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• Research Article

Effects of wet-cupping on blood pressure in hypertensive patients: a randomized controlled trial

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ABSTRACT

BACKGROUND: Although cupping remains a popular treatment modality worldwide, its efficacy for most diseases, including hypertension, has not been scientifically evaluated.

OBJECTIVE: We aimed to determine the efficacy of wet-cupping for high blood pressure, and the incidence of the procedure's side effects in the intervention group.

DESIGN, SETTING, PARTICIPANTS AND INTERVENTIONS: This is a randomized controlled trial conducted in the General Practice Department at King Abdulaziz University Hospital, Jeddah, Saudi Arabia, between May 2013 and February 2014. There were two groups (40 participants each): intervention group undergoing wet-cupping (hijama) in addition to conventional hypertension treatment, and a control group undergoing only conventional hypertension treatment. Three wet-cupping sessions were performed every other day.

MAIN OUTCOME MEASURE: The mean systolic and diastolic blood pressures were measured using a validated automatic sphygmomanometer. The follow-up period was 8 weeks.

RESULTS: Wet-cupping provided an immediate reduction of systolic blood pressure. After 4 weeks of follow-up, the mean systolic blood pressure in the intervention group was 8.4 mmHg less than in the control group (P = 0.046). After 8 weeks, there were no significant differences in blood pressures between the intervention and control groups. In this study, wet-cupping did not result in any serious side effects.

CONCLUSION: Wet-cupping therapy is effective for reducing systolic blood pressure in hypertensive patients for up to 4 weeks, without serious side effects. Wet-cupping should be considered as a complementary hypertension treatment, and further studies are needed.

TRIAL REGISTRATION: *ClinicalTrials.gov* Identifier NCT01987583.

Keywords: blood pressure; hypertension; cupping therapy; randomized controlled trials

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1 Introduction

Hypertension is an important health problem, rated globally as the number one mortality risk factor in 2004[1]. Worldwide, approximately 40% of adults over age 25 are reported to be hypertensive[2]. In Saudi Arabia, the overall prevalence is 25.5% among 15–64 year olds[3]. Despite its prevalence, a real cure for the disease has yet to be discovered. All currently available anti-hypertension medications control blood pressure (BP) for a very limited time, never exceeding a single day, rather than actually being curative. Additionally, these medications are also associated with side effects and increased costs for the patients. As a result, the World Health Organization (WHO) stated that, currently, a more suitable long-acting, single dose/day anti-hypertension medication without side effects, that can also reverse the complications of hypertension, is still needed[4]. Thus, the search continues for a new anti-hypertension remedy.

Cupping is an ancient healing method that has been practiced for centuries in many parts of the world. Cupping therapy can be divided into two broad categories, dry- and wet-cupping. Dry-cupping is the process of using a vacuum on different areas of the body in order to collect blood in that area without any incisions[5]. Wet-cupping (or hijama in Arabic) is the process of using a vacuum at different points on the body, along with the use of incisions (small, light scratches made using a razor), to remove what was previously termed as 'harmful blood' (this represents accumulated blood that is located just beneath the skin surface)[5].

Although cupping remains a popular treatment modality in many parts of the world, its efficacy for most diseases, including hypertension, has not been scientifically studied. A recent systematic review involved searching 15 databases, without language restrictions, and included all relevant trials through June 2009[6]. Only 2 studies met the inclusion criteria, and only one assessed the effects of wet-cupping. In that study, 35 patients with acute hypertension were included, and all patients underwent three wet-cupping sessions every other day on the GV14 (Dazhui) acupuncture point; there was no control group. After a single wet-cupping session, acute hypertension improved in 71% of the patients[7]. The authors of the systematic review concluded that there was no strong evidence suggesting that cupping is an effective treatment for hypertension, and that further research is required[6]. A recent randomized controlled trial (RCT) assessed the efficacy of wet-cupping for the treatment of hypertension. The protocol randomly divided 42 participants into intervention and control groups. After 6 weeks of follow-up, a comparison of the mean BP differences between the intervention and control groups showed a significant difference in systolic BP (SBP), but not in diastolic BP (DBP)[8].

Thus, further evidence is needed to establish the efficacy of wet-cupping for lowering high BP. The present study investigated the efficacy of wet-cupping in lowering BP in hypertensive patients, and assessed the incidence of side effects among the treated participants.

2 Materials and methods

The present RCT was conducted in the General Practice Department at King Abdulaziz University Hospital, Jeddah, Saudi Arabia, between May 2013 and February 2014. *The Declaration of Helsinki* was followed and ethical approval was given by the Unit of Biomedical Ethics at King Abdulaziz University before data collection.

This two-armed study involved an intervention group, undergoing wet-cupping (hijama) in addition to conventional hypertension treatment, and a control group undergoing only conventional hypertension treatment. The study could not be blinded because blinding was impossible for this procedure, unlike that for dry-cupping[9].

2.1 Participants

The participants were included in the study if they had high (grade I or II)[4] BP at the time of the study (SBP ≥ 140 mmHg and/or DBP ≥ 90 mmHg). For patients with diabetes mellitus, high BP was defined as SBP ≥ 130 mmHg and/or DBP ≥85 mmHg[10]. Patients were required to be 19–65 years old, and both men and women were included. Patients were excluded if they had grade III hypertension (SBP ≥ 180 mmHg and/or DBP ≥ 110 mmHg), very high added risk according to the WHO hypertension management guidelines[4], or secondary hypertension, or were pregnant. Patients who had undergone dry-cupping, wet-cupping, or acupuncture within the previous six months were also excluded, as were those who required anti-hypertension medication dose or type changes within the follow-up period.

2.2 Randomization and ethical considerations

After checking for eligibility, written informed consent was obtained, and the participants were randomized into the treatment or control group using block randomization method. To preserve concealment, the randomization was performed using sealed opaque envelopes, such that neither the patient nor the observer could predict the group to which a participant was assigned. The randomization process and patient enrolment into their groups were done by the prime investigator. Patient confidentiality was ensured throughout the study, and participants were free to exit the study whenever they desired.

2.3 Intervention

The hijama procedure, performed on intervention group patients, involved cleaning the target area with an alcohol swab, placing the cup over the area, and starting suction. The cup was then gently removed, and five very superficial incisions were made parallel to each other. After creating

the incisions, the cup was placed over the same area and the suctioning was repeated. The cupping procedure was repeated approximately three times without repeating the incisioning, and then the area was cleaned and dressed. Hijama was performed at four sites (Figure 1). The first site was between the two scapulae, opposite the T1—T3 scapular spine. This is the recommended site for treatment of hypertension in an RCT previously done in Iran[7]. This area is called Al-Kahil in Arabic. The second site was located on the seventh cervical vertebra. This site was used in the uncontrolled observational study performed in China on the efficacy of wet-cupping for hypertension[6], and it is called GV14 in Chinese medicine. The other two sites were on both sides of the neck. They are located two fingers posterior to the angle of the mandible on both sides, just below the skull bone, on the hairline. These two areas are called Al-Akhdaain in Arabic, and they were added because they are recommended areas in Islamic literature for general healing along with Al-Kahil[11].

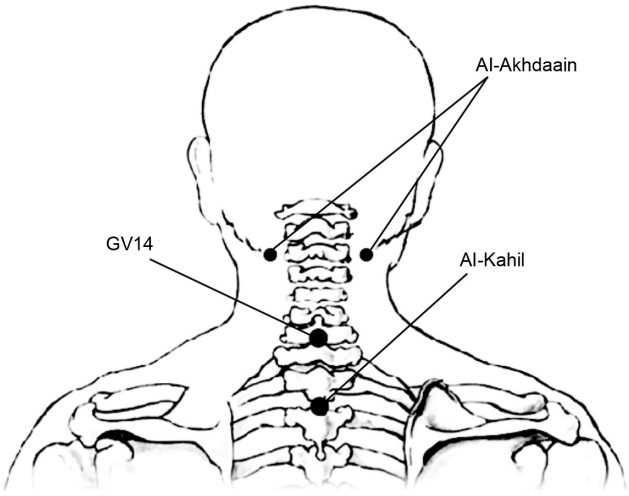

Figure 1 Wet-cupping treatment points

The hijama sessions were repeated 3 times, with a rest day between sessions[6,8]. In Islamic literature, hijama is recommended to be done on days 17, 19, and 21 of the lunar calendar month; these sessions were performed accordingly[11].

2.4 Outcome measures

The main outcome measure in this study was BP measurements. For BP measurement, we followed the BP measurement standards recommended by the *Saudi Hypertension Management Guidelines*[10]. According to these guidelines, the patient rested for 3–5 min before the BP was measured; measurements were performed on both arms during the initial visit. The patient avoided consumption of nicotine or caffeine for 1 h prior to the BP measurement. An appropriate cuff size was used — either a standard or large cuff — according to the upper arm circumference of the participant. All BP measurements were performed with the patient in a sitting position, using a validated, automatic oscillometric sphygmomanometer (705IT; Omron, Kyoto, Japan) to minimize observer bias[12–14]. The instructions provided by the device manufacturer were carefully followed for the measurements. BP was recorded at least twice during each visit, and the mean value was documented.

The potential side effects were those previously published[15]. The occurrence of side effects was evaluated immediately after each hijama session (immediate effects), as well as 4 weeks after the sessions (late effects). The percentage of side effects experienced due to the hijama procedure was calculated.

2.5 Sample size

Based on figures from a previous pilot study[16], we used a standard deviation of ± 15.9 mmHg to calculate the sample size necessary to detect a difference of 10 mmHg between the groups. A sample size of 80 participants, equally divided between the intervention and the control groups, was determined to be sufficient to detect a 10-mmHg change in SBP with 80% power and $\alpha = 0.05$.

2.6 Statistical analysis

Statistical analyses were conducted using SPSS, version 16.0 (IBM, Armonk, NY, USA). BP comparisons were performed between the intervention and control groups at baseline, 4 weeks after intervention, and 8 weeks after intervention using unpaired Student's *t*-test analyses. A second BP comparison was conducted within each group using a paired *t*-test. *P* values < 0.05 were considered significant. Mean BP differences, with 95% confidence intervals, were reported. The percentage of patients experiencing any hijama-related side effect was calculated. An intention-to-treat analysis was used to consider participants lost to follow-up.

3 Results

3.1 Participants' inclusion and exclusion process

During the recruitment period, 318 participants were screened to check for the primary eligibility criteria; 180 individuals were excluded, and 58 refused to participate in the study. The remaining 80 participants were recruited into the study and randomized into the intervention (40 participants) and control (40 participants) groups. Three participants did not attend the 4-week follow-up session and 7 did not attend the 8-week follow-up session. Further, 1 participants from the intervention group and 3 from the control group were excluded at the last follow-up appointment because of changes in their anti-hypertension medications (Figure 2).

3.2 Baseline characteristics' comparison

The intervention and control groups had well-matched

baseline characteristics, without statistically significant differences between any of the baseline variables, except for fasting blood sugar levels, which were significantly higher in the intervention group than in the control group (P = 0.022). The baseline BP measurements were not significantly different (Table 1).

3.3 Conventional anti-hypertension treatment details

Most of the participants in this study were already taking anti-hypertension medications, including 28 in the intervention group and 33 in the control group. The number of anti-hypertension medications used by the participants was not significantly different between the two groups. In addition, the intervention and control groups were compared regarding the class of anti-hypertension medications taken by the participants. There were no significant differences between the two groups in that area (Table 2).

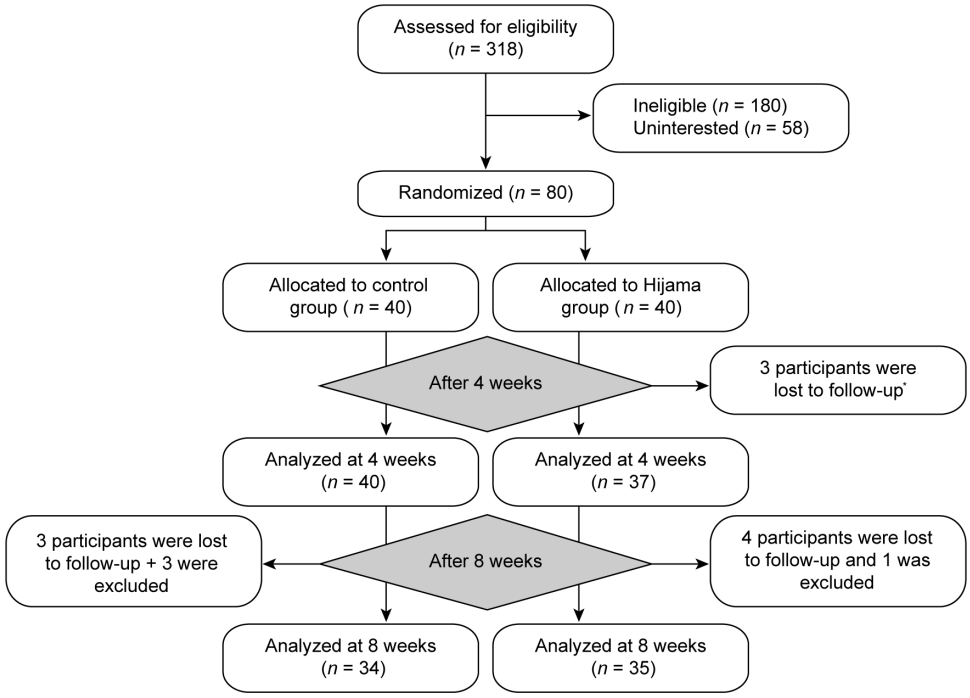

Figure 2 Participant flow chart

*The 3 participants who were lost to follow-up at 4 weeks showed up at the 8 weeks.

Table 1 Comparison of the participants' baseline characteristics

Baseline characteristic	Intervention group (n=40)	Control group (n=40)	P value
Mean age, years (± SD)	52.0 (±9.4)	53.8 (±9.5)	0.409
Male:female ratio	13:27	11:29	—
Diabetes, n (%)	25 (62.5)	23 (57.5)	0.648
Hyperlipidemia, n (%)	26 (65)	22 (58)	0.434
Mean body mass index, kg/m^2 (± SD)	32.1 (±6.2)	33.2 (±6.4)	0.444
Currently smoking, n (%)	3 (7.5)	2 (5.1)	1.0
Family history of premature cardiovascular disease deaths, n (%)	2 (5)	3 (7.7)	0.675
Mean fasting blood sugar, mmol/L (± SD)	8.5 (±4.1)	6.6 (±1.8)	0.022
Mean low-density lipoprotein level, mmol/L (± SD)	3.2 (±1.0)	2.9 (±0.7)	0.160
Mean high-density lipoprotein level, mmol/L (± SD)	1.3 (±0.4)	1.3 (±0.5)	0.621
Mean creatinine level, mmol/L (± SD)	62.0 (±18.0)	54.6 (±24.0)	0.145
Mean potassium level, mmol/L (± SD)	3.9 (±0.7)	5.5 (±8.9)	0.283
Mean thyroid-stimulating hormone level, mIU/L (± SD)	4.8 (±12.2)	2.9 (±2.5)	0.345

SD: standard deviation.

During the entire follow-up period, any participant who had changed his or her anti-hypertension medication was excluded from the study, as mentioned before. The participants' compliance with their anti-hypertension medication schedule was measured, using a validated tool[17–19], at the beginning and end of the study. In addition, histories of the use of anti-hypertensive herbal treatments or other concomitant medications were also obtained. These variables were compared between the intervention and the control groups using chi square or Fisher's exact tests; no significant differences were observed.

3.4 Blood pressure changes during follow-up

At the 4-week follow-up visit, BP measurements were repeated for both groups. The mean SBP and DBP after intervention in the hijama group were significantly different (paired *t*-test) from those at baseline ($P = 0.000$ and 0.042, respectively). In the control group, there were also significant differences (paired *t*-test) in the SBP and DBP compared to those at baseline ($P = 0.016$ and 0.003, respectively). When comparing the mean BP readings between the two groups after 4 weeks of follow-up (Student's *t*-test), there was a significant difference in SBP values ($P = 0.046$) but not in DBP values ($P = 0.681$). The mean difference in SBP values between the two groups after 4 weeks of follow-up was –8.4 mmHg (95% confidence interval, –16.7 to –0.1).

After 8 weeks of follow-up, significant differences persisted within the hijama group, for SBP and DBP ($P = 0.002$ and 0.004, respectively, compared with those at baseline). Similar results were also found for both SBP and DBP in the control group ($P = 0.036$ and 0.022, respectively, compared with those at baseline). When comparing the mean BP readings (independent Student's *t*-test) between the two groups, after 8 weeks of follow-up, the differences in the SBP and DBP values were not significantly different between the groups ($P = 0.129$ and 0.881, respectively) (Table 3).

3.5 Assessment of factors that may affect the participants' blood pressure

As various factors may alter BP results, we repeated the comparisons several times while accounting for these factors. One such factor was the amount of blood collected during hijama. This factor was not included in the original protocol; therefore, a cut-off value for high and low volumes of collected blood was not prospectively determined. The amount of blood collected was recorded using the symbols +, ++, +++ or ++++, and was only recorded during the third hijama session. Nevertheless, we believe that this factor should be accounted for, and hence, the amount of blood collected was estimated as accurately as possible. Therefore, the hijama group was divided into two groups — the lower amount of blood extracted (LABE) group included those with + and ++ (estimated to represent less than 50 mL per session), and the higher amount of blood extracted (HABE) group included those with +++ and ++++ (estimated to represent more than 50 mL per session). Thereafter, both the HABE and LABE groups were compared with the control group. When the LABE

Table 2 Comparison of the class of anti-hypertension medications taken by the participants

Anti-hypertension medication class	Intervention group (n=40)	Control group (n=40)	P value
Angiotensin-converting enzyme inhibitors (%)	18 (45%)	13 (32.5%)	0.251
Calcium channel blockers (%)	10 (25%)	14 (35%)	0.329
Thiazide diuretics (%)	3 (7.5%)	8 (20%)	0.105
β_1 Receptor antagonists (%)	3 (7.5%)	6 (15%)	0.481
Angiotensin-II receptor antagonists (%)	3 (7.5%)	5 (12.5%)	0.712
Loop diuretics (%)	1 (2.5%)	0 (0%)	1.0

Table 3 Blood pressure comparisons between the intervention and control groups after 4 and 8 weeks of follow-up, and the changes from baseline within each group

(Mean ± standard deviation, mmHg)

Group	Systolic BP	Diastolic BP
Hijama group		
At baseline (n=40)	152.0 ± 10.7	85.0 ± 7.9
After 4 weeks (n=37)	140.0 ± 17.7*	82.0 ± 9.9
After 8 weeks (n=35)	143.0 ± 19.8	81.0 ± 10.4
Control group		
At baseline (n=40)	157.0 ± 11.3	86.0 ± 6.4
After 4 weeks (n=40)	149.0 ± 18.5	81.0 ± 12.2
After 8 weeks (n=34)	150.0 ± 15.8	82.0 ± 12.1

*P<0.05, *vs* control group. BP: blood pressure.

group was compared with the control group, the BP results were not significantly different. However, there was a significant difference in SBP at the 4-week follow-up visit when the HABE group was compared with the control group. Finally, we compared the LABE group with the HABE group. The SBP and DBP values were significantly different between these two groups after 4 weeks of follow-up (Table 4).

The other factors that may affect blood pressure outcome were also assessed, including gender, number of hijama sessions, body mass index, compliance with the anti-hypertension medication therapy, and the class of the anti-hypertension medication taken by the patient. None of these factors had a significant effect on the blood pressure outcomes.

3.6 Assessment of wet-cupping's side effects

Serious side effects were not observed in the hijama group. Most of the mild side effects were experienced immediately after hijama and lasted for few hours, but never for more than 48 h. This excludes hijama-site pruritus, which appeared 1–2 d after the session and lasted for a few days. The most common immediate side effects were headache, followed by hijama-site pruritus, dizziness, and feeling tired and sleepy after hijama. Wound infections were not observed 1–2 weeks after the intervention in any of the participants. After 8 weeks of follow-up, the only remaining side effect was a mildly hyperpigmented scar at the hijama site in 10 participants (27.8% of the hijama group) (Table 5). In addition, all of the mentioned side effects were compared between the HABE and LABE groups after the 3rd session, because the amount of blood was only recorded at that time, and there was no significant difference between the two groups (Table 6).

4 Discussion

The results of the present study showed a significant difference in SBP measurements (–8.4 mmHg) between the intervention and control groups after 4 weeks of follow-up. After 8 weeks of follow-up, the hijama effect had disappeared, leaving no significant BP difference between the intervention and control groups. The positive results reported in this study are consistent with those of Zarei *et al*[8] who also reported a significant difference in SBP values between the intervention and control groups after 6 weeks of follow-up. Therefore, hijama produces an effect that lasts for 4–6 weeks.

Table 4 Comparison of the BP values between the higher amount of blood extracted (HABE) group and the lower amount of blood extracted (LABE) group

Measurement (mmHg)	HABE group	LABE group	Mean difference between the two groups	*P* value
Systolic BP at baseline	150 (±12.2)	156 (±9.2)	5.9 (−1.5–13.2)	0.114
Diastolic BP at baseline	85 (±8.3)	85 (±8.1)	−0.2 (−5.8–5.5)	0.957
Systolic BP after 4 weeks	133 (±12.5)	146 (±20.8)	2.8 (0.4–25.1)	0.043
Diastolic BP after 4 weeks	78 (±11.1)	85 (±7.5)	7.0 (0.2–13.7)	0.044
Systolic BP after 8 weeks	141 (±14.2)	144 (±24.4)	3.0 (−13.1–19.2)	0.704
Diastolic BP after 8 weeks	81 (±10.6)	81 (±11.7)	0.2 (−8.5–8.9)	0.963

After 4 weeks of follow-up, the group with a higher amount of blood extracted included 15 participants, whereas the group with a lower volume of blood extracted included 20 participants. After 8 weeks of follow-up, the group with a higher amount of blood extracted included 12 participants, whereas the group with a lower volume of blood extracted included 17 participants. BP: blood pressure.

Table 5 Frequency of adverse events immediately after each hijama session

Side effect	After session 1	After session 2	After session 3	Total frequency	Percentage (based on total number of sessions)
Headache	4	3	6	13	11.8%
Hijama-site pruritus	0	3	5	8	7.3%
Dizziness	5	2	0	7	6.4%
Tired and sleepy	1	3	3	7	6.4%
Nausea	2	0	1	3	2.7%
Pain at hijama site	0	0	2	2	1.8%
Same-day insomnia	1	1	0	2	1.8%
Vomiting	1	0	0	1	0.9%
Bullae formation	0	0	0	0	0%

Table 6 Comparison of the wet-cupping side effects between the higher amount of blood extracted (HABE) group and the lower amount of blood extracted (LABE) group

Side effect	HABE group	LABE group	*P* value
Headache	1	4*	0.336
Hijama-site pruritus	1	3*	0.602
Dizziness	0	0	1.000
Tired and sleepy	0	3	0.228
Nausea	1	0	0.467
Pain at hijama site	1	1	1.000
Same-day insomnia	0	0	1.000
Vomiting	0	0	1.000
Bullae formation	0	0	1.000

*1 missing data.

When comparing the baseline BP measurements with the BP readings at 4 and 8 weeks of follow-up, a significant difference was noted within the hijama group, although similar results were also found within the control group. However, we believe that the BP reduction in the control group may be due to the short follow-up intervals — this may have made the participants more conscious of their BP, and may have led them to improve their diet and lifestyle, possibly positively influencing their BP measurements. However, these reductions were not the result of changes in anti-hypertensive medication types or compliance, as these factors were monitored throughout the study.

An uncontrolled observational study in China measured the BP outcomes of patients immediately after they underwent hijama sessions, and the values were compared with the baseline BP readings[7]. The authors reported a significant difference in the readings, similar to that in the present study; however, we do not believe that this observation is clinically relevant because if hijama does not yield a relatively long-lasting BP reduction, it would not be applicable as a treatment as it is unrealistic to undergo the procedure daily.

The days for hijama procedures in the present study (days 17, 19, and 21 of the lunar month) were chosen according to Islamic literature. Some evidence in the published literature has indicated some relation between the lunar phase and blood pressure[20]. In our previous pilot study, we did not choose specific days for conducting hijama sessions, and we did not observe any positive effect on BP[16]. However, the identification of specific days for performing the hijama procedure requires further research, particularly considering that this variable has not been reported in previous hypertension studies.

Although we assessed many factors that could have affected the hijama procedure outcomes, the amount of blood collected during the hijama session was the only one that showed a positive effect on the BP. As mentioned earlier, hijama patients in the HABE group had better BP outcomes than those in the LABE group. In particular, these groups showed significantly different SBPs and DBPs. However, as this measurement was not prospectively planned, the amount of blood was not accurately measured. Nevertheless, this is an important point that has not been described in previous studies. We believe that a greater number of incisions at each hijama site — 10 to 15 incisions — might yield more blood collection and consequently produce better results. Based on our results, we would not recommend undergoing 3 consecutive sessions, each spaced a day apart, because there was no BP difference between those who did one, two, or three sessions. One session might be enough to achieve the required result. This is area that needs further research.

The BP-lowering mechanism of hijama is unknown. One hypothesized mechanism of action is the "Taibah Theory", which states that hijama drains interstitial fluid, excess intravascular fluid, and noxious metabolic substances. The theory also hypothesizes that hijama stimulates endogenous nitric oxide production and excretion of accumulated vasoactive substances and free radicals, which may cause reduced BP measurements. All these effects are beneficial for treating hypertension, according to the theory[21].

In the present study, hijama was demonstrated to be a generally safe and well-tolerated procedure. The most common immediate side effect was headache, with other less frequent side effects including pruritus, post-procedural sleepiness, dizziness, nausea, and insomnia; only one patient experienced pain at the cupping site. One patient experienced hypotension and vomiting after her first hijama session, immediately after seeing blood accidently spilled from the collection cup; this may have been a vaso-vagal effect. She was stabilized before she left the clinic and her blood pressure returned to normal within a few minutes. That patient did not experience similar reactions following the subsequent two hijama sessions. The only late side effect was the presence of mild hyperpigmented scars that persisted 8 weeks after treatment in 10 of the 36 participants who completed the follow-up visits. Typically, these scars gradually disappeared over time, but this was not confirmed in this study. These side effects, compared with those associated with anti-hypertension medications, are considered mild[4]. In addition, the HABE group did not experience additional side effects.

The present study has several positive factors. One such factor is its originality, since studies describing the effect of wet-cupping on hypertension are very rare. Another positive aspect is the study participants' high follow-up rates. Only three participants (3.75%) were lost to follow-up at 4 weeks and seven (8.75%) at 8 weeks. This study

also involved a larger sample size than previous studies, giving it greater statistical power. Finally, we followed patients for a relatively long period, which made it possible to track the effects of hijama on BP over a long period of time.

This study's most important limitation, and that of all wet-cupping studies performed to date, is the inability to blind the study. This is due to the absence of a well-developed sham wet-cupping method. Although wet-cupping might induce a placebo effect, BP is an objective outcome that is unlikely to have a significant placebo effect. Another limitation is that the timing of the 4-week follow-up appointment was not accurate for all participants in both groups. This was largely overcome at the 8-week follow-up appointment.

5 Conclusion

Wet-cupping therapy effectively reduced SBP in hypertensive patients for up to 4 weeks, without any serious side effects. We recommend the use of this complementary treatment, in conjunction with anti-hypertension medications, to treat hypertension. Additional studies are also needed to investigate the efficacy of wet-cupping alone, without any concomitant anti-hypertension medications. Moreover, additional research on the effect of the number of incisions and the amount of blood collected during the hijama procedure is needed. We also recommend the development of a sham wet-cupping technique to aid future studies.

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7 Conflict of interest disclosure

The authors report the absence of any conflicts of interest with the funding organizations.

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