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Research Article

Cervical Spondylosis

Randomized, Standard Controlled Study Evaluating the Efficacy and Safety of Habb-e-Waja'al-Mafāsil in Managing Cervical Spondylosis

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Background and Objectives: Cervical Spondylosis is a degenerative disease of intervertebral discs and adjacent vertebral bodies of the cervical region due to wear and tear changes. Neck pain, radiculopathy, and stiffness comprise the prime features of cervical spondylosis demanding immediate attention and respite. Despite the advancement in pharmacological, nonpharmacological and surgical interventions, the management remains unsatisfactory due to high cost, adverse effects and unusual eventualities. Hence a clinical trial was done to evaluate the efficacy of herbal formulation, Habb-e-Waja'al-Mafāṣil (HWM), in managing cervical spondylosis (Waja'al-'Unuq). **Methods:** The study is an open-labelled, randomized and standard controlled trial. Sixty diagnosed patients of age group 20 to 70 years were randomly allocated, using a computer-generated chart, in the test group (n=30) receiving HWM (6gm), and the control group (n=30) receiving ibuprofen 1200mg/day, orally in divided doses. The severity score of clinical symptoms and signs; pain, stiffness, swelling, restriction of movement and radiological findings were analyzed at baseline and 30 days. **Results:** Both HWM and ibuprofen significantly reduced the severity score of pain, stiffness, swelling, and restriction of movement (p=<0.001) associated with cervical spondylosis after completion of the treatment protocol. However, no change was observed in radiological findings in either group (p=1). In comparison to the control group, no significant result was noticed in the test group statistically (p=>0.05), except for "restriction of movement" (p=<0.05). **Conclusion:** The herbal formulation, HWM, is equally effective as conventional treatment in managing cervical spondylosis. Therefore, HWM can be prescribed as a safe and cost-effective alternative treatment for cervical spondylosis.

Keywords: Herbal, Radiculopathy, Spondylosis, Unani

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Introduction

Cervical spondylosis is the term widely comprising progressive degenerative changes that affect all cervical spine components. Secondary to multifactorial degenerative changes in the cervical spine, narrowing of the neural foramen most marked at C5-6 and C6-7, may occur [1]. This is one of the most common degenerative disorders of the spine affecting 95% of patients by the age of 65 years [2]. It is a leading cause of musculoskeletal disability in humans with an incidence rate of 83 per 100,000 populations and a prevalence of 3.3 cases per 1000 people and occurs mostly in the fourth and fifth decades of life [3]. One or more cervical nerve roots may be compressed, stretched, or angulated and myelopathy may develop as a result of compression, vascular insufficiency, or recurrent minor trauma to the cord [4]. The symptoms of cervical spondylosis are often divided into three groups a) Main or principal symptoms b) Marginal symptoms c) Inexplicable symptoms. Principal symptoms encompass cervical pain, radiculopathy and myelopathy. Marginal symptoms are those that are linked to cervical spondylosis but are not caused by it. Cervical migraine, shoulder stiffness, frozen shoulder, chest discomfort, tinnitus, blurred vision, dizziness, and other symptoms are some of them. Bilateral arm paralysis that mimics motor neuron disease or amyotrophic lateral sclerosis without developing bulbar palsy or leg paralysis for a long time is an inexplicable symptom. Cervical spondylosis is a frequent and disabling disorder, which is why it has been treated in a variety of ways, including pharmacological, non-pharmacological, and surgical methods. Non-pharmacological and conservative pharmacological treatments include exercise, use of a cervical collar, mechanical cervical traction, massage, acupuncture electrotherapy laser, NSAIDs, opioid muscle relaxants, corticosteroid drugs, and antidepressant drugs [5]. Ibn Zohar (1162AD) stated that the accumulation of Khliṭ luzj mukhāṭī (morbid humors) in the cervical vertebrae causes misalignment of vertebrae thereby developing irritation of the spinal cord resulting in severe pain and weakness of different regions of the body [6]. Unani physicians managed joint disorders with different treatment varieties that is through diet, drug, and regimental therapy, more specifically certain regimens like Takmeed (Fomentation), Ṭilāʾ (liniment), Ḍimād (paste), Roghaniyat (oils), Dalk (massage), Ḥijāma Bilā Sharṭ (dry cupping), Ḥijāma biʾl Nār (fire cupping), Faṣd (venesection) etc. These herbal formulations and regimes are considered to be safe and effective in managing joint disorders and associated symptoms. Therefore, it felt necessary to evaluate the efficacy and safety of an Unani herbal formulation, HWM, for cervical spondylosis in comparison to conventional treatment. The ingredients of HWM are; Sibr (Aloe barbadensis Mill) (140gm), Halela zard (Terminalia chebula) (35gm), Suranjaan (Colchicum autumnale) (35gm), and Saqmooniya (Convolvulus scammonia Linn) (17.5gm). The Formula of HWM has been taken from Kitab Al Hawi of Abu bakr Mohd bin Zakariya Razi [7]. The drug is indicated in several types of joint diseases because of its ingredients possessing anti-inflammatory (muhallil), analgesic (musakkin alam) and purgative (mus'hil) properties. Recently a novel anti-inflammatory compound, C-glucosyl chromone has been derived from aloe vera [8]. Terminalia chebula contains phenolic carboxylic acids like gallic acid, elagic acid and chebulic acid which are anti-inflammatory in action besides other properties [9,10]. Colchicine is the main active principle of Colchicum autumnale widely used for a long time as an anti-inflammatory and analgesic in arthritis [11]. Convolvulus scammonia contains glycosides (scammonin I-VIII) and methylpentosides of jalapinolic acid besides other ingredients makes it is useful for purgation and joint pain in addition to its other uses [12].

Methods

An open-labeled study entitled "Clinical Study of Cervical Spondylosis with Therapeutic Evaluation and Safety of *Habb Waja'al-Mafāṣil (HWM)* in its management" was conducted at Regional Research Institute of Unani Medicine, J&K. An inclusive protocol was framed and approval was obtained from the Institutional Ethics Committee of Regional Research Institute of Unani Medicine, Srinagar (IEC number RRIUM-SGR/MD2018/CT/WU/CS/HWM dated 27-1-2021 and Clinical Trials Registry India number CTRI/2021/03/032263 dated 24-03-2021). After taking consent from each eligible patient, they were randomly distributed into two groups, the Test group and the Control group (figure 1 consort). The crude form of HWM ingredients; *Aloe barbadensis*, *Terminalia chebula, Colchicum autumnale* and *Convolvulus scammonia* were purchased from the licensed drug dealers of Srinagar city and all

The ingredients were properly identified by an expert to ascertain their originality (voucher specimen no. 4285,4286,4287,4288-KASH). The formulation of *Habb* was prepared under the supervision of a pharmacist as per the methods described in the texts and GMP.

Case selection criteria

1. Inclusion criteria

- Clinically diagnosed patients of cervical spondylosis from any gender between 20 and 70 years of age
- Patients who have agreed to sign the informed consent form and follow up the protocol.

2. Exclusion criteria

- Patients below 20 and above 70 years of age
- Trauma, Local wound and psychomotor syndrome
- Patients with a history of systemic diseases like diabetes, cardiovascular diseases, impaired renal and hepatic functions, HIV, TB and COPD.
- Patients who refuse to give written consent for the study.
- Pregnancy and lactating women

The diagnosis was made based on symptoms; pain, stiffness, swelling, and restriction of movement, and an X-ray cervical spine AP/Lateral view. Pain and other disabilities in cervical spondylosis were measured using a visual analogue scale (VAS) and the Northwick Park neck pain questionnaire (NPQ). VAS is a 10 cm numerical Likert scale comprising 0-10 cm where 0 represents no pain and 10 represents worst pain. NPQ is simple to use as an objective measure for monitoring symptoms over time. Safety parameters (CBC, ESR, LFT, KFT) were also observed before and after the study protocol to check for drug safety. After randomization each patient in one group i.e., the test group was given 3 gm *HWM* twice a day and the other group i.e., the control group was given ibuprofen- 400mg thrice a day. After completion of the treatment protocol of 30 days, each case was assessed for subjective and objective parameters once again. 'Before and after' results of 30 patients in each group were thus analyzed to observe the efficacy and safety of both the test and control drug respectively in addition to comparing the results of the two groups, using paired (for intra-group comparison) and unpaired Student T-test (for inter-group comparison). For statistical analysis, recorded data was compiled and entered in a spreadsheet and then exported to the data editor of SPSS version 20.0 and Graph pad Prism software. A p-value of less than =<0.05 was considered statistically significant.

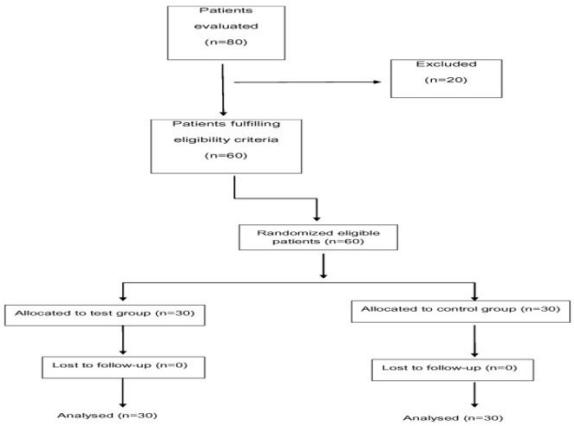

Figure 1. Patients summary (consort diagram)

Results

After completion of the study protocol, the mean and standard deviation of the mean for pain (VAS score) and other features at baseline, i.e., before treatment compared with the values obtained after treatment in both the test and control group (table 1 & 2). The statistical analysis confirms p=<0.001 in both HWM and ibuprofen for all the subjective parameters.

Table 1: Comparison of subjective parameters before and after treatment in the test group

Parameter	Before treatment		After treatment		P-value
	Mean	Standard deviation	Mean	Standard deviation	
Pain	7.3	1.393	3.067	1.202	<0.0001
Stiffness	4.933	1.337	2.067	0.8683	<0.0001
Swelling	4.467	1.871	1.967	0.8503	<0.0001
Restriction of movement	5.6	1.453	2.467	1.008	<0.0001

Table 2: Comparison of subjective parameters before and after treatment in the control group

Parameter	Before treatment		After treatment		P-value
	Mean	Standard deviation	Mean	Standard deviation	
Pain	6.767	1.223	2.8	0.9965	<0.0001
Stiffness	4.233	1.675	1.667	0.7112	<0.0001
Swelling	3.133	1.456	1.633	0.8899	<0.0001
Restriction of movement	5.133	1.697	1.9	0.9229	<0.0001

Furthermore, statistical assessment for comparing the post-treatment results in the test and control group (inter-group comparison) was performed as shown in Table 3, illustrating p=>0.05 for all subjective parameters, except for "restriction of movement".

Table 3: Comparison of subjective parameters between test and control group

Parameter	Test Group		Control group		P-value
	Mean	Standard deviation	Mean	Standard deviation	
Pain	3.067	1.202	2.8	0.996	0.353
Stiffness	2.067	0.868	1.667	0.711	0.056
Swelling	1.967	0.8503	1.633	0.8899	0.143
Restriction of movement	2.467	1.008	1.9	0.9229	0.027

NPQ score alteration assessment and analysis have been drafted in Table 4. The radiological (X-ray) findings show the highest percentage of C5-C6 disc involvement (53.35%) followed by C2-C3 (18.33%), C4-C5 (15%), C3-C4 (8.33%), C4 (3.33%), C2 (1.66%), and there was no improvement in cervical disc features after intervention in either test or control group (P=1).

Table 4. Comparison of NPQ within and between the groups

NPQ	Test		Control		p-value (inter-group)
	Before treatment	After treatment	Before treatment	After treatment	
Mean ± SD	45.9± 16.44	20.9± 6.025	40.0± 12.33	21.57± 6.632	0.681
p-value (intra-group)	<0.0001		<0.0001		

NPQ, Northwick Park Questionnaire; SD, Standard Deviation

Discussion

In this open-labelled, standard controlled study 60 patients were allocated randomly into two groups of 30 each viz, group A (test group) was given HWM and group B (control group) was given Ibuprofen tablets for 30 days with 3 follow-ups. The measures of baseline were compared with the values obtained after the completion of the study and the results obtained after HWM and ibuprofen intervention were also compared with each other. The results of the study demonstrated that treatment with HWM significantly reduced clinical symptoms (table 1) like, pain stiffness, swelling and restriction Of movement (p<0.001). The baseline mean VAS score was 7.3±1.39 and comes out to be 3.067±1.20 after treatment with a p-value <0.0001. The results also depict the mean VAS score after the treatment protocol in the control group (table 2) improved significantly (p-value <0.001). Interestingly table 3, shows an intergroup comparison, i.e., the comparison of mean VAS score between the test and control has not a significant difference which means both treatments are equally effective with p-value =0.353. The improvement in pain in the test group may be due to the anti-inflammatory (Muhallil), and analgesic (Musakkin alam) properties in the ingredients of HWM [13,14].

We can see in the result section, table 1, the mean value of stiffness before treatment was 4.933±1.33 and after treatment, it was 2.067±0.86 with a p-value of <0.0001 which shows that there was a significant improvement in stiffness around the neck with HWM. Similarly, stiffness in the control group was improved from 4.233±1.67 to 1.667±0.71 (table 2). The difference between the efficacy of HWM and ibuprofen in reducing neck stiffness was statistically insignificant, which means both of the treatments were equally effective for stiffness with a p-value of 0.056 (table 3). The reduction in Stiffness in the test group is due to the anti-inflammatory (Muhallil) and Purgative (Mus'hil) activities of the ingredients of the test drug [13-15]. The mean score of swelling in the test group at baseline was 4.467±1.87 and after treatment was 1.967±0.85 which depicts a significant improvement (p=<0.001). In the control group, the mean of swelling before treatment was 3.133±1.45 and 1.633±0.88 after treatment depicting a clear improvement (p=<0.001), but the intergroup comparison again shows a nearly similar effect of both HWM and ibuprofen (p=0.143). The results (table 1) demonstrate significant improvement in the restriction of neck movement in both the test and control group (p=<0.001), however, the effect of HWM was seen much better than ibuprofen (table 3) in this feature (p=0.027, i.e., <0.05). Again the reduction in Swelling and improvement in neck movement by HWM intervention is due to the anti-inflammatory (Muhallil) and Purgative (Mus'hil) activities of its ingredients. [13-16]. It is obvious from the results (table 4) that overall NPQ improved significantly with both HWM and ibuprofen (p= <0.001), but the Unpaired t-test (intergroup comparison) revealed that there was

An insignificant difference between the two (p=0.68) which implies that both the treatments were equally effective. Lastly, no obvious changes in radiological findings were observed in either test or control group. Further, both the test drug formulation and control drug were found safe with no noticeable adverse effects for the proposed period of the treatment protocol.

Conclusion

From the study, it is clear that the test drug formulation, HWM, is safe and equally effective as ibuprofen in managing symptoms associated with cervical spondylosis. Thus this herbal formulation can prove a better cost-effective alternative to conventional medicine for the said purpose.

Ethical declaration

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Authors' contribution

Study design: Safia Husain, Shameem Ahmad Rather

Data acquisition: Safia Husain, Shameem Ahmad Rather

Data analysis: Safia Husain, Shameem Ahmad Rather, Shabir Ahmad Bhat

Drafting of the manuscript: Shabir Ahmad Bhat, Shameem Ahmad Rather

Critical revision of the manuscript: Shameem Ahmad Rather, Shabir Ahmad Bhat

Informed consent: Informed consent was obtained from all individuals included in this study.

Ethical approval: This study protocol complied with the declaration of Helsinki and according to the GCP guidelines. Ethical approval was granted by the Institutional Ethics Committee (IEC no: RRIUM-SGR/MD2018/CT/WU/CS/HWM dated 27-1-2021. The trial was registered prospectively by the Clinical Trials Registry of India- CTRI/2021/03/032263.

Abbreviations

HWM- Habb-e-Waja'al Mafasil

NPQ- Northwick Park Questionnaire

VAS – Visual Analogue Scale

Reference

01. Cervical spondylosis. In: StatPearls [internet]. Treasure Island (FL): StatPearls Publishing; 2022. . *[Crossref][PubMed][Google Scholar]*

02. Effrey M, Daniel S, Edward B. Overview of Cervical Spondylosis, Pathophysiology and Biomechanics. World Spinal Column J. 2011; 2(3): 89-97. *[Crossref][PubMed][Google Scholar]*

03. Reddy RS, Maiya GA, Rao SK. Proprioceptive Reposition Errors in Subjects with Cervical Spondylosis. Int J Health Sci Res. 2012; 1(2): 65-73. *[Crossref][PubMed][Google Scholar]*

04. McPhee SJ, Papadakis MA. Lange Current Medical Diagnosis & Treatment. 58th ed. USA: McGraw Hill; 2019. *p1055 [Crossref][PubMed] [Google Scholar]*

05. Hirpara KM, Butler RJS, Dolan RT, O'Byrne JM, Poynton AR. Non-Operative Modalities to Treat Symptomatic Cervical Spondylosis. Adv Orthop. 2012; 2012:1-5. *[Crossref][PubMed][Google Scholar]*

06. Zohar AMI. Kitabut Taisir Fil Madawa wat Tadbir. New Delhi: CCRUM, Ministry of Health and Family Welfare, Govt of India; 1986: p78-85. . *[Crossref] [PubMed][Google Scholar]*

07. Razi ABMBZ. Kitabul Hawi. New Delhi: CCRUM, Ministry of Health and Family Welfare, Govt of India; 2004, Vol XI. pp75-98,143. *[Crossref][PubMed] [Google Scholar]*

08. Surjushe A, Vasani R, Saple DG. Aloe vera: a short review. Indian J Dermatol. 2008; 53(4):163-166. *[Crossref][PubMed][Google Scholar]*

09. Bhat SA, Rather SA. Cognizance of Halela (Terminalia chebula) in Unani system of medicine. Indo Am J P Sci. 2021; 08(05): 237- 40. *[Crossref] [PubMed][Google Scholar]*

10. Chattopadhyay RR, Bhattacharya SK. Plant review, Terminalia chebula. Pharmacognos Rev. 2007; 23: 145-55. *[Crossref][PubMed][Google Scholar]*

11. Akram M, Alam O, Usmanghani K, Akhter N, Asif HM. Colchicum autumnale: a review. J Med Plant Res. 2012; 6(8): 1489-91. *[Crossref][PubMed] [Google Scholar]*

12. Ansari H, Ansari AP, Qayoom I, Reshi BM, Hasib A, Ahmed NZ, et al. Saqmunia (Convolvulus scammonia L.), an important drug used in unani system of medicine: a review. J drug deliv ther. *2022; 12(5): 231-38 [Crossref][PubMed][Google Scholar]*

13. Khare CP. Indian medicinal plants, An Illustrated Dictionary. New York: Springer Science + business media, LLC; 2007: pp36, 165, 170, 654. . *[Crossref][PubMed][Google Scholar]*

14. Kabeeruddin, M. Makhzanul Mufradāt. 3rd ed. New Delhi: Idara Kitāb-ul-Shifa; 2014. *pp89-90, 259-260, 270, 415 [Crossref][PubMed][Google Scholar]*

15. Hakim MA. Bustānul Mufradāt. New Delhi: Idara Kitab-ul-Shifa; 2015. pp106, 340- 341, 358. *[Crossref][PubMed][Google Scholar]*

16. Baitar ZA. Al Jami‘al Mufarridāt al-Adviya wal Aghzia. New Delhi: CCRUM; 1999, Vol III. pp51, 96-98, 170-173. *[Crossref][PubMed][Google Scholar]*