"EVALUATION OF CLINICAL OUTCOMES OF COLD SALINE, HYDROCORTISONE AND NORMAL SALINE AS AN IRRIGATING SOLUTION DURING SURGICAL REMOVAL OF IMPACTED MANDIBULAR THIRD MOLARS -A RANDOMIZED CONTROL TRIAL"

By

REG.NO. IF0222004

Dissertation

Submitted to the
KLE Academy of Higher Education and Research,
Belagavi, Karnataka

In partial fulfillment
of the requirements for the degree of

MASTER OF DENTAL SURGERY
In
ORAL AND MAXILLOFACIAL SURGERY
(BRANCH III)

DEPARTMENT OF ORAL AND MAXILLOFACIAL SURGERY

KAHER'S KLE VK INSTITUTE OF DENTAL SCIENCES

BELAGAVI, KARNATAKA

2022 - 2025

KLE ACADEMY OF HIGHER EDUCATION AND RESEARCH, BELAGAVI, KARNATAKA

ENDORSEMENT BY THE HEAD OF THE DEPARTMENT AND PRINCIPAL/HEAD OF THE INSTITUTION

This is to certify that the dissertation entitled **"EVALUATION OF CLINICAL OUTCOMES OF COLD SALINE, HYDROCORTISONE AND NORMAL SALINE AS AN IRRIGATING SOLUTION DURING SURGICAL REMOVAL OF IMPACTED MANDIBULAR THIRD MOLARS- A RANDOMIZED CONTROL TRIAL"** is a bonafide research work done by **REG.NO. IF0222004.**

Head of Department
Dr. SANJAY S RAO M.D.S
Professor & Head,
Department of Oral & Maxillofacial Surgery,
KAHER's V K Institute of Dental Sciences,
Belagavi – 590010

Date: 22/4/25
Place: Belagavi

Principal
Dr. ALKA KALE M.D.S.
Principal,
KAHER's V K Institute of Dental Sciences, Nehru Nagar,
Belagavi-590010.

PRINCIPAL
KLE V.K. Institute of Dental Sciences
Nehru Nagar, BELAGAVI-590010.

Date: 22/4/25
Place: Belagavi

UNDERTAKING

I, **REG.NO. IF0222004** hereby declare that the information and the data mentioned in my thesis entitled **"EVALUATION OF CLINICAL OUTCOMES OF COLD SALINE, HYDROCORTISONE AND NORMAL SALINE AS AN IRRIGATING SOLUTION DURING SURGICAL REMOVAL OF IMPACTED MANDIBULAR THIRD MOLARS- A RANDOMIZED CONTROL TRIAL"** belongs to me and is original.

I am aware of the definition of plagiarism as detailed below:

- An act or instance of using or closely imitating the language and thoughts of another author without authorization and the representation of that author's work as one's own, as by not crediting the original author.
- A piece of writing or other work reflecting such unauthorized use or imitation.
- The deliberate or reckless representation of another's words, thoughts or ideas as one's own without attribution in connection with submission of academic work, whether graded or otherwise.

I hereby declare that the thesis prepared by me is original and does not involve plagiarism anywhere. In case at a later stage it is found that I have indulged in plagiarism, then I am solely responsible for the same and the institution is at liberty to take any disciplinary action against me including cancellation of dissertation or any other penalties imposed by the university.

Date:21-04-2025

Place: Belagavi **REG.NO. IF0222004**

PLAGIARISM ACCEPTED LETTER

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)
Nehru Nagar, Belagavi - 590 010, Karnataka State

Accredited 'A+' Grade by NAAC (3rd Cycle) Placed in Category 'A' by MHRD (GoI)

☎: 0831-2470362 Web: http://www.kledental-bgm.edu.in
FAX: 0831-2470640 E-mail:principal@kledental-bgm.edu.in

Date : 19/04/2025 Serial No. : 431

PLAGIARISM CHECK REPORT

Name of the Applicant : **REG.NO. IF0222004**
UG / PG / Ph.D / Staff : PG
Batch & Year : 2022-2025
Department : Department of Oral and Maxillofacial Surgery

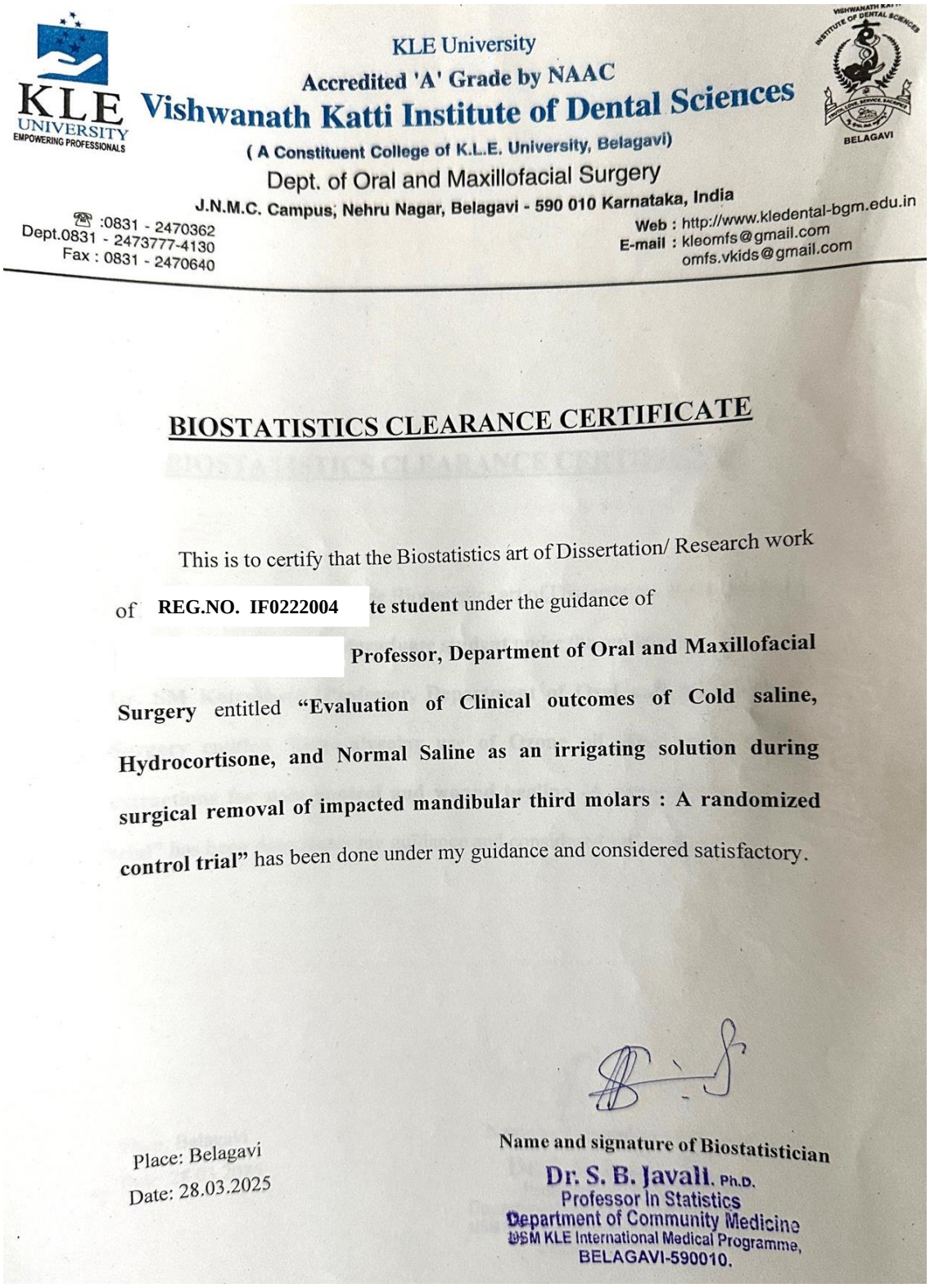
The soft copy of Research Work / Manuscript by **REG.NO. IF0222004** ... entitled
"Evaluation of clinical outcomes of cold saline, hydrocortisone and normal saline as an irrigating solution during surgical removal of impacted mandibular third molar: A Randomised control trial"
under the guidance of .. ..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 .....2.....%, which is **within / not within** the acceptable limits of 10% as per the UGC guidelines.

19/4/2025
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

BIOSTATISTICS CLEARANCE CERTIFICATE



KLE University
Accredited 'A' Grade by NAAC
Vishwanath Katti Institute of Dental Sciences
(A Constituent College of K.L.E. University, Belagavi)
Dept. of Oral and Maxillofacial Surgery
J.N.M.C. Campus, Nehru Nagar, Belagavi - 590 010 Karnataka, India
☎ :0831 - 2470362
Dept.0831 - 2473777-4130
Fax : 0831 - 2470640
Web : http://www.kledental-bgm.edu.in
E-mail : kleomfs@gmail.com
omfs.vkids@gmail.com

BIOSTATISTICS CLEARANCE CERTIFICATE

This is to certify that the Biostatistics art of Dissertation/ Research work of **REG.NO. IF0222004** **te student** under the guidance of **Professor, Department of Oral and Maxillofacial Surgery** entitled **"Evaluation of Clinical outcomes of Cold saline, Hydrocortisone, and Normal Saline as an irrigating solution during surgical removal of impacted mandibular third molars : A randomized control trial"** has been done under my guidance and considered satisfactory.

Place: Belagavi
Date: 28.03.2025

Name and signature of Biostatistician
Dr. S. B. Javali. Ph.D.
Professor in Statistics
Department of Community Medicine
JSM KLE International Medical Programme,
BELAGAVI-590010.

LIST OF ABBREVIATIONS

Pre-op	:	Pre-operative
Post-op	:	Post-operative
Intra-op	:	Intra-operative
M	:	Male
F	:	Female
Hb	:	Haemoglobin
BT	:	Bleeding time
CT	:	Clotting time
RBS	:	Random Blood Sugar
IOPA	:	Intra-oral peri-apical radiograph
OPG	:	Orthopantomogram
VAS	:	Visual Analog Scale

ABSTRACT

Introduction: Mandibular third molars are the most commonly impacted teeth and their surgical removal is one of the most common surgical procedures performed by the Oral and Maxillofacial Surgeon. Most of the available literature supports the use of Cold saline to

reduce the post-operative sequelae of orthopaedic surgeries & implant surgery , namely pain, swelling, but there is not much evidence found in literature to determine if it is effective when used topically as an intraoperative irrigating solution during surgical removal of lower third molar. The present study is deliberated to assess the effect of irrigation with three different Irrigants, namely Cold saline(2-8^{o}), Hydrocortisone and Normal Saline in post operative outcomes and complications like pain, swelling and trismus after surgical extraction of mandibular third molars.

Materials and Method: The present study was a clinical, prospective randomized controlled study. A total of 84 study participants formed the sample size of this study. Study subjects were categorized into three groups: Group I (third molar surgeries using Cold Saline (2-8^{o})), Group II (third molar surgeries using hydrocortisone), and Group III-control group (third molar surgeries using normal saline irrigation). Follow up was on 3rd day and 7th day postoperatively for all the three groups to evaluate pain, swelling, and trismus. Statistical analysis was performed using the Kruskal-Wallis and ANOVA test.

Results: There was a significant reduction in the post operative pain($p<0.001$) and trismus($p<0.001$) on the 3rd and 7th post-operative day after surgical extraction of lower third molar in study groups as compared with control group. The p-value

showed the difference to be statistically significant. However, swelling was statistically significant only on 3rd post-operative day in the study groups (p=0.010) in comparison to the control group, on post operative day 7 swelling parameters were not statistically significant between both the study groups and the control group.

Conclusion: The results of this study indicate that using Cold Saline (2-8^{o}) as an intraoperative irrigating solution is found to be highly effective and economical alternative in reducing the post-operative pain, swelling and trismus caused by surgical removal of impacted teeth.

Keywords: Cold Saline, Hydrocortisone, Mandibular third molar,surgical extraction, Normal saline.

TABLE OF CONTENTS

LIST OF TABLES

LIST OF GRAPHS

LIST OF FIGURES/PHOTOGRAPHS

INTRODUCTION

Eruption time of third molar generally occurs between 17 to 26 years of age.[1] Third molars are frequently observed as partly erupted or failing to erupt entirely, with an average incidence of 22.63% seen over the world.[2] In this niche of oral and maxillofacial surgery the surgically planned extraction of partially/completely erupted 3rd molars is fairly common. Symptoms seen early postoperative tissue responses include discomfort, edema, trismus, and dysphagia, this could Immensely impact the patient's Functional well-being.[3,4] Age shows a significant role in post-op complications after trans-alveolar extraction of mandibular 3rd molar teeth. Elderly individuals experienced higher trismus and facial swelling than younger ones.[4,5] Following the surgically extracting the mandibular molars, irrigating solutions are utilized to reduce bone damage, irrigate the surgical site, and, most importantly, improve the doctors visibility.[6] Cutting bone without a water irrigation generates high number of inflammatory fluid and debris, leading to increased post-surgery discomfort. To mitigate this, various medications, treatment approaches, and delivery methods have been researched to reduce post-operative discomfort. Sabri Cemil Isler et al. did a study where they conducted systematic drilling and Mini screws implantation over the tibial bone of eighteen Sprague Dawley rats, with the help of rotation burs, normal saline, 25°C, and 4°C saline irrigation. Within the normal and cooled groups, bone healing was examined; therefore, osteoblastic activity is greater, and bone marrow shows better response in group 4°C over group 25°C.[7]Corticosteroids, specifically hydrocortisone, were first used in oral surgery in 1952 to reduce post-operative discomfort. Since then, they've been extensively researched in this field for their potential benefits.[8] In oral surgery, corticosteroids are typically given orally, but this may not be suitable for patients with gastrointestinal

issues. However, intravenous administration is a viable alternative, especially during procedures under general anaesthesia. This route has shown promising results in decreasing post-operative edema and pain.[9]

Since most of oral surgical procedures are done on outpatients using local anesthesia, the external use of hydrocortisone as an irrigating solution during the procedure might be a useful approach. This method may help reduce post-operative discomfort and swelling.[10]

Isotonic solutions like Normal Saline is commonly used in irrigation throughout impacted third molar procedures to reduce heat generated from the surgical drill when it comes into proximity to bone while osteotomy in addition to empty the socket filled with bone debris after osteotomy.[11] This study compares the effectiveness of cooled saline, hydrocortisone, and standard saline as irrigating solutions in reducing post-surgical complications - specifically algesia, induration, trismus, and infection – post extraction of lower third molar teeth.

AIMS AND OBJECTIVES

AIM: Evaluate and compare 3 irrigation solutions' efficacy- cold saline (2-8°C), hydrocortisone, and normal saline - used throughout the surgically extraction of impacted lower 3rd molar teeth.

OBJECTIVES:

- The study focuses on evaluating and comparing the impact of 3 irrigating solutions - cold saline (2-8°C), hydrocortisone, and normal saline - on post-operative edema (swelling) after trans-alveolar extraction of mandibular 3rd molar.
- To evaluate and compare the effects of 3 irrigating solutions - cold saline (2-8°C), hydrocortisone, and normal saline - on post-operative pain after trans-alveolar extraction of mandibular 3rd molar.
- To evaluate and compare the impact of 3 irrigating solutions - cold saline (2-8°C), hydrocortisone, and normal saline - on the level of trismus (limited jaw mobility) post-trans-alveolar extraction of mandibular 3rd molar.

REVIEW OF LITERATURE

1. Koerner (1994) offers a detailed manual of impacted third molar extraction, outlining surgical principles and step-by-step procedures.

   The paper stresses proper flap design, removal of bone, tooth splitting, and wound closure to minimize complications. It is still a standard reference for oral surgeons, providing evidence-based algorithms that maximize surgical efficiency while ensuring patient safety, taking into consideration anatomical difficulties and risk factors involved in impacted wisdom tooth extraction.[16]

2. In 1996 a cohort study was conducted on the many diseases related to the excision of impacted mandibular third teeth, Kerstin Knutsson et al. took into account the age of patient, angulation, and level of impaction in addition to calculating the odds ratio. This shows age group of 20 to 29 years, the odds ratio for molars with partial soft tissue coverage and distoangular impacted teeth was highest (5.8 and 6.7, respectively).[35]

3. Study conducted by Abel Garcia et al. (1997), shows that the Investigators scrutinized whether the level of restricted mouth opening and patients experiencing algesia following the removal of impacted lower third molars were correlated with the convolution of the procedure. They stated that surgical extractions had a greater incidence of post-operative trismus than simple forceps extractions did. Regardless of the kind and degree of extraction, pain levels were noticeably low after analgesic administration.[40]

4. The prevalence of the post-operative morbidity following excision of deep seated mandibular third molar teeth was investigated by Zaid H. Baqain et al. in a cohort study in 2008. The degree of the impaction and lingual tissue retraction were noted by the authors as two potential risk factors for trismus. According to their findings, post-operative morbidity rises with age, severity of impaction, and longer operations.[37]

5. In August 2008, Bedrettin et al released an article on the usefulness of saline irrigating solution's temperature to control heat while drilling. The study included fresh frozen edentulous parts of cow mandibles, sectioned into 12x6cm pieces. Temperature-sensitive resistors were used and put about 0.5mm from the cutting cavity walls, at levels of 3,7, and 12mm. The readings from the 3 thermoresistors were examined with the help of the ORIGIN 5.0 program. The author reported that the outermost part of the cutting cavity generated greater heat than the bottom. Thus, irrigation used at room temperature can offer adequate cooling to reduce temperature during drilling. The cooler saline was more efficient in cooling the bone.[28]

6. The review and meta-analysis examined how corticosteroids can reduce post-operative trismus by Markiwicz et al in 2008. Corticosteroids were found to minimize edema and trismus in both the first (1-3 days) & later (>3 days) post-operative stages of therapy.[32]

7. In 2010, Janne Tiigimae-Saar studied the effects of prednisolone on individuals who got their impacted mandibular third teeth extracted in terms of post-operative symptoms. According to the study, prednisolone (30 mg) given prior to surgery considerably reduced edema and trismus after surgery (P 0.05) while collating it to the control group.[31]

8. Gondim et al. (2010) compared postoperative pain by manual vs. ultrasonic irrigation in endodontic treatment in a randomized controlled trial. Outcome revealed that ultrasonic irrigation induced significantly lower postoperative pain ($p<0.05$), which was due to its higher debridement efficiency. Clinical evidence favours ultrasonic systems for minimizing patient discomfort, and they suggest their preferential application in endodontic treatment to enhance postoperative success.[14]

9. Kim et al. (2010) studied thermal effects during low-speed implant drilling in pig rib bone. The research reported that increased drilling velocities (1,500 rpm) produced much more heat ($p<0.05$) than decreased speeds (50 rpm), which is potentially dangerous for thermal osteonecrosis. The findings highlight the needfor controlled drill speeds of less than 50 rpm with irrigation inorder to keep bonetemperatures below 47°C, which are essential safety regulations for implant site preparation.[18]

10. A 2011 study by Sabri et al. investigated the impact of temperature while irrigated on the healing of bones in Sprague-Dawley rats. The study involved osteotomy holes and Mini screw insertion within the tibial bone of 18 rats, with varying irrigation temperatures: uncooled, 25°C, and 4°C saline. The results does not show significant changes in new bone formation between the 25°C and 4°C groups. However, the 4°C group exhibited more osteoblastic activity and more potent bone marrow as contrasted to the 25°C group.[7]

11. A 2011 randomized clinical trial by Gururaj Arakeri investigated the use of Povidone Iodine for irrigation for impacted lower 3rd molar extraction. This study found that Povidone Iodine, at a low dose - 0.5 mg/ml, shows promising results in

reducing post-op edema (swelling) compared to normal saline. This suggests that Povidone Iodine may be a useful irrigating solution for minimizing swelling after impacted lower3rd molar surgery.[30]

12. In a 2011 study, Seidu A. Bello et al. investigated the effect of age, impaction type, and surgery duration depends postoperative tissue reactions after surgically extracted mandibular wisdom tooth. The mouth opening level, according to the authors, was greater in the younger age group on 2nd day and 5th day than in the elder age group patient. In addition, when contrasted to mesioangular and vertical impactions, distoangular and horizontal impactions displayed the largest degree of edema and trismus on days 2 and 5.[35]
13. Benedek(2011) documents the pioneeringdevelopment ofcorticosteroid treatment from 19thcentury beginnings to contemporary clinical uses.Thehistorical background discussessignificant milestones such as Hench's Nobel Prize-winning identification of cortisone's anti-inflammatory properties in 1948, and subsequent massive therapeutic use for rheumatoid arthritis. The article emphasizes theway syntheticmodifications increased drug efficacy while minimizing side effects, greatly changing treatment for inflammatory diseases.[8]
14. Urvi et al. (2014) compared betadine and chlorhexidine irrigation in bilateral impacted third molar extractions. Their split-mouth study proved the better antimicrobial effectiveness of chlorhexidine, with significantly lower postoperative infection rates ($p<0.05$) and better wound healing compared to betadine. The results Favor the use of chlorhexidine as the irrigant of choice in oral surgery, especially for high-risk impaction cases where maximum infection control is needed.[15]

15. A meta-analysis was conducted to identify morphological & demographic determinants of third molar absence by K. Carter in 2015. The researchers demonstrated that the average occurrence of third molar abnormalities is 22.63% globally. They added that across all populations, women experience agenesis at a slightly higher incidence than men.[41]

16. Wei Cheong Ngeow and Daniel Lim reviewed the literature between 2006 and 2015 on corticosteroid usage in the treatment of impacted last molar surgery. They discovered that using methylprednisolone rather than dexamethasone led to a much-decreased frequency of post-operative problems such trismus and facial edema.[39]

17. In this, Rakhshan (2015) has analysed risks leading to post-surgery ache after the extraction of a 3rd molar. Important predictors include surgical difficulty, operating time, patient age and gender, and preoperative infection. This study focuses on the impact of these factors on pain perception and duration and provides clinician insights for improved patient management based on evidence. Barbara, therefore, mentions a thorough preoperative evaluation to anticipate and even tackle postoperative pain, extending further clinical assistance for the protocol regarding the extraction of wisdom teeth.[3]

18. Osunde and Saheeb (2015) examine the influence of age, gender, and surgical difficulty on inflammatory issues following 3rdmolar surgery. Their results show that higher surgical difficulty markedly increases complication risks, whereas younger patients and males have greater inflammation. The research offers evidence-based information for risk stratification and preoperative planning, with implications for personalized management in high-risk groups to reduce

postoperative morbidity. These results maximize patient management in oral surgical practice.[5]

19. In 2016, Hashem M. Al-Shamiri carried out a clinical investigation assessing the impact of preoperative and postoperative dexamethasone medication on difficulties after surgical elimination of mandibular 3rd molar teeth. They demonstrated that preoperative dexamethasone treatment significantly reduced trismus (p=0.021) and pain (p=0.008), regardless of the age, gender, impaction type , or length of procedure.[33]

20. Ghaeminia H. et al (2016). weighed the benefits and drawbacks of surgical extraction vs retention for the treatment of impacted, asymptomatic, healthy mandibular 3rd molar teeth. They concluded that the facts were insufficient to support either. On the other hand, some evidence suggests that preserving an deep seated third molar tooth that is asymptomatic and ailment-free may raise the long-term risk of periodontitis and caries incidence in the second molars adjacent to it.[38]

21. A 2017 study investigated the advantage of using corticosteroids for reduction of post-op issues after impacted lower wisdom tooth extraction. The study found that administering hydrocortisone submucosally and intravenously significantly reduced post-operative edema (swelling). However, it did not have a notable impact on pain reduction. The study suggests that hydrocortisone may be effective in minimizing swelling, but its effect on pain management is limited.[29]

22. In 2019, Hiroki Otake conducted an observational study to see how well oxytetracycline-hydrocortisone ointment coated gauze performed after impacted lower third molars were extracted. They came to the conclusion that the group

given the Oxytetracycline-hydrocortisone ointment developed fewer dry sockets. Additionally, there had been a significant decrease in the quantity of analgesic medications consumed post-operatively.[34]

23. Mercan et al. (2019) investigated thermal effects during drilling with different volumes of irrigation. Their in-vitro test proved that more irrigation (50ml/min) effectively minimized the rise in bone temperature ($p<0.01$) versus lower volumes (10ml/min), avoiding thermal necrosis limits. The result emphasizes irrigation volume's importance for controlling bone temperature, suggesting ≥30ml/min coolant for bone-safe osteotomy procedures.[19]

24. Ghosh et al. (2020) performed a comparative cross-sectional analysis to assess the postoperative management using different irrigation s o l u t i o n s—ozonated water, NS, and povidone-iodine for impacted mandibular 3rd molar surgery. Findings established the higher effectiveness of ozonated water in alleviating ache, swelling, and trismus because of its antimicrobial and anti-inflammatory activity. Povidone-iodine was moderately effective, with normal saline performing worst. The study points towards ozonated water as a valuable, inexpensive alternative for the optimizationof postoperativeoutcomes, advocating its incorporation into standard oral surgical practice.[11]

25. A 2020 pilot study by Vitor et al. involving 28 patients having healthy with impacted third molars present bilaterally to compare the effectiveness of hydrocortisone used for trans-operative irrigation in managing post-operative oedema and pain. The study suggested that using hydrocortisone as irrigating solution during surgery is a helpful and cost-effective method for reducing oedema in both easy and complex impacted lower wisdom teeth surgeries.[22]

26. Vranckx et al. (2021) compared preventive extraction and symptomatic third molar excision, focusing on morbidity postoperatively. The study shows that prophylactic removal causes significantly less damage and recovery time than symptomatic removal. Evidence-based methodology, therefore, gives valuable information to clinical decision-making, such as suggesting that early treatment reduces discomfort and costs to the patient and the health economy. These findings support the re-evaluation of withdrawal time policies for asymptomatic cases.[4]

27. A 2022 pilot study by Agarwal et al. involving 40 patients compared the effectiveness of normal saline versus cooled saline used for irrigation in reducing post-operative associative problems after impacted lower wisdom tooth excision. The research found that the cold saline group had significantly less swelling and ache as collate with the normal saline group. Additionally, the cold saline group experienced fewer infections and faster wound healing.[17]

28. Fernandez et al. (2022) report on a Cochrane systematic review assessing water's effectiveness for wound cleansing in clinical settings. In reviewing 13trials,they determinedthat there was no infection rate difference between water and sterile saline in acute/chronic wounds. The review disproves traditional sterilization methods since clean tap water is just as effective and more affordable. Such evidence-based recommendations facilitaterevising clinical protocols, especially in settings with limited resources, while keeping strict hygiene measures for wound management in place.[13]

29. The information presented by Salas et al. (2022) deals with a concord for systematic reviews along with meta-analysis of platelet-rich fibrin (PRF) for the

3rd molar surgery. The research intends to analyse the efficacy of PRF on wound healing and complication reduction by studying all randomized trials. Evidence quality would be rated using the Cochrane risk-of-bias tools and GRADE criteria. The protocol emphasizes standardized research that can clarify the clinical benefits of PRF in oral surgery.[1]

30. A 2024 study by Faheem et al. compared the potency of cortisone, povidone-iodine, as well as NS used as irrigation solutions throughout obstructed lower third molar removal. The study found that hydrocortisone: Reduced post-operative edema for initial 48 hours, however the impact diminished by the 7th day, was efficient in managing postop discomfort and trismus. Outperformed povidone-iodine in decreasing post-operative ache, oedema as well as trismus. Therefore study suggests that hydrocortisone is a promising irrigating solution for managing post-operative complications after impacted tooth removal.[6]

31. Krishna et al. (2024) assess oxytetracycline hydrocortisone-soaked gauze packing's efficacy to treat postoperative complications from impacted third molar surgery. Their subsequent research illustrates substantial reduction in ache, swelling, and trismus vs standard dry gauze packing. Antibiotic-steroid combination offers improved wound healing without compromising safety. These findings indicate this cost-effective intervention should enhance patient comfort during recovery with clinicians having an easy option in reducing complications during mandibular third molar extractions.[10]

MATERIALS AND METHODS

A patient-oriented, prospective study was planned with individuals who underwent mandibular third molar surgery. Planned study included eighty four patients who came to the "Oral and Maxillofacial Surgery Department, KLE V.K. Institute of Dental Sciences, KAHER, Belagavi", between May 2023 and November 2024 with the complaint of unerupted mandibular third molars and who all were willingly granted consent to participate.

RESEARCH DESIGN

Randomized controlled trial

STATISTICAL ANALYSIS

The statistical analysis used were

- Descriptive statistical analysis was done for demographic details.
- Chi-square test was done to establish association.
- ANOVA- comparison was applied between the three groups.
- Post-hoc test was used for intra group correlation.

POWER AND SAMPLE SIZE ANALYSIS

The formula used to calculate sample size :

$$N = \frac{(Z_{1-\alpha/2} + Z_{1-\beta})^2 * (SD_1^{2} + SD_2^{2})}{(\bar{X}_1 - \bar{X}_2)^2}$$

- Z1-α/2 = Alpha error at 5%
- Z1-β = Beta power at 90%

X_1: Mean of 1st group =34.75

X_2: Mean of 2nd group = 37.30

- Standard deviation of 1st group, S1 = 2.88
- Standard deviation of 2nd group, S2 = 2.70
- N= 25
- N = 28 in each group (final sample size with 10% attrition)

Therefore, the sample size is 84

All participants have to comply with the following requirements.

INCLUSION CRITERIA:

Patients that met the specified criteria were included.:

- Patients belonging to the age category of 18-40 years.
- Patients who have not used any antibiotic/antimicrobial or anti-inflammatory drugs 1 week before surgery.
- Patients having an intermediate surgical severity score on the Pederson index. (4-6).
- Patients with ASA status I and having normal bleeding & clotting times.
- Patients who are non-smokers.

EXCLUSION CRITERIA:

Patients with the following criteria were excluded:

- Non-consenting participants.
- Patients having any systemic disorders.
- Patients who have already received radiation therapy.
- Patients with history of organ transplantation surgery.
- Patients allergic to hydrocortisone or anaesthetic agent.
- Female subjects who are pregnant or lactating..

METHODOLOGY

- The study comprised of 84 randomly selected patients (envelope method) who all are having Lower impacted third molar, diagnosed by known clinical and radiographic measures and were alternatively divided in three distinct categories irrespective of age, gender, difficulty in impaction, and responsiveness to various medicines to eliminate bias..
- Study participants were allocated into three groups :

Group I: Study group I - Cold Saline(2-8◦c) (*n* = 28)

Group II: Study group II- Hydrocortisone(*n* = 28)

Group III: Control group -Normal Saline (*n* = 28)

- The position of impacted tooth was assessed using Pederson's Difficulty Index and tooth with a score of 5 to 6 were append in the study.

PRE-OPERATIVE ASSESSMENT:

- HB
- BT
- CT
- Blood Sugar (Random)
- Orthopantomogram/ Intra-Oral Periapical radiograph

ARMAMENTARIUM AND MATERIALS: (as shown in Figure-1)

- Surgical gloves
- Mouth mirror
- Dental explorer
- 2ml Disposable Syringe
- Gauze piece
- Surgical scalpel blade no. 15
- Straight elevator
- Artery forceps
- Curette
- Bone file
- Needle holder
- Adson's tissue forceps
- Scissors
- Surgical handpiece and bur
- Kidney tray
- Irrigation syringe 20ml
- Surgical drape
- Towel clip
- Konvio Temperature Meter with wired Digital Temperature Sensor
- Refrigerator at BSRC
- Suction tip
- Tweezer
- Langenbeck retractor
- Sponge holder
- Periosteal elevator

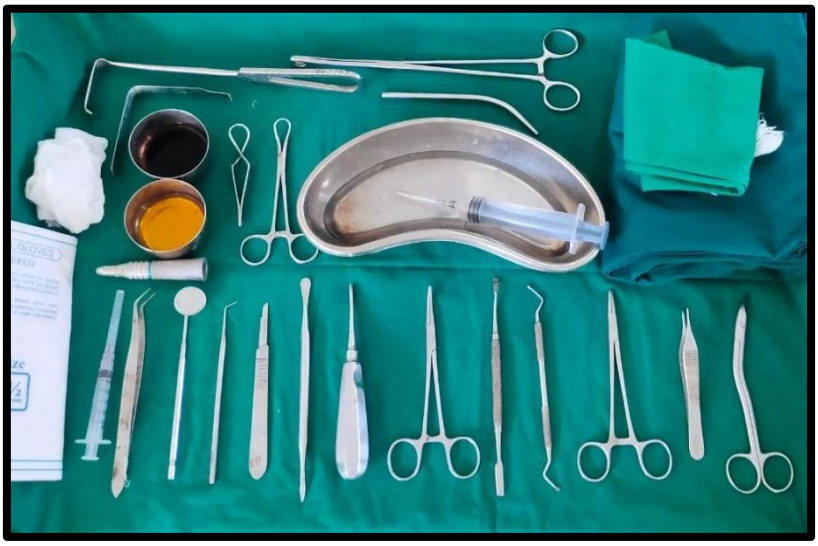


Figure 1 - Armamentarium

Figure 2 - Konvio Temperature Meter with wired Digital Temperature Sensor

Follow up: Performed on the 3rd and 7th day ensuing surgical extraction of 3rd molar.

SURGICAL PROTOCOL FOLLOWED DURING THE RESEARCH

Patients having mandibular impacted third molars evaluated by standard clinical and radiographic measures and fulfilling the inclusion criteria were allocated into three groups of 28 each by computer generated random allocation

↓

Surgical procedure on the assigned patients was performed in the oral surgery department by the same experienced surgeon

↓

The pre-operative inter-incisal distance and facial measurements were noted in millimetres.

↓

Administering 2% lidocaine containing adrenaline 1:80,000 to achieve nerve blockade of the IAN, LN, and LBN.

↓

A muco-periosteal flap was prepared by making a full thickness incision

↓

Flap was elevated and reflected, bone troughing (tooth sectioning if required) was performed using a bur with straight hand piece under abundant irrigating solution with 0.9 % concentration of 250ml of Cold saline(2-8◦c) for Group A, Hydrocortisone 500mg concentration in 250ml normal saline for Group B and 0.9 % concentration of 250ml of Normal saline for Group C.

↓

After completing the extraction, Curettage within the socket was carried out to remove any harmful granulation tissue..

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

↓

The flap was repositioned and secured using (3-0 s il k) sutures.

↓

A pressure (gauze) pack was placed over the extraction site. All patients will receive post-extraction instructions.

↓

Patients of all three groups were prescribed the following drugs:

C. AMOXICILLIN 500mg (TID f o r 5 days)

T. PARACETAMOL 650mg (TID f o r 3 days)

T. PANTEPRAZOLE 20mg (OD f o r 5 days)

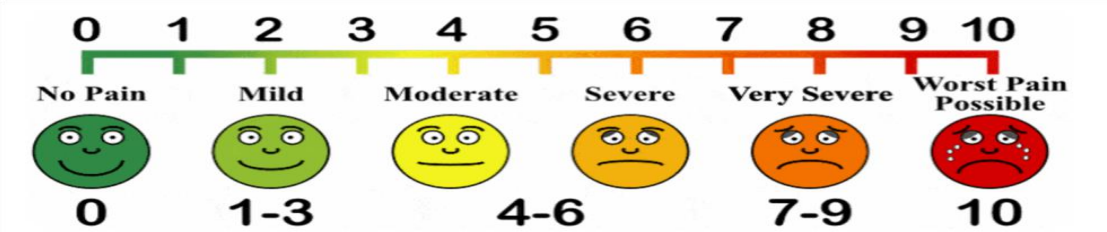
T. IBUPROFEN 400mg SOS. (Rescue drug)

EVALUATION CRITERIA

PAIN

Patients were given a Visual Analog Scale (VAS) having a score of 0 to 10

Score	Intensity of pain
▪ 0	No-Pain
▪ 1-3	Mild-Pain
▪ 4-7	Moderate-Pain
▪ 8-10	Severe-Pain



SWELLING

- To evaluate the swelling, on the surgical side, measurements were taken between the lateral canthus- mandibular angle region, tragus- corner of mouth, and tragus to soft tissue pogonion using a ribbon ruler.

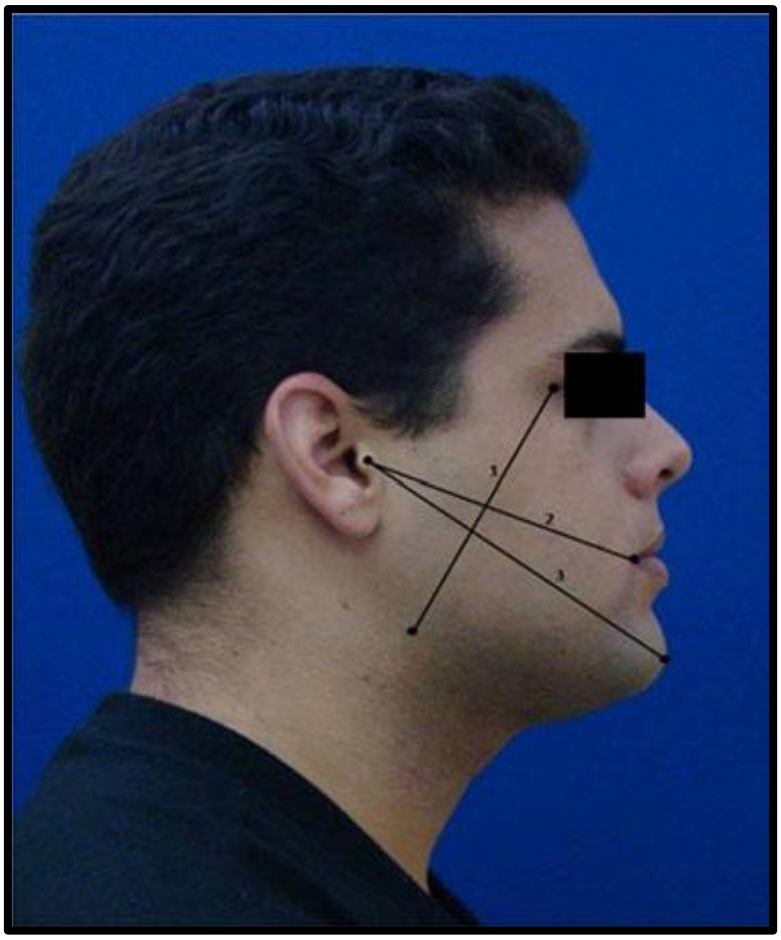


Figure 3 - Oedema Evaluation:

Three linear measurements were recorded using five anatomical landmarks: (1) lateral canthus to angle of mandible, (2) tragus to oral commissure, and (3) tragus to soft tissue pogonion.

TRISMUS

- The mouth aperture was measured using a calliper to get the inter-incisal length in millimetres.

FOLLOW UP

Pain, mouth opening and swelling was documented on the day of surgery, 3nd day and the 7th day post-op.

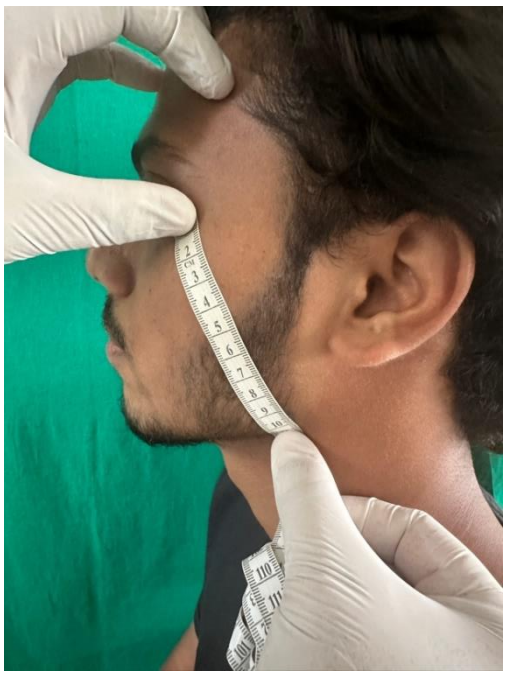


Fig-4a : Group I(Cold Saline)
Pre-op

Fig-4b : Group I(Cold Saline)
Pre-op

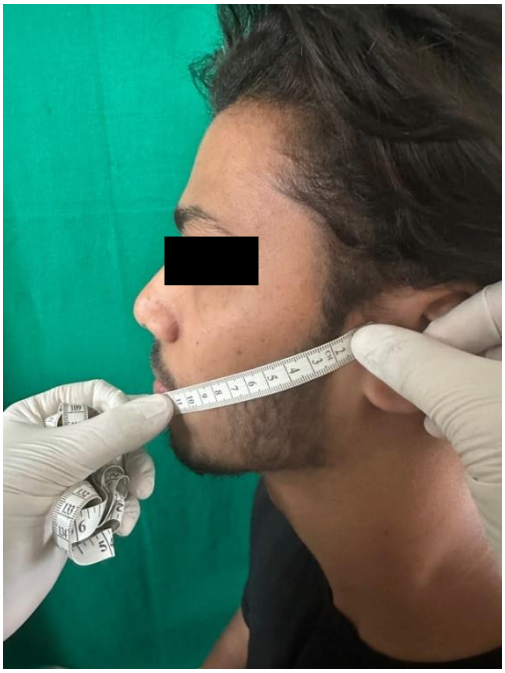


Fig-4c : Group I(Cold Saline)
Pre-op

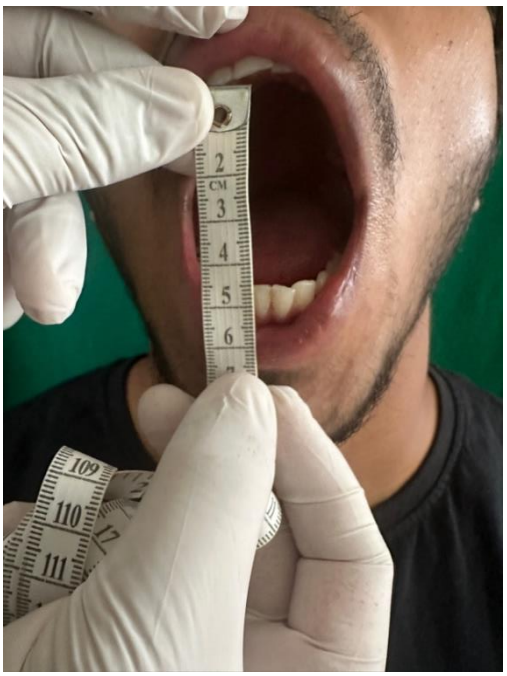


Fig-4d : Group I(Cold Saline)
Pre-op

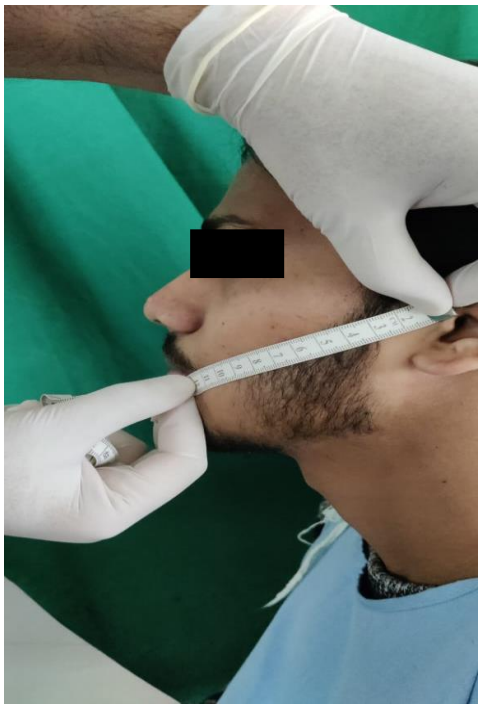


Fig-5a : Group I(Cold Saline) 3rd day Post-op

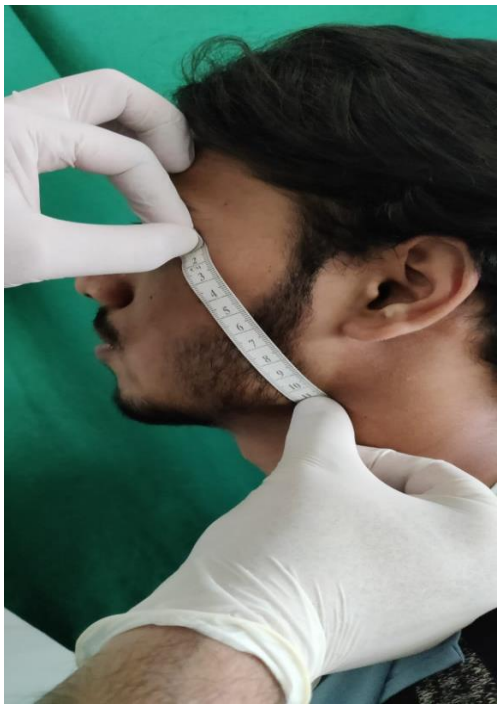


Fig-5b : Group I(Cold Saline) 3rd day Post-op

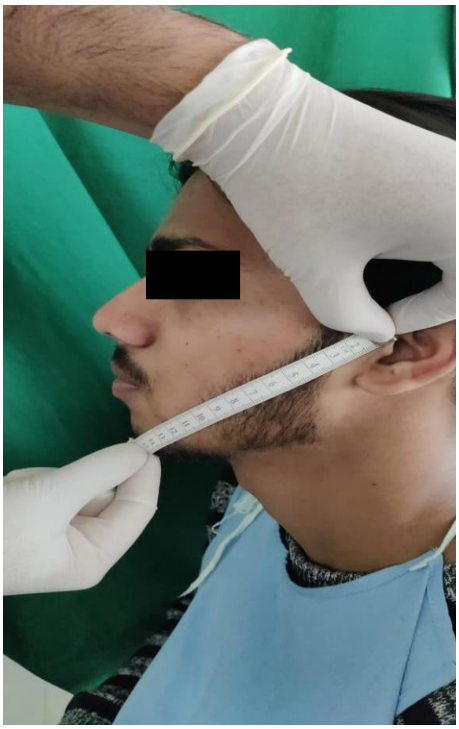


Fig-5c : Group I(Cold Saline) 3rd day Post-op

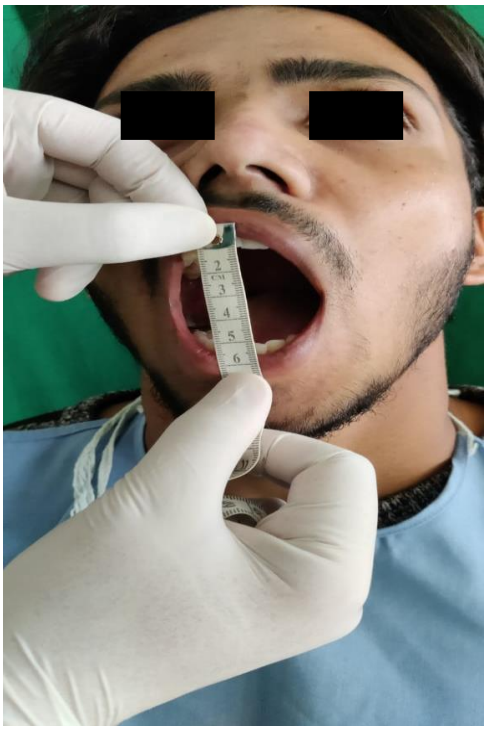


Fig-5d : Group I(Cold Saline) 3rd day Post-op

Fig-6a : Group I(Cold Saline) 7th day Post-op

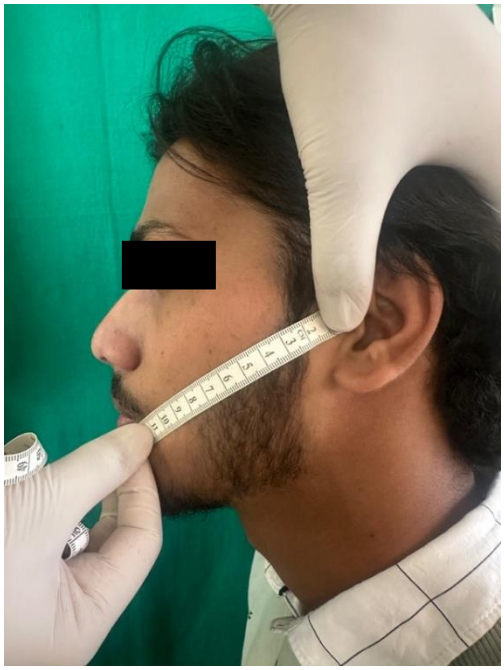


Fig-6b : Group I(Cold Saline) 7th day Post-op

Fig-6c :Group I(Cold Saline) 7th day Post-op

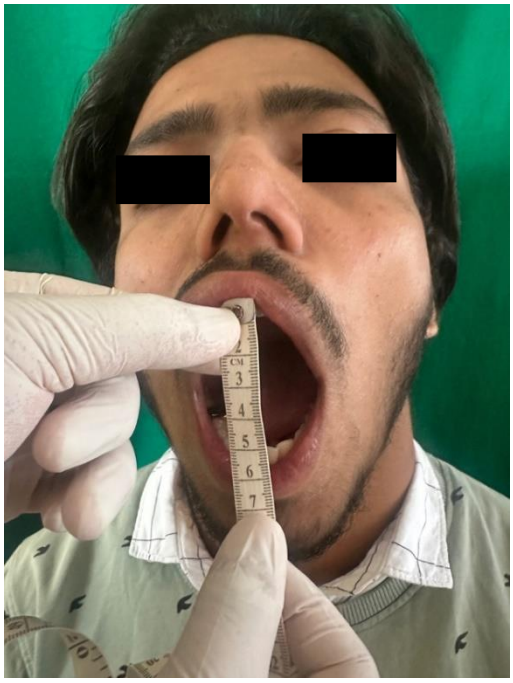


Fig-6d : Group I(Cold Saline) 7th day Post-op

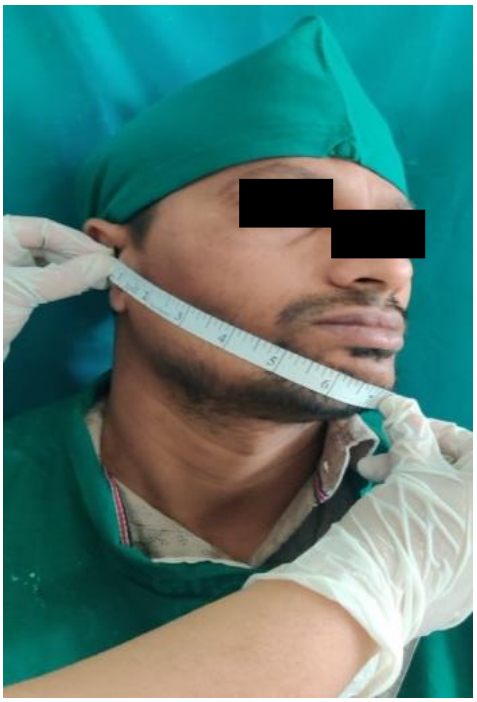


Fig-7a : Group II(hydrocortisone)Pre-op

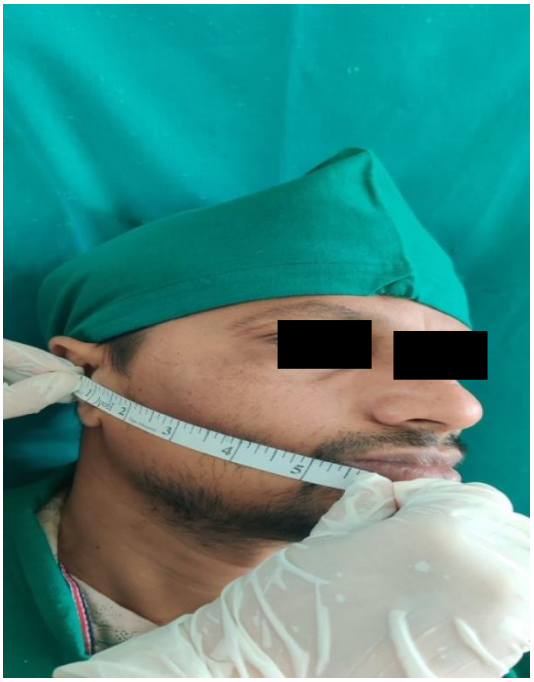


Fig-7b : Group II(hydrocortisone)Pre-op

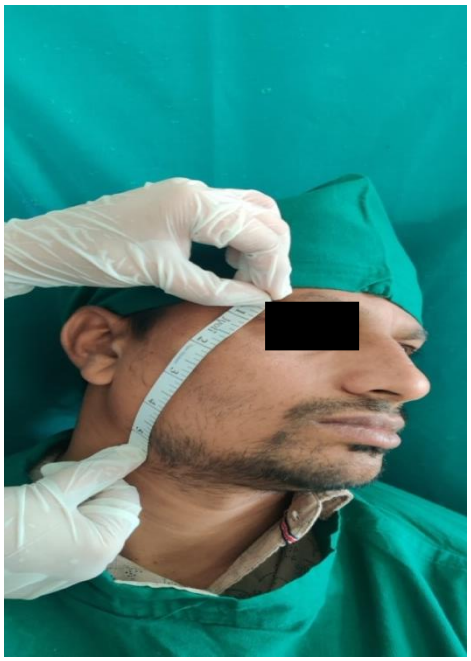


Fig-7c : Group II(hydrocortisone)Pre-op

Fig-7d : Group II(hydrocortisone)Pre-op

Fig-8a : Group II(hydrocortisone)3rd day Post-op

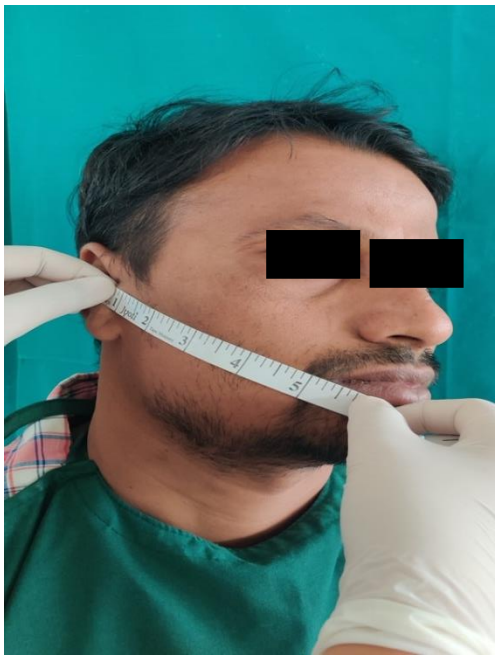


Fig-8b : Group II(hydrocortisone)3rd day Post-op

Fig-8c : Group II(hydrocortisone)3rd day Post-op

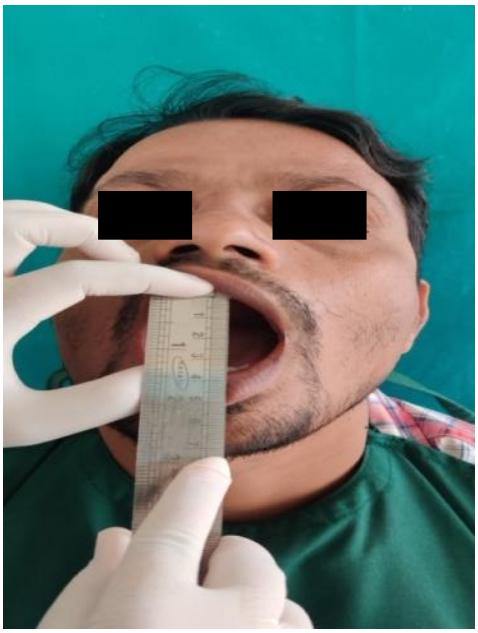


Fig-8d : Group II(hydrocortisone)3rd day Post-op

Fig-9a : Group II(hydrocortisone)7th day Post-op

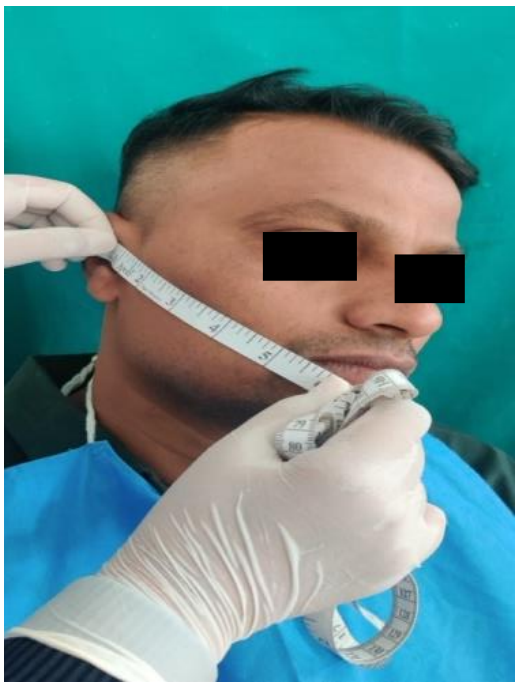


Fig-9b : Group II(hydrocortisone)7th day Post-op

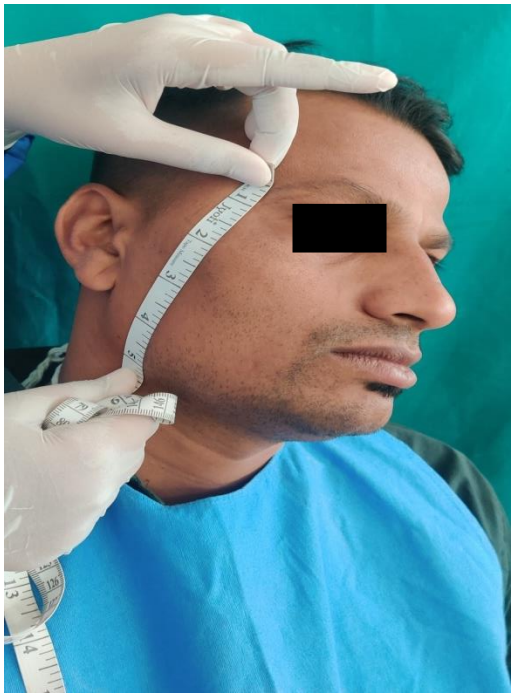


Fig-9c : Group II(hydrocortisone)7th day Post-op

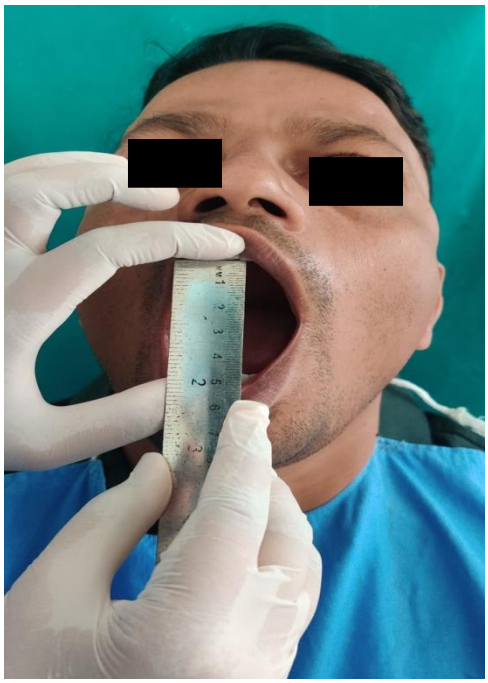


Fig-9d :group II(hydrocortisone)7th day Post-op

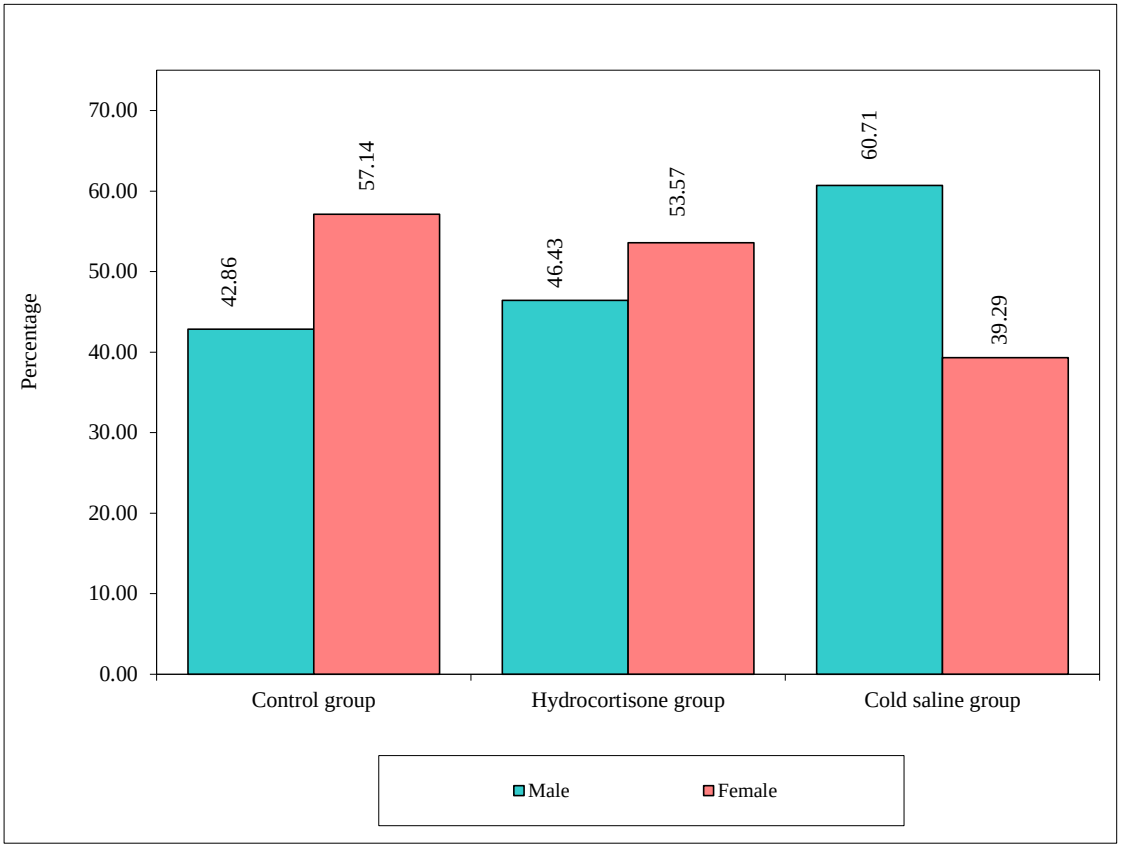
RESULTS

Table 1: Distribution of male and female participants in Cold Saline, Hydrocortisone and control group (Normal saline)

Group	Male	%	Female	%	Total
Control group	12	42.86	16	57.14	28
Hydrocortisone group	13	46.43	15	53.57	28
Cold saline group	17	60.71	11	39.29	28
Total	42	50	42	50	84
Chi-square=2.0000, p=0.3678					

Table 1 provides the allocation of the males and female participants for the three groups Cold Saline, hydrocortisone, and normal Saline. There were 1 7 (males) and 11(Females) in the Cold Saline group, 13(Males) and 15(females) in the hydrocortisone group and 12(males) and 16(females) in the normal saline group. At the outset, there was certainly no substantial association between them.

GRAPH 1: Distribution of males and female participants in Cold Saline, Hydrocortisone and Control Group (Normal Saline)



AGE DISTRIBUTION:-

Table 2: Comparison of Cold Saline, Hydrocortisone & control group (Normal saline) with mean age by one way ANOVA

Group	Mean	S.D	SE.
Control group	26.39	5.07	0.96
Hydrocortisone group	25.93	5.34	1.01
Cold saline group	28	5.23	0.99
Total	26.77	5.23	0.57
F-value	1.2167		
p-value	0.3016		

The mean value for the Cold Saline, hydrocortisone and normal saline were 28 ± 5.23 years, 25.93 ± 5.34 years and 26.39 ± 5.07 years respectively. The absence of statistically significant differences (p=0.3016) indicates comparable baseline characteristics among all three groups.

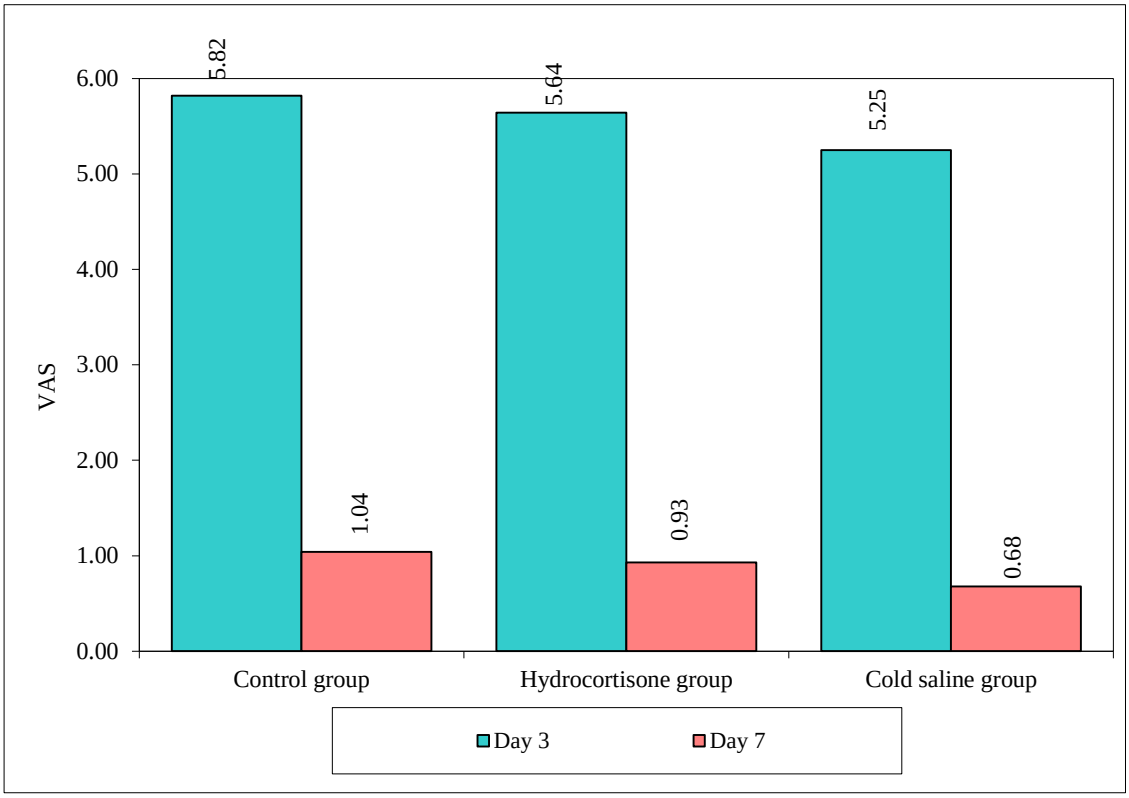
ASSESSMENMT OF PAIN:

Table 3: Comparison of Cold Saline, Hydrocortisone and Control group (Normal Saline) with VAS scores at post-operative 3nd day & 7th day using Wilcoxon matched pairs test.

Group	Time point	Mean	SD	Mean Diff.	% of effect	Z-value	p-value
Control group	Day 3	5.82	1.02				
	Day 7	1.04	0.74	4.79	82.21	4.6226	0.0001*
Hydrocortisone group	Day 3	5.64	1.25				
	Day 7	0.93	0.72	4.71	83.54	4.6226	0.0001*
Cold saline group	Day 3	5.25	1.11				
	Day 7	0.68	0.72	4.57	87.07	4.6226	0.0001*

The comparison of Pain, using mean VAS score, between Cold Saline, hydrocortisone and normal saline, at different time points was conducted using Wilcoxon matched pairs test and depicted in Table 5. All groups showed significant trismus reduction by day 7 (p=0.0001). Cold saline had the greatest improvement (87.07%, mean 0.68±0.72), followed by hydrocortisone (83.54%, 0.93±0.72) and control (82.21%, 1.04±0.74). Despite similar Z-values (4.6226), cold saline demonstrated marginally better efficacy in resolving postoperative jaw stiffness.

Comparison of different treatment time points with VAS scores in three groups



GRAPH 2: Mean VAS score at post-op Day-3 and Day-7 for Cold Saline, Hydrocortisone and Control group (Normal Saline)

Graph 2 Indicates the postoperative pain severity (via VAS) on days 3 and 7, comparing cold saline, hydrocortisone, and standard saline treatments. For Day 3, the scores were 5.25 ± 1.11, 5.64 ± 1.25 and 5.82 ± 1.02 respectively. Similarly, for Day 7, the scores were 0.68 ± 0.72, 0.93 ± 0.72 and 1.04 ± 0.74 for the three groups. The mean score on day 7 for Cold Saline group was 0.68± 0.72 which was less compared to others.

Table 4: Comparison of three groups with VAS scores at Day 3 and Day 7 treatment time points by Kruskal Wallis ANOVA

Times	Control group		Hydrocortisone group		Cold saline group		H-value	p-value
	Mean	SD	Mean	SD	Mean	SD		
Day 3	5.82	1.02	5.64	1.25	5.25	1.11	4.165	0.125
Day 7	1.04	0.74	0.93	0.72	0.68	0.72	4.135	0.127
Difference	4.79	1.03	4.71	1.21	4.57	1.14	0.498	0.78

The cold saline group appears to perform marginally superior in reducing postoperative discomfort compared to the control and hydrocortisone groups, the differences are not statistically significant based on the provided p-values (>0.05). This suggests that all three methods are similarly effective in managing postoperative discomfort in this study setup.

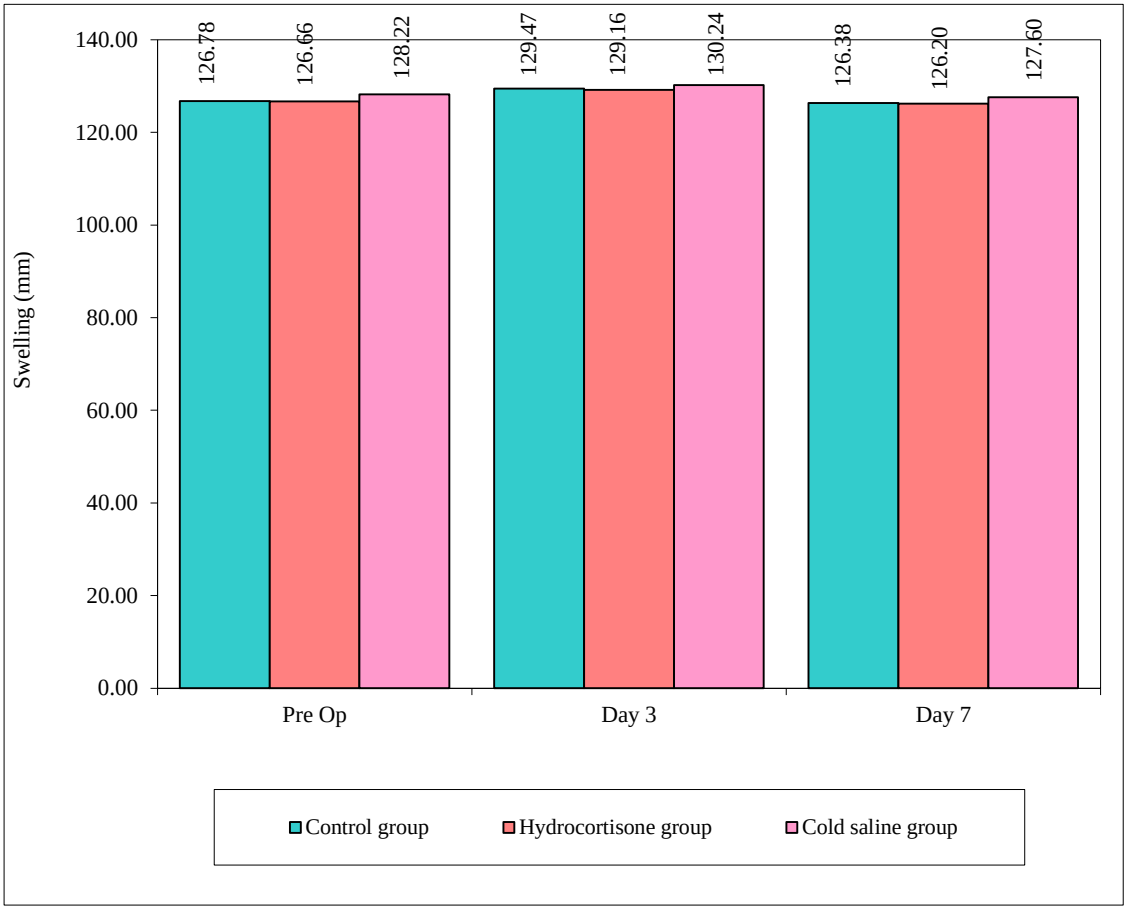
ASSESSMENT OF SWELLING:

Table 5: Comparison of Cold Saline, Hydrocortisone and Control Group (Normal Saline) with swelling scores at pre-op, post-op day 3 and day 7 time points by one way ANOVA

Times	Control group		Hydrocortisone group		Cold saline group		F-value	p-value
	Mean	SD	Mean	SD	Mean	SD		
Pre Op	126.78	6.81	126.66	6.13	128.22	6.96	0.4782	0.6216
Day 3	129.47	6.65	129.16	6.53	130.24	7.26	0.1873	0.8295
Day 7	126.38	6.8	126.2	6.36	127.6	7.6	0.3381	0.7141
Pre-OP to Day 3	2.68	1.95	2.5	1.96	2.02	1.81	0.9062	0.4081
Pre-OP to Day 7	-0.4	1.07	-0.46	1.23	-0.62	1.29	0.2462	0.7824

The comparison of swelling scores between the three groups Cold Saline, hydrocortisone and normal saline was done at three different time points, i.e., at the pre-operative stage, at 3rd day and 7th day, using one way ANOVA and the results have been provided in Table 7. The comparative results of all the three groups were not statistically significant at pre-operative stage and Day 7. Even for the comparison of the mean differences between the three groups at preop – day 7 and day3 -day 7 were found to be statistically insignificant .

GRAPH 3: Mean SWELLING at pre-op, post-op Day 3 and Day 7 for Cold Saline, Hydrocortisone and Control group (Normal Saline)



Graph 3 denotes the mean swelling at Post- op Day 3 and Day 7 in comparison to preoperative measurements for Cooled Saline, hydrocortisone and normal saline. In preoperative stage the score was 126.78, 126.66 and 128.22 respectively. Whereas for Day 3, the scores were 129.47, 129.16 and 130.24 respectively. Similarly, for Day 7, the scores were 126.38, 126.20 and 127.60 for the three groups.

Table 6: Comparison of pre-op, post-op day 3 and day 7 time points with swelling scores in Cold Saline, Hydrocortisone and Control Group (Normal Saline) by using paired t test

Group	Time point	Mean	SD	Mean Diff.	% of effect	t-value	p-value
Control group	Pre Op	126.78	6.81				
	Day 3	129.47	6.65	-2.68	-2.12	-7.2989	0.0001*
	Pre Op	126.78	6.81				
	Day 7	126.38	6.8	0.4	0.32	1.9828	0.0577
Hydrocortisone group	Pre Op	126.66	6.13				
	Day 3	129.16	6.53	-2.5	-1.97	-6.7619	0.0001*
	Pre Op	126.66	6.13				
	Day 7	126.2	6.36	0.46	0.36	1.9554	0.061
Cold saline group	Pre Op	128.22	6.96				
	Day 3	130.24	7.26	-2.02	-1.57	-5.8996	0.0001*
	Pre Op	128.22	6.96				
	Day 7	127.6	7.6	0.62	0.48	2.5248	0.0178*

The comparison of swelling for the three groups Cold Saline, hydrocortisone and normal saline was done at three different time points, i.e., pre-operative stage, Day 3 and Day 7 and the statistical significance between them was synthesized using Paired t test, the results of which have been given in Table 8. Additionally, the post-hoc comparison between two individual time points using all the feasible combinations were done for each group was done using one way ANOVA Test as

well. For Cold Saline the comparison between pre-operative stage and Day 3 and between Day 3 and Day 7 were found to be statistically significant. For hydrocortisone and normal saline, the comparison between all three combinations, i.e., Pre-op-Day 3, Pre-op-Day 7 and Day 3-Day 7 were found to be statistically insignificant. On overall comparison using Repeated Measures ANOVA, the difference between the three time points - Significant intergroup differences were observed through quantitative evaluation.

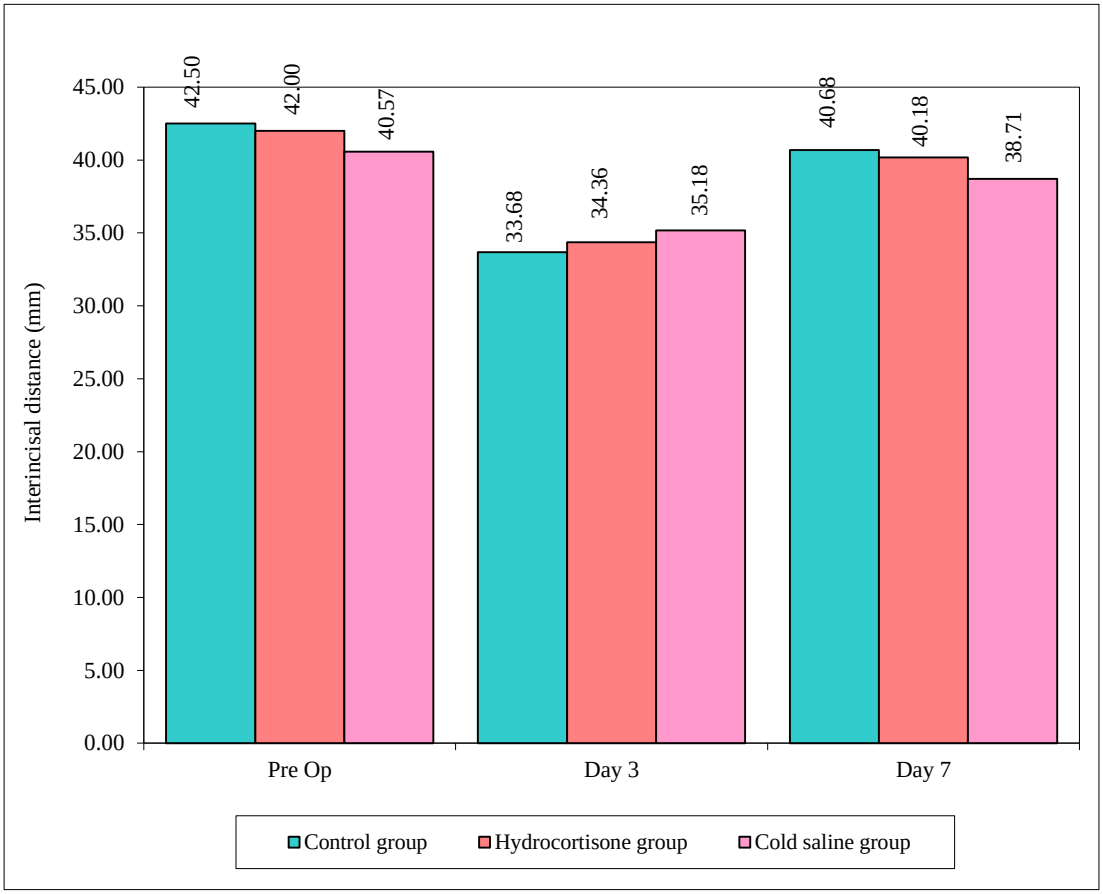
ASSESSMENT OF TRISMUS:

Table 7: Comparison of Cold Saline, Hydrocortisone and Control Group (Normal Saline) with inter-incisal distance scores at pre-operative, post-operative day 3 and day 7 time points by one way ANOVA

Times	Control group		Hydrocortisone group		Cold saline group		F-value	p-value
	Mean	SD	Mean	SD	Mean	SD		
Pre Op	42.50	7.94	42.00	7.55	40.57	5.47	0.5615	0.5725
Day 3	33.68	6.73	34.36	6.69	35.18	5.98	0.3769	0.6871
Day 7	40.68	7.88	40.18	7.45	38.71	5.58	0.5882	0.5577
Pre-OP to Day 3	8.82	4.45	7.64	3.80	5.39	3.47	5.5091	0.0057*
Pre-OP to Day 7	1.82	1.61	1.82	1.81	1.86	1.24	0.0048	0.9952

Table 9 describes the results of comparison of inter-incisal distance scores for Cold Saline, hydrocortisone and normal Saline at Pre-operative stage, Day 3 and Day 7 using one way ANOVA. The comparison between all the three groups at all three time points were quantified to be statistically non-significant ($p<0.001$). The mean divergence between the time points of the three groups (Pre-op-Day 3, Pre-op- Day 7 and Day 3- Day 7) were also calculated and their comparison yielded a statistically insignificant difference as well, except cold Saline Pre-op to Day 3 which is statistically significant.

GRAPH 4: Mean INTER-INCISAL DISTANCE at pre-op, post-op Day 3 and Day 7 for Cold Saline, Hydrocortisone and Control group (Normal Saline)



Graph 4 represents the mean inter-incisal distance on pre-op day in comparison to post-op Day 3 and Day 7 for Cold Saline, hydrocortisone and normal saline. According to preoperative specifics the score was 40.57, 42.00 and 42.50 respectively. Whereas for Day 3, the scores were 35.18, 34.36 and 33.68 respectively. Similarly, for Day 7, the scores were 38.71, 40.18 and 40.68 for the three groups.

Table 8: Comparison of pre-op, post-op day 3 and day 7 time points with inter-incisal distance in Cold Saline, Hydrocortisone and Control Group (Normal Saline) by using paired t test

Group	Time point	Mean	SD	Mean Diff.	% of effect	t-value	p-value
Control group	Pre Op	42.50	7.94				
	Day 3	33.68	6.73	8.82	20.76	10.4951	0.0001*
	Pre Op	42.50	7.94				
	Day 7	40.68	7.88	1.82	4.29	5.9812	0.0001*
Hydrocortisone group	Pre Op	42.00	7.55				
	Day 3	34.36	6.69	7.64	18.20	10.6352	0.0001*
	Pre Op	42.00	7.55				
	Day 7	40.18	7.45	1.82	4.34	5.3354	0.0001*
Cold saline group	Pre Op	40.57	5.47				
	Day 3	35.18	5.98	5.39	13.29	8.2291	0.0001*
	Pre Op	40.57	5.47				
	Day 7	38.71	5.58	1.86	4.58	7.9333	0.0001*

The overall comparison of the three groups Cold Saline, hydrocortisone and normal saline over different points of time was conducted using paired t test and it has been denoted in Table 10. The individual combinations of two different time points for all three of them was done on a post-hoc test. The comparison of the differences between the different combinations of two time points, i.e., Pre-op-Day 3, Pre-op-Day 7 and Day 3-Day 7 for all the three groups were found to be statistically significant ($p<0.001$). Similarly, the overall comparison of the three time points for all three groups were statistically significant ($p<0.001$).

DISCUSSION

The operative management of impacted wisdom teeth constitutes a routine surgical procedure in the field of oral and maxillofacial surgery. Post-operative complications like induration(edema), algesia(pain), and reduced mouth opening can significantly impact patients' quality of life. These symptoms are primarily produced by an inflammatory response to postoperative trauma. Managing these complications is crucial to improve patient outcomes and satisfaction.

Study have explored different irrigating solutions and techniques to minimize these post-operative complications, including the use of cold saline, hydrocortisone, and povidone-iodine.[12]The primary goal of using irrigating solutions during impacted third molar extraction is to prevent heat-induced permanent bone necrosis. Irrigation helps to cool the surgical site, reducing heat generated by drilling and surgical trauma, thereby preventing damage to surrounding bone and tissue.[11] Normal saline has a cleaning effect, which helps remove debris and bacteria from the surgical site, creating a conducive environment for wound healing. However, it does not have any specific properties that directly enhance or accelerate postoperative healing beyond its cleaning effect.[13]

Study have explored different irrigating solutions and pharmacological managements to minimize post extraction discomfort, including nociception(pain), induration(swelling), interincisal distance reduction(trismus) after unerupted wisdom tooth surgery. These discussions aim to identify effective strategies for improving patient outcomes and reducing post-surgical complications.[14]An appropriate irrigating solution during wisdom teeth extraction should have the following characteristics: Easily availability or preparation, Isotonic, Non-irritant, Nontoxic ,Non-haemolytic

,Antiseptic, Economic. These characteristics ensure the solution is safe, effective, and practical for use in surgical procedures.[15]

Therefore, the research focus is to analyse and compare the effectiveness of 3 irrigating solutions - Cold Saline, Hydrocortisone, and Normal Saline - in unerupted mandibular third molar surgery. The goal is to audit their impact on postoperative outcomes, likely focusing on factors such as pain, edema, and healing.

A 1994 study by Koerner demonstrated that sterile water& regular saline can be utilized as efficient irrigating solutions following the surgical extraction of wisdom teeth. This suggests that these solutions are suitable options for maintaining a clean surgical site and promoting optimal healing.[16] In surgical practice, saline solution is commonly used to protect the bone from thermal injury that are produced during osteotomy. The irrigating solution is used over the drill and osteotomy site to cool the area and prevent damage. Many surgeons prefer using cool saline solutions, believing they are more effective than normal solutions in reducing temperature and minimizing thermal damage.[17]

The literature contains conflicting findings concerning the impact of saline application in reducing temperature rise during osteotomy. Some studies suggest that saline application can help reduce temperature, while others indicate that it may not have a significant impact. Additionally, research by Kim et al. found that slow-speed trephination without using irrigating solution did not generate more heat to cause thermal injury, suggesting that the drilling technique itself may modulate in temperature management.[18]

In our research we discovered that study group (cold saline) were much more efficient then hydrocortisone as well as normal saline in lowering post-procedural discomfort subsequent to impacted last molar surgery.

Study done by Agarwal et. al.(2022) concluded that cold saline had significant reduction in post-operative swelling (facial edema), pain as compared to normal saline(control group) on 3rd & 7th post-op day along with less infection and early wound healing in cold saline irrigation cases.[17]While our research shows there is no significant difference among 3 for pain reduction but cold saline appears to perform marginally superior in reducing postoperative discomfort- pain &swelling & trismus compared to control and hydrocortisone group.

There is limited research in the literature regarding the use of cold saline as an irrigating solution during tooth impaction procedures so more research were required for better interpretation and precise results.

Normal saline is a popular choice for irrigation during wisdom tooth removal due to its physiological properties, safety, and isotonic nature. However, cold saline (2-8°C) offers additional benefits, including increased osteoblast activity, enhanced bone marrow dynamics, reduced post-operative swelling and pain, and improved healing. Cooled saline solution may be particularly beneficial during high-speed bone cutting or drilling procedures.[19]

The corticosteroids were used since 1952 in oral surgery, when hydrocortisone was first used for reduction of postoperative discomfort. Since then, extensive research has been conducted on various corticosteroids, dosages, and administration methods to improve patient post-op outcome. The goal of this research is to provide a more comfortable postoperative period and ameliorate the functional status for

patients undergoing oral surgery.[20] The exact mechanism of hydrocortisone's anti-inflammatory effects is not completely understood. However, it is thought to involve both cellular effects and its impact on the microvasculature, potentially influencing various biological pathways to reduce inflammation. Further research is needed to clarify the specific mechanisms involved. In outpatient oral surgery, the oral route remains the most common method of administration, particularly since procedures are often performed under local anesthesia. The oral route offers rapid and nearly complete absorption. While the optimal route of administration is debated, corticosteroids are recommended when significant postoperative soft tissue edema is expected, highlighting their role in managing anticipated swelling.[21]

Postoperative swelling can lead to tissue tension, which in turn can cause additional pain due to the increased pressure and stretching of tissues. This tension-induced pain can contribute to the overall discomfort experienced by patients after surgery, highlighting the importance of effective swelling management.[22] Corticosteroids can reduce edema, which in turn can decrease pain caused by tissue tension. This concept supports the idea that controlling swelling can lead to reduced pain, aligning with Messer and Keller's suggestion that pain and swelling are interconnected. By minimizing swelling, the associated discomfort can be decreased, contributing to improved patient outcomes.[23]

Study done by Faheem et. al. have found that using hydrocortisone as an intraoperative irrigating solution can have a rapid and effective impact on managing postoperative edema. This suggests that hydrocortisone may be beneficial in reducing swelling and associated discomfort after surgery.[6]While in our study we found cold saline shows better results in lowering postoperative edema and pain on day 3rd and

day 7^{th} , as compared control group and it is more efficient then hydrocortisone in reducing pain on7^{rd} day and edema on 3^{th} day post operatively.

This study evidenced that both hydrocortisone and cold saline exhibited clinically meaningful and statistically verifiable enhancements in postsurgical analgesia relative to the saline control group. Notably, the hydrocortisone group (Group II) manifested a significant mitigation in pain on the7th post-operative day, as measured by the VAS score. In contrast, the cold saline group (Group I) showed a better response on the third as well as seventh postoperative day, suggesting that the benefits of each irrigating solution may vary over time.

For Inter-incisal distance(trismus) the mean divergence between the time points of the three groups cold saline, hydrocortisone and normal saline (Pre-op-Day 3, Pre-op- Day 7 and Day 3- Day 7) were also calculated and their comparison yielded a statistically insignificant difference as well, except cold Saline Pre-op to Day 3 which is statistically significant which shows cold saline having better response among other 2 groups.

CONCLUSION

- Cold Saline as an intraoperative irrigating agent, showed effective response in controlling post operative swelling within the first 48 hours. However, on the seventh day there were no statistically appreciable changes seen when Cold Saline was evaluated with hydrocortisone and normal saline.

- On the other hand, cold saline (irrigating solution) showed statistically reliable results in Mitigating post-surgical algesia and trismus, which was followed by hydrocortisone and normal saline.

- This implies that using Cold Saline as an irrigating solution is found to be highly beneficial and inexpensive alternative in reducing the post-surgical algesia, induration and Jaw stiffness(trismus) caused by surgical removal of impacted teeth.

LIMITATION

- Due to less sample size, it was difficult to generalize the results, therefore more research are needed to examine the effect of Cold Saline in managing post-op algesia, induration and Jaw stiffness(trismus) after surgical removal of third molar.

RECOMMENDATION

- Cold Saline may be used routinely as an intra-operative irrigating solution during surgical excision of lower 3rd molar, as it increases patient comfort, controls swelling, alleviates pain and trismus in the immediate post-op period.

- The potential analgesic and anti-inflammatory properties of hydrocortisone make it a prospective contender for reducing discomfort that patients usually experience during there immediate post operative period.

SUMMARY

The current study was a clinical randomized control experiment. A total of 84 participants were categorized into 3 different groups: Group I (Cold saline(2-8^{o}) irrigation), Group II (Hydrocortisone irrigation), and Group III-control group (normal saline irrigation). The follow-up period went on the third and seventh days after surgery to evaluate pain, swelling, and trismus. There was an substantial decrease in postoperative discomfort($p<0.001$) and trismus($p<0.001$) on the 3rd and 7th post-operative day in case of Cold Saline and hydrocortisone. However, swelling was statistically significant only on 3rd post-op day in the study groups ($p=0.010$). The patients who got Cold Saline, hydrocortisone were found to be highly effective in terms of managing post-op swelling compared to the control group, Cold Saline itself was highly effective against pain and trismus, followed by hydrocortisone. This indicates that using cold saline as an intraoperative irrigation solution is found to be highly efficacious and economical alternative in mitigating the post-op pain, swelling and trismus caused by surgically removal of impacted teeth.

.

BIBLIOGRAPHY

1. Salas GA, Lai SA, Verdugo-Paiva F, Requena RA: Platelet-rich fibrin in third molar surgery: systematic review and meta-analysis protocol. Craniomaxillofac Trauma Reconstr. 2022, 15:164-8. 10.1177/19433875211016203
2. Carter K, Worthington S: Morphologic and demographic predictors of third molar agenesis: a systematic review and meta-analysis. J Dent Res. 2015, 94:886-94. 10.1177/0022034515581644
3. Rakhshan V: Common risk factors for postoperative pain following the extraction of wisdom teeth. J Korean Assoc Oral Maxillofac Surg. 2015, 41:59-65. 10.5125/jkaoms.2015.41.2.59
4. Vranckx M, Fieuws S, Jacobs R, Politis C: Prophylactic vs. symptomatic third molar removal: effects on patient postoperative morbidity. J Evid Based Dent Pract. 2021, 21:101582. 10.1016/j.jebdp.2021.101582
5. Osunde OD, Saheeb BD: Effect of age, sex and level of surgical difficulty on inflammatory complications after third molar surgery. J Maxillofac Oral Surg. 2015, 14:7-12. 10.1007/s12663-013-0586-4
6. Ahmed F, Baliga S D, Baliga S S, et al. (February 01, 2024) Efficacy of Hydrocortisone, Povidone-Iodine, and Normal Saline as an Irrigating Solution During Surgical Removal of Impacted Mandibular Third Molars: A Randomized Controlled Trial. Cureus 16(2): e53370. doi:10.7759/cureus.53370
7. Isler SC, Cansiz E, Tanyel C, Soluk M, Selvi F, Cebi Z. The effect of irrigation temperature on bone healing. Int J Med Sci. 2011;8(8):704-8. doi:

10.7150/ijms.8.704. Epub 2011 Oct 22. PMID: 22135616; PMCID: PMC3204439.

8. Benedek TG. History of the development of corticosteroid therapy. Clin Exp Rheumatol. 2011 Sep-Oct;29(5 Suppl 68):S-5-12. Epub 2011 Oct 21. PMID: 22018177.
9. Raakesh N, Ravi V, Ushass P, et al.: Role of corticosteroids in reducing postoperative swelling, pain, and trismus following surgical extraction of impacted mandibular third molars. Int J Oral Care Res. 2017, 5:265-9.
10. Krishna S, Bhaskaran R, Kumar S P, et al. (January 14, 2024) Efficacy of Oxytetracycline Hydrocortisone-Soaked Gauze Pack on Postoperative Sequelae in Lower Third Molar Surgery: A Prospective Study. Cureus 16(1): e52245. doi:10.7759/cureus.52245
11. Ghosh D, Bhardwaj S, Koyalada S, Mahajan B, Verma S, Ettishree, Nayak B. Comparison of efficacy of ozonated water, normal saline, and povidone-iodine after surgical removal of impacted mandibular third molars: A cross-sectional study. J Family Med Prim Care. 2020 Aug 25;9(8):4139-4144. doi: 10.4103/jfmpc.jfmpc_534_20. PMID: 33110822; PMCID: PMC7586537.
12. Rodrigues VP, Deboni MC, Cecchetti MM, et al.: Hydrocortisone irrigation for postoperative control of edema in inferior third molar removal - a pilot study. J Oral Maxillofac Surg Med Pathol. 2020, 32:351-5. 10.1016/j.ajoms.2020.04.004
13. Fernandez R, Green HL, Griffiths R, Atkinson RA, Ellwood LJ. Water for wound cleansing. Cochrane Database Syst Rev. 2022 Sep 14;9(9):CD003861. doi: 10.1002/14651858.CD003861.pub4. PMID: 36103365; PMCID: PMC9473482.

14. Gondim E Jr, Setzer FC, Dos Carmo CB, Kim S. Postoperative pain after the application of two different irrigation devices in a prospective randomized clinical trial. J Endod. 2010 Aug;36(8):1295-301. doi: 10.1016/j.joen.2010.04.012. Epub 2010 Jun 19. PMID: 20647083.
15. Urvi S, Haren P, Hiren P, Bijal B, Hitesh D. Efficacy of chlorhexidine versus betadine as an irrigating agent during removal of bilateral impacted lower third molars. Pak Oral Dent J. 2014; 34(2):264-267.
16. Koerner KR. The removal of impacted third molars. Principles and procedures. Dent Clin North Am. 1994 Apr;38(2):255-78. PMID: 8206177.
17. Agarwal, S., Bargoti, G., Dheer, A., Garg, D. B. G., Dr Birsubhra Roy, kajal Awana, & kajal Awana. (2022). Comparision of Normal Saline Irrigation with Cold Normal Saline in Surgical Removal of Lower Wisdom Tooth: A Pilot Study

UNIVERSITYJOURNALOF DENTALSCIENCES, 8(3). 16-22

18. Kim SJ, Yoo J, Kim YS, Shin SW. Temperature change in pig rib bone during implant site preparation by low-speed drilling. J Appl Oral Sci. 2010 Sep-Oct;18(5):522-7. doi: 10.1590/s1678-77572010000500016. PMID: 21085811; PMCID: PMC4246386.
19. Mercan U, Sumer M, Kaya OA, Keskiner I, Meral DG, Erdogan O. An *In-vitro* study on thermal changes during implant drilling with different irrigation volumes. Niger J Clin Pract. 2019 Mar;22(3):350-354. doi: 10.4103/njcp.njcp_417_18. PMID: 30837422.
20. Gersema L, Baker K. Use of corticosteroids in oral surgery. J Oral Maxillofac Surg. 1992 Mar;50(3):270-7. doi: 10.1016/0278-2391(92)90325-t. PMID: 1542068.

21. Aldhabaan SA, Hudise JY, Obeid AA. A meta-analysis of pre- and postoperative corticosteroids for reducing the complications following facial reconstructive and aesthetic surgery. Braz J Otorhinolaryngol. 2022 Jan-Feb;88(1):63-82. doi: 10.1016/j.bjorl.2020.05.015. Epub 2020 Jun 20. PMID: 32605829; PMCID: PMC9422590.
22. Zabaglo M, Leslie SW, Sharman T. Postoperative Wound Infections. [Updated 2024 Mar 5]. In: StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2025 Jan-. Available from: https://www.ncbi.nlm.nih.gov/books/NBK560533/
23. Skjelbred P, Løkken P. Reduction of pain and swelling by a corticosteroid injected 3 hours after surgery. Eur J Clin Pharmacol. 1982;23(2):141-6. doi: 10.1007/BF00545968. PMID: 6754384.
24. Sener BC, Dergin G, Gursoy B, Kelesoglu E, Slih I. Effects of irrigation temperature on heat control in vitro at different drilling depths. Clin Oral Implants Res. 2009 Mar;20(3):294-8. Doi: 10.1111/j.1600-0501.2008.01643.x. PMID: 19397641.
25. A Comparative Study on the Efficacy of Submucosal Injection of Dexamethasone Versus Methylprednisolone in Reducing Postoperative Sequelae After Third Molar Surgery Lim D, Ngeow WJournal of Oral and Maxillofacial Surgery (2017) 75(11) 2278-2286. https://doi.org/10.1016/j.joms.2017.05.033
26. Arakeri G, Brennan PA: Povidone-iodine: an anti-oedematous agent?. Int J Oral Maxillofac Surg. 2011, 40:173-6. 10.1016/j.ijom.2010.09.012
27. Tiigimae-Saar J, Leibur E, Tamme T. The effect of prednisolone on reduction of complaints after impacted third molar removal. Stomatologija. 2010;12(1):17-22. PMID: 20440092.

28. Markiewicz MR, Brady MF, Ding EL, Dodson TB. Corticosteroids reduce postoperative morbidity after third molar surgery: a systematic review and meta-analysis. J Oral Maxillofac Surg. 2008 Sep;66(9):1881-94. doi: 10.1016/j.joms.2008.04.022. PMID: 18718396.
29. Al-Shamiri HM, Shawky M, Hassanein N. Comparative Assessment of Preoperative versus Postoperative Dexamethasone on Postoperative Complications following Lower Third Molar Surgical Extraction. Int J Dent. 2017;2017:1350375. doi: 10.1155/2017/1350375. Epub 2017 Apr 10. PMID: 28487738; PMCID: PMC5402228.
30. Otake H, Sato Y, Nakatani E, Hawke P, Takei S, Ogino A, Asai H, Abe A, Fukuta K, Adachi M. Oxytetracycline-hydrocortisone ointment reduces the occurrence of both dry socket and post-extraction pain after third molar extraction: An observational study. PLoS One. 2021 Jul 2;16(7):e0254221. doi: 10.1371/journal.pone.0254221. PMID: 34214141; PMCID: PMC8253388.
31. Bello SA, Adeyemo WL, Bamgbose BO, Obi EV, Adeyinka AA. Effect of age, impaction types and operative time on inflammatory tissue reactions following lower third molar surgery. Head Face Med. 2011 Apr 28;7:8. doi: 10.1186/1746-160X-7-8. PMID: 21527036; PMCID: PMC3114767.
32. Baqain ZH, Karaky AA, Sawair F, Khraisat A, Duaibis R, Rajab LD. Frequency estimates and risk factors for postoperative morbidity after third molar removal: a prospective cohort study. J Oral Maxillofac Surg. 2008 Nov;66(11):2276-83. doi: 10.1016/j.joms.2008.06.047. Erratum in: J Oral Maxillofac Surg. 2009 Mar;67(3):706.. Khaisat, Ameen [corrected to Khraisat, Ameen]. PMID: 18940492.

33. Knutsson K, Brehmer B, Lysell L, Rohlin M. Judgement of removal of asymptomatic mandibular third molars: influence of position, degree of impaction, and patient's age. Acta Odontol Scand. 1996 Dec;54(6):348-54. doi: 10.3109/00016359609003550. PMID: 8997432.
34. Ghaeminia H, Nienhuijs ME, Toedtling V, Perry J, Tummers M, Hoppenreijs TJ, Van der Sanden WJ, Mettes TG. Surgical removal versus retention for the management of asymptomatic disease-free impacted wisdom teeth. Cochrane Database Syst Rev. 2020 May 4;5(5):CD003879. doi: 10.1002/14651858.CD003879.pub5. PMID: 32368796; PMCID: PMC7199383.
35. Ngeow WC, Lim D. Do Corticosteroids Still Have a Role in the Management of Third Molar Surgery? Adv Ther. 2016 Jul;33(7):1105-39. doi: 10.1007/s12325-016-0357-y. Epub 2016 Jun 10. PMID: 27287853; PMCID: PMC4939150.
36. Garcia AG, Sampedro FG, Rey JG, Torreira MG. Trismus and pain after removal of impacted lower third molars. Journal of oral and maxillofacial surgery. 1997 Nov 1;55(11):1223-6.

ANNEXURES

ETHICAL CLEARANCE

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)
Nehru Nagar, Belagavi - 590 010, Karnataka State
☎: 0831-2470362 — Web: http://www.kledental-bgm.edu.in
FAX: 0831-2470640 — E-mail:principal@kledental-bgm.edu.in

Sl. No. : 1650

CERTIFICATE

This is to Certify that the synopsis titled

Comparative evaluation of the efficacy of cold saline (2-8°), Hydrocortisone and Normal saline as an irrigating solution during surgical removal of impacted mandibular third molars - A randomized control trial *Submitted by*

Dr. REG.NO. IF0222004 *P. G. Student /*

Staff, Guided by _____ *from Department of*

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

Date : 15/04/25

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

Chairman
Research and Ethical Committee
KLEVK Institute of Dental Sciences
Belagavi

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

Chairman
Research and Ethical Committee
KLE VK Institute of Dental Sciences
Belgaum

ANNEXURE-II

KAHER's KLE VK Institute of Dental Sciences

Department of Oral and Maxillofacial Surgery

Belagavi

"EVALUATION OF CLINICAL OUTCOMES OF COLD SALINE (2-8^{o} C), HYDROCORTISONE AND NORMAL SALINE AS AN IRRIGATING

SOLUTION DURING SURGICAL REMOVAL OF IMPACTED MANDIBULAR THIRD MOLARS -A RANDOMIZED CONTROL TRIAL"

CONSENT TO SURGERY & ANAESTHETICS

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

1. I authorize the performance upon self or Mr./Miss./Mrs._____the following operation (Nature and extent) to be performed under the direction of Dr. _____ and by Dr. _in my own vernacular language.

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 for various investigations.
4. I consent to the administration of anesthetics as may be considered necessary or advisable by the doctor responsible for this service.
5. I consent to the administration of drugs as may be considered necessary or advisable by the doctor responsible for this service.

6. I permit the surgeon to utilize the information given by me and the results obtained from this study for presentation and publication.

7. I permit the surgeon to take my photographs to utilize it for the study and presentation purpose.

8. 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 using hydrocortisone/povidone-iodine as an irrigating solution during the procedure instead of normal saline and its effect on the postoperative pain, swelling and trismus in my vernacular language.

9. 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.

10. 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 3rd

    and 7th day.

Name: Date:

Signature: Mob. No:

Name of the Doctor: _____

Doctor's contact: _____

Hospital contact: _____

के.एल.ई. च्या व्ही.के. दतविज्ञान संस्था
तोंडी आणि मॅक्सिलोफेसियल शस्त्रक्रिया विभाग, बेळगाव

शल्य चिकितसा आणि एनेस्थेटिक्सचा सल्ला

तारीख: वेळ

1. मी, _____ वय _____ वर्ष माहिती दिली आहे अभ्यासात माझ्या सहभाग बद्दल.
2. मी माझे वैयक्तिक तपशील जसे की नाव, वय, लिंग, पत्ता, घेतलेल्या उपचारांचा इतिहास आणि अभ्यासासाठी आवश्यक असलेल्या इतर तपशीलांना माझ्या माहितीनुसार बऱोबर माहिती देण्यास मी सहमत आहे.
3. मी सर्जनला तपासणीसाठी तसेच विविध तपासण्यांसाठी सहकार्य करीन.
4. मी सर्जनला माझ्याद्वारे दिलेली माहिती आणि या अभ्यासामधून मिळालेल्या निकालांचा सादरीकरण आणि प्रकाशनासाठी उपयोग करण्याची परवानगी देतो.
5. मी सर्जनला माझे छायाचित्रे अभ्यास व सादरीकरणाच्या उद्देशाने वापरण्यासाठी घेण्यास परवानगी देतो.
6. मी ह्या अभ्यासामध्ये माझ्या स्वतःच्या इच्छेनुसार आणि इच्छेने सहभाग घेत आहे. मला सर्जनने दात काढायला लागणाऱ्या शस्त्रक्रियेबद्दल पूर्ण माहिती दिली आहे. वेदना, सूज व तोंड उघडायला होणाऱ्या त्रासावर ह्या थेरपीचा परिणाम मला समजेल अशा भाषेत सांगितला गेला आहे.
7. सर्जनने मला ऑपरेशनचे स्वरूप, हेतू आणि वापरली जाणारी सामग्री, उपचारांच्या संभाव्य पर्यायी पद्धती, त्यातील जोखीम होण्याची शक्यता माझ्या स्थानिक भाषेत मला पूर्णपणे स्पष्ट केली आहे. प्राप्त झालेल्या निकालांबद्दल कोणीही कोणतीही हमी किंवा आश्वासन दिले नाही आहे.
8. मी अभ्यासाबद्दल सर्जनने दिलेली वरील माहिती वाचली व समजली आहे आणि अभ्यासात भाग घेण्यास स्वेच्छेने सहमत आहे.

नावः तारीखः

स्वाक्षरी: मोबाइल नंबरः

डक्टरांचे नाव:_____
डॉक्टरांचा संपर्कः_____
हॉस्पिटल _____

ಕೆ. ಎಲ್. ಇ. ವಿ.ಕೆ. ಇನ್ಸ್ಟಿಟ್ಯೂಟ್ ಆಫ್ ಡೆಂಟಲ್ ಸೈನ್ಸಸ್

ಓರಲ್ ಮತ್ತು ಮ್ಯಾಕ್ಸಿಲೊಫೇಶಿಯಲ್ ಸರ್ಜರಿ ಇಲಾಖೆ, ಬೆಲ್ಗಾಮ್
ಸರ್ಜರಿ ಮತ್ತು ಅರಿವಳಿಕೆಗಳಿಗೆ ಸಲಹೆ

ದಿನಾಂಕ: ಸಮಯ: **a.m./ p.m.**

1.ನಾನು, _____ ವಯಸಿನ _____ ವರ್ಷಗಳನ್ನು ತಿಳಿಸಲಾಗಿದೆ
ಅಧ್ಯಯನದಲ್ಲಿ ನನ್ನ ಒಳಗೊಳ್ಳುವಿಕೆ ಬಗ್ಗೆ.

2. ನನ್ನ ವೈಯಕ್ತಿಕ ವಿವರಗಳಾದ ಹೆಸರು, ವಯಸಿಸು, ಲಿಂಗ, ವಿಳಾಸ, ತೆಗೆದುಕೊಂಡ ಚಿಕಿತಸೆಯ ಇತಿಹಾಸ ಮತ್ತು ಅಧ್ಯಯನಕ್ಕೆ ಬೇಕಾದ ಯಾವುದೇ ವಿವರಗಳನ್ನು ನನ್ನ ಜ್ಞಾನದ ಅತ್ಯುತ್ತಮವಾಗಿ ನೀಡಲು ನಾನು ಒಪ್ಪುತ್ತೇನೆ.

3. ನಾನು ಶಸ್ತರಚಿಕಿತಸಕನೊಂದಿಗೆ ಪರೀಕಷೆಗೆ ಮತ್ತು ವಿವಿಧ ತನಿಖೆಗಳಿಗೆ ಸಹಕರಿಸುತ್ತೇನೆ.

4. ನಾನು ನೀಡಿದ ಮಾಹಿತಿಯನ್ನು ಮತ್ತು ಈ ಅಧ್ಯಯನದಿಂದ ಪಡೆದ ಫಲಿತಾಂಶಗಳನ್ನು ಪ್ರಸ್ತುತಿ ಮತ್ತು ಪ್ರಕಟಣೆಗೆ ಬಳಸಿಕೊಳ್ಳಲು ಶಸ್ತರಚಿಕಿತಸಕನಿಗೆ ನಾನು ಅನುಮತಿ ನೀಡುತ್ತೇನೆ.

5. ನನ್ನ ಯಾಚಿತರಗಳನ್ನು ಅಧ್ಯಯನ ಮತ್ತು ಪ್ರಸ್ತುತಿ ಉದ್ದೇಶಕ್ಕಾಗಿ ಬಳಸಿಕೊಳ್ಳಲು ಶಸ್ತರಚಿಕಿತಸಕನಿಗೆ ನಾನು ಅನುಮತಿ ನೀಡುತ್ತೇನೆ.

6. ನಾನು ನನ್ನ ಸಿವಂತ ಆಶಯ ಮತ್ತು ಇಚ್ **will** ಾಶಕ್ತಿಯಿಂದ ಈ ಅಧ್ಯಯನದಲ್ಲಿ ಭಾಗವಹಿಸುತ್ತಿದ್ದೇನೆ ಮತ್ತು ಶಸ್ತರಚಿಕಿತಸಕ ಹಲ್ಲಿನ ಶಸ್ತರಚಿಕಿತಸೆಯ ಹೊರತಿಗೆಯುವಿಕೆ ಸೇರಿದಂತೆ ಕಾರ್ಯವಿಧಾನದ ಸ್ವರೂಪ ಮತ್ತು ಪರಿಣಾಮವನ್ನು ವಿವರಿಸಿದ್ದಾನೆ, 2 ಮತ್ತು 7 ನೇ ದಿನದಂದು ಪಿಎಂಬಿಟಿ ಮೊದಲು ಮತ್ತು ನಂತರ ಮತ್ತು ಶಸ್ತರಚಿಕಿತಸೆಯ ನಂತರದ ಪರಿಣಾಮ ನನ್ನ ಸ್ಥಳೀಯ ಭಾಷೆಯಲ್ಲಿ ನೋವು, ತ ಮತ್ತು ಟಿರಿಸಮಸ್.

7. ಕಾರ್ಯಾಚರಣೆಯ ಸ್ವರೂಪ ಮತ್ತು ಉದ್ದೇಶ ಮತ್ತು ಬಳಸುತ್ತಿರುವ ವಸ್ತುಗಳು, ಚಿಕಿತಸೆಯ ಪರ್ಯಾಯ ವಿಧಾನಗಳು, ಒಳಗೊಂಡಿರುವ ಅಪಾಯ ಮತ್ತು ತೊಡಕುಗಳ ಸಾಧ್ಯತೆಯನ್ನು ನನ್ನ ಸ್ಥಳೀಯ ಭಾಷೆಯಲ್ಲಿ ನನಗೆ ಸಂಪೂರ್ಣವಾಗಿ ವಿವರಿಸಲಾಗಿದೆ. ಪಡೆಯಬಹುದಾದ ಫಲಿತಾಂಶಗಳಿಗೆ ಸಂಬಂಧಿಸಿದಂತೆ ಯಾರಿಂದಲೂ ಯಾವುದೇ ಭರವಸೆ ಅಥವಾ ಭರವಸೆ ನೀಡಲಾಗಿಲ್ಲ.

8. ಅಧ್ಯಯನದ ಬಗ್ಗೆ ಶಸ್ತರಚಿಕಿತಸಕ ನೀಡಿದ ಮೇಲಿನ ಮಾಹಿತಿಯನ್ನು ನಾನು ಓದಿದ್ದೇನೆ ಮತ್ತು ಅರ್ಥಮಾಡಿಕೊಂಡಿದ್ದೇನೆ ಮತ್ತು ಅಧ್ಯಯನದಲ್ಲಿ ಭಾಗವಹಿಸಲು ಸ್ವಇಚ್ **i**ಯಿಂದ ಒಪ್ಪುತ್ತೇನೆ.

ಹೆಸರು: ದಿನಾಂಕ:
ಸಹಿ:

ಮೊಬೈಲ್ ನಂಬರ್.

ವೈದ್ಯರ ಹೆಸರು: ___
ವೈದ್ಯರ ಸಂಪರ್ಕ: _____
ಆಸ್ಪತ್ರೆ ಸಂಪರ್ಕ: _____

ANNEXURE III

KLE Vishwanath Katti Institute of Dental Sciences, Belagavi

Department of Oral and Maxillofacial Surgery

Patient Information Sheet

"EVALUATION OF CLINICAL OUTCOMES OF COLD SALINE (2-8^{o} C), HYDROCORTISONE AND NORMAL SALINE AS AN IRRIGATING SOLUTION DURING SURGICAL REMOVAL OF IMPACTED MANDIBULAR THIRD MOLARS -A RANDOMIZED CONTROL TRIAL"

Dear Patient,

You are invited to take part in a research study related to the use of different irrigating solution during the extraction of your impacted mandibular third molar to evaluate the postoperative responses. I would like to interview you to ask you about the symptoms of the condition and also perform the surgical procedure on you. This research is a part of a MDS, main dissertation at KLE Academy of Higher Education and Research.

Before you decide whether to take part in the study it is important that you understand what the research is for and what you will be asked to do. Please take time to read the following information and discuss it with others if you wish. It is up to you to decide whether or not to take part in this study. If you decide to take part you will be given this information sheet to keep. You will be also asked to sign a consent form. You can change your mind at any time and withdraw from the study without giving any reason. The standard of care you receive will not change whether or not you decide to participate in this study. You are welcome to contact me (@8755238365) if you would like any further information.

The purpose of this research study is the comparative evaluation of the efficacy of Cold Saline, Hydrocortisone and Normal Saline as an irrigating solution during surgical removal of impacted mandibular third molar.

I, _____, age _____ years, have been explained the details of the study undertaken. I am fully satisfied with the procedure and instructions given by Dr. _____ and hereby give my permission to participate in this study. You have been chosen because you have been diagnosed with impacted mandibular third molar needing surgical extraction. The study will involve 84 participants who will be examined and surgical extraction will be performed on them. During this procedure, three different types of irrigating solutions (Cold Saline, Hydrocortisone and Normal Saline) will be used and you will receive either one of them. Irrespective of which irrigating solution is used in the procedure, I assure you that it will not affect the steps of the procedure, duration and outcome of the planned treatment. Multiple photographs will be recorded during the pre-operative and post-operative stage to compare the changes in the post-operative responses like swelling, pain and mouth opening. You will be asked to report for a review and follow-up visit on 3rd and 7th day after the procedure.

The information gained from this research will be used to publish in scientific platforms/ journals without revealing your identity to make recommendations for the best practice and the results of the study may also lead onto further studies into the management of surgical extraction of impacted mandibular third molar.

Place:

_____

Date: Post-Graduate Student (MDS)

Dept. of Oral and Maxillofacial Surgery

Signature of participant:

Contact no:

Address:

ANNEXURE IV - PROFORMA FOR CASE HISTORY

NAME: **AGE: SEX:**

OCCUPATION: **O.P.NO.:**

ADDRESS: **DATE:**

CONTACT NO:

CHIEF COMPLAINT:

HISTORY OF PRESENTING ILLNESS:

PAST DENTAL HISTORY:

PAST MEDICAL HISTORY:

DRUG ALLERGY:

PERSONAL HISTORY:

Smoking/ Alcohol/ Tobacco chewing

GENERAL PHYSICAL EXAMINATION:

EXTRA-ORAL EXAMINATION:

Facial Symmetry:

TMJ:

Lymph Node:

Mouth Opening:

INTRA-ORAL EXAMINATION:

- Soft Tissue Surrounding the Impacted Tooth: Normal/ Inflamed
- Ulcer: Present/ Absent
- Fibrosed: Yes/ No
- Pericoronitis:
- Swelling:
- Discharge:
- Pain/ Difficulty in Chewing:

PROVISIONAL DIAGNOSIS:

INVESTIGATIONS:

IOPA:

OPG:

Routine Blood Investigation**:**

RADIOGRAPH AND CLINICAL CORRELATION:

DIAGNOSIS:

PEDERSONS INDEX:

CLASSIFICATION	VALUE
Spatial relationship	
Mesioangular	1
Horizontal/Transverse	2
Vertical	3
Distoangular	4
Depth	
Level A: High occlusal level	1
Level B: Medium occlusal level	2
Level C: Low occlusal level	3
Ramus Relationship/Space available	
Class I: Sufficient space	1
Class II: reduced space	2
Class III: no space	3

Difficulty index

Very difficult	7-10
Moderately difficult	5-7
Slightly difficult	3-4

TOTAL SCORE:

TREATMENT PLANNING:

DETAILS OF SURGERY:

DATE:

START TIME (INCISION):

END TIME (CLOSURE):

SURGICAL PROCEDURE:

Local Anesthesia:

Incision:

Flap:

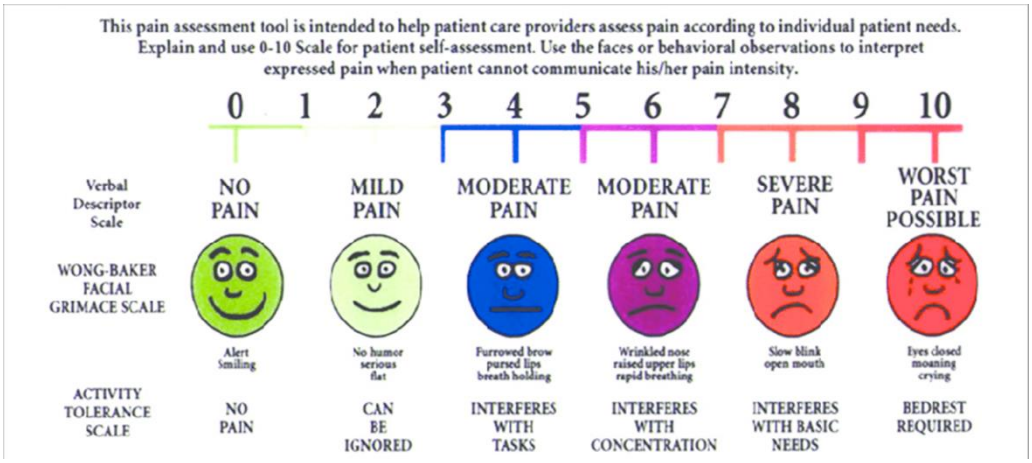
Method of Extraction:

Closure Of Site:

MEDICATION

FOLLOW-UP:

1. **PAIN- V**isual **A**nalog **S**cale (VAS)



3rd DAY	7th DAY

2. **SWELLING**

MEASUREMENT	Preoperative	Post operative day 3	Post operative day 7
The corner of the mouth to the tragus			
The outer canthus of the eye to the angle of the mandible			
The soft tissue pogonion to tragus			

3. TRISMUS

	PRE-OPERATIVE	POST OPERATIVE DAY 3	POST OPERATIVE DAY 7
MOUTH OPENING (MM)			

4. PATIENT LOG-SHEET

POST-OP DAY	T. PARACETAMOL 650mg			T. IBUPROFEN 400mg			C. AMOXICILLIN 500mg		
	MORNING	NIGHT		No. of Tab.	Time		Morning	Afternoon	Night
DAY 0									
DAY 1									
DAY 2									
DAY 3									
DAY 4									
DAY 5									
DAY 6									
DAY 7									

COMPLICATIONS:

- ALVEOLAR OSTEITIS
- PARASTHESIA
- DELAYED WOUND HEALING
- INFECTION:
- ANY OTHER: