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A Clinical Study on the Management of Uterine Fibroid (*Sal'āt- al-Raḥim*) with an Unani Polyherbal Formulation: A Case Report

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ABSTRACT:

In the Unani system of medicine, uterine fibroids are referred to as *Sal'āt-al-Raḥim*. Also known as leiomyomas, these benign tumors are composed of smooth muscle and connective tissue within the myometrium. Uterine fibroids are a major health concern, with their prevalence varying across ethnic groups. Studies suggest that over 50% of women above the age of 45 are affected. This paper presents a case report demonstrating significant symptomatic improvement and normalization of myometrial thickness following Unani treatment. A female patient who presented with lower abdominal pain, lower back pain, dysmenorrhea, and blood clot passage was diagnosed with an intramural fibroid (1.2 × 1.1 cm) in the posterior myometrium. She was treated with an Unani polyherbal formulation in capsule form, consisting of 50% hydro-alcoholic extracts of *Karonda* (*Carissa carandas* Linn), *Khar-e-Khasak* (*Tribulus terrestris* Linn), *Mako* (*Solanum nigrum* Linn), *Beekh-e-Kasni* (*Cichorium intybus* Linn), *Bhumi Amla* (*Phyllanthus niruri* Linn), and *Chirayata Shireen* (*Swertia chirata* Linn). The prescribed dosage included two (500 mg) capsules twice daily after meals, along with *Majoon Dabeedul Ward* (7 gm BD) with plain water for 90 days. The patient was clinically assessed every fortnight and underwent a radiological evaluation after treatment. The post-treatment ultrasonography results were highly encouraging, revealing complete resolution of the uterine fibroid without the need for surgery. The treatment proved to be highly effective, providing significant symptom relief without any observed side effects. This case study highlights the potential of Unani medicine as a successful, non-invasive approach to managing uterine fibroids.

KEYWORDS: *Majoon Dabeedul Ward Sal'āt- al-Raḥim*, Unani polyherbal formulation.

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INTRODUCTION:

Uterine fibroid lesions were historically referred to as "uterine stones" and later as scleromas. In the second century AD, the term "fibroid" was introduced in the 1860s. These fibroids are the most common pelvic tumors in women of reproductive age, affecting over 70% of women worldwide, with a higher prevalence among women of color. In the United States, the prevalence among African American women is about 60% by age 35, increasing to over 80% by age 50. [1] In contrast, the prevalence among Caucasian women is lower, with 40% affected by age 35 and nearly 70% by age 50. Similar patterns are observed in Italy, while Swedish women have a lower incidence. [2-3] In India, uterine fibroids affect approximately 37% of women aged 20–40 and 57% of women aged 40–59. The fibroid pseudo-capsule is a fibro-neurovascular structure that surrounds the fibroid, distinguishing it from normal myometrium. [4] Although benign, uterine fibroids contribute to significant morbidity. They are the leading cause of hysterectomy and a major factor in gynecologic and reproductive disorders, including menorrhagia, pelvic pain, infertility, recurrent miscarriage, and preterm labor. [5-6] In the United States, the estimated annual healthcare cost related to uterine fibroids is around $34 billion, highlighting the substantial societal and financial burden they impose. [7] Their prevalence is increasing, particularly among African American women, though actual incidence rates may be underestimated due to asymptomatic or mildly symptomatic cases. Only 25% to 30% of women report noticeable clinical symptoms. Fibroid pathology involves the expansion of connective tissues and smooth muscle in the uterus. Their growth is influenced by estrogen and progesterone, with elevated estrogen levels promoting development. Infertility may result from the narrowing of the isthmic section of the fallopian tube or obstruction by submucosal fibroids. In rare cases, fibroids can undergo malignant transformation into sarcomas. [8] Risk factors for fibroid growth include both modifiable and non-modifiable elements. These factors comprise age, race, hormonal influences (both endogenous and exogenous), obesity, uterine infections, and various lifestyle choices such as diet, coffee and alcohol consumption, exercise, stress, and smoking. Additional risk factors include advanced age, premenopausal status, nulliparity, family history, hypertension, frequent intake of soybean milk, and food additives. Other contributing factors are obesity, vitamin D deficiency, excessive vitamin E levels, reproductive tract microbiome alterations, endocrine-disrupting chemicals, and adverse early-life environmental exposures. Tobacco and alcohol use also play a role in fibroid development.[9]

Fibroids are commonly classified into three types.

1. **Intramural (or interstitial) fibroids** (75%) develop within the myometrium, the muscular layer of the uterus.
2. **Sub-serosal (or sub-peritoneal) fibroids** (50%) originate as intramural fibroids but grow outward toward the peritoneal cavity, partially or entirely covered by the peritoneum. When these fibroids develop pedicles, they are referred to as pedunculated subserosal **fibroids**.
3. **Submucosal fibroids** (5%) grow beneath the endometrium, extending into the uterine cavity, which can lead to

uterine irregularities and deformation. [10-11]

In the Unani system of medicine, tumors are referred to as "Salaat," a subtype of *Waram-e-Balghami* (phlegmatic swelling). *Salʻāt* is further classified into benign (*Salʻa Salīma*) and malignant (*Salʻa Khabītha*). *Salʻa Salīma* resembles the organ in which it forms, is painless, and does not spread to nearby lymph nodes. Uterine fibroids, known as *Sal'āt-al-Raḥim*, fall under *Salʻa Salīma* in Unani medicine.

The renowned Unani scholar Ibn Hubal Baghdadi (1121–1213 CE) mentioned in his classical work *Kitab-Al-Mukhtarat-Fil-Tibb* that these tumors originate from viscous phlegm (*balgham*). Similarly, Ibn Sina (980–1037 CE) described them under the topic of *Salʻāt* (tumor) as *Dunbula-e-Balghami*, characterized by a lump containing abnormal phlegm (*Ghair Tab'yi Khilth-e-Balgham*), which may be bloody or have a honey-like viscosity. [12] Ali Ibn-e-Abbas Majusi (930–994 CE) also classified it under *Waram-e-Balghami*, describing it as a swelling filled with thick phlegm (*Balgham-e-Ghaleez*). [13]

This condition is further divided into four types:

- *Salʻa Shaḥmiyya* (fat-like)
- *Salʻa ʻAsaliyya* (honey-like)
- *Salʻa Ardahāliyya* (flour-like)
- *Salʻa Shīrāẓiyya* (milk-like)

Treatment involves medications with *Muḥallil-i-Awrām* (resolvent), *Munḍij-i-Balgham* (maturative for phlegm), and *Qābiḍ* (astringent) properties. Soft swellings are directly treated using *Muhallil-e-Waram* and *Qābiḍ* drugs. However, for firm swellings, *Munḍij-i-Balgham* drugs are first used to soften the swelling, followed by the administration of *Muḥallil-i-Awrām* and *Qābiḍ* medications.[14]

Management includes both medical and surgical treatments. Medical treatment involves hormonal drugs like gonadotropin-releasing hormone analogs, which suppress estrogen production. Progesterone, raloxifene, and aromatase inhibitors help shrink fibroids, while danazol reduces bleeding. [15] **Surgical options** include **hysterectomy** (removal of the uterus) and **myomectomy** (removal of fibroids while preserving the uterus).

CASE PRESENTATION:

A 39-year-old married woman presented with complaints of a dull ache in her lower abdomen and lower back, persisting for the past 5–6 months, accompanied by heavy menstrual bleeding over the last 4–5 months. Her current menstrual history reveals a flow duration of 4–5 days, requiring 3–4 fully soaked sanitary pads per day, with a cycle length of 26–28 days. She also experiences dysmenorrhea and has a history of passing clots. This condition has gradually worsened, significantly impacting her daily life. Married for 12 years, she is P2, L2, A1, with her last childbirth occurring approximately 3.5 years ago via Lower Segment Caesarean Section (LSCS). She had a spontaneous abortion at 1.5 months of gestation two years ago. The patient has no history of hypertension, diabetes mellitus, thyroid disorders, chronic illnesses, drug allergies, or blood transfusions. Additionally, there is no family history of benign or malignant diseases. Her treatment history includes the use of allopathic medications, which resulted in serious side effects such as dizziness, anxiety, and headaches.

However, the exact details of the medications were unavailable. She reported that previous treatments did not provide satisfactory relief. Seeking alternative care,

she visited the Outpatient Department (OPD) of *Amraz-e-Niswa-wa-Qabalat* (Gynecology and Obstetrics) at Ayurvedic and Unani Tibbia College, Karol Bagh, New Delhi. Following a review of her medical history and clinical examination, routine blood tests, CT, BT, thyroid profile, and RBS were recommended. She also provided a prior ultrasound scan of her whole abdomen, confirming the presence of an intramural fibroid (1.2 × 1.1 cm) in the posterior myometrium. The endometrial thickness measured 4.8 mm, and the uterus was bulky with dimensions of 94 × 53 × 39mm. [fig:1] No adnexal pathology was observed. Additional findings included mild hepatomegaly with Grade I fatty liver infiltration and bilateral renal calculi. Blood investigations were within normal limits.

THERAPEUTIC INTERVENTION

Medications:

She was treated with a 50% hydroalcoholic extract of an Unani polyherbal formulation containing medicinal ingredients with *Muḥallil-i-Awrām-i-Ahsha* (visceral anti-inflammatory), *Musakkin-i-Alam* (analgesic), and *Qābiḍ* (astringent) properties. The treatment regimen included two capsules (each 500 mg), taken orally twice a day after meals, along with *Majoon Dabeed-ul-ward* (7 gm) for 12 weeks, administered with plain water. The polyherbal extract was sourced from Vital Herbs, Uttam Nagar, Delhi, India. *Majoon Dabeedul-ward* is an Unani pharmacopeial compound drug, marketed by the GMP-certified company Hamdard and formulated as per Bayaz-e-Kabeer, Volume 2. Further details are provided in Table 1.

Diet and lifestyle modifications

The patient was advised to include fiber-rich foods in her diet, such as fruits (like oranges, apples, and grapes), vegetables (including cabbage, broccoli, and green leafy varieties), and whole grains, to promote bowel regularity and aid in lowering estrogen levels. She was also instructed to avoid foods known to increase phlegm production (*Muwallid-i-Balgham Aghziya*), including red meat, junk food, processed items, and high-fat dairy products such as cheese, butter, and ice cream. Additionally, lifestyle modifications were recommended, including regular exercise, stress management, and maintaining a healthy weight, as these are crucial for effectively managing fibroids.

Results:

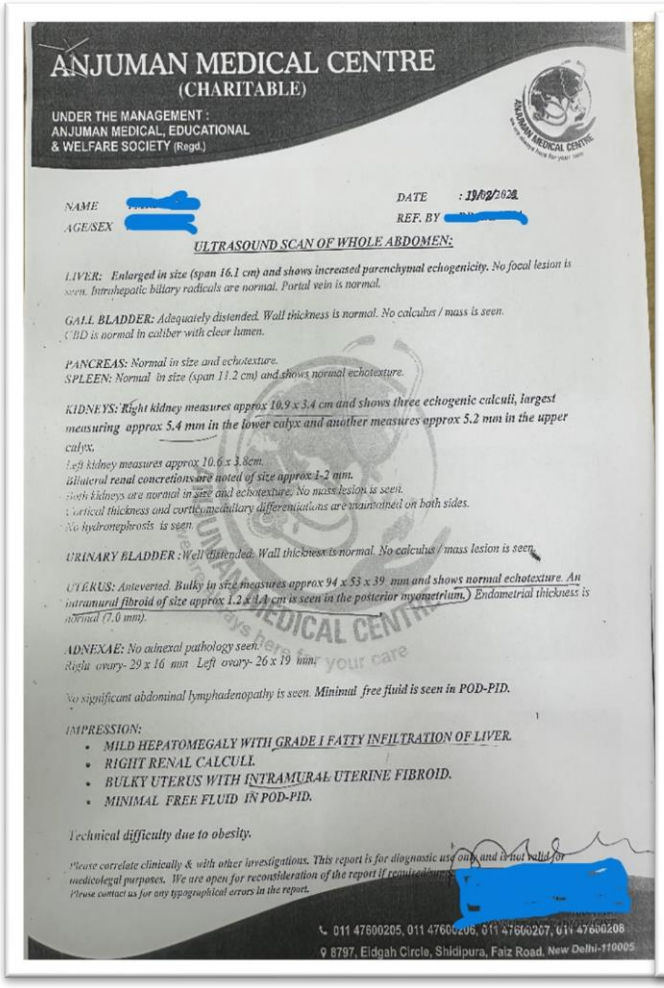
The patient was scheduled for biweekly visits after her menstrual cycle for three months. The treatment response demonstrated excellent and significant improvement both clinically and radiologically. After starting the treatment, the patient's menstrual cycles became regular, with moderate bleeding. Upon completion of the treatment, associated symptoms such as general weakness, fatigue, and pain subsided, with no reported side effects from the proposed Unani formulations. Notably, uterine fibroids were completely resolved after 12 weeks of treatment, as confirmed by USG scan findings, which showed a normal scan. A comparison of pre-treatment and post-treatment conditions is presented in Table 2.

Table-1: Composition of Unani formulation

Test Drugs (Extract)	Part used	Quantity	Mizaj (Temperament)	Actions (Afa'al)
Karonda (Carrisa carandas linn.)	Fruit	166mg	Cold & Dry	*Anti-tumor activity, Anti-carcinogenic effect, Muḥallil-i-Awrām (Anti-inflammatory), Musakkin-i-Alam (Analgesic), Anti-aging, Anti-oxidant, Hepatoprotective* [16]
Khar khasak (Tribulus terristris Linn)	Fruit	100mg	Cold & Dry (2)	*Anti-tumor activity, Muḥallil-i-Awrām (Anti-inflammtory)* [17-18]
Mako (*Solanum nigrum Linn)*	Fruit	42mg	Cold & Dry (2)	*Anti-tumor activity, Anticancer activity, Muḥallil-i-Awrām -i-Ahshah (Visceral Anti-inflammatory), Antioxidant, Musakkin-i-Alam (Analgesic), Hepatoprotective.* [19]
Beekh-e-Kasni (Cichorium intybus Linn)	Root	42mg	Hot & Dry (1,2)	*Muḥallil-i-Awrām-i-Ahsha (Visceral Anti-inflammatory), Muffat-e-sudad (Deobstrutent)Antioxidant, Hepatoprotective effect* [20]
Bhumi amla (Phyllanthus niruri Linn)	Whole plant	50mg	Hot & Dry (1,1)	*Muḥallil-i-Awrām (Anti-inflammatory), Qawi Muffatit e sudad (Deobstrurents), Antioxidant, Anticancerous, Hepatoprotective, Immunomodulatory action, and Cellular protective action, Antispasmodic,* [21]
Chirayata shireen (Swertia chirata Linn)	Whole plant	100mg	Hot & Dry (2,2)	*Muḥallil-i-Awrām (Anti-inflammatory), Anti-carcinogenic, Antioxidant, Hepatoprotective, Anti-mutagenicity Activity* [22]
Majoon Dabidul Ward	Semi-Solid Dosage	7gms	Muraqabbul quwa	

Table 2: Results in Menstrual History and USG Findings

Menstrual history	**Pre-treatment (0^{th} day)**	**Post-treatment (90^{th} day)**
Cycle	Irregular	Regular
Interval	Not fixed	27-29 days
Duration	6-9 days	5-6 days
Flow of Menstruation	Moderate with clots	moderate
Pain	Persistent daily	Mild
Clots	Jelly like++	Absent
Comparative USG Findings	**USG on 19/02/2024 (Fig No:1)**	**USG on 01/06/2024 (Fig No:2)**
Size of Fibroid (USG Findings)	➢ Intramural fibroid (1.2 × 1.1 cm) in the posterior myometrium. The endometrial thickness measured 4.8 mm, and the uterus was bulky with dimensions of 94 × 53 × 39mm ➢ Bilateral renal calculi (1-2mm) ➢ Mild hepatomegaly with Grade I fatty liver infiltration	No Fibroid was seen. The study reveals non-obstructive Bilateral Renal Calculi



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NAME [redacted]
AGE/SEX [redacted]
DATE : 19/02/2024
REF. BY [redacted]

ULTRASOUND SCAN OF WHOLE ABDOMEN:

LIVER: Enlarged in size (span 16.1 cm) and shows increased parenchymal echogenicity. No focal lesion is seen. Intrahepatic biliary radicals are normal. Portal vein is normal.

GALL BLADDER: Adequately distended. Wall thickness is normal. No calculus / mass is seen. CBD is normal in caliber with clear lumen.

PANCREAS: Normal in size and echotexture.
SPLEEN: Normal in size (span 11.2 cm) and shows normal echotexture.

KIDNEYS: Right kidney measures approx 10.9 x 3.4 cm and shows three echogenic calculi, largest measuring approx 5.4 mm in the lower calyx and another measures approx 5.2 mm in the upper calyx.
Left kidney measures approx 10.6 x 3.8cm.
Bilateral renal concretions are noted of size approx 1-2 mm.
Both kidneys are normal in size and echotexture. No mass lesion is seen.
Cortical thickness and corticomedullary differentiations are maintained on both sides.
No hydronephrosis is seen.

URINARY BLADDER : Well distended. Wall thickness is normal. No calculus / mass lesion is seen.

UTERUS: Anteverted. Bulky in size measures approx 94 x 53 x 39 mm and shows normal echotexture. An intramural fibroid of size approx 1.2 x 1.1 cm is seen in the posterior myometrium. Endometrial thickness is normal (7.0 mm).

ADNEXAE: No adnexal pathology seen.
Right ovary- 29 x 16 mm Left ovary- 26 x 19 mm.

No significant abdominal lymphadenopathy is seen. Minimal free fluid is seen in POD-PID.

IMPRESSION:
- MILD HEPATOMEGALY WITH GRADE I FATTY INFILTRATION OF LIVER.
- RIGHT RENAL CALCULI.
- BULKY UTERUS WITH INTRAMURAL UTERINE FIBROID.
- MINIMAL FREE FLUID IN POD-PID.

Technical difficulty due to obesity.

Please correlate clinically & with other investigations. This report is for diagnostic use only and is not valid for medicolegal purposes. We are open for reconsideration of the report if result [redacted]
Please contact us for any typographical errors in the report.

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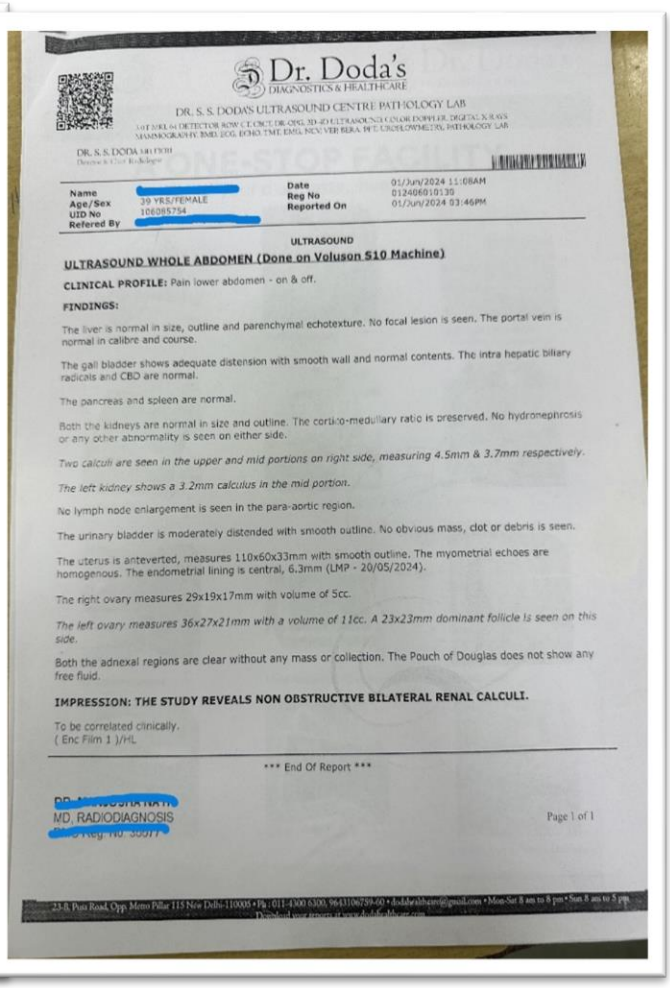

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Reported On 01/Jun/2024 03:46PM

ULTRASOUND

ULTRASOUND WHOLE ABDOMEN (Done on Voluson S10 Machine)

CLINICAL PROFILE: Pain lower abdomen - on & off.

FINDINGS:

The liver is normal in size, outline and parenchymal echotexture. No focal lesion is seen. The portal vein is normal in calibre and course.

The gall bladder shows adequate distension with smooth wall and normal contents. The intra hepatic biliary radicals and CBD are normal.

The pancreas and spleen are normal.

Both the kidneys are normal in size and outline. The cortico-medullary ratio is preserved. No hydronephrosis or any other abnormality is seen on either side.

Two calculi are seen in the upper and mid portions on right side, measuring 4.5mm & 3.7mm respectively.

The left kidney shows a 3.2mm calculus in the mid portion.

No lymph node enlargement is seen in the para-aortic region.

The urinary bladder is moderately distended with smooth outline. No obvious mass, clot or debris is seen.

The uterus is anteverted, measures 110x60x33mm with smooth outline. The myometrial echoes are homogenous. The endometrial lining is central, 6.3mm (LMP - 20/05/2024).

The right ovary measures 29x19x17mm with volume of 5cc.

The left ovary measures 36x27x21mm with a volume of 11cc. A 23x23mm dominant follicle is seen on this side.

Both the adnexal regions are clear without any mass or collection. The Pouch of Douglas does not show any free fluid.

IMPRESSION: THE STUDY REVEALS NON OBSTRUCTIVE BILATERAL RENAL CALCULI.

To be correlated clinically.
(Enc Film 1)/HL

*** End Of Report ***

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Fig-1: USG report before treatmen

Fig-2: USG report after treatment

DISCUSSION:

The treatment of uterine fibroids remains a challenge, as no universally accepted formulation has been proven to cure the condition, with hysterectomy being the only definitive solution. However, Unani medicine offers a range of formulations that may provide potential benefits in managing fibroids and alleviating associated symptoms. In this study, an Unani polyherbal formulation in capsule form was used, comprising 50% hydro-alcoholic extracts of *Karonda* (*Carissa carandas*), *Khar-e-Khasak* (*Tribulus terrestris*), *Mako* (*Solanum nigrum*), *Beekh-e-Kasni* (*Cichorium intybus*), *Bhumi Amla* (*Phyllanthus niruri*), and *Chirayata Shireen* (*Swertia chirata*). The effectiveness of this formulation is likely attributed to the specific medicinal properties of its constituents.

The therapeutic action of the Unani polyherbal formulation is due to the combination of various individual effects, such as. [17]

- *Muḥallil-i-Awrām-i- Ahsah* (Visceral anti-inflammatory)
- *Musakkin-i-Alam* (Analgesic)
- *Qābiḍ* (Astringent)

- *Dafi-i-Rutubat-al-Rahim* (Expellent of uterine fluids)
- Anti-fibroid activity of its constituents

The extracts of these medicinal herbs contain various bioactive compounds, including stigmasterol, β-sitosterol, quercetin, kaempferol, caffeic acid, astragalin, and gallic acid, which exhibit anti-fibroid activity through multiple mechanisms: [23]

1. **Halting cell proliferation** by inducing cell cycle arrest, regulating growth factors or their receptors, and stimulating the apoptotic pathway.
2. **Inhibiting fibrosis** by reducing the expression of profibrotic growth factors, preventing excessive extracellular matrix (ECM) deposition, and arresting activated cells involved in myofibroblastic transformation.
3. **Downregulating inflammatory mediators and glycolytic pathways**, implicated in fibroid growth and progression.

These bioactive compounds modulate and regulate essential biological processes responsible for fibroid development, providing a scientific basis for the efficacy of Unani medicine in fibroid management.

Another formulation, *Majoon Dabeedul Ward*, was administered containing various medicinal ingredients, including: [24]

- *Sumbuluttib* (*Nardostachys jatamansi*)
- *Mastagi* (*Pistacia lentiscus*)
- *Zafran* (*Crocus sativus*)
- *Tabasheer* (*Bambusa arundinacea*)
- *Darchini* (*Cinnamomum verum*)
- *Izkhar* (*Cymbopogon jwarancusa*)
- *Asaroon* (*Asarum europaeum*)
- *Qust Shreein* (*Saussurea lappa*)
- *Gul-e-Ghafis* (*Gentiana olivieri Griseb*)
- *Tukhm-e-Kasoos* (*Cuscuta reflexa*)
- *Majeeth* (*Rubia cordifolia*)
- *Luk-e-Maghsool* (*Coccus lacca*)
- *Tukhm-e-Kasni* (*Cichorium intybus*)
- *Tukh-e-Karafs* (*Apium graveolens Linn*)
- *Zarawand Taweel* (*Aristolochia rotunda*)
- *Habbe-e-Balsan* (*Balanites aegyptiaca*)
- *Ood Hindi* (*Aquilaria agallocha*)
- *Qaranfal* (*Eugenia aromatica*)
- *Heel Khurd* (*Elettaria cardamomum*)
- *Gul-e-Surkh* (*Rosa damascena*)

Majoon Dabeedul Ward is traditionally recommended for inflammation and swelling of the uterus. Its main ingredient, *Rosa damascena*, possesses analgesic and anti-inflammatory properties. Studies conducted on mice using formalin and acetic acid tests have demonstrated the potent analgesic effects of *Rosa damascena* hydroalcoholic extract.

Another key ingredient, *Zafran* (*Crocus sativus*), has been recognized for its antioxidant, anti-tumor, and anti-proliferative properties. In studies involving mice with intraperitoneally transplanted tumors, including sarcoma 180 (*S180*), Ehrlich ascites carcinoma (*EAC*), and Dalton's lymphoma ascites (*DLA*), researchers investigated the anticancer efficacy of *Crocus sativus* extract. The primary sources of its antioxidant activity were identified as carotenoid and flavonoid molecules, including glycosides of kaempferol and crocin.

Additionally, studies on Swiss mice and albino rats have examined the anti-inflammatory and analgesic effects of *Zingiber officinale* (ginger) rhizome extract. The findings suggest that *Z. officinale* contains one or more active compounds with significant analgesic and anti-inflammatory properties.

CONCLUSION:

It is concluded that the herbal formulations *Majoon Dabeedul Ward* and an Unani polyherbal formulation are effective in treating uterine fibroids (*Salʻāt- al-Raḥim*), as evidenced by significant symptom improvement and fibroid resolution. Therefore, these herbal drugs may serve as a potential medicinal treatment option for uterine fibroids, potentially reducing the need for surgical intervention.

Limitations of the Study:

Further clinical studies are needed to assess the efficacy of these drugs in larger sample sizes.

Declaration of patient's consent:

Informed written consent was obtained from the patient before treatment and publication, ensuring that the patient's identity remains undisclosed.

Conflict of interest: The author declares that there is no conflict of interest.

Guarantor*:* The corresponding author is the guarantor of this article and its contents.

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