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Effectiveness of cold therapy in reducing post-surgery oedema, pain and Trismus after impacted mandibular third molar surgery: a randomized observer-blind split-mouth clinical trial

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## Abstract

Pain, swelling, and trismus are the most common undesirable effects seen in the post-op period after impacted mandibular third molar surgeries. To prevent these effects different methods of treatment has been advocated from time to time. Cold therapy is one of the conventional methods used for reducing these undesirable effects after dentoalveolar surgeries. However, there is a lack of knowledge about its effectiveness to prevent these post-op sequelae. This study was aimed to evaluate the effects of local cold application therapy in reducing pain, trismus, and swelling after impacted mandibular third molar surgery. 18 patients (7 males and 11 females) with bilaterally placed symmetrical mandibular impacted third molars were enrolled in this randomized, observer-blind split-mouth clinical trial. The patients were aged between 18-65 years. After surgical removal of the tooth on one side (intervention), ice pack therapy was given for 24 h after surgery; and for the other side (control), no cold therapy was advised. The time interval between the two surgeries was at least 4 weeks and the amount of trismus and facial swelling was measured on day 2 and 7 postoperatively. The pain was measured by VAS scale on day 1, 2, and 7 postoperatively. The amount of pain, and trismus, were not significantly different between the intervention and control sides but the swelling was less with cold therapy. Thus, Cold therapy had some beneficial effects on postoperative swelling, with no effect on pain and trismus after impacted mandibular third molar surgery.

**Keywords:** Impaction, Cold therapy, Post-surgery oedema, Trismus, Surgery

### Introduction

The removal of impacted teeth is one of the most common surgical procedures carried out by oral and maxillofacial surgeons. However, despite the best preoperative preparation and operative procedure, some unavoidable problems such as pain, ecchymosis, facial

swelling, and trismus may occur. Although these postoperative sequelae are expected and considered normal physiological responses to surgery, they are usually unpleasant and may adversely affect the daily activities and quality of life of the patient.

Several treatment measures in the published literature have been advocated from time to time to prevent these post-op sequelae (pain, trismus, and oedema) after impacted tooth surgeries. These modalities include the use of both local and systemic drug therapies (such as corticosteroids enzyme preparations, and non-steroidal anti-inflammatory drugs (NSAIDs), low-level laser therapy, ice packs and surgical drains<sup>1-5</sup>

Corticosteroids and NSAIDs have been widely used to prevent the postoperative sequel after dentoalveolar surgeries. But all these drugs are associated with adverse effects. NSAIDs are associated with GIT upset (gastric ulceration and epigastric pain) and corticosteroids are also associated with gastric irritation, vomiting dizziness etc. Different routes of administration including oral, parenteral, and local injection have been used for this medications<sup>6-10</sup>

Cold therapy is a natural and simple method that has been traditionally used over decades to reduce pain and swelling after various acute musculoskeletal injuries and orthopaedic surgical procedures. In the orthopaedic field, there is enormous evidence-based research that describes the effect of cold therapy in reducing pain and swelling after various orthopaedic procedures. However, despite the long history of cold therapy in the management of the postoperative sequelae of impacted tooth surgery, the effectiveness of this modality has not been sufficiently evaluated and the results of previous studies are not consistent 11-15.

In Previous literature, different cold therapy protocols and cooling devices (ice bags, Hilotherm, chemical packs,

etc.) has been used to evaluate the effectiveness of cold therapy in reducing post-op sequelae after dentoalveolar procedures. Because of the differences in methodology in past studies, the comparison of their results becomes difficult. So, the efficacy of this treatment requires further investigation.

Thus, the present study was conducted to evaluate the effects of cold therapy in reducing pain, trismus, and swelling after mandibular third molar surgery. It was hypothesized that the application of ice packs to the face would have a beneficial effect on these postoperative problems.

### Materials and methods

This was a randomized self-controlled, observer-blind, split-mouth clinical trial wherein the subjects were recruited from the outpatients at the Unit of oral health sciences centre of our institute. The study was conducted from April 2019 to September 2020. The protocol of this investigation was approved by the institutional ethics committee. A total of 18 healthy patients in the age group of 18-65 years of either sex, with bilaterally symmetrical impacted mandibular third molars diagnosed for surgical extraction, were selected. Informed consent was taken from all patients before the study. Patients having the presence of a pathology or a history of previous surgery/fracture in the mandibular third molar area, those on anticoagulant therapy, and under treatment with analgesic and anti-inflammatory medications were excluded from the study. The patients were divided randomly into two groups

- 1. GROUP A (n = 18). Cold therapy was given
- 2. GROUP B (n = 18). No cold therapy was given.

The same patient was allocated to both the groups on respective surgeries. The randomization was done by computer-generated method and allocation of patients to the respective groups by using sequentially numbered opaque envelopes.

## **Preop Evaluation**

Before extraction Orthopantomogram (OPG) was done for every patient to see the position of the impacted mandibular third molars and the difficulty index for each tooth was determined by Winter's WAR (White-amberred) lines. All of the impacted teeth were extracted under local anaesthesia by the same surgeon. After tooth removal on one side, the surgical removal of the tooth on the other side of the mandible was done at least 4 weeks later using the same surgical technique. The local anaesthesia blocks (inferior alveolar nerve block, lingual and long buccal nerve block) was given. After adequate anaesthesia, a modified Ward's incision was given and the mucoperiosteal flap was raised, followed by bone or tooth cutting using a straight hand piece and bur. Copious saline irrigation was done during the whole procedure followed by closure of flap with 3-0 Vicryl. After surgical removal of the tooth on one side (study side), the patients were advised to apply ice packs (ice cubes placed in a non-leachable bag and wrapped in cotton cloth) on the operated side of the face for periods of 25 min followed by resting periods of 25 min during the first 24 h after surgery, during day time when awake. After removal of the contralateral tooth in the same patient, no cold therapy was advised (control side). The patients were allocated to respective groups and no medication was given preoperatively. Postoperatively all the patients were given antibiotics (amoxicillin 500 mg three times daily for 5 days), analgesics (ibuprofen 400 mg three times daily for 2 days), and chlorhexidine gluconate 0.12% mouthwash two times daily for 10 days.

## Post evaluation

Patients were evaluated for pain, swelling and trismus. The assessment was done at different time periods viz Swelling and trismus were evaluated on days 0(preop),2,

and 7 and pain on days 1,2 and 7. The postoperative pain and was evaluated using the Visual Analog Scale (VAS in mm), mouth opening was taken as the maximum distance between upper and lower central incisors, by a linear scale and facial swelling was measured with thread by using four reference points: tragus, gonion (angle of the mandible), outer cantus of the eye and the corner of the mouth. It was calculated as the sum of the two diagonals made between these reference points (a-b+c-d). 10 The opening swelling and mouth was evaluated postoperatively using the same method described for preoperative assessment.

## Statistical analysis

Statistical analysis was carried out using SPSS Statistics version 21 (IBM Corporation, SPS Inc., and Chicago, IL, USA). Results were presented as Mean (SD) for continuous measurements and as frequency (percentage) for categorical measurements. The normality of variables was assessed using the Shapiro- Wilk and Kolmogorov-Smirnov tests. Mann- Whitney U test and Chi-square test were used to find the difference between the two groups.

P-value less than 0.05 were considered to be significant.

### **Results**

Table 1 depicts the age, gender characteristics and difficulty index scores for groups.

The mean mouth opening on day 0 was 45.5 mm and 45.8 mm for Group A and Group B respectively. The Trismus was maximum on day 1 in both groups and gradually improved thereafter. The improvement in mouth opening in group A was comparable to group B and was statistically non-significant (p>0.05) (Table 2).

The mean value of swelling at baseline was 235.2mm and 235.4±4.05 in groups A and B respectively. Post-operatively, the greatest increase in swelling from baseline values was reported on day 2 in both groups. The swelling was more in group B (control group) as

compared to Group A (cold group) it was statistically significant (p = 0.019). On the seventh postoperative day swelling decreased comparably in both groups. (Table 3). The group B patients had a slightly higher mean pain score on all the postoperative days as compared to Group A patients in which cold therapy was instructed. The reduction in pain in group A was comparable to group B and was statistically non-significant. (Table 4).

#### Discussion

The removal of impacted third molars is associated with certain undesirable post-surgical sequelae such as pain, Trismus, and oedema. These undesirable postop sequelae are commonly expected and considered to be the normal physiological responses to surgery. These predictable postoperative complications usually subside within a short period, but they may adversely affect the quality of life of the patient even for a short time, thus needs to be minimized.

Various analgesic and anti-inflammatory drugs have been used to prevent these complications, but all these synthetic drugs are associated with adverse reactions and some drugs may even be contraindicated in many patients with systemic disorders. So, thus a natural therapy may provide an advantage over these drugs by preventing adverse effects.

Ice therapy is a simple natural method that is used widely for the reduction of postoperative sequelae such as pain and swelling. Cold therapy causes deceleration of tissue metabolism through reducing enzyme activities, decreasing the blood flow by vasoconstriction, limiting blood extravasation to the surrounding tissues, decreasing inflammation and oedema, and decreasing nerve conduction. Despite the extensive literature on the effects of cold therapy in reducing pain and oedema after orthopaedic surgeries, but there is a lack of studies evaluating the effects of cold therapy in minimizing the

sequelae of dentoalveolar surgeries 16-19.

So, we aimed to do a split-mouth randomised clinical trial to see the effectiveness of cold therapy in reducing postop complications after mandibular third molar surgeries.

In our study, all the confounding factors like age, sex of the patient, impaction type, surgery time, surgical trauma, and the experience of the surgeon that influence the amount of pain, swelling, and trismus after third molar surgeries were controlled by a randomized, selfcontrolled, split-mouth clinical trial design of the study. In the present investigation, the amounts of postoperative pain, trismus was not significantly different between the intervention and control groups. There was decreased swelling in the patients who were instructed for cold therapy as compared to the control group (Group B). Statistically significant results were seen in decreasing swelling in group A 2<sup>nd</sup> post-op day after tooth removal. This could be due to vasoconstriction of the blood vessels by the cold therapy in the immediate post-op period that resulted in reduced oedema and hence decreased swelling in the group A patients. The studies which favoured the use of cold therapy includes the randomized clinical trial by Laureano Filho et al. who demonstrated that cold therapy reduced oedema and pain but not the trismus after surgery. <sup>20</sup> In a randomized prospective study by Rana et al., the effects of two different cooling therapies (Hilotherm and conventional cooling) on pain, trismus, and facial swelling after third molar surgery were evaluated. That study showed the Hilotherm system to be more effective than conventional cooling in reducing postoperative sequelae<sup>21</sup>.

In an RCT by Van der Westhuijzen et al. On patients who needed surgical removal of bilateral impacted mandibular third molars found no significant difference between the patients who were given cold therapy in contrast to those who were not given concerning postoperative pain,

trismus, or facial swelling. 16

In a randomized clinical trial by Forouzanfar et al., its was found that the use of either 'compression with ice' or 'compression without ice' for 45 min after mandibular third molar surgery was effective in reducing postoperative pain (compared to a non-interventional group) thus indicating no role ice therapy in reducing post-op sequelae. In an experimental animal study by Nusair, identical oral surgeries were performed simultaneously on the right and left sides of the maxilla, and the effect of cold therapy on postoperative facial swelling was assessed. The study showed cold therapy to be ineffective at reducing swelling after intraoral surgery in rabbits.

The present investigation had several strengths, including maximum control of the confounding factors using a randomized, self-controlled, split-mouth clinical trial design, the surgical removal of all impacted teeth by the same surgeon and a conventional method used routinely by dentists and surgeons.

The shortcomings of the present study were the limited postoperative follow-up of the patients (48 h and 7 days after the operation), small sample size and the possible patient noncompliance with the postoperative instructions, especially cold therapy.

In conclusion, cold therapy is a simple inexpensive method that is commonly prescribed by dentists and oral and maxillofacial surgeons for the reduction of pain, Trismus, and swelling after dentoalveolar surgeries. However, the present study demonstrated that cold therapy only decreases swelling with no effect on the pain and Trismus.

Table 1: Baseline characteristics

|                                | Group A Cold Therapy N=18 | Group B No Cold Therapy N=18 | P value |
|--------------------------------|---------------------------|------------------------------|---------|
| Age years mean ± SD            | 37.8±9.58                 |                              |         |
| Sex                            |                           |                              |         |
| Male                           | 7 (45%)                   | 7 (45%)                      |         |
| Female                         | 11(55%)                   | 11(55%)                      |         |
| Difficulty index mean $\pm$ SD | $4.80 \pm 1.15$           | $4.95 \pm 1.2$               | 0.704   |

Table 2: Mouth Opening Reduction or Trismus (mean  $\pm$  SD) values (millimeters)

| Fallow up day                             | Cold Therapy Group A | No Cold Therapy Group B | P Value |
|---|----------------------|-------------------------|---------|
| Preoperative (day0) mean ± SD values      | 45.5±1.7             | 45.8±1.6                | 0.58    |
| Postoperative (day2)mean ± SD values      | 44.40± 0.8           | 44.15±0.7               | 0.32    |
| Postoperative (day7) mean $\pm$ SD values | 45.1±1.2             | 44.8±1.4                | 0.49    |

Table 3: Facial Swelling Measurements mean  $\pm$  SD values (millimeters)

| Fallow up day                         | Cold Therapy Group A | No Cold Therapy Group B | P Value |
|---------------------------------------|----------------------|-------------------------|---------|
| Preoperative (day0) mean ± SD values  | 235.2±4.4            | 235.4±4.05              | 0.9     |
| Postoperative (day2) mean ± SD values | 243.1±5.8            | 247.7±5.4               | 0.019   |
| Postoperative (day7) mean ± SD values | 240.3±3.31           | 239.45±3.42             | 0.45    |

Table 4: Vas Scores on The Postoperative Days 1,2, And 7 mean  $\pm$  SD values (millimeters)

| Fallow up day          | Cold Therapy Group A | No Cold Therapy Group B | P Value |
|------------------------|----------------------|-------------------------|---------|
| Day 1 mean ± SD values | 39.05±3.58           | 40.30±3.6               | 0.30    |
| Day 2 mean ± SD values | 28.30±2.7            | 29.41±4.3               | 0.36    |
| Day 7 mean ± SD values | 12.8±3.34            | 13.35±4.2               | 0.66    |

Figure 1: Mouth opening reduction or Trismus

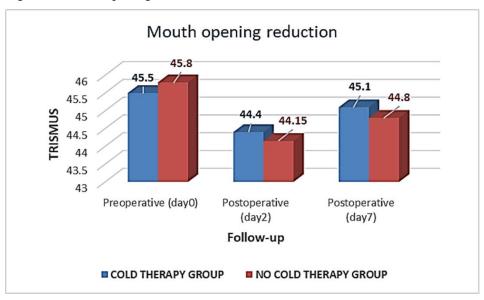


Figure 2: Facial swelling measurements

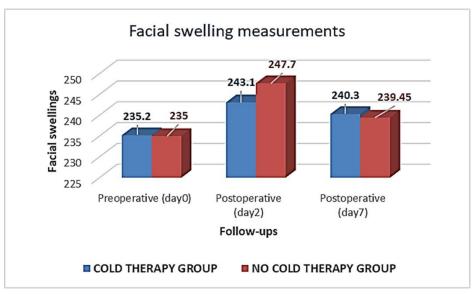
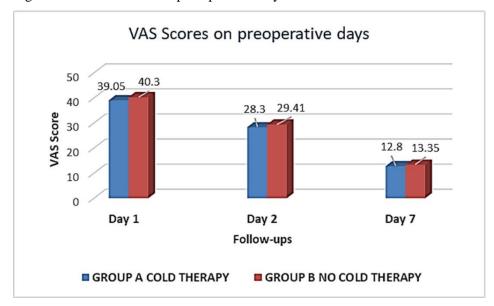


Figure 3: Vas scores on the postoperative days



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