant feeding tube will be inserted in the subcutaneous plane which will be attached to infusion pump. 29 patients will be given bupivacaine 4 mg/kg for 72 hours through the infant feeding tube via infusion pump. The other 29 patients will be given normal saline through the infant feeding tube via infusion pump.

Results: The mean age (years) was 41.45 ± 11.79 in the study population, ranged between 18 to 60 years. Comparison of pain scores (VAS) at different follow -ups between study group at 6 hours had p value of 0.249 and was statistically insignificant. At 12, 24, 48 and 72 hours, the difference of post-operative pain between two groups was statistically significant ($p<0.001$). Length of Hospital stay as significantly less in the intervention group.

TABLE OF CONTENTS

SL.NO	CONTENTS	PAGE NO.
1	INTRODUCTION	1-11
2	OBJECTIVE	12
3	REVIEW OF LITERATURE	13-23
4	METHODOLOGY	24
5	RESULT	29
6	DISCUSSION	30-43
7	CONCLUSION	44-47
8	SUMMARY	48
8	BIBLIOGRAPHY	49
9	ANNEXURES	50-58
10	ANNEXURE I: CONSENT FORM	59-73
	ANNEXURE II: PROFORMA	59-65
	ANNEXURE III: MASTER CHART	66-71

LIST OF TABLES

Table No	Table Description	Page No.
Table 1	Descriptive analysis of study group in the study population	**31**
Table 2	Comparison of mean of age between study group	**32**
Table 3	Comparison of gender between study group	**32**
Table 4	Comparison of diagnosis between study group	**33**
Table 5	Comparison of pain scores (VAS) at different follow -ups between study group	**34**
Table 6	Comparison of median pain score (VAS) between the study groups at different follow-up time periods	**41**
Table 7	Comparison of mean of hospital stay (days) between study group	**41**
Table 8	Comparison of wound infection between study group	**42**

LIST OF FIGURES

Figure No	Figure Description	Page No.
A	Figure of anatomy of pelvis	**7**
A.2	Contents of Inguinal Canal	**8**
1	Bar chart of study group in the study population	**31**
2	Staked bar chart of comparison of pain scores (VAS) at 6 Hours between study group	**36**
3	Staked bar chart of comparison of pain scores (VAS) at 12 Hours between study group	**37**
4	Staked bar chart of comparison of pain scores (VAS) at 24 Hours between study group	**38**
5	Staked bar chart of comparison of pain scores (VAS) at 48 Hours between study group	**39**
6	Staked bar chart of comparison of pain scores (VAS) at 72 Hours between study group	**40**
7	Staked bar chart of comparison of wound infection between study group	**42**
8	Staked bar chart of comparison of Opioid Usage between study group	**43**
9	Staked bar chart of comparison of Nsaid Usage between study group	**43**

LIST OF PHOTOGRAPHS

SL.NO	FIGURE DESCRIPTION	PAGE.NO
1.	Picture showing the full setup of bupivacaine infiltration via infusion pump infiltrating the wound.	**27**
2.	Bupivacaine infusion through an infusion pump as per the weight of the patient.	**27**
3.	Picture showing infant feeding tube into the wound site connected to IV set.	**28**
4.	Intra operative picture showing insertion of infant feeding tube into subcutaneous plain after closing the external oblique aponeurosis.	**28**
5.	0.5% bupivacaine used in the study.	**30**

INTRODUCTION

A hernia is defined as protrusion of whole or a part of a viscus through the wall that contains it. The resulting bulge can cause pain when you cough, bend over, or lift something heavy. Many hernias, though, are painless. An inguinal hernia is not always harmful. However, it does not improve on its own, and complications that could be fatal can develop. An inguinal hernia repair is a common surgical procedure. Approximately 96% of groin hernias are inguinal hernias, with 4% being femoral hernia. In 80% cases, hernias are unilateral. Inguinal hernias, the most prevalent abdominal wall hernia, are nine to one more common in men than in women. Women are more likely to develop femoral hernias.[1]The most frequent and harmful complication following inguinal hernia repair is chronic pain. The signs and symptoms of inguinal hernia include:

i) A bulge on either side of pubic bone that is more noticeable when standing up, particularly if coughing or straining is present.
ii) An aching or burning pain at the bulge
iii) Discomfort or pain in groin, particularly when crouching, coughing, or lifting
iv) A feeling of heaviness or dragging in groin
v) Pressure or weakness in groin
vi) Occasionally, the protruding intestine will descend into the scrotum and cause pain and swelling around the testicles.

Definition of pain; what is chronic pain?

Pain is described by the International Association for the Study of Pain as "an unpleasant sensory and emotional experience related to actual or potential tissue damage or described in terms of such damage." According to this definition, pain just does not have physiological basis but affects human psychology and also subjective component. The majority of authors define the transition between acute and chronic pain in terms of time.[2]Although these distinctions are arbitrary; the measurement is done usually at in interval of 3 to 6 months. Chronic pain is defined as discomfort that lasts longer than the typical recovery period, which is typically thought to be three months. The "appropriateness" of the disorder is a further characteristic taken into account by the IASP. Acute pain has a benefit for the person because it helps for rest and the healing to start. There is no biological benefit to experience chronic pain, i.e., no benefit to the person who is experiencing it. Chronic pain is described as "that which persists beyond the expected time frame for healing or that which occurs in disease processes in which healing may never occur" by NHS.[3] So, a flawed healing process could be the cause of chronic pain. It may be relentless and enduring with no positive effects for the person experiencing it. The distinctions between acute and chronic pain have been highlighted by Sternbach, who contends that “while acute pain is a symptom of disease, chronic pain is the disease itself”. Classifying pain is difficult. The classification is, at best, unclear and inconsistent. There are many different ways to categorize the pain because there is no universal agreement. Anatomy, duration, etiology, body system, and severity are all are used as criterion for the classification of pain.[4,5] Portenoy classified pain as nociceptive, neuropathic, or psychogenic for both acute and chronic conditions.[6]

Nociceptive afferent neurons, which can be somatic or visceral, become persistently activated and produce nociceptive pain. The unpleasant sensation represents the typical, adaptive response of the body in cases of nociceptive pain and pain brought on by tissue inflammation.[7] According to the IASP, neuropathic pain is described as pain that is brought on by or results from a primary nervous system lesion or dysfunction.[8] Persistent insult to the PNS can cause neuronal plasticity which may result in the so called deafferentation syndrome or chronic neuropathic pain. [9] "Niv and Devor" have described neuropathic pain as a "fundamental paradox" as even after injury/insult to the pathway the pain signal paradoxically increases.[7] They contend that it's critical to keep in mind that the conduction pathways we refer to are actually extensions of protoplasm of living cells called neurons, and these cells react actively to injury by changing their biological characteristics.

Pathophysiology of chronic pain

Melzack and Wall's papers from the latter half of the 20th century, which addressed the neurophysiology of pain, may be their most significant works .[10,11] 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. 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.[12]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.

Chronic pain in relation to surgery

Unexpected negative outcomes from surgical procedures can include chronic pain.

The chronic pain, whether it is of benign condition or malignant, can also be treated surgically. A latest study evaluated the results of surgery for chronic pancreatitis with various etiologies. Degree of pain control was one way to gauge the postoperative results. The writers recommend that resection be performed if necessary due to anatomical situations as it is linked to better and longer pain control, with 71.4 percent achieving total control of pain up to 6 yrs after the surgery. Variety of surgical options are available to address the pancreatitis-related chronic pain, and no one surgical approach is better than the others. [13] 18% of women in research that looked at the outcomes of women who underwent hysterectomy surgery for benign diseases underwent the procedure for ongoing pelvic pain. Improvement as reported in symptoms like lower abdominal pain and co-existing symptoms post-surgery. [14] These authors reach the consensus that, while there is some evidence that presacral neurectomy at the time of hysterectomy offers benefit for midline pain, rather than hysterectomy alone, especially in endometriosis.[15] It's also widely acknowledged that malignant processes often include chronic pain. According to research, people with

cancer report more physical hindrance than people with benign chronic pain even though it may be of the same intensity.[16] Over a ten-year period, the anterolateral open cordotomy procedure was assessed for intractable cancer pain. Over the course of three years or until death, the impact of this the same was assessed. The findings demonstrated that at discharge, 95% of survivors experienced an effective pain relief, which decreased to 3/4ths at 6 months and to almost half at the end of 1 year.[17] The 1st research to quantitatively compare chronic post-surgical pain in heterogeneous populations using comparable methodologies was published in 2004.[18] According to this study, there were striking similarities in the prevalence and characteristics of chronic pain among various operative groups. The surgical procedures examined included CABG, inguinal hernia repair, and mastectomy. In this retrospective study, patients who underwent surgery ten years ago were compared for chronic postoperative pain. In this study, 30% of patients with inguinal hernia repair experienced chronic pain.[18]

Adverse effects such as chronic pain after surgery as reviewed. The prevalence of phantom limb pain is estimated to range between 30 and 81 percent. A 60 percent overall incidence rate for stump pain indicates how widespread it is. The incidence of post-thoracotomy pain syndrome is estimated to be around 50%.[20] Following gallbladder surgery, 3-56 percent of people experience chronic abdominal pain. In a recent retrospective study, the frequency, severity, and associated factors of chronic pain were evaluated in a cohort of breast cancer patients. Pain was assessed in patients 6 months after completion of their curative treatment. Even though almost half of those with early-stage breast cancer had chronic pain after treatment, they only reported mild to moderate pain intensity. A study in patients who underwent CABG, 39.3% of people reported having chronic pain following the surgery. The overall

prevalence of chronic pain following cardiac surgery was 39.3%. In patients under the age of 60, the prevalence of chronic pain was 55%, and in patients under the age of 70, it was 34%. Patients having anginal pain prior to surgery, obese patients, and those with lower quality of life scores were more likely to report pain.[21,22] Investigations into chronic pain after caesarean sections have also been conducted 127. Patients undergoing LSCS under general anesthesia, post op pain as found to be a significant problem. [23]

Chronic pain and inguinal hernia repair

Over the past 20 years, inguinal hernia surgery has made significant advancements. However, the typical general surgeon is unsure of the best pre- and postoperative management strategies for patients with an inguinal hernia. Hernia repair techniques have changed over time from sutured to mesh repair. Meshplasty, which is the most popular type of repair, has the benefit of having a low recurrence rate (5%). [24] When an inguinal hernia is repaired using mesh rather than sutures, there is less postoperative pain.[25]The reporting of post-operative pain and discomfort seems to be on the rise, which is one of the perceived drawbacks of this kind of repair.[26-29] Inguinal hernia pain that persists after surgery can be very painful and incapacitating. It affects the person negatively in terms of quality of life and work. Burden on healthcare services is another disadvantage. Almost 3000 hernia repairs are performed per million US population. In United Kingdom, almost 70000 hernioplasties are performed annually.[30] It is a dilemma whether so many hernioplasties or herniorrhaphies are warranted given the incidence of post-herniorrhaphy pain.[31] Avoiding surgeries especially in patients with minimal symptoms due to hernia have

also been considered as per some authors. The best technique has not yet been described. [32]

Preoperative factors

Inguinal hernia repair can result in chronic groin pain, but it's also possible that the pain is coming from a hernia that wasn't previously recognized. Even a clinically small sized hernia may give rise to complaints of pain. Prior unexplained chronic groin pain has been shown to improve in the remaining cases after Lichtenstein's hernia repair in 87 percent of the cases.[33]

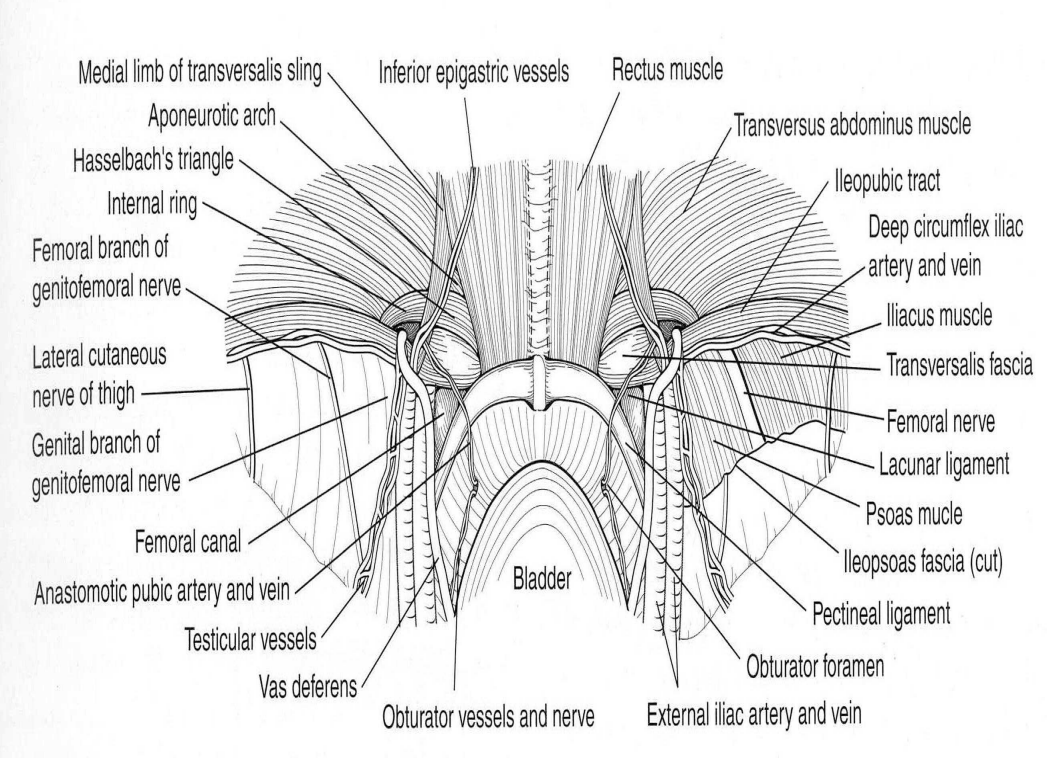


Figure A Anatomy of pelvis

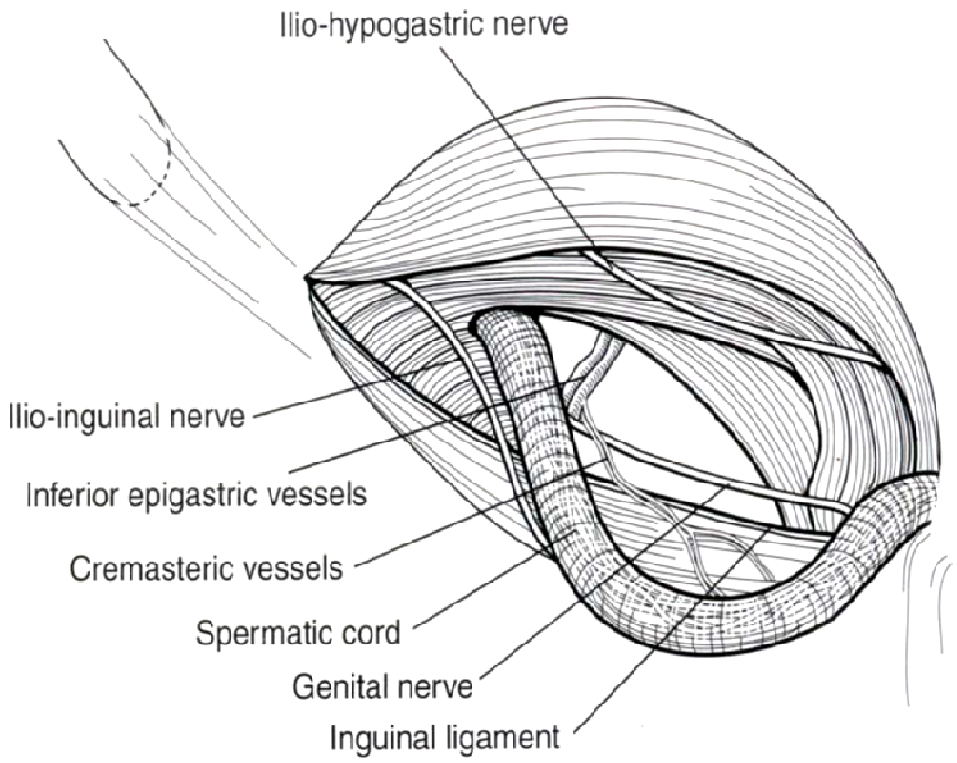


Figure A.2 Contents of Inguinal Canal

Intra-op factors

Neuropathic or nociceptive causes of chronic pain are both possible. Neuropathic pain is typically described as electric, sharp, and shooting pain and is thought to be caused by nerve damage. Contrarily, nociceptive pain, is usually described as dragging dull aching type.[34] Three anatomically and physiologically significant nerves in the groin region may play a role in the development of 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. But it

seems that things are not exactly clear. 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.

Post-operative factors affecting chronic post-surgical pain

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.

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 varies greatly. Use of analgesic drugs are usually restricted due to potential adverse effects. Uncontrolled postoperative pain has a variety of negative effects.[35] 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.[36] 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.[37]

Preemptive pain management entails taking steps to reduce the strength of pain signals entering the spinal cord before making a surgical incision.[38-40] NMDA, a

neuro-transmitter is involved in centrally stimulating nerve fibers responsible for pain, and studies on preemptive analgesia are currently focusing on antagonists of its receptors. However, none of the available NMDA antagonists, such as ketamine and amantadine, are safe to be routinely used for longer periods for analgesia due to risks associated.[41,42] The significance of adequately treating acute postoperative pain after hernia repair has been discussed in a few published reports.[41,42] However there is no convincing literature for the use of these methods over routinely used analgesic methods.[35] Additionally, the majority of research studies on preemptive analgesia's effectiveness involved people who were under general anaesthesia.[40-42] An inguinal hernia repair is a frequent procedure that can be done under GA, SAB or even local. It typically causes moderate to severe pain.[43] According to estimates, chronic postoperative pain affects 5-35 percent of patients having hernia repairs.[44] Utilizing local anesthesia has the added benefit of speeding up patient recovery and discharge while also having fewer complications. However, some procedures are carried out under general or spinal anesthesia due to patient preference or other factors. Narcotics, NSAIDS, and other painkillers are used as part of standard analgesic therapy for inguinal hernia, infiltration of local anesthetics, or centrally acting drugs are all common analgesic treatments for inguinal hernia repair.[37,43] Only a small number of studies have compared the outcomes of the various approaches used to achieve preemptive analgesia. [45] The majority of studies have so far fallen short of demonstrating the benefits of preemptive analgesia as a single mode of therapy. Reviewing all of the available techniques for preemptive analgesia, we find that local an aesthetic infiltration appears to be the simplest and safest technique despite the fact that each technique is constrained by its side effects.[46, 47]

Bupivacaine

Most multimodal analgesic regimens include local anesthetics like lidocaine, bupivacaine, and ropivacaine as essential components. They function well for inducing postoperative analgesia when given peripherally, regionally, neuraxially, and occasionally systemically. Additionally, they are less likely to produce long-term usage, misuse, or death from self-administered overdose than conventional systemic opioid analgesics. Sustained supply of bupivacaine (or another local anesthetic) by infusion catheter or reformulation has been demonstrated to be an effective part of a multimodal approach for the management of postsurgical pain in various trials (Liu et al., 2006; Dasta et al., 2012; Alter et al., 2017).[48-50] It can provide analgesia for up to 24 to 72 hours with a concurrent decrease in opioid use.

The present study has been carried out with an aim to compare the efficacy of bupivacaine with normal saline (placebo) instillation into the incisional wound following hernia surgery and requirement of analgesia in both groups as a part of multi modal analgesia.

OBJECTIVES OF THE STUDY

1. To compare the efficacy of bupivacaine with normal saline(placebo) instillation into the incisional wound following hernia surgery for control of pain by visual analogue scale and requirement of analgesia in both groups as a part of multi modal analgesia.

2. To compare the use of analgesics in patients with saline instillation v/s patients with bupivacaine instillation.

REVIEW OF LITERATURE

There is no doubt that inguinal hernia surgery is continuously developing. However, there is still uncertainty about a technique that a universally accepted. Pain is the commonest and noticeable postoperative complication among such patients. A lot of work has been done on the management of chronic postoperative pain:

Pfeiffer U et al (1991)[51]

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. On POD1 and 2, the analgesia was assessed using a visual analogue score and the amount of intramuscular morphine that was administered during the instillation period. 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 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.

Saxena SK et al (2000)[52] concluded that Bupivacaine wound infiltration is essentially a low-cost, patient-controlled analgesia method that allows the patient to safely customize his analgesic needs. Herniorrhaphy, herniotomy, appendicectomy, and breast lump excisions are the procedures that this technique is best suited for. To lessen the need for narcotic analgesics after major procedures, it may be used as a helpful adjuvant. It would not be inaccurate to say that excluding this approach from patient care might have been a mistake given how widely applicable its simplicity and usefulness are. The study included subjects undergoing variety of surgeries. We only plan on including patients undergoing hernia repair surgery.

Fredman et al (2001)[53]

In their prospective, double-blinded study evaluated the analgesic effectiveness of "patient-controlled" bupivacaine wound instillation in 50 patients being operated on the abdomen. A typical general anesthetic was used in every situation. They found that surgery through a 200 mm incision, repeatedly instilling 0.25 percent bupivacaine using a double-catheter system and an electronic Patient controlled analgesia device fails to lessen pain scores or drug requirements. However, more research is needed to determine whether wound instillation using alternative analgesic protocols is effective.

Suraseranivongse S et al (2003)[54] conducted a study to assess the effectiveness of 0.5 percent bupivacaine with epinephrine for pain relief following pediatric inguinal herniorrhaphy and hydrocelectomy during a 20- or 60-second instillation period. Following the induction of anesthesia, 103 patients (ASA physical status I or II, aged 1 to 12 years) were divided into 4 groups as part of a randomized, double-blind study. Group 1 received an injection of 0.25 mL/kg of normal saline, which was left in the

wound for 20 or 60 seconds before it was closed. Group 2 received 0.25 mL/kg of 0.5 percent bupivacaine and 5 micrograms of epinephrine, which was injected and stayed in the wound for 1/3rd of a min. Group 3 received similar quantity and dose of drug as 2nd group, but the medication stayed in the incision site for 1 minute instead. Group 4: A 0.25 percent bupivacaine and epinephrine ilioinguinal and iliohypogastric block was administered prior to surgery. Monitoring was done using the Aldrete-Kroulik recovery scores and the "Children's Hospital of Eastern Ontario Pain Scale (CHEOPS)". Patients in group 1 were more likely to need analgesics within two hours (73.1%) than other groups. In addition, group 1 had a shorter median time to first analgesic (50 minutes) than the other groups (P.0001). They concluded that after herniorrhaphy and hydrocelectomy in pediatric patients, 0.5 percent Bupivacaine with epinephrine for small instillation periods as 20 or 60 seconds can provide a good analgesic alternative. The length of action was comparable for all examined blocks.

El-Radaideh KM et al (2006)[55]

Did a study to see if SC bupivacaine alone is useful in analgesia and lowering the need for opioids for hernia wounds than SF (subfascial) and SC bupivacaine together. One of two groups was randomly assigned to sixty consecutive male patients who were having an inguinal hernia repaired. Patients in the S/C group (S; n = 30) received 10 mL of 0.25 percent bupivacaine and 10 mL of Normal Saline intravenously, while those in the combination group (C; n = 30) received 10 mL of 0.25 percent bupivacaine and 10 mL of 0.25 percent bupivacaine intravenously, respectively. The surgeon administered all injections during wound closure in a uniform manner. They found that Group S patients had significantly higher VAS pain value at 1h, 12h, and 1 day following surgery (p 0.0001). Group C had a longer first

time to analgesia (p 0.0001). Pethidine intake in groups C and S was significantly different (p = 0.003). In males undergoing open hernia repair, SF along with SC instillation of bupivacaine during wound closure prolongs the time required to first dose of analgesia, lowers the need for early postoperative opioids, and lessens pain.

Jonnavithula N et al (2009)[56] concluded that patients who received wound instillation with 20ml of 0.25% bupivacaine experienced better post- operative analgesia as compared with patients who received saline. The study was done on patients undergoing lumbar laminectomy by instilling 20 ml of normal saline or 0.25% bupivacaine into the wound for 60 sec.

Abbas MH et al (2010)[57]

Uncertainty persists regarding a trial that was done to assess the potential analgesic advantage of local anesthetic administration of the wounds and extraperitoneal region in patients in patients undergoing TEP. Adults who provided consent and were scheduled for unilateral inguinal hernia repairs with laparoscopic TEP were considered for this study. It was done to infiltrate the extraperitoneal space and abdominal incisions with 0.25 percent bupivacaine (Group I) as opposed to NS (Group 2). Using the "short-form McGill pain questionnaire" (SF-MPQ), the Present Pain Index (PPI) score, and the visual analogue scale, pain levels were evaluated at 4h and POD-1 (VAS). The need for oral and injectable analgesics were noted. To gauge their level of satisfaction with the postoperative analgesia, each patient filled out a questionnaire. There were two groups of 20 patients each: group. In terms of age, sex, BMI, and operating time, the two groups were comparable. Each group's subject experienced one minor complication. At 4 hours, and 24 hours postoperatively, there were no significant differences in the "SF-MPQ" scores, "PPI", or Visual Analog

Scale. Following surgery, parenteral and oral analgesics were both used, but with no difference in patient satisfaction.

McCarthy D et al (2012)[58]

Conducted a study mainly to evaluate the effectiveness of LIA in patients who had undergone total hip arthroplasty in comparison to no intervention, placebo, and alternative analgesic methods using the available evidence. Postoperative analgesia scores, joint function/rehab, and hospital stay were taken into account as outcomes. Reviewing the evidence that is currently available and what is known about the pharmacokinetics of local anesthetics and adjuvant medications when administered in this manner, as well as the occurrence of adverse events, were secondary goals. It was concluded that the use of local anesthesia in total hip replacement was a result from a moderate-sized clinical trial. Though local anesthesia was substantially effective, it was better to epidural analgesia, placebo and nil anesthetic.

Bharti N et al (2013)[59]

Conducted a randomized, double-blind study to compare the postoperative analgesic effects of intravenously administered clonidine and bupivacaine-infiltrated wounds. Sixty adults were randomly assigned with an ASA grade of I to II who were having an open cholecystectomy. At the conclusion of surgery, patients in group 1 (the control group) had their wounds infiltrated with 30 ml of 0.25 percent bupivacaine. Following gall bladder removal and 30 ml of 0.25 percent bupivacaine wound infiltration, patients in group 2 received 3 g kg-1 of clonidine intravenously. Patients in group 3 received 30 ml of 0.25 percent bupivacaine and 3 g kg1 of clonidine as a wound infiltration. The procedure used was a standard one for general

anesthesia. On demand, intravenous morphine and diclofenac were given for postoperative analgesia. The number of patients who required rescue analgesia, postoperative pain, and overall morphine consumption during the first 24 hours following surgery were all noted. When compared to the control group, patients receiving clonidine by either route consumed significantly less postoperative morphine (P 0.0001). Nine patients in the i.v. clonidine group and eleven patients in the wound infiltration group all required additional morphine in the control group (P = 0.002). When the control group as compared, pain scores in both clonidine groups were lower at rest for 12 hours and during coughing for 6 hours (P 0.01). Patients who received i.v. clonidine experienced higher levels of sedation (P0.001) and hypotension (P0.01) compared to other groups. When given intravenously or during bupivacaine wound infiltration, clonidine 3 mg kg-1 effectively relieved postoperative pain while lowering the need for morphine. However, wound infiltration had a lower incidence of complications.

Nesioonpour SH et al (2013)[60]

When performed with bupivacaine, it was used a long-acting local anesthetic to provide patients having inguinal hernia surgery under spinal anesthesia with preemptive analgesia, this was done to: In order to show some support for potential advantages of such a practice, research was done. In this clinical trial, local infiltration was investigated and bupivacaine spinal anesthesia was compared to a placebo for repair in patients undergoing inguinal hernia surgery. To prepare the surgical incision site, 30 patients were randomized into two groups, with 10 cc of 0.5 percent bupivacaine given in case group and 10 cc of normal saline was given in the control group. After the effects of the spinal block had worn off, patients were observed for

the use of opioids within the previous 24 hours, nausea, vomiting, and pain according to a numerical rating system. In the first 24 hours, the case group had reduced scores for pain, nausea, vomiting, and postoperative opioid use (P0.001, P = 0.005, P = 0.001, and P0.001). In the first 24 hours following surgery, the proportion of patients who requested at least one analgesic was 64.2% lesser in the case group, whereas the duration of the first analgesic demand was 67% higher in the treatment group (P 0.001 and P 0.001, respectively).

Gupta SL et al (2016)[61]

Took a randomized controlled study to contrast the analgesic effects offered by ropivacaine, a novel amino amide local anesthetic drug, with bupivacaine, a traditional long-acting local anesthetic. 90 patients scheduled for inguinal herniorrhaphy electively were randomly allocated to three groups: i.e., group I received ropivacaine value of 0.5, group II received a ropivacaine value of 0.25, and group III received a bupivacaine value of 0.25. General anesthesia was given. Before making the incision, 20 ml of drugs were injected into the surgical site: 0.5 percent ropivacaine in group I, 0.25 percent ropivacaine in group II, and 0.25 percent bupivacaine in group III. Hemodynamics were monitored intraoperatively every 15 minutes until the procedure was completed, as well as at the time of skin incision, cord cutting, and skin closure. When compared to the other groups, group R 0.25 had higher pain scores at rest, during coughing, and during movements. Additionally, group R 0.25's rescue analgesia time was reduced. At equivalent concentrations, ropivacaine is less effective than bupivacaine.

Hossam A et al (2016)[62]

Conducted a study with a comparison of the effectiveness, safety, and adverse effects of epidural infusion vs continuous wound infusion of bupivacaine for post-cesarean section analgesia utilizing the constant flow PainFusor system. A total of 60 patients with full-term pregnancies, ASA physical status I and II, ages 19 to 42, and elective caesarean sections were divided into two groups at random. All study participants underwent caesarean sections using the same general anesthesia protocol. Continuous surgical wound infiltration was administered to patients in group A, whereas continuous bupivacaine epidural infusion was administered to patients in group B. Using a visual analogue scale, pain was evaluated (VAS). As a last-resort analgesic, 75 mg of diclofenac sodium were given intramuscularly. During their entire study period, the hemodynamic parameters, respiratory parameters, and pain scores at rest did not find significant difference, according to the current study. Only patients who requested analgesia were statistically significantly more likely to be in group A's adverse effects category. Additionally, group B experienced significantly lower pain VAS scores during mobilization on the first postoperative day.

Cui *et al.* (2017)[63] 55 patients who had undergone bilateral microsurgical varicocelectomy under general anesthesia were investigated for the effectiveness and safety of 0.75% ropivacaine instillation into inguinal wounds. At 2-, 4-, and 8-hours following surgery, they discovered that the VAS pain scores and Prince Henry Pain Score in the ropivacaine-infused surgical site were significantly lower than those obtained with a placebo. The study's primary flaw was its limited sample size.

Autagavaia V et al (2019)[64]

Conducted a study to evaluate how well local anesthetic (LA) procedures reduced pain using morphine in the first 24 hours after people underwent laparoscopic ventral hernia repair (LVHR). Search terms like morphine consumption, LA, LVHR post-operative pain, a systematic review was conducted in accordance with PRISMA. Four RCTs were eligible for inclusion. In each study, bupivacaine was compared to normal saline; a study also combined epinephrine with bupivacaine. In one study, the reduction in pain scores at 24 hours was statistically significant but only small (0.08 mg), and it was likely clinically insignificant. Three trials revealed a general decline with morphine use at 24 hours.

Chhatrapati S et al (2019)[65]

Examined the effects of ropivacaine and bupivacaine when administered through surgical drains to patients receiving MRM to provide post-operative analgesia. A total of 40 cc of either bupivacaine (0.125%) or ropivacaine (0.2%) was administered through surgical drains to the patients, who were randomly divided into two groups of 30 each. Every two hours for the first 12 hours following surgery, hemodynamics and visual analogue score were compared. Unpaired t-test was used to compare qualitative and quantitative data, and Chi-Square and Fisher's Exact tests were used to compare the two types of data. In comparison to the ropivacaine group (427.9743.26 minutes), the bupivacaine group's analgesia duration was found to be noticeably longer. (512.3763.06 minutes; p 0.0001). Systolic and diastolic blood pressure were high in the bupivacaine group compared to the ropivacaine group and statistically significant, but clinically insignificant.

Atashkhoii S et al (2020)[66] the fact that pre-emptive incisional and intraperitoneal bupivacaine significantly reduced pain following major gynecologic/abdominal procedures, reduced pain upon awakening and 6 hours after surgery, and provided significant additional supplemental opioid-sparing analgesia for 24 hours. In this study, intraperitoneal and subcutaneous bupivacaine administration was linked to decreased pain ratings and a decrease in the need for meperidine within the first 24 hours following surgery. Additionally, during the 24-hour period, there was minimal nausea and vomiting.

Stamenkovic D et al (2021)[67]

Conducted a narrative review focused on the assessment of information that has been published regarding the use of single shot wound infiltration (WI) or continuous wound infiltration (CWI) in adult patients for the treatment of postoperative pain. They did not grade studies according to their level of evidence or use international criteria such as PRISMA. Authors looked for English-language abstracts in PubMed using the following search terms: "wound infiltration AND postoperative pain AND," "neurosurgery," "cardiac surgery," "trauma surgery," "emergency cases," "thoracic surgery," "abdominal surgery," "breast surgery," "thyroid surgery," "day case surgery," "urology surgery," "gynecology surgery," "orthopedics," "wound infection," and “wound bleeding” published in the past 20 years (the date of literature). After a comprehensive assessment they concluded the frequency of complications with WI techniques is low. Except for patient refusal or local infection, they have no significant contraindications and are quick, easy, and simple to perform. They also have an effect that spares opioids. According to the kind of surgical procedures being performed and the specific needs of each patient,

surgeons will probably accept and encourage using WI more frequently as new studies show the safety of infiltrative techniques.

Kumar M et al (2022)[68]

Conducted a study to evaluate and contrast the efficacy of local infiltration against bupivacaine instillation for postoperative analgesia in patients having lumbar spine surgery. 22 Adult patients undergoing lumbar spine surgery were divided randomly into two groups, patients in group A got 20 ml of 0.25 percent bupivacaine infiltration at the surgical site, while patients in group B received the same treatment but into bilateral paravertebral muscles. Postoperative pain scores were recorded at serial intervals. Time required for first analgesic, total rescue analgesic consumption, and adverse effects were noted. When compared to group B (2.480.58 hours), group A (12.391.56 hours) required significantly more time before the first analgesic was needed (P 0.001). When compared to group A, group B required significantly more rescue analgesia (diclofenac sodium) (135.0046.17 milligrams vs. 93.7533.32 milligrams; P 0.001). The infiltration group required significantly more analgesic. The groups were hemodynamically similar. Hence, patients undergoing laminectomy surgeries benefit from local instillation at surgical site.

MATERIALS AND METHOD

Patients who will be undergoing operation for Inguinal Hernia in KLE Dr Prabhakar Kore Hospital & MRC, Belagavi.

Study design = Randomised Control Trial

Inclusion criteria-

- All cases of elective uncomplicated inguinal hernia.

Exclusion criteria-

- Complicated inguinal hernia.
- Pediatric age group (less than 18 years) and geriatric age group (more than 65 years).

study period: 1 year

Sample size – total sample size of 58 cases,29 in group A and the other 29 in group B (allotted by random sampling: SNOSE)

Sample size calculation:

Formula used for sample size calculation is:

$$n = 2\bar{p}(1-\bar{p})(Z\beta + Z\alpha 2/)2(p1-p2)2$$

Where p1 is the proportion in the first group,

p2 is the proportion in the second group

$\bar{p}$ is the average of both proportions,

for 95% confidence level: $Z\alpha 2/$ values are 1.96

for 90% power $Z\beta$ value is 1.28.

In bupivacaine group, 88% of them had excellent to above average postoperative analgesia [1] and we assume that 50% in control group will have average postoperative analgesia. Using these two proportions, 95% confidence level and with 90% power minimum sample size required for each group is 29 subjects.

Sample size required for the study is 29 samples per each group (29×2= 58 subjects). Larger the sample, better the precision.

STATISTICAL ANALYSIS:

Data will be collected and stored in Microsoft Excel.

Data will be analysed using statistical software R and Microsoft Excel.

Continuous variables will be given in mean ±sd/median (range).

Categorical variables will be represented by frequency.

To check the dependency between attributes Chi-square test will be used.

To compare mean/distribution over groups t-test/ANOVA/Mann-Whitney test/ Kruskal Wallis test will be used.

To compare mean/distributions within time points paired t-test/Wilcoxon's test will be used. To analyse the paired nominal data McNemar's test will be used.

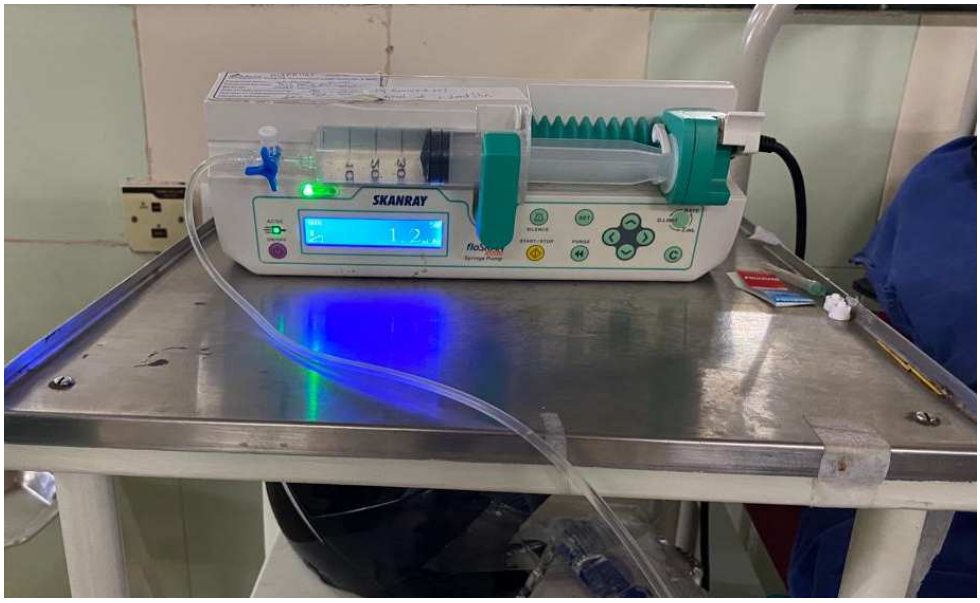
To check the normality of variables Quantile-Quantile (QQ) plot/Shapiro-Wilk's test will be used. P-value less than or equal to 0.05 shows statistical significance.

Procedure: Total sample size of 58 cases,29 in group A and the other 29 in group B. The group A subjects will be control group and group B subjects will be testing group.

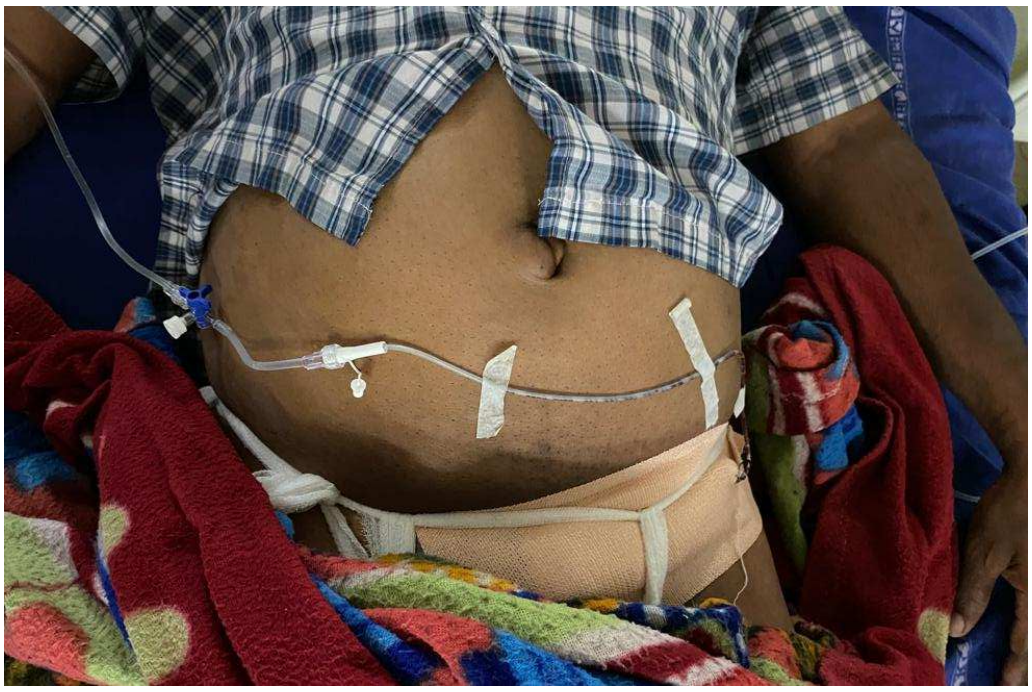
Continuous infusion pumps are a quick and efficient way of postoperative wound infiltration. Continuous infusion pumps specially designed for postoperative patient-controlled analgesia(pca). PCA pumps enable the delivery of continuous medication dosages that offer adequate analgesia during periods of rest and an additional dose during periods of daily activity.

All the patients undergoing operations for inguinal hernia after the closure of external oblique aponeurosis an infant feeding tube will be inserted in the subcutaneous plane which will be attached to infusion pump. 29 patients will be given bupivacaine 4 mg/kg for 72 hours through the infant feeding tube via infusion pump. The other 29 patients will be given normal saline through the infant feeding tube via infusion pump.

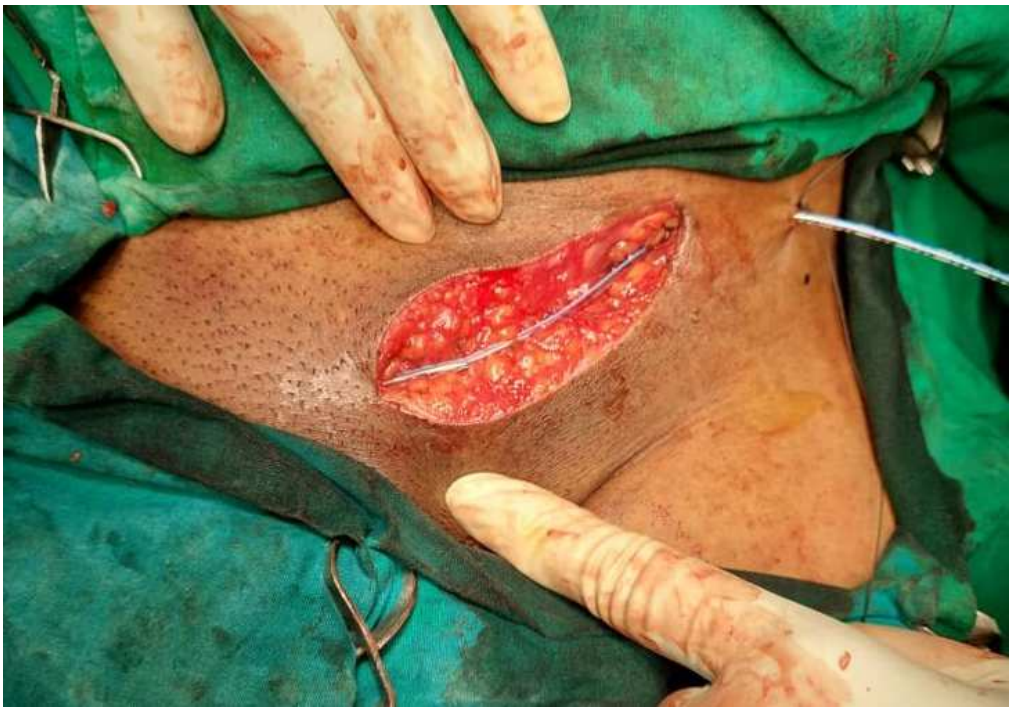
Photograph 1- Showing the full setup of bupivacaine infiltration via infusion pump infiltrating the wound.



Photograph 2- Bupivacaine infusion through an infusion pump as per the weight of the patient.



Photograph 3- Showing infant feeding tube into the wound site connected to IV set.



Photograph 4- Intra operative picture showing insertion of infant feeding tube into subcutaneous plain after closing the external oblique aponeurosis.

Photograph 5- 0.5% bupivacaine used in the study.

RESULTS:

Pain score follow-ups were considered as primary outcome variables. Hospital Stay, Wound Infection, Opioid & NSAID Usage were regarded as secondary outcome factors. The study group was regarded as the main explanatory factor.

For quantitative variables, the mean and standard deviation were used in the descriptive analysis, while frequency and proportion were used for categorical variables. The median and interquartile range were used to summarize non-normally distributed quantitative values (IQR). Data was also displayed using the relevant 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 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.

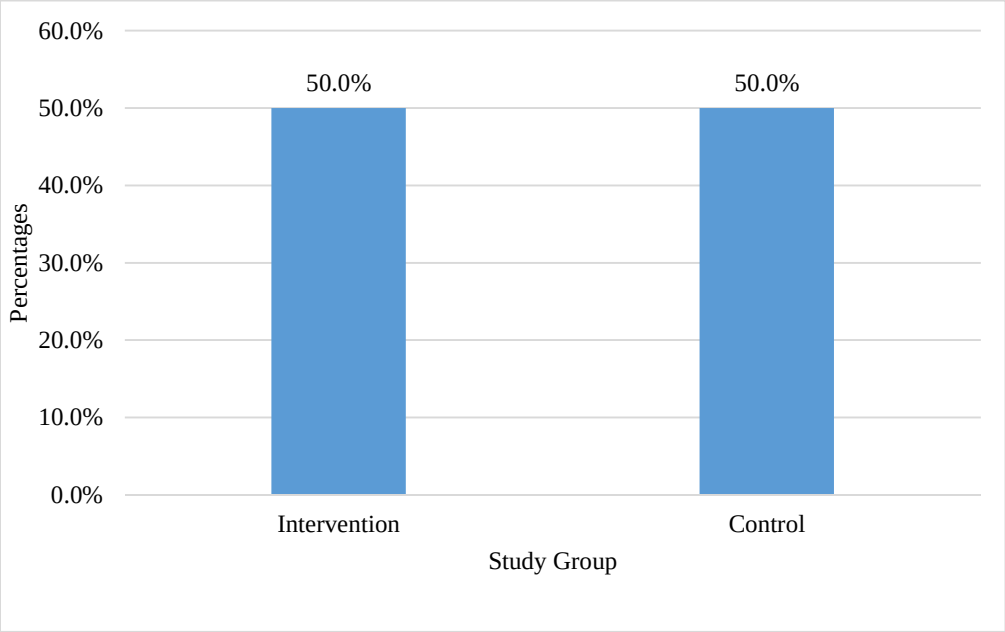
The independent sample t-test was used to compare the mean values of quantitative parameters that were normally distributed amongst study groups (2 groups) Using the Mann Whitney u test, medians and interquartile range (IQR) for quantitative parameters with non-normal distribution were compared between 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 study group in the study population (N=58)

Study Group	Frequency	Percentages
Intervention	29	50.00%
Control	29	50.00%

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



Among the study population, 29 (50%) participants were in the intervention group and the other 29 (50%) were in control group.

Table 2: Comparison of mean of age between study group (N=58)

Parameter	Study Group (Mean± SD)		P value
	Intervention (N=29)	Control (N=29)	
Age	41.45 ± 11.79	45.17 ± 10.61	0.211

The mean age (years) was 41.45 ± 11.79 in the study population, ranged between 18 to 60 years.

Table 3: Comparison of gender between study group (N=58)

Gender	Study Group	
	Intervention (N=58)	Control (N=58)
Male	29 (100%)	29 (100%)

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

Table 4: Comparison of diagnosis between study group (N=58)

Diagnosis	Study Group		Chi square	P value
	Intervention (N=29)	Control (N=29)		
B/L Indirect Inguinal Hernia	1 (3.45%)	2 (6.9%)	*	*
B/L Pantaloon Inguinal Hernia	0 (0%)	2 (6.9%)		
Left Direct Inguinal Hernia	5 (17.24%)	4 (13.79%)		
Left Indirect Inguinal Hernia	3 (10.34%)	3 (10.34%)		
Left Pantaloon Inguinal Hernia	1 (3.45%)	4 (13.79%)		
Right Direct Inguinal Hernia	14 (48.28%)	8 (27.59%)		
Right Indirect Inguinal Hernia	3 (10.34%)	4 (13.79%)		
Right Pantaloon Inguinal Hernia	2 (6.9%)	2 (6.9%)		

No statistical test was applied- due to 0 subjects in the cells

The study included multiple inguinal hernias like bilateral indirect inguinal hernia which were 1 (3.45%) in study group and 2 (6.9%) in control ; Bilateral Pantaloon Inguinal Hernia 2 (6.9%) in control and 0 (0.0%) in intervention ; Left Direct Inguinal Hernia 5 (17.24%) in intervention and 4 (13.79%) in control ; Left Indirect Inguinal Hernia study group contained 3 (10.34%) and 3 (10.34%) in the control ; Left Pantaloon Inguinal Hernia 1 (3.45%) in intervention group and 4 (13.79%) in control ; Right Direct Inguinal Hernia included 8 (27.59%) in control and 14 (48.28%) in intervention ; Right Indirect Inguinal Hernia included 3 (10.34%) in intervention group and 4 (13.79%) in control ; 2 (6.9%) were included in intervention and 2 (6.9%) in control of Right Pantaloon Inguinal Hernia.

Table 5: Comparison of pain scores (VAS) at different follow -ups between study group (N=58)

Pain Scores (Vas)	Study Group		Chi square	P value
	Intervention (N=29)	Control (N=29)		
At 6 Hours				
3	5 (17.24%)	3 (10.34%)	2.781	0.249
4	16 (55.17%)	22 (75.86%)		
5	8 (27.59%)	4 (13.79%)		
At 12 Hours				
2	1 (3.45%)	0 (0%)	*	*
3	12 (41.38%)	1 (3.45%)		
4	16 (55.17%)	25 (86.21%)		
5	0 (0%)	3 (10.34%)		
At 24 Hours				
2	5 (17.24%)	0 (0%)	*	*
3	24 (82.76%)	2 (6.9%)		
4	0 (0%)	25 (86.21%)		
5	0 (0%)	2 (6.9%)		
At 48 Hours				
1	4 (13.79%)	0 (0%)	*	*
2	22 (75.86%)	0 (0%)		
3	3 (10.34%)	26 (89.66%)		
4	0 (0%)	3 (10.34%)		
At 72 Hours				
0	4 (13.79%)	0 (0%)	*	*
1	21 (72.41%)	0 (0%)		
2	4 (13.79%)	26 (89.66%)		
3	0 (0%)	3 (10.34%)		

No statistical test was applied- due to 0 subjects in the cells

Our study includes post operative pain scoring using VAS score after 6,12,24,48 and 72 hours of surgery in both control and study group. The table suggests VAS score of 5 in a greater number of patients in the intervention group 8 (27.59%) as compared to control group 4 (13.79%) initially at 6 hours when the infusion was started. VAS score of 4 was noted in 16 (55.17%) in the intervention group which is less as compared to the control group 22(75.86%). Similarly, VAS score of 3 was noted in 5(17.24%) of the patients in intervention group and 3 (10.34%) patients in control group.

At 12 hours VAS score of 5 was seen in 0(0.0%) in intervention group and 3 (10.34%) in control group showing improvement. Again, VAS score of 4 was seen in 16 (55.17%) in intervention group and 25 (86.21%) seen in control group. as we go to VAS score of 3, we noticed a drop-in control group patient 1 (3.45) than intervention group 12 (41.38%). But we must not forget the use of NSAIDS and opioids in the control group.

Figure 2: Staked bar chart of comparison of pain scores (VAS) at 6 Hours between study group (N=58)

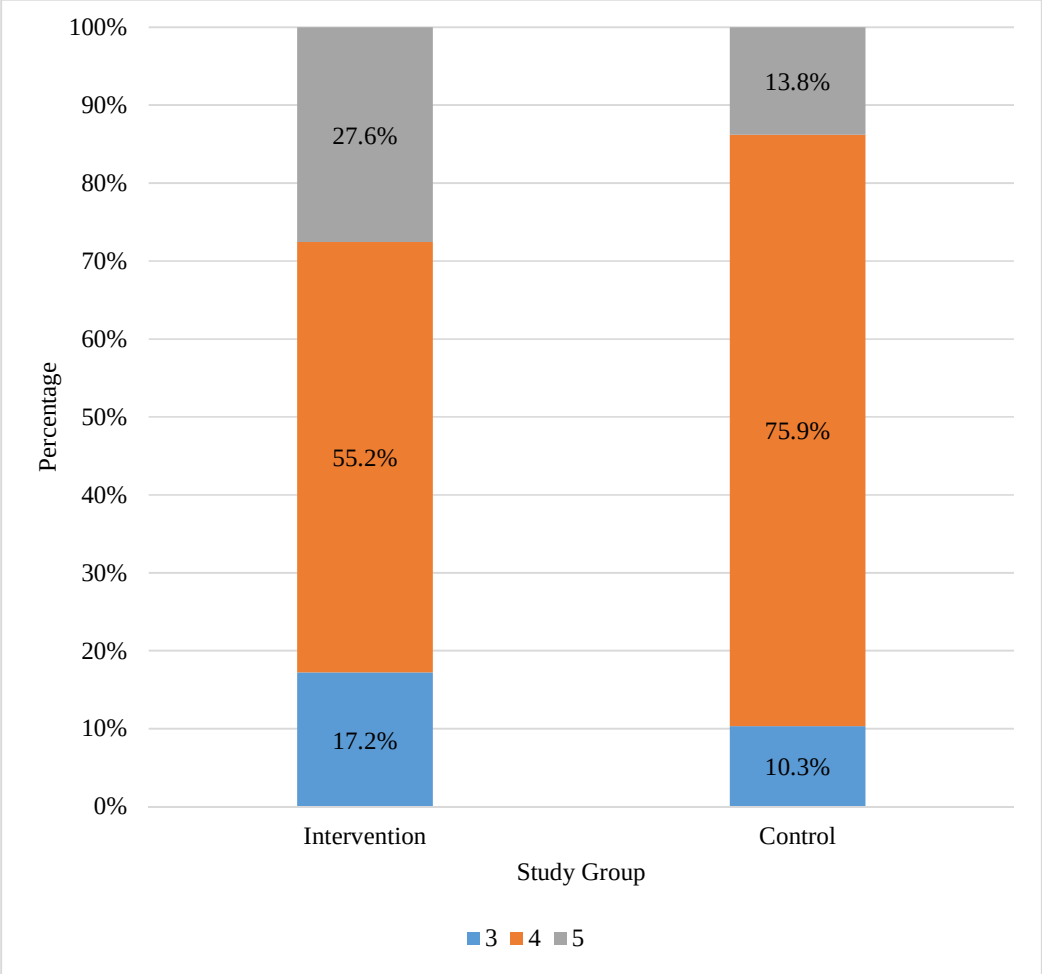


Figure 3: Staked bar chart of comparison of pain scores (VAS) at 12 Hours between study group (N=58)

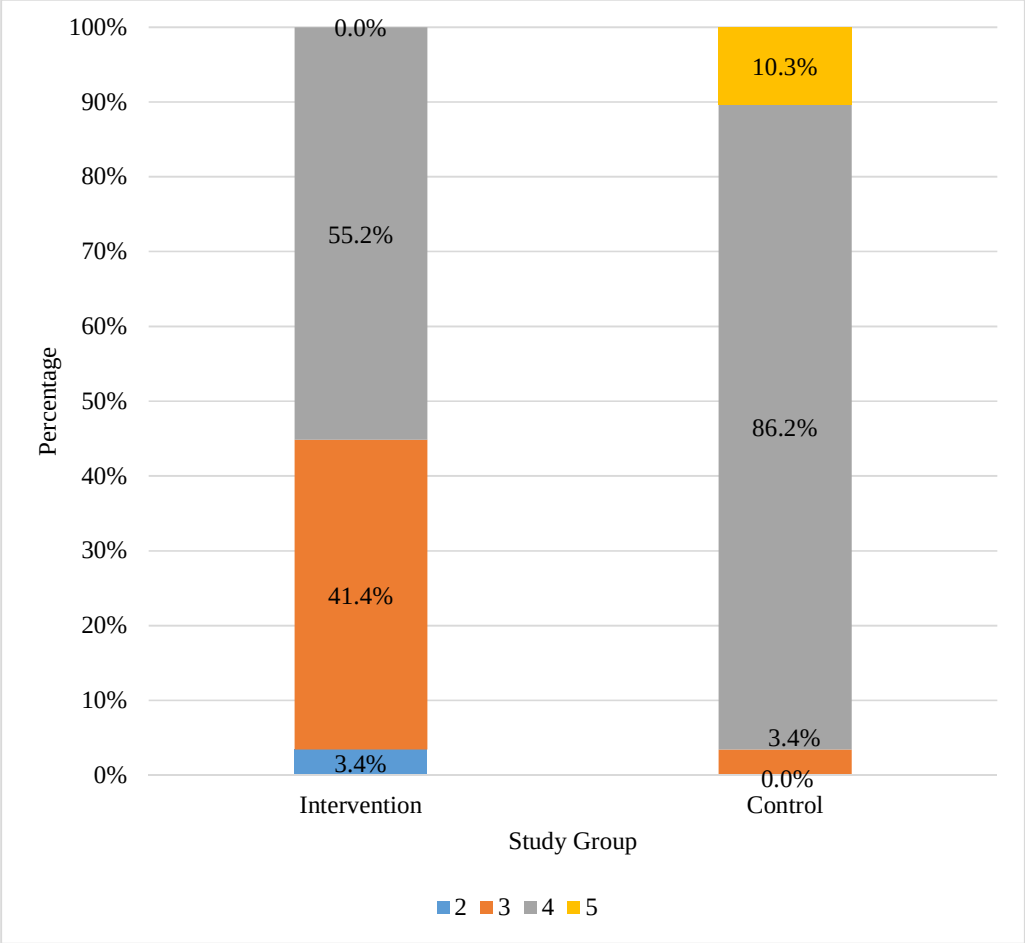


Figure 4: Staked bar chart of comparison of pain scores (VAS) at 24 Hours between study group (N=58)

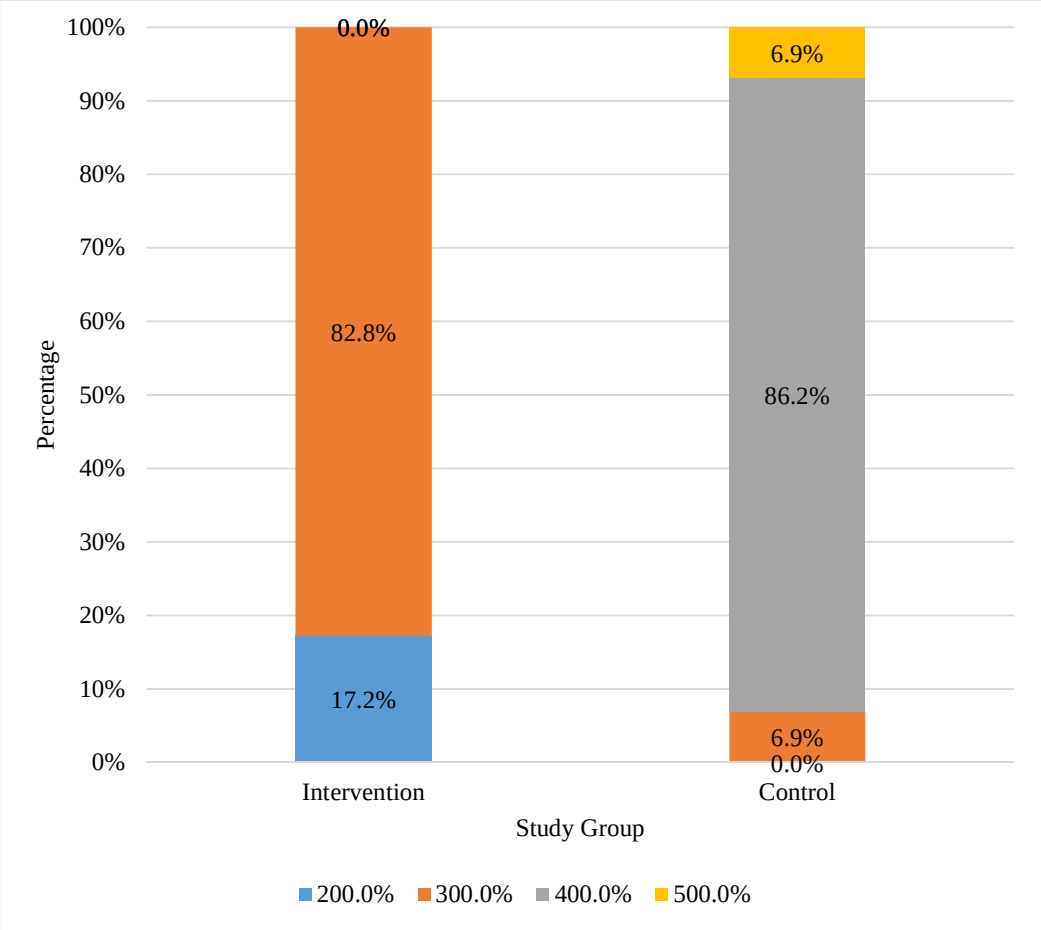


Figure 5: Staked bar chart of comparison of pain scores (VAS) at 48 Hours between study group (N=58)

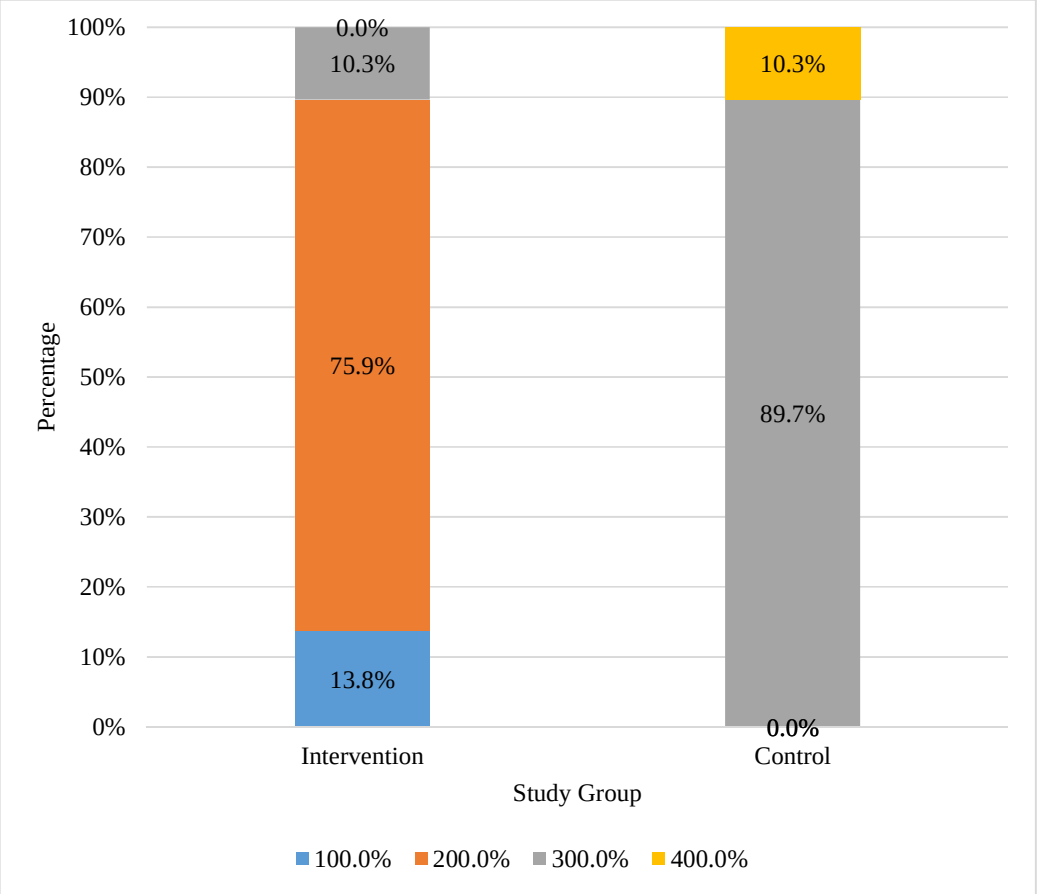


Figure 6: Staked bar chart of comparison of pain scores (VAS) at 72 Hours between study group (N=58)

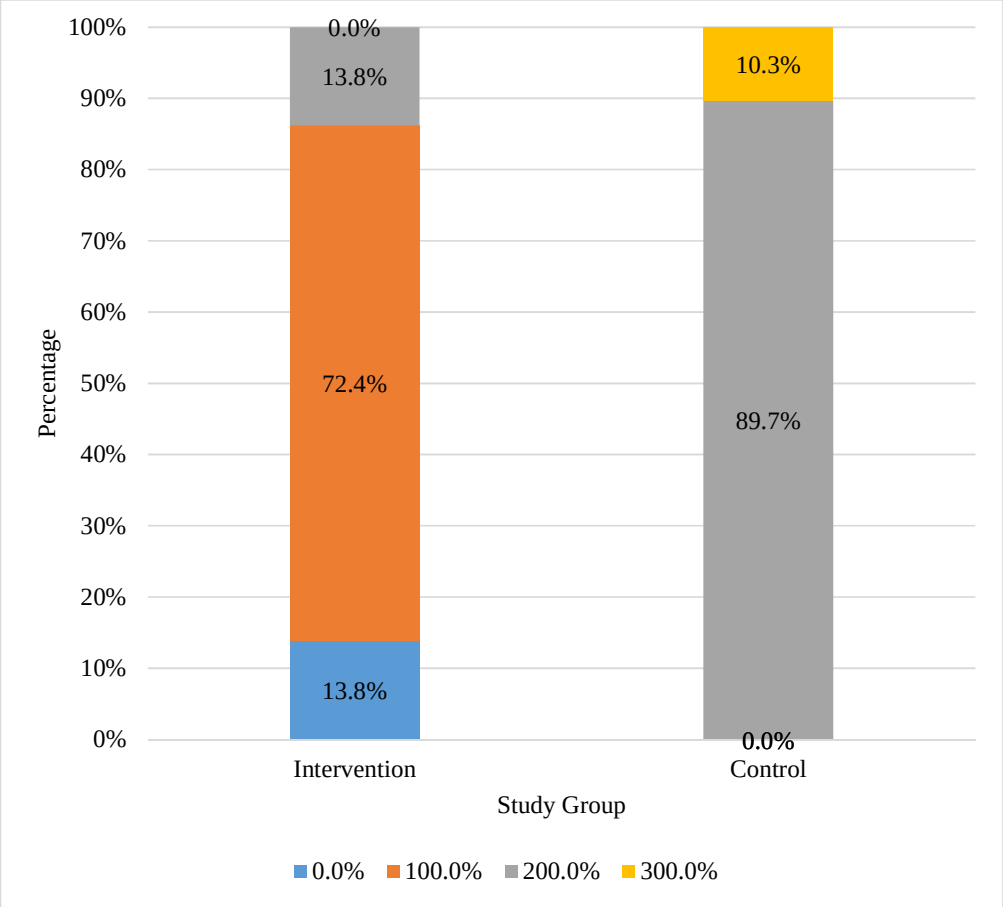


Table 6: Comparison of median pain score (VAS) between the study groups at different follow-up time periods (N= 58)

Pain scores (VAS)	Study Group Median (IQR)		Mann Whitney U test (P value)
	Intervention (N=29)	Control (N=29)	
At 6 hours	4 (4,5)	4 (4,4)	0.618
At 12 hours	4 (3,4)	4 (4,4)	<0.001
At 24 hours	3 (3,3)	4 (4,4)	<0.001
At 48 hours	2 (2,2)	3 (3,3)	<0.001
At 72 hours	1 (1,1)	2 (2,2)	<0.001

At 6th hour, the difference in pain score was statistically insignificant (p value >0.05). At 12 hours, 24 hours, 48 hours and 72 hours the difference in pain scores was statistically significant (p value<0.001).

Table 7: Comparison of mean of hospital stay (days) between study group(N=58)

Parameter	Study Group (Mean± SD)		P value
	Intervention (N=29)	Control (N=29)	
Hospital Stay (days)	3.14 ± 0.35	5.41 ± 0.83	<0.001

The length of Hospital stay between two groups was statistically significant (p<0.001)

Table 8: Comparison of wound infection between study group (N=58)

Parameter	Study Group		Chi square	P-value
	Intervention (N=29)	Control (N=29)		
Wound Infection				
Yes	0 (0%)	29 (100%)	*	*
No	29 (100%)	0 (0%)		
Opioid Usage				
Yes	0 (0%)	9 (31.03%)	*	*
No	29 (100%)	20 (68.97%)		
Nsaid Usage				
Yes	5 (17.24%)	29 (100%)	*	*
No	24 (82.76%)	0 (0%)		

No statistical test was applied- due to 0 subjects in the cells

Figure 7: Staked bar chart of comparison of wound infection between study group (N=58)

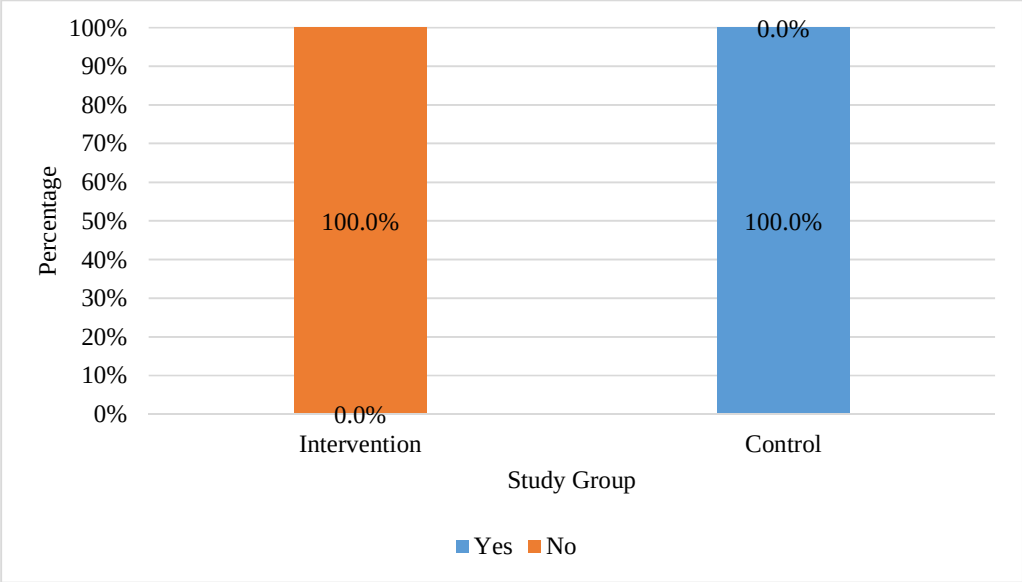


Figure 8: Staked bar chart of comparison of Opioid Usage between study group (N=58)

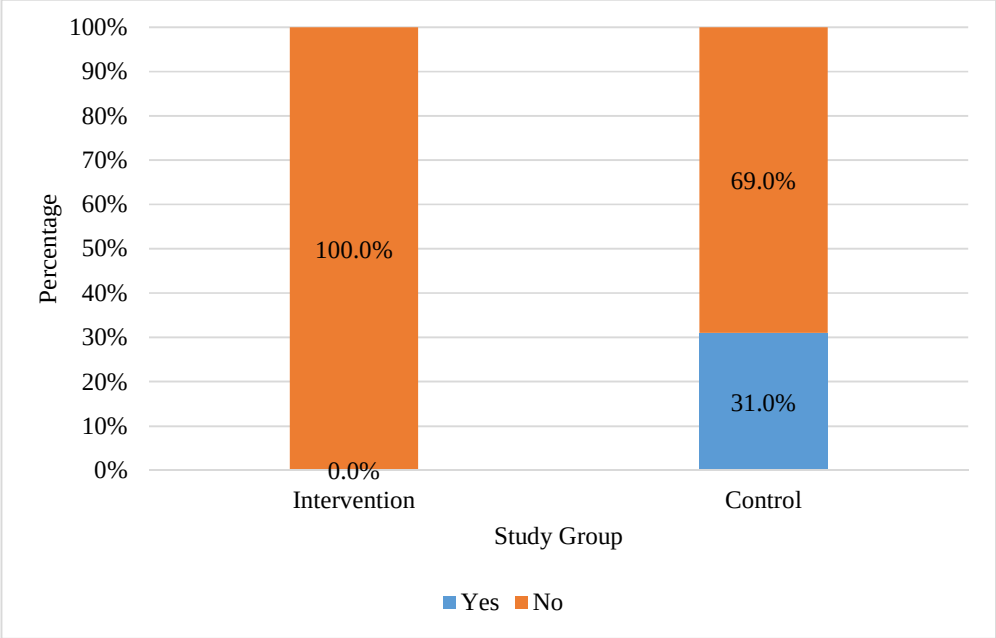
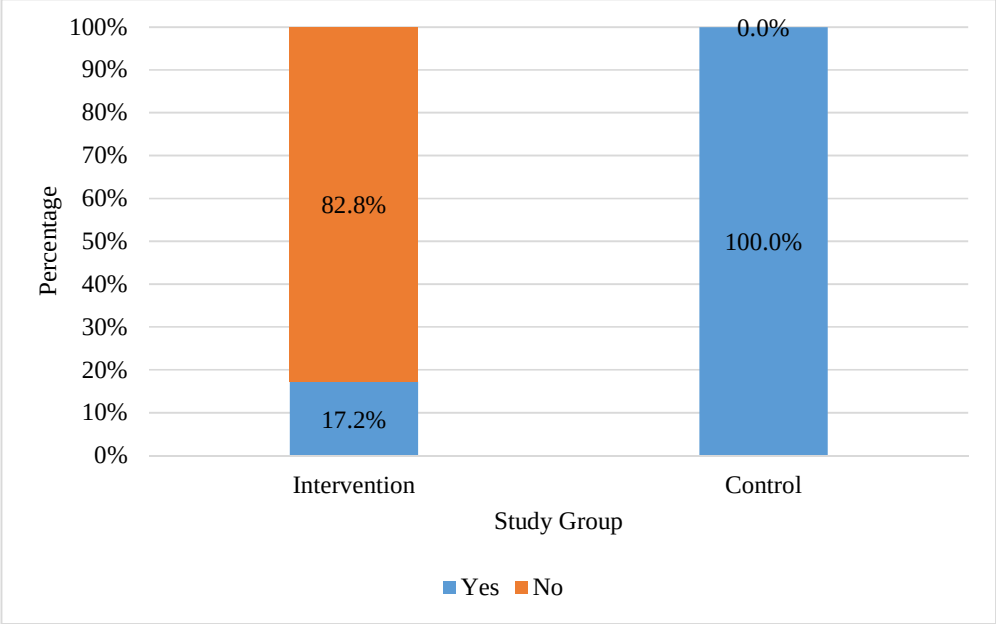


Figure 9: Staked bar chart of comparison of Nsaid Usage between study group (N=58)



DISCUSSION:

The most frequent condition that all general surgeons encounter is a hernia. The patient's post-operative discomfort is the surgery-related consequence that occurs most frequently. For patients' comfort, early discharge from the hospital, and shorter stays, which reduce the need for hospital and patient resources, pain management is crucial.

Adequate pain relief after surgery should be considered a top priority. Good pain control after surgery can offer comfort to the patient and hasten the discharge process once the patient is free of pain. With hernias being repaired under systemic, regional and even regional blocks, the analgesic requirements become even more challenging.

Use of local anaesthesia at the surgical site in concordance with other entities have proven to be useful in certain 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 bupivacaine 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, 48 and 72 hours. The intervention group received 0.5% bupivacaine at 4ml/kg/hr via an infusion pump in the subcutaneous plane while the control group received normal saline. We also studied the number of days of the hospital stay while doing the study to see the efficacy and the prevention of resources. Although the above literature suggests that there might be some effect of Wound infiltration with local anaesthetics, good quality evidence is still lacking and needs further studies before it can be adopted as a routine practice. Such a practice

can effectively reduce post operative opioid usage which will in turn Enhance patient recovery, reduce workload to caretaking staff and provide adequate analgesia. Therefore, some of wound infiltration methods can be used in the ambulatory surgery.

We conducted a year randomized controlled study at a tertiary centre in Karnataka, India with the aim to compare the efficacy of bupivacaine with normal saline(placebo) instillation into the incisional wound of post- operative inguinal hernia surgery patients as a part of multi modal analgesia and to evaluate the incidence of infection after administration of bupivacaine.

A total number of 58 patients were included in the study.

All of our patients were males between 18 -65 years of age.

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

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

As explained in table 5; the 2 groups (intervention and control) suggested that pain as the maximum in the first 6 hours which gradually reduces. The table suggests VAS score of 5 in a greater number of patients in the intervention group 8 (27.59%) as compared to control group 4 (13.79%) initially at 6 hours when the infusion was started. VAS score of 4 was noted in 16 (55.17%) in the intervention group which is less as compared to the control group 22(75.86%). Similarly, VAS score of 3 was noted in 5(17.24%) of the patients in intervention group and 3 (10.34%) patients in control group. As seen in table 6 ; At 6^{th} hour, the difference in pain score was

statistically insignificant (p value >0.05). At 12 hours, 24 hours, 48 hours and 72 hours the difference in pain scores was statistically significant (p value<0.001).

Our study did show lower pain scores in concordance with many of the above-mentioned literature, the difference was statistically significant. In our study the intervention group 82.8% participants did not need any NSAIDS and no opioids were used. As compared to the control group, our intervention also showed a decrease in the usage of opiates and intravenous NSAIDs.

The patients are also discharged sooner as compared to the control group suggesting a shorter length of Hospital stay, no predilection to any complications and even early return to daily activities. The mean of hospital stay in our intervention group was 3.14 ± 0.35 and the control group was 5.41 ± 0.8. Financial and Resource benefits, both to the patients as well as the hospitals/healthcare associates may also act as a driving force to conduct and validate this particular practice.

Complications of Hernia surgeries can be challenging. One such complication is Wound Infection especially in the setting of prosthetic mesh that can act as a source of contamination. Any procedure that risks such grave complications should only be used if it outweighs the risks associated.

Following proper aseptic protocols can reduce the occurrence of such grave complications. There were no cases of wound site infection as the procedure as fully done under aseptic precautions. The safety of this procedure was demonstrated in this study, however the same needs to be demonstrated in other studies. Studies by Suraseranivongse S et al, El-Radaideh KM et al , Cui *et al*. suggest that local anaesthetics like bupivacaine can even be used for local infiltration of surgical sites

and show significant low pain scores. Cui has even excluded to probability of it being due to placebo affect by contrasting the results with a control group, an approach similar to our study.

CONCLUSION:

The effect of instillation of bupivacaine into subcutaneous plain through infusion pump, in reduction of post operative pain after Inguinal Hernioplasty at 12 hours, 24 hours, 48 hours and 72 hours is significantly proven in the current study. It is also shown to lessen the length of hospital stay significantly. Instillation of bupivacaine causes certain relief of pain in post operative management but may require close monitoring of the patients and look for possible complications such as wound infection.

SUMMARY

The study entitled "**COMPARISION OF INTRA INCISIONAL INSTILLATION OF BUPIVACAINE WITH NORMAL SALINE INTO THE WOUND FOR POST OPERATIVE ANALGESIA. A 1 YEAR HOSPITAL BASED RCT STUDY AT KLES DR. PRABHAKAR KORE HOSPITAL AND MRC."**

This study was conducted in a tertiary Care center in North Karnataka where an attempt was made to compare the efficacy of bupivacaine with normal saline (placebo) instillation into the incisional wound following hernia surgery for control of pain by visual analogue scale and requirement of analgesia in both groups as a part of multi modal analgesia and to compare the use of analgesics in patients with saline instillation v/s patients with bupivacaine instillation.

A total number of 58 patients were included with uncomplicated hernias from age between 18-60 years between January 2021 to December 2021. Post operatively pain scoring as done using VAS Score and the use of NSAIDS and opioids were also noted. Another interesting aspect of decreased hospital stay was studied in our research.

Statistical analysis revealed lesser post operative pain at 12, 24, 48 and 72 hours post operatively which was statistically significant. The effect of instillation of bupivacaine into subcutaneous plain through infusion pump in inguinal hernia patients has thus been proved to reduce post operative pain and length of hospital stay in patients undergoing inguinal hernia repair.

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ANNEXURE I – CONSENT FORM

Mr/Mrs/Miss. _____,we are requesting you to enroll yourself in study titled " COMPARISION OF INTRA INCISIONAL INSTILLATION OF BUPIVACAINE WITH NORMAL SALINE INTO THE WOUND FOR POST OPERATIVE ANALGESIA", Conducted by _____, Post Graduate in M.S General Surgery under the guidance of _____, Professor , Department of General Surgery, J N Medical College, Belagavi under KAHER, Belagavi.

Respected sir/madam,

We request you to participate in our study. Your participation in the research is voluntary. Your decision to participate in the study or otherwise will not affect the relationship with KLES Prabhakar kore hospital. If you decide not to participate you are free to withdraw at any time. During the study, your operative outcome will be assessed by some questions.

Purpose of the study

I have been informed by _____, Post Graduate in M.S. General Surgery under the guidance of _____, Professor Department of General Surgery, J.N. Medical College, KLE University, Belagavi is conducting a study to compare the effect of intra incisional wound instillation of bupivacaine versus normal saline for post-operative analgesia at KLE'S DR.Prabhakar Charitable Hospital And Medical Research Centre, Belagavi.

An intra incisional wound infiltration is a method of postoperative analgesia commonly used alone or with other analgesic regimens. It was developed to improve postoperative analgesia, reduce opioid consumption and hasten patient recovery. The use of local

anaesthetics (LAs) instead of opioid minimizes opioid adverse reactions, reduces nursing work, decreases resting pain, pain on motion, and thus allows better patient mobility. Therefore, some of wound infiltration methods can be used in the ambulatory surgery.

Bupivacaine has been shown to have an analgesic effect beyond the duration of its pharmacological action. It has been postulated that bupivacaine suppresses the formation of a hyperexcitable state in the central nervous system which is responsible for the maintenance of post- operative pain.

Study procedure

Once you have signed the informed consent, necessary personal information and detailed medical history will be taken by the investigator. After this based upon randomisation you will be treated with intra-incisional wound instillation of either bupivacaine or normal saline through an infant feeding tube attached to an infusion pump which will be inserted in subcutaneous plain through a separate opening. Your pain post operatively and after instillation of bupivacaine or normal saline will be assessed on the basis of VAS (visual analogue scale)

Potential risks

Allergic reaction and skin irritation to the drug used in the study are the possible risk factors

Benefits

Regional instillation of bupivacaine, a local anaesthetic offers many advantages as follows: pain is cured at close to damaged tissue, and when local anaesthetics are used, they provide analgesia and substantially reduce the need for opioids.

Financial incentive for participation

You will not receive any payment for taking part in this study.

Alternatives

Your participation in this study is entirely voluntary. You are free to refuse to participate or withdraw from the study at any time. You will still receive standard medical care from the hospital. The investigator holds the right to terminate the study at any time

Privacy

To protect my privacy, all the collected information will be given a number rather than using my name. Any information collected during the study will remain confidential. My medical files will be reviewed only at the hospital (or study doctor's office) to check the information and verify the result without breaking my confidentiality.

Authorization to publish results

The information about me will be analysed together with other study participants.

Results of this study will be published and presented to scientific groups for scientific purposes, but I will never be individually identified in the presentation of the study results.

Institutional policy

In case you have any questions related to the study, in future or in case of study related injury or illness, you can contact _____, Department of General Surgery, KLE University's J.N. Medical College, Ph. No. _____ or _____, Professor Dept. Of General surgery, KLE University's J.N Medical College, Belagavi Ph.: _____ or phone number:_____.

Voluntary participation

- Your participation in the study is voluntary. In case you need any further information regarding your rights as study participant, you may contact **DR HARSHA HEGDE** Chairperson, JNMC, IEC& Scientist D, ICMR, National Institute of Traditional Medicine, Belagavi Ph. No: 0831-2473777, Ext. 1529 Mob No: 9480422500

CONSENT TO PARTICIPATE IN RESEARCH STUDY:

I voluntarily agree to take part in this study by signing on the line below. I may withdraw at any time. I am not giving up any of my legal rights by signing this form. My signature below indicated that I have read this entire consent form or it has been read to me, and has been explained to me in my vernacular language and had all my questions answered. I will be given a copy of this consent form.

I understand that I am participating in the trail, Intra instillation of bupivacaine versus normal saline into the incisional wound for post-operative analgesia.

1. I confirm that I have read and understood the information in the patient information sheet. Procedure is explained to me in detail along with information about the advantages and disadvantages of taking part in the study. I have been given the opportunity to discuss all aspects of the trial, to ask questions and hereby consent to participation in the trial outlined above.

2. I understand that the decision to take part in this study is completely voluntary and I am aware that I can choose to withdraw from the study at any point of time.

3. I consent to the photographing or recording of the procedure to be performed including appropriate portions of my body, for medical, scientific or educational purposes provided my identity is not revealed in the pictures or by the descriptive texts accompanying them.

4. I understand that there is no significant risk involved in the test that would be done in this study.

5. No guarantee or assurance has given by anyone as to the results that may be obtained.

6. My signature on this form signifies that I have willingly decided to participate after understanding the above information.

Participant's Name/ legally authorized _____

representative

Signature _____

Name and signature of witness _____

Name and signature of interviewer _____

Date:

Place:

(If a patient has limited ability to read and write, an impartial witness should be present during the entire informed consent discussion and patient's legally acceptable representative should sign on the patient's behalf.) In these instances, the patient his/her thumb impression taken in place of signature.

Patient's legally acceptable representative's statement: NA

I, as the patient's legally acceptable representative was present during the consenting procedure and understand the preceding information describing this study. All of the questions regarding the study and the patient's participation in it have been answered to my satisfaction. I state that all aspects of the study were clearly presented during the consent procedure. The patient is willing to participate in this study and I sign below on his/her behalf testifying to this effect.

Name of the patient:

Name of representative:

Relationship to the patient:

Signature of representative:

Date:

Impartial witness declaration:

By signing the consent form, I attest that the information was accurately explained to and apparently understood by the patient and the representative (if applicable) and that the informed consent was freely given by the patient.

Name of impartial witness:

Signature: Date –

ANNEXURE II: PROFORMA

SCREENING FORM

1. Patient's UHID no. : ☐☐☐☐☐☐☐

1. Age (in years) ☐☐

2. Gender: 1. Male 2. Female ☐

3. Height (in cms): ☐☐☐

4. Weight (in kgs): ☐☐

5. BMI(kg/m^2): ☐☐☐

6. BP :

7. Pulse Rate:

8. Pallor :

9. Icterus:

10. History : Swelling present (no. of days) ☐

Nature of swelling: 1. Reducible ☐
2. Non reducible ☐

11.On Examination: On palpation size of swelling ☐ (in cms)

12.Nature: 1.Reducible ☐

2. Non-reducible ☐

Pain/tenderness: 1. Yes
2. No ☐

13. Investigations: USG (defect size in cms) ☐

14. Diagnosis :

15. DOA (dd/mm/yy) ☐☐☐☐☐☐☐☐

16.DOD (dd/mm/yy) ☐☐☐☐☐☐☐☐

17. Date of interview (dd/mm/yy) ☐☐☐☐☐☐☐☐

18. Address : 1.Belagavi ☐
2.Outside Belagavi

19. Phone: ☐☐☐☐☐☐☐☐☐☐

20. Occupation : 1-Unemployed ☐
2-Unskilled
3-Semi-skilled
4-Skilled
5-Professional

21.Education : 1-Illiterate ☐
2-Primary (1st-7th std)
3-High school (8th-10th std)
4-Intermediate
5-Degree and above

22. Socio-economic status :1-Low
2-Middle
3-High ☐

23. Applicant is willing to give consent : 1-Yes
2-No ☐

24. Outcome 1-Ineligible ☐
2-Eligible but refused. ☐
3-Eligible and participating ☐

PROFORMA

1. Patient UHID no. ☐☐☐☐☐☐☐

2. Age (in years) ☐☐

3. Gender: 1. Male 2. Female ☐

4. Height (in cms): ☐☐☐

5. Weight (in kgs): ☐☐

6. BMI(kg/m^2): ☐☐

7.DOA (dd/mm/yy) ☐☐ ☐☐ ☐☐☐☐

8. DOD (dd/mm/yy) ☐☐ ☐☐ ☐☐☐☐

9. Date of interview (dd/mm/yy) ☐☐ ☐☐ ☐☐☐☐

10. Co-morbidities

11. BP :

12. Pulse Rate:

13. Pallor:

14. Icterus:

15. History: Swelling present (no. of days) ☐

Nature of swelling: 1. Reducible ☐

2. Non reducible ☐

16. On Examination: On palpation size of swelling ☐ (in cms)

17. Nature: 1.Reducible ☐

2. Non-reducible ☐

Pain/tenderness: 1. Yes ☐
2. No

Diagnosis:

Post-operative condition of the patient and wound:

Day 3 :

Day 5 :

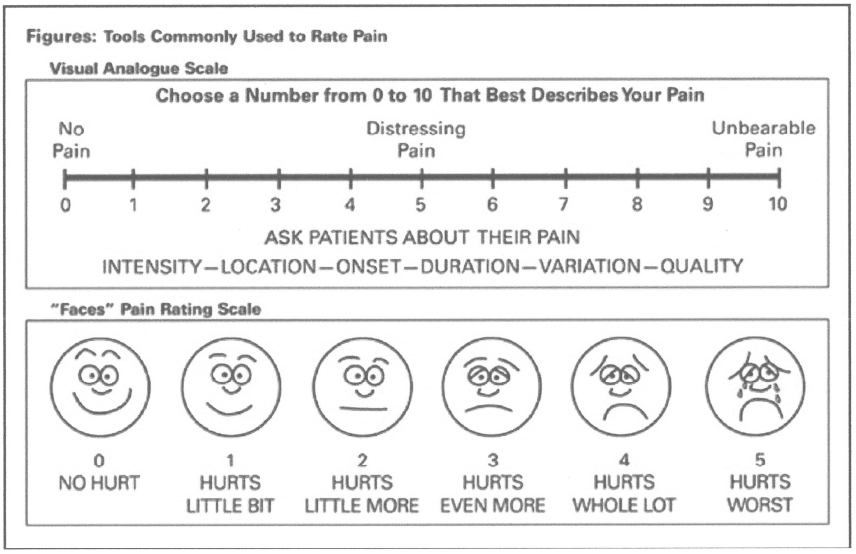
Sutures removed on :

Drugs given during the course of treatment :

ANALYSIS

1) Postoperative hospital stay : Number of Days ☐☐

2) Postoperative pain : by using Visual Analogue Scale ☐



3) Pain recorded at :

4) Post operative analgesic requirement :

5) Wound infection :

6) Post operative complications :

ANNEXURE III: MASTER CHART

Intervention group													
Patient details					Pain scores (VAS)					Other factors			
S.no	IP no.	Age	Sex	Diagnosis	At 6h	At 12 h	At 24h	At 48 hrs	At 72 h	Hospital Stay	Wound Infection	Opiod usage	NSAID usage
1	1065881	59	male	right direct inguinal hernia	5	4	3	3	2	4 days	no	no	no
2	1057364	31	male	right direct inguinal hernia	4	4	3	2	1	3 days	no	no	no
3	1035644	41	male	right direct inguinal hernia	4	4	3	3	2	4 days	no	no	no
4	1035558	35	male	left direct inguinal hernia	4	3	2	1	1	3 days	no	no	yes
5	1058520	28	male	left indirect inguinal hernia	5	4	3	3	2	4 days	no	no	no
6	1054842	28	male	left direct inguinal hernia	4	4	3	2	1	3 days	no	no	no
7	1057500	45	male	right direct inguinal hernia	5	4	3	1	0	3 days	no	no	no
8	1057155	58	male	right direct inguinal hernia	3	3	3	2	1	3 days	no	no	no
9	1059611	55	male	left indirect inguinal hernia	5	4	3	2	1	3 days	no	no	no
10	1036787	42	male	right indirect inguinal hernia	4	4	3	2	1	3 days	no	no	yes
11	159680	46	male	right direct inguinal hernia	5	4	3	2	1	3 days	no	no	no
12	1045492	54	male	left direct inguinal hernia	4	4	3	2	1	3 days	no	no	no
13	1045492	57	male	right indirect inguinal hernia	4	4	3	2	1	3 days	no	no	no
14	1062458	43	male	right pantaloon inguinal hernia	4	4	3	2	1	3 days	no	no	no
15	11066435	25	male	left direct inguinal hernia	4	4	3	2	1	3 days	no	no	no
16	1068780	47	male	left pantaloon inguinal hernia	5	4	3	2	1	3 days	no	no	no
17	1062554	56	male	right indirect inguinal hernia	3	2	2	1	0	3 days	no	no	no
18	1062584	54	male	right direct inguinal hernia	4	3	2	1	0	3 days	no	no	yes
19	1075561	49	male	right direct inguinal hernia	4	3	3	2	2	4 days	no	no	no
20	1075549	35	male	left indirect inguinal hernia	4	3	3	2	0	3 days	no	no	no
21	1075559	59	male	right direct inguinal hernia	4	3	3	2	1	3 days	no	no	no
22	1077725	28	male	left direct inguinal hernia	5	3	3	2	1	3 days	no	no	no
23	1078076	32	male	right direct inguinal hernia	5	4	3	2	1	3 days	no	no	no
24	1093812	28	male	right direct inguinal hernia	4	3	3	2	1	3 days	no	no	yes
25	109347	44	male	b/l indirect inguinal hernia	4	3	3	2	1	3 days	no	no	no
26	1095210	39	male	right direct inguinal hernia	3	3	3	2	1	3 days	no	no	no
27	1097669	36	male	right pantaloon inguinal hernia	4	4	3	2	1	3 days	no	no	yes
28	1100650	24	male	right direct inguinal hernia	3	3	2	2	1	3 days	no	no	no
29	1101507	24	male	right direct inguinal hernia	3	3	2	2	1	3 days	no	no	no

Intervention group														
Patient details					Pain scores (VAS)					Other factors				
S.no	IP no.	Age	Sex	Diagnosis	At 6h	At 12 h	At 24h	At 48 hrs	At 72 h	Hospital Stay	Wound Infection	Opiod usage	NSAID usage	
control group														
30	1106143	57	male	left pantaloon inguinal hernia	5	4	4	3	2	5 days	no	no	yes	
31	1103900	48	male	right direct inguinal hernia	4	4	4	3	2	7 days	no	no	yes	
32	1108216	36	male	right indirect inguinal hernia	4	4	4	3	2	7 days	no	no	yes	
33	118864	59	male	left direct inguinal hernia	4	4	4	3	2	5 days	no	yes	yes	
34	1189889	54	male	b/l indirect inguinal hernia	4	4	4	3	2	5 days	no	no	yes	
35	1117764	38	male	left direct inguinal hernia	4	4	3	3	2	5 days	no	no	yes	
36	118891	53	male	left pantaloon inguinal hernia	4	4	4	3	2	5 days	no	yes	yes	
37	1152589	24	male	right pantaloon inguinal hernia	4	4	4	3	2	5 days	no	no	yes	
38	1167875	45	male	left direct inguinal hernia	3	3	3	3	2	5 days	no	no	yes	
39	1152632	50	male	left indurect inguinal hernia	5	5	5	4	3	7 days	no	no	yes	
40	1152399	21	male	right direct inguinal hernia	4	4	4	3	2	7 days	no	yes	yes	
41	1150517	45	male	right indirect inguinal hernia	4	4	4	3	2	5 days	no	no	yes	
42	1148895	40	male	right pantaloon inguinal hernia	4	4	4	3	2	5 tays	no	no	yes	
43	1125259	54	male	b/l indirect inguinal hernia	4	4	4	3	2	5 days	no	no	yes	
44	1152277	55	male	b/l pantaloon inguinal hernia	5	5	4	3	2	5 tays	no	yes	yes	
45	1151871	45	male	right indirect inguinal hernia	4	4	4	3	2	5 days	no	no	yes	
46	1151594	48	male	left pantaloon inguinal hernia	4	4	4	3	2	5 tays	no	no	yes	
47	1148040	37	male	right direct inguinal hernia	4	4	4	3	2	5 days	no	yes	yes	
48	1151679	33	male	right direct inguinal hernia	4	4	4	3	2	5 days	no	no	yes	
49	1147543	29	male	left indirect inguinal hernia	4	4	4	3	2	5 days	no	yes	yes	
50	1151167	30	male	left direct inguinal hernia	3	4	4	4	3	7 days	no	no	yes	
51	1151172	53	male	b/l pantaloon inguinal hernia	3	4	4	3	2	5 tays	no	no	yes	
52	1151191	44	male	right indirect inguinal hernia	4	4	4	3	2	5 days	no	no	yes	
53	1151112	42	male	right direct inguinal hernia	4	4	4	3	2	5 days	no	no	yes	
54	1151245	48	male	left pantaloon inguinal hernia	4	4	4	3	2	5 tays	no	no	yes	
55	1150575	56	male	right direct inguinal hernia	4	4	4	3	2	5 days	no	yes	yes	
56	1150812	58	male	right direct inguinal hernia	5	5	5	4	3	7 days	no	yes	yes	
57	1149808	49	male	right direct inguinal hernia	4	4	4	3	2	5 days	no	no	yes	
58	1150916	59	male	left indirect inguinal hernia	4	4	4	3	2	5 days	no	yes	yes	