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Comparative evaluation of effects of *Hijama bila Shart* and tens in *Wajaur raqaba* (Cervical spondylosis)

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Abstract
This study was conducted as an open, randomized, controlled, clinical study on 50 patients with 25 each in test and control group. Test group was treated with *Hijama bila Shart* and control group with TENS on alternate days, total 8 sittings were done in 15 days. The objective findings of pre and post treatment were assessed with the help of VAS and Vernon & Mior Cervical Spine Questionnaire.This study reveals that *Hijama* in test group and TENS in control group were found highly significant in the treatment of *Wajaur raqaba* (Cervical spondylosis). In fact a more reduction in mean score (In pain as well as in neck disability) was found in the test group than the control group and the intergroup comparison also shows that a significant difference exist between the groups, which signifies that *Hijama* has superior effect on TENS therapy in the treatment of *Wajaur raqaba* (Cervical spondylosis) on short term basis.

Keywords: *Wajaur raqaba, Hijama bila Shart*, Cervical spondylosis, TENS

1. Introduction
Cervical spondylosis is defined as the osteoarthritis in the cervical spine characterized by degeneration of the intervertebral disc and osteophyte formation [1]. It is considered as the most common progressive disorder in the aging cervical spine [2]. in which a sequence of changes takes place in the intervertebral disc, vertebral bodies, and facet joints. It is seen in 10% of individuals by the age of 25 years and in 95% by the age of 65 years [3]. Most of the individuals with degenerative changes of the cervical spine remain asymptomatic while the symptomatic patients are usually older than 40 years of age [4].There are three main symptom complexes related to cervical spondylosis: neck pain, cervical radiculopathy, and cervical myelopathy [5]. Axial neck pain is the typical presentation of the patients of cervical degenerative disc disease, while pain is the most prominent feature in acute cervical radiculopathy and diminishes as the condition becomes more chronic. It may be described as sharp, achy, or burning and may be located in the neck, shoulder or arm, depending on the nerve root involved. Symptoms of myelopathy are produced by the compression of the spinal cord rather than the nerve root as in case of the cervical radiculopathy, are almost bilateral and can affect the upper and lower limb unlike the radicular symptoms which is usually unilateral and affect the upper limb only. Upper motor neuron signs develop in the limbs with spasticity of the legs appearing first before the arms are involved and patients often feeling insidiously the unsteadiness of gait.
Degeneration of cervical spinal elements is the primary etiological factor in the development of cervical spondylosis. Cervical radiculopathy develops as a result of compression of the nerve root at or near the cervical neural foramen. It may be less commonly caused by some other factors e.g. intraspinal and extraspinal tumors, synovial cyst, and dural arteriovenous fistula & tortuous vertebral arteries [6, 7]. Cervical myelopathy develop as a result of compression of spinal cord or spinal vascular compression; it is also the most common cause of non-traumatic spastic paraparesis and quadriparesis.
As far as *Unani* system of medicine is concerned, the term *Wajaur raqaba* is not mentioned at all in any classical text, but most of the eminent physicians used the term *Wajaul Mafasil* to represent all types of joint pain, and also named them accordingly like *Niqras* (Gout), *WajaulWarik* (Ischial pain), *Irqunnasa* (Sciatica), *Wajaur Rakaba* (Knee pain) etc. Similarly, when *Wajaul Mafasil* occurs in *Fiqrate Unuq* and causes neck pain, it is known as *Wajaur raqaba* (Cervical spondylosis), because here *Waja* stands for pain and *Raqaba* stands for neck. So cervical spondylosis is also described as *Wajaur raqaba* a type of *WajaulMafasil*, and treated as per the line of treatment of *Wajaul Mafasil* asdescribed in *Unani* text.
The management of *Wajaur raqaba* (Cervical spondylosis) in modern medicine includes pharmacological and rehabilitation components. Non-steroidal anti-inflammatory drugs, corticosteroids, analgesics, muscle relaxants, anti convulsants and antidepressants are

frequently used in pharmacological management of the *Wajaur raqaba*(Cervical spondylosis). The rehabilitation components includes exercise oriented treatment, traction, thermal therapy, use of cervical collar, electrotherapy like ultrasound, transcutaneous electrical nerve stimulation etc. Though the use of NSAIDs and corticosteroids etc. provide a significant symptomatic improvement on short term basis, but their prolong use may induce a number of side effects. As for as concerned with the various regimens of physiotherapy used in rehabilitation components definitely they relieve the symptoms but not up to the mark of satisfaction.

In *Unani* system of medicine there are three modes of treatment exist [8-10] viz. – *Ilaj bit Tadbeer* (Regimenal therapy), *Ilaj bid Dawa* (Pharmacotherapy), and *Ilaj bil Yad* (Surgery). Among them *Ilaj bit Tadbeer*is one in which various regimens like *Hijama, Fasd, Dalk, Nutool,Irsale alaq* etc. are used to provide relief to the patients in various diseases successfully. From the above listed regimens *Hijama bila Shart* is one which is commonly prescribed to evacuate *Mawade Fasida* and to provide relief to the patients of *Wajaul Mafasil* but it still lacks the scientific validation. Hence, keeping the above facts in mind, we plan a study to evaluate and compare the effects of *Hijama bila Shart* with TENS in the management of *Wajaur raqaba* entitled as "Comparative evaluation of effects of *Hijama bila Shart* and TENS in *WajaurRaqaba* (Cervical spondylosis)"

2. Materials and Methods

2.1 Study Design: This was an Open, Randomized, Controlled, Clinical Study in subjects with *Wajaur raqaba* (Cervical spondylosis) which compared *Hijama bila Shart* (Dry cupping) versus Transcutaneous Electrical Nerve Stimulation (TENS) with a balanced design, the allocation ratio was 1:1 (25 in test group and 25 in control group). The study was approved by ethics committee of National Institute of Unani Medicine, Bengaluru.

2.2 Setting and Participants: The study was conducted in the Hospital of National Institute of Unani Medicine, Bangalore, affiliated to Rajiv Gandhi University of Health Sciences, Karnataka.Every patients of neck pain was individually questioned for the detailed history of the disease. Patients were clinically examined and their hematological and radiological investigations were carried out if the patients were eligible then informed consent was taken. Findings were recorded on the prescribed case report form designed for the study. The clinical study was conducted during the period of March 2016 to January 2017. The eligibility criteria consisted of age between 20-60 years, both gender, clinically and radiologically confirmed patients of *Wajaur raqaba* (Cervical spondylosis). Exclusion criteria included (1) History of cervical trauma or injury (2) Systemic diseases (e.g. Diabetes and Hypertension) (3) Pregnancy & Lactation (4) Any hemorrhagic disorder (5) Epilepsy (6) Patients on pacemaker.

2.3 Interventions: Before starting the procedure the patients were helped to be in correct posture, most of the patients prefer *Hijama* (Cupping) in sitting position while some feel relaxed in prone position. The area to be cupped was exposed properly and then the hair if present was removed to enable the cups to fix firmly on the body. Site of cupping was cleaned with spirit and betadine, vacuum pump is used to create negative pressure inside the cup, two medium sized cups of diameter 5.5 cm is applied on bilateral supra clavicular fossa and one large sized cup of diameter 6.5 cm is applied on the junction of C7 and T1 vertebra, 3-4 suction was made to create enough negative pressure, the cup was adhered to skin for 10 minutes and the site was observed carefully for any adverse reaction like formation of blister. After 10 minutes cups were removed by pulling up the valves of the cups easily. The cupping was done on alternate days for 15 days a total of 8 sittings were done.

TENS therapy was done on prone position, the intensity of current was adjusted according to the patients tolerability ranging from about 30-60 milliamps, the electrode pads were placed on paravertebral region (cervical) in a crossed pattern, the duration of procedure was 20 minutes on alternate days for 15 days a total of 8 sittings were done.

2.4 Outcome Measures: The primary efficacy measure used a VAS score (range 0-10 mm), the scoring was done on baseline and after the completion of the study i.e. on 15th day where 0 represent no pain and 10 represent worst pain. As the numerical value of scale increases the magnitude of pain also increases respectively. Secondary outcome measures were Vernon & Mior Cervical Spine Questionnaire. It comprises of 10 parameters viz. (1) Pain intensity (2) Personal care (3) Lifting (4) Reading (5) Headaches (6) Concentration (7) Work (8) Driving (9) Sleeping (10) Recreation. The severity of the symptoms were rated as the intensity of the disability increase 0, 1, 2, 3, 4, 5 (0 means absence, and 1-5 indicates increasing severity).

The scores were summed for each patient at each assessment point (based on the involvement of the objective parameters), to obtain a neck pain score, with a maximum value of 50 points.

2.5 Data Analysis. Descriptive and inferential statistical analysis has been carried out in the present study. Results on continuous measurements were presented on Mean ± SD (Min-Max) and results on categorical measurements were presented in Number (%). Significance is assessed at 5 % level of significance. The assumptions on data are made (1) Dependent variables should be normally distributed. (2) Samples drawn from the population should be random. (3) Cases of the samples should be independent.

Student t-test (two tailed, independent) has been used to find the significance of study parameters on continuous scale between two groups (Inter group analysis) on metric parameters. Student t-test (two tailed, dependent) has been used to find the significance of study parameters on continuous scale with in each group.Chi-square/ Fisher Exact test has been used to find the significance of study parameters on categorical scale between two or more groups, Non-parametric setting for Qualitative data analysis. The Statistical software namely SAS 9.2, SPSS 15.0, Stata 10.1, MedCalc 9.0.1, Systat 12.0 and R environment ver.2.11.1 were used for the analysis of the data.

3. Results

3.1 Participants: A total of 250 patients were screened, out of which, 90 patients fulfilled the study criteria were subjected to clinical and laboratory investigation, finally 57 patients were enrolled and randomly allocated to two groups, 28 in group A (Test group) and 29 in group B (Control group), 3 patients in test group and 4 patients in control group were failed to attend the follow up, a total of 50 patients completed the study protocol, 25 in each group. (Figure 1)

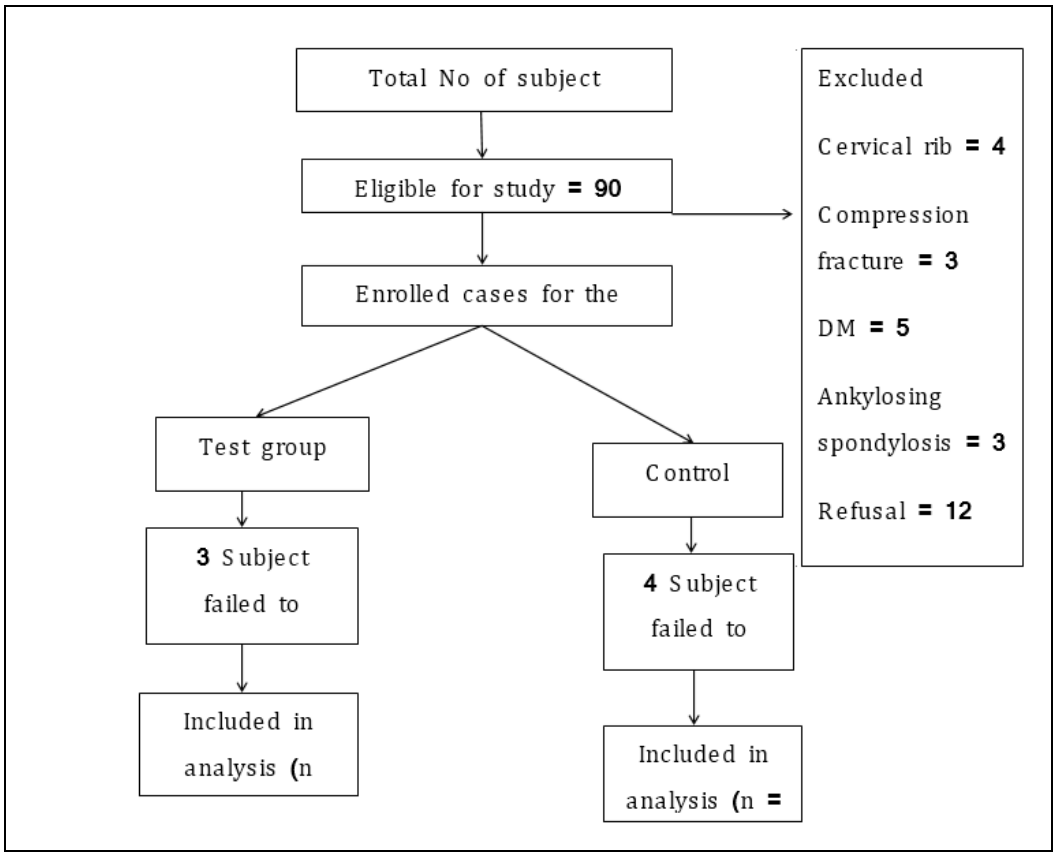

Fig 1: Flow chart of Study Patients (Consort Diagram)

3.2 Baseline characteristic of the patients: Table 1&2 summarizes the main baseline characteristic of the 50 patients. At baseline the demographic characteristic were well balanced among the two groups.

Table 1: Age distribution of patients studied

Age in years	Test group	Control group	Total
<30	0(0%)	1(4%)	1(2%)
30-40	6(24%)	7(28%)	13(26%)
41-50	9(36%)	10(40%)	19(38%)
51-60	10(40%)	7(28%)	17(34%)
Total	25(100%)	25(100%)	50(100%)
Mean ± SD	47.84±9.31	45.32±8.39	46.58±8.86

Samples are age matched with P=0.320, student t test

Table 2: Gender distribution of patients studied

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%)

Samples are gender matched with P=0.733, Chi-Square test

3.3 Primary outcome measure: In present study, values of VAS score (Mean ± SD)in test group at 1st day and 15th day were 5.16 ± 1.21 and 2.36 ± 1.47 respectively. The difference between Mean ± SD scores from baseline and 15thday was found highly significant (p<0.001). The Values of VAS score (Mean ± SD)in control group at day 1st and 15thwere 5.36 ± 1.25 and 3.56 ± 1.36, respectively. The difference between Mean ± SD scores from baseline and 15th day was also found highly significant (p<0.001) when compared using paired t-test. The intergroup comparison at 15th day on VAS scale score between test group and control group was found moderately significant (p<0.01) with a mean difference of 1.20, when compared using unpaired student t- test. (Table 3)

Table 3: between group: Student t test (Unpaired), within group: Student t test (Paired)

Objective Parameters	Test group	Control group	P Value
VAS			
BT	5.16±1.21	5.36±1.25	0.569
AT	2.36±1.47	3.56±1.36	<0.01
P value	<0.001	<0.001	
NDI			
BT	20.20±4.20	19.92±4.42	0.819
AT	11.00±3.73	15.72±4.47	<0.001
P Value	<0.001	<0.001	

3.4 Secondary outcome measures: In present study values of NDI score (Mean ± SD) in test group at 1st day and 15th day was 20.20 ± 4.20 and 11.00 ± 3.73 respectively. The difference between Mean ± SD scores from baseline and 15th day was found highly significant (p<0.001). The values of NDI score (Mean ± SD) in control group at day 1st and 15th was 19.92 ± 4.42 and 15.72 ± 4.47 respectively. The difference between Mean ± SD scores from day 1st and 15th day was also found highly significant (p<0.001) by using paired t-test. The intergroup comparison at 15th day on NDI score between test group and control group was found highly significant (p<0.001) by using unpaired student t- test. As the greater reduction in NDI score was found in test group than control group and the inter group comparison also shows that a highly significant difference exist between the group. So, it is concluded that a greater improvement was found in test group than the control group in reduction of the neck disability score. (Table 3)

3.5 Adverse Events: No adverse effect or reaction was reported by any of the two groups. Therefore, it is presumed that the interventions *Hijama bila Shart*, and TENS therapyare free from any kind of unexpected or unusual effects.

4. Discussion

Cervical spondylosis is a broad term which defines age related degeneration of the intervertebral disc. Nerve fibers and nociceptive nerve endings are present in the peripheral portions of the disc and in the capsule & synovium of the facet joints [11, 12]. Thesedegenerative changes and their associated nerve impingement are responsible for the three clinicalsyn dromes in which *Wajaur raqaba* (Cervical spondylosis) presents. Patho-anatomic changes are generally well visualized on imaging studies and must be correlated with the clinical findings. Most patients with axial neck pain, cervical radiculopathy, or mild cervical myelopathy have a better response to an initial trial of non-operative management. In present study the allocated treatment; *Hijama* in test group and TENS in control group were found highly significant in the treatment of *Wajaur raqaba* (Cervical spondylosis). In fact a more reduction in mean score (in pain as well as neck disability) was found in the test group than the control group and the intergroup comparison was also found significant different which signifies that *Hijama* has superior effect on TENS therapy in the treatment of *Wajaur raqaba* on short term basis. A study done by Baig MG*et al*. concluded that *Hijamabila Shart* is comparatively more effective than *Habbe Gule Aakh* in the treatment of cervical spondylosis [13]. Similarly Lauche R*et al*. concluded that a single application of traditional cupping might be effective in the treatment of chronic non-specific neck pain [14].Thus the above mentioned studies are in line with our study findings.

Hijama (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 disease is the imbalance of *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. According to the modern concept so many theories are given to describe the mechanism of action of *Hijama* (cupping), Hong *et al*. [15] described that *Hijama* (Cupping) therapy works via 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 auto-hemolysis [15]. Gao *et al*. suggested that putting cups on selected part on the skin produces hyperemia or hemostasis which results in a therapeutic effect[16].Taibah theory suggested that when negative pressure (suction force) is applied to the skin it results decrease in pressure (Boyle's law) around capillaries. This causes 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 and breaks tissue adhesions causing decreased pain [17].

5. Conclusion

In present study it is concluded that the allocated treatment; *Hijama* in test groupand TENS in control group were found highly significant in the treatment of *Wajaur raqaba* (Cervical spondylosis). In fact a more reduction in mean score (in pain as well as neck disability) 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* has superior effect on TENS therapy in the treatment of *Wajaur raqaba* on short term basis. Present study has shown no clinically significant adverse effects, and overall compliance to the treatment of two groups was creditable. It is also conclude that due to the available resources this study was conducted with limited parameters and needed more comprehensive parameters based on long term and larger sample size for further exploration of the effects of study method adopted and also to determine their mechanism of action.

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7. Conflict of Interest: There are no conflicts of interest.

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