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The efficacy and safety of dry cupping in cervical spondylosis with optimization of cup application time – A randomized clinical trial

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Abstract

Objectives: Dry cupping therapy (DCT) is considered beneficial in the amelioration of cervical spondylosis (CS) symptoms in Unani medicine. Therefore, the focus of this study was to ascertain the efficacy of DCT and optimal cup application time duration for CS.

Methods: It was a randomized clinical trial involving 45 participants with clinically diagnosed CS. The eligible subjects were randomly categorized into three groups, each having 15 participants. Each of the three groups, i.e., A, B, and C, received DCT daily for 15 days for 8 min, 10 min, and 12 min, respectively. All the participants were evaluated at the baseline, 7th, and 15th days of the trial using the neck disability index (NDI) as well as the visual analogue scale (VAS).

Results: The baseline mean ± SD of NDI and VAS scores were significantly reduced in all the three groups at the end of the trial. Although all three groups were statistically equal in terms of NDI, group-C demonstrated greater efficacy in terms of VAS.

Conclusions: The per-protocol analysis showed that dry cupping effectively alleviated neck pain across all treatment groups. Although, this effect on neck disability index was statistically equal in all three groups, the 12-min protocol was more successful in reducing pain.

Keywords: cervical spondylosis; dry cupping; *Hijama bila Shart*; neck pain; Unani medicine.

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Introduction

Spondylosis is an umbrella term for degenerative changes in the spine that can irritate and/or harm the surrounding nerve roots or the spinal cord [1]. It is a common musculoskeletal disease that affects a large proportion of the population, resulting in significant pain and disability [2]. Degenerative disease of the cervical spine generally occurs due to normal ageing process, affecting roughly two-thirds of the population at some point in their lives, with a peak prevalence in middle age [3]. The highest prevalence is observed in the age bracket of 45–60 years [4]. In the global burden of disease study, neck pain was placed fourth among the top ten causes of years lived with disability [5]. Adults are anticipated to have a lifetime prevalence of 48.5%, while screen-using employees are predicted to have a lifetime prevalence of 55%. Now, it has become the 3rd most commonly diagnosed musculoskeletal condition by MRI in the age group of 51–60 years [6].

Humans have become embroiled in a variety of undesirable activities because of their fast-paced existence and the aeon of technology [7]. Most cases of cervical spine degeneration remain asymptomatic. Although the symptoms manifest themselves commonly after the age of 40, caused by the compression of neural structures. Moreover, genetic predisposition, smoking, physical inactivity, ruptured or slipped discs, prior neck injury, and chronic rheumatoid arthritis can also lead to the evolution of cervical spondylosis (CS) [8, 9].

CS presents with three distinct clinical syndromes: axial neck discomfort, cervical spondylotic radiculopathy, and degenerative cervical myelopathy [10]. Axial neck pain is associated with restricted mobility of the cervical spine, paraspinal muscle spasm, and referred pain. Cervical spondylotic radiculopathy occurs when a cervical nerve root is compressed or irritated mechanically or chemically, typically at its exit from the spinal canal; whereas degenerative cervical myelopathy is a distinct syndrome characterized by neurologic deficits in the upper and lower limbs due to spinal cord compression as a result of degenerative disc and/or facet joint abnormalities [10, 11]. Conventionally, axial neck pain and cervical spondylotic radiculopathy can be managed conservatively

with nonsteroidal anti-inflammatory drugs (NSAIDs) and cervical traction; progressive myelopathy can be treated surgically with laminectomy, partial discectomy, and foraminotomy with or without fusion to prevent further cord compression, vascular compromise, and myelomalacia [12–15], but these procedures are associated with a variety of undesired effects [16].

In conventional medicine, different types of drugs like NSAIDs and analgesics, cervical epidural steroids, etc., have been used for its management, but considering their side effects, long-term use is usually not recommended. Surgical decompression, anterior discectomy, and laminectomy can also be done, but most people avoid surgical interventions due to complications and higher expense; rather, they prefer the conservative and non-operative treatments [11, 17].

Unani medicine, in comparison to mainstream medicine, takes an entirely different approach to diagnosing and managing ailments. It has made substantial contributions to date, with the scientific validation of a number of traditional medicinal formulas [18–21]. Although CS is not explicitly stated in the classical Unani literature, Unani researchers and scholars have regarded it as a subtype of *Waja' al-Mafāsil* [22, 23], which is an umbrella term encompassing all sorts of joint pain and swelling, with some particular terminologies denoting the involvement of specific joint; such as *Waja' al-Zahr* (low back pain), *Waja' al-Warik* (hip joint pain), *Waja' al-Khaṣira* (buttock pain), *Waja' al-Rakba* (knee joint pain), *Waja' al-Aqib* (heel pain), *Irq al-Nasa* (sciatica), *Niqris* (gout), etc. Similarly, the neck pain is referred to as *Waja' al-Raqaba* (cervical spondylosis) [24–26]. Thus, the line of treatment of *Waja' al-Raqaba* is similar to that of *Waja' al-Mafāsil* which includes *'Ilāj bi'l Tadbīr* (regimen therapy) and *'Ilāj bi'l Dawa* (pharmacotherapy) [27]. In*'Ilāj bi'l Tadbīr* (regimen therapy), *Asbāb-i Sitta Ḍarūriya* (six critical living factors based on the Unani concept) are modified to manage the disease. Many regimens, such as *Hijāma* (cupping therapy), *Fasd* (venesection), *Dalk* (massage), *Natūl* (irrigation), *Irsāl-i 'Alaq* (leeching), *Qayy* (emesis), *Idrār-i Bawl* (diuresis), *Hammam* (medicated bath) etc. are often used to evacuate *Fāsid Mawād* (morbid matter) from the body or the affected site to restore the normal health and vitality of the individual [28]. Among all of these regimens, *Hijama bila Shart* (dry cupping) has a significant role in pain management owing to its capacity to divert the causative morbid material [29]. There is a wealth of evidence supporting its efficacy in neck pain management [23, 30], but the optimization of the process in terms of cup application time, cup number, cup size, and interval between the repeated cupping procedures has not been scientifically explored so far. Hence, the current study aims to maximize and scientifically substantiate these variables in the management of CS.

Materials and methods

This study is reported in accordance with the STRICTOC guidelines recommended by Zhang et al. 2020 [31].

Study design and setting

This three-arm randomized clinical trial took place at the Department of *'Ilāj bi'l Tadbīr* (IBT), National Institute of Unani Medicine (NIUM), Bengaluru, India. Participants were recruited from the OPD/IPD of the hospital between October 2020 and January 2021.

Participants

Participants aged 20–60 years with clinically and radiographically confirmed CS were recruited in the trial; while participants with the history of cervical trauma or injury; concomitant skin infections; tuberculosis; posthealed cervical fracture; all types of arthritis except osteoarthritis; kyphosis and lordosis; cervical spine tumors; any undergoing systemic medical or surgical treatment or physical therapy for cervical radiculopathy, corticosteroid use, including oral corticosteroid within 14 days of trial, intramuscular corticosteroid within 30 days, intra-articular corticosteroid within 90 days, and ongoing use of topical corticosteroid at the site of cupping points and cervical rib syndrome were excluded from the study. Similarly, participants not willing or able to follow the study protocol were also excluded.

Sample size estimation

The sample size for this experiment was determined using data from a prior study in which the mean ± SD difference of the NDI score was 16.68 ± 15.05 [32]. Thus, a sample size of 36 (12 patients per group) was calculated with an assumed power and alpha of 80% and 5%, respectively. Assuming a 20% drop-out, the total sample size was 45.

Cupping rationale

Style of cupping: The main goals of this research were the optimization of cup application time as well as ascertaining the efficacy and safety of dry cupping in patients with CS. Therefore, we designed a three-arm, randomized clinical trial in terms of three different cup application time durations, i.e., 8 min, 10 min, and 12 min.

Reasoning for cupping provided: Cupping therapy (CT) is a time-honored healing procedure that entails the placement of cups on specific skin points and the generation of sub-atmospheric pressure via heat or suction. Hippocrates described the cupping application in detail, which was expanded upon and utilized by prominent Arabic physicians like Ibn Sina, al-Zahrawi, and Razi [33].

CT is classified into dry or wet types of cupping. Wet cupping entails bloodletting, whereas dry cupping entails diversion of morbid matter from one site to another without incision [30]. Although, CT has been utilized to treat various ailments, we are unaware of any previous

research examining its efficacy over varying time periods of cup application in CS.

Details of cupping

***Patient posture during the DCT*:** The patients sat or lay prone with their back exposed.
Devices used for cupping: The vacuum was created using plastic cups equipped with a non-return valve and a plastic vacuum pump.
***Name and number of points used for DCT*:** It was done at three different points on three separate occasions. The first two areas were supraclavicular fossae, whereas the third area was the junction of C7 and T1 vertebrae, referred to in Arabic as *al-Kāhil*.
Number of cupping units and cupping time per location: Two medium-sized cups with a diameter of 5.5 cm and one large-sized cup with a diameter of 6.5 cm were utilized. Suction was exercised three times to create sufficient negative pressure, and the cup remained stuck to the skin for eight minutes in group A patients, ten minutes in group B, and twelve minutes in group C.
***Procedure and technique for DCT*:** The participants were instructed to maintain a relaxed posture, either sitting or prone with their backs exposed. The region to be cupped was cleansed with an antiseptic solution. Hairs were removed appropriately to ensure that the cups adhered firmly to the cupping site. Following that, two medium cups were placed bilaterally on the supraclavicular fossae and one cup on the intersection of the C7 and T1 vertebrae. Suction was exercised three times to create sufficient negative pressure, and the cup was adhered to the skin for 8 min, 10 min, and 12 min in groups A, B, and C, respectively. The site was observed for any adverse reactions. After the specified duration, the cups were detached by pulling up their valves.
Responses sought from the patients: Participants in all three groups were told that they might feel suction at first, but that it would go away after a few seconds as the skin receptors adapted to the stretch stimulus [34].

Therapist background

Cupping was conducted by experienced, qualified physicians who practised cupping on a regular basis in the clinical setting.

Rationale for the type of comparator used

Hijama bila Shart (dry cupping) is the one that plays a critical role in pain management owing to its capacity to divert causative morbid material [29]. There is an abundance of research demonstrating the efficacy of dry cupping in neck pain [23, 30] but optimization of the process in terms of cup application time, cup number, cup size, and interval between repeated cupping procedures has not been done so far. Therefore, three cup application time spans were compared to optimize one of these variables.

Randomization

Randomization was accomplished by an allocation concealment strategy that utilized the method of randomly permuted blocks generated through the online randomization plan generator website, http://www.randomisation.com. These three-person randomization blocks were provided to the investigator at the time of enrolment by the Dept. of IBT, NIUM, Bengaluru.

Outcome measures

The primary outcome measures for this study were changes in the NDI and 10 cm VAS, with zero indicating no pain and 10 indicating severe pain. The NDI is a frequently used questionnaire for determining disability in patients suffering from neck pain. It consists of ten variables: (1) pain intensity, (2) personal care, (3) lifting, (4) reading, (5) headache, (6) concentration, (7) work, (8) driving, (9) sleeping, and (10) recreation. Each variable is graded on a scale of 0–5 with 0 representing no severity and 1–5 representing graded severity. The greatest possible score for all variables added together is 50 [35]. Both the NDI and VAS were evaluated at baseline, the 7th and the 15th day of the trial.

Safety and adverse event monitoring

Safety evaluation was done at each visit on the basis of clinical examination and dermal tolerability. If any undesired effect occurred at the local or systemic level, the same was appropriately documented in the case report form.

Withdrawal criteria

Participants were withdrawn from the trial if they experienced adverse event/s requiring extra therapy, voluntarily withdrew, or missed any procedure session.

Statistical methods

The proportion, mean, and standard deviation of all the data were calculated and analyzed using the statistical programme IBM SPSS Statistics v25. The one-way ANOVA, Kruskal-Wallis test, and paired sample t-tests were employed to arrive at the conclusion; $p<0.05$ was considered significant in this study.

Results

Participant flow

A total of 60 participants were screened for eligibility. The study enrolled 45 participants (15 from each group) who met the eligibility criteria of the trial. During the study, 9 participants were dropped, and a total of 36 patients (12 in each group) completed 15 days of protocol therapy and were analyzed statistically (Figure 1).

Clinico-demographic profile

The mean ± SD values of the age of participants in group A, group B, and group C were 40.58 ± 7.77, 45.8 ± 11.46 and

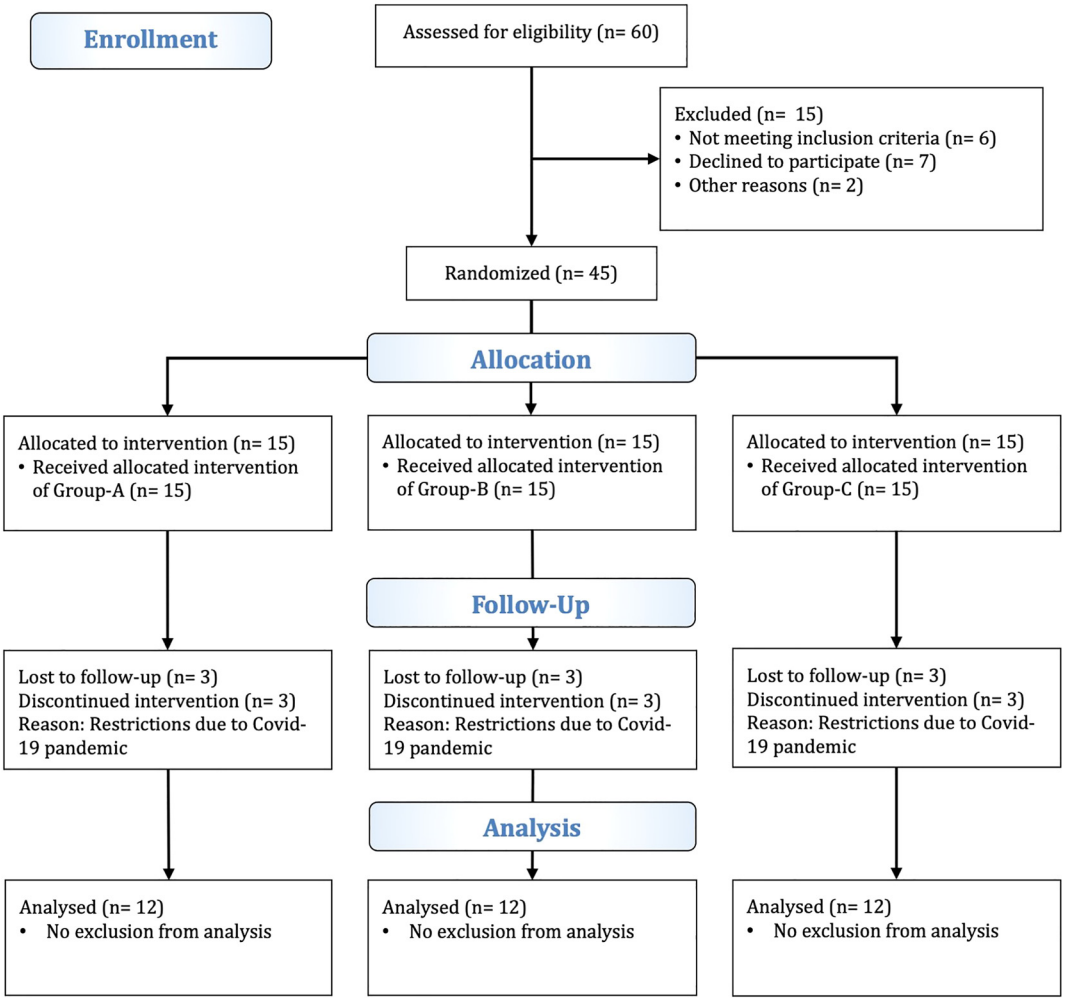

Figure 1: CONSORT flow diagram of the participants studied.

43.6 ± 12.01 years, respectively. The mean ± SD values of the BMI of participants in group A, group B and group C were 25.9 ± 4.33, 23.9 ± 2.71, and 24.2 ± 4.07 kg/m^2 respectively. The mean ± SD values of the pain chronicity of participants in group A, group B and group C were 25.9 ± 4.33, 23.9 ± 2.71, and 24.2 ± 4.07 months, respectively. There were 6 (50.0%) males and 6 (50.0%) females in all three groups. All 12 (100.0%) cases in group A and group B were married, while in group C, 10 (83.3%) were married and 2 (16.6%) were unmarried. Out of 36 participants, the majority, 17 (47.22%) belonged to the upper lower class, (17 (27.77%), followed by the lower-middle 10 (27.77%), upper-middle 8 (22.22%), and lower 1 (2.77%) strata (Table 1).

Change in NDI

The baseline mean ± SD of the NDI score was 18.67 ± 9.16, 23.67 ± 9.37 and 27.17 ± 14.86 in groups A, B and C, respectively, which was significantly reduced to 18.08 ± 8.94 in group A (p=0.027) and insignificantly reduced to 23.00 ± 9.56 and 25.33 ± 11.45 in group B (p=0.104) and group C (p=0.152) on the 7th day. However, on the 15th day, baseline NDI was significantly reduced to 13.50 ± 7.63, 16.17 ± 8.96, and 13.67 ± 6.92 with p-values of 0.004, 0.0001, and 0.002 in groups A, B, and C, respectively. However, the analysis among all three groups unveiled that the difference was statistically insignificant at each follow-up (p>0.05), implying that all time spans of DCT were statistically equal in terms of efficacy (Table 2).

Change in VAS

The baseline mean ± SD of the VAS score was 5.25 ± 1.96, 5.67 ± 1.37, and 6.25 ± 1.96 in groups A, B, and C, respectively, which significantly reduced to 4.92 ± 1.98, 5.17 ± 1.27, and 5.58 ± 1.93 on the 7th day with p-values of

Table 1: Clinico-demographic characteristics of participants who completed the trial therapy.

	Group A (n=12)	Group B (n=12)	Group C (n=12)	p-Value
Demographic parameters				
Age, years	40.58 ± 7.77	45.8 ± 11.46	43.6 ± 12.01	0.482[a]
BMI, kg/m^2	25.9 ± 4.33	23.9 ± 2.71	24.2 ± 4.07	0.395[a]
Chronicity of pain, month	21.08 ± 12.12	32.50 ± 17.06	25.00 ± 15.53	0.184[a]
Marital status				
Married	12 (100.0%)	12 (100.0%)	10 (83.3%)	0.314[b]
Unmarried	0 (0%)	0 (0%)	2 (16.7%)	
Socio-economic status				
Upper middle	2 (16.7%)	1 (8.3%)	5 (41.7%)	0.126[b]
Lower middle	3 (25.0%)	3 (25.0%)	4 (33.3%)	
Upper lower	7 (58.3%)	8 (66.7%)	2 (16.7%)	
Lower	0 (0.0%)	0 (0.0%)	1 (8.3%)	

[a]One way ANOVA, [b]Kruskal-Wallis test.

Table 2: Change in neck disability index of all three groups at different study points.

NDI	Baseline	7th day	15th day	p-Value[a] (within-group)	
				7th day	15th day
Group A	18.67 ± 9.16	18.08 ± 8.94	13.50 ± 7.63	0.027	0.004
Group B	23.67 ± 9.37	23.00 ± 9.56	16.17 ± 8.96	0.104	0.0001
Group C	27.17 ± 14.86	25.33 ± 11.45	13.67 ± 6.92	0.152	0.002
p-Value[b]	0.203	0.210	0.654		–

[a]Paired samples t test, [b]one way ANOVA

0.039, 0.007, and 0.001. Furthermore, on the 15th day, it was significantly reduced to 3.67 ± 2.15, 3.58 ± 1.08, and 2.00 ± 1.35 with p<0.0001 in all three groups. The analysis among all three groups revealed that the difference was statistically insignificant on the 7th day (p=0.646) but significant on the 15th day (p=0.024), inferring statistically similar efficacy of all interventions on the 7th day and greater efficacy of group C on the 15th day (Table 3).

Adverse events

The trial intervention was found to be well tolerated in each group, with no adverse effects during the whole course of the trial.

Discussion

The goal of this study was to find out how well *Hijama bila Shart* (dry cupping) worked for people with cervical spondylosis when they used cups for three different lengths of time.

Out of 36 participants studied, a maximum of 24 (66.7%) cases fell within the age range of 41–60 years, while 12 (33.3%) instances fell within the age range of less than 40 years with mean ± SD; 43.36 ± 10.51. The age data was in agreement with the prevalence data concluded by Mahbub et al. and Lv et al. [4, 7]. Gender-wise, male and female participants were equally distributed. Contrary to these findings, several research studies found that females had a higher prevalence rate [4]. Male prevalence may be

Table 3: Change in VAS score of pain severity at different study points.

VAS	Baseline	7th day	15th day	p-Value[a] (within-group)	
				7th day	15th day
Group A	5.25 ± 1.96	4.92 ± 1.98	3.67 ± 2.15	0.039	0.0001
Group B	5.67 ± 1.37	5.17 ± 1.27	3.58 ± 1.08	0.007	0.0001
Group C	6.25 ± 1.96	5.58 ± 1.93	2.00 ± 1.35	0.001	0.0001
P-value[b]	0.397	0.646	0.024		–

[a]Paired samples t test, [b]one way ANOVA.

increased because of females' aversion to CT due to the procedure's requirement of exposing the back. The majority of participants were married (94.4%). That may be associated with the onset of CS symptoms at advanced age. It was also discovered that most participants (17; 47.2%) came from the upper lower class, followed by 10; 27.7% from the lower middle, 8; 22.2% from the upper middle, and 1; 2.7% from the lower classes. The findings corroborate prior research demonstrating a higher prevalence of CS among load bearing labourers [7, 36, 37], because most of the study participants in this study were labourers and daily wagers.

The per-protocol analysis showed that DCT effectively alleviated neck disability and pain across all durations. Although the effect on NDI was statistically equivalent in all the groups, the 12-min treatment duration (group C) was more effective in the reduction of pain.

Undoubtedly, there is a dearth of credible scientific evidence elucidating the precise process underlying the therapeutic benefit of CT [38]. However, numerous explanations have been promulgated for its effects, both in the traditional and scientific arenas [39]. Unani medical philosophy considers that DCT works by diverting morbid material away from/around the afflicted site of the organ, which results in alleviating pain, decreasing inflammation, eliminating causative biochemicals, decreasing stiffness, and dissolving the *Rīh* (pneuma) [40]. Apart from this, many physicians assert that increased circulation around the cupped area enables toxins and morbid matter buried deep inside the soft tissue layers to ascend to the body surface, ameliorating the pain [39]. Additionally, acupuncture and acupressure share many of the same concepts as CT. Thus, the neural mechanism hypothesis of pain reduction may also be considered for CT [41]. Li et al. observed that cupping benefits are the outcome of a hemodynamic mechanism that facilitates muscular activity, as seen by decreased deoxy-haemoglobin and increased oxy-haemoglobin levels in cupping-treated muscle areas [42].

In a nutshell, it may be concluded that DCT is helpful in alleviating pain and neck disability associated with cervical spondylosis. Additionally, it is inferred that prolonging the duration of cup application greatly reduces neck pain but has no effect on neck disability. However, many limitations should be considered while interpreting study results, including the shorter duration of the trial, smaller sample size, and variations in the number of cups and their size.

Conclusions

The study inferred that *Hijamat bila Shart* (dry cupping) is effective in the alleviation of neck pain and disability associated with *Waja' al-Raqaba* (cervical spondylosis). Moreover, extending the cup application time may reduce neck pain while having no effect on neck disability. Thus, extending the duration of therapy may be preferable to increasing the cup application time for the alleviation of neck disability, while the cup application time may be increased if the primary goal is only pain relief. However, considering the study limitations, well-designed RCTs with a larger sample size and longer duration are vital to establish the scientific evidence.

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Informed consent: Prior to the intervention, eligible individuals were given an oral explanation of the study and written informed consent was obtained.
Ethical approval: This clinical study adhered to the ethical standards of good clinical practise and the Helsinki declaration. The protocol for this study was approved by the institutional review board of the National Institute of Unani Medicine, Bengaluru, India (Ref. no. NIUM/IEC/2018-19/024/IBT/04). Additionally, the study was registered with the Clinical Trials Registry – India (CTRI) under the registration number CTRI/2020/07/026475.

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