"TO ASSESS THE EFFICACY OF ADDING TOPICAL BUPIVACAINE TO ORAL IBUPROFEN IN RELIEVING POST TONSILLECTOMY PAIN OVER ORAL IBUPROFEN ALONE- A RANDOMISED CONTROL TRIAL"

BY

REGISTRATION NO: BE0121012

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Sub: Institutional Ethical Clearance for the study.

With reference to the above, we wish to inform you that your proposed research project titled **"TO ASSESS THE EFFICACY OF ADDING TOPICAL BUPIVACAINE TO ORAL IBUPROFEN IN RELIEVING POST TONSILLECTOMY PAIN OVER ORAL IBUPROFEN ALONE- A RANDOMISED CONTROL TRIAL",** is ethical and justifiable. The proposed research project has been cleared by the JNMC Institutional Ethics Committee.

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LIST OF ABBREVIATIONS

GLOSSARY	ABBREVIATIONS
VAS	Visual Analog Score
NSAID	Non- Steroidal Anti-inflammatory Drugs
LA	Local Anesthesics
COX	Cyclooxygenase
COX-1	Cyclo-oxygenase-1
COX-2	Cyclo-oxygenase-2
COX-3	Cyclo-oxygenase-3
cAMP	cyclic Adenosine Mono Phosphate
LAST	Local Anesthetic Toxicity
IV	Intravenous
FDA	Food and Drug Administration
PDA	Patent Ductus Arteriosus
DRESS	Drug Reaction with Eosinophilia and Systemic Symptoms
GI	Gastrointestinal
TENS	Transcutaneous Electrical Nerve Stimulation
et al	et alii (Latin; ‘and others’)

ABSTRACT

OBJECTIVE: To assess the efficacy of adding topical 0.5% Bupivacaine in relieving post tonsillectomy pain.

INTRODUCTION: Chronic tonsillitis is a highly prevalent disease and tonsillectomy is the most frequently performed operations for it. Many patients experience severe pain post tonsillectomy. Pain results in a prolonged hospital stay, extended recovery following surgery, and higher expenses. Since post tonsillectomy pain is such a common problem it is important to find out an effective yet safe method of managing it. A number of methods have been used like NSAIDs, infiltration of local anesthetics, TENS but the outcomes have not been very effective. A study on use of topical Bupivacaine to relieve pain after tonsillectomy has not been done yet. Hence, the study is designed to test the efficacy of adding topical 0.5% Bupivacaine for 5 minutes post tonsillectomy along with oral Ibuprofen to provide relief from post tonsillectomy pain.

METHODOLOGY: It's a Randomized control trial from June 2023 to May 2024 with a sample size of 60 done at Department of Otorhinolaryngology and Head and Neck Surgery, KAHER, JNMC, Belagavi. Tonsillectomy was performed by dissection and snare technique and hemostasis achieved by pressure gauze/suture ligature. Next both tonsillar fossa was packed with a gauze piece soaked in 5ml of 0.5% Bupivacaine solution for 5 minutes. Anesthesia reversed and patients were asked to express their intensity of pain on Visual Analog Score at 1, 5, 8 hours post operatively. No further analgesic was given over next 5 hours. All patients discharged 24 hours post operatively. Randomization was done by using chit picking method.

RESULTS-Test results at the first, fifth, and eighth hours after tonsillectomy showed a significant reduction in discomfort for the topical Bupivacaine group compared to the non-bupivacaine group.

CONCLUSION- Pain after tonsillectomy is a major factor for long term morbidity and prolonged hospital stay. When it came to lowering postoperative pain, bupivacaine has demonstrated superior efficacy in pain reduction with a longer half-life and lesser or almost none side effects.

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INTRODUCTION

Chronic tonsillitis is a highly prevalent disease and tonsillectomy is the most frequently performed operations with over 530000 procedures carried out in children under the age of 15 each year.[1,2] Many patients experience severe pain post tonsillectomy. Pain results in a prolonged hospital stay, extended recovery following surgery and higher expenses. Perhaps as a result of their lack of resources, inadequate malnourishment, unpleasant living circumstances, ignorance, and insufficient medical attention, low-income individuals had the highest number of cases documented. Regarding the disease's occurrence by occupation, it was found that, during peak cases, 70% of patients were students, 15% were homemakers, 8% were laborers, and 4% were preschoolers. The low immunity of schoolchildren, cross-contamination from crammed classrooms, and inadequate ventilation in classrooms could be the cause of this high prevalence in youngsters.[3]

One of the most frequently performed operations is a tonsillectomy and significant number of patients experience post operative pain. In addition to producing discomfort, anxiety, and even behavioral issues, acute pain can also lead to functional recovery and better long-term functional outcomes when it is managed well . Pain results in a prolonged hospital stay, extended recovery following surgery, and higher expenses. Since post tonsillectomy pain is such a common problem it is important to find out an effective yet safe method of managing post tonsillectomy pain.[4,5] A study on use of topical Bupivacaine to relieve pain after tonsillectomy has not been done yet. Hence, the study is designed to test the efficacy of adding topical 0.5% Bupivacaine for 5 minutes post tonsillectomy along with oral Ibuprofen to provide relief from post tonsillectomy pain.

Bupivacaine has been attributed by several researchers as having the capacity to limit the need for analgesics during the early postoperative hours, when pain is at its worst, and to give continuous postoperative analgesia. Its extended duration of action and exceptional capacity to reduce pain and suffering have been documented as advantageous.[6,7,8]

Post tonsillectomy, a sizable portion of patients experience debilitating pain . Acute pain therapy of the highest caliber can enhance long-term functional outcomes and facilitate functional recovery.[9,10] In addition to producing discomfort, anxiety, and even behavioral issues, acute pain can also lead to functional recovery and better long-term functional outcomes when it is managed well. Dehydration can occasionally arise from post-operative pain, which frequently leads to decreased oral intake. The discomfort, which reaches its highest point four or five days after procedure causes a longer hospital stay, a slower rate of recovery from surgery, and higher costs.[11]

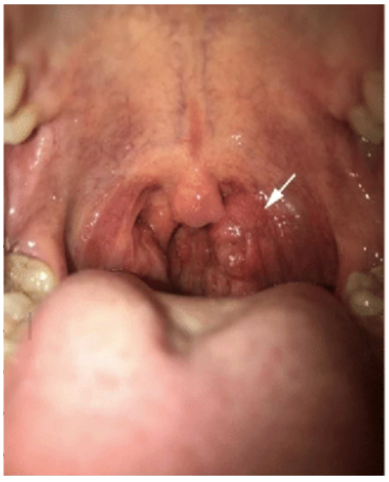


Figure 1. Chronic Tonsillitis.

(Figure taken from a case report done by Berita Kedokteran Masyarakat in February 2021- Persistent tonsillitis may become another symptom of COVID -19 and immunonutrition supports healing process in patient with history of tonsillitis)

Because of the unique operation site and the limitations of the current analgesic program, it is still exceedingly difficult to treat most patients with adequate analgesia, despite recent attempts. Since post-tonsillectomy pain is such a prevalent issue, it's critical to identify a safe and efficient way to treat it.[12] Because crying is associated with increased vascular congestion in the head and neck, appropriate analgesia is therefore required to relieve pain and lower the risk of bleeding.[13,14,15] Surgeons employ various techniques to treat post-operative pain based on their personal preferences. These include of the use of local anesthetics, nerve blocks, NSAIDS, intravenous opioids, steroids, and patient-controlled analgesia. Apart from causing pain to the patient, post-tonsillectomy pain can also lead to weight loss, constipation, fever, missed work or school days, and increased burden on the healthcare system due to hospital readmissions.[16,17]

Sufficient pain management is necessary to guarantee a prompt transition back to oral feeding and hospital release. Among the most prevalent long-acting local anesthesia drugs in applications, topical bupivacaine, is more secure than other comparable anesthetics. It is becoming more and more well-liked as a successful technique for pain management following tonsillectomy or adenotonsillectomy due to its quick beginning of action.[16] One medication in the category of amino amides used as a local anesthetic is bupivacaine. It can be applied topically in the tonsillar bed, locally, or by spraying it on. By attaching itself to the sodium channels, bupivacaine acts by preventing depolarization. The drug can diffuse more easily into pain-transmitting nerve fibers since they are typically thinner, unmyelinated, or lightly myelinated than thicker, more extensively myelinated nerve fibers for touch, proprioception, etc.

Ibuprofen is the NSAID that is frequently prescribed and utilized. COX-1 COX-2 are both non-selectively inhibited by it. Its analgesic and antipyretic roles are noteworthy, even if its anti-inflammatory benefits could prove to be equally potent as those of some other NSAIDs. Its effects emerge from its inhibitory effects on COX, which generate prostaglandins.[18,19,20]

The VAS approach, which was initially employed by Jebeles et al., involves the kid viewing a scale from the point of greatest pain to the point of least pain. The patient rates their own pain and indicates where it falls on the scale.[21,22,23]

There aren't many research on the use of topical bupivacaine after tonsillectomy to help patients feel better and reduce pain. Therefore, the objective of the investigation is to discover if topical 0.5% Bupivacaine applied five minutes after tonsillectomy together with oral Ibuprofen can effectively relieve post-tonsillectomy pain.

OBJECTIVE

- To assess the efficacy of adding topical 0.5% bupivacaine with oral ibuprofen in relieving post tonsillectomy pain.

REVIEW OF LITERATURE

TONSILLECTOMY

- Performed via endotracheal intubation while under general anesthesia. Adults may have it done in the Rose position while under local anesthesia. To stabilize the head, a rubber ring is positioned beneath it.
- Avoiding hyperextension is always advisable.
- The Boyle-Davis mouth gag is shown and activated. Draffin's bipods hold it in place.
- The tonsil is dragged medially after being grabbed with tonsil-holding forceps.
- Incision taken over the mucosal reflection of anterior pillar.
- The tonsil is separated from the peritonsillar tissue and its highest level pole can be cut using a blunt, curved scissor.
- Tonsil grasped and traction is given medially downward until the lower pole is reached.
- The tonsil tightened across tonsillar snare's pedicle and extracted by cutting the pedicle.
- For a few minutes, pressure can be applied to the fossa using a gauze sponge.
- Silk can be employed to tie bleeding points. On the opposing side, the entire procedure is repeated.

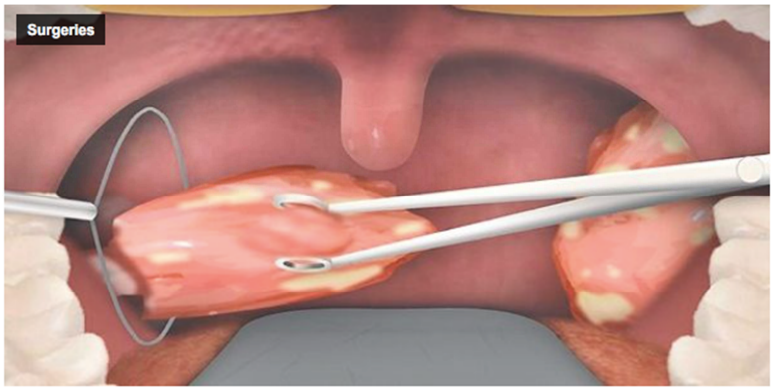


Figure 2. Dissection and snare method.

(Figure taken from a study by Prof. Dr. Fadlullah Aksoy, Department of otorhinolaryngology, Bezmialem Vakif University Medical Faculty Hospital)

INDICATIONS

- Recurrent throat infections. This is the most typical characteristic.
- Abscess located within the peritonsillar fossa. Tonsillectomy is usually performed on children 4-6 weeks after the abscess is treated. The decisive sign of an adult peritonsillar abscess is a second attack.
- Hypertrophy of the tonsils leading to (a) obstruction of the airway (sleep apnea), (b) difficulties in swallowing, and (c) difficulty speaking.
- Suspicions of carcinoma- In children, a unilateral tonsillar swelling may be a lymphoma; in adults, it may be an epidermoid carcinoma.
- Carriers of diphtheria, who have no antibiotic response.
- Carriers of streptococcal infections, who could infect others.
- Extended tonsillitis coupled with foul taste or halitosis that does not improve with medication.
- A patient with valvular heart disease who had recurrent streptococcal tonsillitis.
- Surgery to remove the palate in order to treat sleep apnea disease.

- Neural shunt for the glossopharynx.
- Styloid process removal.

According to a 2019 study by Hidaya Qarqani Bukhari et al, bacterial infections are more common in children between the ages of 6 and 12 and are more common in the lower socioeconomic groups. The preteen age group (6–12 years) had the highest number of tonsillitis cases among the age groups that were recorded (69%), followed by the teenage groups (13–18 years) (18%), and the children (4-5 years) (17%). After receiving treatment for tonsillitis, follow-up data revealed that the illness had returned in 70.3% of instances and had not returned in 27.6% of cases. Antibiotics were used to treat peritonsillar abscesses in 4.21% of the patients, who also received incision and drainage therapy.[3]

CONTRAINDICATIONS

- Less than 10% of hemoglobin is present.
- Acute tonsillitis, is present. There is more bleeding when there is an acute infection.
- Toddlers under three. They pose poor surgical risks.
- Cleft palate, either visible or hidden.
- The illness von Willebrand. bleeding diseases, such as sickle cell disease, hemophilia, aplastic anemia, leukemia, or purpura.
- During the polio pandemic.
- Unsupervised systemic ailments, which includes asthma, heart disease, diabetes, or hypertension.
- Tonsillectomy should be avoided when a woman is menstruating.

POSTOPERATIVE CARE

- Patient should be in coma position until they have completely recovered from anesthesia.
- Watch for nose and lip bleeding.
- Keep an eye on your breathing, pulse, and blood pressure, among other vital indications.
- When the patient is well enough, he can start fluids. In a diet, solid meals eventually take the place of soft food.
- The patient obtains three or four condy's or salt water gargles each day. - Cleansing the mouth with simple water after every meal might help maintain oral hygiene.
- Analgesics like paracetamol can relieve discomfort that starts in the throat and spreads to the ear. Analgesics are safe to take up to thirty minutes before meals. Ibuprofen and aspirin should be avoided since they may trigger bleeding and decrease platelet adhesiveness.
- Adequate antibiotic for a week can be taken orally or intravenously.
- Patient discharged twenty four hours post procedure.[24]

According to a study by Reginald F. Baugh et al., promoting pain management following tonsillectomy and teaching caregivers about the significance of controlling and reevaluating pain are crucial steps in averting long-term morbidity.[1]

OTHER METHODS OF TONSILLECTOMY

1. The Guillotine method.
2. Electrocautery.
3. Laser tonsillectomy.
4. Laser tonsillotomy.
5. Intracapsular tonsillectomy.
6. Harmonic scalpel.
7. Plasma-mediated ablation technique.
8. Simultaneous tonsillectomy.
9. Cryosurgical technique: Cryoprobe is applied to the tonsil, freezing it, and then allowing it to defrost. There are two applications, each lasting three to five minutes. Necrosis will occur in tonsillar tissue, which will then fall off and leave a granulating surface behind. Because of the thrombosis of veins brought on by freezing, bleeding is reduced. [24]

BUPIVACAINE

Bupivacaine is a common amide-type local anesthetic used in surgery for prolonged blocking of peripheral and central nerves. It is sold as rac-bupivacaine, the racemate of R- and S-bupivacaine, and it possesses a single chiral center. While both enantiomers are active, S bupivacaine exhibits a longer duration of neural blockage and a decreased susceptibility to cardiovascular and central nervous system damage. As a result, levobupivacaine, often known as S-bupivacaine, was introduced into clinical use. The propyl homolog of bupivacaine has undergone a parallel development that has resulted in the creation of ropivacaine, the S-enantiomer. For constant anesthesia, bupivacaine does not need epinephrine to be present, and it

prolongs the length of post-operative analgesia. Bupivacaine has been attributed by several researchers as having the capacity to limit the need for analgesics during the early postoperative hours, when pain is at its worst, and to give continuous postoperative analgesia. Its extended duration of action and exceptional capacity to reduce pain and suffering have been documented as advantageous.[25]

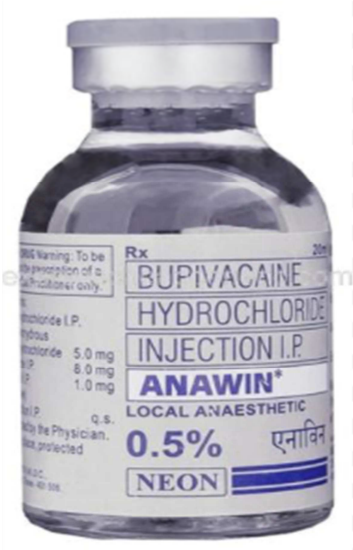


Figure 3. Bupivacaine

(Source- Internet)

Regional, epidural, spinal, and local injection all use local anesthetics. Increasing the threshold for electrical excitation, local anesthetics arrest nerve cells from producing an action potential. This exercise goes over the bupivacaine's mode of action, adverse event profile, toxicity, dosage, pharmacodynamics, and monitoring. It is important for interprofessional team members to know these details when treating patients when local anesthetic is necessary.

MECHANISM OF ACTION

Three structural elements are present in all local anesthetics: an ionizable amine group, an ester (procaine) or an amide (bupivacaine) as a linking group, and an aromatic ring. Furthermore, the two chemical characteristics of all LAs influence their activity.

1. Solubility of fatty acids
2. The pKa measurement for dissociation

Local anesthesia medications penetrate nerve fibers as a neutral-free substrate. An action potential is produced through the axon to transmit nerve impulses; When LAs attach to the sodium ions channel and impede the sodium ions permeability needed to generate the action potential, local anesthesia results. Voltage-gated Na+ channels are selectively inhibited in their open form by local anesthetics.

Through their interaction approaching the Na+'s inside surface channel, cationic along with ionized structures hinder conduction. Additionally, LAs with pKa on lower level have a quicker start of action, they are not in charged state and diffuse to the cellular part of the Na+ channel more quickly. Action potentials are propagated in muscle tissue, dendrites, and axons via membrane proteins called Na+ channels. When vascular smooth muscle conduction is reduced or eliminated, Na+ channel blockage causes relaxation. This causes the heart's refractory time to lengthen and pacemaker activity to diminish. Because bupivacaine dissociates from blocked sodium channels more slowly than other drugs, it elevates the prospect of ventricular rhythm disturbances and lengthens the peak rate of discharge. This activity is specific to bupivacaine. In addition to eliciting a dose-dependent coronary depression, LAs

can also attach to and disable myocardial voltage-gated calcium and K+ channels, both of which may interrupt Ca2+ signaling inside the heart muscle.

In addition, local anesthetics, by binding to beta-adrenergic receptors prevent synthesis of cAMP triggered by adrenaline. This may account for the resistance of bupivacaine injury to conventional approaches for resuscitation.

Different neural tissues respond differently to local anesthetics. Neuronal conduction is entirely hindered by blocking two or three of the Ranvier nodes, which are followed by depolarizing currents in nerves. Since smaller fibers have shorter internodal lengths, local anesthetics block them more quickly.

ADMINISTRATION

There are three different concentrations of bupivacaine available: 0.25%, 0.5%, and 0.75%. Administration methods include spinal anesthesia, caudal blocks, local infiltration, peripheral nerve, and epidural anesthesia/analgesia for labor pain. In order to prolong the anesthetic effects of LA for nerve blocks, adjuvants are frequently used. It has been demonstrated that using the LA in conjunction with alpha 2 agonists greatly extends duration of anesthesia. The risk of injecting into a blood vessels structure will probably lower provided the nerve and its associated tissue are visualized. This also improves the early diagnosis of the occurrence, which lowers the likelihood that the bloodstream would become toxically high in bupivacaine.

ADVERSE EFFECTS

The technique, the tissue's blood supply, the placement, the depth/duration of anesthetic required, and patient's physique all influence the dosage. Blood thinners, antidepressants, and ergot medicines used to treat migraine headaches may interact with bupivacaine. Rarely do immunologic responses to local anesthetics occur. Rarely do allergic responses to amide-type local anesthetics without preservatives get documented. When ester local anesthetics or preservatives are used, an anaphylactic reaction seems more likely; events using local anesthetics that contain epinephrine are frequently mislabeled as allergic reactions. Preservatives like methylparaben, which are used with local anesthetics, might also cause reactions in patients.

Benzocaine or prilocaine are commonly linked to methemoglobinemia; nevertheless, there are case reports that link bupivacaine to the condition in rare cases. Methemoglobinemia can be asymptomatic at low concentrations (1% to 3%), but at larger concentrations (10% to 40%), symptoms such as cyanosis, grayish skin coloring, tachypnea, dyspnea, weariness, disorientation, syncope, and weakness may be present.

CONTRAINDICATIONS

Hypersensitivity to the medicine or any of its ingredients, amide anesthetic hypersensitivity, injection site infection, intravenous regional anesthesia, and intra-articular continuous infusion are among the contraindications. Patients with hypersensitivity to sulfite, liver derangement renal impairment, heart block, reduced cardiac function, hypovolemia, hypotension and old, disabled, critically sick patients must be treated carefully by clinicians.

MONITORING

- Continuous EKG.
- Oxygen saturation.
- Blood pressure.

Request that if any participant experience numbness in or around mouth and around their lips, metallic taste, ringing sensation in the ears, trembling, or unsettling symptoms they must get therapy according to guidelines and the administration of bupivacaine must cease promptly if the patient experiences any of these symptoms.

TOXICITY

While the signs and symptoms of most local anesthetics are similar, there may be differences in the ratio of toxicity to heart and nerves, with bupivacaine being the most toxic to the heart. Toxicology occurs in only 1 in 1000–1 in 10,000 cases. If you experience atypical neurological or cardiovascular signs and symptoms, you should bear in mind about local anesthetic toxicity (LAST). The risk of toxicity is also influenced by the location at which the local anesthetic is administered. Bupivacaine levels succeeding 2.5 to 3.5 mg/kg; most commonly leading to toxicity is either intentional direct intravenous administration/ fast vascular absorption of medication.

Toxicity signs/symptoms may occur rapidly/delayed. Patients very seldom show signs of toxicity at dosages quite below the upper limits. It seems that an uncommon l-carnitine deficiency-related disease is the cause of this toxicity. Bupivacaine given subcutaneously at dose as low as 1.1 mg/kg may cause cardiac toxicity in afflicted patients. There are case reports outlining these instances of low dose toxicity in individuals who subsequently had l-carnitine deficiencies found in

them. This model was validated in a study using rats, and it was discovered that this impact could be counteracted by administering more l-carnitine.[26]

A 2018 study by Ahmed El Daly et al. found that topical application of the tonsillar bed with a local anesthetic results in a significant reduction of postoperative throat pain and referred otalgia. It is recommended to use bupivacaine during tonsillectomy surgery as it demonstrated a longer duration of pain reduction following the procedure.[4]

J.P. Fawcett et al., stated that Bupivacaine offered continuous post-operative analgesia following oral surgeries for hours. Additionally, they mentioned that although both enantiomers of bupivacaine are active, S-bupivacaine causes a longer-lasting neural blockade and has a lesser tendency to be harmful to the central nervous system and the cardiovascular system.[25]

IBUPROFEN

Ibuprofen, first invented in 1961, is now one of the most commonly used NSAIDs in the world. Ibuprofen is still the only medication used today for pain relief in inflammatory diseases and rheumatic disorders, however some research is being done to develop new medications or treatments. One such study focuses on developing hybrid medicines that combine an NSAID and a carbonic anhydrase inhibitor to treat rheumatoid arthritis pain. It is approved by FDA for mild to moderate discomfort and also over-the-counter pain medication for the same. Ibuprofen's efficacy as a pain reliever for various pain conditions is frequently examined in relation to other NSAIDs, with an emphasis on novel therapeutic

strategies or COX-2 inhibitors. Ibuprofen has showed promise in the treatment of postoperative pain.

Even though ibuprofen is already well known for being an effective pain reliever, researchers are constantly seeking for ways to improve its effectiveness when used in clinical settings. Ibuprofen is another antipyretic that has FDA approval that reduces fever. NSAIDs are far more frequently used to treat fever in children, and majority of the current experiments is aimed at improving its efficacy to treat pediatric fever. A review of the literature conducted in 2017 found that there was not enough evidence to support ibuprofen or acetaminophen (paracetamol) being more beneficial than the other in treating fever.

In six of the studies that were examined, ibuprofen was found to have a minor difference; nonetheless, the data were insufficient to draw the conclusion that ibuprofen was linked to better outcomes. Only after the first cycle of treatment did patients with refractory fevers respond better to alternating doses of acetaminophen and ibuprofen than to monotherapy of either medication.

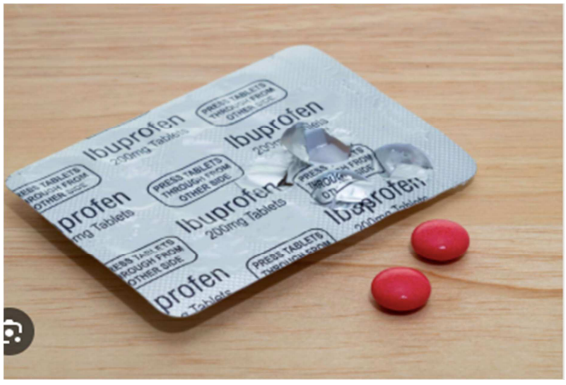


Figure 4. Tab. Ibuprofen

(Source- Internet)

MECHANISM OF ACTION

Smooth muscle tone, vascular permeability, platelet aggregation, and cell proliferation are just a few of the physiological processes that are regulated by the molecules known as eicosanoids, which are produced as a consequence of metabolic pathways. Similar to cyclooxygenase system byproducts, eicosanoids are implicated in angiogenesis, autoimmune diseases, cancer, inflammation, and atopy. The cyclooxygenase pathway is involved in the manner that ibuprofen is currently advised to be used. The three isoforms of the COX pathway are COX-1 (PGH synthase), COX-2, and COX-3. The isoform COX-1 react quite consistently to most physiological or pathological events. Conversely, there is a strong inducible influence of mitogenic and inflammatory stimuli on COX-2 expression. The most well-known of them are tumor necrosis factors, vascular endothelial growth factor, fibroblast growth factor, and transforming growth factor. The majority of the function of the COX-3 isoform is still unknown despite considerable research into it.

This mechanism provides the analgesic, antipyretic, and anti-inflammatory effects of non-selective NSAIDs like ibuprofen. When ibuprofen is administered specifically, COX-1 is suppressed more potently than COX-2. This might be having a consequence on many research efforts assessing the varying efficacy of selective inhibitors of COX-2 in managing a variety of maladies frequently dealt with ibuprofen. Apart from its widely recognized roles in inflammation, it has been deduced that COX-2 is mainly generated during the initial phases of carcinogenesis. Increased expression of COX-2 has been detected in majority of human malignancies, such as colorectal, lung, breast, esophageal, and pancreatic tumors. Moreover, data demonstrates that NSAIDs reduce the viability of malignant cells, including those

with and without overexpressed COX-2, indicating the possibility of other pathways being involved in the anticancer effects of the medications.

ADMINISTRATION

The majority of the world's population may easily obtain ibuprofen in convenient forms for use over-the-counter. Common dose forms are ingestible capsules, suspensions, tablets, chewable tablets, IV solutions, topical gels, and combination kits. Adults and toddlers alike are usually recommended to take oral medications with food or milk. Inpatient settings commonly use IV treatment when oral delivery is neither feasible or convenient. For adults, the infusion should last at least 30 minutes; for youngsters under 10, it should last 10 minutes. Lysine with ibuprofen is a popular IV combination. Although total parenteral nutrition may still be used in the same manner, ibuprofen should not be given in conjunction with it. Instead, total parenteral feeding should be stopped for fifteen minutes prior to and following ibuprofen administration. Emerging studies aim to investigate the potential of administering ibuprofen and other IV drugs or nutrients at the same time.

ADVERSE EFFECTS

Ibuprofen is known to cause bleeding into the stomach, which can lead to gastritis, ulcers, bleeding, or perforations. The usage of ibuprofen inhibits COX isoforms, which lower prostaglandin levels and aid in the release of mucus that coats and shields the stomach. While COX-2 specific NSAIDs show a lower prevalence of gastrointestinal issues—a fact that should be especially concerning for juvenile patients—non-selective NSAIDs have a more noticeable impact on this phenomenon. Ibuprofen is used more frequently than other NSAIDs since it is relatively safe. A

recent surveillance research found that NSAIDs had nephrotoxic effects even in people with normal kidney function. Ibuprofen consumption is also linked to decreased renal function. NSAIDs and kidney function have been thoroughly examined since a substantial warning sign for damage to renal cells triggered by ibuprofen is dehydration.

Skin eruption is another common adverse effect of using ibuprofen; these are mainly caused by the drug being applied topically or by drug hypersensitivity. A rash may be a sign of a rather serious ibuprofen-related condition- drug reaction with eosinophilia and systemic symptoms (DRESS) syndrome. Ibuprofen or other NSAIDs have been linked to similar severe drug reactions in previous cases documented in the literature.

CONTRAINDICATIONS

Ibuprofen should not be taken by patients hypersensitive or allergic to aspirin, other NSAIDs, or the medicine itself. Ibuprofen has been linked in a number of case studies to post-usage sickness. NSAIDs are one of the pharmacological types most frequently associated with hypersensitivity responses. The most frequent diagnosis is urticaria/angioedema due to cross-intolerance to other medications, such as quinolones and amoxicillin-clavulanic acid.

Premature infants necrotizing enterocolitis, bleeding diathesis, thrombocytopenia, renal impairment, and congenital heart problems like PDA should not receive the drug. Aside from this, it has been shown that giving ibuprofen to babies younger than six months of age does not cause any additional negative effects,

and when these conditions are satisfied, it is still advised for use in pediatric populations.

MONITORING

Reducing the side effects should be the goal of appropriate monitoring for ibuprofen users. Pain management and gastrointestinal symptoms should be evaluated clinically as they may point to the onset of gastritis, GI bleeding, or desensitization to ibuprofen's analgesic effects. Furthermore, blood pressure needs to be monitored, especially for older or hypertensive people. Renal function monitoring is particularly recommended because NSAIDs are nephrotoxic in both at-risk populations and normal individuals. Ibuprofen users are typically not assessed for liver function; however, reports of NSAID-induced liver impairment in children may suggest that patients in high-risk categories or high-risk subgroups ought to be investigated.

Contrary to acetaminophen-induced liver injury, which has a remedy, NSAID-induced liver damage is incurable, even though it is significantly less common than acetaminophen-induced liver damage according to prior research. The increasing number of children taking ibuprofen implies that more research on NSAIDs and liver function should focus on this area.

TOXICITY

Because cyclooxygenase pathway inhibition affects a variety of cellular activities across numerous organ systems, ibuprofen may be hazardous to the body. Even at therapeutic dosages, ibuprofen has a minor risk of adverse gastrointestinal and renal events; prostaglandins and thromboxanes are vital in maintaining the renal blood flow and the stomach mucosal layer. Ibuprofen is the most frequently

implicated NSAID in an overdose (29%), either when used alone or in combination with other analgesics. Overdose is a typical cause of patient presentation with ibuprofen toxicity

Nowadays, Reye syndrome is becoming a more uncommon occurrence, mostly as a result of national initiatives to reduce aspirin use that started in the 1980s. Because they cause the same kind of damage to mitochondrial membranes, NSAIDs are hepatotoxic and in rare cases can trigger Reye syndrome. Furthermore, there is still much to learn about the mechanism underlying how NSAIDs affect liver function. Like other commonly used drugs, ibuprofen's environmental prevalence and the potential long-term effects of exposure are causes for growing worry. Research now demonstrates possible ways to use solar radiation, mineral particles, and bacterial strains to bioremediate ibuprofen in the atmosphere. It has also been demonstrated that the breakdown products of ibuprofen are not as hazardous as ibuprofen itself. Additionally, research has demonstrated that the medication has no mutagenesis potential and only mild toxicity to the studied species. Still, there is worry about any potential indirect effects that environmental ibuprofen may have on menstruation, ovulation, inflammation, and pain—processes that are mediated by prostaglandins.[27].

According to a Bushra R et al. overview, Ibuprofen's safety, good tolerance, and rather broad spectrum of indications make it appropriate for self-medication. It can be taken and is considered the safest conventional NSAID overall.[18]

VAS SCORE

A line, usually measuring 100 mm in length, with two descriptions at either end, such as "no pain" and "extreme pain," represents the extremes of pain intensity on the visual analog scale (VAS). The VAS is scored by calculating the distance from the point of the line that indicates "no pain," and patients assess their pain by marking a spot on the line that represents their level of discomfort. In clinical trials, VASs are among the most popular metrics for assessing pain intensity.

Others have since reported using the scale to gauge pain in patients with rheumatology undergoing pharmaceutical pain management. Although several anchor pain descriptors have been employed, there doesn't seem to be a good reason to choose one set of descriptions over another.[28]

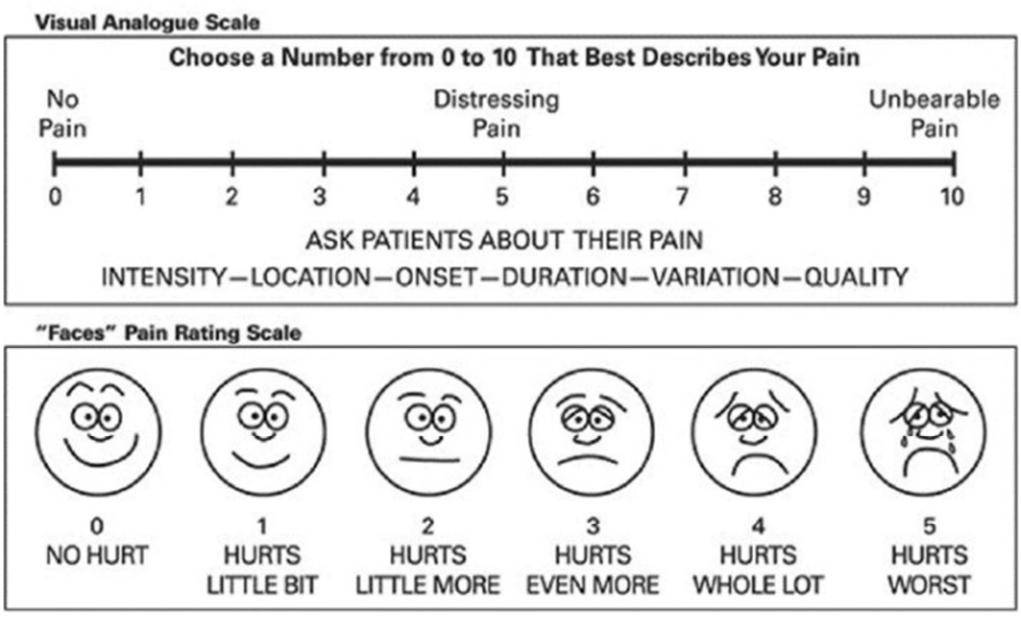


Figure 5. VAS Score

(Figure taken from an article done by Faezeh Ghaderi on Effect of pre-cooling injection site on pain perception in pediatric dentistry: a randomized clinical trial)

METHODOLOGY

Source of Data :-Patients diagnosed with Chronic Tonsillitis in the age group of 5 - 35years presenting to ENT OPD at the KLES Dr. Prabhakar Kore Hospital and Medical Research Centre, Belagavi.

Study Design :- Randomized Control Trial

Study Period :- 1year 01/06/2023 to 30/05/2024

Sampling technique :- Diagnosed cases of Chronic Tonsillitis presenting to ENT & HNS OPD at the KLES Dr. Prabhakar Kore Hospital and Medical Research Centre, Belagavi.

Sample Size:

N=60

The two-proportion formula for the minimal sample size is $n = \frac{(z_\alpha + z_\beta)^2 \bar{p}(1-\bar{p})}{d^2}$

where p_1 and p_2 are the proportions of the two groups.

$p = \frac{p_1 + p_2}{2}$ and $d = p_1 - p_2$

z_α is linked with the level of significance and z_β is linked with the power of the test. For 5% level of the significance $z_\alpha = 1.96$ and $z_\beta = 0.84$ for 80% power of the test.

The parameter considered is the percentage of the cases having no pain after 1 hour post operation

By taking proportion of cases with anxiety, p_1 = 60% and p_2 = 12.5% the sample size obtained is 30.

There would be two groups with minimum size of 17.

To make the study more confirmative the sample size will be raised to 30.

There will two groups with size 30 each.

Inclusion Criteria:

- All patients in 5 – 35 years age range.
- Participants with history of repeated attacks of chronic tonsillitis requiring tonsillectomy.

Exclusion Criteria :-

- Those with acute tonsillitis.
- Those with bleeding diathesis.
- Those with suspicions of tonsillar malignancy.
- Those with hypersensitivity to Bupivacaine and ibuprofen.

Data collection procedure:

- One day prior to surgery, each participant was admitted.
- The chit-picking method was used to randomize the data.
- Each patient, or the parents of pediatric participants, provided written informed consent. Additionally, a 10-point Visual Analog Scale was taught to them for rating their level of pain, with 0 representing nil discomfort and 10 representing excruciating pain.

- A thorough history and examination in otorhinolaryngology was performed.
- For every patient, a same aesthetic protocol was adhered to.
- The Dissection and Snare technique was used to complete the tonsillectomy.
- Suture ligation and pressure gauze were used to establish hemostasis. Following hemostasis, a piece of gauze with 5 milliliters of 0.5% bupivacaine solution placed into each tonsillar fossa for five minutes. Anesthesia changed.
- All patients received oral Ibuprofen between one and three hours after surgery.
- For the next five hours, no more analgesic was administered.
- On the Visual Analog Score, each patient was asked to rate their grade of pain at 1, 5, and 8 hours following surgery.
- Following surgery, patients were released 24 hours later.

Data processing and analysis/statistical analysis:

The comparison of two groups was the main goal of the study. The mean and standard deviation for the continuous quantitative variables were computed. The unpaired student's t test and other appropriate statistical methods were used to compare the intergroup continuous variables. Two quantitative variables were compared using the student's paired t test.

Using the Fisher's exact test or the Chi-square test, the relationship between the outcome, clinical and demographic factors were examined. When comparing discrete variables, the median was used to represent the discrete variables. Appropriate graphs were employed to illustrate the contrast. P-value of less than 5% (0.05) was termed significant for every test.

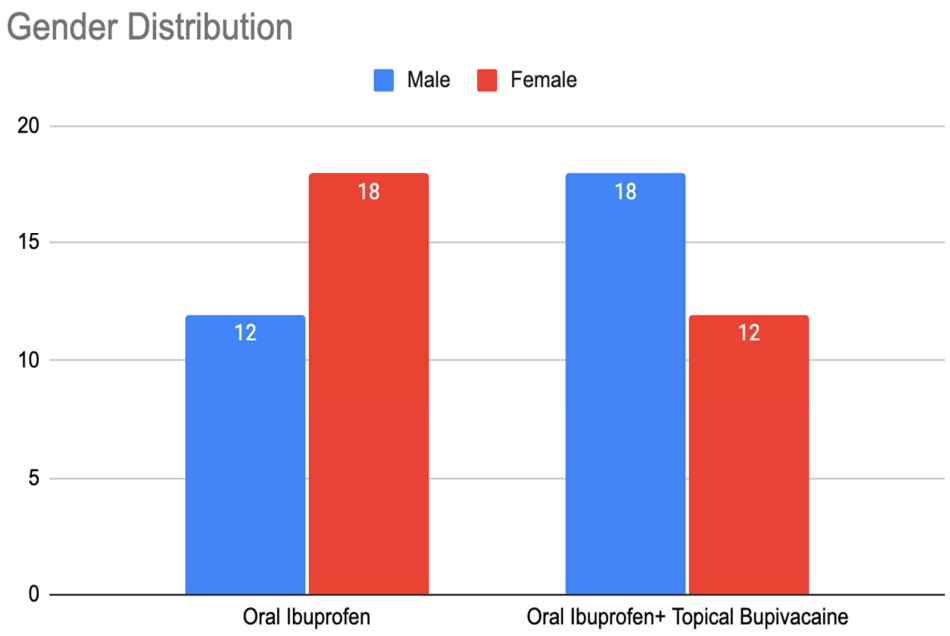
RESULTS

1. Gender distribution

Mean age in oral ibuprofen group was 16 ± 8.07 years while the mean age in the oral ibuprofen+ topical bupivacaine group was 12.6 ± 3.94 years. 18 participants (60%) in the test group were male whereas 12 participants (40%) in the control group were male.

60 participants were enrolled in the study, 30 in both the groups.

- Of the 60 patients who were involved in the study, female preponderance was seen in control group and male preponderance was seen in the test group



Graph 1- Gender Distribution

Table 1 Sex distribution of the sample

Gender	Number		Percentage	
	Control	**Test**	**Control**	**Test**
Female	18	12	60	40
Male	12	18	40	60
Total	30	30	100100	

2. <u>Age wise distribution of patients</u>

It was observed that maximum subjects in the control group were in 10-14 age group and maximum subjects in test group were in 15-19 age group.

In this study, patients within the age group of 5-35 years were included.

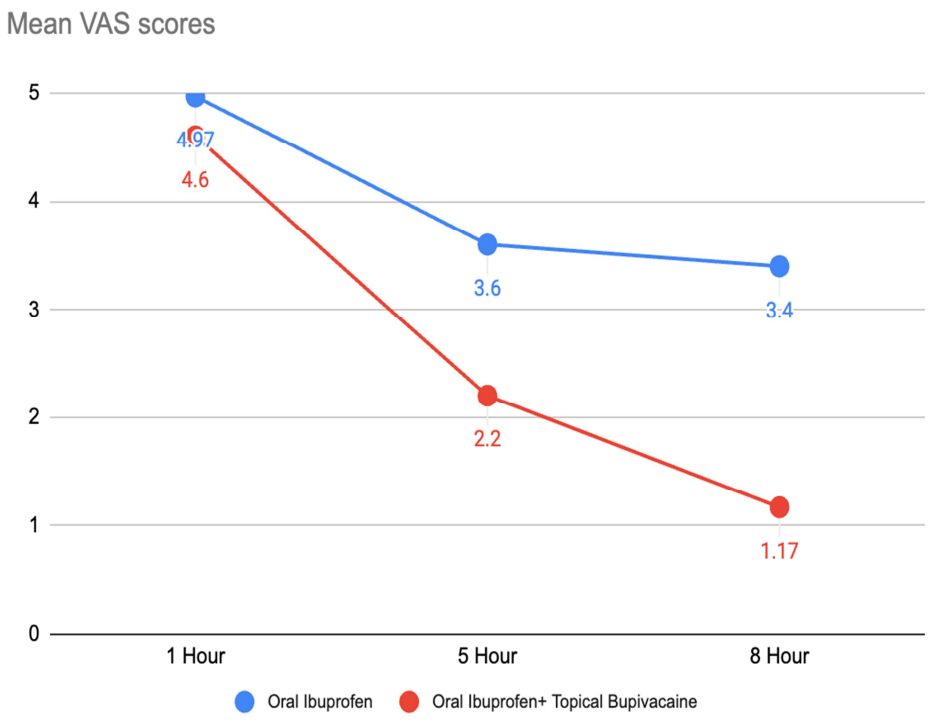
Table 2 Age wise distribution of patients

Age	Number		Percentage	
	Control	Test	Control	Test
<5	2	0	6.67	0
5-9	4	7	13.33	23.33
10-14	17	7	56.67	23.33
15-19	6	8	20	26.67
20-24	1	4	3.33	13.33
25-29	0	1	0	3.33
30-35	0	3	0	10

3. **Mean VAS Score**

- In test group at 1st hour - 4.6 ± 0.49, at the 5th hour was 2.2 ± 0.89 and at the 8th hour was 1.17 ± 0.65.
- In control group at 1st hour - 4.97 ± 0.18, at the 5th hour was 3.60 ± 0.49 and at the 8th hour was 3.40 ± 0.56.

In this study, Visual Analog Score was used to express the intensity of pain experienced by them post tonsillectomy procedure. The scoring was done by asking the patients to rate the pain severity based on the charting given and calculate the Mean VAS at 1st, 5th and 8th hour postoperatively.



Graph 2- Mean VAS Score

Table 3 -25th Percentile

Descriptives	SL. NO	1ST HOUR	5TH HOUR	8TH HOUR
N	Test	30	30	30
	Control	30	30	30
Missing	Test	0	0	0
	Control	0	0	0
Mean	Test	4.60	2.20	1.17
	Control	4.97	3.60	3.40
Median	Test	5	2	1
	Control	5	4	3
Standard Deviation	Test	0.498	0.887	0.648
	Control	0.183	0.498	0.563
Minimum	Test	4	1	0
	Control	4	3	2
Maximum	Test	5	4	3
	Control	5	4	4
25th Percentile	Test	4.00	2.00	1.00
	Control	5.00	3.00	3.00

Table 4- Group descriptives

Descriptives	Group	N	Mean	Median	SD
1st hour	Test	30	4.60	5.00	0.498
	Control	30	4.97	5.00	0.183
5th hour	Test	30	2.20	2.00	0.887
	Control	30	3.60	4.00	0.498
8th hour	Test	30	1.17	1.00	0.648
	Control	30	3.40	3.00	0.563

Result- Since the VAS score is ordinal data and was not normally distributed, Mann Whitney U test was applied to compare the VAS scores at 1st, 5th and 8TH hours across the test and control group. The difference in VAS scores were found to be statistically significant ($p<0.001$) at 1st, 5th, 8th hour with effect sizes of 0.367, 0.973, 0.787 respectively.

Table 5- Independent Samples t-test

		Statistics	P	Mean difference	SE difference	Effect size
1st hour	Mann-Whitney U	285.0	< .001	-5.62	Rank biserial correlation	0.367
5th hour	Mann Whitney U	12.0	< .001	-2.00	Rank biserial correlation	0.973
8th hour	Mann-Whitney U	12.0	< .001	-2.00	Rank biserial correlation	0.973
Note. H_a μ test$\neq$ μ control						

DISCUSSION

Our study demonstrated that the incidence of acute tonsillitis was influenced by population dispersion. In our study of 60 volunteers, the pre-teenage group (10–14 years old) had the greatest number of tonsillitis cases followed by the adolescent groups (15–20years old), youngsters (5–10 years old). For age range of 6 to 12 years, Middleton et al. reported similar results. Cross-contamination from crowded classrooms, limited ventilation, and the children's compromised immune systems could all be contributing factors to this high incidence in school-age children.[3]

When it came to the incidence of the condition by sex, it was discovered that, at its highest point, 60% of tests and 60% of controls group were male. Therefore, we found no evidence of a significant gender correlation in our study.

The majority of patients handle the process well. Patients in the younger age range have a lower pain threshold than do adolescents and adults, which is where the issue lies. To measure the amount of pain experienced, our study used a subjective scoring method called the Pain Analog Score for adults and the Visual Analog Score for children.

In addition to improving oral intake and lowering the risk of infection, dehydration, and hemorrhage following surgery, minimizing discomfort after a tonsillectomy is crucial for the patient's comfort.[6] Surgeons employ various techniques to treat post-operative pain based on their personal preferences. These include of the use of local anesthetics, nerve blocks, NSAIDS, intravenous opioids, steroids, and patient-controlled analgesia. Pain impulses that enter the central nervous system during surgery may cause hyperexcitability even under general anesthesia.

These impulses can be blocked by preoperative analgesic drugs or local anesthetic agent injection, which has a preventative analgesic effect. Many ideas, such as the central biassing mechanism, neuropharmacology, peripheral blocking mechanism, and gate control theory, have been proposed. Despite the fact that TENS demonstrated sufficient pain reduction compared to other analgesic regimens, no larger studies have been conducted, therefore there is not enough evidence to support the method's true effectiveness. There is no proof that any specific stimulation parameter and pain alleviation are related. In this investigation, visual analogue scales were utilized due of their demonstrated sensitivity in evaluating pain. Compared to other comparable anesthetic drugs, topical bupivacaine, along-acting local anesthetics, has a higher safety profile. It is becoming more and more well-liked for treating pain following tonsillectomy or adenotonsillectomy.[13]

Objective of our project was to deduce if topical 0.5% Bupivacaine applied five minutes after tonsillectomy together with oral Ibuprofen can effectively relieve post-tonsillectomy pain. Very few studies have been done on the use of topical bupivacaine to relieve post-tonsillectomy discomfort and provide patients with pain relief. Bupivacaine, an amino amide group of drugs can be applied topically in the tonsillar bed, locally, or by spraying it on.[16] In order to stop sodium from entering nerve cells and causing depolarization, as well as the production and conduction of nerve impulses, bupivacaine binds to the inner surface of cells of sodium channels. It lowers the action potential, slows propagation of nerve impulses, and raises the threshold for electrical stimulation in the neuron.[26] The drug can diffuse more easily into pain-transmitting nerve fibers because these nerve fibers are often thinner, either unmyelinated or lightly myelinated.

The VAS was chosen to depict pain since it is one of the most dependable and consistent pain scales. In our study VAS has been used in all age groups. The patients were scored on their severity of pain which closely resembled pictorial representation of their pain in the scoring system. In our investigation, both group showed a substantial difference at the fifth and eighth hour, with the effect of bupivacaine being highly significant at the first hour which was vividly concluded by the VAS.

LIMITATIONS

- Limited sample size. As the study period is restricted to one year because of academic purposes, it was not possible to obtain larger sample size.
- Another limitation was that all tonsillectomies in our study were not performed by a single surgeon. This was because it was not possible to reach the required sample size by one surgeon performing all the surgeries.

CONCLUSION

- Pain post tonsillectomy is a major factor for long term morbidity and prolonged hospital stay.
- Bupivacaine is a helpful drug for pain management following tonsillectomy due to its hyper-analgesic properties.
- Test results at the first, fifth, and eighth hours after tonsillectomy showed a significant reduction in discomfort for the topical Bupivacaine group compared to the non-bupivacaine group.
- When it came to lowering postoperative pain, bupivacaine has demonstrated superior efficacy in pain reduction with a longer half-life and lesser or almost none side effects.

SUMMARY

- Pain after tonsillectomy is a major barrier to the rehabilitation of patients thus it is crucial to find effective ways to manage the pain. Importance of pain management lies in the fact that greater the pain, higher will be the dehydration; which will lead to longer hospital stay, which in turn may lead to hospital acquired infections and hence delayed recovery. Therefore, pain management becomes utmost important for the recovery of the patient.
- Numerous methods for pain management post tonsillectomy have been used like oral analgesia but has not shown significant improvement in pain post tonsillectomy.
- Several researchers have suggested that bupivacaine can provide continuous postoperative analgesia and reduce the need for analgesics during the early postoperative hours, when pain is at its worst.
- Bupivacaine infiltration for post tonsillectomy pain have been tried but due to its systemic involvement, there were cases of cardiac side effects like arrythmias hence its use is controversial.
- 0.5% Bupivacaine which is a long-acting local anesthetic is comparatively safer and more efficacious compared to the local anesthetics belonging to the same class and hence can be safely used for post operative analgesia.
- Our study demonstrates that major pain following tonsillectomy can be controlled by topically applying 0.5% bupivacaine to the tonsillar fossa without any side effects or complications.

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ANNEXURE I - CONSENT FORM

INFORMED CONSENT

"TO ASSESS THE EFFICACY OF ADDING TOPICAL BUPIVACAINE TO ORAL IBUPROFEN IN RELIEVING POST TONSILLECTOMY PAIN OVER ORAL IBUPROFEN ALONE- A RANDOMISED CONTROL TRIAL"

PRINCIPAL INVESTIGATOR : REG. NO:- BE0121012

GUIDE :

INTRODUCTION AND PURPOSE: The present study is conducted among patients with chronic tonsillitis attending the out-patient department of ENT & HNS in KLE's Dr.Prabhakar Kore Charitable Hospital and Medical Research Centre, Belagavi. You are requested to participate in the study and your participation is completely voluntary.

PROCEDURE: If you agree to participate in this study, the relevant data will be collected as per the proforma and the final diagnosis will be confirmed. After getting inducted in the study, you will be evaluated post tonsillectomy for pain relief after the planned intervention.

BENEFITS: Patient will not be eligible for any kind of monetary benefits or free services by virtue of your participation in the study.

RISKS: Methods applied to do the study are safe.

COST OF PARTICIPATION: The cost of the Investigation will be borne by the Study Subject. The other indirect expenses will be borne by the Investigator.

PRIVACY AND CONFIDENTIALITY: The results of the study maybe published in journals for scientific purposes. However, your identity will not be revealed. All information collected will be coded so that no one other than the investigator will know your identity.

WITHDRAWAL FROM THE STUDY: You can withdraw from the study at any time ifyou wish to do so.

AUTHORIZATION TO PUBLISH THE RESULTS: The researcher may use the information gathered from this study for presentation in scientific meetings. However, your identity will not be revealed.

QUERIES AND CONTACT: If you have any questions about rights as a research participant you can contact **Dr. Harsha Hegde** ,Chairperson, JNMC, IEC & Scientist D, ICMR, National Institute of Traditional Medicine.

CONSENT SUMMARY:

I have been explained all the contents of this consent form in my local language and having understood and clarified all my queries about the study to the best of my knowledge, I hereby give my voluntary consent for participation in the study. I do sign the informed consent form in front of an eyewitness whom I recognize.

Name and Signature/ left thumb impression of the participant:

Legally authorised Relative:

Name and Signature/ left thumb impression of the eyewitness (Relative)

Name and signature of the interviewer:

Signature of the guide:

Date:

ANNEXURE II- PROFORMA

"TO ASSESS THE EFFICACY OF ADDING TOPICAL BUPIVACAINE TO ORAL IBUPROFEN IN RELIEVING POST TONSILLECTOMY PAIN OVER ORAL IBUPROFEN ALONE- A RANDOMISED CONTROL TRIAL"

Name:

Age:

OP/IP no:

Sex: Date of assessment:

Address: Date of discharge:

Occupation: Diagnosis:

CLINICAL PROFILE:

Chief Complaint:

History of Present Illness:-

Past History:

Personal History:

Family History:

Treatment history:

	DRUGS TAKEN	DURATION
Tab Augmentin		
Tab Pan		
Cap MVBC		
Betadine mouth gargles		
Tab Ibuprofen		
Other medications		

I. General Physical Examination -

Build:

Nourishment:

Blood Pressure:

Pulse:

Respiratory Rate:

Pallor :

Icterus :

Clubbing :

Cyanosis :

Lymphadenopathy :

Edema :

II) ENT Examination

1. **THROAT EXAMINATION:**

   Oral Cavity

   - Lip
   - Labial Mucosa
   - Gingivolabial sulcus
   - Buccal Mucosa
   - Gingivobuccal sulcus
   - Gums
   - Teeth
   - Hard palate
   - Anterior 2/3rd of tongue

Oropharynx

- Anterior Pillar
- Tonsillar fossa
- Posterior Pillar
- Soft Palate
- Uvula
- Posterior pharyngeal wall

Indirect Laryngoscopy

- Base of tongue
- Median glossoepiglottic fold
- Lateral glossoepiglottic fold
- Epiglottis
- Pyriform fossa
- Aryepiglottic fold
- Arytenoids
- True vocal cord

2. <u>NECK EXAMINATION:-</u>

3. <u>EAR EXAMINATION:</u>

External Examination

Right Left

- Pinna
- Pre auricular area
- Post auricular area
- External auditory canal

- Tragal tenderness
- Mastoid tenderness
- Tympanic membrane

TUNING FORK TESTS:

Rinne's test 256 Hz

512 Hz

1024 Hz

Weber's test:

Absolute Bone Conduction test:

FACIAL NERVE EXAMINATION

4. NOSE EXAMINATION

External appearance

- Root
- Bridge
- Dorsum
- Alae
- Tip
- Columella

Cold spatula test

Anterior Rhinoscopy

Posterior Rhinoscopy

Paranasal Sinus Examination

DIAGNOSIS

ANNEXURE III- PHOTOGRAPHS

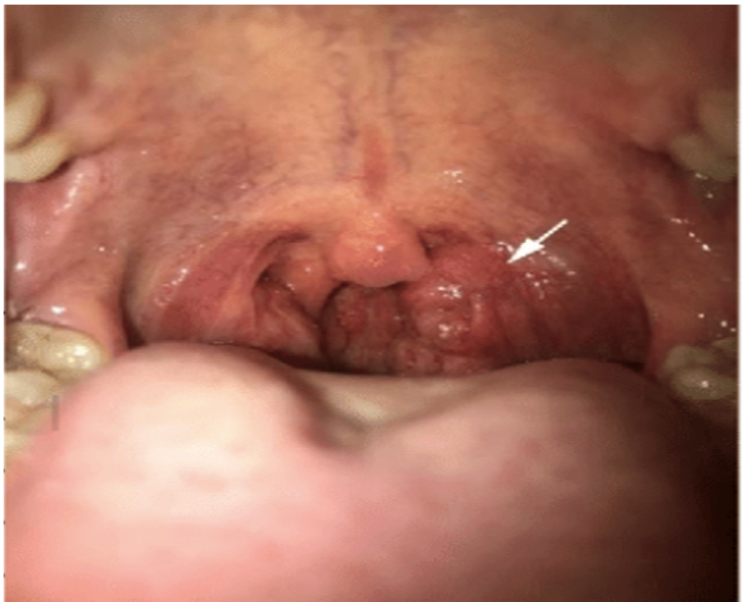

IMAGE 1- Chronic Tonsillitis

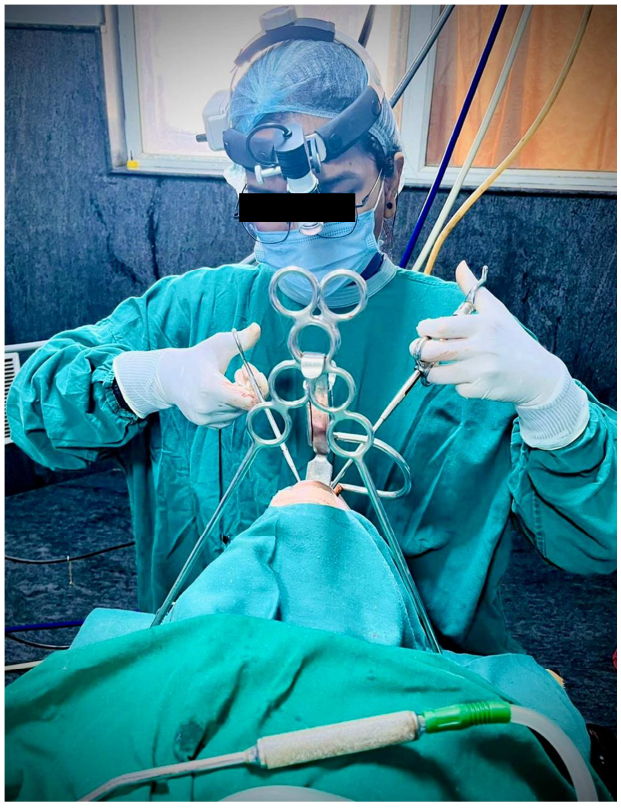

IMAGE II- Tonsillectomy

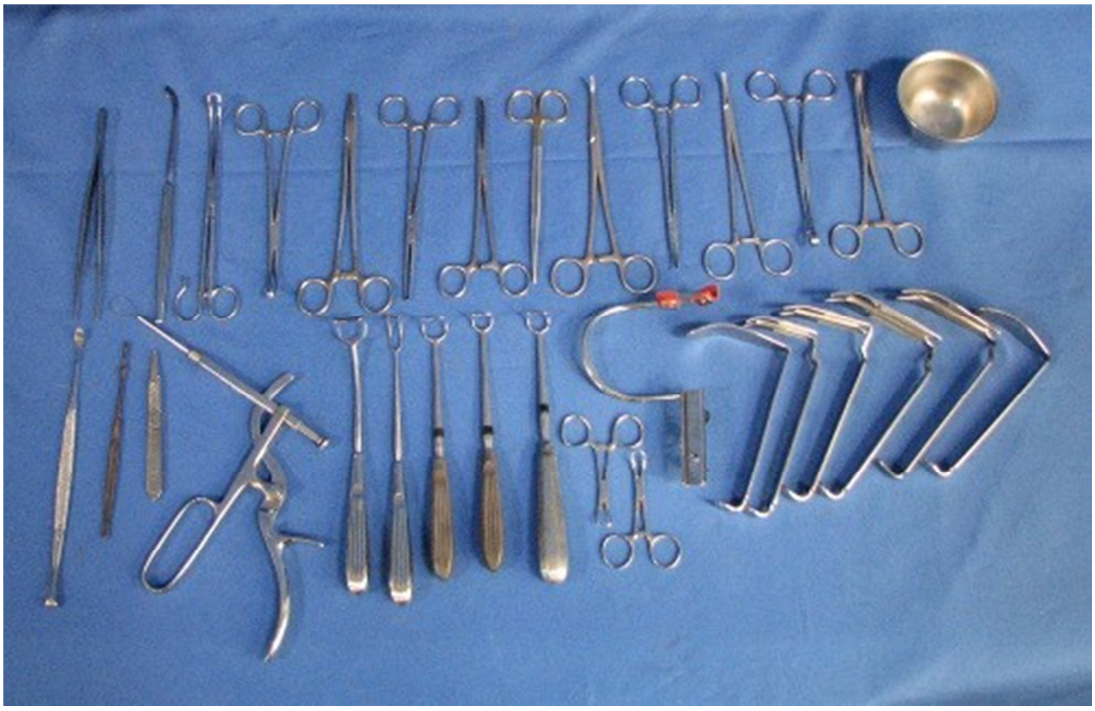

IMAGE III- Instruments

IMAGE IV- Bupivacaine

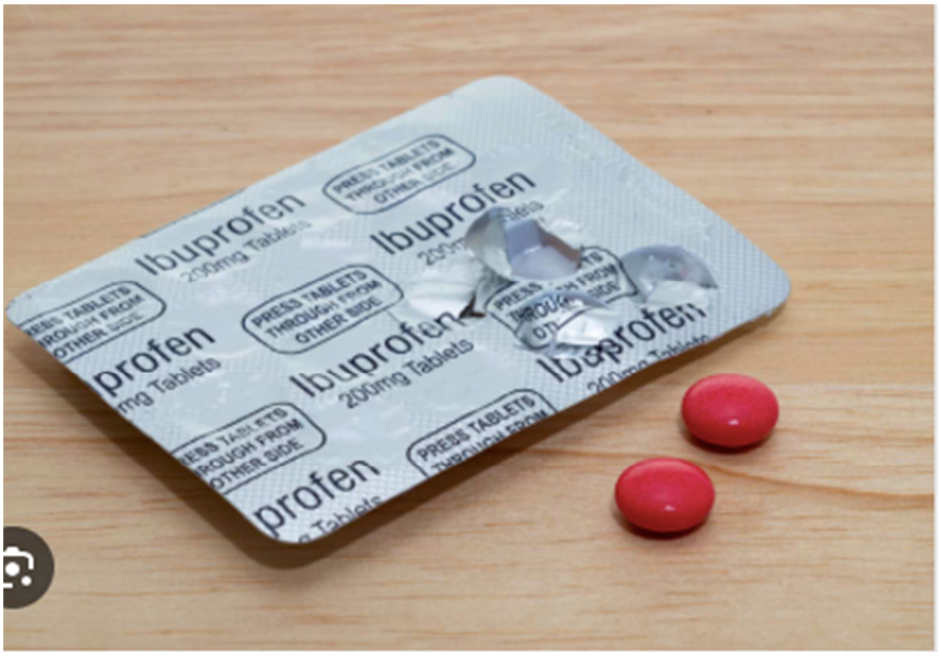

IMAGE V- Ibuprofen

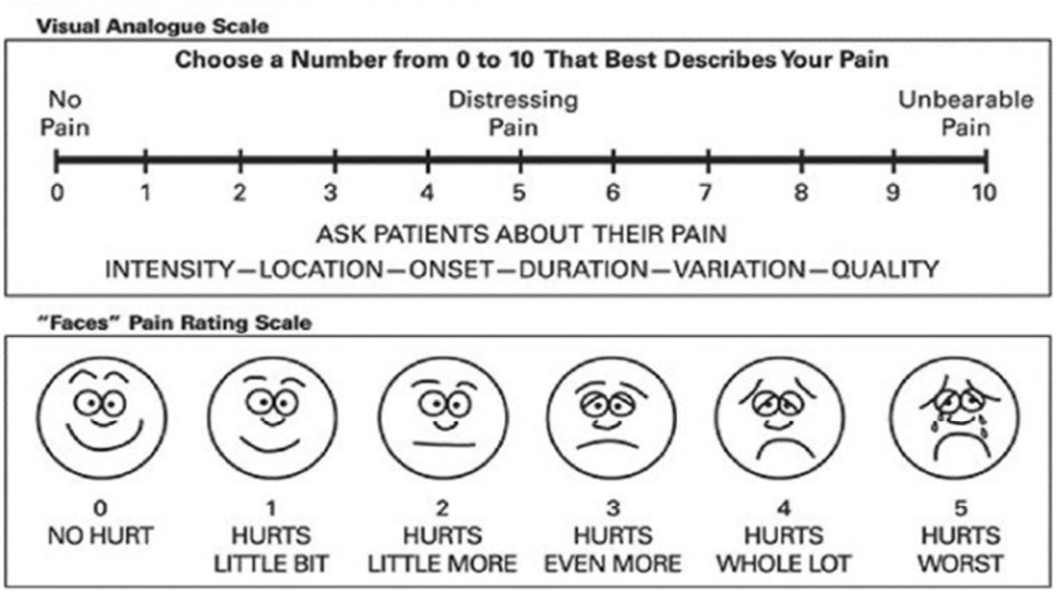

IMAGE VI- VAS Score

ANNEXURE IV- MASTERCHART

SL. NO.	NAME	AGE	SEX	IP NO.	1ST HOUR	5TH HOUR	8TH HOUR	VAS Score
1	Jeevan Badiger	23	Male	1557854	4	2	1	7
2	Basangouda Badiger	12	Male	10098865	4	2	2	8
3	Siddharth Nagannavar	7	Male	10002492	5	3	3	11
4	Mahantesh	13	Male	1208616	4	2	1	7
5	Madhavanand	7	Male	10874533	5	3	2	10
6	Kempanna Mudhol	30	Male	1208712	4	2	1	7
7	Madan	8	Male	1202347	5	3	1	9
8	Sairaj	8	Male	1203860	5	3	2	10
9	Amitha	8	Female	12223435	4	2	1	7
10	Yahiya	15	Female	11222133	4	2	1	7
11	Vijay Mudalgi	11	Male	1180931	5	2	2	9
12	Sudha	10	Female	1183095	5	3	2	10
13	Pradeep	14	Male	1180932	5	2	2	9
14	Savita Dinnmani	19	Female	1173998	5	1	1	7
15	Sunanda Nalanatti	36	Female	1176779	4	1	1	6
16	Sneha Kullar	21	Female	1176777	4	1	1	6
17	Radha Mallapur	23	Female	1177018	4	1	0	5
18	Sandhya Kuddagol	19	Female	1176778	4	2	0	6
19	Ishwary Metri	16	Female	1177376	4	1	0	5
20	Sumit	12	Male	1196638	5	3	1	9
21	Maruti Dabadi	36	Male	1173549	4	1	1	6
22	Ajeeta Gadad	16	Male	1173561	5	1	1	7
23	Sangeeta Solhapure	20	Female	1162373	5	2	1	8
24	Shilpa Gadad	13	Female	1173552	5	3	1	9
25	Suraj Sattigeri	25	Male	1169516	5	2	1	8
26	Deepa Hulikatti	15	Female	1163070	5	2	1	8
27	Pankaj Rathod	6	Male	1168108	5	3	1	9
28	Harsha Hanji	7	Male	1168685	5	4	1	10
29	Ganesh Patil	15	Male	1168743	5	3	1	9
30	Prathamesh Hujare	15	Male	1169508	5	4	1	10

CONTROL

SL. NO.	NAME	AGE	SEX	IP NO.	1ST HOUR	5TH HOUR	8TH HOUR	VAS Score
1	Riddhi Kulkarni	4	Female	10098422	5	4	4	13
2	Jeevan	21	Male	11432567	5	3	3	11
3	Ranjana	14	Female	10003767	5	4	3	12
4	Shivkumar	10	Male	10003538	5	4	4	13
5	Shlok	13	Male	10003853	5	4	4	13
6	Pratham	11	Male	10008405	5	3	3	11
7	Yashoda Rathod	16	Female	1206184	5	3	3	11
8	Niyathi	10	Female	11072612	5	4	4	13
9	Shraddha	9	Female	10001944	4	3	3	10
10	Suraj	10	Male	11971724	5	4	3	12
11	Hanamanth	11	Male	12332145	5	4	3	12
12	Sulochana	10	Female	11322456	5	4	3	12
13	Vaishnavi		Female	11424556	5	4	4	13
14	Lakkappa Chanargi	14	Male	1155225	5	3	3	11
15	Arif shingargon	14	Male	1162911	5	3	3	11
16	Priya Shelake	15	Female	1165291	5	4	4	13
17	Sarvesh warke	13	Male	1165290	5	4	3	12
18	Sai	5	Male	1197384	5	3	3	11
19	Sulochana		Female	1234564	5	3	2	10
20	Vaishnavi		Female	1113245	5	4	4	13
21	Vaibhavi Narvade	15	Female	1183958	5	3	3	11
22	Ummehani Shaikh	7	Female	1163190	5	4	4	13
23	Sheetal Uppar	19	Female	1170352	5	4	4	13
24	Shreya Itagi	12	Female	1175231	5	3	3	11
25	Rakesh Belavi	12	Male	1157338	5	4	4	13
26	Sudha Tolin	10	Female	1183095	5	3	3	11
27	Vaishnavi Pujari	17	Female	1181739	5	4	4	13
28	Anand Hanchinamani	14	Male	1156781	5	3	3	11
29	Khushi Virupakshi	15	Female	1155975	5	4	4	13
30	Amruta Naik	10	Female	1165918	5	4	4	13