

The Use of Wet Cupping for Persistent Nonspecific Low Back Pain: Randomized Controlled Clinical Trial

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Abstract

Objectives: To evaluate the effectiveness and safety of wet cupping therapy as a single treatment for persistent nonspecific low back pain (PNSLBP).

Design: Randomized controlled trial comparing wet cupping versus no treatment in PNSLBP.

Setting: Outpatient clinic in three secondary care hospitals in Saudi Arabia.

Patients: Eighty eligible participants with PNSLBP for at least 3 months were randomly allocated to an intervention group ($n=40$) or to a control group ($n=40$).

Interventions: Six wet cupping sessions within 2 weeks, each of which were done at two bladder meridian (BL) acupuncture points among BL23, BL24, and BL25. Only acetaminophen was allowed as a rescue treatment in both groups.

Outcome measures: The Numeric Rating Scale (NRS), McGill Present Pain Intensity (PPI), and Oswestry Disability Questionnaire (ODQ) were used as outcome measures. Numbers of acetaminophen tablets taken were compared at 4 weeks from baseline. Adverse events were recorded.

Results: At the end of the intervention, statistically significant differences in the three outcome measures favoring the wet cupping group compared with the control group were seen: NRS score, 29.2 (95% confidence interval [CI], 24.6–33.8) versus 57.9 (95% CI, 53.3–62.6), respectively; PPI score, 1.17 (95% CI, 0.96–1.4) versus 2.3 (95% CI, 2.1–2.7); and ODQ score, 19.6 (95% CI, 16.5–22.7) versus 35.4 (95% CI, 32.3–38.5) ($p=0.0001$). This improvement continued for another 2 weeks after the end of the intervention. Acetaminophen was used less in the wet cupping group, but this difference was not statistically significant. No adverse events were reported.

Conclusions: Wet cupping is potentially effective in reducing pain and improving disability associated with PNSLBP at least for 2 weeks after the end of the wet cupping period. Placebo-controlled trials are needed.

Introduction

LOW BACK PAIN IS A VERY COMMON health problem and a leading cause of activity limitation and work absence worldwide. A global review of the prevalence of low back pain in the adult general population has shown its 1-year prevalence to be 38%, with a lifetime prevalence of ap-

proximately 40%.¹ In 80% of cases, the condition has no identifiable cause and can be labeled as nonspecific low back pain; accordingly, it is a diagnosis of exclusion.²

Persistent nonspecific low back pain (PNSLBP) is a common, chronic, recurrent, and disabling condition that can be resistant to treatment. As with most chronic illnesses, patients tend to seek alternative therapies to relieve pain and discomfort

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even if those therapies have no sufficient scientific evidence.³ Patients usually look to traditional therapies for help in relieving their pain and discomfort. Wet cupping is very common in the Middle East and is also practiced in Asia and Europe. In Saudi Arabia, it is the third most common traditional practice after spiritual healings and herbal medicine.⁴

Growing evidence suggests that wet cupping can be effective in certain conditions, especially musculoskeletal pain and migraine.⁵⁻⁸ The aim of this study was to evaluate the effectiveness and safety of wet cupping in the treatment of PNSLBP.

Methods

This randomized, controlled, open-label, parallel trial evaluated the effectiveness and safety of wet cupping in PNSLBP. The protocol was modified from the protocol used by Kim et al.⁹ in their published pilot clinical trial.

PNSLBP was defined as low back pain persisting for at least 12 weeks without recognizable specific causes, such as known abnormality (such as infection, tumor, osteoporosis, fracture, structural deformity, inflammatory disorder [e.g., ankylosing spondylitis], radicular syndrome, or cauda equina syndrome).¹⁰

The trial was conducted in three hospitals in three different cities in Saudi Arabia: King Fahad Hospital in Madinah, King Fahad Hospital in Jeddah, and King Salman Hospital in Riyadh City. Field work was conducted from April to September 2014. At each site the team consisted of an orthopedic consultant, a trained cupping provider, and a medical assistant.

Men and women age 18 to 60 years who met the definition were recruited. The orthopedic consultant obtained a detailed history and performed a medical examination, including radiography and magnetic resonance imaging, ensure that the low back pain was nonspecific. Patients were excluded if they were not suitable for wet cupping because of such medical conditions as hematologic diseases, anticoagulant use, or any other chronic illnesses; had received cupping therapy in the last 3 months; or had received any therapy for NSLBP in the preceding 2 weeks.

Sample size was calculated on the basis of the assumptions that the minimum clinical improvement is 15 points (standard deviation, 20) on the 100-point Numerical Rating Scale (NRS).¹¹ This resulted in 30 patients in each group. With allowance for a 30% dropout rate, 45 patients were planned to be recruited in each group.

Participants were randomly assigned to the intervention group or control group using a block randomization method wherein randomization numbers were generated through <https://www.sealedenvelope.com>. Sealed opaque envelopes with serial numbers were used to conceal allocation. Before allocation, a 7-point Likert scale question was used to evaluate the patients' expectation regarding prognosis of using wet cupping therapy for their condition.

The study protocol was approved by the Ethical committee in the Saudi Ministry of health (approval number MOH044) and is registered at <http://ClinicalTrials.gov> (identifier: NCT02012205). All participants provided written informed consent, and a contract research organization monitored research quality.

Intervention

Participants allocated to the intervention groups received three sessions of wet cupping therapy per week for 2 weeks.

In each session, two out of six treatment points were selected from the bilateral bladder meridian (BL): BL23, BL24 and BL25. Details on the intervention procedure have been published before.⁹

A maximum of three 500-mg acetaminophen tablets per day were allowed for both groups. All other medications, alternative therapies, and physical therapy were prohibited for 4 weeks. No advice for stretching or strengthening exercises was given.

Outcome measures

Pain and functionality were measured at baseline, 2 weeks (after the intervention period), and 4 weeks (2 weeks after the end of cupping session). The primary outcome was the difference in NRS score for pain from baseline to the end of the 2-week treatment period (primary end point). Secondary outcome measures were the change in McGill Present Pain Intensity questionnaire (PPI)¹² and change in score on the Oswestry Disability Questionnaire (ODQ).¹³ The number of acetaminophen tablets used during the 4 weeks of the study was also assessed. Validated Arabic versions of all outcome measures were used.¹⁴⁻¹⁶

The NRS is used to assess pain in general in the past week on a scale ranging from 0 to 100, where 0 represented "no pain" and 100 represented "extreme pain."¹⁷ Fifteen points was used as the minimum clinically important difference (MCID).¹¹

The ODQ consists of 10 questions addressing common daily activities. Each question has six answer options, scored from 0 to 5; 0 reflects "no restriction in daily activities," and 5 reflects "the most restrictions in daily activities." The total score was calculated as [(total score/total possible score) multiplied by 100]. Ten points was used as the MCID for ODQ score.¹¹ Adverse events were assessed throughout the study and during each visit. Severity of adverse events was classified according to the criteria of the World Health Organization.¹⁸

Statistical analysis

Because the intention-to-treat concept was adopted, the last-observation-carried-forward method was used for the amendment of missing data. Statistical analysis of the outcome variables was conducted with a Wilcoxon rank-sum test or the analysis of covariance. The baseline values for NRS, ODQ, and PPI variables were used as a covariate. Baseline NRS score was also used as a covariate for acetaminophen tablets used at the end of the study. *p*-values less than 0.05 were considered to represent statistically significant differences. Data entry and statistical analysis were conducted using SPSS software, version 20 (IBM, Armonk, NY).

Results

Of the 123 participants screened for the eligibility, 80 were eligible for the study. Eligible participants were randomly allocated to the two groups, 40 in the intervention group and 40 in the control group. Three from the intervention group and two from the control group were lost to follow up. These participants travelled outside the city for emergency reasons and could not continue the study (Fig. 1). Baseline characteristics were similar in both groups (Table 1).

The NRS scores for pain after 2 weeks (the primary end point after intervention) showed a statistically significant

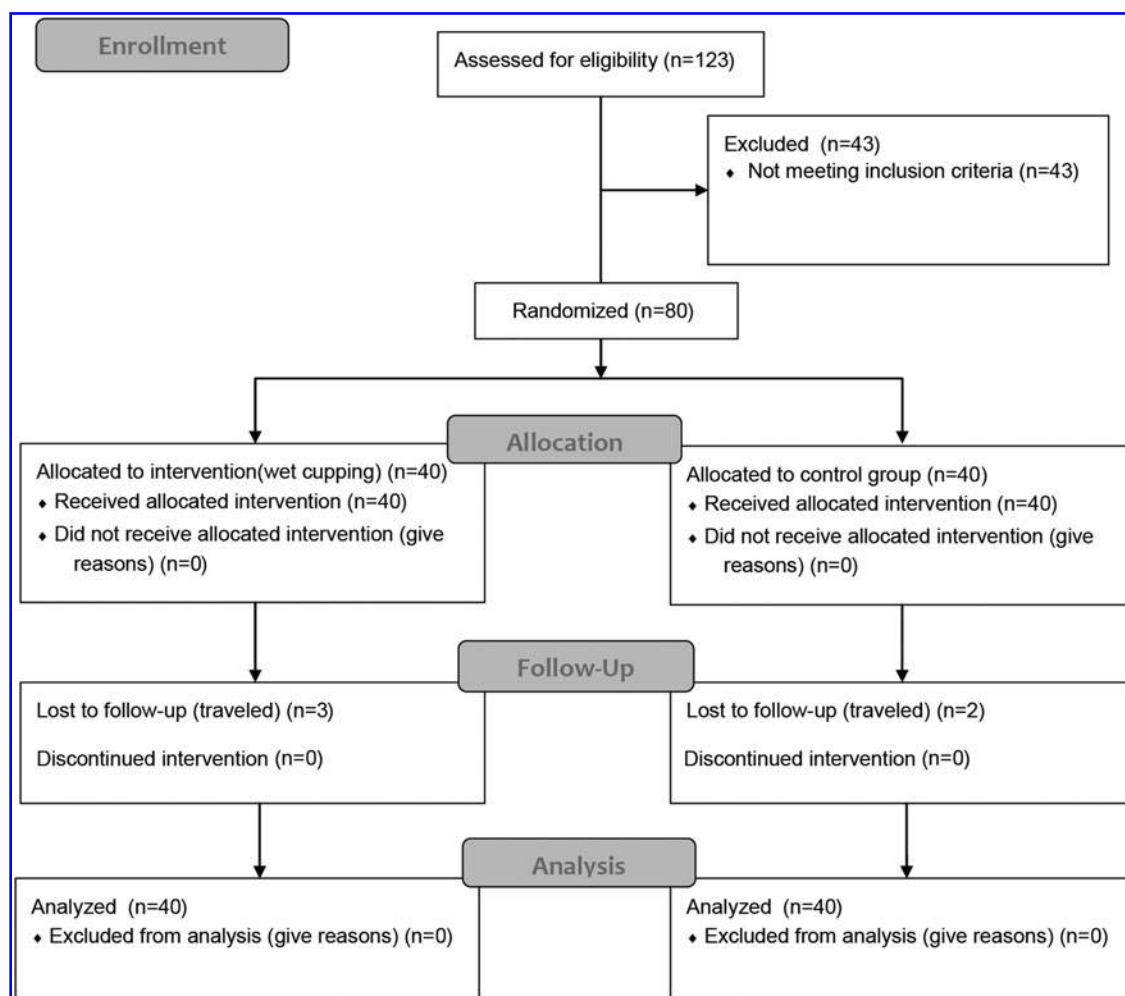


FIG. 1. CONSORT (Consolidated Standards of Reporting Trials) flow diagram.

decrease in the wet cupping group compared with the control group. This significant difference was also maintained at 4 weeks (2 weeks after completion of the intervention) (Table 2). Figure 2 shows the follow-up of the NRS score during the study in both groups. In addition, 31 of 40

(77.5%) patients in the wet cupping group showed an MCID (–15) after 2 weeks compared with only 1 of 40 patients in the control group ($p=0.0001$).

The total ODQ score (percentages) showed a statistically significant decrease in the wet cupping group compared with the control group at 2 and 4 weeks (Table 2). In the wet cupping group, 24 of 40 patients showed an MCID of –10 after 2 weeks compared with only 1 of 40 in the control group ($p=0.0001$).

The PPI showed the same pattern, with a statistically significant decrease in the wet cupping group compared with the control group (Table 2).

Within the wet cupping group, the NRS, ODQ, and PPI showed a statistically significant decrease at the primary end point (day 14) compared with the baseline data (day 0). Two weeks after the end of wet cupping (secondary end point at day 28), NRS and ODQ scores were significantly lower compared with the primary end point at the end of the intervention (day 14). This was not the case for PPI, the decrease for which was not statistically significant ($p=0.065$).

Although the mean number of acetaminophen tablets taken during the 4 weeks of the study was higher in the control group, no significant difference was found.

No adverse events were reported in this study.

TABLE 1. SAMPLE CHARACTERISTICS AND BASELINE DATA IN INTERVENTION (WET CUPPING) AND CONTROL GROUPS

Characteristic	Wet cupping group (n=40)	Control group (n=40)	p-Value
Age (y)	36.48 ± 9.3	36.43 ± 9.4	
Men/women (n/n)	22/18	17/23	0.37
Expectation of prognosis on Likert scale	4.88 ± 0.9	4.87 ± 1.1	0.98
Age at onset (y)	31.88 ± 9.2	32.48 ± 9.4	0.77
Duration of illness (y)	4.45 ± 4.8	3.85 ± 3.9	0.54
NRS score	60.50 ± 19.7	56.25 ± 17.5	0.31
ODQ score	38.33 ± 19.2	32.05 ± 15.9	0.11
PPI score	2.35 ± 1.2	2.13 ± 0.96	0.35

Unless otherwise noted, values are the mean ± standard deviation. NRS, Numeric Rating Scale; ODQ, Oswestry Disability Questionnaire; PPI, Present Pain Intensity.

TABLE 2. COMPARISON OF OUTCOME MEASURES BETWEEN WET CUPPING AND CONTROL GROUPS

Outcome measure	Wet-cupping group (n=40)	Control group (n=40)	p-Value
NRS score			
2 wk	29.2 (24.6,33.8)	57.9 (53.3,62.6)	0.0001
4 wk	24.4 (19.7–29.1)	56.3 (51.6–60.9)	0.0001
ODQ score			
2 wk	19.6 (16.5–22.7)	35.4 (32.3–38.5)	0.0001
4 wk	15.2 (11.6–18.8)	35.9 (32.3–39.5)	0.0001
PPI score			
2 wk	1.17 (0.96–1.4)	2.3 (2.1–2.7)	0.0001
4 wk	0.98 (0.7–1.2)	2.3 (2.1–2.6)	0.0001
No. of acetaminophen tablets (4 wk)	6.5 (0.4–12.4)	13.3 (7.5–19.1)	0.1

CI, confidence interval.

Discussion

The dropout rate in our study was lower than expected: <7% compared to the expected 30% drop out. This result may support the feasibility of providing 6 sessions within 2 weeks.

Unlike an earlier Korean study,⁹ the current study showed statistically significant differences in favor of the wet cupping group compared with the control group across the three outcome measures: NRS, ODS, and PPI. This can be explained not only by the larger sample size in our study but also by the fact that in the Korean study both groups were given eight types of stretching and strengthening exercise. Accordingly, the improvement in the wait-listed group in the Korean study could be attributed to the exercise, even without receiving the wet cupping intervention, and this decreased the differences between the intervention and wait-listed groups.

The wet cupping technique used in the current protocol differs from the techniques usually used in the Middle East. The standard technique involves cupping–puncture–cupping, whereas the study protocol entailed puncture–cupping. In addition, scarification with a sharp surgical blade is generally used, as opposed to the puncture with auto-lancet ap-

plied here. Cupping sites were also different and included additional sites away from the lower back region.¹⁹

The mechanism of action of wet cupping is still not clear, and many theories have been proposed. Wet cupping may act as a nociceptive stimuli, which would trigger diffuse noxious inhibitory control,²⁰ or by the removal of oxidants, which would decrease oxidative stress.²¹ Nitrous oxide release, as shown in acupuncture, may be also a theoretical mechanism of action.²² The short- and long-term effects of wet cupping may be explained by a combination of mechanisms, including the affective component of chronic pain.²³

Legacy outcome measures such as the ODQ are widely used, but a consensus on outcome measures for NSLBP and for pain are needed. An international steering committee consisting of researchers, clinicians, and patient representatives was formed to develop a core set of outcomes for clinical trials on NSLBP. This can help avoid the heterogeneous reporting of outcomes in clinical trials and facilitate comparison of results and performance of meta-analyses.²⁴

The current study was not a placebo-controlled trial and thus could not neutralize the placebo effect. However, the study was multicenter and involved five consultants, five cupping providers, and clinical research associates to monitor the quality of the study; this can minimize the effect of placebo but cannot neutralize it. Strong belief, especially religious drive, toward wet cupping can exaggerate the placebo effect, although the procedure is still a physical contact intervention. Researchers have observed that people who expect acupuncture to work report improvement in their symptoms even when they receive sham treatment.²⁵

Sham cupping device was recently developed but still must be evaluated further.²⁶ More objective pain outcome measures, such as pain mediators, are needed.

The added value of this study was far more than the clinical trial itself. For the first time, three cupping clinics were opened in three secondary-care government hospitals, where a model of integrated medicine involving multidisciplinary health care workers was established. A patient satisfaction survey was conducted regarding the patients' condition and the use of cupping in the hospitals. In addition, a workshop including medical insurance companies was conducted to discuss how to extend medical insurance to cover integrated complementary therapies. A secondary objective of this study was to build capacities in the field of complementary medicine research within the modern health care system in the Saudi Ministry of Health.

The result of this study supports the use of wet cupping in reducing pain and improving disability associated with PNSLBP, at least for 2 weeks after the end of wet cupping. Further follow-up studies are important to determine how frequent wet cupping must be to sustain a longer period of improvement. In the absence of placebo, the actual effect size of wet cupping cannot be determined. Placebo-controlled clinical trials are needed.

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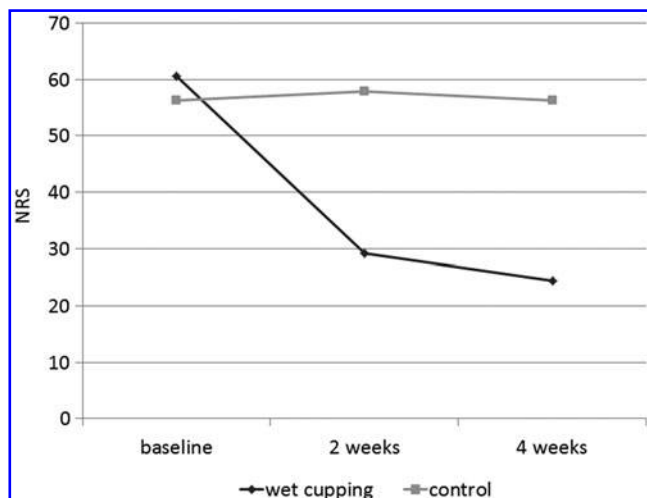


FIG. 2. Scores on Numeric Rating Scale (NRS).

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Author Disclosure Statement

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