# "Comparative evaluation of efficacy of Lignocaine HCL and Bupivacaine HCL used as a local drug delivery system for pain control after impacted mandibular third molar surgery: A single blinded randomized controlled trial"


**By**

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This is to certify that the dissertation entitled **"Comparative evaluation of efficacy of Lignocaine HCL and Bupivacaine HCL used as a local drug delivery system for pain control after impacted mandibular third molar surgery: A single blinded randomized controlled trial"** is a bonafide research work done by **REG.NO. – IF0221001.**

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I, **REG.NO. – IF0221001** hereby declare that the information and the data mentioned in my dissertation entitled **"Comparative evaluation of efficacy of Lignocaine HCL and Bupivacaine HCL used as a local drug delivery system for pain control after impacted mandibular third molar surgery: A single blinded randomized controlled trial"** belongs to me and is original.

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# ABTRACT

**BACKGROUND:** Pain is a multifaceted sensation comprising both physiological and psychological reactions triggered by a harmful stimulus. It is a most common post-operative sequalae associated with third molar surgery. This causes discomfort to patient and causes emotional and functional deficit. Non-steroidal anti-inflammatory drugs have been used to manage the post-operative pain. NSAIDs have various complications and to eliminate that long-acting anaesthetic drugs can be used alternatively. Local drug delivery reduces systemic toxicity by sustained release of the drug to the target site.

**OBJECTIVE:** To assess the efficacy of 2% Lignocaine HCL and 0.5% Bupivacaine HCL soaked in Absorbable gelatin sponge in reducing post-operative pain associated with impacted mandibular third molar surgery.

**MATERIALS AND METHODS:** A single blinded, randomised controlled trial was conducted on 72 patients who underwent surgical extraction of mandibular third molar surgery. Patients were divided randomly into three groups. Group 1(n=24) patients received 0.9% normal saline-soaked Absorbable gelatin sponge (AGS) placed in the extraction socket. Group 2 (n=24) received 2% plain lignocaine HCL while group 3 received 0.5% plain bupivacaine HCL soaked AGS in the extraction socket. Post-operative pain was assessed using Visual analogue scale at 4hr, 8hr, 12hr, 24hr, post-operative day 2, 3, 4, 5, 6 and 7. Patient satisfaction score, rescue analgesic drug and adverse effects like oedema & trismus were also assessed.

**RESULTS:** The study showed that there was significant($p<0.05$) reduction in post-operative pain in the bupivacaine group as compared to lignocaine and control group

at post-operative 4-hour, 8-hour, 12-hour, day 1, day 2 and day 4. Patient's satisfaction towards the pain control was significant in the bupivacaine group at all intervals with $p<0.05$. There was no significant difference with respect to intake of rescue drug within the three groups $p=0.075$. But there was less intake of analgesic drug in bupivacaine group as compared to others. Adverse effect like postoperative oedema and trismus had no significant difference between the three groups.

**CONCLUSION**: 0.5% Bupivacaine soaked in absorbable gelatin sponge when placed in the extraction socket after impacted mandibular third molar surgery is an effective and safe method to reduce post-operative pain. It has a positive response of the patient towards the pain control and decreased the intake of analgesics as well.

**KEYWORDS**: Impacted mandibular third molar, Bupivacaine, Lignocaine, Absorbable Gelatin Sponge, Post-operative pain.

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# INTRODUCTION

The eruption of third molars typically occurs between the ages of 18 and 24, exhibiting considerable variability in eruption timing. Eruption failure is highly prevalent, leading to the extraction of wisdom teeth becoming most frequently performed surgical procedures globally. (1) Approximately 90% of the general population possesses mandibular third molars, and about 33% of individuals experience the presence of at least one impacted molar.(2) The elevated occurrence of impacted wisdom teeth can be ascribed to a combination of genetic and environmental factors.(3)

Similar to any surgical procedure, this intervention poses inherent risks due to its utilization of nerve blocks, incisions, bone manipulation, and the use of foreign materials for closure. Potential complications range from minor concerns such as discomfort, inflammation, and restricted jaw movement to more serious conditions like alveolar osteitis and lingual nerve paraesthesia. Compared to individuals in good health, patients undergoing surgery for impacted third molars frequently encounter a reduced quality of life post-surgically, primarily due to effects like pain, swelling, and trismus.(4)

Complications associated with the extraction of third molars can vary, with incidence rates ranging from 4.6% to 30.9%. These complications may manifest either during the surgery itself or emerge in the post-surgical phase.(5) Factors linked to complications in the removal of third molars encompass age, gender, medical history, oral contraceptive use, presence of pericoronitis, oral hygiene status, smoking, impaction type, the relationship of the third molar to the inferior alveolar nerve, surgical duration and technique, surgeon expertise, the number of teeth extracted, utilization of

perioperative antibiotics, application of topical antiseptics, administration of intra-socket medications, and the chosen anaesthetic technique.(5,6) Effectively addressing post-surgical dental pain is crucial to eliminate unnecessary patient discomfort, enhance quality of life, and decrease healthcare costs associated with extra clinical visits.(7)

After dental surgery, the usual approach to managing post-surgical pain involves the use of orally administered analgesics. These medications work by either inhibiting inflammatory mediators or interfering with central mechanisms of pain perception (like opioids). While these drugs are highly effective in alleviating pain, their oral delivery necessitates consistent self-medication and comes with the risk of adverse systemic effects. These potential complications include sleep disturbances, nausea, neurological issues, circulatory/respiratory depression, and the risk of developing addiction.(8,9) Opioid analgesics, while highly effective in pain management, are often misused due to their potential for addiction. The misuse of these analgesics can lead to numerous serious complications, contributing to significant public health and social issues.

Alternatively, anaesthetic drugs can be used for post-surgical pain management after third molar extraction. Local anaesthetics are substances that induce temporary loss of sensory, motor, and autonomic functions when administered at suitable dose. This leads to alterations in electrophysiological activity within nerve fibres, neurons, and muscle cells. Among the commonly used agents, Lignocaine Hydrochloride (HCl) and Bupivacaine Hydrochloride (HCl) have gained prominence, each exhibiting distinct pharmacological profiles.

Lignocaine, possessing an amide structure, serves as a local anaesthetic known for its fast onset and moderate duration of action. Due to these characteristics, it is well-suited for applications involving infiltration, regional, and superficial anaesthesia. Bupivacaine possesses an amide structure and is classified as a long-acting local anaesthetic. It exhibits four times the local anaesthetic potency of lidocaine and has a duration of action that is two to three times longer. Additionally, Bupivacaine demonstrates higher lipophilicity compared to short-acting local anaesthetic agents. (10)

Local anaesthetics typically exhibit a brief duration of action, with the majority of drugs having effects lasting less than eight hours. For instance, a solitary injection of Bupivacaine leads to the attainment of maximum plasma drug concentration within 30–45 minutes, followed by complete elimination after 6 hours.(11) The sustained release of local anaesthetics could enhance dental pain management by extending the duration of drug effectiveness and mitigating toxicity through the gradual uptake of drugs into the systemic circulation.(12,13) The administration of a local anaesthetic agent into the post-extraction socket has been suggested as a method to alleviate post-surgical pain. However, the implementation of local delivery therapeutics necessitates a mechanism to retain the agent within the oral environment for a sufficient duration, thereby extending the effectiveness of the drug and diminishing its toxicity by slowing down the uptake of the drug into the systemic circulation.(14)

Gelfoam, a widely used absorbable gelatin sponge which serves as a carrier for local drug delivery in various medical applications. Due to its biocompatibility and ability to absorb and hold fluids, Gelfoam provides an effective platform for delivering medications directly to specific target areas.

In this study, we aim to compare the efficacy of a long-acting local anaesthetic drug, Bupivacaine and an intermediate acting anaesthetic drug, Lignocaine in reducing post-surgical pain with its sustainable release when placed in the socket using absorbable gelatin sponge after impacted mandibular third molar surgery.

## AIM AND OBJECTIVE

### AIM

The aim is to check the efficacy of Lignocaine HCL and Bupivacaine HCL soaked in Absorbable gelatin sponge when placed in the extraction socket after surgical removal of lower wisdom teeth.

### OBJECTIVES

To assess the efficacy of Lignocaine HCL and Bupivacaine HCL soaked in Absorbable gelatin sponge in reducing:

- Post-surgical pain.
- Patient satisfaction towards pain control.
- Rescue analgesic dose required.
- Adverse effects like post-surgical edema and trismus.

### NULL HYPOTHESIS

There is no effect on post-surgical pain on using Lignocaine HCL or Bupivacaine HCL soaked in Absorbable gelatin sponge in the extraction socket after surgical removal of lower wisdom teeth.

### RESEARCH HYPOTHESIS

There is effect on post-surgical pain on using Lignocaine HCL or Bupivacaine HCL soaked in Absorbable gelatin sponge, in the extraction socket after surgical removal of lower wisdom teeth.

## REVIEW OF LITERATURE

1. In 2012, Gamli and colleagues conducted a study wherein they utilized Gelfoam soaked in 20ml 0.25% bupivacaine to pack the bone defect at the iliac site. The control group received saline for the purpose of a placebo effect. The bupivacaine group had 11 patients and saline group had 8 patients. The post-surgical opioid requirement was recorded between 24 and 48 hours after surgery. VAS scale was recorded at 24 and 48-hour intervals. According to the study findings, no evident difference in VAS was seen in between the two. However, a notable distinction was observed in opioid usage, with a lesser amount required in Group B. (15)

2. Dashow et al in 2008 did a retrospective cohort study in which they used bupivacaine-soaked sponge (BAS) along with infiltration of bupivacaine at iliac crest graft site on 118 cleft lip/palate patient which required alveolar bone grafting. It was compared with no BAS group, in which only bupivacaine infiltration alone was used at the surgical site. Assessment was done on the basis of post-surgical, total pain and opioid medication required and length of hospital stay. Significant difference was seen in BAS group having lower pain score, less requirement of total pain and opioid medication and shorter hospital stay. (16)

3. In a RCT conducted by Dr. Saeed and colleagues in 2009, 200 patients who had laparoscopic cholecystectomy (LC) surgery grouped into 4 categories.

Group A comprised 50 patients, in whom bupivacaine in Gelfoam was placed in the bed of gallbladder. Group B had bupivacaine infiltration at the trocar site. In Group C, half of the required dose of 2mg/kg of 0.5% bupivacaine was infiltrated at both the trocar and gallbladder sites, while Group D received normal saline infiltration at both sites.

Post-surgical pain, including intra-abdominal pain, incisional and shoulder pain, was checked using a verbal rating scale at 4h, 8h, 12h, and 24h post-surgically. Significant differences were observed in visceral pain and shoulder pain using the verbal rating scale in Group A compared to Group D. (17)

4. In 2018, Mohamed and colleagues conducted a RCT involving 105 patients who underwent caesarean section. The study checked the potencyof Gelfoam soaked in either 20ml of 0.9% saline (Group C), 20ml of bupivacaine (Group B), or a combination of 0.25% bupivacaine and 2% lidocaine (Group BL). Post surgical pain levels was checked using the VAS scale at 1hr, 2hr, 4hr, 8hr, 12hr, 18hr, and 24hr intervals. First request for pain medication was recorded, patients requiring pain medications and the total pain medication required within the first 24 hours. It was found that post-surgical pain, the time until the first request for analgesia, patients requiring pain medication, and the total amount of analgesic medication required were less in Group B and BL with respect to Group C. (18)

5. In 2021, Shabat conducted a prospective, single-blinded RCT involving 40 patients who had surgical removal of wisdom teeth. Post-surgical pain levels were evaluated at 4 hours and 12 hours after surgery using the NRS scale. In

the control group, comprising 20 patients, an absorbable gelatine sponge (AGS) soaked in 3ml of normal saline was placed in the extraction socket, while in the study group, AGS soaked in 3ml of 0.5% plain bupivacaine was used. A evident difference in post-surgical pain was seen in the study group after 4 hours. All patients were prescribed ibuprofen 400mg TID for 5 days, and none of the patients required additional analgesics. (19)

6. In 2012, Yassen and colleagues conducted a comparative study involving 150 female patients who underwent normal delivery with mediolateral episiotomy. The patients were categorized into 3 groups: Group 1 was provided with 1% lidocaine infiltration at the episiotomy site, Group 2 received 1% lidocaine and 0.5% bupivacaine infiltration at the site, and Group 3 had an absorbable gelatine sponge soaked in 0.5% bupivacaine placed at the site followed by 1% lidocaine infiltration. Post-surgical pain levels were assessed at 0, 1, 1.5, 2, 6, & 24 hrs using the VAS scale. The time of first request for analgesics and the total amount of required pain medicines within the first 24 hours were also recorded. The results indicated that Group 3 exhibited significantly lower pain scores at 1, 1.5, 2, 6, and 24 hours compared to Groups 1 and 2. Additionally, Group 2 showed lower scores with respect to Group 1 at the same time intervals. Group 3 also demonstrated a lower requirement for analgesic dosage and a shorter duration of analgesic requirement compared to the other groups. (20)

7. In 2023, Ashwini Ekka and colleagues conducted a trial involving 98 patients who underwent lumbar laminectomy. These patients were categorized into 3: Group P received Gelfoam in 0.9% NaCl, Group R received Gelfoam soaked in 10ml of 0.5% ropivacaine and 2ml of 0.9% NaCl, and Group RD received Gelfoam soaked in 10ml of 0.5% ropivacaine and 2ml of dexamethasone (8mg).

   Duration of analgesia, 24-hour rescue analgesic consumption, pain scores, hemodynamic parameters, and adverse effects were monitored. Pain levels were assessed at 0, 1, 2, 4, 8, 12, 18, and 24 hours using the VAS scale. The time for first pain medication requirement was significantly prolonged in Group R and RD. Moreover, the need for analgesics was lowest in Group RD, followed by Group R and Group P. The use of Gelfoam in 0.5% ropivacaine and 2 mL dexamethasone epidurally led to prolonged post-surgical analgesia. (21)

8. In 2021, Prakash and colleagues conducted a experiment with 96 patients receiving lumbar laminectomy. Three groups of patients were created: Group D got Gelfoam absorbed in 0.1 mg of dexmedetomidine, Group B got Gelfoam soaked in 5ml of 0.25% isobaric bupivacaine, and Group C got Gelfoam soaked in 0.9% normal saline. The first request for an analgesic, the total rescue medication in the first 24 hours, the VAS was used to measure post-surgical pain, and side effects were noted for up to 48 hours. Group C had the greatest total rescue dose, followed by groups B and D. Group D experienced a longer first rescue analgesic time, and both group D and group B had considerably reduced post-surgical pain. (22)

9. In 2018, K Kumari and colleagues conducted a RCT involving 90 patients who had lumbar laminectomy. These individuals were divided into three groups: Group P received Gelfoam absorbed in 0.9% NaCl, group L received Gelfoam absorbed in levobupivacaine and 2ml of 0.9% NS, and group LD received Gelfoam soaked in 10ml of 0.25% levobupivacaine and 2ml of dexamethasone. The study recorded various parameters including duration of analgesia, 24-hour rescue analgesic consumption, pain scores using the VAS scale at intervals of 0, 1, 2, 4, 8, 12, 18, and 24 hours, hemodynamic parameters, and adverse effects. The time of first pain medication requirement was more in group LD compared to groups L and P. Group LD also exhibited the lowest requirement for analgesics, followed by groups R and P. Throughout all observed time intervals, group LD consistently showed the lowest mean VAS pain scores, while group P demonstrated the highest VAS score. Post-surgical complications were least frequent in group LD.(23)

10. Reza Saebi et al in 2022 did a trial in which 42 patients were included who underwent lumbar discectomy. Patients were categorized into 2 groups, experiment group received Gelfoam soaked with 2cc of dexamethasone (8mg) and 4cc of 0.5% bupivacaine and was placed in irritated nerve root foramina. While the control group received Gelfoam soaked in 6cc of normal saline. Post-surgical pain was measured using VAS at 3, 6, 12 and 24hr. Significant difference was seen in post-surgical low back pain was seen after 3 hours and after 6 hours in lower extremity pain.(24)

11. In 2008, Kafali and colleagues conducted a trial involving 48 females who had mediolateral episiotomy. Group 1 patients received local 1% lignocaine infiltration up to 20ml, while group 2 patients received 1% local lignocaine infiltration along with a bupivacaine-soaked sponge placed in the episiotomy wound. Post-surgical pain was assessed at 0, 1, 1.5, 2, 6, and 24 hours using the VAS scale. Significant reductions in post-surgical pain were observed in Group 2 at all-time intervals. Additionally, the total pain medication requirement was lower in group 2.(25)

12. Simavli et al in 2014 conducted a trial on 164 patient who underwent caesarean section. The study group received bupivacaine soaked Gelfoam placed subcutaneously and the control group received no intervention. Post-surgical pain was recorded at 1, 4, 8, 12, 18, 24, 36 and 48h. At all intervals pain score was evidently lower in the study group. Rescue pain drugs requirement was lower in study group. Complications like post-surgical nausea, vomiting were lower in study group.(26)

13. In 2019, Ideh Talimkhani and colleagues conducted a clinical trial involving 46 patients who underwent surgical removal of wisdom teeth. The intervention group received bupivacaine and a placebo of mefenamic acid, while the control group received mefenamic acid capsules and a placebo of bupivacaine. Post-surgical pain was assessed at 2, 4, 6, 8, 10, and 12-hour intervals using

the VAS scale. Patients who received bupivacaine experienced a mean post-surgical pain score that peaked at four hours, followed by noticeable improvement. Administration of bupivacaine resulted in evidently decrease in pain levels compared to mefenamic acid capsules taken at various intervals.(27)

14. In 2017, Toshiyuki Suzuki and colleagues did a trial to check efficacy and safety. The study involved 99 patients who underwent extraction, distributed into 5 categories: Group 1 - the control group underwent routine extraction, Group 2 - received the PLGA matrix with lidocaine, Group 3 - single SRLS sheet 100mg, Group 4 double SRLS sheet 100mg (200mg), and Group 5 - four SRLS sheets 100mg (400 mg). Post-surgical pain intensity, satisfaction with post-surgical pain relief, adverse events, and post-surgical rescue pain medication use (time, dose) were recorded through patient interviews.

    Post-surgical pain was checked using the VAS scale at 4 hours, 8 hours, day 1 to day 7 after extraction. Satisfaction was checked at day 1 to day 7. Plasma lidocaine concentrations were measured at 24 hours and 7 days after tooth extraction. Since there was no evident differences between categories, it was stated that SRLS membranes could hold therapeutic potential in post-extraction pain management. (28)

15. P.J Chapman in 1986, conducted a crossover trial in 20 patients who underwent removal of lower wisdom teeth. On the control side Lignocaine

was administered and on the intervention side Bupivacaine was administered. Post surgical pain was assessed using VAS at 4h, 8h and 12 h. It was concluded that there was statistically significant reduction in post operative pain in patients receiving Bupivacaine.(29)

16. Jaiswal et al in 2019, published an article explaining the role of bupivacaine in dentistry. Long-acting local anesthetics, such as bupivacaine, are known to have promising results in pain reduction intra and post operatively. They are also helpful for prolonged dental treatments. Even though bupivacaine has fewer side effects at the regular dosages there could be certain toxic effects when using bupivacaine as a pain reliever in a dental context, caution must be used.(30)

17. In 2019, A. Tache and colleagues conducted a systematic review encompassing 15 articles focused on pain management protocols in iliac grafts for cleft alveolus management. The reviewed protocols included various approaches such as simple methods, intravenous analgesia, local aesthetic infiltration at the donor site, anesthetic-absorbed in sponge usage, neural blocks, and uniterrupted infusion at the donor site. However, due to insufficient data and inconsistencies in pain assessment scales, no significant conclusions could be drawn from the review. (31)

18. In 2023, Kun-Min Tsai and colleagues published a study involving patients who underwent hemorrhoidal surgery. One hundred forty-three patients were provided gauze in epinephrine, while the other group were provided an absorbable gelatin sponge. Post-surgical pain was assessed and compared using the VAS scale at 8 hours, the first day, the second day, and the 14th day. Post-surgical hemorrhage was also evaluated. Secondary outcomes such as the length of hospital stay, post-surgical complications, the patients requiring extra conservative management due to complications within 2 weeks of surgery, the duration of first post-surgical defecation. were examined. The study concluded that absorbable gelatin sponge exhibits superior hemostatic properties in the initial days following surgery compared to epinephrine-soaked gauze.(32)

19. In 2014, J.P.R Brown and colleagues published an editorial concerning patients undergoing general anesthesia for Caesarean section. One group received a bupivacaine absorbed in gelatin sponge placed between the abdominal fascia and skin, while the other group received no intervention during abdominal closure. Post-surgical pain at 48 hours was compared between the two groups using the VAS scale, revealing a evident reduction in post-surgical pain in the interventional group. Additionally, post-surgical nausea and vomiting were also less frequent in the interventional group.(33)

20. In 2020, Jazib Nazeer and colleagues conducted study involving 300 patients undergoing impacted mandibular third molar surgery. These participants were categorized into three categories of 100 each. Group 1 was given 2% lignocaine with epinephrine, Group 2 received 0.75% ropivacaine, and Group 3 received bupivacaine. Post-surgical pain was evaluated using both the VAS and VRS scales. The study concluded that patients receiving ropivacaine experienced superior post-surgical analgesia compared to those receiving lignocaine and bupivacaine.(34)

21. In 2013, De Souza and colleagues conducted a split-mouth, trial involving 40 patients. On one side (the control side), a preoperative block of bupivacaine with adrenaline was administered, followed by supplementation with saline as a placebo. On the other side (the study side), supplementation was given with bupivacaine with 1:200,000 epinephrine. Post-surgical pain was checked using the VAS scale at 30 minutes and 1, 2, 4, 6, 8, 10, 12, 24, 36, 48, and 72 hours. The results of the study were inconclusive. (35)

22. In 2015, Brajkoviü and colleagues did a trial involving 102 patients undergoing removal of lower wisdom teeth. These patients were categorized into three groups, each with either 3 mL lidocaine epinephrine, 0.5% bupivacaine, or 0.5% levobupivacaine. Post-surgical pain was checked using the VRS scale at 2, 4, 6, 8, 12, 16hour, day 1 and day 2. The groups receiving

bupivacaine and levobupivacaine demonstrated effective pain control when compared to lidocaine with epinephrine. (36)

23. In 2014, Saoud and colleagues conducted non-RCT involving 100 patients undergoing spinal surgery for lumbar spine. Participants were categorized into two of fifty patients each. In one group, abgel soaked in morphine was administered, while in the other group, intravenous morphine was administered over 4 hours. Post-surgical pain was checked using the VAS scale at 12 hours, day 1, 36 hours, and day 2. The study concluded that epidurally placed morphine-soaked in Abgel following spine surgery is a method of analgesia compared to IV morphine.(37)

24. In 2013, Kevin O'Neill and colleagues conducted trial involving 40 patients who had iliac crest bone graft. The treatment group had 20 patients who received bupivacaine at the iliac bone site, while the control group comprised 20 patients who received saline at the same site. Post-surgical pain was checked using both the VAS and NRS scales at a mean of 5 weeks and up to a follow-up of 20 weeks. Additionally, post-surgical patient satisfaction was measured. The study concluded that bupivacaine at the surgical location of the iliac crest bone graft can provide potent analgesia. (38)

25. In 2018, M.K. Giri and colleagues conducted a prospective trial involving 60 patients undergoing segment laminectomies. These subjects were categorized

into three of 20 each. In Group K, gelfoam measuring 5*1cm and soaked in ketamine diluted with NS was utilized. In Group N patients, gelfoam in nalbuphine diluted with NS, while in category C, gelfoam in NS was placed in the surgical location just before wound closure. Post-surgical pain was checked using the VAS scale at various time interval. Additionally, post-surgical analgesia requirement, time of ambulation, discharge, and post-surgical side were checked. The study concluded that gelfoam soaked in ketamine could serve as an effective method for pain control in laminectomy.(39)

26. In 2014, Sandeep Kundra and colleagues conducted a similar study involving 150 patients undergoing lumbar laminectomy. These subjects were categorized into two of 75 each. Category 1 received absorbable gelatin sponge absorbed in morphine in the surgical location, while Group 2 received a saline absorbed in gelfoam, with 1mg/ml morphine instilled in the intact epidural space.

    PR, MAP, RR, $O_2$saturation, VAS, and sedation score using a 5-point ordinal scale were evaluated hourly for the first six hrs, followed by assessments at 2-hour intervals until 12 hours, and then at 4-hr intervals until day 2. The study observed and concluded that gelfoam soaked in morphine, when placed epidurally, can be beneficial for post-surgical analgesia with fewer complications.(40)

27. In 1997, M. Geraldine Cunniffe and colleagues conducted a study involving 105 patients undergoing laparoscopic surgery. Subjects were categorized two groups. Group A, the control group, comprised 50 participants who were provided with normal saline dome irrigation with 500 mL saline, whereas Group B were provided irrigation with bupivacaine in 500 mL saline. Shoulder tip pain was checkedd using the VAS immediately after surgery, at 4 hours, 10 hours, and 24 hours post-surgically. The study concluded that irrigation with bupivacaine significantly reduces shoulder tip pain following laparoscopic surgeries.(41)

28. In 2010, Khiavi and colleagues conducted a trial involving 34 patients undergoing b/l removal of lower wisdom teeth during a single surgical session. The extraction sockets were randomly irrigated with either 0.5% bupivacaine HCL plain (without vasoconstrictor) or with 4ml of NS. Post-surgical pain was checked through VAS scale at 1 hr, 6 hr, 12 hrs, and 24 hrs. The study concluded that irrigation of the extraction socket with bupivacaine significantly reduces post-surgical pain after wisdom teeth removal.(42)

29. In a prospective trial conducted by Yilmaz et al. in 2013, involving patients undergoing FESS, a total of 41 patients were categorized into two: group 1 comprising 20 patients received 5 mL of levobupivacaine HCL(chirocaine), while group 2 comprising 21 patients received 5 mL of NS. Post-surgical pain was checked using the VAS (0-100) scale at 30 minutes, 1, 2, 8 , 12, and 24

hours. The study concluded that the use of levobupivacaine-soaked PVA sponge can be a potent method for post-surgical pain control in patients undergoing FESS.(43)

30. Hermans et al. conducted a trial involving 40 patients undergoing lumbar decompression surgery. The intervention group received 0.25% bupivacaine, while the control group received 0.9% NaCl. Post-surgical pain was checked using the NRS scale at 2 hrs, 4 hrs, 6 hrs, day 1, and day 2. The study concluded that administering an intraoperative epidural bupivacaine bolus is a safe and efficient method to reduce early post-surgical discomfort after lumbar decompression surgery. This analgesic technique could serve as a helpful adjuvant for individuals undergoing decompressive lumbar spine surgery.(44)

31. In 2021, Asha Garg et al. conducted a RCT involving 80 primigravida women who underwent vaginal deliveries with mediolateral episiotomy. The participants were put into two groups. Group 1, consisting of 40 patients were given 15-20 ml lidocaine locally infiltrated at the episiotomy site, with a Spongostan-sponge soaked in 10ml saline placed at the episiotomy bed. Group 2, also comprising 40 patients, received, in addition to the 15-20 ml lidocaine, Spongostan- soaked with 10 ml of 0.5% bupivacaine placed in the episiotomy location. Post-surgical pain was checked using the VAS at 0, 1, 2, 6, 12, and 24 hours. The study concluded that Spongostan-soaked with bupivacaine

offers various advantages over Spongostan soaked with saline, including better pain relief and exemption from systemic side effects of analgesics.(45)

32. In 2012, Khan et al. conducted a trial involving 206 patients who had lap-chole surgery. Patients were categorized into two groups: Group L with 106 patients and Group B with 100 patients. Group L were given 2% lignocaine diluted in saline, while Group B were given 0.5% bupivacaine diluted in saline. Post-surgical pain was assessed at 0, 4 hs, 8 hr, 12 hr, and day 1 using both the VAS and the Verbal Rating Scale. Additionally, the post-surgical use of additional analgesia was evaluated. The study found a marginally significant difference and concluded that both lignocaine and bupivacaine are equally effective in controlling post-surgical pain. (46)

33. In 2018, Adelusi et al. conducted a trial involving 252 patients undergoing intra-alveolar tooth extraction. Group A were provided with bupivacaine with epinephrine, while Group B were provided with lidocaine with epinephrine. Pain score was checked before giving local anesthetic agent, at 10 minutes after the giving LA, and post-surgically at 1, 3, 6, 9, 12, 24, 36, and 48 hours. Patient satisfaction was also recorded using an ordinal scale. The consumption of post-surgical analgesics was lower, and patient satisfaction was higher in the bupivacaine group. Therefore, the study concluded that bupivacaine tends to provide more potent post-extraction analgesia when compared to lignocaine.(47)

34. Peyvandi et al. conducted a trial in 2016 on patients undergoing elective tonsillectomy or adenotonsillectomy. Sixty patients were put into three category of 20 patients each. The peritonsillar bed was injected with 0.5% bupivacaine epinephrine in Group 1, 2% lidocaine with epinephrine in Group 2, and normal saline with 0.001% epinephrine in Group 3. The severity of pain was checked using the VAS at 5 hours, 10 hours, and 20 hours post-surgically. Post-surgical pain wasmilder in the bupivacaine category compared to the lidocaine and saline groups. The study concluded that bupivacaine, when infiltrated into the peritonsillar bed, can reduce pain on the first post-surgical day.(48)

35. In 2020, Gupta conducted trial involving 250 patients who had removal of posterior teeth. The patients were distributed into three groups comprising 86, 84, and 80 patients, respectively. Group 1 were given lignocaine, Group 2 had bupivacaine, and Group 3 received ropivacaine. Intraoperative vital signs, post-surgical pain, and analgesic effects were assessed. Post-surgical pain was noted using the VAS and the VRS, revealing a evident difference in post-surgical analgesia among all three groups. The study concluded that the most potent and effective post-surgical analgesia was achieved in the ropivacaine group.(49)

36. In 2020, Agrawal conducted a controlled trial involving 50 patients undergoing surgical removal of wisdom teeth. Subjects were distributed into

two categories: Group 1 were given lignocaine with adrenaline, while Group 2 were given bupivacaine without vasoconstrictor. Post-surgically, the time of complete disappearance of numbness, the onset of pain, and the number of pain medication were noted at 2 hr, 4 hrs, 8 hrs, 12 hrs, and 24 hours. Patients were instructed to indicate their subjective post-surgical pain intensity on a VAS from 'no pain' to 'worst pain' on the questionnaire. A evident difference in pain was observed only at the 8th hour. Therefore, the study concluded that more effective pain control was achieved with bupivacaine compared to lignocaine.(50)

## METHODOLOGY:

### STUDY DESIGN:

A single blinded randomized controlled trial

### SOURCE OF DATA:

The research was carried out on individuals presenting to the Department of Oral and Maxillofacial Surgery at KLE VK Institute of Dental Sciences, K.A.H.E.R, Belagavi, who were experiencing issues related to impacted mandibular third molars. All patients provided informed written consent for the procedure. Institutional ethical committee approval was obtained for the study. (Annexure 1,2)

### INCLUSION CRITERIA:

- Patients who are ready to participate in the study.
- Patients belonging to the age category of 18-50 years.
- Patients who have not used any antibiotic/antimicrobial or anti-inflammatory drugs 1 week before surgery.
- Patients with moderate surgical difficulty score on Pederson's index (5-6).
- Patients with ASA status I and having normal bleeding & clotting times
- Patients who are non-smokers.

### EXCLUSION CRITERIA:

- Patients who are not ready to participate in the study.
- Patients with presence of any systemic disorders.
- Patients with previous history of radiation therapy.
- Patients who had undergone organ transplantation.
- Patients allergic to anaesthetic agent.
- Pregnant or lactating female subjects.

**LABORATORY DETAILS:**

- Hb, BT, CT, RBS
- OPG/IOPA

**SAMPLE SIZE ESTIMATION:**

The sample size can be calculated using the formula

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

At 95% confidence level, $Z_{1-\alpha/2} = 1.96$

At 95% power $Z_{1-\beta} = 1.64$

Standard deviation in the 1st group, $S_1 = 2.43$

Standard deviation in the 2nd group, $S_2 = 3.14$

N = 24 in each group.

Therefore, the sample size is **72**

**METHODOLOGY:**

- A total of 72 patients with mandibular impacted third molar diagnosed by established clinical and radiographic parameters and who meet the inclusion criteria were distributed into three categories of 24 each by computer generated random allocation:

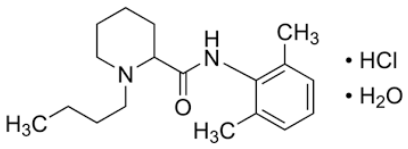
- **Group A: Control group I -** removal of lower wisdom teeth with NS-soaked Absorbable Gelatin sponge placed in the socket followed by routine closure. (n = 24)

- **Group B: Study group II** – removal of lower wisdom teeth with 2% plain Lignocaine HCL soaked Absorbable Gelatin Sponge placed in the socket followed by routine closure. (n = 24)

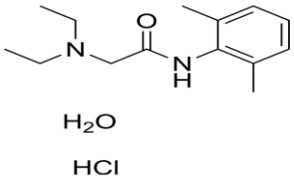
- **Group C: Study group III -** removal of lower wisdom teeth with 0.5% plain Bupivacaine HCL soaked Absorbable Gelatin Sponge placed in the socket followed by routine closure. (n = 24)

**Materials used:**

1. 0.5% plain Bupivacaine hydrochloride: "1-butyl-*N*-(2,6-dimethylphenyl) piperidine-2-carboxamide; hydrochloride", **C18H29ClN2O**




2. 2% plain lignocaine hydrochloride: "2-(diethylamino)-*N*-(2,6-dimethylphenyl) acetamide; hydrochloride", **C14H23ClN2O**




3. Absorbable gelatin sponge: Goodwill Hemosponge, measuring 10x10x10mm in size.

**PREPARATION OF THE DRUG:**

1. 3ml of Normal saline was poured in a Petri dish.

   Absorbable gelatin sponge (10mm*10mm*10mm) was soaked in the Petri dish for 5 minutes and then placed in the extraction socket.

2. 3ml of 2% plain Lignocaine was poured in a Petri dish.

   Absorbable gelatin sponge (10mm*10mm*10mm) was soaked in the Petri dish for 5 minutes and then placed in the extraction socket.

3. 3ml of 0.5% plain Bupivacaine was poured in a Petri dish.

   Absorbable gelatin sponge (10mm*10mm*10mm) was soaked in the Petri dish for 5 minutes and then placed in the extraction socket.

**METHODOLOGY WITH FLOWCHART:**

Individuals diagnosed with mandibular impacted third molars based on established clinical and radiographic parameters and meeting the inclusion criteria were randomly divided into three groups of 24 each using computer-generated random allocation.

↓

Assigned patients underwent surgical procedure in the oral surgery unit by the same experienced surgeon.

↓

Local anaesthesia was given with 2% lignocaine plus adrenaline 1:80,000.

↓

A full thickness ward's incision was made to prepare a muco-periosteal flap

↓

Flap was elevated and reflected; bone guttering (tooth sectioning if required) was done

↓

After completing the extraction, curettage was performed to remove any unhealthy granulation tissue.

↓

Extraction socket was inspected for any sharp bony margins and removed if present followed by copious irrigation.

↓

After this, group I received Normal saline soaked AGS placed in the socket, in Group II 2% plain Lignocaine HCL soaked AGS was placed in the socket and in Group III 0.5% plain Bupivacaine HCL soaked AGS was placed in the socket.

↓

The flap was repositioned and sutured with 3-0 silk sutures except the releasing incision.

↓

A pressure pack was placed on the extraction site. All patients received post-extraction instructions.

↓

Patients of all three groups were prescribed the following drugs:

CAP. AMOXICILLIN 500mg q8h for 5 days

TAB. PARACETAMOL 650mg q8h for 3 days

TAB. PANTEPRAZOLE 40mg OD for 5 days

TAB. IBUPROFEN 400mg SOS. (Rescue drug)

**FOLLOW UP:** On the 2$^{nd}$ and 7$^{th}$ day after surgical extraction of third molar.

Patient were given log sheet to record VAS scale, Patient satisfaction score and analgesic rescue drugs.

## EVALUATION CRITERIA:

Primary outcome and variables were:

### POST-SURGICAL PAIN:

Patients were provided with a Visual Analogue Scale with a score of 0-10.

- Post-surgical pain was assessed immediately after extraction and then post-op 4h, 8h, 12h, day 1 to day 7 after tooth extraction.

### POST-SURGICAL PAIN SATISFACTION:

It was assessed by using a 5-grade scale:

| Score | Level of Satisfaction |
|---|---|
| 1 | Dissatisfied |
| 2 | Rather-dissatisfied |
| 3 | Neither |
| 4 | Rather satisfied |
| 5 | Satisfied |

Post-surgical pain satisfaction was assessed immediately after extraction and then post-op 4h, 8h, 12h, day 1 to day 7 after tooth extraction.

### POST-SURGICAL SUPPLEMENTAL ANALGESIC RESCUE TIME AND DOSE:

It was assessed by self-reporting from the patient on the $2^{nd}$ day and $7^{th}$ day.

**ASSESSMENT OF ADVERSE EFFECT:**

Adverse effect like edema, trismus was assessed on the follow up day, i.e., 2nd day and 7th day.

Reduced mouth opening was assessed by measuring the inter-incisal distance by using a caliper.

Edema was assessed by measuring the distance between:

1. Corner of the eye to angle of mandible
2. Tragus to pogonion
3. Tragus to corner of the mouth.

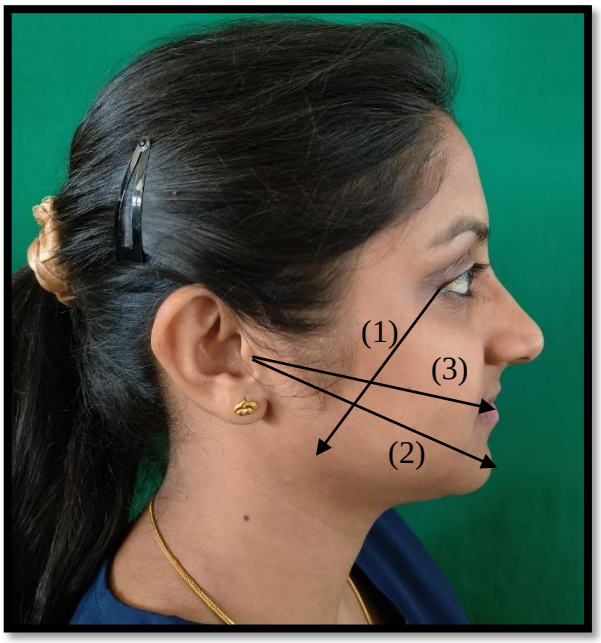



**IMAGE 2: ASSESSMENT OF SWELLING**

**SURGICAL ARMAMENTARIUM:**

- Surgical gloves
- Mouth mirror
- Dental explorer
- Tweezer
- 2ml disposable syringe
- Suction tip
- Sponge holder
- Gauze piece
- Surgical scalpel blade no. 15
- Langenbeck retractor
- Periosteal elevator
- Straight elevator
- Artery forcep
- Curette
- Bone file
- Needle holder
- Adson's tissue forcep
- Suture cutting scissor
- Surgical handpiece and burs
- Kidney tray
- Irrigation syringe 20ml
- Surgical drape
- Towel clip
- 2% Lignocaine HCL

- 0.5% Bupivacaine HCL
- Absorbable gelatin sponge (10*10*10mm)

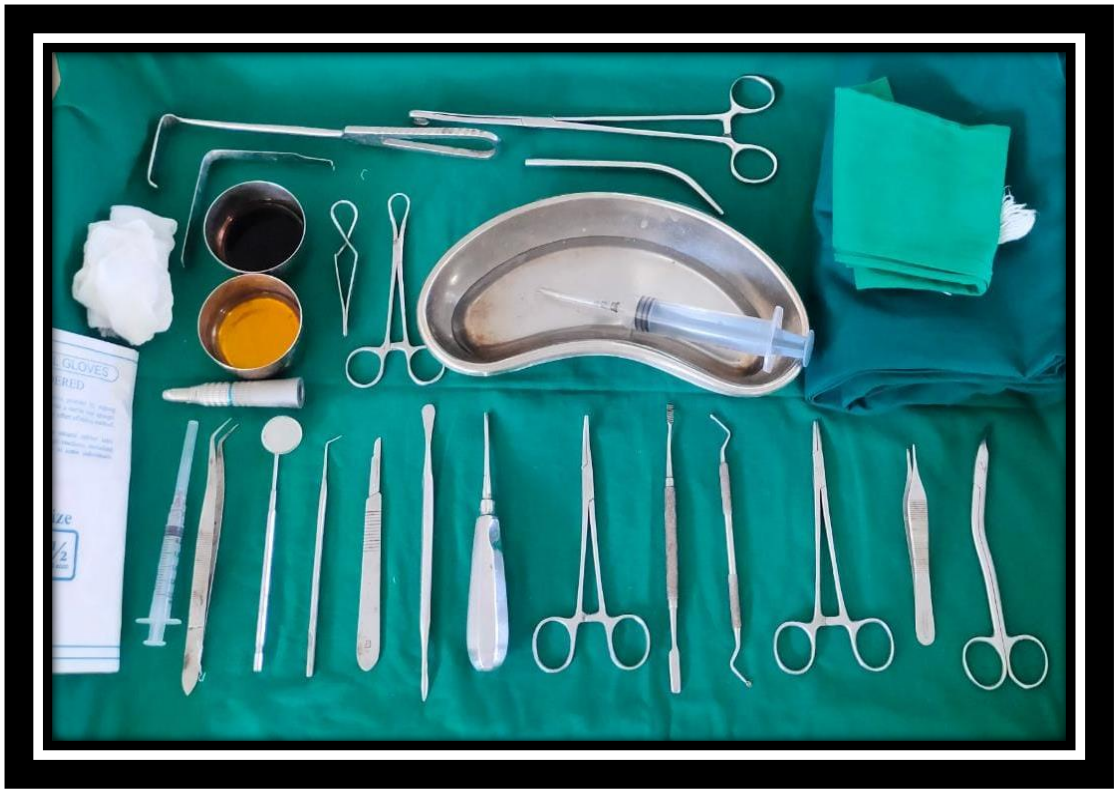


**IMAGE 3: ARMAMENTARIUM FOR SURGICAL EXTRACTION**

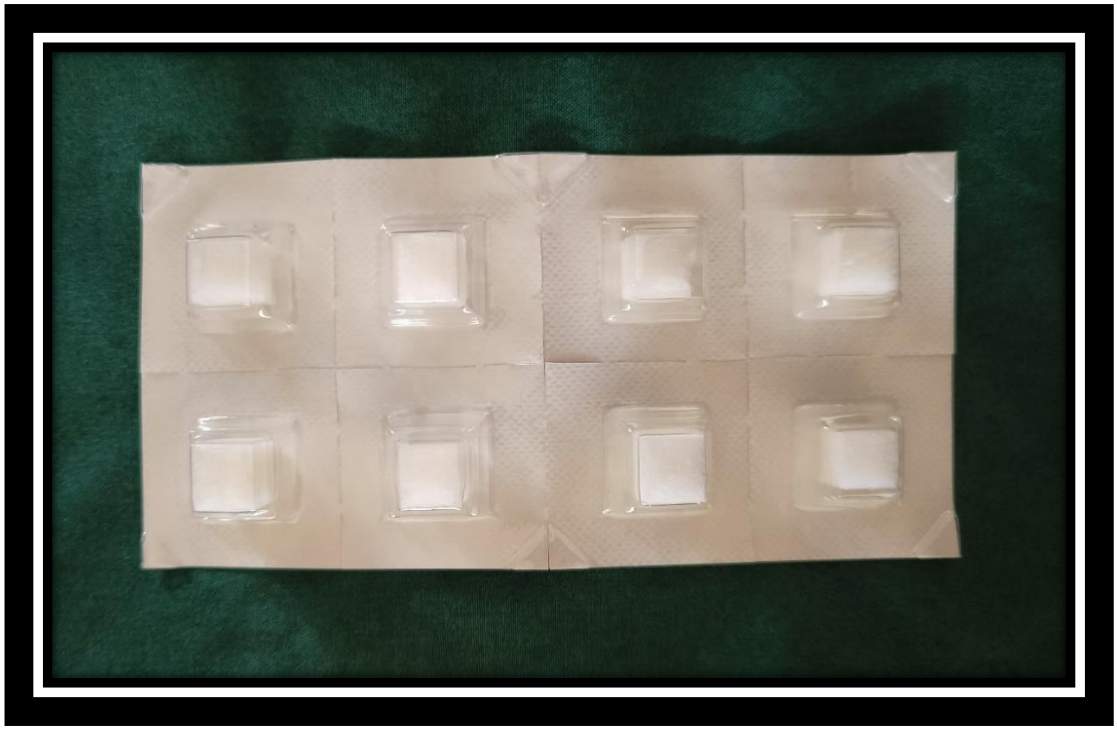


**IMAGE 4: ABSORBABLE GELATIN SPONGE**


**IMAGE 5: 2% PLAIN LIGNOCAINE HCl**

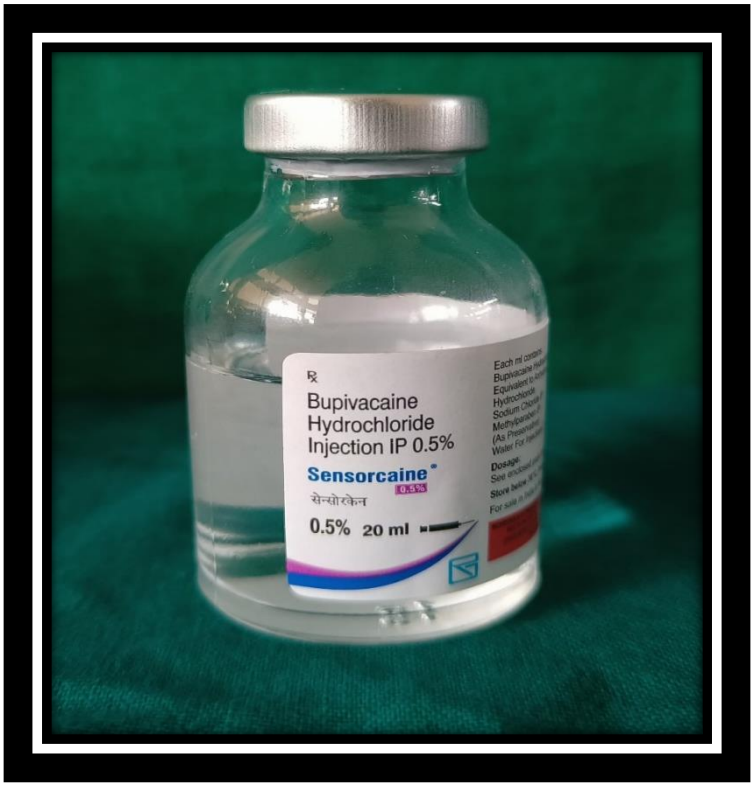



**IMAGE 6: 0.5% PLAIN BUPIVACAINE HCl**

## DATA COLLECTION METHODS AND ANALYSIS:

Data collection was done using log sheet that was provided to the patient on the day of extraction and was collected on the follow up Day 7. (Annexure 3)

Photographs for evaluating oedema and trismus were taken pre-operatively, post-surgical day 2 and on post-surgical day-7. (Figure 6-17)

## PRE-OPERATIVE PATIENT'S PHOTOGRAPHS

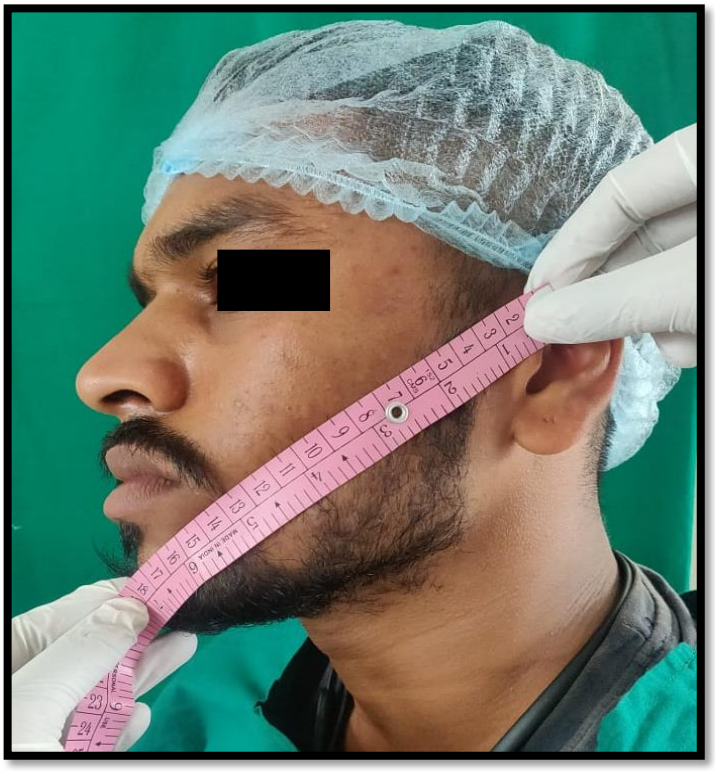


**IMAGE 7: Tragus to Pogonion**

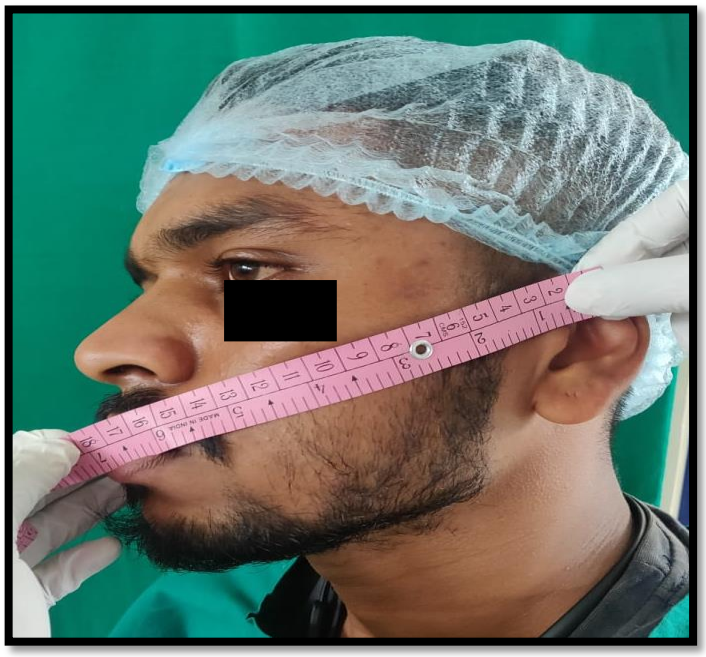


**IMAGE 8: Tragus to corner of the mouth**

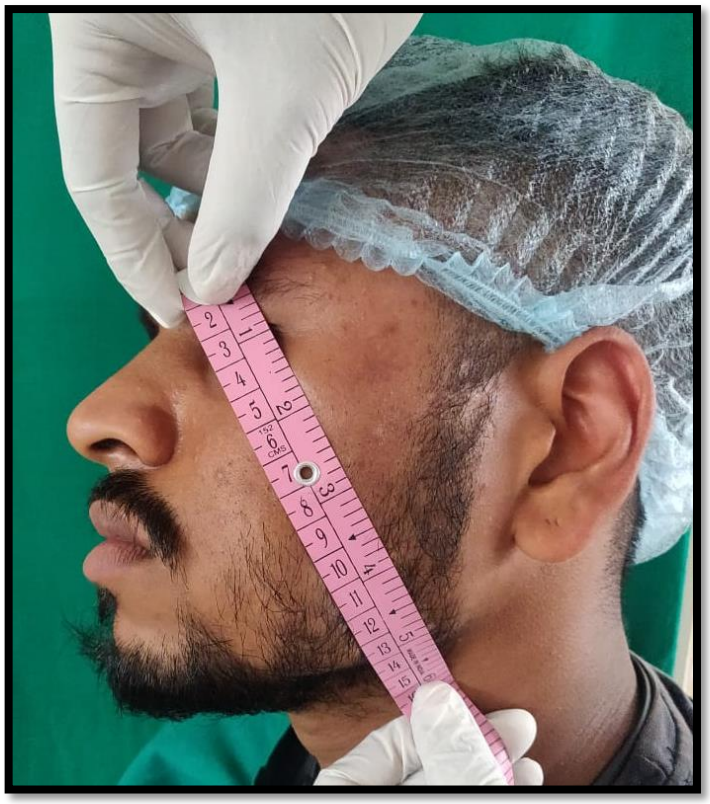


**IMAGE 9: Corner of the eye to angle**

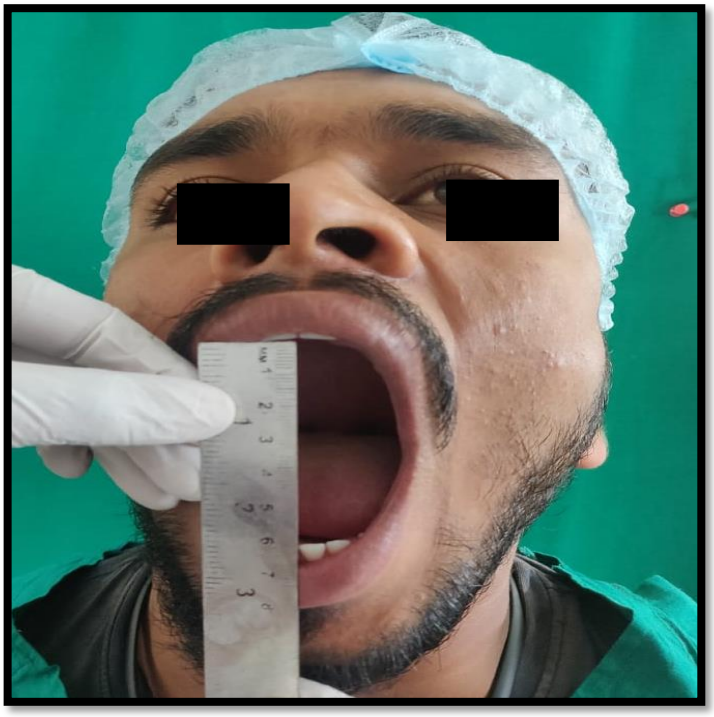


**IMAGE 10: Interincisal distance**

## POST-SURGICAL DAY-2 PATIENT'S PHOTOGRAPHS

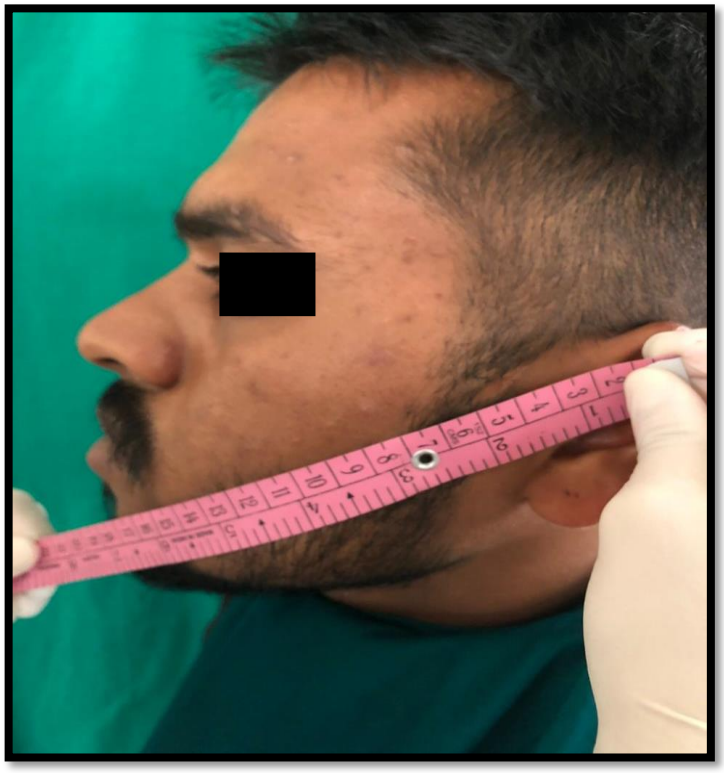


**IMAGE 11: Tragus to Pogonion**

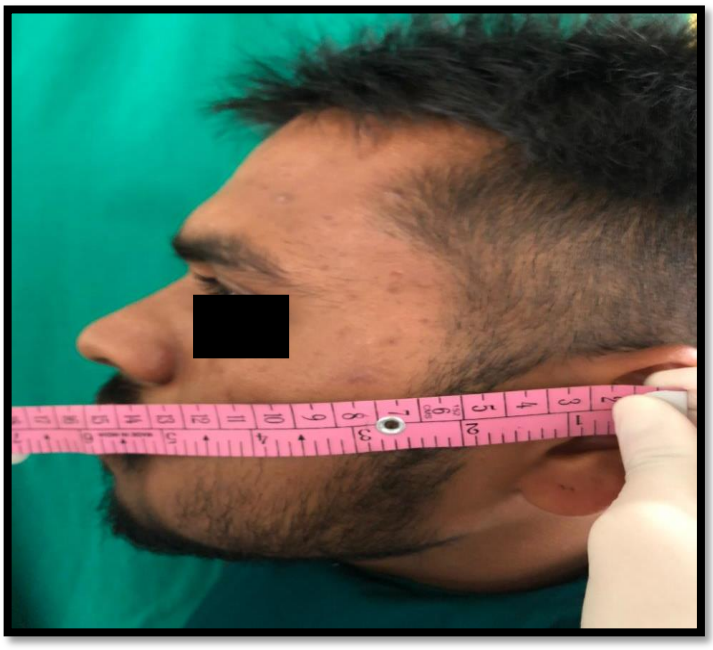


**IMAGE 12: Tragus to corner of the mouth**

**IMAGE 13: Corner of the eye to angle**

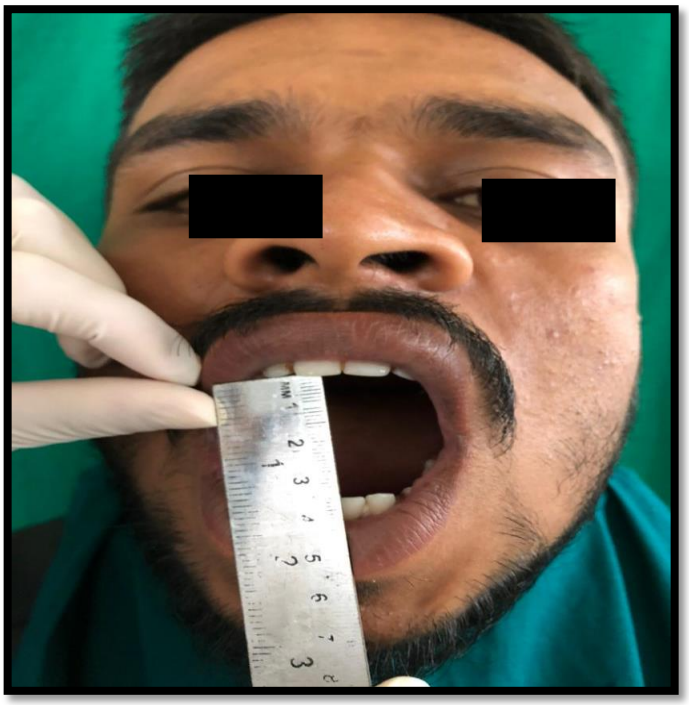


**IMAGE 14: Interincisal distance**

## POST-SURGICAL DAY-7 PATIENT'S PHOTOGRAPHS

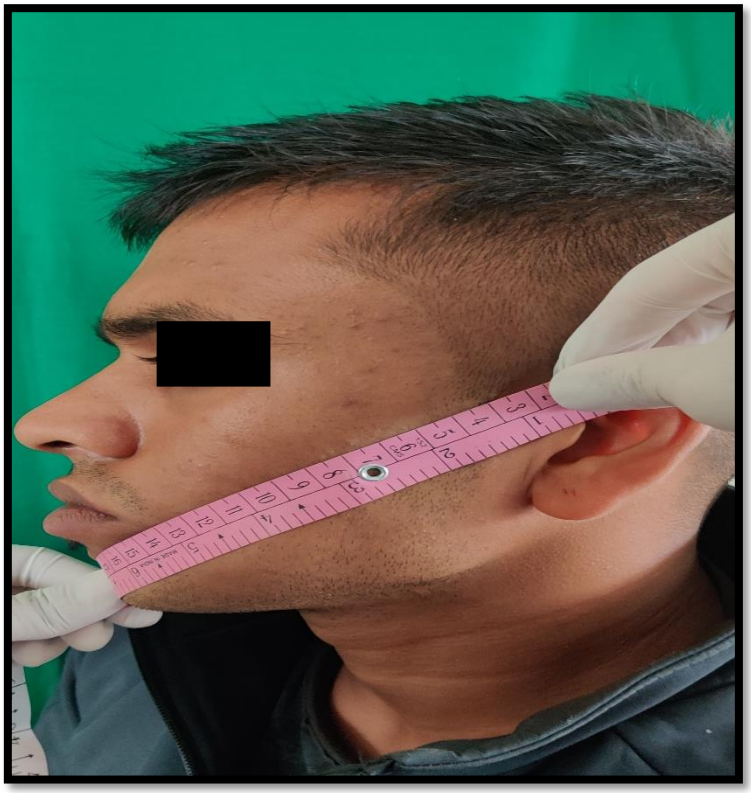


**IMAGE 15: Tragus to Pogonion**

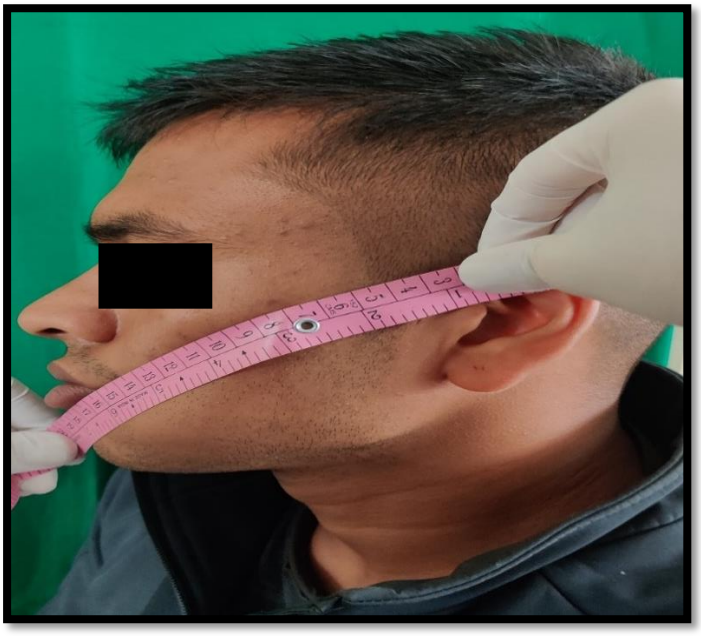


**IMAGE 16: Tragus to corner of the mouth**

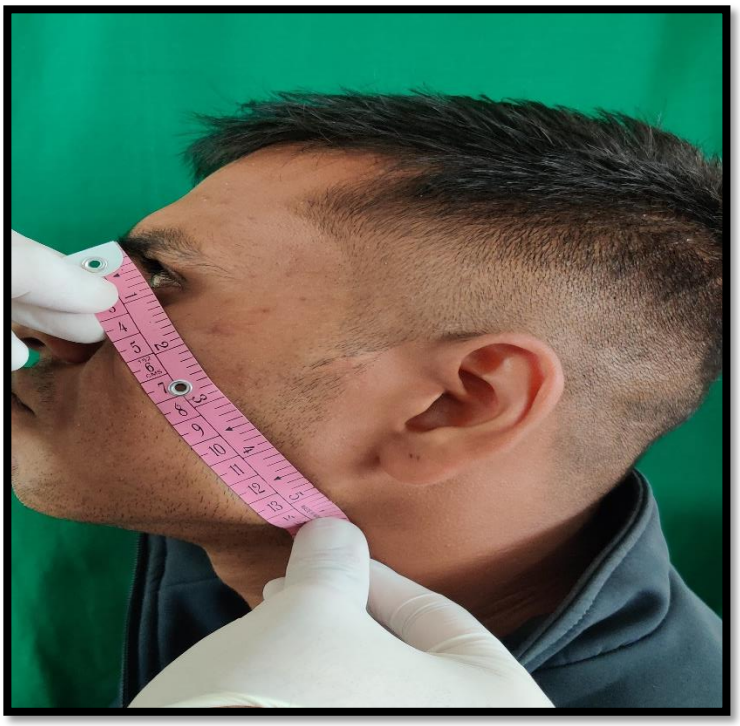


**IMAGE 17: Corner of the eye to angle**

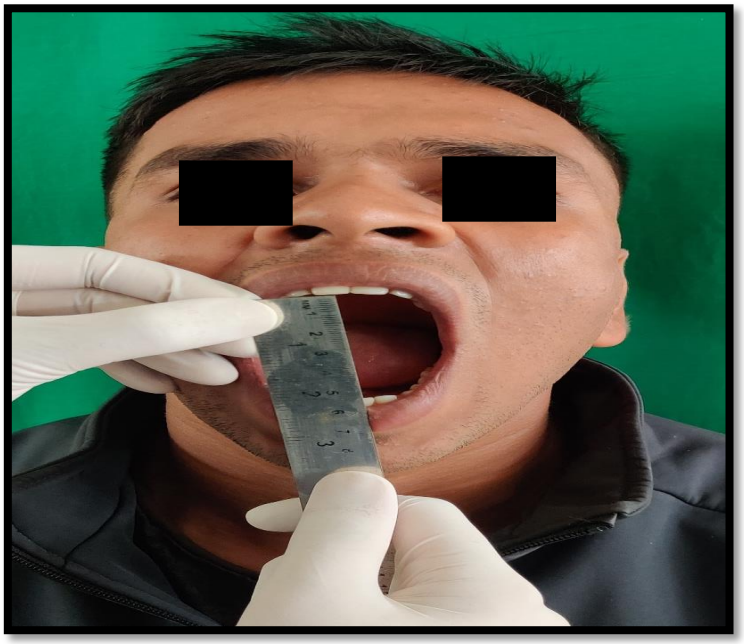


**IMAGE 18: Interincisal distance**

# RESULTS

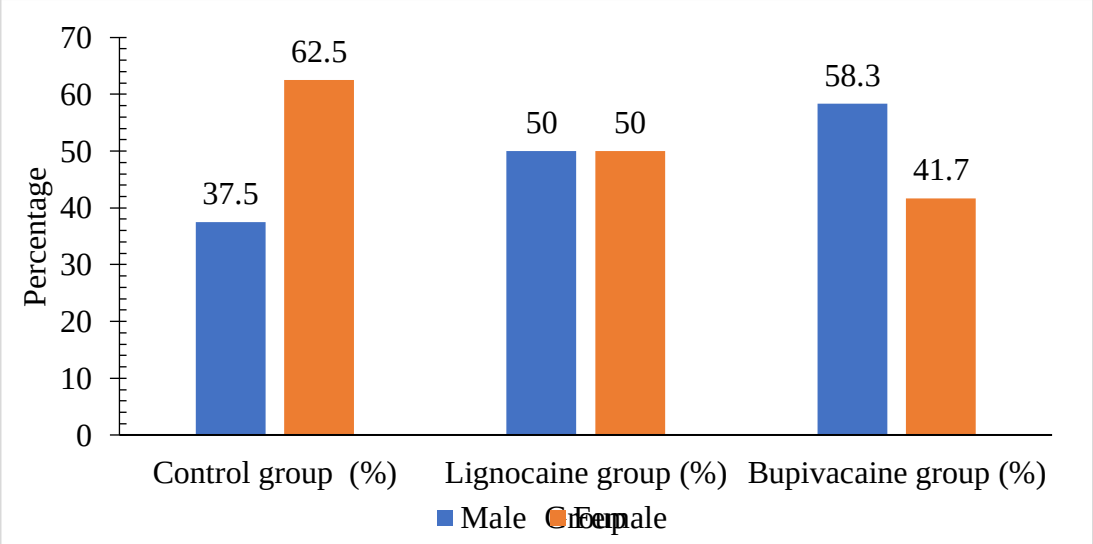
## DEMOGRAPHIC DATA

In the study, seventy-two patients were included (35 male and 37 females). Control group included 9 male and 15 female patients. Lignocaine group had equal distribution of male and female patients, i.e., 12 in each group. Bupivacaine group included 14 male and 10 female patients.

**Table 1: Distribution of male and female participants in Control group, Lignocaine group and Bupivacaine group**.

| Sex | Control group (%) | | Lignocaine group (%) | | Bupivacaine group (%) | |
|---|---|---|---|---|---|---|
| | **n** | **%** | **n** | **%** | **n** | **%** |
| **Male** | 9 | 37.5 | 12 | 50 | 14 | 58.3 |
| **Female** | 15 | 62.5 | 12 | 50 | 10 | 41.7 |

**Graph 1: Graphical distribution of male and female participants in Control group, Lignocaine group and Bupivacaine group**.

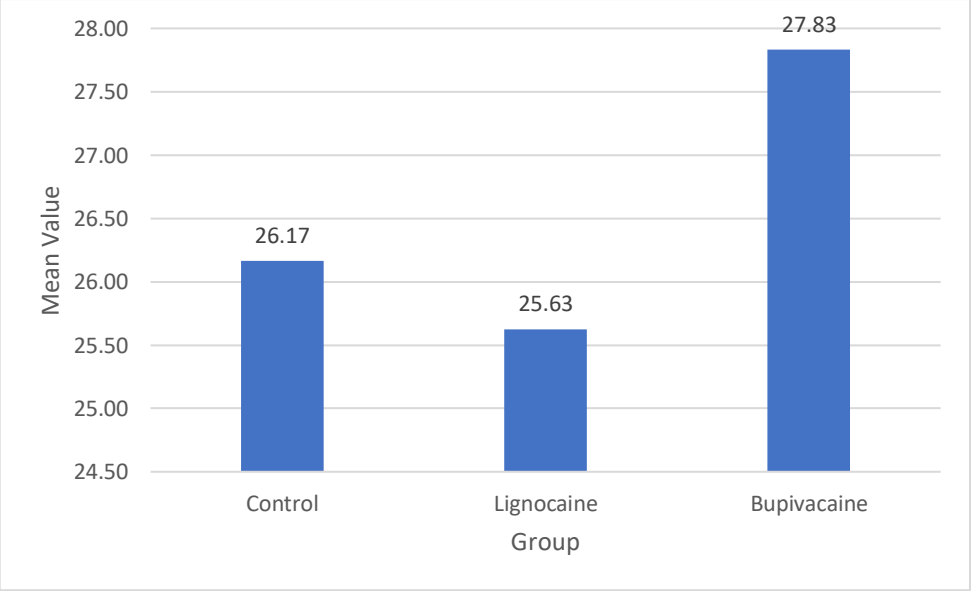


## AGE DISTRIBUTION:

**Table 2: Comparison of Control group, Lignocaine group and Bupivacaine group with mean age by Kruskal-Wallis test**

| Group | N | Mean | SD | SE | H Value | p value |
|---|---|---|---|---|---|---|
| **Control** | 24 | 26.17 | 5.39 | 1.1 | 2.03 | 0.361 |
| **Lignocaine** | 24 | 25.63 | 5.56 | 1.14 | | |
| **Bupivacaine** | 24 | 27.83 | 5.57 | 1.14 | | |
| **Total** | 72 | 26.54 | 5.51 | 0.65 | | |

**Graph 2: Graphical representation of mean age comparison of Control group, Lignocaine group and Bupivacaine group by Kruskal-Wallis test**




The mean age value for the control group, lignocaine group and bupivacaine group were 26.17 ± 5.39 years, 25.63 ± 5.56 years, and 27.83 ± 5.57 years respectively. The comparison between them were not found to be statistically significant (p=0.361) which denotes no baseline difference between the three groups.

**PEDERSON'S INDEX**

**Table 3: Comparison of Control group, Lignocaine group and Bupivacaine group with mean Pederson's difficulty index scores by Kruskal-Wallis test**

| Group | N | Mean | SD | SE | H Value | p value |
|---|---|---|---|---|---|---|
| **Control** | 24 | 5.46 | 0.51 | 0.1 | 0.111 | 0.946 |
| **Lignocaine** | 24 | 5.42 | 0.5 | 0.1 | | |
| **Bupivacaine** | 24 | 5.46 | 0.51 | 0.1 | | |
| **Total** | 72 | 5.44 | 0.5 | 0.06 | | |

**Graph 3: Graphical representation of Pederson's difficulty index comparison of Control group, Lignocaine group and Bupivacaine group by Kruskal-Wallis test**

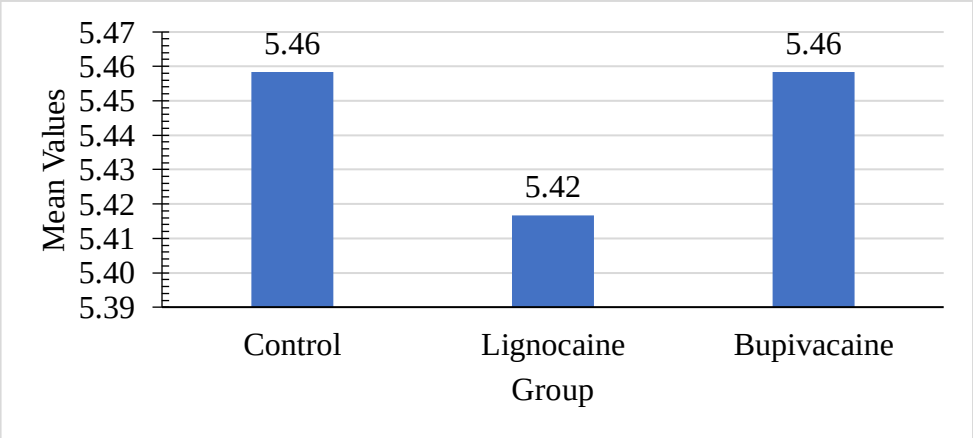



Table 3 provides the mean, SD and SE values of Pederson's difficulty index for the three groups control, lignocaine and bupivacaine and also compares them using Kruskal-Wallis test. The mean value for control group was 5.46 ± 0.51, and for lignocaine it was 5.42 ± 0.50 while for bupivacaine, it was 5.46 ± 0.51. The baseline difference between them were not evidently significant. (p=0.946)

**PAIN ASSESSMENT:**

The comparison of Pain, using mean VAS score, between control group, lignocaine group and bupivacaine group was conducted using Generalised Linear Model (GLM). The data was expressed in terms of mean and SD.

**TABLE 4: Mean comparison of VAS between different 3 Groups**

| Group | Control | Lignocaine | Bupivacaine |
|---|---|---|---|
| | **Mean ± SD** | **Mean ± SD** | **Mean ± SD** |
| | **5.61 ± 3.162** | **5.50 ± 3.066** | **4.46 ± 2.415** |
| **Control** | ---- | ---- | ---- |
| **Lignocaine** | 0.12 p=0.483 | ---- | ---- |
| **Bupivacaine** | 1.15 p<0.001* | 1.03 p<0.001* | ---- |

Table 4 showed a evident difference in mean of VAS between the groups (control and Bupivacaine) and (Bupivacaine and Lignocaine) with $p<0.05$, however there was no evident difference between (control and Lignocaine, $p=0.483$), all comparison being independent of time points.

When comparison was done amongst different time intervals, a significant difference in means of VAS score was seen in all time periods except between time periods ($4^{th}$ hour vs 8th hour, $12^{th}$ hour) and ($8^{th}$ hour and $12^{th}$ hour) There was significant reduction in VAS mean value across times independent of groups with $p<0.001$.

There was decrease in VAS with passage of time (from24 hrs onwards) as compared to baseline.

**TABLE 5: Comparison of three groups (Control, Lignocaine, Bupivacaine) with mean VAS scores at different time points**

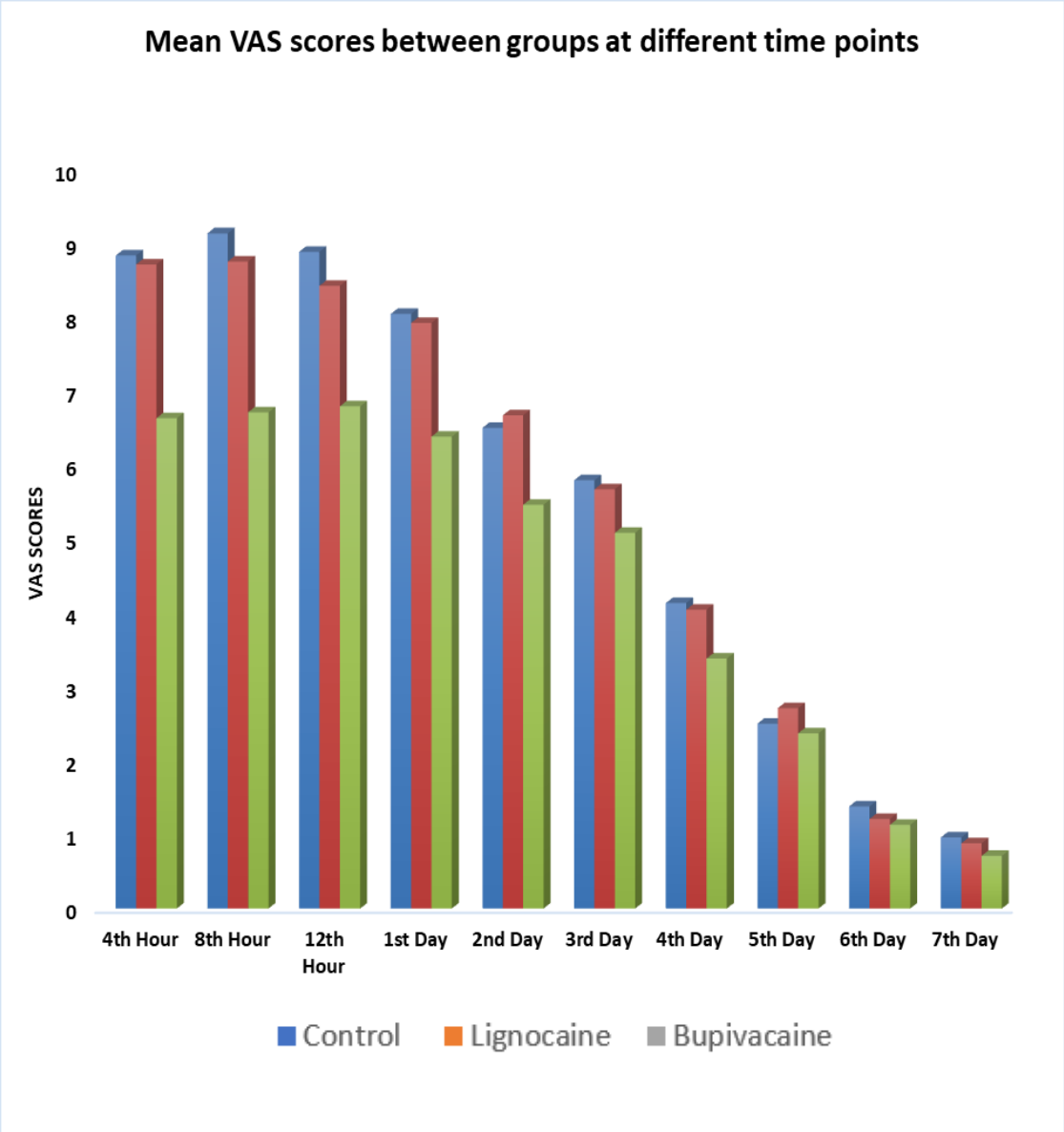
| | | Control-Lignocaine | Control-Bupivacaine | Lignocaine - Bupivacaine |
|---|---|---|---|---|
| **4th Hour** | | | | |
| **Control** | 8.83 ± 0.816 | | | |
| **Lignocaine** | 8.71 ± 0.69 | 0.125 p =1.00 | 2.208 p<0.001* | 2.083 p<0.001* |
| **Bupivacaine** | 6.63 ± 0.824 | | | |
| **8th Hour** | | | | |
| **Control** | 9.13 ± 0.797 | | | |
| **Lignocaine** | 8.75 ± 0.737 | 0.375 p= 0.23 | 2.417 p<0.001* | 2.042 p<0.001* |
| **Bupivacaine** | 6.71 ± 0.624 | | | |
| **12th Hour** | | | | |
| **Control** | 8.88 ± 0.797 | 0.458 p= 0.14 | | |
| **Lignocaine** | 8.42± 0.83 | | 2.083 p<0.001* | 1.625 p<0.001* |
| **Bupivacaine** | 6.79 ± 0.721 | | | |
| **1st Day** | | | | |
| **Control** | 8.04 ± 0.99 | | | |
| **Lignocaine** | 7.92 ± 0.766 | 0.125 p=1.0 | 1.667 p<0.001* | 1.542 p<0.001* |
| **Bupivacaine** | 6.38 ± 0.924 | | | |
| **2nd Day** | | | | |
| **Control** | 6.5 ± 0.834 | | | |
| **Lignocaine** | 6.67 ± 0.963 | -0.167 p=0.258 | 1.04 p<0.001* | 1.208 p<0.001* |
| **Bupivacaine** | 5.46 ± 0.884 | | | |

| | | | | |
|---|---|---|---|---|
| **3rd Day** | | | | |
| **Control** | 5.79 ± 1.062 | 0.125 p=1 | 0.708 p =0.103 | 0.583 p= 0.239 |
| **Lignocaine** | 5.67 ± 1.274 | | | |
| **Bupivacaine** | 5.08 ± 1.06 | | | |
| **4th Day** | | | | |
| **Control** | 4.13 ± 0.9 | 0.083 p=1.0 | 0.750 p = 0.022* | 0.667 p=0.05* |
| **Lignocaine** | 4.04 ± 0.806 | | | |
| **Bupivacaine** | 3.38 ± 1.096 | | | |
| **5th Day** | | | | |
| **Control** | 2.5 ± 1.18 | -0.208 p=1.0 | 0.125 p=1.0 | 0.33 p=0.792 |
| **Lignocaine** | 2.71 ± 1.042 | | | |
| **Bupivacaine** | 2.37 ± 0.824 | | | |
| **6th Day** | | | | |
| **Control** | 1.38 ± 0.875 | 0.167 p=1.00 | 0.25 p=0.849 | 0.083 p= 1.00 |
| **Lignocaine** | 1.21 ± 0.721 | | | |
| **Bupivacaine** | 1.13 ± 0.797 | | | |
| **7th Day** | | | | |
| **Control** | 0.96 ± 0.751 | 0.083 p=1.0 | 0.25 p= 0.714 | 0.167 p=1.0 |
| **Lignocaine** | 0.88 ± 0.68 | | | |
| **Bupivacaine** | 0.71 ± 0.751 | | | |

**Table 5 demonstrated** comparison at different periods on with respect to VAS scores in all 3 groups (Control, Lignocaine, Bupivacaine). There was no evident difference between Control and Lignocaine at any time point of the study. There was

no significant difference between any groups on 3rd Day, 5th Day, 6th Day and 7th Day. Evident significant difference was seen between (Control – Bupivacaine), (Lignocaine-Bupivacaine) on 4th Hour, 8th Hour, 12th Hour, 1st Day, 2nd Day and 4th Day with $p<0.05$*

**Graph 4: Graphical representation of comparison of all three groups at all time interval on the basis of mean VAS.**



**Patient Satisfaction Score (PSS) towards pain control:**

The comparison of patient satisfaction towards pain, using mean PSS score, between control group, lignocaine group and bupivacaine group was conducted using Generalised Linear Model (GLM). The data was expressed in terms of mean and standard deviation.

**TABLE 6: Mean comparison of PSS between different 3 Groups**

| **Groups** | **Control** | **Lignocaine** | **Bupivacaine** |
|---|---|---|---|
| | **Mean ± SD** | **Mean ± SD** | **Mean ± SD** |
| | **2.38 ± 1.084** | **2.27± 1.033** | **3.67± 0.811** |
| **Control** | ---- | ---- | ---- |
| **Lignocaine** | O.12 p=0.372 | ---- | ---- |
| **Bupivacaine** | 1.40 p<0.001* | 1.28 p<0.001* | ---- |

**Table No 6** showed a evident difference in mean of PSS between the groups (control and Bupivacaine) and (Bupivacaine and Lignocaine) with p<0.05, however there was no evident difference between (control and Lignocaine, p=0.372), all comparison being independent of time points.

Evident difference was seen between all the days among all the groups with p<0.001* except for ($8^{th}$hour vs $12^{th}$ hour, $1^{st}$ Day) and ($12^{th}$ hour vs $1^{st}$ Day). There was significant increase in PSS mean value across times independent of groups with p<0.001.

There was increase in PSS with passage of time (from $8^{th}$ hrs onwards.) as compared to baseline.

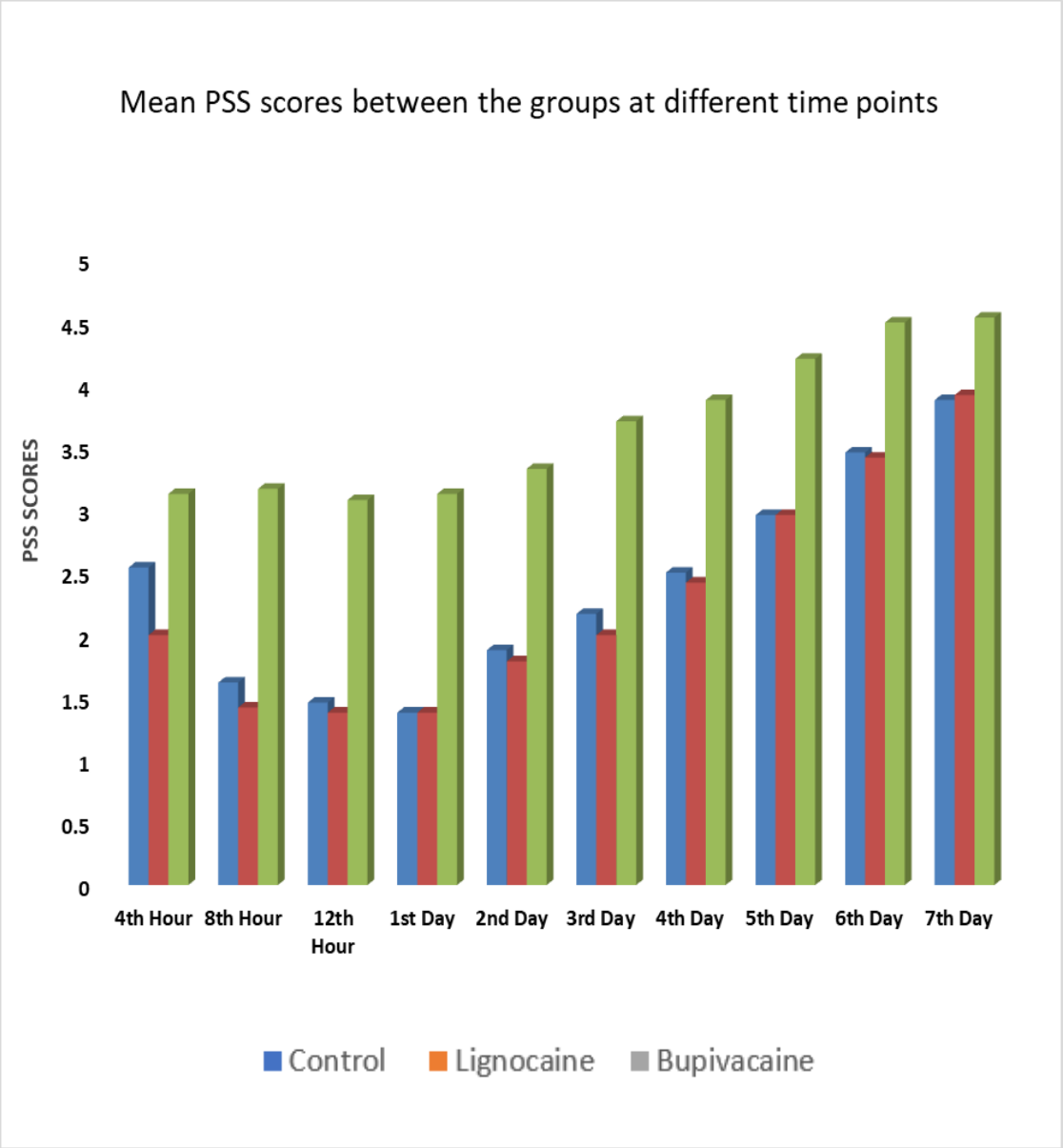
**Table 7: Comparison of three groups (Control, Lignocaine, Bupivacaine) with mean PSS scores at different time points**

| | | Control-Lignocaine | Control-Bupivacaine | Lignocaine - Bupivacaine |
|---|---|---|---|---|
| **4th Hour** | | | | |
| **Control** | 2.54 ± 0.721 | | | |
| **Lignocaine** | 2 ± 0.722 | p=0.03* | p=0.017* | p<0.001* |
| **Bupivacaine** | 3.13 ± 0.68 | | | |
| **8th Hour** | | | | |
| **Control** | 1.62 ± 0.647 | | | |
| **Lignocaine** | 1.42 ± 0.504 | p=0.579 | p<0.001* | p<0.001* |
| **Bupivacaine** | 3.17 ± 0.48 | | | |
| **12th Hour** | | | | |
| **Control** | 1.46 ± 0.588 | | | |
| **Lignocaine** | 1.38 ± 0.495 | p=1 | p<0.001* | p<0.001* |
| **Bupivacaine** | 3.08 ± 0.584 | | | |
| **1st Day** | | | | |
| **Control** | 1.38 ± 0.576 | | | |
| **Lignocaine** | 1.38 ± 0.495 | p=1 | p<0.001* | p<0.001* |
| **Bupivacaine** | 3.13 ± 0.612 | | | |
| **2nd Day** | | | | |
| **Control** | 1.88 ± 0.797 | | | |
| **Lignocaine** | 1.79 ± 0.588 | p=1 | p<0.001* | p<0.001* |
| **Bupivacaine** | 3.33 ± 0.637 | | | |
| **3rd Day** | | | | |
| **Control** | 2.17 ± 0.816 | | | |
| **Lignocaine** | 2 ± 0.659 | p=1 | p<0.001* | p<0.001* |

| | | | | |
|---|---|---|---|---|
| **Bupivacaine** | 3.71 ± 0.55 | | | |
| **4th Day** | | | | |
| **Control** | 2.5 ± 0.659 | p=1 | p<0.001* | p<0.001* |
| **Lignocaine** | 2.42 ± 0.504 | | | |
| **Bupivacaine** | 3.88 ± 0.612 | | | |
| **5th Day** | | | | |
| **Control** | 2.96± 0.806 | p=1 | p<0.001* | p<0.001* |
| **Lignocaine** | 2.96 ± 0.624 | | | |
| **Bupivacaine** | 4.21 ± 0.658 | | | |
| **6th Day** | | | | |
| **Control** | 3.46 ± 0.779 | p=1 | p<0.001* | p<0.001* |
| **Lignocaine** | 3.42 ± 0.504 | | | |
| **Bupivacaine** | 4.5 ± 0.59 | | | |
| **7th Day** | | | | |
| **Control** | 3.88 ± 0.9 | p=1 | p = 0.011* | p = 0.018* |
| **Lignocaine** | 3.92 ± 0.766 | | | |
| **Bupivacaine** | 4.54 ± 0.588 | | | |

**Table 7** demonstrated a comparison at different time period with respect to PSS scores in all 3 groups (Control, Lignocaine, Bupivacaine). There was no significant difference between Control and Lignocaine at any time point of the study except at 4th hour. Statistically significant difference was seen between (Control – Bupivacaine), (Lignocaine -Bupivacaine) on all the time point of the study with p<0.05

**Graph 5: Graphical representation of comparison of all three groups at all time interval on the basis of mean PSS.**



## TOTAL ANALGESIC RESCUE DRUG:

Rescue analgesic, Tab. Ibuprofen 400mg SOS was prescribed to patients and was recorded in the log sheet.

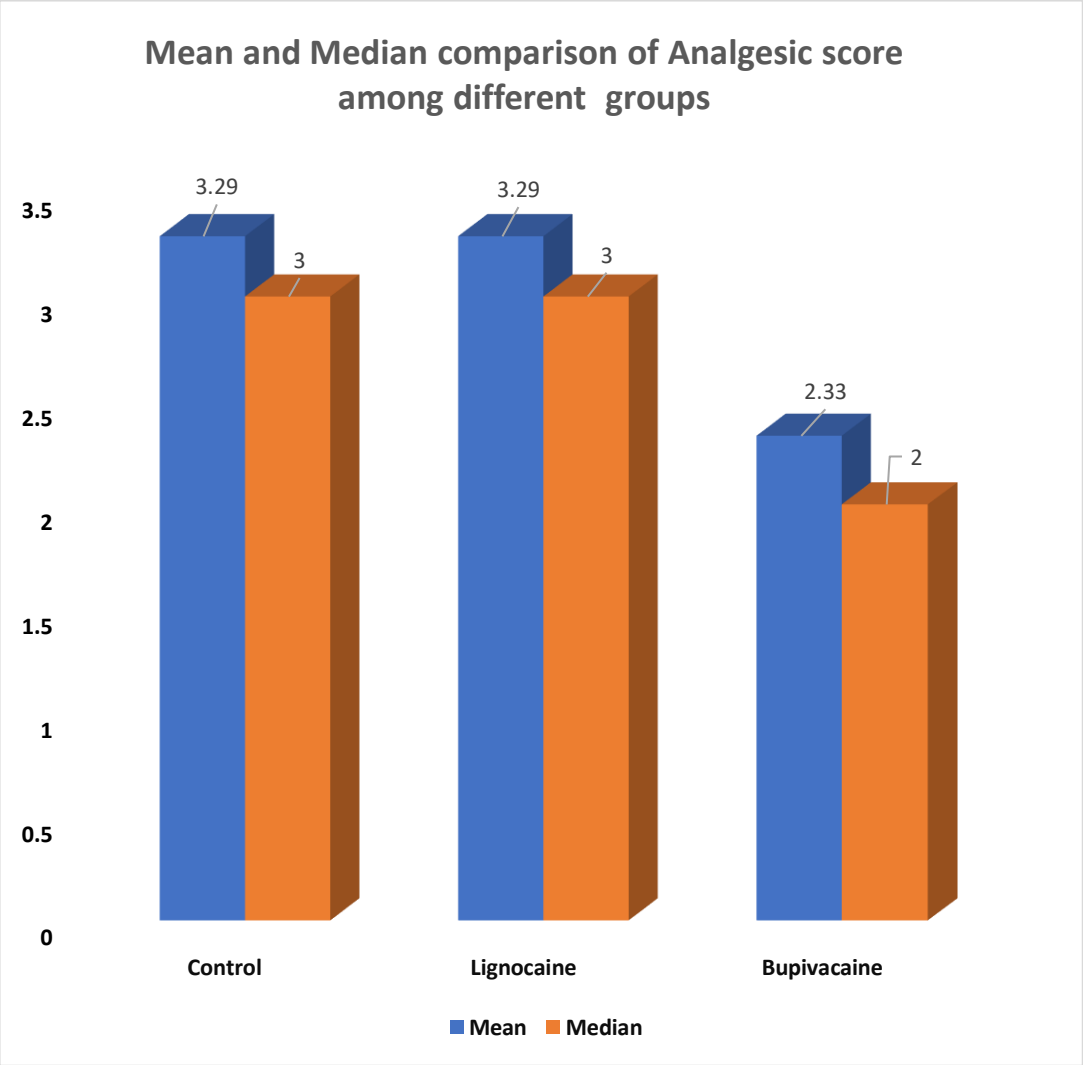
Comparison was done within all three groups with respect to total analgesic rescue drug taken by conducting Kruskal Wallis test.

**Table No. 8: Comparison of Total Analgesic rescue by Kruskal Wallis Test**

| Kruskal Wallis Test | | | | | | |
|---|---|---|---|---|---|---|
| **Group** | **Mean** | **Std. Deviation** | **Median** | **Mean Rank** | | **p-value** |
| **Control** | 3.29 | 1.628 | 3 | 40.38 | 5.193 | p=0.075 |
| **Lignocaine** | 3.29 | 1.628 | 3 | 40.38 | | |
| **Bupivacaine** | 2.33 | 1.167 | 2 | 28.75 | | |
| **Total** | 2.97 | 1.538 | 3 | | | |

Table No. 8 demonstrated that there was less intake of analgesic drug in case of bupivacaine with mean value of 2.33 as compared to lignocaine and control group with the mean value of 3.29 each. The Kruskal Wallis test revealed that there was no significant difference between mean ranks of the three groups Therefore there was no evident difference in the distribution of three groups with respect to rescue analgesic intake with $p>0.075$.

**Graph 6: Graphical representation of comparison of mean value and median of total rescue analgesic drug taken between all three groups.**




Graph 6 shows mean value and median of the total analgesic rescue drug taken by the three groups. Control group and lignocaine group has a mean intake of 3.29 each while bupivacaine group has a mean intake of 2.33.

## ASSESSMENT OF SWELLING:

Post-surgical oedema assessment was carried out through Generalized Linear Model tests.

**TABLE 9: Mean Comparison Swelling values at Different time points**

| | **PRE-OP** | **POST OP Day 2** | **POST OP Day 7** |
|---|---|---|---|
| | **(Mean ± SD)** | **(Mean ± SD)** | **(Mean ± SD)** |
| | **126.75 ± 6.83** | **129.24± 7.07** | **126.13 ± 7.15** |
| **PRE-OP** | --- | | |
| **POST OP Day 2** | 2.5 p<0.001* | ---- | |
| **POST OP Day 7** | 0.622 p<0.001* | 3.10 p<0.001* | ---- |

**TABLE 10: Mean comparison of Swelling values between different 3 Groups**

| | **Control** | **Lignocaine** | **Bupivacaine** |
|---|---|---|---|
| | **Mean ± SD** | **Mean ± SD** | **Mean ± SD** |
| | **127.11± 7.22** | **127.15 ± 6.81** | **127.87 ± 7.39** |
| **Control** | ---- | | |
| **Lignocaine** | 0.0365 p=0.986 | ---- | |
| **Bupivacaine** | 0.7572 p-0.71 | 0.72 p=0.716 | ---- |

Table 9 demonstrated comparison of swelling at different time points. Evident difference was seen between all the days among all the groups with p<0.001*. There was increase in swelling on post-surgical Day 2 day and there was significant reduction of swelling on post-surgical 7$^{th}$ day as compared to Pre-Op and Post-op Day 2.

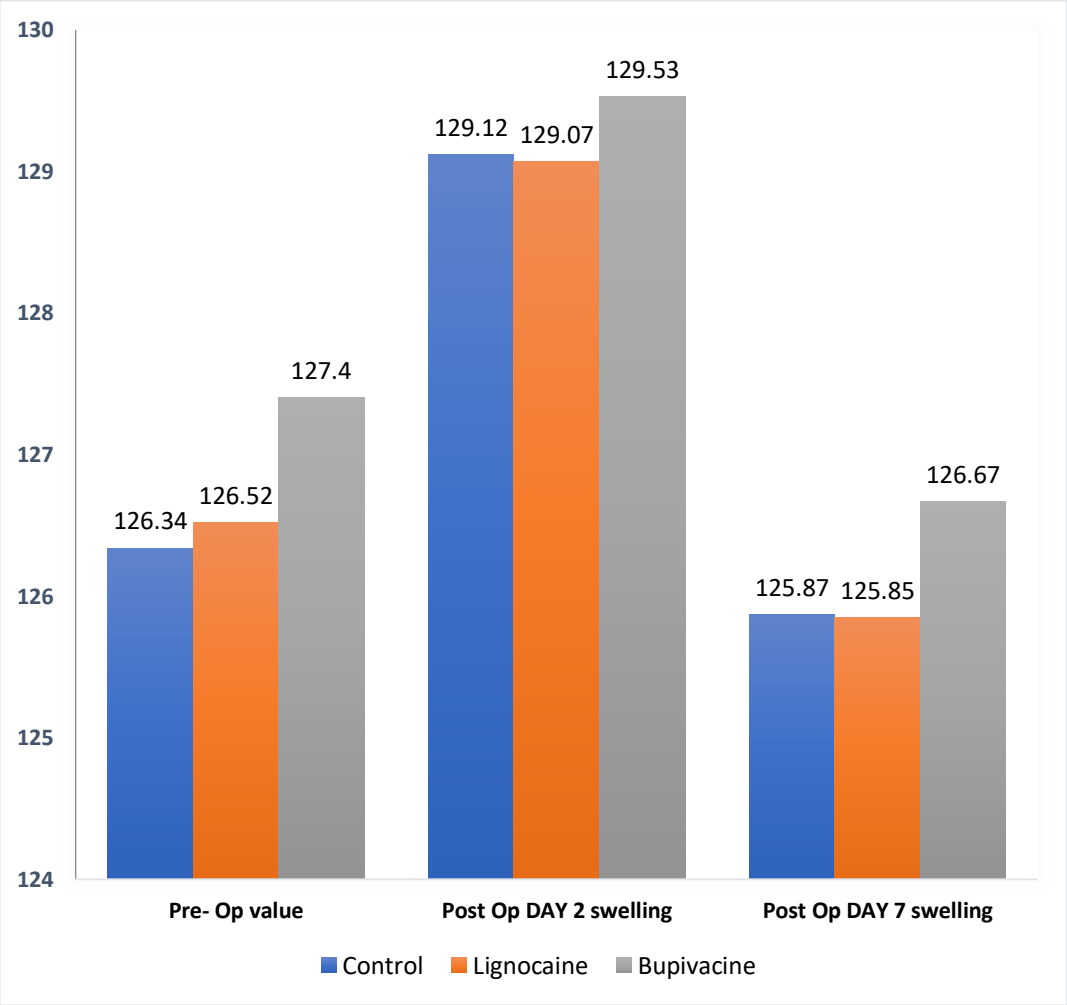
Pair wise comparison of three groups with mean Swelling scores was done in table 10 and according to the GLM, no significant difference in mean of Swelling between the groups (control and Bupivacaine) and (Bupivacaine and Lignocaine) and (Control and Bupivacaine) with p>0.05

**Table 11: Comparing mean differences of swelling between time points (Pre-op, post-op day 2 and post-op day 7) among the three groups (control, lignocaine, and bupivacaine)**

| | **Pre-op and post-op day 7** | | **Post-op day 2 and day 7** | | **Pre-op and post-op day 2** | |
|---|---|---|---|---|---|---|
| | **Mean** | **SD** | **Mean** | **SD** | **Mean** | **SD** |
| **Control** | -0.47 | 1.1379 | -3.2479 | 1.93326 | 2.7779 | 2.03478 |
| **Lignocaine** | -0.6704 | 1.39758 | -3.2246 | 2.06041 | 2.5542 | 2.04888 |
| **Bupivacaine** | -0.7267 | 1.34876 | -2.8517 | 1.793 | 2.125 | 1.92443 |
| **Control vs Lignocaine** | p =0.595 | | p= 0.999 | | p=0.7 | |
| **Control vs Bupivacaine** | p=0.496 | | p=0.758 | | p=0.263 | |
| **Bupivacaine vs Lignocaine** | p= 0.881 | | p=0.782 | | p=0.461 | |

When comparison was done at different time intervals with respect to Swelling between the three groups (Control, Lignocaine, Bupivacaine), there was no significant difference between the groups at any time point of the study with p>0.05

**Graph 7: Comparison of mean swelling value amongst the three groups (control, lignocaine, and bupivacaine) between different time interval.**




Graph 7 denotes the mean swelling at Post-surgical Day 2 and Day 7 in comparison to preoperative measurements for control, lignocaine, and bupivacaine. In preoperative stage the score was 126.34, 126.52 and 127.04 respectively. Whereas for Day 2, the scores were 129.12, 129.07 and 129.53 respectively. Similarly, for Day 7, the scores were 125.87, 125.85, 126.67 for the three groups.

**Assessment of trismus:**

Trismus assessment was carried out through Generalized Linear Model tests.

**Table 12: Mean Comparison Inter incisal distance (IID) at Different time points.**

| | **Pre-Op** | **Post-Op 2** | **Post-Op 7** |
|---|---|---|---|
| | **Mean ± SD** | **Mean ± SD** | **Mean ± SD** |
| | **41.79 ± 7.69** | **33.96 ± 6.78** | **39.82 ± 7.62** |
| **Pre-Op** | --- | --- | --- |
| **Post Op 2** | 7.833 p<0.001* | --- | --- |
| **Post Op 7** | 1.972 p<0.001* | 5.861 p<0.001* | --- |

**TABLE 13: Mean comparison of Inter Incisal Distance between different 3 Groups**

| | **Control** | **Lignocaine** | **Bupivacaine** |
|---|---|---|---|
| | **Mean ± SD** | **Mean ± SD** | **Mean ± SD** |
| | 38.88 ± 8.99 | 38.96 ± 8.53 | 37.74 ± 6.49 |
| **Control** | --- | --- | --- |
| **Lignocaine** | 0.083 p=1.0 | --- | --- |
| **Bupivacaine** | 1.139 p=1.0 | 1.22 p= 1.0 | --- |

In table 12, The GLM model showed a significant difference in means in all time periods

There was significant reduction in inter incisal distance mean value across times independent of groups with p<0.001.

Pair wise comparison of three groups with mean IID scores was done in table 13 and it showed insignificant difference in mean of IID between the groups (control

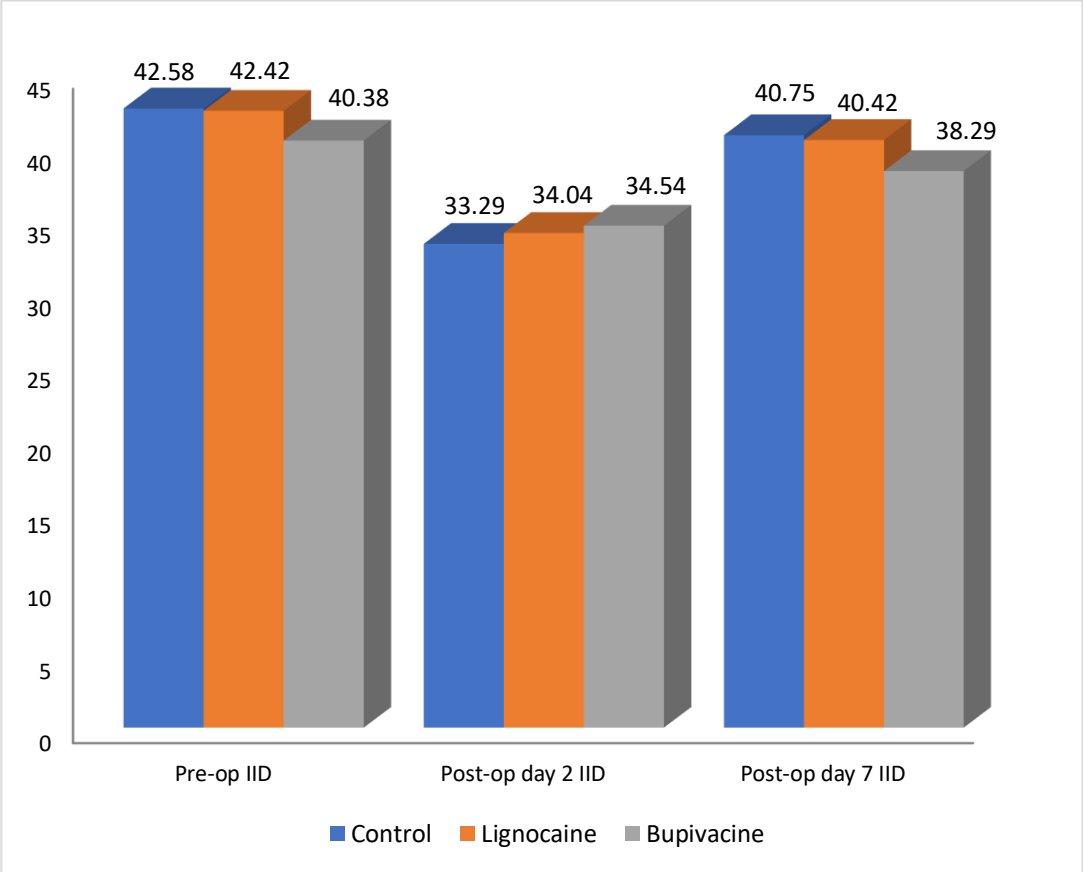
and Bupivacaine) and (Bupivacaine and Lignocaine) and (control and Lignocaine) with p>0.05.

**Table 14: Comparing mean differences of inter incisal distance between time points (Pre-surgical, POD 2 and POD7) among the three groups (control, lignocaine, and bupivacaine)**

| | **Pre-op and post-op day 2** | | **Post-op day 2 and day 7** | | **Pre-op and post-op day 7** | |
|---|---|---|---|---|---|---|
| | **Mean** | **Std. Deviation** | **Mean** | **Std. Deviation** | **Mean** | **Std. Deviation** |
| **Control** | -9.2917 | 4.72256 | 7.458 | 3.91185 | -1.8333 | 1.88049 |
| **Lignocaine** | -8.375 | 4.3819 | 6.375 | 3.68088 | -2 | 1.88818 |
| **Bupivacaine** | -5.8333 | 3.3965 | 3.75 | 3.06807 | -2.0833 | 1.1389 |
| **Control vs Lignocaine** | p=0.453 | | p = 0.297 | | p= 0.937 | |
| **Control vs Bupivacaine** | p= 0.006* | | p= 0.001* | | p = 0.863 | |
| **Lignocaine vs Bupivacaine** | p=0.04* | | p=0.001* | | p =0.984 | |

When comparison at different periods was done with respect to Inter Incisal Distance in all 3 groups (Control, Lignocaine, Bupivacaine), there was no significant difference seen between them (Control – Bupivacaine), (Lignocaine -Bupivacaine) (Control – Bupivacaine) with p>0.05.

**Graph 8: Comparison of mean swelling value amongst the three groups (control, lignocaine, and bupivacaine) between different time interval.**




Graph 8 denotes the mean inter incisal distance at Post-surgical Day 2 and Day 7 in comparison to preoperative measurements for control, lignocaine, and bupivacaine. In preoperative stage the score was 42.58, 42.42 and 40.38 respectively. Whereas for Day 2, the scores were 33.29, 34.04 and 34.54 respectively. Similarly, for Day 7, the scores were 40.75, 40.42, 33.29 for the three groups.

## DISCUSSION:

Local anaesthesia is essential for performing surgical extraction of third molars, and its effectiveness in dentistry today ensures that the procedure is painless.(51) Any practical and safe method of decreasing the duration of post-surgical pain is beneficial to the patient, particularly if it also reduces the intensity of the pain.(52) Local anesthetics hinder the creation and transmission of nerve signals by elevating the threshold required for nerve excitation, delaying the spread of nerve impulses, and reducing the pace at which action potentials develop.(53) Surgery involving bone guttering for third molars can result in considerable physical and mental discomfort for the patient post-surgically. Long-acting local anaesthetics used by their local delivery post-surgically can prove beneficial in such cases due to their extended anaesthetic effects and delayed onset of pain.

Lignocaine is the most utilized local anaesthetic agent owing to its cost-effectiveness and rapid onset. With a pKa of 7.85, it swiftly diffuses through interstitial tissues within lipid-enriched neuronal fibres, resulting in a quick onset of action. Bupivacaine (1-butyl-2', 6'-pipecoloxylidide) was initially synthesized by B af Ekenstam in 1957 and introduced for clinical use in 1963. As a long-acting amide-type local anaesthetic, it exhibits an extended duration of action compared to lignocaine due to its higher lipid solubility and protein-binding capacity. Its onset of action ranges from 1 to 10 minutes, providing a duration of action lasting up to 2–9 hours with a half-life of approximately 2.7 hours. In terms of potency, it is four times greater than lignocaine when administered in equal dosages.(56)

Various mode of local delivery of anaesthetic drugs has been used to reduce pain in third molar surgery such as lignocaine sheet(56), intra-socket catheter(57), irrigation of socket with anaesthetic drugs(42), anaesthetic block after extraction(58) and absorbable gelatin sponge(59). Absorbable gelatin sponge soaked in anaesthetic drug is a simple mechanism for local drug delivery and does not require much skill. Gelfoam® is an FDA-approved gelatin-based sponge that has been a staple for surgeons and dentists for many years. When used judiciously, Gelfoam® is fully absorbed, resulting in minimal tissue reaction.. Numerous variables, including the volume administered, the place of application, and the degree of saturation with blood

or other fluids, influence how well Gelfoam® absorbs. Gelfoam® usually absorbs fully in soft tissues in 4–6 weeks without causing an excessive amount of scar tissue to form.(37)

Wu and colleagues utilized a microfibrillar hemostatic-sponge as a novel method to administer morphine, aiming to prolong pain relief. Their study showed that the creation of a fibrin clot delays the dispersion of the medication, effectively trapping morphine within the clot and extending its duration of action.(60) According to a study by Saoud (37) Gelfoam soaked in morphine acts in a similar manner and offers a satisfactory post-surgical analgesia. In this present study we aimed to compare the efficacy of Absorbable gelatin sponge soaked in bupivacaine as compared to lignocaine after mandibular third molar extraction.

Absorbable gelatin sponge soaked in bupivacaine has been used in many other surgical sites to control post-surgical pain and has shown promising results. Many studies have used gelatin sponge soaked in Bupivacaine in iliac crest surgical site after alveolar bone grafting. A significant difference has been seen in the post operative pain and reduction in post-surgical opioid use.(15,16) Dr. Saeed et al(17) used Bupivacaine-soaked sponge in gallbladder bed after laparoscopic cholecystectomy to reduce post-surgical visceral pain. Most commonly Gelfoam has been used as a carrier for analgesic/anaesthetic drugs in cases of lumbar laminectomy or discectomy cases, where it was placed in the surgical site to reduce the need of opioids and prolong analgesia.(21–24,37,39,40,61) Other than this Gelfoam soaked in bupivacaine or any other analgesic has also been used in caesarean wounds(18,26,33,62), episiotomy procedures(20,25,45), hemorrhoidal surgery(32) and in FESS procedure(43).

Gelfoam is commonly used in third molar surgery to achieve haemostasis. It is easily available, cost effective and can be used as a local drug delivery agent for third molar socket. Shabat et al(59) used bupivacaine soaked in Gelfoam and placed in extraction socket after third molar surgery. He found that it had a significant difference in early post-surgical pain, i.e., after 4h and 8 hours of extraction.

Similarly, in our study we studied upon 3 groups. Group 1 was treated as placebo in which normal saline soaked Gelfoam was placed in extraction socket.

Group 2 received 2% plain lignocaine soaked Gelfoam and group 3 received 0.5% plain bupivacaine soaked Gelfoam in the extraction socket.

The research indicated a notable decrease in post-surgical pain within the bupivacaine group compared to both the lignocaine and control groups. This significant finding was observed at various intervals: 4 hr, 8 hr, 12 hrs, day 1, day 2, and day 4 post-operation. Additionally, patients expressed significant satisfaction with pain management in the bupivacaine group across all intervals. No significant variance was found regarding the utilization of rescue pain medication among the three groups. However, there was a lower consumption of analgesic drugs in the bupivacaine group compared to the others. Adverse effect was recorded in terms of post-surgical oedema and trismusThe results showed that there was no discernible difference between the three groups, indicating that there had been no negative reaction to the intervention. When soaking in Gelfoam, none of the groups (control, lignocaine, or bupivacaine) displayed any notable complications, ensuring the patient's safety throughout the intervention.

Bupivacaine's effectiveness over lignocaine in providing superior results stems from its extended duration of action as an anaesthetic agent. Unlike lignocaine, which tends to have a shorter duration of action, bupivacaine offers prolonged pain relief, making it particularly advantageous for procedures requiring longer anaesthesia.(47)

Furthermore, bupivacaine's sustained release minimizes the possibility of an excessive buildup of the medication in the body and its negative consequences by enabling regulated drug release over a longer period of time. Sponge soaked with buprivacaine appears to be a reasonably priced option, with a simple application procedure that may be completed even in areas with limited resources.(18)

Bupivacaine provides extended pain relief post-surgery, improving patient comfort and compliance to post-surgical instructions. Its lower incidence of side effects compared to other anaesthetics promotes smoother recoveries, reducing the likelihood of nausea, dizziness, or cardiovascular issues. This enhances overall patient satisfaction and recovery experiences.(20)

**CONCLUSION:** Bupivacaine soaked in absorbable gelatin sponge when placed in the extraction socket after impacted mandibular third molar surgery is an effective method to reduce post-surgical pain. Significant reduction in pain was seen until day 2. Patient's acceptance and compliance towards this treatment was significantly satisfactory throughout the follow-up. Bupivacaine-soaked Absorbable gelatin sponge also reduces the intake of analgesics and their associated complications. And it did not have any significant adverse effect like post-surgical oedema or trismus.

**LIMITATIONS:**

Because of the limited sample size, generalizing the results was challenging. Thus, more research is needed to determine how well bupivacaine works to treat trismus, edema, and discomfort following wisdom tooth extraction surgery.

**REFERENCES:**

1. Khiavi RK, Pourallahverdi M, Pourallahverdi • Ayda, Saadat •, Khiavi G, Sina •, et al. Pain Control Following Impacted Third Molar Surgery with Bupivacaine Irrigation of Tooth Socket: A Prospective Study. Dental Clinics, Dental Prospects J Dent Res Dent Clin Dent Prospect [Internet]. 2010 [cited 2023 Dec 24];4(4):105–9. Available from: http://dentistry.tbzmed.ac.ir/joddd

2. Albanese M, Zangani A, Manfrin F, Bertossi D, De Manzoni R, Tomizioli N, et al. Influence of Surgical Technique on Post-Operative Complications in the Extraction of the Lower Third Molar: A Retrospective Study. Dent J (Basel) [Internet]. 2023 Oct 1 [cited 2023 Dec 24];11(10). Available from: /pmc/articles/PMC10605236/

3. Suarez-Cunqueiro MM, Gutwald R, Reichman J, Otero-Cepeda XL, Schmelzeisen R. Marginal flap versus paramarginal flap in impacted third molar surgery: A prospective study. Oral Surg Oral Med Oral Pathol Oral Radiol Endod [Internet]. 2003 [cited 2023 Dec 24];95(4):403–8. Available from: https://pubmed.ncbi.nlm.nih.gov/12686924/

4. Sisk AL, Hammer WB, Shelton DW, Joy ED. Complications following removal of impacted third molars: The role of the experience of the surgeon. Journal of Oral and Maxillofacial Surgery [Internet]. 1986 Nov [cited 2024 Jan 29];44(11):855–9. Available from: https://linkinghub.elsevier.com/retrieve/pii/0278239186902211

5. Bouloux GF, Steed MB, Perciaccante VJ. Complications of Third Molar Surgery. Oral Maxillofac Surg Clin North Am [Internet]. 2007 Feb [cited 2024 Jan 29];19(1):117–28. Available from: https://linkinghub.elsevier.com/retrieve/pii/S1042369906001130

6. Bui CH, Seldin EB, Dodson TB. Types, Frequencies, and Risk Factors for Complications after Third Molar Extraction. Journal of Oral and Maxillofacial Surgery. 2003;61(12):1379–89.

7. Practice Guidelines for Acute Pain Management in the Perioperative Setting [Internet]. 2004. Available from: http://www.anesthesiology.org,

8. Menhinick KA, Gutmann JL, Regan JD, Taylor SE, Buschang PH. The efficacy of pain control following nonsurgical root canal treatment using ibuprofen or a combination of ibuprofen and acetaminophen in a randomized, double-blind, placebo-controlled study. Int Endod J [Internet]. 2004 Aug [cited 2024 Jan 29];37(8):531–41. Available from: https://pubmed.ncbi.nlm.nih.gov/15230906/

9. Becker DE. Pain Management: Part 1: Managing Acute and Postoperative Dental Pain. Anesth Prog [Internet]. 2010 Jun 1 [cited 2024 Jan 29];57(2):67–79. Available from: https://anesthesiaprogress.kglmeridian.com/view/journals/anpr/57/2/article-p67.xml

10. Velioglu O, Calis AS, Koca H, Velioglu E. Bupivacaine vs. lidocaine: a comparison of local anesthetic efficacy in impacted third molar surgery. Clin Oral Investig. 2020 Oct 1;24(10):3539–46.

11. Hu D, Onel E, Singla N, Kramer WG, Hadzic A. Pharmacokinetic profile of liposome bupivacaine injection following a single administration at the surgical site. Vol. 33, Clinical Drug Investigation. 2013. p. 109–15.

12. Skolnik A, Gan TJ. New formulations of bupivacaine for the treatment of postoperative pain: Liposomal bupivacaine and SABER-Bupivacaine. Vol. 15, Expert Opinion on Pharmacotherapy. Informa Healthcare; 2014. p. 1535–42.

13. Lambrechts M, O'Brien MJ, Savoie FH, You Z. Liposomal extended-release bupivacaine for postsurgical analgesia. Vol. 7, Patient Preference and Adherence. 2013. p. 885–90.

14. Hersh E V., Moore PA. Comment on controlling dental post-operative pain and the intraoral local delivery of drugs. Vol. 31, Current Medical Research and Opinion. Taylor and Francis Ltd; 2015. p. 2185–7.

15. Gamli M, Dalgic A, Ornek D, Horasanli E, Kilci O, Un C, et al. Evaluation of The Efficacy of Bupivacaine Soaked in Gelfoam ® at the Iliac Crest Bone Graft Site. 2012.

16. Dashow JE, Lewis CW, Hopper RA, Gruss JS, Egbert MA. Bupivacaine administration and postoperative pain following anterior lliac crest bone graft for alveolar cleft repair. Cleft Palate-Craniofacial Journal. 2009 Mar;46(2):173–8.

17. Dakheel Saeed S, Al-Dabbagh AA. The Effect of Placing 0.5% Bupivacaine-Soaked… The Effect of Placing 0.5% Bupivacaine-Soaked Gelfoam in the Gallbladder Bed on Pain after Laparoscopic Cholecystectomy. Vol. 13, Zanko J. Med. Sci. 2009.

18. Mohamed OS, Nour El-Din NM, Abd El-Zaher HA, Ali NS. A comparative study of bupivacaine versus bupivacaine-lidocaine soaked gel-foam in caesarean section wounds. Vol. 29, MJMR. 2018.

19. Shabat MA, Bede SY. Effect of the local application of bupivacaine in early pain control following impacted mandibular third molar surgery: A randomized controlled study. Dent Med Probl. 2021 Oct 1;58(4):483–8.

20. Shaker N, Mbchb Y, Mbchb NR. Evaluation and Comparison the Efficacy of Bupivacaine Socked Spongostan and Bupivacaine Infiltration in Relieving Post Episiotomy Pain. Comm. Med. 2012.

21. Ekka A, Suman S, Kumar T, Tiwari P, Oraon P, Lakra L. Comparison of postoperative analgesic effects of gelfoam soaked with ropivacaine 0.5% and gelfoam soaked with dexamethasone 8 mg with placebo in single-level lumbar laminectomy. Anesth Essays Res. 2023;0(0):0.

22. Prakash A, Giri M, Kumar S, Pandey C, Malviya D, Mishra S. Effect of gelfoam soaked epidural dexmedetomidine or bupivacaine for postoperative analgesia in lumbar laminectomy: A prospective randomized clinical study. Anesth Essays Res. 2021;15(1):67.

23. Kumari K, Kamal M, Singariya G, Kishan R, Garg S, Thanvi S. Effect of epidural levobupivacaine with or without dexamethasone soaked in gelfoam for postoperative analgesia after lumbar laminectomy: A double blind, randomised, controlled trial. Indian J Anaesth. 2018 Jul 1;62(7):509–15.

24. Saebi R, Shakeri A, Mohammadi A, Dalvandi M, Kamali A. Efficacy of intraoperative epidural dexamethasone and bupivacaine in reduction of pain and disability following lumbar discectomy. J Family Med Prim Care [Internet]. 2022 [cited 2024 Feb 2];11(5):1810. Available from: https://pubmed.ncbi.nlm.nih.gov/35800519/

25. Kafali H, Iltemur Duvan C, Gözdemir E, Simavli S, Öztürk Turhan N. Placement of Bupivacaine-soaked Spongostan in Episiotomy Bed Is Effective Treatment Modality for Episiotomy-associated Pain. J Minim Invasive Gynecol. 2008 Nov;15(6):719–22.

26. Simavli S, Kaygusuz I, Kinay T, Akinci Baylan A, Kafali H. Bupivacaine-soaked absorbable gelatin sponges in caesarean section wounds: Effect on postoperative pain, analgesic requirement and haemodynamic profile. Int J Obstet Anesth. 2014 Nov 1;23(4):302–8.

27. Talimkhani I, Jamalpour MR, Babaei H, Faradmal J. Comparison of Intra-Socket Bupivacaine Administration Versus Oral Mefenamic Acid Capsule for Postoperative Pain Management Following Removal of Impacted Mandibular Third Molars. Journal of Oral and Maxillofacial Surgery. 2019 Jul 1;77(7):1365–70.

28. Suzuki T, Kosugi K, Suto T, Tobe M, Tabata Y, Yokoo S, et al. Sustained-release lidocaine sheet for pain following tooth extraction: A randomized, single-blind, dose-response, controlled, clinical study of efficacy and safety. PLoS One. 2018 Jul 1;13(7).

29. Chapman PJ. A controlled comparison of effectiveness of bupivacaine for post-operative pain control. Aust Dent J. 1988;33(4):288–90.

30. Suresh Jaiswal R, Pandey C, Speedie A, Jaiswal R, Lanjewar S, Dondulkar Y. Role of Bupivacaine in Dentistry [Internet]. Vol. 6, International Journal of Oral Health and Medical Research. Available from: www.ijohmr.com

31. Tache A, Mommaerts MY. Pain management at iliac donor sites after grafting of alveolar clefts. Vol. 51, International Journal of Oral and Maxillofacial Surgery. Churchill Livingstone; 2022. p. 62–9.

32. Tsai KM, Kiu KT, Yen MH, Yen YC, Tam KW, Chang TC. Comparison the effect of gelatin sponge and epinephrine-soaked gauze for hemostasis and pain control after hemorrhoidal surgery. Sci Rep. 2023 Dec 1;13(1).

33. Brown JPR, Douglas MJ. Bupivacaine-soaked gelatin sponges: Solution for a painful problem? Vol. 23, International Journal of Obstetric Anesthesia. Churchill Livingstone; 2014. p. 299–301.

34. Nazeer J, Kumari S, Haidry N, Kulkarni P, Aastha, Gautam A, et al. Comparison of efficacy of lignocaine, ropivacaine, and bupivacaine in pain control during extraction of mandibular posterior teeth. Natl J Maxillofac Surg. 2021 May 1;12(2):238–43.

35. de Souza AMM, Horliana ACRT, Simone JL, Jorge WA, Tortamano IP. Postoperative pain after bupivacaine supplementation in mandibular third molar surgery: splint-

mouth randomized double blind controlled clinical trial. Oral Maxillofac Surg. 2014 Dec 1;18(4):387–91.

36. Brajković D, Biočanin V, Milić M, Vučetić M, Petrović R, Brković B. Kvalitet analgezije nakon hirurškog vađenja donjih umnjaka: Randomizovana, duplo slepa studija efikasnosti levobupivakaina, bupivakaina i lidokaina sa adrenalinom. Vojnosanit Pregl. 2015 Jan 1;72(1):50–6.

37. Saoud K, Sabry H, Ramzy O. Original Article Comparison of Epidural Morphine Soaked Gel Foam and Continuous Intravenous Morphine Using PCA in the Management of Postoperative Pain Following Lumbar Spinal Fixation Surgery. Vol. 29, Egyptian Journal of Neurosurgery.

38. O'Neill KR, Lockney DT, Bible JE, Crosby CG, Devin CJ. Bupivacaine for pain reduction after iliac crest bone graft harvest. Vol. 37, Orthopedics. Slack Incorporated; 2014.

39. Giri MK, Singh V, Pal P, Mishra LS, Gopal NN, Professor A, et al. A prospective randomized comparative study of gelfoam soaked nalbuphine vs. ketamine placed in epidural space during lumber spine surgery for postoperative analgesia [Internet]. Vol. 22, PAIN & INTENSIVE CARE. Available from: www.apicareonline.com

40. Kundra S, Gupta V, Bansal H, Grewal A, Katyal S, Choudhary AK. Comparative study of epidural application of morphine versus gelfoam soaked in morphine for lumbar laminectomy. J Anaesthesiol Clin Pharmacol. 2014 Jan;30(1):46–52.

41. Cunniffe MG, Mcanena OJ, Dar MA, Calleary J, Flynn N. A Prospective Randomized Trial of Intraoperative Bupivacaine Irrigation for Management of Shoulder-tip Pain following Laparoscopy. 1998.

42. Khiavi RK, Pourallahverdi M, Pourallahverdi • Ayda, Saadat •, Khiavi G, Sina •, et al. Pain Control Following Impacted Third Molar Surgery with Bupivacaine Irrigation of Tooth Socket: A Prospective Study [Internet]. Vol. 4, Dental Clinics, Dental Prospects J Dent Res Dent Clin Dent Prospect. 2010. Available from: http://dentistry.tbzmed.ac.ir/joddd

43. Yilmaz S, Yildizbaş Ş, Güçlü E, Yaman H, Yalçin Sezen G. Topical levobupivacaine efficacy in pain control after functional endoscopic sinus surgery. Otolaryngology - Head and Neck Surgery (United States). 2013 Nov;149(5):777–81.

44. Hermans SMM, Lantinga-Zee AAG, Droeghaag R, Van Santbrink H, Van Hemert WLW, Reinders MK, et al. Single-dose epidural bupivacaine vs placebo after lumbar decompression surgery: A Randomized controlled trial. Available from: https://doi.org/10.1101/2023.08.20.23294347

45. Garg A, Goyal SS, Bedi M, Kaur G. Section: Obstetrics and Gynaecology International Journal of Contemporary Medical Research Section: Obstetrics and Gynaecology To Evaluate and Compare the Efficacy of Adding Spongostan Soaked with Bupivacaine at Episiotomy Bed in Relieving Post Episiotomy Pain, A Randomized Prospective Study. Available from: www.ijcmr.com

46. Khan MR, Raza R, Zafar SN, Shamim F, Raza SA, Pal KMI, et al. Intraperitoneal lignocaine (lidocaine) versus bupivacaine after laparoscopic cholecystectomy: Results of a randomized controlled trial. Journal of Surgical Research. 2012 Dec;178(2):662–9.

47. Adelusi E, Adelusi EA, Abiose OB, Gbolahan OO. Post Intra-Alveolar Extraction Analgesia of Bupivacaine and Lidocaine: A Randomized Controlled Clinical Trial [Internet]. 2019. Available from: https://www.researchgate.net/publication/353983160

48. Peyvandi A, Roozbahany NA, Niknazar S, Mahani MH. Comparison of Peritonsillar Infiltration of Lidocaine and Bupivacaine for Management of Postoperative Pain of Tonsillectomy [Internet]. Vol. 2, Journal of Hearing Sciences and Otolaringology. 2016. Available from: www.journalhso.com

49. Gupta P. Comparison of Efficacy of Local Anesthetic Drugs Lignocaine, Ropivacaine, and Bupivacaine in Pain Control during Extraction of Mandibular Posterior Teeth. Journal of Datta Meghe Institute of Medical Sciences University. 2022 Jul 1;17(3):563–7.

50. Agarwal P. COMPARATIVE EVALUATION OF BUPIVACAINE AND LIGNOCAINE FOR IMPACTED MANDIBULAR THIRD MOLAR REMOVAL. World J Pharm Res. 2017 Apr 1;698–705.

51. Velioglu O, Calis AS, Koca H, Velioglu E. Bupivacaine vs. lidocaine: a comparison of local anesthetic efficacy in impacted third molar surgery. Clin Oral Investig. 2020 Oct 1;24(10):3539–46.

52. Chapman PJ, Macleod AWG. A Clinical Study of Bupivacaine for Mandibular Anesthesia in Oral Surgery.

53. Balakrishnan K, Ebenezer V, Dakir A, Kumar SK, Prakash D. Bupivacaine versus lignocaine as the choice of locall anesthetic agent for impacted third molar surgery a review. Vol. 7, Journal of Pharmacy and Bioallied Sciences. Wolters Kluwer Medknow Publications; 2015. p. S230–3.

54. Suzuki T, Kosugi K, Suto T, Tobe M, Tabata Y, Yokoo S, et al. Sustained-release lidocaine sheet for pain following tooth extraction: A randomized, single-blind, dose-response, controlled, clinical study of efficacy and safety. PLoS One. 2018 Jul 1;13(7).

55. Talimkhani I, Jamalpour MR, Babaei H, Faradmal J. Comparison of Intra-Socket Bupivacaine Administration Versus Oral Mefenamic Acid Capsule for Postoperative Pain Management Following Removal of Impacted Mandibular Third Molars. Journal of Oral and Maxillofacial Surgery. 2019 Jul 1;77(7):1365–70.

56. de Souza AMM, Horliana ACRT, Simone JL, Jorge WA, Tortamano IP. Postoperative pain after bupivacaine supplementation in mandibular third molar surgery: splint-mouth randomized double blind controlled clinical trial. Oral Maxillofac Surg. 2014 Dec 1;18(4):387–91.

57. Shabat MA. The Effect Of Local Application Of Bupivacaine In Pain Control Following Impacted Mandibular Third Molar Surgery: A Randomized Controlled Study.

58. Wu MH, Wong CH, Niu CC, Tsai TT, Chen LH, Chen WJ. A comparison of three types of postoperative pain control after posterior lumbar spinal surgery. Spine (Phila Pa 1976) [Internet]. 2011 Dec 1 [cited 2024 Mar 11];36(25):2224–31. Available from: https://pubmed.ncbi.nlm.nih.gov/21325985/

59. Malhotra AK, Wilson JR. Topical epidural steroids after lumbar spine surgery: do the benefits observed after microdiscectomy extend to lumbar fusion? Vol. 37, Journal of Neurosurgery: Spine. American Association of Neurological Surgeons; 2022. p. 473–5.

60. Mohamed O, Nour El-Din N, Abd El-Zaher H, Ali N. Analgesic efficacy and safety of absorbable gelatin sponge soaked with bupivacaine or bupivacaine and lidocaine in Cesarean section wounds. Minia Journal of Medical Research. 2022 Oct 1;33(4):96–104.

**ANNEXURE I: PATIENT CONSENT FORM**

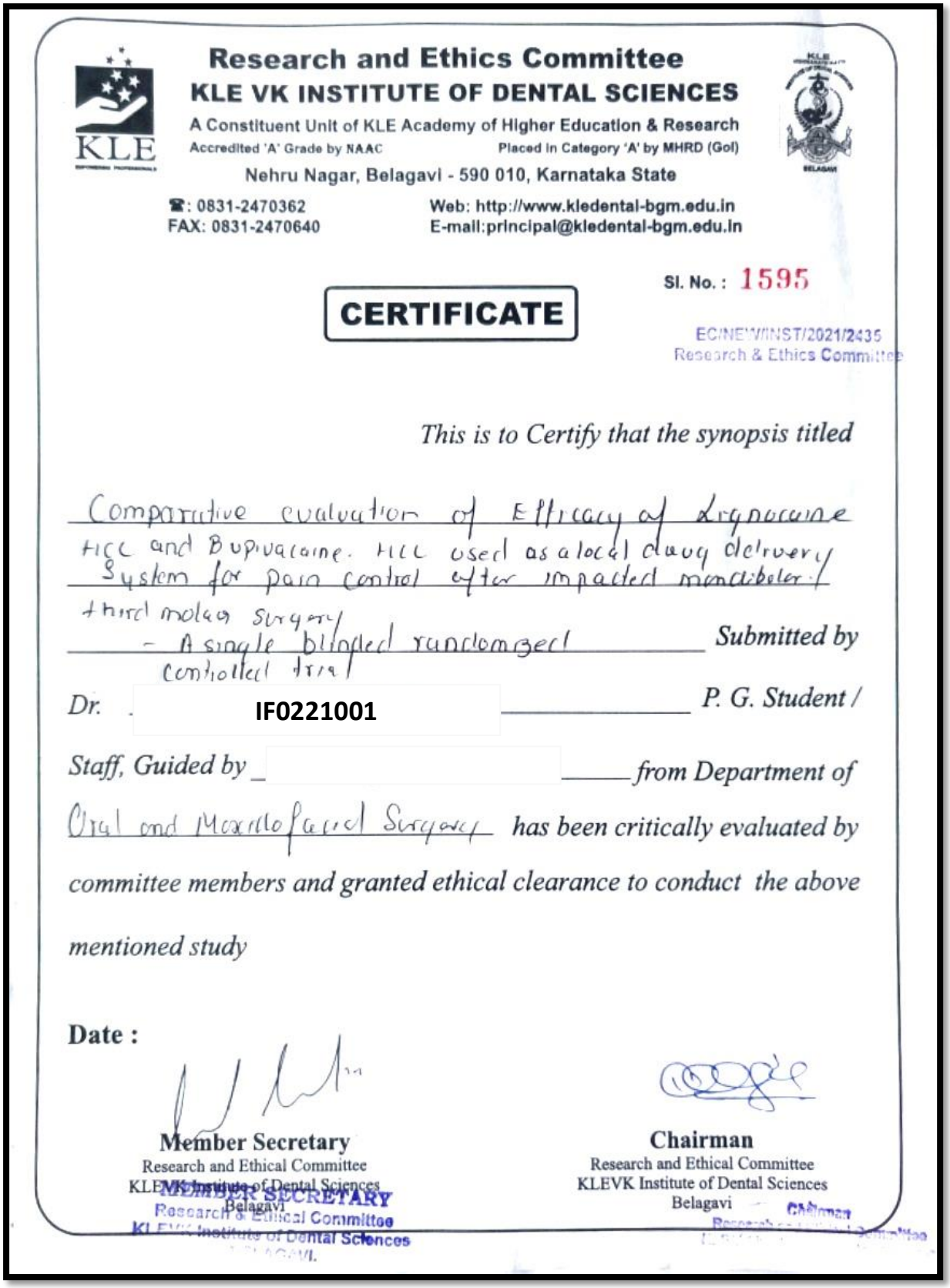
**K.L.E.'s V.K. Institute of Dental Sciences**
**Department of Oral and Maxillofacial Surgery, Belgaum**
**CONSENT TO SURGERY & ANAESTHETICS**

Date: Time: a.m./ p.m.

1. I,_____aged_____years have been informed about my involvement in the study.
2. I agree to give my personal details like name, age, sex, address, history of treatment taken and any other details required for the study to the best of my knowledge.
3. I will cooperate with the surgeon for examination and also for various investigations.
4. I permit the surgeon to utilize the information given by me and the results obtained from this study for presentation and publication.
5. I permit the surgeon to take my photographs to utilize it for the study and presentation purpose.
6. I am participating in this study with my own wish and will and the surgeon has explained the nature and the effect of procedure including surgical extraction of tooth and placing 2% Lignocaine HCL or 0.5% Bupivacaine HCL soaked in absorbable gelatin sponge and its effect on the early postoperative pain in my vernacular language.
7. The nature and purpose of the operation and the materials being used, possible alternative methods of treatment, the risk involved and the possibility of complications have been fully explained to me in my vernacular tongue. No guarantee or assurance has been given by anyone as to the results that may be obtained.
8. I have read and understood the above information given by surgeon about the study and willingly agree to participate in the study and willingly agree to come for follow up on the 2nd and 7th day.

Name: Date:
Signature: Mob. No:

**ANNEXURE II: ETHICAL CLEARANCE CERTIFICATE**



**Research and Ethics Committee**
**KLE VK INSTITUTE OF DENTAL SCIENCES**
A Constituent Unit of KLE Academy of Higher Education & Research
Accredited 'A' Grade by NAAC | Placed in Category 'A' by MHRD (GoI)
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Sl. No. : 1595

**CERTIFICATE**

ECINEW/INST/2021/2435
Research & Ethics Committee

*This is to Certify that the synopsis titled*

Comparative evaluation of Efficacy of Lignocaine HCL and Bupivacaine. HCL used as a local drug delivery System for pain control after impacted mandibular third molar Surgery - A single blinded randomized controlled trial

*Submitted by*

*Dr.* IF0221001 *P. G. Student /*

*Staff, Guided by* _____ *from Department of*

Oral and Maxillofacial Surgery *has been critically evaluated by committee members and granted ethical clearance to conduct the above mentioned study*

**Date :**

**Member Secretary**
Research and Ethical Committee
KLEVK Institute of Dental Sciences
Belagavi

MEMBER SECRETARY
Research & Ethical Committee
KLE VK Institute of Dental Sciences
BELAGAVI.

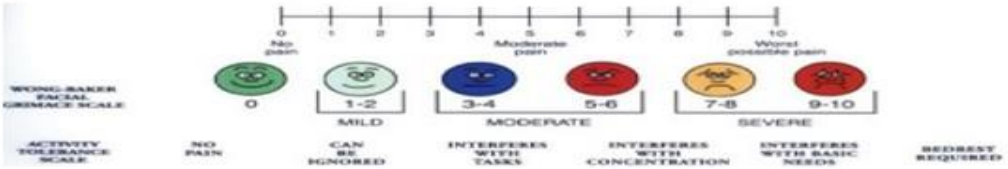
**Chairman**
Research and Ethical Committee
KLEVK Institute of Dental Sciences
Belagavi

Chairman
Research and Ethical Committee

**<u>ANNEXURE III:</u> PATIENT LOG SHEET**

# PATIENT LOG SHEET

**POSTOPERATIVE PAIN CONTROL:**




| Post op: | Pain score |
|---|---|
| 4 hours | |
| 8 hours | |
| 12 hours | |
| 24 hours | |
| 2 days | |
| 3 days | |
| 4 days | |
| 5 days | |
| 6 days | |
| 7 days | |

**PATIENT SATISFACTION TO PAIN CONTROL:**
Scores: 1: Dissatisfied, 2: Rather dissatisfied, 3: Neither, 4: Rather satisfied, 5: Satisfied

| Post op: | Patient satisfaction score |
|---|---|
| 4 hours | |
| 8 hours | |
| 12 hours | |
| 24 hours | |
| 2 days | |
| 3 days | |
| 4 days | |
| 5 days | |
| 6 days | |
| 7 days | |

**ANALGESIC RECORD:**

**IBUPROFEN 400mg, to be taken on an emergency basis.**

| **Post op day** | **Morning** | **Afternoon** | **Night** |
|---|---|---|---|
| **Day 1** | | | |
| **Day 2** | | | |
| **Day 3** | | | |
| **Day 4** | | | |
| **Day 5** | | | |
| **Day 6** | | | |
| **Day 7** | | | |

**ANNEXURE IV: BIOSTATISTICIAN CERTIFICATE**

K L E VISHWANATH KATTI
INSTITUTE OF DENTAL SCIENCES
(A Constituent unit of KLE Academy of Higher Education & Research
Formerly known as KLE University) Deemed-to-be-University u/s 3 of the UGC Act, 1956)
J.N.M.C. Campus, Nehru Nagar, Belagavi-590 010, Karnataka, India
Accredited 'A+' grade by NAAC (3rd Cycle) Placed in Category 'A' by MHRD (GoI)
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## *Biostatistics Clearance Certificate*

This is to certify that Biostatics aspect of the Dissertation/Research work of **IF0221001** **Post Graduate Student,** under the guidance of **Professor, Department of Oral & Maxillofacial Surgery,** entitled **"Comparative evaluation of efficacy of Lignocaine HCL and Bupivacaine HCL used as a local drug delivery system for pain control after impacted mandibular third molar surgery: A single blinded randomized controlled trial"** has been done under my guidance and considered satisfactory.

Place: Belagavi

Date :

Name & Signature of Biostatistician

Ms. Anjali J. Patil
Lecture in Statistics
Dept. of Community Medicine
J.N. Medical College, Belagavi

Dept. of Community Medicine J.N. Medical College

**<u>ANNEXURE V</u>: PLAGIARISM CERTIFICATE**

## Scientific Correspondence and Review Committee


**KLE VK Institute of Dental Sciences**

**A Constituent Unit of KLE Academy of Higher Education and Research**
**(Deemed-to-be-University u/s 3 of the UGC Act, 1956)**
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Date : 10.4.2024 Serial No. : 175

### PLAGIARISM CHECK REPORT

Name of the Applicant **IF0221001**
UG / PG / Ph.D / Staff : POST GRADUATE
Batch & Year : 2021- 2024
Department : ORAL AND MAXILLOFACIAL SURGERY

The soft copy of Research Work / Manuscript by **IF0221001** entitled
"COMPARATIVE EVALUATION OF EFFICACY OF LIGNOCAINE HCL AND BUPIVACAINE HCL USED AS A LOCAL DRUG DELIVERY SYSTEM FOR PAIN CONTROL AFTER IMPACTED MANDIBULAR THIRD MOLAR SURGERY - A SINGLE BLINDED RANDOMIZED CONTROL TRIAL"
under the guidance of .....has been submitted for Anti-Plagiarism check to the Scientific Correspondence & Review Committee of KLE VK Institute of Dental Sciences using "Turn-it-in" software.

The scan has been carried out and the scanned output reveals a Similarity Index of ..... 4 %, which is **within** / **not within** the acceptable limits of 10% as per the UGC guidelines.

10/04/2024

**Member Secretary**
Scientific Correspondence and Review Committee
KLEVK Institute of Dental Sciences
KAHER-Belagavi

**Chairman**
Scientific Correspondence and Review Committee
KLEVK Institute of Dental Sciences
KAHER - Belagavi