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

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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 fortest 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 incomparison 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 *Ghaleez 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 occurence 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

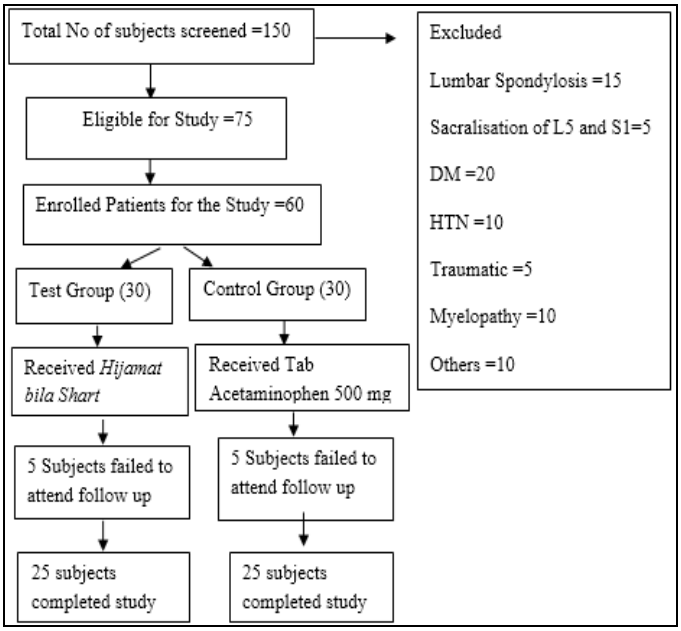
inside the cup so that it get attached on the body surface [7-11].These regimes are not properly documented and validated till date. However, the efficacy of dry cupping has been uncertain in the previous studies, most of the studies did not have control groups and there is lack of well-designed randomized controlled trials to investigate the efficacy of dry cupping, especially in the management of *Waja-uz-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 clearancefrom 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 toexpose 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, upto 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 2 female patients and cupping blisters were reported by 3 male patients of Test group during the treatment but all the patients completed their treatment.No recurrence was reported during follow up.Results on continuous measurements were presented on Mean ± SD (Min-Max). level of significance set at 5%, Student t test (Unpaired) and (paired) was used to find the significance between two groups (for Inter and intra group analysis) [12-15].

Table 1: Distribution of studied patients according to Age group

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

Table 2: Distribution of studied patients according to Gender

Gender	Test group	Control group	Total
Female	5(20%)	6(24%)	11(22%)
Male	20(80%)	19(76%)	39(78%)
Total	25(100%)	25(100%)	50(100%)

Table 3: Comparison of studied patients according to VAS Score

VAS Score	Test group (Mean ± SD)	Control group (Mean ± SD)	P value
0 day	7.48±1.12	7.88±1.09	0.208
14th day	5.96±1.34	6.28±1.28	0.391
21st day	5.08±2.04	7.04±1.67	<0.001**
P value from 0 day			
• 14th day	<0.001**	<0.001**	
• 21st day	<0.001**	<0.01*	

* Moderately significant, ** Strongly significant

Table 4: Comparison of studied patients according to OLBPS Score

OLBPS Score	Test Group (Mean ± SD)	Control Group (Mean ± SD)	P value
0 day	19.76±4.66	18.88±6.90	0.600
14th day	15.24±5.02	14.20±6.36	0.524
21st day	12.88±6.13	15.80±6.47	0.108
P value from 0 day			
• 14th day	<0.001**	<0.001**	
• 21st day	<0.001**	<0.001**	

** Strongly significant
Between group: Student t test (unpaired)
Within Group: Student t test (paired)

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 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 *Mavad-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 21th 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 21th 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 21th 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 21stday it seems moderatly 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 0.524and 0.108 on 21th 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±5.02and at 21st day12.88±6.13. In Control group, OLBPS score at 0 day was 18.88±6.90, at 14th day 14.20±6.36 and 21th 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 congurent 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 Tabaee 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* (diverson 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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