Chiang Mai Dental Journal

Original Article

A Randomized Controlled Trial on Short-term Therapeutic Effects of Thai Herbal Compresses versus Warm Placebo Compresses on Myogenous Temporomandibular Disorder Pain

Siriporn Chaimano[1], Surawut Pongsiriwet[1], Pattriyaporn Boonyawong[1], Suruedee Tayati[1], Nutchapon Chamusi[1], Worakanya Buranaphatthana[1], Poramate Pitak-Arnnop[2]

[1]Department of Oral Biology and Diagnostic Sciences, Faculty of Dentistry, Chiang Mai University, Thailand

[2]Department of Oral and Maxillofacial Surgery, University Hospital of Giessen and Marburg, Germany

Received: April 10, 2021 • Revised: May 24, 2021 • Accepted: May 27, 2021

Corresponding Author: ***Siriporn Chaimano*** *Assistant Professor, Department of Oral Biology and Diagnostic Sciences, Faculty of Dentistry, Chiang Mai University, Chiang Mai 50200, Thailand. (E-mail:* ***siripornchaimano@gmail.com****)*

Abstract

Objectives: The aim of this study was to estimate and compare the short-term therapeutic effect on myogenous pain in temporomandibular (TMD) patients receiving Thai herbal compress (THC) or warm placebo compress (PC).

Methods: Using a placebo-controlled, double-blind, randomized clinical trial, the investigators enrolled a sample composed of subjects with myogenic TMD pain (M-TMD-P) who underwent pain treatment with THC or PC. The predictor variable was treatment group (THC or PC). The outcome variable was 1-month improvement of M-TMD-P, recorded as visual analogue scale (VAS) of pain intensity experienced over the past week, characteristic pain intensity (CPI) scores, pain-related disability scores (PDS) and pain-free maximal jaw opening. Other variables were demographic and diagnostic. Descriptive and bivariate statistics were computed. Statistical significance was set at $p \leq 0.05$, single-tailed test of hypothesis.

Results: The sample was composed of 31 subjects (n=16 in THC group). Both THC and PC were linked to the significantly decreased average VAS scores, CPI and PDS within the same group. Pain-free maximum mouth opening was significantly improved in the THC group only ($p=0.028$). However, these improved variables were not significantly different between THC and PC.

Conclusions: In the setting of M-TMD-P, THC had the only superior benefit on pain-free maximum mouth opening over conventional PC. M-TMD-P patients with limited jaw opening should be treated with THC. The authors cannot comment on the efficacy of THC in comparison to other pain treatment methods, e.g. analgesics or physiotherapy.

Keywords: herbal, myogenous pain, randomized clinical trials, temporomandibular disorders, Thai herbal compress

Introduction

Clinical manifestations of temporomandibular disorders (TMDs) principally include pain of the muscles of mastication and/or preauricular area, joint sounds, irregular temporomandibular jaw (TMJ) movement (e.g. deviation on mouth opening), resulting in difficulties in chewing, speaking, and orofacial parafunctions.[1-3] Patient education and self-care, including warm and/or cold compression, and massage, play an important role in the treatment for TMD.[4,5] Previous studies highlighted that warm compression for TMD increases regional blood flow of muscles of mastication via an aerobic energy metabolism in the muscles.[6] This improved blood flow effectively eliminates metabolic products, offers better nutrient supply, as well as increases substances for wound healing.[7]

In Thailand, herbal compresses are frequently used in conjunction with traditional massage or as a stand-alone therapy in order to relieve muscle pain, inflammation and stress.[8] The heating herbs not only increase energy flow, but also improve circulation, relax muscles, and stimulate nerves.[8] Multiple herbal ingredients elicit analgesic, antiinflammatory, and muscle relaxant properties.[9-13] These include Plai or Cassumunar ginger *(Zingiber cassumunar Roxb.* or *Zingiber montanum (J. Koenig) Link ex A. Dietr.),* turmeric *(Curcuma longa L.),* and camphor.[8,10]

The main purpose of the study was to address the following question: "Among TMD patients, does the Thai herbal compress (THC), when compared with warm placebo compression (PC), improve the signs and symptoms of with myogenic TMD pain (M-TMD-P)?" The null hypothesis was that the improvement of M-TMD-P is equal between the 2 treatment groups (THC vs. PC). The alternative, one-tailed hypothesis was that the improvement of M-TMD-P is higher in the THC group than in the PC group. The specific aim of this study was to implement a randomized clinical trial (RCT) designed to estimate and compare the improvement of M-TMD-P in subjects receiving THC or PC.

Materials and Methods

Study design and sample description

To address the research question, the investigators designed and implemented a practical, double-blind, placebo-controlled, RCT after receiving the ethical approval from the institutional ethical committee (Approval No. 45/2017). The study sample was derived from the population of subjects who presented to the TMD clinic, Chiang Mai Dental School, for evaluation and treatment of M-TMD-P between November 30, 2017 and March 30, 2020. The investigator (the first author) screened the subjects for study eligibility and initiated the consent process at the initial visit, including a review of the study rationale and protocol. All patients received patient education supplemented with self-care instruction for myogenous pain. The patients were reassured by the dentist, who explained the problem, the suspected etiology, and the prognosis that it is in fact a benign disorder. The dentist explained normal jaw muscle function and stressed that overuse of these muscles could be the major cause of their complaints. The patients were told to pay close attention to their jaw muscle activity, to avoid bad oral habits and excessive mandibular movement, and to keep to a soft diet. A written consent was obtained prior to the treatment begins.

To be considered for study inclusion, the subjects requested to have M-TMD-P identified by patient history and clinical examination according to the Diagnostic Criteria for Temporomandibular Disorders (DC) 2014.[14,15] The sample was limited to subjects with recurrent or persistent pain for > 3 months including pain following jaw activities change and/or spontaneous pain of > 30-mm on a 100-mm VAS during the last week before receiving the treatment.

Subjects excluded from the study had pre-existing conditions that could affect the treatment outcomes, including objective evidence of osseous TMJ pathology or dysfunction (e.g. arthrogenous TMD with pain or radiographic alterations in the TMJs), other orofacial pain diseases (e.g. migraine or cluster headache), neurologic or psychiatric disorders diagnosed by physicians, and history of pain medication abuse or current abuse, as well as those who received other TMD treatments within the past 1 month, or deferred the study participation.

In addition to patient consenting and receiving the ethical approval, the investigators followed the Declaration of Helsinki's ethical guidelines and the CONSORT Statement for RCTs throughout the study.

Study variables

Predictor variable

The primary predictor variable was treatment group. It was a binary variable, active treatment (THC) or placebo (PC). PC is a Plai-scented compress ball without herbal ingredients. The patients in both groups received instruction on how to use a compress ball, THC or PC, by the TMD specialist. The compress balls are applied on the painful muscle(s) at least once a day for twenty minutes.[16] Two compress balls should be steamed in a stacked electric steamer pot for twenty minutes. After that, the first moderately warm ball (approximately 40ºC)[6] was applied to the jaw muscle(s). The first ball was replaced with the second one when it was slightly lukewarm. The two herbal balls were alternately steamed and alternately used until a recommended duration is achieved. After each application, the balls were wrapped in a plastic bag and kept in the freezer until they could be reused. This study employed the reuse of herbal balls daily for one month according to the manufacturer's suggestion. Each subject was randomly assigned to 1 of the 2 study limbs; active treatment (THC) or placebo (PC). Subjects were randomized equally between the 2 groups. The randomization protocol was developed before any subjects were assigned. Consecutively numbered, double-sealed envelopes were prepared containing the treatment assignment. The research co-ordinator maintained control over the envelopes with a log of each number and assigned treatment. Immediately before the procedure the next consecutively numbered envelope was opened by the research co-ordinator, who forwarded the information to the dentist, who advice the patients to use the ball compresses, based on randomization assignment. The treatment dentist and study subject were blinded to the true nature of each ball.

Outcome variables

The primary outcome variable was improvement of M-TMD-P, which was estimated using 4 outcome parameters: 1) visual analog scale (VAS) and grade chronic pain scale (GCPS), 2) characteristic pain intensity (CPI) scores, 3) pain-related disability scores (PDS), 4) pain-free maximal jaw opening. The measurement methods of these parameters were extensively described by other authors.[14,17] The secondary outcome was compliance rate in relation to the treatments.[17]

The outcomes were evaluated twice before and 1 month after the treatment. During the 1-month follow-up visit, the signs and symptoms of TMD were subjectively and objectively investigated for both groups by the same clinician (the first author), who performed the initial visit and was blind to the treatment group assignment. No additional TMD treatment, such as splints, drugs, or occlusal adjustment, was provided to the patients in either group during the treatment period. Patients with treatment failure were apt to other TMD treatments (splints, drugs, or for the education group, or home PT) after the study end, or were reevaluated in collaboration with other clinicians.

Other variables

Data were collected on 2 other sets of heterogeneous variables grouped as demographic (patient's age and gender) and diagnostic (disease type according to DC 2014). These variables were used primarily for descriptive purposes, to assess success of randomization, and for secondary data analysis.

Data management and analyses

Prior to entry, all data were reviewed for accuracy and completeness. The investigators designed and implemented the data sheet and data entry programs, including appropriate checks for accuracy. A database was constructed, and analyses were completed using SPSS (Version 17; SPSS Inc, Chicago, IL, USA).

Data analyses included calculating the descriptive and bivariate statistics for categorical and continuous data elements. The primary analysis of interest was to measure the association between treatment (THC or PC) and improvement of M-TMD-P using the paired *t*-test. The independent samples T test was used to determine numerical variables between group differences.

Results

During the study interval, 41 subjects were screened for study eligibility, of which 31 (75.6%) subjects were enrolled in the study. Ten (24.4%) subjects failed to return for follow-up or complete the study protocol and were subsequently excluded from the final sample (Figure 1). The final study comprised 31 subjects with the mean age of 28±10.9 years (range, 16-56). Table 1 shows patient characteristics.

Table 2 summarizes the binary relationship between treatment group and improvement of outcome variables. In the THC group, the mean VAS, CPI and PDS were significantly decreased (p=0.001, p<0.001, p=0.012, respectively), and significantly increased pain-free maximum mouth opening (p=0.028). In the placebo group, there were significant reductions of average VAS, CPI and PDS (p=0.001, p=0.001, p=0.004, respectively). However, pain-free maximum mouth opening was not significantly changed in the PC group (p=0.11).

Table 3 shows the comparison of the improvement in outcome variables between THC and PC. The improvement in outcome variables including pain intensity (VAS), CPI, PDS, and pain-free maximum mouth opening were not significantly different between THC and PC. The compliance rate of the compress ball application in both groups was similar. The mean of compliance rate in the THC group was 82.08 and the mean of compliance rate in the PC group was 82.31 (p=0.581). The patients in both THC and PC had applied the compress ball for the maximum of 30 days and the minimum of 15 days.

Table 1: Baseline demographic and clinical characteristics of completers (16 for THC group and 15 for PC group).

Characteristics	Mean ± SD
Age (y)	28±10.9
Pain intensity (100-mm VAS)	56±17.6
Pain-free maximum opening (mm)	32.42±6.8
Characteristic Pain Intensity (CPI)	57.6±16.1
Pain Disability Score (PDS)	34.5±29
Characteristics	**n/%**
Female: male	28(90.3): 3(9.7)
Local myalgia	17(54.8%)
Myofascial pain with referral	18(58.1%)
Headache attributed to TMD	6(19.4%)

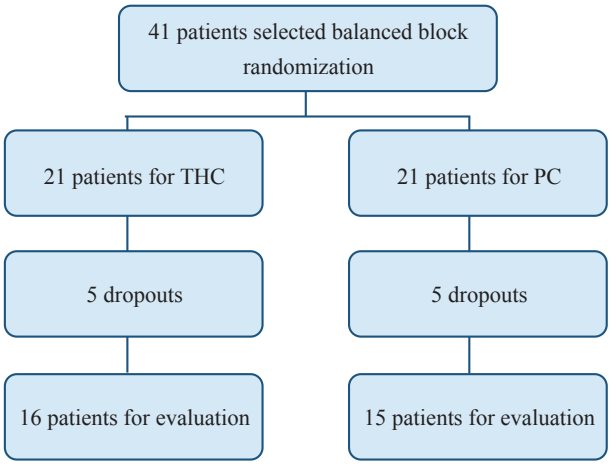

Figure 1: Study design (THC=Thai Herbal Compress, PC=Placebo Compress)

Table 2: Primary study variables and analyses

Parameter	THC			PC		
	Baseline	Follow-up	*p* value	Baseline	Follow-up	*p* value
Pain intensity (100-mm VAS)	57.8±19.1	26.7±21.8	0.001	54±16.2	22.2±21.4	0.001
Pain-free maximum jaw opening (mm)	31.1±5.1	35.3±7.9	0.028	33.9±8.2	39.3±6.8	0.110
CPI	58.3±18.4	7.9±4.1	<0.001	56.9±13.9	6.8±4.1	0.001
PDS	35.2±29.6	7.9±4.1	0.012	33.8±29.4	6.8±4.1	0.004

Note: THC, Thai herbal compression; PC, warm placebo compression; VAS, visual analogue scale; CPI, characteristic pain intensity; PDS, pain disability score

Table 3: Comparison of the improvement in outcome variables between THC and PC

Parameter	THC	PC	*p* value
Pain intensity (100-mm VAS)	31.6±16.1	33.3±18.9	0.783
Pain-free maximum jaw opening (mm)	5.1±8.0	5.4±11.3	0.935
CPI	51.5±15.9	50.0±12.7	0.774
PDS	18.4±20.2	17.1±14.4	0.831
Compliance rate (%)	82.1±16.5	82.3±18.9	0.581

Note: THC, Thai herbal compression; PC, warm placebo compression; VAS, visual analogue scale; CPI, characteristic pain intensity; PDS, pain disability score

Discussion

The purpose of this study was to determine whether the use of THC when compared with placebo improved pain-related parameters and limited jaw opening in M-TMD-P patients. The authors hypothesized that pain-related parameters and limited jaw opening would be better in the THC group than in the PC group. The specific aim of this study was to implement a practical clinical trial to compare pain-related parameters and limited jaw opening in subjects with M-TMD-P receiving THC or PC.

The results of this study could partially confirm the hypothesis. Both THC and PC were linked to the significantly decreased average VAS scores, CPI and PDS within the same group. However, pain-free maximum mouth opening was significantly improved in the THC group only (p=0.028). The improvement of these outcome variables were not significantly different between THC and PC. These results suggested that THC has a superior benefit over PC only on increased mouth opening.

The effectiveness of the Thai herbal compress in the treatment of myogenous pain could be explained by the thermal and chemical properties of the compress ball. Many studies have shown that the heat by warm compression could reduce muscle tension and improve muscle organization.[5-7,18] The main ingredient of the Thai herbal compress ball that could help with the myogenous pain is Plai (Zingiber montanum). Plai is used extensively in the external application of herbs in Thailand as it is especially beneficial for the skin and tissue layers of the body. It helps with coagulation, contusions sprains, and strains.[8]

Two studies showed the efficacy of Plai cream for the treatment of myogenous pain.[19] Manimmanakorn *et al.* concluded that the administration of 14% Plai cream was a useful alternative in the management of delayed onset muscle soreness. Using 14% Plai cream over 1 week substantially reduced muscle soreness symptoms compared to 7% Plai cream or a placebo cream.[20] Cheecharoan *et al*. found that after applied 14% Plai cream for 2 weeks, the mean pain scores in patients with muscle strain decreased from baseline to the end of the study. However, there was no difference in pain reduction in the 2-week period between patients with muscle strain using Plai cream and those given placebos, but Plai cream tended to reduce pain in the long term.[21] Recently, there was a study supported that the Thai herbal compress might be more efficacious than standard/ recommended therapy in patients with osteoarthritis and muscle pain.[10]

In this study, the compliance rate of the compress ball application in both groups was approximately 80% which was considered relatively high. In contrast, the study by Wig *et al.* demonstrated that the mean compliance rate of heat application during 2 weeks was 30.5. Over one fourth of those advised to use heat packs were 0% compliant (35.7% of 28 patients). They suggested the possibilities of low compliance rate may result from a lack of improvement in the short-term thermal therapy and this may cause a transient increase in symptoms until the muscle becomes fully warmed.[17] Furthermore, the treatments that required special equipment could have the lowest compliance rate when compared with the others.[22]

The treatment outcomes, including pain intensity, CPI and PDS, of the patients with the PC also significantly ameliorated. This result supported that warm compress could relieve myogenous pain of the TMD patients.[5] In addition, the placebo effect might lead to the improvement of the PC group. In this study, the placebo compress ball was designed to have the same shape, size, weight and scent as the Thai herbal compress ball. The patients in the PC group may believe that the placebo compress ball had the Thai herbs and it could correct their disorders.

However, this study had small number of participants due to time and budget limitation. Furthermore, we cannot conclude that Plai itself could reduce or improve myogenous pain of the TMD patients. Therefore, the larger number of subjects and the increased amount of Plai might be needed in the future studies to demonstrate the efficacy of Plai in the treatment of myogenous TMD pain.

Conclusions

This study results suggested that both THC and PC reduce pain intensity, CPI, and PDS. However, only THC can help improve the pain-free maximum mouth opening in M-TMD-P patients. Therefore, THC should be used in TMD patients suffering from limited jaw opening or movement.

Acknowledgments

The authors would like to thank Dr. Thanapat Sastraruji for statistical analyses and the staff of the TMD Clinic, Faculty of Dentistry, Chiang Mai University.

References

1. Zarb GA, Carlsson GE, Sessle BJ, Mohl ND. *Temporomandibular joint and masticatory muscle disorders.* 2nd ed. Copenhagen: Munksgard; 1994: 174.
2. Greene CS. Managing patients with temporomandibular disorders: a new "standard of care". *Am J Orthod Dentofacial Orthop* 2010; 138: 3-4.
3. Leeuw Rd, Klasser GD, American Academy of Orofacial P. *Orofacial pain : guidelines for assessment, diagnosis, and management.* 5th ed. Chicago: Quintessence Publishing Co, Inc; 2013: 130.
4. Leeuw Rd, Klasser GD, American Academy of Orofacial P. *Orofacial pain : guidelines for assessment, diagnosis, and management.* 6th ed. Hanover Park, IL: Quintessence Publishing Co, Inc.; 2018: 281.
5. Riley JL, 3rd, Myers CD, Currie TP, Mayoral O, Harris RG, Fisher JA, *et al.* Self-care behaviors associated with myofascial temporomandibular disorder pain. *J Orofac Pain* 2007; 21: 194-202.
6. Okada K, Yamaguchi T, Minowa K, Inoue N. The influence of hot pack therapy on the blood flow in masseter muscles. *J Oral Rehabil* 2005; 32: 480-486.
7. dos Santos J, Jr. Supportive conservative therapies for temporomandibular disorders. *Dent Clin North Am* 1995; 39: 459-477.
8. Jacobsen N, Salguero CP, Wells T, Salguero CP, Salguero P. *Thai herbal medicine : traditional recipes for health & harmony.* 2nd ed. Forres, Scotland, United Kingdom: Findhorn Press; 2013: 66 - 118.
9. Chiranthanut N, Hanprasertpong N, Teekachunhatean S. Thai massage, and Thai herbal compress versus oral ibuprofen in symptomatic treatment of osteoarthritis of the knee: a randomized controlled trial. *Biomed Res Int* 2014; 490512.
10. Dhippayom T, Kongkaew C, Chaiyakunapruk N, Dilokthornsakul P, Sruamsiri R, Saokaew S, *et al.* Clinical effects of thai herbal compress: a systematic review and meta-analysis. *Evid Based Complement Alternat Med* 2015; 942378.
11. Koontongkaew S, Meesuk L, Aupaphong V, Ayudhaya TD, Poachanukoon O. Inhibitory effect of Zingiber cassumunar extracts on lipopolysaccharide-induced cyclooxygenase-2 and matrix metalloproteinase expression in human gingival fibroblasts. *J Periodontal Res* 2013; 48: 507-516.
12. Akuri M, Barbalho S, Val Rs, Guiguer E. Reflections about osteoarthritis and Curcuma longa. *Phcog Rev* 2017; 11: 8-12.
13. Lee HJ, Hyun EA, Yoon WJ, *et al. In vitro* anti-inflammatory and anti-oxidative effects of Cinnamomum camphora extracts. *J Ethnopharmacol* 2006; 103: 208-216.
14. Ohrbach R. Diagnostic Criteria for Temporomandibular Disorders: Assessment Instruments [monograph on the Internet] Buffalo: A Consortium Focused On Clinical Translation Research; 2014 [cited 2017 Nov 8] [Available from: https://ubwp.buffalo.edu/rdc-tmdinternational/tmd-assessmentdiagnosis/dc-tmd/.
15. Schiffman E, Ohrbach R, Truelove E, *et al.* Diagnostic Criteria for Temporomandibular Disorders (DC/TMD) for Clinical and Research Applications: recommendations of the International RDC/TMD Consortium Network* and Orofacial Pain Special Interest Group. *J Oral Facial Pain Headache* 2014; 28: 6-27.
16. Michelotti A, Steenks MH, Farella M, Parisini F, Cimino R, Martina R. The additional value of a home physical therapy regimen versus patient education only for the treatment of myofascial pain of the jaw muscles: short-term results of a randomized clinical trial. *J Orofac Pain* 2004; 18: 114-125.
17. Wig AD, Aaron LA, Turner JA, Huggins KH, Truelove E. Short-term clinical outcomes and patient compliance with temporomandibular disorder treatment recommendations. *J Orofac Pain* 2004; 18: 203-213.
18. Okeson JP. *Management of temporomandibular disorders and occlusion*. 8th ed. St. Loius: Elsevier Health Sciences; 2019: 277.
19. Chongmelaxme B, Sruamsiri R, Dilokthornsakul P, *et al.* Clinical effects of Zingiber cassumunar (Plai): A systematic review. *Complement Ther Clin Pract* 2017; 35: 70-77.
20. Manimmanakorn N, Manimmanakorn A, Boobphachart D, Thuwakum W, Laupattarakasem W, Hamlin MJ. Effects of Zingiber cassumunar (Plai cream) in the treatment of delayed onset muscle soreness. *J Integr Med* 2016; 14: 114-120.
21. Cheechareoan S, Pathanawiriyasirikul T, Manmee C, Janpol K. Efficacy of Plai Cream in Adult Patients with Muscle Strain: A Randomized, Double-Blind, Placebo-Controlled Trial. *J Med Assoc Thai* 2016; 99(Suppl 2): 147-152.
22. Lutz RW, Silbret M, Olshan N. Treatment outcome and compliance with therapeutic regimens: long-term follow-up of a multidisciplinary pain program. *Pain* 1983; 17: 301-308.