Effects of cold therapy in the treatment of mandibular angle fractures: hilotherm system vs ice bag



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Ida Barca*°, Walter Colangeli*°, Maria Giulia Cristofaro*, Amerigo Giudice**, Elio Giofrè*, Anna Varano*, Mario Giudice*

University of Magna Graecia, Catanzaro, Italy *Department of Oral and Maxillo Facial Surgery (Chairman Prof. M. Giudice) **Department of Dentistry °These authors contributed equally to research

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AIM: To evaluate the effectiveness of Hilotherm, a recently introduced cooling system, in controlling postoperative edema and pain and to compare the results with those obtained with conventional cryotherapy.

MATERIAL OF STUDY: The investigators selected 40 patients with unilateral angle fracture of the jaw and divided them into two groups, cryotherapy with ice bag (A group), and Hilotherapy system (B Group); both groups with the same drug treatment. Facial swelling was preoperatively quantified measuring skin segments (called α , β , γ and δ), pain and patient satisfaction were measured for each with questionnaires.

RESULTS: Data analysis showed better decrease of soft tissue edema and better pain control with Hilotherapy system in post-surgical treatment.

DISCUSSION: The cooling procedures described are ice packs, gel packs or cold compresses. An alternative to conventional cooling methods is Hilotherapy (HilothermGmbH, Ludwigsburg, Germany) a water-circulating cooling device that permits continuous cooling through a face polyurethane preshaped mask.

CONCLUSIONS: The results of this study suggest that Hilotherm is the better method for patient's postoperative edema and pain management when compared to conventional cooling probably due to possibility of mean temperature control and to greater patient's compliance.

KEY WORDS: Cold therapy, Cooling methods, Mandibular fractures

Introduction

Mandible is a prominent bone of the human face and is often involved in trauma injuries. Many studies have shown that mandibular fractures account for the majority of all facial fractures¹⁻³. Unifocal mandible fractures frequently affected the body and the angle ⁴. Prompt diagnosis is important to avoid

functional complications such as restricted mouth open-

ing, difficulty for chewing and swallowing. In most cases the mandibular bone fractures leads to an important degree of tissue trauma leading to an inflammatory reaction and soft tissue swelling. Also fractures surgery is associated with side effects like postoperative swelling, pain, inflammation and limited mouth opening due to muscle spasm (trismus)⁵. Pain is typically brief and peaks in intensity in the early postoperative period, while facial swelling characteristically reaches its maximum 24-48h after surgery ⁶.

These symptoms can affect the patient's quality of life. We can use pharmacological therapy to reduce or eliminate these side effects (corticosteroids ⁷, non-steroidal anti-inflammatory drugs ⁸, a combination of corticosteroids and non-steroidal anti-inflammatory drugs ⁹ or enzyme preparations like serratiopeptidase ¹⁰ In addition,

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Correspondence to: Ida Barca, M.D., Department of Maxillo Facial Surgery, University of Magna Graecia, Viale Europa, località Germaneto, Catanzaro, Italy (e-mail: barca.ida@gmail.com)

there are also non-pharmacological methods, such as manual lymph drainage ¹¹, softlaser ^{12,13} and cryotherapy ¹⁴⁻¹⁸. Cryotherapy or cold therapy is the local or systemic application of cold for therapeutic purposes and has been in use since at least the time of Hippocrates ¹⁹.

Local cold compression treatment (cryotherapy) reduces metabolism and controls inflammation and hemorrhage 14,20,21, decreases the excitability of free nerve endings and peripheral nerve fibres, increasing the pain threshold ²². A literature review shows pour scientific evidence of trials regard either positive or negative effects of cold therapy in oral and maxillofacial surgery 15, 23 .There are different cooling procedures described, such as ice packs, gel packs or cold compresses. An alternative to conventional cooling methods is Hilotherapy (HilothermGmbH, Ludwigsburg, Germany) a water-circulating cooling device that permits continuous cooling through a face mask. The aim of this study is to evaluate the efficacy of Hilotherapy in controlling postoperative edema and pain as well as patient comfort and to compare this cooling therapy to conventional methods as ice bag in the treatment of mandibular angle fractures.

Material and Method

The trial was carried out in the department of Oral and Maxillofacial Surgery at the "Magna Graecia" University of Catanzaro between 1 January 2012 and 31 December 2013. Written informed consent was obtained from each patient. Forty patients, undergoing surgery for displaced unifocal fracture of the mandibular angle, were selected.

Fig. 1: A) The figure demonstrates the Hilotherm device. A maximum of 2 masks can be connected to 1 Hilotherm device. The temperature can be adjusted from 10 to 30 °C. B) Front view of a patient wearing the mask.



We preliminarily collected information about past illnesses and diseases and conducted a standard blood test. Surgical treatment was made under general anesthesia by nasal intubation. In all cases, the mandibular angle fractures were treated with two 2-mm locking plates by transbuccal access. Potential participants were excluded from the study because of missing the follow-up examination, intake of anti-inflammatory and anti-edema therapy 72 hours before, as well as blood coagulation disorders and allergic reactions to pharmaceuticals and antibiotics.

The patients were divided randomly into 2 treatment groups after surgery: 20 patients were treated with conventional cooling using ice bag (A group), 20 patients received continuous cooling using Hilotherapy device (Hilotherm GmbH, Ludwigsburg, Germany), that consists of a mobile electric cooling unit, with adjustable digital thermostat and a closed-loop chilled distilled water flowing in internal manifolds and rubber masks conformed to the anatomical regions of the facial(B group) (Fig. 1 A-B). In the second group (B) the preshaped thermoplastic polyurethane mask has been applied immediately after surgery (time 0), maintaining a temperature of 12 °C for 24 hours (time 1) and 15 °C for the next 24 hours (time 2). Both groups had the same post-operative drug treatment which included 1 g ampicillin as the sodium salt plus 0.5 g sulbactam as the sodium salt intramuscularly for 5 days, betamethasone 4 mg intramuscularly in the first post-operative day and analgesic drug (paracetamol 1000 mg) intravenously as needed. During the study the following parameters were assessed: swelling, pain analgesic requirements and patient satisfaction.



Measurement of Facial Swelling

The soft tissue edema was calculated for each patient at time 0 (immediate post-operative period), time 1 (24 hours) and time 2 (48 hours) by measuring in millimeters of skin segments called α , β , γ and δ marking preoperatively with permanent marker as fixed reference points the tragus, the wing of the nose, the labial commissure, the pogonion and gonion. The sum of the segments examined ($\alpha + \beta + \gamma + \delta$) at time 0, 1 and 2 for each patient of the two study groups A and B was calculated and graphed (Fig. 2). It was also indicated by the symbol N the line of mean values ($\alpha + \beta + \gamma + \delta$) measured contralateral to the fracture.

PAIN ANALYSIS

Postoperative pain analysis was conducted with the administration to patients of the Faces Pain Scale test associated with a visual analogue scale (VAS) at 24 hours (time 1) and at 48 hours (2) after surgery, where the patients rated their pain on a score from 0 to 10, with 0 describing a situation without pain and 10 denoting



Fig. 2: Skin segments, measured in millimeters, called α , β , γ and δ marking preoperatively with permanent marker as fixed reference points the tragus, the wing of the nose, the labial commissure, the pogonion and gonion.



Fig. 3: Image of Faces Pain Scale test associated with a visual analogue scale (VAS) from 0 to 10, with 0 describing a situation without pain and 10 denoting maximum intensity of pain.

maximum intensity of pain (Fig. 3). It also takes into account the number of vials of steroids and painkillers administered in addition to the standard treatment protocol for both study groups.

PATIENT SATISFACTION

Each patient was asked to complete a questionnaire on the third postoperative day. They were asked how they evaluated satisfaction and convenience of the cooling therapy on a subjective base.

The grading scale ranged from 1 to 3, where 1 stands for not relief, and 3 for total relief.

Results

The analysis of data related to group B showed a more rapid decrease of the edema after 48 hours of cryotherapy treatment with return to values nearest to normal (N values) than in group A; also the physiological increase of edema in 24 hours following surgery is significantly reduced in group B as showed in Fig. 4 A-B. The subjective evaluation of pain indicates a more postoperative comfort of the group B in the 24 and 48 hours following surgery. In fact the number of vials of painkillers requested in addition to standard treatment protocol is lower in patients of group B (Fig. 5 A-B). Regarding patient satisfaction, which was assessed at third day after surgery, a significant difference between hilotherapy and conventional cool packs could be detected. Patients treated with hilotherapy had a significantly greater satisfaction. This study suggests that continuous cooling hilotherapy system reduces postoperative swelling and pain in the mandibular angle fractures patients, where compared with ice pack use. In fact Hilotherapy has proven useful in reducing patients demand for postoperative analgesic / anti-inflammatory drugs and antiedema drugs administration. Furthermore, satisfaction of patients treated with hilotherapy was greater when compared to patients who received conventional cooling.

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Fig. 4: A-B) The histograms show a more rapid decrease of the edema after 48 hours of cryotherapy treatment with return to values nearest to normal (N values) than in group A; also the physiological increase of edema in 24 hours following surgery is significantly reduced in group B.



Fig. 5: A-B) The graphs demonstrate a more post-operative comfort of the group B in the 24 hours following surgery with a greater number of patients without pain or with tolerable pain.

Discussion

Biological effects of cooling therapy on metabolic, vascular, neural, and muscular sites are known.

Cryotherapy, according to Van't Hoff law, decreases biochemical reactions and determines antinflammatory action, slowing down cell metabolism and decreasing production and release of inflammation chemical mediators (serotonin, histamine, bradykinin). The anti-edema effect is related to vasoconstriction, minimizing blood extravasation. The intensity of vasoconstriction reaches the highest value at a temperature of 15°C. Furthermore, low temperature slows down peripheral nerve conduction and thus reduces the pain. It has been proven that 1°C reduction in temperature causes 2.4m/s reduction in peripheral nerve conduction, reaching complete loss of nerve conduction at 10°C to 15°C ¹⁹. Cold temperature, also, decreases muscular tone and spasticity. The effect of cryotherapy on muscles is related to the application time. If temperature reduction is limited in time and related to cutaneous area, there is an increase of muscular tone for α -motoneuron stimulation by cutaneous receptors. For long application time, there will be muscular tone reduction ^{24,25}. Cryotherapy traditional methods such as ice packs use a 0°C temperature, which obstructs lymphatic drainage and decreases cell metabolism. Typical variable temperature ranges of ice-packs decrease methodical efficacy. These factors suggest the utility of a system that could maintain the desired temperature over a fixed period of time. Hilotherapy system fulfils these requirements.

Conclusions

Hilotherm system represents a simple, easy-to-use and cost effective treatment alternative to the use of cold compresses for both, patients and medical staff. In fact this method reduces the need to change the ice packs regularly with high levels of patient satisfaction and compliance. It shows also better outcomes with regard to pain and swelling probably for the best possible fit for masks and constant temperature control. So this cold technique, that hasn't adverse effects, is acquiring a greater role in oral and maxillofacial surgery as well as other clinical fields.

Riassunto

La crioterapia dopo interventi di chirurgia maxillo-facciale è una metodica comunemente utilizzata sia a fini analgesici che di riduzione dell'edema e dell'ecchimosi dei tessuti molli. Hilotherapy è costituito da un'unità mobile elettrica refrigerante dotata di un termostato digitale regolabile e da un circuito chiuso di acqua distillata refrigerata che scorre all'interno di collettori e di maschere in gomma specificatamente conformate per i distretti anatomici del massiccio facciale.

Abbiamo selezionato 40 pz affetti da frattura unifocale di angolo mandibolare e suddivisi in 2 gruppi, crioterapia con ice-bag (gruppo A) e Hiloterapy System (Gruppo B); entrambi sottoposti a medesimo trattamento farmacologico di base (antibiotico-antiedemigeno-antidolorifico). L'analisi dei dati ha dimostrato come l'utilizzo dell'Hiloterapy System nel post-operatorio per 48 ore a temperatura modulata ha garantito un più rapido decremento dell'edema dei tessuti molli e un miglior controllo del dolore, con conseguente minor richiesta di farmaci anti-infiammatori ed anti-dolorifici, rispetto al gruppo A.

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