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Case Report

## Effect of *Habb-e-Gule-Aak* (Unani pharmacopeial compound formulation) and *Riyazat* in the management of Non-specific Low back pain (*Waja' uz-Zahr*): A Case series

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### Abstract

**Background:** Low back pain has been a significant public health issue since long time, resulting in loss of functional productivity and medical costs. Nonspecific low back pain (NSLBP) or pain for which there is no known cause, affects about 85% of sufferers. Although there are conservative treatments accessible in the conventional medical system, like NSAIDs, which produces certain side effects. Unani system of medicine is the ancient system of medicine which deals with prophylactic and therapeutic management of many illnesses with no or least adverse effects.

**Objectives:** To evaluate the effect of Unani compound pharmacopeial drug i.e., *Habb-e-Gule-Aak* (HGA) and exercises of lumbo-pelvic muscles (strengthening and stretching) in the management of NSLBP.

**Materials and Methods:** Five patients with a primary report of chronic NSLBP (>6 months) without radiculopathy were treated with 2 pills of HGA twice daily for 30 days. The effectiveness of therapy was assessed on baseline, 15<sup>th</sup> day and 30<sup>th</sup> day using a numeric rating scale (NRS) to measure pain reduction and Oswestry disability index (ODI) to assess the decrease in lower back disability in NSLBP.

**Results:** HGA and exercises of lumbo-pelvic muscles (strengthening and stretching) significantly reduced pain and disability in NSLBP.

**Conclusion:** This case series is preliminary research of the use of multiple modalities in the management of NSLBP. It is envisaged that additional experimental research will be done to demonstrate the efficacy of this combination in treating people with NSLBP.

**Keywords:** *Habb-e-Gule-Aak*, *Ilaj Bit Tadbeer*, Lower back Exercise, Non-Specific Low back pain, Unani medicine

## Introduction

The most prevalent kind of musculoskeletal disorders associated with the spine is low back pain, which affects 84% of people. Additionally, 23% of all occurrences of low back pain are found to have chronic low back pain, which is low back pain that is untreated and lasts longer than 12 weeks<sup>1</sup>. According to Ribeiro et al. (2018), over 85% of chronic low back pain has no known cause or diagnosis and is categorized as chronic non-specific low back pain. The term "non-specific low back pain" (NSLBP) refers to a type of low back pain that is not caused by a specific pathology (such as osteoporosis, radicular syndrome, tumor, structural deformity, infection such as pott's spine, or cauda equina syndrome)<sup>2</sup>. It is usually defined as pain, muscle tension, or stiffness localised below the costal margin and above the inferior gluteal folds. The most important symptoms

of non-specific low back pain are pain and disability<sup>3</sup>. The term *Waja' uz-Zahr* is used to describe the Low back pain under the broad heading *Waja' al-Mafasil* in Unani medicine. Hakim Ghulam Jeelani (20th century) described different causative factors of *Waja-uz-Zahr* such as *Takan*, *Laghri* and excessive labour etc. He stated that the main causes of *Waja' uz-Zahr* and *Waja' al-Mafasil* is the *Kham Madda* (morbid matter) which gets accumulated of in joint spaces<sup>4</sup>. Eminent Unani physicians described a number of treatments including pharmacological and non-pharmacological approaches under two essential modes i.e., *Ilaj Bit Tadbeer* (Regimenal therapy) and *Ilaj bi'd Dawa'* (pharmacotherapy) in the management of NSLBP in their manuscripts such as *Zarawand*, *Hulba*, *Tukm-e-karafs*, *Habb-ul-rshad*, *Ajwain*, *Darchini*, *Zanjbeel*, *Ushq*, *Sakbeenaj*, *Anzroot*, *Hilliyoona*, *Suranjan*, *Sibr*, *Hijamah* (Cupping therapy), *Takmeed* (fomentations), *Dalk* (Massage therapy), *Riyazat*

(Exercise therapy) and *Inkebab* (steam therapy) etc<sup>5,6</sup>. There is some evidence that analgesics, antidepressants and nonsteroidal anti-inflammatory medications are helpful treatments in NSLBP. Other therapies (such as steroid injections, lumbar supports, and traction) are not supported by any research<sup>7</sup>. Dyspepsia or vomiting to more serious injuries including gastroduodenal ulceration, bleeding, and gastrointestinal lesions are among the GI system side effects associated with the use of NSAIDs<sup>8</sup>. Additionally, several studies have shown hepatotoxicity<sup>9-11</sup>. Due to these significant adverse effects of pharmacological medications in conventional medicine an attempt has been made to evaluate the effects of *Habb-e-Gule-Aak* (Unani pharmacopeial compound formulation) and *Riyazat* in the management of Non-specific Low back pain (*Waja' uz-Zahr*).

*Habb-e-Gul-e-Aak* (HGA), a polyherbal pharmaceutical drug (pills), is mentioned in almost all pharmacopoeias, formularies, and Qarabadeen in Unani system of medicine. It has been used for a long time to treat inflammatory disorders, both acute and chronic, although it has been noted to be most beneficial in chronic conditions, particularly those affecting the joints and bones, such as *Waja' al-Mafasil*, *Niqris*, *Waja' al-Warik*, etc. Available literature state that it is an effective drug for treating *Waja' al-Mafasil* patients<sup>12-14</sup>. Hippocrates, father of medicine, wrote in the fifth century BC: "All parts of the body, if used in moderation and exercised in labours to which each is accustomed, become thereby healthy and well developed and age slowly; but if they are unused and left idle, they become liable to disease, defective in growth, and age quickly." Several ancient Unani Scholars, including Hippocrates, Galen, Razi, and Avicenna, wrote about the curative properties of *Riyazat*. *Riyazat* is an action that is taken voluntarily with the intent of *Tanqiyae mawad* (evacuating waste material). It is crucial for both the preservation of health and the avoidance of sickness, as well as the treatment of some illnesses<sup>15,16</sup>. When joint mobilization is used to treat NSLBP, the distribution of synovial fluid in the joint cartilages and disc improves, which results in lessening the resistance to joint movement<sup>17</sup>. Additionally, lumbopelvic stabilization training improves motor control in NSLBP by stabilizing the muscles responsible for maintaining posture<sup>18</sup>. Patients with LBP have showed pain relief from stretching exercises involving the lumbopelvic

supporting muscles, such as the gluteal, hamstring, and quadriceps muscles<sup>19</sup>.

## 2. Materials and Methods

### 2.1 Inclusion Criteria

Five patients selected from the OPD of Ajmal Khan Tibbia College, AMU, Aligarh with the persistent LBP as their primary complaint were assessed. Patients having a primary report of LBP (between T12 and the gluteal fold) qualified as inclusion criteria for the present study. Age between 18 and 65, low back pain without radiating below the knee from 6 months or more than 6 months duration, and a modified Oswestry disability index (ODI) score of greater than 30.

### 2.2 Exclusion Criteria

Patients on surgical or non-surgical management within the past six months, signs of nerve root compression (muscle weakness, hyporeflexia, and paresthesia), and any medical red flags such as tumor, vertebral fracture, osteoporosis, prolonged history of steroid use, ankylosing spondylitis, severe liver disorders and kidney impairments were excluded.

### 2. Procedure of application of Interventions

Five patients selected from the OPD of Ajmal Khan Tibbia College, AMU, Aligarh with the complaints of pain over lower back which aggravates during prolonged sitting, bending and walking from last 6 months to 2 years. On examination there are restriction in movements without local tenderness and swelling. Patients had no history of metabolic disease, hypertension and tuberculosis. On general examination their vitals were within normal limit and no abnormality was detected through systemic examination. *Habb-e-Gule-Aak* (HGA) prepared in the Ajmal Khan Tibbia College dawakhana as per the guidelines of the Bayaz-e-Kabeer, Vol. 1<sup>12</sup>. HGA 2 pills has been given twice daily for 30 days. Information about ethnopharmacological properties of ingredients of *Habb-e-Gule-Aak* are listed in table1. Patients have been explained about strengthening and stretching of lumbopelvic muscles. Four exercises have been selected for this case series (1) supine abdominal draw-in (2) double leg bridge (3) side plank static holds (4) prone bridging on elbows with single leg hip extension. All exercises have been advised for 10 repetitions twice daily<sup>20</sup>.

**Table 1: Ethnopharmacological properties of ingredients *Habb-e-Gule-Aak***

Botanical names	Unani names	Therapeutically active constituents	Effects as per Unani Medicine	Associated Pharmacological activity
<i>Calotropis procera</i>	<i>Gul-e-Aak</i>	calotropenyl acetate	<i>Muhallil</i> (anti-inflammatory), <i>Musakkin</i> (analgesic) <sup>21,22</sup>	Anti-inflammatory, Analgesic <sup>23</sup>
<i>Zingiber officinale</i> Rosc.	<i>Zanjabeel</i>	Gingerols, (6)-Shogaol, zingiberene, [6]-gingerol	<i>Muhallil</i> (anti-inflammatory), <i>Musakkin</i> (analgesic) <sup>24</sup>	Antiarthritic, Anti-inflammatory, antioxidant <sup>25-27</sup>
<i>Bambusa arundinacea</i> Retz	<i>Barg-e-Bans</i>	Arginine, cysteine, histidine	<i>Musakkin</i> (analgesic) <sup>28</sup>	Anti-inflammatory, Antiarthritic <sup>29,30</sup>
<i>Piper nigrum</i> Linn	<i>Filfil siyah</i>	Piperine, Dihydro-pipericide	<i>Musakkin</i> (analgesic), <i>Muhallil</i> (anti-inflammatory) <sup>31</sup>	Antiarthritic, Anti-inflammatory, Analgesic <sup>32</sup>

### 3. Case presentation

#### 3.1 Case report 1

A 34 years old male with a history of severe, intermittent low back pain since eight months with a chief complaint of non-radiating low back pain. He was assessed on NRS and found the score 7 on 10 points Likert's scale, pain aggravated while bending and climbing stairs. His ODI score was 52 (severe disability).

#### 3.2 Case report 2

A 26 years old female with a history of severe, intermittent low back pain since 1 year with a chief complaint of non-radiating low back pain. She was assessed on NRS and found the score 5 on 10 points Likert's scale, with severe pain while bending and climbing stairs. His ODI score was 36 (moderate disability).

#### 3.3. Case report 3

A 61 years old female with a history of low back pain which was non radiating in nature since 6 months. Pain was started after prolonged travelling. Pain score was 4 at NRS and ODI was 48 (severe disability).

#### 3.4. Case report 4

A 47 years old female with a history of low back pain which was non radiating in nature started after lifting

heavy weight since 2 years. Pain was started after prolonged travelling. Pain score was 8 at NRS and ODI was 57 (severe disability).

#### 3.5. Case report 5

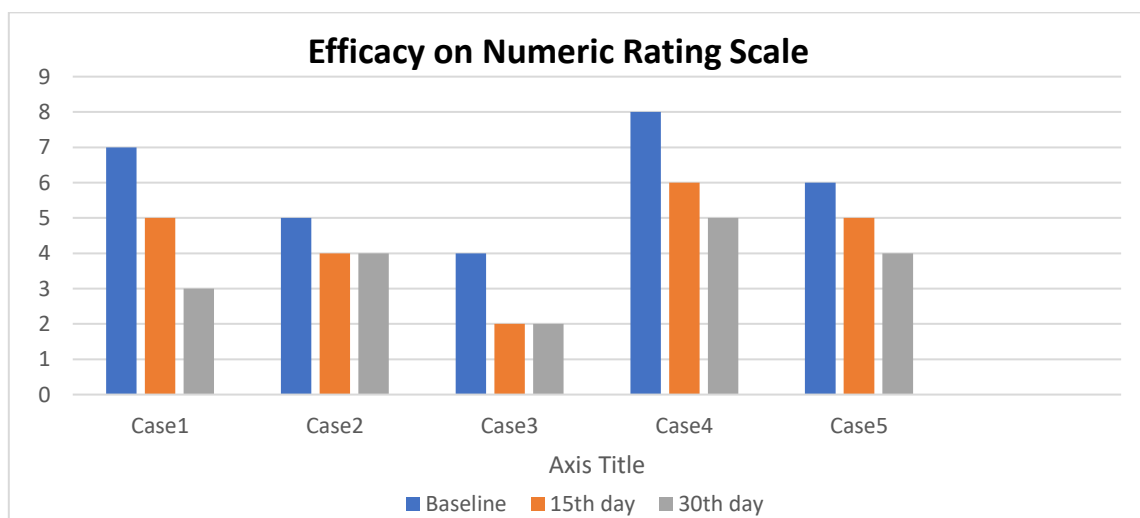
A 20 years old female student with a history of low back pain which was non radiating in nature aggravated by prolonged sitting since 18 months. Pain score was 6 at NRS and ODI was 41 (moderate disability).

### 4. Results

Low Back pain was assessed according to NRS and ODI on baseline, 15<sup>th</sup> and 30<sup>th</sup> day. As depicted in Table 2, NRS score in Case 1 was 7 at baseline, 5 on fifteenth day and 2 on thirtieth day. NRS score in Case 2 was 5 at baseline, 4 on fifteenth day and 3 on thirtieth day. NRS score in Case 3 was 4 at baseline, 2 on fifteenth day and 1 on thirtieth day. In Case 4, NRS score was 8 at baseline, 6 on fifteenth day and 3 on thirtieth day. In Case 5, NRS score was 6 at baseline, 5 on fifteenth day and 3 on thirtieth day. ODI score in Case 1 was 52 at baseline, 43 on fifteenth day and 38 on thirtieth day. In Case 2, ODI score was 36 at baseline, 28 on fifteenth day and 20 on thirtieth day. In Case 3, ODI score was 48 at baseline, 39 on fifteenth day and 21 on thirtieth day. In Case 4, ODI score was 57 at baseline, 43 on fifteenth day and 31 on thirtieth day. In Case 5, ODI score was 41 at baseline, 32 on fifteenth day and 19 on thirtieth day (Figure 1& 2).

**Table 2. Efficacy of Interventions on NRS**

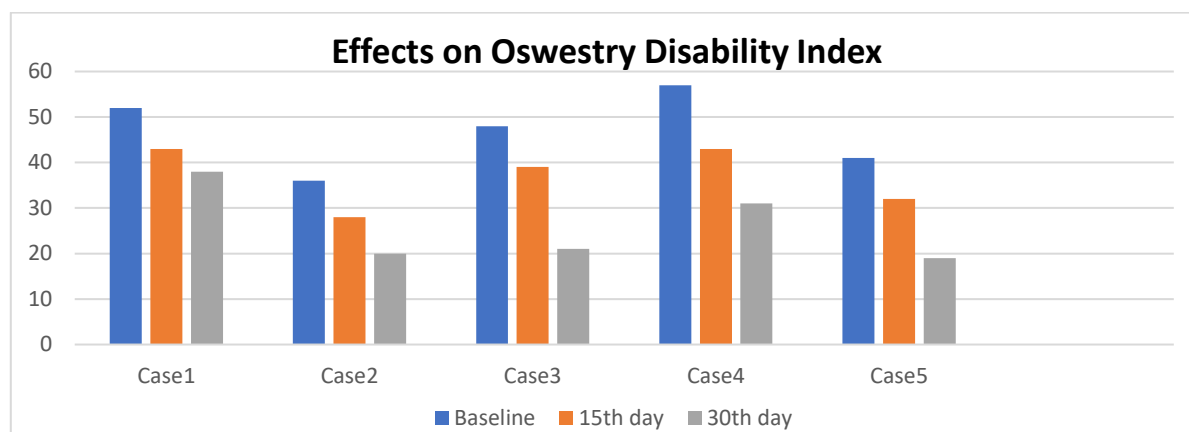
Parameters	Numeric Rating Scale (NRS)					
	Case1	Case2	Case3	Case4	Case5	Mean±S.D
Baseline	7	5	4	8	6	6±1.58
15 <sup>th</sup> day	5	4	2	6	5	4.4±1.51
30 <sup>th</sup> day	3	4	2	5	4	3.6±1.14
Improvement in percentage	57%	40%	50%	37.5%	33.3%	



**Figure 1: Efficacy of intervention on NRS**

**Table 3: Efficacy of Interventions on ODI**

Parameters	Oswestry disability index (ODI)					
	Case1	Case2	Case3	Case4	Case5	Mean±S.D.
Baseline	52	36	48	57	41	46.8±8.4
15 <sup>th</sup> day	43	28	39	43	32	38±8.0
30 <sup>th</sup> day	38	20	21	31	19	25.8±8.3
Improvement in percentage	26.9%	44.4%	56.2%	45.6%	53.6%	

**Figure 2: Efficacy of intervention on ODI**

## Discussion

Low back pain, which affects 84% of people, is the type of musculoskeletal disorder that is related with the spine. A form of low back pain that is not caused by a specific pathology is referred to as "non-specific low back pain" (NSLBP). The adverse effects of commonly given drugs, such as NSAIDs for the treatment of pain, are well documented. Unani medicine is an ancient approach that can heal many diseases with minimal or no adverse effects. The Unani system of medicine is a traditional medical practice that focuses on the prevention and treatment of various illnesses. Under the umbrella term *Waja' al-Mafasil*, low back pain is referred to as *Waja' uz-Zahr* in Unani medicine. HGA, a pill form of the polyherbal Unani medication. Although it has been reported to be most helpful in chronic musculoskeletal disorders. Hippocrates, Galen, Razi, and Avicenna were a few of the early Unani scholars who wrote about *Riyazat's* therapeutic benefits. Patients with LBP have reported pain reduction from stretches and exercises that target the gluteal, hamstring, and quadriceps muscles, which support the lumbopelvic region<sup>20</sup>. In the present case series HGA and *Riyazat* have been implicated in the management of NSLBP. The outcome measures NRS and ODI have been used for the assessment of the improvement in signs and symptoms at baseline, 15<sup>th</sup> and 30<sup>th</sup> day. On the analysis, there is significant reduction in the signs and symptoms has been noted. The positive effects noticed in this study were due to the synergistic effects of HGA and strengthening and stretching exercise of lumbopelvic muscles. Significant anti-inflammatory activity was present in the ethanol extract of the flowers of *Calotropis procera*<sup>23</sup>. The methanol extract of *Bambusa*

*arundinacea's* leaves has been investigated and found to have anti-inflammatory effects<sup>29</sup>. Piperine's analgesic efficacy in mice was assessed was found significantly effective<sup>31</sup>. *Zingiber officinale dense* extract was found to have strong antinociceptive and anti-inflammatory effects on the model of AITC-induced inflammation in mice. Additionally, the antiarthritic properties of ginger and its bioactive ingredients were evaluated<sup>25,33</sup>.

## Conclusion

This case series is preliminary multimodal research in the management of NSLBP. Based on this case series, it can be stated that lumbopelvic strengthening and stretching exercises combined with Unani drug formulation are effective in lowering NSLBP pain and disabilities. It is envisaged that additional experimental and clinical research should be carried out in order to demonstrate the efficacy of this combination in treating patients of NSLBP.

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