"COMPARATIVE EVALUATION OF THE EFFICACY OF HYDROCORTISONE, POVIDONE-IODINE AND NORMAL SALINE AS AN IRRIGATING SOLUTION DURING SURGICAL REMOVAL OF IMPACTED MANDIBULAR THIRD MOLARS - A RANDOMIZED CONTROL TRIAL"

By

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LIST OF ABBREVIATIONS

SR. NO.	ABBREVATIONS	FULL FORM
1	Pre-op	Pre-operative
2	Post-op	Post-operative
3	Intra-op	Intra-operative
4	M	Male
5	F	Female
6	Diff.	Difference
7	Hb	Hemoglobin
8	BT	Bleeding time
9	CT	Clotting time
10	RBS	Random Blood Sugar
11	IOPA	Intra-oral peri-apical radiograph
12	OPG	Orthopantomogram
13	VAS	Visual Analog Scale
14	PVP-I	Povidone-iodine

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 Surgeons. Most of the available literature supports the use of corticosteroids to reduce the post-operative sequelae of lower third molar surgery, namely pain, swelling and trismus, 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 normal saline, hydrocortisone and povidone iodine 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 105 study participants formed the sample size of this study. Study subjects were categorized into three groups: Group I (third molar surgeries using hydrocortisone), Group II (third molar surgeries with povidone-iodine irrigation), and Group III-control group (third molar surgeries using normal saline irrigation). Follow up was on 2^{nd} day and 7^{th} 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 2^{nd} and 7^{th} post-operative day after surgical extraction of lower third molar in study groups in comparison to the control group. The p-value showed the difference to be statistically significant. However, swelling was statistically significant only on 2^{nd} post-operative day in the study groups ($p=0.010$) in

comparison to the control group, where as 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 hydrocortisone 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: Hydrocortisone, Mandibular third molar, Normal saline, Povidone iodine.

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INTRODUCTION

Eruption of third molars is generally seen in between 17 to 26 years of age. [1] Third molars are commonly seen as partially erupted or they fail to erupt completely, with a prevalence rate of 22.63 % seen across the globe.[2] Surgical removal of partially or fully erupted third molars are very commonly practiced in the field of Oral and Maxillofacial Surgery. The symptoms of the initial postoperative tissue reactions include pain, oedema, trismus, and dysphagia, this may have a major impact on the patient's quality of life.[3] Following surgical excision of impacted third molar teeth, age has a considerable impact on post-operative morbidity. Ones who were older had more trismus and facial oedema than younger patients.[4,5]

During the surgical extraction of mandibular molars, irrigating solutions are used to minimise damage to the bone, irrigate the surgical site, and most importantly improve the dentist's vision. A substantial amount of inflammatory exudate and debris are produced while cutting bones without using water spray, which increases postoperative discomfort. Different pharmacological and therapeutic strategies, including anti-inflammatory medications, dosages, and delivery methods, have been extensively studied in the literature to lessen postoperative discomfort.

Since hydrocortisone was first employed in oral surgery in 1952 to lessen postoperative discomfort, corticosteroids have been investigated in this field.[6] The most typical method of administering corticosteroids in oral surgery is orally, but there are several circumstances when this is not advised, such as in patients with gastrointestinal problems. It is noteworthy that the intravenous route can be regarded as one of the greatest choices when the procedure is carried out under general

anaesthesia, as well as it delivers positive outcomes in postoperative edema and pain control.[7]

However, the vast majority of these operations are done as outpatients while the patient is under local anaesthetic. The topical application of hydrocortisone as a trans-operative irrigating solution may be beneficial in this situation.

In 1956, H. A. Shelanski reported the effective antimicrobial discovery of povidone-iodine.[8] In 2010, Arakeri found that using povidone iodine (PVP-I) as a coolant during the extraction of an impacted lower third molar resulted in an incidental perceived decrease in postoperative edema in addition to its haemostatic effect.[9]

Normal saline, an isotonic solution, is typically utilised in irrigation during impacted third molar treatments to lessen heat produced by the surgical drill while coming in contact with bone during osteotomy and also to clear the socket of bone debris after osteotomy.

The purpose of the current research is to examine how effectively hydrocortisone, povidone-iodine, and normal saline, irrigating solutions perform to manage post-operative sequelae such as pain, swelling, trismus, and infection after surgical extraction of mandibular third molars.

AIM AND OBJECTIVES OF THE STUDY

AIM: To evaluate and compare the efficacy of hydrocortisone, povidone-iodine and normal saline as an irrigating solution during surgical removal of impacted mandibular third molars.

OBJECTIVES:

- To evaluate and compare the postoperative edema on using hydrocortisone, povidone-iodine and normal saline as an irrigating solution during surgical removal of impacted mandibular third molars.
- To evaluate and compare the postoperative pain on using hydrocortisone, povidone-iodine and normal saline as an irrigating solution during surgical removal of impacted mandibular third molars.
- To evaluate and compare the level of trismus on using hydrocortisone, povidone-iodine and normal saline as an irrigating solution during surgical removal of impacted mandibular third molars.

REVIEW OF LITERATURE

1. In a study conducted on the use of hydrocortisone as an intra-operative irrigating solution for impacted inferior third molar surgeries, Vitor Rodrigues et al. (2020) discovered that it resulted in 69% less post-operative discomfort in comparison to the control group, making it a practical and affordable alternative to control post-operative oedema in surgical extractions of impacted inferior third molars.[10]

2. A study was done in 2017 on the use of corticosteroids to lessen edema, trismus, and post-operative pain after the extraction of impacted mandibular third molars. They discovered that administering hydrocortisone submucosally and intravenously significantly reduced postoperative edema. It had no appreciable impact on pain, though.[7]

3. Gururaj Arakeri in 2011 conducted a randomized clinical trial on the use of Povidone Iodine as an irrigating solution for the extraction of impacted lower third molars and demonstrated that Povidone Iodine, when used at a low dosage (0.5 mg/ml), was particularly successful in minimizing postoperative edema when compared to normal saline.[9]
4. A 2014 pilot study by Hamid Mahmoud Hashemi and colleagues shown that using povidone iodine solution at a low concentration is a safe and effective way to reduce the unavoidable postoperative edema and trismus following impacted third molar operations.[11]
5. Varsha A. Jadhao et al. carried out a cross-sectional study in 2018 to compare and evaluate the effectiveness of Povidone Iodine, Chlorhexidine, and Normal Saline as irrigating solutions for extraction of impacted lower third molars. The

study showed the extraordinary effectiveness of povidone iodine (0.5%) and chlorhexine (0.12)—in reducing the unavoidable and expected postoperative sequelae.[12]

6. In the year 2020, Dibakar Ghosh and associates carried out a cross-sectional study on the extraction of impacted mandibular third molars using Povidone Iodine, normal saline, and ozonated water. They demonstrated that the incidence of development of alveolar osteitis was considerably decreased ($p<0.1$) in comparison to the control group when Povidone Iodine was used in low doses as an irrigating solution.[13]
7. In 2010, Janne Tiigimae-Saar studied the effects of prednisolone on patients who had their impacted mandibular third teeth removed 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) in comparison to the control group.[14]
8. The effectiveness of corticosteroids in reducing post-operative trismus was the subject of a review and meta-analysis by Markiwicz et al in 2008. They discovered that corticosteroids reduced oedema and trismus in the early (1-3 days) and late (>3 days) post-operative phases of the therapy.[15]
9. In 2016, Hashem M. Al-Shamiri carried out a clinical trial comparing the effects of preoperative versus postoperative dexamethasone medication on complications following mandibular third molar surgical extraction. They demonstrated that preoperative dexamethasone treatment significantly reduced trismus ($p=0.021$) and pain ($p=0.008$), regardless of the patient's age, gender, type of impaction, or length of surgery.[16]

10. 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 reduction in the quantity of analgesic medications consumed after surgery.[17]
11. In 2008 an evidence-based assessment on the benefits and drawbacks of utilizing Povidone Iodine irrigation to prevent surgical site infections was conducted by Josie Chundamala and James G. Wright. The analysis revealed that using Povidone Iodine as an irrigating solution significantly reduced the rate of infection at the surgical site compared to using regular saline, water, or no irrigation. [33]
12. In 2018, Esra Yuce et al. conducted a randomized control study on the effects of various Povidone iodine concentrations on post-operative sequelae following impacted third molar surgery. They found that when used as an irrigant, 3% Povidone Iodine Solution showed noticeably better effects when compared to 0.5% and 1%, in the reduction of post-operative facial edema and trismus.[18]
13. In a 2011 study, Seidu A. Bello et al. investigated the impact of patient age, impaction type, and duration of surgery on postoperative tissue reactions following impacted mandibular third molar surgery. The mouth opening level, according to the authors, was higher in the younger age group on days 2 and 5 than in the older age group. 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.[5]

14. In 1996 a cohort study was done on the several pathologies connected to the extraction of impacted mandibular third molars, Kerstin Knutsson et al. took into account the patient's age, angular location, and degree of impaction in addition to calculating the odds ratio. In the 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).[19]

15. In research on the quality of life connected to oral health, Adebayo Aremu Ibikunle et al. (2016) compared prednisolone administered orally versus submucosally after extraction of the third molar. The authors found that post-operative complications were statistically less common in patients who had prednisolone submucosally injected than in those who received oral prednisolone.[20]

16. The prevalence of post-operative morbidity following extraction of impacted mandibular third molars was studied 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.[4]

17. Ghaeminia H. et al (2016). weighed the benefits and drawbacks of surgical extraction against retention for the management of impacted, asymptomatic, disease-free mandibular third molar teeth. They concluded that the facts were insufficient to support either. On the other hand, some evidence suggests that preserving an impacted third molar tooth that is asymptomatic and disease-free may raise the long-term risk of periodontitis and caries incidence in the second molars adjacent to it.[21]

18. Wei Cheong Ngeow and Daniel Lim reviewed the literature between 2006 and 2015 on the use of corticosteroids in the management of impacted third molar surgeries. They discovered that using methylprednisolone rather than dexamethasone led to a much-decreased frequency of post-operative problems such as trismus and facial edema.[22]

19. In a study by Abel Garcia et al. (1997), the researchers examined whether the degree of trismus and pain experienced by patients following the extraction of impacted inferior third molars were correlated with the complexity of the procedure. They stated that surgical extractions had a higher incidence of post-operative trismus than simple forceps extractions. Regardless of the kind and degree of extraction, pain levels were noticeably low after analgesic administration.[3]

20. A systematic study and meta-analysis on the morphological and demographic predictors of third molar agenesis was carried out by K. Carter in 2015. The researchers showed that the average rate of third molar agenesis is 22.63% globally. They added that across all populations, women experience agenesis at a slightly higher incidence than men.[2]

21. A 1999 study by Irja Ventii et al. examined how the clinical status of adults third molars changed over the course of 12 years of observation. The majority of the individuals had unerupted or partially erupted teeth throughout the first set of six years, however during the following six years, the subjects either had fully erupted third molars or had them extracted. Therefore, they came to the conclusion that third molars continue to evolve and change clinically at least until the age of 32.[1]

22. Tom D. Spies et al. (1952) in an observational investigation revealed that employing synthetic cortisone therapy considerably improved the condition of several lesions in the head and neck region. The temporary disappearance of TMJ discomfort and edema with cortisone medication was noted in patients with acute rheumatoid arthritis. They came to the conclusion that in certain individuals, cortisone therapy, when administered correctly, can produce the most satisfying results.[6]

MATERIALS AND METHODS

A prospective, in-vivo clinical investigation was conducted with people who had their mandibular third molars surgically removed. This study included one hundred and five patients who reported to the Department of Oral and Maxillofacial Surgery at KLE's V.K. Institute of Dental Sciences, KAHER, Belagavi, between May 2021 and November 2022 with the complaint of impacted mandibular third molars and those who granted consent to participate.

STUDY 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 comparison.

SAMPLE SIZE ESTIMATION: The sample size was calculated using the formula

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

- At 90% confidence interval $Z_{1-\alpha/2} = 1.64$
- At 80% power $Z_{1-\beta} = 0.85$
- Standard deviation in the I^{st} group S1 = 3.16
- Standard deviation in the II^{nd} group S2 = 3.46
- N = 35 in each group.

Therefore, the sample size is **105**

All the participants had to meet the following criteria.

INCLUSION CRITERIA: Patients fulfilling the following 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 with moderate surgical difficulty score on Pederson's 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:

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

METHODOLOGY

- The study comprised of 105 randomly selected patients (envelope method) with mandibular impacted third molar, diagnosed by established clinical and radiographic parameters and were alternatively grouped in three groups irrespective of age, sex, difficulty in impaction and their response to various drugs to eliminate bias.
- Study participants were categorized into three groups:

Group I: Third molar surgeries with Hydrocortisone irrigation (*n* = 35)

Group II: Third molar surgeries performed using Povidone-Iodine irrigation (*n* = 35)

Group III: Third molar surgeries done with Normal Saline irrigation (control group) (*n* = 35)

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

PEDERSON'S 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 1: Sufficient space	1
Class 2: reduced space	2
Class 3: no space	3

Difficulty index

Very difficult	7-10
Moderately difficult	5-6
Slightly difficult	3-4

- All the patients were screened for inclusion and exclusion criteria.

PRE-OPERATIVE ASSESSMENT:

- Hemoglobin
- Bleeding time
- Clotting time
- Random Blood Sugar
- 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
- Suction tip
- Tweezer
- Langenbeck retractor
- Sponge holder
- Periosteal elevator

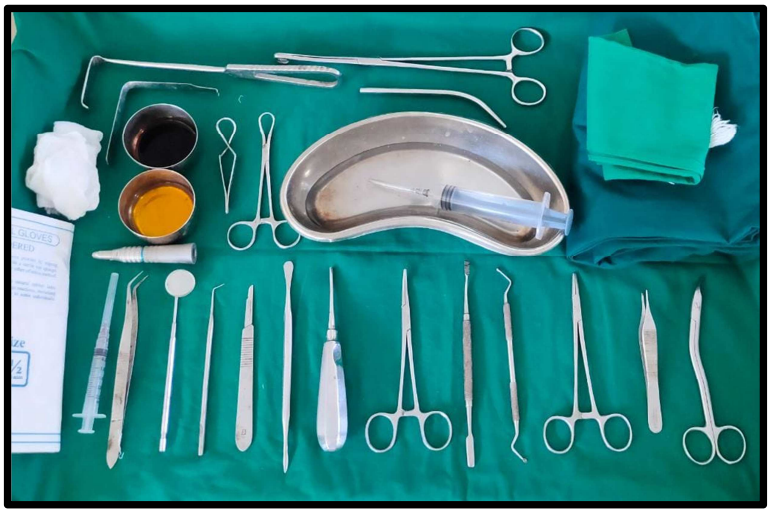


Figure 1 - Armamentarium

Follow up: was done on the 2nd and 7th day of surgical extraction of third molar.

SURGICAL PROTOCOL FOLLOWED DURING THE RESEARCH

Patients with mandibular impacted third molar diagnosed by established clinical and radiographic parameters and who met the inclusion criteria were divided into three groups of 35 each by computer generated random allocation

↓

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

↓

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

↓

Local anaesthesia was given by blocking the inferior alveolar nerve, lingual nerve, long buccal nerve with 2% lignocaine plus adrenaline 1:80,000.

↓

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

↓

Flap was elevated and reflected, bone guttering (tooth sectioning if required) was performed using a bur on a straight hand piece under abundant irrigation with Hydrocortisone 500mg concentration in 250ml normal saline for Group I, Povidone-iodine 0.5mg concentration per ml in 250ml of normal saline for Group II and 0.9 % concentration of 250ml of Normal saline for Group III.

↓

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

↓

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

↓

The flap was repositioned and sutured with 3-0 silk sutures.

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

↓

Patients of all three groups were prescribed the following drugs:

CAP. AMOXICILLIN 500mg q8h for 5 days

TAB. PARACETAMOL 650mg q12h for 3 days

TAB. PANTEPRAZOLE 20mg OD for 5 days

TAB. IBUPROFEN 400mg SOS. (Rescue drug)

EVALUATION CRITERIA

PAIN

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

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

TRISMUS

- Mouth opening was checked by measuring the inter-incisal distance in millimetres with a caliper.

SWELLING

To evaluate the swelling, distance between corner of the eye and the angle of mandible, tragus and corner of the mouth, tragus and the soft tissue pogonion on the side of surgery was measured using a ribbon ruler.

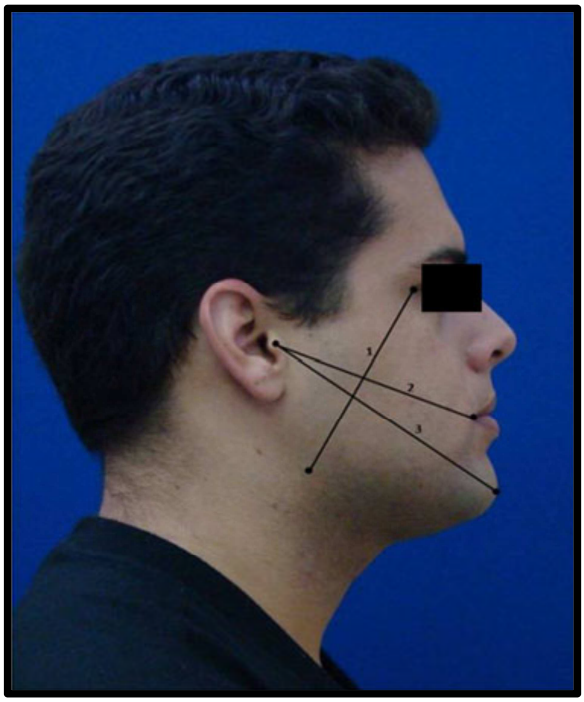


Figure 2 - Edema measurements:

Three linear distances for four fixed anatomical Points: 1 - distance between corner of the eye and the angle of mandible, 2 - tragus and corner of the mouth, 3 - tragus and the soft tissue pogonion.

FOLLOW UP

Pain, mouth opening and swelling was assessed on the day of surgery, 2nd day and the 7th day post-operatively.

PATIENTS IN STUDY GROUP I

Figure 3 - Pre-operative photos study group I (case)

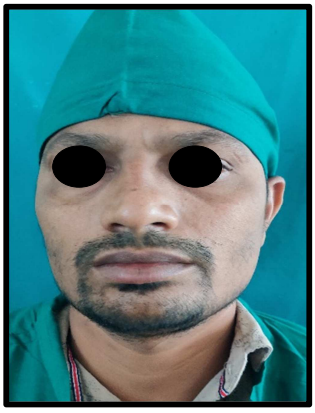


Figure 3a - Profile photo

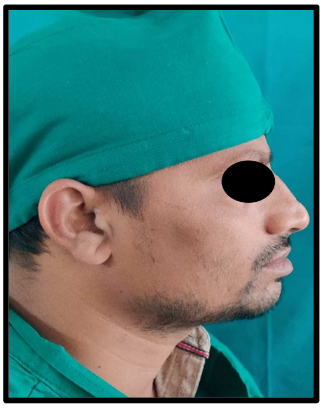


Figure 3b - Lateral profile

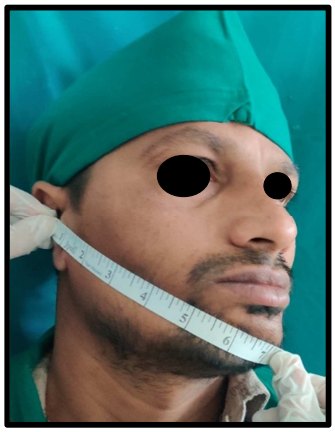


Figure 3c - Measurement from tragus to soft tissue pogonion

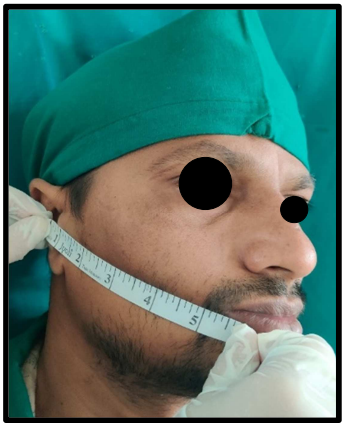


Figure 3d - Measurement from tragus to corner of mouth

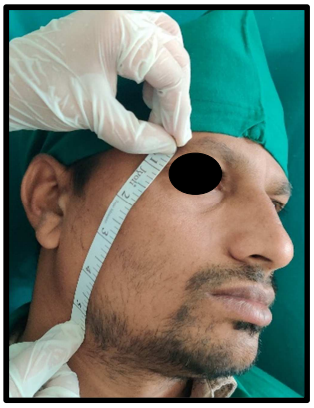


Figure 3e - Measurement from Lateral Canthus to Angle of Mandible

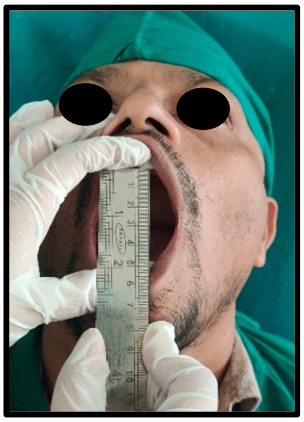


Figure 3f - Measurement of Inter-incisal distance

Figure 4 - Post-operative day 2 photos study group I (case)

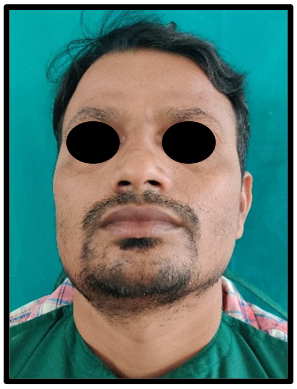


Figure 4a - Profile photo

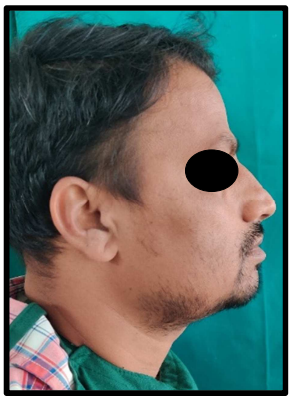


Figure 4b - Lateral profile photo

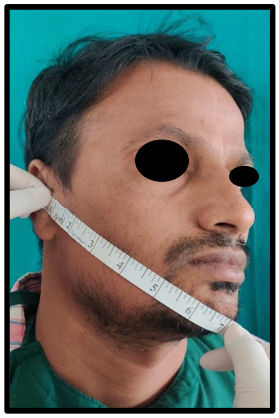


Figure 4c - Measurement from tragus to soft tissue pogonion

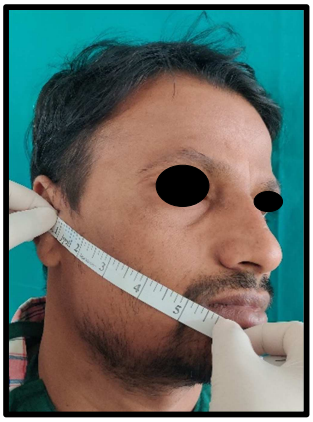


Figure 4d - Measurement from tragus to corner of mouth

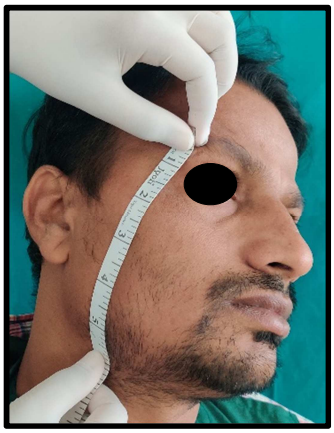


Figure 4e - Measurement from Lateral Canthus to Angle of Mandible

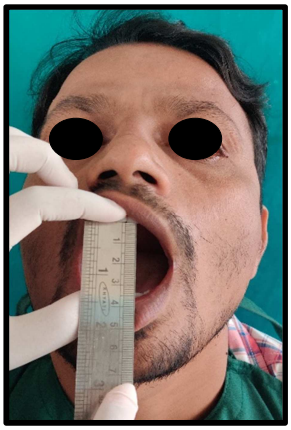


Figure 4f - Measurement of Inter-incisal distance

Figure 5 - Post-operative day 7 photos study group I (case)

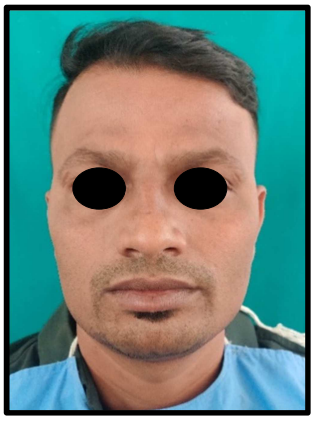


Figure 5a - Profile photo

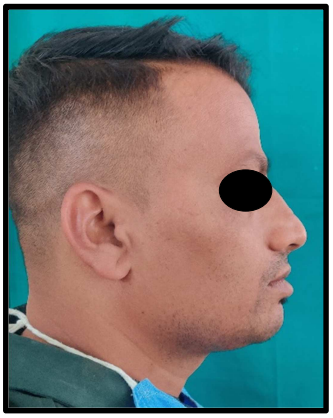


Figure5b - Lateral profile photo

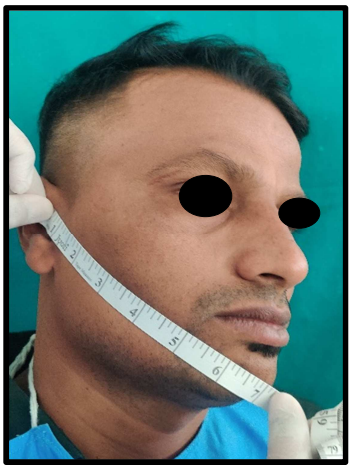


Figure 5c - Measurement from tragus to soft tissue pogonion

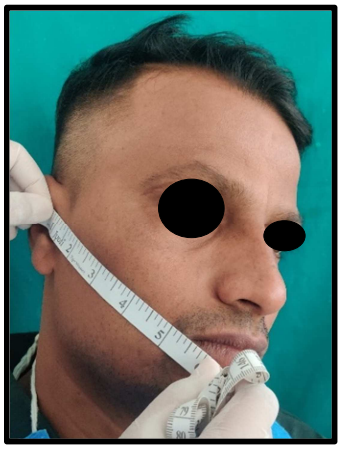


Figure 5d - Measurement from tragus to corner of mouth

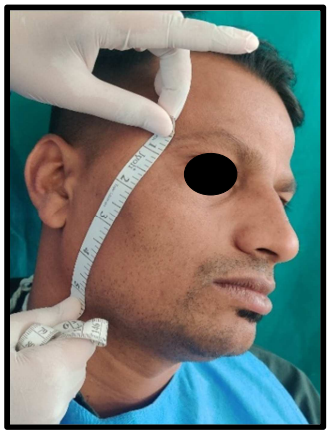


Figure 5e - Measurement from Lateral Canthus to Angle of Mandible

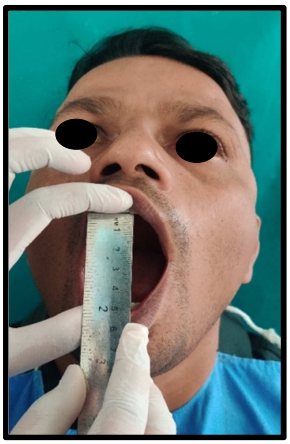


Figure 5f - Measurement of Inter-incisal distance

PATIENTS IN STUDY GROUP II

Figure 6 - Pre-operative photos study group II (case)

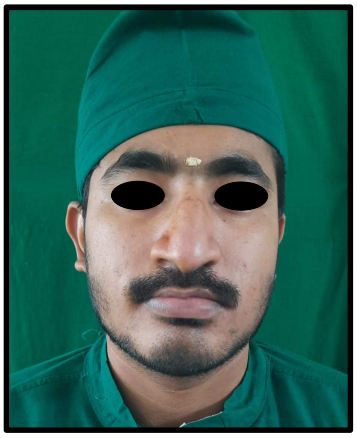


Figure 6a - Profile photo

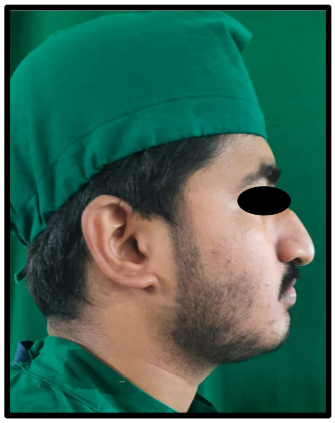


Figure 6b - Lateral profile

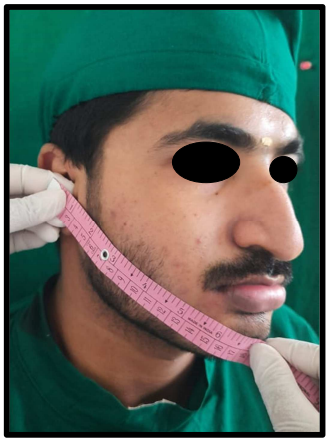


Figure 6c - Measurement from tragus to soft tissue pogonion

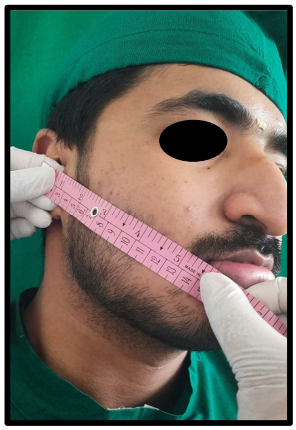


Figure 6d - Measurement from tragus to corner of mouth

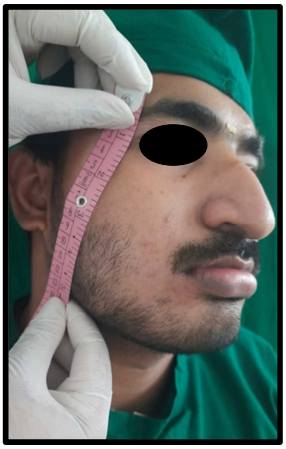


Figure 6e - Measurement from Lateral Canthus to Angle of Mandible

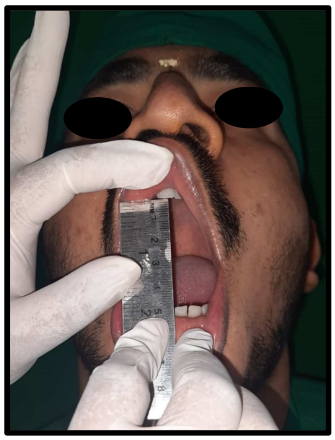


Figure 6f - Measurement of Inter-incisal distance

Figure 7 -Post-operative day 2 photos study group II (case)

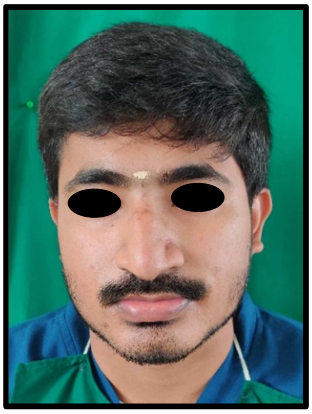


Figure 7a - Profile photo

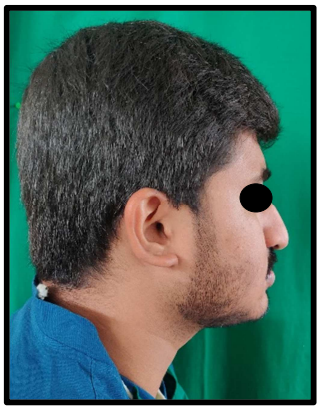


Figure 7b - Lateral profile

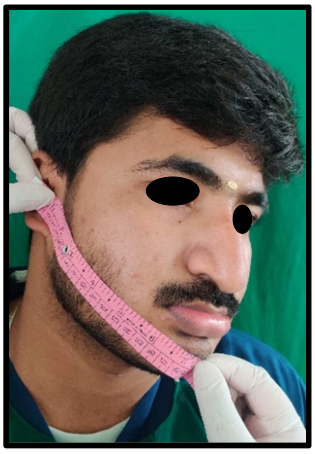


Figure 7c - Measurement from tragus to soft tissue pogonion

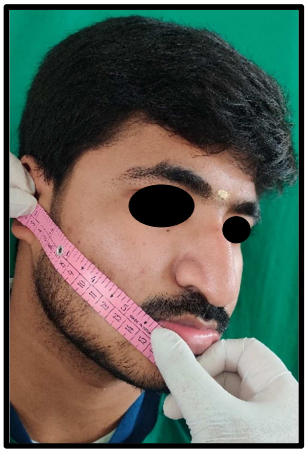


Figure 7d - Measurement from tragus to corner of mouth

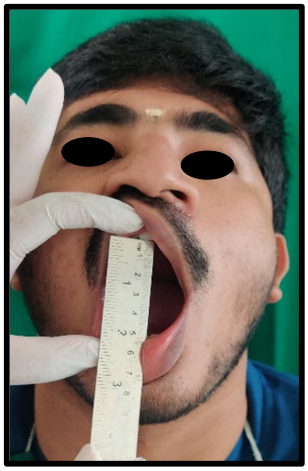


Figure 7e - Measurement from Lateral Canthus to Angle of Mandible

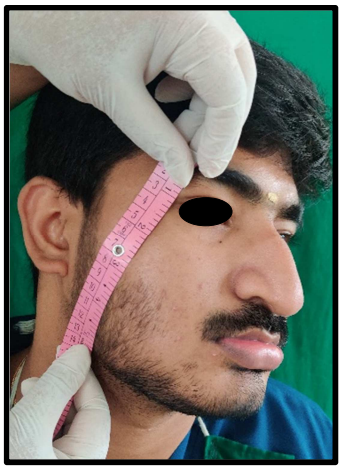


Figure 7f - Measurement of Inter-incisal distance

Figure 8- Post-operative day 7 photos study group II (case)

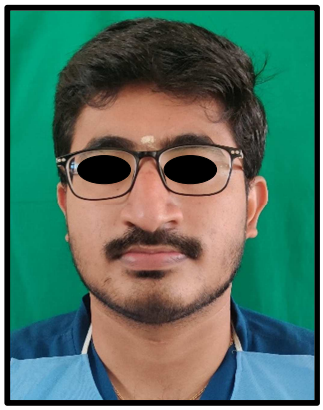


Figure 8a - Profile photo

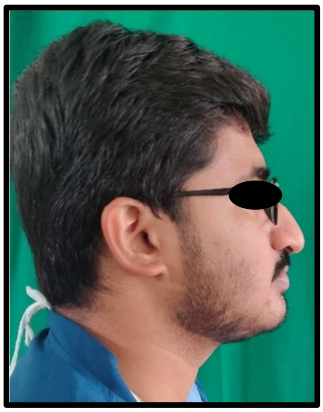


Figure 8b - Lateral profile

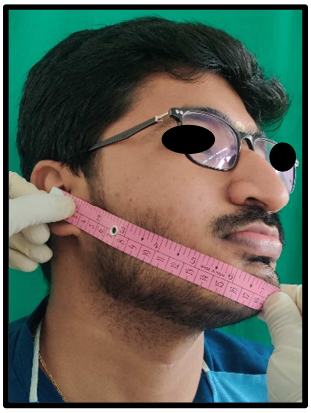


Figure 8c - Measurement from tragus to soft tissue pogonion

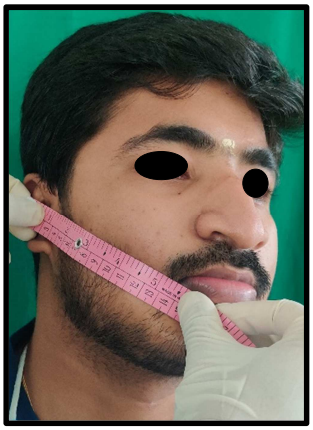


Figure 8d - Measurement from tragus to corner of mouth

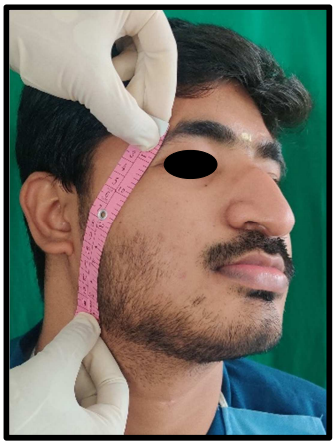


Figure 8e - Measurement from Lateral Canthus to Angle of Mandible

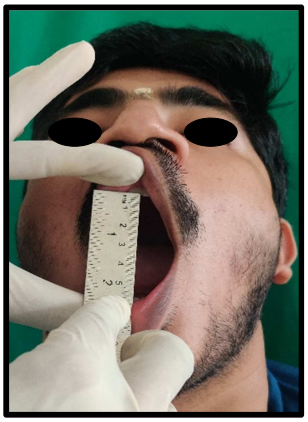


Figure 8f - Measurement of Inter-incisal distance

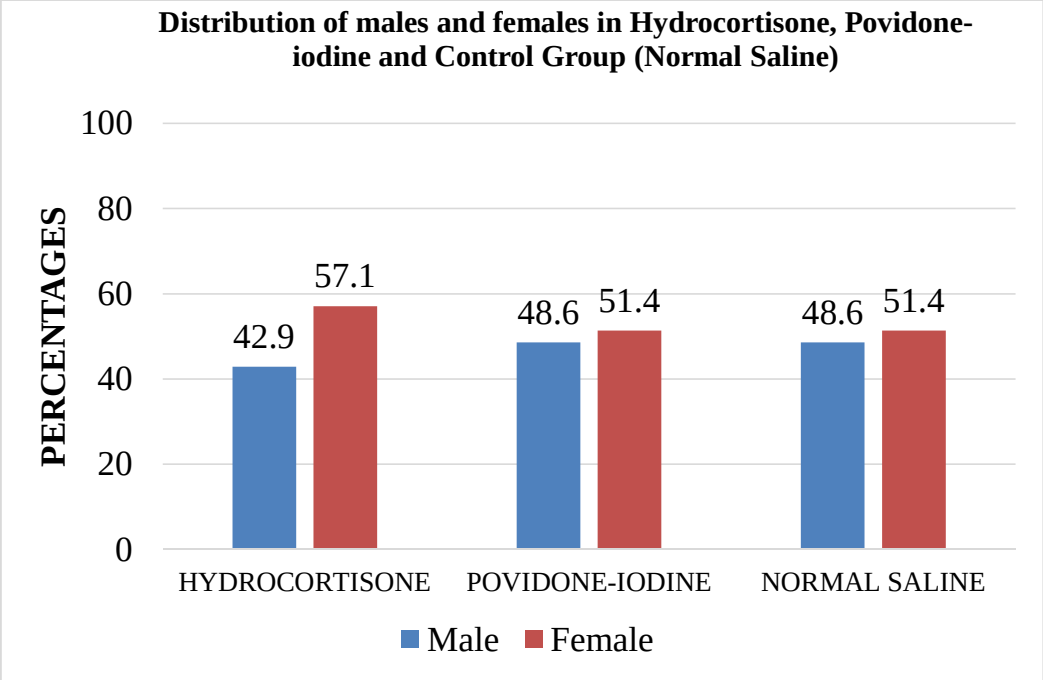
RESULTS

Table 1: Distribution of male and female participants in Hydrocortisone, Povidone-iodine and control group (Normal saline)

Sex	HYDROCORTISONE	%	POVIDONE-IODINE	%	NORMAL SALINE	%	Total
Male	15	42.9	17	48.6	17	48.6	49
Female	20	57.1	18	51.4	18	51.4	56
Total	35	100	35	100	35	100	105

Table 1 provides the distribution of the males and female participants for the three groups hydrocortisone, povidone-iodine and normal Saline. There were 15 males and 20 females in the hydrocortisone group, 17 males and 18 females in the povidone-iodine group and 17 males and 18 females in the normal saline group. There was no statistically significant association between them at the baseline.

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



AGE DISTRIBUTION:-

Table 2: Comparison of Hydrocortisone, Povidone-iodine and control group (Normal saline) with mean age by Kruskal-Wallis test

Groups	Mean	SD	SE	Kruskal Wallis H-value	P-value
HYDROCORTISONE	26.28	5.14	0.870	1.409	0.494
POVIDONE-IODINE	27.85	5.59	0.945		
NORMAL SALINE	26.68	5.44	0.921		

The mean value for the hydrocortisone, povidone-iodine and normal saline were 26.28 ± 5.14 years, 27.85 ± 5.59 years and 26.68 ± 5.44 years respectively. The comparison between them were not found to be statistically significant (p=0.494) which denotes no baseline difference between the three groups.

PEDERSON INDEX:-

Table 3: Comparison of Hydrocortisone, Povidone-iodine and control group (Normal Saline) with mean Pederson's difficulty index scores by Kruskal-Wallis test

Groups	Mean	SD	SE	Kruskal Wallis H-value	P-value
HYDROCORTISONE	5.45	0.50	0.085	2.402	0.301
POVIDONE-IODINE	5.31	0.47	0.079		
NORMAL SALINE	5.48	0.50	0.085		

Table 3 provides the mean, standard deviation and standard error values of Pederson's difficulty index for the three groups hydrocortisone, povidone-iodine and normal saline and also compares them using Kruskal-Wallis test. The mean value for hydrocortisone was 5.45± 0.50, and for povidone-Iodine it was 5.31 ± 0.47 while for normal saline, it was 5.48 ± 0.50. The baseline difference between them were not found to be statistically significant. (p=0.301)

GRAPH 2: Mean Pederson's difficulty index for Hydrocortisone, Povidone-iodine and Control Group (Normal Saline)

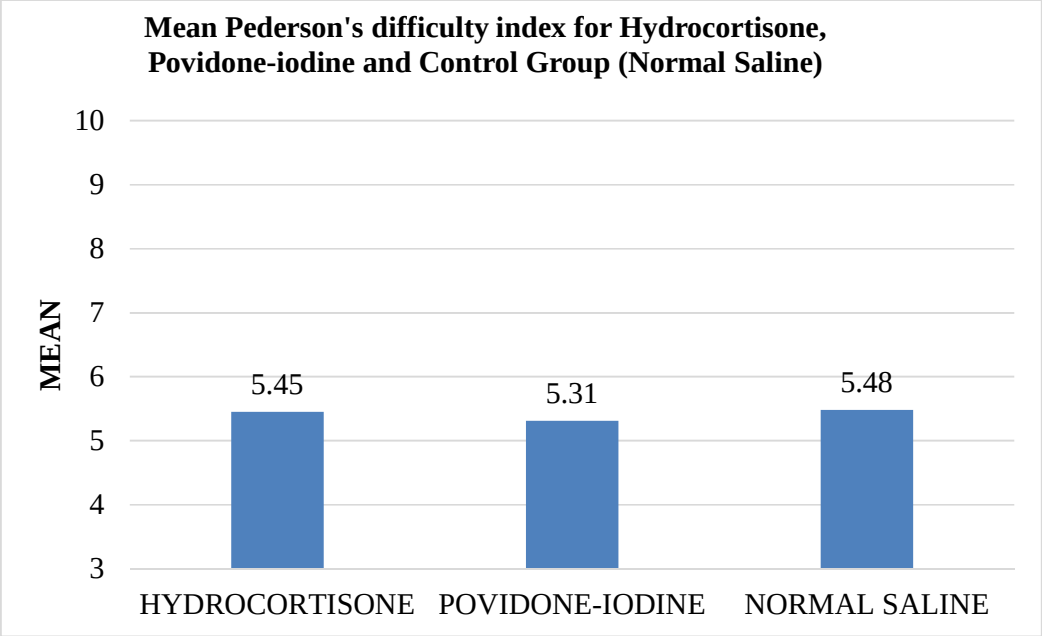


Table 4: Comparison of Hydrocortisone, Povidone-iodine and control group (Normal Saline) with mean Pederson's difficulty index

Index	HYDROCORTISONE	%	POVIDONE-IODINE	%	NORMAL SALINE	%	Total
5	19	54.3	24	68.6	18	51.4	61
6	16	45.7	11	31.4	17	48.6	44
Total	35	100	35	100	35	100	105

Table 4 provides the descriptive results of the Pederson's difficult index as well as the comparison between hydrocortisone, povidone-iodine and normal saline using Chi-Square test. 19, 24 and 18 patients had a Pederson difficult index score of 5 respectively. The score of 6 was seen in 16 patients using hydrocortisone, 11 patients using povidone-iodine and 17 patients using normal saline. The baseline comparison was done using Chi-Square test and the difference between them were not found to be statistically significant. (p=0.1268)

ASSESSMENMT OF PAIN:

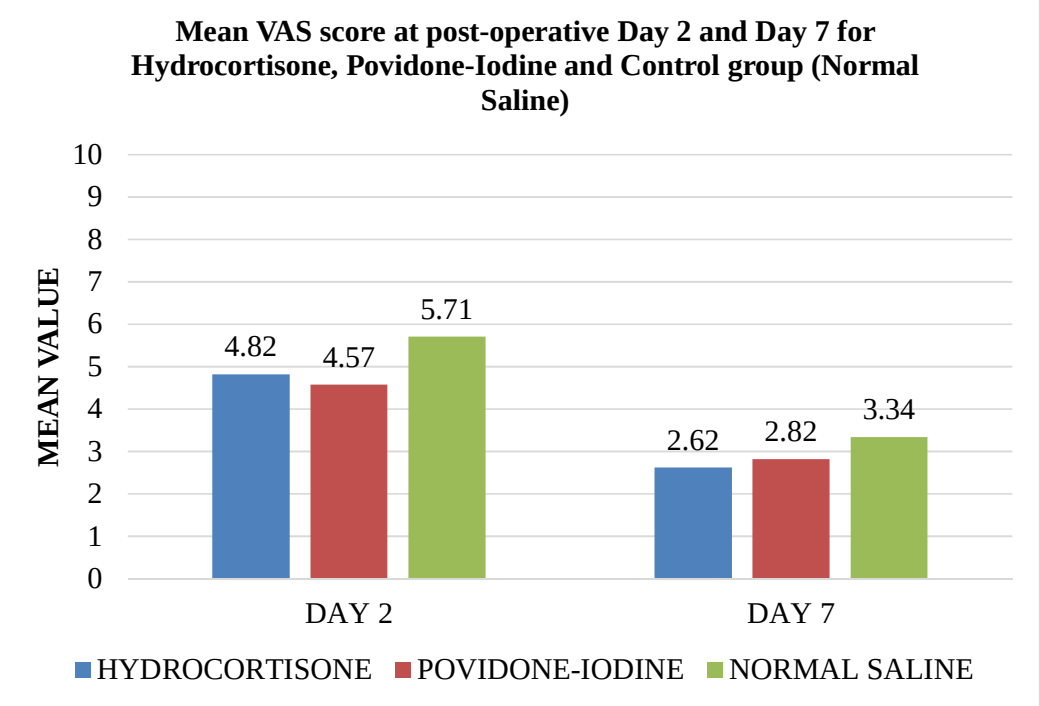
Table 5: Comparison of Hydrocortisone, Povidone-iodine and Control group (Normal Saline) with VAS scores at post-operative 2nd day & 7th day using Kruskal-Wallis test.

Time points	Groups	Mean	SD	H-value	P-value
Day 2	HYDROCORTISONE	4.82	0.70	34.980	<0.001*
	POVIDON-IODINE	4.57	0.60		
	NORMAL SALINE	5.71	0.45		
Day 7	HYDROCORTISONE	2.62	0.59	13.091	<0.001*
	POVIDON-IODINE	2.82	0.70		
	NORMAL SALINE	3.34	0.48		
Day 2-Day 7	HYDROCORTISONE	2.20	0.11	21.889	<0.001*
	POVIDON-IODINE	1.75	-0.10		
	NORMAL SALINE	2.37	-0.03		

*p<0.05

The comparison of Pain, using mean VAS score, between hydrocortisone, povidone-iodine and normal saline, at different time points was conducted using Kruskal-Wallis test and depicted in Table 5. The difference between the three groups were found to be statistically significant ($p<0.001$) for both Day 2 and Day 7. Moreover, the comparison of mean difference between Day 2 and Day 7 for hydrocortisone, povidone-iodine and normal saline was found to be statistically significant as well.

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



Graph 3 denotes the Mean VAS score for Pain at Post-operative Day 2 and Day 7 for hydrocortisone, povidone-iodine and normal saline. For Day 2, the scores were 4.82 ± 0.70, 4.57 ± 0.60 and 5.71 ± 0.45 respectively. Similarly, for Day 7, the scores were 2.62 ± 0.59, 2.82 ± 0.70 and 3.34 ± 0.48 for the three groups. The mean score on day 7 for hydrocortisone group was 2.62 ± 0th.59 which was less compared to others.

Table 6: Comparison of pain scores at post-operative day 2 and day 7 in Hydrocortisone, Povidone-iodine and Control Group (Normal Saline) by Wilcoxon Signed Rank test

Groups	Time points	Mean	SD	Z-value	P-value
HYDROCORTISONE	Day 2	4.82	0.70	5.406	<0.001*
	Day 7	2.62	0.59		
POVIDONE-IODINE	Day 2	4.57	0.60	5.387	<0.001*
	Day 7	2.82	0.70		
NORMAL SALINE	Day 2	5.71	0.45	5.282	<0.001*
	Day 7	3.34	0.48		

*p<0.05= statistically significant

Table 6 describes the comparison of Pain, using Mean VAS score, between Day 2 and Day 7 for the three groups, i.e., hydrocortisone, povidone-Iodine and normal saline. The mean VAS score was less for hydrocortisone group on day 7 when compared to others. The difference between the two time points was found to be statistically significant for all of them with a consistent p-value of less than 0.05 (p<0.001).

ASSESSMENT OF SWELLING:

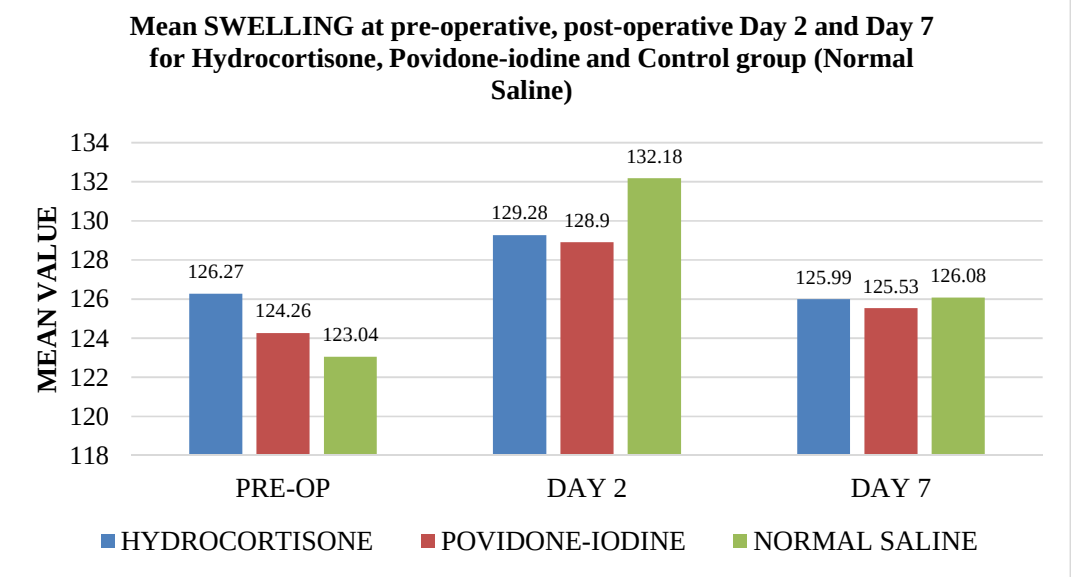
Table 7: Comparison of Hydrocortisone, Povidone-iodine and Control Group (Normal Saline) with swelling scores at pre-operative, post-operative day 2 and day 7 time points by Kruskal-Wallis test

Variable	Groups	Mean	SD	SE	H-value	P-value
Pre Op	HYDROCORTISONE	126.27	6.56	1.109	1.802	0.170
	POVIDONE-IODINE	124.26	6.33	1.071		
	NORMAL SALINE	123.04	8.45	1.429		
Day 2	HYDROCORTISONE	128.90	5.80	0.982	2.278	0.010*
	POVIDONE-IODINE	129.28	6.58	1.113		
	NORMAL SALINE	132.18	8.40	1.420		
Day 7	HYDROCORTISONE	125.99	6.57	1.111	0.051	0.941
	POVIDONE-IODINE	125.53	5.79	0.979		
	NORMAL SALINE	126.08	8.66	1.463		
Pre Op - Day 2	HYDROCORTISONE	-2.63	0.76	0.127	0.893	0.022*
	POVIDONE-IODINE	-5.02	-0.25	-0.042		
	NORMAL SALINE	-9.14	0.05	0.009		
Pre Op - Day 7	HYDROCORTISONE	0.28	-0.01	-0.002	1.366	0.785
	POVIDONE-IODINE	-1.27	0.54	0.092		
	NORMAL SALINE	-3.04	-0.21	-0.034		
Day 2 - Day 7	HYDROCORTISONE	2.91	-0.77	-0.129	1.795	0.658
	POVIDONE-IODINE	3.75	0.79	0.134		
	NORMAL SALINE	6.1	-0.26	-0.043		

*$p<0.05$

The comparison of swelling scores between the three groups hydrocortisone, povidone-iodine and normal saline was done at three different time points, i.e., at the pre-operative stage, at Day 2 and Day 7, using Kruskal-Wallis test and the results have been provided in Table 7. The comparative results between the three groups were not found to be statistically significant at pre-operative stage and Day 7, however the comparison between them at Day 2 was statistically significant. Even for the comparison of the mean differences between the three groups at preop – day 7 and day2 -day 7 were found to be statistically insignificant but for preop - day 2 it was found to be statistically significant.

GRAPH 4: Mean SWELLING at pre-operative, post-operative Day 2 and Day 7 for Hydrocortisone, Povidone-iodine and Control group (Normal Saline)



Graph 4 denotes the mean swelling at Post-operative Day 2 and Day 7 in comparison to preoperative measurements for hydrocortisone, povidone-iodine and normal saline. In preoperative stage the score was 126.27, 124.26 and 123.04 respectively. Whereas for Day 2, the scores were 128.90, 129.28 and 132.18 respectively. Similarly, for Day 7, the scores were 125.99, 125.53 and 126.08 for the three groups.

Table 8: Comparison of pre-operative, post-operative day 2 and day 7 time points with swelling scores in Hydrocortisone, Povidone-iodine and Control Group (Normal Saline) by using Repeated Measures ANOVA test

Groups	Time points	Mean	SD	Mean Diff.	SD Diff.	p-value	Repeated measures	
							F-value	P-value
HYDROCORTISONE	Pre Op	126.27	6.56	2.633	0.580	<0.001*	59.318	<0.001*
	Day 2	128.90	5.80					
	Pre Op	126.27	6.56	0.279	0.186	0.429		
	Day 7	125.99	6.57					
	Day 2	128.90	5.80	2.911	0.770	<0.001*		
	Day 7	125.99	6.57					
POVIDONE-IODINE	Pre Op	124.26	6.33	5.019	0.250	<0.001*	230.777	<0.001*
	Day 2	129.28	6.58					
	Pre Op	124.26	6.33	1.268	0.454	0.025*		
	Day 7	125.53	5.79					
	Day 2	129.28	6.58	3.946	0.790	<0.001*		
	Day 7	125.53	5.79					
NORMAL SALINE	Pre Op	123.04	8.45	9.133	0.213	<0.001*	926.79	<0.001*
	Day 2	132.18	8.40					
	Pre Op	123.04	8.45	3.038	0.264	<0.001*		
	Day 7	126.08	8.66					
	Day 2	132.18	8.40	6.095	0.256	<0.001*		
	Day 7	126.08	8.66					

- $p<0.05$

The comparison of swelling for the three groups hydrocortisone, povidone-iodine and normal saline was done at three different time points, i.e., pre-operative stage, Day 2 and Day 7 and the statistical significance between them was synthesized using Repeated Measures ANOVA 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 Wilcoxon signed Rank Test as well. For hydrocortisone, the comparison between pre-operative stage and Day 2 and between Day 2 and Day 7 were found to be statistically significant. For povidone-iodine and normal saline, the comparison between all three combinations, i.e., Pre-op-Day 2, Pre-op-Day 7 and Day 2-Day 7 were found to be statistically significant. On overall comparison using Repeated Measures ANOVA, the difference between the three time points for all the three groups were found to be statistically significant as well.

ASSESSMENT OF TRISMUS:

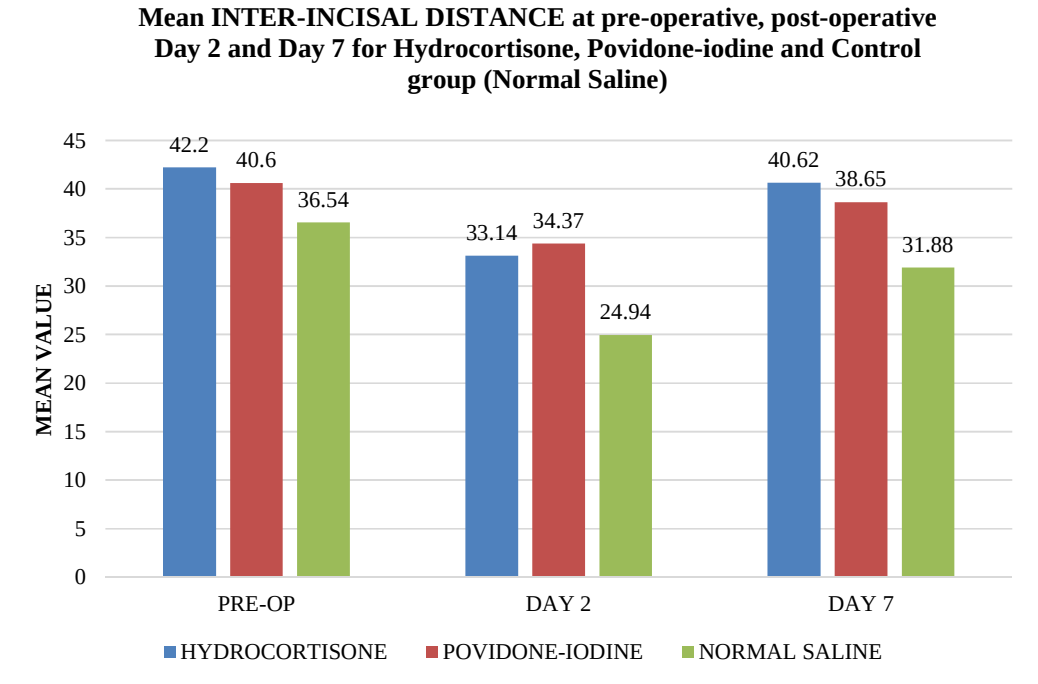
Table 9: Comparison of Hydrocortisone, Povidone-iodine and Control Group (Normal Saline) with inter-incisal distance scores at pre-operative, post-operative day 2 and day 7 time points by Kruskal-Wallis test

Variable	Groups	Mean	SD	SE	H-value	P-value
Pre Op	HYDROCORTISONE	42.20	7.58	1.281	12.044	<0.001*
	POVIDONE-IODINE	40.60	3.11	0.526		
	NORMAL SALINE	36.54	2.62	0.444		
Day 2	HYDROCORTISONE	33.14	5.99	1.013	48.947	<0.001*
	POVIDONE-IODINE	34.37	3.40	0.575		
	NORMAL SALINE	24.94	2.96	0.502		
Day 7	HYDROCORTISONE	40.62	7.35	1.243	30.449	<0.001*
	POVIDONE-IODINE	38.65	3.32	0.562		
	NORMAL SALINE	31.88	2.70	0.457		
Pre Op - Day 2	HYDROCORTISONE	9.06	1.59	0.268	16.346	<0.001*
	POVIDONE-IODINE	6.23	-0.29	-0.049		
	NORMAL SALINE	11.6	-0.34	-0.058		
Pre Op - Day 7	HYDROCORTISONE	1.58	0.23	0.038	8.904	<0.001*
	POVIDONE-IODINE	1.95	-0.21	-0.036		
	NORMAL SALINE	4.66	-0.08	-0.013		
Day 2 - Day 7	HYDROCORTISONE	-7.48	-1.36	-0.23	-3.228	<0.001*
	POVIDONE-IODINE	-4.28	0.08	0.013		
	NORMAL SALINE	-6.94	0.26	0.045		

*p<0.05

Table 9 describes the results of comparison of inter-incisal distance scores for hydrocortisone, povidone-iodine and normal Saline at Pre-operative stage, Day 2 and Day 7 using Kruskal-Wallis test. The comparison between all the three groups at all three time points were found to be statistically significant ($p<0.001$). The mean difference between the time points of the three groups (Pre-operative-Day 2, Pre-operative- Day 7 and Day 2- Day 7) were also calculated and their comparison yielded a statistically significant difference as well.

GRAPH 5: Mean INTER-INCISAL DISTANCE at pre-operative, post-operative Day 2 and Day 7 for Hydrocortisone, Povidone-iodine and Control group (Normal Saline)



Graph 5 represents the mean inter-incisal distance on pre operative day in comparison to post-operative Day 2 and Day 7 for hydrocortisone, povidone-iodine and normal saline. According to preoperative specifics the score was 42.2, 40.6 and 36.54 respectively. Whereas for Day 2, the scores were 33.14, 34.37 and 24.94 respectively. Similarly, for Day 7, the scores were 40.62, 38.65 and 31.83 for the three groups.

Table 10: Comparison of pre-operative, post-operative day 2 and day 7 time points with inter-incisal distance in Hydrocortisone, Povidone-iodine and Control Group (Normal Saline) by using Repeated Measures ANOVA test

Groups	Time points	Mean	SD	Mean Diff.	SD Diff.	p-value	Repeated measures	
							F-value	P-value
HYDROCORTISONE	Pre Op	42.20	7.58	9.057	0.755	<0.001*	73.629	<0.001*
	Day 2	33.14	5.99					
	Pre Op	42.20	7.58	1.571	0.324	<0.001*		
	Day 7	40.62	7.35					
	Day 2	33.14	5.99	7.486	0.621	<0.001*		
	Day 7	40.62	7.35					
POVIDONE-IODINE	Pre Op	40.60	3.11	6.229	0.164	<0.001*	703.061	<0.001*
	Day 2	34.37	3.40					
	Pre Op	40.60	3.11	1.943	0.142	<0.001*		
	Day 7	38.65	3.32					
	Day 2	34.37	3.40	4.286	0.162	<0.001*		
	Day 7	38.65	3.32					
NORMAL SALINE	Pre Op	36.54	2.62	11.60	0.446	<0.001*	331.072	<0.001*
	Day 2	24.94	2.96					
	Pre Op	36.54	2.62	4.657	0.323	<0.001*		
	Day 7	31.88	2.70					
	Day 2	24.94	2.96	6.943	0.406	<0.001*		
	Day 7	31.88	2.70					

The overall comparison of the three groups hydrocortisone, povidone-iodine and normal saline at different time points was conducted using Repeated Measures ANOVA 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 basis using Wilcoxon signed rank test. The comparison of the differences between the different combinations of two time points, i.e, Pre-operative - Day 2, Pre-operative - Day 7 and Day 2 - 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 found to be statistically significant ($p<0.001$).

DISCUSSION

The removal of mandibular third molar is one of the most common procedures in oral and maxillofacial surgery. Patients usually complains of postoperative swelling, pain and trismus associated with the inflammatory response to surgical trauma as the main factors affecting their quality of life in the immediate post operative period.[20]

The fundamental objective of employing irrigating solutions during the surgical extraction of impacted third molars is to avoid heat-induced permanent bone necrosis. Normal saline has a cleaning effect that aids in the healing of wounds but does not immediately contribute to postoperative healing.[13] To reduce postoperative discomfort, different irrigating solutions and pharmacological managements have been frequently discussed in literature.

In oral and maxillofacial surgery, povidone iodine has been used mainly as an irrigant for alveolar sockets after extraction.[23] In a 2011 study, Arakeri and Brennan utilized 0.5 mg/mL PVP-I as the cooling and irrigating solution for the surgical extraction of impacted third molars. They observed that it significantly reduced postoperative edema.

In this context, they hypothesised that the impact is brought on by chemotaxis and leukotriene B4 suppression, which prevent neutrophil accumulation. An additional benefit of PVP-I irrigation is the enhancement of the "anionic chemo mechanical effects" of saline solution, which accelerates bone/tooth cutting rate by adding an additional anion (iodine) to saline.[24]

In this research, PVP-I was utilised as an irrigant throughout the whole surgical removal of impacted third molars at a concentration comparable to that employed in the study by Arakeri and Brennan.[9]

Corticosteroids in oral surgery have been studied since 1952,[6]where hydrocortisone was used to reduce postoperative discomfort. Since that time, a number of additional corticosteroids, dosages, and administration methods have been researched to offer a more comfortable postoperative period and enhance the quality of life for patients. It is uncertain how hydrocortisone works to reduce inflammation. It is presumably connected to both cellular effects and how they affect the microvasculature.[25]

The body naturally produces hydrocortisone (cortisol), which is around 15-30mg in a normal adult, but can be provided up to 300 mg in times of need.[26–28] Corticosteroids need to be administered at higher dosages than the basal secretion in order to have an anti-inflammatory effect. However, there hasn't been a single study that can demonstrate the ideal corticosteroid dosage, ideal method of administration, or optimal timing.

The most popular method of drug administration in oral surgery is per oral. Additionally, the intravenous approach is employed, particularly when the third molar extraction is carried out under general anaesthesia. Because of its effectiveness in reducing pain and edema as well as in preventing nausea and vomiting, this might be regarded as one of the finest methods of administration.[10,14]

However, as these procedures are typically done under local anaesthesia in an outpatient setting, the oral route continues to be the most popular choice.

Additionally, it guarantees a quick and nearly total absorption. Although the relative merits of different routes are always in discordance. Corticosteroids should be used if considerable postoperative soft tissue edema is anticipated.[10,14]

In this context, the study was created to assess the effectiveness of normal saline, povidone iodine, and hydrocortisone as irrigating solutions on impacted mandibular third molar surgery.

In the present study it was found that hydrocortisone as an intraoperative irrigating solution, was more effective than betadine and saline in controlling post operative swelling on the second day, after surgical removal of impacted mandibular third molar with statistically significant difference ($p < 0.01$). However, the comparison of the same irrigating solutions on post operative day 7 was statistically insignificant.

In addition, postoperative swelling, causes tissue tension which leads to additional tension-induced pain.[29] Corticosteroids' capacity to diminish edema could enhance its analgesic impact by reducing pain brought on by tissue tension. This idea is in line with Messer and Keller's assertion that pain and swelling are connected, and that the discomfort would be low if swelling could be controlled.[30]

However, inconsistent findings from several studies had been found. In contrast to the control group, some studies using a single dose of prednisolone or dexamethasone postoperatively showed substantial differences in edema, trismus, and discomfort,[14,31] while others found conflicting results.[32,33]

On the contrary, some studies have shown that using hydrocortisone as an intraoperative irrigating solution has a rapid and effective effect on managing postoperative edema.[10]

One of the most used tools for measuring pain intensity is the VAS score, which has been proven to be a reliable and consistent way to measure unique pain as well as a straightforward, subdued, reproducible, and widely accepted method to evaluate pain.[12]

The current study showed a statistically significant result on postoperative pain control in both the study groups when compared to normal saline. According to VAS score there was a meaningful reduction in pain seen in the study group II (PVP-I) on second postoperative day, contrariwise study group I (hydrocortisone) manifested better response on the 7th postoperative day in comparison to the rest.

In third molar extractions, several authors have demonstrated that intraoperative irrigations with povidone-iodine solution also reduced edema and trismus. They contend that povidone-iodine solution, when used in relatively low concentration, exhibited anti-inflammatory properties in addition to its antibacterial properties.[11,12,17]

In a study conducted in 2010, Kang S-H and colleagues discovered that methyl-prednisolone dosages under 20 mg looked to be ineffective for treating post-operative pain.[34]

In their study, Janne Tiigimae-Saar et al. discovered that the combination of a single dosage of prednisolone and etorikoxib is effective at treating edema, trismus, and postoperative pain following third molar surgery.[14]

It has to be noted that, in the studies reviewed, pain was assessed subjectively and was not the only primary outcome measured. This led to a variety of pain outcomes following third molar operations. The degree of pain is also influenced by a number of variables, including surgical trauma, a person's pain threshold, and their psychological well-being.[30]

In the current analysis, when trismus was examined between the study and control group, both study groups have showed a statistically significant decrease in trismus. Study group II (PVP-I) patients had the maximum inter-incisal distance on the second postoperative day. But study group I (hydrocortisone) participants had the least overall trismus on the seventh postoperative day. At one week, the maximum interincisal opening was not different from preoperative measurement in the two groups, especially in group I.

The time course for trismus and associated restriction in oral function observed in the current study is consistent with results showing that trismus peaks on Day 1 or Day 2 postoperatively and often resolves by Day 7.[16,31]

According to Cho et al, there was minimal trismus at the 7-day evaluation. Additionally, the highest subjective ratings for trismus, which were measured 48 hours after surgery, were improved by day 7, and these outcomes are consistent with the current study.[35]

CONCLUSION

- Hydrocortisone as an intraoperative irrigating agent, showed effective response in controlling post operative swelling within the first 48 hours.
- However, on the seventh day there was no statistically appreciable difference seen when hydrocortisone was compared to povidone-iodine and normal saline.
- On the other hand, hydrocortisone as an irrigating solution showed statistically promising results in managing postoperative pain and trismus, which was followed by povidone-iodine and normal saline.
- This implies that using hydrocortisone as an irrigating solution is found to be highly beneficial and inexpensive alternative in reducing the post-operative pain, swelling and trismus caused by surgical removal of impacted teeth.

LIMITATION

- Due to small sample size, it was difficult to generalize the results, therefore further studies are needed to evaluate effect of hydrocortisone in managing post-operative pain, swelling and trismus following surgical removal of third molar.
- Following the surgical extraction of the third molar, efficacy of cold saline could have been evaluated in lowering post-operative pain, swelling, and trismus.

RECOMMENDATION

- Hydrocortisone and povidone-iodine can be used routinely as an intra-operative irrigating solution during surgical extraction of lower third molar, as it increases patient comfort, controls swelling, alleviates pain and trismus in the immediate post operative period.
- The potential analgesic and anti-inflammatory properties of hydrocortisone make it a prospective contender for reducing discomfort that patients usually experience in the immediate post operative period.

SUMMARY

The present study was a clinical randomized controlled trial. A total of 105 participants were categorized into three groups: Group I (hydrocortisone irrigation), Group II (povidone-iodine irrigation), and Group III-control group (normal saline irrigation). Follow up period was on 2^{nd} day and 7^{th} day postoperatively to evaluate pain, swelling, and trismus. There was a significant reduction in the post operative pain($p<0.001$) and trismus($p<0.001$) on the 2^{nd} and 7^{th} post-operative day in case of hydrocortisone and PVP-1. However, swelling was statistically significant only on 2^{nd} post-operative day in the study groups ($p=0.010$). The patients who got hydrocortisone and povidone-iodine were found to be highly effective in terms of managing post operative swelling compared to the control group, hydrocortisone itself was highly effective against pain and trismus, followed by povidone-iodine. This indicates that using hydrocortisone 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.

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ANNEXURES - I

ETHICAL CLEARANCE

Research and Ethics Committee
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KLE University
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Sl. No. : 1465

CERTIFICATE

This is to Certify that the synopsis titled

Comparative evaluation of the efficacy of Hydrocortisone, Povidone-iodine and Normal Saline as an irrigating solution during surgical removal of impacted mandibular third molars: A randomised control trial.

Submitted by Dr. _____ 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 : 5/5/21

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

Chairman
Research and Ethical Committee
KLEVK Institute of Dental Sciences
Belagavi

ANNEXURES - II
BIOSTATISTICS CLEARANCE CERTIFICATE

KLE V.K. Institute of Dental Sciences
(A Constituent unit of KLE Academy of Higher Education & Research
Deemed-to-be-University u/s 3 of the UGC Act, 1956)
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Biostatistics Clearance Certificate

This is to certify that the Biostatistics aspect of the Dissertation / Research work of

Post Graduate Student, under the guidance of

Professor & Head, Department of Department of Oral and Maxillofacial Surgery, KAHER's KLE VKIDS, entitled **"COMPARATIVE EVALUATION OF THE EFFICACY OF HYDROCORTISONE, POVIDONE-IODINE 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.

Dr. J. B. Bagad.

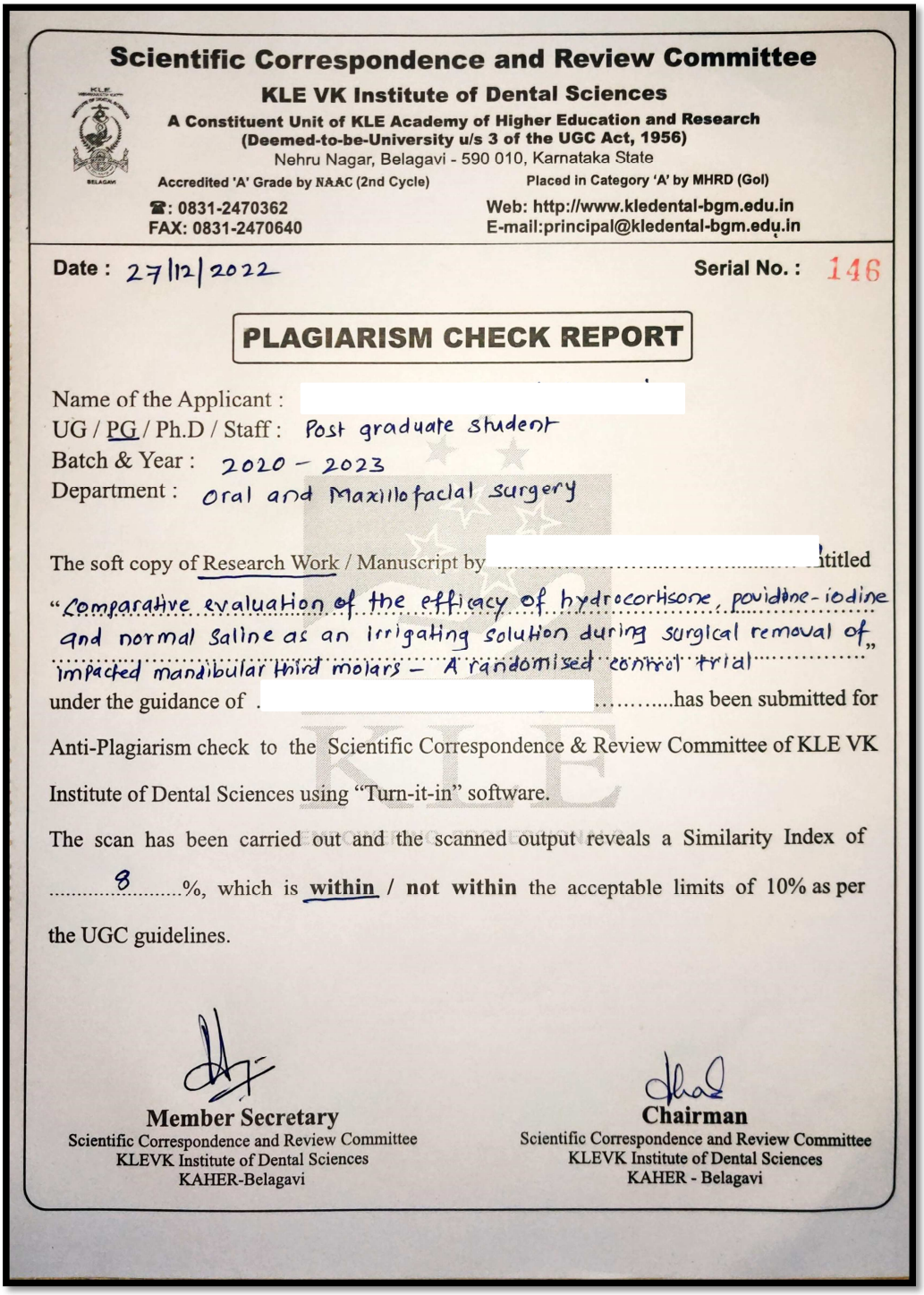
Name & Signature of Biostatistician

Place: Belagavi
Date: 26/12/2022

DEPARTMENT OF EPIDEMIOLOGY & BIOSTATISTICS • KAHER'S BELAGAVI

ANNEXURE-III

PLAGIARISM CHECK REPORT



Scientific Correspondence and Review Committee

KLE VK Institute of Dental Sciences

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Date : 27/12/2022 **Serial No. :** 146

PLAGIARISM CHECK REPORT

Name of the Applicant :
UG / PG / Ph.D / Staff : Post graduate student
Batch & Year : 2020 – 2023
Department : Oral and Maxillofacial surgery

The soft copy of Research Work / Manuscript by ..... titled "Comparative evaluation of the efficacy of hydrocortisone, povidone-iodine and normal saline as an irrigating solution during surgical removal of impacted mandibular third molars – 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 8%, which is **within** / **not within** the acceptable limits of 10% as per the UGC guidelines.

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

ANNEXURE-IV

KAHER's KLE VK Institute of Dental Sciences
Department of Oral and Maxillofacial Surgery
Belagavi

"COMPARATIVE EVALUATION OF THE EFFICACY OF HYDROCORTISONE, POVIDONE-IODINE AND NORMAL SALINE AS AN IRRIGATING SOLUTION DURING SURGICAL REMOVAL OF IMPACTED MANDIBULAR THIRD MOLARS: A RANDOMIZED CONTROL TRIAL"

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

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

1. I 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 also 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 2nd and 7th day.

Name: Date:
Signature: Mob. No:

Name of the Doctor: Dr.
Doctor's contact:
Hospital contact:

ANNEXURE V

KLE Vishwanath Katti Institute of Dental Sciences, Belagavi
Department of Oral and Maxillofacial Surgery

Patient Information Sheet

"Comparative evaluation of the efficacy of Hydrocortisone, Povidone-Iodine and Normal Saline as an irrigating solution during surgical removal of impacted mandibular third molar- 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 (@9740994481) if you would like any further information.

The purpose of this research study is the comparative evaluation of the efficacy of Hydrocortisone, Povidone-Iodine 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 105 participants who will be examined and surgical extraction will be performed on them. During this procedure, three different types of irrigating solutions (Hydrocortisone, Povidone-Iodine 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 2nd 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.

Dr.
Post-Graduate Student (MDS)
Dept. of Oral and Maxillofacial Surgery

Place:
Date:
Signature of participant:
Contact no:
Address:

ANNEXURE VI - 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:

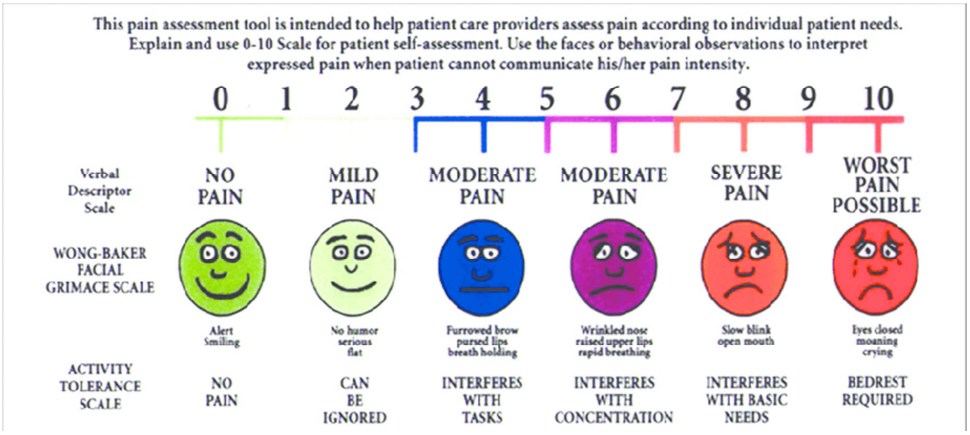
Method of Extraction:

Closure Of Site:

MEDICATION

FOLLOW-UP:

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



2nd DAY	7th DAY

2. SWELLING

MEASUREMENT	Preoperative	Post operativeday 2	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 2**	**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: