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Evaluating Facial Cryotherapy for Postoperative Sequelae of Third Molar Surgery: A Randomized Observer-blind Split Mouth Clinical Trial

[1]Mesgarzadeh Ali Hossein, [2]Goshaderu Abbas and [2]Shahamfar MohamadReza
[1]National Public Health Management Center, School of Dentistry, Department of Oral and Maxillollofacial Surgery, Tabriz University of Medical Sciences, Iran
[2]National Public Health Management Center, School of Dentistry, Tabriz University of Medical Sciences, Iran

Abstract: The effect of cryotherapy on pain, swelling and trismus following third molar surgery was evaluated using an observer blind split mouth clinical trial. Twenty patients undergoing surgical extraction of symmetrically bilateral impacted mandibular third molar were studied. Each patient received two operations 5 week apart. Randomly allocated to side and appointment, each patient received cryotherapy immediately after surgery for 25 min every houre for 24 h while receiving no intervention on the other side to serve as control. Clinical examination of pain, swelling and trismus were performed 24 and 48 h postoperatively. Analysis data of each side determined no significant reduction of pain or trismus either on fist or second postoperative days. However, swelling significantly decreased. We conclude that cryotherapy may be used for controlling of swelling; however, based on our findings, we can not attribute the same for pain or trismus.

Key words: Cryotherapy, third molar surgery, postoperative sequelae, trismus, swelling, pain

INTRODUCTION

Surgical removal of impacted third molars constitutes a large proportion of maxillofacial surgery procedures. No exception to other injuries and surgical procedures, dentoalveolar operations too, involve a post-surgical sequelae often involving pain swelling and dysfunction. Many complex molecular and biochemical factors are known to be involved in these processes, the key of which is thought to be initiation of inflammatory procedures triggered by surgical injuries and trauma (Capuzzi *et al*., 1994). Though numerous pharmacological regimens such as Non-Steroidal Anti-inflammatory Drugs (NSAIDs) by decrease in prostaglandin synthesis or glucocorticoide with their membrane stabilizing and anti-exudative effect have so far been proposed to bring these surgical side effects under control, cryotherapy (cold therapy or ice therapy) remain least costly, with least side effects, easily applicable and with a wide spectrum of action (Macauley, 2001; Jutte *et al*., 2001; Guirro *et al*., 1999; Knight, 2000).

Cryotherapy referring to local or systemic application of cold for therapeutic purposes has long been used to control inflammation, pain and edema in addition to reduction of spasticity and facilitation of movement. Several pathways through which cryotherapy implement its effect have been proposed some of which typically include slowing of nerve conduction velocity resulting in analgesic response to cold and increased pain threshold, decrease in muscle spasticity, slowing in metabolism rate and control of hemorrhage (Lehmann, 1990; Cameron, 1999; Ernst *et al* ., 1994; Lee at al., 1978; Price *et al*., 1993; Weston *et al*., 1994). However, despite frequent use of cryotherapy in orthopedics, rehabilitation and physiotherapy, as indicated by the many reports in medical literature, there seems to be insufficient scientific evidence in oral and maxillofacial surgery in this regard. This happens when the need for better patient care has more than ever moved the dental profession towards evidence based practice in which the practitioner combines clinical expertise at treating a condition with latest research of the literature on the treatment procedures (Sacket *et al*., 2000). This study was conducted to investigate and analyze the effect of cryotherapy on post-operative sequelae of third molar surgery namely pain, trismus and edema of orofacial tissues.

MATERIALS AND METHODS

Twenty otherwise healthy patients with bilateral symmetrical mandibular third molar impaction with age

Corresponding Author: Mesgarzadeh Ali Hossein, National Public Health Management Center, School of Dentistry, Department of Oral and Maxillollofacial Surgery, Tabriz University of Medical Sciences, Iran

ranging from 17-47 and a mean age of 26 underwent a randomized observer blind split mouth clinical trial. The sample included 17 male and 3 female individuals who were selected from patients attending the maxillofacial department clinic, Tabriz state dental school that needed to remove their mandibular wisdom teeth. The method used for gathering the sample population was convenience sampling. Before initiation of the research program, the study protocol was reviewed by the university review board and was approved by the special committee for ethics and humanity. Prior to entry to the research study, informed consent from each patient was obtained separately and in special forms provided by the local ethics committee. A detailed medical history accompanied with a general examination by the attending clinic physician from all participating patients was taken prior to the study. The inclusion criteria for patients to enter the study was to have generally healthy body, no systemic disease, a good oral hygiene, no prior trismus history, existence of bilaterally and symmetrically identical third molar impaction with the same impaction position and same degree of difficulty, identical required surgical procedures, lack of pericoronitis, partial or full impaction in bone and full coverage with alveolar mucosa.

Pregnant or lactating women were excluded from the study. Patients were required to have adequate cooperation in home with the research team, though to this end, a nurse was actively in contact with the patients in home. Patients were strictly prohibited from using any kind of analgesic, anti-inflammatory or antibiotic drug 48 h prior to the surgery.

Preoperative procedures: After patient selection and general physical examination, before surgery, maximum mouth opening for determination of a base line for trismus measurement was recorded by measuring the inter-incisal distance between maxillary and mandibular central right incisor using a standardized millimeter scale device. This was done after one minute of mouth stretching. For measurement of swelling an inter-landmark linear distance measuring was used. This was conducted by measuring the linear distance from attachment spot of earlobe to skin to the Commissure of Lip (Co-L) and linear distance from outer canthus of eye to the angle of mandible (Ca-A). Before initiating the program we assessed the reliability of the facial linear measurements. To this end 6 non surgical patient with different face forms were examined for daily face sizes every day for 3 consecutive days. The analysis of the measured values for consistency determined a mean agreement of 99% which overtook the set priori aim of 95%. All measurements in the current study were repeated twice and the average value was then registered. Severity of pain perception by the patient was assessed via a pain rating scale featuring a simplified Visual Analogue Scale (VAS) 10 centimeter in length where "0" implied no pain and "10" as most sever pain imaginable. This scale was further divided into four intervals. (0-2.5 = no pain, 2.5-5 = mild pain, 5-7.5 = moderate pain and 7.5-10 = maximum pain)

Surgical procedures: After preliminary examinations mentioned, patients underwent surgical extraction of mandibular third molars. Each patient required two operations with a 5 week interval. Cryotherapy intervention was randomly allocated to side (right or left) and to appointment (first or second). Due to the cross over nature of the study each patient served as their own control. Furthermore, when assessing the outcome, the investigators were blind as to whether which side was treated with cryotherapy. Relevant details including those of intervention (cryotherapy) was registered in special forms for further perusal. The operation was performed under local anesthesia. All surgeries were performed by one senior resident under direct supervision of one maxillofacial surgery professor with the same surgical technique. Local anesthesia was provided using an inferior alveolar nerve block and long buccal block administering an average of 3 cartridges of 1.8 m for each side's surgery. Each cartridge was a 2% lidocaine hydrochloride containing 1: 100000 epinephrine vasoconstrictor.

The standardized surgical technique was strictly followed by the surgeon. The incision was followed by providing a triangular full thickness flap with releasing incision on mesial of the second molar which was then followed by ostectomy of the surrounding bone with a no.8 round carbide bur. The surgery went on by sectioning the impacted tooth with a fissure bur. All the surgical procedures were performed under persistent irrigation with sterile saline solution to minimize soft and hard tissue damage as well as providing a better visual scope. After tooth removal, the flap was repositioned and sutured with a 3-0 silk suture and a reverse cutting Fs-2 needle.

Cryotherapy procedures: After fulfillment of surgical procedures, in due cryotherapy side patients were immediately prescribed with standardized tissue compatible ice packs. All ice pouches had similar amount and size and were strapped and enveloped with a water proof bag. The Cold pack application was applied for 25 min every hour for the next 24 h during the Patients wake time. Patients were adequately instructed on the cryotherapy application by a member of the research team

to make sure it was handled in an effective way. The first hour of the cryotherapy was done in the clinic and in presence of the surgeon and the rest in patients home. Patients were asked to record details regarding application of each ice packs in formatted forms distributed amongst them in order to supervise compliance. No side effect attributable to cryotherapy was observed in this study, nor did any condition enunciate patient withdrawal from the study. Patient compliance was excellent with a nurse regularly in contact with the patients supervising their performance while in addition, gathering the patient self reported forms at the end of the second postoperative day.

The other due surgery was conducted with a five week interval on the control side without application of cryotherapy.

Post-operative procedures

For evaluating efficacy of cryotherapy on trismus: Investigators measured the inter-incisal distances (the maximum mouth opening) 24 and 48 h after surgery and compared it with the baseline marks. This was done for both cryotherapy treated and control side, while the investigators were blind as to the allocation of the side being evaluated.

For evaluating efficacy of cryotherapy on facial edema: Facial swelling rate was assessed two times, respectively 24 and 48 h after surgery by the method previously described and then were compared with the pre operative baseline grades in both sides. The actual swelling rate was determined by subtracting the base line grade from the post-surgical one. Swelling proportion was reached through multiplying the co-l distance by the ca-a distance on the surgery day one day (= 24 h) and two days (= 48 h) after surgery and dividing independently each two latter days' grade to the grade registered on the surgery day.

For evaluation of efficacy of cryotherapy on facial pain: Pain was assessed once before surgery and two times, respectively 24 and 48 h after surgery. The pain was assessed by previously described 10 centimeter Visual Analogue Scale (VAS) with "0"and 10, respectively standing for the least pain and most sever imaginable pain. All the patients were instructed and assisted in this regard by a trained nurse both at clinic and at home during which regular periodic phone contacts were made.

Study design and statistical analysis: This study was designed on a randomized split mouth observer blind clinical trial format. The patients were selected from referees to the maxillofacial department clinic, Tabriz State dental School. Relevant pieces of information regarding each patient were registered separately in standardized forms for analysis of the data. Data analysis was performed utilizing SPSS version 12 computer soft ware. Analysis of bilateral relationships between continuous variables was conducted by cross table chi-square analysis. An alpha value < 0.05 was considered to be significant.

RESULTS

Baseline characteristics of patients are described in Table 1. At baseline there was no significant difference between characteristics of the patients or teeth. The bilateral teeth regarding each patient were checked for having the same degree of impaction, difficulty of extraction and angulations. Majority of patients had mesioangular teeth impaction while a number of others presented distoangular impaction.

Mouth opening ability: Analysis of mouth opening abilities registered on 24 and 48 h after surgery indicated no significant difference in mouth opening abilities between treated and control side in neither of the postoperative times evaluated ($p>0.05$). However, in either of the postoperative times, a non-significant improvement in degree of trismus in cryotherapy side than control side was observed, though the mouth opening abilities in the 2 sides were close to each other (Fig. 1) The mean preoperative mouth opening ability values in either cryotherapy or control occasions was 47 mm (the base line maximum mouth opening value). The corresponding postoperative mean values, respectively for cryotherapy and control side were reduced to 33.6 and 32.4 on 24 h and to 34.8 and 33.2, 48 h after surgery.

Pain values: Utilizing a graded Visual Analogue Scale (VAS), we measured the pain values on the first and second post operative day. Statistical analysis of data on pain values registered on the 24 and 48 h postoperatively, determined no significant difference in cryotherapy than control side ($p>0.05$). Though the mean pain value in cryotherapy side either on 24 or 48 h were slightly lower than those of control side, neither of them gained a statistically significant difference (Fig. 2). While the mean

Table1: Baseline characteristics and surgical variables

Age	No.	Sex	No.	Impaction type	
17-27	11	Male	16	Mesioangular	17
27-37	5	Female	4	Distoangular	3
37-47	4				
Total	20	Total	20	Bone impaction	11
				Partial soft	
Mean	26.2			tissue impaction	9

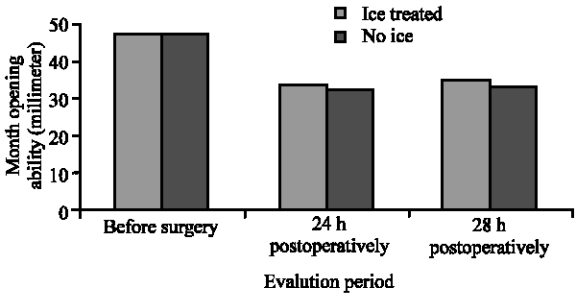

Fig. 1: Maximum mouth opening abilities for cryotherapy side and control side before surgery, on 24 and 48 h after surgery

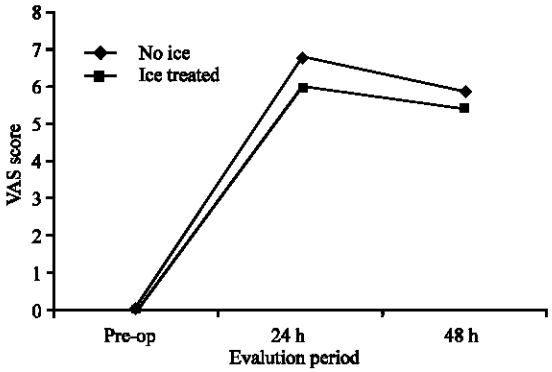

Fig. 2: Coparison of mean registered pain values on 24 h after surgery for cryotherapy side and control side

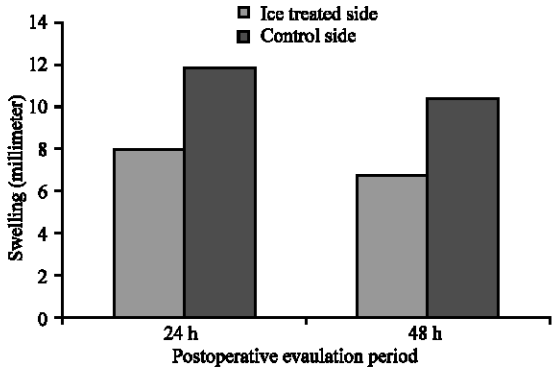

Fig. 3: Coparison of mean registered swelling values for cryotherapy side and control side on 24 h after surgery for

pain value on postoperative 24 h in cryotherapy and control side was, respectively 6.02 and 6.8, the respective values for its following day (on 48 h) were 5.46 vs. 5.87 (Fig. 2).

Swelling values: Swelling was assessed two times on 24 and 48 h after surgery in either ice treated or control side. Statistical analysis of the swelling values for both 24 and 48 h postoperatively, indicated a statistically significant improvement in swelling values in cryotherapy than control side ($p<0.05$).

The mean facial swelling value for ice pack treated side on the first and second postoperative day was, respectively 7.93 mm and 6.7 3 mm while the corresponding values for the control side were, respectively 11.81 and 10.44 mm (Fig. 3).

DISCUSSION

Despite the extensive use of cryotherapy in management of acute musculoskeletal injuries, few investigations have actually examined the effect of cryotherapy alone on maxillofacial surgeries. The general effects of ice have been demonstrated in number of animal models and human studies. Ice reduces temperature, blood flow and metabolism. The proposed analgesic effect of cryotherapy is one of the primary reasons clinicians use it in the management of injuries including maxillofacial surgeries. Slowing of nerve conduction velocity has been proposed to be the likely mechanism for the analgesic response to cold (Lee *et al*., 1978). This effect may last up to 30 min after application. Retarding secondary injury is an important theoretic benefit of cryotherapy (Knight, 1995, 1976; Merrick, 2002)

Knight (1995) proposed that hypoxic injury is a significant problem after injury. Cryotherapy by slowing the rate of chemical reactions reduces the demand for oxygen which subsequently leads to longer tissue survival during hypoxia.

Inappropriate cold implementation may result in tissue necrosis due to continued vasoconstriction, ischemia and thrombosis (Cameron, 1999). Some resources have suggested that ice pack application not exceed 24 h since, further application may not be more effective and perhaps does no good for the patient (Peterson *et al*., 2003). Furthermore, some contraindications for cryotherapy have also been identified. Patients with cold intolerance, abnormal response to cold and improper blood circulation are some typical exceptions to cryotherapy (Cameron *et al*., 1999). The clinician should clearly take these conditions into account when managing a cryotherapy candidate. Patients with hypertension, weak sensation ability, the very young and the very old should also be given extra attention since such patients may frequently be more exposed to improper thermal adjustment or may have limited communicatory potency (Cameron *et al*., 1999). In spite of the many effects attributed to cryotherapy, perhaps more important question is the question whether ice application improves treatment outcomes. A lot of controversy has been going on among the dental professionals in the clinical efficacy of cold application. A study by Bleakely *et al*., (2004)

reported that cold seemed to be more effective in limiting swelling and decreasing pain in short tem. However, the long term effects of cryotherapy and it effect on tissue repair is not clear. Forsgren *et al*. (1985) in a cross over study evaluated the effect of external local cold application on post operative course of oral surgery. Patients in that study were treated postoperatively with cold dressings after the first or second operations. They found no evidence of improvement in post operative course of surgery either in short term or long term basis. The effect of cold therapy was also assessed in a case-control intervention study (Van der Westhuijzen *et al*., 2005). They randomized 60 patients requiring general anesthesia for removal of bilaterally impacted third molars into one of the 2 treatment groups: One group received bilateral facial ice packs after surgery, while the other group received no form of cold therapy. The ice application in the experimental group was implemented in the patients' recovery room continuously for the next 24 h postoperatively. They also used a package of analgesic/anti-inflammatory regimen of paracetamol, ibuprofen and codeine phosphate for all patients. The facial swelling and trismus was evaluated on the postoperative 24 h and pain was assessed on the 4 h, the evening of the surgery and the following morning. At the end of the research program, they found no significant benefit by adding ice therapy to the standardized analgesic/anti-inflammatory regimen package in controlling post surgical pain, swelling or trismus values. However, the results of that study may have been partly overshadowed by the potent doses of analgesics used which in result could hide the therapeutic effects of ice therapy. In current study we eliminated the factor of pharmacological intervention to evaluate the sole and pure effects of ice on post operative sequelae. As a result no kind of medication was used in this study. We found no significant reduction in pain values of ice treated side in comparison with control side, on either of the postoperative days, nor did we find any meaningful improvement in trismus values in intervention side. However, facial swelling values for cryotherapy side significantly decreased either on the first or second postoperatively day. This is especially noticeable when we take into account the fact that postoperative swellings impose significant adverse effects on daily life of the patients (Sisk *et al*., 1986). In a study by Savin *et al*. (1995) it was indicated that one out of three patients who had undergone third molar extraction, was inflicted by socializing problems for at least one week due to the surgical sequelae (notably swelling) of third molar extraction.

These facts certainly are noteworthy enough for the dental profession to put more attention into patients post surgical issues to minimize discomfort after surgical procedures.

Numerous modalities have been proposed to abate the post operative complications of third molar surgery. These typically include interventions implemented either preoperatively, on the operation or post operatively. Verbal sedation, as well as long acting local anesthetics, glucocorticosteroids and non steroidal anti inflammatory drugs have been evaluated for this purpose (Dionne *et al*., 1984; Graziani *et al*., 2006). Acute post-surgical pain following third molar extraction is primarily a consequence of inflammation caused by tissue injury. The 2 latter pharmacological interventions have been well documented in having anti inflammatory effects. Despite the differences in recommended dosage required, a lot of studies using oral rout administration of glucocorticoide has reported clinical improvement in pain swelling and trismus (except for Nathanson and Seifert), though these results require further investigations (Bystedt and Nordenram., 1985; Caci and Gluck, 1976; Hooley and Francis ,1969). NSAIDs have also been proved effective in abating pain after surgical procedures (Goodman and Gillman, 1985). Some proposed therapeutic interventions for alleviating trismus include ultrasonic therapy, medication therapy and cryotherapy. Other proposed interventions to limit post operative sequelae, put forward by several resources include using a gauze drain impregnated with chlortetracycline conventional buccal approach, lingual splint and marginal and Paramarginal flap; though none have been proved in controlling the pain (Akota *et al*., 1998; Suarez-cunqueiro *et al*., 2003; Chiapesco*et al*., 1995; Sisk *et al*., 1986; Souza *et al*., 1992).

Assessment of facial swelling values induced by surgical procedures has been proven to be most problematic. Some techniques used to evaluate swelling have been demonstrated in Table 2. These typically include 1, 2 and 3- dimensional measurements. Though no single technique has been proven to be superior or more accurate, the desire to recruit large number of patients and the practicality of a low cost reliable technique has made the linear measurement a feasible choice. However, one of the limitations of the current study is that despite using an objective rather than subjective method for measurement of facial swelling values, still the method used may lack the sensitivity to mark a degree of difference in actual swelling values. Therefore, a void seems to exist in terms of a clinically feasible and more accurate means of measuring swelling values. These limitations may be addressed in further studies. In the

Table 2: Some methods described by literature for measurement of facial swelling

1-dimensianal	2-dimensional	3-dimensional
Calipers	Frontal photographs	Stereophotographictechnique
Face-bow	Modified face-bow	Face-bow with lateral plates
Impression tray	Cephalostat	
Ultrasonography	Computed tomography	

Data derived from (Pederson *et al.,* 1985)

current study the cryotherapy intervention turned out to be effective and useful in controlling facial swelling in patients. Compression of the tissues is usually considered a confounding factor associated with cryotherapy. In the current study, the exact cryotherapy technique was meticulously adhered to avoid such interfering factors, in order to make a better evaluation. This might account for the parts of our results suggestive of bare effectiveness of mere cold application on pain and trismus. Though the effects of a meticulously adhered cold application can not be overlooked, the clinical therapeutic efficacy of routine cold application might partly be associated with some other factors namely coincident application of compression and cold. As also suggested in a number of previous physiotherapy and orthopedic studies, simultaneous ice and compression appear to be substantially more effective than ice alone. These studies indicate that ice does not seem to be more effective than compression in the post operative course and attribute in part some healing effects of cold therapy either on compression or a placebo induced effect (Scarcella and Cohn, 1995; Edwards *et al*., 1996; Konrath *et al*., 1996; Daniel *et al*., 1994). Indeed, at present it does not appear possible to derive a definite answer. Further investigations would help clarify the subject.

CONCLUSION

The overall findings from our study demonstrated that use of cryotherapy can be useful in terms of abating swelling values in patients' post operative course; however we can not attribute the same for other factors like pain or trismus since our cryotherapy could not exert any substantial improvement in the corresponding values. We suggest further controlled trials with larger sample sizes. Other types of post operative therapy methods like low level laser therapy may also be evaluated for this purpose.

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