

Post-operative pain reduction: meta-analysis of hilotherapy verses conventional facial cooling

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Introduction

Craniofacial surgery causes post-operative pain and impaired neurological scores.¹⁻⁴ Regional cooling using ice or cold water reportedly improves these outcomes (Fig. 1).⁴⁻⁸ hilotherapy (Fig. 2) delivers cooled water to the skin via an anatomically designed face mask at 15°C (Fig. 2).^{8,11} A meta-analysis of Hilotherapy for post operative facial pain and neurological outcome scores was performed in patients having received post operative Hilotherapy (Group A) or standard facial cooling using ice packs (Group B). The primary outcome measures of this study were the standardised mean differences for post operative neurological outcomes and pain scores between hilotherapy and ice packs.

Figure 1. Cooling mechanism

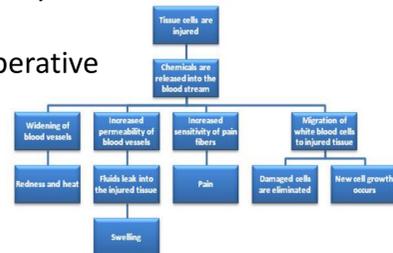


Figure 2. Hilotherapy Device



Hilotherapy provides a solution to facial cooling via a contoured facial mask. Hilotherapy is cold water delivered at a controlled temperature to parts of the body subjected to trauma either through injury or surgery, at a temperature that is controlled by the Hilotherapy system (below left). This cooling is delivered by ergonomic cuffs and masks. Conversely, facial cooling using ice packs is usually done with a cold compress with ice for over 45 minutes post-surgery, sometimes being intermittent.^{3,5,6,7}

Results (2)

The forest plot (Fig. 4; right), demonstrates improved post operative neurological outcomes. Forest plot (Fig. 5) of post operative pain reduction at 48 hours in each study demonstrates lower mean postoperative pain scores in patients receiving hilotherapy compared to those receiving ice pack cooling, as indicated by SMD's of ≤ 0 . Study size is represented by individual square size. Bottom diamond represents pooled effects analysis.

Figure 4. Post operative neurological outcomes

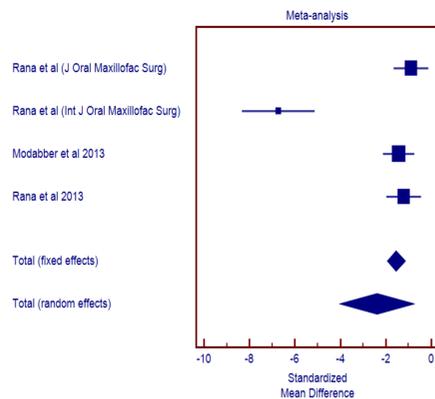
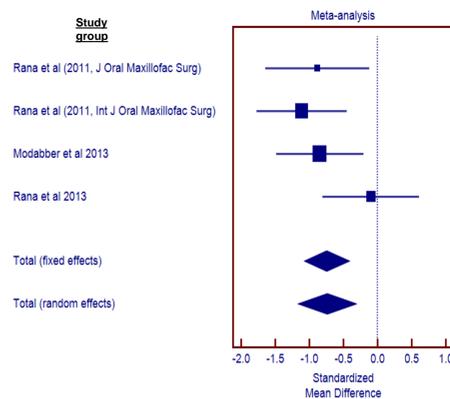


Figure 5. Post operative pain at 48 hours



Above (Fig. 4) demonstrates improves neurological scores of the facial region for patients receiving Hilotherapy. A moderate degree of variation between patient cohorts was detected suggesting heterogeneity; Cochran's Q associated p values reached levels of significance for heterogeneity ($p=0.05$). We therefore present all tabulated SMD results (Table 1) using the random effects meta-analysis model to account for potential heterogeneity between cohorts. The standardized mean difference (SMD) is used when studies report efficacy of a continuous measurement, such as pain rating scores, patient reported outcomes of neurological scores. The SMD is sometimes named "effect size", interpreted as the number of times the treatment may increase or decrease the given outcome compared to the comparator (either placebo or alternative treatment; ice pack cooling in this study).
SMD = $\frac{\text{new treatment improvement} - \text{comparator improvement}}{\text{pooled standard deviation}}$

Table 1. Summary data extracted

Demographic / Outcome	Mean value \pm SEM	Results range	Studies (n)	Reference
Age (years)	29.4 \pm 2.5	24 -36	4	5,6,7,8
Number of patients (study n)	36.5 \pm 3.2	30 - 42	4	5,6,7,8
Receiving hilotherapy (%)	50.0 \pm 0.0	50	4	5,6,7,8
Hilotherapy post operative pain reduction (48 hours), 10 point VAS scale, mean reduction	-2.305	95% CI mean reduction from -3.489 to -1.121	4	5,6,7,8
Mean pain score 48 hours (A; hilotherapy) vs Verses Mean pain score 48 hours (B; conventional cooling)	3.218 \pm 0.2963 vs 5.523 \pm 0.5484	$p < 0.01$		
Mean post operative pain reduction (\geq day 4 \leq day 10), 10 point VAS scale (hilotherapy)	-0.6925	95% CI from -1.446 to 0.06088	4	5,6,7,8
SMD for pain reduction (48 hours)	-2.387	95% CI from -4.035 to -0.738	4	5,6,7,8
SMD for pain reduction (\geq day 4 \leq day 10)	-1.305 \pm 0.653	95% CI from -2.596 to -0.0131	5	5,6,7,8
SMD Patient reported outcome (Scale: 1 as very good, 4 as poor)	-3.620 \pm 0.997	95% CI from -5.591 to -1.648	4	5,6,7,8

Discussion

- Hilotherapy reduces the temperature of the anatomical region following surgical intervention
- Hilotherapy significantly improved patient reported outcomes (Fig. 3), which might relate to reduced facial pain, functional outcomes and swelling in the post operative period
- There is a limited amount of evidence for hilotherapy. All RCT's analysed were performed sub-optimally (lack of blinding, variable cooling regimens, low numbers of participants)

Conclusion

- Hilotherapy appears to be effective in improving facial neurological scores (Fig. 4) and reducing post operative facial pain (Fig. 5).
- Clinical equipoise remains over hilotherapy, due to the small number of studies available for analysis (n=5).
- We suggest multi-centre well designed randomised controlled trials comparing hilotherapy to ice-based facial cooling methods are performed.

References

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Methods

A systematic database search was conducted using keywords, according to the established Preferred Reporting Items for Systematic Reviews and Meta-Analyses guidelines. Published series of patients receiving Hilotherapy were retrieved, against strict inclusion criteria.

Patient demographics and surgical results from each series were extracted. Data were analysed using MedCalc Statistical Software.⁹ Mean patient characteristics, and the standardized mean difference (SMD) with 95% confidence intervals were calculated between Groups A and B. All studies were scrutinised by 2 independent researchers before final inclusion. Exclusion criteria precluded poorly designed studies lacking comparison groups and those with inadequate data reporting. Inclusion criteria stated series must describe hilotherapy and cold therapy as comparators with outcome data provided.

Results (1)

Analysed papers were published between the years 2011 to 2013, with 146 patients included from 5 surgical trials.^{5,6,7,8} There were 73 patients in Groups A and B respectively. Six trials of hilotherapy around the facial region were identified. One trial was excluded, for lack of concealment, blinding and incomplete data reporting.^{2,3}

Figure 3. Patient reported satisfaction following hilotherapy

Mean difference in satisfaction outcome scores between groups were significant; SMD -1.053, 95% CI -1.487 to -0.6192. Mean PRO for hilotherapy was 1.677 \pm 0.1233 vs ice cooling 2.730 \pm 0.2219. Patients completed an outcome score sheet with low scores indicating high satisfaction and high scores indicating lower post operative satisfaction. Blinding to therapies was not stated in any study.

