



EVALUATION OF THE EFFICACY OF TWO DIFFERENT PATCHES FOR THE MANAGEMENT OF MYOFASCIAL PAIN: A RANDOMIZED CONTROLLED CLINICAL STUDY

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ABSTRACT

Objectives: The aim of this study was to compare lidocaine and methyl salicylate patches for the treatment of myofascial pain.

Materials and methods: Thirty patients with myofascial pain in their head and neck muscles were randomly divided into three groups. Group one (10 patients) was treated with methyl salicylate patches. Group two (10 patients) was treated with lidocaine patches. Group three (10 patients) served as the control group and received plain patches with no active ingredients. Each patient received one patch, which was replaced by the patient every 12 hours. The patients were instructed to remove the last patch 12 hours before their visit on day five. All evaluations (pain intensity, degree of mouth opening, range of motion, and disability) were repeated on day five (12 hours after removal of the last patch) and day nine (after four days of follow-up).

Results: A significant reduction in pain intensity, a significant increase in mouth opening and lateral movement and significant improvement in quality of life were observed after treatment with methyl salicylate and lidocaine patches.

Conclusions: Methyl salicylate and lidocaine patches are effective for the treatment of myofascial pain.

KEYWORDS: Myofascial pain; methyl salicylate patches; lidocaine patches

INTRODUCTION

Myofascial pain syndrome (MPS) is defined as a disorder that affects the muscles, fascia or both. Usually, this syndrome is accompanied by pain in an affected area and/or a zone of reference, autonomous

phenomena and dysfunction of the affected muscle. MPS in the maxillofacial area commonly affects the masseter and lateral and medial pterygoid temporalis muscles. ⁽¹⁾ The syndrome involves a complex set of sensory, motor and autonomic symptoms that are caused by myofascial trigger points (TPs). ⁽²⁾

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A TP evokes pain after palpation and/or causes pain radiation towards a reference zone, as well as a local twitch response. It can be latent or active.

An active TP causes specific pain during muscle movement, preventing full extension of the muscle and decreasing the range of motion. Latent TPs are pressure sensitive, and such TPs become painful only during palpation. They can be a predisposing factor for muscular dysfunction.⁽³⁾

In most cases, MPS presents as deep somatic pain that is tensive, constrictive or cramp-like, fairly well discriminated, variable in intensity, continuous or intermittent, and present at rest or only with movement, with sudden or gradual onset.⁽⁴⁾ Musculoskeletal pain affects approximately 85% of the population at some point during their lives. According to the literature, the major cause of pain is MPS, and the mean prevalence of this condition among middle-aged adults (30–60 years of age) is reported to be 37% in men and 65% in women.^(5,6)

Traditional approaches to treat MPS have included medication, including muscle relaxants, such as cyclobenzaprine and thiocolchicoside, which is considered to be a muscle relaxant with anti-inflammatory and analgesic effects, in addition to thermal modalities and massage.⁽⁷⁾

MATERIALS AND METHODS

Patient sampling

Thirty patients were randomly chosen from those treated at the outpatient clinic of the Oral and Maxillofacial Surgery Department, Faculty of Dentistry, Suez Canal University. Patients were 20 to 45 years of age and of either sex (18 females and 12 males). They were diagnosed based on clinical and subjective criteria.

Before applying the patches to healthy and intact skin, the following steps were taken.

1- Patients rated their baseline pain intensity levels

at rest and with movement using a 100-mm visual analogue scale (VAS), where 0 indicates no pain, 20 indicates slight pain, 40 indicates mild pain, 60 indicates moderate pain, 80 indicates severe pain, and 100 indicates extreme pain (i.e., the worst pain, intolerable).

- 2- The degree of mouth opening was measured by calibrating the inter incisal distance (normal interincisal distance ranges from 40 to 55 mm).
- 3- The range of motion (lateral movement) was recorded as the maximum horizontal opening (measured by a ruler, in mm) at the midline between the upper central incisors and the midline between the lower central incisors.
- 4- Disability resulting from painful symptoms (measured as pain-related interference in usual daily activity, mood, work activity or quality of life) was assessed

Random allocation of patients into three groups (ten in each group)

Group one was treated with a methyl salicylate patch. Group two was treated with a lidocaine patch, and group three served as the control group and was treated with plain patches that had no active ingredients. Each patient received one patch that was placed on the masseter muscle (**figure 1**)



Fig. (1) Photo of application of a patch (methyl salicylate) on masseter muscle.

of the affected side and was replaced by the patient every 12 hours; the patient was instructed to remove the last patch 12 hours before their visit on day five.

All evaluations (i.e., pain intensity [measured on a VAS], degree of mouth opening [measured by a ruler, in mm, between the upper and lower incisors], range of motion or lateral movement [measured by a ruler from the midline between the upper incisors to the midline between the lower incisors], and disability [measured on a scale from 1 to 100]) were recorded prior to treatment and repeated on day five (12 hours after removing the last patch) and day nine (after four days of follow-up).

Drugs used

- 1- Methyl salicylate (Salonpas)
 - 10% methyl salicylate and 3% 1-menthol
 - Hisamitsu company
 - **menthol** (menthol) menthol 31.5mg
 - **methyl- salicylate** (salicylic acid) methyl salicylate 10.5 mg
- 2- Lidocaine (Versatis)
 - 5% lidocaine
 - Grünenthal company
 - Each adhesive patch contained 700 mg of lidocaine (50 mg per g of adhesive) in an aqueous base.
 - When a lidocaine patch is used, only $3\pm 2\%$ of the applied dose is expected to be absorbed. At least 95% (665mg) of the lidocaine will remain in a used patch. The mean peak blood concentration of lidocaine is approximately $0.13 \mu\text{g/mL}$.
- 3- Placebo (Iwakim)
 - Free of any active ingredients
 - BM company

Statistical analysis was performed using IBM® SPSS® (SPSS Inc., IBM Corporation, NY, USA) Statistics Version 21 for Windows.

RESULTS

Pain intensity level

Differences between the treated groups within each time frame

Non-parametric one-way ANOVA (Kruskal-Wallis) showed significant differences in the pain intensity level scores ($p=0.049$, ≤ 0.001 and ≤ 0.001) among the tested groups for each follow-up period. According to the Mann-Whitney U test, group 2 had the lowest pain intensity scores during the pretreatment and follow-up periods. Insignificant differences were observed between group 1 and group 2 after 5 days and 9 days of follow-up. Both groups showed a significant reduction in pain intensity levels compared to those in group 3 for both follow-up periods (**Figure 2**).

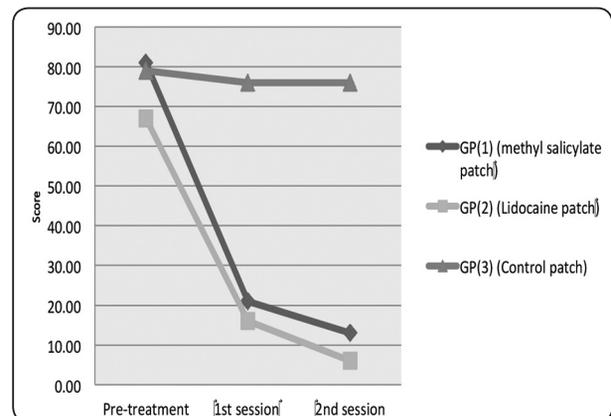


Fig. (2) Histogram showing the mean pain intensity scores for different follow-up periods.

Effect of medication for each follow-up period

Non-parametric one-way ANOVA (Kruskal-Wallis) showed significant differences in pain intensity level scores ($p\leq 0.00$, ≤ 0.001 and 0.837) for each follow-up period in each group. The Mann-Whitney U test showed a significant reduction in the

pain intensity scores after the first session (5 days), followed by a highly significant reduction in pain intensity after 9 days in groups 1 and 2 compared to the pretreatment scores. An insignificant reduction in pain intensity was observed in group 3 after both follow-up periods.

Degree of mouth opening

Difference between the treated groups at each time

The mean and standard deviation (SD) for the degree of mouth opening (in mm) for each group for each follow-up period is shown in Figure 3. An insignificant difference was observed among groups 1, 2 and 3 in the mean degree of mouth opening (p=0.676) before the start of treatment. A significant increase was observed in the degree of mouth opening for groups 1 and 2 after the 5-day and 9-day follow-up periods compared to that in group 3.

Effect of medication for each follow-up period

After examining the mean and SD for the degree of mouth opening (in mm) for the different follow-up periods for each treated group, the following observations were made.

- An insignificant difference was observed between the different follow-up periods in group

3 for the mean degree of mouth opening (p=0.0.896).

- A highly significant increase in the degree of mouth opening was observed after the first session (5 days), followed by a slightly larger increase in the degree of mouth opening after session 2 (9 days) for groups 1 and 2.

Range of motion (lateral movement)

Differences between the treated groups within each time period

The means and SD for the range of motion (lateral movement, in mm) for the different groups regarding each follow-up period are presented (Figure 4). An insignificant difference was observed among groups 1, 2 and 3 for the mean range of motion (lateral movement, in mm, p=0.508) before the start of treatment. A highly significant increase was found in the range of motion (lateral movement, in mm) for groups 1 and 2 after the 5-day and 9-day follow-up periods compared to that in group 3.

Effect of medication for each follow-up period

After examining the mean and SD of the degree of lateral movement (in mm) for the different follow-up periods for each treated group, the following observations were made.

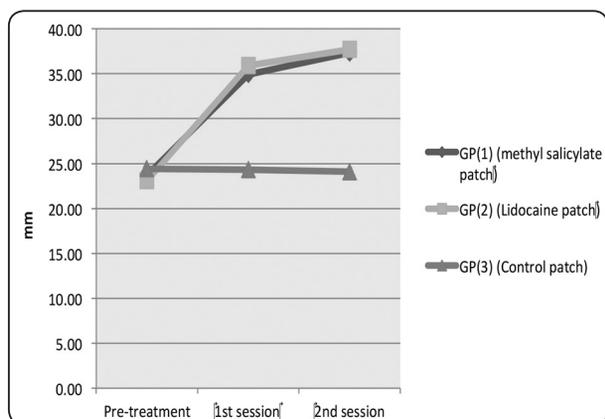


Fig. (3) Histogram showing the mean degree of mouth opening (mm) for different follow-up period for each treated group.

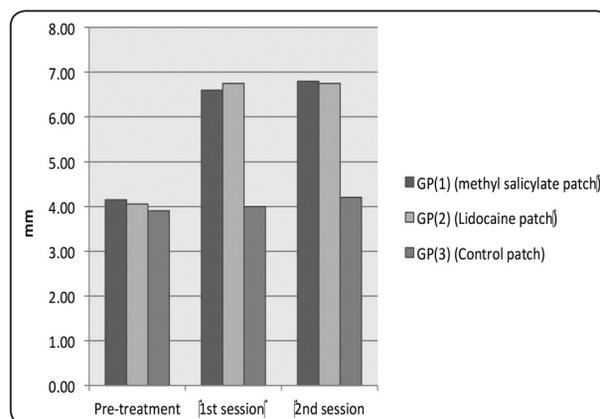


Fig. (4): Histogram showing the mean Range of motion (lateral movement) (mm) for different follow-up period for each treated group.

- An insignificant difference was observed between the different follow-up periods for group 3 for the mean degree of mouth opening ($p=0.578$).
- A highly significant increase was found in the degree of mouth opening after the first session (5 days), followed by a slightly larger increase in the degree of mouth opening after session 2 (9 days) for groups 1 and 2.

Daily activity

Differences between the treated groups within each time period

Non-parametric one-way ANOVA (Kruskal-Wallis) showed significant differences in the pain intensity level scores ($p=0.973$, ≤ 0.001 and

≤ 0.001) among the different tested groups for each follow-up period. An insignificant difference was observed between groups 1 and 2 after the 5-day and 9-day follow-ups. Both groups showed a slightly increased reduction in the daily activity level compared to that in group 3 for both follow-up periods (**Figure 5**).

Effect of medication for each follow-up period

Non-parametric one-way ANOVA (Kruskal-Wallis) showed significant differences in the daily activity scores ($p \leq 0.00$, ≤ 0.001 and 0.791) for each

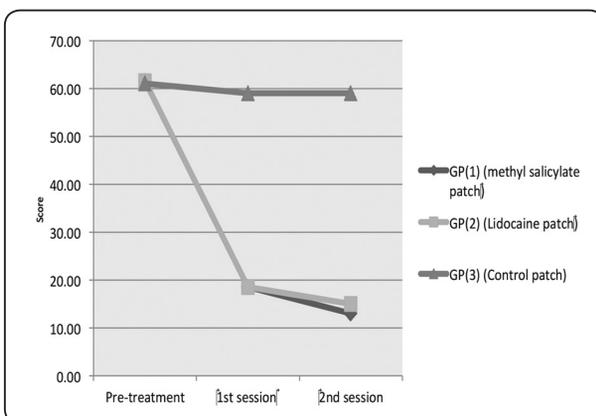


Fig. (5) Histogram showing the mean Daily activity scores for different follow-up periods.

follow-up period for each group. The Mann-Whitney U test showed a significant reduction in the pain intensity scores after the first session (5 days), followed by an insignificant reduction in the daily activity score after 9 days in groups 1 and 2. An insignificant difference in the daily activity score was observed after the different follow-up periods for group 3.

DISCUSSION

The current study investigated and compared the efficacy of methyl salicylate and lidocaine patches for the management of myofascial pain.

In previous studies, such as those by Wetzel D. *et al* (8) and Lobo Sl. *et al*, (9) the results showed that salicylate containing topical agents may be effective for the treatment of a number of painful conditions, including low back pain, temporomandibular joint with masseter muscle pain, dental pain, and ankle sprains. Most of these trials were limited by small treatment group sizes, the use of different preparations, the lack of validity, and inconsistency in the measured outcomes. (10) However, the present study used a well-controlled clinical trial model and validated pain assessment methods to examine the efficacy and tolerability of the tested patches in patients with mild to moderate muscle pain.

In our study, after using methyl salicylate patches, the pain intensity level was significantly reduced. A significant increase was also observed in the degree of mouth opening after the first session, followed by a slightly greater increase in the degree of mouth opening after the second session ($p < 0.05$).

The quality of life and degree of lateral movement were also investigated. The methyl salicylate patches produced a significant increase in the degree of lateral movement and significant reductions in the pain intensity scores for daily activity assessments ($p < 0.05$) after the first session, followed by a slightly increased reduction in daily activity after the second session.

The results of the present study are consistent with the results of Higashi Y, Kiuchi T, and Furuta K.⁽¹¹⁾ After using lidocaine patches, the pain intensity level was significantly reduced, according to the pain intensity score, after the first session (fifth day), followed by a slightly increased reduction after the second session (ninth day). In terms of the degree of mouth opening, lateral movement and quality of life, a significant increase was observed in the degree of mouth opening and lateral movement, with improvements in the quality of life ($p < 0.05$).

These results are consistent with those of Affaitati G. *et al*,⁽¹²⁾ who reported that lidocaine patch treatment of active TPs (in a study of sixty patients) produced significant relief of myofascial pain symptoms and the associated disability. In addition, desensitization of somatic tissue hypersensitivity in the painful areas (TPs and target areas) was significantly greater in patients treated with the lidocaine patch than in those treated with a placebo. All patients who received lidocaine patches experienced reductions in the number of acute pain episodes and the mean pain intensity at rest and during movement. Affaitati G. *et al*⁽¹²⁾ investigated pain-related interference with daily activity, work activity, mood, and quality of life.

Patients in the study by Affaitati G. *et al* who received the lidocaine patch did not request any additional analgesic therapy on the fourth day after the suspension of treatment. However, choosing a lidocaine patch versus a local anaesthetic injection is inconvenient, as injecting a drug for a treatment cannot be compared with topical application of the same drug or even another drug.⁽¹²⁾

According to the available literature, no previous comparisons have been performed between methyl salicylate and lidocaine patches for management of myofascial pain. However, in the current study, lidocaine patches decreased the intensity of pain slightly more than methyl salicylate patches.

The assessment of the degree of mouth opening showed a slightly greater increase for lidocaine

patches than for methyl salicylate patches. However, lateral movement records showed a slight increase for methyl salicylate compared to lidocaine patches, and the quality of life showed slightly more improvement with lidocaine patches than with methyl salicylate patches.

Therefore, we conclude that the topical application of methyl salicylate or lidocaine patches can be effective in decreasing myofascial pain. Compared to methyl salicylate patches, lidocaine patches showed a slightly better reduction in pain intensity, with a slight increase in the degree of mouth opening and a slight improvement in the quality of life. However, the methyl salicylate patches showed a slightly greater increase in lateral movement than the lidocaine patches.

Conflicts of interest

The authors have reported no conflicts of interest concerning the materials or methods used in this study.

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