Original Article

Effect of ischemic compression performed by family caregivers on myofascial pain syndrome and the care burden of the families of patients: a multicenter open-label randomized comparative study

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Background: Ischemic compression is a manual therapy technique for myofascial pain. This study aimed to verify the effect of ischemic compression performed by family caregivers on myofascial pain syndrome (MPS) in patients and on the family's care burden.

Methods: This multicenter, open-label, randomized, comparative study included patients with myofascial pain and their family caregivers who were randomized into the following groups: ischemia compression (performed by a family caregiver), sham ischemia compression, or untreated control. The effectiveness and safety of ischemic compression and the burden on family caregivers were evaluated. The primary endpoint was the rate of 50% or more improvement in the patient's mean numerical rating scale pain score in the previous 24 hours, 14 days after starting the intervention. The secondary endpoint was the rate of change in the family caregivers' reaction assessments.

Results: A total of 75 patients and caregivers (70 patients with cancer and family caregivers) who received home medical care were enrolled at three facilities. The study completion rate was 94.7%, and there were no adverse events. The rate of 50% or more improvement in the numerical rating scale score was 64.0% in the ischemic compression group, 16.0% in the sham ischemic compression group, and 4.0% in the control group ($P<0.001$). Caregivers' self-esteem was significantly lower in the ischemic compression and sham ischemic compression groups than in the control group. However, there was no significant difference between the two groups ($P=0.370$).

Conclusions: Ischemic compression for myofascial pain in patients performed by family caregivers can increase the analgesic effect in patients and self-esteem in family caregivers.

Trial Registration: The University Hospital Medical Information Network Clinical Trials Registry (approval number: UMIN000036605).

Keywords: Ischemic compression; myofascial pain syndrome (MPS); family caregivers; analgesic effect; self-esteem

Submitted Aug 15, 2021. Accepted for publication Nov 12, 2021.

doi: 10.21037/apm-21-2276

View this article at: https://dx.doi.org/10.21037/apm-21-2276

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Introduction

Myofascial pain syndrome (MPS) is a functional disorder characterized by pain. The diagnostic criteria established by Rivers indicate that the myofascial trigger point (MTrP) needs to be palpated, and patient pain needs to be reproduced with palpation of the MTrP (1). According to the US Centers for Disease Control and Prevention, three main conditions that cause daily life disability include heart disease, arthritis, and back pain (2). Of the patients with cancer, 11.9–45% complained of back pain and experienced MPS (3-5). To the best of our knowledge, there have been no reports on the prevalence of MPS in patients receiving home care. Continuous muscle contraction due to the same posture or postural restriction has been reported as a mechanism for MTrP formation (6). Patients receiving home care (especially patients with cancer) often have the same posture due to decreased activity, and the prevalence rate of MPS is expected to be high. In addition, the decreased activity is expected to be related to psychological stress (7). Psychological stress has been reported to be associated with low back pain in mice. One report found that more than half of patients with cancer have MPS with psychological stress (8).

No standard treatment has been established for patients with MPS (9). Clinically, trigger point injections of a local anesthetic into the MTrP, dry needling, acupuncture, and manual treatment are available treatment options (10-13). Ischemic compression is a manual therapy technique that inactivates MTrP by pressing it with a finger to make it ischemic. This ischemic compression has been reported to improve MPS pain and pressure pain thresholds within a short period (14-17). The less invasiveness related to the non-penetration and convenience has been identified as a feature of ischemic compression. Although it is common for family caregivers to perform ischemic compression in daily life, to our knowledge, no studies have suggested that ischemic compression performed by non-health workers is helpful.

Family caregivers experience great emotional distress due to the burden of caring. Decreased quality of life (QOL) and a high prevalence of psychiatric disorders among family caregivers have been reported (18). Family caregivers of patients with cancer feel guilty that they are not doing enough for their patients (19). The QOL of family caregivers during home palliative care is associated with self-esteem during care and affirmation of care (20,21). One of the factors affecting the low QOL of family caregivers is the degree of patient distress (22). Thus, intervention by family caregivers to improve patient conditions can decrease the distress of caregivers (23).

We hypothesized that ischemic compression in areas involved in MPS by the family caregiver in patients receiving home care rapidly improves the pain and threshold for tenderness, thereby providing favorable effects on the self-esteem of the family caregiver. We present the following article in accordance with the CONSORT reporting checklist (available at https://apm.amegroups.com/article/view/10.21037/apm-21-2276/rc).

Methods

Objective

The objective of this study was to verify the effects of ischemic compression performed for MPS by family caregivers on (I) myofascial pain in patients and (II) on the care burden of the family.

Study design

We conducted a multicenter open-label randomized comparative study to assess the differences in patient interventions for MPS by family caregivers. The present study was conducted from 2019 to 2020 at three clinics in urban and rural areas of Japan. The study adhered to the principles of the Declaration of Helsinki (as revised in 2013). The study was approved by the Medical Ethics Committee of Kansai Medical University (reference number: 2019021) and informed consent was obtained from all patients. This study was registered with the University Hospital Medical Information Network Clinical Trials Registry (approval number: UMIN000036605) on May 11, 2019.

Study participants

Patients and their family caregivers who met the following eligibility criteria were included in the study: (I) received home medical care from the institutions that participated in this study; (II) met the Rivers' MPS diagnostic criteria (1); and (III) had MPS with a numerical rating scale (NRS) score of 3 or higher over the last 24 hours. MPS is diagnosed according to the following criteria: (I) a tender spot found on palpation with or without referral of pain; (II) recognition of pain symptoms by the patient on palpation of a tender spot; and at least three of the following: (III) muscle stiffness or

spasm; (IV) limited range of motion of an associated joint; (V) pain that worsens with stress; and (VI) palpation of a taut band and/or nodule associated with a tender spot (1). The exclusion criteria included the following: (I) patients and family caregivers with mental disorders (e.g., mood disorder, cognitive impairment); (II) patients with rheumatoid pathologies (e.g., fibromyalgia, polymyalgia rheumatica); (III) patients and family caregivers younger than 20 years; and (IV) patients wanting to use superficial massage or new medication in the near future. Family caregivers were defined as the most direct caregivers in the family, such as relatives and spouses, and were limited to one person living together with the patient or visiting at least three times a week.

Procedure

Upon enrollment and after obtaining written informed consent, the study participants were randomly allocated to three groups using the permuted block method with a block size of 4 and a 1:1:1 allocation ratio for the three study groups: ischemic compression, sham compression, and control groups. Allocation and data management were performed by the Research Secretariat of Kansai Medical University, which was not involved in direct participant care. Each participant was automatically informed of their allocation after obtaining consent. Concurrently, clinicians responsible for the present study were automatically informed of the participant allocations. The allocation process was concealed by the clinicians involved in the statistical analysis. All participant data were anonymized.

In the ischemic compression group, a 30-s continuous compression with the thumb was performed three times by a family caregiver for the MTrP with a 30-second interval between each repetition. The degree of continuous compression was defined as the maximum pressure at which the patient could tolerate the pressure pain, and the degree of compression increased when the pressure pain began to decrease. In the sham compression group, interventions that were similar to those of the ischemic compression group were performed, although the degree of continuous compression was the minimum pressure at which the patient felt pressure pain. In the control group, no specific therapy for MTrP was performed by family caregivers. In all groups, the patients were marked with ink at the location of the MTrPs by the clinicians. All groups were given a pamphlet with specific intervention details. The method of ischemic compression in this pamphlet was based on previous studies (14-17). For the ischemic compression and sham compression groups, direct instruction on the technique was given by the clinicians to family caregivers for approximately 5 minutes on day 0 (T0, the day before the start of the intervention). Patients were assessed by clinicians to ensure that they had been treated as indicated and properly on day 14 (T1, 14 days after the start of the intervention). During the intervention period, there was no use of superficial massage or new medication that could interfere with the response to the intervention in all groups. The study participants were not allowed to cross from one group to another until the end of the study. If a patient in the sham compression group or the control group desired ischemic compression, it was performed after the study period.

Ischemic and sham compressions for MPS at the two most painful areas were performed for patients by family caregivers three times a week for 2 weeks (six sessions in total). Among all groups, analgesic treatments for MPS were continued. Evaluations were performed at T0 and T1. The following information was obtained during the pre-observation period: patient demographic information, primary illness, Eastern Cooperative Oncology Group performance status (ECOG PS), number of MTrPs, duration of pain, analgesic drug use, personalized pain goal score, family caregiver demographic information, caregiver relationship with the patient, and duration of home medical care. The following information was obtained at T0 and T1: patient pain intensity score, pressure pain thresholds, adverse events, and family caregiver care burden score. The data were collected at the patients' homes by clinicians who were responsible for the present study.

In this study, ischemic compression was not performed within the last 24 h of the T1 evaluation.

Measures

Pain intensity

Patients evaluated their average pain intensity (PI) during the previous 24 hours using an 11-point NRS ranging from 0 (no pain) to 10 (worst possible pain) (24). Pain scores of 1–4 indicated mild PI, 5–6 indicated moderate PI, and 7–10 indicated severe PI (25). The reliability and validity of this scale were established (26). For multiple MPS areas with different NRS scores, the average NRS score was used. The best cutoff point for the NRS rate of change was reported to be 50% when determining the proportion of patients with clinically significant pain improvement (27).

Personalized pain goal

One way to ensure that pain management goals are tailored to individual needs is to use a personalized pain goal (PPG), which relies on the patient criteria for meaningful pain relief. PPGs were assessed by asking patients the following question: "What is the maximum level of pain that would allow you to achieve comfort in physical, functional, and psychosocial domains?" Patients responded using 11-point NRS scores ranging from 0 (I feel comfortable and at ease at an NRS score of 0 points) to 10 (I feel comfortable even at an NRS score of 10 points). The median PPG score of patients with cancer was 3 (28).

Pressure pain thresholds

A 10-mm-diameter attachment to a digital ergometer (Digital force gages RZ series AIKOH, Osaka, Japan) was pressed against the skin on the patient's MTrP to measure the minimum pressure (pressure pain threshold; PPT) at the MTrP site at which the patient felt pain. PPT was measured twice, and the average score was used. The validity of measuring PPT at the MTrP site has been verified previously (29).

Japanese version of the caregiver reaction assessment (CRA-J)

The CRA-J is a multidimensional tool for assessing the care burden and a self-report questionnaire comprising 18 items scored with a rating scale of 1–5. A high CRA-J score indicates a high burden of care. The CRA-J includes the following five domains: impact on schedule (five items), caregiver's self-esteem (five items), lack of family support (four items), impact on health (two items), and impact on finances (two items). The reliability and validity of the care burden for the families of home care patients have been verified, and it has a high internal consistency with a Cronbach's coefficient alpha of 0.73–0.89 for each domain (30).

Adverse events

Adverse events were assessed using the Common Terminology Criteria for Adverse Events v.5.0 (Japan Clinical Oncology Group version) (31).

Outcomes

The primary endpoint was the rate of improvements of 50% or more in the mean NRS pain score of the patients within the last 24 h 14 days after starting the intervention. The secondary endpoints were the rate of change in the PPT for the patient's MTrP, the presence of adverse events, and the rate of change in the caregiver reaction assessment scores of family caregivers.

Sample size calculation

In a previous study (11), the average NRS change for cervicogenic headache originating from MTrP 2 weeks after the onset of treatment was 2.38±2.98 [mean ± standard deviation (SD)] for the ischemic compression group and 0.14±1.39 for the control group. Based on this test, 60 participants (n=20 in each group) were required when the significance level of the test was 5% on both sides, and the detection power was 90%. Thus, 75 people were selected, taking into consideration a withdrawal rate of 20%.

Statistical analysis

Data are reported as the mean and SD, median with interquartile range, or frequencies (%) with the confidence interval (CI), as appropriate. We used the Kruskal-Wallis test and Pearson's chi-squared test for the following dependent variables: age, sex, ECOG PS, MPS site, number of MTrPs, duration of pain, PPT, NRS score (day 0), PPG score (day 0), analgesic drug use, and CRA-J score (day 0). The improvement of 50% or more in the NRS score before and after the intervention, which is the primary endpoint, was analyzed using Cochran's Q test. Changes in the NRS scores, PPT, and CRA-J scores were analyzed using the Wilcoxon signed-rank test. For comparisons of the groups, we used the time-course as the intra-participant factor and the group as the inter-participant factor for the Friedman test, and multiple comparisons were corrected using the Bonferroni method.

The main analysis was based on the intention-to-treat principle, and no study participants were excluded from the analysis. If participants withdrew from the study, the NRS scores, PPT, and CRA-J scores after withdrawal were replaced with scores just before withdrawal. The withdrawal cases included those for which the principal investigator decided that participation should be discontinued due to adverse events or progression of the underlying disease, the participant wished to discontinue participation, or a new analgesic was added during the study period.

Statistical significance was set at $P<0.05$. Statistical analyses were conducted using SPSS version 25.0 J for

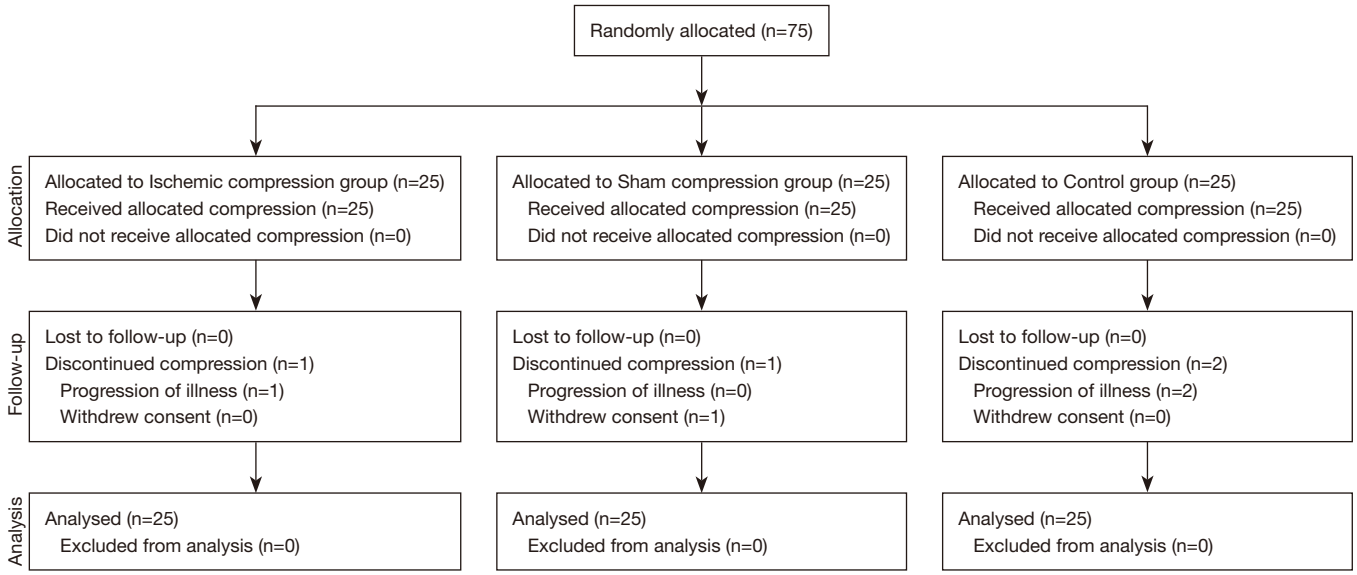

Figure 1 CONSORT diagram.

Macintosh (SPSS, Inc., IBM Corp., Chicago, IL, USA).

Patient and public involvement

Patients or the public were not involved in the design, conduct, reporting, or dissemination plans of our research.

Results

All 75 participants (70 were patients with cancer and family caregivers) were randomized, and 71 participants (94.7%) completed the study (*Figure 1*). On T1, all patients who were followed up were confirmed by clinicians to have received appropriate interventions when indicated. *Table 1* shows the demographic and clinical characteristics of the study participants. The demographic and clinical characteristics and measures for patients in the ischemic compression, sham compression, and control groups are presented in *Table 2*. No significant difference was noted in any measure between the groups. The MPS sites were found only in the upper and lower back, but not in other areas (*Figure 2*).

Primary outcome analysis

The rate of improvements of 50% or more in the NRS score for patients 14 days after the intervention was 64.0% (90% CI: 47.9–80.1%) for the ischemic compression group, 16.0% (90% CI: 3.7–28.3) for the sham ischemic compression group, and 4.0% (90% CI: –2.5% to 10.5%) for the control group (P<0.001; *Figure 3*). The changes in the mean NRS scores before and after the intervention for the three groups were compared, and the results are presented in *Table 3*. The ischemic compression group had significantly lower NRS scores at T1 than the sham compression and control groups (P=0.010 and P<0.001, respectively). There was no difference between the sham compression and control groups (P=0.407).

When limited to patients with cancer (70 patients), the rate of improvements of 50% or more in the NRS score for patients 14 days after the intervention was 60.9% (90% CI: 43.8–78.0%) for the ischemic compression group, 8.7% (90% CI: –0.9% to 18.3%) for the sham ischemic compression group, and 4.2% (90% CI: –2.6% to 11.0%) for the control group (P<0.001).

Secondary outcome analysis

The mean pressure pain thresholds for the three groups before and after the intervention were compared, and the results are presented in *Table 3*. The ischemic compression group had a significantly higher pressure pain threshold at T1 than the sham compression and control groups (P<0.001 for both). There was no difference between the sham compression and control groups (P=1.000). No adverse events were observed in any of the patients or family caregivers.

Table 1 Demographic and clinical characteristics of study participants

Characteristics	Values
Patients	
Age (years), mean (SD)	75.3 (12.1)
Sex, n (%)	
Male	41 (54.7)
Female	34 (45.3)
Primary illness (cancer), n (%)	70 (93.3)
Primary cancer site, n	
Lung	11
Gastrointestinal	25
Liver, pancreas, biliary system	13
Gynecological	6
Urological	6
Others	9
Primary illness (non-cancer), n (%)	5 (6.7)
Old cerebral infarction	2
Amyotrophic lateral sclerosis	1
Chronic heart failure	1
Liver cirrhosis	1
ECOG PS, n (%)	
0–2	12 (16.0)
3–4	63 (84.0)
Family caregivers	
Age (years), mean (SD)	62.4 (14.0)
Sex, n (%)	
Male	20 (26.7)
Female	55 (73.3)
Relationship with the patients, n (%)	
Wife	29 (38.7)
Husband	11 (14.7)
Daughter	19 (25.3)
Son	6 (8.0)
Mother	2 (2.7)
Others	8 (10.7)
Duration of home medical care (months), mean (SD)	3.7 (9.3)
CRA-J score, mean (SD)	
Impact on schedule	16.9 (4.9)
Caregiver's self-esteem	16.2 (3.8)
Lack of family support	9.0 (4.6)
Impact on health	6.7 (3.1)
Impact on finances	6.3 (3.2)

SD, standard deviation; ECOG PS, Eastern Cooperative Oncology Group performance status; CRA-J, Japanese version of the Caregiver Reaction Assessment.

The mean CRA-J scores before and after the intervention were compared among the three groups, and the results are presented in *Table 4*. The ischemic compression and sham compression groups showed significantly lower caregiver self-esteem scores (higher caregiver self-esteem) at T1 than the control group (P<0.001 and P=0.010), but there was no significant difference between the ischemic compression and sham compression groups (P=0.370). When limited to patients with cancer (70 family caregivers), the ischemic compression and sham compression groups showed significantly lower caregiver self-esteem scores (higher caregiver self-esteem) at T1 than the control group (P<0.001 and P=0.005), but no significant difference was noted between the ischemic compression and sham compression groups (P=0.349).

Discussion

To the best of our knowledge, this study is the first to evaluate the analgesic effect of ischemic compression by family caregivers of patients with myofascial pain and its effect on the care burden of the family.

The results of this study provide two important perspectives. First, ischemic compression for MPS by family caregivers was found to be useful for intractable pain associated with MPS. The reported pain severity was moderate among patients (median NRS score, 6.0) (25), and PPG was not achieved. The average pain duration of MPS was 6 months or more, which suggests chronic pain (32). Patients receiving home care, especially patients with cancer,

Table 2 Comparison of the demographic characteristics, clinical characteristics, and measures between the ischemic compression, sham compression, and control groups

Characteristics	Ischemic compression group (n=25)	Sham compression group (n=25)	Control group (n=25)	P value
Age (years), mean (SD)	78.6 (8.9)	74.4 (13.9)	72.8 (12.6)	0.217
Sex (female), n (%)	12 (48.0)	10 (40.0)	12 (48.0)	0.813
ECOG PS, n (%)				0.226
0–2	6 (24.0)	2 (8.0)	4 (16.0)	
3–4	19 (76.0)	23 (92.0)	21 (84.0)	
Site of MPS, n (%)				0.533
Upper back	9 (36.0)	12 (48.0)	11 (44.0)	
Lower back	16 (64.0)	13 (52.0)	14 (56.0)	
Number of MPS, mean (SD)	1.3 (0.4)	1.1 (0.4)	1.2 (0.4)	0.786
Duration of pain (months), mean (SD)	6.4 (5.3)	6.5 (6.2)	7.3 (5.7)	0.824
PPT, kPa (day 0), mean (SD)	23.9 (9.1)	24.4 (6.9)	25.7 (6.7)	0.672
NRS score (day 0), median [IQR]	7 [5–7.5]	7 [5–8.5]	5 [5–8]	0.400
PPG score, median [IQR]	3 [2–4]	3 [2–3]	2 [2–3]	0.373
Analgesic drug use, n (%)				
None	8 (32.0)	12 (48.0)	7 (28.0)	0.305
Use	17 (68.0)	13 (52.0)	18 (72.0)	
Opioid	12 (48.0)	8 (32.0)	10 (40.0)	0.524
Family caregivers				
Age (years), mean (SD)	63.6 (15.5)	61.0 (13.8)	62.6 (13.0)	0.807
Sex (female), n (%)	21 (84.0)	18 (72.0)	16 (64.0)	0.282
CRA-J score, mean (SD)				
Impact on schedule	17.2 (4.3)	16.7 (5.1)	16.6 (5.2)	0.887
Caregiver's self-esteem	15.3 (4.0)	17.3 (4.0)	16.0 (3.3)	0.160
Lack of family support	8.4 (3.3)	9.8 (5.7)	8.8 (4.5)	0.544
Impact on health	7.2 (2.0)	6.9 (4.4)	6.2 (2.4)	0.531
Impact on finances	5.3 (2.7)	6.3 (2.2)	6.3 (3.2)	0.094

SD, standard deviation; ECOG PS, Eastern Cooperative Oncology Group performance status; MPS, myofascial pain syndrome; PPT, pressure pain thresholds; PPG, personalized pain goal; NRS, numerical rating scale; IQR, interquartile range; CRA-J, Japanese version of the Caregiver Reaction Assessment.

have less time to live or less physical strength, and it is remarkable that the moderate and chronic pain improved significantly during the 2 weeks of intervention. A systematic review of ischemic compression by clinicians for shoulder pain showed immediate and short-term positive effects (33). In addition, ischemic compression was not performed within the last 24 hours before the T1 evaluation in this study, which suggests that this significant improvement was not a transient effect that occurred only during the ischemic compression, but there was a continuous effect. During the T1 evaluation, the PPT at the MTrP site was significantly higher for the ischemic compression group. This result suggests that ischemic compression may have an analgesic effect by inactivating MTrP. The mechanism of PPT-related

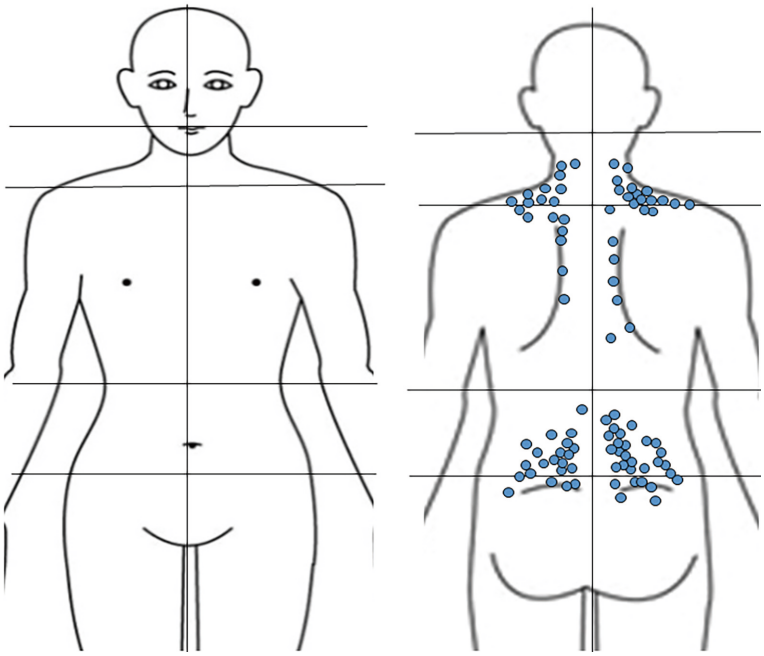

Figure 2 The MPS site (dots). MPS, myofascial pain syndrome.

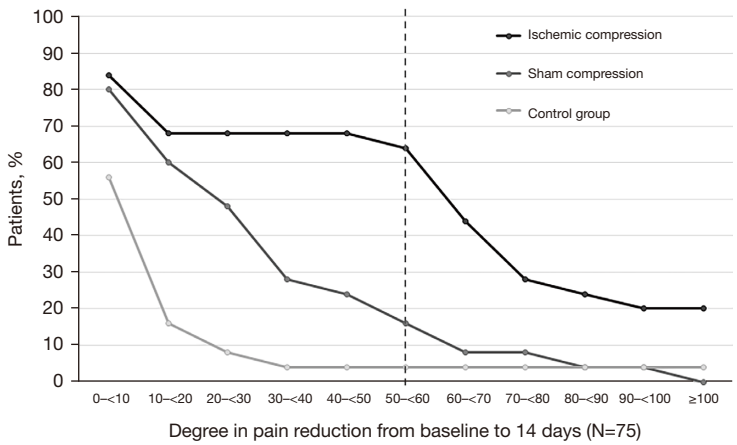

Figure 3 The percentage of patients achieving various levels of pain reduction from baseline to 14 days.

Table 3 Change in the numerical rating scale scores and the pressure pain threshold before and after intervention between the ischemic compression, sham compression, and control groups

Characteristics	Ischemic compression group (a)			Sham compression group (b)			Control group (c)			P value	Multiple comparison
	T0	T1	P value	T0	T1	P value	T0	T1	P value		
NRS score, mean (SD)	6.2 (1.9)	3.5 (2.7)	<0.001	6.8 (2.0)	5.4 (2.3)	0.015	6.1 (2.1)	6.4 (2.5)	0.574	0.005	a > b*, a > c***
PPT (kPa), mean (SD)	23.9 (9.1)	35.8 (13.5)	<0.001	24.4 (6.9)	23.5 (6.2)	0.166	25.7 (6.7)	24.3 (8.4)	0.164	<0.001	a > b***, a > c***

*, P<0.05; ***, P<0.001. NRS, numerical rating scale; PPT, pressure pain threshold; SD, standard deviation.

Table 4 The Japanese version of the Caregiver Reaction Assessment scores before and after the intervention between the ischemic compression, sham compression, and control groups

CRA-J score, mean (SD)	Ischemic compression group (a)			Sham compression group (b)			Control group (c)			P value	Multiple comparison
	T0	T1	P value	T0	T1	P value	T0	T1	P value		
Impact on schedule	17.2 (4.3)	16.3 (4.0)	0.024	16.7 (5.1)	17.3 (5.4)	0.170	16.6 (5.2)	18.0 (6.1)	0.031	0.526	
Caregiver's self-esteem	15.2 (4.0)	11.6 (4.3)	<0.001	17.3 (4.0)	13.3 (4.5)	<0.001	16.0 (3.3)	17.2 (3.3)	0.005	0.001	a > c***, b > c**
Lack of family support	8.4 (3.3)	8.6 (3.1)	0.647	9.8 (5.7)	10.1 (5.4)	0.692	8.8 (4.5)	10.3 (4.8)	0.001	0.736	
Impact on health	7.2 (2.0)	6.2 (1.8)	0.004	6.9 (4.4)	6.6 (2.5)	0.702	6.2 (2.4)	6.7 (2.4)	0.233	0.414	
Impact on finances	5.3 (2.7)	5.3 (2.8)	1.000	7.2 (4.2)	6.8 (1.9)	0.488	6.3 (3.2)	6.4 (2.4)	0.746	0.882	

**, P<0.05; ***, P<0.001. CRA-J, Japanese version of the Caregiver Reaction Assessment; SD, standard deviation.

inactivation is unknown, but it may reduce the nociception generated by MTrP.

This study cannot be compared with others because there are no other reports on ischemic compression performed by family caregivers. Furthermore, our search revealed no reports of ischemic compression for MPS performed by medical staff for home care or patients with cancer. There was a report of four sessions of ischemic compression performed by medical staff within 2 weeks for a cervicogenic headache originating from MPS with an intergroup change score of 2.55 (95% CI: 0.80–4.30) (14), which is similar to the findings of this study. In this study, the rate of improvements of 50% or more improvement in the average NRS pain score in the patients during the previous 24 hours and 14 days after the onset of the intervention was very high (64.0%). An improvement of 33% or more in the NRS pain score a day after the local anesthetic trigger point injection in patients with cancer was reported to be 59%, and the rate of improvement in the NRS pain score of 50% or more after 1 week was 48.8% (4,8).

Second, the self-esteem of caregivers, which is a domain of the CRA-J for family caregivers, showed that the burdens for the ischemic compression group and the sham ischemic compression group were significantly reduced compared with that for the control group, although there was no significant difference between the two groups. The self-esteem of caregivers has been reported to play a role in increasing satisfaction in the relationship with end-of-life patients (21), while care stress shows a negative correlation with the self-esteem of caregivers (34). In this context, it is significant that the intervention by the family caregiver to improve the patient's symptoms increased their self-esteem about caring for the family member. Family caregiver interventions to improve the patient's condition have been reported to reduce family distress (23), while the self-esteem of the caregiver did not show a significant difference between the ischemic compression and sham compression groups, in which the patient's analgesia was and was not observed, respectively. This result suggests that increased caregiver self-esteem may be poorly correlated with the symptom relief of the patient, which results in improvements of the patient's condition. One study reported that the holding of the hands of patients with cancer by family caregivers did not significantly increase the patient's autonomic functioning, but significantly increased the family caregiver's autonomic functioning, resulting in family self-care (35).

Despite concerns about the physical burden on family caregivers due to ischemic compression, there was no negative effect on their health, which is one of the domains of the CRA-J. The patients in this study were older, and most patients had advanced cancer with a decreased ECOG PS. Therefore, it was expected that the care burden of family caregivers would be high, although the degree of the care burden remains unknown because the CRA-J has no cutoff value. Care for patients with chronic illnesses is associated with a high care burden and chronic stress for caregivers (36). In contrast, the physical condition of family caregivers of patients with cancer was reported to be more associated with their subjective care burden than with the severity of their condition (37). The protocol for ischemic compression by family caregivers remains undetermined; however, three sessions per week are considered appropriate because of the usefulness of this study for patients and

the low burden on family caregivers. For the duration of ischemic compression, it has been reported that there is no difference in the effect between 30 and 60 s (15).

The limitations of our study are as follows: (I) the procedure was not consistent because the interventions were administered by family caregivers and non-supervised by clinicians; (II) the results cannot be generalized because homecare patients are mostly patients with cancer (however, the results of the main outcome were similar even when the study was limited to patients with cancer and their family caregivers); (III) there was selection bias due to the eligibility assessment, which was based on non-continuous registration; (IV) it was not possible to evaluate changes in analgesia over time through the six sessions of the ischemic compression because there were only two evaluation points; (V) it was not possible to compare the effects on different sites of MPS due to the small number of cases in this study; and (VI) there is no previous study on the interventions by family caregivers to improve the patient conditions for their self-esteem, and we were unable to compare the results of our study with others.

Conclusions

Ischemic compression for myofascial pain performed by family caregivers can increase the analgesia for patients and the self-esteem of family caregivers.

Acknowledgments

The authors thank the Research Secretariat of the Kansai Medical University Hospital. We also thank Jodi Smith, PhD ELS, from Edanz Group (https://en-author-services.edanz.com/ac) for editing the draft of this manuscript.
Funding: This work was supported by the Sasakawa Memorial Health Foundation.

Footnote

Reporting Checklist: The authors have completed the CONSORT reporting checklist. Available at https://apm.amegroups.com/article/view/10.21037/apm-21-2276/rc

Data Sharing Statement: Available at https://apm.amegroups.com/article/view/10.21037/apm-21-2276/dss

Peer Review File: Available at https://apm.amegroups.com/article/view/10.21037/apm-21-2276/prf

Conflicts of Interest: All authors have completed the ICMJE uniform disclosure form (available at https://apm.amegroups.com/article/view/10.21037/apm-21-2276/coif) and report that this work was supported by the Sasakawa Memorial Health Foundation. The authors have no other conflicts of interest to declare.

Ethical Statement: The authors are accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved. The study adhered to the principles of the Declaration of Helsinki (as revised in 2013). The study was approved by the Medical Ethics Committee of Kansai Medical University (reference number: 2019021) and informed consent was obtained from all patients.

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Cite this article as: Hasuo H, Hashimoto K, Iwamoto H, Miwa N, Kawashima T, Oda A, Sekimoto G. Effect of ischemic compression performed by family caregivers on myofascial pain syndrome and the care burden of the families of patients: a multicenter open-label randomized comparative study. Ann Palliat Med 2022;11(4):1179-1190. doi: 10.21037/apm-21-2276

