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Clinical evaluation of *Hijamat Bila Shurt* (Dry cupping) in the management of *Waja ul zahar* (Low Back Pain) - A randomized, single blind, standard controlled study

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Abstract

Wajaul Zahar (Low back pain) is the most common pain in the lumbosacral region seen in general practice, about 20% of such cases need to be referred to orthopedics clinics. Around 60-80% of the world's population experiences back pain some time in their lives. The pain is short lived and responds to symptomatic measures. Around 200,000 years ago the Neanderthal man did not experience back pain because they were not yet fully vertical as human beings assumed upright posture the manifestation of back pain grew almost proportionately to the progress in civilization.

Ilaj bil Hijamat (Cupping therapy) is one of the oldest methods of treatment for LBA which was used by Unani physician (since ancient time till date). It is used locally for diversion of humors causing pain at the back by creating negative pressure by vacuum pump (cupping cups). Interventions were given in a total of 40 patients, in 20 patients was applied *hijamat bila shurt* for six sittings at 0, 3, 6, 9, 12 and 15th day and 20 patients were administered diclofenac sodium 50 mg twice a day for 15 days. The result was clinically significant in both therapies, but *hijamat bila shurt* was more effective in comparison to diclofenac sodium.

Keywords: *Wajaul zahar*, *Hijamat bila shurt*, diclofenac, VAS

1. Introduction

Wajaul Zahar (Low back pain) is the most common pain in the lumbosacral region seen in general practice, about 20% of such cases need to refer orthopaedic clinics. *Wajaul Zahar* becomes a major social and health problem with frequent cause of activities limitation in people specifically among individuals less than 45 years of age. It is the 2nd most frequent reason to visit physician, the 5th most cause for hospitalization and 3rd most cause for surgical procedures. Some of the survey reports revealed that the world's population experience's back pain and reported its consequences as a loss of more than 50 million days of work each year, approximately 1.4 working days per person per year. 25% of all disabling occupational injuries and 10-15% of all sickness related absence significantly increase in the last 30 years with low back pain. In 4th century B.C Hippocrates (460-377 BC) defined back pain with its causes as predominance of phlegm, later it was a concern for centuries, but in the early twentieth century distraction of the sacroiliac joint was considered as the cause of back pain, whereas, the most striking cause is supposed to be musculoskeletal origin. Only a small number of patients with back pain will have definable pathology with or without radicular's symptoms or musculoskeletal or degenerative disorders that do not require specific treatment and often are self-limiting. *Wajaul Zahar* is usually treated with oral or parenteral administration of NSAID's, which will cause several side effects.

Unani system of medicine there are three methods of treatment: *Illaj bil Tadabeer* (Regimenal therapy), *Illaj bil Dawa* (Pharmacotherapy) and *Illaj bil Yad* (Surgery). *Hijamat* is an important regimen of *Ilaj bil tadabeer*. *Hijamat* is an Arabic name of cupping derived from the word *hijama*, which means sucking. It works on the principle of *imalae mawad* (diversion/ shunting of morbid matter/ fluid) from the affected area. [1-10].

2. Methodology

The clinical study was conducted in Hospital of National Institute of Unani Medicine, Bangalore. Before embarking upon the patients, a comprehensive protocol was chalked out

with the ethical clearance for bio-medical research from institutional ethical committee of National Institute of Unani Medicine (NIUM). After the ethical clearance, clinical study was started by enrolling eligible patients from the OPD and IPD into test and control groups by random allocation.

2.1 The Inclusion Criteria

(1) Clinically and radiologically diagnosed patients, (2) Either sex, (3) Patient in age group of 20-60 years, (4) LBP due to faulty posture, (5) LBP due to osteoarthritis, (6) LBP due to lumbar spondylitis (7) LBP due to lumbar spondylolisthesis, (8) Agreed to sign the informed consent and follow the protocol.

2.2 The Exclusion Criteria

(1) Age less than 20 years and more than 60 years, (2)

Pregnancy and lactation, (3) Systemic illness such as Liver, Kidney, Cardiac disorders, Diabetes mellitus, Hypertension, Osteomyelitis, Tuberculosis, Overweight and Spinal injuries. (4) Congenital causes of the backache. (5) Spinal deformity, (6) Referred pain, (7) Trauma etc.

2.3 The Subjective parameters

Low back pain, Tenderness in the low back and Difficulty in movements (DOM).

2.4 The objective parameters

The efficacy was assessed by the Visual Analogue Scale (VAS), ten point scales.

Safety was assessed by clinically and radiological examinations. Adverse events were recorded at every visit after the base line visit.

Table 1

	Grade	Nature of pain	Pain associated with
Grades of pain	0-0	No pain	No pain
	1-3	Mild pain	Pain after walking a distance of 200 meter.
	4-6	Moderate pain	Pain after walking a distance of 100 meter.
	7-10	Severe Pain	Pain at household activities.
		Nature of tenderness	Characteristic tenderness
Grades of tenderness	0-0	No Tenderness	No tenderness
	1-3	Mild Tenderness	Mild, barely perceptible (patient says it is tender)
	4-6	Moderate Tenderness	Patient says it is tender, winces and pulls back
	7-10	Severe Tenderness	Patient does not allow palpation, not allow to press
		Nature of movement	Characteristic of movement
Grades of difficulty in movement	0-0	No Difficulty	No difficulty in movement
	1-3	Mild	Difficulty after movement a short distance
	4-6	Moderate	Difficulty after movement a long distance
	7-10	Severe	Unable to movement

2.5 The duration of protocol

The total duration of protocol therapy was 15 days.

2.6 The sample size

The sample size was fixed as 40 patients, divided into two groups, Group A: 20 Patients: *Hijamat Bila Shurt* (Dry cupping) and Group B: 20 Patients: Tab. Diclofenac sodium (DS).

2.7 Treatment Procedure and Follow Up

Group A, patients were treated with *Hijamat bila shurt* (HBS) in 6 sittings (0, 3rd, 6th, 9th, 12th, and 15th days) with an interval of two days. The selected patients were subjected to *Hijamat bila shurt* over Lumbosacral region with six cups (06) of same calibers (No. 6) manual suction cups were applied bilaterally parallel over the low back area, and left it for 20 minutes. Group B, patients were treated with standard control Diclofenac sodium 50 mg orally twice a day for 15 days.

2.8 Assessment of Mizaj

In each selected patient mizaj was assessed based on the *Ajnase Ashra* mentioned in Unani literature. Separate temperament assessment Performa has been enclosed with each case report form.

2.9 Investigation

(1) X-ray L-S spine. (2) Blood investigation: Hemoglobin, TLC, DLC, ESR and RBS. (3) Urine: Routine and microscopic was carried out to rule out for Albumin, Sugar, Pus cells and RBCs. (4) LFT: SGOT, SGPT and Serum Alkaline Phosphates. (5) RFT: Serum creatinine, Blood urea.

3. Allocation of patients

Total number of patients screened 52 of the *Wajaul Zahar* were enrolled in the study. Out of which 40 patients were completed course of treatment. 12 patients did not complete follow-up.

3. Result

It was a comparative evaluation of test and control groups. The 40 patients were completed the study out of 52 patients because 12 patients were drop out.

The response was noted on a five point scale. *Excellent response* = improvement of three grades. *Good response* = improvement of two grades. *Poor response* = improvement of one grade. *No response* = no change in the grade. *Worse response* = increase of the grade.

Statistical analysis: Quantitative analysis of the data was expressed as median with range and differences between two groups were compared by *Kruskall Wallis (Non parametric ANOVA)* test with port his Dunn's multiple pair comparison test.

Table 2: Demographic data of patients on entry

Parameters	Hijamate bila shurt & Diclofenac sodium
Age (years) mean	20 60
Weight (kg) mean	68 56
Sex ratio (male & female)	4:1
Mizaj	Damvi 20%, Balghami 75%, 05% Safravi and 00% Saudavi
Dietary habit	85% Mixed and 15% Vegetarian
Community	Muslim 60% and 40% Hindu
Marital status	90% Married and 10% Unmarried
Occupation	45% Laborers, 20% House wife, 15% Auto driver, 10% Tailor, 5% Student and Policemen.
X-ray Finding	70% Normal study, 30% Degenerative,
Body weight	40% 71-80 kg, 30% 61-70 kg, 20% 51-60 kg, 10% 41-50.
Responses	Excellent in 35%, Good in 40%, Poor in 20% and No response in 5%.

Table 2(A): Effect of HBS & Diclofenac sodium on VAS for pain in LBP.

Groups	Baseline	1 st	2 nd	3 rd	4 th	5 th
A	4 (2, 6)	4 (2, 6)	3 (2, 5)	2.5 (1, 4)	2 (1, 3) *	2 (0, 2) **
B	4 (2, 6)	-	-	-	-	2 (1, 4) Δ

N = 20 patients in each group, test used *Kruskal-Wallis* (Non parametric ANOVA) test with port his Dunn's multiple pair comparison test.

* $P < 0.05$ compared with respect to baseline score group A, ** $p < 0.01$

Δ $p < 0.05$ compared with respect to baseline score group B, Δ $p < 0.01$

Table 2(B): Effect of HBS & Diclofenac sodium on VAS for tenderness in LBP.

Groups	Baseline	1 st	2 nd	3 rd	4 th	5 th
A	4 (2, 6)	4 (2, 6)	3 (2, 5)	2.5 (1,5)	2 (1, 5)	2 (0, 5) *
B	4 (2, 6)	-	-	-	-	2.5 (1, 5) Δ

N = 20 patients in each group, test used *Kruskal-Wallis* (Non parametric ANOVA) test with port his Dunn's multiple pair comparison test.

* $P < 0.05$ compared with respect to baseline score group A, * $p < 0.01$

Δ $p < 0.05$ compared with respect to baseline score group B, Δ $p < 0.01$

Table 2(C): Effect of HBS & Diclofenac sodium on VAS for difficulty of movement in LBP.

Groups	Baseline	1 st	2 nd	3 rd	4 th	5 th
A	4 (2, 6)	4 (2, 6)	3 (2, 5)	2.5 (1, 4)	2 (1, 3)	2 (0, 3) *
B	4 (2, 6)	-	-	-	-	2 (1, 4) Δ

N = 20 patients in each group, test used *Kruskal-Wallis* (Non parametric ANOVA) test with port his Dunn's multiple pair comparison test.

* $P < 0.05$ compared with respect to baseline score group A, * $p < 0.01$

Δ $p < 0.05$ compared with respect to baseline score group B, Δ $p < 0.01$

4. Discussion

The study was conducted to evaluate the efficacy of a *Hijamat Bila Shurt* with diclofenac in *Wajaul Zahar*. They were treated accordingly, on completion of 15 days treatment the responses were assessed based on ten points scale and Visual Analogue Scale. The discussion regarding demographic data, clinical symptoms and objective and subjective parameters findings are as follows.

In this study a maximum of 18 (45%) of the patients aged between 41-60 years were recorded which coincides with API's description as the highest prevalence of LBP is in persons aged between 45- 65 years [11].

This study reveals that the prevalence of the disease is more in male, as because out of 40 patients 32 (80%) were found to be male only, which is highly contrary to the description of Harrison's principles of internal medicine, but this may be due to the high enrollment of the male patients [12].

Out of 40 patients both in test and control group, 24 (60%) belongs to Muslim community and 16 (40%) Hindu community. This is may be due to the high number of patients attending NIUM hospital.

As far as the marital status of the patients concerned, 36 (90%)

were married and 4 (10%) were unmarried.

In this study, out of 40 patients, 34 (85%) were found to be having mixed dietary habit, whereas 06 (15%) were of vegetarian.

A maximum of 30 (75%) of *Balghami mizaj* patients were found in this study followed by 08 (20%) *Damavi* and 2 (5%) *Safravi*. No patient with *Saudavi mizaj* was found. This finding is in accordance to the description given by Ibn Sina, Ahmed bin Mohammed Tabri that disease is more frequent in people with *Balghami Mizaj* [13, 14].

This study reported that the high incidence of *Wajaul Zahar* with 18 (45%) was found in labourers, followed by 08 (20%) house wife, 06 (15%) auto driver, and 04 (10%) tailor, 02 (5%) student, and 02 (5%) policemen. This resembles the incidence rate mentioned by Harrison principles of internal medicine as 50% of working labour adults were the victims of the disease [12].

Out of 40 patients of *Wajaul Zahar*, 16 (40%) had high body weight that is between 61-70 kg, followed by 10 (25%) between 51-60 kg, 08 (20%) between 71-80 kg, 04 (10%) between 41-50 kg and 02 (5%) were between 81-90 kg.

X-ray findings in this study evidences that out of 40, 28 (70%)

patients of *Wajaul Zahar* presented normal study, and 12 (30%) with degenerative findings, which inversely reflects the reports mentioned in the text book of medicine described by Souhami. R. L and J. Moxham as 25% of the case of LBP were found with normal study and 50% with degenerative findings^[15].

Before starting the treatment in Group – A, 17 (85%) patients, has pain in moderate grade and 3 (15%) patients, severe pain. After the treatment 12 (60%) patients came down from moderate to mild degree. Only 8 (40%) patients remained in moderate grade. In Group –B, 15 (75%) patients, has pain in mild grade 2 (10%) in moderate and 3 (15%) patients in severe grade. After treatments 14 (70%) patients in mild and 5 (25%) patients in moderate grade, only one patient in severe grade, Before starting the treatment in Group A, 7 (35%) patients, has tenderness in mild 13 (65%) in moderate tenderness. After the treatment, 1 (5%) patient improved completely, after the treatment 15 (75%) patients came down from moderate to mild degree. Only 4 (20%) patients remained in moderate grade. In Group –B, 6 (20%) patients, has tenderness in mild grade 14 (80%) in moderate grade. After the treatments 18 (90%) patients, came down from moderate to mild degree.

As shown in the out of total number of patients, Before starting the treatment in test group – A, 11 (55%) patients, has difficulty of movement in mild, 9 (45%) in moderate difficulty of movement. After the treatment, 16 (80%) patients in mild, 1 (5%) patients in moderate degree. In control group – B, 15 (75%) patients, has difficulty of movement in mild grade 1 (5%) in moderate grade. After the treatments 17 (85%) patients, came down from moderate to mild degree. 2 (10%) patients in moderate degree only.

Mean VAS scores before treatment in Group A was 4.30, Group B 4.57, after treatment it was found to be at 2.35 in Group A, 2.79 in Group B. This data statistically found significant in all groups at p values < 0.001. A significant improvement ($P = < 0.001$: *Kruskall – wallis*) was observed in test group when the pre and post values of pain, Tenderness and difficulty of movement were compared between the test and control groups.

5. Conclusion

Hijamat bila shurt (Dry cupping) and Diclofenac sodium are clinically significant in management of *Wajaul zahar* (Low back pain). But *Hijamat bila shurt* was more effective in comparison to Diclofenac sodium. In conclusion to develop side effects free and alternate treatment for the Low back pain, it is decided to assess the effect of *Hijamat bila shurt*. No adverse effects have been reported while using the *Hijamat bila shurt* during the study. Each group evidence relief in pain, tenderness and difficulty of movement after the third follow up on wards. On the basis of the above safety markers in the study, it can say that the *Hijamat bila shurt* is quite effective and safe in treating patients of *Wajaul Zahar*.

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