Efficacy of Hijamat-Bila-Shart (dry cupping) in Waja-uz-Zahr (Low back pain): An open randomized controlled clinical trial

Abuzar Lari, Mohd Nayab, Mohammad Tausif and Javed AH Lari

Abstract
This was a randomized controlled clinical study we have investigated the effect of Hijamat-bila-Shart in Waja-uz-Zahr. Total 60 patients were enrolled randomly assigned for test group (n=30) and control group(n=30). Test group received Hijamat-bila-Shart, a total 8 sittings were scheduled alternately for 14 days, and control group received Tablet Acetaminophen 500mg BD for the 14 days. The assessment was done by Visual analogue scale (VAS) and Oswestry low back pain scale (OLBPS) at 0 day, 14th day, and 21st day. On intergroup comparison of pain at 14th day, P value was 0.391, suggested no significant difference in both group but at 21st day, P value was 0.001, showed highly significant differences between the groups. On intragroup comparison both group were found significant. On intergroup comparison of disability no difference seen at 14th and 21st day, in intragroup comparison both group found significant. In this trial, Hijamat-bila-Shart was found effective in comparison of Tablet Acetaminophen for relieving symptoms of Waja-uz-Zahr. So it can be concluded that Hijamat-bila-Shart may be an effective regime in the management of Waja-uz-Zahr.

Keywords: Hijamat-bila-Shart, Waja-uz-Zahr, VAS, OLBPS

Introduction
Waja-uz-Zahr (Low back pain) is a common disorder, described as discomfort in the lumbosacral region, which involves muscles, nerves, bones of the back [1]. It is not a definite disease; rather it is an indication that may arise from a variety of causes and many individuals may remain undiagnosed. Most of the cases of LBP have a common reason, such as muscle strain or a specific and diagnosable condition such as degenerative disc disease or a lumbar herniated disc [2]. Unani physicians described Waja-uz-Zahr as a pain which remains constant in the lumbar and lumbosacral region and does not radiate downwards. This pain may arise from internal muscles, external muscles, ligaments, or other structures surrounding in lumbosacral region due to alteration of Mizaj (Sue Mizaj). This abnormal temperament (Sue Mizaj) is due to surplus Burudat and accumulation of raw Phlegm (Kham Balgham). Pain may also arise due to accumulation of Ghalez Riyah in the lumbar and lumbosacral region [3]. It affects all ranges of the population, however, its burden is often considered trivial. As part of the Global Burden of Disease Study (GBD) 2010, the expert group showed that LBP comes under the top ten high burden diseases and injuries with an average number of DALYs (disability-adjusted life years) more than HIV, RTA injuries, tuberculosis, lung cancer, chronic obstructive pulmonary disease and preterm birth complications [4]. Lifetime prevalence is upto 85% in developed countries, which makes 2nd only to the common cold. It was noticed that 37% of backache was attributed to profession, with two fold difference across regions; the suffering proportion was higher for men than women, because they have higher percentage in the labour work and in occupations with heavy lifting. The first occurrence of LBP is typically highest in the third decade of life and overall prevalence increases with age until the 60-65 years age group and then gradually declines [5, 6]. In the management of low back pain, the medical fraternity depends on using of Physiotherapy, exercise, analgesic, NSAIDs, skeletal muscle relaxants and opioid analgesics etc. But the results are not up to satisfactory level. Apart from this there are various documented severe side effects of orally used analgesic and NSAIDs. Scholars of Unani medicine used various regimes for the successful and beneficial treatment of Waja-uz-Zahr. In which Hijamat-bila-Shart a regime which use frequently for the management of Waja-uz-Zahr, Hijamat-bila-Shart is a method used for Imala-e-Mavad (diversion of morbid material). In Ancient time, Hollowed out animals horns (Singhi) were used for the procedure of Hijamat-bila-Shart. Now a days, these animal horns are replaced by sophisticated plastic and glass cups in which vacuum pump is used to create negative pressure.
inside the cup so that it get attached on the body surface [7-
11].These regimes are not properly documented and validated
till date. However, the efficacy of dry cupping has been
uncertain in the previous studies, most of the studies did not
have control groups and there is lack of well-designed
randomized controlled trials to investigate the efficacy of dry
cupping, especially in the management of Waja-uc-Zahr.
Therefore, to evaluate the efficacy of Hijamat-bila-Shart
this study was conducted.

Materials and Methods
Study design & Subjects
This was an open randomized controlled clinical trial
evaluating the efficacy of Hijamat-bila-Shart. Patients of low
back pain recruited from OPD and IPD of (NIUM) after
getting ethical clearance from the Institutional Ethical
Committee (IEC) of NIUM. This study stretched from March
2016 to January - 2017. The Inclusion criteria was: Clinically
and Radiologically diagnosed patients of LBP, both gender
included, age 20-60 years, no radiation of pain to other
region, willing to participate in the study and follow the
instruction. Patients were excluded if they had major trauma,
systemic disorders, pregnant and lactating women, LBP
secondary to a malignant or autoimmune disease, congenital
deformities of the spine (except for lordosis or scoliosis).
Duration of treatment was 14 days and total duration of
protocol was 21 days. Each subject was fully informed about
experimental procedure and asked to sign an informed
consent statement before taking part in the trial. Certain
investigations were carried out with an aim to exclude the
patients and to establish the safety of the intervention used in
the study. A total of 150 patients was screened, out of which
75 cases fulfilled the study criteria. Finally 60 cases,
including 20% expectancy of drop out, were enrolled and
randomly allocated into two groups by using lottery method,
viz., test group and control group, comprising of 30 patients
in each group.

Flow chart of the patients

Procedure of Study
Patients of test groups were subjected to the Hijamat-bila-
Shart (Dry cupping) on every alternate day for 14 days i.e 0,
2nd, 4th, 6th, 8th, 10th, 12th and 14th daywhile patients of control
group were given Tablet Acetaminophen 500 mg twice in a
day for 14 days. Scorings of the patients were noted before
starting the treatment i.e 0 day, and after the completion of
treatment i.e.14th day. Another scoring was done on 21st day
i.e. one week later after completion of treatment to find out
the sustained effect of therapy.

Procedure of Hijamat-bila-Shart (Dry Cupping)
Patient was asked to lie-down comfortably on the bed in
prone position and asked to expose the required area. Hairs
were removed, if found in order to fix the cups firmly on the
body surface. Area of cupping was cleaned with sprit or
betadin, followed by the application of four large sized cups
having diameter of 5.5cm, on lumbo-sacral region. Negative
pressure was created with the help of sophisticated vacuum
pump. Four complete suctions were taken in each cup to
maintain the uniformity among the cups, up to 20 minutes.

Outcome assessment
Visual Analogue Scale (VAS) & Oswestry Low back pain
scale (OLBPS).

Follow up during treatment & after the treatment
Total duration of treatment was 14 days and there were 2 follow
ups for the assessments. 1st assessment was done before
starting the treatment on 0 Day and 2nd was done after
the treatment on 14th day. Once the patient completed the
treatment, he/she was asked for follow up after 1 week of
treatment on 21st day, to find out the sustained effect of
therapy.

Result
It was a comparative evaluation of test and control groups.
Total 50 patients were completed the study out of 60 patients,
10 patients were drop out. The reason for the dropout
included insufficient time, dissatisfaction, worsening of
symptoms and other reasons etc. Fever, body ache were
reported by 3 male patients of Test group and cupping blisters
were reported by 2 female patients and it was reported during follow up.

<table>
<thead>
<tr>
<th>Age in years</th>
<th>Test group</th>
<th>Control group</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>20-30</td>
<td>6(24%)</td>
<td>8(32%)</td>
<td>14(28%)</td>
</tr>
<tr>
<td>31-40</td>
<td>10(40%)</td>
<td>10(40%)</td>
<td>20(40%)</td>
</tr>
<tr>
<td>41-50</td>
<td>7(28%)</td>
<td>6(24%)</td>
<td>13(26%)</td>
</tr>
<tr>
<td>51-60</td>
<td>2(8%)</td>
<td>1(4%)</td>
<td>3(6%)</td>
</tr>
<tr>
<td>Total</td>
<td>25(100%)</td>
<td>25(100%)</td>
<td>50(100%)</td>
</tr>
<tr>
<td>Mean ± SD</td>
<td>36.96±9.05</td>
<td>35.88±8.16</td>
<td>36.42±8.55</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Gender</th>
<th>Test group</th>
<th>Control group</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Female</td>
<td>5(20%)</td>
<td>6(24%)</td>
<td>11(22%)</td>
</tr>
<tr>
<td>Male</td>
<td>20(80%)</td>
<td>19(76%)</td>
<td>39(78%)</td>
</tr>
<tr>
<td>Total</td>
<td>25(100%)</td>
<td>25(100%)</td>
<td>50(100%)</td>
</tr>
</tbody>
</table>
Table 3: Comparison of studied patients according to VAS Score

<table>
<thead>
<tr>
<th>VAS Score</th>
<th>Test group (Mean ± SD)</th>
<th>Control group (Mean ± SD)</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>0 day</td>
<td>7.48±1.12</td>
<td>7.88±1.09</td>
<td>0.208</td>
</tr>
<tr>
<td>14th day</td>
<td>5.96±1.34</td>
<td>6.28±1.28</td>
<td>0.391</td>
</tr>
<tr>
<td>21st day</td>
<td>5.08±2.04</td>
<td>7.04±1.67</td>
<td>&lt;0.001**</td>
</tr>
</tbody>
</table>

P value from 0 day

- 14th day: <0.001**
- 21st day: <0.001**

* Moderately significant, ** Strongly significant

Table 4: Comparison of studied patients according to OLBPS Score

<table>
<thead>
<tr>
<th>OLBPS Score</th>
<th>Test group (Mean ± SD)</th>
<th>Control group (Mean ± SD)</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>0 day</td>
<td>19.76±4.66</td>
<td>18.88±6.90</td>
<td>0.600</td>
</tr>
<tr>
<td>14th day</td>
<td>15.24±5.02</td>
<td>14.20±6.36</td>
<td>0.524</td>
</tr>
<tr>
<td>21st day</td>
<td>12.88±2.13</td>
<td>15.80±6.47</td>
<td>0.108</td>
</tr>
</tbody>
</table>

P value from 0 day

- 14th day: <0.001**
- 21st day: <0.001**

** Strongly significant

Discussion

The objective of this trial was to evaluate the efficacy of Hijamat-bila-Shart (Dry Cupping) in Waja-uz-Zahr (Low Back Pain). A total of 60 patients of either sex were divided into test group and control group comprising of 30 patients in each group. 25 patients in each groups completed the treatment. Both group patients treated accordingly, after 14 days of treatment the responses were assessed Visual Analogue Scale (VAS) and Oswestry low back pain scale (OLBPS). The discussion regarding demographic data, and objective parameters findings are as follows.

As shown in table no. 1. Out of 50 patients, 20 (40%) patients were observed in the age group 31-40 years. This data shows a higher incidence of Waja-uz-Zahr in patients between the age group 31-40 years. This data coincides with the studies conducted by Gunnar BJ Anderson, D. Hoy et al and Hanan SA [16, 5, 2]. They reported that the incidence of low back pain was highest in the third decade of the life. The eminent Unani scholar, Razi, also quoted in his treatise “Al-hawi-fit-Tibb” that Waja-uz-Zahr is not found in children which indicates the prevalence of it during Sin-e-Shabab which lasts from 25-40 years [17]. In table no. 2. Out of 50 patients, 39 (78%) patients were found male, 11 (22%) patients were female. This data coincides with the studies conducted by Punnet L et al and Hanan S.A they reported the incidence of LBP was highest in males because men has higher exposure due to higher rates of participation in heavy work or in office work at different educational level [6, 2]. Razi also stated that Waja-uz-Zahr is not found in females due their Mizaj-e-Barid and excretion of Movad-e-Fasida through regular menstrual cycle indicating the prevalence of disease more in males [17]. Low back pain was assessed by using VAS. On b. As more reduction in pain score was seen in test group as compare to control group so we concluded that the better result in test group in comparison to control group. The mean score on 0 day in Test group was 7.48±1.12, on 14th day it was 5.96±1.34, on 21st day it was 5.08±2.04. In Control group at 0 day, the mean score was 7.88±1.09, on 14th day it was 6.28±1.28 and on 21st day it was 7.04±1.67. The mean scores of VAS were compared from baseline statistically using Student t-test (paired) for intragroup comparison. In Test group the difference between the mean scores at 14th and 21st day with respect to baseline was found highly significant (p<0.001). While in control group, when it was compared from baseline to 14th day, it also was found highly significant (p<0.001) but on 21st day it seems moderately significant with respect to baseline (p<0.01). In level of disability on inter group comparison of mean score on 0 day, p value is 0.600, this reveals that homogenous data lies in both Test and Control groups. On 14th day by using t-test (unpaired), p value is 0.524 and 0.108 on 21st day. It is proved that statistically there is no significant difference immerged in both group after the intervention. On Intragroup comparison in Test group, OLBPS mean score at 0 day was 19.76±4.66, at 14th day 15.24±5.02 and at 21st day 12.88±6.13. In Control group, OLBPS score at 0 day was 18.88±6.90, at 14th day 14.20±6.36 and 21st day 15.80±6.47. When the mean scores of OLBPS in both the groups, were compared from baseline statistically using Student t-test (paired), it was found that the difference between the mean scores at 14th and 21st day was highly significant in Test as well as Control group (p<0.001). Results showed that patients in both test and control groups reported improvement, but the patients in the test group, who received Hijamat-bila-Shart (dry cupping) treatment scored significantly less on measures of pain and disability then the patients who received standard conventional treatment. We conclude that Hijamat-bila-Shart showed great results as an effective treatment for minimizing the nonspecific low back pain. This results congruent with Singh B et al [18]. Pain and tenderness is due to accumulation of Kham Balgham and Ghaleez Riyah in lumbar region, this accumulated Ghair Tabee Balgham produces condition of congestion, stagnation or blockage in lumbar structures and during movements pressure is exerted in these structures results pain. Hijamat-bila-Shart act on the principle of Imala-e-Mavad (diversion of morbid matter). The suction, applied during cupping, breaks up that congestion, stagnation, or blockage, restoring a free flow of humours. cupping also distract the pathogenic heat, toxins and inflammation by bringing them to the surface for release. By improving the blood circulation and breaking adhesion or blockages and congestions of offending waste matter, toxins and morbid humors, Hijamat-bila-Shart improves the eliminative functions and the evacuation of wastes from the organism. Unani Scholars advised that proper or timely elimination of wastes from the body forms an important aspect of hygiene. Whether it be constipation, urinary retention, or even suppressed menses, the undue retention of anything that should be expelled is a major cause of morbidity and disease [19, 20].

Conclusion

Hijamat-bila-Shart (Dry cupping) and Acetaminophen both are therapeutically effective in management of Waja-uz-Zahr (Low back pain). But Hijamat-bila-Shart was more effective in comparison to Acetaminophen. On above results Each group showed efficacy in objective parameter (VAS and OLBPS) at 14th day but after stopping the treatment, on final assessment that was on 21st day, it was found that the mean difference was more in test group in comparison to control group revealing the sustained efficacy of Hijamat-bila-Shart. Even, pain is increased in control group after stopping the treatment. In conclusion to develop side effects free and alternate treatment for the Low back pain, it is decided to assess the efficacy of Hijamat-bila-Shart. No adverse effects have been reported while using the Hijamat-bila-Shart during the study. On the basis of the above safety markers in the study, it can say that the Hijamat-bila-Shart is quite effective and safe in treating patients of Waja-uz-Zahr.
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Conflict of Interest: There are no conflicts of interest.

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References