

Original Article

Wet-Cupping Is Effective on Persistent Nonspecific Low Back Pain: A Randomized Clinical Trial

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ABSTRACT **Objective:** To compare the possible effects of wet-cupping therapy with conventional therapy on persistent nonspecific low back pain (PNSLBP). **Methods:** In this randomized clinical trial, 180 participants with the mean age of 45 ± 10 years old, who had been suffering from PNSLBP were randomly assigned to wet-cupping and conventional groups. The wet-cupping group was treated with two separate sessions (4 weeks in total) on the inter-scapular and sacrum area. In the conventional group, patients were conservatively treated using rest (6 weeks) and oral medications (3 weeks). The primary and the secondary outcome were the quantity of disability using Oswestry Disability Index (ODI), and pain intensity using Visual Analogue Scale (VAS), respectively. **Results:** There was no significant difference in demographic characteristics (age, gender, and body mass index) between the two groups ($P > 0.05$). Therapeutic effect of wet-cupping therapy was comparable to conventional treatment in the 1st month follow-up visits ($P < 0.05$). The functional outcomes of wet-cupping at the 3rd and 6th month visits were significantly increased compared to the conventional group. Final ODI scores in the wet-cupping and conventional groups were 16.7 ± 5.7 and 22.3 ± 4.5 , respectively ($P < 0.01$). **Conclusion:** wet-cupping may be a proper method to decrease PNSLBP without any conventional treatment. The therapeutic effects of wet-cupping can be longer lasting than conventional therapy. (Registration No. IRCT2013021672741)

KEYWORDS low back pain, chronic, wet-cupping therapy, traditional medicine, Chinese medicine, alternative medicine, conservative treatment

Thirty-eight percent of the general population experiences low back pain (LBP) at least once in a year.⁽¹⁾ Importantly, in 80% of all patients, the symptoms are not attributed to specific etiological or neurologic causes; therefore, it can be labeled persistent nonspecific low back pain (PNSLBP).⁽²⁻⁵⁾ Hence, it is a diagnosis of exclusion, after other diagnoses have been ruled out.^(6,7) PNSLBP is defined as muscle pain and discomfort, localized below the costal margin and above the inferior gluteal folds, without any association with radiculopathy, spinal stenosis, vertebral fractures or tumor.⁽¹⁾ PNSLBP causes significant morbidity and has, in addition to its potentially debilitating physical aspects, a negative financial impact resulting from time lost from work and increased medical expenses up to 65% in the last 10 years.⁽⁸⁾

The management of LBP comprises a range of different intervention strategies including rest, massage, dynamic exercises and non-steroidal anti-inflammatory drugs (NSAIDs) medications, none of which can be viewed as a gold standard treatment.^(9,10) Therefore, most patients after failure of these treatments tend to try "alternative complementary medicine". These

days, pain is the most common reasons for seeking alternative treatment including chiropractic, yoga, acupuncture, and herbal medicine.⁽³⁾

Wet-cupping is a traditional therapy dating back at least 3,300 years in East Asia and Middle East and eventually spread to Europe. Recent studies have shown the therapeutic effect of wet-cupping therapy on musculoskeletal disorders.^(3,9,11) Cupping was widely used in the 19th century by Asian and European physicians. During the past few years, interest in cupping has increased and this could be due to inefficiency of conventional therapy in modern medicine.^(5,12-15) Arslan, et al⁽²⁾ and AlBedah, et al⁽⁶⁾ in their recent pilot studies evaluated the effect of wet-cupping therapy on neck and shoulder pain.^(2,6)

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Although they stated that wet-cupping therapy has potential therapeutic effect in nonspecific neck and upper shoulder pain, they recommended future full-scale randomized controlled trials to provide more evidence. Also, in the recent systematic review in 2015, Cao, et al⁽¹²⁾ concluded that wet-cupping may be beneficial for pain-related conditions. However, a firm conclusion could not be drawn due to the insufficient number of included reviews and the low quality of the original studies.

In this study, we evaluated the effectiveness and safety of short and intermediate-term of wet-cupping therapy on PNSLBP, and compared the possible effects of wet-cupping with conventional therapy on PNSLBP.

METHODS

Inclusion Criteria

In this randomized clinical trial, patients' eligibility with PNSLBP was evaluated to participate in the study. PNSLBP is defined as an intermittent, recurrent, episodic LBP that arising from a muscular spasm that continues for at least 12 weeks without recognizable specific causes such as radicular syndrome, infection or tumor.⁽⁶⁾ Men and women aged 16–65 years old with nonspecific chronic LBP that their recent episode last at least 4 weeks or more were recruited.

All participants provided written informed consent. Therapeutic protocol and randomizing were explained to all patients before participating in the study. Guilan University of Medical Sciences Ethics Committee approved the study and the study was registered in the Iranian Registry of Clinical Trials (No. IRCT201302167274N7).

Exclusion Criteria

Exclusion criteria were: (1) specific LBP caused by pathological entities, such as malignancies; (2) severe or progressive neurodegenerative diseases, or intervertebral disc prolapse during last 3 years; (3) hematologic disorders (anticoagulant use or hemophilia); (4) undergone cupping or alternative therapies during the previous 3 months and any therapies for PNSLBP during the previous 2 weeks; (5) radicular symptoms such as radiating pain due to discopathy or spinal disorders; (6) localized tenderness on spinal processes; and (7) Visual Analogue Scale (VAS) score <4 at the first visit.

Grouping and Intervention

The sample size was calculated based on the primary outcome of study by Farhadi, et al⁽⁷⁾ with 95% confidence level and 90% test power and 5 point for clinical difference. With allowance for a 20% lost to follow up rate, we calculated 90 patients for each arm. Patients were randomly assigned to two groups using random block (Figure 1).

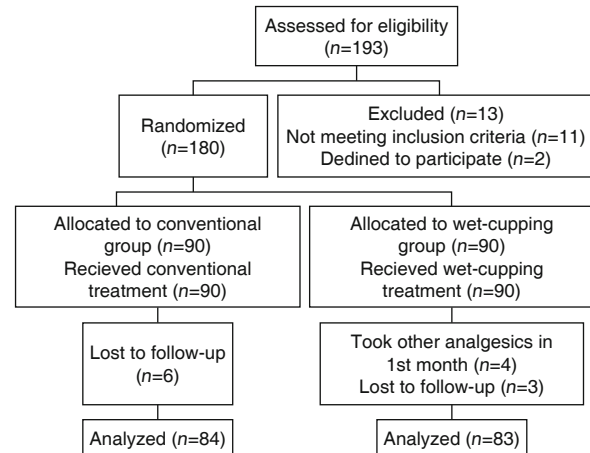


Figure 1. Flow Chart of Study of Wet-Cupping Treatment for PNSLBP Patients

Totally 180 participants (98 females and 82 males) with the mean age of 45 ± 10 years old were randomly assigned to two groups. Mean body mass index (BMI) in all patients was 28.7 ± 4.1 , and mean pain intensity and Oswestry Disability Index (ODI) score in all patients before treatment were 7.3 ± 1.2 and 35.0 ± 4.0 , respectively. There was no significant difference in demographic characteristics (age, gender, and BMI) between the two groups ($P > 0.05$, Table 1).

Table 1. Demographic Characteristics and Baseline Assessment ($\bar{x} \pm s$)

Item	Wet-cupping (90 cases)	Conventional (90 cases)	P-value
Age (Year)	43 ± 11	46 ± 10	0.160
Gender (Male/female, Case)	39/51	43/47	0.549
BMI (kg/m ²)	28.3 ± 3.8	29.1 ± 4.3	0.153
VAS score	7.3 ± 1.2	7.4 ± 1.3	0.495
ODI score	35.3 ± 4.0	35.6 ± 3.1	0.452

A physician with 2-year experience in wet-cupping and traditional medicine performed all wet-cupping treatment. Vacuum cups were applied in two locations, as recommended in traditional Iranian medicine for treatment of nonspecific LBP: (1) on the inter-scapular area around the T2–T4 on day 1; (2) on the sacrum area, between the lower vertebrae and the coccyx

bone, 2 weeks after the first treatment. The size of vacuum cup used was based on expert preference (75 or 120 cm³). Each wet-cupping treatment procedure was repeated 5 times and lasted about 20 min. The total treatment course was 4 weeks. Wet-cupping therapy steps were described previously.⁽⁷⁾ The conventional treatment for LBP was applied for the control group including resting and prohibiting heavy weight lifting (6 weeks), oral NSAIDs and short-acting muscular relaxants administration (3 weeks).

Observation Index

The primary outcomes including pain intensity, patients' disability, and quality of life were measured using the ODI.⁽¹⁶⁾ The ODI, a specific index to quantify disability of LBP consists of 10 questions addressing common daily activities. Each question has 6 answer options, scored from 0 to 5; 0 reflects "no restriction in daily activities," and 5 reflects "the most restrictions in daily activities". The range of total score for each patient will be between 0 to 50. The secondary outcome, pain intensity, was measured using VAS. Both scores were measured on pre-treatment visit and on 1st, 3rd and 6th months post-treatment follow-ups.

Statistical Analysis

Kolmogorov-Smirnov were initially utilized to test the normality of variables and it was revealed that none of the scores had a normal distribution. Data were expressed as median (interquartile range, IQR). Therefore, Mann-Whitney U test and Wilcoxon tests were used to compare the scores in follow-up intervals. The repeated measure ANOVA was utilized to assess the trend of changes in each score, and to adjust the effect of wet-cupping on each score with the control of age and BMI, the ANCOVA test was applied. SPSS software 19 (Chicago, IL, USA) was used to analyze the data and the *P*-values of 0.05 or less were considered to be statistically significant.

RESULTS

In the 1st month follow-up, both groups showed a significant therapeutic effect ($P < 0.0001$). The therapeutic effect of the two groups was comparable ($P > 0.05$). However, in the 3rd and 6th month follow-ups, wet-cupping group had lesser VAS scores than conservative therapy (both $P < 0.000$, Table 2).

The changes in the VAS scores from baseline to the endpoint, evaluated by repeated measure

Table 2. Comparison of VAS Scores between Groups [median (IQR)]

Group	Time	VAS score	VAS score changes upto baseline
Wet-cupping (90 cases)	Baseline	7.0 (6.0–9.0)	—
	1st month	5.0 (2.0–4.0) [△]	4.0 (3.0–6.0)
	3rd month	2.0 (1.0–3.0) ^{*△}	5.0 (4.0–6.0) [*]
	6th month	1.0 (0–1.0) ^{*△}	6.0 (4.0–6.0) [*]
Conventional (90 cases)	Baseline	7.0 (6.0–9.0)	—
	1st month	3.0 (2.0–4.0) [△]	4.0 (3.0–6.0)
	3rd month	2.0 (1.0–3.0) [△]	4.5 (3.5–5.5)
	6th month	2.0 (1.0–3.0) [△]	5.5 (3.5–6.0)

Note: ^{*} $P < 0.01$ vs. conventional group, [△] $P < 0.01$ vs. baseline

ANOVA, showed a significant difference between the two groups. In 1st month follow-up the mean changes in VAS score in the wet-cupping group was similar to conventional group ($P > 0.05$). In 3rd month follow-up the mean changes in VAS scores were higher in wet-cupping ($P < 0.05$). In 6th month follow up, wet-cupping possessed significantly better pain alleviation ($P < 0.05$). The changes in the ODI scores from baseline to the final follow-up was similar to VAS score changes between the two groups ($P < 0.05$, Table 3).

Table 3. Comparison of ODI Scores between Groups [median (IQR)]

Group	Time	ODI score	ODI score changes upto baseline
Wet-cupping (90 cases)	Baseline	35.0 (31.0–39.0)	—
	1st month	25.0 (18.0–26.0)	12.0 (8.0–17.0)
	3rd month	23.0 (19.0–27.0) [*]	13.0 (11.0–15.0) [*]
	6th month	17.0 (11.0–20.0) [*]	18.0 (16.0–22.0) [*]
Conventional (90 cases)	Baseline	35.0 (33.0–39.0)	—
	1st month	25.5 (17.0–28.0)	12.0 (7.0–16.0)
	3rd month	24.0 (21.0–29.0) [*]	11.0 (9.0–13.0) [*]
	6th month	24.0 (17.0–25.0) [*]	12.0 (11.0–16.0) [*]

Note: ^{*} $P < 0.01$ vs. conventional group, [△] $P < 0.01$ vs. baseline

In the 1st month follow-up, pain intensity and ODI in the two groups decreased with a similar gradient. As the time passed, the conventional treatment showed lower therapeutic effect, but the wet-cupping group remained effective. So, at the end of the follow-up period the results of the wet-cupping group outweigh the conventional therapy.

None of the patients in the wet-cupping group experienced side effects including edema, laceration, infection or severe pain on wet-cupping location. Although there were no evidences of any dermal infections or deep scars, 17 patients (18.9%) had mild

to moderate superficial scars with mild ecchymosis that faded away in the final follow-up.

DISCUSSION

The result of this study implies that the immediate response (1st month follow-up) of wet-cupping therapy for patients suffering from PNSLBP was as effective as conventional treatment and the significantly better response in pain intensity reduction was observed at short-term follow-up (3rd and 6th months visits). Patients in the conventional group who had access to oral NSAIDs had effective improvement in the short time, however, during longer follow-up, it was diminished. On the other hand, therapeutic response of wet-cupping continued for 6 months.

In a study conducted by Farhadi, et al⁽⁷⁾ it was reported that the pain due to PNSLBP in patients undergone 3 wet-cupping sessions was significantly improved compared to "usual care" group. Kim, et al⁽⁴⁾ randomly assigned patients suffering from PNSLBP in two groups, wet-cupping therapy, and control. Although patients in the interventional group experienced less pain compared to the control group, it was not statistically significant ($P>0.05$). Even though the number of acetaminophen pills taken by wet-cupping group was less than control, but the ODI score was comparable. The ODI score in our study was similar, but we compared the changes rate between two periods of time, which showed the efficiency of wet-cupping method in decreasing pain intensity and functional recovery. In another study in 2016, 60 patients with nonspecific neck and shoulder pain were treated using wet-cupping therapy. The pain was significantly decreased in patients but this study was nonrandomized and there was no control group to compare the result with conventional therapy.⁽²⁾

In a systematic review by Kim, et al⁽¹⁷⁾ the wet-cupping therapy was considered a safe procedure with rare or minor complications. In 3 clinical trials on 126 patients, there were only 4 cases reported to experienced complications including skin laceration, hematoma, and severe site pain which are a directly caused by materials or techniques. For instance, sharper cups could induce more compressive stress on skin, consequently more severe pain on cupping site.⁽¹⁸⁾ In our study, we used the rolled rim cup to prevent pain due to wet-cupping therapy. In addition, oblique incisions were applied to prevent scar formation after wet-cupping therapy.

Despite the common use of wet-cupping therapy, the mechanism of action is not fully known. Meng XW, et al⁽¹⁹⁾ found that wet-cupping therapy could improve analgesic effects in patients with nerve-root type cervical spondylosis by increasing local blood perfusion of acupunct points. Tagil, et al⁽²⁰⁾ hypothesized that one of the mechanisms of wet-cupping action may be through oxidative balance. They showed that oxidant factors levels were higher in blood drawn by wet-cupping compared to venous blood. Hence, wet-cupping therapy was able to evacuate more oxidant factors and subsequently alleviating the pain, one may suggest other theories including neural, hematological and/or psychological effects.^(2,5)

Critics may be considered that part of this improvement after alternative traditional medicine, even very little, could be related to placebo effect due to the religious belief of the general population. It has been reported that a positive attitude toward traditional medicine resulted in better outcome even with placebo therapy (expectancy theory).⁽²¹⁾ Another important factor that plays a role in efficiency of wet-cupping therapy is psychological interactions between patient and therapist during the treatment. Consulting during treatment can trigger psychosocial, and lifestyle of the patient. Patients with chronic LBP avoid performing daily activities that exacerbate the pain, this results in isolation from social interaction, depression, and anxiety, and therefore, exacerbates the chronic pain. Overall, the psychosocial effect of traditional medicine should not be neglected; one may say that this effect should be viewed as a positive and valuable medical intervention.

The study had several methodological strengths. The patients were assigned randomly. Also, we were able to compare the cumulative effect of both groups using the score changes between follow-up visits. Additionally this study was performed by a therapist with at least 2-year experience in traditional medicine and evaluating the patients by an orthopedic surgeon to avoid the therapist bias. However, the research had limitations. Control patients did not receive a placebo intervention. Future research might consider having a waiting list or sham therapy to be able to compare the placebo effect.⁽²²⁾

Many of the therapeutic methods were tested via trial and error and had been wiped out from medicine after showing no specific efficacy over time. Wet-cupping

therapy has been able to surpass this challenging trials and still playing a role as an adjuvant therapy in modern medicine. More clinical trials with high quality, less methodological flaws and clear data are necessary to evaluate the actual therapeutic effect of this method.

In conclusion, wet-cupping therapy may be a proper method to decrease PNSLBP without any complications, and can be remained more effective than conventional treatments.

Conflict of Interest

All named authors hereby declare that they have no conflicts of interest to disclose.

Author Contributions

Mardani-Kivi M is responsible for study planning and designing, writing and revising the manuscript; Montazar R and Azizkhani M conducted the study design, data collecting, and manuscript writing; Hashemi-Motlagh K collected and analyzed the data, wrote and revised the manuscript.

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