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Imrana Hafeez
Professor & HOD Moalejat, AU Medical College and ACN Hospital, Aligarh, Uttar Pradesh, India

Zoheb Alam Khan
Assistant Professor, NIUM, Ghaziabad, Uttar Pradesh, India

Hamid Ali
Assistant Professor, Department of Amraze Jild Wa Tazeeniyat, A & U Tibbia College and Hospital,Karol Bagh, New Delhi, India

Corresponding Author:
Zoheb Alam Khan
Assistant Professor, NIUM, Ghaziabad, Uttar Pradesh, India

Comparative efficacy of Hijama Bila Shart and TENS in the management of chronic non-specific low back pain: A randomized controlled study

Imrana Hafeez, Zoheb Alam Khan and Hamid Ali

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Abstract

Background: *Waja'uz zahr* (Low Back Pain) is not a definite disease; rather it is an indication that may arise as a result of pathology from a variety of disorders. Low back pain is frequently described as discomfort in the lumbosacral region. It affects approximately 60-85% of population resulting in a major burden to society. In *Unani* system of medicine, many physicians have mentioned numerous drugs and regimens in their classical texts for the treatment of *Waja'uz zahr.* So keeping this in mind, one such regimen *Hijama bila shart* was selected.

Objective: The objective of present study was to evaluate the effect of *Hijama bila shart* in the management of *Waja'uẓ zahr* (Chronic non-specific Low back pain).

Materials and Methods: The study was conducted as an Open, randomized, controlled, clinical study between September 2018 to March 2020 and a total of 40 patients, having low back pain, were included in this study. The enrolled patients were randomly allocated into two groups: A (n=20) and B Groups (n=20). The patients of group A were treated with *Hijama bila shart* while the patients of group B were given TENS. Total 8 sittings were done in 14 days. The patients were assessed using the Visual Analog Scale (VAS) and Oswestry Disability Index (ODI), before (0 Day) and after the treatment (14th Day). The results of both the therapies were compared and statistically analyzed.

Results: After intervention, in test group, highly significant (p<0.001) reduction was observed in VAS scale (95.95±0.51 to 3.05±0.39) as well as ODI score(26.6±4.16 to 9.95±4.07) while in the control group there was moderately significant reduction in VAS scale (6.05±0.88 to 4.2±0.61) as well as ODI score (26.3±4.54 to 13.85±3.08).

Conclusion: This study reveals that *Hijama bila shart* in test group and TENS in control group were found significant in the treatment, but *Hijama Bila Shart* had a slight edge over TENS. *Hijama bila shart* appears to be effective in reducing pain and increasing function and quality of life in patients with *Waja'uẓ zahr.*

Keywords: *Unani*, Low back pain, *Waja'uẓ zahr*, *Hijama bila shart*, TENS

Introduction

Low back pain (LBP) is one of the most prevalent, vexing, and diagnostically challenging medical conditions affecting humanity. It results in more impairment than any other medical problem globally [1, 2]. Low back pain is pain or discomfort in the lumbar area, situated below the costal border (12th rib) and above the gluteal folds, which may or may not radiate to the thigh [3, 4]. In the Unani system of medicine, *Waja'* (pain) is seen as a discordance inside the body, resulting from abrupt alterations in *Mizaj* (temperament), specifically *Sui mizaj mukhtallif* (disturbed temperament) and *Tafarruqe ittasal* (disruption of continuity). The newly generated aberrant temperament may manifest as *Har* (Hot) or *Barid* (Cold), in contrast to the original temperament [5, 6]. The experience of pain is a significant expression of these changed temperaments. In traditional Unani literature, *Waja'uz zahr* is categorized under the primary heading of *Waja'ul mafasil*. *Waja'uz zahr* is characterized as a condition in which pain emanates from the internal and peripheral muscles, as well as the ligaments encircling the lumbar and lumbosacral areas, resulting from an imbalance in *Mizaj (Su-i-Mizaj)*. This *Su-i-Mizaj* results from an excess of *Burudat* and the buildup of *Kham Madda* [5].

Low back pain is the most prevalent occupational condition worldwide, affecting 60%-80% of individuals at some stage in their lives. The yearly incidence of low back pain is estimated at 5% per year, with a corresponding prevalence ranging from 60% to 90%.

The prevalence was greater in males (10.1%) than in women (8.7%) [7]. Low back pain is divided into specific and generic categories, which are further classed as acute or chronic. Non-specific low back pain is characterized as low back pain that cannot be linked to a discernible, identifiable particular disease (e.g., infection, tumor, osteoporosis, lumbar spine fracture, structural deformity, inflammatory illness, radicular syndrome, or cauda equina syndrome) [8]. Non-specific low back pain is often classified into three subtypes: acute, sub-acute, and chronic low back pain. This classification is based on the length of the back discomfort [9]. Acute low back pain lasts less than 6 weeks, sub-acute low back pain persists between 6 and 12 weeks, and chronic low back pain endures for 12 weeks or more [10, 11]. The management of low back pain poses difficulties for both patients and healthcare practitioners [12]. Although The conventional medical system offers effective treatment options for low back pain, including rest, physiotherapy such as TENS and superficial thermotherapy, systemic or topical medications like NSAIDs, muscle relaxants, and corticosteroids; traction, lumbo-sacral belts, and surgery [13, 14]. However, their results are unsatisfactory and have been dismissed due to adverse effects or surgical complications.

Complementary and alternative medicine treatments have gained popularity over the last two decades owing to discontent with conventional medicine and patients' desire for more involvement in their medical decision-making [15]. Contemporary pain relief methods are mostly short-term and exhibit significant side effects; however, the Unani approach to pain management sustains hope via a comprehensive methodology including particular techniques such as *Ḥijama, Faṣd, Dalk*, and *Abzan*. In instances of *Su-i-Mizaj* and the accumulation of *Akhlaṭ-i-fasida* (morbid humors), the treatment approach should focus on *Tanqiya* and *Tadeel*, which aim to restore and normalize the *Mizaj* and *Akhlaṭ*, the primary sources of discomfort. This is accomplished through various *Tadabīr* or regimens, including *Hijama, Fasd*, Dalk, and *Nutool*. Among the aforementioned regimens, *Hijama bila Shart* is often recommended to eliminate *Mawade Fasida* and alleviate the symptoms of *Waja'uz zahr*; nonetheless, it remains devoid of scientific support. Due to the severe adverse effects of pharmacological treatments for the condition, the pursuit of a reasonably safe and effective therapeutic approach has been a focal point for study in medical science. Therefore, considering the aforementioned facts, we want to conduct research to assess and compare the effects of *Hijama bila shart* and TENS in the treatment of *Waja'uz zahr* in chronic non-specific low back pain.

Methodology

Study Design: This open, randomized, controlled clinical trial aimed to evaluate the efficacy of *Hijama Bila Shart* (Dry Cupping) in managing chronic non-specific low back pain (*Waja'uz Zahr*). The study was conducted from September 2018 and March 2020. Ethical clearance was obtained from the Institutional Ethics Committee, and the study adhered to the Declaration of Helsinki guidelines.

Participant Selection: A total of 180 patients presenting with chronic low back pain were screened, out of which 55 met the eligibility criteria. Clinical and laboratory investigations were conducted to confirm eligibility, and 46 patients provided written informed consent. Of these, 40 patients completed the study protocol, as six patients were lost to follow-up.

Inclusion and Exclusion Criteria

Participants were eligible if they were aged 20 to 60 years, of either gender, diagnosed with chronic non-specific low back pain without radiating symptoms, and willing to participate and adhere to the study protocol. Exclusion criteria included a history of major trauma or systemic disorders, pregnancy or lactation, prolapse of intervertebral discs, low back pain secondary to malignancy or autoimmune conditions, and congenital spinal deformities other than lordosis or scoliosis.

Randomization and Group Allocation

Participants were randomly assigned to one of two groups using a lottery method. Group A (Test Group) received *Hijama Bila Shart*, while Group B (Control Group) received Transcutaneous Electrical Nerve Stimulation (TENS). Due to the nature of the interventions, blinding of participants and practitioners was not feasible. Each group received eight treatment sessions over a 14-day period, with assessments conducted on Days 0, 2, 4, 6, 8, 10, 12, and 14.

Intervention Details

Hijama Bila Shart (Group A) Participants were positioned comfortably, either in a sitting or prone position. The lumbosacral area was cleaned with spirit and betadine, and hair was removed as necessary to ensure proper cup adherence. Two medium-sized cups (diameter 5.5 cm) were applied bilaterally to the paravertebral lumbosacral region. Negative pressure was created using a vacuum pump with 3-4 suctions per cup, and the cups were retained for 10 minutes. Adverse reactions, such as blister formation, were monitored during each session.

TENS Therapy (Group B) Participants were positioned in the prone position. Electrode pads were placed in a crossed pattern over the lumbar paravertebral region. The intensity of stimulation was adjusted to the patient's tolerance, ranging from 0 to 60 milliamps. Each session lasted for 20 minutes.

Outcome Measures

Primary Outcome Pain intensity was measured using the Visual Analog Scale (VAS) [16].

Secondary Outcomes Functional disability was assessed using the Oswestry Disability Index (ODI) [17]. Additional assessments included tenderness and difficulty in walking, evaluated using a four-point scale (0 = none, 1 = mild, 2 = moderate, 3 = severe).

Baseline Investigations

To exclude participants with underlying conditions specified in the exclusion criteria, the following investigations were conducted:

- X-ray imaging of the lumbosacral spine (AP and lateral views).
- Hemoglobin percentage (Hb%), total leukocyte count (TLC), differential leukocyte count (DLC), and erythrocyte sedimentation rate (ESR).
- Random blood sugar (RBS) levels (participants with RBS >200 mg/dl were excluded).
- Electrocardiogram (ECG).

Data Collection and Statistical Analysis

Data were collected at baseline and after the intervention. Continuous variables were expressed as mean ± standard deviation (SD), while categorical variables were presented as frequencies and percentages. Paired t-tests were used for within-group comparisons, and independent t-tests were used for between-group comparisons. A p-value of <0.05 was considered statistically significant. Statistical analysis was performed using SPSS version 25.0.

Ethical Considerations

All participants were informed about the study objectives, procedures, and potential risks. Written informed consent was obtained prior to participation. The confidentiality of patient data was maintained throughout the study, which adhered to international ethical standards.

Results and Discussion

Table 1: Summary of Patient Demographics, Intervention Effects, and Comparative Outcomes Between Group A (Hijama) and Group B (TENS)

Age (Mean \u00b1 SD)	**39.7 \u00b1 7.72**	**42.6 \u00b1 9.99**	**0.28 (NS)**
Gender			
Male	15	11	1.76 (NS)
Female	5	9	
VAS (Mean \u00b1 SD)			
Day 0	5.95 \u00b1 0.51	6.05 \u00b1 0.88	<0.0001
Day 14	3.05 \u00b1 0.39	3.2 \u00b1 0.61	
ODI (Mean \u00b1 SD)			
Day 0	26.6 \u00b1 4.16	26.3 \u00b1 4.54	0.03
Day 14	9.95 \u00b1 4.07	13.85 \u00b1 3.08	
Tenderness			<0.001
No tenderness (Day 14)	70%	65%	
Walking Difficulty			<0.001
No difficulty (Day 14)	80%	65%	
Hemoglobin (Hb%)	14.29 \u00b1 1.25	13.64 \u00b1 1.39	0.03
Total Leukocyte Count (TLC)	6990 \u00b1 2311.28	7850 \u00b1 1579.31	0.25
Erythrocyte Sedimentation Rate (ESR)	6.55 \u00b1 2.93	9.75 \u00b1 7.88	0.08

Age: In present study, the maximum no of subjects 17 (42.5%) were in the age group of 31-40 years, followed by 12 (30%) in the age group of 41-50 years, and 6(15%) in the age group of 51-60 years respectively; Only 5 (12.5%) were below the age of 30 years. Mean age of the patient enrolled was 41.15±8.93. This data shows a higher incidence in patients below the age group of 31-40 years, which coincides with the studies conducted by D. Hoy *et al*. which found the incidence of LBP highest in the third decade of life, these results are further supported by *Zakaria Razi*, who have quoted the same in his book Al Hawi, that the prevalence of *Wajaul mafasil* is more in the age of *Sin- e-Shabab* (age of maturity) which last from 25 to 40 years [18].

Gender: Our study population comprised predominantly of males 26 (65%) while remaining 14 (35%) was females (Figure no. 3). In several studies the higher prevalence of LBA has been documented in women [19], which does not coincide with our observation, the reason may be the negligence on the part of the women.

Marital status: As far as the marital status of the patients is concerned, 39 (97.5%) were married and 1 (2.5%) unmarried. This indicates that LBP is more common among unmarried patients; which strongly coincides with the studies conducted by A Charlotte*et al*. and Sanchez SJ et.al [20, 21]. Our observation is also in conformity with the etiology mentioned by *Akbar Arzani* in *Tibb e Akbar* and *Jurjani* in *Zakhira Khawarzam Shahi*, that indulge in excessive sexual life is one of the cause of *Waja'uz zahr* [22].

Duration of pain: In relation to the duration of pain, 13 (32.5%) subjects were having pain since 4 months, followed by 9 (22.5%) subjects who complained history of pain since 5 months, 7(17.5%), 5 (12.5%) and 4 (10%) subjects were having history of pain since 6, 8 and 3 months respectively. 1 (2.5%) each have duration of pain since 1 and 2 months respectively. Our study somehow coincides with Ganesan S *et al*, which showed that duration of pain is more in low back pain patients [23].

Assessment parameters

VAS (Visual Analogue Scale): In test group, highly significant reduction was observed in VAS Scale from baseline 5.95±0.51 to 3.05±0.39 after 14 days of intervention and mean difference was 2.9 (p<0.001). In Control group moderately significant reduction was observed in VAS Scale from baseline 6.05±0.88 to 4.2±0.61 after 14 days of intervention and mean difference was 1.85, (p<0.01). On analysis of data, it was found that test group (*Hijama*) lead to greater reduction than control group (TENS) in mean difference (2.9 v/s 1.85) after 14 days, and this difference was highly significant (p<0.001). (Fig no 9)

OLBP: In test group highly significant reduction was observed in OLBP Score from baseline 26.6±4.16 to 9.95±4.07 after 14 day of intervention and mean difference was 16.65, (p<0.03). In Control group moderately significant reduction was observed in OLBP Score from baseline 26.3±4.54 to 13.85±3.08 after 21 day of intervention.(Table no 10,11) On analysis the data, it was found that test group *Hijama*) lead to greater reduction than control group (TENS) after 14 days, and this difference was highly significant (p<0.001).

Tenderness in low back: Tenderness was assessed on a 4 point arbitrary scale of 0, 1, 2, 3 i.e. nil, mild, moderate and severe respectively. In group A, at baseline 2 patients (10%) had no tenderness, 8 patients (40%) had mild tenderness, 3 patients (15%) had moderate tenderness and 7 patients

(35%) had severe tenderness. At the end of 14 days of treatment 14 patients (70%) had no tenderness, 6 patients (30%) had mild tenderness, and 0 patients (0%) had moderate and severe tenderness. Paired proportion test was applied. There was an improvement with respect to baseline (p<0.001**). (Table no 12) In group B, at baseline 2 patients (10%) had no tenderness, 7 patients (35%) had mild tenderness, 6 patients (30%) had moderate tenderness and 5 patients (25%) had severe tenderness. At the end of 14 days of treatment 13 patients (65%) had no tenderness, 5 patients (25%) had mild tenderness, and 1 patient (5%) had moderate tenderness and severe tenderness. Paired proportion test was applied. There was an improvement with respect to baseline (p<0.001**) but Group A tenderness improvement has an edge over improvement of Group B.

Difficulty in walking

Difficulty in walking was assessed on a 4 point arbitrary scale of 0, 1, 2, 3 i.e. nil, mild, moderate and severe respectively. In group A, at baseline 5 patients (25%) had no difficulty in walking, 5 patients (25%) had mild difficulty in walking, 6 patients (30%) had moderate difficulty in walking and 4 patients (20%) had severe difficulty in walking. At the end of 14 days of treatment 16 patients (80%) had no difficulty in walking, 3 patients (15%) had mild difficulty in walking, 1 patient (5%) had moderate difficulty in walking and 0 patients (0%) had severe difficulty in walking. Paired proportion test was applied. There was an improvement with respect to baseline (p<0.001**). (Table no 14) In group B, at baseline 5 patients (25%) had no difficulty in walking, 4 patients (20%) had mild difficulty in walking, 8 patients (40%) had moderate difficulty in walking and 3 patients (15%) had severe difficulty in walking. At the end of 14 days of treatment 13 patients (65%) had no difficulty in walking, 5 patients (25%) had mild difficulty in walking, and 1 patient (5%) had moderate difficulty in walking and severe tenderness. Paired proportion test was applied. There was an improvement with respect to baseline (p<0.001**) but in Group A difficulty in walking improvement has an edge over improvement of Group B.

Pain and tenderness in *Waja'uz zahr* originates due to the accumulation of *Akhlate Fasida (*mainly *Ghair Tabyee Balgham*) in the joint structures of lumbosacral region that leads to *Sue Mizaj Barid* (sue mizaj mukhtalif) [2]. As the pain fibers are present in the structures of the lumbosacral joints like capsules, tendons, ligaments, blood vessels etc. Thus the pressure exerted on these structures due to accumulated fasid *madda*, *riyah*, disc protrusions, osteophytes, trauma or by simple *Sue mizaj mukhtalif*, gives rise to pressure symptoms i.e. low back pain and tendernes.

Hijama bila shart (Dry Cupping) is one of the oldest and most effective methods of treatment practiced in *Unani* system of medicine. As it is clearly described in Unani text that the main cause of the disease is the imbalance of Akhlat (Humour), when it accumulates in a particular organ, it causes the abnormal functioning. In case of *Hijama bila Shart* (Dry cupping) which works on the principle of *Imalae Mawad*, causes the diversion of morbid matter from one site to another, when these morbid matters are gets away from the diseased part the *Tabiyat Mudabbarae Badan* takes in the part and helps the body to restores the normal condition.

There is converging evidence that *Hijama bila shart* can induce comfort and relaxation on a systemic level and the resulting increase in endogenous opioid production in the brain leads to improved pain control [24] Many theories have been suggested to explain numerous effects of *Hijama* therapy and its mechanisms of action [25]. Several researchers proposed biological and mechanical processes associated with the Hijama session. For instance, reduction of pain may result from changes in biomechanical properties of the skin as explained by the "Pain-Gate Theory" (PGT) [26], "Diffuse Noxious Inhibitory Controls" (DNICs) [27] and "Reflex Zone Theory" (ZRT) [28].

Many other theories are also given to describe the mechanism of action of *Hijama* (cupping), Hong *et al*. [29] described that *Hijama* (Cupping) acts by creating specific changes in local tissue structures as a result of local negative pressure in the cups used which stretches the nerve and muscle causing an increase in blood circulation and causing autohemolysis, while Gao *et al* [30] suggested that putting cups on selected part on the skin produces hyperemia or hemostasis which results in a therapeutic effect. Another theory *Taibah theory* suggested that when negative pressure (suction force) is applied to the skin, it causes decrease in pressure (Boyle's law) around capillaries. This results in increased capillary filtration, local collection of filtered fluids, lymph and interstitial fluids and their retention inside skin up lift part. This dilutes chemical substances, inflammatory mediators, and nociceptive substances, bathes nerve endings in collected fluids and breaks tissue adhesions causing decreased pain [31].

Conclusion

In present study, the allocated treatment; i.e. *Hijama bila shart* in test group (Group A) was highly significant but TENS in control group (Group B) was found moderately significant in the treatment of *Waja'uz zahr*. In fact a more reduction in mean score was found in the test group than the control group and the intergroup comparison on completion of the treatment protocol was also found significantly different, which signifies that *Hijama bila shart* has superior effect on TENS therapy in the treatment of *Waja'uz zahr*.

Limitations

Present study has shown no clinically significant adverse effects, and overall compliance to the treatment of two groups was creditable. Some of the potential limitations are inherent in this study which comprises small sample size, short duration of the study and limited parameters of assessment. Thus, it is recommended that future clinical trial should be done on larger sample size, for longer duration involving other comprehensive assessment scales.

Conflict of Interest

Not available.

Financial Support

Not available.

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