





Efficacy of Ice Pack Therapy After Impacted Third Molar Surgery: A Randomized Controlled Clinical Trial

Gömülü Yirmi Yaş Diş Çekimi Sonrası Soğuk Uygulamasının Etkinliği: Randomize Kontrollü Klinik Çalışma

 Nur ALTIPARMAK,^a
 Burak BAYRAM,^a
 Nurettin DİKER,^b
 Kenan ARAZ^a

^aDepartment of Oral and Maxillofacial Surgery, Başkent University Faculty of Dentistry, Ankara

^bDepartment of Oral and Maxillofacial Surgery, Bezmialem Foundation University Faculty of Dentistry, İstanbul

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Correspondence:
 Nurettin DİKER
 Başkent University Faculty of Dentistry,
 Department of Oral and Dental Surgery,
 Ankara,
 TURKEY/TÜRKİYE
 dikernurettin7tp@gmail.com

ABSTRACT Objective: The aim of the present study is to evaluate the effects of ice pack therapy on post-operative swelling, trismus and pain perception following impacted third molar surgery. **Material and Methods:** Eighteen patients and bilateral third molars were included to this study. At the end of the first operation, cold application was not recommended to patients. Following the second surgery, cold application for 24 hours was added to the recommendation list. Swelling, pain and mouth opening were evaluated for each post-operative period. **Results:** Mean Visual Analogue Scale scores of cold application group were slightly lower than control group, although differences between the groups was not statistically significant ($p=0.06$). At the seventh post-operative day inter-incisal distance in the cold application group was still higher. However, no statistically significant differences were found between the two groups concerning the trismus at the seventh post-operative day ($p=0.259$). Swelling was lower in the cold application group at the both third and seventh postoperative day however, the differences were not statistically significant ($p=0.926$). **Conclusion:** According to results in the present study, ice pack therapy following impacted third molar surgery has no effect on post-operative swelling, trismus and pain perception.

Keywords: Molar, third; cryotherapy; complications; pain; edema; trismus

ÖZET Amaç: Bu çalışmanın amacı; gömük yirmi yaş diş çekimi sonrası soğuk uygulamasının post-operatif şişlik, trismus ve ağrı üzerine etkilerinin değerlendirilmesidir. **Gereç ve Yöntemler:** Bu çalışmaya 18 hasta ve bilateral gömülü yirmi yaş dişleri dahil edilmiştir. İlk diş çekimini takiben soğuk uygulaması önerilmeyen hastaların, ikinci diş çekimlerini takip eden 24 saat boyunca soğuk uygulamaları önerilmiştir. Post-operatif periyotta şişlik, ağrı ve ağız açıklığı değerlendirilmiştir. **Bulgular:** Soğuk uygulanan grupta görsel analog skala skoru ortalamalarının kontrol grubuna göre daha düşük olduğu fakat bu farklılığın istatistiksel anlamlı olmadığı tespit edilmiştir ($p=0.06$). Post-operatif yedinci günde soğuk uygulanan gruptaki interinsizal mesafenin daha fazla olduğu, buna rağmen iki grubun post-operatif yedinci gündeki değerleri trismus açısından karşılaştırıldığında anlamlı bir farklılık olmadığı gözlenmiştir ($p=0.259$). Post-operatif üçüncü ve yedinci günlerde şişliğin soğuk uygulanan grupta daha az olduğu tespit edilmiştir ancak istatistiksel olarak anlamlı farklılık gözlenmemiştir ($p=0.926$). **Sonuç:** Bu çalışma sonucunda yirmi yaş diş çekimi sonrası soğuk uygulamasının post-operatif şişlik, trismus ve ağrı algısı üzerine etkisinin olmadığı gösterildi.

Anahtar Kelimeler: Azı dişi, üçüncü; kriyoterapi; komplikasyonlar; ağrı; ödem; trismus

In most cases, extraction of wisdom tooth causes a trauma which results in an inflammatory response.¹ Some postoperative symptoms may occur such as edema, pain, limitations in mouth opening and dysfunction as a consequence of the third molar surgery. Pain reaches its peak level at the early postoperative period.^{2,3}

The therapeutic benefits of systemic and local cold application have been known since Hippocrates.⁴ Local cold application reduces the magnitude of postoperative symptoms. Even though cold application has been utilized extensively in various areas, its necessity for the reduction of postoperative symptoms is still inconclusive. Although studies exist that have shown the application has been conducive to alleviating postoperative pain, the number of studies is still insufficient to fully determine the necessity.^{1,4-6}

This study plans to ascertain the efficiency of applying cold application when compared to not applying it in the early 24 hour period following wisdom teeth extraction.

MATERIAL AND METHODS

Twenty patients were included to the study who required bilateral mandibular third molar extractions and were operated at the Oral and Maxillofacial Surgery Clinic of Baskent University between 1st June and 1st September 2017. The trial was conducted as a randomized, split-mouth and a single-blind desing. As a split-mouth study, ice pack application was randomly assigned to either the right or left side of each patient's dentition. Therefore, for each patient, ice pack therapy was applied after third molar extraction on one side and not on the other. Postoperative parameters were recorded by an author who did not attend the surgery and was not aware of which group the participant belonged to during evaluation. The study was approved by the local ethics committee at Baskent University located in Ankara, Turkey, and written informed consent was obtained from each patient prior to participation in the study. This research was funded by Baskent University Research Fund (D-KA 15/07).

Patients aged between 18 and 30 years (mean age 20,84) with bilateral symmetrical bony mandibular third molar impactions were included in this study. Detailed medical histories were recorded for each patient to ensure that the participants had no systemic disease (American Society of Anesthesiologists status I). Patients' orthopantomographs

were examined to confirm that the bilateral mandibular third molars had the same Winter and Pell and Gregory classification.⁷ Patients were excluded if they required unilateral extractions, had previous or current gastric ulcers, had allergies or hypersensitivities to any common medications, or were pregnant or breastfeeding. Teeth with local inflammation, the occurrence of any postoperative complications, differences in angulation between the occlusal plane and long axis of the tooth greater than 15° between the right and left third molars, and differences in surgery time greater than 20 minutes were also excluded from the study.

SURGICAL TECHNIQUE

The participants were operated by one surgeon with 8 years of experience in impacted third molar extraction. The surgeon adhered to a predetermined surgical technique. A uniform local anesthetic technique that included inferior alveolar, buccal and lingual nerve blocks with 4% articaine and 1:100,000 epinephrine was used. All extractions required triangular mucoperiosteal flaps and bone removal with a surgical handpiece (W&H Alegria HE-43, Salzburg, Austria) and surgical burs (Meisinger #HM1-016-HP, Colorado, USA) under a continuous spray of sterile saline solution. The flap was repositioned and the incision sutured with simple interrupted sutures using 3-0 silk with a reverse cutting needle (Doğsan, Trabzon, Turkey).

The patients' sex, age and Pell and Gregory classification of the mandibular third molars, as well as the date and duration of the operations were recorded on an information form. All patients received the same postoperative prescription of 1000 mg amoxicillin-clavulanic acid and 100 mg flurbiprofen twice daily for five days after the surgery. The patients were also instructed to rinse their mouth with chlorhexidine gluconate 0.2% mouthwash three times a day for 1 week after the surgery.

At the end of the first operation, cold application was not recommended to the patients and this group of teeth was noted as the control group on the information form. The second surgery was performed at least 3 weeks after the first surgery to

allow full recovery from the previous operation. The same anesthetic and surgical technique was used for the second surgery; however, cold application for 24 hours, except during sleep, was added to the postoperative instructions and a cold thermo-gel wrapped in a disposable towel was given to each patient. The second group of teeth was noted as the cold application group on the information form. The patients were advised to change the thermo-gel every hour for a cold one and to apply the thermo-gel for 5 minutes at a time followed by 5 minutes of resting to prevent skin complications due to cold application.

ASSESSMENT PARAMETERS

Restriction of mouth opening (trismus) was assessed by measuring the interincisal distance before surgery (T0) and on the third (T1) and seventh (T2) days following surgery.⁷ Interincisal distance was measured between the upper and lower incisors with a Vernier-calibrated sliding caliper (Aesculap AA847R, Center Valley, Pennsylvania, USA).

Facial swelling was evaluated by measuring the distances between the labial commissure and tragus at T0, T1 and T2.⁸ These points were marked with a fine tip pen to ensure reproducible measurements. A flexible ruler (Medbar, İzmir, Turkey) was used for the measurements. The edema coefficient was calculated using the following formula:⁹ $E_c = ((\text{postoperative distance} - \text{preoperative distance}) / (\text{preoperative distance})) \times 100$.

The patients' pain perception was assessed using a 10 cm visual analogue scale (VAS) where 0 meant no pain and 10 meant most severe pain imaginable.⁷

Additional analgesic medication used by patient were recorded at the postoperative visits.

STATISTICAL ANALYSIS

The statistical analysis was completed using statistical software (PASW Statistics 18.0, USA). Homogeneity and normality of distributions were confirmed by statistical analysis. For comparison of homogenous and normally distributed data, independent Student's t-test was used. All data are expressed as the mean \pm standard deviation. For all

tests, statistical significance was accepted for p-values less than 0.05.

RESULTS

Only 18 of the 20 patients enrolled, completed the protocol. One patient was excluded because of postoperative bleeding while the other dropped out of the study because of inadequate data. The clinical and demographic distributions of the 18 patients in the study are listed in Table 1.

On the third postoperative day, increased VAS scores were observed that gradually decreased between the third and seventh postoperative days in both groups. Mean VAS scores of the cold application group were slightly lower than the control group at both the third and seventh postoperative days; however, the difference between the groups was not statistically significant (T1 control: 22.2 ± 3.8 , T1 cold application: 18.8 ± 3.3 , $p=0.635$; T2 control: 13.8 ± 3.3 , T2 cold application: 12.1 ± 1.9 , $p=0.06$) (Figure 1).

In both groups, surgical intervention caused a decrease in interincisal opening. On the third postoperative day, mouth opening in the control group was restricted more than in the cold application group, but the difference was not significant (Figure 2). On the seventh postoperative day, the interincisal distance in the cold application group was still greater than the control group; however, the

TABLE 1: Demographic distribution of patients.

Age (mean \pm standard deviation)	20.84 \pm 2.96
Sex	
Female	33%
Male	67%
Impaction type (Winter classification)	
Mesioangular	23%
Vertical	38.5%
Horizontal	38.5%
Impaction type (Pell-Gregory classification)	
Class 3, Position A	12%
Class 3, Position B	44%
Class 3, Position C	44%

Demographic distribution of patients, position (According to the Pell-Gregory classification) and angulation (Winter classification) of impacted third molars.

difference was not significant (T1 control: 35.21 ± 1.69 , T1 cold application: 35.84 ± 1.68 , $p=0.446$; T2 control: 37.94 ± 1.25 , T2 cold application: 38.47 ± 1.12 , $p=0.259$) (Figure 2).

The edema coefficient was lower in the cold application group on both the third and seventh postoperative days; however, none of the variables were statistically significant for the edema coefficient (T1 control: 7.34 ± 0.98 , T1 cold application: 5.12 ± 0.94 , $p=0.736$; T2 control: 3.50 ± 0.56 , T2 cold application: 2.74 ± 0.62 , $p=0.926$). A decrease in facial swelling was noted between the third and seventh postoperative days in both groups. However, 13 of 18 patients' swelling did not return to baseline by the seventh postoperative day (Figure 3).

None of the patients required additional analgesic medication during post-operative period.

DISCUSSION

Eighteen patients and bilateral third molars were included to this study. At the end of the first operation, cold application was not recommended to patient. Following the second surgery, cold application for 24 hours was added to the recommendation. All patients received the same postoperative prescription of 1000 mg amoxicillin-clavulanic acid and 100 mg flurbiprofen twice daily for five days after the surgery. The patients were also instructed to rinse their mouth with chlorhexidine gluconate 0.2% mouthwash three times a day for 1 week after the surgery.

Effective pain control is crucial in dentistry. A retrospective analysis demonstrated that ibuprofen is effective for treating moderate to severe postoperative pain. Numerous studies conducted in patients with postoperative dental pain after third molar surgery confirmed the analgesic effects of ibuprofen in these patients. Non-steroidal anti-inflammatory drugs (NSAIDs) are among the most widely prescribed analgesics for management of post-operative pain in dental patients and also NSAID drugs are more effective than analgesic drugs at all doses so NSAID drugs are usually recommended for routine use after this procedure unless the patient have GIS problems.^{10,11} In this study

none of the patients had GIS problems so all of them received 100 mg flurbiprofen.

Cold therapy is a treatment method that is used to decrease the body temperature by means of local or systematic application of some kinds of physical agents. The aim of cold application is to decrease the blood flow regarding temperature. Continuation of cold therapeutic applications for 15 to 30 minutes become effective by slowing down the blood flow and body metabolism. The physiological effects of cold application are as follows: vasoconstriction of blood vessels, blood flow to the region decreases, edema and inflammation

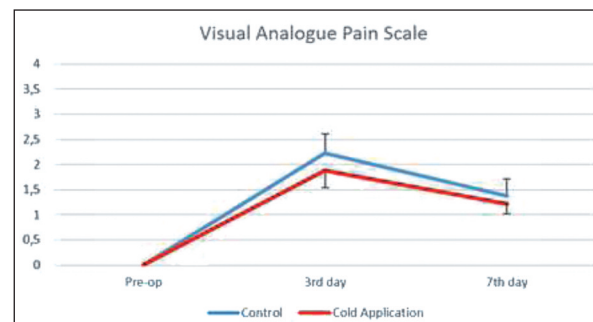


FIGURE 1: Mean VAS scores of cold application and control groups.

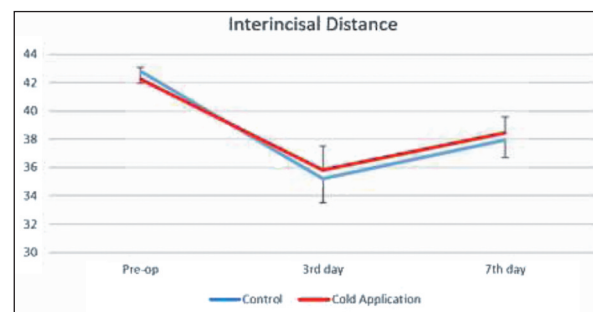


FIGURE 2: Mouth opening in cold application and control groups.

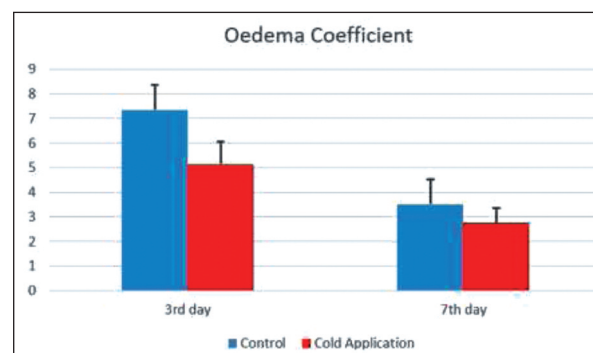


FIGURE 3: Swelling in cold application and control groups.

decreases, slowdown in cell metabolism and a decrease in local oxygen demand due to the vasoconstriction effect of the cold. Cold therapy also induces muscle constriction which reduces muscle stress, pain and inflammation.^{8,9,12} The main function of cold application in oral and maxillofacial surgery is to generate vasoconstriction and to allow the bleeding to be controlled. This results in the reduction of metabolism at the site of the cold application and enables the growth of bacteria to be controlled.^{1,13,14}

It should be noted that the application of ice on a certain area like the jaw results in the cutaneous layer to be rapidly chilled, however its impact on the deeper tissues is significantly reduced and occurs at a much slower rate. It should not be neglected that exposure to the extreme cold for a long period of time causes damage or even death of cells.

There are numerous studies in literature which present evidence that ice pack application after impacted third molar surgery decreases facial pain and swelling in the postoperative period.¹⁵⁻¹⁸

In contrast, van der Westhuijen et al.¹ stated that ice application in the early 24 hours of postoperative period after the impacted third molar surgery does not have a statistically significant impact in decreasing pain and swelling. Other authors have also expressed similar apprehensions.¹⁹⁻²¹

In a controlled clinical study by Forouzanfar et al. 45 minutes of compress without cold application and 45 minutes of cold compress application after the impacted third molar surgery were compared.²² It was observed that, both methods decreased the pain and that cold compress application was not a superior alternative to the solely compress application.

In a clinical trial by Zandi, thirty patients with bilateral symmetrical mandibular impacted third molars were enrolled.²³ Ice pack therapy was given for 24 hours to the intervention side after surgical removal of the tooth; for the control side, no cold therapy was applied. The authors stated that cold therapy did not reduce these postoperative symptoms.

Even though impacted third molar surgery is performed according to certain standards such as

asepsis, hemostasis and controlled manipulation, frequent postoperative problems such as varying intensities of pain, edema and trismus may occur. This is an expected consequence in surgical procedures involving both hard and the soft tissues. Postoperative edema, pain and trismus are related to various factors. Operation time, experience of the surgeon, gender and age of the patient, angulation and the degree of embeddedness of the impacted tooth are some of those factors.^{1,21,23} As impacted lower third molar surgery is the most common oral surgery procedure and that this surgery has a high incidence of postoperative pain, edema and trismus, it is vital that the inflammatory process and the effectiveness of ice therapy in combatting that process be studied. It is still undetermined whether ice therapy, which is commonly recommended after the frequently conducted third molar surgery, has a statistically significant impact in alleviating postoperative complications. Furthermore, it should be discussed whether postoperative recommendation including cold application is in need of updates especially when considering the possible side-effects of misapplications of cold. In the present study the authors focused on these questions and a randomized, self-controlled, split-mouth clinical trial design was used to exclude or control these confounding factors. Only patients with symmetrical bone impacted mandibular third molars were included and all of the surgeries were performed by the same surgeon. Since continuous cold therapy increases the chance of tissue ischemia and damage due to vasoconstriction, the patients were prescribed to apply the ice intermittently.^{3,24} Although pain, trismus and facial swelling, as well as the extent of patient satisfaction, were reduced by cold therapy, there were no significant differences between the intervention and control groups of this study which is in line with the results of the studies by Van der Westhuijen et al.¹, Forouzanfar et al.²² and Zandi et al.²³

CONCLUSION

According to results in the present study, ice pack therapy following impacted third molar surgery has

no effect on post-operative swelling, trismus and pain perception. To prevent ice therapy related complications surgeon may not recommend to apply ice after impacted third molar surgery. However, more sophisticated cooling therapies may have effects on deep layers of tissues, so further researches is needed for clarification of this issue. Furthermore, there are some other matters to keep in mind such as whether or not the patients are following the recommended cold application directions as this would effect the results. Likewise, individuals in different socioeconomic groups can influence the outcome of the study as well. Many additional factors like these have to be studied as they may cause the clinical trial results to be contradictory.

Source of Finance

During this study, no financial or spiritual support was received neither from any pharmaceutical company that has a direct connection with the research subject, nor from a company that provides or produces medical instruments and ma-

terials which may negatively affect the evaluation process of this study.

Conflict of Interest

No conflicts of interest between the authors and / or family members of the scientific and medical committee members or members of the potential conflicts of interest, counseling, expertise, working conditions, share holding and similar situations in any firm.

Authorship Contributions

Idea/Concept: Nur Altıparmak, Burak Bayram, Nurettin Diker, Kenan Araz; **Design:** Nur Altıparmak, Burak Bayram, Nurettin Diker; **Control/Supervision:** Nur Altıparmak, Burak Bayram, Nurettin Diker, Kenan Araz; **Data Collection and/or Processing:** Nur Altıparmak, Nurettin Diker; **Analysis and/or Interpretation:** Nur Altıparmak, Burak Bayram, Nurettin Diker, Kenan Araz; **Literature Review:** Nur Altıparmak, Nurettin Diker; **Writing the Article:** Nur Altıparmak, Burak Bayram, Nurettin Diker; **Critical Review:** Burak Bayram, Kenan Araz; **References and Fundings:** Nur Altıparmak, Burak Bayram, Nurettin Diker, Kenan Araz; **Materials:** Nur Altıparmak, Burak Bayram, Nurettin Diker, Kenan Araz.

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