Journal of Integrated Community Health
Volume 8, Issue 1 - 2019, Pg. No. 21-32
Peer Reviewed & Open Access Journal

Research Article

Effectiveness of Fire Cupping (Hijamah Nariya) versus dry warm Fomentation (Takmeed Yabis) in Chronic Neck Pain - A Randomized Control Trial

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DOI: https://doi.org/10.24321/2319.9113.201904

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How to cite this article:
Raheem A, Nazli T, Saeed A, Alvi R, Kalaivani M. Effectiveness of Fire Cupping (Hijamah Nariya) versus dry warm Fomentation (Takmeed Yabis) in Chronic Neck Pain - A Randomized Control Trial. *J Integ Comm Health* 2019; 8(1): 21-32.

Date of Submission: 2019-12-27
Date of Acceptance: 2020-02-22

A B S T R A C T

Objectives: The primary objective was to compare the effectiveness of fire cupping versus dry warm fomentation in reducing pain and tenderness in patients with Chronic Neck Pain (CNP) and the secondary objective was to compare the effectiveness of both interventions in improving Cervical Range of Motion (CROM) and Quality of Life (QoL).

Methods: In this randomized controlled trial 70 patients with CNP were block randomized into two groups; fire Cupping Group (CG) or dry warm Fomentation Group (FG). Response to treatment was assessed using Visual Analogue Scale (VAS), CROM and Neck Disability Index (NDI). Impact of disease on patient's QoL was assessed using Short Form 36 Health Survey Questionnaire (SF-36).

Result: On intention-to-treat (ITT) analysis, the maximum reduction in pain was achieved in CG than in FG, the mean VAS scores in CG leads to much earlier reduction of pain as compared to FG (p=0.001). The mean CROM in both the groups increased from baseline, though the increase was higher in the CG. A low NDI score signifies less disability, the median percentage NDI score in CG was 12 (0-24) which is lower than FG 18 (0-46.7) and the difference between the two groups was statistically significant (p=0.0012). In the SF-36, subscale bodily pain, the difference between the two groups was statistically significant (p=0.0452).

Conclusion: Both the regimens are effective in reducing pain and increasing CROM while, earlier reduction in pain occur significantly greater extent with CG.

Keywords: Chronic Neck Pain, Fire Cupping, Hijamah, Fomentation, Takmeed, VAS, CROM, NDI, SF-36

Introduction

Neck Pain (NP) is one of the major public health problems with prevalence ranges from 16.7% to 75.1% globally,[1] however, it accounts for 31% of all musculoskeletal disorders seen in India.[2] When it lasts longer than three months with no clear cause then it is referred to as non-specific CNP. National Institute of Health Statistics survey indicated that NP was the third common cause of pain (15%) after the most common low back pain (27%) and migraine pain (15%).[3] CNP causes substantial disability particularly in people during their employment year and also puts a huge impact on day to day activities of the patient and their families, communities, and businesses rendering it a vast medical and socioeconomic burden on the society as there is no curative treatment available, the course of the disease has a frequent relapse. However, palliative treatment options are in the form of analgesics, muscles relaxant, opiates, and antidepressant that often help alleviate pain promptly but the relief is frequently temporary and none of the treatment options have been clearly shown to provide lasting pain relief also in the long term are frequently associated with gastrointestinal and renal side effects. Therefore, most people adjusted their activity pattern and lifestyle due to aggravating pain which puts a great impact on the patient's QoL and leaves them morbid.

Though, in Unani the arthritis including CNP can be managed well with regimenal therapy such as cupping. According to review article published in Public Library of Science (PLOS ONE), it has shown positive results in many previous studies proving its efficacy in musculoskeletal disorders.[4] Takmeed has also been claimed to decrease pain and muscle spasm and provide some degree of immediate pain relief. But no Randomized Controlled Trial (RCT) has investigated the effectiveness of Hijamah nariya (fire cupping) in comparison to Takmeed yabis (dry warm fomentation) in potli form in non-specific CNP. Therefore, this study is an attempt to evaluate the effectiveness of fire cupping versus dry warm fomentation to decrease the severity and extent of pain with local management so that it no longer interferes with the patient's QoL.

Methods

This study was carried out as a superiority randomized controlled clinical trial after getting approval from the Institute's Ethics Committee, Jamia Tibbiya Deoband, Deoband, Uttar Pradesh. Patients clinically diagnosed for NP attending Out Patient Department (OPD) and Indoor Patient Department (IPD) of Jamia Tibbiya Hospital Deoband and Shamim Ahmed Saeedi Unani Specialty Hospital for Joints Pain, Deoband, Uttar Pradesh were screened for the study between December 2014 to September 2015.

Of the 112 patients screened during this period, 70 (62.5 %) patients older than 18 yr of age with NP of more than 3 months with and without radiological changes were included after obtaining informed written consent. Patients younger than 18 yr of age, pregnant and lactating women, patient having any skin lesion or burn, those who received any systemic therapy in the previous two weeks, those with severe somatic illness requiring specific treatment or pain resulting an operation and those who were unsure of complying with the treatment protocol were excluded.

The study consisted of two phases, an initial 14 days phase of treatment to evaluate the response to therapy and a follow-up phase of another 7 days to determine the relapse rate. A detailed history, physical examination including assessment of Cervical Range of Motion (CROM) and neck disability and baseline investigations were done for all patients. The patients were allocated to two treatment groups with block randomization (block size of 6) using numbered sealed envelopes, procured from the Department of Biostatistics, All India Institute of Medical Sciences, New Delhi.

Study Interventions

Fire Cupping Group (CG) (Study Group)

Patients received Hijamah nariya bila shart (fire cupping with no scarification therapy) on every alternate day. Treatment was given for a period of 14 days and followed up after stopping treatment for another week. After ensuring the skin condition, the spirit/ alcohol soaked cotton was clamped with forceps and lit using a matchstick or spirit lamp and speedily placed into the glass cup and then quickly removed and then the inverted cup was placed on the skin. Once placed, the cups can be left in place; the negative pressure in the cups causes the skin and superficial muscle layer to be lightly drawn into the cup that tugs the skin upwards. The remaining cups were applied one after another on the upper back between the shoulders. Each cupping session lasted for about 10 to 15 minutes or until the appearance of erythema. Cups were removed from the patient's body with great care followed by a gentle massage. The session of cupping was repeated every alternate day up to 14 days and residual redness typically settled down in a few days time. This therapy did not cause any intense pain however, patients experienced a kind of pinching sensation followed by a relaxed feeling.

Fomentation Group (FG) (Control Group)

Patients received Takmeed yabis (dry warm fomentation) therapy on every alternate day. The treatment session of Takmeed was repeated every alternate day up to 14 days but the patients were followed up after stopping treatment for another one week for relapse. In the present study, the formulation of a Potli (tight compress) has been taken from the Unani literature comprising bajra/pearl millet (*Pennissetum glacum*), saboos-e-gandum (*Triticum aestivum*), namak (sodium chloride) and bareek reg (fine sand) in an equal ratio (50g each).[5] All ingredients were wrapped in a clean white muslin cloth and rolled up into a

ISSN: 2319-9113
DOI: https://doi.org/10.24321/2319.9113.201904

tight round pouch weighed 200 g and then tied tightly with the help of hemp or string. Before performing Takmeed on an individual patient, two sets of compresses were kept ready for use, one set of Potli was placed on the heat source (hot plate or on a towel warmer) and heated it up to a preferable temperature which was not much hot but bearable for ten minutes, while the other set was simply placed directly then gently touched and rolled on the upper back on each side of the spine. The two potli compresses were alternately heated and used until each treatment session was achieved. This study allowed the use of compress for three treatment visits.

The main study outcome was the change of VAS pain scores from baseline to the follow-up visits. In the treatment phase, patients in both groups were treated for 14 days and response to treatment was assessed at day 7, 14 and 21 using VAS, and secondary outcome measures such as CROM and NDI.[6-7] Impact of disease on patient's quality of life (QoL) was assessed using Health-related QoL: Short Form 36 Health Survey Questionnaire (SF-36)[8] at baseline and on day 21.

The Endpoints of treatment was taken as either complete disappearance of pain or 2 weeks (14 days) whichever was earlier and was followed up after stopping treatment for another one week (day 21) for any relapse. Patients were withdrawn from the study if the patient himself withdraws consent from the study for any reason or there was aggravation of the pain or patient develops unacceptable adverse effects of therapy at any time of the study.

Statistical Analysis

The sample size calculation was based on an earlier study in which the mean±SD VAS score after fomentation was 6.2±2.29,[9] the largest clinically acceptable effect for which superiority can be declared is a change in VAS assessed the pain of 1 unit. The true difference is assumed to be 2.5 units with a standard deviation of 2.29. The sample size estimated was 35 per group with 80% power and a 5% level of significance. Hence, taking into consideration a 10 lost to follow-up, 70 patients were randomized. The statistical analysis was carried out using Stata 12.0 (College Station, Texas, USA). Data were presented as number (%) or mean± standard deviation (SD) or as median (min-max) wherever appropriate. Baseline categorical variables were compared between the groups using Chi-square test/ Fisher's exact test and continuous variables were compared using Student's t-test for independent samples/ Wilcoxon rank sum test. Primary outcome pain which was measured over day 0, 07, 14 and 21, analysed compared between the groups using Generalized Estimating Equation (GEE) method. Secondary outcomes which followed a normal distribution were analyzed between the groups using the GEE method and which were not following normal distribution was analyzed using the Wilcoxon rank sum test. The p value, 0.05 was considered statistically significant. Intention-to-treat (ITT) analysis was performed by the last observation carried forward approach to determine the superiority of CG *vis-a-vis* FG. An intragroup analysis was done to assess the response within each group where mean/ median of each response parameters (VAS, CROM, and NDI) in CG on day 0 was compared with mean on day 07, 14 and 21. A similar analysis was done for the FG. Intergroup analysis was done by comparing the mean/median of percentage reduction in the response parameters in both the groups at each follow-up visit. The percentage change in the response parameter from day 0 (baseline) was calculated for each patient at each follow-up visit (day 07, 14 and 21) and the mean/ median of the percentage change in both the groups was determined.

Result

A total of 112 patients with CNP were screened between December 2014 and September 2015, and of these, 70 patients were randomized with 35 patients in each group. The CONSORT flow chart of patient recruitment in the study is shown in Figure 1. The demographic and disease profile of the patients were noted and the data adjusted for baseline clinical characteristics *viz*. duration of disease, shoulder radiating pain and worsening of pain due to tilting of neck backward which were statistically significant at baseline (Table 1).

Table 1.Demographical & Clinical profile of patients in Cupping group (CG) and Fomentation group (FG)

	CG (n=35)	FG (n=35)	p value
Age (years), Mean±SD	45.8±10.1	46.7±11.5	0.7492
Gender, n (%)			
Male	16 (45.7)	10 (28.6)	0.138
Female	19 (54.3)	25 (71.4)	
BMI, Mean±SD	27.4±4.1	26.2±4.6	0.2366
Family history, n (%)	7 (20)	12 (34.3)	0.179
Smokers, n (%)	8 (22.9)	8 (22.9)	1.0
Marital Status, n (%)			
Single	2 (5.7)	1 (2.9)	0.555

ISSN: 2319-9113
DOI: https://doi.org/10.24321/2319.9113.201904

Married	33 (94.3)	34 (97.1)	
Socio Economic Status, n (%)			
26-29 upper	9 (25.7)	7 (20.0)	0.142
16-25 upper middle	6 (17.1)	6 (17.1)	
11-15 middle lower middle	18 (51.4)	13 (37.1)	
<5-10 lower upper lower	2 (5.7)	9 (25.7)	
Duration of symptoms, Median (min-max)	12 (3–72)	24 (6–120)	0.0748
Age of onset, Median (min-max)	42.7 (21.5–61)	43 (23.5–63)	0.9483
Co-Morbidities, n (%)			
Diabetes	6 (17.1)	4 (11.4)	0.495
Hypertension	5 (14.3)	4 (11.4)	0.721
Obesity	8 (22.8)	5 (14.3)	0.356
Associations, n (%)			
Repitative stress	26 (74.3)	25 (71.4)	0.788
Lifting heavy weights	13 (37.1)	19 (54.3)	0.150
Treatment History, n (%)			
NSAID	15 (42.9)	16 (45.7)	0.367
Unani/ Ayurvedic	3 (8.6)	7 (20.0)	
Physiotherapy	3 (8.6)	1 (2.9)	
Don't know	7 (20.0)	8 (22.9)	

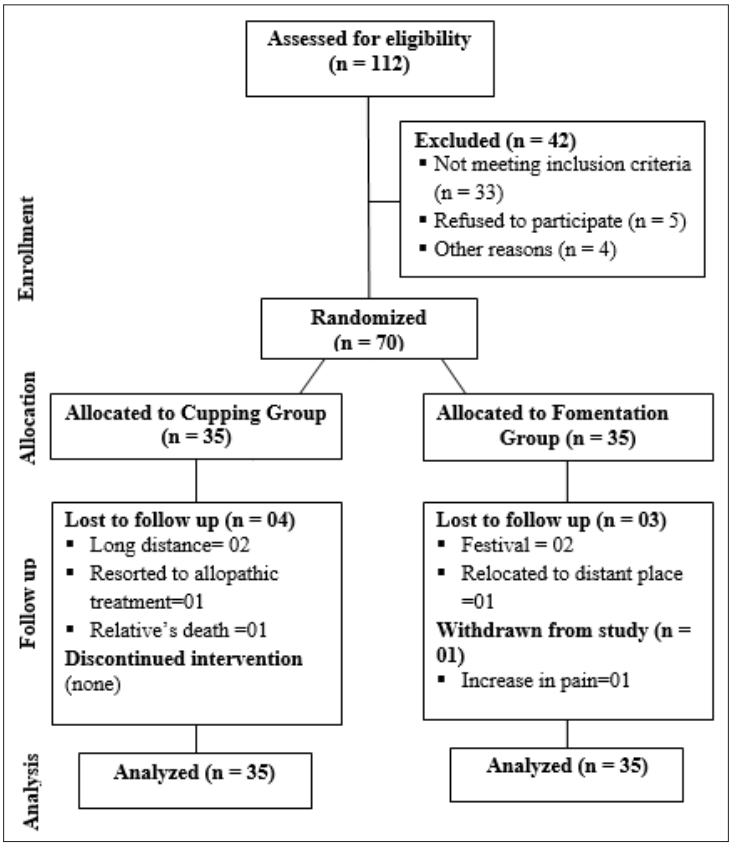

Figure 1.CONSORT flowchart showing therapeutic response to fire Cupping and Fomentation intervention in patients with chronic non-specific neck pain

ISSN: 2319-9113
DOI: https://doi.org/10.24321/2319.9113.201904

Change in Visual analogue Scale (VAS)

The main study outcome was the change of VAS pain scores from baseline to day 07, day 14 and day 21. Intergroup analysis done between the two groups showed that mean VAS score in CG and FG was 98.6±8.5 and 100±0 respectively which was not statistically significant (p=0.076) at the baseline. On day 07, the mean VAS score was lower in CG than in FG which was statistically significant [Diff. (95% C.I.): -18.0 (-24.9, -11.09)] with p value of < 0.001. The data was adjusted for few baseline clinical characteristics *viz*. duration of disease, shoulder radiating pain and worsening of pain due to tilting of neck backwards which were statistically significant at baseline and even after adjusted the data, the CG difference between the mean VAS scores was found to be statistically significant with p value <0.001. On day 14, the maximum reduction in pain was achieved in the CG than in the FG [Diff. (95% C.I.): -30.3(-39.9 -20.2); p=0.001] which was maintained on day 21 [Diff. (95% C.I.): -30.3(-40.1, -20.0); p=0.001]. To assess the response within each group, an intragroup analysis was done and the mean VAS score in each group on day 0 was compared with the mean VAS score at each follow-up visit on day 07, 14 and 21. We observed that mean VAS score was found to be decreasing significantly in both the groups, there was a statistically significant reduction in mean VAS scores at all time intervals *viz* day 0 *vs* day 07, day 0 *vs* day 14, day 0 *vs* day 21 (p< 0.001) (Table 2, Figure 2).

Change in Cervical Range of Motion (CROM)

The mean values of CROM in both CG and FG increased from baseline, though the increase was higher in the CG in comparison to FG. The effect started on day 07 itself in flexion, extension and right lateral rotation. However, in the remaining movements the effect was seen from day 14 onwards (Table 3, Figure 3).

Table 2.Difference in VAS scores in Cupping group (CG) and Fomentation group (FG) in patients with chronic non-specific neck pain at variable time points

Day	CG n=35	FG n=35	Unadjusted		Adjusted[a]	
			Diff. (95% C.I.)	p value	Diff. (95% C.I.)	p value
0	98.6±8.5	100±0	-1.4 (-4.2, 1.4)	0.314	-3.14 (-6.6, 0.3)	0.076
07	55.5±16.6	73.5±12.3	-18.0 (-24.9, -11.1)	0.001*	-19.8 (26.7, -12.9)	0.001*
14	20.6±18·8	50.7±21·6	-30.3 (-39.9,-20.2)	0.001*	-31.9 (-41.4, - 2.3)	0.001*
21	20.0±19·1	50.1±21.9	-30.3 (-40.1, -20.0)	0.001*	-31.9 (-41.5, - 2.2)	0.001*

Data presented as Mean±SD and numbers (%); * p value <0.05, statistically significant.

[a]Data were adjusted for disease duration, shoulder radiating pain and worsening of pain due to tilting neck backwards.

Cupping group (CG): 0 *vs* 07, 0 *vs*14, 0 *vs* 21, p< 0.001, statistically significant.

Fomentation group (FG): 0 *vs* 07, 0 *vs14*, 0 *vs* 21, p< 0.001, statistically significant.

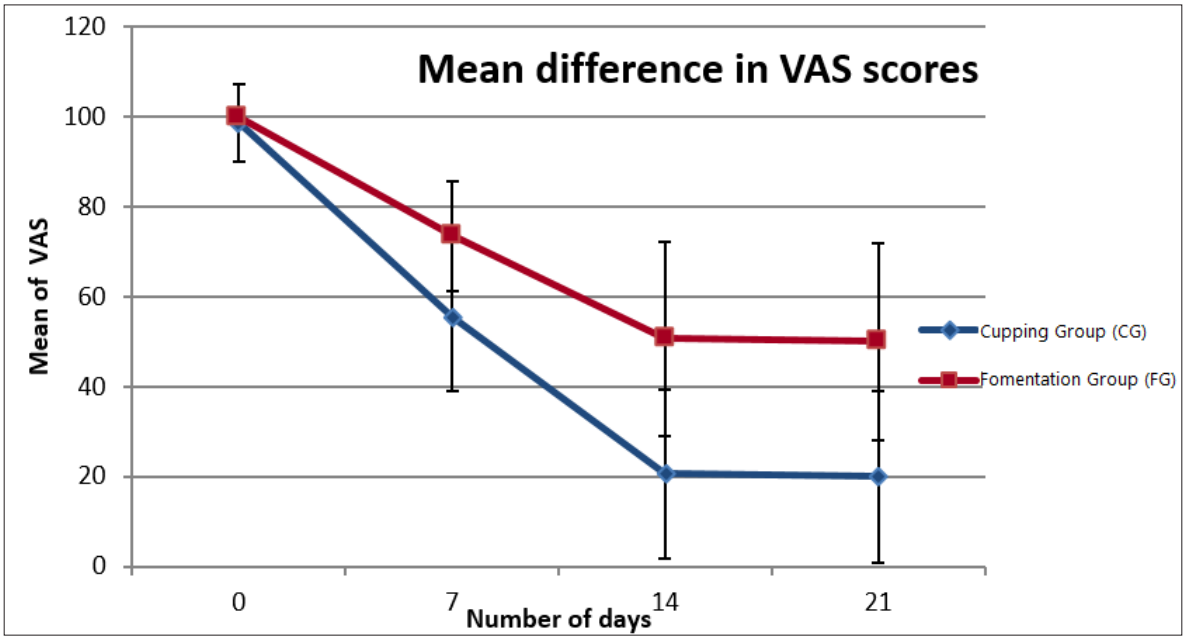

Figure 2.Line diagram showing mean values of VAS over a period of time in Cupping group (CG) and Fomentation group (FG)

ISSN: 2319-9113
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Table 3.Comparison of mean values of CROM between the Cupping group (CG) and Fomentation group (FG) in patients with chronic non-specific neck pain at variable time points

	CG (n=35)	FG (n=35)	Diff. (95% C.I.)	p value
Flexion				
Day 0	22.5±7.1	21.5±8.0	1.0 (-2.5,4.5)	0.578
Day 07	31.5±7.7	27.7±7.3	3.8 (0.4,7.4)	0.031*
Day 14	41.6±8.9	34.4±7.1	7.2 (3.4,11.1)	0.001*
Day 21	41.8±8.8	34.4±7.1	7.4 (3.6, 11.2)	0.001*
Extension				
Day 0	33.9±11.5	31.4±8.7	2.5 (-2.20, 7.3)	0.294
Day 07	40.9±9.3	35.7±8.5	5.2 (1.1,9.4)	0.013*
Day 14	47.5±6.5	39.6±7.5	7.9 (3.9,11.8)	0.001*
Day 21	47.4±6.8	39.7±7.5	7.7 (3.7,11.7)	0.001*
Right Rotation				
Day 0	35.1±9.6	35.8±8.5	-0.7 (-4.9,3.5)	0.729
Day 07	41.7±9.4	39.9±8.9	1.8 (2.5,5.9)	0.421
Day 14	48.0±6.4	43.7±7.2	4.3 (0.9, 7.7)	0.013*
Day 21	48.0±6.4	43.7±7.2	4.3 (0.9, 7.7)	0.013*
Left Rotation				
Day 0	37.5±8.4	35.8±9.0	1.7 (-2.3,5.8)	0.407
Day 07	43.3±8.2	40.4±8.7	2.9 (-1.1,6.8)	0.154
Day 14	48.9±7.2	44.5±8.3	4.4 (0.8,8.0)	0.016*
Day 21	49.1±7.2	44.5±8.3	4.6 (1.0,8.2)	0.012*
Right Lateral Rotation				
Day 0	28.0±6.8	28.8±7.4	-0.8(-4.1, 2.5)	0.636
Day 07	37.5±6.5	32.8±7.1	4.7 (1.4, 7.8)	0.004*
Day 14	44.7±5.9	37.1±6.5	7.6 (4.6, 10.7)	0.001*
Day 21	44.9±5.7	37.1±6.5	7.8 (4.8, 10.9)	0.001*
Left Lateral Rotation				
Day 0	26.4±6.6	27.4±7.8	-1.0 (-4.4, -2.3)	0.538
Day 07	34.0±6.6	32.2±7.8	1.8 (-1.5, 5.3)	0.284
Day 14	41.1±4.5	37.6±7.2	3.5 (0.55, 6.4)	0.020*
Day 21	41.4±4.2	37.7±7.2	3.7 (0.75, 6.5)	0.014*

Data presented as Mean±SD * p <0.05, statistically significant.

Cupping Group (CG): 0 *vs* 07, 0 *vs* 14, 0 *vs* 21, p< 0.001, statistically significant.

Fomentation Group (FG): 0 *vs* 07, 0 *vs* 14, 0 *vs* 21, p< 0.001, statistically significant.

Change in Neck Disability Index (NDI)

NDI median percentage scores were obtained on day 0, day 07 and day 14 of the treatment phase and after stopping the treatment on day 21 with 35 patients in each CG and FG. The NDI was decreased significantly in our study, at baseline median percentage score in the CG is 40 (14-70) and 51 (20-73) in the FG. The difference between both the groups was found to be statistically significant (p=0.0038). On day 07, the median percentage score of NDI in CG was 22 (0–40) which was lower than FG with the median percentage score of NDI 26.7 (0-67) and the difference between the two groups was statistically significant (p=0.0006). On day 14, the median percentage score of NDI was 12 (0-24) which is lower than the FG with the median percentage score of NDI 18 (0-46.7) and the difference between the two groups was statistically significant (p=0.0011). Similarly, on day 21

ISSN: 2319-9113
DOI: https://doi.org/10.24321/2319.9113.201904

the median percentage score of NDI was 12 (0-24) which is lower than the FG with the median percentage score of NDI 18 (0-46.7) and the difference between the two groups was statistically significant (p=0.0012) (Table 4).

To assess the response within each group, an intragroup analysis was done. The median percentage score of NDI in CG on day 0 was compared with the median percentage score of NDI on day 07, 14 and 21. A similar analysis was done for the FG. We observed that in both the groups, there was a statistically significant reduction (p=0.001) in a median percentage score of NDI at all time intervals *viz.* day 0 *vs* 07, day 0 *vs* 14, and day 0 *vs* 21 (Table 4, Figure 4).

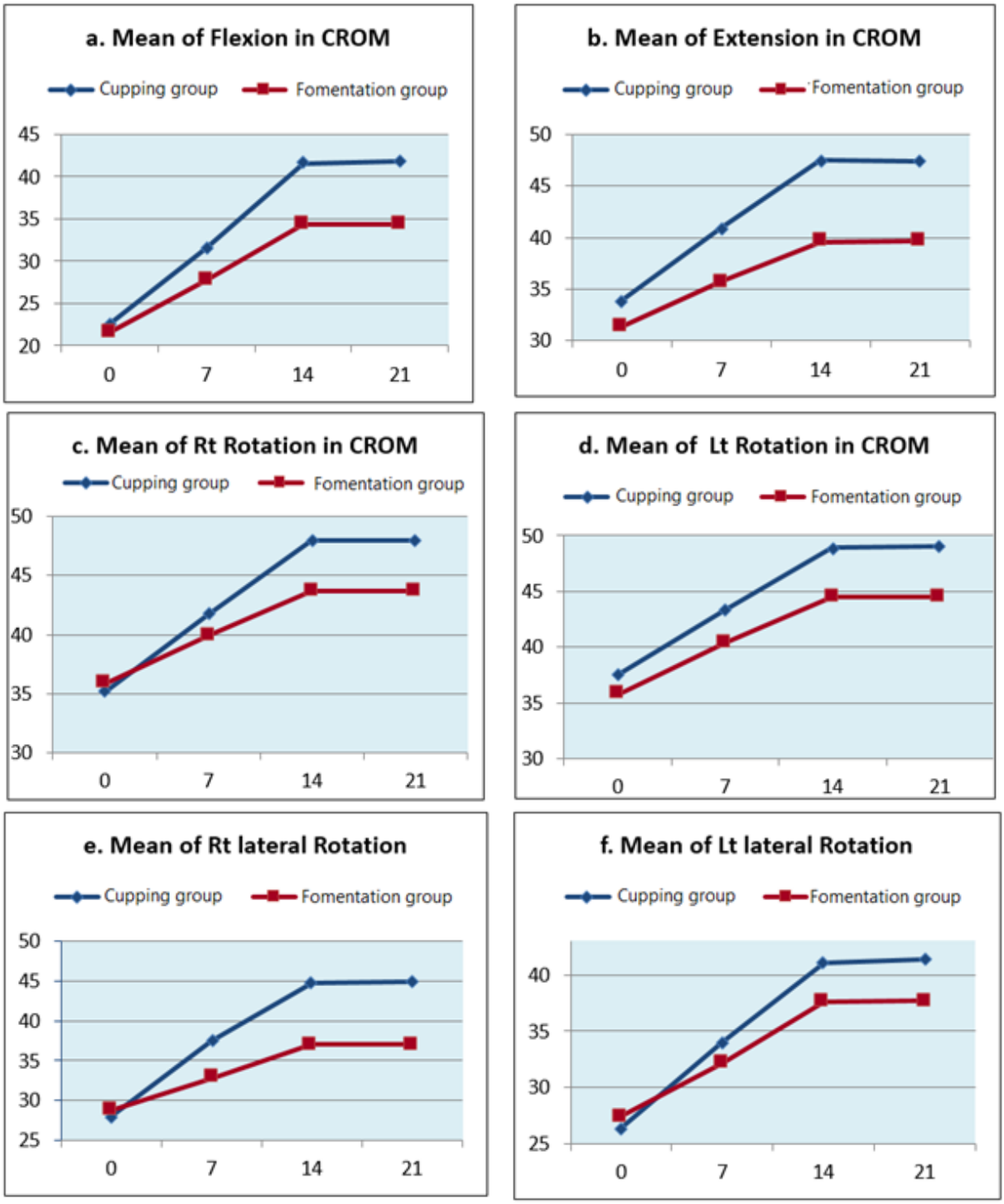

Figure 3.Line diagram showing trend in the mean values of different movements of CROM in Cupping group (CG) and Fomentation group (FG)

ISSN: 2319-9113
DOI: https://doi.org/10.24321/2319.9113.201904

Table 4. Comparison of median of NDI between the Cupping group (CG) and Fomentation group (FG) in patients at variable time points

NDI score	CG (n=35)	FG (n=35)	p value
Day 0	40 (14–70)	51 (20–73)	0.0038*
Day 07	22 (0–40)	26.7 (0–67)	0.0006*
Day 14	12 (0–24)	18 (0–46.7)	0.0011*
Day 21	12 (0–24)	18 (0–46.7)	0.0012*

Data presented as Median (min-max); * p <0.05, statistically significant.
Cupping group (CG): 0 *vs* 07, 0 *vs* 14, 0 *vs* 21, p< 0.001, statistically significant.
Fomentation group (FG): 0 *vs* 07, 0 *vs* 14, 0 *vs* 21, p< 0.001, statistically significant.

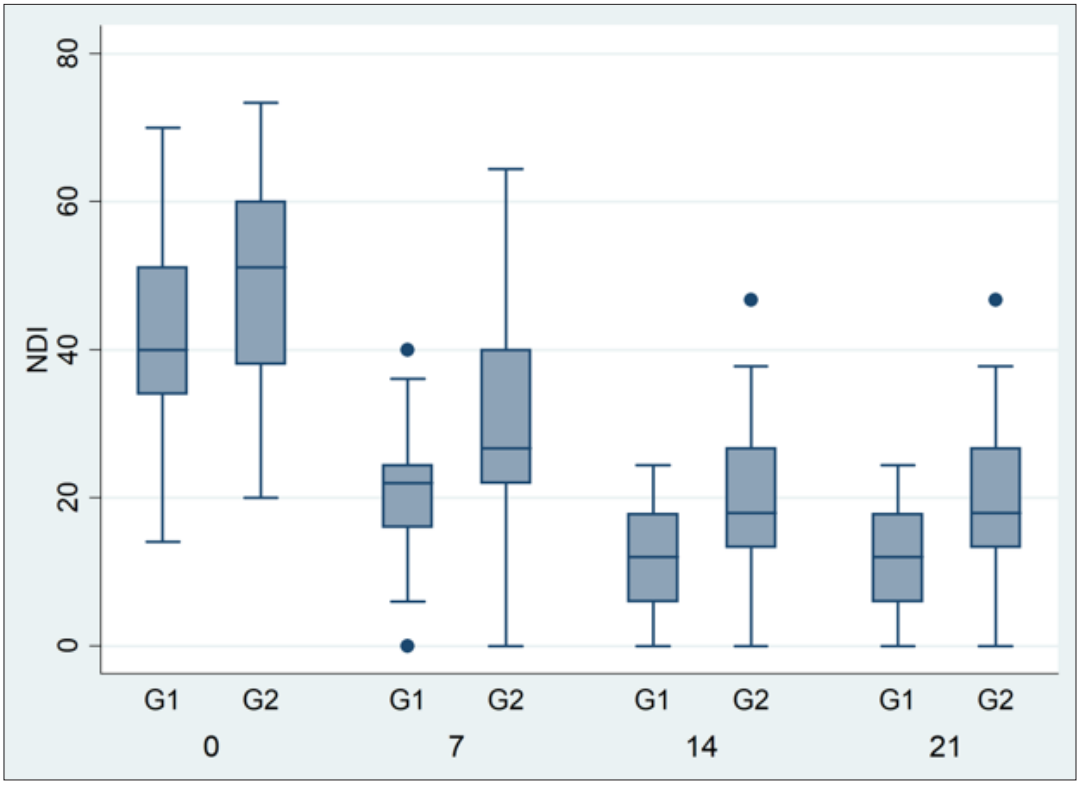

Figure 4.Box -whisker's plot showing NDI values over a period of time between the fire Cupping group (G1) and Fomentation group (G2)

Change in Short Form-36

The mean scores of Quality of Life (QoL) SF-36 in both the groups were calculated on day 0 and day 21. All the subscales of quality of life were found to be statistically not significant between the two groups except bodily pain subscale. In the subscale bodily pain on day 21, the baseline mean scores in the CG is 64.3 and 73.4 in the FG (Table 5). The difference between both the groups was found to be statistically significant (p=0.0452). To assess the response within each group, an intragroup analysis was done. The mean score of each subscale SF-36 at baseline was compared with the mean score obtained on day 21 in both groups. In the CG all the subscales had a better mean score of QoL except energy/ fatigue (p=0.2416) and emotional wellbeing (p=0.3796). However, in the FG there is no change in the QoL mean score role limitation due to emotional health (p=0.1094), emotional wellbeing (p=0.1328) and social function (p=1.00) (Table 5).

Discussion

In the present study, intervention fire Cupping *(Hijamah nariya)* compared with dry warm Fomentation (*Takmeed yabis*) for 14 days where patients were evaluated for the response on day 07, day 14 and day 21 using a subjective parameter, 100 mm VAS (Visual Analogue Scale) to measure neck pain intensity and objective parameters such as NDI and CROM to measure functional disability. The impact of the disease on the patient's QoL was also assessed using SF-36.

ISSN: 2319-9113
DOI: https://doi.org/10.24321/2319.9113.201904

Table 5.Comparison of SF-36 domain before and after the treatment between Cupping group (CG) and Fomentation group (FG)

	CG (n=35)	FG (n=35)	Diff. (95% C.I.)	p value
Physical functioning				
Pre	74.8±14.5	74.6±17.4	0.2 (-7.4,7.8)	0.9555
Post	84.1±12.8	81.9±16.9	2.2 (-5.4,9.8)	0.5641
p value	0.001*	0.001*		
Role limitation due to physical health				
Pre	52.1± 47.0	59.3±48.2	-7.2 (-29.8, 15.6)	0.5322
Post	80.8±37.2	76.6±41.3	4.2 (-15.8, 24.2)	0.6760
p value	0.0059*	0.0498*		
Role limitation due to emotional health				
Pre	51.4±48.7	58.1±48.7	-6.7 (-29.9, 16.6)	0.5691
Post	84.5±34.1	73.1±44.2	11.4 (-8.7, 31.5)	0.2606
p value	0.0025*	0.1094		
Energy/Fatigue				
Pre	64.0±19.1	68.3±18.8	-4.3 (-13.3, 4.7)	0.3466
Post	69.5±16.4	73.4±16.4	-3.9 (-12.3, 4.4)	0.3523
p value	0.2416	0.0192*		
Emotional wellbeing				
Pre	75.3±15.7	80.3±16.2	-5.0 (-12.6, 2.6)	0.1946
Post	77.8±12.0	83.1±16.2	-5.3 (-12.6, 1.9)	0.1462
p value	0.3796	0.1328		
Social function				
Pre	60.4±17.5	68.6±18.5	-8.2 (-16.8, 0.39)	0.0611
Post	64.1±12.8	68.1±21.6	-4.0 (-13.1, 5.0)	0.3750
p value	0.0082*	1.00		
Body pain				
Pre	50.2±23.9	60.3±24.4	-10.1 (-21.6, 1.4)	0.0854
Post	64.3±17.0	73.4±18.0	-9.1 (-18.0, -0.2)	0.0452*
p value	0.0007*	0.0006*		
General health				
Pre	44.4±13.2	46.9±12.2	-2.5 (-8.6, 3.6)	0.4142
Post	54.2±14.4	52.7±12.1	1.5 (-5.3, 8.2)	0.6631
p value	0.0017*	0.0001*		

Data presented as Mean±SD; * p <0.05, statistically significant.

The main study outcome was the change of VAS pain scores from baseline to the follow-up visits on day 07, day 14 and day 21 after treatment. Based on VAS scores obtained at all the time points on day 07 and day 14 of the treatment phase and after stopping the treatment on day 21, the reduction in the mean VAS pain score was statistically significant in each CG and FG (p<0.001). However, the reduction in the mean VAS pain score is more in CG vis-à-vis FG and this was seen as early as on day 07 and continued on day 14 and day 21 (Table 2).

In the CG, at the end visit on day 21, 79.7% improvement in mean VAS score was noted which was statistically significant (p< 0.001) higher than the FG in which only 49.9% improvement in mean VAS score was noted, however,

ISSN: 2319-9113
DOI: https://doi.org/10.24321/2319.9113.201904

which was statistically significant (p< 0.001). Improvement in VAS score was also noted in the previous studies done to a variable extent with cupping. In a similar study done by Kim *et al.*,[10] comparing cupping with heating pad in 40 patients, demonstrated 51.7% and 25.6% improvement in VAS scores in the cupping and heating pad group respectively, suggesting that cupping was more effective than the use of a heating pad for improving pain in 3 weeks (p=0.025) which is similar to our study result.

A study by Lauche *et. al* demonstrated that patients of the cupping therapy group who received 5 dry cupping therapy sessions had 42.6% improvement in VAS scores and significantly less pain than the patients who did not receive cupping during that period (p=0.01).[11] In another similar study by Chi *et al.* 30.6 % improvement in the pain VAS score was noted just after fire cupping.[12] Lauche *et al*. found that home-based cupping therapy was more effective than progressive muscle relaxation in patients with CNP as evident by 28.7 % improvement in mean VAS scores assessed at 12 weeks of therapy after cupping.[13]

A number of studies have been reported on patients with CNP using NDI a well-validated self-reported questionnaire, a low NDI score signify less self-rated disability and vice versa. At all the time points the reduction was significant between the CG and FG (Table 4). The median value for both the groups was found to be decreasing on day 07, 14 and 21 significantly. The NDI scores obtained in our study when compared to baseline NDI scores showed 70% improvement which is comparable to a similar study in which the heating pad was used as a comparator to the cupping therapy, the mean NDI score also significantly reduced in the cupping group when compared with the heating pad group at 3 weeks of treatment (p=0.0039).[10]

To assess the response within each group, an intragroup analysis was done between CG and FG, we observed that there was a statistically significant reduction in median percentage score of NDI at all time intervals *viz.* day 0 *vs* 07, day 0 *vs* 14 and day 0 *vs* 21 with p=0.001 and 70% and 64.7% reduction of NDI scores in CG and FG respectively (Table 4). Similarly, in a study where a series of five dry cupping treatments were given to a group of patients, there was a reduction of 23.3 % in the NDI score after cupping therapy which appeared to be effective in relieving non-specific CNP.[11] Another study later by Lauche *et. al* demonstrated a decline of 18.7% in NDI score after 12 weeks of treatment by home-based cupping in an RCT at non-clinical setting.[13]

Several studies have shown significant increase in the CROM in flexion and extension in patients with CNP. Liu *et.al* has reported that after the Chinese herbal fomentation, ROM was significantly higher (p<0.05) than that of plain fomentation without medicine.[14] A noteworthy finding in the present investigation is a significant increase in ROM of all neck movements with both the interventions and the effect started on day 07 itself in flexion, extension, and right lateral rotation, however, in the remaining movements the effect was seen from day 14 onwards with statistically significant result (p=0.001), an important observation with which has not been reported previously (Table 3).

We also looked at the psychological impact of pain in our patients. QoL was measured by SF-36 in many trials. Romy Lauche's research team has conducted various meaningful clinical research studies and reviews on the effectiveness of cupping for NP. Lauche *et al.* reported significant differences in the SF-36 subscales for bodily pain (p=0.006) in patients with CNP with dry cupping therapy with 28.6 % in improving bodily pain.[11] However, in another study by Lauche *et al.* which compared cupping massage to progressive muscle relaxation in patients with non-specific CNP, there is no significant difference in any of the subscales of SF-36 reported.[13] Cramer *et al.* also did RCT for CNP with pulsating cupping and reported the significant difference in the quality of life (p=0.002).[15] To investigate the long-term effects of cupping therapy after 2 years in patients with CNP, Leem *et. al* noted that health-related quality of life: SF-36 increased on the subscales bodily pain and 25.6% of the patients reported an increase in pain of at least 30% implying that some patients with NP might experience long-term effects after the cupping therapy, this finding cannot be generalized to all patients. [16]

However, in our study, we noted each subscale of SF-36 (self-reported disability-related questionnaire to NP) in each patient with NP on day 0 and day 21 and all subscales scores of patients were compared and calculated the mean percentage change on day 21. According to the QoL questionnaires (SF-36), there was no statistical difference noted between the CG and FG in all the subscale scores *viz*. on physical functioning, role limitations due to physical health problems, role limitations due to personal or emotional problems, emotional well-being, social functioning, energy/ fatigue and general health except subscale bodily pain scores p=0.0452. SF-36 increased on the subscales bodily pain in both the groups (Table 5). Therefore, there is a definite reduction of pain, mean reduction in scores of subscale Bodily Pain (BP) was statistically superior in CG and FG on day 21.

The exact mechanism of action of cupping is not known, however, various theories have been proposed as vasodilatation, hyperemia, stretching the muscle and connective tissue and thereby decreasing TGF-b1 and collagen synthesis which are known to generate fibrosis and connective tissue stiffness that may further enhance microcirculation, cellular metabolism, and regeneration.[17-19] Cupping therapy is valuable in restoring the balance between Yin-Yang by strengthening the body resistance,

ISSN: 2319-9113
DOI: https://doi.org/10.24321/2319.9113.201904

ejecting the pathogenic factors, and promoting blood circulation to alleviate the pain. Emerich *et al.* measured in parallel, the metabolic changes in the tissue under the cupping glass and pressure pain threshold. It was found that cupping is able to increase the lactate/ pyruvate ratio after 160 minutes, indicating an anaerobic metabolism in the surrounding tissue with abrupt increased pressure pain thresholds in some areas.[20]

Adverse Effects

No major clinical side effects were reported by the subjects or observed by the clinician during the study except aggravation of pain in one patient.

Conclusion

Both the interventions, fire Cupping (*Hijamah nariya*) and dry warm fomentation (*Takmeed yabis*) are effective in reducing pain and increasing CROM in non-specific CNP patients, however, it occurs significantly greater extent with cupping group as compared to fomentation group. Moreover, fire Cupping intervention leads to a significantly earlier reduction of pain in non-specific CNP. The results of this study suggest that pain reduction is comparable to other studies on dry cupping therapy and the study outcome supports the efficacy of fire Cupping (*Hijamah nariya*) as a complementary therapy for treating non-specific CNP.

Acknowledgement

Authors acknowledge Prof. S. Shakir Jamil, Ex-Director General, CCRUM; Dr Anwer Saeed, Secretary JTD; Prof Shaista Parveen, Head of Dept. of Medicine, JTD for providing facilities and their cooperation for conducting the study. Hakim Abdul Hannan, Ex-Joint Director, CCRUM for his constant guidance and support.

Conflict of Interest: None

References

1. Hoy D, March L, Woolf A, Blyth F, Brooks P, Smith E et al. The global burden of neck pain: estimates from the Global Burden of Disease 2010 study. *Ann Rheum Dis* 2014; 73(7): 1309-1315. Available from: https://ard.bmj.com/content/73/7/1309.long [PubMed].
2. Gupta BD, Aggarwal S, Gupta B, Gupta M, Gupta N. Effect of Deep Cervical Flexor Training vs. Conventional Isometric Training on Forward Head Posture, Pain, Neck Disability Index in Dentists Suffering from Chronic Neck Pain. *J Clin Diagn Res* 2013; 7(10) 2261-2264. [PubMed/ Google Scholar].
3. National Center for Health Statistics, Health, United States, 2006, with chartbook on trends in the health of Americans. Available from: http://www.cdc.gov / nchs/data/hus/hus06.pdf. Accessed 17 January 2007.
4. Cao H, Li X, Liu J. An updated review of the efficacy of cupping therapy. *PLoS One* 2012; 7(2): e31793. [PubMed/ Google Scholar].
5. M. Kabeeruddin, Al Qarabadeen. CCRUM publication, New Delhi, 2006.
6. Riddle DL, Stratford PW. Use of generic versus region specific functional status measures on patients with cervical spine disorders. *Phys Ther* 1998; 78(9): 951-996. Available from: https://academic.oup.com/ptj/article/78/9/951/2633333 [PubMed/ Google Scholar].
7. Norkin CC, White DJ. Measurement of joints motion. A guide to Goniometry, 2 ed., FA Davis, Philadelphia, 1995. Available from: https://www.scirp.org/(S(lz5mqp453edsnp55rrgjct55))/reference/ReferencesPapers.aspx?ReferenceID=1163640.
8. Jr Ware JE, Sherbourne CD. The MOS 36 ItemShort Form Health Survey (SF 36). I. Conceptual framework and item selection. *Med Care* 1992; 30(6): 473-483. [PubMed/ Google Scholar].
9. Prasath RA. A comparative study to assess the effectiveness of infra-red radiation and hot water fomentation on pain among patients with osteoarthritis of knee. *J Sci* 2014; 4(1): 1-3. Available from: http://webcache.googleusercontent.com/search?q=cache:f3g9JOm3qRIJ:www.journalofscience.net/doi/MzRrYWxhaTE0Nzg1MjM2OQ%3D%3D+&cd=1&hl=e n&ct=clnk&gl=in.
10. Kim TH, Kang JW, Kim KH, Lee MH, Kim JE, Kim JH et al., Cupping for Treating Neck Pain in Video Display Terminal (VDT) Users: A Randomized Controlled Pilot Trial. *J Occup Health* 2012; 54(6): 416-426. Available from: https://onlinelibrary.wiley.com/doi/abs/10.1539/joh.12-0133-OA [PubMed/ Google Scholar].
11. Lauche R, Cramer H, Choi KE, Rampp T, Saha FJ, Dobos GJ et al. The influence of a series of five dry cupping treatments on pain and mechanical thresholds in patients with chronic non-specific neck pain- A randomized controlled pilot study. *BMC Complement Altern Med* 2011; 11: 63. Available from: https://bmccomplementmedtherapies.biomedcentral.com/articles/10.1186/1472-6882-11-63 [PubMed/ Google Scholar].
12. Chi LM, Lin LM, Chen CL, Wang SF, Lai HL, Peng TC. The effectiveness of cupping therapy on relieving chronic neck and shoulder pain: A randomized controlled trial. *Evidence-based Complementary and Alternative Medicine* 2016; 7358918. Available from: https://www.hindawi.com/journals/ecam/2016/7358918/ [PubMed/ Google Scholar].
13. Lauche R, Materdey S, Cramer H, Haller H, Stange R, Dobos G. Effectiveness of home-based cupping massage compared to progressive muscle relaxation in patients with chronic neck pain-a randomized controlled trial. *PLoS ONE* 2013; 8(6): 1-9. Available from: https://journals.plos.org/plosone/article?id=10.1371/journal.

pone.0065378 [PubMed/ Google Scholar].
14. Liu ZY, Liu BG, Lin X. Kinematic effect of Chinese herbal fomentation on patients with chronic neck pain. *Chin J Integr Med* 2014; 20(12) 917-922. Available from: https://link.springer.com/article/10.1007%2Fs11655-014-2010-4 [PubMed/ Google Scholar].
15. Cramer H, Lauche R, Hohmann C, Choi KE, Rampp T, Musial F et al. Randomized controlled trial of pulsating cupping (pneumatic pulsation therapy) for chronic neck pain. *Komplementmed* 2011; 18(6): 327-334. Available from: https://www.karger.com/Article/Abstract/335294 [PubMed/ Google Scholar].
16. Leem J. Long-term effect of cupping for chronic neck pain. *Integr Med Res* 2014; 3(4): 217-219. [PubMed/ Google Scholar].
17. Xu PC, Cui SL, Derrik ACW et al., Preliminary observation on effect of cupping on the skin surface temperature of patients with back pain. *World J Acupuncture–Moxibustion* 2014; 24(4): 59-61. Available from: https://www.sciencedirect.com/science/article/abs/pii/S1003525715600307 [Google Scholar].
18. Liu W, Piao SA, Meng XW, Wei L. Effects of cupping on blood flow under skin of back in healthy human. *World J Acupuncture − Moxibustion* 2013; 23(3): 50-52. Available from: https://www.sciencedirect.com/science/article/abs/pii/S1003525713600616 [Google Scholar].
19. Kim JI, Lee MS, Lee DH, Boddy K, Ernst E. Cupping for Treating Pain: A Systematic Review. *Evid Based Complement Alternat Med* 2009; 467014. Available from: https://www.hindawi.com/journals/ecam/2011/467014/ [PubMed/ Google Scholar].
20. Emerich M, Braeunig M, Clement HW, Lüdtke R, Huber R. Mode of action of cupping-local metabolism and pain thresholds in neck pain patients and healthy subjects. *Complement Ther Med* 2014; 22(1): 148-158. [PubMed/ Google Scholar].

ISSN: 2319-9113
DOI: https://doi.org/10.24321/2319.9113.201904