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Contents

Review Article

The Concept of Anemia in Unani System of Medicine: A Preventive Healthcare Approach

Abstract

Anemia is a significant global public health concern, particularly affecting young children, menstruating adolescent girls and women, as well as pregnant and postpartum women. According to the World Health Organization, 40% of children aged 6–59 months, 37% of pregnant women, and 30% of women aged 15–49 years worldwide are anemic. In classical Unani literature, anemia is referred to as *Sū'-al-Qinya*, derived from the Arabic words "*Su*" meaning "defect" and "*Qinya*" meaning "treasure" or "assets." Together, they suggest a defect in the body assets. *Sū'-al-Qinya* implies a decrease in the amount of blood in the body, a change in its composition, and a reduction of the number of *Kurriyāt-e-Ḥamra* (red blood cells). This paper is intended to elucidate the concept of anemia and its preventive measures in the Unani System of Medicine. A comprehensive review of classical Unani texts was conducted to gain insight into the concept of anemia in the Unani system of medicine and the various Unani remedies for managing this condition. In addition, various research databases such as PubMed, Google Scholar, and Science Direct were utilized to gather all available information on *Sū'-al-Qinya*. Iron deficiency anemia is a prevalent nutritional deficiency that predominantly affects women. Unani physicians have long been cognizant of this issue and have employed various iron preparations to address iron deficiency anemia. According to ancient Unani literature, the cause of *Sū'-al-Qinya* is attributed to the abnormal cold temperature of the liver. Unani physicians have used medications that stimulate the innate heat of the liver to prevent this condition.

Keywords: *Anemia, iron deficiency anemia, preventive approaches, Sū'-al-Qinya*

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Introduction

Anemia is a medical condition characterized by a reduced ability of the blood to carry oxygen. It can be attributed to a decrease in the number of red blood cells or a lower amount of hemoglobin (Hb) in the blood. The World Health Organization (WHO) defines anemia as a Hb level <13.0 g/dL in adult males, <12.0 g/dL in adult nonpregnant females, and <11.0 g/dL in pregnant females.[1] Anemia, also known as *Sū'-al-Qinya*, results in qualitative and quantitative blood derangement, leading to an inability to carry out normal bodily functions. WHO describes anemia as a condition where the blood Hb levels are lower than normal due to a deficiency of essential nutrients, regardless of the cause of these deficiencies. Iron deficiency is the most common worldwide cause of anemia, though other factors such as folate, Vitamin B12, and Vitamin A deficiencies, chronic inflammation, parasitic infestations, and inborn disorders may also lead to anemia.[1-3]

Anemia is a widespread public health issue that affects both developing and developed countries, with significant implications for human health and societal and economic development. It can occur at any stage of life but is more common in pregnant women and young children. In 2002, iron deficiency anemia was considered a main contributing factor to the global disease burden. It is a major public health concern for females, as about 25%–50% of girls become anemic by the time they reach menarche (the first occurrence of menstruation). The need for iron increases during adolescence, and this need further rises due to regular menstrual blood loss. In developing countries, the high iron demands are often unmet due to poor diets, low iron availability, and frequent parasitic infections, leading to a higher incidence of anemia in women and girls. Therefore, an adolescent who becomes pregnant soon after menarche is likely to start pregnancy with depleted iron stores.[4]

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Anemia affects one-third of the global population and is associated with increased illness and death among women and children, adverse birth outcomes, reduced work productivity in adults, and compromised cognitive and behavioral development in children. Preschool children and women of reproductive age are particularly vulnerable to these effects.[5]

Materials and Methods

A comprehensive review of classical Unani texts was undertaken to acquire knowledge about the concept of anemia in the Unani system of medicine and the various Unani remedies for managing this condition. In addition to this, various research databases such as PubMed, Google Scholar, and Science Direct were utilized to compile all available information on *Sū'-al-Qinya.*

Unani Concept

Sū'-al-Qinya is a term derived from two Arabic words "*Su*" and "*Qinya,*" meaning defect and treasure or assets. Combining these two words gives us "*Sū'-al-Qinya,*" a term that refers to a defect in the asset or treasure of the body. In classical Unani literature, *Sū'-al-Qinya* is defined as a condition caused by a decrease in the amount of blood and an alteration in its constituents, including the number of Red Blood Cells (*Kurriyat-e-Hamra*). When the liver becomes functionally weak due to an alteration in its temperaments, it can lead to a deterioration of the whole body. One of the major causes of *Sū'-al-Qinya* is the liver's severe dysfunction due to changes in its temperament.[6,7]

Sū'-al-Qinya, also known as iron deficiency anemia, is a disorder of the blood that refers to the deterioration in the quality or quantity of blood due to decreased iron levels in the body. According to *Abu al-Hassan Ali ibn Sahl Rabban al-Tabri*, a physician from the 8th century, the liver is the reservoir of blood, and excessive bleeding during menstruation can decrease the blood in the liver and disrupt its functions. Furthermore, if the temperament of the liver alters due to coldness, the blood in the body becomes deficient, leading to paleness, weak pulses, increased appetite, and pale lips.[8,9]

Hakim Mohammed Kabiruddin referred to *Sū'-al-Qinya* as "*Faqr-al-Dam*" or "*Qillat-al-dam*" and linked it to most signs and symptoms of anemia. In addition, he described *Khizra* (Chlorosis) as a type of *Sū'-al-Qinya* that affects young girls. He explained that this condition involves an alteration in the constituents of the blood, leading to a decrease in the size of RBCs (Microcytosis), reduced substance (Hypochromic), and an increase in fibrinous material in the blood.[10] *Ibn Sina* used the term *Sū'-al-Qinya* to describe anasarca caused by liver weakness. *Hakim Shareef Khan* mentioned that *Sū'-al-Qinya* means a defect in the blood.[6]

In the 10th century, *Abul Hasan Ali Bin Abbas Majusi* described in *Kamil-us-Sana* that the inability to form blood may be due to a problem in the liver, which is responsible for blood formation, or a problem in the stomach where digested nutrients from food are unable to be transformed into blood.[11]

Ismail Jurjani, in his book *Zakhira-e-Khwarizam Shahi*, described that the disease *Sū'-al-Qinya* develops when the liver becomes functionally weak, leading to alterations in the temperament, resulting in the deterioration of the whole body, mimicking anasarca.[12]

To sum up, *Sū'-al-Qinya* is a condition caused by a decrease in the amount of blood and an alteration in its constituents, including a decrease in the number of red blood cells. Liver malfunction and alterations in its temperament are the primary causes of *Sū'-al-Qinya*, which can lead to iron deficiency anemia. The term has been used by several physicians throughout history to describe various conditions related to blood quality and quantity.[9]

Pathogenesis

Tabri in *Al-Mualijat-ul-Buqratia* described that the cold temperament of the liver can alter its normal functioning, leading to a deficiency of blood and resulting in paleness.[7] According to *Shaikh* and *Jurjani*, a change in the liver's temperament may result in an inability to produce pure blood, thereby leading to the condition known as *Sū'-al-Qinya*. When combined with excessive consumption of a cold and wet diet, the liver's compromised functioning may lead to incompletely metabolized phlegm. This phlegm has the potential to disseminate throughout the body, permeating every pore, and consequently contributing to the onset of anasarca.[11]

Etiology (*Asbāb*)

Ḍu'f al-Kabid is a condition that arises from changes in the *mizaj* of the *jigar*, leading to *Sū'-al-Qinya*. When *Sū'-al-Qinya* is present, normal *jigar* functions are disrupted. According to *Ibn Sina* and *Jurjani*, the occurrence of *Ḍu'f al-Kabid* (debility of the liver) along with *fasād-e-jigar* precedes the condition known *istisqā*, and is referred to as *Sū'-al-Qinya/ Faqr-al-Dam.*[8,13,14]

In some cases, *Sū'-al-Qinya* may result from the cessation of *Ṭaba'ī hayḍ* (normal menstrual cycle) and subsequent blood flow obstruction. Gaseous waste products of black bile, known as *Sawdawi asbab*, can also lead to *Sū'-al-Qinya.*[4]

In addition, *Sū'-al-Qinya* may occur due to *ta'ffun-i-hawā* (polluted and contaminated air), potentially resulting in fatality from inhalation of infected air or residing in impure air. *Nafs-al-dam*, *qay-al-dam*, *is'hāl-al-dam*, *bawl-al-dam*, *fasād-i-mi'dā*, *is'hāl-e-muzmin*, tuberculosis, and various physical and mental stressors are identified as common causes.[4] Moreover, menstrual disorders (*hayḍ ki kharābī*) such as *usr-e-tams*, *kasrat-e-tams*, and *awrām-e-raḥim* may contribute to *Sū'-al-Qinya.*[4,15]

Sign and Symptoms

The clinical manifestations of anemia include general debility, pallor of the skin, mucous membranes, and conjunctiva, as well as fatigue, palpitations, tachycardia, stomatitis, dyspnea, koilonychia, pica, anorexia (particularly in pediatric patients), headache, decreased hematocrit and Hb levels, and reduced serum ferritin (serum iron).[1,16,17]

Prevalence of Anemia among Adolescents

Anemia is a significant public health issue in India, particularly among adolescents. According to the National Family Health Survey-4 (2015-2016), 54% of adolescent girls aged 15–19 had a prevalence of anemia, indicated by a Hb level of <12 gm/dL. In the state of Haryana, the Comprehensive National Nutrition Survey (2017) found that anemia prevalence in adolescent girls, as assessed through venous samples, was 41%, nearly double the prevalence observed in boys (22%).[18]

Globally, anemia affected 1.93 billion people in 2013, causing a total of 61.5 million years lived with disability. The prevalence was highest in Africa and the Southeast Asia region. As Per WHO guidelines regarding iron deficiency anemia, nutritional anemia represents a significant public health concern in India, mainly attributable to iron deficiency. A population-based study shows that 28.4% of 14,300 Indian adolescents were anemic, with the major causes being Vitamin B12 deficiency (25.6%), iron deficiency (21.3%), dimorphic anemia (18.2%), and anemia of inflammation (3.4%). Furthermore, small studies conducted among adolescents from different parts of India reported the prevalence of anemia as follows: 61.5% in Gujarat, 52.5% in Madhya Pradesh, 41.1% in Karnataka, 50% in Bihar, and 56.3% in Uttar Pradesh.[19,20] Jharkhand in eastern India had the highest prevalence of anemia at 99.9%.[21] The prevalence of anemia was reported to be 59% in a study conducted in Delhi.[22]

A recent study revealed that anemia was more prevalent among adolescent girls than boys. A greater percentage of adolescent girls had moderate-to-severe anemia compared to adolescent boys. This disparity may be attributed to the onset of the menstrual cycle in girls, which leads to physiological blood loss. Moreover, the prevalence of moderate-to-severe anemia was higher among older adolescent girls than younger ones. Older adolescent girls may be at a stage where they get married and become pregnant, which further impacts their anemia status.[20]

The most important factors causing iron deficiency anemia:

- Inadequate diet: An insufficient intake of nutrients such as iron, folic acid, Vitamin A, Vitamin B12, and Vitamin D due to poor diet[23]
- Medication and food that inhibit iron absorption: This includes antacids, aspirin, non-steroidal anti-inflammatory drugs, and excessive intake of phytate, phosphate, oxalate, and tannins[23]
- Overweight and obesity: Iron deficiency may be related to a poor diet high in calories, an increased need for iron associated with body weight, genetic factors, a sedentary lifestyle, and continuous inflammatory processes[24,25]
- Malnutrition: Conditions such as malabsorption syndrome and excessive iron loss in addition to an inadequate diet can lead to iron deficiency anemia[23]
- Adolescent athletes: The prevalence of iron deficiency ranges from 5 to 7.5% due to factors such as "sports anemia" caused by various factors including dilutional pseudoanemia, mechanical intravascular hemolysis, and iron loss[26]
- Blood loss: Resulting from injury, accidents, or blood donation[23]
- Iron loss can occur due to parasitic infections and gastrointestinal conditions such as esophagitis, angiodysplasia, atrophic gastritis, colitis, *Helicobacter pylori* infection, coeliac disease, inflammatory bowel disease, and other conditions[23]
- Genitourinary iron loss may result from paroxysmal nocturnal hemoglobinuria and glomerulonephritis[23]
- Pregnancy, childbirth, and the use of intrauterine devices[23,27]
- Menstrual abnormalities: Heavy menstrual bleeding can lead to iron deficiency and iron deficiency anemia in women of reproductive age. Iron deficiency anemia is less common in adolescent boys due to the physiological increase in Hb levels caused by sexual maturation, iron deficiency may be more common within this age group as a result of blood volume expansion and the increase in muscle mass.[23,28]

Preventive Strategies for Anemia in the Unani System of Medicine

It is advisable to avoid consuming foods that can alter the temperament of the liver, which can lead to coldness and decreased innate heat of the liver. Foods that are moist, spicy, and hard to digest should also be avoided. It is also recommended to avoid the use of cold water. Bathing in water that contains sulfur, borax, and alum is helpful. Rough cloth massage using hot oil can be done for better results. Avoid taking a bath or engaging in sexual intercourse immediately after a meal. Rolling over warm sand and soil is also beneficial. Mild *istifrāgh* with *Ayārij* and *Ḥabbul Nīl* helps to remove hard, sticky, and vitiated phlegmatic fluid from the body.[1]

'Ilāj bi'l-Tadbīr

These techniques stimulate blood circulation, eliminate toxins from the body, and aid in the production of pure blood, which is essential for vital activities: Exercise, Massage, Fomentation, Dry bath, Steam bath, Emesis, and Oil immersion.[9,17]

'Ilāj bi'l-Ghiza

It is essential to adhere to a diet rich in high-quality food that encompasses all essential minerals, proteins, and nutrients. The consumption of a plain broth (*shorba*) derived from goat's meat or *yakhni* (a specialized broth made from goat bones and meat) enriched with spices is highly recommended. In addition, it is advisable to include *yakhni* made from chicken, gray francolin (*teetar*), common quail (*bater*), and Chukar partridge (*Chakor*) and mix with spices without the use of *ghee*. Furthermore, the incorporation of green vegetables and fruits such as spinach (*Palak*), bananas, pomegranates, oranges, guavas, and dates is encouraged. A balanced and nutrient-dense diet containing eggs, fish, milk, butter, and easily digestible food items is paramount. For additional supplementation, *Arq Badiyan* (a distillate of *Foeniculum vulgare*), *Arq mako* (a distillate of *Solanum nigrum*) or iron water can be used. *Kaleji* serves as an abundant source of iron and aids in the production of fresh blood in the body.[17]

'Ilāj bi'l-Dawā

Several drugs are used in compound formulations or single forms.

Mufrad Dawā (Single Drug)

- *'Ām* (*Mangifera indica*)[29]
- *Anār* (*Punica granatum*)[29,30]
- *Mawīz Munaqqa* (*Vitis vinifera*)[31]
- *Za'frān* (Crocus sativus)[32]
- *Darchini* (*Cinnamomum zeylanicum*)[33]
- *Khajoor* (*Phoenix dactylifera*)[34]
- *Asārūn* (*Asarum europaeum*)[29]
- *Halela* (*Terminalia chebula*)[1]
- *Balela* (*Terminalia bellerica*)[1]
- *Āmla* (*Emblica Officinalis*)[29]
- *Qaranfal* (*Eugenia caryophyllata*)[35]
- *Bisfāyij* (*Polypodium vulgare*)[1]
- *Maṣṭagī* (*Pistacia lentiscus*)[36]
- *Lahsun* (*Allium sativum*)[1]
- *Zarāwand Madharj* (*Aristolochia longa*)[29]
- *'Arq-i-Gulāb* (*Rosa damascena*)[1]
- *Rāyi* (*Brassica Juncea*).[37]

Murakkab Dawā (Compound Drugs)

- *Majun-e- Dabeed-ul-Ward*[1]
- *Majun Khoobsul Hadee*[1]
- *Jawarish Amla*[1]
- *Qurs Kushta Faulad*[38]
- *Sharbat-e-Maweez*[39]
- *Sharbat-e-Faulad*[40]
- *Sharbat-e-Afsanteen*[12]
- *Sharbat-e-Anarain* (Syrup of pomegranate)[38]
- *Sharbat-e-Ananas* (Syrup of pineapple).[12]

Unani physicians recommend the following measures to prevent Iron deficiency anemia:

- *Kushta Faulad* 2 *biranj* with *Sharbat-e-Anar* 20 ml, administered twice daily for a period of 5 to 6 months[9,17]
- *Jawarish-e-Jalinoos* 6 gm, *Jawarish-e-Amla* 6 gm with *Kushta Faulad* or *Kushta Khabsul Hadeed* 2 grains, to be taken twice daily over a 5 to 6-month duration[9]
- *Majun Khabsul Hadeed* 6 gm to be consumed twice daily[9]
- Kushta Faulad 2 grains or *Kushta Khabsul Hadeed* 2 grains to be taken with *Gulqand* 25 gms before bedtime[9,17]
- *Haleela zard* 1 tola, *Barg-e-Sana Makki* 7 gms, *Shahm-e-Hanzal* 7 gms, *Turbud* 9 gms, *Rewand Cheeni* 7 gms, *Sibrzard* 7 gms; all ingredients are to be ground, mixed with *Gheekawar*, and formed into pills, to be taken twice daily.[9]

Conclusion

Iron deficiency anemia is a widespread nutritional deficiency among menstruating and reproductive-aged females in India and is recognized as a significant health issue in the region. The primary preventive measure for most patients is iron therapy administered at appropriate doses and for a sufficient duration. Upon reviewing the literature, it becomes evident that a comprehensive approach to anemia prevention as outlined in classical Unani literature encompasses multidimensional strategies such as pharmaceutical interventions, dietary adjustments, and regimen-based therapies. These strategies are advantageous due to their cost-effectiveness, accessibility of home remedies, and straightforward health practices, and can significantly mitigate anemia. Several iron preparations such as *Sharbat-i-Faulād*, *Sharbat-e-Dīnār*, *Sharbat-i-Afsantīn*, *Ma'jūn-e-Dabīd-ul-Ward*, and *Sharbat-i-Anār* are used by Unani physicians for leveraging their hepatotonic and hematogenic properties for the prevention of iron deficiency anemia.

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Conflicts of interest

There are no conflicts of interest.

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Original Article

Clinical Evaluation of *Jawārish-i-Kamūnī* and *'Arq-i-Bādiyān* in *Sū' al-Haḍm* (Dyspepsia)

Abstract

Background: *Sū' al-Haḍm* (Dyspepsia) is one of the most common ailments in nowadays sedentary lifestyle. The are many efficacious medicines for the treatment of Dyspepsia in the Unani system of medicine, and *Jawārish-i-Kamūnī* and *'Arq-i-Bādiyān* are among them. **Objective:** The study is planned to evaluate the safety and efficacy of Unani pharmacopeial formulations *Jawārish-i-Kamūnī and 'Arq-i-Bādiyān* in patients of *Sū' al-Haḍm* (Dyspepsia). **Materials and Methods:** This *Sū' al-Haḍm* (Dyspepsia) study was a single-arm, open-label, with 60 clinically diagnosed cases of Dyspepsia belonging to 18–55 years of age, either sex, who had agreed to sign the informed consent form and follow the protocol. The patients were treated with Unani formulations, i.e., 5 g of *Jawārish-i-Kamūnī* orally twice and 60 ml *'Arq-i-Bādiyān* orally twice with water after meals for 2 weeks with two follow-ups. The assessments of subjective and objective parameters were done every week and recorded in a case record form. The results were recorded in terms of the percentage of efficacy calculated from the gastrointestinal symptom rating scale analyzed statistically. **Results:** The subjective parameters like abdominal pain, heartburn, acid regurgitation, eructation, nausea and vomiting, and abdominal distention were significantly improved by 59.85%, 57.23%, 61.14%, 62.87%, 52.38%, and 79.70%, respectively, as compared to baseline with $P < 0.0001$. No significant adverse changes were observed in safety parameters during and after the trial. **Conclusion:** It can be concluded that the Unani formulations *Jawārish-i-Kamūnī and 'Arq-i-Bādiyān* are safe and effective in Dyspepsia treatment.

Keywords: *'Arq-i-Bādiyān, dyspepsia, jawārish-i-kamūnī, sū' al-haḍm*

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Introduction

In the Unani system of medicine, the concept of digestion is explained in terms of the functional capacities of the organs involved in the process of digestion. The whole process of digestion in the stomach is governed by *Quwā Arba'a* (Four faculties). If they function properly, the digestion remains normal, and if *Quwā* is disturbed, then the process of digestion gets disturbed. These faculties have their own focused tasks in the stomach for the process of digestion. They work stepwise in the process of digestion. These faculties are (1) *Quwwat Jādhiba* (Absorptive Faculty), (2) *Quwwat Māsika* (Retentive Faculty), (3) *Quwwat Hāḍima* (Digestive Faculty), and (4) *Quwwat Dāfi'a* (Expulsive Faculty).[1]

Sū' al-Haḍm (Dyspepsia) is a condition in which the ingested food is not digested completely and becomes *Fāsid* (Morbid) in *Mi'da* (Stomach) and produces *Raddi Kayfiyat* (Morbid properties) in the stomach. It is also known as *Fasād al-Haḍm*. It is assumed that the disease mostly occurs due to excess intake of diet (*Ghidhā'*) or the morbid properties of diet.[1-4] In this disease, organs of the body do not absorb their diet for their nourishment. If an organ absorbs a morbid diet, then it will not accommodate according to the shape, structure, and consistency of the organ, and can lead to ascites, cancer, and vitiligo.[1,3]

If the diet is not of morbid properties but is excess in quantity, then the body absorbs the required diet and excretes out the remaining diet in undigested form. When the diet is less in quantity then it may get burned and become morbid due to increased process of digestion.[2] If the stomach digests the light diet in long duration, then it is known as delayed digestion.[1-3] When the stomach does not interact with the food completely, then it is known as *Tukhma*.[5]

If the cause of *Sū' al-Haḍm* (Dyspepsia) is present in *Mi'da* (Stomach), it can be

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due to *Sū'-i-Mizāj Sāda* (Abnormal temperament not associated with the matter or substance) or *Sū'-i-Mizāj Māddi* (Abnormal substantial temperament) of the stomach, or it can be due to *Tahalhul al-Mi'da* (Gastromalacia), which leads to the weakening of the digestive process, or it may increase the process of digestion.[2] *Sū'-i-Mizāj Sāda* (abnormal temperament not associated with the matter or substance) is difficult to treat in comparison to *Sū'-i-Mizāj Māddi* (Abnormal substantial temperament) because, in the case of *Sū'-i-Mizāj Māddi*, *Tanqiya* (Elimination of morbid material from the body) is needed.[1,6]

Dyspepsia can also be caused by the dominance of heat and cold in the stomach, or it can be due to the quantity and quality of diet, or *Tadbīr* (Regime) of food, in such a way that the stomach is not capable of digesting the diet. Excessive air can also be responsible for dyspepsia.[1,7]

In case of *Sū'-i-Mizāj Mi'da*, indications of dominancy of *Harārat* (Heat) in the temperament of the stomach are loss of appetite, less spitting, burned (Smoky) belching, thirst, dryness in the mouth, and there may be mild fever. *Rāzi* said if Dyspepsia is due to heat, then use *Qarīz* (Special type of bread), *Bārid Mizāj Sabziyān* (Vegetables of cold temperament), and *Mubarridāt* (Medicines of cold temperament) to cure it.[2,7,8] Indications of dominancy of *Burūdat* (Cold) are increased appetite, excess spitting, and excessive sour belching. When *Burūdat* (Cold) dominates then it inhibits the *Harārat Gharīziyya* (Innate heat) and produces sourness, excess of morbid gases, lack of thirst, and unchanged diet in vomiting. If the patient is new, then ask the patient first to vomit and then use stomach tonics, and if the patient is old, then ask the patient first to vomit, after that do *Tanqiya* (Elimination of morbid material from the body) and then use stomach tonics. In case of a cold, we advise the patient to use *Sarī al-Haḍm Ghidhā'* (Easily digestible diet) such as chicken soup and mutton soup.[2,3,7,8]

If dyspepsia is caused by *Rutūbat* (Wetness), it will be treated on the basis of *Sū'-i-Mizāj Ratab* (Moist morbid temperament) of the stomach. Pigeon meat can be given in *Ghidhā'* (Diet). If the dyspepsia is caused by *Yubūsat* (Dryness), it will be treated on the basis of *Sū'-i-Mizāj Yābis* (Dry morbid temperament) of the stomach. Soup of chicken and other meats could be advised as a diet. If *Sū' al-Haḍm* is due to the diet of morbid properties such as fish, beef, curd, and eggs, then try to vomit; if there is difficulty in vomiting, then advise potent Jawarish.[2]

Signs and symptoms of *Sū' al-Haḍm* (Dyspepsia) include burned belching,[1,3,7] sour belching,[1,5,7] nausea, vomiting, lack of thirst anorexia, distaste, heartburn, acid regurgitation (Sour water in the mouth again and again), abdominal distention, abdominal pain (Mild pain on *Fam-i-Mi'da*), loose motion of white color, undigested food in stool, bad smell of stool, constipation, white colored urine, feeling of weakness, headache, palpitation, and mild fever.[1,2,5,7,9]

It has to remember that prolonged dyspepsia can lead to epilepsy and psychoneurosis.[6] *Jalinūs* used to give *Arq-i-Afsantīn* to the patients of dyspepsia.[7] After *Tanqiya* (Elimination of morbid material from the body), *Riyādat* (Exercise), *Hammām* (Bathing), and pouring the hot water on the stomach and keeping the hands and feet in cold water, provide improvement in digestion.[4]

In the classical Unani texts, *Sū' al-Haḍm* is broadly explained and well correlated with a gastrointestinal disorder, dyspepsia. Dyspepsia (*Sū' al-Haḍm*) is the term used to describe symptoms such as nausea, heartburn, acidity, abdominal pain or discomfort, bloating or fullness, and wind or belching which are thought to originate from the upper gastrointestinal tract. There are many causes, including some arising outside the digestive system. Heartburn and other reflux symptoms are separate entities and are considered elsewhere. Although symptoms often correlate poorly with the underlying diagnosis, a careful history is important to detect "alarm" features requiring urgent investigations and they are weight loss, anemia, vomiting, hematemesis, melaena, dysphagia, and palpable abdominal mass, and to detect atypical symptoms which might be due to problems outside the gastrointestinal tract. Dyspepsia affects up to 80% of the population at some time in life, and many patients have no serious underlying disease.[10,11] Patients under 55 years without alarm symptoms can be treated without investigation. Patients over 55 years with recent onset dyspepsia or those with alarm symptoms and younger patients unresponsive to empirical treatment should be urgently investigated by upper gastrointestinal endoscopy. This will rule out peptic ulcer disease, medication-related ulceration, malignancy, and other rarer causes.[10,12]

Gastrointestinal Symptom Rating Scale: An interview-based rating scale consisting of 15 items for assessment of gastrointestinal symptoms in gastrointestinal disorders has been developed and named as Gastrointestinal Symptom Rating Scale. The scale is easy to apply and has proved to be useful. In the present study, out of 15 items of the gastrointestinal symptom rating scale (GSRS), 6 items related with dyspepsia, including abdominal pain, heartburn, acid regurgitation, eructation, nausea and vomiting, and abdominal distention, will be taken into account for assessment of efficacy.

Materials and Methods

Study design and location

The study was an open-label and single-arm which was conducted at the Regional Research Institute of Unani Medicine, Kolkata.

Ethical consideration

Approval of this study was obtained from the Institutional Ethical Committee (IEC No: RRIUM-HWH/IEC/2014-

15/08/21). Before the recruitment of the patients, the study was registered in the Clinical Trials Registry of India (CTRI No: CTRI/2015/02/005528).

Sample size

This is single-arm study. Sample size was calculated 60 participants, taking 80% power and 95% confidence level.

Participants and inclusion and exclusion criteria

Sixty-seven (67) patients of Dyspepsia (*Sū' al-Haḍm*) were screened, and sixty patients (60) were registered to the study. Recruitment of the patients was done from the outpatient department of the Regional Research Institute of Unani Medicine, Kolkata, during 2014–16. Selection of these cases was done as per the inclusion criteria; the patients of either sex in the age group of 18–55 years having abdominal discomfort with any of the symptoms such as abdominal pain, heartburn, acid regurgitation, eructation, nausea and vomiting, and abdominal distension were incorporated in the study. Patients with dysphagia, inflammatory bowel disease (ulcerative colitis and Crohn's disease), palpable abdominal mass, history of Zollinger Ellison syndrome, history of sudden weight loss, history of long-term medication, known cases of cancer, anemia/hematemesis/melena, known cases of severe hepatic, renal or cardiac ailments, diabetes mellitus, history of tobacco chewing, smoking, alcohol, drugs, with pregnant women and lactating mothers were excluded from the study. The patients were enrolled for the study after getting their written informed consent, and after that, they were subjected to hematological and biochemical investigations. Hematological investigations included hemogram (hemoglobin, erythrocyte sedimentation rate, total leukocyte count, differential leukocyte count [DLC: neutrophils, eosinophils, basophils, lymphocytes, monocytes]), urine examination (routine and microscopic), and stool examination (routine and microscopic). Biochemical investigations included liver function test (LFT) comprising serum bilirubin, serum glutamic oxaloacetic transaminase, serum glutamic pyruvic transaminase, and alkaline phosphatase, and kidney function test (KFT) comprising serum creatinine, blood urea, and serum uric acid, and blood glucose random at baseline.

Study drug, dosage schedule, and mode of administration

The following Unani pharmacopeial formulations *Jawārish-i-Kamūnī and 'Arq-i-Bādiyān* used in the study were procured from the National Research Institute of Unani Medicine for Skin Disorders, Hyderabad. The research drugs *Jawārish-i-Kamūnī* and *'Arq-i-Bādiyān* were administered orally for 2 weeks [Table 1]. *Jawārish-i-Kamūnī* is constituted with six ingredients and *Arq-i-Bādiyān* is composed of two ingredients [Tables 2 and 3] No concomitant treatment was allowed during the study.

Assessment of efficacy

The efficacy of study drugs was assessed on the basis of improvement in symptoms of *Sū' al-Haḍm* (Dyspepsia) for which GSRS were applied. The parameters for assessment of efficacy of the formulations were abdominal pain, heartburn, acid regurgitation, eructation, nausea and vomiting, and abdominal distension. These parameters were graded accordingly: no symptom = 0, occasional symptom = 1, prolonged or frequent symptoms = 2, and severe or continuous discomfort = 3. The percentage efficacy was calculated by the reduction in score at completion of treatment. For overall evaluation of efficacy, relief in symptoms and signs was calculated, and patients were divided into four groups on the basis of the comfort they had received. Patients in the relief category of 90%–100%, 60%–89%, 30%–59%, and <30% were labeled as cured, relieved, partially relieved, and not relieved, respectively. The clinical follow-up of all the cases was carried out at intervals of 1 week to 2 weeks. The hematological and biochemical investigations were conducted at baseline and at the end of the study.

Assessment of safety

The safety of trial drugs was evaluated by biochemical investigations and clinically by monitoring adverse effects which were carefully sought at each follow-up. *Mizāj* (Temperament) of the patients was assessed as per the parameters described in Unani classical literature.[13] The clinical and laboratory findings observed in every case were recorded on a separate case report form designed especially for a clinical study on *Sū' al-Haḍm* (Dyspepsia).

Statistical analysis

The clinical, hematological, and biochemical parameters at baseline and follow-ups were statistically analyzed using Student's paired *t*-test. The significance level of ($P < 0.05$) was used in this study.

Results

Flow of participants

Total of 67 patients were screened, and 60 patients were registered and completed the study. Out of 60 patients, 3 were cured, 39 were relieved, 12 were partially relieved, and 6 were not relieved [Flow Chart 1].

Table 1: Study drug management

Study drug	Form	Route of administration	Dose	Frequency	Instructions
Jawārish-i- Kamūnī	Semisolid	Oral	5 g	Twice daily	Take with water
'Arq-i-Bādiyān	Liquid	Oral	60 mL	Twice daily	After meals

Baseline characteristics

The mean age of all registered patients was 36.82 years. Among 60 registered patients, males and females were 43 and 17, respectively. The incidence of patients in the age groups of 18–30 years, 31–40 years and 41–50 years, and more than 50 years was 20, 19, 18, and 3, respectively. Phlegmatic temperament (*Balghamī al-Mizāj)* was dominant in the maximum registered patients (35 patients) [Tables 4-6].

Efficacy assessment

After 2 weeks of treatment with research drugs *Jawārish-i-Kamūnī* and *'Arq-i-Bādiyān*, there was significant improvement in symptoms and signs of *Sū' al-Haḍm* (Dyspepsia). The mean scores of abdominal pain, heartburn, acid regurgitation, eructation, nausea and vomiting, and abdominal distention before treatment were 1.32, 1.73, 1.93, 2.02, 0.63, and 1.33, respectively, while after treatment they were 0.53, 0.74, 0.75, 0.75, 0.30, and 0.27, respectively. So the improvement in abdominal pain, heartburn, acid regurgitation, eructation, nausea and vomiting, and abdominal distention were 59.85%, 57.23%, 61.14%, 62.87%, 52.38%, and 79.70%, respectively which were statistically significant [Table 7 and Figure 1].

Out of 60 completed patients of *Sū' al-Haḍm* (Dyspepsia), 3 cases (5.00%) were cured, 39 cases (65.00%) were relieved and 12 cases (20.00%) were partially relieved, and 6 cases were not relieved [Table 8 and Figure 2].

Table 2: Composition of *Jawārish-i-Kamūnī*

Unani name	Scientific name	Weight
Zeera Siyāh Mudabbar	*Cuminum cyminum* L.	350 g
Berg-i-Suddāb	*Ruta graveolens* L.	350 g
Filfil Siyāh	*Piper nigrum* L.	350 g
Zanjabīl	*Zingiber officinale* Roscoe	350 g
Boora-i-Armani	*Borax*	100 g
'Aṣl or *Qand Safaid*	*Honey or Sugar*	5 kg

Table 3: Composition of *'Arq-i-Bādiyān*

Unani name	Scientific name	Weight
Bādiyān	*Foeniculum vulgare* Mill.	1 part
Aab	*Oxidane* (Water)	20 parts

Table 4: Sex wise distribution of the cases (*n*=60)

Sex	Number of case (%)
Male	43 (71.67)
Female	17 (28.33)
Total	60 (100)

Table 5: Age-wise distribution of the cases (*n*=60)

Age group (years)	Number of cases (%)
18–30	20 (33.33)
31–40	19 (31.67)
41–50	18 (30.00)
>50	3 (5.00)
Total	60 (100)

Table 6: Distribution of the cases according to the *Mizāj* (Temperament)

Temperament (*Mizāj*)	Number of cases (%)
Sanguineous (*Damawī*)	6 (10.00)
Phlegmatic (*Balghamī*)	35 (58.33)
Bilious (*Ṣafrāwī*)	19 (31.67)
Melancholic (*Sawdāwī*)	0
Total	60 (100)

Safety assessment of study drug

The mean values of hematological and biochemical parameters at baseline and after 2 weeks of treatment are shown in Tables 9 and 10. The differences in the values of LFTs and KFTs before and after treatment were found within normal limits, revealing the safety of the study drug.

Adverse events and drug reaction

The study drug was found well-tolerated, and no adverse event/reaction was reported during or after the study.

Discussion

In the present study, among 60 enrolled patients of *Sū' al-Haḍm* (Dyspepsia), males and females were 43 and 17, respectively. The incidence of patients in the age groups of 18–30 years, 31–40 years, 41–50 years, and >50 years was 20, 19, 18, and 3, respectively. This finding indicates that the prevalence of *Sū' al-Haḍm* (Dyspepsia) is not selective for age group. In the present study, it was observed that a maximum number of patients (55 among 60) were having nonvegetarian habits. This data coincides that intake of *Radī' al-Ghidhā'* (Diet providing little nourishment) leads to *Sū' al-Haḍm* (Dyspepsia).[1] In this study, it was also found that *Balghamī* (Phlegmatic) temperament and *Sū'-i-Mizāj Bārid* are very common in phlegmatic persons which is one of the important causes of *Sū' al-Haḍm* (Dyspepsia).[7]

The objective of the study was to assess the safety and efficacy of the test drug. The mean values of haematological and biochemical investigations at baseline and after treatment with the test drug were within normal range, and no considerable adverse reaction was reported. And the studied drug was well tolerated which shows that the study drug is safe. Assessment of the efficacy of the research drug was done using A Visual Analogue Scale. After 2 weeks of treatment with research drugs *Jawārish-i-Kamūnī* and *'Arq-i-Bādiyān*, there was significant improvement in symptoms and signs of *Sū' al-Haḍm* (Dyspepsia), i.e., Abdominal pain, heartburn, acid regurgitation, eructation, nausea and vomiting, and abdominal distention were

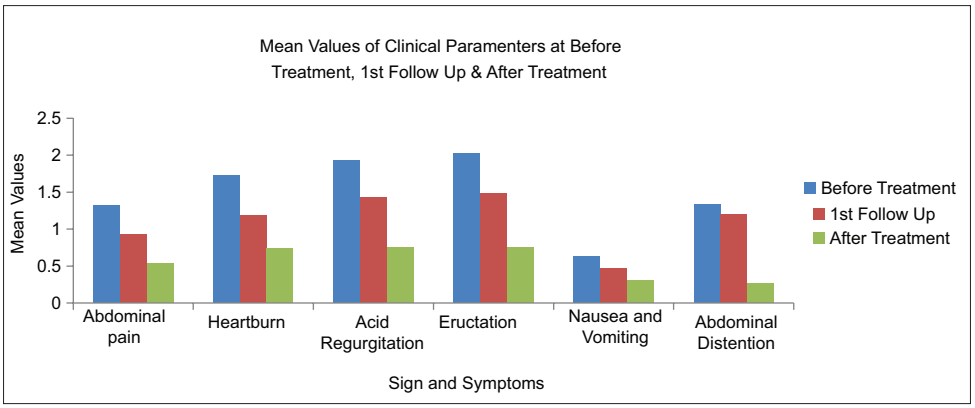


Figure 1: Effect of Unani pharmacopeial formulations, *Jawārish-i-Kamūnī* and *'Arq-i-Bādiyān* on different symptoms associated with *Sū' al-Haḍm* (Dyspepsia)

Table 7: Effect of Unani pharmacopeial formulations, *Jawārish-i-Kamūnī and 'Arq-i-Bādiyān* on different symptoms associated with *Sū' al-Haḍm* (Dyspepsia)

Signs and symptoms	BT, mean±SD	1st follow-up, mean±SD	AT, mean±SD	Improvement (%)
Abdominal pain	1.32±0.97	0.93±0.97	0.53±0.74*	59.85
Heartburn	1.73±1.06	1.18±1.12	0.74±0.80*	57.23
Acid regurgitation	1.93±0.97	1.43±1.02	0.75±0.73*	61.14
Eructation	2.02±0.85	1.49±0.95	0.75±0.75*	62.87
Nausea and vomiting	0.63±0.78	0.47±0.70	0.30±0.53*	52.38
Abdominal distention	1.33±1.10	1.20±1.10	0.27±0.48*	79.70

*The mean values are extremely significant (P<0.0001). SD: Standard deviation, BT: Before treatment, AT: After treatment

Table 8: General therapeutic response

	Cured (90%–100%)	Relieved (60%–89%)	Partially relieved (30%–59%)	Not relieved (0%–30%)	Total
Number of cases (%)	3 (5.00)	39 (65.00)	12 (20.00)	6 (10.00)	60 (100.00)

Table 9: Mean values of hematological investigations at baseline and after treatment

Hematological investigations	Period	Mean±SD	*P*
Hb (g%)	BT	13.09±1.48	>0.05
	AT	12.85±1.85	
ESR (mm/h)			
1st h	BT	25.13±15.12	>0.05
	AT	24.32±14.13	
TLC (mm^3)	BT	8031.67±1212.30	>0.05
	AT	7788.33±1201.80	
DLC			
Neutrophils	BT	60.50±7.99	>0.05
	AT	61.18±7.35	
Lymphocytes	BT	33.52±7.54	>0.05
	AT	32.23±6.40	
Monocytes	BT	4.67±3.57	>0.05
	AT	4.52±2.51	
Eosinophils	BT	1.15±0.94	>0.05
	AT	1.25±0.47	

BT: Before treatment, AT: After treatment, SD: Standard deviation, ESR: Erythrocyte sedimentation rate, DLC: Differential leukocyte count, TLC: Total leukocyte count, Hb: Hemoglobin

59.85%, 57.23%, 61.14%, 62.87%, 52.38%, and 79.70% improved, respectively, which were statistically significant.

The possible pharmacological actions of research drugs *Jawārish-i-Kamūnī* and *'Arq-i-Bādiyān* which lead to such promising results in the clinical features, may be as follows:

Jawārish-i-Kamūnī has *Hāḍim* (Digestive) and *Daf'-i-Tabkhīr* (Antiflatulent) properties. *'Arq-i-Bādiyān* possesses *Muḥallil-i-Riyāḥ* (Antiflatulent) activity.[14] *Jawārish-i-Kamūnī* contains *Zeera Siyāh Mudabbar*, *Berg-i-Suddab*, *Filfil Siyah*, *Zanjabīl*, *Boora-i-Armani,* and *'Aṣl* or Qand Safaid as constituents. *Zeera Siyāh* possesses *Kāsir-i-Riyāḥ* (Carminative) and *Muqawwī-i-Mi'da* (Stomach tonic) properties, *Berg-i-Suddab* shows *Kāsir-i-Riyāḥ* (Carminative) activity, *Filfil Siyah* is *Hāḍim* (Digestive) and *Muqawwī-i-Mi'da* (Stomach tonic), *Zanjabīl* has *Hāḍim* (Digestive) and *Kāsir-i-Riyāḥ* (Carminative) actions while *Bol-i-Armani* has *Muḥallil-i-Riyāḥ* (Antiflatulent) activity.[15] *'Arq-i-Bādiyān* contains only *Bādiyān* as a constituent which has *Muqawwī-i-Mi'da* (Stomach tonic), *Mufattiḥa* (Deobstruent), and *Kāsir-i-Riyāḥ* (Carminative) properties.[15] The properties of individual ingredients of *Jawārish-i-Kamūnī* and *'Arq-i-Bādiyān* also indicate their use in *Sū' al-Haḍm* (Dyspepsia).

There was no significant change found in hematological and biochemical investigations at baseline and after the

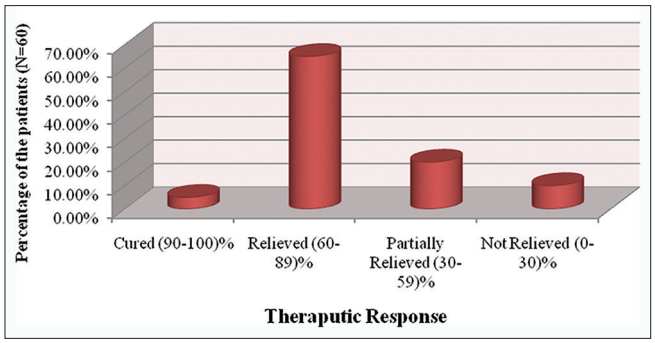


Figure 2: General therapeutic response

Table 10: Mean values of biochemical investigations at baseline and after treatment

Biochemical investigations	Period	Mean±SD	*P*
SGOT (Units/mL)	BT	34.27±17.20	>0.05
	AT	32.58±8.20	
SGPT (Units/mL)	BT	37.33±24.34	>0.05
	AT	33.53±9.89	
ALP (K and A units/L)	BT	158.83±25.91	>0.05
	AT	170.92±25.57	
Serum bilirubin (mg%)	BT	0.87±0.33	>0.05
	AT	0.83±0.21	
Serum creatinine (mg%)	BT	0.76±0.14	>0.05
	AT	0.74±0.15	
Serum urea (mg%)	BT	21.77±5.06	<0.05
	AT	25.28±5.75	

BT: Before treatment, AT: After treatment, SD: Standard deviation, SGOT: Serum glutamic oxaloacetic transaminase, SGPT: Serum glutamic pyruvic transaminase, ALP: Alkaline phosphatase

treatment. Results are shown in Tables 9 and 10. Hence, on the basis of the above findings, these drugs were found safe at the given dosage schedule for the symptomatic relief in *Sū' al-Haḍm* (Dyspepsia).

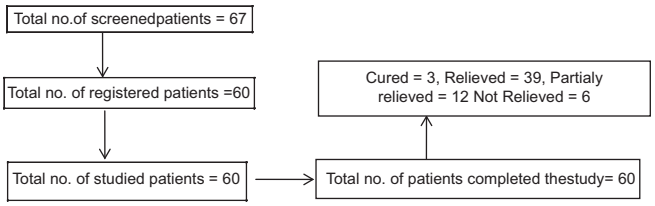
Hence, overall results of the study indicate the safety and efficacy of Unani pharmacopeial formulations *Jawārish-i-Kamūnī* and *'Arq-i-Bādiyān* in the treatment of *Sū' al-Haḍm* (Dyspepsia).

Study limitation

The outcome of the study may be biased because this study was single-arm and it had no control group, and further, this study was on a small sample size and there was a short duration of treatment.

Conclusion

It was found that the overall result of the Unani Pharmacopeial formulations *Jawārish-i-Kamūnī* and *'Arq-i-Bādiyān* was good and statistically significant. The subjective parameters such as abdominal pain, heartburn, acid regurgitation, eructation, nausea and vomiting, and abdominal distention showed significant relief by the tested Unani drugs. There were no considerable adverse reactions



Flow Chart 1: Enrollment of patients

reported during this trial. On the basis of the above facts, it can be decided that Unani pharmacopeial formulations *Jawārish-i-Kamūnī* and *'Arq-i-Bādiyān* are safe and effective in the treatment of *Sū' al-Haḍm* (Dyspepsia). There is a need of more high-quality studies on a larger sample size to evaluate further the efficacy of these Unani Pharmacopeial formulations.

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Conflicts of interest

There are no conflicts of interest.

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Original Article

Efficacy of Unani Formulation in *Bawāsīr-i-Ghāyra* (Internal Haemorrhoids) of the First and Second Degree: An Observational Clinical Study

Abstract

Background: Hemorrhoidal disease is a common proctological disorder which creates physical as well as psychological disturbances and affects the quality of life. The *Ḥab* prepared from *Halaila kāblī*, *Kahrubā Shama'ī*, *Muqil*, *Āb-i-Gandanā,* and *Roghan-i-gāo* has a specific action in the treatment of *Bawāsīr-i-Ghāyra* (internal hemorrhoids). It has the property of evacuation of *Sawdā* and is hemostatic as well as laxative. **Aim:** The present study aimed to evaluate the effect of Unani Formulation in *Bawāsīr-i-Ghāyra* ↑ of the first and second degree. **Materials and Methods:** Thirty patients of 1st and 2nd-degree internal hemorrhoid who fulfilled the protocol criteria were enrolled for an observational clinical study from June 2019 to Feb 2020. Patients were given Unani formulation in the form of *Ḥab* and instructed to take 4 *Ḥab* (580 mg each), orally thrice daily for 45 days. The efficacy outcome was assessed by an arbitrary grading scale. The outcomes were analyzed using appropriate statistical methods. The safety was assessed by employing pertinent biochemical parameters and reporting adverse drug reactions. **Results:** Data analysis showed improvement in subjective parameters; there was 100% relief in bleeding per rectum ($P < 0.001$), 16.7%, improvement in mucus discharge per rectum ($P = 0.251$), and 33.3% improvement in itching per rectum ($P = 0.077$) at the end of the treatment. The objective parameter bleeding point showed an improvement of 56.7% ($P < 0.001$) and for the sphincter spasm improvement of 30.0% ($P = 0.103$) at the end of the trial. No significant changes in biochemical indices between pre- and post-treatment were recorded. No adverse drug reactions were reported throughout the study period. **Conclusion:** The result inferred that the test drug is safe and effective in improving the severity of symptoms of first and second-degree *Bawāsīr-i-Ghāyra* and can be used as an alternative to conventional treatment. However, further studies with control and a larger sample size are needed to ascertain the study findings.

Keywords: *Bawāsīr-i-Ghāyra, unani formulation, Muqil, Kahrubā Shama'ī*

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Introduction

Hemorrhoids have afflicted people since the beginning of time and ever since they began to walk. Among the documented references to this disease are physicians treating hemorrhoids in Egyptian palaces as early as 2500 BC. The Edwin Smith and Ebers' Papyri (1700 and 1500 BC), as well as those from India, China, Greece, and Rome, have documented hemorrhoids management.[1] Hemorrhoid is a common anorectal disease with annoying and disturbing symptoms. It results due to aging where supporting tissue weakens, causing distal displacement of cushions and distension of veins, and sometimes tissue prolapse.[2] The exact prevalence is unknown because most of the individuals are asymptomatic.[3] The most noteworthy finding was that one in four adults over 30 years of age had this disease. The prevalence of hemorrhoids rises with age, peak between the ages of 45 and 65. Hemorrhoids may occur in females during pregnancy or after childbirth. Despite the presence of estrogen receptors in hemorrhoid tissues, elevated pelvic pressure, influence the hemorrhoid growth. Younger and middle-aged persons may have external hemorrhoids more frequently than elderly adults.[1] In India, approximately 40,723, 288 people are reported to have hemorrhoids. One million new cases are reported annually, at the rate of 47/1000, increasing with age.[4] The exact cause of hemorrhoid is unknown, few predisposing factors are temperament, habits, and sedentary lifestyles. It is common in individuals with chronic diarrhea, constipation, and less fiber diet.[5]

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The term haemorrhoids are derived from two Greek words, *haima*; blood and *rhoos*; flowing. The term pile has been derived from Latin word "Pila" which means "a ball or a mass." John Andrene remarked that common people call them piles and the aristocracy calls them hemorrhoids, the French call them figs.[5] Recent studies described the development of internal hemorrhoids may be due to portal hypertension, varicose vein, infection, anal hypertonia, etc.[6] The term "hemorrhoid" was originally used by renowned scholar Hippocrates (*Buqrat*), who described it as "the flow of blood from the veins of the anus.[7]

Internal Hemorrhoidal disease is most commonly classified by the Golighers' classification system, first described in 1975.[6]

- Grade I – protrude into the anal canal without prolapse
- Grade II – prolapsing beyond the anal canal but reduce spontaneously
- Grade III – prolapsing outside the anal canal on straining, requiring manual reduction
- Grade IV – prolapsed constantly, irreducible.

Symptoms attributed to hemorrhoids include bleeding, pain, pruritus, fecal seepage, prolapse, and mucus discharge. Classically, they occur in the 3, 7, and 11 o'clock positions with the patient in the lithotomy position.[6]

First-line therapy for hemorrhoids typically involves dietary modification with adequate fluid and fiber intake, along with avoiding straining and limiting prolonged time on the toilet. Active management for the disease includes sclerotherapy, Barron's band ligation, cryosurgery, infrared photocoagulation, and surgical intervention such as Milligan-Morgan, Closed Ferguson haemorrhoidectomy, and stapled hemorrhoidopexy.[6,8,9]

These modalities not only produce adverse effects but also create physical and psychological disturbances and affect the quality of life. In view of the high prevalence and nonavailability of affordable treatment without side effect, the present study was aimed to evaluate the efficacy of Unani formulation which is mentioned in *Ṭib-e-Akbar* written by *Hakim Akbar Arzānī*, "*Halaila kāblī*, *Kahrubā Shama'ī*, *Muqil*, *Āb-i-Gandanā*, and *Roghan-i-gāo*.[10] *Halaila kāblī* has the property of evacuation of *Sawdā*, *kahrubā,* and *Āb-i-Gandanā* act as hemostatic and *Muqil* has hemostatic as well as laxative properties and *Rogan gao* is used as a binding agent.[11,12]

Materials and Methods

Study design and setting

The current study was a single-arm open labeled with pre- and post-analysis clinical trial design. The trial was carried out in the Hospital of the National Institute of Unani Medicine (NIUM), Bengaluru from July 2019 to February 2020.

Ethical considerations

The study protocol was in compliance with the Declaration of Helsinki and standards provided by the International Committee on Harmonization of Good Clinical Practice (ICH-GCP) guidelines. Before the commencement of the trial, the study protocol was submitted to the institutional ethical committee (IEC number; NIUM/IEC/2016-17/029/Jar/02) of NIUM, Bengaluru, and was approved. The trial was registered by the Clinical Trial Registry under clinical trial registration number CTRI/2019/05/025738. All the participants were explained about the study and provided verbal and written informed consent forms, after getting their signed written informed consent they were enrolled in the study.

Sample size

The sample size was estimated considering the mean and standard deviation of a previous similar study with α error 0.05 and β error of 0.20. The sample size was calculated by the following formula. The formula used to calculate sample size is $n = ([Z\alpha/2 + Z\beta]\ 2 \times [2(\sigma)2])/(\mu 1 - \mu 2)2$ which gives a sample of 30.

Inclusion criteria

(1) Clinically diagnosed patients of I and II-degree hemorrhoids confirmed by proctoscopy, (2) patients of either sex between 18 and 60 years of age, and (3) patients who have agreed to sign the written informed consent and follow the protocol.

Exclusion criteria

(1) Patients suffering from III and IV-degree internal hemorrhoids, (2) hemorrhoids associated with other anorectal diseases such as Rectal polyp, Fissure in Ano, fistula in ano, carcinoma of rectum, and anal canal, (3) pregnant and lactating women, and (4) patients with known severe systemic illnesses.

Method of preparation of drug

Composition of the test drug (Ghani, 2011).

- *Halaila kāblī* (*Terminalia chebula*): 30 daram (90 g)
- *Kahrubā Shama'ī* (*Pinus succinifera* L.): 10 daram (30 g)
- *Muqil* (*Commiphora mukul*): 40 daram (120 g)
- *Āb-i-Gandanā* (*Allium ascalonicum*): q.s
- *Roghan-i-gāo:* q.s.

The research drug was prepared according to the pharmacopeial procedure at NIUM pharmacy. The drugs were identified by the pharmacist of the NIUM pharmacy and confirmed with S. Noorunnisa (Senior Assistant Professor, C-RMR the Institute of Trans-Disciplinary Health Sciences and Technology). The authentication numbers of the test drugs (*Halaila kāblī*, *Kahrubā Shama'ī*, *Muqil*, *Gandanā*) are 5267, 5268, 5269, and 5270, respectively. All the ingredients were cleaned and then powdered by

adopting the Unani pharmacopeial method. *Ḥab* were prepared and dispensed to the participants at every follow-up in a transparent polypack containing 180 *Ḥab*. Patients were instructed to take 4 *Ḥab* (580 mg each) orally, thrice daily. The intervention was taken for 45 days.

Study duration and follow-up

Once participants had fulfilled the inclusion criteria, written informed consent was obtained and baseline scores for subjective parameters were recorded and the assigned intervention and relevant instructions were given to participants. Patients were asked to attend the outpatient department fortnightly for the first 45 days, where they were clinically assessed, scores were recorded, and patients were given supplies of the same intervention. One follow-up at 15 days after the cessation of the treatment protocol was done to monitor the participants and record any recurrence of symptoms. Participants were asked about any adverse effects throughout the duration of the trial period. After completion of the trial, the baseline scores and post-follow-up without treatment scores were statistically analyzed in order to evaluate the efficacy of the treatment. Noncompliance with the trial protocol and adverse reaction to the intervention were considered to be withdrawal criteria.

Study outcome measure

The study outcome was based on assessing subjective and objective parameters. Subjective parameters were the bleeding per rectum, mucous discharge per rectum, and itching per rectum. An arbitrary grading scale was adopted for the assessment of the nature of bleeding and mucus discharge per rectum. Scores interpreted as 0 = No discharge per-rectum/No bleeding; + (mild) = Scanty mucus/blood discharge per-rectum; + + (moderate) = Moderate degree of mucus/blood discharge per-rectum and +++ (severe) = Profuse degree of mucus/blood discharge per-rectum. The objective parameters were rectal examination by proctoscopy to assess bleeding point and sphincter spasm.

Statistical analysis

The statistical software, namely SPSS version 22.0 (IBM Corp., Armonk, NY, USA) and R environment version 3.2.2 (R Foundation for Statistical Computing, Vienna, Austria), were used for the analysis of the data, and Microsoft Word and Excel (Microsoft Corporation, Redmond, WA, USA) were used to generate graphs, tables, etc. Student's-*t*-test (two-tailed, dependent) has been used to find the significance of study parameters on a continuous scale within each group. Paired Proportion test has been used to find the importance of proportion in paired data.

Results

Patient dispositions and baseline characteristics

A total of 40 patients were screened for the study, 4 patients refused to give their consent and 6 patients did not meet the inclusion criteria. Finally, 30 patients were enrolled in the study after taking written informed consent. The patients were clinically assessed by history taking and physical examination and other required laboratory parameters. All the enrolled subjects completed the course of treatment [Figure 1]. The baseline characteristics of study participants are shown in Table 1.

Efficacy outcomes

The effect of test drug formulation on subjective parameters bleeding per rectum, mucous discharge per rectum, and itching per rectum, were assessed at baseline (BT), 15th (F1), 30th (F2), 45th (F3), and 60th (F4) days, and evaluated based on arbitrary grading score scale as shown in Table 2. The objective parameters, examination by proctoscopy to assess bleeding point, and sphincter spasm were evaluated at

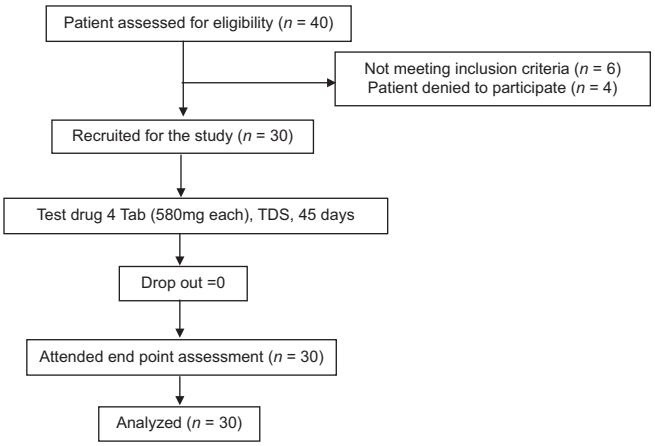

Figure 1: Study flow chart

Table 1: Baseline characteristics: Expressed in mean, standard deviations, and percentage

Clinical profile	*n* (%)
Age (years)	37.07±11.83
Sex	
Male	22 (73.3)
Female	8 (26.7)
Socioeconomic status	
Upper middle	11 (36.7)
Lower middle	17 (56.7)
Upper lower	2 (6.7)
Lower	0
Food	
Vegetarian	2 (6.7)
Mixed	28 (93.3)
Habitat	
Rural	16 (53.3)
Urban	14 (46.7)
Bowel habit	
Regular	1 (3.3)
Constipation	29 (96.7)
BMI (kg/m^2)	25±4.01

BMI: Body mass index

baseline (BT), 15th (F1), 30th (F2), 45th (F3), and 60th (F4) days as are summarized in Table 3. In intragroup comparison using paired *t*-test, the results of the present study demonstrated 100% relief in bleeding per rectum. It showed an improvement of 63.3% (absence of bleeding) which is strongly significant with $P < 0.001$. The patient presented with mucus discharge per-rectum showed improvement of 16.7% (absence of mucus discharge) with $P = 0.251$ which is not significant. Patients presented with itching per rectum showed improvement of 33.3% (absence of itching per rectum), which is suggestive significance with $P = 0.077$. The objective parameter bleeding point showed an improvement of 56.7% (absence of bleeding point) with $P < 0.001$ and for sphincter spasm, there was an improvement of 30.0% with $P < 0.103$ and both are significant.

Safety assessment

Biochemical laboratory findings at the baseline and after the treatment are shown in Table 4. The results indicated that there was no significant change in serum glutamic-oxaloacetic transaminase, serum glutamic pyruvic transaminase, serum alkaline phosphatase, serum creatinine, and blood urea. No adverse effects of the study drug were reported by any of the patients during the treatment period.

Table 2: Effect of intervention on subjective parameters

Subjective parameters	Number of patient (%)					
	Baseline (BT)	15th day (F1)	30th day (F2)	45th day (F3)	60th day (F4)	Percentage difference
Bleeding*						
Nil	11 (36.7)	13 (43.3)	25 (83.3)	30 (100)	30 (100)	63.3
Mild	9 (30)	17 (56.7)	5 (16.7)	0	0	−30.0
Moderate	7 (23.3)	0	0	0	0	−23.3
Severe	3 (10)	0	0	0	0	−10.0
Mucus discharge**						
Nil	25 (83.3)	27 (90)	29 (96.7)	30 (100)	30 (100)	16.7
Mild	5 (16.7)	3 (10)	1 (3.3)	0	0	−16.7
Moderate	0	0	0	0	0	0
Severe	0	0	0	0	0	0
Itching per rectum***						
No	20 (66.7)	24 (80)	30 (100)	30 (100)	30 (100)	33.3
Yes	10 (33.3)	6 (20)	0	0	0	−30.0

*Improvement of 63.3% (absence of bleeding) at the end of protocol, Is significant with $P<0.001$**, paired proportion test, **Improvement of 16.7% (absence of mucus discharge) at the end of protocol, is not significant with $P=0.251$; paired proportion test, ***Improvement of 33.3% (absence of itching per rectum) at the end of the protocol, is significant with $P=0.077$+; paired proportion test. BT: Before treatment

Table 3: Effect of intervention on objective parameters

Objective parameters	Number of patient (%)					
	Baseline (BT)	15th day (F1)	30th day (F2)	45th day (F3)	60th day (F4)	Percentage difference
Bleeding point*						
−ve	13 (43.3.7	18 (60)	24 (80)	27 (90)	30 (100)	56.7
+ve	17 (56.7)	12 (40)	6 (20)	3 (10)	0	−56.7
Sphincter spasm**						
−	21 (70)	29 (96.7)	30 (100)	30 (100)	30 (100)	30.0
+	8 (26.7)	1 (3.3)	0	0	0	−26.7
++	1 (3.3)	0	0	0	0	−3.3

*Improvement of 56.7% (absence of bleeding point) at the end of the protocol is significant with $P<0.001$, Paired proportion test,
**Improvement of 30.0% (absence of spasm) at the end of protocol is significant with $P=0.103$ paired proportion test. BT: Before treatment, −: Absent, +: Mild, ++: Moderate/Severe

Table 4: Effect of intervention on safety parameters

Biochemical parameters	BT	After treatment	difference	*t*	*P**
Blood urea (mg/dL)	24.07±5.98	22.70±4.20	1.704	1.569	0.129
Serum creatinine (mg/dL)	0.94±0.17	0.87±0.25	0.076	1.746	0.092
SGOT (IU/L)	23.72±7.39	24.22±7.05	−0.846	−0.892	0.381
SGPT (IU/L)	26.93±11.47	26.04±10.42	1.148	1.776	0.087
ALP (IU/L)	86.27±25.35	82.63±22.81	3.630	1.974	0.059

*Student's *t*-test (two tailed, paired). BT: Before treatment, ALP: Alkaline phosphatase, SGOT: Serum Glutamic-Oxaloacetic Transaminase, SGPT: Serum Glutamic Pyruvic Transaminase

Discussion

Hemorrhoids are a common anorectal disease. Even though the vast majority of people can be successfully managed with conservative treatment, some patients will require surgery at some point in their lives.[13] Using several conservative approaches such as lifestyle modification, moderate physical activity, limiting the consumption of alcohol and fat, adequate fluid intake, fiber-rich diet, topical ointments, and phlebotonic drugs, the disease in the early stage can be effectively managed.[14,15] Drugs such as haemostatics, laxatives, topical corticosteroids, calcium dobesilate, nifedipine, and nitroglycerine can be used locally as well as internally.[16] Grade I and II hemorrhoids are also treated by rubber band ligation, infrared coagulation, radiofrequency ablation, and sclerotherapy. However, the complications are bleeding, pain, and recurrence.[17,18]

In the present study, we evaluated the efficacy of Unani formulation containing *Halaila kāblī*, *Kahrubā Shama'ī*, *Muqil*, *Āb-i-Gandanā*, and *Roghan-i-gāo*.[10] The significant improvement in symptoms associated with hemorrhoids is attributed to the pharmacological actions of Unani formulation and its ingredients.

The fundamental cause of the majority of hemorrhoids, according to the Unani system of medicine, is the buildup of melancholic blood (*Sawdāvi khilt*), a blood that has undergone biochemical alteration and is accumulated in anorectal veins.[19] *Halaila kāblī* (*T. chebula*) has evacuation property of *Sawdā*, *Kahrubā Shama'ī* (*Pinus succinifera* Linn) act as hemostatic.[11,12,20] According to reports, the resin of the *Muqil* (*Commiphora mukul*) tree has astringent, anti-thrombotic, laxative, anti-inflammatory, analgesic, and hepatoprotective qualities, and it appears to work at the microcirculatory level. These properties cover the main therapeutic goals of hemorrhoids treatment. According to Avicenna (Ibn Sina), *Commiphora Mukul* can be used topically or taken orally and is one of the effective monotherapies for hemorrhoids. It possesses hepatoprotective, astringent, and laxative properties.[21]

The improvement in constipation might be the due laxative property of *Terminailia chebula*. *T. chebula* contains gallic acid, ellagic acid, and anthraquinones which are beneficial for evacuation and to increase stool volume, allowing the gastrointestinal tract particularly its glands (Brunner's glands) to perform well and alleviate constipation. The improvement in sphincter spasm might be due to venoprotective and venotonic effect of *T. chebula*. *T. chebula* also has anti-inflammatory and analgesic effect due to the presence of gallic acid, ellagic acid, chebulinic acid, and corilagin. It lowers the serum levels of pro-inflammatory cytokines such as tumor necrosis factor-, interleukin-6 (IL-6), and IL-1 and blocks the enzyme cyclooxygenase and prostaglandin formation.[22] *Āb-i-Gandanā* (Allium ascalonicum) shows antimicrobial, antioxidant, and anti-inflammatory properties, hence effective in haemorrhoids.[23,24] *Roghan-i-Gāo* is used as a binding agent for making pills.

The beneficial effects on overall symptoms of internal hemorrhoids of the first and second degree may be attributed to the pharmacologic effects of Unani formulation like other traditional medicines and can be a potential treatment option. However, these results are too preliminary to reach the therapeutic application. One of the main rationales for choosing treatment options for any health condition and population is if the intervention does no harm and has the potential for benefit. In the current study, the test drug was well tolerated without any adverse effect found on safety assessment during the protocol, which suggests the test drug was safe throughout the treatment period.

Conclusion

The result inferred that the test drug is safe and effective in improving the severity of symptoms of first and second-degree *Bawāsīr-i-Ghāyra* (internal hemorrhoids) and can be used as an alternative to conventional treatment. The main limitations of this study are the small number of participants, the absence of a control group, and a follow-up time period that may lessen the strength of the study outcome. The encouraging results portrayed in this study can be used to determine the power of future double-blind, randomized placebo-controlled trials with larger sample size which are needed to confirm these results.

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Conflicts of interest

There are no conflicts of interest.

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Original Article

Psoriasis Beyond the Skin: A Dermatology Life Quality Index-based Exploration of Life Quality – A Cross-sectional Study as Per STROBE Compliance

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Abstract

Background: Psoriasis is a chronic and immune-mediated inflammatory skin disease with significant psychological and social repercussions. In addition to physical symptoms, patients often endure stigma, emotional stress, and lifestyle limitations. **Objective:** To assess the impact of psoriasis on patients' quality of life (QoL) using the Dermatology life quality index (DLQI) and advocate the integration of QoL assessments in routine clinical dermatology practice. **Design:** A descriptive, cross-sectional, and observational study was conducted at Ajmal Khan Tibbiya College, AMU, Aligarh. **Setting:** Outpatient and inpatient departments of Amraz-e-Jild wa Zohrawiya, Ajmal Khan Tibbiya College, Aligarh Muslim University. **Participants:** Fifty patients clinically diagnosed with psoriasis. **Methods:** The DLQI questionnaire was administered to assess the QoL across multiple domains including symptoms, daily activities, work, relationships, and treatment impact. Scores were analyzed and categorized into five effect levels from "no effect" to "very severe effect." **Results:** About 52% of participants reported severe QoL impairment, 28% moderate, and 12% very severe. Daily functioning and emotional well-being were the most adversely affected domains. **Conclusions:** Psoriasis imposes a significant burden on patients' lives beyond visible symptoms. DLQI is a valuable tool in clinical dermatology for recognizing this hidden burden and guiding holistic patient management.

Keywords: *Cross-sectional study, dermatology life quality index, psoriasis, psychosocial impact, quality of life, STROBE*

Introduction

Psoriasis is a persistent and immune-mediated inflammatory skin condition that affects approximately 2% of the global population.[1,2] It manifests through erythematous plaques, scaling, and itching, but its implications extend far beyond the skin. The disease can interfere with daily activities, social relationships, and occupational responsibilities.[3] It is associated with social humiliation, discomfort, physical impairment, pain, and mental anguish.[3] Due to its visibility, patients often face stigma and social rejection, mistakenly perceived as contagious. This can lead to individuals being separated from society and experiencing emotions of lack of self-worth, sadness, social exclusion, and stigmatization.[4] Moreover, itching and soreness might interfere with essential daily routines including bathing, getting dressed, and sleeping. Hand and leg psoriasis makes it difficult for patients to work in certain professions, participate in certain sports, and even care for their families. Psoriasis exerts a substantial impact on the quality of life (QoL) of people.[5,6] Several researchers have explored the various ways of how psoriasis impacts the lives of patients, as well as methodologies for quantifying the handicap created.[7]

These psychosocial impacts are as critical as physical symptoms and warrant holistic care. Tools such as the dermatology life quality index (DLQI) enable clinicians to quantify these impacts effectively.[8] The DLQI is a checklist consisting of ten questions including various areas linked to dermatological disorders such as symptoms, changes in behaviors, hobbies, dressing pattern, pleasure and public interactions, and others.

Therefore, the present and observational study was designed to determine the influence of psoriasis on patient's QoL with

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the use of DLQI, so that the potential quantity of counseling could also be estimated apart from drug management.

Methods

Study design and setting

A cross-sectional, descriptive, and observational study was conducted at the Outpatient and Inpatient Departments of Amraz-e-Jild wa Zohrawiya, Ajmal Khan Tibbiya College, Aligarh Muslim University, Aligarh, India. Data collection spanned from October 2024 to April 2025.

Participants

A total of 50 patients with clinically confirmed psoriasis were included in the study.

Inclusion criteria

- Age ≥10 years
- Clinical diagnosis of plaque psoriasis
- Ability and willingness to provide written informed consent
- Ability to complete the DLQI questionnaire independently or with minimal assistance.

Exclusion criteria

- Coexisting major psychiatric disorders impairing judgment or self-reporting
- Patients on concurrent treatment for other chronic dermatoses.

Variables

- Exposure Variable: Psoriasis (clinically diagnosed)
- Outcome variable: QoL, measured via DLQI score
- Demographic Variables: Age, gender, and socioeconomic status [Table 1].

Data collection

The DLQI questionnaire, consisting of 10 items covering six domains (symptoms, daily activity, leisure, work/school, personal relationships, and treatment), was administered. Each item is scored from 0 ("not at all") to 3 ("very much"). Total scores range from 0 to 30 [Table 2].

Dermatology life quality index scoring interpretation

- 0–1: No effect
- 2–5: Mild effect
- 6–10: Moderate effect
- 11–20: Severe effect
- 21–30: Very severe effect.

Bias control

To minimize bias:
- All participants were briefed using a standard script
- Assistance was provided for illiterate participants without influencing answers
- No identifiers were attached to the data sheets.

Sample size

The study used a convenience sample of 50 patients due to time and resource constraints.

Statistical methods

Description statistics (frequency, percentage) were used for categorical variables. Data were entered and analyzed using Microsoft Excel (Microsoft corporation, Redmond, WA, USA) and SPSS Statistics Version 16.0 (SPSS Inc., Chicago, IL, USA).

Observations and Results

Table 1: Sociodemographic profile

Variable	Category	Frequency, *n* (%)
Age (years)	10–20	7 (14)
	20–40	23 (46)
	40–60	18 (36)
	>60	2 (4)
Gender	Male	29 (58)
	Female	21 (42)
SES	Upper	12 (24)
	Middle	19 (38)
	Lower	19 (38)

SES: Socioeconomic status

Table 2: Dermatology life quality index score

DLQI score range	QoL impact	Frequency (%)
0–1	No effect	1 (2)
2–5	Mild effect	3 (6)
6–10	Moderate effect	14 (28)
11–20	Severe effect	26 (52)
21–30	Very severe effect	6 (12)

DLQI: Dermatology Life Quality Index, QoL: Quality of life

Discussion

Our data demonstrate that psoriasis causes a detrimental influence on patients' QoL, and therefore, building the required coping skills must be prioritized. This further demonstrates that psoriasis places a significant strain on patients' ability for carrying out routine tasks. Dubertret *et al*. conducted a research study in Europe in 2002 utilizing a self-administered questionnaire to analyze the influence of psoriasis on European patients.[9] It was shown that 77% of individuals with psoriasis perceived it as a major issue affecting their everyday lives. The Psoriasis Disability Index was used to evaluate the impact of psoriasis during the study. However, the study concluded that psoriasis had the greatest impact on daily activities such as clothing selection and sports-related activities. Domains most affected were daily activities, emotional health, and social participation. These findings mirror those of another international study.[7]

Another research conducted in Germany analyzed patients' mean DLQI score and found that people with psoriasis had

significantly lower QoL, with a mean DLQI of 10.6. Key areas affected included everyday tasks and medications.[10] These findings are consistent with our investigation. As a result, the detrimental influence on these patients' QoL needs to be taken seriously. Clinicians should always provide thorough counseling on the disease's noncontagious nature, alongside pharmacological management.

Limitations

- Small sample size
- Single-center study limits generalizability
- Cross-sectional design prevents the assessment of changes over time
- Absence of a control group.

Conclusions

Psoriasis significantly reduces the patients' QoL. This study supports the use of DLQI as an essential component of dermatological evaluations. Integrating psychosocial support and patient-centered communication is critical for comprehensive management. Physicians should look beyond the visible lesions and explore the emotional and social dimensions of the disease.

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Conflicts of interest

There are no conflicts of interest.

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Original Article

Standardization and Toxicity Study of *Kushta Marjan Sada*

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Abstract

Background: *Kushta* (calx) is a blend of metals, metallic oxides, nonmetals, and their compounds, minerals, and some plant-origin drugs. It is the finest Unani dosage form. Despite being distinguished for therapeutic use, very few *kushta* (s) have been standardized on scientific parameters and evaluated for their toxicity. **Aims and Objectives:** This study is strategized for the standardization and toxicity study of *Kushta Marjan Sada* (KMS), a Unani pharmacopeial preparation. **Materials and Methods:** Classical, conventional, and analytical methods have been used for standardization. Acute and sub-acute toxicity studies have been carried out according to OECD guidelines (423). The parameters for standardization included classical tests, such as luster test, fineness test, floating test, curd test, lemon test, and wall stick test. Conventional tests included moisture content, pH, quantitative elemental analysis, and powder characterization. For the toxicity study, body weight, food intake, organ weight, skin changes, and motility as general observation and hematology, LFT, RFT, and histopathology as specific parameters were taken. **Results:** Some heavy metals were detected, but within the permissible limit. The drug seemed to be safe; however, a chronic toxicity study is needed to establish complete safety. **Conclusion:** No data on the standardization and toxicity of KMS are available. Hence, our findings may be considered as a standard for future reference.

Keywords: *Kushta, Marjan, standardization, toxicity, Unani medicine*

Introduction

The use of natural resources is a common practice of traditional systems of medicine. Although medicinal plants have been the backbone of these systems, nonetheless, animals and minerals also serve as drugs. Animals proved to be a therapeutic arsenal that has played a significant role in the healing practices, not only as a drug but also as a tool for drug discovery. Two hundred animal-origin drugs have been described in Unani Medicine.[1] These are usually shells, coverings, flesh, fat, organs, bones, glands, blood, milk, secretions, excretions, teeth, hooves,[2-4] horns, feathers, hairs, nails, shells, castings, and even the pathological products and whole animal. Animal shells and coverings are an excellent source of calcium, magnesium, iron, etc. However, they need to be investigated scientifically before use.[5] Hard coverings and shells of animals are used as fine powder, i.e., *Kushta* (calx).[6,7] However, despite claimed efficacy, most *kushta*(*s*) have not been evaluated scientifically.

Classical parameters for the authentication of drugs, such as taste, odor, and color, are of little significance now because of subjectivity. Evaluation of the elemental part in *kushta* (s) is critical to determine the quality, as some trace elements can be harmful to the recipient.

In Unani medicine, toxicity studies have not been carried out in a well-organized manner to give a precise result, but rather have been described under the heading of *Maḍarrat* (harmful effects) that are observed after giving a specific dose directly to a human being.

Marjan (*Corallium rubrum*), commonly known as coral, is used in the form of calx in Unani Medicine. In Unani medicine, it is used as an astringent,[5,8-13] a Nervine tonic,[8,10] and an antiphlegm and bile agent.[8]

Materials and Methods

Materials

Kushta Marjan Sada (KMS), serum glutamic-oxaloacetic transaminase (SGOT), serum glutamic pyruvic transaminase (SGPT), and BUN Kit manufactured by

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Prism Diagnostics Pvt. Ltd., Mumbai; Albumin, Total Protein and Serum Creatinine Kits manufactured by AD, India; Uric acid Kit manufactured by Linear Chemicals SL, Spain; Total Cholesterol and Triglyceride Kits manufactured by Spintect, SA., Spain; HDL-C Cholesterol assay Kit manufactured by Beijing Leadman Biochemistry Co. Ltd., Beijing, were procured from the local market of Bangalore. Healthy Wistar rats of either sex, weighing 150–200 g, were procured from a registered breeder of Bangalore.

Dose of the test drugs

The therapeutic dose of KMS for humans mentioned in Unani literature is 125–250 mg.[14] The dose for Wistar rats was calculated by multiplying the human therapeutic dose by a conversion factor of 7.[15] The maximum dose, i.e., 250 mg, when converted, was found as 30 mg/kg. Since, at this dose, the drug is supposed non-toxic, a starting dose of 300 mg was selected for the acute toxicity study. Further higher doses were taken according to OECD guidelines.[16] For the sub-acute toxicity study, the doses were selected on the basis of findings of acute toxicity.

Standardization

Classical methods

Test for luster

A small amount was taken in a Petri dish and was observed through a magnifying glass for any luster in daylight.

Test for fineness

A small amount was taken between the thumb and index finger, rubbed to see that the *Kushta* has entered into the lines of the finger, and easily washed out.

Test for floating

A small amount was sprinkled over the still water in a beaker to observe whether the particles floated over the surface of the water.[6,14,17]

Curd test

A pinch of calx was mixed with a small amount of curd in a clean and dry Petri dish to observe any color change.

Lemon test

A pinch of calx was mixed with lemon juice to observe any color change.

Wall stick test

A pinch of calx was examined by throwing it on the wall to check whether it sticks to the wall.

Conventional methods

Moisture content

Moisture content was determined by the loss-on-drying method. A known amount (500 mg) of calx was placed in a known weight of a thin porcelain dish in a hot air oven at a temperature between 100°C and 105°C. The weight of the drug was continuously monitored after every 2 h, followed by cooling of the drug in a desiccator until the weight of the drug remained constant. The constant weight was then subtracted from the weight of the drug taken, and the percentage of moisture was determined.

Determination of ash value

Total ash

A sample of *Kushta* (500 mg) was incinerated in a silica dish at a temperature not exceeding 500°C, then it was cooled and weighed, and the percentage of total ash was calculated.

Acid-insoluble ash

The ash was boiled with 25 mL of dilute hydrochloric acid for 5 min. The insoluble matter was collected on Whatman ashless filter paper, washed with hot water, and ignited at a temperature not exceeding 500°C, and weighed after cooling and the percentage of acid-insoluble ash was calculated.

Water-soluble ash

The ash was boiled with 25 mL of distilled water for 5 min. The insoluble matter was collected on an ashless filter paper, washed with hot water, and ignited. The weight of insoluble ash was subtracted from the weight of the total ash, giving the weight of the water-soluble ash. The percentage of water-soluble ash was calculated.

Powder characterization

Bulk density and tapped density

The volume of the packing was determined by the Jolting volumeter. Ten g weighed calx was carefully added to the cylinder. The initial volume was noted, and the sample was then tapped until no further reduction in volume was observed and calculated by the given formulas.

Bulk Density = Mass/Bulk Volume

Tapped Density = Mass/Tapped Volume

Hausner ratio

Hausner ratio = Vo/Vf, where Vo = Unsettled apparent volume, Vf = final tapped volume.

Carr's index

Carr's index = Taped Density − Poured Density/Taped Density × 100

Determination of pH

A Systronic digital pH meter (model 152-R) equipped with a combined electrode was used. Before the experiment, the instrument was calibrated by using buffer solutions of

4.00, 7.00, and 9.20. The test drug (100 mg) was taken to determine the pH in 1% and 10% solutions.

Analytical tests

Quantitative elemental analysis

Quantitative elemental analysis was done by the Atomic Absorption Spectroscopy method (AAS).

Toxicity studies

The toxicity study was started after the approval of the protocol by the Institutional Animal Ethics Committee (IAEC) of the National Institute of Unani Medicine, Bangalore vide Reg. no. IAEC/IX/03/IA.

Acute toxicity study

An acute toxicity study was carried out according to OECD Guidelines (423). The animals were kept under standard laboratory conditions throughout the experiment, housed in propylene cages at 22°C (±3°C), humidity at 45%–55% with a 12-h light and dark cycle, and had free access to feed and water *ad libitum*. Wistar rats weighing 150–200 g, 8–12 weeks old, were randomly selected and kept in their cages for 5 days before dosing to acclimatize to the laboratory conditions. Before starting the dose, animals were examined physically and behaviorally to rule out infectious and other diseases. The animals were fasted for 18 h, but water was withdrawn only for 4 h. The animals were weighed, and the test drug was administered by the oral route. The initial dose was selected as 300 mg/kg, then it was increased with two different doses, i.e., 2000 mg and 5000 mg/kg body weight.[16] First 4 h, the animals were observed individually for various toxic signs, especially any toxic behavior, changes in skin, fur, eyes, respiration, and circulation. Attention was directed to observations of tremors, convulsions, salivation, diarrhea, lethargy, sleep, and coma. Up to 24 h, toxic behavior number of mortalities was recorded. Up to 14 days, if no mortality, the weights of the animal and food intake were recorded once weekly. The results were compared with the control.

Sub-acute toxicity study

Since, in the acute toxicity study, no remarkable toxic effect was observed even at 5000 mg/kg, therefore, a sub-acute toxicity study was thought reasonable to conduct. In this study, 1/5th of 5000 mg/kg was selected. The dose was calculated by the formula of Miller and Tainter, and 1000 mg/kg was the starting dose.[18] The first sign of toxicity appeared on the 5th day at a dose of 405 mg/kg. This dose was continued for 14 days. The animals were sacrificed on the 15th day under over overdose of Thiopentone sodium (50 mg/kg). Blood was collected through cardiac puncture for hematological and biochemical examination. The liver and kidneys were dissected out. After gross examination, these viscera were preserved in a container containing 10% formalin solution for histopathological examination.

Sub-acute toxicity was carried out by the method of Ghosh.[19] Wistar rats of both sexes (equal sex ratio; weighing 150–200 g) were divided into two groups, each consisting of 6 animals, one control and one test group. The animals were dosed at 1000 mg/kg, which caused acute toxicity. Further dose was increased by Miller's formula[18] until the sign of toxicity appeared, after that the dose was fixed and administered for 2 weeks. Control group animals were administered 5% gum acacia.

The animals were carefully observed for the development of any toxic signs at different time intervals, i.e., 0, 30 min, 4, 8, 12, 24 h, and then daily for 14 days. Animal mortality was recorded during the treatment period.[20] For sub-acute toxicity, the body weight of the animals was taken weekly during the experiment.[18] Food intake was measured periodically. A known amount of diet was given to the animals daily. Early in the morning, the feed was reweighed, and the amount consumed was calculated by difference.[6] General behavior, skin color, skin pigmentation, body hair loss, palpable mass, motility, tremor, and convulsions 108 were observed weekly for 14 days.[18] At the end of the experiment, all the animals were sacrificed after 12 h of fasting by an overdose of Thiopentone sodium. Blood was drawn and collected in an ethylenediaminetetraacetic acid (EDTA) EDTA-containing tube for hematological examination and in a centrifuge tube for biochemical examination. The results were compared with the control.

Hematology

Hemoglobin was estimated by the hemoglobin reagent cyanmethemoglobin method by an auto-analyzer (Star 21 Plus).[6,20] An Improved Neubauer Hemocytometer was used for red blood cell (RBC) and white blood cell count.[6,20]

Biochemistry

SGOT and SGPT were estimated by the optimized UV Kinetic (IFCC) method. Blood Urea was estimated by the Urea Kin GLDH method. Serum Creatinine was estimated by Modified Jaffe's method, Kinetic and End point. Serum albumin was estimated by the BCG method. Total protein was estimated by the Buret method. Uric acid was estimated by the MR method. Total cholesterol was estimated by the Cholesterol LQ (CHOD–POD) liquid method. Triglyceride was estimated by the Triglyceride LQ. GPO–POD liquid method. HDL–HDL-Cholesterol Assay Kit, Direct method, estimated HDL-C.

Histopathology

Liver and kidneys were dissected out and examined grossly and were preserved in 10% formalin buffer overnight, dehydrated, and embedded in paraffin through isokinetic processing. Sections of 5-µm thickness were cut, stained with routine hematoxylin and eosin; Histopathological changes were examined under a binocular microscope. The results were compared with the control group.

Analysis of data

Data were expressed as mean ± standard error of the mean, and the values for the test and control groups were compared by using the' test. The significance level was considered ($P < 0.05$).

Results

Classical tests

The result is shown in Table 1.

Conventional methods

Moisture content estimated by the loss on drying method, pH in 1% and 10% aqueous solutions at 35°C, the mean value of bulk density and tapped density, the mean value of Hausner ratio and Carr's index, the mean percentage of the total ash, acid insoluble ash, and water-soluble ash are shown in Table 2.

Elemental analysis

Elements and heavy metals estimated by AAS are shown in Table 3.

Acute toxicity

No abnormal signs were observed in any of the animals fed with KMS at doses of 300, 2000, and 5000 mg/kg. No mortality was observed in any animal up to 24 h. However, one rat died at the dose of 300 mg/kg on the 11th day of treatment, and four rats died at the dose of 5000 mg/kg. Out of four rats, two died on the 6th day, one on the 7th day, and one on the 13th day.

Sub-acute toxicity

General observation

Body weight in KMS significantly decreased ($P < 0.05$) when compared with the control. The weight of organs was also nonsignificant. Food intake significantly decreased ($P < 0.001$) when compared with the control. The effect on organ weight was statistically nonsignificant. No pigmentation on skin, keratosis, convulsion, tremor, or palpable mass was observed in any group [Table 4].

Hematological analysis

Hematological parameters were statistically nonsignificant when compared with the control. Detailed results are shown in Table 4.

Biochemical analysis

Biochemical parameters were nonsignificant except SGPT [Table 5].

Histopathology

Liver

Liver parenchyma showed intact architecture in the control group. KMS-treated parenchyma showed intact architecture. Some hepatocytes in the perivenular region, periportal region, and mid-zonal region showed degenerative changes.

Table 1: Classical tests

Tests	Results
Test for luster	No luster found
Test for fineness	Particles entered the finger lines
Floating test	Particles floated on the water surface
Curd test	No color change observed
Lemon test	No color change observed
Wall stick test	Stuck on the wall

Table 2: Elements and heavy metals analysis

Particulars	Results
Iron as Fe (ppm)	341.6
Sulfur (%)	1.93
Calcium as Ca (%)	9.52
Magnesium as Mg (%)	1.73
Lead as Pb (ppm)	<0.1
Cadmium as Cd (ppm)	<0.1
Mercury as Hg (ppm)	0.4
Arsenic as ash (ppm)	3.3

Table 3: Powder characterization

Parameters	Result
Moisture	0.34±0.03
pH (1% solution)	11.44±0.19
pH (10% solution)	12.17±0.03
Bulk density (g/ml)	0.82±0.05
Taped density (g/ml)	1.271±0.067
Hausner ratio	1.566±0.17
Carr index	34.80±6.48
Total Ash	91.39±1.31
Acid-insoluble ash	58.64±0.85
Water-soluble ash	21.02±5.06

Table 4: Effect on body weight, organ weight, food intake, and hematology as compared with the control

Parameters	0th day	8th day	15th day
Body weight			
Control	151.8±3.619	169.5±4.992	184.3±9.050
KMS	164.3±5.57	141.8±8.19	131.8±6.65$^{b,c**\ ***}$
Organ weight	**Liver**		**Kidney**
Control	5.798±0.38		0.5946±0.09
KMS	4.48±0.55		0.52±0.04
Food intake (300 mg)			
Control	159.9±6.205		
KMS	93.57±8.488***		
Hb (g/dl)	12.88±0.5282		13.75±1.408
RBC	3.025±0.1592		3.025±0.1592
TLC	4683±388.7		3808±635.3

RBC: Red blood cell, Hb: Hemoglobin, KMS: *Kushta Marjan Sada*, TLC: Total leukocyte count, b**P<0.01, c***P<0.001

The periportal region showed mild inflammatory infiltrations. The central veins appeared congested [Figures 1 and 2].

Kidney

Intact architecture was observed in the control group. The KMS-treated group showed normal architecture, normal glomeruli. Few tubules showed eosinophilic material in the lumen [Figures 3 and 4].

Discussion

Like most metals, minerals, hard shells, and animal coverings cannot be used as it is; therefore, they are calcined at a high temperature, usually above 500°C, to convert them into fine powder as oxide (*Kushta*). Since most *Kushta* (s) are made up of metals and minerals, there is a chance of the presence of heavy metals even after conversion into oxide form, which can be harmful if they cross the permissible limit. *Marjan* is an animal-origin drug and is used as *Kushta* mainly as a calcium supplement. Reports on its physicochemical properties and toxicity are lacking.

Crude drugs always contain moisture; their estimation is an important parameter for assessing the quality of crude drugs. It is interesting to note that a drug that has already been subjected to 5000 or above should not contain moisture. But there is a chance when it is exposed to air

Table 5: Effect of *Kushta Marjan Sada* on liver and kidney functions compared with control

Parameters	Groups	
	Control	KMS
SGOT (mg/dl)	139.4±6.41	148.0±9.10
SGPT (mg/dl)	45.42±3.38	51.49±4.32*
Albumin (g/dl)	3.629±0.30	3.178±0.24
Total protein (g/dl)	2.449±0.09	2.445±0.14
Serum creatinine (mg/dl)	0.57±0.12	0.4218±0.07
Blood urea (mg/dl)	48.81±1.10	37.63±4.59**
Serum uric acid (mg/dl)	1.196±0.13	3.141±0.79

KMS: *Kushta Marjan Sada*, SGOT: Serum glutamic-oxaloacetic transaminase, SGPT: Serum glutamic pyruvic transaminase, **P*<0.05, ***P*<0.01

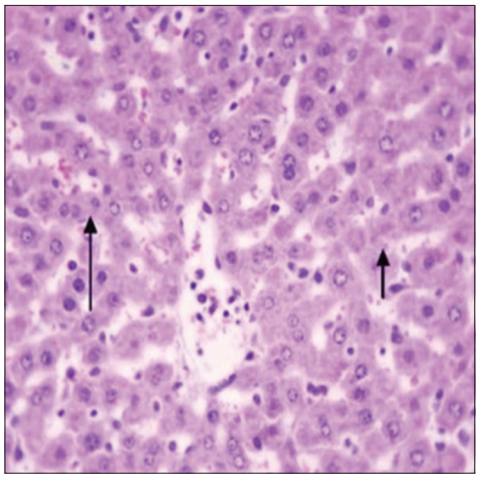

Figure 1: Histopathology of Liver short arrow shows normal architect of liver- Control

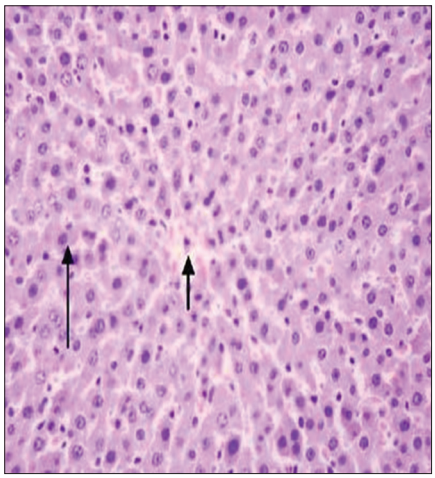

Figure 2: Histopathology of Liver short arrow shows aggregates of inflammatory infiltration. KMS-treated group

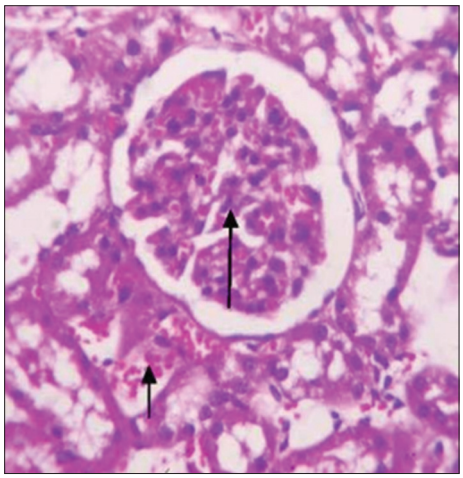

Figure 3: Histopathology of Kidney arrow showing normal architecture - Control

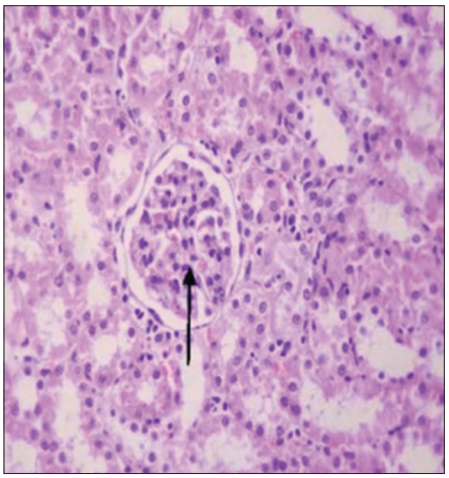

Figure 4: Histopathology of Kidney Long arrow shows normal cellularity, short arrow shows inflammatory infiltration - KMS-treated group

and during storage. This parameter was applied in our study. Moisture content in most *Kushta* (s) remains within 2%;[6,21,22] our findings were within these limits. The pH of a drug affects its absorption. A change in pH of the solution can change the physical properties and absorption of the drug. It is also important for the stability of many drugs.[23] We observed the pH as 12.47 ± 0.017 in 1% and 12.61 ± 0.021 in 10% aqueous solutions. Reports on other *Kushta* (s) show pH between 10% and 12%.[21] Therefore, our findings are within the limit.

Ash value is another important parameter. It is again interesting to note that a material which has already been ignited at a temperature exceeding 450°C and above should leave no inorganic material like oxalate and phosphate. Even though some researchers have taken ash values of *Kushta.*[21] Surprisingly, in their studies as well as in our study, ash was observed, i.e., when the *Kushta* (s) were again burnt at a further 450°C; there was a loss in weight of *Kushta*. In some drugs, elemental parts remain even after burning at high temperatures. This finding is also supported by elemental analysis, in which elements such as Ca, S, Fe, Mg, Cd, As, and Hg were found in ionic forms, but within acceptable limits. This finding suggested that for making *Kushta,* especially that of animal origin drugs, the temperature should be increased from the temperature recommended. Different samples at different temperatures should also be burnt and standardized individually for a specific temperature for a particular drug.

Since *kushta* is a fine powder, parameters for powder characterization such as Bulk density, tapped density, Carr‘s index, and Hausner ratio can be useful. Bulk density is a reliable parameter for checking the quality of powder. It is a property of granules and other divided solids. Tapped densities, Carr‘s index, and Hausner ratio are also determined for bulk density. These parameters were applied in our study. These findings showed that the *Kushta* (s) are of fine quality because the flowability of fine powder is less than coarse powder. These tests also strengthen the classical methods; therefore, recommended for the standardization of other *Kushta* (s).

Physicochemical parameters usually determine the quality of drugs. But toxicity studies are the ultimate evidence of the safety of drugs. The test drug was subjected to acute and sub-acute toxicity studies. There was no remarkable change with respect to general observation except loss of weight and food consumption; however, relatively evident ($P < 0.001$) as compared to the control. This finding may not necessarily be due to gross toxicity because the animals developed an ulcer in the mouth, which may have resulted in less consumption of food and consequently loss of weight.

Hematology is a reliable parameter for the assessment of toxicity. In our study, we observed a reduction in RBC count ($P < 0.01$) when compared to the control. This may be due to the destruction of RBC. Total leukocyte count and hemoglobin % did not change remarkably.

The liver and kidneys are important targets for toxic agents. Therefore, SGOT and SGPT, total protein, and albumin are reliable determinants of liver injury of liver and blood urea, serum creatinine, and serum uric acid are important determinants of renal injury. Similarly, estimation of triglyceride, total cholesterol, and HDL-C may also help know toxicity as these are indicators of disturbance in lipid metabolism. In our study, we observed increased SGPT ($P < 0.05$). Since other parameters did not change remarkably, this finding is of little importance. In RFT, blood urea is the principal indicator. Heavy metal causes tubular necrosis, leading to an increased level of blood urea. We observed increased blood urea. The rest of the parameters did not change remarkably, hence are of little importance in our study.

Histopathological changes were of a mild degree, and the nature of the changes observed in this study was not very severe.

On the basis of findings, the drug seemed to be safe, even though it should not be considered entirely safe till a chronic study is carried out because most metallic calx exert a remote effect due to accumulation in the body.

Conclusion

The above findings are suggestive of the test sample as safe. However, further toxicity studies are required to prove complete safety. The standardization parameters revealed some heavy metals in the kushta, but within the permissible limit. Our findings should be considered as standard, as no data are available to compare with.

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Conflicts of interest

There are no conflicts of interest.

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Traditional Healing for Jaundice: A Case Series on Unani Therapeutic Success

Abstract

Jaundice (*Yarqān Aṣfar*) is a common clinical manifestation of liver diseases, characterized by yellowish discoloration of the skin and sclera due to elevated bilirubin levels. The Unani system of medicine offers various herbal formulations with hepatoprotective and choleretic properties. This case series evaluates the efficacy of Unani interventions in managing jaundice. Three male patients (aged 17, 42, and 53 years) with varying durations of jaundice were treated at the Department of Moalajat, National Institute of Unani Medicine, Bangalore. Clinical assessment, liver function tests, and ultrasonographic findings confirmed hepatocellular involvement. The therapeutic regimen included *Arq-e-Mako*, *Arq-e-Kasni*, *Majoon Dabeedul Ward*, and *Hab-e-Rewand*, administered twice daily after food. All patients demonstrated significant clinical improvement, including resolution of jaundice, fatigue, itching, and nausea. Liver function tests showed marked reductions in serum bilirubin and liver enzyme levels from baseline to posttreatment. Notably, the most severe case (Case 3) exhibited substantial biochemical recovery. This case series underscores the potential of Unani medicine as an effective approach for jaundice management. The observed symptomatic relief and biochemical improvements suggest that Unani interventions may offer a safe and holistic alternative for hepatic disorders. Further large-scale studies are warranted to validate these findings.

Keywords: *Arq-e-Kasni, Arq-e-Mako, hepatic disorders, jaundice, Yarqān Aṣfar*

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Introduction and Background

In the Unani system of medicine, jaundice is referred to as *"Yarqān Aṣfar*."[1] *Ibn Sina* in *Al-Qānūn Fi'l-Tibb* describes jaundice (*Yarqān Aṣfar*) as the telltale yellowing of the skin, caused by an imbalance of bile in the body. This could be due to hepatitis (*Waram al-Kabid*), biliary obstruction (*Sudad-i-Majārī-i-Marāra*), or conversion of blood into yellow bile (*Ihāla al-Dam ila'l-Safrā*), characterized by yellowing of the skin, eyes, urine, and stool (except in obstructive cases, where stool appears whitish) along with symptoms such as right hypochondriac pain, nausea, loss of appetite, thirst, bitter taste, gastric discomfort, and itching.[2] *Razes*, in *Al-Hawi*, describes the causes as liver, bile duct, and vascular abnormalities, *Buḥrān* (disease crisis), and biliary canaliculi obstruction. Galen links jaundice to insect bites, toxic food, toxemia (hemolysis), and bile imbalance, further classifying it into obstructive (*Yarqān Suddī*) and hepatic (*Waram al-Kabid*) types.[3] Jaundice, or icterus, is a clinical sign of elevated serum bilirubin levels.[4] Hyperbilirubinemia is frequently observed in both primary and hospital care settings, often due to liver lesions. It can result from excessive bilirubin production, impaired hepatic uptake, defective conjugation, or biliary excretion abnormalities.[5] Bilirubin, a byproduct of heme breakdown, was historically considered harmful. Its high levels indicate liver disease severity and are essential in most liver prognosis scoring systems.[6] Liver diseases associated with hyperbilirubinemia also present with abnormalities in liver function tests. Hepatocellular injury and cholestatic disorders are frequent findings.[4] The Unani system of medicine offers numerous formulations for the treatment of *Yarqān Aṣfar* (jaundice). Some key formulations include *Qurs-i Zarishk, Qurs-i Ghafis, Qurs Afsanteen, Qurs Ward, Qurs Tabasheer, Qurs Kafoor, Sharbat-i Rewand, Sharbat-i Afsanteen, Arq Kasni, Arq Makao, Sharbat-i Nilofar, Sharbat Dinar, Majoon Dabeedul Ward, and Tiryaq-i-Kabeer.*[2,7,8]

Case Series

All three cases are presented with complaints of yellowish discoloration of

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skin and eyes with varying durations; cases were assessed based on their medical histories, clinical presentations, and diagnostic results.

Case 1

A 53-year-old male patient was admitted to the Department of Moalajat (Inpatient Department [IPD]), National Institute of Unani Medicine, Bangalore. The patient's symptoms began gradually, with complaints of yellowish discoloration of the skin and eyes, nausea, and decreased appetite for the past 3 months, along with generalized weakness for 2 months. He also reported itching all over his body for 1 month. The patient had a positive history of alcohol use for the previous 15 years, and there was no history of fever or abdominal pain.

Case 2

A 42-year-old male was admitted to the Department of Moalajat (IPD), National Institute of Unani Medicine, Bangalore, with complaints of yellowish discoloration of the skin and eyes for the past 2 months. He also reported loss of appetite and a persistent feeling of fullness in the abdomen for 1.5 months, along with gradually increasing weakness in the body.

Case 3

A 17-year-old male patient was admitted in Department of Moalajat (IPD), National institute of Unani Medicine Bangalore, with complaints of yellowish discoloration of skin, eyes, and urine from the past 6 months, symptoms were gradual in onset later increased since past 1 month along with this he also complained of itching all over body, reduced appetite associated with nausea and malaise from 2 months, there was history of fever on and off, he had history of alcohol use for past 1 year with daily consumption.

Clinical Findings

Clinical and demographic profile of all three participants, along with ultrasonographic findings and hepatic viral markers, is shown in Table 1.

The findings on physical and systemic examination of all three participants are shown in Table 2.

Timeline of the Protocol

Details of the treatment period, along with symptoms before starting treatment and after completion of treatment, are shown in Table 3.

For each case, the entire course of treatment lasted for 15 days; all three participants were given *Arq-e-Mako* 60 mL, *Arq-e-Kasni* 60 mL, *Majoon Dabeedul Ward* 8 g, and *Hab-e-Rewand* 2 tablet. Twice daily after food.

Assessment Parameters

Assessment parameters for the effectiveness of treatment included

1. Improvement in clinical symptoms
   a) Resolution of yellowish discoloration of the skin and sclera
   b) Improvement in fatigue, nausea, itching, and appetite.
2. Biochemical parameters.
   a) Serum bilirubin (total, direct, and indirect)
   b) Liver enzymes (AST, ALT, and alkaline phosphatase [ALP]).

Therapeutic Measures

After obtaining informed consent from all the participants, they were given

1. *Arq-e-Mako* 60 mL twice daily after food
2. *Arq-e-Kasni* 60 mL twice daily after food
3. *Majoon Dabeedul Ward* 8 g twice daily after food
4. *Hab-e-Rewand* 2 tablets twice daily after food.

The details of medications used, along with their composition, dosage, pharmacological actions, and therapeutic uses, are shown in Table 4.

Outcomes

All the patients were regularly monitored throughout the treatment period; all three patients showed alleviation of symptoms and improvement in liver function tests assessed with the help of the following parameters. Improvement in biochemical parameters is mentioned in Table 5.

Liver function test - The liver plays a vital part in the body's metabolism, digestion, detoxification, and removal of toxins. The liver function tests include Alanine aminotransferase (ALT) and Aspartate aminotransferase (AST), ALP, gamma-glutamyl transferase, serum bilirubin, prothrombin time, the international normalized ratio, total protein, and albumin.[12]

The liver enzymes are aspartate aminotransferase and alanine aminotransferase. These enzymes must be in the

Table 1: Clinical and demographic details of patients

Patient number	Age (years)	Sex	Profession	Disease duration (months)	History of alcoholism with duration (years)	HBsAg	USG findings
Case 1	53	Male	Coolie	3	Present ×15	Negative	Hepatomegaly
Case 2	42	Male	Farmer	1	Present ×20	Negative	Hepatomegaly
Case 3	17	Male	Painter	6	Present ×1	Negative	Hepatosplenomegaly with edematous gallbladder

USG: Ultrasonographic

normal range: AST = 24 UI/mL and ALT = 20 UI/mL. Increased levels of liver enzymes appear in diseases of the liver.[13] All three cases showed improvement in liver enzyme levels from baseline to completion of treatment. In SGOT, Case 1 improved from 136 to 21, Case 2 from 128 to 99, and Case 3 from 437 to 84. SGPT Case 1 improved from 283 to 23 and Case 3 from 499 to 90. In ALP, Case 2 improved from 198 to 109, and Case 3 improved from 349 to 204.

Serum bilirubin - The typical range for normal serum bilirubin levels is 1.5 mg/dL.[14] There was a significant reduction in total bilirubin levels compared from baseline to completion of treatment. Case 3 improved from 17.30 to 2.19, Case 2 from 1.6 to 1.4, and Case 1 from 3.1 to 1.12. The improvement in direct bilirubin levels was. Case 1 improved from 1.1 to 0.52, Case 2 from 1.00 to 0.80, and Case 3 from 9.68 to 1.72.

Figure 1 shows graphical presentation of serum bilirubin levels before and after treatment, and Figure 2 demonstrates graphical presentation of liver enzyme levels before and after treatment.

Discussion

Jaundice is a prevalent clinical manifestation of liver dysfunction, often resulting from hepatocellular injury, bile duct obstruction, or hemolysis.[3] This case series highlights the therapeutic potential of Unani medicine in managing jaundice (*Yarqān Aṣfar*), as demonstrated through the successful treatment of three patients with varied disease durations. The Unani formulations administered in this study were selected based on their hepatoprotective, anti-inflammatory, and choleretic properties. *Arq-e-Mako* and *Arq-e-Kasni* are well-documented in Unani literature for their efficacy in reducing hepatic inflammation and promoting strong liver health;[9,10] *Majoon Dabeedul Ward* is a compound formulation known for its hepatoprotective and detoxifying effects, while *Hab-e-Rewand* aids in digestion and increasing the activity of the liver, aiming in removing the cause of the disease.[11] The combination of these formulations aimed to address hepatic inflammation, enhance liver function, and promote bile excretion, ultimately leading to symptomatic relief and biochemical improvements in all three cases. Clinical improvement was evident across all patients, as seen in the resolution of jaundice, reduction in fatigue, itching, and nausea, along with the restoration of appetite. The improvement in systemic symptoms corresponded with a marked decline in serum bilirubin and liver enzyme levels, reinforcing the therapeutic impact of Unani interventions. Notably, Case 3, which presented with the highest baseline bilirubin and

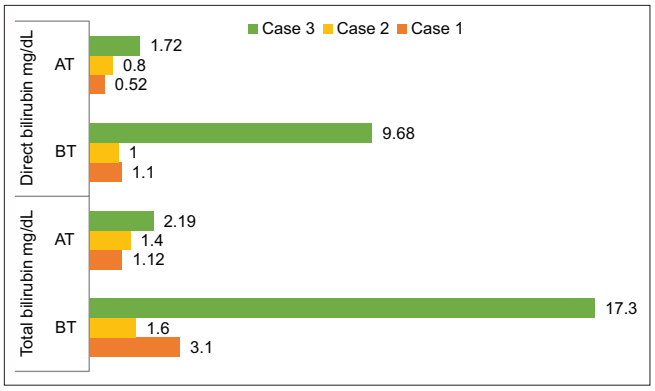

Figure 1: Scores of serum bilirubin after treatment and before treatment. AT: After treatment, BT: Before treatment

Table 2: Findings on examination

	Findings	Case 1	Case 2	Case 3
Physical examination	Yellowish discoloration of skin	Present	Present	Present
	Icterus	positive	Slightly positive	positive
	Clubbing	Negative	Negative	Negative
Systemic examination	Per abdominal examination	Soft, mild tenderness present in epigastric, right hypochondriac region	Soft, nontender	Soft, tenderness present over epigastric, right and left hypochondriac region Right and lower borders of the liver were palpable, with soft echotexture

Table 3: Timeline of the treatment

Serial number	Timeline of intervention	Complaints
Case 1 – 53-year-old male	September 23, 2024	Yellowish discoloration of the skin and eyes, nausea, reduced appetite, generalized weakness, itching all over the body
	October 7, 2024	All symptoms reduced
Case 2-42-year-old male	October 28, 2024	Yellowish discoloration of skin and eyes, loss of appetite, fatigue, and feeling of fullness in the abdomen
	November 13, 2024	Improvement in all symptoms
Case 3-17-year-old male	November 14, 2024	Yellowish discoloration of skin, eyes, and urine, itching all over the body, reduced appetite, nausea, and malaise
	November 28, 2024	Reduction in all symptoms

Table 4: Description of therapeutic intervention used

Medicine	Ingredients	Dosage	Pharmacological actions and therapeutic uses
Arq-e-Mako	*Mako khushk* and *Aab* *Solanum nigrum* L.	60 mL × BD	Nafae Yarqān, Muqawwī-i-Kabid, Musakkin-i-Ḥarārat, useful in Waram-i-Jigar, *Yarqān*, Waram-i-Ṭiḥāl haar, Waram-e ahsha, Ḍu‘f al-Kabid[9,10]
Arq-e-Kasni	*Tukhm-i-Kasni* and *Aab* *Cichorium intybus* L.	60 mL × BD	Muḥallil-i-waram (anti-inflammatory), Musakkin (sedative), useful in Waram al-Kabid (hepatitis), Yarqān (jaundice)[10]
Majoon Dabeedul Ward	*Sumbul-ut-Teeb* - *Nardostachys jatamansi* (D. Don) DC. *Qaranful* - *Syzygium aromaticum* (L.) Merr. and L.M.Perry *Mastagi* - *Pistacia lentiscus* L. *Majeeth* - *Rubia cordifolia* L. *Zafran* - *Crocus sativus* L. *Lukh Maghsool* - *Kerria lacca* *Tabasheer* - *Bambusa bambos* (L.) Voss. *Tukm-e-Kasni* - *Cichorium intybus* L. *Darchini* - *Cinnamomum verum* J.Presl *Tukm-e-Karafs* - *Apium graveolens* L. *Izkhar* - *Cymbopogon jwarancusa (Jones ex Roxb.) Schult* *Zarawand Taweel* - *Aristolochia long*a L. *Asaroon* - *Valeriana wallichii* DC. *Habb-e-Balsan-Balsamodendron opobalsamum* (L.) Kunth ex DC. *Qust Shirin* - *Saussurea lappa* (Decne.) Sch. Bip. *Ood-e-Hindi* - *Aquilaria agalloch*a Roxb. *Gul-e-Ghafis* - *Gentiana olivieri* Griseb. *Heel Khurd* - *Elettaria cardamomum* (L.) Maton *Tukhm i Kasoos* - *Cuscuta reflexa* Roxb. *Waaraq-e-Gul-e-Surkh* - *Rosa damascena* Mill	8 g × BD	Muḥallil-i-waram, Mudirr-i-Bawl Useful in Ḍu‘f al-Kabid, Waram-i-Jigar, Ḍu‘f al-Mi‘da[11]
Hab-e-Rewand	*Rewand Chini* - *Rheum emodi* Wall. ex Meisn. *Shora Qalmi* - *Potassium nitrate* *Naushadar* - *Ammonium chloride*	2 × BD	Mudirr-i-Bawl, Muḥarrik-i-Kabid[11]

Table 5: Biochemical parameters at baseline and after treatment

	Bile pigments				Liver enzymes					
	Total bilirubin (mg/dL)		Direct bilirubin (mg/dL)		ALT (U\L)		AST (U\L)		ALP (IU\L)	
	BT	AT	BT	AT	BT	AT	BT	AT	BT	AT
Case 1	3.1	1.12	1.1	0.52	136	21	283	23	127	112
Case 2	1.6	1.4	1.00	0.80	128	99	37	52	198	109
Case 3	17.30	2.19	9.68	1.72	437	84	499	90	349	204

AT: After treatment, BT: Before treatment, ALP: Alkaline phosphatase, ALT: Alanine aminotransferase, AST: Aspartate aminotransferase, ALP: Alkaline phosphatase

transaminase levels, exhibited substantial improvement by the end of the treatment, suggesting the potency of Unani therapy even in severe cases.

Conclusion

This case series highlights the efficacy of Unani therapeutic interventions in the management of jaundice. The significant symptomatic relief and biochemical improvements observed in all three cases underscore the potential of Unani medicine as an effective and safe treatment modality. Integrating Unani formulations into clinical practice could provide a holistic and natural approach to managing hepatic disorders; further, scientific exploration and validatory studies with bigger sample sizes and comparisons with traditional treatments are warranted to confirm these results.

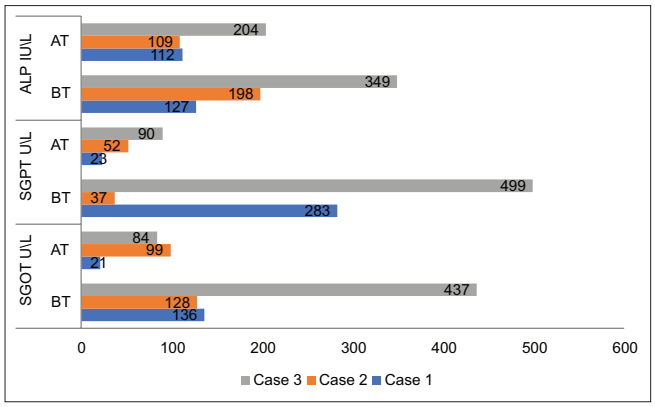

Figure 2: Scores of liver enzymes before and after treatment. AT: After treatment, BT: Before treatment, ALT: Alanine aminotransferase, AST: Aspartate aminotransferase, ALP: Alkaline phosphatase

Declaration of patient consent

The authors certify that they have obtained all appropriate patient consent forms. In the form, the patients have given their consent for their images and other clinical information to be reported in the journal. The patients understand that their names and initials will not be published, and due efforts will be made to conceal their identity, but anonymity cannot be guaranteed.

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Conflicts of interest

There are no conflicts of interest.

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