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Efficacy of *hijamah bil – Shart* (Wet Cupping) on *Irq Al-Nasa* (Sciatic Pain): A Randomized Controlled Clinical Trial

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ABSTRACT

Objectives: To validate the safety and efficacy of regimen *Hijamah bil-Shart* (wet cupping) in the management of *Irq al-Nasa* (sciatic pain). **Material and methods**:Arandomized controlled clinical trial was performed at Majeedia Unani hospital, New Delhi on 68 patients of sciatica, fulfilling the inclusion criteria and were randomized into two groups (test group and control group) equally in each group. A total 60 patients completed the study with 30 patients in each group. In the patients of test group, *Hijamahbil-Shart* (Wet Cupping)was performed weekly by one cup on *saaq* (calf muscle) (diameters 5 cm; height of 5 cm) and another disposable cup (diameter 3cms; height of 3 cm) on *kaab* (below medial malleolus) on affected side, for a duration four weeks and *Hab-e-Suranjan*two tablets orally given twice a day for four weeks. The control group was given only *Hab-e-Suranjan*two tablets twice a day for 4 weeks.The pre, mid and post treatment effects were assessed on the basis of objective responses onclinical parameters such as leg pain, pain radiating to foot or toes, numbness and paraesthesia, tingling, pins and needles and muscle weakness. Safety evaluation was performed withhaematological and biochemical parameters before and after the completion of treatment (0 and 28thday). **Results**: Extremelysignificant results with ($p<0.001$**) were observed in the above mentioned clinical symptoms. **Conclusion**: *Hijamah bil-Shart* (wet cupping) could be an effective therapy for the management of pain in patients of *Irq al-Nisa* (sciatic pain) without any adverse effects. Clinical trial registry: CTRI/2018/03/017999

Keywords- *Irq al-Nasa* (sciatic pain), *Hijamah bil-Shart* (wet cupping) leg pain, muscle Weakness, *Hab-e-Suranjan*.

INTRODUCTION

Irq al-Nasa has been described as an arthralgia characterized by hip joint pain which radiates toward the groin up to the ankle and sometimes to phalanges depending upon the increasing quantity of morbid humours in foot (1,2,3,4). *Irq al-Nasa* could be related to the clinical entity sciatic pain or lumbosacral radiculopathy in the conventional medicine, that is defined in the form of pain radiating along the course of the sciatic nerve and is frequently felt in the back, buttocks, posterior of the thighs, legs and the foot (5). Sciatic neuropathy is among the most common peripheral neuropathies, since it is estimated to affect 5 in every 10000 western adults. Thus, it represents a social problem both in terms of patients suffering and health costs for treating the progression of the disease (6).

Owing to range of definitions a wide variation has been found in the prevalence of sciatica fluctuating from 1.6% to 43 % (7,8). However, currently it has been established that sciatica is a major health related problem and results in significant disability with longer pain episodes and repeated use of health services (8).

The aims of management of *Irq al-Nasa* (sciatic pain) encompass reduction in pain, prevention of chronic disability and improvement in quality of life in both Unani as well as conventional systems of medicine. However, in conventional system of medicine, in spite of tremendous developments, the treatment of sciatica remains palliative and depends mainly on modalities that include pain medications since surgery carries a significant burden of adverse effects. Owing to these adverse effects a major portion of these patients seek Unani treatment for alleviation of symptoms associated with this disorder.

MATERIAL AND METHODS

The trial was approved by the Board of Studies of Jamia Hamdard and registered under the clinical trial registry of India vide registration number **CTRI/2018/03/017999** After taking informed consent, a total of 71 diagnosed patients of sciatica were registered and out of which 68 patients fulfilling the inclusion criteria were enrolled for the study and randomized into two groups (test group and control group). 60 patients 30 patients in each group) completed the study while eight patients dropped out and it was attributed to difficulty to follow up on specified time and noncompliance. In both the groups, the duration of protocol therapy was 28 days. In the patients of test group, *Hijama bil Shart* was performed weekly by one cup on*saaq*(calf muscle) and one cup on *kaab* (below medial malleolus) on affected side,for a duration four weeks and *Hab-e-Suranjan* two tablets orally given twice a day for four weeks. Procedure of *Hijama bil Shart* (wet cupping), The patient was asked to lie on prone position and sites of *Hijamah bil- Shart saaq* (calf muscle) and the *kaab* (below medial malleolus) were identified on the affected side. The whole part was prepared with antiseptic lotion. The sterile disposable cups were placed on the selected sites, one on *saaq* (calf muscle) (diameters 5 cm; height of 5 cm) and another disposable cup (diameter 3cm; height of 3 cm) on *kaab* (below medial malleolus) and after rarefying the air inside the cups by manual suction they were left for a period of 3 to 5 minutes and then removed. This resulted in local hyperaemia helpful in the evacuation of morbid blood. The same area was scarified by multiple scarification technique with sterile 11 gauge surgical blade on both sites and cups were applied. A moderate pressure (where the suction is one third of height of thecup) inside the cup was maintained and not more than 20 ml of blood was drained during one session. The area was cleaned properly with antiseptic gauze and aseptic dressing was applied for about 24 hours and strict aseptic precautions were taken throughout the procedure.In patients of control group, only *Hab-e-Suranjan*, two tablets orally were giventwice a day for four weeks.

Table: 1 Baseline characteristics of the Patients

Characteristic		**Test Group (n=30)**	**Control Group (n=30)**	**P Value**
Age group — %	**18-30**	10(33.3%)	5(16.7%)	
	31-40	9(30%)	11(36.7%)	
	41-50	4(13.3%)	7(23.3%)	
	51-60	5(16.7%)	5(16.7%)	
	61-65	2(6.7%)	2(6.7%)	
Mean ± SD		39.97±11.95	42.53±11.62	0.402
Gender	**Female**	15(50%)	17(56.7%)	0.605
	Male	15(50%)	13(43.3%)	
Religion	**Hindu**	7(23.3%)	12(40%)	0.267
	Muslim	22(73.3%)	18(60%)	
	Sikh	1(3.3%)	0(0%)	
Marital status	**30(100%)**	30(100%)	30(100%)	1.000
	0(0%)	0(0%)	0(0%)	
Eating Habits	**Mixed**	23(76.7%)	14(46.7%)	0.017
	Veg	7(23.3%)	16(53.3%)	

Eligible participants will meet all of the following criteria: Patients of either sex between the age of 18 and 65 years, Already diagnosed patients of sciatica presenting with all or some of the following signs and symptoms: Unilateral leg pain greater than low back pain**,** Pain radiating to foot or toes**,** Numbness and or paraesthesia in the same distribution**,** Tingling, pins and needles sensation**,** Muscle weakness.

Patients will be excluded if they meet any of the following criteria: Patients below 18 years and above 65 years of age, Pregnant and lactating females, Patients of previous back surgery/ lumbar spine surgery, Patients of spinal tumours and vertebral fracture, Patients of developmental spine deformities, Patients of bleeding disorders, Patients on anticoagulant treatment/ disseminated intravascular coagulation, Patients taking any other conservative treatment for sciatica (NSAIDS, corticosteroids, acupuncture etc.), Patients with systemic disorders like chronic liver, kidney or heart disease, Patients of uncontrolled diabetes mellitus, Terminally ill patients.

The patients were enrolled on the basis of history, clinical examination and investigations. The pre, mid and post treatment effects were assessed on the basis of objective responses on **Clinical parameters**, **leg pain, pain radiating to foot or toes, numbness and paraesthesia, tingling, pins and needles and Muscle Weakness**. The patients were followed up and evaluated on days 7, 14, 21 and 28. The data was recorded on a Case Record Form and subjected to statistical analysis by SPSS 18.0, and R environment ver.3.2.2.

For evaluation of the safety of test therapy, all the patients were assessed on clinical, haematological and biochemical parameters before and after the completion of treatment (0 and 28thday). The test therapy as well as control therapy did not raise any significant safety issue during the study as no significant change was observed in haematological parameters and biochemical parameters i.e. liver function test and kidney function test. Same was the case with control group. Similar finding have been attributed to the test drug *Habb-e-Suranjan* viz a viz safety profile by other researchers also.

RESULTS:

Table: 2 Effect of *Hijamah* (Wet cupping) in comparison of *Habb-e-suranjan*				
Leg pain	**0 day**	**14 day**	**28 day**	**% change**
Test Group (n=30)				
• 0	0(0%)	0(0%)	4(13.3%)	13.3%
• 1	0(0%)	11(36.7%)	17(56.7%)	56.7%
• 2	7(23.3%)	17(56.7%)	2(6.7%)	0.0%
• 3	23(76.7%)	2(6.7%)	2(6.7%)	-70.0%
Control Group (n=30)				
• 0	0(0%)	0(0%)	1(3.3%)	3.3%
• 1	0(0%)	1(3.3%)	7(23.3%)	23.3%
• 2	5(16.7%)	25(83.3%)	15(50%)	33.3%
• 3	25(83.3%)	4(13.3%)	7(23.3%)	-60.0%
P value	0.748	0.004**	0.007**	
Pain radiating to foot or toes				
Test Group (n=30)				
• 0	0(0%)	0(0%)	0(0%)	0.0%
• 1	0(0%)	0(0%)	1(3.3%)	3.3%
• 2	8(26.7%	9(30%)	19(63.3%)	-36.6%
• 3	22(73.3%)	21(70%)	10(33.3%)	-40.6%
Control Group (n=30)				
• 0	0(0%)	2(6.7%)	0(0%)	0(0%)
• 1	1(3.3%)	3(10%)	1(3.3%)	3.3%
• 2	7(23.3%)	12(40%)	20(66.7%)	43.4%
• 3	22(73.3%)	13(43.3%)	9(30%)	-43.3%
P value	1.000	0.045*	1.000	-
Numbness and paraesthesia				
Test Group (n=30)				
• 0	10(33.3%)	11(36.7%)	11(36.7%)	-3.4%
• 1	1(3.3%)	2(6.7%)	9(30%)	26.7%
• 2	6(20%)	14(46.7%)	8(13.3%)	-6.7%
• 3	13(43.3%)	3(10%)	2(6.6%)	-36.7%
Control Group (n=30)				
• 0	11(36.7%)	11(36.7%)	11(36.7%)	0.0%
• 1	0(0%)	1(3.3%)	7(23.3%)	23.3%
• 2	7(23.3%)	15(50%)	11(36.7%)	-13.4%
• 3	12(40%)	3(10%)	1(3.3%)	-36.7%
P value	1.000	1.000	0.779	-
Tingling, pins and needles				
Test Group (n=30)				
• 0	22 (73.3%)	21(70%)	21(70%)	-3.3%
• 1	0 (0%)	4(13.3%)	5 (16.7%)	16.7%
• 2	5 (16.7%)	5(16.7%)	4(13.3%)	-3.4%
• 3	3 (10%)	0(0%)	0(0%)	-10.0%
Control Group (n=30)				
• 0	9(63.3%)	18(60%)	18(60%)	-3.3%
• 1	1(3.3%)	3(10%)	6(20%)	16.7%
• 2	5(16.7%)	8(26.7%)	6(20%)	-3.3%
• 3	5(16.7%)	1(3.3%)	0(0%)	-16.7%
P value	0.728	0.674	0.751	-
Muscle Weakness				
Test Group (n=30)				
• 0	0(0%)	1(3.3%)	8(26.7%)	26.7%
• 1	0(0%)	8(26.7%)	17(56.7%)	56.7%
• 2	13(43.3%)	19(63.3%)	5(16.7%)	-26.7%
• 3	17(56.7%)	2(6.7%)	0(0%)	-56.7%
Control Group (n=30)				
• 0	0(0%)	0(0%)	1(3.3%)	3.3%
• 1	0(0%)	6(20%)	7(23.3%)	23.3%
• 2	8(26.7%)	23(76.7%)	14(46.7%)	20%
• 3	22(73.3%)	1(3.3%)	8(26.7%)	-46.0%
P value	0.279	0.578	<0.001**	-

Leg pain: [Table 2; Figure 1]

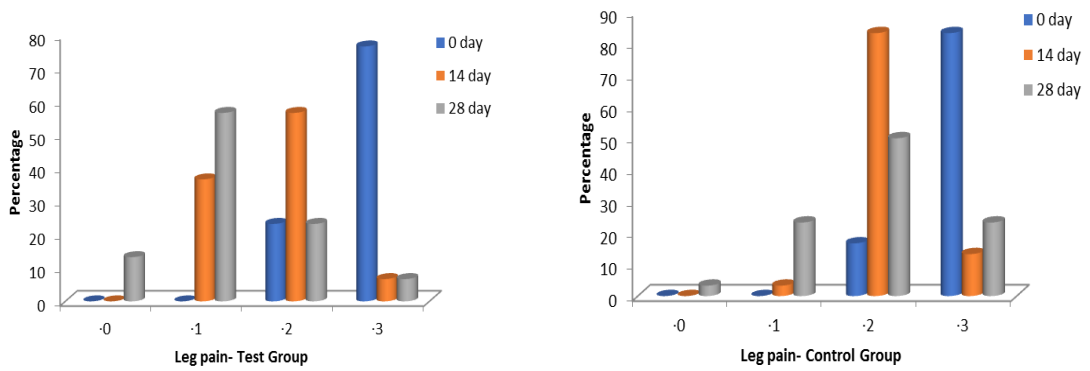

Figure 1: Effect on leg pain test versus control

Before treatment, in the test group, 23 patients (76.7%) had leg pain of grade 3 and 7 (23.3%) had leg pain of grade 2 while in control group 25 patients (83%) had leg pain of grade 3 and 5 patients (16.7%) had leg pain in grade 2. At the same point of time, no patient was having pain in grade 1 or grade 0 in either of the groups. After initiation of treatment, in both the groups, a significant reduction in patients with grade 3 leg pain was observed on the 14th day follow up {test group 23 patients (76.7%) to 2 patients (6.7%) whereas in the control group 25 patients (83.3%) to 4 patients (13.3%)}. In test group, at day 28 follow up, only 2 patients (6.7 %) had grade 3 leg pain while the number of patients with grade 1 and grade 0 leg pain
Increased substantially from 0 (0%) to 17 (56.7%) and 0 (0%) to 4 (13.3%) respectively. Similarly, in control group at day 28 follow up, considerable decrease was observed in patients with grade 3 leg pain {25 patients (83.3%) to 7 patients (23.3%)} while the number of patients with grade 1 and grade 0 increased from 0 (0%) to 7(23.3%) and 0(0%) to 1(3.3%) respectively. Although the observed changes in leg pain grades were significant in both the groups, at the end of treatment, a higher percentage change was observed in test group with 13.3 % falling in no pain category in comparison to 3.3 % in the control group. Similarly, in test group 56.7% increase was observed in patients with grade 1 leg pain in comparison to 23.3 % increase in control group. Comparing the test group with the control group, it was found to be extremely significant on day 14 and day 28.

Pain radiating to foot or toes [Table 2; Figure 2]

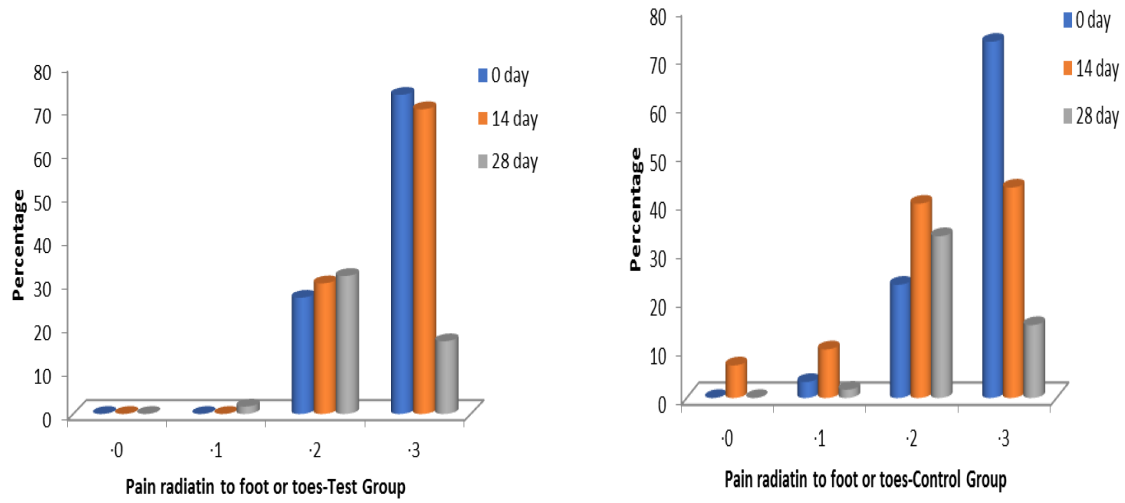

Figure 2: Effect on pain radiating to foot or toes, test versus control

In both the groups, 22 (73.3%) patients were having grade 3 (severe) pain radiating to foot or toes before treatment which dropped to 10 (33.3%) in test group and 9(30%) in control group after the treatment.

Numbness and paraesthesia in the same distribution [Table 2; Figure 3]

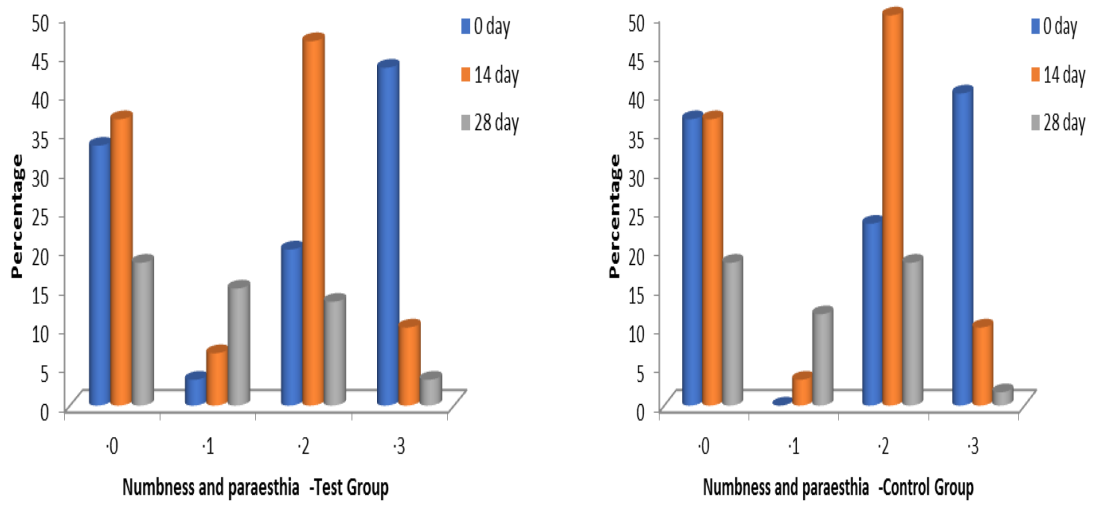

Figure 3: Effect on numbness and paraesthesia, test versus control

Before treatment, in test group, 20 patients (13-severe, 6- moderate & 1- mild) had numbness and paraesthesia in the same distribution while in control group 19patients (12-severe, 7- moderate) had numbness and paraesthesia in the same distribution. In majority of patients of test group, the numbness and paraesthesia in the same distribution improved from grade 3 to either grade 2 or grade 1 posttreatment. Similarly, improvement was also observed in control group with majority of patients reporting grade 2 or grade 1 numbness and paraesthesia in the same distribution after treatment.

Tingling, pins and needles [Table 2; Figure 4]

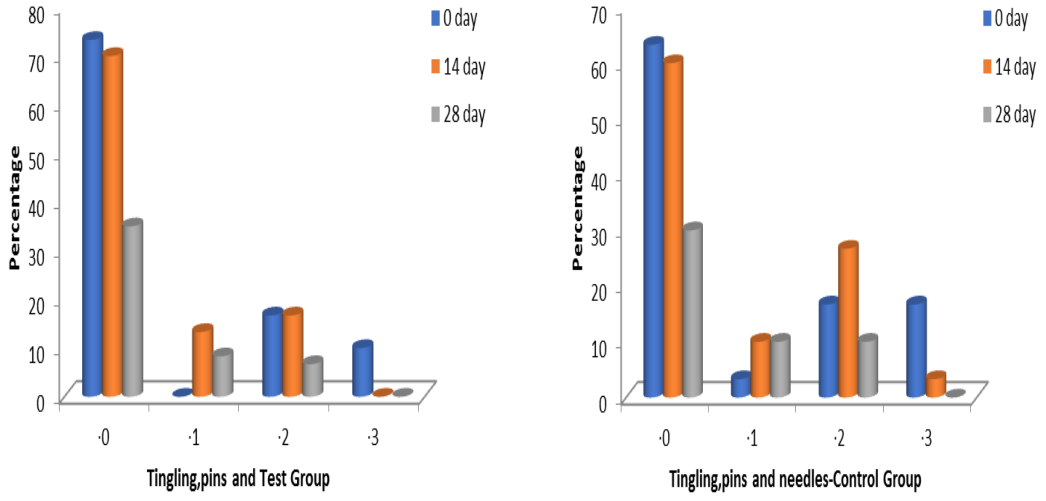

Figure 4: Effect on tingling, pins and needles, test versus control

Majority of patients in both the groups (22 patients in test group and 19 patients in control group) did not present with tingling, pins and needles before treatment. Before treatment, 3 patients in test group and 5 patients in control group had grade 3 tingling, pins and needles, however, at the end of treatment none of the patients in either of the groups reported grade 3 tingling, pins and needles. The symptom receded to either grade 1 or grade 2 in both the groups signifying the efficacy of both test as well as control treatment.

Muscle Weakness [Table 2; Figure 5]

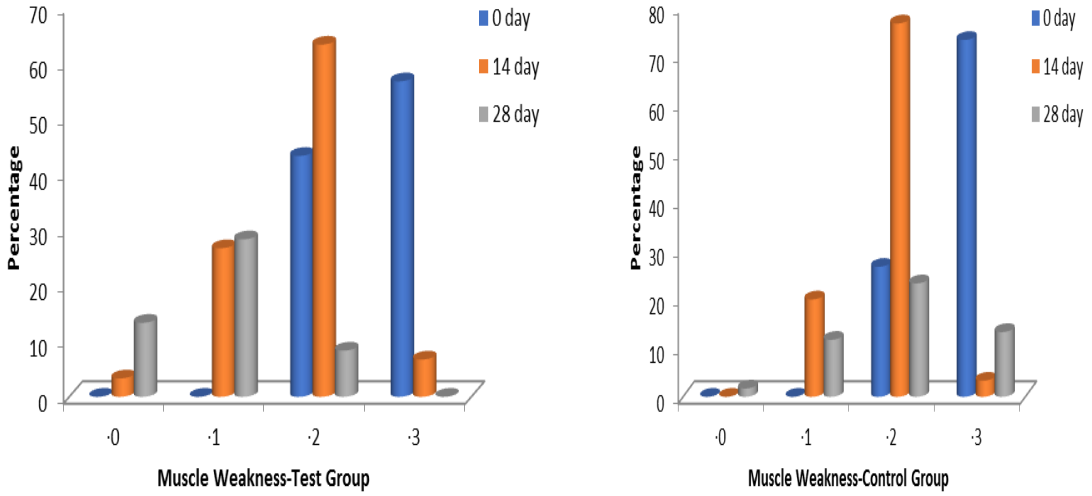

Figure 5: Effect on muscle weakness, test versus control

Before treatment, in the test group, 17 patients (56.7%) had muscle weakness of grade 3 and 13 patients (43.3%) had muscle weakness in grade 2 while in control group 22 patients (73.3%) had muscle weakness of grade 3 and 8 patients (26.7%) had muscle weakness in grade 2. At the same point of time, no patient was having muscle weakness in grade 1 or grade 0 in either of the groups. After initiation of treatment in both the groups, a significant reduction in patients with grade 3 muscle weakness was observed at 14th day follow up {test group 17 patients (56.7%) to 2 patients (6.7) whereas in control group 22 patients (73.3%) to 1(3.3)}.In test group, at day 28 follow up, no patient had grade 3 muscle weakness while the number of patients with grade 1 and grade 0 muscle weakness increased substantially from 0 (0%) to 17 patients (56.7%) and 0 (0%) to 8 patients (26.7%) respectively. Similarly in control group, at day 28 follow up, considerable decrease was observed in patients with grade 3 muscle weakness {22 patients (73.3%) to 8 patients (26.7%)} while the number of patients with grade 1 and grade 0 increased from 0(0%) to 7 (23.3%) and 0 (0%) to 1 (3.3%) respectively. Although the observed changes in muscle weakness grades were significant in both the groups but a higher percentage change was observed in test group with 8 patients(26.7 %) falling in grade 0 muscle weakness category at the end of treatment in comparison to 1 patient (3.3 %) in the control group. Similarly, in test group 56.7% increase was observed in patients with grade 1 muscle weakness in comparison to 23.3 % increase in control group.

DISCUSSION:

Both the groups were successful in alleviating leg pain, since both the groups were administered *Habb-e-Suranjan* revalidating its efficacy in *Waja al-Mafasil*but at the same time, the observations are suggestive that *Hijamah bil-Shart* (wet cupping) has provided additional analgesic effect in test group. *Hijamah bil-Shart* has been practiced traditionally for relieving pain (9,10,1).Analgesic effects of cupping has been already validated by various clinical trials conducted earlier ((11,12,13,14,15,16). Nociceptive activation also contributes to chronic pain and wet cupping mayalleviate pain by means of anti-nociceptive effects and by counter irritation. However, at present, it is unclear to what extent cupping induces such mechanisms (17).

Paraesthesia is a common accompanying feature of most compressed nerve radiculopathies. The relief in this symptom could be assumed most likely to the decompressive effect of *Hijamah bil-Shart*as it removes congestion and subsequently pressure on sciatic nerve, although the explanation remains speculative. According to the double-crush hypothesis, first proposed in 1973 by Upton and McComas, proximal lesions (such as those of cervical radiculopathies or musculoskeletal pain syndromes in referred zones) may predispose patients to neural injury at distal sites; accordingly, non-symptomatic impairment of axoplasmic flow along a nerve might eventually cause a symptomatic neuropathy. Wet cupping applies negative local vacuum pressure to subcutaneous muscle and tissue, causes local bloodletting, and has lymph-flow modulating effects. It may have altered tissue perfusion and metabolism, and may have subsequently affected nerve function. However, it remains unclear whether cupping works via its effects on proximal nerve function (17).

One of the causes of muscular weakness is immobility, which in this study, could be attributed to pain. Since the results of the present study as well as several previous studies conducted by various scholars suggests the pain relief by *Hijamah bil-Shart*, it subsequently also increases the mobility of the limb which in turn reduces muscle weakness. Also, *Hijamah bil-Shart* increases the vascularity of the area, further increasing muscular strength.

Conclusion

After execution of study and analysis of observed data, it could be concluded that *Hijama bil-Shart* (wet cupping)is effective therapy for the management of pain in patients of *Irq al-Nisa* (sciatic pain). The therapy is safe without any recorded side effects on safety parameters and exhibits fair improvement in quality of life when assessed on various questionnaire and tools.

SOURCE OF SUPPORT: Nil

CONFLICT OF INTEREST: There are no conflicts of interest.

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