Effects of Pulsatile Cupping on Body Pain and Quality of Life in People with Suboptimal Health: A Randomized Controlled Exploratory Trial

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ABSTRACT

Objective: The curative effect of pneumatic pulsatile cupping on pain has been shown. This study was conducted to investigate effects of the pulsating frequency of pneumatic pulsatile cupping, compared with traditional cupping (TC), on body pain and quality of life (QoL) in people with suboptimal health status (SHS).

Materials and Methods: Ninety-six participants with SHS were randomized to low-frequency (LF; $n=24$) or high-frequency (HF; $n=24$) pulsating cupping, traditional cupping (TC; $n=24$), or wait-list (WL; $n=24$) groups. The LF, HF, and TC groups received 4 sessions of cupping over 2 weeks. Visual analogue scale (VAS; 0–100 mm) pain level and Short-Form-36 (SF-36) QoL measurements were taken before and after the intervention.

Results: Both LF and HF reduced pain significantly (VAS: -28.26 ; 95% confidence interval [CI] -36.18 to -20.34 ; and -31.88 , 95% CI -39.81 to -23.96 ; both $P=0.000$) and improved QoL more than WL (SF-36, Bodily Pain dimension: 1.46 , 95% CI: 0.85 to 2.07 ; and 1.75 , 95% CI: 1.14 to 2.36 , both $P=0.000$). Compared to TC, LF and HF significantly reduced pain (VAS: -7.92 , 95% CI: -15.75 to -0.08 , $P^{LT}=0.048$; and -11.54 , 95% CI: -19.38 to -3.70 , $P^{HT}=0.004$) and improved QoL (SF-36, Bodily Pain dimension: 0.61 , 95% CI: 0.01 to 1.21 , $P^{LT}=0.046$; and 0.90 , 95% CI: 0.30 to 1.50 , $P^{HT}=0.004$). There was no significant difference between LF and HF.

Conclusions: This study showed that, in patients with SHS, pulsatile cupping therapy could have a more-favorable effect to relieve body pain, compared to TC. LF and HF pulsation produced equivalent pain relief. Further studies investigating the underlying mechanism are needed.

Trial registration: This trial was registered in the Chinese Clinical Trial Registry (ChiCTR-INR-16009345).

Keywords: pulsatile cupping therapy, pulsating frequency, traditional cupping, pain-predominant suboptimal health

INTRODUCTION

WITH ECONOMIC DEVELOPMENT and the increasing pace of life, there is a growing concern about the importance of health in modern society. Suboptimal health status (SHS) is defined as a state characterized by disturbances in psychologic behaviors or physical characteristics, or, in some

indices of medical examination, with no typical pathologic features,^{1–3} and refers to a status between healthy and diseased manifested in reduced vitality, function, and adaptive capacity lasting for at least 3 months.^{4,5} The main symptoms of SHS include nonspecific pain (such as back pain and chest pain, etc.), fatigue, sleeping disorders, forgetfulness, mild anxiety and depression, and functional disorders of different

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organ systems (digestive, cardiovascular, respiratory, urinary).^{1,2,6} According to an investigation by the World Health Organisation, people with suboptimal health today include ~60%–70% of the total population,⁷ and SHS is also becoming a global issue.⁸ SHS can be divided into various types according to the predominant symptoms.

Pain in individuals with suboptimal health is characterized by obvious body pain and is the most frequently reported type of SHS.^{9–11} Pain-related SHS leads to impaired quality of life (QoL), frequent hospital visits, and incurrence of significant medical expenses.^{1,2} Therefore, it has become increasingly important to seek scientifically validated therapies that can be used effectively and simply to treat SHS symptoms, particularly body pain.

Complementary and alternative therapies are the most common methods used to treat painful syndromes, and the more intense the pain is, the more it leads to higher potentials for using such methods. Frequently used treatments include acupuncture, massage, etc.^{12–15} Cupping therapy is an ancient medical technique^{16,17} and is broadly used in China because of its noninvasive simple operation and rapid effects.¹⁸ In clinical practice, cupping is mainly used to relieve muscle tension and fatigue and to increase a patient's general feeling of well-being.¹⁹ There is initial scientific evidence that cupping therapy can reduce musculoskeletal pain, such as neck pain^{20–22} and low-back pain.^{23,24} A 2017 study showed that cupping therapy had a significant effect on penetration enhancement of transdermal drug delivery, and cupping's potential mechanisms were closely associated with changes in the stratum corneum and biologic regulation of the skin.²⁵

The current authors' research group developed a pulsatile cupping device. With this device, stimulation with an adjustable vacuum and adjustable vibration frequencies can be performed on acupoints or channels according to the different conditions involved in patients' diseases. This mechanical device utilizes a micro-vacuum pump to produce a pulsating vacuum instead of the stable vacuum created by traditional cupping (TC). Pneumatic pulsatile therapy combines the effects of cupping and massage, and the curative effect of this modernized technology has been confirmed for pain. A study reported that a pulsatile cupping device relieved symptoms of patients with osteoarthritis (OA) of the knee and might be used as an analgesic treatment in health-care services.²⁶ Another group of researchers studied the effect of pulsatile therapy on a treatment group, compared to a wait-list group, in patients with chronic neck pain. Good effects of pulsatile cupping on pain and QoL after 5 sessions were observed in this trial.²⁷ However, these previous studies did not investigate the effects of a pulsatile cupping device, compared to TC. Meanwhile, the relationship between the pulsatile frequency and its therapeutic effect is unclear.

Therefore, the aim of this study was to observe the effects of different vibration-frequency effects, compared to TC, on body pain and QoL in people with SHS. The effects of

different pulsating frequencies on body pain were also observed to provide evidence for optimizing the parameters of the device for treating body pain in patients with SHS.

MATERIALS AND METHODS

Design

This was a 4-group, randomized controlled exploratory clinical trial. After telephone interviews, potential participants were invited to be assessed for study eligibility. The potential participants were also informed about the study details. Eligible participants were randomized to a low-frequency (LF) pulsating cupping group or a high-frequency (HF) pulsating cupping group, a traditional cupping control group (TC), or a wait-list (WL) control group, according to computer-generated random numbers (generated with SPSS Statistics Client 22.0). The Medical Ethics Committee of Beijing University of Chinese Medicine, Beijing, China, approved the study protocol (Beijing, China, approval no. 2015BZHYLL0152). All study participants gave their informed consent in writing before randomization. The file authorized by the Medical Ethics Committee also provided the study authors with the legal right to publish the participants' data. In addition, the consents signed by the participants also gave the study authors the right to publish data for each of the participants no matter where and when this publication would occur.

At baseline assessment, participants filled out questionnaires relating to age, height, weight, and sex, and body pain measurements were taken. Measurements with a 0–100-mm visual analogue scale (VAS) and with a QoL instrument (Short Form–36 [SF-36]) were performed before and after the intervention. (Fig. 1).

Sample Size

In a pilot study ($n=8$) by the current authors' on SHS-related pain, the mean and standard deviation (SD) in each group, using a VAS, were determined (LF, mean $\pm$ SD: 32.5 $\pm$ 17.67; HF, mean $\pm$ SD: 26.5 $\pm$ 9.19; TC, mean $\pm$ SD: 35.0 $\pm$ 21.21; WL, mean $\pm$ SD, 45.0 $\pm$ 7.07). By the sample-size determination with an error of 5%, an effect power of 90% was established, using the following formula²⁸:

$$n = \psi^2 \left(\sum_{i=1}^k s_i^2 / k \right) / \left[\sum_{i=1}^k \left(\bar{X}_i^2 - \bar{X} \right)^2 / (k-1) \right]$$

To allow for 20% possible dropouts, the sample size in each group was determined to be 24.

Participants

Participants were recruited by means of recruiting posters and were initially screened via a standardized telephone

FIG. 1. Study design. VAS, visual analogue scale; SF-36, Short Form-36.

interview between October 2016 and August 2017. Potential participants were told to visit the study physician with their routine physical examination reports for the first appointment. According to the Clinical Guideline of Chinese Medicine on Sub-health,^{4,29} the diagnostic criteria of pain-predominant SHS include: (1) the chief complaint was persistent or recurrent body pain lasting more than 3 months; and (2) routine physical examination shows no major organic diseases, or physiologic or mental diseases.^{3,30}

Eligible participants met the following inclusion criteria: (1) fulfillment of the diagnostic criteria as above; (2) age 18–65; (3) having pain that mostly occurs in the neck, shoulder, back, limbs, and joints without contraindications for cupping (such as skin scars at local pain areas, infected skin diseases, or coagulopathy, etc.); and (4) subjective pain intensity at baseline ≥ 40 mm on a 100-mm VAS.

Participants were excluded if they fulfilled one or more of the following criteria: (1) body pain due to rheumatism, OA, scapulohumeral periarthritis, cervical spondylosis, thoracic or lumbar spondylopathy; (2) history of mental illness or family history of psychiatric disorders; and/or (3) use of manual therapy, massage, or acupuncture in previous 1 month or other complementary therapies for body aches during the study period.

Interventions

Cupping was performed by the study physicians, who were trained in cupping and performed cupping regularly in a clinical setting. Participants in 3 different treatment groups received 4 cupping sessions over a period of 2 weeks, having 1 session every 3–4 days.

FIG. 2. Pulsating cupping devices. (A) One tube connects with a *Bian*-stone cup. In the bottom of the *Bian*-stone cup, a micro-camera is set and connected wirelessly to a computer to monitor color changes in the cup. (B) One tube connects with an acrylic cup to show the vibrations at various frequencies. (C) Schematic diagram of the device shows complex stimulation (vacuum and vibration) performed on the local tissues of the skin. min, minutes.

The LF and HF participants were given cupping, using the mechanical pulsating cupping device. This device integrated the advantages of a local vacuum and vibrations of various frequencies (Fig. 2A–C; patent application No. 201310532658.2, Beijing University of Chinese Medicine). There are two tubes in the device. Each individual tube is connected to a *Bian*-stone cup (Fig. 2A) or an acrylic glass cup (Fig. 2B) of different sizes.³¹ With this mechanical device, pulsating electromechanical suction (maximum: 100 mbar) is applied to acrylic glass cups or *Bian*-stone cups that can be placed on the areas of the skin to be treated. *Bian*-stone is a unique material made from *Sibin* stone in China and is commonly used for skin scraping and cupping in acupuncture clinics. *Bian*-stone therapy was believed to promote energy metabolism in channels.³² For this study, *Bian*-stone cups with a diameter of 7 cm were used for the LF and HF groups due to this cup's better effect on the body's channels. The vacuum pressure was gradually adjusted to the highest intensity each participant could tolerate. The LF and HF features of the device were designed to make it possible to observe the effects of different pulsating frequencies on the pain in patients with SHS.

The pulsating frequency of the LF was alternated 30 times/minute, while the pulsating frequency of the HF was 80 times/minute. Each participant was asked to lie down in a prone position with pain regions bared, enabling examination of the most obvious tender points. Then 2 *Bian*-stone cups were placed on the determined local tender points. The cups were removed after 10 minutes.

TC with a fire-flicking method was used for the TC group. The diameter of the glass cups (6.5 cm, Beijing Jianlekang Medical Instrument Co., Ltd, China) was approximately equal to the diameter of *Bian*-stone cups used in the pulsating cupping groups. The cupping procedure was as follows: (1) an alcohol swab was ignited; (2) the burning swab was placed quickly inside the cup and withdrawn; (3) two cups were placed over 2 tender points; and (4) the cups were removed after 10 minutes (Fig. 3).

Participants in the WL received no cupping intervention for the duration of the study (2 weeks). These participants were told to lie down for 10 minutes in a quiet and comfortable environment, twice per week. Participants in the WL were offered an opportunity to receive the same cup-

ping treatment as the treatment groups after the trial was concluded.

Outcome Measures

Pain. Participants were asked to rate the intensity of their body soreness on a VAS graded from 0 mm ("no pain at all") to 100 mm ("worst pain imaginable").³³ The scale was as follows: 0 points = no pain at rest and activity; 10–30 points = no pain at rest, mild pain during daily activities; 40–60 points = slight pain at rest, pain could be aggravated after daily activities; and 70–100 points = severe pain at rest or during daily activities. Baseline and postintervention pain scores were recorded on a case report form.

Health-related QoL. Health-related QoL was assessed using the SF-36-health survey questionnaire.³⁴ The Chinese version of SF-36 was translated by the Department of Social Medicine, at Zhejiang University Medical School.^{35,36} This version of the 36-item reliable instrument was used to assess 8 dimensions of general health: (1) Physical Functioning; (2) Physical Role Functioning; (3) Bodily Pain; (4) General Health Perceptions; (5) Vitality; (6) Social Role Functioning; (7) Emotional Role Functioning; and (8) Mental Health). This instrument also had 2 sum scores (Physical Component and Mental Component). Scores ranged from 0 to 100, with higher ratings indicating better QoL.

Safety. Any adverse events were monitored throughout the study by the physicians and the participants. The questionnaires relating to adverse events included burns, blisters, or infections caused by relevant experiences.

Statistical Analysis

The data were analyzed with the Statistical Package for Social Sciences software (version 22.0, IBM, License number: 20150408-LSBJ). The data were analyzed with a one-way analysis of variance test or a Kruskal–Wallis test.

A paired-samples *t*-test was used to comparing the VAS and SF-36 scores before and after the intervention. A least significant difference (LSD) test was used to compare the intensity of pain (VAS) and QoL (SF-36) among the groups.

FIG. 3. Applications of the pulsating cupping device (A) and traditional cupping (B) with the fire-flicking method (B) at tender points.

All outcome measures were analyzed based on the intention-to-treat population. Missing data were replaced by carrying the last observation forward. The data were presented as mean $\pm$ standard deviation (SD). Adjusted means with 95% confidence intervals (CIs) are also presented. A P -value of <0.05 was considered to be statistically significant for all statistical tests.

RESULTS

CONsolidated Standards Of Reporting Trials Flowchart

Participants were recruited between October and August 2016. After the first telephone screening, 163 participants were invited for further evaluation; 96 of them fulfilled the study criteria and agreed to participate in the study. Of these 96 participants, 24 were randomized to the LF group, 24 to the HF group, 24 to the TC group, and 24 to the WL group. One participant in the WL was excluded because the patient underwent massage and acupuncture treatment during the study period. Figure 4 shows a flowchart of participants' recruitment.

Sample Characteristics

All baseline values were comparable among the 4 groups; see Table 1. One half of the participants in the study were

female. The average ages were: 28.58 (LF group); 27.45 (HF group); 26.88 (TC group); and 27.13 (WL group). Pain intensity on the VAS in each group was generally high with mean values of ~ 50 mm in the 4 groups. No significant differences between groups at baseline were found in demographic characteristics, intensity of pain, etc.

Pre- and postintervention scores are presented in Tables 2 and 3 and are described in detail below.

Pain

Analysis of pain intensity showed a significant difference postintervention in the 3 treatment groups. The LF group had 31.25 mm less pain on the VAS after 4 treatment sessions ($P=0.000$). The HF group had 33.00 mm less pain on the VAS after treatment ($P=0.000$). There was also a significant difference in the TC group (19.17 mm less pain, $P=0.000$). Pain intensity was not reduced in the WL group ($P=0.862$). See Table 2.

Between-group comparisons of postintervention VAS scores showed that all 3 treatment groups (LF, HF, and TC) had significantly reduced VAS scores, compared to the WL control group, respectively (-28.26 , 95% CI: -36.18 to -20.13 , $P^{LW}=0.000$; -31.88 , 95% CI: -39.81 to -23.96 , $P^{HW}=0.000$; and -20.34 , 95% CI: -28.26 to -12.42 , $P^{TW}=0.000$). Compared to the TC group, the LF and HF groups had significant pain reductions, respectively (-7.92 , 95% CI: -15.75 to -0.08 , $P^{LT}=0.048$; and -11.54 , 95% CI: -19.38 to -3.70 , $P^{HT}=0.004$). See Table 3.

FIG. 4. CONsolidated Standards Of Reporting Trials flowchart of recruitment and study conditions. Pulsating groups: LF, low-frequency; HF, high-frequency. Other groups: TC, traditional cupping; WL, wait-list. VAS, visual analogue scale; min, minutes.

TABLE 1. BASELINE DEMOGRAPHIC AND VAS CHARACTERISTICS (MEANS $\pm$ SD)

Characteristics	LF (n=24)	HF (n=24)	TC (n=24)	WL (n=23)	P
Age (years)	28.58 $\pm$ 6.55	28.58 $\pm$ 5.48	26.88 $\pm$ 4.46	27.13 $\pm$ 5.99	0.942
BMI (kg/m ²)	22.04 $\pm$ 2.56	21.82 $\pm$ 2.98	21.69 $\pm$ 2.50	21.28 $\pm$ 2.74	0.807
History (years)	1.34 $\pm$ 0.93	1.42 $\pm$ 0.90	1.26 $\pm$ 1.01	1.01 $\pm$ 0.94	0.280
Sex (F/M)	9/15	13/11	10/14	9/14	0.659
VAS	55.21 $\pm$ 14.10	53.33 $\pm$ 11.10	51.04 $\pm$ 10.00	51.96 $\pm$ 11.46	0.814

Participants were asked to rate their average pain intensity on a 100-mm VAS to measure their body pain.

Groups: LF, low-frequency pulsating cupping group; HF, high-frequency pulsating cupping group; TC, traditional cupping group; WL, wait-list group. VAS, visual analogue scale; SD, standard deviation; BMI, body mass index; F, female; M, male.

QoL

Analysis of pain intensity showed a significant difference postintervention in the LF and HF groups. The LF group had an improvement of 3.77 in the Physical Component score after 4 treatment sessions (-3.47 ; 95% CI: -5.41 to -1.54 ; $P=0.001$). The HF group had an improvement of 2.55 in the Physical Component score after treatment (-2.55 ; 95% CI: -4.55 to -0.56 ; $P=0.014$). There were no significant differences within the TC or WL groups. Meanwhile, Mental Component scores did not improve in all groups. See Figure 5.

A significant difference in SF-36 scores was only observed in the Bodily Pain dimension of the SF-36 ($F=12.809$; $P=0.000$) among the 4 groups. See Table 4. No significant differences were found in the Physical Component score, Mental Component score, and the subscale dimensions of the SF-36, including Role-Physical, General Health Perceptions, Vitality, Social Function, Role-Emotional, and Mental Health (all $P>0.05$).

To observe the effects of different intervention methods on Bodily Pain, an LSD test between any 2 groups was conducted. After cupping, all 3 treatment groups (LF, HF, and TC) had a higher QoL than the WL group, respectively (SF-36, Bodily Pain: 1.46, 95% CI: 0.85–2.07, $P^{LW}=0.000$; 1.75, 95% CI: 1.14–2.36, $P^{HW}=0.000$; and 0.85, 95% CI: 0.24–1.45, $P^{TW}=0.007$). Moreover, the LF and HF pulsating cupping groups had more relief of their Bodily Pain, compared to the TC group (0.61, 95% CI: 0.01–1.21, $P^{LT}=0.046$; and 0.90, 95% CI: 0.30–1.50, $P^{HT}=0.004$). There were no significant differences in Bodily Pain values between the LF and HF groups ($P>0.05$) See Table 5.

Safety

No adverse events were reported during the study. To ensure safety, the bottom of the *Bian*-stone cup had a micro-camera connected to a computer (Fig. 3). Thus, the skin color at the local cupping areas were monitored well in real time to avoid causing blisters.

DISCUSSION

Principal Findings

To the best of the current authors' knowledge, this is the first exploratory trial to observe the effects of different pulsating frequencies on pain and QoL, compared with TC, in people with SHS.

Upon completion of the trial, participants who received either pulsating cupping or TC therapy showed significant decreases on the VAS. According to the QoL scale, the pulsating cupping therapy also significantly relieved Bodily Pain.

In addition, the results of this trial were that pulsating cupping showed better analgesic effects compared to TC.

Interpretation

In recent years, SHS has aroused widespread interest. Traditional Chinese Medicine (TCM) interventions—including cupping, acupuncture, and massage—have been given increasing attention, particularly in China, for treatment of body pain.³⁷ Many studies showed that noninvasive acupoint-stimulation therapies, especially cupping, had

TABLE 2. WITHIN-GROUP COMPARISONS OF VAS SCORES BEFORE AND AFTER THE TREATMENT (MEANS $\pm$ SD)

VAS	LF (n=24)	HF (n=24)	TC (n=24)	WL (n=23)
VAS (before)	55.21 $\pm$ 14.10	53.33 $\pm$ 11.10	51.04 $\pm$ 9.10	51.96 $\pm$ 11.46
VAS (after)	23.96 $\pm$ 15.88	20.33 $\pm$ 10.72	31.88 $\pm$ 16.86	52.22 $\pm$ 9.58
95% CI	31.25 (24.17; 38.33)	33.00 (26.96; 39.04)	19.17 (13.04; 25.29)	−0.26 (−3.34; 2.82)
P^a	0.000	0.000	0.000	0.862

^a P -values indicate the VAS scores that were detected and compared before and after treatment within each group.

Groups: LF, low-frequency pulsating cupping group; HF, high-frequency pulsating cupping group; TC, traditional cupping group; WL, wait-list group. VAS, visual analogue scale; SD, standard deviation; CI, confidence interval.

TABLE 3. BETWEEN-GROUP COMPARISONS OF VAS SCORES (MEANS $\pm$ SD)

Groups	Group difference (95% CI)	P^a
LF vs. HF	3.63 (−4.12; 11.46)	$P^{LH}=0.361$
LF vs. TC	−7.92 (−15.75; −0.08)	$P^{LT}=0.048$
LF vs. WL	−28.26 (−36.18; −20.34)	$P^{LW}=0.000$
HF vs. TC	−11.54 (−19.38; −3.70)	$P^{HT}=0.004$
HF vs. WL	−31.88 (−39.81; −23.96)	$P^{HW}=0.000$
TC vs. WL	−20.34 (−28.26; −12.42)	$P^{TW}=0.000$

^a P -values are from between-group comparisons of any 2 groups using least significant difference test.

Groups: LF, low-frequency pulsating cupping group; HF, high-frequency pulsating cupping group; TC, traditional cupping group; WL, wait-list group.

VAS, visual analogue scale; SD, standard deviation; CI, confidence interval.

confirmed effects on body pain, were inexpensive, and produced few side-effects.^{16–24} The device used in the current study was designed to combine the effects of cupping and massage through applying a pulsating vacuum to tender points; therefore, its positive effects on body pain in people with SHS were shown.

Only a few trials have evaluated the effectiveness of pulsatile cupping for addressing various diseases so far. The results of those studies showed that pulsatile cupping could be of valuable clinical use and could help patients who have various kinds of pain.^{26,27} However, those previous studies did not compare pulsatile cupping with other complementary and alternative therapies, such as TC and massage. The optimal frequency also had not been assessed in those trials.

Pulsating cupping was considerably more effective for relieving pain than TC in the current study. QoL also largely improved after treatment. The pulsatile cupping device in this study integrated the effects of cupping and massage. The device performed complex stimulation on the local tissues of the skin, subcutaneous tissues, and even as deeply as the muscles. Participants in the current study mainly suffered from neck pain and low-back pain. People who have

nonspecific pain have been shown in some studies to have impaired blood flow and inflammation of local neural tissues caused by ischemia due to muscle spasm.^{38,39} Mechanically, cupping therapy might help reduce deoxyhemoglobin and obtain more oxyhemoglobin, which enhances local oxygen uptake, and promotes blood microcirculation⁴⁰ and hemodynamic activity.^{41–43} In addition, cupping influences musculoskeletal pain by altering signal processing at the level of the nociceptor, spinal cord, and brain.^{43,44} Physiologically, cupping activates the immune system and stimulates mechanosensitive fibers; thus, the result is a reduction of pain.^{45–47}

Moreover, lifting and kneading muscle tissue by means of a pulsating vacuum might simulate massage.^{26,27} Massage can reduce pain sensations through psychophysiologic mechanisms.⁴⁸ Massage can expand local capillaries, accelerate blood circulation, and increase the amount of oxygen in tissues.¹¹ The device used in this study might have induced similar effects and increased muscle circulation. However, the physiologic effects of low-amplitude oscillation sucking of skin and underlying tissues have not yet been investigated systematically.

Proponents of TCM believe that the main pathologic mechanism of pain involves “channel obstruction due to Stagnation of Qi and Blood” and “poor nourishment due to Deficiency of Qi and Blood.” Therefore, any method of dredging the channels, and moving Qi and invigorating Blood, can help eliminate pain. According to the classical theory of channels, pulsating cupping might be an effective method for relieving pain by unblocking the channels.

In the current study, commonly used acupoints were selected for treating the pain of patients with SHS; these points were mainly concentrated in the region along the Governor Vessel, Bladder Channel, and local tender points. It might be that cupping at local tender points had a better effect for dredging channels, moving Qi, and invigorating Blood, which then alleviated the local physical pain effectively.

With the development of *Bian*-stone therapies, *Bian*-stone therapy's obvious therapeutic and analgesic effect on

FIG. 5. Within-group comparisons of the Short Form-36 (SF-36) Physical Component Score (A) and Mental Component Score (B) before and after the treatment (means $\pm$ standard deviations). Pulsating groups: LF, low-frequency; HF, high-frequency. Other groups: TC, traditional cupping; WL, wait-list. * $P < 0.05$, ** $P < 0.01$ (within-group comparisons).

TABLE 4. COMPARISONS OF POSTINTERVENTION SCORES OF SF-36 IN 4 GROUPS (MEANS $\pm$ SD)

SF-36	LF (n=24)		HF (n=24)		TC (n=24)		WL (n=23)		ANOVA	
	Before	After	Before	After	Before	After	Before	After	F	P
Physical Function	27.75 $\pm$ 2.51	29.00 $\pm$ 1.38	28.04 $\pm$ 2.27	28.75 $\pm$ 1.67	28.04 $\pm$ 2.05	28.38 $\pm$ 1.44	28.00 $\pm$ 2.30	28.52 $\pm$ 2.06	0.650	0.585
Role-Physical	6.83 $\pm$ 1.31	7.04 $\pm$ 0.95	7.08 $\pm$ 1.06	7.08 $\pm$ 1.28	6.25 $\pm$ 1.42	6.29 $\pm$ 1.46	6.57 $\pm$ 1.16	6.39 $\pm$ 1.47	2.446	0.069
Bodily Pain	7.88 $\pm$ 1.00	9.53 $\pm$ 0.88	8.26 $\pm$ 1.08	9.82 $\pm$ 0.79	8.24 $\pm$ 1.19	8.91 $\pm$ 1.30	8.40 $\pm$ 1.37	8.07 $\pm$ 1.14	12.809	0.000
General Health	15.96 $\pm$ 1.83	16.33 $\pm$ 2.43	16.88 $\pm$ 2.69	17.17 $\pm$ 2.46	16.67 $\pm$ 2.94	16.63 $\pm$ 2.84	17.00 $\pm$ 2.59	16.96 $\pm$ 2.67	0.475	0.701
Perception										
Vitality	16.67 $\pm$ 2.94	17.92 $\pm$ 2.90	17.29 $\pm$ 2.69	18.63 $\pm$ 2.73	16.46 $\pm$ 1.08	16.83 $\pm$ 3.41	16.78 $\pm$ 3.41	17.00 $\pm$ 3.42	1.703	0.172
Social Function	7.88 $\pm$ 1.19	8.13 $\pm$ 1.27	8.20 $\pm$ 1.25	8.58 $\pm$ 1.21	7.96 $\pm$ 1.08	7.92 $\pm$ 1.14	8.35 $\pm$ 1.27	8.44 $\pm$ 1.41	1.365	0.259
Role-Emotional	4.46 $\pm$ 1.22	4.79 $\pm$ 1.22	4.88 $\pm$ 1.54	5.13 $\pm$ 1.03	4.54 $\pm$ 1.10	4.75 $\pm$ 1.15	4.61 $\pm$ 1.31	4.26 $\pm$ 1.29	2.152	0.099
Mental Health	20.25 $\pm$ 3.45	20.46 $\pm$ 3.66	22.42 $\pm$ 2.98	22.63 $\pm$ 3.46	20.79 $\pm$ 4.50	21.42 $\pm$ 4.17	21.78 $\pm$ 2.98	21.87 $\pm$ 3.08	1.500	0.220
Physical Component score	58.43 $\pm$ 3.82	61.90 $\pm$ 3.80	60.26 $\pm$ 5.15	62.82 $\pm$ 3.98	59.20 $\pm$ 5.07	60.20 $\pm$ 4.51	59.96 $\pm$ 5.22	59.93 $\pm$ 5.67	2.186	0.095
Mental Component score	49.25 $\pm$ 7.21	51.29 $\pm$ 8.01	52.79 $\pm$ 5.79	54.96 $\pm$ 6.83	49.75 $\pm$ 7.89	50.92 $\pm$ 8.45	51.52 $\pm$ 7.40	51.57 $\pm$ 7.06	1.442	0.236

Groups: LF, low-frequency pulsating cupping group; HF, high-frequency pulsating cupping group; TC, traditional cupping group; WL, wait-list group. SF-36, Short Form-36; SD, standard deviation; ANOVA, analysis of variance.

pain has been confirmed.^{49–51} In the current study, *Bian*-stone cups were made by using a special *Sibin* stone with ultrasound, far-infrared, and microcrystal properties,⁴⁹ and by using a micro-camera to monitor well in real-time to avoid causing blisters. The comfort of using *Bian*-stone cups was superior to the traditional glass cups, as was reported by participants. In terms of diagnostic significance for future studies, the *Bian*-stone cups also captured the digital data of the cupping marks and enabled an objective analysis of the color of the cupping marks.

Teut et al., in their 2012 study, reported the beneficial effects of pulsatile cupping on pain and QoL after 8 sessions.²⁶ In the current study, although there were no significant differences in Physical Component Score, Mental Component Score, and some other dimension subscales in the SF-36, the pulsating-cupping groups with high or low vi-

bration frequency showed an increasing trend, particularly in the subscales of Physical Function and Physical Component Score (Fig. .5). This might have been due to the high Physical Function scores of the participants at baseline; thus, the cupping did not affect the physical functions of the participants. Meanwhile, the number of treatments was not enough, which might have led to no significant difference emerging.

Strengths of the Study

A strength of this trial was that the effects of pulsating cupping and comparisons with TC were investigated. The actions of different pulsating frequencies were also investigated. The results of the current study are of high clinical interest regarding application of the pulsating cupping device with optimal stimulation parameters. Moreover, instead of glass cups, more-comfortable *Bian*-stone cups were used for the pulsating cupping with micro-cameras to monitor cupping marks to ensure safety.

Limitations of the Study

As an exploratory trial, certain limitations have to be considered. Due to the specific nature of the intervention, blinding of both participants and study physicians was not possible. Moreover, the interests of participants in pulsating cupping and requests for this treatment might have been a bias. Another limitation was the lack of a long-term follow-up.

CONCLUSIONS

The results of this study suggest that pulsating cupping produces a more-satisfactory effect on bodily pain in

TABLE 5. BETWEEN-GROUP COMPARISONS OF BODILY PAIN VALUES (MEANS $\pm$ SD)

Groups	Group difference (95% CI)	P ^a
LF vs. HF	−0.29 (−0.89; 0.31)	P ^{LFH} = 0.337
LF vs. TC	0.61 (0.01; 1.21)	P ^{LFT} = 0.046
LF vs. WL	1.46 (0.85; 2.07)	P ^{LFW} = 0.000
HF vs. TC	0.90 (0.30; 1.50)	P ^{HFT} = 0.004
HF vs. WL	1.75 (1.14; 2.36)	P ^{HFw} = 0.000
TC vs. WL	0.85 (0.24; 1.45)	P ^{TW} = 0.007

^aP -values are from between-group comparisons of any two groups using LSD Test.

Groups: LF, low-frequency pulsating cupping group; HF, high-frequency pulsating cupping group; TC, traditional cupping group; WL, wait-list group.

SD, standard deviation; CI, confidence interval.

patients with SHS than TC does. The beneficial effect of pulsating cupping appeared to be independent of the pulsating frequency. HF (80 pulses/minute) and LF (30 pulses/minute) appeared to be equally beneficial. Further studies investigating the mechanism of this therapy are needed.

The raw data underlying the conclusions made in this study are available from the corresponding author on reasonable request.

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AUTHOR DISCLOSURE STATEMENT

No competing financial interests exist.

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