FEDERAL UNIVERSITY OF RIO GRANDE DO SUL

INTEGRATED RESIDENCY IN ORAL HEALTH

ORAL AND MAXILLOFACIAL SURGERY

IS CRYOTHERAPY BENEFICIAL AFTER SURGICAL REMOVAL OF IMPACTED LOWER THIRD MOLARS? – A RANDOMIZED SPLIT MOUTH CLINICAL TRIAL

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ABSTRACT

Third molar extraction is a common oral surgical procedure often associated with postoperative pain, edema, and functional limitation. Effective postoperative management plays a key role in minimizing morbidity and promoting patient comfort. Strategies such as cryotherapy may contribute to improved recovery and quality of life after surgery. **Objective:** to investigate the effects of cryotherapy on postoperative outcomes (pain intensity, edema, trismus and quality of life) following mandibular third molar extraction. **Materials and Methods:** This study was designed as a randomized split-mouth clinical trial. The sample consisted of 17 patients (34 mandibular third molars with equivalent levels of impaction) who underwent bilateral surgical extraction. The surgical sites were allocated into two groups according to postoperative care: Group A (control side—without cryotherapy) and Group B (test side—with postoperative cryotherapy using ice packs). All intraoperative and postoperative procedures, instructions, and medications were identical for both groups. Patients were evaluated for pain intensity, trismus severity, presence of edema, and quality of life for up to seven days postoperatively (D7). The evaluator was aware of the postoperative intervention applied. Repeated-measures ANOVA was used to analyze each outcome variable, and associations between continuous variables were assessed using Pearson's correlation test. Statistical significance was set at 5% ($P < 0.05$). **Results:** Overall, postoperative pain intensity was lower in patients who received cryotherapy. Group A reported significantly higher pain intensity on postoperative days 1 and 3. No signs of trismus were observed in Group B at the end of the follow-up period, whereas Group A presented restricted mouth opening at D7. Both groups exhibited edema on postoperative day 2 (D2); however, complete regression of edema by D7 was observed only in Group B. Additionally, a significant association between pain intensity and trismus severity was identified in Group A at D7. Quality-of-life assessment revealed significant differences in three questionnaire items favoring Group B, including greater perceived improvement, better mouth opening, and reduced difficulty sleeping. **Conclusion:** The findings suggest that postoperative cryotherapy is effective in reducing pain intensity and trismus following mandibular third molar extraction. Moreover, this physical therapy modality appears to enhance pain tolerance and patients' self-perceived healing.

Key-words: Third Molar; Cryotherapy; Surgery, Oral

SUMÁRIO

1 INTRODUCTION

Oral surgical procedures of any kind, from the extraction of a retained third molar to the rigid internal fixation of a mandibular fracture, may cause postoperative complications such as edema, trismus, and pain and interfere with the quality of life of patients. These aspects are important physiological responses but when observed at high intensity and duration, they may harm this critical period of surgical recovery.

No consensus in the literature allows defining a gold-standard protocol as postoperative conduct but most surgeons try to control the complication factors with drug therapies, from analgesics to anti-inflammatory drugs (steroidal or not).[1] Overall, there is an underestimating of non-pharmacological maneuvers[2,3] such as an effective instruction on the need for absolute rest and oral cavity hygiene, as well as cryotherapy, which is a common approach in the health field although often used empirically. The topical application of ice reduces the temperature of the skin and its adjacent tissues by 2 to 4 cm in depth, resulting in cold-induced neuropraxia and decreasing the threshold of nociceptor activation and the speed of conduction of nerve pain signals.[4] This consequentially reduced blood flow through vasoconstriction, which may decrease the intensity of the inflammatory response of soft tissues to trauma.[5]

The benefits of cryotherapy are not a consensus in the literature and this situation is often justified by the lack of a solid and effective treatment protocol, although the most used approach is applying ice to the region every 30 minutes in the first days.[6] This conflict in the evidence can be seen in publications with results indicating that cryotherapy has no significant influence on edema and trismus[7], while other aspects report a positive increase in pain relief and other postoperative symptoms. The major unknown is still the actual influence of this therapy on pain levels.[6]

Considering the extensive use of cryotherapy in third molar surgeries and the lack of agreement of scientific findings on its effectiveness, the present study evaluated whether the use of ice has a beneficial potential capable of reducing the intensity and duration of pain, as well as reducing edema and trismus and improve the quality of life.

2 OBJECTIVES

2.1 GENERAL OBJECTIVE

To investigate the effects of cryotherapy on postoperative outcomes (pain intensity, edema, trismus and quality of life) following mandibular third molar extraction

2.2 SPECIFIC OBJECTIVES

- Measure the interincisal distance (in millimeters) on postoperative days 0, 2, and 7.
- Evaluate trismus by measuring the maximum interincisal opening with the patient seated and the tragus–ala plane parallel to the ground, using the average of three consecutive mouth openings.
- Compare the levels of postoperative discomfort associated with anesthetic agents using a visual analog scale (VAS).

3 JUSTIFICATION

Cryotherapy with ice is widely used in the postoperative period as a non-pharmacological strategy for controlling these signs and symptoms, due to its potential to reduce local blood flow, inflammatory response, and nerve conduction. However, despite its routine use in clinical practice, there is still controversy in the literature regarding the actual effectiveness of ice application after third molar extraction. Therefore, it is relevant to scientifically evaluate the effects of postoperative cryotherapy following this procedure in order to support evidence-based clinical decisions and optimize postoperative recovery management.

4 MATERIALS AND METHODS

The study is designed as a randomized, controlled, split-mouth clinical trial. Patients that don't receive cryotherapy are defined as group A (GA), while patients receiving cryotherapy with ice are classified as group B (GB).

4.1 SAMPLE CALCULATION

The sample size was calculated based on a previously published study[8], which adopted a significance level of 5% ($p < 0.05$), a statistical power of 90%, and a margin of error of 5%, resulting in a required sample size of 40 surgical sites. In the baseline study, pain perception during local anesthesia was compared between acupressure and cryotherapy using a split-mouth design involving 20 patients. Similarly, the present study employed a split-mouth design, with procedures performed on 20 patients, yielding a total of 40 surgical sites.

4.2 ETHICAL ASPECTS

The study will be conducted in accordance with the Guidelines and Regulatory Standards of the National Health Council (Resolution No. 466/12), which establishes the ethical guidelines for research involving human subjects in Brazil.

The benefit of participating in the research is indirect, as the patient contributes to the discovery of scientific evidence that will serve as the foundation for safer and more effective treatment.

Patient personal data, collected through direct contact with the participant during the study, will not be disclosed, and confidentiality will be ensured for all participants. This data will be stored in a Google Drive spreadsheet linked to the researchers' institutional email address.

Surgical procedures and the participant's participation in the project may present certain surgical and confidentiality risks inherent to participation, which are outlined in the Informed Consent Form (APPENDIX A).

This study was approved by the Research Ethics Committee of the Faculty of Dentistry and by the CEP (CAAE: 17700019.7.0000.5347) of the Federal University of Rio Grande do Sul (UFRGS; Porto Alegre, RS, Brazil).

4.3 TYPE OF STUDY

The study is a randomized, controlled, split-mouth clinical trial.

4.4 SAMPLE

The sample selection consisted on patients referred to the Federal University of Rio Grande do Sul's Dentistry School. The selected patients require bilateral extraction of lower third molars under local anesthesia in two different surgical times. There will be no change to the routine care for patients volunteering in the study. The surgical procedures will be performed by the research team responsible for this study. Participants of both sexes, aged 18 to 50 years, were included in the study if they presented an indication for bilateral surgical removal of mandibular third molars in similar positions according to Pell and Gregory classification.[9] Additional inclusion criteria comprised the absence of systemic comorbidities, local conditions free of inflammatory or infectious processes, no history of allergy to the prescribed medications, and no recent or chronic use of antibiotics, anti-inflammatory drugs, corticosteroids, or analgesics. Participants were excluded from the study if they used medications other than those prescribed by the surgeon, failed to provide the required data, belonged to Group A (control) but used postoperative ice packs, or belonged to Group B (test) and did not use ice packs as instructed by the researchers. There were three dropouts due to noncompliance with postoperative recommendations and the use of non-prescribed medication, resulting in 34 procedures performed in 17 patients.

Postoperative consultations were conducted for follow-up, suture removal, and the evaluation and treatment of any potential postoperative complications.

The selection of the control group and experimental groups were determined by a simple randomization in the immediate postoperative period. One surgical site didn't receive cryotherapy (GA), while the other site received cryotherapy with ice (GB).

4.5 SURGICAL TECHNIQUE

All surgical procedures were performed by a team composed of two trained and calibrated surgeons, exclusively during the morning period. Each patient was treated by the same surgeon for both surgical procedures. A standardized surgical protocol was applied in all cases and included anamnesis, clinical examination, and collection of vital signs (blood pressure and heart rate).

Patients were positioned in the dental chair and underwent antisepsis of the oral cavity and adjacent extraoral region using 0.12% aqueous chlorhexidine. After establishment of a sterile surgical field, local anesthesia was administered via inferior

alveolar, lingual, and buccal nerve blocks using 2% mepivacaine with 1:100,000 epinephrine. A mucoperiosteal incision was made extending from the retromolar area to the mesial aspect of the second molar, with a relaxing incision in an open L-shaped design to expose the underlying bone. Under copious saline irrigation, ostectomy was performed in the distobuccal region using a #6 round bur, and odontosection was carried out when necessary using a 702 surgical bur. Following tooth removal, wound closure was achieved with simple interrupted sutures using 4-0 silk sutures.

Prior to the first surgical procedure, maximum mouth opening was measured in millimeters using a measuring tape to determine the interincisal distance. In cases where maxillary or mandibular incisors were absent, the occlusal edges were used as reference points. This measurement was used as a baseline parameter for comparison between procedures.

4.6 POSTOPERATIVE CARE

In the immediate postoperative period following the first surgical procedure, the allocation of postoperative care—with or without cryotherapy—was randomized using a simple draw. Allocation was determined by the selection of a folded paper indicating Group A or Group B and was supervised by a third party to ensure allocation concealment. When the first surgical site of a patient was assigned to Group A (control), the contralateral site in the second surgical procedure was assigned to Group B (test), and vice versa.

Group A (control) did not receive postoperative cryotherapy. Group B (test) was instructed to apply standardized ice packs (11 × 8.5 × 1 cm), provided by the research team, positioned diagonally to cover both the mandibular angle and the cheek on the operated side. Cryotherapy was initiated immediately after surgery under surgeon supervision and continued for the first 12 postoperative hours, consisting of 30-minute applications followed by 30-minute intervals (total of 12 applications). During the intervals, patients were instructed to store the ice packs in a freezer until the next application.

All participants received identical pharmacological postoperative instructions (APPENDIX B) for both interventions, including paracetamol[1] 1 g every 6 hours for 3 days and mouth rinses with 0.12% aqueous chlorhexidine digluconate twice daily for 7 days, starting on the day following surgery. In cases of persistent pain, trismus, or edema that significantly interfered with daily activities despite the use of prescribed analgesics, patients were instructed to use rescue medication consisting of codeine 30 mg every 4 hours as needed.

4.7 STUDY VARIABLES

The outcome variables of this study were postoperative pain, trismus, local edema, and changes in quality of life following mandibular third molar extraction. Postoperative assessments were performed by the research team, consisting of two calibrated surgeons and one supervising professor, on postoperative days 0 (day of surgery), 2, and 7. The following evaluation protocols were applied:

a) Pain assessment: postoperative pain was assessed using a visual analog scale[5] (VAS– APPENDIX C) ranging from 0 to 10, in which 0 represented no pain, 1–3 mild pain, 3.1–6 moderate pain, and 6.1–10 severe pain. Patients completed the scale at home daily until postoperative day 7.

b) Trismus assessment: trismus was evaluated by measuring maximum mouth opening with the patient seated and the tragus–ala plane parallel to the ground. Patients were instructed to open their mouths three consecutive times, and the mean value was recorded. Measurements were obtained as the interincisal distance in millimeters using a measuring tape. In the absence of maxillary or mandibular incisors, the occlusal edges were used as reference points. Measurements were recorded on postoperative days 0, 2, and 7.

c) Edema assessment: facial edema was measured using the method described by Gabka and Matsumura.[10] Three linear facial measurements were obtained in millimeters with a measuring tape: tragus to pogonion, tragus to oral commissure, and lateral canthus to mandibular angle. The mean of these three measurements was calculated to quantify edema. This assessment was performed preoperatively and on postoperative days 2 and 7.

d) Quality of life assessment: quality of life was evaluated using a questionnaire adapted from the OHIP-14[11] (APPENDIX D), consisting of 14 dichotomous (yes/no) questions addressing daily functional limitations. The questionnaire included items related to chewing and swallowing ability, dietary changes, alterations in taste, mouth opening, voice changes, speech intelligibility, facial appearance, sleep disturbances, and ability to perform work-related activities. The questionnaire was provided to participants on the day of surgery and completed on postoperative days 0, 2, and 7. At the conclusion of the evaluation period following the second intervention, participants also answered the question: “Which intervention did you perceive as resulting in greater postoperative improvement?”

4.8 STATISTICAL ANALYSIS

Data normality was assessed using the Kolmogorov–Smirnov test. Parametric analyses were applied to compare groups (control side vs. test side) and postoperative time points (from day 0 to day 7). Continuous variables, including pain intensity (VAS scores), maximum mouth opening (mm), and facial edema (mm), were expressed as means ± standard deviation (SD).

A two-way repeated-measures analysis of variance (ANOVA), followed by Fisher's least significant difference (LSD) post hoc test, was used to evaluate the main effects of time and treatment, as well as their interaction, for pain intensity, trismus, and edema. Pain reports were also qualitatively analyzed based on the frequency distribution of pain categories (no pain, mild pain, moderate pain, and severe pain) for both groups.

Associations between pain intensity and trismus or edema were assessed using Pearson's correlation coefficient. Trismus and edema were additionally evaluated using the formulas (Baseline − Postoperative) and (Postoperative − Baseline), respectively. Qualitative data related to quality of life were presented as percentages.

All statistical analyses were performed using SPSS software (version 20.0; IBM Corp., Armonk, NY, USA). Statistical significance was set at $P < 0.05$.

5 RESULTS

5.1 POSTOPERATIVE PAIN INTENSITY

The analysis demonstrated significant main effects of treatment ($F_{(1,16)} = 5.063$, $p = 0.039$) and time ($F_{(7,112)} = 6.254$, $p < 0.001$) on postoperative pain intensity (Table 1). Overall, pain scores were higher in Group A than in Group B (2.0 ± 1.2 vs. 1.3 ± 1.1; $F_{(1,16)} = 5.063$, $p = 0.039$).

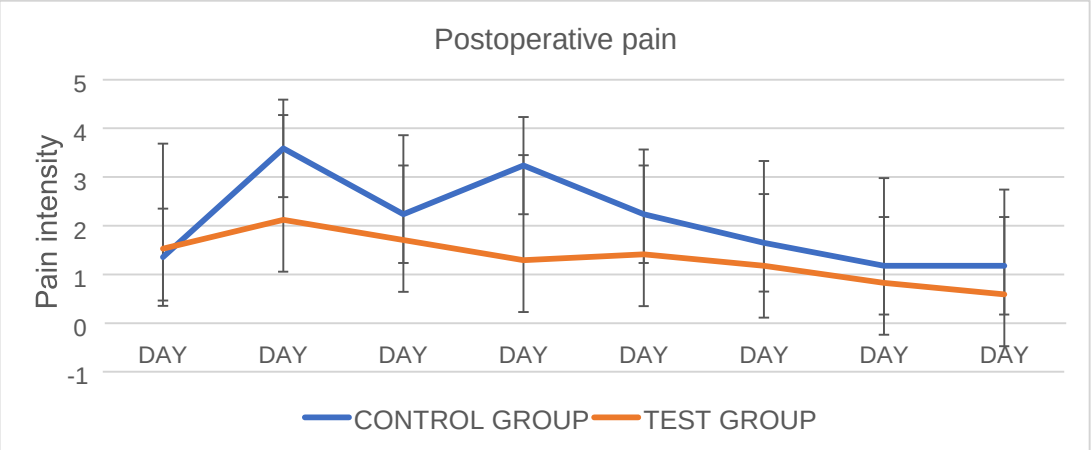


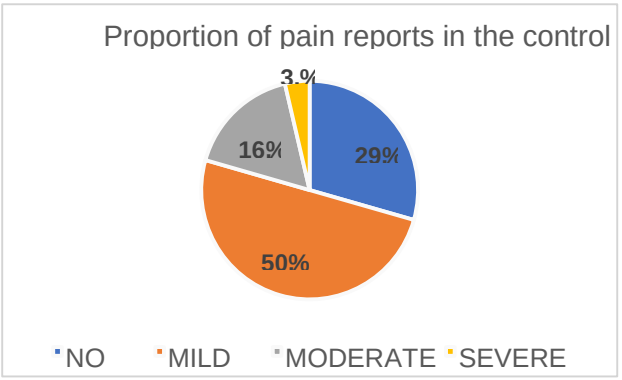
Table 1: Average pain levels on every post-operative day for each group. (*) indicates statistical differences between control and test groups.

In Group A, pain intensity was significantly higher on postoperative days 1 (3.59 ± 0.59; p = 0.014) and 3 (3.24 ± 0.55; p = 0.005) compared with day 0 (1.35 ± 0.54). No significant differences were observed between day 0 and the remaining postoperative time points (p > 0.05).

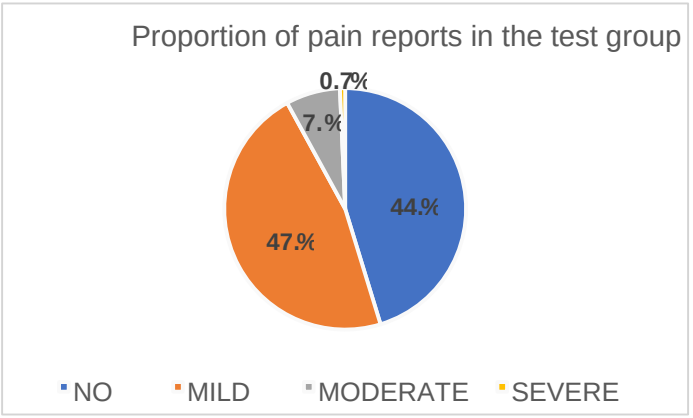
On the test side (Group B), no significant differences in pain intensity were observed between day 0 and any postoperative evaluation (p > 0.05), suggesting that cryotherapy effectively prevented postoperative pain exacerbation.

A significant interaction between treatment and time was also observed ($F_{(7,112)}$ = 2.689, p = 0.013). Pain intensity was higher on postoperative day 1 (Group A: 3.59 ± 0.59 vs. Group B: 2.12 ± 0.42; p = 0.017) and day 3 (Group A: 3.24 ± 0.55 vs. Group B: 1.29 ± 0.33; p = 0.007) in the control group compared with the cryotherapy group.

Postoperative pain was absent in 29.4% of control cases and 44.1% of cryotherapy cases. Mild pain was reported by 50.0% of participants in Group A and 47.8% in Group B, whereas moderate pain occurred in 16.9% and 7.4% of cases, respectively. Severe pain was reported by 3.7% of control cases and 0.7% of cryotherapy cases (Graphics 1 and 2).



Graphic 1: Prevalence of reports of moderate to severe pain (4-10 in visual analogic scale) in the total number of reports of pain (1-10 in visual analogic scale) in the control group after day 2 (last day of analgesic medication).



Graphic 2: Prevalence of reports of moderate to severe pain (4-10 in visual analogic scale) in the total number of reports of pain (1-10 in visual analogic scale) in the test group after day 2 (last day of analgesic medication).

When moderate-to-severe pain reports were isolated and compared with the need for rescue medication after suspension of the standard analgesic regimen, 80% of participants in Group A required rescue medication, whereas no participant in Group B required additional analgesia.

5.2 TRISMUS

Cryotherapy did not significantly affect maximum mouth opening during the postoperative period ($F_{(1,16)} = 0.006$, $p = 0.93$). However, a significant effect of time ($F_{(2,32)} = 45.410$, $p < 0.001$) and a significant interaction between treatment and time ($F_{(2,32)} = 4.703$, $p = 0.016$) were observed.

Mouth opening decreased on postoperative day 2 compared with baseline in both the control group (43.8 ± 8.9 vs. 30.1 ± 12.2; $p < 0.001$) and the cryotherapy group (39.3 ± 8.8 vs. 31.4 ± 7.9; $p < 0.01$). In Group A, mouth opening remained significantly reduced on postoperative day 7 compared with baseline (43.8 ± 8.9 vs. 37.8 ± 13.6; $p = 0.005$). In contrast, Group B showed recovery of mouth opening by day 7, with values comparable to baseline (39.3 ± 8.8 vs. 40.5 ± 8.5; $p = 0.43$) (Table 2).

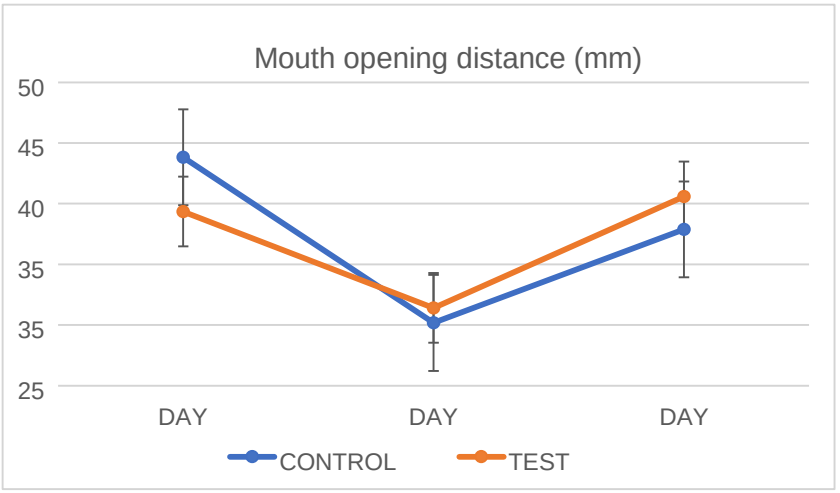


Table 2: Average of maximal mouth opening values on days 0, 2 and 7 post-op.

Correlation analysis revealed no significant association between pain intensity

and trismus in Group B on postoperative days 2 (r = 0.15, p = 0.54) or 7 (r = 0.11, p = 0.66). In contrast, a significant positive correlation was observed in Group A on postoperative day 7 (r = 0.62, p = 0.005), indicating that greater pain intensity was associated with increased mouth opening restriction. No correlation was found on postoperative day 2 in Group A (r = 0.30, p = 0.23) (Table 3).

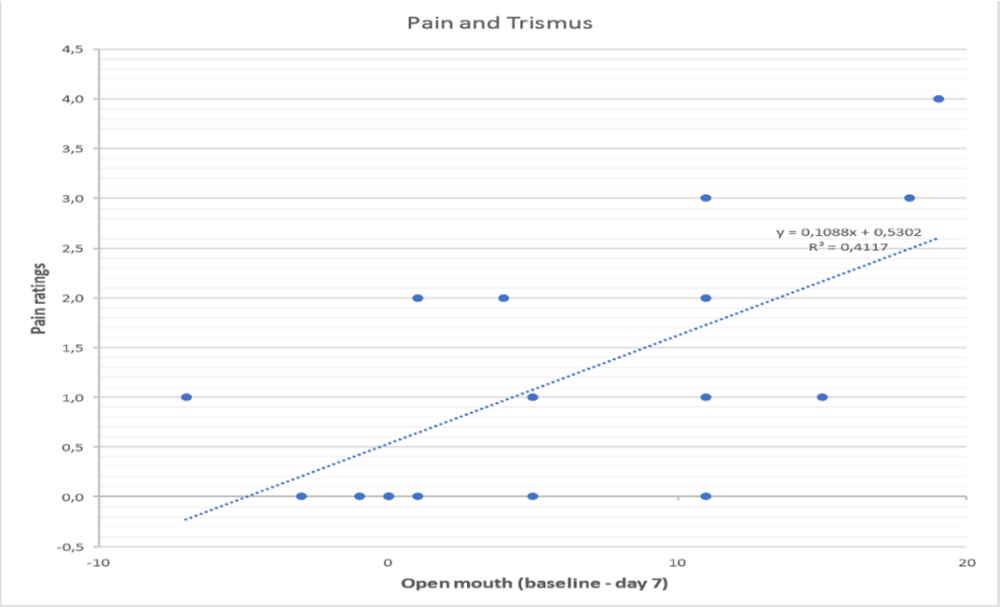


Table 3: Correlation between pain and trismus for control group.

5.3 EDEMA

Time significantly affected postoperative edema ($F_{(2,32)}$ = 10.34, p < 0.001), whereas treatment ($F_{(1,16)}$ = 0.516, p = 0.48) and the interaction between factors ($F_{(2,32)}$ = 1.533, p = 0.23) did not.

Both groups exhibited greater edema on postoperative day 2 compared with baseline (Group A: 123.0 ± 5.1 vs. 126.2 ± 7.8, p = 0.02; Group B: 123.1 ± 7.1 vs. 126.3 ± 7.5, p = 0.005). No significant differences were observed between baseline and postoperative day 7 in either Group A (123.0 ± 5.1 vs. 126.1 ± 7.8; p = 0.86) or Group B (123.1 ± 7.1 vs. 123.5 ± 8.7; p = 0.71), indicating resolution of edema by the end of the evaluation period in both groups (Table 4).

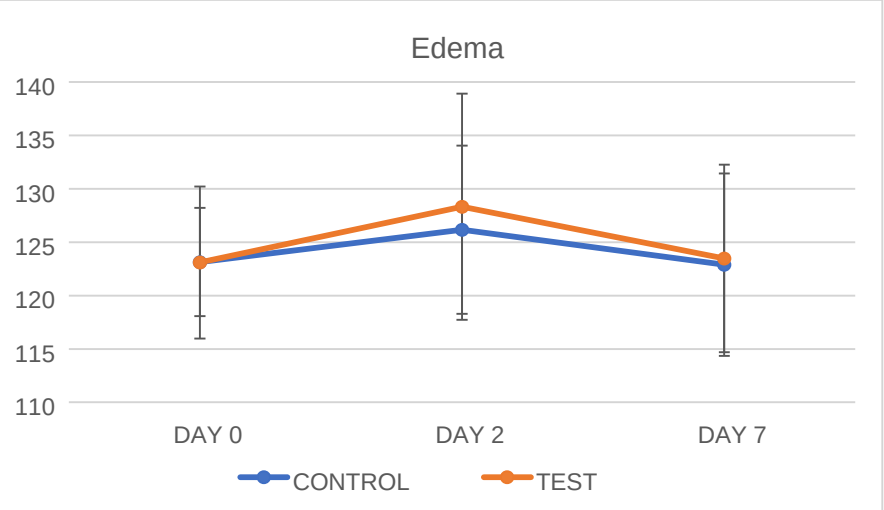


Table 4: Average of edema values on days 0, 2 and 7 post-op.

5.4 QUALITY OF LIFE

Among the 14 items of the OHIP-14 questionnaire, only three showed significant differences between groups. Regarding mouth opening, 31% of participants in Group A still reported difficulty opening the mouth on postoperative day 7, compared with 23.5% in Group B. Concerning sleep disturbances, Group A showed an approximate 40% reduction in complaints between postoperative days 2 and 7, whereas Group B demonstrated a reduction of approximately 66.6%.

When participants were asked which intervention resulted in greater postoperative improvement, all patients who underwent the control protocol in the first surgery (100%) preferred the cryotherapy intervention. Among those who received cryotherapy during the first procedure, 83% also indicated preference for the cryotherapy side.

6 DISCUSSION

Cryotherapy was effective in reducing both the intensity and duration of postoperative pain episodes, as well as shortening the period of mouth opening limitation. Additionally, its use in the postoperative period resulted in a reduced need for rescue medication and a greater patient-perceived improvement over time. These findings support the consolidation of a cryotherapy protocol, contributing to a more predictable postoperative course and improving the management of postoperative complications.

As shown in Table 1, differences in mean pain scores during the first 72 postoperative hours (from day 0 to the end of day 2) appear to be related to the lack of consolidation of the inflammatory response under pharmacological analgesia alone. Pain modulation was only stabilized after postoperative day 3 in both groups, as also reported by Sukegawa et al.[12] However, cryotherapy demonstrated a

beneficial synergistic effect when combined with analgesic medication, resulting in lower pain scores during this critical period. In contrast, analgesic therapy alone was insufficient to adequately control pain in the control group, which exhibited two distinct peaks in pain intensity at 24 and 72 hours postoperatively.

The benefit of cryotherapy for the test group was particularly evident between postoperative days 2 (the last day of analgesic medication) and 3 (the first day without medication). During this transition, pain levels increased in the control group and remained consistently higher than those observed in Group B, even during the consolidation phase of the inflammatory response. These findings suggest that the greater differences in pain intensity are directly associated with the absence of cryotherapy in the control group, despite the use of analgesics.

Pain severity distribution over the seven postoperative days further reinforced these findings (Graphics 1 and 2). Proportionally, extractions performed without cryotherapy were associated with a significantly higher likelihood of moderate-to-severe pain. From a clinical perspective, the absence of cryotherapy increased the probability of requiring rescue medication. This observation is particularly relevant for patients with systemic diseases who already require complex pharmacological regimens, increasing the risk of drug interactions, as well as for individuals susceptible to medication dependence, for whom minimizing drug exposure is essential.

A strong association was also observed between higher pain intensity reports and increased requests for rescue medication in the control group. These results indicate that failure to use cryotherapy may increase reliance on pharmacological interventions to manage postoperative discomfort, which could otherwise be mitigated through a simple and low-cost intervention such as ice pack application for 30 minutes over a 12-hour period. Therefore, the proposed cryotherapy protocol can be considered a safe and effective approach that enhances postoperative predictability, facilitates complication control, and promotes greater patient engagement in self-care.

Trismus represents a multifactorial postoperative response influenced by surgical trauma, including ostectomy, extracellular fluid extravasation, tissue hemorrhage, and muscle fiber incision. Given the simultaneous occurrence of these factors, significant benefits of cryotherapy are not expected before consolidation of the inflammatory response, which explains the absence of intergroup differences during the first 72 postoperative hours. However, when comparing immediate postoperative measurements with those obtained on postoperative day 7, the control

group exhibited significantly greater mouth opening limitation (Table 2), indicating a longer duration of trismus. This finding is supported by the statistically significant correlation between pain intensity and trismus observed exclusively in the control group (Table 3), suggesting that higher pain levels are associated with prolonged mouth opening restriction. These results were further corroborated by the quality-of-life questionnaire, which revealed greater difficulty in mouth opening among control participants.[13]

Edema did not show statistically significant differences between groups (Table 4), consistent with previous reports.[14] It is hypothesized that superficial ice application may be insufficient to significantly reduce edema due to its limited penetration into deeper muscular and facial tissue planes, thereby restricting its vasoconstrictive effects.

Regarding quality of life, three variables demonstrated notable percentage differences between groups. First, participants in the cryotherapy group reported less difficulty sleeping, likely reflecting the superior pain control achieved with this intervention. Second, when asked which procedure resulted in greater postoperative improvement, all 11 participants who initially underwent the control protocol reported greater improvement following the cryotherapy intervention.[15] Participants described a reduction in burning or heat sensations and perceived a faster recovery trajectory compared with the non-cryotherapy procedure, consistent with the pain outcomes shown in Table 1. Third, patients treated with cryotherapy reported less difficulty opening their mouths, which appears to be closely related to their lower subjective pain perception. As demonstrated in Tables 1 and Graphic 2, the greater reduction in pain intensity in the test group was reflected in a lower proportion of participants reporting functional limitation.

7 CONCLUSION

Postoperative cryotherapy was effective in reducing pain intensity and duration, decreasing the need for rescue medication, and shortening the period of mouth opening limitation after mandibular third molar extraction. This intervention also improved patients' perception of recovery and contributed to a more predictable postoperative course. However, cryotherapy did not demonstrate a significant effect on postoperative edema.

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APPENDIX A – FREE AND INFORMED CONSENT FORM

CPPG OR CAAE PROJECT NUMBER: 17700019.7.0000.5347

PROJECT TITLE: "IS CRYOTHERAPY BENEFICIAL AFTER SURGICAL REMOVAL OF IMPACTED LOWER THIRD MOLARS? – A RANDOMIZED SPLIT MOUTH CLINICAL TRIAL"

You, _____, are being invited to participate in the research entitled “Is Cryotherapy Beneficial After Surgical Removal of Impacted Lower Third Molars? – A Randomized Split-Mouth Clinical Trial”, which will be conducted at the School of Dentistry of the Federal University of Rio Grande do Sul (UFRGS).

The main objective of this study is to evaluate the real benefits of cryotherapy (application of ice packs) on the following postoperative outcomes: edema (swelling), pain, trismus (limitation of mouth opening), and quality of life.

After the surgical removal of impacted mandibular third molars, it is common to experience pain, swelling, and difficulty opening the mouth due to tissue manipulation during the procedure. Therefore, this study aims to assess whether the application of ice packs to the operated area can reduce swelling, pain, and limitation of mouth opening.

Your participation in this study is voluntary, and you may withdraw at any time without any harm or prejudice. By agreeing to participate, you consent to complete questionnaires related to quality of life, pain, trismus, and edema, as well as to follow the postoperative instructions provided by the dentists performing the surgery. You also agree to attend postoperative follow-up appointments on the 1st, 2nd, and 7th days after surgery. Transportation costs for these visits will be reimbursed.

The benefits of participating in this study are both indirect and direct. Indirectly, you will contribute to the generation of scientific evidence that may support more effective postoperative treatments for impacted third molar removal. Directly, you will receive surgical treatment for your impacted teeth.

The surgical procedures and participation in the study may involve inherent surgical and confidentiality risks, including:

Surgical risks: Possible complications include paresthesia (abnormal and unpleasant sensations such as burning or numbness), oral injuries, infection of facial spaces, hemorrhage, and mandibular fracture. If any of these complications occur, they will be managed appropriately by the research team, including the prescription of neuroregenerative agents, antibiotics, antiseptics, or immediate clinical intervention. Contact phone numbers of the researchers are provided for any postoperative complications in addition to the scheduled follow-up visits.

Research participation risks: There is a potential risk of breach of confidentiality in specific situations, such as when disclosure is necessary to ensure the best possible care, when it is the last available resource, or when a serious physical condition requires intervention by other healthcare professionals. To minimize this risk, only information strictly necessary for clinical management will be disclosed, and only with your consent whenever possible.

The use or non-use of ice packs after surgery will be determined by random allocation (drawing lots). If you are assigned to the cryotherapy group, ice packs will be provided by the researchers and should be applied immediately after surgery. The ice packs should be applied to the external area corresponding to the surgical site for 30 minutes, followed by 30-minute intervals between applications, during the first 12 hours after surgery.

Postoperatively, you will be instructed to use pain medication (Paracetamol 500 mg, two tablets every 6 hours for 3 days) and to perform mouth rinses with 0.12% chlorhexidine solution. These medications will not be provided by the researchers and must be obtained through public health units or commercial pharmacies. Participants will also be responsible for the cost of a panoramic radiographic examination and transportation to the Teaching Dental Hospital of UFRGS. Transportation expenses for the day of surgery (day 0) and follow-up visits (days 2 and 7) will be reimbursed in cash by the researchers, based on the equivalent cost of two public transportation bus fares (round trip) in Porto Alegre on the scheduled dates.

All collected data will be stored for a minimum period of five years. This Informed Consent Form must be signed in two copies, one retained by the participant and the other by the researchers.

Contacts:

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Research Assistants: Gabriela Carvalho Massa – Phone: +55 (51) 99784-2610

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UFRGS Research Ethics Committee: +55 (51) 3308-3738

(Office hours: Monday to Friday, 8:00 a.m. to 12:00 p.m. and 2:00 p.m. to 6:00 p.m.)

UFRGS Ethics Committee Address: Av. Paulo Gama, 110 – Room 317

The participant declares that they have read and understood the information provided and agree to participate in this study.

_____ _____

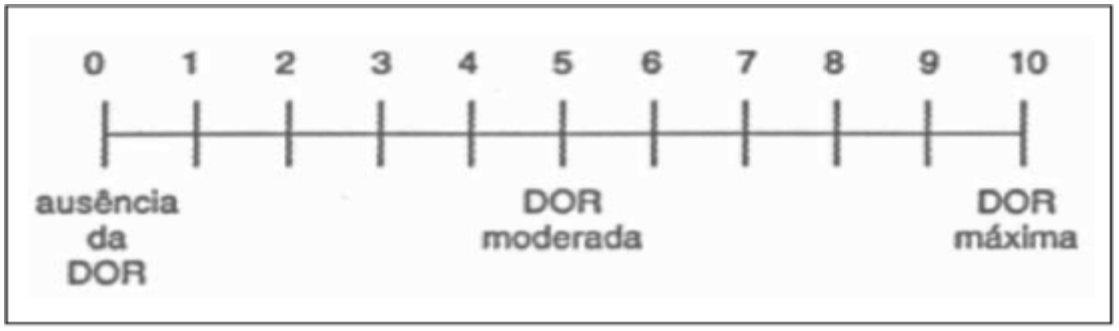
Signature Phone number (landline and mobile)

Date: / /

APPENDIX B – POSTOPERATIVE CARE PROTOCOL

- Bite firmly on a gauze pad for 20 minutes in case of delayed bleeding.
- Avoid grainy or bran-based foods until the suture is removed.
- Rest, keeping your head elevated above the rest of your body.
- Avoid strenuous physical activity and sun exposure for 7 days.
- Brush your teeth normally 24 hours after surgery.
- Gently brush the surgical site until the suture is removed.
- Do not rinse your mouth for 48 hours.
- Avoid spitting.
- Do not smoke until discharge from surgery.
- Medication:
- Paracetamol 500mg, 2 tablets every 6 hours for three days.
- Rinse with 10mL of 0.12% chlorhexidine digluconate aqueous solution for 1 minute every 12 hours for seven days, starting 24 hours after surgery.
- In case of persistent bleeding, severe pain, or fever (temperature greater than or equal to 37.8°C), contact your doctor.

APPENDIX C – VAS FOR ASSESSING POSTOPERATIVE



A 10-cm visual analog scale is used to measure the patient's pain during the stipulated periods. It is used postoperatively for each operated side.

APPENDIX D – OHIP QUESTIONAIRE (ORAL HEALTH IMPACT PROFILE)

	Pre-op	Second day post-op	Seventh day post-op
Did you have difficulty chewing?			
Did you have difficulty swallowing?			
Did you avoid certain foods?			
Have you lost your sense of taste in certain foods?			
Can you open your mouth normally?			
Are you able to taste the food normally?			
Have you noticed any change in your voice?			
Did you have any difficulty speaking?			
Did other people have any difficulty understanding you?			
Has your appearance changed?			
Do you look unusual?			
Are you having trouble sleeping?			
Do you wake up during the night?			
Are you having difficulty performing daily tasks?			