Extended Abstracts: Peppermint

Primary Literature

1) Gobel H, Fresenius J, Heinze A, Dworschak M, Sokya D. Effectiveness of oleum menthae piperitae and paracetamol in the therapy of headache of the tension type [Abstract]. Nervenarzt 1996; 67(8): 672-81. [Article in German]

Study Objective:

The objective of this study was to compare effectiveness of peppermint oil and acetaminophen (paracetamol) for acute treatment of tension-type headaches.

Methods:

Design: Placebo-controlled, cross-over trial

Allocation: Concealed

Blinding: Double-blinded

Follow-up period: 4 episodes of tension type headaches.

Setting: Undefined; at home or wherever the episode TTH occurs

Participants: n=41

Subjects ranged from ages 18-65 years old, and had to meet the IHS diagnostic criteria for episodic TTH, but not for migraines. Exclusion criteria were not provided.

Intervention:

Acetaminophen 1000mg + placebo oil (small amount of peppermint for smell) applied to forehead and temples

Placebo tablet + peppermint oil 10% in ethanol applied to forehead and temples

Outcomes: Subjective pain relief and headache intensity at 15, 30, 45, and 60 minutes. Patient reported adverse effects.

Patient Follow-up: Unknown

Main Results:

Compared to the application of placebo, a 10% peppermint oil in ethanol solution significantly reduced the clinical headache intensity after 15 minutes (p < 0.01). This significant clinical reduction of the pain intensity continued over the one hour observation period. There was no significant difference between the efficacy of 1,000 mg of acetaminophen and 10% peppermint oil in ethanol solution. No adverse effects were reported.

Conclusions:

For the treatment of acute tension type headache, 10% peppermint oil in ethanol solution demonstrated non-inferiority compared to acetaminophen 1000mg with no adverse effects reported.

Comments/Clinical Appraisal

The article was published in German, only an English abstract was available for appraisal.

The primary internal validity threats surround the use of subjective scales for pain. Patients used a headache diary and scored their headache intensity on a scale from 0-10 which leaves much to the patient for interpretation. No information was available with respect to how the oil was administered beyond body location and whether patients continued to rub after initial application. This may confound results since manual manipulation and acupressure may be effective in relieving tension type headaches. The placebo oil preparation as well was reported to contain only trace amount of peppermint oil, however no indication was given whether this could easily be distinguished from the treatment oil based on smell potency. No information was available regarding exclusion criteria, funding for the trial or if any biases existed amongst the authors.

With respect to external validity of the study, the study was performed in a community setting using patient subjective pain scales which are used in real clinical practice settings. It was performed on a German population, where traditional remedies are much more popular. This may skew results as the population is accustomed to natural and traditional treatments and which may not be widely used in a North American population.

2) Gobel H., Schmidt G., Soyka D. Effect of peppermint and eucalyptus oil preparations on neurophysiological and experimental algesimetric headache parameters.

Study Objective:

The objective of this study was to compare effectiveness of peppermint oil and acetaminophen (paracetamol) for acute treatment of tension-type headaches.

<u>Methods:</u> Design: Placebo-controlled, four-fold crossover trial

Allocation: Unknown

Blinding: Double-blinded

Follow-up period: 4 episodes of tension type headaches.

Setting: Undefined

Participants: n=32

Subjects ranged from 20-30 years old, with a body weight not more than 10% of normal and no serious illness. Exclusion criteria included: female patients (avoiding the possibility of menstrual cycle effects), more than 10 days of tension type headache per year, skin abnormalities on forehead and temples, nicotine consumption, alcohol and drug abuse, taking other medications, any basic disease. Headaches occurring during the study disqualified patients.

Intervention:

1:10g peppermint oil + 5g eucalyptus oil in ethanol
10% (w/v) peppermint oil in 90% ethanol
5% (w/v) eucalyptus oil in 90% ethanol
90% ethanol
All sponged over the forehead and temples at 0, 15, 30minutes.

Outcomes: Sensitivity of experimentally-induced pain through patient reported pain intensity (0-50). The application of mechanical pressure and thermal pain induction to the skull to mimic the effects of tension type headache.

Patient Follow-up: 4 Experimental Sessions

Main Results:

10% Peppermint Oil (w/v) in ethanol reduced subjective pain reporting by 27% (p < 0.01). With all other formulations there was no significant difference in pain reporting from baseline.

Conclusions:

For the treatment of acute tension-type headache, 10% peppermint oil in ethanol solution resulted in the greatest reduction in pain sensitivity.

Comments/Clinical Appraisal

The primary internal validity threats surround the use of subjective scales for pain. Patients used a subjective scale from 0-50 and scored their headache intensity, which leaves much to the patient for interpretation. There was no description of the blinding process which is concerning given the fact that potent aromatic oils were used and could easily be distinguished by intensity of smell. Furthermore, no information was provided on the randomization process. It is interesting that individuals with skin abnormalities on the forehead were excluded however no adverse events were reported with administration. No information was available regarding funding for the trial or if any biases existed amongst the authors.

The most concerning aspect of this trial is its external validity. Induction of pain similar to a tension type headache may not be the same as the pain experienced by someone suffering from a tension type headache. Further, the authors excluded individuals who did experience a headache during the experiment which suggests that this trial may not be applicable to tension type headache treatment. The population studied was young and relatively healthy men with no comorbidities, which is only a small fragment of those who actually experience tension type headaches. As well, the setting of the trial was in a controlled laboratory setting and not in a community based setting, which may also threaten the applicability of these results.

Overall this was an experimental trial at best with little clinical meaning beyond hypothesis generation.

Secondary and Tertiary Literature

3) Keifer D, Ulbricht C, Abrams T, Basch E, Giese N, Giles N, Kirkwood C, Miranda M, Woods J. Peppermint (mental xpiperita) an evidence based systematic review by the Natural Standard Research Collaboration. Journal of Herbal Pharmacotherapy 2007; 7(2):91-143

Study Objective:

To review the evidence for the use of peppermint through a literature search and expert panel consensus.

Scope:

Trials were included that investigated peppermint for any indication or reasons. No restrictions were placed on language or quality of publication.

Methods:

Electronic search of common medical databases (AMED, CANCERLIT, CINAHL, CISCOM, the Cochrane Library, EMBASE, HerbMed, International Pharmaceutical Abstracts, Medline, and NAPRALERT) using the common and scientific name of peppermint. A blinded review of the literature by a three-member editorial board was conducted and consensus was reached regarding the quality of data from each study.

Design: Review, Expert Opinion

Main Results:

Peppermint in Tension Type Headache

Upon review of literature for the use of peppermint in tension type headache, the authors concluded that good scientific evidence existed for this indication. Criteria for good scientific evidence was met when 1-2 properly conducted trials show a statistically significant benefit and there is supporting evidence in basic science, animal studies, or theory.

Conclusion:

10% peppermint oil (w/v) in ethanol has good scientific evidence to support its use in tensiontype headaches; however the trials that form that basis of this support have major methodological flaws and require further well-designed studies.

Comments/Critical Appraisal:

In regards to internal validity, the authors provided a systematic method in terms of search criteria and clearly outlined exclusion and inclusion criteria. This review did not limit their search to high quality data, which is likely a result of the area of study. Because poor quality studies are included, it may skew perception that there are many studies available. However many studies are of poor design and are methodologically flawed. No discussion was made as to how consensus was reached among the editorial board or how conflict was resolved. As well, the authors did not report any funding sources or conflicting interests. Given this is a review to update the Natural Standard Database it is likely compensation was involved for external authors.

There are few limitations of this systematic review concerning external validity. Many of the authors involved in evaluating these trials were already involved in complementary and alternative medicine. This may skew their perception of good quality trials from those of general practitioners involved in western medicine. As a result, general health practitioner may not interpret literature with the same optimism.

This systematic review simply contributes expert opinion that in the realm of natural health products, the use of peppermint oil for treatment of tension-type headaches has good evidence to support its use.

4) Fumal A., Schoenen J. Tension-type headache: current research and clinical management. The Lancet Neurology 2008; 7(1): 70-3

Study Objective:

The aim of this paper was to review the etiology, diagnosis, and evidence-based treatments of tension-type headaches.

Scope:

Studies included were identified by the author on the basis of originality and relevance from 1960 to 2007 (publication date).

Methods:

No systematic search strategy was employed for this publication. A literature review was conducted of the MEDLINE and Cochrane database using the search terms "tension-type headache, epidemiology. Pathophysiology and treatment". Books were used from the author's own collection. Only English language articles were included.

Design: Review

Main Results:

Upon a review of the literature for peppermint in tension-type headache, the author's found that peppermint oil was superior to placebo in the treatment of tension-type headache. However, it was not significantly different from acetaminophen treatment.

Conclusion:

There is no scientific basis for the use of muscle relaxants in the treatment of tension-type headaches.

Comments/Critical Appraisal:

With respect to internal validity, the author explicitly stated that the articles were chosen based on the author's interest and a subjective assessment of originality to the subject area with no systematic criterion used to evaluate the literature. As a result, the review is largely biased towards the author's subjective interpretation of the literature and more of an opinion paper than a review article. No conflicts of interest were stated.

With respect the external validity of this article, the author writes the review from a western perspective of medicine. As a result, clinicians trained in western medicine may draw similar conclusions as the author with regard to peppermint oil in tension-type headaches.

5) Lenaerts M. Alternative Therapies for Tension-type Headache. Current Pain and Headache Reports 2004; 8:484-488.

Study Objective:

The aim of this paper was to review recent literature and appraise alternative therapies for tension-type headache.

Scope:

Studies included were those identified by the author. No other discussion of scope was disclosed.

Methods:

No methodology was reported in selection of literature.

Design: Review

Main Results:

Upon review of the literature for peppermint in tension-type headache, it was concluded that this treatment appeared to alleviate an attack.

Conclusion:

A 10% peppermint oil solution demonstrates comparable efficacy to 1000mg of acetaminophen.

Comments/Critical Appraisal:

With respect to internal validity, no methodology, inclusion, or exclusion criteria were discussed in this review. As a result, the review is largely biased towards the author's subjective interpretation of the literature and more of an opinion paper than a review article. No conflicts of interest were stated.

With respect the external validity of this article, the author writes the review from a complementary and alternative medicine practitioner's bias. As a result, clinicians trained in western medicine may not draw similar conclusions as the author with regard to peppermint oil in tension-type headaches and the quality of the studies included in the review.

Extended Abstracts: Tiger Balm

Primary Literature

1) Schattner P, Randerson D. Tiger Balm as a treatment of tension headache. A clinical trial in general practice [Abstract]. Australian Family Physician. 1996; 25(2): 216-220.

Study Objective:

The objective of this study was to assess the efficacy of a topical Tiger Balm in the treatment of acute tension headache.

Methods:

Design: Randomised, three group comparison

Allocation: Concealed

Blinding: Double-blinded

Follow-up period: Unknown

Setting: Undefined; at home or wherever the episode TTH occurs

Participants: n=26

Subjects ranged from ages 18-65 years old. Subjects were recruited through replies to newspaper advertisements. Exclusion criteria were not provided.

Intervention:

Acetaminophen 1000mg Tiger Balm applied to temples every 30 minutes Topical Placebo

Outcomes: Subjective Pain Relief, Headache intensity

Patient Follow-up: Unknown

Main Results:

There was a statistically significant difference in headache relief between Tiger Balm and placebo. The difference between Tiger Balm and acetaminophen was not significant with respect to subjective pain relief and headache intensity.

Conclusions:

For the treatment of acute tension type headache, Tiger Balm demonstrated non-inferiority compared to acetaminophen and an improvement in efficacy compared to placebo.

Comments/Clinical Appraisal

The primary internal validity threats surround the use of subjective scales for pain. Patients used a headache diary and scored their headache intensity on a scale from 0-10 which leaves much to the

patient for interpretation. No information was available with respect to how the balm was administered beyond body location and whether patients continued to rub after initial application. This may confound results since manual manipulation and acupressure may be effective in relieving tension type headaches. The placebo preparation was not adequately described and no indication was given whether this could easily be distinguished from the treatment based on smell. No information was available regarding exclusion criteria, funding for the trial or if any biases between the authors.

With respect to external validity of the study, the study was performed in a community setting using patient subjective pain scales that are used in real clinical practice settings. It was performed on an Australian population, which may not be similar to a North American population in terms of lifestyle and habits.

Secondary and Tertiary Literature

2) Yarnell E, Abascal K. Botanical Medicines for Headache. Alternative and Complementary Therapies 2007; 25: 149-152.

Study Objective:

To review the evidence for the use of botanical medicines in headache

Scope:

No restrictions were placed on language or quality of publication.

Methods:

No methods were reported.

Design: Review

Main Results:

The author claims that application of Tiger Balm is a traditional practice and is supported by a clinical trial involving subjects with tension-type headaches.

Conclusion:

Tiger Balm is not inferior to acetaminophen 1000mg and is superior to placebo in the acute treatment of tension type headache.

Comments/Critical Appraisal:

In regards to internal validity, the author did not provide a systematic method in terms of search criteria and did not clearly outline exclusion and inclusion criteria. As a result, this paper is largely biased to the author's opinion and should not form the basis for use of Tiger Balm in headache. As well, the authors did not report any funding sources or conflicting interests.

There were a few limitations of this systematic review concerning external validity. Many of the authors involved in evaluating these trials were those already involved in complementary and alternative medicine. This may skew their perception of good quality trials from those of general practitioners involved in western medicine. As a result, general health practitioner may not interpret literature with the same optimism.

This review simply contributes opinion to the use of Tiger Balm in tension-type headache.

3) Fumal A., Schoenen J. Tension-type headache: current research and clinical management. The Lancet Neurology 2008; 7(1): 70-3

Study Objective:

The aim of this paper was to review the etiology, diagnosis, and evidence based treatments of tension-type headaches.

Scope:

Studies included were those identified by the author on the basis or originality and relevance from 1960 to 2007 (publication date).

Methods:

No systematic search strategy was employed for this publication. A literature review was conducted of the MEDLINE and Cochrane database using the search terms "tension-type headache, epidemiology. Pathophysiology and treatment". Books were used from author's own collection. Only English language articles were included.

Design: Review

Main Results:

Upon review of the literature for Tiger Balm in tension-type headache, the authors found that Tiger Balm was superior to placebo in the treatment of tension-type headache. However, it was not significantly different from acetaminophen.

Conclusion:

There is no scientific basis for the use of muscle relaxants in the treatment of tension-type headaches.

Comments/Critical Appraisal:

With respect to internal validity, the author explicitly stated that the articles were chosen on the author's interest and subjective assessment of originality to the subject area with no systematic criterion used to evaluate the literature. As a result the review is largely biased towards the authors' subjective interpretations of the literature included and more of an opinion paper than a review article. No conflicts of interest were stated.

With respect the external validity of this article, the author writes the review from a western perspective of medicine. As a result, clinicians trained in western medicine may draw similar conclusions as the author with regard to tiger balm in tension-type headaches.

4) Lenaerts M. Alternative Therapies for Tension-type Headache. Current Pain and Headache Reports 2004; 8:484-488.

Study Objective:

The aim of this paper was to review recent literature and appraise alternative therapies for tension-type headache.

Scope:

Studies included were identified by the author. No other discussion of scope was disclosed.

Methods:

No methodology was reported in selection of literature.

Design: Review

Main Results:

Upon the author's review of the literature for Tiger Balm in tension-type headache, it was concluded that this treatment appeared to alleviate an attack.

Conclusion:

Tiger Balm applied topically to the temple has comparable efficacy to 1000mg of acetaminophen.

Comments/Critical Appraisal:

With respect to internal validity, no methodology, inclusion, or exclusion criteria were discussed in this review. As a result the review is largely biased towards the author's subjective interpretation of the literature and more of an opinion paper than a review article. No conflicts of interest were stated.

With respect the external validity of this article, the author writes the review from a complementary and alternative medicine practitioner's bias. As a result, clinicians trained in western medicine may not draw similar conclusions as the author with regard to tiger balm in tension-type headaches and the quality of the studies included in the review.

5) Gladstone J., Dodick D. Current and emerging treatment option for migraine and other primary headache disorders. Expert Review Neurotherapeutics 2003; 3(6) : 845

Study Objective:

The aim of this paper was to review recent literature and appraise alternative therapies for tension-type headache.

Scope:

Studies included were identified by the author. No other discussion of scope was disclosed.

Methods:

No methodology was reported in selection of literature.

Design: Review

Main Results:

Upon a review of the literature for Tiger Balm in tension-type headache, the authors concluded that this treatment was superior to placebo and had similar efficacy compared to acetaminophen.

Conclusion:

There is no scientific basis for the use of muscle relaxants in the treatment of tension-type headaches.

Comments/Critical Appraisal:

With respect to internal validity, no methodology, inclusion, or exclusion criteria were discussed in this review. As a result the review is largely biased towards the authors' subjective interpretations of the literature and more of an opinion paper than a review article. No conflicts of interest were stated.

With respect the external validity of this article, the author writes the review from a western perspective of medicine. As a result, clinicians trained in western medicine may draw similar conclusions as the author with regard to Tiger Balm in tension-type headaches.