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EFFECT OF INTRACANAL CRYOTREATED CHLORHEXIDINE ON POSTOPERATIVE PAIN AFTER ROOT CANAL TREATMENT – A RANDOMIZED CONTROLLED CLINICAL TRIAL

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ABSTRACT

Introduction: Pain management during and after root canal treatment stands as a pivotal aspect of endodontic care. Post-endodontic pain may stem from microbial, mechanical, or chemical factors, or a combination thereof. Effectively managing this pain is integral for a practitioner's success. Diverse techniques have been explored to mitigate postoperative pain, encompassing preprocedural analgesics, prolonged local anaesthesia, optimal instrumentation, proper irrigant use, occlusal adjustments, and psychological interventions. Cryotherapy, a novel pain management approach utilized in sports medicine and general surgery, has shown promise in postoperative care. Using cold materials to reduce tissue temperature and successfully manage pain is known as cryotherapy. **Aim:** This study sought to assess the efficacy of intracanal cryotreated chlorhexidine in managing postoperative pain following single-visit RCT in patients presenting symptomatic irreversible pulpitis/apical periodontitis. **Materials and Methods:** 62 patients receiving a single-visit randomized controlled trial were split equally into two groups (n = 31 each) for the purpose of the study. Group A received room temperature chlorhexidine (20 millilitres for five minutes per canal), and Group B received cryotreated chlorhexidine (20 millilitres kept between 2℃-4℃ for five minutes per canal). Patients were taught how to complete the VAS scale and record their preoperative VAS score prior to therapy. Post-treatment, patients were contacted at 6, 24, and 48 hours to assess post-endodontic pain. Additionally, the number of patients consuming analgesics at these time points was recorded. Statistical analysis employed Mann-Whitney U Test for inter-group VAS score comparisons, Wilcoxon Signed Ranks Test for intra-group VAS score comparisons, and Chi-square test for analgesic intake. A significance level of $P \leq 0.05$ was applied. **Results:** Cryotreated chlorhexidine exhibited superior pain control over room temperature chlorhexidine, reflected in lower postoperative pain scores at 6, 24, and 48 hours. Both groups displayed a decline in pain trends throughout the postoperative period. Analgesic consumption decreased over 48 hours in both groups without significant differences between them. **Conclusion:** Flushing the canal with cold chlorhexidine proved effective in controlling post-endodontic pain. This strategy shows potential as an essential step in endodontic therapy for the relief of pain following endodontic surgery.

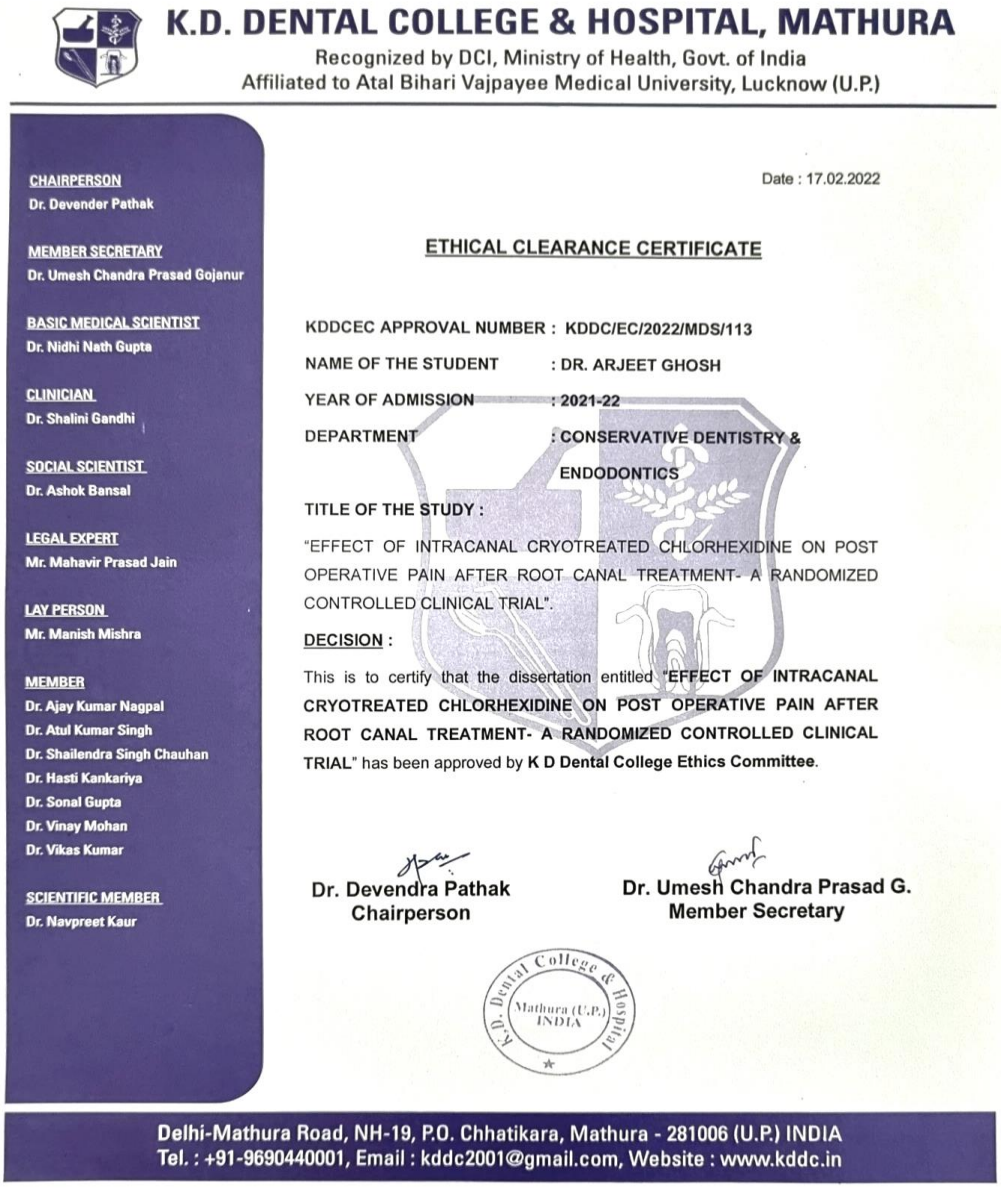
KEYWORDS: Additionally, the number of patients consuming analgesics at these time points was recorded.

INTRODUCTION

Patients primarily attend dental clinics to seek for immediate relief from pain. Certain dental procedures may cause patients to experience discomfort following surgery. Either a periodontal or endodontic (usually) cause could be the source of the pain.

Despite the fact that endodontic pain is more prevalent, it is important to distinguish between periodontal and endodontic origin pain in order to provide a correct diagnosis, which will enable appropriate pain management for any dental discomfort and reduce the risk of complications following surgery. By exercising extra caution during the endodontic treatment procedure, this pain may be reduced. The randomized controlled trial must be carried out to the highest possible standard at every stage. A few instances include precisely calculating the working length, disocculding the teeth, performing proper biomechanical preparation with the appropriate instruments in the right order, utilizing irrigants wisely and as thoroughly as feasible, and employing magnifying tools dental loupes and endodontic microscopes, for example.[1]

INSTITUTIONAL ETHICAL COMMITTEE CERTIFICATE



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KDDCEC APPROVAL NUMBER : KDDC/EC/2022/MDS/113
NAME OF THE STUDENT : DR. ARJEET GHOSH
YEAR OF ADMISSION : 2021-22
DEPARTMENT : CONSERVATIVE DENTISTRY & ENDODONTICS

TITLE OF THE STUDY :

"EFFECT OF INTRACANAL CRYOTREATED CHLORHEXIDINE ON POST OPERATIVE PAIN AFTER ROOT CANAL TREATMENT- A RANDOMIZED CONTROLLED CLINICAL TRIAL".

DECISION :

This is to certify that the dissertation entitled "EFFECT OF INTRACANAL CRYOTREATED CHLORHEXIDINE ON POST OPERATIVE PAIN AFTER ROOT CANAL TREATMENT- A RANDOMIZED CONTROLLED CLINICAL TRIAL" has been approved by K D Dental College Ethics Committee.

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Chairperson

Dr. Umesh Chandra Prasad G.
Member Secretary

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Postendodontic pain usually lasts for the initial 24 to 48 hours following obturation,[2] though it can sometimes last some days.[3]

Even when the endodontist has treated the patient according to accepted norms, postendodontic pain is prevalent.[4] Postendodontic pain frequencies vary from 1.53 to 53 percent.[5]

Inadequate biomechanical preparation, irrigant extrusion, intracanal medicament dressing, supra occlusion, missed canals, periapical lesions, extrusion of debris through apical foramen, and maintaining the apical patency during biomechanical preparation are common factors that influence the prognosis following root canal therapy.[6]

Many methods have been devised to control pain following surgery, like the use of corticosteroids and

prophylactic analgesics, long-lasting anaesthesia, crown-down root canal preparation, and occlusal reduction.[7–11]

Ibuprofen is more effective at managing post-procedural pain as per recent studies on the use of NSAIDS for pain management following RCT.[12]

Cryotherapy has long been used in surgical procedures and injury during sports for pain reduction and postoperative care.[13,14] It has been used to treat lower back pain, tendonitis, sprains, arthritis, injuries during sport, runner's knee, discomfort and swelling after hip or knee replacement surgery, as well as swelling while wearing a splint or plaster cast.[15]

Van't Hoff's law states that applying cold to the skin and subcutaneous tissues inhibits neural receptors, reduces cellular metabolism, and causes vasoconstriction. Applying cold essentially removes heat from tissues, causing them to become colder.[16] Vasoconstriction happens at lower temperatures, which prevents oedema formation.[17–19] Vasoconstriction also reduces the metabolism of cells, which lowers their oxygen requirement and controls the generation of free radicals within tissues. It has also been observed that as temperature rises, inflammatory enzyme levels rise.[20]

It has been demonstrated that applying cold locally to the skin can change pain threshold and lessen pain.[14,16,21] The ability of nerves to conduct signals is also impacted by cryotherapy.[22]

Specialized nerve endings called nociceptors are triggered when tissue is damaged. Thermoreceptors represent an additional category of pain receptors, as they are temperature-sensitive nerve endings that respond to variations in temperature. Cryotherapy can activate these thermoreceptors and prevent nociception in the spinal cord.[16]

Cryotherapy has been used in dentistry to treat pain and swelling following intraoral surgical procedures, including implant placement, periodontal surgery, and extractions.[23]

The application of saline solution which was kept at 2.5°C for a duration of five minutes has the potential to decrease the outer surface temperature of the root by over 10 degrees Celsius and alleviate periradicular tissue irritation.[24]

Through intracanal delivery by a negative pressure irrigation with a 2.5°C saline solution, Vera et al. report that the outer root surface temperature was lowered by over 10°C and sustained long enough to potentially have an anti-inflammatory effect in the surrounding periapical tissue.[25]

Imperial Chemical Industries (Manchester, UK) produced chlorhexidine as an antiseptic agent in the 1950s. In addition to being a component in toothpaste and mouthwash, chlorhexidine is frequently used as an antiseptic in medical practice.[26]

Chlorohexidine is a chemical with a pale straw hue that is nearly odourless. It is extensively employed in the fields of veterinary medicine, dentistry, and food science. A core hexamethylene chain connects the two symmetric 4 cholorophenyl rings and two biguanide groups of CHX, a synthetic cationic bis-guanide. 2% Chlorohexidine as an irrigant possesses broad spectrum of antimicrobial activity and substantivity and less toxicity, but it does not have tissue dissolving properties and also cannot remove smear layer so chlorhexidine cannot be used as main root canal irrigant.[27]

But there is no research on whether or not cryotreated chlorhexidine lessens the pain after RCT.

AIM

The aim of the investigation was to assess the effectiveness of intracanal cryotreated chlorhexidine on postoperative pain management following single-visit RCT in patients with symptomatic irreversible pulpitis/apical periodontitis.

OBJECTIVES

- To estimate the effectiveness of cryotreated chlorhexidine and room temperature chlorhexidine in reducing pain after single-visit RCT using various parameter likes – pain after 6 hours, 24 hours and 48 hours using VAS.
- To evaluate the number of patients among the two experimental groups taking analgesic after 6 hours, 24 hours and 48 hours of RCT.

MATERIALS AND METHOD

1. Source of Data

Department of Conservative Dentistry & Endodontics, Kanti Devi Dental College, UP, Mathura.

2. Data Collection

A. Sample size

i. Sixty-two adult patients aged between 18-70 years was participated in this clinical study.

ii. Two groups of sixty-two patients were randomly assigned. 31 patients in each group.

GROUP A: In each canal, 20 millilitres of room temperature chlorhexidine was used as irrigation for five minutes.

GROUP B: In each canal, 20 millilitres of cryotreated chlorhexidine kept between 2℃-4℃ was irrigated for five minutes.

iii. In the pursuit of rigorous statistical analysis for our thesis, G*Power software was employed, configuring a nuanced effect size of 0.8 alongside a critical significance level of 0.05, attaining a robust 85% statistical power. The derived sample size stands at 62, meticulously allocated with parity, yielding 31 participants per group, which is 1:1 distribution per arm.

$$n = \frac{2 \times (Z\alpha/2 + Z\beta)^2}{\delta^2}$$

Where

- $Z\alpha/2$ = 1.96 (for α = 0.05)
- $Z\beta$ = 1.036 (for a power of 0.85)
- δ = 0.8 (effect size)

Using the formula: n = $[2 \times (1.96 + 1.036)^2] \div 0.8^2$

- Initial calculation yields n ≈ 28.05 (per arm). So, total= 2x 28.05= 56
- Considering an anticipated attrition rate of around 10.7%, Final chosen sample size: 62.

So, considering an anticipated attrition rate of around 10.7%, we have adjusted the sample size upwards to account for potential dropouts. So, after considering the 10% attrition rate, the final chosen sample size is 62.

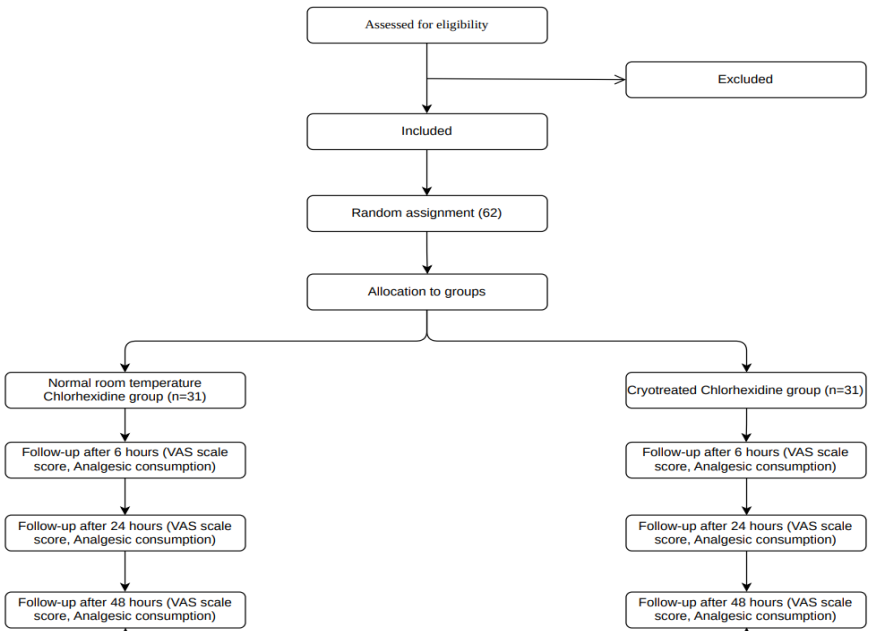
B. Study Design

This research was designed as a randomized clinical experiment to determine the impact of intracanal cryo-treated chlorhexidine on the discomfort experienced by patients after receiving a root canal treatment due to apical periodontitis or symptomatic irreversible pulpitis in teeth with single roots. The study setting was K.D. Dental College & Hospital, Mathura, UP. Institutional ethics board accepted the research protocol.

Study Setting [Fig 1].

Fig 1: Study setting (K.D. Dental College & Hospital, Mathura).

Study flowchart



C. Method of data collection

Following recruitment of patients they were asked to report the preoperative VAS score. After the RCT the same patients were asked over telephone at three different time points (6, 24, 48 hours) about the postoperative VAS pain score. In addition, they were also asked to report whether they had taken analgesic or not. All of these responses were recorded on the patient's chart using the 10-point Visual Analogue Scale.

D. Feasibility: We have made sure that resources are available for data gathering and analysis while evaluating feasibility. A reasonable schedule has been set, taking into account any obstacles. Participant confidentiality has been ensured by addressing ethical considerations. The goals of this study are to be realistic, attainable, and methodologically sound.

3. Inclusion Criteria

i. Patients who signed the informed consent form and were between the ages of 18 and 70.
ii. Individuals who need endodontic treatment.
iii. Healthy patients without systemic disease.
iv. A tooth that exhibits signs of symptomatic irreversible pulpitis.

4. Exclusion criteria

i. Patients unwilling to take part in the trial and who refused to give informed consent.
ii. Medically compromised.
iii. Pregnant woman.
iv. Those receiving antibiotic treatment.
v. Those taking analgesics.
vi. Teeth with calcified canals.
vii. Teeth with incomplete apex formation.
viii. Sinus opening.
ix. Periapical abscess.

5. Discontinuation Criteria

i. Improper Obturation
ii. Sealer Extrusion
iii. Unable to contact patients for follow-up

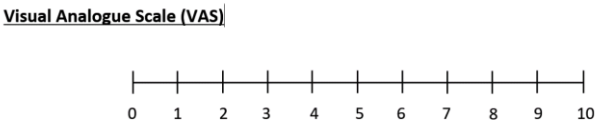
6. METHODOLOGY

Randomization

For random selection of the irrigation solution, 62 paper slips were coded either Group A or Group B (31 for each irrigation solution) and placed in a closed envelop. Each patient picked a slip before the initiation of treatment and was administered the irrigation solution that corresponded to the slip picked by the patients randomly. Each patient was assigned a separate evaluation sheet along with the consent form.

Pre- Operative instructions

The patients' pretreatment pain scores were noted and they were taught how to use a visual analogue scale (VAS) to assess their level of discomfort before therapy. A 10-centimeter straight horizontal line with numbers at each centimetre was part of the VAS. The criteria were as follows: zero for no pain, 1 to 3 for mild pain, 4 to 6 for moderate pain, 7 to 9 for severe pain, and 10 for worst pain.



i. Detailed Methods

1. At first patients with single rooted anterior tooth with symptomatic irreversible pulpitis were selected.
2. Electric pulp testing and cold tests were used to determine vitality.
3. The patient received a local anaesthetic (1:80,000 epinephrine mixed with 2% lidocaine).
4. A rubber dam was utilized to isolate the teeth.
5. Using an Endo access bur size 2, the access cavity was created with plenty of water cooling.
6. Using an apex locator and stainless-steel #10 K-files, the working length was measured. After that Using an IOPA radiograph, it was verified.
7. The K-file with a size of 20 was manually instrumented.
8. Canal was prepared with an endomotor running at 300 RPM and Protaper Universal Rotary files up to file F3.
9. Using 10 no. K files, apical patency had been maintained during the shaping process.
10. Throughout the entire preparation procedure, 10 ml of 3% NaOCl was injected into each canal between files using a 30 G double-side vented irrigation needle.
11. Canals were irrigated with normal saline. The temperature of the cold chlorhexidine was maintained for the five-minute irrigation period by keeping the irrigation syringes, which were used one at a time, in a special box that was filled with ice after being taken out of the refrigerator and a digital thermometer was placed inside the box to confirm the 2°C–4°C temperature range.
12. Following shape and cleaning, patients were divided into two groups.

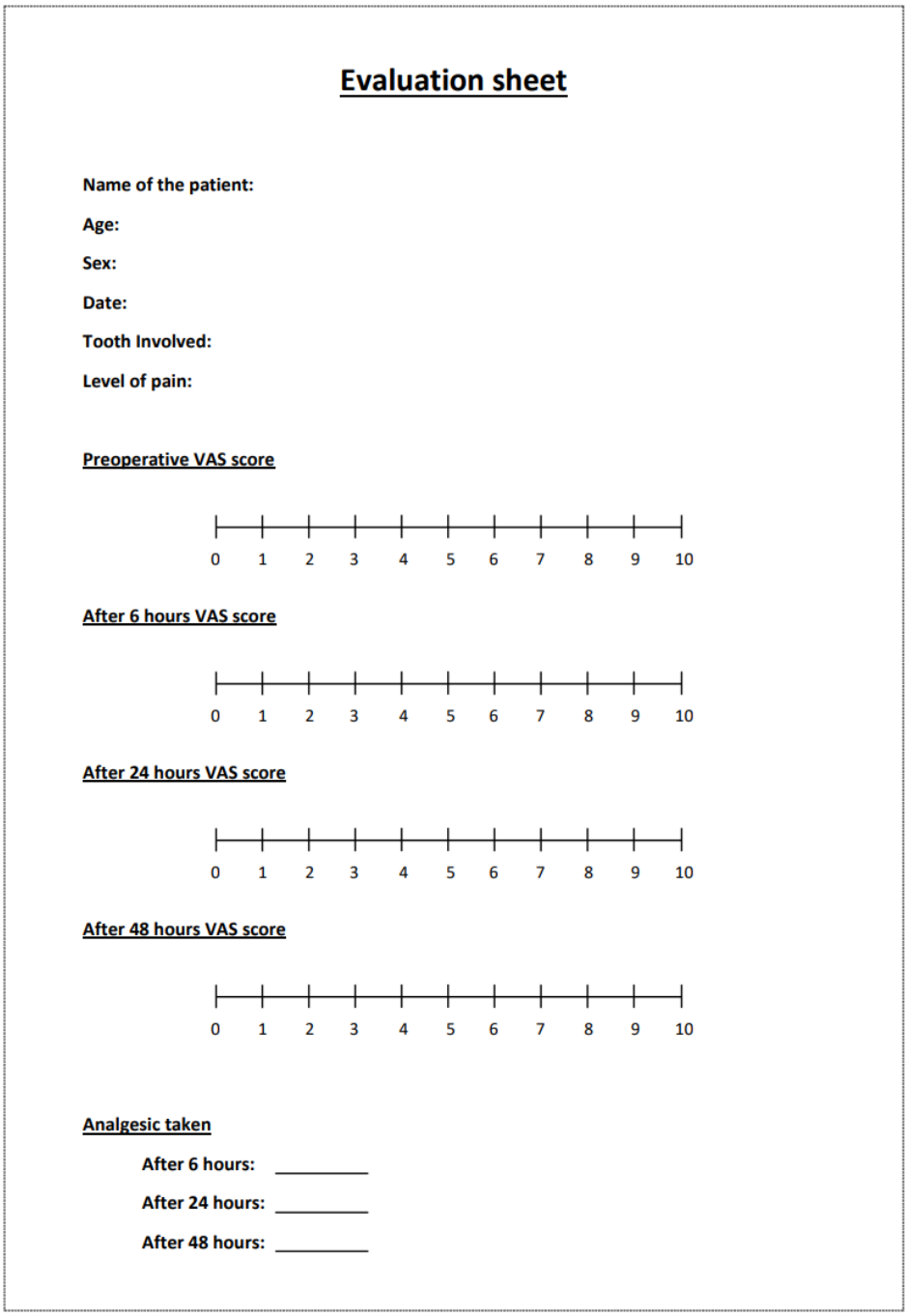
Group A: (Room temperature group) and Group B: (Cryotreated group).

13. In group A, 20 ml of chlorhexidine at ambient temperature was irrigated for 5 minutes in each canal. While In group B, 20 ml of cryotreated chlorhexidine kept at 2–4°C was irrigated [Fig 24] for 5 minutes in each canal.

(By storing the irrigation syringes, which were used one at a time, in a special box that was filled with ice after being taken out of the refrigerator and a digital thermometer was placed inside the box to confirm the 2°C–4°C temperature range, the temperature of the cold chlorhexidine was maintained for the five-minute irrigation period.)

14. Following the irrigation process, each canal was given one last saline rinse and dried with paper points of the proper size.
15. During the same visit, the canal was sealed using resin-based sealant and gutta-percha cones of the proper size.
16. After that, an IOPA radiograph was taken to confirm that the root canal had been properly obturated; any inappropriate obturation was removed from the study.

ii. Evaluation Sheet



Evaluation sheet

Name of the patient:

Age:

Sex:

Date:

Tooth Involved:

Level of pain:

Preoperative VAS score

0 1 2 3 4 5 6 7 8 9 10

After 6 hours VAS score

0 1 2 3 4 5 6 7 8 9 10

After 24 hours VAS score

0 1 2 3 4 5 6 7 8 9 10

After 48 hours VAS score

0 1 2 3 4 5 6 7 8 9 10

Analgesic taken

After 6 hours: _____

After 24 hours: _____

After 48 hours: _____

iii. Armamentarium list

1. Electric pulp tester (Parkell, Inc. USA) [Fig 2]
2. Endo frost (Coltene-Roeko, Germany) [Fig 3]
3. 2% lignocaine with epinephrine 1:80000 (Lignox, Indoco remedies ltd. India) [Fig 4]
4. 24 G, 3 ml syringe (Sterilife, India) [Fig 5]
5. Rubber dam kit (Coltene-Hygenic, Germany) [Fig 6,7]
6. Endo access bur #2 (Dentsply Maillefer, Switzerland) [Fig 8]
7. No. 10, 15, 20 K files (Dentsply- M access, Switzerland) [Fig 9]

8. Electronic apex locator (Woodpecker- Woodpex III, China) [Fig 10]
9. RVG (Vatech, India)
10. Endomotor (Dentsply Sirona- X smart plus, Switzerland) [Fig 11]
11. Protaper universal rotary file SX-F3 (DentsplyMaillefer, Switzerland) [Fig 12]
12. Double side vented 30G irrigation needle (Master clean 2) [Fig 13]
13. 5 ml Syringe (Suyash, India) [Fig 14]
14. Digital thermometer (DKP Medicams, India) [Fig 15]
15. Digital Stopwatch (Taksun, China) [Fig 16]
16. 3% NaOCl (Chemident, India) [Fig 17]
17. 0.9% Saline (KRPL, India) [Fig 18]
18. 2% Chlorhexidine (Safe Endo, India) [Fig 19]
19. Box containing ice [Fig 20]
20. Protaper universal paper points F3 (Dentsply Maillefer, Switzerland) [Fig 21]
21. Protaper universal Gp F3 (Dentsply Maillefer, Switzerland) [Fig 22]
22. AH Plus sealer (Dentsply Maillefer, Switzerland) [Fig 23]

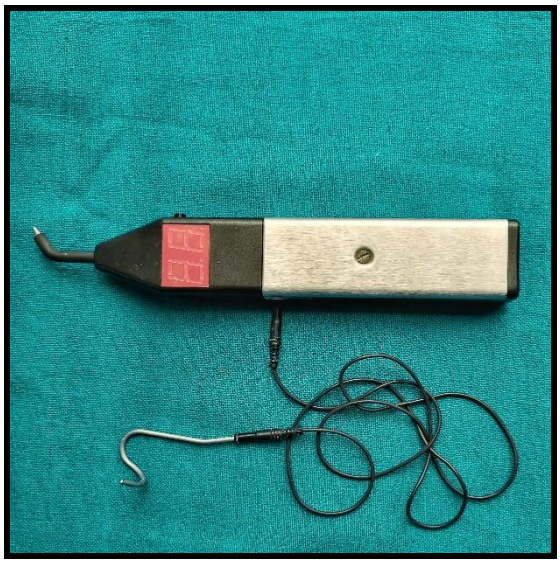


Fig.2: Electric pulp tester.

Fig.3: Endo frost.

Fig.4: Local anaesthesia.

Fig.5: 24G, 3ml syringe.

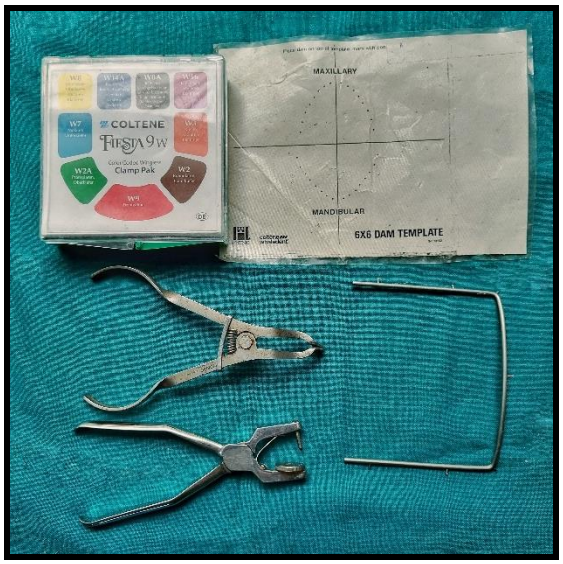


Fig. 6: Rubber dam kit.

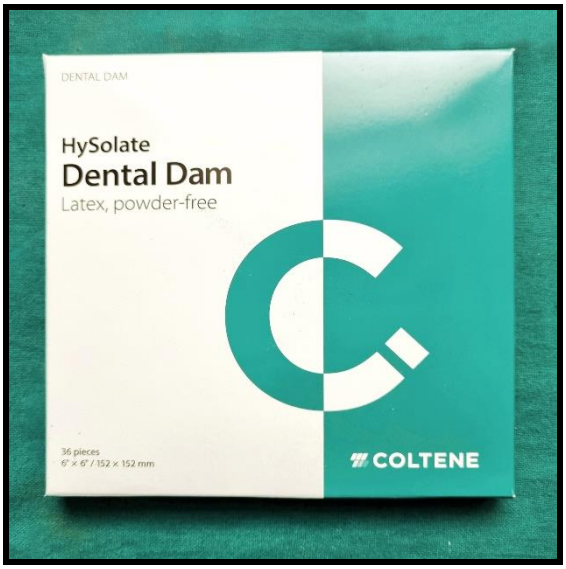


Fig. 7: Rubber dam.

Fig. 8: Endo access bur #2.

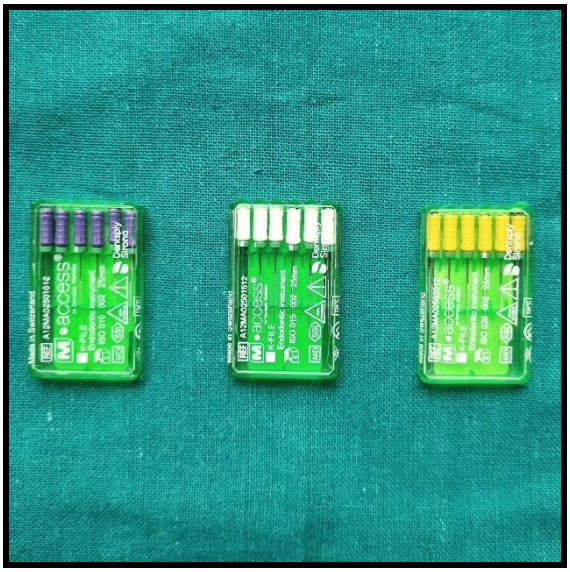


Fig. 9: No. #10, #15, #20 K files.

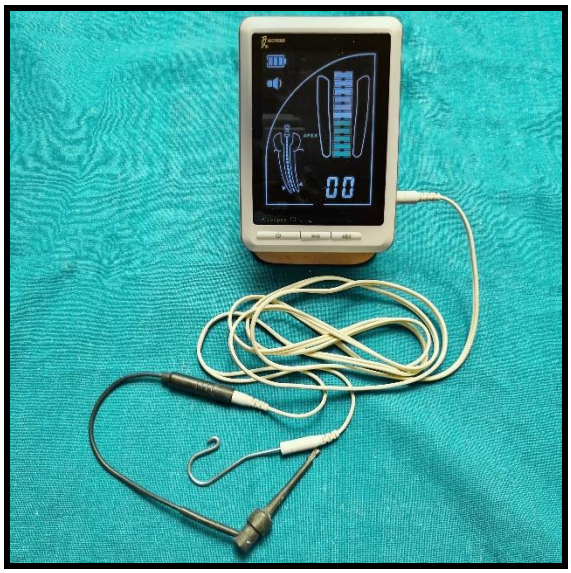


Fig 10: Electronic apex locator.

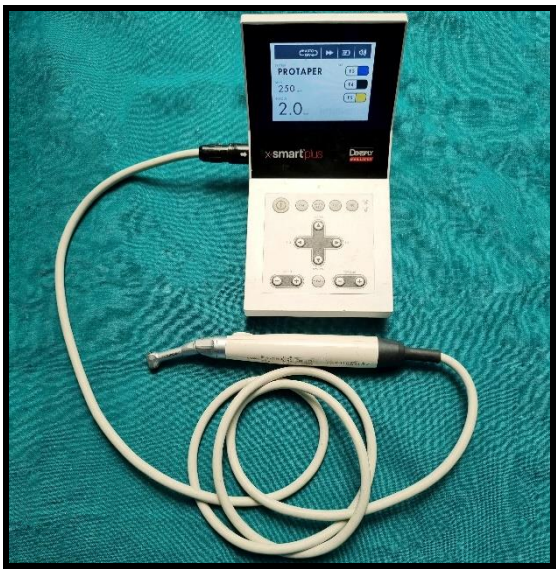


Fig 11: Endomotor.

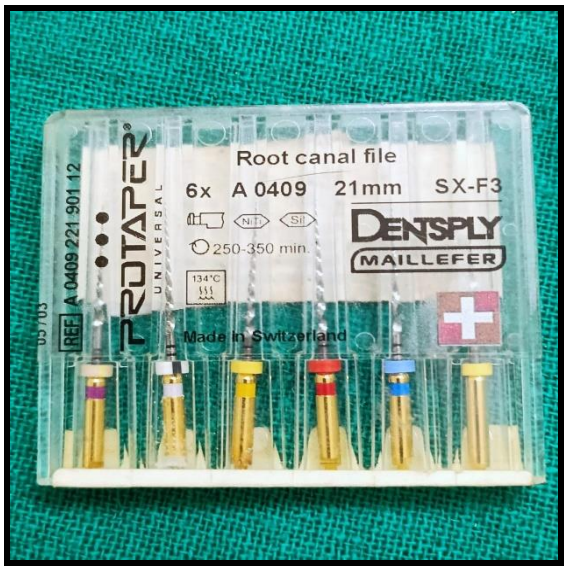


Fig 12: Proateper Universal rotary files.

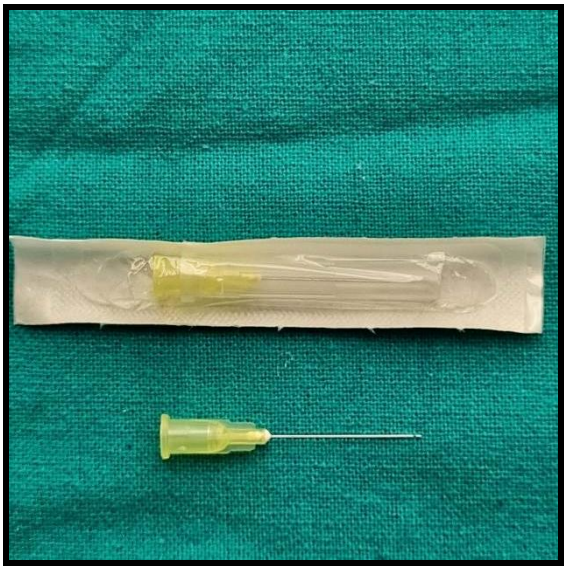


Fig 13: Double side vented irrigation needle.

Fig 14: 5ml Syringe.

Fig 15: Digital thermometer.

Fig 16: Digital stopwatch.

Fig 17: 3% NaOCl.

Fig 18: 0.9% Saline.

Fig 19: 2% Chlorhexidine.

Fig 20: Box containing ice.

Fig 21: Protaper universal paper point #F3.

Fig 22: Protaper universal Gp #F3.

Fig 23: AH Plus sealer.

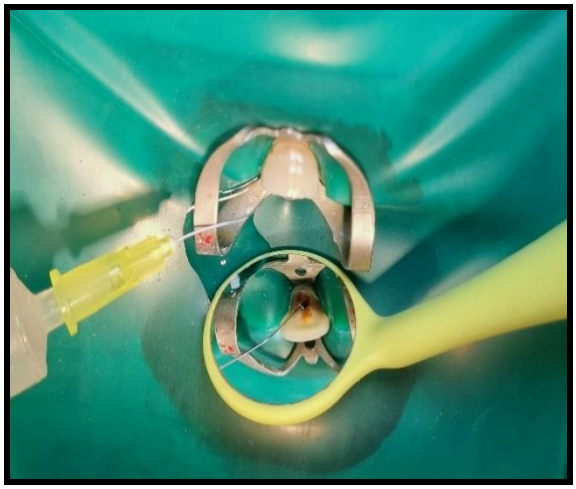


Fig 24: Irrigation.

7. Stastical Analysis

Microsoft Excel 2021 and SPSS 21 applications were used to analyze the data.

Mann-Whitney U Test is used to compare the VAS score readings between groups A and B before treatment, at 6 hours, 24 hours, and 48 hours to determine which irrigating solution is more effective at reducing postoperative pain.

Using the Wilcoxon Signed Ranks Test, an intragroup comparison was conducted between groups A and B at various time intervals (pre-operative, 6 hours, 24 hours, and 48 hours).

The analgesic intake of groups A and B is compared at 6-, 24-, and 48-hour intervals using the chi square test.

The threshold of significance for differences was set at $P < 0.05$ for all tests that were run.

RESULT AND OBSERVATIONS

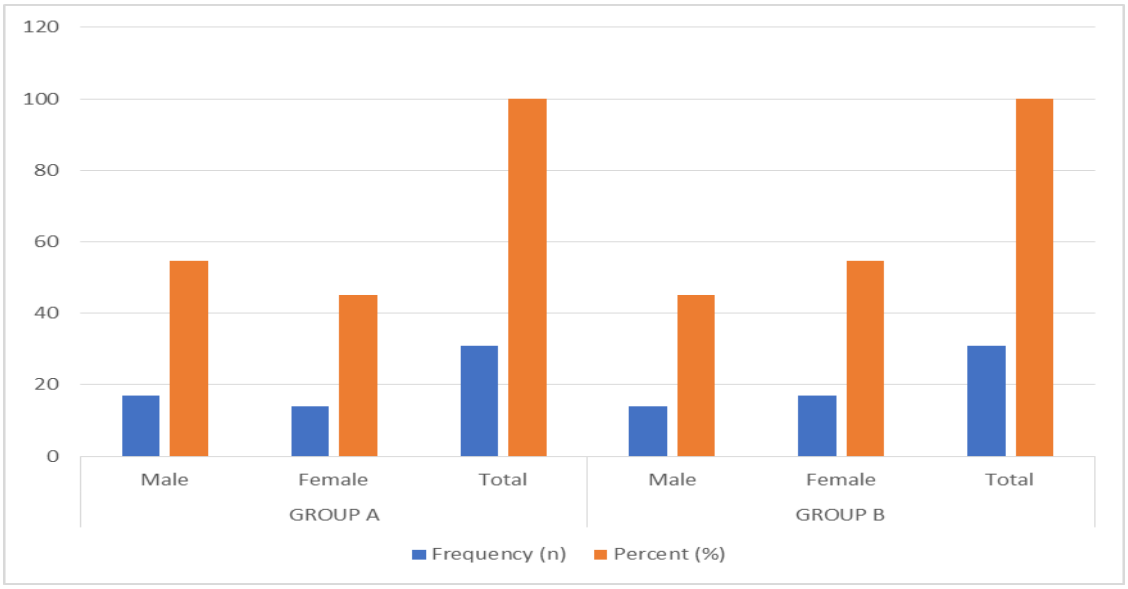
This randomized controlled trial's objective was to evaluate how intracanal cryotreated chlorhexidine affected patients' postoperative discomfort following root canal therapy. The 62 single-visit RCTs of 62 teeth on 62 patients ranging in age from 17 to 64 made up the study sample.

Patients were divided into two different groups (Group A and Group B) equally at random. Group A will irrigate each canal for five minutes with 20 millilitres of chlorhexidine at room temperature, whereas Group B will irrigate each canal for five minutes with 20 millilitres of cryotreated chlorhexidine kept between two and four degrees Celsius.

There were 17 male patients and 14 female patients with in the 17 to 63 years of age in group A and 15 male and 16 female patients between 18 to 64 years of age in group B (*Table 1*) [*Graph 1*]. Mean age 40.03 in group A and 38.32 in Group B (*Table 2*) [*Graph 2*].

Table 1: Gender wise description of study population in group A and group B.

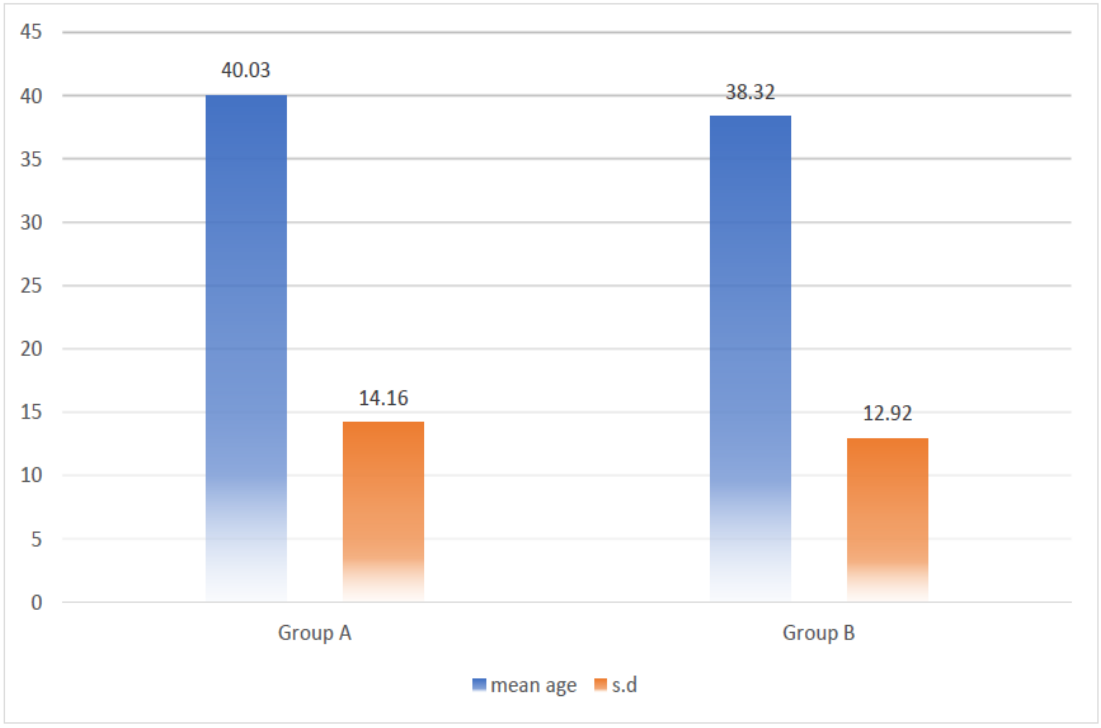
Groups	Gender	Frequency (n)	Percent (%)
Group A (Room temperature)	Male	17	54.8
	Female	14	45.2
	Total	31	100.0
Group B (Cryotreated)	Male	15	48.4
	Female	16	51.6
	Total	31	100.0



Graph 1: Gender wise graphical representation of study population in group A and group B

Table 2: Age wise distribution of study population in group A and Group B.

Groups	Mean age of study population	Standard deviation	Minimum age	Maximum age
Group A (Room temperature)	40.03	14.16	17	63
Group B (Cryotreated)	38.32	12.92	18	64



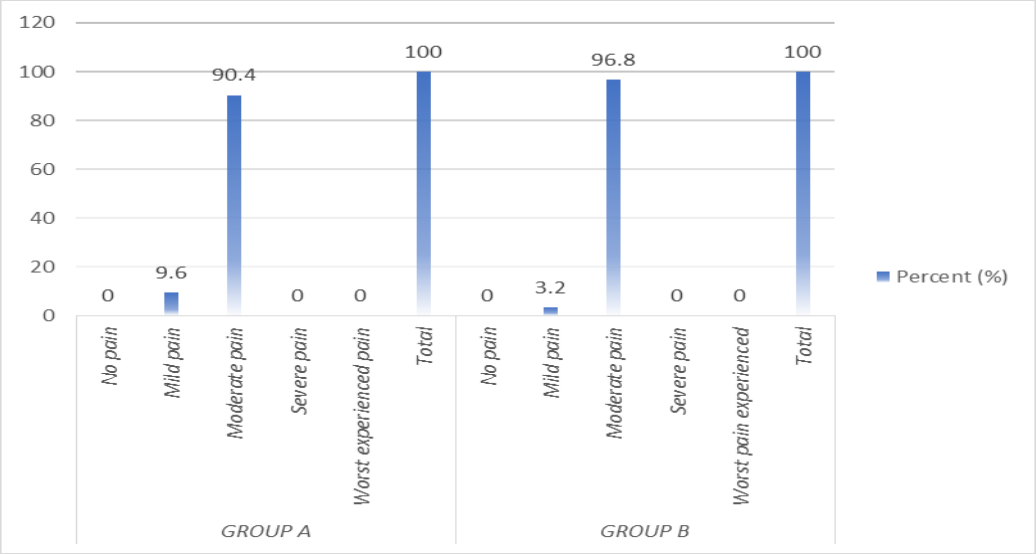
Graph 2: Graphical representation of mean age and standard deviation of study population in group A and Group B.

Preoperative VAS score comparison of pain

Preoperative VAS score showed that 3 patients had mild pain and 28 patients had moderate pain in group A and 1 patient had mild pain and 30 patients had moderate pain in group B (*Table 3*) [*Graph 3*].

Table 3: Pre operative VAS score in group A and group B.

Groups		VAS score / Pain intensity	Frequency (n)	Percent (%)
Group A (Room temperature)	No pain	0	0	
	Mild pain	3	9.6	
	Moderate pain	28	90.4	
	Severe pain	0	0	
	Worst pain	0	0	
	Total	**31**	**100.0**	
Group B (Cryotreated)	No pain	0	0	
	Mild pain	1	3.2	
	Moderate pain	30	96.8	
	Severe pain	0	0	
	Worst pain	0	0	
	Total	**31**	**100.0**	



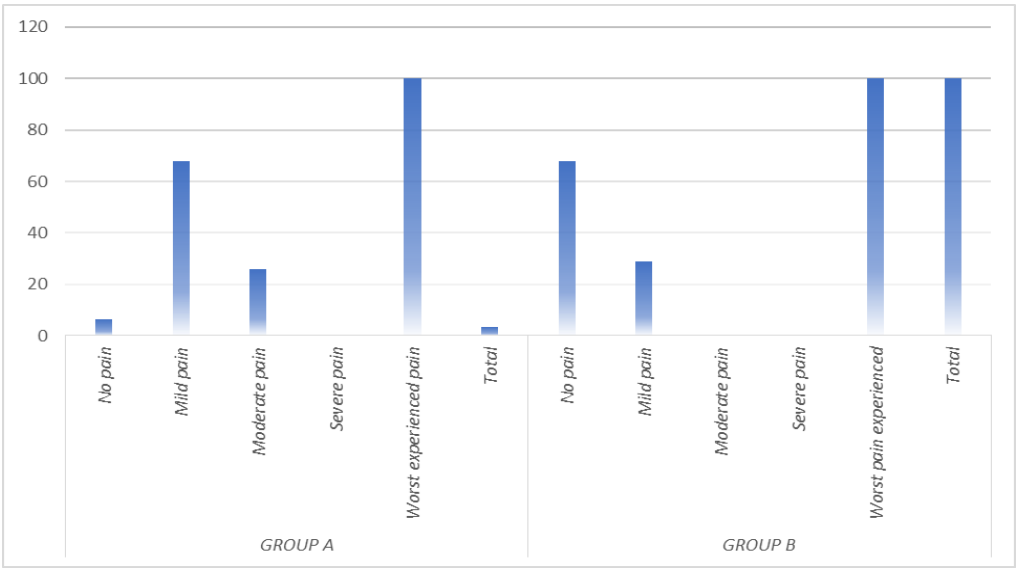
Graph 3: Graphical representation of preoperative VAS score (in %) in group A and group B.

After 6 hours VAS score of pain

After six hours in group A, two patients reported mild discomfort, twenty-one reported moderate pain, and eight reported severe pain; nevertheless, neither the greatest pain nor no pain was reported by any patients. In group B, there was no patient who reported severe or worst-case pain; instead, 21 patients reported mild pain, 9 patients reported moderate discomfort, and 1 patient reported no pain at all (Table 4) [Graph 4].

Table 4: Pain level after 6 hours of treatment in group A and group B

Group	VAS score/ Pain intensity	Frequency (n)	Percent (%)
Group A (Room temperature)	No pain	0	0
	Mild pain	2	6.5
	Moderate pain	21	67.7
	Severe pain	8	25.8
	Worst pain	0	0
	Total	**31**	**100.0**
Group B (Cryotreated)	No pain	1	3.2
	Mild pain	21	67.7
	Moderate pain	9	29.0
	Severe pain	0	0
	Worst pain	0	0
	Total	**31**	**100.0**



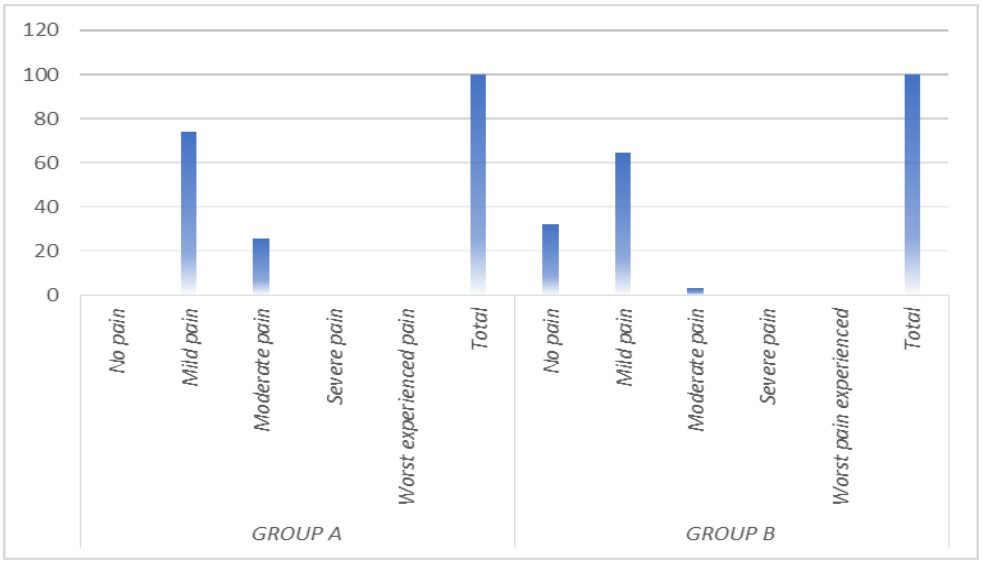
Graph 4: Graphical representation of VAS score (in %) in group A and group B after 6 hours of treatment.

After 24 hours VAS score of pain

Twenty-three individuals in group A reported light pain, eight reported moderate pain, and none reported severe or worse pain after a 24-hour period. 10 patients in group B reported no pain, 20 reported mild pain, 1 reported moderate pain, and no patients reported severe pain or the worst kind of pain (Table 5 [Graph 5].

Table 5: Pain level after 24 hours of treatment in group A and group B.

Groups	VAS score / Pain intensity	Frequency (n)	Percent (%)
Group A (Room temperature)	No pain	0	0
	Mild pain	23	74.2
	Moderate pain	8	25.8
	Severe pain	0	0
	Worst experienced pain	0	0
	Total	**31**	**100.0**
Group B (Cryotreated)	No pain	10	32.3
	Mild pain	20	64.5
	Moderate pain	1	3.2
	Severe pain	0	0
	Worst pain experienced	0	0
	Total	**31**	**100.0**



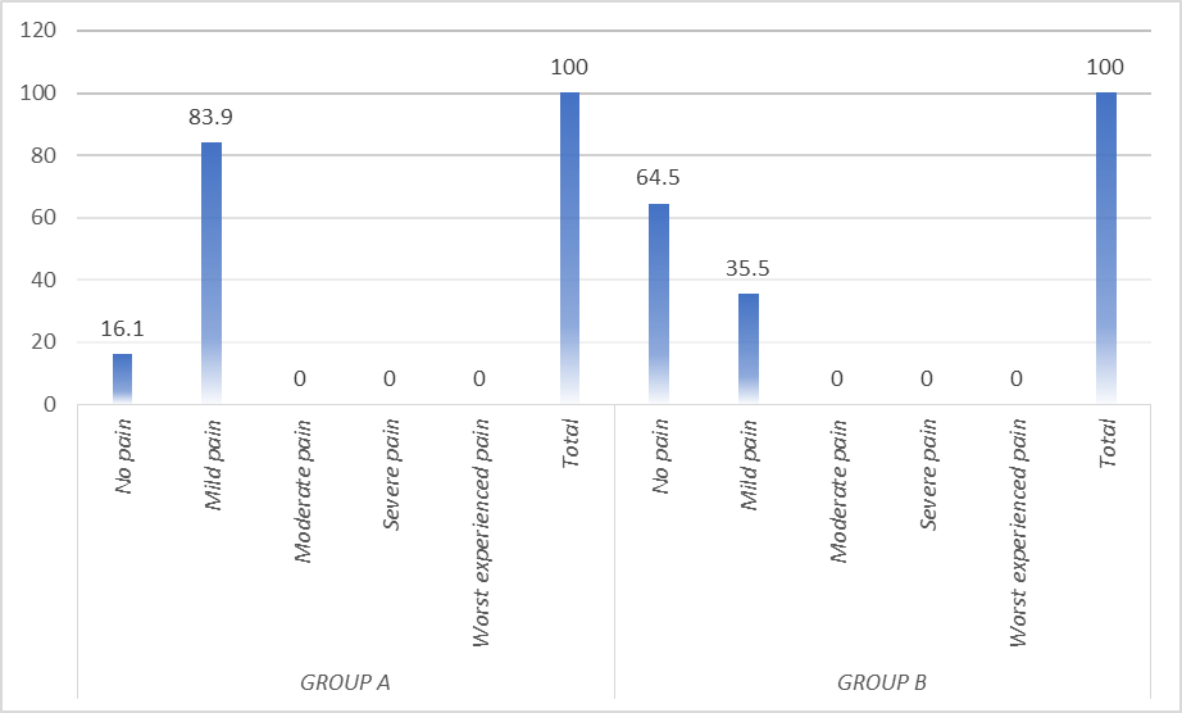
Graph 5: Graphical representation of VAS score (in %) in group A and group B after 24 hours of treatment.

After 48 hours VAS score of pain

In group A, five patients reported no pain at all after 48 hours, 26 reported light discomfort, and none reported moderate, severe, or worse pain. Group B had 20 patients who reported no pain, 11 individuals who reported mild pain, and no patients who reported moderate, severe, or worst pain (Table 6) [Graph 6].

Table 6: Pain level after 48 hours of treatment in group A and group B.

Groups	VAS score/ Pain intensity	Frequency(n)	Percent (%)
Group A (Room temperature)	No pain	5	16.1
	Mild pain	26	83.9
	Moderate pain	0	0
	Severe pain	0	0
	Worst experienced pain	0	0
	Total	**31**	**100.0**
Group B (Cryotreated)	No pain	20	64.5
	Mild pain	11	35.5
	Moderate pain	0	0
	Severe pain	0	0
	Worst experienced pain	0	0
	Total	**31**	**100.0**



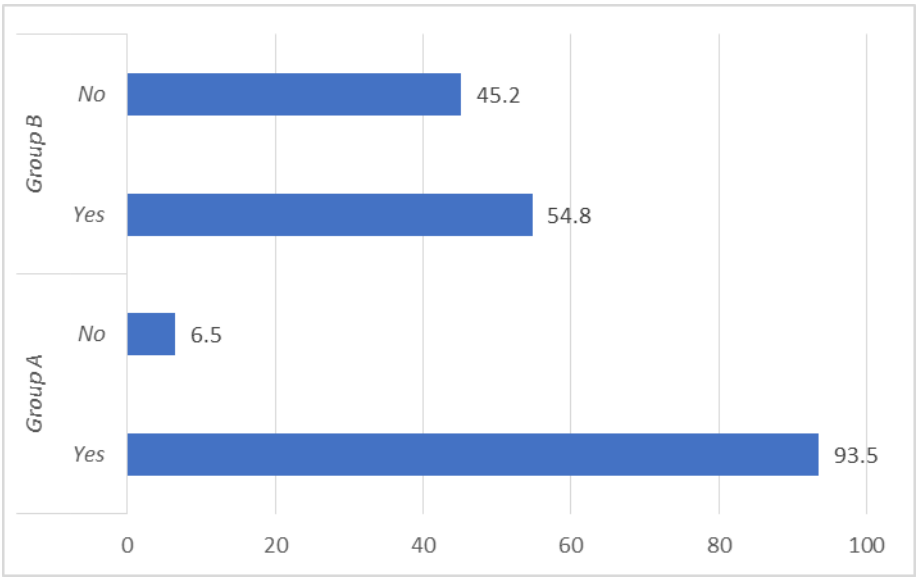
Graph 6: Graphical representation of vas score (in %) in group A and group B after 48 hours of treatment.

After 6 hours analgesic consumption

In group A after 6 hours 29 patients out of 31 taken analgesic and in group B 17 patients taken analgesic out of 31 patients (*Table 7*) [*Graph 7*]

Table 7: Analgesic taken after 6 hours of treatment in group A and group B.

Groups	Analgesic taken	Frequency (n)	Percent (%)
Group A (Room temperature)	Yes	29	93.5
	No	2	6.5
	Total	**31**	**100.0**
Group B (Cryotreated)	Yes	17	54.8
	No	14	45.2
	Total	**31**	**100.0**



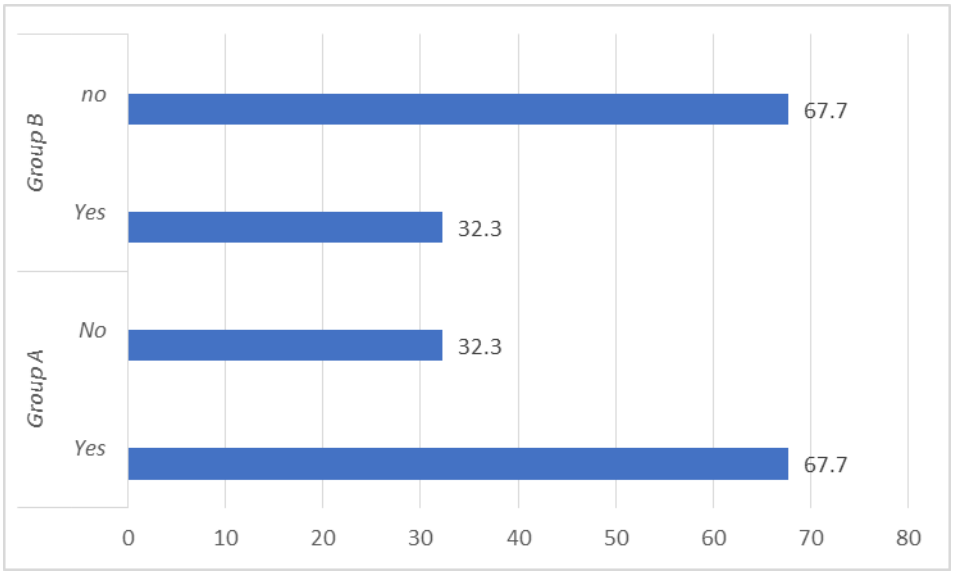
Graph 7: Graphical representation of analgesic consumption in group A and group B after 6 hours of treatment.

After 24 hours analgesic consumption

In group A after 24 hours 21 patients out of 31 taken analgesic and in group B 10 patients taken analgesic out of 31 patients (*Table 8*) [*Graph 8*].

Table 8: Analgesic taken after 24 hours of treatment in group A and group B.

Groups	Analgesic taken	Frequency (n)	Percent (%)
Group A (Room temperature)	Yes	21	67.7
	No	10	32.3
	Total	**31**	**100.0**
Group B (Cryotreated)	Yes	10	32.3
	No	21	67.7
	Total	**31**	**100.0**



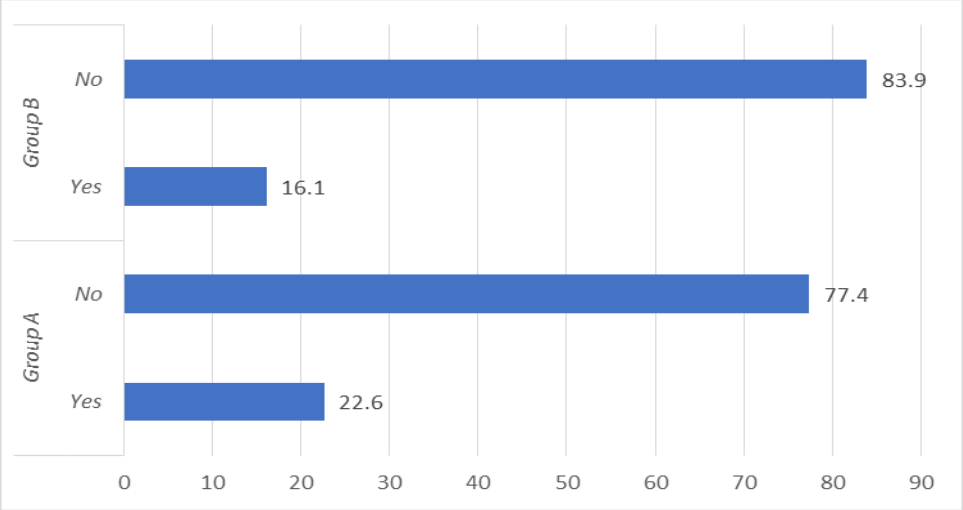
Graph 8: Graphical representation of analgesic consumption in group A and group B after 24 hours of treatment.

After 48 hours analgesic consumption

In group A after 48 hours only 7 patients out of 31 taken analgesic and in group B 5 patients taken analgesic out of 31 patients (*Table 9*) [*Graph 9*].

Table 9: Analgesic taken after 48 hours of treatment in group A and group B.

Groups	Analgesic taken	Frequency (n)	Percent (%)
Group A (Room temperature)	Yes	7	22.6
	No	24	77.4
	Total	**31**	**100.0**
Group B (Cryotreated)	Yes	5	16.1
	No	26	83.9
	Total	**31**	**100.0**



Graph 9: Graphical representation of analgesic consumption in group A and group B after 48 hours of treatment.

INTERGROUP COMPARISION OF PAIN

Comparison of pain between group A and group B was done by using Mann Whitney U test (*Table 10*).

Table 10: Mann-Whitney U Test was used for intergroup comparison of VAS between group A and group B.

VAS score	Groups	N	Mean Rank	P value
Pre operative pain	Group A	31	30.50	0.30
	Group B	31	32.50	
	Total	62		
Pain after 6 hours	Group A	31	42.69	
	Group B	31	20.31	**0.00***
	Total	62		
Pain after 24 hours	Group A	31	38.71	
	Group B	31	24.29	**0.00***
	Total	62		
Pain after 48 hours	Group A	31	39.00	
	Group B	31	24.00	**0.00***
	Total	62		

p value ≤ 0.05 is considered statistically significant

Comparison of preoperative VAS of pain

In group A mean rank of VAS score was 30.50 and in group B mean rank was 32.50. So, there is no statistically significant difference obtained on pre operative comparison of VAS score between group A and group B with p value obtained was p = 0.30.

Comparison of VAS of pain after 6 hours

In Group A mean rank of VAS score was 42.69 and in Group B mean rank was 20.31. So, between groups A and B, there was a statistically significant difference. on comparison of VAS score, 6 hours after treatment with p value obtained was p = 0.00 **Comparison of VAS of pain after 24 hours.**

In Group A mean rank of VAS score was 38.71 and in Group B mean rank was 20.31. So, the difference between groups A and B was statistically significant. on comparison of VAS score, 24 hours after treatment with p value obtained was p = 0.00.

Comparison of VAS of pain after 48 hours

In group A mean rank of VAS score was 39 and in Group B mean rank was 24. So, the difference between groups A and B was statistically significant on comparison of VAS score, 48 hours after treatment with p value obtained was p = 0.00.

INTRA GROUP COMPARISION OF GROUP A

Intra group comparison was done using Wilcoxon Ranked Test for both the groups (*Table 11,12*)

Table 11: Wilcoxon Signed Ranks Test for intra group comparison of vas scores in group A.

		N	Mean Rank	p value
Pain after 6 hours (Group A) - Preoperative pain (Group A)	Negative Ranks	1	6.00	**0.007***
	Positive Ranks	10	6.00	
	Ties	20		
	Total	31		
Pain after 24 hours (Group A) - Preoperative pain (Group A)	Negative Ranks	20	10.50	**0.00***
	Positive Ranks	0	0.00	
	Ties	11		
	Total	31		
Pain after 48 hours (Group A) - Preoperative pain (Group A)	Negative Ranks	30	15.50	**0.00***
	Positive Ranks	0	0.00	
	Ties	1		
	Total	31		
Pain after 24 hours (Group A) - Pain after 6 hours (Group A)	Negative Ranks	26	13.50	**0.00***
	Positive Ranks	0	.00	
	Ties	5		
	Total	31		
Pain after 48 hours (Group A) - Pain after 6 hours (Group A)	Negative Ranks	31	16.00	**0.00***
	Positive Ranks	0	.00	
	Ties	0		
	Total	31		
Pain after 48 hours (Group A) - Pain after 24 hours (Group A)	Negative Ranks	13	7.00	**0.001***
	Positive Ranks	0	.00	
	Ties	18		
	Total	31		

p value ≤ 0.05 is considered statistically significant

In Group A there was statistically significant difference obtained on intragroup comparison of pre operative VAS score with VAS score obtained 6 hours, 24 hours and 48 hours after treatment with p value obtained was 0.007, 0.00 and 0.00.

There was statically significant difference obtained on comparison of VAS score obtained 6 hours after treatment with VAS score 24 hours and 48 hours after treatment with p value obtained was 0.00, 0.00 respectively.

There was statically significant difference obtained on comparison of VAS score obtained 24 hours and 48 hours after treatment with p value obtained was 0.001.

INTRA GROUP COMPARISION OF GROUP B

Table 12: Wilcoxon Signed Ranks Test for intra group comparison of vas scores in group B.

		N	Mean Rank	p value
Pain after 6 hours (Group B) - Preoperative pain (Group B)	Negative Ranks	22	12.02	**0.00***
	Positive Ranks	1	11.50	
	Ties	8		
	Total	31		
Pain after 24 hours (Group B) - Preoperative pain (Group B)	Negative Ranks	29	15.00	**0.00***
	Positive Ranks	0	.00	
	Ties	2		
	Total	31		
Pain after 48 hours (Group B) - Preoperative pain (Group B)	Negative Ranks	30	15.50	**0.00***
	Positive Ranks	0	.00	
	Ties	1		

	Total	31		
Pain after 24 hours (Group B - Pain after 6 hours (Group B)	Negative Ranks	17	9.00	**0.00***
	Positive Ranks	0	.00	
	Ties	14		
	Total	31		
Pain after 48 hours (Group B - Pain after 6 hours (Group B)	Negative Ranks	28	14.50	**0.00***
	Positive Ranks	0	.00	
	Ties	3		
	Total	31		
Pain after 48 hours (Group B - Pain after 24 hours (Group B)	Negative Ranks	11	6.00	**0.001***
	Positive Ranks	0	.00	
	Ties	20		
	Total	31		

p value ≤ 0.05 is considered statistically significant

In Group B there was statistically significant difference obtained on intragroup comparison of pre operative VAS score with VAS score obtained 6 hours, 24 hours and 48 hours after treatment with p value obtained was 0.00, 0.00 and 0.00.

There was statically significant difference obtained on comparison of VAS score obtained 6 hours after treatment with VAS score 24 hours and 48 hours after treatment with p value obtained was 0.00, 0.00 respectively.

There was statically significant difference obtained on comparison of VAS score obtained 24 hours and 48 hours after treatment with p value obtained was 0.001.

INTRA GROUP COMPARISION OF ANALGESIC CONSUMPTIONS

Chi Square Test was used for comparison of analgesic intake between 2 groups (*Table 13,14,15*).

Table 13: Analgesic intake using Chi Square Test in group A and group B after 6 hours.

		Analgesic taken after 6 hours (Group B)		Total	P value
		Yes	No		
Analgesic after 6 hours (Group A)	Yes	15	14	29	0.185
	No	2	0	2	
Total		17	14	31	

p value ≤ 0.05 was considered statistically significant

Table 14: Analgesic intake using Chi Square Test in group A and group B after 24 hours.

		Analgesic taken after 24 hours (Group B)		Total	P value
		Yes	No		
Analgesic after 24 hours (Group A)	Yes	5	16	21	0.14
	No	5	5	10	
Total		10	21	31	

p value ≤ 0.05 was considered statistically significant

Table 15: Analgesic intake using Chi Square Test in group A and group B after 48 hours.

		Analgesic taken after 48 hours (Group B)		Total	P value
		Yes	No		
Analgesic after 48 hours (Group A)	Yes	1	6	7	0.88
	No	4	20	24	
Total		5	26	31	

p value ≤ 0.05 was considered statistically significant

Stastically no significant difference was obtained on comparison of analgesic intake between group A and group B with p value obtained was greater than 0.05.

DISCUSSION

Patients should take great care to avoid pain both before and after dental treatment, as dental anxiety is frequently caused by a dread of pain. Even with appropriate treatment protocols, one of the main issues with endodontic treatment is postoperative pain. Numerous clinical studies have revealed a range of pain levels, from 1.5 to 53%, even though the eradication or decrease of post-endodontic pain is a key factor in the effectiveness of endodontic treatment.

It is challenging to look at the role of a single component in postoperative pain because multiple factors influence how postoperative pain is perceived. Preoperative discomfort, for example, has been shown to be predictive of more frequent and severe postoperative pain and is suggestive of a prior damage to the periradicular area.[9,28]

Acute inflammation resulting from mechanical, microbiological, and/or chemical damage to the periapical tissues is the cause of periradicular inflammation.[29] Inflammation is the term for the body's response to damage, and it is defined by a series of events that include a reaction of an inflammatory nature, a pain-sensing sensory response, and a healing process.[30] The inflammatory response progresses through three distinct phases: the cellular, vascular, and quiet phases.

The earliest inflammatory mediators are released by the cells residing in the injured tissue during a silent phase. Vasodilation and enhanced vascular permeability are observed in the vascular phase, while leukocyte infiltration to the site of injury characterizes the cellular phase. Pain, hyperalgesia (an excessively unpleasant response to noxious stimuli), and allodynia (a nociceptive response to a normally harmless stimulus) are the sensory reactions to inflammation. Tissue cell division, neovascularization, and reinnervation of healed tissues are steps in the repair process.[30]

The initial phase of an inflammatory response is known as the silent phase. It is dependent on how the local cells in the injured tissue respond. Mast cells as well as macrophages are two of these resident cells that are important in signalling the body to tissue damage because they release mediators such as prostaglandins, nitric oxide (NO), cytokines, histamine, and kinins.

Vasomotor mediators are released by resident cells after that., the vascular phase, the second phase of the inflammatory process, takes place. Protease Activating Receptors (PARs)[31,32] are involved in the regulation of motor activities linked to the inflammatory response as well as vascular permeability. Calcitonin Gene-Related Peptide (CGRP) and substance P are two neuropeptides that are released when sensory afferents receive a signal from PARs. These neuropeptides cause vasodilatation and enhanced permeability in vascular beds.[33,34]

These two vascular processes cause plasma from the circulation to leak into the inflammatory tissues, which promotes leukocyte migration from the blood into the tissues. This starts the cellular phase of the inflammatory response, which is the third stage of the reaction.

The cellular phase of the inflammatory response begins as soon as circulating leukocytes arrive at the site of inflammation. In order to transmigrate across the endothelial cell barrier and be directed to the site of inflammation, circulating leukocytes roll onto the venular endothelial surfaces and attach to the endothelium. These rolling, adhesion, and transmigration processes are controlled by an array of adhesion molecules that are expressed by leukocytes as well as the endothelium. Leukocyte adhesion, rolling, and transmigration across the endothelium are all known to be induced by thrombin.[30]

In dentistry, a number of methods for managing pain during surgery have been established. These methods include the use of corticosteroids and preventive analgesics, long-lasting anaesthesia, crown-down root canal preparation, and occlusal reduction.

The use of cryotherapy has become a more popular method for treating post-operative pain. It has been demonstrated that cryotherapy is effective in lowering the quantity of leukocytes that cling to capillary endothelium walls. As a result, fewer of these kinds of cells migrate to the damaged tissues, which lowers inflammation and endothelial dysfunction.[23]

A decrease in local temperature following cryotherapy triggers the first physiologic tissue reaction, which lowers cellular metabolism. As a result, the damage is limited because cells utilize less oxygen and blood flow is decreased due to vasoconstriction.[35] It also affects peripheral nerve terminals by reducing both the velocity of painful nerve impulses and the threshold required to activate tissue nociceptors.[36] Through the reduction of pain signal conduction velocity and tissue nociceptors' activation threshold, cryotherapy produces a local anaesthetic effect.

Cryotherapy reduces secondary hypoxia injury by decreasing the size of the injured area and cellular metabolism, according to certain studies. Also used to treat sports injuries, tendonitis, runner's knee, arthritis, sprains, pain, and swelling after replacement of knee joint, discomfort in the lower back, and pain or swelling underneath a cast or splint.[37]

Cryotherapy has been utilized in dentistry to treat pain and oedema following intraoral surgical operations, including implant insertion, periodontal surgery, and extractions. In an in vitro investigation, George et al.[38] discovered that cryotherapy of nickel-titanium endodontic files can increase their resilience to cyclic fatigue, lowering the possibility of file separation.

In an in vitro study, Vera et al.[25] examined the role of cryotherapy in endodontics for the first time. They found that when a saline solution kept at 2.5°C was administered intracanally along with negative pressure irrigation, they found that the external root surface temperature was reduced by more than 10°C and stayed there long enough to potentially have a local anti-inflammatory action in the periradicular tissues. The

exterior root surface's lower temperature may limit inflammatory responses and lessen the release of chemicals that cause pain, which would minimize edema in the periapical area. It has been demonstrated that cryotherapy slows down peripheral nerve transmission. The conduction velocity of nerve fibres diminishes with decreasing temperature until it ceases entirely.

This randomized controlled clinical study aimed to evaluate the variation in postoperative pain following the application of cryotreated and room-temperature chlorhexidine irrigant.

To rule out the potential impacts of the existence of infected necrotic pulps and the administration of intracanal medication, the current study exclusively enrolled teeth with vital pulps that underwent single-visit root canal therapy. Anterior teeth with single root were chosen to standardize every tooth.

An electric pulp tester and a cold test were used to perform a pulp vitality test prior to treatment. We confirmed pulp viability when bleeding from the pulp chamber during access cavity preparation was observed visually, since this has been the gold-standard procedure for determining pulp vitality. This enabled us to rule out test results that were falsely positive for teeth with non-vital pulps.[39]

Patients with preexisting medical conditions were excluded from the study as well as issues related to systemic health may have an impact on the outcomes.

A disadvantage of the study was that not all potential sources of discomfort could be managed, even with all the precautions taken.

To ensure that no other source of pain or drug interaction could exacerbate the pain following endodontic therapy, only patients without a non-contributing history who had not used analgesic medication previously were included.

When opposed to the step-back technique, the step-down or crown-down approach results in a reduced likelihood of post-endodontic discomfort. This could be because, as various studies have indicated, pushing the debris past the apical foramen is a likely scenario. when using the step-back technique.[40,41] The step-down approach significantly lowers the chance of extrusion producing periapical inflammation by removing the majority of tissue debris and germs before beginning apical instrumentation.[42] Early coronal flaring is suggested by the development of rotating instruments. The advantages of early coronal flaring, according to Stabholtz et al (1995),[43] are as follows: more apical placement of irrigation needle; the establishment of a sufficient coronal escape path for debris and irrigants; and the removal of the cervical third's pulp contents before the middle and apical thirds.

According to Rosenberg et al (1998),[44] patients whose teeth initially show pulp vitality, percussion sensitivity, preoperative pain, and/or the lack of a periradicular radiolucency should not experience postoperative pain if their occlusal reduction is performed. Recent research, yet, did not discover a statistically significant variation in discomfort following occlusal reduction.[9]

After six hours of therapy, postendodontic pain in both groups showed the greatest values, which began to decrease during the monitoring periods, according to the study results.

This may be explained by the possibility that the endodontic treatment irritated the periapical area, triggering a local inflammatory reaction that resulted in postendodontic discomfort that subsided as the periapical area healed. These outcomes concurred with those of Barnett and Siqueira.[4]

In this study, post-endodontic discomfort was gradually reduced in all groups. These findings are consistent with those of Pak and White,[45] who discovered that although postendodontic pain is common, it decreases within a day of the RCT and then stays low until it reaches a minimal degree.

According to an in vitro study by Vera et al.,[25] the surface of roots temperature is capable of being lowered by more than 10°C by applying a 2.5°C saline irrigant for five minutes, which is why the researchers utilized this temperature for the cryotherapy group.

Twenty millilitres of room temperature chlorhexidine are used for irrigation in Group A, while twenty millilitres of cold chlorhexidine are used in Group B. In the cryotherapy group, the cold irrigant is left in the canal for approximately five minutes using a side-vented gauge-size 30-sized needle. To make the sole difference in irrigant temperature, the final irrigation regimen was standardized for both Groups A and B.

Additionally, Vera et al.[24] used the EndoVac (Kerr Endo, Orange Country, CA, USA) negative apical pressure device to get rid of the vapour lock effect and make sure cold irrigant was continuously delivered to the apical third. By reducing apical extrusion, EndoVac usage has also been shown to reduce the likelihood of periapical inflammatory reactions.[46,47]

During the root canal treatment of every patient in the current investigation, a standard needle irrigation method using a side-vented 30 G needle placed 2 mm less than the measured working length was used.

Since not all dental clinics have EndoVac available, it was not employed in this study. Negative apical pressure devices have been demonstrated to cause much less irrigant extrusion and postoperative pain than conventional needle irrigation.[46,47] As a result, the

needle was inserted 2 mm less than the working length, as advised by earlier research, to provide a safe irrigation procedure.[48,49] Patients in this trial reported less postoperative discomfort than the control group, even in cases when traditional side-vented needle irrigation was combined with cryotherapy.

One of the possible causes of postoperative pain is preoperative discomfort. We limited our investigation to symptomatic teeth with moderate pain levels (VAS score of 1-6) since treating symptomatic teeth is typically more necessary in clinical settings than treating asymptomatic teeth. In order to standardize all of the patients and evaluate the impact of cryotherapy in an actual clinical context, this was done for two reasons.

Preoperative pain values were thought to have minimal effects because our analysis revealed no appreciable variation in the baseline preoperative pain levels between the two groups.

To gauge the degree of postoperative pain, we used a 10-cm VAS scale with a range of 0 to 10. The VAS consisted of a straight horizontal line of 10 cm and numbered every centimetres. The criteria were as follows: no pain represented by 0, mild pain represented by 1 to 3, moderate pain represented by 4 to 6, severe pain represented by 7 to 9, and the worst agony is represented by 10.

We trained and assisted all patients in registering baseline pain scores, which familiarized them with the process and reduced the likelihood of errors occurring when keeping track of the pain score during the duration of the follow-up.

Chlorhexidine is used because it possesses substantivity qualities and higher antibacterial properties than any other irrigant.[27]

Cryotherapy may have reduced postoperative pain because it promotes vasoconstriction, which has an antioedematic effect. It also decreases blood and oxygen delivery to the area, which lowers cellular metabolism and limits tissue damage. Moreover, cold lowers the quantity of leukocytes that migrate to the site of damage, which lowers inflammation and endothelial dysfunction. Additionally, it slows down the transmission of painful nerve impulses and lowers the threshold needed to activate tissue nociceptors, both of which have an impact on peripheral nerve terminals. Since sodium hypochlorite was the irrigant utilized, the cryo treatment might have increased its antibacterial efficiency and further decreased the number of microbes, which might have further contributed to the reduction of discomfort after receiving a root canal treatment.

CONCLUSION

The effectiveness of cryotreated chlorhexidine in comparison with normal room temperature chlorhexidine was assessed in this study which shed light on the irrigation variations in temperature and its usefulness in root canal treatment. We compared two groups of patients in a parallel clinical trial which revealed that cryotreated CHX is more effective is managing postoperative pain with less number of analgesics taken by the partients at different time points (6, 24 and 48 hrs).

The clinical importance of this study is paramount as very few studies in the existing literature has compared the effectiveness of various temperatures in chlorhexidine irrigation. As far as we are aware, this is the first and only study in endodontics to compare various types of therapy. Throughout the history of endodontics, there have been conflicting and contradictory findings about various irrigation procedures, materials, and consistencies for root canal irrigation. However, effectiveness of such irrigating solutions at different temperatures is quite void and scarce. The rationale to conduct the study was to fill the gap in the currently available literature on the subject.

The usefulness of this research in clinical practice is unparalleled. This will help clinicians, endodontists and students to make informed decisions about the usage of chlorhexidine at different temperatures and their efficacy in reducing pain at different time points as measured by the intake of analgesics.

This study had a lot of advantages as well as drawbacks. The study was cost-effective, easy to conduct, less complicated and patient compliant. However, the drawbacks include the less sample size for which the external validity may be questionable. This can be considered as a pilot for further mega randomized controlled trials and can be used as a valuable reference.

Throughout the history of endodontics, root canal irrigation is indispensable and the value it holds in root canal treatment is quite magical. While our study contributes significantly to the understanding of chlorhexidine irrigation in endodontics, there are avenues for further exploration. One such area is the investigation of the long-term effects of cryotreated chlorhexidine on root canal outcomes, including success rates and the incidence of post-treatment complications such as reinfection. Additionally, future research could explore the potential synergistic effects of combining cryotreated chlorhexidine with other adjunctive therapies, such as passive ultrasonic irrigation or photodynamic therapy, to enhance its antimicrobial efficacy and overall treatment outcomes.

Furthermore, our study underscores the importance of evidence-based decision-making in clinical practice. By providing clinicians and endodontists with robust empirical data on the efficacy of cryotreated chlorhexidine, we empower them to make informed treatment decisions that prioritize patient comfort and

long-term success. However, it is essential to recognize that clinical decision-making should always be guided by a comprehensive understanding of the available evidence, as well as consideration of individual patient factors and preferences.

In conclusion, our study represents a significant contribution to the field of endodontics by elucidating the comparative efficacy of cryotreated chlorhexidine in root canal treatment. By demonstrating its superiority in managing postoperative pain and reducing analgesic consumption, we provide valuable insights that can inform clinical practice and improve patient outcomes. In order to improve patient care, we must carry out more study and innovate in order to deepen our understanding of root canal irrigation procedures and to optimize treatment protocols.

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