



The effectiveness of wet-cupping for nonspecific low back pain in Iran: A randomized controlled trial

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Available online 24 June 2008

KEYWORDS

Low back pain;
Wet-cupping;
Hijama;
Iran

Summary

Objectives: To determine the efficacy of wet-cupping for treating persistent nonspecific low back pain.

Background: Wet-cupping therapy is one of the oldest known medical techniques. It is still used in several contemporary societies. Very minimal empirical study has been conducted on its efficacy.

Design: Randomized controlled trial with two parallel groups. Patients in the experimental group were offered the option of referral to the wet-cupping service; all accepted that option. The control group received usual care.

Setting: Medical clinic in Kermanshah, Iran.

Participants: In total, 98 patients aged 17–68 years with nonspecific low back pain; 48 were randomly assigned to experimental group and 50 to the control group.

Intervention: Patients in the experimental group were prescribed a series of three staged wet-cupping treatments, placed at 3 days intervals (i.e., 0, 3, and 6 days). Patients in the control group received usual care from their general practitioner.

Main outcome measures: Three outcomes assessed at baseline and again 3 months following intervention: the McGill Present Pain Index, Oswestry Pain Disability Index, and the Medication Quantification Scale.

Results: Wet-cupping care was associated with clinically significant improvement at 3-month follow-up. The experimental group who received wet-cupping care had significantly lower levels of pain intensity ([95% confidence interval (CI) 1.72–2.60] mean difference = 2.17, $p < 0.01$), pain-related disability (95% CI = 11.18–18.82, mean difference = 14.99, $p < 0.01$), and medication use (95% CI = 3.60–9.50, mean difference = 6.55, $p < 0.01$) than the control group. The differences in all three measures were maintained after controlling for age, gender, and duration of lower back pain in regression models ($p < 0.01$).

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Conclusions: Traditional wet-cupping care delivered in a primary care setting was safe and acceptable to patients with nonspecific low back pain. Wet-cupping care was significantly more effective in reducing bodily pain than usual care at 3-month follow-up.
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Introduction

Low back pain (LBP) is among the most debilitating, most expensive, and most common complaints patients raise during routine physical examinations worldwide.^{1,2} It is widespread in many countries, and is associated with substantial financial costs and loss of quality of life. For example, the World Health Organization reports that LBP affects over 80% of people at some point in their life, and from 4 to 33% of a population at any one time.³ Data from specific nations support these data. In Canada, Finland and the United States, more people are disabled from working as a result of back pain than from any other group of diseases.⁴ Over 60% of Americans, 40% of the adult population in Britain, and 62% of adults in African countries, are reported to experience low back pain at some point in their lives, and between 10 and 30% of populations in these nations suffer from chronic low back pain at any point of time.^{1,2,5,6}

In Iran, where the present study was conducted, the limited data available suggest the prevalence of LBP in Iranians who work in industry and in Iranian school-age children were 21 and 17.4%, respectively.^{7,8}

Western medicine typically treats low back pain with a combination of physical therapy; activity modification and rest; pain-relieving and anti-inflammatory medications; and, in extreme cases, surgery. These treatment options demonstrate mixed efficacy and success. In many cases, an acceptable amount of pain is relieved through typical Western medical treatment techniques. However, in other cases some pain remains; in some cases, typical Western treatments are completely ineffective.⁹

Wet-cupping is an ancient medical technique, with documented use dating to several ancient cultures^{10–13} and contemporary practice in many parts of the European and Eastern world, including Iran. Application of the wet-cupping technique itself is rather straightforward. A glass cup is applied to the skin, and a partial vacuum created inside the cup. After a few minutes, superficial incisions are made to the skin, and bloodletting induced through replacement of the cup with vacuum. This process is repeated a few times.

Despite use in Iranian (and other) cultures both historically and today, the effectiveness of wet-cupping to treat nonspecific low back pain is unknown. We implemented a randomized controlled trial comparing two treatments design to test the efficacy of wet-cupping to treat continuous referrals for nonspecific low back pain in an outpatient care clinic in Iran. Three outcome measures were used: pain intensity, medications used, and pain-related disabilities in function. We hypothesized the group randomly assigned to wet-cupping treatment would have less pain, would use fewer medications, and would report fewer pain-related dis-

abilities following treatment compared to a ‘‘usual care’’ control group.

Methods

Sample size, study design and participants

Nonspecific low back pain has been characterized as an ‘‘intermittent, recurrent, episodic problem’’ and includes four type of pain: local, referred, radicular, and that arising from secondary (protective) muscular spasm.^{14,15} The study used a two-group randomized controlled trial design to treat nonspecific low back pain. Patients in the experimental group received wet-cupping treatment. Patients in the control group received usual care, which consisted of a combination of medication and physician-recommended exercises. The protocol for both treatment groups is detailed below.

A priori power calculations, allowing for a 10–15% dropout rate, indicated that 16 patients were needed in each group to detect a difference in outcome between the groups at 90% power, a 5% significance level, and an expected effect size of $d=0.61$ based on pilot research indicating a mean change of 2.71 points at 3 months (S.D. 4.451) on the Medication Quantification Scale.¹⁶ This sample size was also estimated to give a power of 90% to detect a difference of 0.68 points on the PPI scale of McGill Pain Questionnaire.¹⁷ A difference of 1 point is generally considered to be clinically significant on this scale.

We subsequently tripled the target number of recruited patients to allow for between-wet-cupping effects to be tested. We wanted to review the wet-cupping effect according to ‘‘duration of LBP’’ and in patient who have ‘‘the history of surgery for LBP’’.

Fig. 1 illustrates patient enrollment patterns. Identified patients included a total of 106 consecutively referred patients diagnosed with nonspecific low back pain. Inclusion criteria included: (a) lower back pain persisting for 4 weeks or more; (b) age 17–68 years; and (c) current episode of low back pain having at least a 4-week duration. Exclusion criteria included possible spinal pathology (e.g., carcinoma), severe or progressive motor weakness or central disc prolapse, pending litigation (e.g., workplace injury), bleeding disorders (e.g., hemophilia), and current treatment with wet-cupping. Five patients were excluded due to one or more of those criteria. Three other patients were excluded because the back pain resolved before treatment began. Ninety-eight patients were therefore included in the trial. Patients were randomized to two groups in a double-blind manner by the sealed opaque envelope technique. Forty-eight were assigned to the wet-cupping treatment condition, and fifty to the usual-care treatment (Fig. 1). All

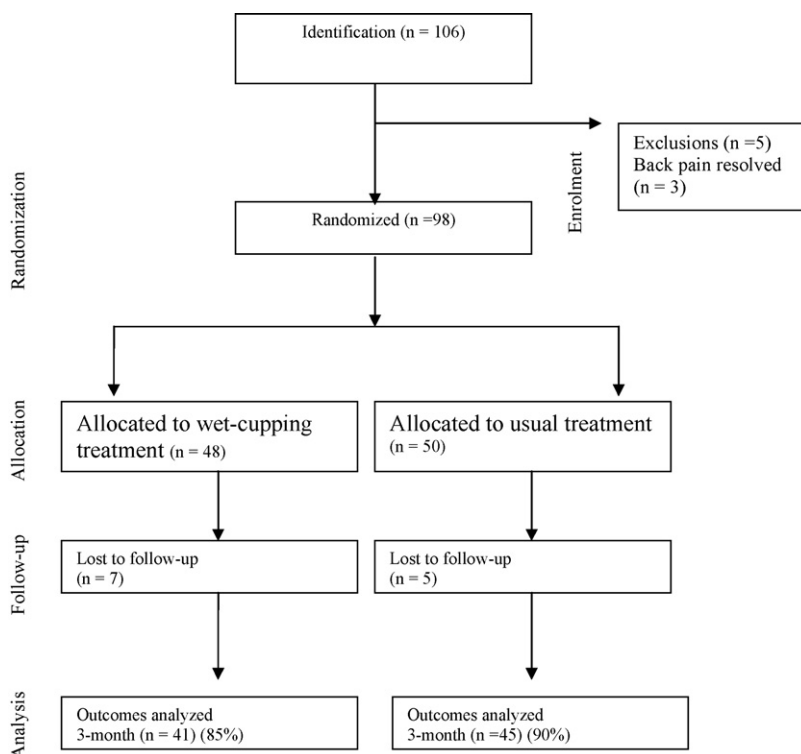


Figure 1 Patients progress through the trial: CONSORT flowchart.

protocols were approved by the Kermanshah University of Medical Sciences (KUMS) Local Research Ethics Committee.

The wet-cupping technique

For ethical reasons, patients randomly assigned to the wet-cupping treatment were offered the opportunity to refuse consent to the research and accept usual treatment instead. No patients accepted this option; all chose to receive the wet-cupping treatment as assigned randomly. The treatment itself was performed using standard techniques in Iranian medical centers.^{18–20} Vacuum cups with plastic vessels were applied in three stages, as recommended in traditional Iranian medicine for treatment of nonspecific low back pain: (a) between the two scapulas, opposite to T1–T3 Scapular spine, in Phase 1 (day = 0); (b) the sacrum area, between the lumbar vertebrae and the coccyx bone, in Phase 2 (day = 3); and (c) the calf area, in the middle surface of gastrocnemius muscle, in Phase 3 (day = 6) (Fig. 2).^{18–20} The size of vacuum cup used was based on the size of the patients' body (75 or 120 cm³). We used primarily 120 cm³, and occasionally 75 cm³ for the thinnest patients.

During the third stage, the calf area was treated based on the lower back pain experienced. If the back pain was on only one side, the calf on that side of the body was treated. If the back pain was double-sided, we treated both calf areas.

Each wet-cupping treatment procedure lasted about 20 min and was conducted in five steps:

(1) *Primary sucking*: The cup is placed on the selected site and the air inside the cup rarified via electrical suction (or, rarely due to technical reasons, manual suction).

The cup clings to the skin and is left for a period of 3–5 min.

- (2) *Scarification*: Superficial incisions are made on the skin using the "multiple superficial incisions" technique with sterile surgical blades size 15–21 for incision. In the "multiple superficial incisions" technique, we applied multiple superficial incisions. As a result, after healing of the wound, the scar lesion does not remain.
- (3) *Bloodletting*: The cup is placed back on the skin, using the same manner described above, until it is filled

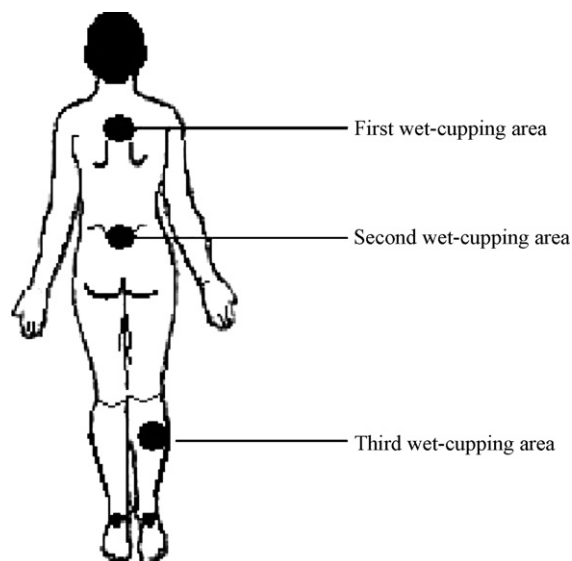


Figure 2 Anatomical areas of wet-cupping for low back pain.

Table 1 Demographic profiles at baseline by allocation group means (standard deviations)

| Characteristic | Intervention group (n = 48) | Control group (n = 50) |
|--|--------------------------------|---------------------------|
| Age (years) | 44.9 (14.8) | 41.8 (13.9) |
| Gender | 64% male | 74% male |
| Duration of lower back pain (months) | 52.7 (71.7) | 55 (49.7) |
| Previous back surgery | 8.3% yes | 10% yes |

with blood from the capillary vessels. The volume of blood varied across patients (e.g., it tended to be lower in obese patients). Our experience is that treatment effects are unrelated to the volume of blood. In fact, the duration is more important than the blood volume released. Each phase of wet-cupping was divided based on a time period of 3–5 min and re-scarification was not conducted.

- (4) *Removal*: The cup is removed, and the process repeated three times.
- (5) *Dressing*.

The “usual care” treatment

The “usual care” control group received the standard treatment for low back pain in Iranian clinics. This treatment included: (1) encouragement for early return to usual activities, excluding heavy manual labor, (2) activity alteration to minimize symptoms, (3) acetaminophen, or NSAIDs, (4) short duration muscular relaxants or opioids (optional, based on patient preference), (5) bed rest—not more than 2 days (optional, based on patient preference), and (6), spinal manipulation exercises.¹⁵

Measures

Basic demographic information was collected at baseline. Three measures were used to assess pain, disability, and functioning at both baseline and 3 months post-intervention:

the Medication Quantification Scale Version III (MQS),¹⁶ the Present Pain Intensity Scale (PPI) of the McGill Pain Questionnaire,¹⁷ and the Oswestry Pain Disability Index (ODI).^{21,22}

The PPI is a standard and well-used index of current pain. Patients rate their current pain on a 6-point scale from “no pain” to “excruciating”. The ODI is a measure designed specifically to assess lower back pain. It includes 10 items that target various physical activities (e.g., lifting, walking, sleeping) that are frequently painful for individuals with lower back pain. Each item is scored on a 6-point scale, yielding a possible range of 0–60. The MQS is a quasi-quantitative measure of the strength, dosage, and quantity of pain medications used by patients. It has strong psychometric properties.¹⁶

Analysis plan

Following descriptive analyses, the primary analyses were conducted in two steps. First, we computed basic independent samples *t*-tests comparing the intervention and control groups on all three outcome measures (pain intensity, pain-related disability, and medication). Second, we computed three linear regressions, predicting the three outcome measures based on group as well as age, sex, duration of lower back pain, and previous back surgery.

As in most intervention research, there was a small amount of missing data in this research due to patient loss to follow-up. This study achieved a high follow-up rate at 3 months (85 and 90% in the wet-cupping and usual care groups, respectively). A comprehensive analysis of the known characteristics of patients indicated that there was no evidence of any difference between the randomly assigned groups in those lost to follow-up. Consistent with intention-to-treat principles, missing data from participants who did not complete the trial were imputed using “the mean of nearby points” techniques.

Results

Table 1 illustrates baseline descriptive data for the intervention and control subsamples. As shown, the control and intervention groups were quite similar in age, sex, duration

Table 2 Means (standard deviations), Mean difference, 95% confidence interval (CI) and *p*-value for intervention and control groups and comparing both groups (two-tailed tests)

| Measure | Control group | Intervention group | Mean difference | 95% CI | | <i>p</i> -Value |
|-----------------------|---------------|--------------------|-----------------|--------|-------|-----------------|
| | | | | Lower | Upper | |
| PPI baseline | 2.7 (0.9) | 2.7 (0.8) | 0.0 | −0.4 | 0.3 | 0.9 |
| PPI post-intervention | 2.8 (1.3) | 0.7 (0.9) | 2.2 | 1.7 | 2.6 | <0.01 |
| ODI baseline | 30.9 (9.8) | 31.4 (6.6) | −0.5 | −3.9 | 2.9 | 0.8 |
| ODI post-intervention | 30.6 (11.6) | 15.6 (6.7) | 15.0 | 11.2 | 18.8 | <0.01 |
| MQS baseline | 9.0 (9.4) | 9.1 (4.8) | 0.9 | −2.1 | 3.9 | 0.6 |
| MQS post-intervention | 9.7 (9.6) | 3.2 (3.8) | 6.6 | 3.6 | 9.5 | <0.01 |

Note: PPI = Present Pain Intensity Scale of the McGill Pain Questionnaire. ODI = Oswestry Pain Disability Index. MQS = Medication Quantification Scale.

Table 3 Linear regression models predicting outcome change scores based on demographic, pain history, and group assignment

| Predictor | PPI | | | ODI | | | MQS | | |
|--|-------|----------------|----------|--------|------------------|----------|-------|----------------|----------|
| | B | 95% CI | p-Values | B | 95% CI | p-Values | B | 95% CI | p-Values |
| Age | 0.01 | -0.01 to 0.02 | 0.47 | 0.03 | -0.07 to 0.13 | 0.55 | 0.00 | -0.05 to 0.05 | 0.97 |
| Sex (1 = male, 2 = female) | -0.04 | -0.55 to 0.47 | 0.88 | 0.40 | -2.72 to 3.52 | 0.80 | 0.33 | -1.22 to 1.88 | 0.68 |
| Duration of low back pain (per month) | 0.01 | 0.01 to 0.10 | <0.01 | 0.04 | 0.01 to 0.06 | <0.01 | -0.02 | 0.01 to 0.30 | 0.02 |
| Previous spinal surgery (1 = y, 2 = n) | 0.43 | -0.37 to 1.23 | 0.29 | 6.39 | 1.19 to 11.30 | 0.01 | 1.25 | -1.20 to 3.70 | 0.31 |
| Group (1 = control, 2 = intervention) | -2.18 | -2.63 to -1.73 | <0.01 | -15.35 | -18.11 to -12.61 | <0.01 | -5.57 | -6.94 to -4.20 | <0.01 |

Note: PPI = Present Pain Intensity Scale of the McGill Pain Questionnaire. ODI = Oswestry Pain Disability Index. MQS = Medication Quantification Scale. B = Unstandardized coefficients. For PPI: $F(5, 92) = 22.6, p < 0.01$; for ODI: $F(5, 92) = 30.8, p < 0.01$; for MQS: $F(5, 92) = 16.0, p < 0.01$.

of pain, and previous surgeries. They also scored similarly on all three baseline measures (see Table 2). Independent samples *t*-tests comparing these differences were all non-significant.

As shown in Table 2, the control and intervention groups were vastly different ($p < 0.01$) in their scores of pain intensity, pain-related disability, and medication use 3 months following the treatment. That is, the intervention group reported strong declines in pain intensity, pain-related disability, and medication use during the post-intervention assessment. The control group showed essentially no change in pain intensity and pain-related disability, and only modest change in medication use.

Table 3 illustrates the results of linear regression models predicting change in all three outcome measures from baseline to follow-up. Note that change in scores (the difference between post-intervention and baseline) serves as the dependent variable in these models; this score was preferred over use of post-intervention scores because it allows us to compensate for baseline levels of functioning. As shown, group assignment was a significant and strong predictor in all three models. Those individuals in the wet-cupping intervention group reported less pain intensity, less pain-related disability, and less medication use than those in the usual care group. Duration of pain also emerged as a predictor of the three outcomes in the linear regression models, with better outcomes in individuals with a shorter duration of pain. Finally, previous spinal surgery was a significant predictor of pain-related disability, with those patients who had a history of surgery reporting more pain-related disability.

Discussion

Although wet-cupping has been used traditionally to treat lower back pain in Iranian and other cultures for centuries,^{19,20} this study represents one of the first controlled empirical tests of its efficacy. Results suggest that patients in both the experimental and control groups reported improvement, but the patients in the experimental group, who received wet-cupping treatment, scored significantly lower on measures of pain, disability, and medication use than the patients who received only usual care. We conclude that wet-cupping shows great promise as an effective treatment for nonspecific low back pain. These results are congruent with those reported in an unpublished dissertation testing the efficacy of wet-cupping on treating lower back pain²³ and in published work testing the efficacy of wet-cupping to reduce risk factors of heart disease,²⁴ Brachialgia paraesthetica nocturna,²⁵ and migraine and tension headaches.¹⁸

The physiological mechanisms through which wet-cupping might function remain unknown. It has been suggested that the effects of wet-cupping can be divided into several components, including neural, hematological, immune and psychological effects¹⁸⁻²⁶. In particular, the "pain suppression" mechanism of wet-cupping might be through influence on three neurological systems: (a) the "analgesia" system in the brain and spinal cord (including the periaqueductal gray and periventricular areas, the Raphae magmus nucleus, and the Nucleus reticularis

paragigantocellularis); (b) the brain's opiate system (endorphins and enkephalins), and (c) most influential, through inhibition of pain transmission by simultaneous tactile sensory signals.²⁷ Moreover, diffuse noxious inhibitory controls (DNICs) might contribute partially to the pain-relieving effect witnessed.²⁸

An alternative hypothesis, also plausible, is that wet-cupping may function in a manner similar to acupuncture: it may stimulate particular parts of the body that include the release of neurotransmitters, endogenous opioid-like substances, and activation of c-fos within the central nervous system.²⁹ Future research is needed on these topics.

Patients in our study experienced very minimal adverse effects from the wet-cupping treatment. The most significant side effect from wet-cupping therapy is fainting during the wet-cupping (vaso-vagal shock). This was seen only in younger patients (7% ($n = 3$) of patients, all in the age 17–30 group), all of whom had no previous history of bloodletting or wet-cupping. To treat vaso-vagal shock, we asked patients to sit or lie in bed for 5–10 min. A second concern about wet-cupping side effects is transmission of contagious infections such as B and C HPV or HIV. Historically, this concern arose from the fact that in ancient Persian traditional medicine, a ram's horn was used for wet-cupping and was shared by many patients, causing high potential for transmission of infectious disease. In contemporary society, of course, we use sterile methods (sterile surgical blade and disposable cup) and have no indication of infection in our patients. Therefore, besides the three patients who experienced vaso-vagal shock, we have no evidence of adverse effects during the research.

Strengths, limitations, and future directions

This research had several methodological strengths. The sample was recruited directly from a primary care clinic.³⁰ Follow-up rates were excellent, with 85% and 90% of patients in the experimental and control groups, respectively, providing data 3 months post-intervention. Despite these strengths, the research also had limitations. One prominent limitation was our choice of treatment for the control group. Usual care commonly entailed a mixture medication and recommended back exercises. Control patients did not receive a sham wet-cupping intervention. We considered alternative options for the control group, but each had limitations. Use of dry-cupping or acupuncture, for example, offers many advantages but might have evoked the same response as wet-cupping. Given the strength of our current findings, future research might consider using dry-cupping, acupuncture, or other complementary medicine techniques in an RCT compared to wet-cupping treatment.

Critics might also be concerned about the possibility of a placebo effect arising from wet-cupping treatment. We emphasize that a placebo effect may not be a negative factor; if the cupping treatment is effective due partially to nonspecific placebo effects, this should be viewed as a positive medical intervention. Cultural issues, including the long tradition of using cupping in Iranian society, might enhance placebo effects. Despite these facts, we believe the placebo effect is not likely to be the primary mechanism behind the efficacy of wet-cupping, largely because the control group

received an equivalent amount of attention and medical care.

Relatedly, critics might be concerned that the wet-cupping treatment was efficacious not because of the physiological action of suction and scarification, but rather because of the psychological interactions between patient and therapist during the treatment. We believe this unlikely given the strength of our findings, but future research should evaluate this issue.

A final limitation of the study is the fact that patients in the trial were aware of their group assignment, which was difficult to hide given the experimental design. This awareness may have created biased assessments of patients' LBP scores. Most important, the difference between groups is far larger (odds ratio for response = 42.78, $p < 0.001$, CI 95% 11.85–154.46) than empirical estimates of bias from failure to blind (odds ratio 1.2).³¹ Lack of bias is also implied by similar results in research using wet-cupping to treat other illnesses and medical conditions.^{18,24,25}

Finally, our study was limited somewhat by the short follow-up period. We were able to demonstrate the positive effects of wet-cupping for 3 months, but long-term efficacy remains to be tested.

Conclusion

Results from the present study suggest that wet-cupping is associated with greater short term clinical benefit than usual care. No adverse effects were reported from subjects after the treatment.

Acknowledgments

The authors would like to thank the patients who participated in this study. Financial support for this project was provided by the Kermanshah University of Medical Sciences (KUMS).

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