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Review Article

Ma'jūn-i-Flāsafa: An Important Compound Formulation of Unani System of Medicine for the Management of *Amrāḍ-i-Bārid raṭab* (Phlegmatic Diseases)

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Abstract

Ma'jūn-i-Flāsafa is a compound formulation of the Unani System of Medicine and is prescribed in the management of *Amrāḍ-i-Bārid raṭab* (Phlegmatic diseases), particularly in the elderly population. In Unani medicine, *Ma'jūn-i-Flāsafa* is safe and has used extensively since ancient times. This paper aims to present a comprehensive review of *Ma'jūn-i-Flāsafa* in the management of *Amrāḍ-i-Bārid raṭab* (Phlegmatic diseases) as mentioned in Unani literature, with special reference to its *Mizāj* (temperament). The bibliographic database was collected for review on *Ma'jūn-i-Flāsafa* from Google Scholar, Research Gate, PubMed, Science Direct, and Scopus. The search was conducted using the terms "*Ma'jūn*," "*Ma'jūn Falāsafa*," "*Mizāj*," "Ethnobotanical," "*Stoneless raisins*," *"Zingiber officinalis," and "Pinus gerardiana*." The literature was also compiled from the published Urdu and English Unani books. Further, the authors assessed the *Mizāj* (temperament) of *Ma'jūn-i-Flāsafa* by different methods available in renowned classical Unani textbooks and found that the temperament of *Ma'jūn-i-Flāsafa* is hot and dry, which also justifies its efficacy in the management of *Amrāḍ-i-Bārid raṭab* (Phlegmatic diseases). Sufficient information with respect to physicochemical standardization, preclinical studies (animal studies), and ethnomedicinal properties of *Ma'jūn-i-Flāsafa* are available but very few clinical studies have been conducted.

Keywords: *Amrāḍ-i-Balghamī, ethnobotanical, Ma'jūn-i-Flāsafa, tonic, unani system*

Introduction

The conceptual framework of the Unani System of Medicine (USM) is composed of seven essential factors known as *Umūr Ṭabī'yya* (IUMT-3.1.0, factors of existence). These factors are the essential components of the human body and include *Arkan* (elements), *Mizāj* (temperament), *Akhlāṭ* (humors), *A'ḍā* (organs), *Arwāḥ* (Pneuma or/ Vital Spirit), *Quwā* (Faculties/Powers), and *Af'āl* (Functions). The *Arkan* are the primary substances of the body that are four in number, namely, *Nar* (fire), *Bād* (air), *Mā'* (water), and *Arḍ* (soil). The *Rukn*, singular of *Arkān*, is associated with *Kaifiyat* (quality) which are *Kaifiyat fā'ila* (*Ḥarārat* and *Barūdat*) and *Kaifiyat Munfa'ila* (*Ratūbat* and *Yabūsat*). Each *Rukn* bears one of two *Kaifiyat fa'ila* and one of two *Kaifiyat Munfa'ila* so that *Rukn Nār* possess *Ḥarārat* and *Yabūsat*, *Rukn Bād* possesses *Ḥarārat* and *Ratūbat*, *Rukn Mā'* possess *Barūdat* and *Ratūbat*, and finally, *Rukn Arḍ* possess *Barūdat* and *Yabūsat*. One or more *Arkān* react after mixing to form new *Kaifiyāt* (qualities) that are called *Mizāj* (Temperament).[1] Similar to the human body, all entities in the world have their specific *Mizāj*, including drugs of all categories, namely, *Nabātāt* (plants), *Ḥaiwānāt* (animals), and *Jamādāt* (minerals). *Akhlāṭ* are body fluids that formed after digestion and metabolism of food in the liver, namely, *Dam* (Blood), *Balgham* (phlegm), *Ṣafrā'* (yellow bile), and *Sawdā'* (black bile) with possess their specific *Mizāj* such as *Ḥār raṭab*, *Bārid raṭab*, *Ḥār yābis,* and *Bārid yābis,* respectively. Hippocrates (460-377 BC), the Father of Medicine, proposed the Humoural theory which states that "Health is a state of equilibrium between all *Akhlāṭ* in terms of *Kaifiyat* (Quality) and *Kammiyat* (Quantity) and disease reciprocal of it". Therefore, in USM, all *Amrāḍ* (diseases) came in the categories of four humours and are managed accordingly based on *'Ilāj bi'l-Ḍid* (Heterotherapy) such as *Amrāḍ-i-Bārid raṭab* treated

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through *Ḥār yābis* therapies and medicines. The diagnosis and treatment are thus done according to the temperament of the patient.[2] Unani treatment methods include *'Ilāj bi'l-Tadābīr* (Regimenal therapy), *'Ilāj bi'l-Ghidhā* (Dietotherapy), *'Ilāj bi'l-Dawā* (Pharmacotherapy), and *'Ilāj bi'l-Yad* (Surgery). The basic principles of all approaches in USM have *'Ilāj bi'l-Ḍid*.[3] The pharmacotherapy includes numerous *Mufrad* (single drugs), namely, *Aftīmūn*, leaves of *Adūsa*, *Zarāwand* root, etc., as well as *Murakkab* (compound formulations) such as *Ma'jūn*, *Iṭrīfal*, *La'ūq*, *Jawārish*, and *Khamīrah* to prevent and reverse the *Su'-i-Mizāj* (*Amrāḍ*) successfully in USM since antiquity.[4,5]

Unani medicines are used in different dosage forms to yield the desired results, modulate the potency, increase efficacy, and detoxify the harmful effects of drugs to eliminate any of their side effects. *Ma'jūn* (electuary) is a semisolid Unani dosage form used since ages which is prepared in any of the bases of purified '*Asl* (Honey), *Qand safaid* (Sugar), *Turanjabīn* (*Tamarix indica* gum), and *Shīr-i-khisht* (*Fraxinus ornus* exudate).[6]

The *Ma'jūn* is a commonly used compound formulation with semisolid in consistency.[7] The word *Ma'jūn* derived from the Arabic word *'Ajan*, and its literal meaning is dough.[4,5] The *Ma'jūn-i-Flāsafa* is termed as *Mādda al-Ḥayāt* (Elixir of life). The *Ma'jūn-i-Flāsafa* in USM is also called as old man stick because it is very useful in old age as a general tonic, for improving mental health, and also physical weakness. Initially, *Ma'jūn-i-Flāsafa* was formulated by Andromakhas for philosophers or mentally engaged persons.[8] The *Ma'jūn-i-Flāsafa* composed of 15 ingredients with their specific quantity. These contents are mixed in a medium (*Qiwām*) in the form of solid and liquid. These mediums are usually formed by sugar and water according to the National Formulary of Unani Medicine.[9] In this review paper, authors also assessed the *Mizāj* (temperament) of *Ma'jūn-i-Flāsafa* by different methods available in renowned classical Unani textbooks and found that *Mizāj* (temperament) of *Ma'jūn-i-Flāsafa* is *Ḥār yābis*. Hence, the *Ma'jūn-i-Flāsafa* can be used in *Bārid raṭab* (cold-Moist) *amrāḍ* of the body, which also justifies the concept of *'Ilāj Bi'l Ḍid* of USM.

In this paper, authors have tried to compile all traditional and scientific information related to *Ma'jūn-i-Flāsafa* in terms of ethnopharmacology of content, method of preparation, standardization of *Ma'jūn-i-Flāsafa,* and also focuses to evaluate the *Mizāj* of *Ma'jūn-i-Flāsafa* by prescribed Unani methods which are mentioned in authentic classical textbooks.

Methodology

It is well known that *Ma'jūn-i-Flāsafa* is the renowned compound formulation of USM. Literature was obtained by using the database from Science Direct, Scopus, PubMed, Medline, Elsevier, Research Gate, Google Scholar, and Springer. The classical textbook of USM also provides valuable data, namely, *Khazain-Al-Advia*, *Muhit-i-Azam*, *Makhzan-Al-Mufradāt*, *Qarābādīn Najm-Al-Ghani*, *Bustān-Al-Mufradāt*, *Qarābādīn-i-A'zam*, *Kitāb Al-fath fi Al-Tadawī*, *Qarābādīn-i-Kabīr*, *Qarābādīn-i-Majīdi*, *Bayāz Khās*, *Uṣūl al-Ṭib*, National Formulary of Unani Medicine, and Hamdard Pharmacopoeia.[2,9,10] The botanical books, namely, Compendium of Indian Medicinal Plants, Flora Medica, Indian Materia medica; Indian Medicinal Plants, Handbook of Medicinal Herbs, and Glossary of Indian Medicinal Plants also described properties of herbs used in *Ma'jūn-i-Flāsafa*. The keywords that were used, namely, *Ma'jūn*, *Ma'jūn-i-Flāsafa*, *Mizāj*, Ethnobotanical, *Stoneless raisins*, *Zingiber officinalis*, *Piper nigrum*, *Piper longum*, *Cinnamomum officinalis*, *E. officinalis*, *Terminalia bellerica*, *Plumbago zeylanica*, *Aristolochia rotunda*, *Orchis mascula*, *Matricaria chamomilla*, *Cocos nucifera*, *M. chamomilla*, *Pinus gerardiana*, *Z. officinalis*, *Dārṣīnī*, *Āmla*, *Balela*, *Shītraj Hindi*, *Zarāwand Madahraj*, *Tha'lab*, *Bābūna*, Coconut, and Chilgoza.[7]

Results and Discussion

Ingredients and preparation of *Ma'jūn-i-Flāsafa*

Ma'jūn-i-Flāsafa is compounds of *Mawaiz Munaqqa* (Stoneless raisins), *Zanjabīl* (*Z. officinalis*), *Filfil Siyāh* (*P. nigrum*), *Filfil Darāz* (*P. longum*), *Dārṣīnī* (*Cinnamomum officinalis*), *Āmla* (*Emblica officinalis*), *Post-i-Balela* (*Terminalia belerica*), *Shītraj Hindi* (*Plumbago zaylenica*), *Zarāwand Madahraj* (*A. rotunda*), *Tha'lab Miṣrī* (*O. mascula*), *Tukhm* and

Table 1: Ingredients, their scientific name, and quantity of each single drug present in *Ma'jūn-i-Flāsafa*

Unani name	Scientific name	Weight (g)
Mawaiz Munaqqa	*V. vinifera*	450
Zanjabeel	*Z. officinale*	150
Filfil Siyāh	*P. nigrum*	150
Filfil Darāz	*P. longum*	150
Dārṣīnī	*C. officinalis*	150
Āmla	*E. officinalis*	150
Post-i-Balela	*T. bellirica*	150
Shītraj Hindi	*P. zeylanica*	150
Zarāwand Madahraj	*A. rotunda*	150
Tha'lab Miṣrī	*O. mascula*	150
Beikh-i-Bābūna	*M. chamomilla*	150
Maghze Nārjīl	*C. nucifera*	150
Tukhm-i-Bābūna	*M. chamomilla*	75
Maghz-i-Chilghoza	*P. gerardiana*	150
Qand Safaid	White sugar	7000

M. chamomilla: Matricaria chamomilla, P. gerardiana: Pinus gerardiana, C. nucifera: Cocos nucifera, O. mascula: Orchis mascula, A. rotunda: Aristolochia rotunda, P. zeylanica: Plumbago zeylanica, T. bellirica: Terminalia bellirica, E. officinalis: Emblica officinalis, C. officinalis: Cinnamomum officinalis, P. longum: Piper longum, P. nigrum: Piper nigrum, Z. officinale: Zingiber officinale, V. vinifera: Vitis vinifera

Table 2: Pharmacopeial name, botanical name, part of use, *Mizāj*, doses, *Af'āl*, and *Isti'mālāt*

PN	Botanical name	Part of use	*Mijāz*	Dose (when used in single form)	*Af'āl*	*Isti'mālāt*
MM	*V. vinifera*	Raisins	*Ḥār raṭab, Ḥār yābis*	5–10 g	*Mufattih, Mukhrij-i-Balgham, Mulayyin, Muḥallil-i-Riyāḥ, Muqawwī-i-Kabid, Muqawwī-i-Mida, Muqawwī-i-Bah, Muqawwī-i-Qalb, Amrāḍ-i-Balghami, Munjiz-i-Akhlat*	*Nisyān, Qabḍ, Kāsir-i-Riyāḥ*
ZJ	*Z. officinale*	Rhizome or root	*Ḥār yābis*	7 g	*Mulayyin, Hadim, Muqawwī-i-Kabid, Muqawwī-i-Mida, Muqawwī-i-Bah, Mulattif, Muqawwī-i-Dimāgh, Muḥallil, Musakhkhin, Mushil-i-Balgham*	*Kāsir-i-Riyāḥ, Raṭūbat-i-Mi'da, Raṭūbat-i-Kabid, Raṭūbat-i-Dimāgh, Burudat-i-Mida, Mizāj-i-Barid, Ḍu'f al-Ishtiha, Ḍu'f al-Bah, Istisqa, Ḍu'f al-Haḍm, Awram-i-Balghami, Balghami-i-Amrāḍ, Waja al-barid, Nisyan*
FS	*P. nigrum*	Dried unripe fruits	*Ḥār yābis*	4–9 g	*Muḥallil-i-Awram, Muḥallil-i-Riya, Muḥallil, Muqawwī-i-Hafiza, Muqawwī-i-Kabid, Mudir-i-Hyad, Mudir-i-Bawl, Amrāḍ-i-Dimag Barid, Mukhrij-i-Balgham Hadim, Muqawwī-i-Mida Muqawwī-i- A'sab, Munaffith-i-Balgham, Muqwwi-i-Bāh, Musakhkhin*	*Barudat-i-Mida, Barudat-i-Kabid, Amrāḍ-i-Balghami, Qabd, Kasir-i-Riya Fasad-i-Balgham, Duf al-hadam, Awram-i-Balghami, Raṭūbat-i-Dimagh*
FD	*P. longum*	Fruits	*Ḥār yābis*	4.5 g	*Hadim, Muqawwī-i-Mida, Muqawwī-i-Bah, Yabūsat-i-Raṭūbat, Mudir-i-Hayd, Amrāḍ-i-Barid Raṭab, Muḥallil-i-Mawad barid, Amrāḍ-i-Dimag, Amrāḍ-i-Dimag barida, Musaffi-i-Dam, Musakhkhin, Mulattif-i-Balgham*	*Su'al-i-Balghami, Duf al-Bah, Istisqa, Kāsir-i-Riyāḥ, Amrāḍ-i-Balghami*
DC	*C. zeylanicum*	Bark leaves	*Ḥār yābis*	1–10 g	*Muḥallil, Mufattiḥ, Musakhkhin, Muqawwī, Hadim, Musaffi, Mudirr-i-Hayd, Musakkin-i-Alam, Mufarriḥ, Munaffith-i-Balgham, Muqawwī, Mudirr-i-hayd, Mudirr-i-bawl, Muqawwī-i-Bah, Mundij-i-Akhlāṭ, Kasir-i-Riyāḥ, Muqawwī-i-A'da' Ra'īsa*	*Buhha al-Sawt,* Istisqa, Nisyan, *Barudat-i-Mida, Barudat-i-Jigar, Barudat-i-Dimag, Duf al-Mida,* Nervousness, *Duf al-Bah, Duf al-Mida, Ihtibās al-Tamth, Sudā'-i-bārid, Nisyān, Hāḍim*
AA	*E. officinalis*	Fruit	*Bārid yābis*	2–8 g	*Muṣaffī-i-Dam, Qabid, Mukhrij-i-Balgham, Muqawwī, Muqawwī-i-A'dā' Ra'īsa, Muqawwī-i-Sha'r*	*Barūdat-i-Mida, Barūdat-i-Qalb, Barudat-i-A'da', Nisyan, Muqwwi-i-Sha'r, Ḍu'f al-Quwwat-i-Hadim, Qabd, Nisyan, Duf al-Qalb, Duf al-Mida, Duf al-DimagDuf al-Kabid*
PB	*T. bellirica*	Fruit	*Bārid yābis*	1–10 g	*Muqawwī-i-A'ṣāb, Muqawwī-i-Mi'da, Muqawwī-i-Aḥshā', Mushtahī, Qati'-i-Raṭūbat, Mushil*	*Istirkha'-i-Mi'da, Butlan al-Ishtiha', Hāḍim*
SH	*P. zeylanica*	Roots	*Ḥār yābis*	0.5–7 g	*Mushil-i-Akhlāt, Mushil-i-Akhlāt lazijah, Muḥallil-i-Riyāḥ, Mushil-i-Balgham, Mukhrij-i-Janin, Muqawwī, Muḥallil, Hadim, Muharrik-i-Bah*	*Kasir-i-Riya, Waj-al-Mufasil Bakghami, Duf al-hadm, Burudat-i-Mida, Burudat-i-Kabid*
ZM	*A. rotunda*	Root	*Ḥār yābis*	3–7 g	*Muḥallil, Mukhrij-i-balgham, Mudirr-i-Hayd* (20), (12) *Muqawwī-i-Bah, Mufattih, Musakkin-i-Alam, Munaqqī Mulattif-i-akhlat, Mushil-i-balgham*	*Ihtibas-i-hayd, Amrāḍ-i-balghamia, Ḍu'f al-bah, Barudat-i-Mida*

Contd...

Table 2: Contd...

PN	Botanical name	Part of use	*Mijāz*	Dose (when used in single form)	*Af'āl*	*Isti'mālāt*
SM	*O. mascula*	Tuber, root	*Ḥār raṭab*	4–9 g	*Muqawwī-i-Bāh Amrāḍ-i-Dimag, Muḥallil-i-Awaram Balghami, Amrāḍ-i-Balghami, Muwallid-i-Khun*	*Duf al-Bah, wasting disease*
BB	*M. chamomilla L*	Flower, roots	*Ḥār yābis*	Flower/root - up to 3.5 g	*Muḥallil-i-waram, Kāsir-i-Riyāḥ, Musakhkhin, Muqawwī, Musakkin-i-Alam, Mulayyin-i-Am'a', excrete Rādi' al-akhlat, Mudirr-i-Bawl, Munaffith-i-Balgham, Mudirr-i-Hayd, Munaqqi-i-badan, Mufattiḥ, Mudirr-i-'Araq, Mushil-i-Balgham*	*Qati'-i-Bah, Amrāḍ Ḥumma Balghamiyya, 'Usr al-tanaffus, Ihtibās-i-Hayḍ, Ḍu'f al-Mi'da, Istisqa*
MN	*C. nucifera*	Fruit	*Ḥār raṭab Ḥār yābis*	6 ratti–24 g	*Muqawwī, Musakkin-i-Ḥarārat Gharīzī, Mukhrij-i-Khilṭ Fāsid, Amrāḍ-i-Dimāgh bārid, Amrāḍ-i-Bārida, Muqawwī-i-Bāh, Tiryaq-i-Sumum, Muqawwī-i-Ḥarārat Gharīzī, Mukhrij-i-Balgham*	*Barudat-i-Mida, Barudat-i-Mathana, Barudat-i-Kulya, Humma-i-Balghamia, Istisqā'*
MC	*P. gerardiana*	Fruits	*Ḥār raṭab Ḥār yābis)*	6–14 g	*Mulayyin, Muḥallil, Musakhkhin, Muqawwī, Munḍij, Muffatiḥ, Munaffith-i-Balgham, Muqawwī-i-Qalb, Muqawwī-i-Bāh, Kāsir-i-Riyāḥ, Hāḍim, Mudir-i-Bawl*	*Waja' al-Mafāṣil Bārida, Istisqā, Duf al-Badan, Mizāj-i-Bārid*

M. chamomilla: Matricaria chamomilla, P. gerardiana: Pinus gerardiana, C. nucifera: Cocos nucifera, O. mascula: Orchis mascula, A. rotunda: Aristolochia rotunda, P. zeylanica: Plumbago zeylanica, T. bellirica: Terminalia bellirica, E. officinalis: Emblica officinalis, P. longum: Piper longum, P. nigrum: Piper nigrum, Z. officinale: Zingiber officinale, V. vinifera: Vitis vinifera, C. zeylanicum: Cinnamomum zeylanicum, MC: *Maghz-i-Chilgoza,* MN: *Maghze Nārjīl,* BB: *Bābūna,* ZM: *Zarawand Madahraj,* SH: *Sheetraj Hindi,* PB: *Post-i-Balela,* FD: *Filfil Darāz,* FS: *Filfil Siyāh,* ZJ: *Zanjabeel,* MM: *Mawaiz Munaqqa,* AA: *Āmla,* SM: *Tha'lab Miṣrī,* DC: Dārṣīnī, PN: *Pharmacopeial name*

Beikh-i-Bābūna (*M. chamomilla*), *Maghz-i-Nārjīl* (*C. nucifera*), *Maghz-i-Chilghoza* (*P. gerardiana*), and *Qand Safaid* (White sugar).[8,9] *Qiwām* was formed by using *Āb* (water) mixed with a *Qand Safaid* (White sugar) in a specific ratio and then boiled till up to a consistency of two *tars* was obtained. *Āb-i-lemu* (lemon juice), *Satt-i-lemu* (lemon extract), or *Shibb-i-Yamani* (Alum) were added before making *Qiwām* to purified and prevent crystallization at cooling. *Joshānda* of *Mawaiz Munaqqa* (450 g) was formed by boiling in 3.75 L water till 1/4th quantity remained then crushed manually and filtered. Powder of *Maghz-i-Chilgoza* and *Maghz-i-Nārjīl* were prepared by crushing and filtering through sieved number 40 separately. The rest of the drugs were grinding and filtered separately through sieved number 80 to convert into fine powder.[11] After that, *Joshānda* of *Mawīz Munaqqa* mixed with *Qiwām* and then boiled up to a suitable consistency of two *tars* was obtained. Then, the powder of the remaining drugs was mixed into *Qiwām* slowly one by one and stirred simultaneously with a wooden spoon to make it a homogenous consistency of *Ma'jūn*.[8,11]

Ingredients of *Ma'jūn-i-Flāsafa* and their scientific name[9,12]

The *Ma'jūn-i-Flāsafa* is a compound formulation that contains 14 single Unani drugs along with white sugar mentioned in NFUM. The individual content, scientific name, and quantity of each single drug present in *Ma'jūn-i-Flāsafa* are mentioned in Table 1.[7,13,14]

Description of *Ma'jūn-i-Flāsafa*

The ingredients present in *Ma'jūn-i-Flāsafa*, their pharmacopeial name (Unani name), scientific name, parts used, their *Mizāj* (temperament), doses, pharmacological actions, and their uses in USM are described in detail in the Table 2.[14-23]

The chemical constituents, pharmacological actions, and their therapeutic uses in the modern system of medicine are also described in detail in Table 3.[8,14,20,24-28]

Various parameters of physicochemical standardization of *Ma'jūn-i-Flāsafa* and their standard values present are mentioned in Table 4.[8,29]

Studies done on *Ma'jūn-i-Flāsafa*

Rashid *et al*. (2015) conducted a study on the *Ma'jūn-i-Flāsafa* and found that *Ma'jūn-i-Flāsafa* significantly increases the weight ($P < 0.001$), appetite score ($P < 0.001$), grip strength score ($P < 0.001$), and dementia score ($P < 0.001$) in elderly people. The study revealed that the test drug appeared to be promising in the health promotion of the elderly and exhibited significant effects in the improvement of weight, grip strength, appetite, memory, and hemoglobin content hence can be

Table 3: Pharmacological action, therapeutic uses, and chemical constituents

PN	Pharmacological actions	Therapeutic uses	Chemical constituents
MM	Antioxidant, cardioprotective, anti-hypercholesterolemic, hepatoprotective, antidiabetic, anti-inflammatory, laxative, diuretic, expectorant, blood purifier, antialopecic, antiarthritic, anti-atherosclerotic, aphrodisiac, astringent, cardioprotective, immunostimulant, lipolytic, tonic	Ischemia, anemia, wasting disease, dyspepsia, heart diseases, constipation, hoarseness, diabetes, alopecia, atherosclerosis, edema, gastrosis, hypercholestremia, nervousness, water retention	Flavonoids, polyphenols, procyanidins, anthocyanins, stilbene
ZJ	Anti-oxidant, anti-inflammatory, immuno-modulatory, antitumorigenic, anti-apoptotic, antihyperglycemic, anti-hyperschlesteromic, anti-hyperlipidemic, cardiotonic, stomachic, appetizer, expectorant, aphrodisiac, laxative, antidiabetic, anti-atherosclerotic, antiobesity, hepatoprotective, neuroprotective, gastroprotective, cardioprotective, diuretic, antidepressant, emmenagogue, stimulant, tonic	Arthritis, rheumatism, sprains, muscular aches, pains, hypercholesterolemia, carminative, indigestion, diabetes, obesity, constipation, memory impairment, alopecia, anorexia, anxiety, atherosclerosis, cold, congestion, dizziness, dysmenorrhea, edema, head cold, impotence, hoarseness	Volatile oil (zingiberene, curcumene, and farnesene), nonvolatile (gingerols, shogaols, paradols and zingerone)
FS	Carminative, stimulant, cognitive activity, fertility activity, antioxidant, anti-inflammatory activity, hepatoprotective activity, digestive activity, antidepressant activity, immunomodulatory activity, abortifacient, diuretic emmenagogue, expectorant, tonic	Amnesia, arthritis, hepatotoxicity, depression, dyspepsia, indigestion enhance bioavailability, constipation, anemia, ascites, sore throat, alopecia, skin disease, hoarseness, amenorrhea, abortifacient, cold, constipation, dysmenorrhea dyspepsia, cold lethargy, high cholesterol, water retention	Piperine, piperatine, piperidine, piperine
FD	Immunomodulator, stimulant, hepatoprotective, antioxidant, anti-inflammatory, antifertility, antihyperlipidemic, anti-obesity, melanin-inhibiting, cardioprotective, antidepressant, anti-hypercholesteromic, cardiotonic, carminative, expectorant, emmenagogue, abortifacient, laxative, tonic, aphrodisiac, diuretic	Free radicals induce oxidative damage, dyslipidemia, hyperpigmentation, depression, infertility, obesity, hepatotoxicity, ascites, cold, constipation, dyspepsia, drowsiness, dysmenorrhoea, edema, hoarseness, immunodepression, inflammation, nervousness	Piperine, methyl piperine pellitorin
DC	Stimulant, carminative, antioxidant, cordial, estrogenic, expectorant, lipolytic, tonic, anti-inflammatory, gastroprotective, increase sexuality, cognitive impairment	Amenorrhea, anorexia, cold, dysmenorrhea, dyspepsia, gastrosis, impotence, indigestion, bloating	Essential oil, cinnamaldehyde, tannin, cinnzeylanin, eugenol, cinnzeylanol
AA	Antioxidant, hypolipidemic activity, antidepressant activity, immunomodulatory activity, anti-inflammatory activity, hypoglycemic activity, hepato-protective, immunomodulation, cardioprotective, anti-atherosclerotic, memory enhancing activity, diuretic, astringent, carminative, anabolic, laxative, tonic	Degenerative disease, hypercholesteremia, hyperglycaemia, depression, hair growth, indigestion, dyspepsia, anemia, food absorption, constipation, alopecia, atherosclerosis, ascites, water retention	Chebulinic acid, chebulagic acid, emblicanin, citric acid, pectin, gallic acid, tannin, gum, albumin, crude cellulose, mineral matter and moisture
PB	Anti-diabetic, antioxidant activity, immunological, hepatoprotective, cardioprotective, antihyperlipidemic, astringent, tonic, expectorant, laxative, aphrodisiac diuretic	Degenerative disease, hyperglycemia, to enhance immunity, hypercholesterolemia, atherosclerosis, dyspepsia, flatulence, constipation, sore throat, edema, hoarseness of voice, anemia, lethargy, water retention	Bellericanin, tannic, resins gallic acid
SH	Anti-inflammatory, hypolipidemic, antidiabetic, memory-inducing, immunomodulators, antifertility, antioxidant, hepatoprotective, abortifacient, antiatherosclerosis, digestive, astringent, carminative, aphrodisiac, diuretic, expectorant, laxative, stimulant, tonic	Acute inflammation, hyperlipidemia, diabetes, amnesia, infertility, anxiety, dyspepsia, alopecia, amenorrhea, anemia, anorexia, ascites	Plumbagin, napthoquinone, coumarins, enzymes, glucose, fructose, steroids
ZM	Emmenagogues	Amenorrhea	Alkaloid aristolochine
SM	Astringent, demulcent, expectorant, nutritive, restorative, invigorator, sexual tonic, hypocholesterolemic, hypoglycaemic, tonic	Wasting disease, weakness, loss of sexual power, hyperglycemia, high cholesterol	Glucoside, starch, mucilage, sugar, glucans, glucomannans, protein, albumen

Contd...

Table 3: Contd...

PN	Pharmacological actions	Therapeutic uses	Chemical constituents
BB	Stimulant, carminative, bortifacient, anti-inflammatory, carminative, diuretic, emmenagogue, neurotonic, stimulant, tonic, immunostimulant, antioxidant	Dyspepsia, metrorrahgia, flatulence, amenorrhea, anemia, anorexia, bloating, dysmenorrhea, dyspepsia, gastrosis, indigestion, nervousness, swelling, water retention, gastric trouble	Volatile oils, salicylic acid, 3% of a glycoside, chamazulene, apigenin, sesquiterpene, chamillin
MN	Antioxidant, cardioprotective, anti-atherosclerotic, anticholecystitic, hypolipidemic immunostimulatory, antidiabetic, hepatoprotective, hormone-like effects, laxative, analgesic, anti-hypercholesterolemic, anti-inflammatory, diuretic, aphrodisiac, astringent, immunomodulator, tonic	To promote growth of hair, alopecia, amenorrhea, dysmenorrhea, constipation, impotence, inflammation, sore throat, water retention dyspepsia	Enzyme - investin oxydase catalase, milk - histidine, arginine, lysine, tyrosine, trptophan, proline, alanine, oil - lauric, myristic, fatty acid and fat, lignin, gum, albumin, tartaric, manitol, palmitic
MC	Carminative, stimulant, expectorant, anodyne, hypo-cholesteromic, hypolipidimic, diuretic, expectorant, cardioprotective, aphrodisiac	Chronic arthritis, dyslipidimia	Chilgoza nut - carbohydrates (21.6%), proteins (15.9%), fats (49.9%), moisture content (7.5%), fibre (2.2%) and mineral matter (2.90%)

MC: *Maghz-i-Chilgoza*, MN: *Maghze Nārjīl*, BB: *Bābūna*, ZM: *Zarawand Madahraj*, SH: *Sheetraj Hindi*, PB: *Post-i-Balela*, FD: *Filfil Darāz*, FS: *Filfil Siyāh*, ZJ: *Zanjabeel*, MM: *Mawaiz Munaqqa*, AA: *Āmla*, SM: *Tha'lab Miṣrī*, DC: Dārṣīnī, PN: Pharmacopeial name

Table 4: Standardization of *Ma'jūn-i-Flāsafa*

Properties	Feature
Appearance	Semi-solid
Color	Blackish brown
Smell	Pleasant
Taste	Sweet tending bitter
Alcohol-soluble matter	69.40%
Water-soluble matter	55.83%
Successive extractives	
Petroleum ether (60–80)	1.79
Chloroform	0.37
Ethyl alcohol	10.53
pH of 1% aqueous solution	4.6
pH of 10% aqueous solution	4.61
Bulk density at 25°C	1.362
Total ash	1.8%
Water-soluble ash	0.99%
Acid-soluble ash	0.38%
Volatile oils	0.126% v/w
Saponification value	216.36
Iodine value	93.30
Acid value	14.59
Alkaloids	2.21%
Total phenolics	0.81%
Tannins	0.078
Resins	1.835%
Aglycones	0.140
Reducing sugars	28.55%
Nonreducing sugar	22.36%
Crude fibers	1.95%
Total nitrogen	0.4902%
Sodium	0.3294% w/w of drug
Calcium	0.0756% w/w of drug
Potassium	0.4800% w/w of drug

safely recommended as a prophylactic measure in old age to counter the effects of aging.[8]

Another study was done by Ahmad *et al.* (2020) and it was stated that the *Ma'jūn-i-Flāsafa* and *Roghan-i-Surkh* are found to be effective in the management of poststroke disability. The two groups significantly differ ($P < 0.001$) on the Barthel index.[30]

Ahmad *et al.* (2022) conducted a study on the role of *Ma'jūn-i-Flāsafa* and *Safūf 'Āqar Qarḥā* in the management of hypothyroidism, in which it was observed that all-subjective (Tiredness, cold intolerance, constipation, weight gain, and loss of hair) and objective parameter (T_4, T_3 and thyroid-stimulating hormone [TSH]) were significantly improved ($P < 0.05$). The TSH was significantly improved in 26.7% of patients ($P = 0.013$) in the test group and 50% of patients ($P = 0.06$) in the control group at baseline and after treatment. No significant difference (inter-group $P > 0.05$) was observed in all subjective and objective parameters between groups at baseline and after treatment except free T_4. The test intervention has an effect on subjective and objective parameters but the control group was superior to the test group.[30]

Tabulated description of *Ma'jūn-i-Falsafa* [Tables 3 and 4]

The Ma'jūn-i-Flāsafa is a renowned ancient Unani formulation with several ingredients that are commonly used by Unani scholars. The present review evaluates the properties of *Ma'jūn-i-Flāsafa* as a whole and its content also. The abovementioned tables are described all content of *Ma'jūn-i-Flāsafa* in terms of pharmacopeial name, botanical name, part used, *Mizāj*, Dose, *Af'āl*, *Isti'mālāt*, pharmacological action, therapeutic uses, and chemical

constituent. The properties mentioned in the above table such as pharmacopeial name, part used, *Mizāj,* and *Af'āl* taken from renowned classical textbooks of Unani medicine while pharmacological action, therapeutic uses, and chemical constituents were taken from the conventional botanical book and research articles of several authentic journals. The table provides a quick review of all ingredients of *Ma'jūn-i-Flāsafa* to the researcher. The pharmacological action review included in the tables revealed that *Ma'jūn-i-Flāsafa* exerts several actions such as antioxidant, cardioprotective, antihypercholesterolemic, hepatoprotective, antidiabetic, anti-inflammatory, laxative, diuretic, expectorant, blood purifier, anti-alopecic, antiarthritic, anti-atherosclerotic, aphrodisiac, astringent, immunostimulant, lipolytic, and Tonic. Therapeutic uses also mentioned in the table such as arthritis, rheumatism, sprains, muscular aches, pains, hypercholesterolemia, carminative, indigestion, diabetes, obesity, constipation, memory impairment, alopecia, anorexia, anxiety, atherosclerosis, cold, congestion, dizziness, dysmenorrhea, edema, head cold, impotence, and hoarseness. The functions of *Ma'jūn-i-Flāsafa* according to Unani literature include *Kāsir-i-Riyāḥ*, *Raṭūbat-i-Mida*, *Raṭūbat-i-Kabid*, *Raṭūbat-i-Dimag*, *Burudat-i-Mida*, *Mizāj-i-Bārid*, *Ḍu'f al-Ishtihā*, *Ḍu'f al-Bāh*, *Istisqā'*, *Ḍu'f al-Haḍm*, *Awrām-i-Balghamī*, *Balghami-i-Amrāḍ*, *Waja' al-bārid*, and *Dāfa'-i-Nisyān*. The therapeutic use of content is *Muqawwī*, *Musakkin-i-Ḥarārat Gharīzī*, *Mukhrij-i-Khilṭ Fāsid*, *Amrāḍ-i-Dimāgh bārid*, *Amrāḍ-i-Bārida*, *Muqawwī-i-Bāh*, *Tiryāq-i-Samūm*, *Muqawwī-i-Ḥarārat Gharīzī*, *Mukhrij-i-Balgham*, *Mulayyin*, *Muḥallil*, *Musakhkhin*, *Muqawwī*, *Munḍij*, *Muffatiḥ*, *Munaffith-i-Balgham*, *Muqawwī-i-Qalb*, *Kāsir-i-Riyāḥ*, *Hāḍim,* and *Mudir-i-bawl*.[11,29,31] Therefore, tabulated descriptions of *Ma'jūn-i-Flāsafa* will be helpful to the researchers for future studies on *Ma'jūn-i-Flāsafa*.

Conclusion

It is well known that *Ma'jūn-i-Flāsafa* is a renowned compound formulation of USM. Traditionally, it is used to manage various pathological ailments of the nervous system, gastrointestinal system, genitourinary system, and cardiovascular system, especially *Bārid raṭab* condition.[8,9,12,32,33] In USM, the age of human beings is divided into four stages named as *Asnān-i-Arba'a or A'mār-i-Arba'*. The last of *A'mār-i-Arba'* is referred to as *Sin-i-Shaykhūkhat* (Senile age). The *Sin-i-Shaykhūkhat* individuals have *bārid raṭab* temperament.[34-36] Ancient Unani physicians prescribed *Ma'jūn-i-Flāsafa* for the elderly for their as a preservative of mental and physical health. That's why *Ma'jūn-i-Flāsafa* is called Old Man Stick in USM. The individual ingredients of *Ma'jūn-i-Flāsafa* exert various pharmacological actions and therapeutic uses as described in the USM. Therefore, based on individual ingredient properties, further research on *Ma'jūn-i-Flāsafa* is required to evaluate the new therapeutic indications as well.

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Conflicts of interest

There are no conflicts of interest.

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Review Article

Raphanus raphanistrum subsp. *sativus* (L.) Domin – A Food and Drug Used in the Unani System of Medicine

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Abstract

In recent years, increasing attention has been given to traditional medicine. Medicinal plants have been used traditionally in India for the management of various ailments of the body. Nutraceuticals have received considerable interest because of their presumed safety and potential nutritional and therapeutic effects. *Raphanus raphanistrum* subsp. *sativus* (L.) Domin syn. *Raphanus sativus* L. (radish) is an edible plant. It is grown and consumed throughout the world for its culinary and medicinal properties. In the Unani system of medicine, a detailed description is given about the health benefits of radish and its use as a food and medicine. All the parts of the plant including root are utilized in the Unani system of medicine as a single drug in various dosage forms or as one of the ingredients of polyherbal or herbo-mineral formulation for the management of various ailments, particularly for liver and kidney disorders. With recent researches, it has been attributed with several pharmacological properties. It contains flavonoid, saponin, tannin, glycosides, steroids, carbohydrates, vitamins, and minerals which indicate its medicinal and nutritional value. Radish has numerous pharmacological activities but comparatively little number of studies have been conducted on its nutritional aspect. Hence, we wish to explore the important health effects of *R. raphanistrum* in the light of Unani medicine.

Keywords: *Medicinal food, nutraceuticals, pharmacology, phytochemistry, radish, Unani medicine*

Introduction

Since ancient times people have been observing nature carefully and were able to find plants for food, medicine, clothes, shelter, and fuel in their direct environment.[1] The blurring of food and medicine is not new; it is a common theme across multiple contexts and cultures. It was Hippocrates who famously stated *let your food be your medicine and your medicine be your food*. India is rich with plant-based medicine and food, drawing on various traditional systems of medicine for nutrition, promotion of the health as well as for the prevention of various systemic disorders.[2] Health is described as a state of complete mental and physical well-being. It is affected by many factors including environmental factors, genetic factors, and age. The homeostasis typical for health is maintained as well as affected by food and medicines. The prevention and control of risk factors are the important aspects in keeping homeostasis. With the rapid development of centralized food preparation and fast food, old traditions, and common knowledge of "what to eat and when" are disappearing.[1] Diets high in fruits and vegetables are widely recommended for their health-promoting properties. Most countries have dietary recommendations that include fruits and vegetables.[3]

Unani system of medicine uses all three natural sources (*Mawālīd-i-Thalātha*) i.e., plant, animal products, and minerals-either as food or as medicine in different forms for the management of various ailments of the body.[4,5] The root of *Raphanus raphanistrum* is used as a vegetable and salad all over the world and is particularly important component of the Indian diet, because it contains a rich and a rare combination of phytochemicals. Roots of the plant are traditionally used for culinary and medicinal purposes.[6,7] All the parts of the plant, including leaf, seed, and root, are utilized in the Unani system of medicine as a single drug or as one of the ingredients of polyherbal formulation for the treatment of various ailments of the body.[8] The present study reviews the description and uses of *R. raphanistrum* in the Unani

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system of medicine and scientific studies conducted on it to substantiate the use of radish in Unani system of medicine in various systemic disorders.

Methodology

A comprehensive review of the literature on *R. raphanistrum* was commenced using the bibliographic database namely, PubMed, Google Scholar, ScienceDirect, and Scopus. The search was conducted using the terms "*Raphanus raphanistrum*" OR "*Raphanus sativus"*, Studies on "*Raphanus sativus*". Books, monographs, and reports on *Raphanus sativus* L. published in Urdu and English were used to compile the information. Standard Unani Medical Terminology published by Central Council for Research in Unani Medicine in collaboration with the World Health Organization was used to translate the Unani terminology. Glossary of Indian medicinal plants, National Formulary of Unani Medicine, Unani pharmacopeia, and several indexed journals were consulted for the botanical and English names. Plant names cited throughout the manuscript were checked for the currently accepted valid names through www.wfoplantlist.org. Other relevant reference books, articles, peer-reviewed indexed journals, and other published works available on online bibliographic database and the journals which follow COPE (Committee on Publication Ethics, www.publicationethics.org) guidelines were used to retrieve the online literature. The inclusion criteria covered studies and review articles on *Raphanus sativus* L. published in English while unpublished data were excluded. The full-text of each included article was critically reviewed, and valuable information was summarized.

Botanical Description

Raphanus sativus L. (Brassicaceae/Cruciferae) commonly known as radish in English; *mūlī* in Hindi and *fajl* in Arabic and *Turb* in Persian.[9,10] Greek name of the genus *Raphanus* means "quickly appearing."[9,11] It is an herb found throughout the world for its root and leaves and throughout India in gardens and plains. It is mostly used as a vegetable, salad, or for seasoning.[12,13] It is cultivated all over India up to 5000 m and in many other temperate and warm countries.[14] In India, it is cultivated in Uttar Pradesh, Punjab, Maharashtra, and Gujarat.[15] It is an annual herb; root is small, growing rapidly. Stem 0.2–0.6 cm high, flexuose, fistular, branched in the upper part, glabrous or hispid. Lower leaves on hairy petioles 3 cm long. Lyrate-pinnatifid 3–4 rarely 5 jugate, terminal lobe, suborbicular or shortly ovate, rounded at the apex, with the margin crenate, and confluent in lateral lobes. All leaves roughly pilose and bright green. Flowers scented-sepals 6.5–10 mm long oblong, sometimes brown red; petals 1.5–2.2 cm long, blade obovate sub-marginate at the apex white or lilac with yellow or purple veins. Root is white cylindrical and fleshy with tiny rootless from the surface.[14]

Chemical Constituents

Preliminary phytochemical investigation of seed indicated the presence of alkaloids, glycosides, steroids, tannins, carbohydrates, and flavonoids.[16] The fleshy root and seeds contain trans-4-methyl-thiobutenyl isothiocyanate glucoside (the pungent principle), cyanidin-5-glucoside-3-sophoro side, pelargonidin diglycoside, cyaniding diglycoside, 5-methyl-L-cysteine sulphoxide (methiin), steroidal sapogenins, and sulphorophene. The seeds of the radish contain a high percentage of oil.[17] Seed and root contain fixed oil, essential oil, a sulphated volatile oil resembling mustard seed oil. Oil contains sulfur and phosphoric acid.[13] Chromatographic analysis of these oils showed their complete similarities to cottonseed oil. Radish seeds oil contains 1.21 μmol of total alkenyl glucosinolates (AG/g), consisting mostly of progoitrin and gluconapin. Total protein was 6.5%. Two chitinases, designated RRC-A and RRC-B, were isolated from the roots. Both compounds had a molecular weight of 25 kDa. Arabinogalactan proteins (AGPs) were isolated from the primary and mature roots of the radish.[17] The ascorbic acid content is two times greater in roots than in leaves while total phenolic contents for radish leaves were almost two times higher than roots. Total flavonoid levels in leaves were four times higher than the roots.[18] In addition, it contains vitamins B_1, B_2, B_3, B_5, B_6, B_9, and C as well as calcium, iron, magnesium, manganese, zinc, potassium, and phosphorous.[7,15] The radish leaves contain more Vitamin A and C and calcium than the root.[19] The enzymes present are phosphatase, catalase, sucrose, amylase, alcohol dehydrogenase, and pyruvic carboxylase.[15]

Description of *Raphanus Sativus* L. in the Unani System of Medicine

Radish is a vegetable which is consumed raw and in cooked form by the people. The plant is 1–2 feet high. It has white color flowers and legumes are similar to mustard and it contains 5–7 seeds which are slightly bigger than the mustard seeds. Seeds are bitter and spicy while the roots and leaves are sweet and slightly pungent. Two variety have been mentioned in Unani medicine one is wild variety and other is cultivated.[20]

Mizāj (temperament) is one of the basic concepts of the Unani system of medicine. The *Mizāj* of drugs has been articulated in terms of four *kaifiyāt* (qualities) viz. *ḥār* (hot), *bārid* (cold), *yābis* (dry), and *raṭab* (moist).[21] The degree of *Mizāj* depends on the relative proportion of these four *kaifiyāt* and the drugs of a particular temperament are categorized accordingly. Its roots are hot in the first degree and moist in the second degree. Whereas green leaves are hot and moist in the first degree and seeds are hot and dry in the second degree. Various pharmacological action of *Raphanus sativus* L. have been mentioned in the Unani system of medicine *viz*., root is resolvent, demulcent, digestive, carminative, diuretic, and lithotriptic. Seeds are

resolvent, *musakkin* (substance which help in neutralizing the heat of humors), and tonic.[10] The fresh juice of leaves is diuretic, laxative; roots are used for urinary complaints, hemorrhoids, gastrodynic pains, and various gastric ailments. The seeds are expectorant, digestive, diuretic, laxative and carminative, antitussive, and stomach tonic. It is also an excellent food remedy for stone, gravel, and scorbutic conditions. The root extract has been reported to have anti-urolithiatic properties and used for urinary complaints and syphilitic diseases.[22,23]

In the Unani system of medicine, radish is used as household remedy of many diseases such as jaundice, gallstone, liver diseases, rectal prolapse, indigestion, and other gastric pains.[10] Almost all the Unani physicians have discussed its mechanism of action in rational way and relation to meal, such as it is not suitable for stomach. It causes eructation and if it is taken after meal, it loosens the bowels and acts as a diuretic and calorific. It helps in digestion if taken after meal while its intake before meal makes the food "floating" in the stomach and prevents its long stay for adequate digestion. It causes flatulence but its seeds are dissolving and highly attenuant. It acts an emetic when its peels are used with *Sikanjabīn* (oxymel) and useful for ascites. Its local application is recommended in pleural and splenic pain. It acts as a galactogogue. Leaf juice removes hepatic obstructions and jaundice and is effective in dropsy. Some people believe that its leaves are digestive, but basically, its substance is emetic in nature. Radish clear acne when applied with the flour of *Ārad-i-Shailam* (Rye flour, *Lolium perenne* L.). The application of peel of radish helps in reducing blemishes. Radish juice (leaf juice is instilled in the nose) reduces jaundice; it also reduces splenic pain, burning micturition, dysuria, and also acts as a lithotriptic.[20]

The seeds of radish are strongest in action followed by other parts: peel, leaves, and pulp, respectively. However, boiled radish is considered more nutritious. The seeds of cultivated and wild radish increase thirst when used with vinegar, act as emetic, diuretic and dissolve splenic inflammations (*Waram-i-Ṭiḥāl*). Its seeds are anti-flatulent and purge-out undigested food. It also acts as an appetizer and relives hepatic pain. Seeds are being used as carminative, anti-inflammatory, aphrodisiac, diuretic, and emmenagogue. Powder of seed along with hot water is useful in hoarseness of voice. Application of its seed with vinegar helps in healing gangrenous ulcers and ringworm. When applied with white hellebore and vinegar, it removes *pityriasis nigra.* If radish juice is mixed Rye flour and applied locally, it enables growth of hair in case of alopecia. Its seeds are useful in all kinds of hyperpigmentation, scars, and freckles.[24]

Although radish is used both as food and medicine, it is not free from toxic effect. Unani physicians state that its seeds are toxic to hot temperament person as well as for liver, kidney, and throat.[8] Radish is also toxic to head and teeth. Thus, its toxic effect is improved to certain extent through some specific corrective procedures (*'Amal-i-tadbīr*) to reduce its toxicity. However, if the application of corrective measures is not feasible then another drug which serves as a corrective agent (*Muṣliḥ*) is either admixed or used concurrently with the first drug to reduce its likely undesirable effects. *Muṣliḥ* (correctives) for seed of *Raphanus Sativus* L. are *Kathīra* (*Astragalus gummifer* Labill.), sugar, and *Sapistān* (*Cordia myxa* L.). For radish salt, honey and cumin soaked in vinegar are used as *muṣliḥ*.[10,25]

Abdāl-i-Adwiya, (substitution of drugs) is one of the important principles, which deals with the rules pertaining to drug substitution. Unani literature has vividly explained the substitutes of single drugs. *Badal* (substitute) for seed of *Raphanus sativus* L. are *Ispand* (*Peganum harmala* L.) and *Hālūn* (*Lepidium sativum* L.).[20]

Raphanus sativus L. as a single drug in the form of powder, paste, and decoction or in combination with other drugs have been widely used for treatment of various skin and other systemic diseases. It is also an important ingredient of several polyherbal formulations *viz.*, *Labūb-i-Kabīr*, *Roghan-e-Turb*, *Kushta Ḥajrul Yahūd*, and *Namak-i-Mūlī* which are used for the management of afore-mentioned ailments of the body.[24]

Ethnomedicinal Uses of *Raphanus Sativus* L.

Different parts of radish, including roots, seeds, and leaves, are used for medicinal purposes. Seeds are believed to have emmenagogue properties. Juice of fresh roots is considered powerful antiscorbutic. Root is an effective medicine for hemorrhoids and gastrodynia and is also used in urinary and syphilitic complaints, as it relieves dysuria and strangury.[26] A decoction of dry radish is given orally in piles. Extract of the dry root is given for hiccough, influenza, dysentery, colic, and urinary troubles.[15] The leaves, seeds, and old roots are used in the treatment of asthma and other chest complaints. It is taken orally in the treatment of indigestion, abdominal bloating, flatulence, acid regurgitation, diarrhea, and bronchitis. The root is antiscorbutic, antispasmodic, astringent, cholagogue, digestive, and diuretic. Radish is also an excellent food remedy for calculi, gravel, and scorbutic conditions. Seeds and leaves are diuretic, carminative, laxative, and lithotriptic.[27] The seeds also have antidote properties. It is mentioned by Ibn Hubal Baghdādī (1122–1213 AD) that if a person who has eaten radish is bitten by a scorpion, the toxin will not have any effect. It also acts as an antidote to snake poison and other poisons.[24]

Pharmacological Studies Conducted on *Raphanus sativus* L.

Antifungal activity

A basic 9-kD protein was purified from seeds of radish, the 43 amino-terminal amino acids show extensive sequence identity with nonspecific lipid transfer proteins from other

plant species. The radish seed nonspecific lipid transfer protein-like protein inhibits the growth of several fungi *in vitro*.[28]

Anti-urolithiatic activity

The aqueous extract of *R. sativus* bark was used to evaluate its anti-urolithiatic and diuretic activity in Wistar rats of either sex. Urolithiasis was induced by the implantation of zinc disc into the rat's bladder. Result showed the dose-dependent reduction (in doses of 40, 70, and 140 mg/kg) in the size of stone with diuretic activity. The aqueous extract of *R. sativus* (140 mg/kg *p.o.*) showed 90.78% reduction in the stone deposition as compared to the control group.[29]

Gastroprotective activity

Oral administration of 2 and 4 ml/200 g, b.w. freshly-squeezed radish juice significantly inhibited gastric ulcer formation induced by necrotizing agents in rats.[30] The ethanolic extract, chloroform fraction, ethyl acetate fraction, and AQR have offered significant protection against acetic acid-induced ulcers. While in pylorus ligation-induced ulcer model the ethanolic extract, ethyl acetate fraction, and AQRS showed significant protection by decreasing the ulcer index, total acidity, and free acidity.[31]

Antioxidant activity

The ethanol extracts of two varieties have potent antioxidant ability and they can act as radical scavengers for free radicals, especially in the concentrations of 100, 150, and 200 mg/ml, at these concentrations red and white radish seeds extracts have nonsignificant difference from that of ascorbic acid with scavenging activity of 100%. Antioxidant activity is highly correlated with increasing of concentration.[32] Aqueous and methanolic extract of leaves and radish root revealed antioxidant activity but leaves show more significant effect.[33]

Diuretic activity

Diuretic activity of aqueous extract of root was investigated in Wistar rat in dose of 100, 300, and 400 mg/kg. Result showed that extract increases sodium ion excretion than potassium, which is a very essential quality of a good diuretic. It is reported previously that flavonoids glycosides are endowed with diuretic activity. It may therefore presume that the diuretic activity may be due to the presence of flavonoids in the test extracts.[12]

Anti-cancer activity

This study investigated the effects of the ethanol extract of aerial parts of radish (ERL) on breast cancer cell proliferation and gene expression associated with cell proliferation and apoptosis in MDA-MB-231 human breast cancer cells. The MDA-MB-231 cells were cultured in the presence or absence of various concentrations of ERL. ERL significantly ($P < 0.05$) decreased cell proliferation after 48 h of incubation.[34]

Antidiabetic activity

Antidiabetic activity of leaves in petroleum ether, chloroform, methanol, and aqueous (400 mg/kg) extract on alloxan-induced diabetic Wistar rats showed that aqueous extract reduced blood glucose more than other extract and petroleum ether showed least reduction in blood glucose.[35]

Antibacterial activity

In another study, the researchers evaluated the antibacterial activity of radish seed using the *in vitro* agar-well diffusion assay. In this study, ethanol, methanol, ethyl acetate, chloroform, benzene, and aqueous hot and cold extracts were used for the analysis against *Staphylococcus aureus*, *Escherichia coli*, *Pseudomonas aeruginosa*, *Shigella sonnei*, *Salmonella typhi*, *Proteus vulgaris*, *Klebsiella pneumonia*, and *Salmonella paratyphi.* Ethanolic and methanolic extracts showed maximum antibacterial activity and least in aqueous cold extract when compared with chloramphenicol and ciprofloxacin.[9]

Anti-inflammatory activity

The anti-inflammatory activity of leaf and root juice in carrageenan-induced paw edema test showed statistically significant inhibition (41.90% and 28.46%, respectively) in paw volume when compared with control. In formalin-induced paw edema, test statistically significant inhibition of root and leaf juice was observed.[11]

In another study, leaves powder was fractionated into n-hexane, chloroform, ethyl acetate, n butanol, and water-soluble fractions. LPS-stimulated RAW264.7 cells were treated with each fraction. It was found that the chloroform fraction significantly inhibited nitric oxide release in LPS-stimulated RAW264.7 cells with a half maximal inhibitory concentration value of 196 μg/mL. In addition, the mRNA and protein expression levels of inducible nitric oxide synthase, measured using reverse transcriptase-polymerase chain reaction and western blotting, respectively, were reduced in a concentration-dependent manner. Furthermore, the expression of NF-κB, the key regulator of the transcriptional activation of the inflammatory cytokine genes, was reduced by the chloroform fraction.[36]

Laxative activity

Fresh leaves juice and aqueous extract of *R. sativus* in doses of 250, 500, and 750 mg/kg, *p.o.* were evaluated for the laxative activity in male Wistar rats. Significant increase in fecal output in loperamide-induced constipation and laxative activity was observed.[37]

Hypoglycemic and hypo-cholesterolemic activity

A recent animal study evaluated hypoglycemic and hypo-cholesterolemic activity of white radish leaves, white

radish roots, and red radish root aqueous extract in 100, 200 and 400 mg/kg, b.w./day/rat. The highest effect was found in the red radish root extract at 400 mg/kg; also, there was a significant decrease in TG, TC, LDL-c, and increase in the HDL-c parameter. The effects were attributed to the phenolic compounds, particularly ferulic acid, sinapic acid, catechin, coumaric acid, vanillic acid, caffeic acid, gallic acid, syringic acid, rutin, and protocatechuic acid. In the white radish root and leaves, catechin was the most abundant phenolic acid, while coumaric acid was the most abundant phenolic acid in red radish roots. Vanillic acid was present in equal proportion in both roots.[38]

Protection against sodium arsenite-induced toxicity

In a recent study, the ameliorating effects of *Raphanus sativus* leaves (RSLs) were evaluated against Sodium arsenite (Sa)-induced adverse effects in Swiss albino mice. It was observed that lactate dehydrogenase, alkaline phosphatase, alanine aminotransferase, and aspartate aminotransferase (AST) activities were significantly higher in "Sa" treated mice than those in the control group. Test drug significantly reduced "Sa" induced elevation of the activities of these enzymes in serum significantly. Serum butyrylcholineesterase activity and high-density lipoproteins cholesterol levels in "Sa" treated mice were significantly lower than the control group, and the food supplementation of test drug could significantly prevent the reduction of "Sa" mediated serum butyryl cholinesterase activity and high-density lipoproteins cholesterol levels. RSL could also reduce the "Sa" induced elevation of serum urea level significantly. The study suggests the protective effects of RSL on "Sa" induced perturbation of blood indices are related to the hepatic, cardiovascular, and kidney dysfunction.[39]

Gut stimulatory activity

The crude extract of RSLs showed a dose-dependent spasmogenicity in guinea-pig ileum and colon. The effect was insensitive to atropine pretreatment but was completely abolished by pyrilamine indicating involvement of histaminergic (H1) receptors. The contractile effect at high doses (3.0–5.0 mg/ml) was followed by relaxation. Extract also enhanced the transit of charcoal meal in mice at 30–100 mg/kg. The petroleum spirit, chloroform, and aqueous fractions all showed histaminergic activity in ileum; aqueous fraction being more potent.[40]

Hepatoprotective activity

This work screened the hepatoprotective and antioxidant activity of ethanol (ERS) and aqueous (ARS) extracts of leaves of *Raphanus sativus* in CCl_4 model in rats. The extracts were subjected to antioxidant tests (total reducing power and total phenolic content). The test drugs were given in a dose of 300 mg/kg for both ERS and ARS extract for 7 days. A dose-dependent increase in the oxidative potential was observed in both the extracts with total phenolic content 70.1 and 44.4 GAE/g extract for ERS and ARS respectively. ERS showed a significant increase in levels of AST, alanine transaminase (ALT), and alkaline phosphatase as compared to negative control (percentage hepatoprotection = 45.3%) while ARS group showed 30% hepatoprotection.[41]

Cardiotoxic activity

Cardiotoxic activity of leaves extract (70% ethanol) of *Raphanus sativus* L. was evaluated in adult male albino rats. The serum was analyzed for marker enzymes, *viz.* AST, ALT, lactate dehydrogenase, and creatine phosphokinase. Result of cardiac marker enzymes and histopathological study showed that biochemical markers increase significantly in comparison to normal control. This could be due to the histaminergic activity leading to toxicity.[42]

Discussion

In the Unani System of Medicine, there is a unique concept of food medicine (*Dawā' Ghidhā'ī*) and medicinal food (*Ghidhā' Dawā'ī*). Substances used mainly for their medicinal properties but also having nutritional value are called Food Medicine (*Dawā' Ghidhā'ī*), for example, Almond, Fig, etc. Therefore, they not only treat a disease but also nourish the patient. The substances which are used mainly as food but also have some medicinal properties are known as medicinal food (*Ghidhā' Dawā'ī*), for example, egg, Bengal gram, etc. They have the advantage of being very safe.[43] *R. raphanistrum* is one such drug which is used for medicinal purpose but also used as a food. The leaves and roots are used as vegetable but the seeds are exclusively used for its beneficial effect in a number of ailments. Though it is used as common vegetable, have various medicinal activities.[44] However, it is not investigated much for its nutritional value. The medicinal properties described by Unani physicians and its ethnomedicinal reports are validated by scientific studies *viz.*, antimicrobial, antidiabetic, diuretic, antifertility, antioxidant, hypertensive, nephroprotective, gastro protective, hepatoprotective, etc.[45]

Hepatoprotective activity of roots of *R. sativus* has been demonstrated in many studies.[41] Antidiabetic activity has also been verified by two studies in which one study reported that aqueous extract of radish leaves showed significant protection and maximum reduction in blood glucose and least by Petroleum ether extract.[46] Another study reported that *R. sativus* root juice has significant hypoglycemic as well as antidiabetic potential.[47] The drug also has gastroprotective and antiulcer effects. The nonspecific gastroprotective activities of the extracts may be the result of a combined effect of the different phytoconstituents present as some of the bioactive constituents have been associated with gastro protective and antiulcer effect. The flavonoid compounds were proved to have anti-secretory and cytoprotective properties

also believed to increase capillary resistance and cause an improvement in microcirculation. Further, the leaves contain a flavonoid (kaempferol) which is known to have gastric cytoprotective effect. Apart from this it is also rich in saponins and tannins, which have been shown to exhibit antiulcer properties. Tannins generally have vasoconstrictive and protein precipitating effects, precipitation of protein at ulcer sites forms impervious protective pellicle which renders the lesion less permeable to toxic substances and more resistant to attack of proteolytic enzymes.[31]

Anti-inflammatory activity of radish leaves and root juice against acute and chronic inflammation model has showed significant effect. However, leaf juice compared to root juice produced more significant effect in both models. The credit again goes to flavonoids, phytosterols, and tannins which directly or indirectly may inhibit the main inflammatory mediators.[11] Ethanolic and methanolic extracts showed maximum antibacterial activity against all the bacterial strains.[9] Crude ethanol red radish seed extract was more pronounced against *Streptococcus pyogenes* and *E. coli*.[48] One more study showed that root tended to be more active than the stem and leaf extracts in inhibiting the bacterial growth. However, the antibacterial activity of *R. sativus* was well correlated with allyl isothiocyanate, phenyl isothiocyanate, and benzyl isothiocyanate for all organisms except for *Enterococcus faecalis*, whose inhibitory effect was more related to 4-(methylthio)-3-butenyl isothiocyanate.[49]

The crude extract of *Raphanus sativus* L. leaves showed a dose-dependent spasmogenicity in guinea-pig ileum and colon. The effect was insensitive to atropine pretreatment but was completely abolished by pyrilamine indicating involvement of histaminergic (H1) receptors. The petroleum ether, chloroform, and aqueous fractions showed histaminergic activity in ileum; aqueous fraction was found to be more potent. The study shows the presence of a histaminergic component along with a weak spasmolytic factor thus providing sound mechanistic basis for the traditional use of the plant in constipation.[40] In addition, aqueous extract of the bark (tubercles) showed anti-urolithiatic and diuretic activity.[29]

Botanical derivatives obtained from the medicinal plants usually contain several compounds endowed with a polyhedric mechanism of action, which often act synergistically on the same target. Research has shown that the complex mixture of phytochemicals in fruits and vegetables provides a better protective effect on health than single phytochemicals.[50] Various pharmacological activities of radish are attributed due to the occurrence of a wide range of secondary metabolites, including alkaloids, phenolics, flavonoids, coumarins, carotenoids, antioxidant enzymes, terpenes, glucosinolates, and other compounds[48] with total phenolic content 70.1 and 44.4 GAE/g extract for ethanol and aqueous extract, respectively.[31,41] Flavonoids present in the plant rich diet represent a range of polyphenolic compounds naturally occurring in these foods. In this sense, radish leaves are an excellent source of bioactive compounds with high impact on the nutrition and health of consumers.[18] The polyphenols such as sinapic acid and ferulic acid and flavonoids (kaempferol) present in the *R. sativus* have antioxidant properties. Beevi *et al*. used HPLC to identify polyphenols such as catechin, protocatechuic acid, syringic acid, vanillic acid, ferulic acid, sinapic acid, o-coumaric acid, myricetin, and quercetin in leaves and stem extract of *R. sativus*. The flavonoid compounds have the ability to reduce the production of ROS, the inhibition of protein and DNA synthesis and the apoptosis caused by carcinogenic chemicals (i.e. aflatoxin) and showed good scavenging power, in accordance with the observed inhibition of NO production.[32,51] Study showed the protective effects on H_2O_2-induced oxidative damage in human fetal lung fibroblast (MRC-5) cells.[52]

Since ancient times, *Raphanus sativus* L. has been used as a natural drug against many toxicants. It was observed that lactate dehydrogenase, alkaline phosphatase, alanine aminotransferase, and AST activities were significantly higher in Sa treated mice. *Raphanus sativus* significantly reduced 'Sa' induced elevation of the activities of these enzymes in serum. Results showed that the protective or ameliorating effects of RSL on Sa-induced perturbation of blood indices are related to the hepatic, cardiovascular, and kidney dysfunction. Therefore, RSL may be useful to reduce arsenic toxicity in human in future.[39]

Based on above information, it is summarized that radish commonly used vegetable and drug is rummage-sale in Unani medicine for its various beneficial effects, especially in the treatment of liver and stomach disorders. Although the number of studies are carried out on various parts of radish, most of the studies are preliminary in nature as only single study on any aspect is not a guarantee of definite activity in particular system. Since radish is used as a vegetable, but there is no report for its safety profile and no clinical study is reported till date and it should also be investigated for its nutritional value. Therefore, there is a strong need for further research using different animal models and well-designed controlled clinical trials to prove its effectiveness in liver and kidney diseases and safety of the drug.

Conclusion

The documentation of Unani medicinal plants along with their uses in the health care system is very important. In this review, properties of radish described in Unani literature, phytochemical and pharmacological studies conducted so far have been reported. This review offers detailed and systematic information about the concerned drug, which may prove to be useful for researchers; it was also observed that all the functions described by Unani physicians in the classical literature were proved by various pharmacological studies.

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Conflicts of interest

There are no conflicts of interest.

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Review Article

The *Arkān* vs. Elements – An Analysis of Classical Unani Concepts and Contemporary Understanding

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Abstract

Purpose: This article focuses on various definitions of *Arkān*, translated into English as Elements, and its understanding and developments from ancient to the modern. It is interesting to note that many definitions and concepts of elements have been put forward over the centuries, yet all of them are essentially similar to each other, although with scientific development, different entities have been cited as elements. Thus, it becomes necessary to review the basics of the concept *Arkān* so that to understand its concept which the ancient as well as modern scientists have put forward. **Background:** *'Ilm Ṭibb* or Unani medicine is described as "*the study of the science by which we learn the various states of the human body, in health and when not in health and the means by which health is likely to be lost, and when lost, is likely to be restored*." The basics of the science are described under the term *Umūr Ṭabī'iyya* (factors of existence), which includes the basic factors which make up the living human body. The factors are seven in numbers, and each one is considered essential for survival. The loss or alteration in their physiochemical state leads to a disease or even to death. *Arkān* (elements) it is the first of *Umūr Ṭabī'iyya* and makes up the structural part, as well as contributes to the genesis of temperament. **Methodology:** This article systematically analyzes the Unani literature. Particularly, the review focuses on synonyms of *Arkān* and put forth various definitions of *Arkān* given by different physicians; it also keeps in sight the modern discoveries regarding the elements to obtain an accurate view and to put forth a convincing report. **Conclusion:** Unani physicians analyze *Arkān* by various ways such as definition, number, and utility and were best according to their time period. The presently-used term for *Arkān* is the element as the definition is concerned. *Arkān* are the familiar representative of the different physical states that matter can adopt and it serves as the basic requirement for the formation of everything in this world including the human-beings.

Keywords: *Arkān, elements, 'Ilm Ṭibb, Umūr Ṭabī'iyya*

Introduction

Ibn Sinā stated that "*Arkān* are primary structural and functional constituents of human body. They are simple substances which cannot be subdivided into bodies having different forms. It is their combination and organization that the various orders of things are formed in nature." Hence, *Arkān* are the basic requirement for the formation of *Mawālīd Thalātha* (three kingdoms of nature), i.e., *Mā'daniyāt* (mineral), *Nabātāt* (plants), and *Ḥaiwānāt* (animals).[1,2]

Unani system of medicine is based on a holistic understanding of the human body existence and functioning of materialistic world as a whole or its unit(s). Therefore, human body is supposed to be as a unit and unani medicine discusses the structure and function of the human body on the basis of its materialistic components. The basic unit of matter is the *Arkān* or elements.[3]

In this regard, Unani physicians follow Aristotelian concept of *Asbāb-i-wujūd* (causes of existences). *Aristotle* suggested that the reason for anything coming about and performing can be attributed to four different types of causes, i.e.,

1. *Asbāb Māddiya* (material causes)
2. *Asbāb Ṣūriyya* (formal causes)
3. *Asbāb Fā'ila* (efficient causes) and last factor is
4. *Asbāb Tamāmiyya* (final causes) as *Af'āl* (action/functions).[4,5]

Thus, by taking in account the said causes of existence, Unani medicine describes the structure and function of the human body. The subject to exercise the same is *Umūr Ṭabī'iyya* (factors of physis). There

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are seven factors supposed to be on which the existence of body depends, and these factors has been derived from four cause of existence. *Asbāb Māddiya* (material cause) comprises of; *Arkān* (elements), *Akhlāṭ* (humors), *A'ḍā'* (organs), and *Arwāḥ* (life spirit, pneuma), *Asbāb Ṣūriyya* (formal) comprises of; *Mizāj* (temperament) and *Quwā* (faculty/power), and *Asbāb Fā'ila* (efficient) also known as *Asbāb Tamāmiyya* (final cause) comprises *of; Af'āl* (action/functions).[4,5] Here is a point to be noted that *Asbāb Fā'ila* do not come under the seven factors of physis but unavoidable in the sense of biological response and maintenance.

The topic being discussed here is *Arkān* which comes under the *Asbāb Māddiya*. *Arkān* are there to provide the matter for the body. As matter is found in three states; solid, liquids, and gas, human body is composed of the same. *Akhlāṭ* (humors) correspond to the liquid state, *A'ḍā'* (organs) to the solid state, and Arwāh (pneuma) represent the gaseous state.[6,7]

Abū Sahl Masīḥī (d. 1010 AD) reports in his book *Kitābul Mi'a* that "it is not only the organs that are formed by *Usṭuqussāt*, but also the *Akhlāt* (liquids) and *Arwāḥ* (gases) found inside the body are the compounds of *Usṭuqussāt*." Hence, three types of states are there in human body, solid, liquid, and gases, and the material of all of which is provided by *Arkān*.[8] Just after showing the importance of *Arkān* in the composition of human body, it becomes necessary to review the whole concept given by various Unani physician, and in this article, an effort has been made to find out the definitions, number, and the characteristics of *Arkān* in the existing Unani as well as modern literature.

Literal meaning of *Arkān*

The literal meaning of *Arkān* (the constituent) is the primary component of any compound, whether organic and inorganic. Physicians of different time period use different words or terms for denoting the *Arkān*. *'Anāsir*, *Usṭuqussāt*, *Asl*, *Umm'ahāt*, *Ajzā' Awwaliyya* are the various synonyms used for *Arkān*. Among all of these, *'Anāṣir* (singular: *'Unṣur*) and *Usṭuqussāt* (singular: *Usṭuqus*) are frequently used by *Rāzī*, *Abū Sahl Masīḥī*, and *'Alī Ibn 'Abbās Majūsī* while *Ahmad Ṭabrī* used *Umm'ahāt* for *Arkān Arba'a. Ibn Sina* prefers *Arkān* (singular: *Rukn*) and *'Anāṣir* and the other scholars of later period adopted *'Anāṣir* to describe the primary component of any compound.[9]

Definition of the *Arkān*

Conventionally, *Arkān* are described by the Unani physicians in many ways which are as follows:

Hippocrates (460-370 B. C.) states that "the body of individual is composed of four basic elements, which together are termed as *'Anāṣir Arba'a; Nār* (fire), *Mā'* (water), *Rīḥ* (air) and *Arḍ* (earth). These four elements possess four different qualities, i.e., *Ḥar* (hot), *Bārid* (cold), *Yābis* (dry), and *Raṭab* (wet). The admixture of these four elements results in the formation of four biological fluids or *Akhlāṭ* (humors) as *Dam* (blood), *Balgham* (phlegm), *Ṣafrā* (bile), and *Sawdā* (black bile)."[10]

Jālīnūs (Galen) (131–210 AD) says in his *Risāla Kitāb fī al-Anāṣir* that "Since *'Unṣur* is the smallest part of whatever thing may possess that *'Unṣur*. *Basīṭ* (simplest thing) is defined in two ways either by *Hiss* (perception) or by *Tabī'yat* (nature). *A'ṣāb* and *'Iẓām* are simplest according to the *Hiss* (perception) but by virtue of their *Tabīy'at* (nature); these are the compounds of *Nār* (fire), *Mā'* (water), *Hawā* (air) and *Arḍ* (earth). In true sense, *Basīṭ* is that part which is simplest and primary by nature not the one which appears (percepts) to be simple and primary, as they are perceived as *Basīṭ* by *'Ilm-e 'aqlī* not by *Ilm-e ḥis*."[11]

Rabban Ṭabarī (775–890 AD) says in *Firdaws al-Ḥikmah fī al-Ṭibb* that *"Mufrad* (single/uncompounded) substances are *basīṭ* in nature and these are classified into four: Two of which are *Fā'ila* (active/efficient causes) that are *Ḥarārat* (hotness) and *Burūdat* (coldness) while the other two are *Munfa'ila* (passive causes) that are *Ruṭūbat* (wetness) and *Yubūsat* (dryness). Compounds formed *Ḥarārat* (hotness), *Burūdat* (coldness), *Ruṭūbat* (wetness), and *Yubūsat* (dryness) are four in number which are stated as *Nār* (fire), *Mā'* (water), *Hawā* (air), and *Arḍ* (earth). *Mufrad* substances were present before the formation of any compounds which later combine to form the compounds."[3]

Muhammad bin Zakariya Rāzī (865–925 AD), says in his book *Kitāb al-Murshid*, "*Usṭuqussāt* are the simple substances which participate in the formation of the compounds. Human bodies, plants and minerals are the compound of *Nār* (fire), *Mā'* (water), *Hawā* (air), and *Arḍ* (earth), and therefore, these are *Usṭuqussāt* (*'Anāṣir*) for them."[12]

Ali Ibn Abbas Majoosi (930–994 AD), says in his book *Kamil al-Sina'a al-Ṭibbiyya* that "*Usṭuqussāt* is the smallest part of a compound. Being extremely small, it is not further divisible. *Basīṭ* means that its *jawhar* (substance) is single, having uniform parts. In other words, all the ingredients are analogous/similar to each other without having any difference in their nature and properties. *Ajsam Basita* may be of two types. The first type cannot be divided into parts possessing varying properties, like *Nār* (fire), *Mā'* (water), *Hawā* (air) and *Arḍ* (earth). The second type is related to the stones and the minerals which apparently appears to be simple having similar component, but in actual, they are compounded with four *Usṭuqussāt*, i.e., *Nār* (fire), *Mā'* (water), *Hawā* (air), and *Arḍ* (earth)."[7]

Abu Sahl Masihi (d. 1010 AD) says in his book *Kitab al-Mi'a* that "The primary substances in the nature are four in number, i.e., *Nār* (fire), *Mā'* (water), *Rīḥ* (air) and *Arḍ* (earth). These are called as primary substances, because they are not composed of other substances except

themselves. On the contrary, all entities in nature are made of these substances either directly or indirectly." *Ibn Sina* (980–1037 AD) has defined *Arkān* in *Al-Qānūn fī al-Ṭib* as "*Arkān* are primary constituents of humans body. They are simple substances which cannot be subdivided into bodies having different forms. It is their combination and organization that the various orders of things are formed in nature."[8]

Abu Hasan Ahmad Bin Ahmad Tabri (d. 985 AD) says in his book *Mu'alajat al-Buqratiyya 'Unṣur* represents the constitution of human bodies. *Hayūlā* (primordial matter) is equally a topic of concern for all material bodies. The basic difference between *Hayūlā* and *'Unṣur* is that *Hayūlā* is common as compared to *'Unṣur*. *'Unṣur* basically expresses the constitution of human bodies, according to which *'Unṣur Nār* will be different from *'Unṣur Mā'* but *Hayūlā* for both of them will be the same. The relationship between *Hayūlā* and *'Unṣur* will be similar to that of genus and species, in which species is particular whereas genus is common/general. In the same way, *'Unṣur* is particular whereas *Hayūlā* is common. He says that "Usṭuqussāt, 'Anāṣir Ṭabī'ya, Umm'ahāt, and Uss, all of these are used to denote Nār (fire), Mā' (water), Rīḥ (air), and Arḍ (earth)." They are named so, because they serve as roots and act as the primary principles for the forming bodies. *Um* (mother) is the precursor of child birth because child comes to existence through mother. Similarly, *'Anāṣir Arba'a* are called as *Umm'ahāt*. Hence, they are known by names *Uss* or *Mubādī* because they serve as the base and underlying principle for the universe.[13]

Ismail Jurjānī (1121–1213 AD) in *Zakhīra Khwārazm Shāhī* says that "Everything in this universe including *Mawālīd Thalātha* is formed by the amalgamation of *Āg* (fire), *Āb/Mā'* (water), *Rīḥ* (air), and *Arḍ* (earth) and in matter of everything that is present under the sky and these four are known as *Arkān* in Arabic language and is also written as *'Anāsir*. It has similarity in all of its parts and neither of its part is different from another. If any part is taken out from it, they all will have same *Ṭabī'at* and same functions."[14]

Ibn Hubal Baghdadi (d. 1213 AD) in *Kitāb al-Mukhtārāt fī al-Ṭib* says that "*Arkān* are the primary bodies for *Mawālīd Thalātha*, i.e., mineral, plants and animal kingdom. Hence, whenever they are seen from the point of formation (*Tarkīb*), they are called as *Arkān* or *'Anāṣir*, and in terms of dissociation, they are called as *Usṭuqussāt*, as according to the physicians, the most simplest part of any compound is *Usṭuqus* which has reached its utmost level in dissociation."[15]

'Ala' al-Din 'Ali ibn Abi al-Hazm ma'ruf bi Ibn al-Nafis Qarshi (1210–1288 AD) says in *Mujaz al-Qanun* that "*Arkān* are four in numbers. *Arkān* are those simple bodies from which *Mawālīd Thalātha* comes into existence. There is nothing in this world which is not made up of *Arkān*. Things that are formed by *Arkān* are known as *murakkab* (compound). The word, *Basīṭ* is used in this context which means whenever these bodies are disintegrated by any means, then the components produced by their disintegration will never have the same properties. Antonym of *Basīṭ* is *murakkab*, which is formed by the combination of bodies having different properties. *Arkān* is also known as *'Anāṣir* and *Usṭuqussāt*." Later on, *Mujaz al-Qānūn* is further analyzed by the physicians in the form of *Ifāda Kabīr Mufaṣṣal* which is the translation and elaboration done by *Hakim Kabiruddin* (1894–1976 AD). In this book, same definition of *Arkān* has been followed as mentioned above.[12,16]

Gazrooni in his book named *Kulliyāt-i-Ṣadīdī* states that "The functional unit of any compound is considered as *Rukn* whereas the part of any compound according to the primary composition is regarded as *Unṣur*. It is also named as *Usṭuqus*, with respect to its utmost dissociation. However, implication of the word *Rukn* has been confined for *Arkān Arba'a*. *Arkān* are the simple and primary bodies for *Mawālīd Thalātha* (animals, plants, and minerals). *Basīṭ* is actually used in theology (for God), but in the context of *Arkān*, *Basīṭ* denotes the body which do not have any parts, like that of unit (state of being one) or particle. This *Basīṭ* is same to that of *Mutashābihal al-ajzā'* in which a perceptible part will be similar to that of whole in name as well as in properties for example part of a bone is also called as bone and a part of muscle is also a muscle. Beside this, *Basīṭ* can be perceived as a substance which does not contain distinct parts or which consist of parts having similar properties such as water and fire, and this type of *Basīṭ* is actually meant here. These are four in number."[17]

In *Kulliyāt-i-Qānūn* (Translated and elaborated by *Hakim Muhammad Kabir Uddin* [1894–1976 AD]), *Ibn-e Sina* writes that "*Arkān* are the simple bodies which provide primary components for the human body, etc.; they cannot be subdivided into bodies having different forms. The *Mawālīd Thalātha* in this universe are formed by their amalgam."[2] *Kulliyāt-i-Qānūn* is basically the translation and elaboration of *Ibn Sina's Al Qanun fī all-Ṭibb.* This book follows the same definition of *Arkān* as cited by *Ibn Sina* that has been mentioned earlier. Likewise, there are other books too, that follows exactly the same definition of *Arkān* like *Qanoon Asri* by *Hakim Muhammad Ilyas* (1880–1963 AD) and *Kulliyat-i-'Aṣrī* by *Prof. Syed Ishtiyaq Ahmed*.[18]

Burhanuddin Nafīs describes in his book *Kulliyāt-i-Nafīsī* that has been translated by *Hakim Muhammad Kabir Uddin* as *Tarjuma wa Sharah Kulliyāt-i-Nafīsī* that "*Arkān* are four in number (fire, air, water, and earth). These four are called *Arkān* because everything in this universe is formed through anabolism and catabolism. *Arkān* are the constituents of everything."[19]

Hakim Mohammad Sadique Ali Khan in *Zaad-e-Gareeb* or *Makhazin ul taleem* states that "*Arkān* are those

simple bodies which represents the primordial, basic, and fundamental unit for the humans and the others. The ultimate or the uttermost parts that will be obtained on dissolution of these bodies, will be considered its primary constituents. *Basīṭ* means that it cannot be divided into parts that have different forms and nature. *Arkān* are four in numbers: *Āg* (fire), *Mā'* (water), *Rīḥ* (air), and *Arḍ* (earth)."[20]

Ḥakīm Sayyed Mohammad Kamaluddin Hussain Hamdani in *Daqaiqul Kulliyāt* interprets that "The literal meaning of '*Unṣur* is 'substance/matter' and conventionality, it is the primordial constituent for *Mawālīd Thalātha* (mineral, plant, and animal kingdom). All the things in nature are formed by the combination and organization of these constituents. They cannot be divided into those entities that are having different forms and functions. In fact, all the compounds including *Mawālīd Thalātha*, get dissolved into these simpler components because of which these are known as *Usṭuqus* and *Usṭuqus* is that substance toward which everything dissolves. As these constituents form part of any compound, they are referred to as *Rukn*, which literally means root. These primordial constituents are also called as *Aṣl* (basic), because of the transformation or alteration of one part toward the other since everything returns to its *Asl* (origin/basic)."[21]

Dr. Ahsanullah in his book *Unani Tibb k nazaryat par naqadana nazar* writes that *"Arkān* is placed first amongst the *Umūr Ṭabī'iyya* (factors of life) and are also called as *Usṭuqus* or *'Anāṣir*. They are considered four in numbers: *Unṣur Arḍ*, *Unṣur Nār*, *Unṣur Mā'*, *Unṣur Hawā'*. All of them are different from each other in terms of *mahiyat* (essence), place, name, and *Af'āl* (functions) but they possess similarity in terms of simplicity. As this property is common to all elements, that is why they all are known as *Arkān.*"[22]

Some technical jargons

Basīṭ, *Mufrad*, *Mutashābiha al-Ajzā'* and *Mutashābihal al-Imtijāz.*

Unani physician had used some of the terminologies such as *Basīṭ* and *Mufrad* in defining the concept of *Arkān*. The literal meaning of *Basīṭ* is expanded, simple, unmixed, but conventionally, it is that substance which does not contain any parts having different properties. Its antonym is *Murakkab* (compound) which consist of components, having different properties.[23] Gruner, in his book "A treatise on the Canon of Medicine" has described *Basīṭ* as "Simplicity is that quality in virtue of which a substance has neither constitutive nor quantitative parts." Another word that is used to describe simplicity is *Mutashābihal al-ajzā'*, which implies that the smallest part of any body exactly resembles the whole.[24] Aristotle recognized that most ordinary, material things are composed of multiple substances, although he thought that some of them could be composed of a single, pure substance (simple substance). Thus, he gave a criterion of purity/simplicity that would individuate a single substance. His criterion was that pure substances are *homoeomerous or homogenous*: they are composed of like parts at every level. "If combination has taken place, the compound *must* be uniform-any part of such a compound is the same as the whole, just as any part of water is water" in physical appearance. Similarly, any part of bone is bone, any part of muscle is muscle in its physical appearance.[7]

Mufrad is another word that is also being used for *Arkān* which literally means unique, single or being only one of its kind or unlike anything else. A substance is said to be *Mufrad* to denote its uniqueness which means that it is distinctive or individual in its existence with respect to others. *Mutashābihal al-Imtijāz* implies that a composite body is made up of different types of components having varying properties. Beside this, *Basīṭ* can be perceived as a substance which does not contain distinct parts or which consist of parts having similar properties. Hence, if a compound is made up of more than one component but of similar properties and functions, then it will also be considered as *Basīṭ.*[2]

Concept of *Arkān Arba'a*

Concept of four *Arkān* i.e. Fire, Air, Water and Earth was firstly suggested by Empedocles (490–430 BC) as the primary matter for everything in this universe. Each of them ware everlasting, but they could be mixed in different proportions, and thus produce the changing complex substances that we find in the world. After that, Aristotle (384–322 BC) relates each of the four elements *Nār* (fire), *Mā'* (water), *Rīḥ* (air), and *Arḍ* (earth) proposed by Empedocles to two of the four sensible qualities (i.e. hot, cold, wet, and dry). Air is hot and wet, fire is hot and dry, earth is cold and dry, and water being cold and wet.[25]

Regarding the *Arkān Arba'a*, scholars of that time provided various illustrations in which Hippocrates says that "there are four physical qualities, i.e. *Ḥarārat* (hotness), *Burūdat* (coldness), *Ruṭūbat* (moisture) and *Yubūsat* (dryness). Coldness is necessary for our body especially when we are affected from heat or temperature. Uneasiness from the moisture proves the existence of dryness in our body. The pain from the dryness makes sure that there is presence of contra property of dryness in our body. All these four properties, in spite of being '*arẓī* cannot come into existence without a particular location or position which are specified for coldness and dryness. In this way, these two qualities, namely coldness and dryness altogether are integrated/conjoined with Earth and the location of coldness and moisture are conjoined with Water." Hence, these are the four basic substances, i.e., Air, Water, Earth, and Fire which take part in the formation of everything of this universe.[26]

Present status of *Arkān* (the elements/constituents)

Till 13th century, these four elements Earth, Air, Fire, or Water were identified as the basic constituents of all

things. The word element is derived from old French *element* (10c.), from Latin *elementum* meaning rudiment, first principle, matter in its most basic form (translating Greek *stoikheion*). By the late 14th century, the definition of an element evolved to mean the "simplest component of a complex substance." Since 1590s, Element means "proper or natural environment of anything" from the old notion that each class of living beings had its natural abode in one of the four elements.[27]

The early chemist of 17th century began trying to understand matter by practical means. The skeptical chemist *Robert Boyle's* (1627–1691) definition of element is nothing very controversial by the standard of times: He says that "Elements are the certain primitive and simple or perfectly unmingled bodies; which not being made of any other bodies, or of one another, are the ingredients of which all those called perfectly mix bodies are immediately compounded, and into which they are ultimately resolved."[28]

Antoine-Laurent de Lavoisier (1743–1794) a famous French scientist, also considered as the father of modern chemistry, has defined element as the "last point which analysis is capable of reaching," or a substance that cannot be decomposed to simpler substance."[27,28] The definition of the Element given by Lavoisier is followed till now. At present, element is defined as a substance that cannot be chemically interconverted or broken down into simpler substances and are primary constituents of matter. Modern sense in chemistry is from 1813 but is not essentially different from the ancient one.[29]

Elements in human body

The theory of *Arkān Arba'a* was prevalent till 17th century. At the beginning of 18th century, this concept was rejected, and it was ascertained that a total of 118 elements are present in nature instead of four. Of the 118 chemical elements present in the periodic table, only 26 elements are present in the human body. Although all are important, 11 are called *major elements.* Four of these major elements – carbon, oxygen, hydrogen, and nitrogen – make up about 96% of the material in the human body. Calcium makes up about 1.5% of the material in human body, Phosphorus occurs in amounts of about two-thirds of calcium, and makes up about 1% of a person's body weight. The other major minerals (potassium, sodium, chlorine, sulfur, and magnesium) make up only about 0.85% of the weight of the body. Together, these eleven chemical elements (H, C, N, O, Ca, P, K, Na, Cl, S, Mg) make up 99.85% of the body. The 15 remaining elements are present in amounts that are <0.15% of body weight and are called *trace elements*. The main elements that compose the human body are shown in the Table 1 from most abundant (by mass, not by fraction of atoms) to least abundant.[30,31]

Discussion

- The definitions of *Arkān* during the centuries from the antiquity up to now is analyzed in this article. Unani physicians were of the view that *Arkān* should be the one which is *Basīṭ*, i.e., it should be indivisible and indestructible. From the definitions, it is concluded that *Arkān* are the basic matter for the constitution of everything in this world. For modern scientists, elements are simple unmingled bodies that cannot be broken down into simpler substances. These elements are basically the representative of *Arkān,* and in modern, they are known by the name, elements
- For the Unani physicians, air, water, fire and earth were *Mutashābiha al-Ajzā'.* They thought them to be made up of similar components and smaller part of it resembles the whole, in its macroscopic appearance. However, at present, all of them come under the category of *Mutashābihal al-mizāj.* Smallest part of water does not resemble the whole as water has been proved to be the compound of further smallest particles, i.e., oxygen and hydrogen. Terminologies such as *Basīṭ* and *Mufrad* are best suited over the modern elements of the periodic table. These elements are indivisible as well as unique or individual in its existence with respect to others
- This implies that conceptually, *'Anāṣir*, *Usṭuqussāt*, *Asl*, *Umm'ahāt*, *Ajzā' Awwaliyya*, and elements, all are same. They were called by different names in different time period and in different languages. The logic and philosophy behind the elementology is same that was very described in classical Unani literature, and the evidence of their logically based philosophy can be seen easily in their manuscripts as has been shown in this article
- The concept of *Arkān Arba'a* was proposed on the basis of four basic qualities, i.e., *Ḥarārat* (hotness), *Burūdat* (coldness), *Ruṭūbat* (moisture), and *Yubūsat* (dryness) which were prevalent at that time period. But nowadays, this concept has been studied further and scientists have discovered 26 elements which are found inside the human body[32]
- Hence, it is evident that the concept of *Arkān*, which are considered the basic building blocks of the human

Table 1: Percentage distribution of major elements in the body

Element	Symbol	Percentage in body
Oxygen	O	65.0
Carbon	C	18.5
Hydrogen	H	9.5
Nitrogen	N	3.2
Calcium	Ca	1.5
Phosphorus	P	1.0
Potassium	K	0.4
Sulfur	S	0.3
Sodium	Na	0.2
Chlorine	Cl	0.2
Magnesium	Mg	0.2
Others		<1.0

body, is similar to the concept of elements. Similar to the definition of *Arkān* given by Unani scholars, elements are also described as the tiniest particles which possess distinct and recognizable physical and chemical properties, and cannot be broken down into smaller particles while retaining their identifiable properties. This indicates that the understanding behind the classical Unani theory of *Arkān*, and the description of elements by contemporary scholars is rooted in the same concept-to ascertain the basic structural entities of the human body. The tiniest particles were earlier identified as earth, water, air, and fire as most of the science of that era were based on naked-eye observations. With the development in physics, it has been discovered that atoms are the tiniest particles to exist with identifiable physical and chemical properties. Given the dynamic nature of sciences, it will not be surprising if further smaller particles are discovered, which satisfy the definition of "elements"[33]

- Another significant development in the field has been the classification of elements based on their characteristics, such as earth, water, fire, and air elements, categorized according to their properties and distribution in body tissues. Hence, it is accepted in present era that each element has its own unique qualities which determine the temperament and characteristics of the human body.[33]

This article is just to drive focus only on the definitions of *Arkān* to validate by analyzing the knowledge of the definition of elements and its applied aspects.

Conclusion

The different definitions of *Arkān* (elements) put forward by various Unani physician are same in essence. According to above analysis, there is no difference regarding the basics of *Arkān* (Elements) as described in classical Unani medicine and contemporary understanding of the concept. It is the dictum of science that it progresses with time, so the enlightenment regarding the *Arkān* has also been advanced and has attained its form in terms of elements today. After the interpretation of the definitions of *Arkān*, it can be concluded that the whole knowledge collected by Unani scholars as seen in their manuscripts is logically correct and valid in the present era. Hence, the progress and development in Unani literature is imperative, but the definitions, terminologies, logics, and Greek-oriented philosophies must be retained, propagated, and interpreted in the same form as these are described in original Unani texts.[34]

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Conflicts of interest

There are no conflicts of interest.

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Original Research Article

Clinical Evaluation of *Dawaul Shifa*, Lifestyle Modifications, and Yoga in Hypertension Patients under NPCDCS (Unani) Project

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Abstract

Background: Noncommunicable diseases (NCDs) often called as lifestyle diseases or chronic diseases are defined as the medical conditions that are known to affect individuals over an extensive period of time, i.e., these are noninfectious diseases which are of long duration and generally are of slow progression. The four identified major NCDs are cardiovascular diseases (CVDs) such as hypertension (HTN), ischemic heart disease and stroke; diabetes; chronic respiratory diseases (chronic obstructive pulmonary diseases and asthma); and Cancer. HTN is one of the leading causes of the global burden of diseases. In 2015, approximately 19.2% and 14% of all deaths were attributed to systolic blood pressure (BP) ≥10–115 mmHg and systolic BP ≥140 mm Hg, respectively. **Aims and Objective:** Keeping in view of the current burden of NCDs (HTN and diabetes), a collaborative pilot project of Directorate General of Health Services and Ministry of AYUSH was launched namely Integration of AYUSH systems in National Program for Prevention and Control of Cancer, Diabetes, CVDs and Stroke (NPCDCS) known as NPCDCS-AYUSH Integration Project. **Material and Methods:** In this study, patients of HTN were divided into two groups, Group A received Allopathic Medicine + Lifestyle interventions/*Ilaj bit Tadbeer* and Yoga while Group B received Unani formulation (*Dawaul Shifa* 1g/day) + Allopathic Medicine + Lifestyle interventions/ *Ilaj bit Tadbeer* and Yoga. **Result and Conclusion:** There is a significant decrease in systolic as well as diastolic BP in both groups. In Group B, many patients reported lower dose requirement or withdrawal of allopathic medicines.

Keywords: *Dawaul Shifa, hypertension, lifestyle interventions, Unani, yoga*

Introduction

India is among an epidemiological transition, with increasing the prevalence of noncommunicable diseases (NCDs). Targeting the risk factors for NCDs is recognized as an essential preventive strategy.[1] NCDs are a result of a combination of genetic, physiological, environmental, and behavioral factors. Globally, cardiovascular diseases (CVDs) account for most NCD deaths, i.e., 17.7 million people annually, followed by cancers (8.8 million), respiratory diseases (3.9 million), and diabetes (1.6 million). The country profile for India suggests that the mortality rate due to NCDs is over 60% (5.87 million) of premature mortality.[2]

Keeping in view of the current burden of NCDs, a collaborative pilot project of Directorate General of Health Services and Ministry of AYUSH was launched namely Integration of AYUSH systems in National Program for the Prevention and Control of Cancer, Diabetes, CVDs and Stroke (NPCDCS) known as NPCDCS-AYUSH Integration Project. The project on integration of Unani Medicine in NPCDCS was officially launched by Central Council for Research in Unani Medicine in June 2016 at Lakhimpur–Kheri District, Uttar Pradesh and is being implemented in all the 17 Community Health Centers (CHCs) and one District Hospital of Lakhimpur Kheri. Under NPCDCS AYUSH (Unani) project at Lakhimpur Kheri, patients were screened for different NCDs (diabetes, hypertension [HTN], hyperlipidemia, etc.).[2]

High blood pressure (BP) is ranked as the third most important risk factor for attributable burden of disease in South Asia. HTN exerts a substantial public health burden on cardiovascular health status and healthcare systems in India. HTN is directly responsible for 57% of all stroke deaths

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and 24% of all coronary heart disease (CHD) deaths in India. The WHO rates HTN as one of the most important causes of premature death worldwide.[3] The rates for HTN in percentage are projected to go up to 22.9 and 23.6 for Indian men and women, respectively, by the year 2025.[4]

HTN epidemiological studies from India in the past 20 years have shown that the prevalence of HTN (diagnosed by systolic BP >140 mmHg and/or diastolic BP >90 mmHg) in urban locations has stabilized to about 25%–30% (R^2 = 0.08), but it has increased in rural populations from 15% to 25% (R^2 = 0.04).[5]

In India, about 33% urban and 25% rural Indians are hypertensive. Of these, 25% rural and 42% urban Indians are aware of their hypertensive status. Only 25% rural and 38% of urban Indians are being treated for HTN. One-tenth of rural and one-fifth of urban Indian hypertensive population have their BP under control.[3]

The prevalence of HTN, especially in adults has risen dramatically during the last two decades from 5% to 20%–40% in the urban areas and 12%–17% in the rural areas. About 16% of ischemic heart disease (IHD), 21% of peripheral vascular disease, 24% of myocardial infarction, and 29% of stroke are caused by HTN. A decrease of 10 mmHg systolic or 5 mmHg diastolic BP may result in an approximately 20%–25% lower risk of CHD and 40% lower risk of stroke.[6]

Diabetes prevalence is high in HTN patients suggesting the importance of insulin resistance.[7] The national prevalence of overweight, obesity, HTN, and diabetes was 14.6%, 3.4%, 5.2%, and 7.1%, respectively. The highest prevalence of these conditions/diseases at the national level was seen among those aged 35–49 years (54 years for men), especially women living in the urban areas. HTN prevalence is now becoming more concentrated among the poor. Recent study showed that for better prediction of risk of HTN, sex, and ethnicity-specific adiposity indicator should also be used in the clinical practice.[8]

According to its etiology, the HTN has been divided in two types:[9]

1. Primary HTN
2. Secondary HTN.

In most of the people, there is no identifiable cause of high BP. This type of BP is termed as primary (essential), HTN tends to develop gradually over many years.

In some people, high BP is caused by an underlying condition. This type of BP is termed as secondary HTN, tends to appear suddenly and cause higher BP than primary HTN. Various conditions and medications can lead to secondary HTN, for example, endocrine disease (hyperthyroidism and Cushing's syndrome), kidney diseases (glomerulonephritis, polycystic kidney disease, and renal artery stenosis), CVDs (coarctation of aorta), and use of oral contraceptive pills, steroids, and alcohol.

In the classical literature of Unani medicine, the term *Zaghṭ Al-Dam Qawī* does not exist. Modern Unani physicians and authors use the term *Zaghṭ Al-Dam Qawī. Zaghṭ Al-Dam Qawī* is present term, basically the Urdu translation of HTN. However, the condition called "*Imtilā*" has been widely discussed by all the Unani scholars in the history.

When studied thoroughly the clinical features of *Imtilā* in the classical literature of Unani Medicine corresponding with the clinical features as encountered in the patients of HTN. Therefore, we can correlate that both these terms, *Imtila* and HTN to the same context. Unani Physicians such as *Ibn-e-Sina*, *Zakariya Razi*, and *Majoosi* classified *Imtila* in two types:[10-12]

1. *Imtilā-ba-ḥasbul au'iya*
2. *Imtilā-ba-ḥasbul quwā.*

Imtilā-ba-ḥasbul au'iya (repletion in regard to vessels) is an increase in blood volume leading to increase vascular pressure. Unani physicians have also attributed decrease in the lumen of blood vessels as a cause for increased vascular pressure. They have described heaviness of head and visual disturbances as symptoms of *Imtilā* and rupture of blood vessels in the form of epistaxis, hemoptysis, and hemorrhage as its complications.[10]

As the prevalence of HTN is increasing and it is associated with complications such as IHD, chronic kidney disease, stroke, and allopathic treatment for HTN is associated with adverse effects. Unani Medicine and Yoga are safe

Table 1: Age-wise distribution of the patients

Age group (years)	Groups		Total, *n* (%)
	A, *n* (%)	B, *n* (%)	
30–40	13 (18.84)	19 (24.36)	32 (21.77)
41–50	15 (21.74)	18 (23.08)	33 (22.45)
51–60	26 (37.68)	26 (33.33)	52 (35.38)
>60	15 (21.74)	15 (19.23)	30 (20.40)
Total	69 (100)	78 (100)	147 (100.00)
Mean±SD	52.13±10.33	51.03±11.4	

SD: Standard deviation

Table 2: Sex-wise distribution of the patients

Sex	Groups		Total, *n* (%)
	A, *n* (%)	B, *n* (%)	
Male	32 (46.38)	47 (60.26)	79 (53.75)
Female	37 (53.62)	31 (39.74)	68 (46.25)
Total	69 (100)	78 (100)	147 (100.00)

Table 3: Dietary habitwise distribution of the patients

Diet	Group		Total, *n* (%)
	A, *n* (%)	B, *n* (%)	
Nonveg	36 (52.17)	56 (71.79)	92 (62.58)
Veg	33 (47.83)	22 (28.21)	55 (37.42)
Total	69 (100)	78 (100)	147 (100.00)

for the long-term use. Hence, a clinical study was planned on the patients of HTN under NPCDCS AYUSH (Unani) project.

Materials and Methods

In the present, open-label and clinical study, patients were selected from OPDs of CHCs of Lakhimpur Kheri (UP), under Integration of Unani Medicine in NPCDCS. Integration of Unani Medicine in NPCDCS is joint pilot project of Ministry of AYUSH and Ministry of Health and Family welfare, Government of India. Detailed clinical examination was performed as per the case record form (CRF). Written informed consent taken from the all the patients before enrollment in the study. The study was carried out during 2019–2020. Patients were selected in the study based on the following criteria:

Table 4: Mizāj-wise distribution of the patients

Mizāj (temperament)	Group		Total, *n* (%)
	A, *n* (%)	B, *n* (%)	
Damwī (sanguine)	23 (33.33)	31 (39.74)	54 (36.73)
Sawdāwī (melancholic)	2 (2.9)	0	2 (1.36)
Safrāwī Mizāj (bilious)	16 (23.19)	11 (14.1)	27 (18.37)
Balghamī (phlegmatic)	28 (40.58)	36 (46.15)	64 (43.54)
Total	69 (100)	78 (100)	147 (100.00)

Table 5: Other characteristics-wise distribution of the patients

Particular	Group		Total, *n* (%)
	A, *n* (%)	B, *n* (%)	
Family history			
No	66 (95.65)	78 (100)	144 (97.96)
Yes	3 (4.35)	0	3 (2.04)
Alcohol use			
No	65 (94.2)	72 (92.31)	137 (93.20)
Yes	4 (5.8)	6 (7.69)	10 (6.80)
Tobacco use			
No	45 (65.22)	41 (52.56)	86 (58.50)
Yes	24 (34.78)	37 (47.44)	61 (41.50)
Physical inactivity			
No	62 (89.86)	71 (91.03)	133 (90.47)
Yes	7 (10.14)	7 (8.97)	14 (9.52)

Inclusion criteria

- Age 30–70 years
- Systolic BP ≥140 mmHg, diastolic BP ≥90 mmHg.

Exclusion criteria

- Pregnancy and lactation
- Any major systemic illness (malignancy, cirrhosis of liver, liver failure, and renal failure, etc.)
- Patients on corticosteroids and hormonal treatment.

Sample size

A total of 147 patients of HTN completed the follow-up, 69 in Group and 78 in Group B.

Duration of study

The total duration of treatment was 8 weeks.

Efficacy and safety parameters

Subjective parameters included headache, irritability, giddiness, and sleeplessness assessed at baseline and after the completion of the study using an arbitrary scale where in 0 stood for no symptom/sign, (1) stood for mild; (2) for moderate; and (3) for severe condition. The objective parameters consisted of systolic and diastolic BP, lipid profile including total cholesterol; triglyceride; high-density lipoprotein; low-density lipoprotein (LDL), and very LDL, liver function test (LFT) (S. bilirubin, SGOT, and SGPT), and renal function test (RFT) (blood urea and serum creatinine), were performed at baseline and after the completion of the study at 8 weeks.

Follow-up

Follow-up of the patients done at the interval of every 2 weeks. On every follow-up, vitals (pulse, BP, and temperature) and signs and symptoms were recorded in the CRF.

Statistical analysis

Baseline and follow-u*P* values of the clinical subjective parameters and objective parameters were statistically analyzed using Wilcoxon signed-rank test and Student's paired *t*-test. The result was expressed as the mean ± SD $P < 0.05$ has been considered as statistically significant and $P < 0.01$ and $P < 0.001$ have been considered as statistically highly significant.

Table 6: Effect of combined therapy on subjective parameters

Subjective parameters	Group							
	A		B		A		B	
	BT, mean±SD	AT, mean±SD	BT, mean±SD	AT, mean±SD	Mean percentage change from BT	*P*	Mean percentage change from BT	*P*
Headache	1.42±0.85	0.28±0.45	1.81±0.79	0.21±0.44	80.28 ↓	<0.001	88.39 ↓	<0.001
Irritability	0.94±0.94	0.09±0.28	0.95±0.88	0.09±0.33	90.42 ↓	<0.001	90.52 ↓	<0.001
Giddiness	0.87±0.77	0.16±0.37	0.91±0.87	0.1±0.35	81.60 ↓	<0.001	89.01 ↓	<0.001
Sleeplessness	1.23±0.88	0.19±0.43	1.26±0.76	0.14±0.42	84.55 ↓	<0.001	88.88 ↓	<0.001

BT: Before treatment, AT: After treatment, SD: Standard deviation

Table 7: Effect of combined therapy on the objective parameters

Objective parameters	Group							
	A		B		A		B	
	BT, mean±SD	AT, mean±SD	BT, mean±SD	AT, mean±SD	Mean percentage change from BT	*P*	Mean percentage change from BT	*P*
Systolic BP	155.94±10.97	124.96±13.17	163.1±16.97	124.62±12.61	19.87 ↓	0	23.59 ↓	0
Diastolic BP	91.59±4.65	77.04±6.06	94.41±8.93	77.51±6.88	15.89 ↓	0	17.90 ↓	0
Serum cholesterol	182.13±45.29	165.99±34.47	191.4±38.43	177.17±32.15	8.86 ↓	0	7.43 ↓	0
Serum triglycerides	142.22±69.06	151.01±68.64	166.23±76.67	157.67±56.08	6.18 ↑	0.31	5.15 ↓	0.24
HDL	53.62±10.45	48.26±14.09	53.16±18.75	49.97±17.31	10.00 ↓	0	6.00 ↓	0
LDL	98.22±35.79	89.2±33.33	104.86±33.18	99.41±32.26	9.18 ↓	0.02	5.20 ↓	0.02
VLDL	29.83±16.49	32.26±14.88	35.19±21.15	34.09±17.05	8.15 ↑	0.19	3.13 ↓	0.46
Blood urea	26.47±7.47	26.74±8.96	27.1±9.71	29.17±9.79	1.02 ↑	0.82	7.64 ↑	0.03
Serum creatinine	0.75±0.25	0.73±0.23	0.8±0.19	0.78±0.18	2.67 ↓	0.48	2.50 ↓	0.19
SGOT	35.32±24.42	32.78±10.92	34.13±13.4	36.81±20.92	7.19 ↓	0.36	7.85 ↑	0.25
SGPT	34.07±27.48	34.21±22.67	36.11±25.74	33.45±22.19	0.41 ↑	0.95	7.37 ↓	0.38
Serum bilirubin	0.61±0.31	0.57±0.24	0.64±0.31	0.62±0.25	6.56 ↓	0.16	3.13 ↓	0.55

BT: Before treatment, AT: After treatment, BP: Blood pressure, HDL: High-density lipoprotein, SD: Standard deviation, LDL: Low-density lipoprotein, VLDL: Very LDL, SGOT: Serum glutamic-oxaloacetic transaminase, SGPT: Serum glutamic pyruvic transaminase

Table 8: Response of treatment-wise distribution of the patients

Response	Group	
	A, *n* (%)	B, *n* (%)
<25% relief	6 (8.7)	1 (1.28)
25%–50% relief	25 (36.23)	20 (25.64)
≥50% relief	38 (55.07)	57 (73.08)
Total	69 (100)	78 (100)

Treatment schedule and duration

All the patients of HTN were divided into two groups, Group A received Allopathic Medicine + Lifestyle interventions/*Ilaj bil Tadbeer* and Yoga while Group B received Unani formulation (*Dawaul Shifa* 1g/day) + Allopathic Medicine + Lifestyle interventions/Ilaj bit Tadbeer and Yoga. Patients of Group A were also taking allopathic medicine (Atenolol and Amplodipine etc.) as prescribed by the Allopathic Medical officer of the concerned CHCs.

Dawā ul Shifā is a pharmacopoeial formulation taken from Unani Pharmacopoeia of India Part II, Vol II. The composition of *Dawā ul Shifā* is given below.[13]

1. *Asrol Rauwolfia serpentina* Benth.ex .Kurz, UPI Root 10 g
2. *Filfil Siyāh Piper nigrum* L., UPI Fruit 10 g.

In lifestyle interventions/*'Ilāj bi'l Tadbīr* patients were advised brisk walk 30 min at least 5 days in a week, low salt diet, low fat diet, avoid junk and smoked foods, preserved foods, alcohol, carbonated drinks, etc. Avoid excess of nonvegetarian diet, Salt intake should be restricted to <5g/day, stop tobacco chewing and smoking.[14,15]

In Yogic Management, patients were advised selected practices of *Sukshmavyayama* and different *Asanas* such as *Tadasana*, *Katichakrasana*, *Trikonasana*, *Pawanmuktasana*, *Vajrasana*, *Shashankasana*, *Vakrasana*, *Bhujangasana*, and *Shavasana*. All the yogic practices were advised by yoga instructor.[2,14]

Results and Discussion

Out of 147 patients of HTN, 52 (35.38%) patients were found in the age group of 51–60 years, 33 (22.45%) patients in 41–50 years, 32 (21.77%) in 30–40 years, and 30 (20.40%) in the group of >60 years [Table 1]. These findings correspond with the previous studies.[16,17]

Out of 147 patients of HTN, 79 (53.75%) patients were male and 68 (46.25%) patients were female [Table 2]. These findings suggested that HTN is more common in males than females and this finding is in agreement with the findings of Rai *et al.*, 2020.[18]

Data revealed that 92 (62.58%) patients were nonvegetarian while 55 (37.42%) patients were vegetarian [Table 3]. This finding suggested that HTN is more prevalent in nonvegetarian and it corresponds with the finding of Agarwal *et al.*, 1994.[19]

Out of 147 patients of HTN, 54 (36.73%) patients had *Damwī Mizāj*, 2 (1.36%) had *Sawdāwī Mizāj*, 27 (18.37%) were of *Safrāwī Mizāj*, and 64 (43.54%) were of *Balghamī Mizāj* [Table 4]. This study revealed that HTN is more prevalent in *Damwī* and *Balghamī Mizāj*.

Out of 147 patients, the family of history of HTN was present in three (2.04%) patients. In modifiable risk factors, alcohol use present in 10 (6.80%) patients, tobacco use present in 61 (41.50%) patients, and physical inactivity was present in 14 (9.52%) Patients [Table 5]. In a study by Bhadoria *et al. (*2014), the cardiovascular risk factors and prevalence of HTN were evaluated in a Central Indian state. It was found that the overall prevalence of HTN was

Table 9: Overall response of the intervention on conventional treatment

Overall response of the intervention	Number of patients (%) in hypertension Group A	Number of patients (%) in hypertension Group B
Withdrawal of allopathic medicine	4 (5.80)	22 (28.20)
Partial reduction in dose/number of allopathic medicines taken	15 (21.73)	25 (32.05)
No withdrawal/reduction in allopathic medicine taken	50 (72.46)	31 (39.74)
Total	69	78

14.8% in the rural areas and 17% in the urban areas. Family history was positive in 4.5% people in the rural areas and 19.4% in the urban areas. In the rural areas, 26.7% people had a history of alcoholism compared to 21.7% in urban areas. Habit of tobacco smoking was reported by 23.9% and 8.9% people in rural and urban areas, respectively; while 42.7% rural patients and 43.7% urban patients reported a habit of tobacco chewing. Physical inactivity (sedentary/mild activity) was reported by 23.5% people in the rural areas and 35% people in the urban areas.[20]

In subjective parameters of HTN, statistical analysis revealed that significant improvement seen in headache, irritability, giddiness, and sleeplessness, $P < 0.001$ in both groups groups [Table 6].

In HTN, Group A and Group B significant mean reduction is seen in systolic as well as diastolic BP, and lipid profile. In safety parameters (LFT and RFT), no significant changes were seen, $P > 0.05$ i.e., result is not statistically significant, as shown in Table 7. *Asrol* (*Rauwolfia serpentina*) and *Filfil siyah* (*Piper nigrum*) are the ingredients of *Dawaul shifa*. *Asrol* has sedative, tranquilizing, anaesthetic, antiarrythmic, hemostatic, and blood purifier effect.[21,22]

Filfil Siyah has diuretic (*Mudir-e-baul*), digestive, resolvent (*Muhallil-e-warm*), nervine tonic (*Muqqavi asab*), local anesthetic (*Mukhadir*), and bioavailability enhancer of the drug.[23,24] Reduction of systolic and diastolic BP occurred mainly due to the above-mentioned actions of *Asrol*, *Filfil siyah*, and effect of Allopathic medicine, Yoga and lifestyle modifications.

As per the patients view on relief from the treatment, in HTN Group A out of 69 patients, six (8.7%) patients got < 25% relief, 25 (36.23%) patients got 25%–50% relief, and 38 (55.07%) patients got more than 50% relief [Table 8].

In HTN, Group B out of 78 patients, one (1.28%) patient got < 25% relief, 20 (25.64%) patients got 25%–50% relief, and 57 (73.08%) patients got more than 50% relief [Table 8].

Out of 69 patients of HTN Group A, four patients (5.80%) patients reported withdrawal of allopathic medicine after the intervention of combined therapy (Unani/Allopathic Medicine, lifestyle modifications, and yoga) and 15 (21.73%) patients reported reduction in dose/number of allopathic medicines taken. However, 50 (72.46%) patients reported no withdrawal/reduction of allopathic medicine [Table 9].

Similarly, out of 78 patients of HTN Group B, 22 (28.20%) patients reported withdrawal of allopathic medicine after the intervention of combined therapy (Unani/Allopathic Medicine, lifestyle modifications, and yoga) and 25 (32.05%) patients reported reduction in dose/number of allopathic medicines taken. However, 31 (39.74%) patients reported no withdrawal/reduction of allopathic medicine [Table 9]. This reduction/withdrawal of Allopathic medicine is most likely due to cumulative effect of Unani/Allopathic Medicine, lifestyle modifications and yoga.[14,25,26]

Conclusion

On the basis of above results, it can be concluded that by comparing the overall response of intervention on conventional treatment in HTN, Group A and Group B showed that withdrawal/partial reduction of allopathic medicine is more in HTN Group B, so it revealed that by advising Unani Medicine and Yoga along with conventional treatment number/dose of allopathic drugs may be reduced and the patients of HTN may be prevented from the adverse effects of allopathic drugs. Thus NPCDCS-AYUSH integration project is a model of successful operationalization of integration of AYUSH systems, in NPCDCS for the prevention and control of NCDs.

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Conflicts of interest

There are no conflicts of interest.

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Original Research Article

Safety Evaluation of a Unani Pharmacopeial Formulation *Qurṣ Mafāṣil Jadīd* on the World Health Organization Parameters

Abstract

Background: Unani Medicine literature encompasses a number of effective and safe drugs useful in the treatment of arthritis. Unani physicians have been using such drugs for centuries for the treatment of arthritis with a good recovery rate. Despite the fact that arthritis requires a longterm treatment, the drugs have not been reported to cause any major side effects. "Qurṣ Mafāṣil Jadīd" is one of the Unani compound formulations used for joint disorders but we have no safety data available for the said drug. The World Health Organization has launched guidelines (2007) for the safety studies of plant materials for medication as well as food items to prevent the harmful effects of toxic material found in the soil and environment. **Aims and Objectives:** So this formulation was subjected for safety studies (Heavy Metals Estimation, Microbiological Determination, Mycotoxin (Aflatoxin) Estimation and Pesticidal Residue Estimation). **Materials and Methods:** The test drug (Qurṣ Mafāṣil Jadīd) was studied to evaluate the presence of heavy metals, if any by using ICPMS, microbiological determination test, aflatoxins determination and pesticidal residue estimation. **Results:** This study demonstrated that heavy metals, microbial load, aflatoxins and pesticide levels were found within permissible limits. **Conclusion:** So based on the findings the formulation was found safe.

Keywords: *Qurṣ Mafāṣil Jadīd, heavy metals, microbiological, mycotoxine, pesticidal residue, safety*

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Introduction

Herbal and traditional medicines are becoming increasingly popular in the recent decades. While the use of herbal medicines has been the tradition in most East Asian countries since many centuries, a similar trend is being observed in other nations including Korea, United States, etc. Herbal and natural medicines are being preferred by the people for many reasons including a means of health maintenance, for avoiding the adverse effects of conventional medicines, and for their gentle nature of action.[1,2] On the other hand, with the growing market for herbal drugs and supplements, the recent years have witnessed a rise in newer herbal products. With the rising costs of research and development, the quality control of these products has become a new area of concern.[3] Some research studies and systematic reviews have also shed light on the toxic and adverse effects of herbal products, which necessitates the strict implementation of safety standards for herbal healthcare products.[2] In this context, in 2007, the World Health Organization (WHO) formulated a set of guidelines for the safety standards of herbal medicines, which contain the maximum permissible standards for contaminants and residues in herbal medicines.[4]

The Unani system of Medicine contains a description of a number of effective and safe drugs useful in the treatment of arthritis. The Unani physicians have been using such drugs successfully for centuries for the treatment of arthritis with a good recovery rate. Many single and compound Unani drugs when subjected to experimental and clinical studies have shown very promising results. For instance, *Būzīdān* (*Pyrethrum umbelliferum* Boiss),[5] *Suranjān Shīrīn* (*Colchicum autumnale* L.),[6] *Bisfāyij* (*Polypodium vulgare* L.),[7,8] and *Suranjān talkh* (*Colchicum luteum*),[8] are some of the most commonly used drugs for their anti-arthritic and anti-inflammatory activity. Many Unani compound formulations such as *Ma'jūn Sīr 'Alvī Khān*,[9,10] *Ma'jūn Suranjān*,[11]

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Majūn Azārāqī,[12] *Ḥabb-i-Gul-i-Ākh*,[13] *Habb-i-Ḥudār*,[14] and a pharmacopoeial compound formulation of three drugs (*Suranjān talkh*, *Ṣibr,* and *Zanjabīl*)[15] have been reported to possess significant anti-arthritic and anti-inflammatory activity. However, questions are raised time and again over the safety standards of Unani and other herbal medicines.[16] Furthermore, many of the pharmacopoeial and even nonpharmacopoeial preparations which produce significant anti-inflammatory, analgesic, and anti-arthritic activity are yet to be scientifically studied. The safety and efficacy of a polyherbal pharmaceutical formulation depend on the authenticity of raw material. Therefore, the standardization of its ingredients is also mandatory to work out, for example, the market sample of "*Kāla Dhatūra*" obtained from Hyderabad was not found to be the seeds of *Datura metel* L. but consisted of the seeds of *Argemon mexicana* Linn.[17] In case of Polypharmaceutical preparation, the use of adulterated drugs and use of drugs less than the prescribed quantity or total absence of the costly ingredients such as Musk, Amber, and Saffron affect the quality of formulation. As per the guidelines of WHO 2007, it is very necessary to evaluate a herbal drug single or polyherbal pharmaceutical drug on parameters of safety studies. In the present study, an anti-arthritic Unani compound formulation "*Qurṣ Mafāṣil Jadīd*" mentioned in *Qarābādīn Majīdi*[18] was investigated on the parameters safety studies such as heavy metals estimation, microbiological determination, mycotoxin (Aflatoxin) estimation, and pesticidal residue estimation.

Methodology

According to the "*Qarābādīn Majīdi*" the Unani formulation contains the following ingredients:

(1) *Suranjān Talkh* (*Colchicum luteum* L.- Dried Corm) 25 g
(2) *Haldī* (*Curcuma longa* L.- Dried Rhizome) 25 g
(3) *Ṣamagh-i-'Arabī* (*Acacia arabica* Willd.— Powder) 5 g.

The raw materials were purchased from the local market of Aligarh and the sample were authenticated in pharmacognosy section of the Department of Ilmul Advia, Faculty of Unani Medicine, Aligarh Muslim University, Aligarh, and found within range of standards as mentioned in API, 1999, 2001 and UPI, 2007. The two ingredients of formulation *Suranjān Talkh* and *Haldī* were powdered in an electric grinder and *Ṣamagh-i-'Arabī* (Gum acacia) is used as powder (S.D. Fine Chemical Ltd). All the three ingredients were mixed together to make *Lubdī* (dough). The mixture was dried in shed and then powdered in a mortar. This powdered material in the requisite degree of fineness mixed and damped with a moistening agent (purified water) in sufficient quantity (Q.S). The moistened material was made into granules by passing through a sieve (12 No.). In this formulation, some excipients such as *Sang-i-Jarāḥat* and Magnesium sulfate in fine powdered form and liquid paraffin in minute quantities (0.25–0.50% w/w) were mixed in granules before passing it to the dye of tablet making machine for the purpose of anti-cacking, preservation, drying, and lubrication. After that the processed drug was passed through the dye and 500 mg tablets were made by automatic tablet making machine in Dawākhāna Ṭibbiya College, AMU.[18-22]

After making of tablet QMJ, it was subjected to safety studies, which was done at Delhi Test House, New Delhi.

Safety studies

Heavy metals estimation

The test drug (Q.M.J.) was studied to evaluate the presence of heavy metals, if any by using ICP-MS.

Sample preparation

Protective cap and the seal from Teflon vessel was removed (Microvave Digestive System) present inside the protective casing. 0.1 g of sample was taken in cleaned vessel. 5 ml of HNO3 (Nitric acid), 5 ml of de-ionized water was added and the vessel was closed. Out of all the vessels, one was kept for acid blank only (without sample). Teflon compressor kit was used to create vacuum inside the vessels. The seal and protective cap was put back, tightened the venting screw till they are fingers tight. The vessels were fitted in the Rotor to their numbers, now; Microwave Digestive System was switched on. After that, the vessels were taken out one by one carefully and decant the sample in the 100 ml volumetric flask; the volume was made up to 100 ml with deionized water. The sample was filtered with 0.45 micromembrane filter papers and put the filtrates in the sample containers to be nebulized into the ICP-MS.[23]

Calculation

Final (Conc.) in ppm = Measured Conc. # D.F./Sample weight (g) # 100

Where D.F. is the dilution factor.

Microbiological determination test

Method: Total bacterial count

The sample was pretreated being examined as described below:

Water soluble products: 10 g drug was dissolved in 90 ml sterile-buffered sodium chloride solution pH 7.0 and serially diluted up to 10 to the power 5 dilution.

Water in soluble (nonfatty): 10 g drug was dissolved in 90 ml sterile-buffered sodium chloride solution pH 7.0 + 0.1 w/v polysorbate 80, mix well and serially diluted up to 10^5 dilution.

Water insoluble (fatty): 10 g drug was dissolved in 5 g Polysorbate 20, heated at 40c + 85 ml sterile-buffered sodium chloride solution, maintained at 40°C for 30 min. and serially diluted up to $10 - {}^{5}$ dilution.

Media: Casein soyabean digest agar.

Incubation temperature and duration: 30°C to 35°C for 5 days.

Method: Total yeast and mold count

The sample was pretreated being examined as described below.

Water soluble products: 10 g drug was dissolved in 90 ml sterile-buffered sodium chloride solution pH 7.0 and serially diluted up to 10^5 dilution.

Water insoluble (nonfatty products): 10 g drug was dissolved in 90 ml sterile-buffered sodium chloride solution pH 7.0 + 0.1% w/v polysorbate 80, mix well and serially diluted up to 10^5 dilution.

Water insoluble (fatty products): 10 g drug was dissolved in 5 g polysorbate 20, heated at 40°C 85 ml sterile-buffered sodium chloride solution, maintained at 40°C for 30 min and serially diluted up to 10^5 dilution.

Media: Sabouraud dextrose agar with antibiotics.

Incubation temperature and duration: 20°C to 25°C for 5 days.

Method for Specific Pathogen

For *Escherichia coli:* 1 g pretreated sample was added in 50 ml nutrient broth, shacked well, allowed to stand for 1 h and shacked again and incubated at 37°C for 18-24 h.

For *Salmonella:* 1 g pretreated sample was added in 100 ml nutrient broth, shacked well, allowed to stand for 1 h and shacked again and incubated at 35°C–37°C for 24 h.

For *Staphylococcus aureus*: 1 g pretreated sample was added in 100 ml soya been casein digest medium, incubated at 35°C–37°C for 24–48 h.

For *Pseudomonas aeruginosa:* 1 g pretreated sample was added in 100 ml soyabeen casein digest medium, incubated at 35°C–37°C for 24–48 h.[23]

Mycotoxin estimation

Sample preparation

Two grams sample was blended at high speed with 20 ml of 60% acetonitrile/water for two min. The blended sample was centrifuged for ten min using 1600 (a v), the supernatant was retained, diluted 2 ml of filtrate with 48 ml of phosphate-buffered saline (PBS, pH 7.4) to give a solvent concentration of 2.5% or less; methanol/water extract should be prepared by taking 2 ml of sample and diluting with 14 ml of PBS (pH 7.4) to give a solvent concentration of 10% or less. The sample diluent was passed through the immunoaffinity column at a flow rate of 5 ml/min. The column should be then washed by passing 20 ml of distilled water through the column at the flow rate of approximately 5 ml/min. The column was dried rapidly passing air through it. 1.5 ml of distilled water was added to the sample elute. 500micro l of sample was injected onto the Liquid chromatography-tandem mass spectrometry (LCMS-MS) (LC- Perkin, MS Applied Bio System. Model N0.2000, Mobile Phase. A- Water 100%, B- CAN 100%, Column oven temperature = 30, Column-ZORBAX Rx c18, narrow base 2.1 × 150 mm – 5 micron, Flow = 0.750 ml). The aflotoxin concentration was quantified by comparing sample peak heights or areas to the total aflatoxin standard (R-Biopharm).

Pesticidal residue estimation

2 g sample drug was taken in 5 ml Ethyl acetate, extraction was made for two min. and then centrifuged for two min. at 10,000 rmp, the supernatant layer was taken and 1 ml was injected to Gas chromatography-tandem mass spectrometry (GCMS).[20]

Observations and Results

The results of various assays for toxins in *Qurṣ Mafāṣil Jadīd* are provided in Tables 1-4.

Discussion

It is estimated that nearly 70%–80% of the people globally use some form of herbal medicine, often without informing the healthcare practitioners. In some cases, these herbal formulations or drugs may be adulterated or substandard, leading to unpleasant outcomes. Moreover, there are also reports of some adverse effects with such self-medication

Table 1: Determination of heavy metal content

Test for heavy metals (mg/kg)	Test results	Permissible limits
Lead as Pb	6.319	Not more than 10 ppm
Mercury as Hg	0.590	Not more than 1 ppm
Arsenic as As	0.159	Not more than 3 ppm
Cadmium as Cd	Not detected	Not more than 0.3 ppm

Table 2: Determination of microbial load

	Test results	Permissible limits
Test for microbiology (CFU/g)		
Total bacterial count	17,600	Not more than 1×10^5 CFU/g
Total fungal count	760	Not more than 1×10^3 CFU/g
Any specific pathogens/g		
Escherichia coli	Absent	Absent
Salmonella	Absent	Absent

Table 3: Determination of aflatoxins

Total aflatoxins (mg/kg)	Results	Permissible limits
Aflatoxin B1	Not detected	Not more than 0.5
Aflatoxin B2	Not detected	Not more than 0.1
Aflatoxin G1	Not detected	Not more than 0.5
Aflatoxin G2	Not detected	Not more than 0.1

Table 4: Determination of pesticide levels

	Results	Permissible limits
Organochlorine pesticides (mg/kg)		
Aldrin and dieldrin (sum of)	Not detected	0.05
Chlordane	Not detected	0.05
DDT	Not detected	1.0
Endosulfan	Not detected	3.0
Organophosphorus pesticides (mg/kg)		
Diazinon	Not detected	0.5
Ethion	Not detected	2.0
Parathion	Not detected	0.5
Chlorpyrifos	Not detected	2.0
Chlorpyrifos methyl	Not detected	0.1
Synthetic pyrethroids (mg/kg)		
Cypermethrin	Not detected	1.0
Permethrin	Not detected	1.0

DDT: Dichloro-diphenyl-trichloroethane

including alteration of drug activity, toxicity, and presence of heavy metals which leads to several complications. Hence, adhering to the scientifically approved standards is imperative to drug safety, in both conventional and herbal drugs. Determination of safe levels of chemicals and biological material in the drugs is also an important aspect of making the drug suitable for use.[24] Therefore, safety study such as determination of heavy metals, for example, lead, cadmium, arsenic, and mercury, determination of pesticide residue, aflatoxin estimation, and microbial load evaluation is necessary for herbal drugs as per the WHO guidelines (1998) because they may cause serious side effects in human beings if the crude drugs are mixed or contaminated with these agents.[25] In this context, we conducted this study to assess *Qurṣ Mafāṣil Jadīd*, a unani pharmacopeial formulation, on the WHO standard of safety.

Heavy metals such as lead, arsenic, mercury, and copper are commonly used in most traditional medicines. Although they exert important therapeutic effects, their concentration beyond the permissible limits may cause several complications and disorders such as toxic effects, liver, and kidney failure. In some cases, severe side effects such as agranulocytocis, Cushing's syndrome, coma, and excessive increase of the international normalized ratio have also been reported.[26] In the present study, on *Qurṣ Mafāṣil Jadīd*, in determination of heavy metals such as lead, arsenic, mercury, and cadmium, it was found to be as 6.319 ppm, 0.159 ppm, and 0.590 ppm, respectively, and cadmium was not detected. All the three heavy metals detected were found in the range of permissible limits [Table 1].

Pesticide contamination of medicinal plants, as well as their formulations has been increasingly reported. In recent studies, it has been found that about 75% of samples may contain at least one organochlorine pesticide. Most pharmacopoeias have assay methods and residual limits for the pesticides. The analytical methods for qualitative and quantitative determinations of multiple pesticide residues include Gas Chromatography (GC), High Performance Liquid Chromatography (HPLC), Gas Chromatography-Mass Spectrometry (GC/MS), High Performance Liquid Chromatography-Mass Spectrometry (HPLC/MS), and Supercritical Fluid Chromatography (SFC), capillary electrophoresis, and enzyme linked immunosorbent assay.[27] In pesticidal residue determination in *Qurṣ Mafāṣil Jadīd*, the organochlorine pesticides such as aldrin, dieldrin, chlordane, Dichloro-diphenyl-trichloroethane (DDT), Endosulfan, Organophosphorus pesticides like Diazinon, Ethion, Parathion, Chlorpyrifos, Chlorpyrifos methyl, and Synthetic Pyrethroids such as Cypermethrin and Permethrin were not detected [Table 2].

Medicinal herbs and supplements can be contaminated by various fungi during various processes like harvesting, handling, storage, and distribution. Poor conditions of storage, distribution, and transportation are also conductive to fungal growth. Mycotoxins are the natural toxins produced by many fungal species, like *Fusarium*, *Aspergillus*, and *Penicillium*. These compounds can cause adverse effects such as carcinogenic, genotoxic, teratogenic, nephrotoxic, hepatotoxic, and dermatotoxic effects in human beings and animals.[28] In the present study, mycotoxins (Aflatoxin B1, Aflatoxin B2, Aflatoxin G1, and Aflatoxin G2) were also not found in the test drug [Table 3].

Due to their natural origin, herbal drugs are more prone to microbiological contaminants. Further, microbial contamination may occur during harvesting and processing. Furthermore, the microbial contamination of herbs and products may result from improper handling during production and packaging. The most likely sources of contamination are microbes from the ground and processing facilities (contaminated air, microbes of human origin, etc.), hence, they also indicate unhygienic manufacturing conditions.[29] In the present study, in microbial load evaluation, it was found to be within limit as total bacterial count 17,600 cfu/g and total fungal count 760 cfu/g. Any specific pathogen such as *E. coli* and *Salmonella* was found to be absent [Table 4].

Conclusion

It is evident after the safety and purity evaluation of *Qurṣ Mafāṣil Jadīd* that the formulation satisfies all prescribed norms of WHO. This also validates that the Unani principles which include collection of raw material, processing, and making them into formulations is well-researched and based on keen observation and experimentation. This also makes it imperative that more Unani formulations should be evaluated on the prescribed safety standards to enable their use on a larger scale.

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Conflicts of interest

There are no conflicts of interest.

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Maghz-i-Nārjīl	C. nucifera	150
Tukhm-i-Bābūna	M. chamomilla	75
Maghz-i-Chilgheza	P. gerardiana	150
Qand Sufeid	White sugar	7000

M. chamomilla: Matricaria chamomilla, P. gerardiana: Pinus gerardiana, C. nucifera: Cocos nucifera, O. mascula: Orchis mascula, A. rotunda: Aristolochia rotunda, P. zeylanica: Plumbago zeylanica, T. bellirica: Terminalia bellirica, E. officinalis: Emblica officinalis, C. officinalis: Cinnamomum officinalis, P. longum: Piper longum, P. nigrum: Piper nigrum, Z. officinale: Zingiber officinale, V. vinifera: Vitis vinifera

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Hafiz, Khadija Abdul; Ahmad, Kaleem; Ahmad, Haqeeq

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