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Research Article

Essential Oils Effect (Ping-On) on Temporalis Muscle Pain in Patients with Headaches Attributed to Temporomandibular Disorders

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Abstract:

Objectives: This study compared the effectiveness of temporalis muscle pain management using three topical ointments in patients with headaches attributed to temporomandibular disorders.

Method: 30 female patients (mean age 27.1±13.4 years) diagnosed with headaches attributed to temporomandibular disorders participated in a randomized, double-blinded, placebo-controlled trial. They were either treated with Ping-On ointment (G1), Vaseline with menthol (smelling placebo) (G2), or colored Vaseline (odorless placebo) (G3) for eight weeks. Outcome measurements were as follows: (i) pain intensity at the temples as assessed by visual analogue scale (VAS); (ii) anterior temporalis muscles pressure pain threshold (PPT) obtained with an algometer (Somedic ®); and (iii) maximum tolerable pressure pain (MTPP) in anterior temporal muscles recorded with the same device. Measurements were performed at baseline (T0), repeated after 4 weeks (T1), and 8 weeks (T2).

Results: At T0, all groups had similar scores in the outcome variables. Based on VAS values, all topical medications reduced the perception of pain at the temples (P<0.05) without any significant differences between groups. As for PPT at T2, only Ping-On and Vaseline with menthol increased pain threshold and maximum pain tolerance compared with the colored Vaseline (P<0.05). Conclusion: Ping-on topical application on temporalis muscles is effective in the management of temporalis muscle pain in patients with headaches attributed to temporomandibular disorders, with significantly different treatment outcomes as far as objective PPT measurements are concerned. Patient expectation and natural course of symptoms might explain the subjective improvement in VAS pain levels in placebo groups.

Keywords: Complementary medicine, aromatherapy, muscle pain, essential oils, temporomandibular disorders.

Introduction

Temporomandibular disorders (TMD) represent a group of painful conditions that involve the temporomandibular joint (TMJ) and the masticatory muscles.[i] Masticatory muscle disorders and headaches attributed to temporomandibular disorders are part of the classification of Diagnostic Criteria for Temporomandibular disorders (DC/TMD)[ii iii]

Management of TMD should be based initially on conservative and reversible approaches.[iv v vi vii viii ix] Complementary/alternative medicine (CAM) management of TMD muscle pain disorders includes conservative approaches such as topical ointments with analgesic and anti-inflammatory products.[ix x xi xii xiii xiv]

Local massage with topical Chinese medicinal herb ointments, such as Ping-on®, has been shown to be effective in reducing jaw muscle pain.[xv xvi] Its main ingredients include essential oils (EOs) (peppermint oil, 18%; menthol, 20%; natural camphor, 6%; birch oil, 6%; sandalwood oil, 3%; eucalyptus oil, 4%; bee wax, 8%; and aromatic oil, 3%). It does not contain antibiotics, steroids, cortisone, or preservatives, and is based on petrolatum (e.g. Vaseline®). [xv] (http://druginfo.nlm.nih.gov/drugportal/ProxyServlet?mergeData=true&objectHandle=DBMaint&APPLICATION_NAME=drugportal&actionHandle=default&nextPage=jsp/drugportal/R

esultScreen.jsp&TXTSUPERLISTID=0008009038&QV1=PETROLATUM) These EOs may contribute towards aromatherapy and anti-inflammatory effects.[xvii] [xviii] [xix] Scientific information about their use for TMD management is scarce.

The aim of this study was to assess the effectiveness of Ping-On® ointment in the management of temporalis muscle pain in patients with headache attributed to temporomandibular disorders (DC/TMD). Our hypothesis was that Ping-on® ointment decreases reported pain in temporalis muscles, pressure pain threshold stimuli, and maximum tolerable pain compared with two placebos.

Materials and Methods

A randomized, double-blind, placebo-controlled clinical trial was designed. Ethical approval was obtained from the Research Department at Universidad del Desarrollo Concepción (UDDC) in accordance with the Helsinki declaration.[xx] Subjects were recruited at UDDC by public invitation using bill posters. Thirty consecutive female subjects aged between 18 and 55 years were recruited (mean age 27.1±13.4). A specialist evaluated participants using the DC/TMD at the beginning of the study (T0), at 4 weeks (T1) and 8 weeks (T2). The aims, procedures, and possible risks and benefits of the study were explained to them and informed consent was obtained.

The inclusion criteria for the study were females over 18 years of age complaining of headaches attributed to temporomandibular disorders. Exclusion criteria were: appliance users; prolonged treatment with NSAIDs, antidepressants, anxiolytics, or muscle relaxants; systemic diseases related to muscle pain; other types of headaches; acute infections or significant diseases in the suprascapular unit; treated or untreated depressive disorder; dental disease; pregnancy or breastfeeding; and allergies.

Participants were block randomized and blindly allocated to one of the three treatment groups: Ping-on® (G1), smelling placebo (Vaseline® and menthol (20:1)) (G2), and odorless placebo (Vaseline®) (G3). Everyone involved in randomizing, preparing and handing out the ointments was not a part of the research team. Researchers could not see the ointments and were instructed not to ask participants any questions about them. All containers were airtight and opaque and were the original Ping-on® ointment ones. Participants were asked neither to bring the ointment to the clinic, nor to apply the ointment on the day of assessment. All assessments were done in the morning.

Participants were shown thoroughly how to rub the ointment over the temporalis muscles without massage and asked to apply it four times a day. The same researcher evaluated participants at T0, T1 and at T2.

During assessments, standardized evaluations were done for: Visual Analog Scale (VAS) for pain, pressure pain threshold (PPT), and maximum tolerable pressure pain (MTPP). Upon application of 1kg digital palpation, any reported pain was measured using a 100 mm VAS. To assess PPT and MTPP, the most painful area of the anterior temporalis muscle was identified and a pressure algometer (Somedic SenseLab AB, Sösdala, Sverige) was applied on it. Before recording each procedure, participants had been instructed how to differentiate between pain and pressure, where pain was described as an unpleasant sensation or feeling. Measurements were recorded in kPa and participants were instructed to stop the pressure recording procedure as soon as they felt any pain. Subsequently, in a separate attempt, participants were instructed to stop the recording when they felt the maximum tolerable pain. The pressure values displayed by the algometer under both conditions were recorded.

Statistical analysis

The Kolmogorov-Smirnov test was performed to analyze data distribution. Depending on whether or not the data followed a normal distribution, parametric (i.e. ANOVA), or non-parametric (i.e. Kruskal-Wallis) tests were performed in order to compare all groups at all observation points for VAS, PPT and MTPP. The T-test (parametric) and Wilcoxon test (non-parametric) were used to analyze changes over time within each group. All statistical analyses were performed with SPSS software (IBM, Milan, Italy).

Results

Visual Analogue Scale

Table 1 shows VAS scores in the right and left temporalis muscles at T0, T1 and T2 for all groups. No differences were found between groups ($P > 0.05$)

Pain Pressure Threshold

i) Between groups

Table 2 shows the average of PPT. At T0 there were no differences between groups ($P > 0.05$). At T1, PPT in the left temporalis muscle PPT increased in all groups, with differences between them ($P=0.01$). At T2, in the right and the left temporalis muscles, PPT was higher in G1 compared with G2 and G3 ($P<0.03$). In G1 the average PPT was higher than 190 kPa (1.93 Kg/cm^2).

ii) Changes over time

Changes of PPT over time for each group are shown in table 3. In G1, PPT showed a significant difference between T0, T1 and T2 in both temporalis muscles ($P<0.006$). In G2, there were differences in the left temporalis muscle between T0 - T1 and T1 – T2 ($P<0.03$) (table 3). In G3, there were changes between T1 and T2, but not between T0 and T1, nor T0 and T2 (table 3). Changes in PPT between T0 and T2 were significant only in G1. Averages of PPT at T0, T1 and T2 in all groups are shown in table 4-A.

Maximum tolerable pain pressure

i) Between groups

Regarding MTPP, at T0 there were no differences between groups ($P>0.09$) (table 2). In all groups at T1, MTPP

increased in both temporalis muscles and at T2 MTPP was higher in G1 compared with G2 and G3 (P<0.02) (table 2). In G1 the MTPP average was higher than 259.9 kPa.

ii) Changes over time

In G1 and G2, MTPP showed a significant difference between T0, T1 and T2 on both sides (P<0.05). There was a difference in MTPP between T1 and T2 in G3 (P<0.005), but changes between T0 and T2 did not show any differences (P>0.06) (table 3).

Averages of MTPP at T0, T1 and T2 in all groups are shown in table 4-B.

Discussion

The results of this study suggest that Ping-on® ointment is effective in the management of temporalis muscle pain in patients with headaches attributed to temporomandibular disorders regarding a decrease in reported pain and an increase in PPT. As far as PPT is concerned, the effectiveness of Ping-on (G1) seems to be superior than G2 and G3 placebos. Moreover, the smelling placebo between G2 and G3 appears to be effective over pain compared with the odorless one.

The reported VAS pain levels decreased in all groups and there were no differences between them neither at baseline nor at follow-up. VAS assessed only subjective intensity and the additional quantitative measurements were obtained using a pressure algometer.[xxi xxii xxiii xxiv] There was no correlation between pressure pain intensity and pain threshold between patients. These results are in agreement with the study of Sanches et al[xxv] who showed no correlation between both types of evaluation. This demonstrates the placebo effect on pain reduction and how patient expectation, or prior information, might generate such a response.[xxvi xxvii xxviii]

Combination of these findings suggests that the placebo response is more important for the subjective evaluation of treatment effectiveness than the objective. Part of the response to placebo analgesia may be regulated by: endogenous opioid mechanisms;[xxix xxx] a learning model such as conditioning;[xxxi] patient outcome expectation;[xxxii] what the treatment means to the patient from a philosophical base,[xxxiii] or by culture and gender.[xxxiv] So, patient expectation and their prior knowledge might have affected our results and might have contributed to a higher risk of bias.

Regarding pain, we considered pain threshold under pressure and maximum tolerance to pain pressure.

The pressure recommended for testing PPT according to DC/TMD is 1 kgf/cm^2 (98.06 kPa)[xxxv] and a new device (palpeter)[xxxvi] has been proposed to apply a standardized force. In this study, the averages of pressure applied to generate pain were higher than recommended thus, the amount of applying force during exam should be reconsidered.

Pain threshold under pressure

At T0, PPT was similar in all groups (P>0,2). PPT increased in G1 and G2, but not in G3. Differences between G1 and G2 were significant.

Increasing the average PPT between T0 and T2 in G1 was higher than in G2 and increasing the PPT between T0 and T2 in G2 was higher than in G3 (table 4). The PPT increased in the group where anti-inflammatory effect of natural essential oils [xvi xvii xxiii] was expected due to their topical application. Current studies indicate that some essential oils have a penetrating effect with a low skin irritation potential. This effect is possible because essential oils can cross the stratum corneum lipid barrier improving skin penetration of drugs.[xxxvii xxxviii] Concerning their anti-inflammatory effects, it has been shown that they can restore prostaglandin E2 levels, histamine, serotonin, and tumor necrosis factor-alpha by inhibiting their release in inflammatory fluids.[xxxix xl] Nevertheless, in G2, the ointment contained only 5% menthol just to give it some odor. Many plant essential oils (volatile oils) can also act through their aromatic effects. In fact, botanical sources such as lavender, chamomile, rosemary, peppermint, geranium, eucalyptus, and sandalwood have been analyzed in the management of headaches.[xvii] (PDQ Cancer Complementary and Alternative Medicine Editorial Board. Aromatherapy and Essencial Oils (PDQ®) Health professional version. September 2015.) Some studies have shown that odors can produce specific effects on human neuropsychological and autonomic function. Those effects influence mood, perceived health and arousal.[xli] Perhaps this is the reason why G2 works. So, the big difference between G1 and G2 might be an anti-inflammatory effect.

Maximum tolerance to pain pressure

Concerning maximum tolerable pain, at T0 all subjects responded between 140.4 and 214.5 kPa (1.4 and 2.1 kgf/cm^2) but there were no differences between groups (P>0.09). However, differences between them were significant in each control group.

Ping-On® and Vaseline with menthol had good clinical results when MPTT was applied, but G1 displayed better results than G2. There are no specific MTPP studies with essential oils in the literature. Based on the results and on discussion above, inflammatory pain can be managed with Ping-on® due to its potential effect in decreasing inflammatory mediators. So, if PPT increases, an increase of MTPP will be expected, although there are other variables to consider (e.g. mood, gender, ethnicity, and genetic polymorphisms) that could affect a person's capacity to tolerate pain.[xlii xliii xliv]

Conclusions

Due to its anti-inflammatory effect as well as a minor odor effect, topical application of Ping-on® on the temporalis muscle has been effective in the management of temporalis muscle pain in patients with headaches attributed to temporomandibular disorders, with significantly different treatment outcomes as far as objective PPT measurements are concerned.

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