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Original Article - Clinical Study (Unani)

A randomized controlled clinical study to evaluate the efficacy of *Hijamah* (wet cupping) in *Irq-un-Nasa* (Sciatica)

Mohd. Yaqoob[1], Yasmeen Shamsi[2], Mohd. Wasi Akhtar[3], Abhinav Jain[4], Roohi Azam[5], Sohrab A. Khan[6]*

ABSTRACT

Background: Sciatica is "pain in the lower back and hip which radiates to the distribution of the sciatic nerve due to its affection". In the Unani system of medicine, sciatica is known as *Irq-un-Nasa; Hijamah* (wet cupping) is recommended as one of the treatment options for its management. In the modern system of medicine, sciatica is treated by NSAIDs and/or spinal surgery. **Objectives:** This study was conducted to evaluate the safety and efficacy of *Hijamah* to manage sciatica. **Materials and Methods:** This was an open-label, prospective, and randomized controlled clinical study. *Hijamah* (wet cupping) was done on *Warik* (gluteal depression) and *Fakhiz* (lateral aspect of mid-thigh) of the affected side in group A patients (n=27); and on *Saaq* (over calf muscle) and *Kaab* (below lateral malleolus) in group B patients (n=25) on day 0, day 14 and day 28. **Results:** The pain (VAS score) was reduced from 65.52 ±8.90 to 20.18±10.96 ($p<0.001$) in group A; 65.40±9.03 to 21.00±10.99 ($p<0.001$) in group B patients. The bothersomeness (SBI score) was reduced from 14.67±4.21 to 5.37±3.00 ($p<0.001$) in group A patients; 14.88±3.28 to 4.00±2.87 ($p<0.001$) in group B patients. The disability (MSBQ score) was reduced from 7.33±1.46 to 1.63±1.04 ($p<0.001$) in group A patients; 7.36±2.32 to 1.24±1.01 ($p<0.001$) in group B patients. **Conclusion:** The study has revealed that *Hijamah* (wet cupping) is an effective regimen and treatment modality for the treatment of Sciatica, and *Hijamah* can be adopted as a better alternative to NSAIDs and spinal surgery.

KEYWORDS: *Cupping therapy; Hijamah; Irq-un-Nasa; Maine Seattle Back Questionnaire (MSBQ); Sciatica; Sciatica Bothersomeness Index (SBI)*

INTRODUCTION

Sciatica is generally defined as "pain in the lower back and hip which radiates to the distribution of the sciatic nerve due to affection of sciatic nerve".[1] Actually, sciatica is a symptom and a clinical condition rather a specific diagnosis.[2] Sciatic nerve is a widest and longest nerve in the human body, which is made up of L4 to S3 nerve roots combine at the pelvis to form the sciatic nerve. It exits the pelvis through the greater sciatic foramen below the Piriformis muscle and descends between the greater trochanter of the femur and ischial tuberosity of the pelvis at the back of the thigh, divides into the tibial nerve (medial division) and common peroneal/fibular nerves (lateral division) at a varying level proximal to the knee. [3,4]

In Unani system of medicine, sciatica is known as *Irq-un-Nasa*, and is described under the umbrella of joints pain (*Waja-ul-Mafasil*). There are three subtype of joints pain viz. *Irq-un-Nasa* (sciatica), *Waja-ul-Warik* (hip joint pain) and *Niqras* (gout).[5] Eminent scholar Rabban Tabri (780-850 AD) wrote, *Irq-un-Nasa* is a neuritic pain of thigh that radiates towards the toes.[6] Zakariya Razi (865-925 AD) described *Irq-un-Nasa* as a subtype of *Waja-ul-Mafasil*, which develops due to the collection of thick morbid phlegm within the joints (hip joint). This pain is felt at the gluteal region (gluteal depression), thigh and near the knee, and when it becomes severe then radiates to the toes.[7]

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[1,2,3]*Department of Moalajat, SUMER, [4]Department of Radiology, HIMSR, [5]Department of Mahiyatul Amraz, [6]Department of Allied Health Sciences, Jamia Hamdard, New Delhi, India

According to Ibn-e-Sina (980-1037 AD), *Irq-un-Nasa* is a subtype of *Waja-ul-Mafasil*, in which the pain initiates from the hip joint and radiates to the back of the thigh; and sometimes to the knee, ankle and up to the toes. Ibn-e-Sina further explains that due to its chronicity and excess of morbid matter, the affected leg and thigh become weak and asthenic, which ultimately results in the inability to bend or to stand upright.[8]

The major cause of sciatica is Lumbo-sacral bulging or Herniated Disc. A herniated disc occurs when the nucleus breaks through the annulus. Approximately 90% cases of sciatica is a consequence of herniated disc. Less common causes of sciatica are Lumbar Spinal Stenosis, Trauma, Piriformis Syndrome, and Spinal Tumors etc.[9,10]

According to the Unani system of medicine the cause of *Irq-un-Nasa* may be the derangement of *Khilt-e-Safra* (bilious humor), prolonged sun exposure causing dryness of fluid in the hip joint (synovial fluid) or an admixture of *Khilt-e-Radi* (morbid humor) with blood. [6] Locally it is the *Nufooz* (infiltration) of abnormal humors in the fluid of the hip joint, such as *Ghair tabayi Balgham*, *Safra* or *Dam* (abnormal phlegm, bilious humor or sanguine), or admixture of *Balgham* (phlegm) and *Safra* (bilious humor). Moreover, when such morbid humor stays in this joint for a prolonged period, it may become thick and hard in consistency, resulting in *Tahajjur-al Mafasil Warik* (stiff hip join) and even *Irq-un-Nasa*.[7] The predisposing factors mentioned in Unani system of medicine are sedentary life style, physical inactivity, and excessive use of *Hammam* in full stomach, eating at an inappropriate time and quantity, poor quality/temperament (*Kaifiyat*) diet, excessive use of alcohol in breakfast, intercourse after taking food.[11]

Sciatica is mainly diagnosed clinically, based on the person's symptoms/history and findings on examination. History of leg pain more troublesome than back pain or moderate to severe pain below the knee should raise suspicion of sciatica. The inquiry is made about the onset and distribution of pain, and associated symptoms such as tingling sensation, numbness, or muscle weakness in the legs. It is proposed that clinical criteria such as unilateral leg pain, mono radicular distribution of pain and positive straight leg raise (SLR) test or Lasègue's test are diagnostic parameters for sciatica.[12]

Available treatments in modern medicine are analgesics or non-steroidal anti-inflammatory drugs, acupuncture, epidural steroid injections, spinal manipulation, traction therapy, physical therapy, behavioral treatment, multidisciplinary treatment.[13] The available evidence does not clearly show favorable effects of NSAIDs, corticosteroids, antidepressants, or opioid analgesics in the immediate effect, even compared with placebo and they have many side effects in vitals in human body.[14] While surgical intervention and correction of any structural abnormalities such as disc herniation, epidural hematoma, epidural abscess or tumor are the last option for treating Sciatica.

Cupping therapy is a simple procedure in which negative pressure is applied to the skin through sucking cups, by creating vacuum, followed by scarification and removal of morbid matter with blood. In Unani system, *Hijamah* (wet cupping) is recommended for various subtypes of *Waja-ul Mafasil* (arthralgia) and other diseases also including I*rq-un-Nasa*.[6-8,11] The prevalence rate of sciatica differs widely among studies and exact data on the prevalence of sciatica is lacking partly due to different perceptions of sciatic symptoms. A recent review of sciatica prevalence studies reported a substantial variation in estimates ranging from 1.6%-43%. [15] This clinical trial was designed keeping in view of the emphasis given to the *Hijamah* in Unani literature in the management of sciatica, and success stories published recently in various scientific journals, and most importantly to assess the efficacy of *Hijamah* to manage Sciatica in order to avoid extensive spinal surgery. The study also aimed at finding out the better sites of effectiveness of *Hijamah*.

METHODOLOGY

Study Design and Setting

This study was carried out in the Postgraduate Department of Moalajat, School of Unani Medical Education and Research (SUMER), Jamia Hamdard, New Delhi. The study was started after getting ethical clearance and approval from Institutional Ethics Committee Jamia Hamdard, and registration in Clinical Trials Registry-India (Vide Registration No. CTRI/2019/05/018946, dated 06/05/2019).

This study was an open-label, prospective, and randomized controlled clinical study. The duration of protocol therapy was 42 days with visits of patients on 0 Day (Baseline), 14th, 28th, 42nd Day; the study was carried out during June 2019 to March 2020.

The subjects for the clinical trial were recruited from OPD and IPD of Majeedia Unani Hospital, Jamia Hamdard. Diagnosed patients of Sciatica according to inclusion and exclusion criteria were enrolled after getting their written consent. All the patients were randomly allocated according to a computer-

generated randomization sheet into Group A and Group B, with 30 patients in each. Finally 52 patients completed the trial, 3 patients from Group A and 5 patients from Group B could not complete their follow up due to covid-19 pandemic and nationwide lockdown in India in 2020 (Fig 1).

Inclusion Criteria

- Clinically diagnosed patients of sciatica between 18 to 65 years of age of all genders were selected for screening with all or some symptoms of sciatica viz. leg pain greater than low back pain radiating towards the foot, positive straight-leg-raising test, numbness, and/or tingling sensation in the same distribution.
- Having mild to moderate pain.
- Willingness of the patients to accept *Hijamah* (wet cupping).

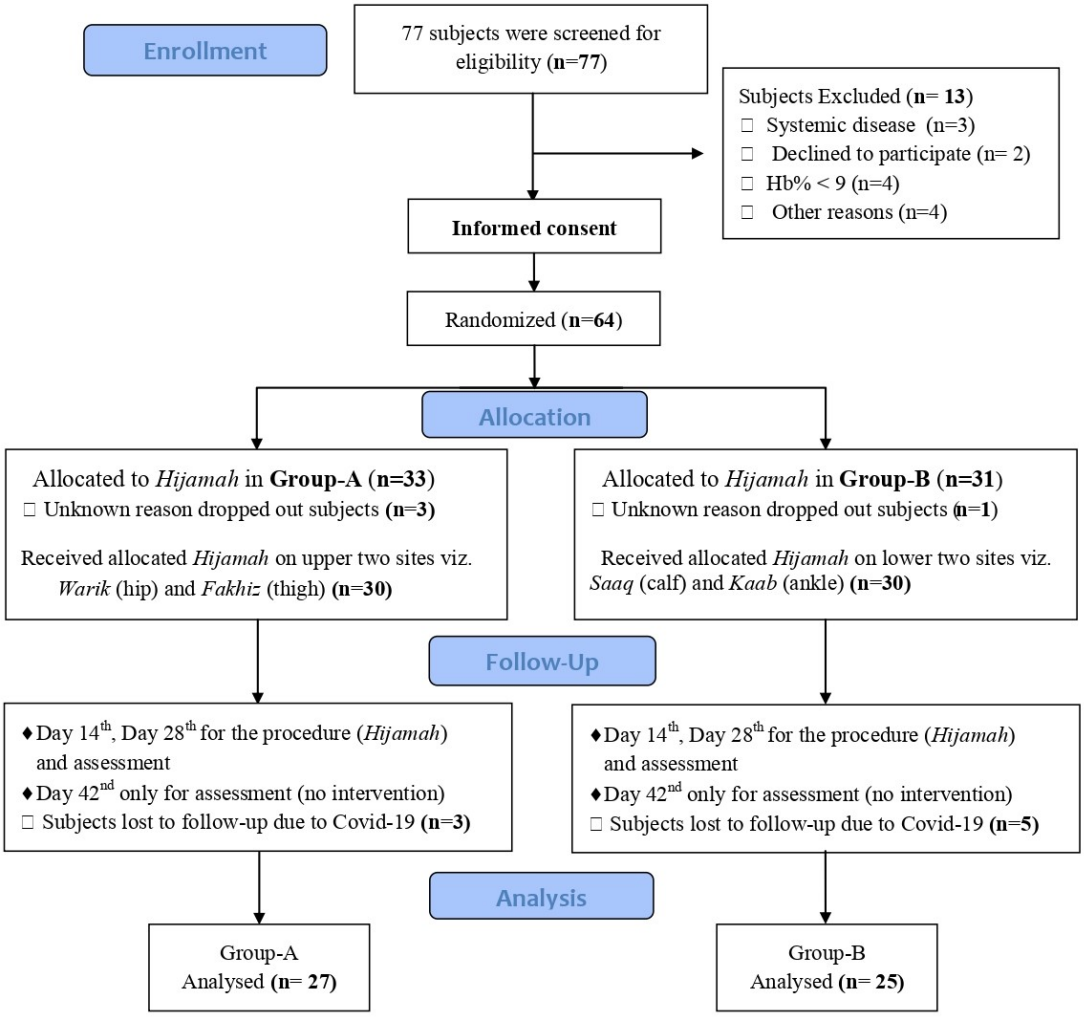
Exclusion Criteria

- Pregnant and lactating women, patients of previous back surgery/lumbar spine surgery, patients of spinal tumors, gross/fixed developmental deformity, cauda equine, or vertebral fracture were not included in the study. Patients with malignancy or any liver, kidney, or heart disease, motor weakness/muscle wasting, suffering from psychiatric disorders, bleeding disorders, anemia (Hb< 10 gm%), HIV/AIDS, Hepatitis B, Hepatitis C and patients on anticoagulant therapy were also not included.
- Patients with a history of stroke, severe hypertension, and uncontrolled diabetes mellitus were also excluded from the study; moreover, patients taking any other conservative treatment concomitantly for sciatica (NSAIDs, corticosteroids, physiotherapy, acupuncture, etc.) were also not included in the study.

Investigations

- Following investigations were carried out keeping in view the inclusion and exclusion criteria and the feasibility of the intervention:
- MRI Lumbo-Sacral spine
- Hemoglobin with ESR, BT, CT and Blood Sugar Fasting & post-prandial
- LFT, KFT, Vit. B12, Thyroid profile, HbA1c, HBsAg. HCV, HIV I & II

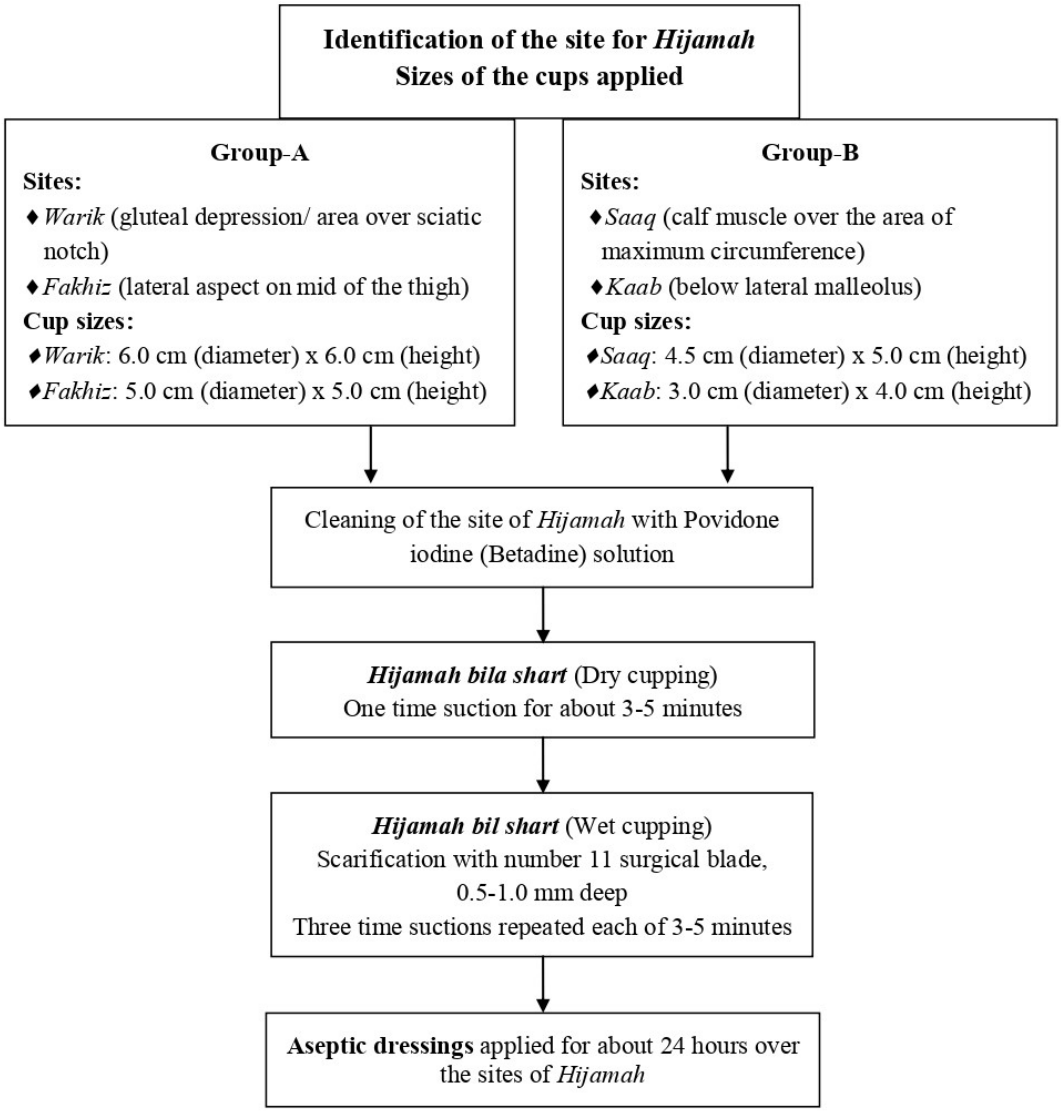
Fig. 1: Consort Flow Chart



Intervention

The therapeutic intervention *Hijamah* (wet cupping) was done on *Warik* (gluteal depression/area over sciatic notch) [7,8,16-18] and *Fakhiz* (lateral aspect of mid high) [19,20] of the affected side in group A patients.

Fig 2: Details of Intervention of Procedure *Hijamah* (Wet Cupping)



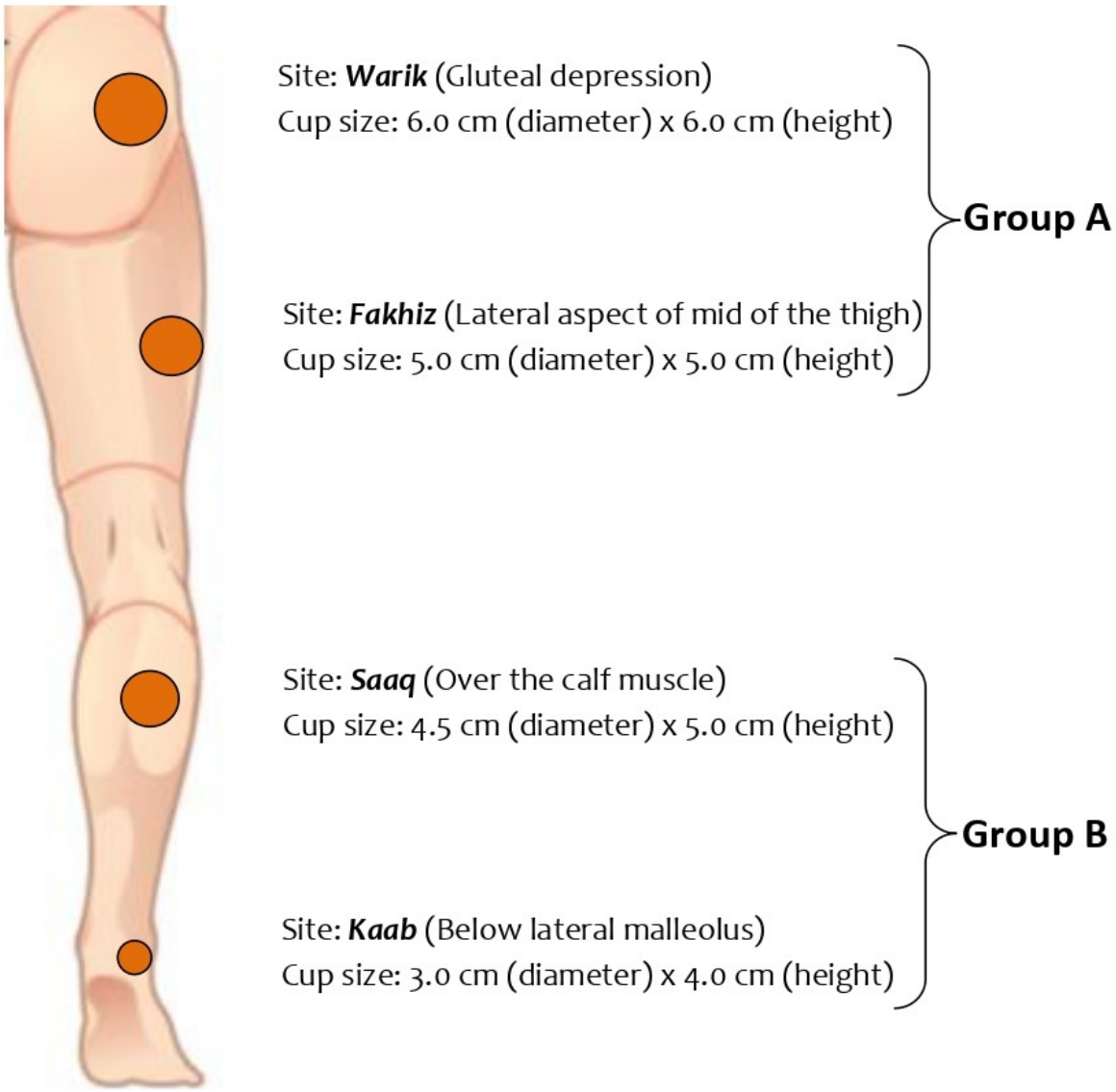
In group B patients *Hijamah* was done on *Saaq* (calf muscle over the area of maximum circumference) [11] and *Kaab* (below ankle joint/below lateral malleolus) [21,22] of the affected leg (Fig 2).

The procedure was carried out step-wise as mentioned in flow diagram (Procedure of *Hijamah*), and maximum 20 ml blood was drawn in one session. In every patient the *Hijamah* was done on day 0, day 14th and day 28th; and on last follow-up (day 42nd) the intervention was not done, as the last follow-up was only for assessment (Fig 3).

Assessment Parameters

The sciatic pain was evaluated using visual analogue scale (0-100 VAS), and further assessment of the intervention was done using specific questionnaires viz. Sciatica Bothersomeness Index (SBI) for the assessment of bothersomeness, Maine Seattle Back Questionnaire (MSBQ) for the assessment of disability; and quality of life was assessed by SF12v2 with reference to physical health, bodily pain and mental health.

Fig 3: Sites of *Hijamah* and Cups Used for the management of Sciatica



Statistical Analyses

The data was collected on approved Case Report Form, and tabulated in the form of maser chart, and analyzed using different statistical tests. Student's paired t test was applied for the analysis of the scores within the group; whereas chi-square test was applied for the analysis of severity of Pain, Bothersomeness, Disability and QoL according to categories. To compare both the groups Mann-Whitney U test was applied.

RESULTS

In baseline observations pertaining to the demographic parameters are recorded in Table-1, showing predominance of male, and patients belonging to age group 36-45 years. According to occupation, maximum patients were housewives or servicemen, while married patients outnumbered unmarried patients. Family history of sciatica was absent in most of the patients, whereas most of the patients were having pain in right leg with mild to moderate severity.

Table 2 and 3 summarize the effectiveness of treatment/intervention on Severity of pain [according to visual analogue scale (VAS)], on Bothersomeness [according to Sciatica Bothersomeness Index (SBI)] and on Disability caused [according to Maine Seattle Back Questionnaire (MSBQ)]. The effect of the intervention on quality of life is summarized in table 4.

The observations and results showed tremendous improvement in all the parameters with statistical significance. A marked reduction in pain intensity after *Hijamah* in both the groups is highly appreciable, as most of the patients who had moderate pain shifted to mild pain category after treatment; however only one patient shifted to no pain category (in group A).

Bothersomeness was reduced to the extent that almost all the patients were not bothered about their

pain, numbness, muscle weakness, etc., after the treatment.

DISCUSSION

Disability due to sciatica was reduced to the extent that no case remained in severe disability or moderate disability category; rather, shifted to no disability or mild disability category after the treatment.

Quality of life of all patients related to General health, Bodily pain, and mental health was also significantly improved.

The reduction in pain by Hijamah therapy may be due to several factors, as under:

In the procedure of *Hijamah* therapy, first *Hijamah Bila Shart* (dry cupping) was done; *Hijamah Bila Shart* diverts the morbid matter from the site of inflammation to the under-surface of Hijamah as per the concept of Unani medicine, this is referred as *Imala-E-Qareeb*. [23] Morbid matter (that may be considered as "chemotactic factors/inflammatory mediators" as per *Taiba* Theory) causing inflammation and pain in and around the sciatic nerve, gets dispersed and diverted towards the site of *Hijamah*. This diverted morbid matter then gets extracted out by performing *Hijamah Bil Shart* (wet cupping); in Unani medicine, this is referred to as *Tanqiya-E-Mawad*.

Table 1: Demographic Observations and details of affected leg and severity of pain

Parameters	Group A	Group B	Total
Age in Years			
15-25	4 (14.8%)	3 (12.0%)	7 (13.5%)
26-35	5 (18.5%)	6 (24.0%)	11 (21.2%)
36-45	7 (25.9.3%)	7 (28.0%)	14 (26.9%)
46-55	7 (25.9%)	6 (24.0%)	13 (25.0%)
56-65	4 (14.8%)	3 (12%)	7 (13.5%)
Gender			
Male	16 (59.3%)	13 (52.0%)	29 (55.8%)
Female	11 (40.7%)	12 (48.0%)	23 (44.2%)
Occupation			
Businessman	2 (7.4%)	1 (4.0%)	3 (5.8%)
House wife	7 (25.9%)	11 (44.0%)	18 (34.6%)
Laborer	7 (25.9%)	3 (12.0%)	10 (19.2%)
Serviceman	9 (33.3%)	8 (32.0%)	17 (32.7%)
Student	2 (7.4%)	2 (8.0%)	4 (7.7%)
Marital Status			
Married	25 (92.6%)	23 (92.0%)	48 (92.3%)
Unmarried	2 (8.0%)	2 (8.0%)	4 (7.7%)
Family History of Sciatica			
Present	7 (25.9%)	3 (12.0%)	10 (19.2%)
Absent	20 (74.1%)	22 (88.0%)	42 (80.8%)
Affected Leg			
B/ L	1 (3.7%)	0 (0.0%)	1 (1.9%)
Left	10 (37.0%)	11 (44.0%)	21 (40.4%)
Right	16 (59.3%)	14 (56.0%)	30 (57.7%)
Severity of Pain			
Mild pain (5-44 mm)	2 (7.4%)	0 (0.0%)	2 (3.8%)
Moderate pain (45-74 mm)	25 (92.6%)	25 (100.0%)	50 (96.2%)

Table-2: Efficacy of *Hijamah* (wet cupping) on different parameters according to Score

Assessment Parameters	Group A (N=27)	Group B (N=25)
Effect of treatment on severity of Pain (according to VAS score)		
Pre Treatment	65.52 ±8.90	65.40±9.03
Post Treatment	20.18±10.96	21.00±10.99
Difference	45.33±12.87	44.40±12.72
Statistics (Paired t-test)	**t=18.364 p<0.001**	**t=17.446 p<0.001**
Effect of treatment on Bothersomeness (according to SBI Score)		
Pre Treatment	14.67±4.21	14.88±3.28
Post Treatment	5.37±3.00	4.00±2.87
Difference	9.30±2.92	10.88±3.38
Statistics (Paired t-test)	**t=16.545 p<0.001**	**t=16.081 p<0.001**
Effect of Treatment on Disability (according to MSBQ score)		
Pre Treatment	7.33±1.46	7.36±2.32
Post Treatment	1.63±1.04	1.24±1.01
Difference	5.70±1.65	6.12±2.42
Statistics (Paired t-test)	**t=17.856 p<0.001**	**t=12.641 p<0.001**

Table-3: Efficacy of *Hijamah* (wet cupping) on different parameters according to Category

SEVERITY OF PAIN (according to VAS score)	**Group A**		**Group B**	
	Pre Treatment	Post Treatment	Pre Treatment	Post Treatment
No pain (0-4 mm)	0 (0.0%)	1 (3.7 %)	0 (0.0%)	0 (0.0%)
Mild pain (5-44 mm)	2 (7.4%)	20 (74.1%)	0 (0.0%)	24 (96.0%)
Moderate pain (045-74 mm)	25 (92.6%)	6 (22.2%)	25 (100.0%)	1(4.0%)
Total	27 (100.0%)	27 (100.0%)	25 (100.0%)	25 (100.0%)
Statistics	**Chi-square Test p< 0.001**		**Chi-square Test p< 0.001**	
	Mann-Whitney U, p.0.05 (0.148)			
BOTHERSOMENESS (according to SBI Score)	**Group A**		**Group B**	
	Pre Treatment	Post Treatment	Pre Treatment	Post Treatment
Not Bothersome (0-8)	3 (11.1%)	17 (63.0%)	0 (0%)	23 (92%)
Somewhat Bothersome (9-16)	3 (11.1%0	9 (33.3%)	6 (24.0%)	1 (4.0%)
Extremely Bothersome (17-24)	21 (77.8%)	1 (3.7%)	19 (76.0%)	1 (4.0%)
Total	27 (100%)	27 (100%)	25 (100%)	25 (100%)
Statistics	**Chi-square Test p<0.001**		**Chi-square Test p<0.001**	
	Mann-Whitney U test, p<0.05 (0.019)			
DISABILITY (according to MSBQ score)	**Group A**		**Group B**	
	Pre Treatment	Post Treatment	Pre Treatment	Post Treatment
No disability (0-1)	0 (0%)	12 (44.4%)	0 (0%)	15 (60%)
Mild disability (2-5)	2 (7.4%)	15 (66.6%	4 (16%)	10 (40%)
Moderate disability (6-9)	23 (84.2%)	0 (0%)	15 (60%)	0 (100%)
Severe disability (10-12)	2 (7.4%)	0 (0%)	6 (24%)	0 (0%)
Total	27 (100%)	27 (100%)	25 (100%)	25 (100%)
Statistics	**Chi-square Test p<0.001**		**Chi-square Test p<0.001**	
	Mann-Whitney U test, p>0.05 (0.267)			

Hijamah is a procedure in which blood from superficial and tiny blood vessels (located in skin and muscles) is extracted through which noxious substances (toxins) are also expelled out.24 Scarification effectively expels out the noxious matter that has accumulated close to the skin, and it

Table 4: Efficacy of *Hijamah* (wet cupping) on Quality of Life (QoL)

Quality of life according to "General Health"	**Group A**		**Group B**	
	Pre Treatment	Post Treatment	Pre Treatment	Post Treatment
Low Quality of Life (0-39)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Average Quality of Life (40-79)	18 (66.7%)	5 (18.5%	16 (64%)	0 (0%)
High Quality of Life (80-100)	9 (33.3%)	22 (81.5%	9 (36%)	25 (100%)
Total	27 (100%)	27 (100%)	25 (100%)	25 (100%)
Statistics	**Chi-square test p<0.001**		**Chi-square test p<0.001**	
	Mann-Whitney U test p<0.05 (0.025)			
Quality of life according to "Bodily Pain"	**Group A**		**Group B**	
	Pre Treatment	Post Treatment	Pre Treatment	Post Treatment
Low Quality of Life (0-39)	2 (7.4%)	0 (0%)	0 (0%)	0 (0%)
Average Quality of Life (40-79)	24 (88.9%)	3 (11.1%)	25 (100%)	0 (0%)
High Quality of Life (80-100)	1 (1.9%)	24 (88.9%)	0 (0%)	25 (100%)
Total	27 (100%)	27 (100%)	25 (100%)	25 (100%)
Statistics	**Chi-square Test p<0.001**		**Chi-square Test p<0.001**	
	Mann-Whitney U test p>0.05 (0.089)			
Quality of life according to "Mental Health"	**Group A**		**Group B**	
	Pre Treatment	Post Treatment	Pre Treatment	Post Treatment
Low Quality of Life (0-39)	0 (0%)	0 (0%)	0 (36%)	0 (0%)
Average Quality of Life (40-79)	24 (88.9%)	0 (%)	25 (100%)	0 (0%)
High Quality of Life (80-100)	3 (11.1%)	27 (100%)	0 (0%)	25 (100%)
Total	27 (100%)	27 (100%)	25 (100%)	25 (100%)
Statistics	**Chi-square Test p<0.001**		**Chi-square Test p<0.001**	
	Mann-Whitney U test p>0.05 (1.00)			

withdraws thin blood rather than thick blood.8 *Hijamah* evacuates the morbid matters from the site of pain; reduce plethora and hence reduced pain. [25,26]

According to current understanding, *Hijamah* works in different ways to resolve the inflammation and to alleviate pain like, it activates the immune system; excretes the excessive and accumulated interstitial fluid consisting of pathological (morbid) substances; improves the blood circulation and thereby decreasing the peripheral resistance and; improves the excretory function of the skin and thereby decreasing the underlying congestion; releases endogenous opioids (endorphins) resulting in pain relief.[27-30] *Hijamah* serves all the purpose of *Ilaj bil Tadbeer* (regimental therapy) viz., *Tanqiya-e-Mawad* (removal of matter), *Tahleel-e-Waram* (resolution of swelling) and *Taskeen-e-Alam* (alleviation of pain) at the same time.

Sciatica Bothersomeness Index (SBI) includes response regarding pain, numbness/tingling sensation in foot or groin, weakness in the leg or foot, and pain while sitting. All these components in the SBI are indicative of sciatic nerve compression; hence, the improvement in the bothersomeness index may be due to a reduction in inflammation of the sciatic nerve by the *Hijamah*. *Hijamah* also inhibits the inflammatory chemicals at the site of inflammation and simultaneously reduces the congestion in and around the affected nerve. Once the inflammation is reduced the compression over the nerve by surrounding tissue/bone also decreases and the swollen nerve gets reverted to normal, consequently the muscle power is improved producing relief in symptoms.

CONCLUSION

The *Hijamah* as a regimen is found as effective as mentioned in the descriptions of *Hijamah* in classical Unani literature. The overall results in both groups were almost equal; however, a little better improvement was noted in Group B, where *Hijamah* was done at distal parts viz. *Saaq* (over calf muscle) and *Kaab* (below ankle joint). This might be due to the superficial location of the sciatic nerve at these sites as compared to the sites of Group A. Therefore, it may be concluded that *Hijamah* (wet cupping) is an effective and safe regimen and treatment modality in the management of sciatica and it can be adopted as a better alternative to NSAIDs and spinal surgery.

LIMITATION AND SCOPE

Since the sample size of this study was small due to limitations of time and resources, it is suggested and proposed to conduct such kind of studies on larger sample size to generate data large enough to establish the efficacy and safety of *Hijamah* and to develop SOPs as well.

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