Developing and validating a sham cupping device

Myeong Soo Lee, Jong-In Kim, Jae Cheol Kong, Dong-Hyo Lee, Byung-Cheul Shin

ABSTRACT

Objectives The aims of this study were to develop a sham cupping device and to validate its use as a placebo control for healthy volunteers.

Methods A sham cupping device was developed by establishing a small hole to reduce the negative pressure after suction such that inner pressure could not be maintained in the cup. We enrolled 34 healthy participants to evaluate the validity of the sham cupping device as a placebo control. The participants were informed that they would receive either real or sham cupping and were asked which treatment they thought they had received. Other sensations and adverse events related to cupping therapy were investigated.

Results 17 patients received real cupping therapy and 17 received sham cupping. The two groups felt similar sensations. There was a tendency for subjects to feel that real cupping created a stronger sensation than sham cupping (48.9±21.4 vs 33.3±20.3 on a 100mm visual analogue scale). There were only mild to moderate adverse events observed in both groups.

Conclusion We developed a new sham cupping device that seems to provide a credible control for real cupping therapy by producing little or no negative pressure. This conclusion was supported by a pilot study, but more rigorous research is warranted regarding the use of this device.

INTRODUCTION

Cupping therapy is an ancient medical technique that has been used in several cultures in East Asia, Europe and the Middle East for over 2000 years. It is a physical treatment that involves suctioning the skin through a plastic or glass cup to create negative pressure over a painful area or acupuncture point. A Korean survey in 2006 showed that 93.5% of 6708 Oriental medicine doctors use cupping treatments in their clinical fields.

Cupping has been used for a number of conditions, although chronic pain, including lower back pain and headaches, is the primary condition treated with cupping therapy. In a Korean survey, 2001 Oriental medicine doctors reported performing cupping therapy on patients with (in order of decreasing frequency) musculoskeletal disorders, internal diseases, stroke and paralytic diseases, obesity and dermatological conditions. Cupping is divided into two varieties. Wet cupping involves incision, lancing or scarification of the skin, whereas dry cupping does not; both involve the localised application of negative pressure. The treatment (retention) time for cupping is 5 min on average (range: 1–15 min) for both wet and dry cupping. The survey also reported that suctioning was performed three times to create a vacuum inside the cup using a gun-shaped suction device.

Placebo controls are very important in clinical trials because they control for non-specific treatment effects that can be produced by a patient’s desire for symptomatic relief. In addition, they make it possible for patients to be blinded as to which treatments they are given, either real or sham. Among recently published randomised clinical trials (RCTs) for cupping, however, almost all used conventional medicine, standard care or no treatment as the control intervention. This methodology reduces the quality of RCTs for cupping and highlights the need to establish a sham cupping device. To date, however, no sham cupping device has been available.

We recently developed a novel sham cupping device and conducted a pilot study to evaluate its use in a clinical trial setting. Our objectives were to develop a sham cupping device and to investigate whether this device could be distinguished from the real cupping jar when used in the same procedure on healthy subjects.

METHODS

Developing a sham cupping device

The placebo cupping device was developed by modifying a disposable cupping jar (Hansol Medical Co, Gyung-Gee province, Licensed by Ministry of Welfare: 437, Item License: #9 in Korea) that was commercially available and commonly used.

During regular cupping treatment, the base of the jar is fixed to the skin by negative pressure from the jar after the air inside is sucked out. A negative pressure of 600–610 mm Hg is generally formed in the cupping jar after three applications of suction with a manual vacuum gun. The sham cupping jar, on the other hand, produces little or no negative pressure due to a hole of 0.2 mm in diameter on the surface of the jar. Instead, the sham cupping jar has adhesive on the base of the jar to attach it to the skin without negative pressure.
This novel placebo cupping jar makes it possible to attach the jar to the skin without any negative pressure inside the jar. This sham cupping device is 35.7 mm in diameter, 47.9 mm in height, and 36.9 cm³ in volume and contains a hole located on the side, 30 mm from the base (figure 1).

Study protocol to test validity
To validate the sham cupping device, after receiving the approval of the institutional review board of the Oriental medicine hospital of Wonkwang University, 51 volunteers were enrolled as experimental subjects from August 2008 to February 2009 using an internet website, advertisements and announcements.

The inclusion criteria of the study were as follows: age 19–65 years, healthy subjects, a lack of problems expressing thoughts and no experience with cupping therapy in the past 2 years. Participants with cupping experience within the past 2 years or with any signs of disease were excluded.

After screening 51 volunteers, 17 subjects were excluded: 13 were not acceptable based on our inclusion criteria, and four declined to give written informed consent after hearing the possibility of being included in the sham cupping group.

Prior to beginning the study, the purpose and format were explained to the subjects as follows:

We will apply two styles of cupping, which may or may not differ in type, at bilateral Shenshu (BL23) points located on the lower back. When either style of application is completed, we will ask you to complete a questionnaire regarding whether you felt anything on your skin. If you take part in this clinical trial, you will have an equal chance of receiving either a real cupping treatment or a sham cupping treatment, based on a statistical method.

After obtaining written informed consent approved by the Ethics Committee, 34 subjects met our inclusion criteria and were randomly allocated to either the real cupping treatment group or the sham cupping treatment group. Participants underwent one session of cupping therapy, either real or sham, and completed a questionnaire regarding masking, cupping sensations and adverse events (figure 2).

Randomisation and blinding
The random allocation sequence was computer-generated with SPSS V.14.0 for Windows, using a block size of four.
Although it was impossible to blind the practitioner to the treatment type, the participants and assessor were blinded as to which treatment the subjects were given.

**Allocation concealment**
Group assignment, which was concealed by the pharmacy department at the research hospital using sealed opaque envelopes, was not exposed to the practitioner or the assessor at the time of enrolment.

**Treatment procedures**
The practitioner, a specialist in acupuncture and moxibustion with 7 years of experience and a license from the Ministry of Health and Welfare of Korea, performed both the real and sham dry cupping procedures. All subjects were lying face down, and the practitioner dressed the selected site with the subjects in the prone position using a povidone scrub prior to treatment. The participants then rested for 5 min to allow the surface of skin to dry.

The practitioner created a vacuum inside the cupping jar by removing the air using a portable manual vacuum gun for 10 s for a series of six applications of suction. Two cupping jars were applied bilaterally on the lower back to the acupuncture points of Shenshu (BL23). The cupping procedure was performed in the same manner using either the real or placebo cupping jars. Each session lasted approximately 15 min. In both groups the centre of the jar was placed on the selected site (BL23; on the vertebral region, 4.5 cm lateral to the inferior border of the L2 spinous process).

After 15 min of treatment, the practitioner removed the cupping jar. Post-treatment dressing was done in the same manner as described above.

**Assessment**
After treatment, the participants were asked to complete a questionnaire. The main questions were as follows:
1. ‘Which treatment do you think you received?’ with the following three choices: real cupping treatment, sham cupping treatment or don’t know
2. ‘Did you have any sensations during dry cupping?’ with a yes or no response
3. ‘What sensations did you experience?’ with the following options: pressing, inflating, painful, squeezing, relaxing, refreshing, burning, pulling or hot tingling sensations
4. ‘Where was the feeling of cupping located?’ with the answers being the cupping area, a broad area around the cupping jar or the whole lower back area
5. ‘How much sensation did you feel?’ using a 100-mm visual analogue scale (0 mm: not at all; 100 mm: very strong).

**Adverse effects**
During the entire treatment procedure, participants were asked to report any discomfort or illness that might have been related to the cupping procedure. The assessor also evaluated the problems, if any existed, on the skin area or whole body.

**Data description**
The treatment and control group data from the pretreatment and post-treatment questionnaires were summarised as the mean±SD or number (%).

**RESULTS**

**Characteristics of the participants**
The participants included 11 male (32.4%) and 23 female (67.6%) subjects with a mean age of 42.9±15.5 years (range: 22–64). In both groups, 11.8% of the subjects had experience with cupping therapy as a treatment, while 80% of the subjects in the real cupping group and 94% in the sham group had observed cupping therapy (table 1).

**Masking test and cupping sensations**
Among all the subjects, 41% in the real cupping group and 59% in the sham group reported no knowledge of their group assignment (table 2).

**Table 1** General characteristics of subjects

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>Real cupping group (n=17)</th>
<th>Sham cupping group (n=17)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sex</td>
<td>Male 8</td>
<td>Female 9</td>
</tr>
<tr>
<td></td>
<td></td>
<td>14</td>
</tr>
<tr>
<td>Age (years, mean±SD)</td>
<td>40.2±16.7</td>
<td>45.5±14.1</td>
</tr>
<tr>
<td>Have you ever experienced cupping therapy?</td>
<td>Yes 2</td>
<td>Yes 2</td>
</tr>
<tr>
<td></td>
<td>No 15</td>
<td>No 15</td>
</tr>
<tr>
<td>Have you ever seen cupping therapy? (2 missing in real cupping)</td>
<td>Yes 12</td>
<td>Yes 16</td>
</tr>
<tr>
<td></td>
<td>No 3</td>
<td>No 1</td>
</tr>
</tbody>
</table>
Some kind of sensation during cupping was felt in 88% of the real group and 76% of the sham group, which included pressing (33% vs 31%; real vs sham, respectively), inflating (13% vs 23%), pain, squeezing, and so on. Interestingly, the strength of the sensation was stronger in the real group than in the sham group (table 2).

Adverse events

Based on the subjects’ reports, only one subject in the sham cupping group (6%) reported an inconvenient painful sensation such as pinching. Based on the assessor’s report, however, both redness (35% vs 29%; real vs sham, respectively) and ecchymoses (35% vs 6%) were seen.

DISCUSSION

Within the context of this pilot study, the sham cupping treatment created similar sensations compared to genuine cupping treatment. In addition, there were similar adverse events. The strength cupping pressure was the only difference between the two groups. This probably indicates successful subject blinding, which could facilitate rigorous research in cupping clinical trials adopting a randomised, sham-controlled, subject-blind, assessor-blind approach. This device makes it possible to evaluate the effects of cupping in placebo-controlled trials using a rigorous scientific research methodology.

In recent years, many investigators have attempted to address the challenging methodological issue of appropriate placebo controls for acupuncture research, as also seen in moxibustion research. Due to the lack of a sham or placebo cupping device, however, the quality of clinical trials of cupping has generally been poor.

RCTs of cupping therapy have used drugs, usual care, heating pads or no treatment as control treatments compared to dry or wet cupping treatments. All of these reported positive or nearly positive effects of cupping therapy compared to the control intervention. Why are there no negative studies among RCTs of cupping? Unblinded clinical trials generally exaggerate therapeutic effects and are more open to bias. This is why placebo controls must be adopted as control interventions instead of carrying out unblinded or uncontrolled studies. The goal of cupping is to increase local circulation in order to reduce pain, swelling and inflammation in conditions such as muscle strain or trauma. This treatment has not only been used in Asia; it is said that Napoleon was treated with cupping using the horns of water buffalo for a stomach ache.

The feeling of cupping was not strong or unpleasant in our study; however, the strength of the sensation was stronger in the real treatment than in the placebo, despite a similar sensation in the awareness of which treatment had been received. This raises the small possibility of unblinding with our sham cupping device if it is placed on a more sensitive part of the body. It is possible that unblinding in the sham group could be significantly greater with a large study. There is the additional factor; in a clinical trial patients are likely to look at the areas that have been cupped when they go home, and if they do not see raised, red patches they may be able to guess they had the sham treatment. In future advances for this device, or further development of another sham cupping device, these points should be considered for complete patient blinding.

Another important issue in clinical trials is safety. Based on the results of our clinical trial, dry cupping treatment on the back seems to be safe. Redness, ecchymoses, petechiae, oedema and erythema are all part of cupping therapy but are not typically severe, generally disappearing after 1–2 weeks with no additional treatment. Severe side effects from cupping therapy have been reported, however, including burns, suction bullae as a complication of prolonged cupping, keloids and vasovagal shock. Such adverse reactions are extremely rare when cupping is conducted with care.

One limitation of our study was the small sample size for interpreting the results. However, this is a pilot study to test the use of sham cupping for future trials to specify the non-specific effects for certain conditions. We are now planning a series of RCTs to test the efficacy of

---

Table 2  Questionnaire after cupping

<table>
<thead>
<tr>
<th>Question</th>
<th>Real cupping group (n=17)</th>
<th>Sham cupping group (n=17)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Which device was used?</td>
<td>Real</td>
<td>7</td>
</tr>
<tr>
<td></td>
<td>Sham</td>
<td>3</td>
</tr>
<tr>
<td></td>
<td>Don’t know</td>
<td>7</td>
</tr>
<tr>
<td>Was there any sensation during cupping?</td>
<td>Yes</td>
<td>15</td>
</tr>
<tr>
<td></td>
<td>No</td>
<td>2</td>
</tr>
<tr>
<td>What did you feel during cupping? (missing: real (2), sham (4))</td>
<td>Pressing</td>
<td>5</td>
</tr>
<tr>
<td></td>
<td>Inflating</td>
<td>2</td>
</tr>
<tr>
<td></td>
<td>Hot tingling</td>
<td>1</td>
</tr>
<tr>
<td>Where were the sensations? (missing: real (2), sham (2))</td>
<td>Cupping area</td>
<td>13</td>
</tr>
<tr>
<td></td>
<td>Broad area around cupping</td>
<td>1</td>
</tr>
<tr>
<td>How much sensation do you feel? (100 mm VAS) (mean ± SD)</td>
<td>48.9±21.4</td>
<td>33.3±20.3</td>
</tr>
</tbody>
</table>

VAS; visual analogue scale.
cupping for several pain conditions. This study can be helpful going forward for more rigorous trials or the further development of another sham cupping device.

In conclusion, our novel sham cupping device was probably suitable as a cupping control in the context of this pilot study. More rigorous RCTs for specific conditions will be needed to test the non-specific effects of cupping adopting a subject-blind method with novel sham cupping devices.

Acknowledgements The authors wish to acknowledge all participants who volunteered in the study. The authors thank Sun-Mi Choi who funded a professional proof reading service for this manuscript.

Funding J-IK and B-CS input their own money to this study.

Competing interests The sham cupping device was patented as ‘KIDM sham cupping device’ (Korea patent number 10-2009-0083013). MSL is employed as researchers at KIDM. J-IK and D-HL were working as researchers during this study.

Ethics approval The study was approved by the Wonkwang University Hospital Ethics Committee (WKISIRB-AR reference: 2008-4).

Provenance and peer review Not commissioned; externally peer reviewed.

Contributors MSL and J-IK developed the sham cupping device and design the experimental procedures, interpretation of the data, drafting the manuscript and critical revision of the article. D-HL and JCK contributed to experimental set-up and procedures of the study. B-GS designed the experimental procedures, interpretation of the data, drafting the manuscript and critical revision of the article.

REFERENCES


Summary points

► We developed a sham cupping device for blinded clinical trials.
► The cup has a hole which releases the pressure inside.
► In this small reliability study, the device seemed to successfully blind most volunteers.
Developing and validating a sham cupping device

Myeong Soo Lee, Jong-In Kim, Jae Cheol Kong, Dong-Hyo Lee and Byung-Cheul Shin

Acupunct Med published online July 19, 2010

Updated information and services can be found at:
http://aim.bmj.com/content/early/2010/07/18/aim.2010.002329

These include:

References
This article cites 30 articles, 2 of which you can access for free at:
http://aim.bmj.com/content/early/2010/07/18/aim.2010.002329#BIBL

Email alerting service
Receive free email alerts when new articles cite this article. Sign up in the box at the top right corner of the online article.

Notes

To request permissions go to:
http://group.bmj.com/group/rights-licensing/permissions

To order reprints go to:
http://journals.bmj.com/cgi/reprintform

To subscribe to BMJ go to:
http://group.bmj.com/subscribe/