

Effect of Unani Formulation in the Management of Menorrhagia (Kasrat-e-tams), Clinical Study

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Abstract

Menorrhagia is a common complaint of reproductive age group, denotes cyclic regular bleeding which is excessive in amount and duration or both. This leads to weakness, pallor, giddiness, discomfort and inconvenience in routine life. The incidence is reported to be 12.6-23.17% for gynecological admission in India. The present study was planned to evaluate the clinical efficacy and safety of 'Gulnar' capsules in the management of menorrhagia in reproductive age group. This study was carried out in OPD and IPD of Department of Qabalat wa Amraze Niswan, Faculty of Unani medicine A.K. Tibbya College, A.M.U Aligarh, during the period 2009-2010. Patients of menorrhagia above the 12 years of age & below 45 years (reproductive age group), during the period with complaints of increase in amount or duration of menstrual flow included in the study. Patients were interviewed and detailed history, clinical examination and laboratory diagnosis, Ultrasonography were done to exclude systemic and other diseases. Two 'Gulnar' capsules were given twice daily to patients from first day of menstruation for 5 days up to three consecutive cycles, and patients were called for follow-up for next three menstrual cycles. On the basis of result it was concluded that this unani formulation is effective in menorrhagia.

Key words: Menorrhagia, Humor, Temperament, Gulnar capsule.

Introduction

Menorrhagia is an abnormally heavy and prolonged menstrual flow at regular intervals. Clinically menorrhagia is defined as total blood loss exceeding 80 ml/per cycle or menses lasting longer than 7 days. Menstrual disturbances in the form of menorrhagia are a common problem during reproductive age group (Hall berg, 1984) Normal menstruation in women of reproductive age is an indicator of health. During the active reproductive era menstruation occurs at approximately 28 days intervals (Naaz, 2009). Menorrhagia is a common debilitating condition, it affects approximately 20% of healthy women (i.e., it adversely affects life styles). The World Health Organization reports that 18 million women aged 30-55 year perceive their menstrual bleeding to be exorbitant (Goldrath, 1995). Report shows that only 10 % of women experiences blood loss severe enough to cause anemia or to be clinically defined as menorrhagia (Hall berg, 1964; Fraser, 2001; Warner, 2004). An appropriate assessment of blood loss can be made from pads and tampon count (Higham, 1990). In practice, measuring menstrual blood loss

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is difficult. Thus, the diagnosis is usually based upon the patient's history. A normal menstrual cycle is 21-35 days in duration, with bleeding lasting an average of 7 days and flow measuring 25-80 ml (Lentz, 2007) Patients who lose more than 80 ml of blood, especially repetitively, are at risk for serious medical sequel. These women are likely to develop iron-deficiency anemia as a result of their blood loss. Menorrhagia is the most common cause of anemia in premenopausal women. (Noorhasan, 2010). According to Ibn-e-Sina (980-1037). Normal menstruation is that 'Which is average in quantity (Miqdar) and normal in quality (kafiyat) and is discharged at the time which is normal for nature and health of women & cleans her body by removing harmful constituents of her body. Normal blood is that in which all humors (akhlat) are in normal proportion with respect to their quality and quantity. Normal menstrual cycle is 30 days including days of menstrual flow (Ibn-e –Sina, 980-1037).

Menorrhagia at pubertal age according to Unani can be described on the basis of gradual change of the temperament of ages as well as of concerned organ i.e. uterus, ovaries and arteries and mucous membrane, The Basics of unani tibb is laid on the concept of akhlat (Humors)and there respective mizaj (temperament). So according to the principal, Ilaj –biz-zid such therapy should be given which should help the tabiyat to bring the temperament to normal as well as have Habis (astringent) Qabiz (haemostatic) effect (Naaz, 1996).

According to Tibb-e-Unani, the human body is considered to be composed of following seven natural principals of body known as **Al-Umur-al-tabiya**. These factors are responsible for maintenance of health. Disturbances in any one of these can lead to disease. (Zaman, 2002; Ahmad, 1980)

Umur-al tabiya

1. Al arkan or anasir (Element)
2. Al mizaj (Temperament)
3. Al akhlat (Humors/body fluids)
4. Al aaza (Organ and membranes)
5. Al arwah (Pneuma or vital sprit)
6. Alquwah (Faculties or powers)
7. Al af-'al (Functions)

In addition to above seven Umur e tabiya the following **Asbabe sitta zaroorya** (six essential causes) are also considered, which influence the human body to preservation of health or causation of disease. They are; (Jerjani, 1902)

1. AL-hawa al- muheet (Atmospheric air)
2. Al -makool wal- mashroob (Food and Drink)
3. Al- harkat wa sukoon e- badaniya (Physical and body movement and repose)
4. Al- harkat wa sukoon e- nafsaniya (Mental or physical movement and repose)
5. Al- naum wal- yaqza (Sleep and wakefulness)
6. Al-istefragh wal- ihtebas (Evacuation and retention)

Etiopathology of menorrhagia according to Unani concept

Unani physicians have described the etiopathology of kasrate tams under the following categories; (Majoosi, 1899; Husain, 2007; Jarjani, 1903)

1. *Ghalbae khoon (excessive congestion of blood)*: The increase in volume of blood (plethora) is either due to increased production of blood or decrease utilization of blood by body tissues, thereby increasing its volume in blood vessels. Tabiyat (The body defensive mechanism) plays its part by eliminating the excess blood from the body, either via nose, gums, and piles or in females by menorrhagia (kasrat-e tams).
2. *Ghalbae safra (dominance in bile)*: (Riqqat wa hiddat khooon) Sometimes the dominance of khilte safra alters the temperament of blood to hot. Blood becomes more liquefied by increasing the heat, making the blood vessels of uterus more fragile, resulting excessive uterine bleeding.
3. *Ghalbae balgham (dominance of phlegm)*: When there is a dominance of khilte balgham in blood, it weakens the uterine musculature and blood vessels. Khilte balgham (phlegm) by its virtues of mizaj "barid rataab" (cold and wet) increase the fluidity of blood, hence result in excessive flow of menstrual bleeding.
4. *Ghalbae soda (dominance of black bile)*: Emotional disturbances, worry, fright, anxiety, depression etc, are due to elevation of one's temperament to soudavi (Black bile), these change cause disturbances in menstrual cycle.

5. *Zof-e- reham (uterine debility)*: Frequent pregnancies, abortions and excessive intercourse weakens the uterine musculature, this alters the constricting power of uterine blood vessels and relax uterine muscles. There by resulting in excessive pain less menstrual bleeding.
6. *Soo–e- mizaj –e- reham*: The various pathological conditions in the genital tract such as polyps, ulcers or surgery alter the temperament of uterus which weakens the muscles and vessels of uterus result in excessive menstrual flow.

According to Jarjani (1903) following are causes of menorrhagia:

Uterine diseases: Weakness of uterus & uterine vasculature. Ulcers in uterus, polyp or uterine fibroid uterus, change in uterine temperament, uterine rupture, and rupture of uterine vessels

Change in blood; Increase in quantity of blood, Increase in fluidity of blood.

According to Al-majoosi (1899); Razi (2001); Tabri (1994) and Khan (1940) causes of menorrhagia are:

Weakness of retaining power (*Quwwate maseka*) of the uterus. Increase in the amount of blood or any humor (*Khilt*) and decrease in its weight. Increase in fluidity of blood. Rupture of uterine vessels. Quantity of body fluid increases leading to weakness in power of retention leads to menorrhagia. Dominant humors i.e. *khilte safra*, *khilte balgham*, *khilte sauda*, Uterine fibroid & polyps. According to Akber Arzani, 1956 menorrhagia occur when, Quantity of blood increases (*Imtela-ud-dam*) in body & *tabiyat* want to get rid of it.

Causes of Menorrhagia According to modern concept

The etiology of menorrhagia includes hormonal, mechanical, and clotting abnormalities. Hormonal causes include: an ovulation, hypothyroidism, Mechanical causes include: Uterine Polyps, Uterine Fibroids, Intrauterine devices, cancer, Atopic pregnancy, endometriosis, and endometritis. Clotting abnormalities include: vitamin K deficiency, and circulating inhibitors of coagulation (Hawkins & Bourne, 2008). It is important to evaluate younger patients for vonWillebrand's Disease (vWD), a bleeding disorder in which heavy menstrual bleeding is a common clinical manifestation (Rakel, 2005)

Methodology

The present study was conducted (2009-2010) on 80 clinically diagnosed patients of Menorrhagia, from IPD and OPD of Department of Qabalat wa

Amraze Niswan, Ajmal Khan Tibbiya College, A.M.U., Aligarh, (After obtaining their consent to participate in the study) to evaluate the clinical efficacy and safety of unani compound formulation (Gulnar capsule) in the management of menorrhagia in reproductive age group. The drugs chosen in the study have haemostatic, styptic and astringent effects which increases the constructive power of the uterine vessels by virtue of their cold and dry temperament.

Formulation composition

S. No.	Unani name	Botanical/Scientific name	Part used
1.	Gulnar	<i>Punica granatum</i>	Flower
2.	Gil-e- aramane	<i>Bole aramnaic</i>	Clay
3.	Samaghe arbi	<i>Acacia arabica</i>	Gum
4.	Gul-e- surkh	<i>Rosa damascena</i>	Flower
5.	Aqaqia	<i>Acacia arabica</i>	Leaves Extract
6.	Kateera	<i>Sterculia urens</i>	Gum

All of the above giving Advia-e-mufreda, powdered and prepared as a capsule of 250 mg.

1. Gulnar (*Punica granatum*) (Nadkarni,1989; Hakeem, 2002; Chopra, 1956)

Family: Punicaceae;

It is the male abortive flower of *Punica granatum* collected and used as an effective unani drug. This shrub much valued for its fruit and for the healing properties of its root, leaves, bark, flowers, and fruit rind.

Temperament; Cold¹ & dry in 2⁰ (Nadkarni, 1989)

Cold &Wet (Safiuddin,1999)

Part used: - fruit, rind of fruit, root seed, flowers .fruit juice.

Part under study: - flower

Action and uses: - Flowers of gulnar farsi, *Punica granatum* Linn are 3.8-5cm long and as much across, mostly solitary, sometimes 2-4 together, reported for astringent and styptic properties and are also beneficial in the treatment of diarrhoea and dysentery. Bark of the tree and rind of fruit are astringent and stomachic. This is used as a desiccative cicatrizing, highly astringent used in prolapse of rectum, menorrhagia, and wounds healing ulcers of mouth, prolapse of uterus. Flower buds powdered, and given as best astringent in nasal hemorrhage.

Gulnar with other styptic is recommended in excessive menstrual flow. It is locally used in the form of zemaad, farzja, Humool, Aabzan, & Huqna in kasrate tams. Gulnar is one of the effective ingredients in oral formulation used in kasrate tams (Husain, 2007).

Chemical constituents: Iron, Calcium, Phosphorus, Protein & Minerals.

2. Gile armani (*Bole aramnaic*) (Nadkarni, 1989; Hakeem, 2002; Safiuddin, 1999).

It is a calcareous mineral, often made into small cakes and stamped with certain compression. It is usually prepared by mixing pipe clay or common chalk with oxide of iron or red ochre. Temperament: Cold 1^o and dry 2^o

Action and uses: It is an astringent, styptic, absorbent, and antiseptic, cicatrizing, haemostatic, and refrigerant. It is used as a powdered and paste.

3. Samagh-e-arbi (*Acacia arabica*) (Nadkarni, 1989; Hakeem, 2002; Safiuddin, 1999)

It is a dried gum obtains from the stem and branches of *Acacia arabica*, and other parts of Acacia. It is found throughout the greater part of India, Ceylon, Baluchistan, Waziristan, Arabia Egypt and Tropical Africa.

Parts used: Bark, Gum, Leaves, Seeds and pods.

Temperament: Cold and dry in grade 2nd.

Action and uses: It acts as a general stabilizer in emulsion, lozenges, demulcent properties. aphrodisiac, nutritive and expectorant. Bark is a powerful astringent, pods are expectorant. It is highly astringent to bowel, cough, sore throat, mouth ulcers, hemorrhoids', prolapse of rectum, conjunctivitis, gonorrhoea, for stopping the bleeding, white discharge and menorrhagia.

Chemical constituents: Gum contains Arabic acid combined with calcium, magnesium, and potassium; also small quantity of malic acid, sugar, moisture 14 per cent, ash 3-4 percent. Pods contain about 22.44 per cent tannin. Bark contains large quantity of tannin.

4. Kateera (*Sterculia urens*) (Nadkarni, 1989, Hakeem, 2002; Safiuddin, 1999)

It is found through out India, also called Karaya gum. Indian tree, native to the mountain regions of central and eastern India.

Temperament: cold and dry.

Action and uses: It acts as glutinous demulcent and as a musakkin. It is effective in the treatment of hemoptesis, epistaxis, cough, sore throat, ulcerative colitis. Also used as a haemostatic substance, prolapse of rectum and in hemorrhagic conditions.

Chemical constituents: gum contains music acid and ash 4 %. It is cooling and used for making sweet meats; mucilage has no adhesive power. It is partially acetylated polysaccharide containing about 37% uronic acid, 8% acetyl group.

5. Aqaqia (*Acacia arabica*) (Nadkarni, 1989; Hakeem, 2002; Safiuddin, 1999).

It is the extract of the leaves, and gum of *Acacia arabica*.

Temperament: Cold & wet 2⁰

Action and uses: Demulcent, styptic, tonic, aphrodisiac, nutritive, and expectorant.

It is highly astringent for bowel, cure bronchitis, heals fractures, also used in healing old ulcer.

6. Gul-e-surkh (*Rosa damascena*) (Nadkarni,1989; Chopra,1956; Hakeem, 2002; Safiuddin, 1999)

Rosa damascene with its red flower is the most important and cultivated in several places in Bengal, Kashmir, Punjab, Patna and Ghazipur. Several species and forms are cultivated in India.

Temperament: Cold and dry in grade 2nd. Some Unani physicians says Murakkabul quwah.

Parts used: flower, flower buds, petals, stamens, and volatile oil.

Action and uses: mildly astringent, aperients, carminative and refrigerant, cardiac tonic. It is cooling and astringent and used to relieve uterine hemorrhage.

Chemical constituents: volatile essential oil, fat, resin malic, tartaric and tannic acid. quercitanin glucoside, gallic acid, quercitannic acid, volatile oil and red colorings matter.



Fig. 1: Gulnar (*Punica granatum*)



Fig. 2: Gile armani (*Bole aramnaic*)



Fig. 3: Kateera (*Sterculia urens*)



Fig. 4: Samagh-e-arbi (*Acacia arabica*)



Fig. 5: Aqaqia (*Acacia arabica*)



Fig. 6: Gul-e-surkh (*Rosa damascena*)

Materials and Methods

Patients of menorrhagia were selected from OPD & IPD of department of Qabalat-wa-Amraze Niswan, Ajmal Khan Tibbia Collage, A.M.U., Aligarh.

Inclusive criteria: Patients of menorrhagia above the 12 years of age & below 45years (reproductive age group). Case clinically diagnosed of menorrhagia; Patients agree to follow the protocol of the study.

Exclusion criteria: Patients of menorrhagia with fibroid uterus, ovarian cyst, with other uterine or ovarian pathology and systemic diseases.

Drug dose and their mode of administration

Two capsules (250 mg each) of Gulnar were given orally twice a day, Treatment was giving (from first day of menstrual period up to five days) for three consecutive menstrual cycles and patients were call for follow up for three menstrual cycles, and no side effects were noted.

Observations

Assessment of 80 patients was done according to the subjective parameters such as amount of blood flow, duration of blood flow, amount of pads used per day & clots pass during menses. Headache, backache, white discharge.

Results and Discussion

80 patients suffering from menorrhagia were treated with Gulnar capsule from first day of menstrual period for five days, up to three menstrual cycles and again for three cycles as follow up. The response of the drug was assessed on the basis of signs and symptoms. The drug was found effective in the treatment of menorrhagia. It has been observed that maximum numbers of patients were in the age group of 33-43year (table 1). Maximum no of patient were married 50 and unmarried 30. Out of 50 married patient 29 patients having parity p4 to p5, 18 patients had p1-p3. Two patients had more than 6 children. Only one patient was with no issue. This study shows that patients having mutiparity were much prone to developed menorrhagia in all married patients (Table 2). It has been observed out of 80 patients, 35 were assessed Safravi, 11 patients Damvi, 28 Balgami and 6 of Saudavi temperament. This study shows that patients having bilious &phlegmatic temperament were much prone to developed menorrhagia in all age groups (table 3). There is some increment in hemoglobin percent of patients after treatment (table 4). Out of 80 patients, 17 patients complained pain in lower abdomen during

menses and 47 patients complained pain in lower abdomen during menses at the end of treatment only 7 left with pain before menses & 15 left with pain during menses. Out of 80 patients, 25 patients had low backache. At the end of treatment only 5 patients were left with back pain. Out of 80 patients 12 patient feel giddiness, completely relived this symptom at the end of treatment. Out of 80 patients 17 had loss of appetite and at the end of treatment only 5 left with this problem. It has been observed out of 80 patients 25 were found to have white discharge at base line phase, in which at the end of treatment only 7 patients left with this complain. 18 patients were found palpitation; at the end of treatment only 7 were left with this problem. Out of 80 patients 50 patients had clots passes during menstrual blood flow, at the end of treatment only 15 patient left with this complain and 75 had profuse menstrual discharge, at the end of treatment only 29 patient left with this complain. Out of 80 patient 55 have duration of menstrual blood flow 8-12 days At the end of treatment phase only 14 patients with prolonged menstrual flow were left. 9 (Table 5)

Table 1: Distribution of patients according to the age.

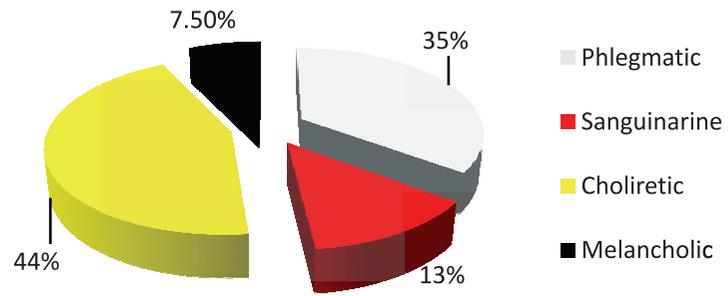
Age in year	No of patients	Percentage
13-23	30	37%
24-33	19	24%
34-43	31	39%

Table 2: Classification of patients according to their parity.

S. No.	Parity	No of patient	Percentage
1	P1-p3	18	22.5%
2	P4-p5	29	36.2%
3	More then 6	2	2.5%
4	No issue	1	1.25%
5	Total no	50	100%

Table 3: Showing classification according to temperament.

S. No.	Temperament	No of cases	%
1	Phlegmatic (Balghami)	28	35%
2	Chloeretic (Safravi)	35	44 %
3	Sangunarine (Damvi)	11	13 %
4	Melancholic (Saudavi)	6	7.5 %



Showing classification according to temperament.

Table 4: Response of drug on Hb% of menorrhagic patients.

Hb%	11-9	9-8	Below 8
Patient Hb% Base line	4	25	51
1.	5	26	49
2.	5	28	47
3. Pt, Hb% after three Tt cycle	10	30	40
4.	13	37	30
5.	15	42	23
6. Pt, Hb% after follow up	22	38	20

Table 5: Showing response of Gulnar capsules on sign & symptom.

Follow up	Pain before menses	Pain during menses	Profuse bleeding	Low backache	White discharge	Palpitation	Giddiness	Loss of Appetite	clots passes	duration of flow 8-12 days
Base line patient	17	47	75	25	25	18	12	17	50	67
1	15	42	70	22	20	16	12	16	47	60
2	15	30	67	15	17	14	10	11	41	57
3	10	25	55	11	13	14	8	10	38	45
4	10	21	49	8	13	8	5	8	31	37
5	8	19	40	6	10	9	5	7	20	20
6	7	15	29	4	8	7	3	5	15	14

Results

S. No	Drug	Complete remission	Partial remission	No response	No. of patients
1.	Gulnar	39	25	16	80
2.	Percentage	48.75%	31.25%	20%	100%

The result showed out of 80 patients treated with Gulnar capsule 39 showed complete remission, 25 were showed partial remission, and 16 patients showed no response.

Conclusion

This study shows that maximum number of patients were anemic at base line, most probably due to excessive loss of blood during menses, poor nutrition. There is gradual increase in patients Hb% during treatment, this may be due to decrease blood flow, proper nourishment (advice) & also iron constituents present in ingredients of 'Gulnar' capsules.

During the study patients did not report any adverse effect like gastritis, irritation, vomiting, headache, body ache, vertigo, and excessive thirst, no change in blood pressure and pulse during and final visit of the study. The clinical study concluded that the unani compound formulation (Gulnar capsule) is effective and safe in menorrhagia in reproductive age group.

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