

Adverse Effect of Unani Pharmacopoeial Formulation *Qurs-E-Mulayyin*

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Abstract

Case Report

Introduction: Herbal drug formulations, including Unani medicine, are widely used but can cause adverse effects if not properly administered. This case study reports an adverse drug reaction (ADR) to *Qurs-e-Mulayyin*, an Unani compound prescribed for chronic constipation. **Methods:** A 45-year-old female presented with chronic constipation and was prescribed multiple Unani medications, including *Qurs-e-Mulayyin*. After the third dose, she experienced severe vomiting, diarrhea, dizziness, and weakness. To assess the causality of this ADR, the patient was evaluated using the Naranjo ADR Probability Scale and De-challenge method. **Results:** The ADR was attributed to the presence of Croton tiglium and Saqmoonina in *Qurs-e-Mulayyin*, known for their strong purgative effects. After discontinuing the medication, the patient's symptoms resolved within 36 hours. **Discussion:** The case highlights the potential risks of Unani medications with hot and dry temperaments and emphasizes the need for careful patient monitoring. ADR reporting is crucial for preventing similar incidents. **Conclusion:** *Qurs-e-Mulayyin* should be administered with caution, and any adverse effects should be promptly reported for regulatory review.

Keywords: Unani medicine; *Qurs-e-Mulayyin*; Chronic constipation; Unani formulations; Pharmacovigilance; Adverse effect.

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INTRODUCTION

Over the last three decades, the use of herbal drug formulation and supplements has expanded dramatically, with not less than 80% of people globally using them [1]. According to WHO report, approximately 80% of developing-country populations rely on traditional healthcare systems for primary care [2, 3].

Unani System of Medicine (USM) is an ancient system of medicine that uses a variety of treatments through herbs, mineral and animals' resource of drugs. Unani physicians follow two types of drug regimens based on single herbs and other is compound preparation. Compound preparations may be of classical, pharmacopoeial and propriety/patent. The selections of drug for any ailments depend upon the choice of physicians.

There is a misconception that Unani drugs are safe and have no negative effects on the body because of its natural ingredients. It is true to some extent, but not entirely. Unani doses can have adverse effects if they are

not prepared on standard parameters or if they are not detoxified before being added to a dosage form if necessary [4]. Unani drugs of all origins (plant, animal, and mineral) are categorized into four degrees depending on their temperament (*Mizaj*) and modes of action; all of which help to reduce adverse drug reactions. The greater the degree, the greater the chances of negative consequences [5, 6]. However, the drugs of higher degree especially 3rd and 4th one can be administered safely after a particular detoxification process (*Mudabbar*) [4, 5]. The cause of adverse drug responses in herbal medicine can vary, but risks connected with parenteral usage are higher because all medications are formulated for external or internal use [6]. Fault in purification, preparation, packaging, dosing and adulteration of herbals with prescription medications is a concern in many nations.

CASE PRESENTATION

Here I am going to present an adverse effect of a compound Unani pharmacopoeial drug *Qurs-e-Mulayyin* used for the Chronic Constipation in last week

of March 2024. A female patient of age 45 year comes to OPD of Govt. Tibbi College and Hospital, Patna for consultation and treatment of Chronic Constipation along with Knee Joint and Low Back pain. The patient was thoroughly examined and interrogated for the severity of knee joint pain, low back pain, and chronic constipation over past one year.

- *Mizaj* (Temperament): Bilious (Safravi)
- *Asbabe Sitta Zarooriya* factor: relevantly altered
- Air/Eatables: Altered dietary habit
- *Harkat- Sukoon badni/ nafsani*: Anxious and irritable
- *Naum/Yaqza*: Inadequate sleep
- *Ehtebas/ istefragh*: Ghair tabai Ehtebas/Constipation
- Social History: She denies alcohol, tobacco and illicit drug use. She is married and a home maker.
- Allergies: No known medicine, food, or environmental allergies.
- Past Medical History: NAD
- Past Surgical History: NAD
- Physical Examination: Gait- Normal, Mild crepitus/grinding present in left knee.
- Vitals: Temperature 97.8 F; heart rate 70; respiratory rate 22; blood pressure 100/80;

- General: Well, appearing but anxious and irritable, a pleasant female with conscious mind.
- Respiratory: She has a regular respiratory rate with no any abnormal sounds.
- Cardiovascular: She has a normal heart rate.
- Gastrointestinal: Bowel sounds normal. No bruits or pulsatile mass.

After examination in PSM OPD she was provisionally diagnosed with Chronic constipation, Knee joint pain and Low back Pain and prescribed pharmacopeial preparations *Habb-e-Azaraqi*, 1*BD (Twice a Day) manufactured by New Shama (Lab Batch No. B-0477), *Habb-e-Tinkar*, 2* BD(Twice a Day), manufactured by New Shama (Lab Batch No. A4584), *Qurs-e-Mulayyin 2* at bed time with luke warm water, manufactured by Hakeem Baqai's Medicare (Lab Batch No.020), *Habb-e-Suranjan*, 2*BD(Twice a Day), manufactured by New Shama (Lab Batch No. B2024), Roghan Surkh, Local Application, manufactured by New Shama (Lab Batch No. A4579). The ingredients, therapeutic actions and uses of these Unani pharmacopeial are as follows.

Habb-e-Azaraqi: Habb-e-Azaraqi is a pharmacopeial Unani formulation having following ingredients and their Therapeutic actions (Table 1) and uses. Batch No. B-0477

Table 1: Pharmacopeial Unani formulation

Type	Name	Weight	Degree of Mizāj [9]
Azaraqi Mudabbar	<i>Strychnos nux-vomica</i>	100 mg	Hot ⁴ Dry ⁴
Filfil Siyah	<i>Piper nigrum</i>	50 mg	Hot ³ Dry ³
Filfil Daraz	<i>Piper longum.</i>	50 mg	Hot ² Dry ²
Arq Ajwain	<i>Ptychotis ajowan</i>	50 mg	Hot ³ Dry ³

- **Action:** *Muqawwi-ī-Dimāgh* (Braintonic), *Muqawwi-ī-'asāb* (Nervetonic), *Muharrik-ī-a 'sāb* (Nervine stimulant) [7, 8].
- **Therapeutic use** *Sara* (Epilepsy), *Fālij* (Hemiplegia), *Laqwa* (Facial palsy), *Ra 'sha* (Tremor), *Niqras* (Gout), *Waja 'al Mafāšil* (Polyarthritis) [10].
- **Dose** 250 to 500 mg.

Habb-e-Tinkar: Habb-e-Tinkar is a pharmacopeial Unani formulation having following ingredients and their therapeutic (Table 3) actions and uses. Batch No. A-4584.

Table 3: Pharmacopeial Unani formulation

Type	Name	Weight	Degree of Mizāj
Suhaga Biryani	<i>Borax dehydrated</i>	29 mg	Hot ³ Dry ³ [11]
Ajwain khurasani	<i>Hyoscyamus niger</i>	37mg	Cold ³ Dry ³ [12]
Filfil Siah	<i>Piper nigrum.</i>	174 mg	Hot ³ Dry ³ [12]
Sibr Zard	<i>Aloe barbadensis</i>	260 mg	Hot ² Dry ² [11]

- **Action and uses** Habb-e-Tinkar helps to remove heaviness as well as weakness of the stomach, boosts appetite, aids in

anorexia, gas and chronic constipation, relieves flatulence and relieves stomach ache [7].

- **Dose of the medicines**
500-1000mg

ingredients and their therapeutic (Table 4) actions and uses. Batch No. 020

Qurs-e-Mulayyin: Qurs-e-Mulayyin is a pharmacopoeial Unani formulation having following

Table 4

<i>Unani Name</i>	<i>Botanical/Scientific Name</i>	<i>Weight</i>	<i>Degree of Mizāj</i>	<i>Chemical composition</i>	<i>Action/(s)</i>
<i>Gulab</i>	<i>Rosa damascena</i>	26.3 mg	Cold ² Dry ² [12]	Terpene, Glycosides, Flavonoids, Anthocyanin, Myrcene, Vitamin C. [15]	Laxative, Prokinetic effect. [15]
<i>Elwa</i>	<i>Aloe barbadensis</i>	78.9 mg	Hot ² Dry ² [11]	Lignin, Saponin, Salicylic acid, Amino acid, Anthraquinones. [16]	Anti-bacterial, Analgesic, Laxative, Anti-ageing. [16]
<i>Usara e Rewand</i>	<i>Rheum emodi</i>	26.3 mg	Hot ² Dry ² [12]	Anthraquinones, Stilbene, Flavonoids, Oxalic acid, Lignins, Phenols. [17]	Anti-inflammatory, Anti-oxidant, Anti diabetic, Anti-ulcer, Hepatoprotective, Nephroprotective. [17]
<i>Sana</i>	<i>Cassia angustifolia</i>	105.2 mg	Hot ² Dry ¹ [12]	Anthraquinones, Flavonoids. [18]	Laxative, purgative, Anti-inflammatory, Anti-oxidant, Anti diabetic, Anti-ulcer, Hepatoprotective, Nephroprotective. [18]
<i>Haleela Zard</i>	<i>Terminalia chebula</i>	105.2 mg	Cold ¹ Dry ² [12]	Tannins, Flavonoids, Sterols, Amino acids, Resins, Fructose [19]	Laxative, Astringent, Anthelmintic, Expectorant, Nervine tonic, Gastrointestinal Hypermotility. [19]
<i>Haleela Kabli</i>	<i>Terminalia chebula</i>	105.2 mg	Cold ¹ Dry ² [12]	Tannins, Flavonoids, Sterols, Amino acids, Resins, Fructose. [19]	Laxative, Astringent, Anthelmintic, Expectorant, Nervine tonic [19]
<i>Turbud</i>	<i>Operculina turpethum</i>	2.63 mg	Hot ² Dry ¹ [12]	Resins, Flavonoids, Glucosides, Terpethinic acid, Jalapine, Saponin, Ramnose. [20]	Purgative, Antipyretic, Cathartic, Anthelmintic, Expectorant, Carminative. [20]
<i>Habb us Salateen</i>	<i>Croton tiglium</i>	2.63 mg	Hot ⁴ Dry ⁴ [12]	Glycosides, Amino acid, Resin, Saponin, Flavonoids, Alkaloids, Steroids, Linoleic acid, Oleic acid, Elcosenoic acid. [21] Phorbol esters, crotonic acid. [22]	Purgative, Irritant, Expectorant, Detergent, Larvicidal [13]
<i>Saqmoonnia</i>	<i>Convovulus scammonia</i>	1.578 mg	Hot ³ Dry ³ [12]	cammonin resin, dihydroxy cinnamic acid, beta-methylesculetin, ipuranol, surcose, reducing sugar and starch [23]	Purgative, vasorelaxant, anti-platelet aggregation, anticancer and cellular protective effects [23]
<i>Asl us soos</i>	<i>Glycyrrhiza glabra</i>	26.3 mg	Hot ¹ Dry ¹ [12]	Glycyrrhizin, glycyrrhizinic acid, isoliquiritin, and glycyrrhizic acid. [24]	Anti-atherogenic, anti-cancer, anti-diabetic, anti-microbial, antispasmodic, anti-inflammatory, and anti-asthmatic. [24]
<i>Sang e Jarahat</i>	<i>Talc</i>	6.312 mg	Cold ² Dry ² [12]	Silica, Magnesia, Cao. [25]	Astringent, Haemostatics. [25]
<i>Samagh e Arabi</i>	<i>Acacia arabica</i>	13.15 mg	Cold ⁰ Dry ⁰ [12]	Arabic acid, Calcium, Magnasium, potassium carbonate, Malic acid, Sugar, Tannins, Mucilage.	Anti-inflammatory, Antitumor, Antiplatelet, Astringent, Haemostatic. [25]

- **Action:** Mulaiyyan (*Emollient*), Mushil (*Purgative*), Daf-e-alam (*Analgesic*) [26, 27].

Therapeutic use: *Qabz* (Constipation), *Qulanj* suddi (colic), *Suda-e-muzmin* (Chronic Headache) [28].

- **Dose:** 500 to 1000 mg.

Habb-e-Suranjan: Habb-e-Suranjan is a pharmacopoeial Unani formulation having following ingredients and their therapeutic (Table 5) actions and uses. Batch No. B-2024

Table 5: Pharmacopoeial Unani formulation

Type	Name	Weight	Degree of Mizāj
Elwa	<i>Aloe barbadensis</i>	20 mg	Hot ² Dry ² [11]
Tukhm e Soya	<i>Anethum sowa</i>	20 mg	Hot ² Dry ¹ [11]
Turbud Safaid	<i>Operculina turpethum</i>	55 mg	Hot ² Dry ¹ [12]
Habbul Neel	<i>Indigofera tinctoria</i>	20 mg	Hot ³ Dry ³ [11]
Suranjan Shireen	<i>Cholchicum autumnale</i>	47 mg	Hot ² Dry ² [12]
Gugul	<i>Commiphora mukul</i>	9 mg	Cold dry [11]
Mastagi	<i>Pistacia lentiscus</i>	9 mg	Hot ² Dry ² [12]

Action: Anti-inflammatory, Analgesic [14].

Therapeutic use: *Wajaul Mafasil* (Arthritis), *Niqris* (Gout), *Irqun nisa* (Sciatica) [7].

- **Dose of the medicines:** 180-360mg

OBSERVATION

The patient began taking the medication on the evening of March 29, 2024, and continued until the following evening. After the second dose the next evening, she experienced mild abdominal discomfort. She took the third dose overmorrow evening, which led to severe side effects: vomiting three times and diarrhoea four times. Her condition worsened significantly, causing dizziness, weakness, and difficulty in walking confidently.

Concerned, her guardian contacted the physician, who immediately called her in for an examination. After a thorough check-up, it was determined that her abdominal pain and discomfort were due to the vomiting and diarrhoea. The physician advised her to stop taking *Qurs-e-Mulayyin* immediately and to monitor her condition for the next 12 hours, with instructions to seek medical attention if there was no improvement.

Fortunately, her condition started to improve within those 12 hours. She began feeling better. Her health continued to improve steadily over the next 12 hours. After 36 hours, she was back to her normal self, able to read, walk, and carry out her tasks without any difficulty. No longer she experienced vomiting, diarrhoea, or dizziness. Upon evaluating the patient using the Naranjo Adverse Drug Reaction (ADR) Probability Scale, the score falls between 5 and 8, indicating a probable ADR.

DISCUSSION

If we look on the ingredients of *Qurs-e-Mulayyin* it reveals that 7 ingredients are hot and dry in temperament and 4 ingredients are cold and dry temperament. As per the Unani text, *saqmoonia* (*Convovulus scammonia*.) and *habb us salateen* (*Croton tiglium*) is the chief ingredient of *Qurs-e-Mulayyine* having hot and dry of 3rd degree of temperament, hot and dry of 4th degree of temperament respectively [12]. Active ingredients of *saqmonia* works when it reaches to the duodenum, in the duodenum active principle reacts with bile, and a chemical reaction occurs between it and taurocholate and glycocholate of sodium and it converted into a powerful purgative, which acts on intestinal mucosa and there is increase oozing of fluid which results in increase peristaltic movement and flatulence and finally leads to watery diarrhea. First motion is soft but later on, watery stool passes away [29,30]. This action is purely local. *Saqmonia* does not act via blood circulation, it only acts locally on intestinal mucosa [30] also when *saqmonia* administered in weak, deliberated persons in a large dose more than therapeutic doses it acts as a strong intestinal irritant and lethal to the subject [31]. *Croton tiglium* seeds, known as *Jamāngoṭa* in Hindi, Marathi, and Urdu is well-known for its toxicity (severe purgative action). The toxicity of *C. tiglium* seeds may be due to the presence of phorbol esters and crotonic acid along with other constituents [22]. *Croton tiglium* is the most powerful laxative [32,33], which have stimulative action on bowel movement causing severe cramps during defecation and loose stools. *Croton tiglium* oil increase or decrease gastrointestinal motility by affecting contractile frequency and amplitude of intestinal smooth muscle depending on the dose of oil [33]. Active proteins of *Croton tiglium* as to oral medication can cause injury in the digestive tract, which manifested as congestion, bleeding, serious edema and other symptoms. Oral administration of the proteins caused gastrointestinal edema by increasing the intestinal

permeability. Oral medication of croton oil is able to cause gastrointestinal edema and diarrhea [34]. The three most common and distinctive signs of the presence of *Croton tiglium* in diarrhoea, cholera, cholera infantum, and cholera morbus are yellow, watery faeces, abrupt emesis, and discomfort [35]. In this case, after discontinuing *Qurs-e-Mulayyin* following a careful observation and examination, the patient's health improved significantly. The patient reported feeling better within 24 hours and returned to normal within 36 hours after stopping the medication.

CONCLUSION

Herein, we have discussed the adverse effects of *Qurs-e-Mulayyin*. We have described how ADRs are predicted, prevented, detected and managed. This type of adverse effects encourages physicians and researchers to be vigilant in their patients and report suspected cases to regulatory authorities and pharmaceutical corporations. However, doctors regarded as trustworthy sources of information, are frequently consulted when such effects occur.

According to the material in this report, *Qurs-e-Mulayyin* should be supplied with instructions to immediately report any reactions to the authorities. The reporting of such incidents may provide data for the analysis of ADRs related to other herbal medications. Therefore, ordinary individuals may be urged to take the medicine with care.

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