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Hilotherapy for the management of perioperative pain and swelling in facial surgery: a systematic review and meta-analysis

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Abstract

Hilotherapy is the application of cold compression at a regulated temperature through a face mask. Studies that have evaluated its efficacy have focused on postoperative oedema, pain, and the patient's comfort. However, there is no clear consensus in favour of its use, so we have made a systematic review and meta-analysis to evaluate relevant published reports. We searched PubMed, EMBASE, MEDLINE, the Cochrane Database of Systematic Reviews, and the Cochrane Central Register of Controlled Trials to identify studies. Sixty-one records were screened, six of which met the inclusion criteria and four of which were suitable for meta-analysis. All data suitable for meta-analysis were derived from studies of elective and traumatic facial skeletal surgery. Hilotherapy was associated with significant reductions in facial pain on postoperative day 2 ($p < 0.00001$), and facial oedema on days 2 ($p = 0.0004$) and 3 ($p = 0.02$). Patients reported more comfort and satisfaction with hilotherapy than with cold compression ($p < 0.00001$). The effect of hilotherapy on ecchymosis and formation of haematomas remains uncertain. Well-designed, randomised, controlled trials of its use after aesthetic facial surgery are required.

Keywords: Hilotherapy; Hilotherm®; cryotherapy; facial surgery; orthognathic surgery; oedema; facial pain; post operative cooling

Introduction

Cryotherapy is a traditional way of minimising pain, swelling, and discomfort after trauma or facial surgery, but the quality of evidence is poor (Collier J et al. Facial cooling following orthognathic surgery-pilot data and recommendations for a multi-centre study. Paper presented at the annual scientific meeting of the British Association of Oral and Maxillofacial Surgeons, 2012)[1–3] and there have even been concerns that it may impair microvascular blood flow and lymphatic drainage, and cause cold burns or nervous injury. [4,5]

Hilotherapy (Hilotherm®, Hilotherm GmbH, Ludwigshafen, Germany) uses a prefabricated, facially-contoured, polyurethane mask to channel a current of cool, sterile water adjacent to the skin to provide regulated cryotherapy perioperatively.[6] As it provides a way of standardising cryotherapy, it can be evaluated in a randomised, controlled trial. Published studies have given conflicting results, and to draw conclusions about its efficacy we have evaluated the evidence systematically.

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Methods

Search

We searched PubMed, EMBASE (OvidSP), Medline (OvidSP), the Cochrane Database of Systematic Reviews, and the Cochrane Central Register of Controlled Trials, using medical subject heading (MeSH) and free-text terms. We also scrutinised the online trials registers ClinicalTrials.gov and the national research register for completed, discontinued, and ongoing trials about the use of cryotherapy and hilotherapy in facial surgery. The search was made in accordance with the Cochrane Highly Sensitive Search Strategy guideline in the *Cochrane handbook for systematic reviews of interventions*. [7] The review is reported in line with the Preferred Reporting Items for Systematic Reviews and Meta-analyses (PRISMA) statement. [8]

Inclusion criteria

We included randomised controlled trials that compared facial cooling by hilotherapy with standard dressings or cold compression after facial reconstructive or aesthetic procedures in both adults and children. Where there were two or more clinically homogeneous studies, data were pooled in a meta-analysis.

Exclusion criteria

Prospective, comparative, and case-control studies were mentioned in the text, but not analysed further. Published abstracts, posters, and theses were excluded.

Outcome measures

Primary outcome measures were oedema and pain. Secondary outcome measures were tolerance, haematoma, and ecchymoses. In three of four trials included, facial oedema was measured using 3-dimensional volumetric morphometric imaging software. In the case of elective facial surgery a preoperative scan was used to establish a reference volume. In the case of emergency facial surgery for trauma a late postoperative scan was used to establish a reference volume. In the remaining trial, facial oedema was evaluated from a series of measurements made from the fixed point of the tragus.[9] The final trial qualitatively evaluated facial oedema and ecchymosis at routine postoperative review and was excluded from further analyses. [10] A visual analogue scale (VAS) of 0-10 was used to evaluate facial pain in four of the studies while one used a scale of 1-4 where 1 indicated no pain and 4 indicated severe pain. [10]

Collection and analysis of data

Studies were assessed for risk of bias. [11] For all studies included in the meta-analysis we recorded details of participants, operation, temperature of the hilotherapy, comparative technique, and outcomes. Continuous outcomes were calculated using the mean difference and 95% CI for each trial. For dichotomous outcomes we calculated risk ratios (RR) and 95% CI for each trial. We used both random-effect and fixed effects models in our meta-analysis: in a fixed-effect analysis the true effect size is assumed to be the same in all included studies, while in a random-effects model the true effect size varies between studies. The summary effect is the estimate of the mean of these effects. In practice, the random-effects model gives more weight to smaller studies than the fixed-effects model does. Our rationale was to use the random-effects model a priori as we assumed there to be variance between studies, but we calculated the variance within each study and if it was low we used the fixed effects model. For more details please refer to *Introduction to meta-analysis* by Borenstein et al., [12] Variance (statistical heterogeneity) was calculated both with the chi square test and the I^2 statistic. A chi square test with $p < 0.10$ or an $I^2 > 50\%$ were taken to indicate significant heterogeneity. Heterogeneous data were pooled using the random-effects model while homogeneous data were pooled using the fixed-effect model.

As all studies of oedema, pain, and patients' satisfaction that we included used the same scales, the forest plots were calculated using mean difference, not standardised mean difference. In accordance with the limited number of trials included for each outcome, we did not construct a funnel plot to investigate reporting bias. For statistical analysis we used Review Manager (RevMan) (version 5.3, Copenhagen: the Nordic Cochrane Centre, the Cochrane Collaboration, 2014).

Results

General

Sixty-one abstracts and seven full texts were assessed for eligibility. Six trials involving 286 patients met the inclusion criteria [9,10,13–16] and four were suitable for meta-analysis (Fig. 1). [13–16] Men accounted for around half of all study participants and for 62 of 74 (84%) of participants in the two studies of facial trauma. All trials used Hilotherm® at 14-15 °C. In all but one the hilotherapy mask covered the middle and lower thirds of the face, and in the remaining case it covered the upper and middle thirds. [13] In each case hilotherapy was started immediately postoperatively, but the regimen varied thereafter from a single application of 45 minutes after third molar extractions [15] to a continuous period of 48 hours, or 48 -72 hours after orthognathic surgery. [9,14] The Hilotherm® masks are shown in Fig. 2.

The control arm comprised cool compresses in four studies and dressings alone in only one.[10] In the remaining study, both controls were incorporated into the study design.[9] Four of the six trials evaluated facial oedema objectively, using the same 3-dimensional volumetric morphometric imaging

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