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# A preliminary study on the efficacy and safety of Unani compound drug *Safoof Habis ud dam* in cases of *Kasrat-e-Tams* (Heavy Menstrual Bleeding)

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About 10-35% of women report experiencing heavy periods during their reproductive years. There is still no effective treatment for this problem in modern medicine emphasizing on the importance of various traditional medications in this regard. Using modern scientific standards, the Unani compound medicine *Safoof Habis ud dam's* clinical, biochemical, and haematological therapeutic efficacy and safety were evaluated in this study at the Regional Research Institute of Unani Medicine (RRIUM), Aligarh, between 2016 and 2022. A total of 77 people were selected from the patient pool who visited the outpatient department (OPD) of the institute. Starting on the days of the menstrual cycle for three consecutive cycles, patients were given 2.5 g powder of the Unani compound medicine *Safoof Habis ud dam* orally twice a day after meals for nine days each month. The statistical findings were evaluated using one-way analysis of variance (ANOVA) followed by Dennett's test. The current study finds that the Unani compound medications were safe, non-toxic, and successful in treating severe menstrual bleeding. Large population studies are recommended for future research.

**Keywords**: Heavy Menstrual Bleeding (HMB), *Kasrat-e-Tams*, Unani compound drug (*Safoof Habis ud dam*)

**IPC Code:** Int CI[25]: A61K 9/00, A61K 36/00

Heavy menstrual bleeding (HMB) is defined as prolonged (>7 days) or excessive blood loss during the menstrual period, estimated to be greater than or equal to 80 mL every menstrual cycle[1]. About 5%-10% of patients have uterine polyps, 20%-30% of cases have fibroids, and endometriosis (present in 5% of cases) all contributing to HMB. HMB[2,3] can also be brought on by other illnesses such coagulation problems and endocrine abnormalities. About 10% to 15% of women report experiencing heavy periods at some point during their reproductive years; only 5% of whom seek medical attention for possible HMB[4]. It is a problem that affects s‘nemowphysical, emotional, and social activities as well as quality of life[5]. It can also result in consequences such as iron deficiency anemia, rising medical costs, anxiety, and depression[6]. The prevalence rate of heavy menstrual bleeding (HMB) among women who were of reproductive age was 37.9%[7].

Several modern drugs, such as gonadotropin-releasing hormone agonists, oral contraceptives, non-steroidal anti-inflammatory drugs (NSAIDs), medicated intrauterine devices (IUDs) and a range of surgical techniques, including dilation and curettage, endometrial resection, and ablation, and hysterectomy are used to treat HMB. There are specific side effects concerned to certain medications[8-11].

Since herbal medications, including Unani drugs, have a varying effect on excessive menstrual bleeding and have minimal to no side effects, there is currently a focus on these safe and effective treatments for HMB. Thus, the current study’s objective is to evaluate *Safoof Habis ud dam*'s safety and efficacy in patients using Unani compound medicine. The Unani System of Medicine has employed a number of single and compound drugs to treat excessive menstrual bleeding[12].

### Review of previous work

A review of recent literature (2013-2024) indicates that several Unani Medicines, such as *Safoof Habis-ud-dam*, which is a compound drug comprised of the ingredients [Lodh pathani (*Symplocos racemosa* Roxb), Khurma (*Phoenix dactylifera* Linn), Rasaut (*Berberis aristata*), and Talmakhana (*Asteracantha*

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*longifolia* Linn), Golnar (*Punica granatum* L.), Ginger (*Zingiber officinale*)] have been used for the treatment of HMB. However, very little work has been done on scientific lines on the present test drug *Safoof Habis-ud-dam*. Hence, present investigations have been carried-out to validate the efficacy and safety of this drug involving clinical, biochemical and hematological parameters and provide reliable treatment for HMB.

## Methodology

### Study design

The study was multicentric, open-label, and uncontrolled clinical study. The Central Council for Research in Unani Medicine (CCRUM), New Delhi, was the source of *Safoof Habis ud dam*, a Unani compound medicine. The study was carried out at the Regional Research Institute of Unani Medicine (RRIUM), Aligarh, between 2016 and 2022. 128 female patients between the ages of 19 and 45 years who had signs and symptoms that met the predetermined inclusive/ exclusive criteria were selected from the pool of patients who presented to the Out Patient Department (OPD).

Total 128 cases were registered; 77 cases completed the study and 51 cases were dropout. Dropout of patients was due to:

1. Patients did not attend the follow-up due to pregnancy.

2. Some patients did not turn up for last follow up as they had to travel out of station.

*Safoof Habis ud dam* was tested for safety and effectiveness using clinical, symptomatological, biochemical, and haematological parameters.

### Ethical consideration

Every participant in the study provided written, informed consent. The RRIUM, Aligarh on December 28, 2016, received approval for this investigation from its institutional ethics committee (Ref: 8-22/2014-15/RRI-ALG/Misc./169).

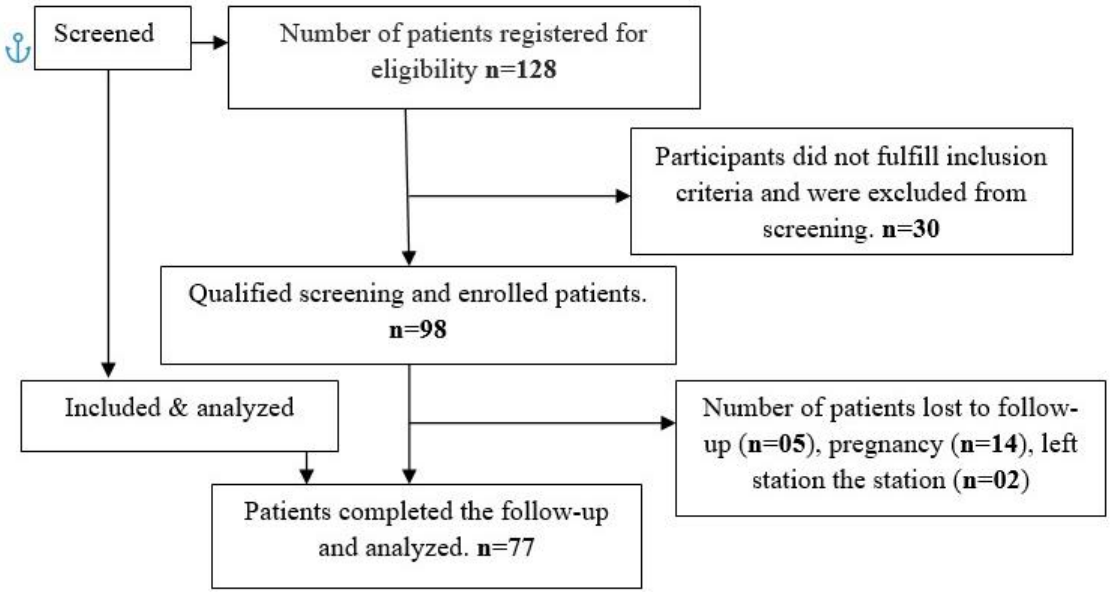
### Medication, dosage, and administration method

The Unani medicine "*Safoof Habis ud dam*" was administered 2.5 g orally twice a day from first day of menstruation upto 9$^{th}$ day for three consecutive menstrual cycles. The hematological and biochemical assays were performed at baseline, then after fourteenth day (1$^{st}$ follow-up) and at the end of the trial (Table 1) (90$^{th}$ days)[13].

Table 1 — Constituents of *Safoof Habis ud dam: NFUM* part-1[13]

| S. no. | Ingredients (Botanical/Chemical) name | Quantity |
|---|---|---|
| 1 | Sang-e-Jarahat (Hydrated magnesium silicate) | 2 parts |
| 2 | Samagh-e-Palas (*Butea monosperma* Lam.) Kuntze | 3 parts |
| 3 | Mayeen Kalan (*Tamarix gallica* Linn.) | 1 part |
| 4 | Sadaf sadiq (True shell) | 1 part |
| 5 | Gil-e-Armani (Silicate of alumina) | 1 part |
| 6 | Damm-ul-Akhwain (*Dracaena cinnabari*) | 1 part |
| 7 | Qand Safaid (*Saccharum officinarum* L.) | 9 parts |

**Flow diagram of study participants**



**Composition of test drugs**

***Selection standards***

*Inclusion criteria*

Patients were enrolled based on the following criteria:

1. Women between the ages of 19 and 45 who are neither menopausal nor gravid.
2. Individuals who have menorrhagia as demonstrated by:

i. abnormal menstrual loss over 80 mL each cycle, as determined by the menstrual pictogram[14].

ii. The period of menstruation longer than six days (7-10)[15].

*Exclusion criteria*

1. Prolonged menstrual bleeding associated with structural or histological abnormalities followed by symptoms such as such pelvic pain, pressure feelings, or bleeding even after menstruation.
2. Individuals who have been bleeding profusely during their periods since menarche.
3. Individuals who may have a coagulation issue based on their personal or family history.
4. Individuals who utilize intrauterine contraceptives.
5. Individuals with long-term medical conditions such as hypertension, tuberculosis, etc.
6. Postmenopausal bleeding.
7. Individuals of HMB undergoing hormone replacement therapy.
8. Situations such as endometriosis where HMB is not the primary menstrual symptom.
9. Women who are nursing or pregnant.

**Assessment of Mizaj, (Temperament)**

At baseline, a temperament (mizāj) assessment was conducted. The patients' temperaments were evaluated using the 10 predetermined factors found in the *Ajnas-e-ashra*.

**Evaluation of the follow-up**

Patients underwent clinical evaluations on baseline (0 day), 1st follow-up (14 days) and post-treatment follow-up (90 days). The follow-up sheet contained the objective and subjective clinical observations.

**Criteria for evaluating efficacy**

The efficacy of the medicine was assessed in patients who were having significant menstrual bleeding using the following guidelines.

**Clinical assessment**

***Subjective standards***

*Chart for Assessing Blood Loss Picture (PBAC)*

The following modifications were seen in the clinical assessment of various indications and symptoms:

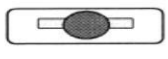
The menstrual pictogram was to calculate the research drug's effectiveness, as shown below. In reality, the menstruation pictogram is a PBAC[16] method. It provides more details about blood loss from tampons. When changing sanitary gear, it also accounts for the amount of blood lost in the lavatory. The blood loss is expressed in mL, which is the same as the actual volume lost.

**Collection of blood serum**

At each investigation, a vein was punctured to obtain blood samples. 1.0 mL of blood was treated with ethylene diamine tetra acetic acid (EDTA) for assessment of various hematological parameters. 2.0-2.5 mL of blood was allowed to coagulate for various biochemical parameters, and the serum was separated by centrifugation.

**Biochemical investigation**

Following biochemical parameters were analysed during the study: serum glutamate pyruvate transaminase (SGPT, E.C. 2.6.1.2) and serum

| Feminine Pad | Type | Score | Tampon | Type | Score | Extraneous | Type | Score |
|---|---|---|---|---|---|---|---|---|
|  | Day | 1 mL |  | Light | 0.25 mL |  | Light | 1 mL |
| | Night | 1 mL | | Medium | 0.5 mL | | | |
| | | | | Heavy | 1.0 mL | | | |
| | | | | Super | 1.0 mL | | | |
|  | Day | 2 mL |  | Light | 0.5 mL |  | Moderate | 3 mL |
| | Night | 3 mL | | Medium | 1.0 mL | | | |
| | | | | Heavy | 1.5 mL | | | |
| | | | | Super | 2.0 mL | | | |
|  | Day | 3 mL |  | Light | 1.0 mL | | | |
| | Night | 6 mL | | Medium | 1.5 mL | | | |
| | | | | Heavy | 3.0 mL | | | |
| | | | | Super | 4.0 mL | | | |
|  | Day | 4 mL |  | Light | 3.0 mL |  | Heavy | 5 mL |
| | Night | 10 mL | | Medium | 4.0 mL | | | |
| | | | | Heavy | 8.0 mL | | | |
| | | | | Super | 12.0 mL | | | |

glutamate oxaloacetate transaminase (SGOT, E.C. 2.6.1.1.)[17], serum alkaline phosphatase enzyme (S-ALP, EC. 3.1.3.1)[18], blood urea[19], serum creatinine[20], total bilirubin[21] and uric acid[22].

#### Hematological examination

Following hematological parameters were analysed as per standard protocol[23]. Hemoglobin (Hb), erythrocyte sedimentation rate (ESR), red blood cells (RBC), total leucocyte counts (TLC), and differential leucocyte counts (DLC) that include polymorphs, lymphocyte, and eosinophil counts.

#### Statistical evaluation

Data analysis was done statistically using one-way analysis of variance (ANOVA) by Dennett's test. The values were considered significant when the p-value was less than 0.05.

## Results and Discussion

#### Demographic evaluation

A total of 77 female subjects with heavy menstrual bleeding (HMB) were found in the demographic study.

Female subjects in reproductive age 52 (67.53%) with a mean age of 30.75 years had higher prevalence than those at puberty age 19 (24.68%) of mean age of 19 years followed by female participants over 40 years old, at age 07 (9.1%), had a mean age of 45 years (Table 2). A similar conclusion had been reported by earlier researchers[24]. The prevalence is higher in married patients 47 (61.04%) than in single women 30 (38.96%) (Table 2). A similar conclusion had been reported by earlier researchers[25]. The incidence of patients who were housewife [57 (74.03%)] was larger than students [16 (20.78%)] followed by teachers 04 (5.20%).

Table 2 shows that there were higher incidences of lower income group 52 (67.53%) than middle income group 24 (31.17%) based on socioeconomic status. Patients who were not vegetarians had 73 (94.81%) more instances than vegetarians, [04 (5.20%) (Table 2)]. Similar observations had been previously made by other researchers[26,27]. Body Mass Index (BMI) in the study was assessed as per WHO guidelines. The results showed that 19 female subjects (24.68%) had BMI <18.5 kg/m$^2$ (under weight), 30 female subjects (38.96%) had BMI >18.5 kg/m$^2$ (normal weight), and 14 subjects (18.18%) had BMI >25 kg/m$^2$ (overweight) and 14 subjects (18.18%) had BMI >30 kg/m$^2$ (obese). Our result showed no association between BMI with

Table 2 — The distribution of patients with heavy menstrual bleeding based on demographic profile

| Characteristic | | Number of female & % | Mean age (in years)±SD |
|---|---|---|---|
| 1. Age (In years): | i. Puberty age <19 yrs | 19 (24.68%) | 19.00±0.00 |
| | ii. Reproductive age (20-40 yrs) | 52 (67.53%) | 30.75±6.78 |
| | iii. > 40yrs | 06 (7.79%) | 45.00±2.16 |
| 2. Marital status | i. Married | 47 (61.04%) | |
| | ii.Unmarried | 30 (38.96%) | |
| 3. Occupation | i. Housewife | 57 (74.03%) | |
| | ii. Student | 16 (20.78%) | |
| | iii. Teaching | 04 (5.20 %) | |
| 4. SES | i. LIG | 52 (67.53%) | |
| | ii. MIG | 24 (31.17%) | |
| | iii. HIG | 01 (1.30%) | |
| 5. Dietary Habits: | i. Non-vegetarian | 73 (94.81%) | |
| | ii. Vegetarian | 04 (5.20%) | |
| 6. BMI | i. BMI <18.5 kg/m$^2$ (Under weight) | 19 (24.68%) | |
| | ii. BMI > 18.5 kg/m$^2$ (Normal weight) | 30 (38.96%) | |
| | iii. BMI >25 kg/m$^2$ (Over weight) | 14 (18.18%) | |
| | iv. BMI > 30 kg/m$^2$ (Obese) | 14 (18.18%) | |
| 7. Anaemia (12 g/dL) | | 30 (38.95%) | |
| 8. Any associated Nausea/vomiting at the time of menstruation | | 30 (38.95%) | |
| 9. Any passage of clot during menstruation: | | 37 (48.05%) | |
| 10. Temperament: | i. Sanguine | 15 19.48%) | |
| | ii. Phlegmatic | 17 (22.08 %) | |
| | iii. Bilious | 45 (58.44 %) | |
| | iv. Melancholic | NilNil | |

SES: Socio-Economic Status; LIG: Lower income group, MIG: Middle income group, HIG: Higher income group; BMI: Body Mass Index, SD-standard deviation

longer periods and periodic menstrual blood loss. It may be due to smaller sample size but some authors have claimed that higher BMI was associated with irregular monthly cycles, longer periods, and periodic menstrual blood loss; as BMI is considered a powerful forecaster of menstrual irregularity[28,29]. It was observed that 30 (38.95%) female subjects were anemic associated with nausea/vomiting and 37 (48.05%) had clot at the time of menstruation. Some researchers previously reported similar findings[30]. The occurrences were highest in bilious patients, 45 (58.44%), sanguine patients, 15 (19.48%), and phlegmatic patients, 17 (22.08%) (Table 2). Many authors had reported similar interpretations[31].

**Association between length of menstrual cycle and Body Mass Index (BMI)**

There were 77 female subjects in total. Five of these subjects had a short menstrual cycle (less than 24 days) and fell into one of four categories: BMI<18.5 kg/m$^2$ (under weight), BMI> 18.5 kg/m$^2$ (normal weight), BMI>25 kg/m$^2$ (over weight) or BMI >30 kg/m$^2$ (obese). The remaining 72 female subjects had normal menstrual cycle (25-35 days) and fell into one of the four categories: BMI <18.5 kg/m$^2$ (under weight), BMI> 18.5 kg/m$^2$ (normal weight), BMI>25 kg/m$^2$ (over weight) or BMI >30 kg/m$^2$ (obese). These were 19 (25%), 30 (40.00%), 14 (18.88%), 14 (18.18%) respectively. Our investigation did not find any female subjects with a menstrual cycle length of more 35 days across all BMI categories (Table 3). Similar conclusions had been made by the other authors[32].

**Safety evaluation**

Patients received 2.5 g powder of the Unani compound medication *Safoof Habis ud dam* orally twice a day after meals for nine days per month starting on the first day of the menstrual cycle and continuing for three successive cycles.

**Biochemical studies**

***Tests for liver function and kidney function***

The results of the liver and kidney functions tests showed no significant discernible alterations in the safety evaluation. Thus, it may be concluded that there was no adverse or negative reaction to the Unani formulations. Thus, the drug's safety is complied with (Table 4). Safety evaluation has been done based on biochemical and hematological evaluations.

**Hematological evaluation**

There had been no significant discernible changes in the levels of hemoglobin, RBCs, (TLC), (ESR), (DLC) (Table 5).

**Clinical evaluation**

***Subjective standards***

*Amount of blood loss*

In contrast to baseline to different treatment of follow-ups, there was a significant decrease in the amount of menstrual blood loss, 24.86% ($p<0.0001$) on the first follow-up (14$^{th}$ days) and 38.49% ($p<0.0001$) on the post-treatment follow-up (90$^{th}$ days) (Table 6 & Fig. 1). The other researchers have also noted similar conclusions[33].

Table 3 — Association between length of menstrual cycle and body mass index (BMI) in heavy menstrual bleeding (HMB) patients

| Menstrual cycle length | Under weight BMI <18.5 kg/m$^2$ | Normal weight BMI > 18.5kg/m$^2$ | Overweight BMI >25 kg/m$^2$ | Obese BMI >30 kg/m$^2$ |
|---|---|---|---|---|
| Short cycle length (<24 days) n=5 | Nil | 1 (20%) | 2 (40%) | 2 (40%) |
| Normal cycle length (25-35 days) n=72 | 18 (25%) | 31 (43.06%) | 11 (15.28%) | 12 (16.67%) |
| Long menstrual cycle length (>35 days) | Nil | Nil | Nil | Nil |

Table 4 — Effect of Unani compound drugs *Safoof Habis ud dam*in the levels of SGPT, SGOT and serum alkaline phosphatase, blood urea and serum creatinine, bilirubin and uric acid in *Kasrat-e-Tams* (Heavy Menstrual Bleeding)-patients

| Parameter → / Group ↓ | SGPT (IU/L) | SGOT (IU/L) | Serum Alkaline Phosphatase (IU/L) | Blood urea (mg %) | Serum Creatinine (mg %) | Biliruibin (mg %) | Uric acid (mg %) |
|---|---|---|---|---|---|---|---|
| (Baseline) | 18.15 | 18.75 | 73.44 | 19.78 | 0.87 | 0.71 | 3.80 |
| (0$^{th}$ -Day) | ±12.49 | ±11.60 | ±31.77 | ±6.40 | ±0.14 | ±0.23 | ±1.05 |
| 1$^{st}$ Follow-Up | 17.83 | 21.27 | 71.96 | 19.34 | 0.84 | 0.71 | 4.00 |
| (14$^{th}$ -Days) | ±17.23$^{\bullet}$ | ±27.66$^{\bullet}$ | ±28.66$^{\bullet}$ | ±5.26$^{\bullet}$ | ±0.14$^{\bullet}$ | ±0.45$^{\bullet}$ | ±1.27$^{\bullet}$ |
| Post-treatment | 20.56 | 19.47 | 73.81 | 18.66 | 0.83 | 0.67 | 3.92 |
| (90$^{th}$-Days) | ±32.55$^{\bullet}$ | ±16.99$^{\bullet}$ | ±33.37$^{\bullet}$ | ±5.19$^{\bullet}$ | ±0.13$^{\bullet}$ | ±0.25$^{\bullet}$ | ±1.19$^{\bullet}$ |
| | p<0.51 | p<0.70 | p<0.91 | p<0.46 | p<0.17 | p<0.70 | p<0.50 |

[$^{\bullet}$P is not significant]

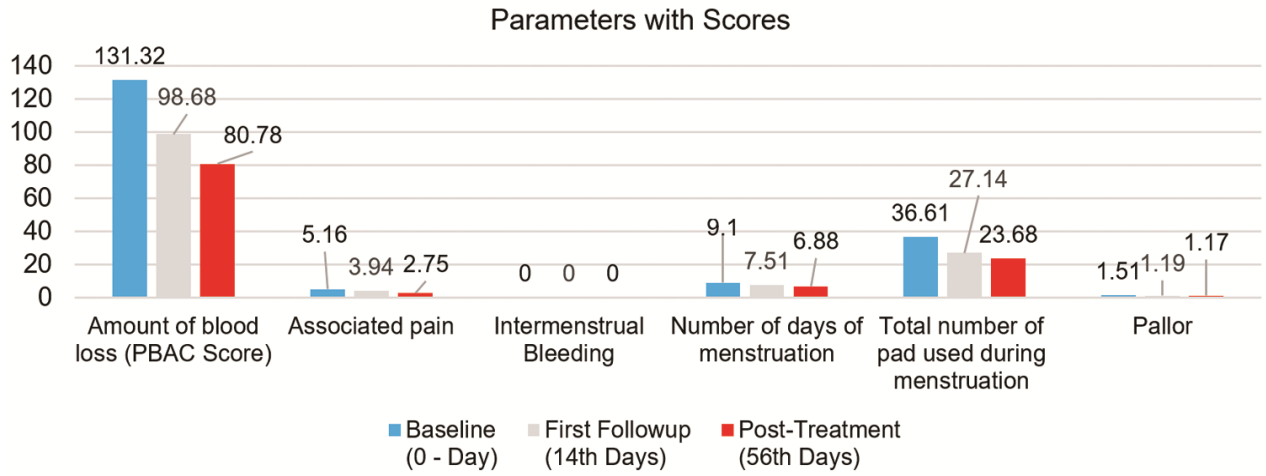



Fig. 1 — Graph showing effect of Unani compound drug *Safoof Habis ud dam* in reducing different symptoms of *Kasrat-e-Tams* (heavy menstrual bleeding) patients

Table 5 — Impact of Unani compound medicine in the level of haemoglobin, RBC, TLC, ESR, polymorph, lymphocyte, and eosinophil counts, as well as erythrocyte sedimentation rate (ESR), in *Kasrat-e-Tams* (Heavy Menstrual Bleeding)-patients

| Parameter → / Group ↓ | Haemoglobin (g %) | R.B.C. ($10^6$ mm$^3$) | T.L.C. ($10^3$/mm$^3$) | E.S.R (mm/h) | Differential Leucocytes Counts (DLC) | | |
|---|---|---|---|---|---|---|---|
| | | | | | Polymorph (%) | Lymphocyte (%) | Eosinophil (%) |
| (Baseline) | 10.7 | 3.80 | 6.40 | 43.00 | 63.00 | 32.00 | 5.00 |
| (0st-Days) | ±1.74 | ±0.53 | ±2.53 | ±12.25 | ±11.15 | ±11.25 | ±2.14 |
| 1st Follow-Up | 10.28 | 3.77 | 6.20 | 45.00 | 64.00 | 33.00 | 3.00 |
| (14th -Days) | ±1.86• | ±0.55• | ±2.09• | ±10.54• | ±10.43• | ±9.58• | ±2.37• |
| Post-Treatment | 10.28 | 3.75 | 6.39 | 43.00 | 63.00 | 33.00 | 4.00 |
| (90th -Days) | ±1.64• | ±0.54• | ±2.44• | ±10.47• | ±11.17• | ±10.21• | ±1.83• |
| | p<0.66 | p<0.81 | p<0.84 | p<0.50 | p<0.76 | p<0.90 | p<0.11 |

[•p is not significant]

Table 6 — Impact of *Safoof Habis ud dam*, a Unani compound medication, on symptoms in patients with *Kasrat-e-Tams* (heavy menstrual bleeding)

| Group → / Parameter ↓ | Baseline (0-Day) | 1st Fup (14th -Days) | Post-treatment (90th -Days) |
|---|---|---|---|
| i. Amount of blood loss (PBAC Score) | 131.32 ±38.40 | 98.68 ±23.84*** | 80.78 ±19.49*** |
| ii. Associated pain | 5.16 ±1.85 | 3.94 ±1.64*** | 2.75 ±1.48*** |
| iii. Intermenstrual Bleeding | No | No | No |
| iv. Number of days of menstruation | 9.10 ±1.15 | 7.51 ±1.47** | 6.88 ±1.16*** |
| v. Total number of pad used during menstruation | 36.61 ±6.54 | 27.14 ±7.40*** | 23.68 ±6.66*** |
| vi. Pallor | 1.51 ±0.50 | 1.19 ±0.40*** | 1.17 ±0.37*** |

[***p<0.001 is highly significant]

**Associated pain**

Comparing the observation related pain during menstruation to the baseline values at various therapeutic follow-ups, there was a significant decrease of 23.64% (p<0.0001) on the first follow-up (14th days) and 46.71% (p<0.0001) on the post-treatment follow-up (90th days) (Table 6 & Fig. 1)[34]. Associated pain assessment was done using Visual Anolog Scale VAS score with a range of 0-10 points[35].

**Number of days of menstruation**

In contrast to the initial day's baseline results to different treatment follow-ups, there had been a significant substantial decrease in the number of days of menstruation, 17.47% (p<0.001) on the first follow-up (14th days) and 24.30% (p<0.0001) on the fourth follow-up (90th days) (Table 6 & Fig. 1). Similar intervention has been made by the other authors[36].

**Total amount of pads utilized during menstruation**

By contrasting the total number of pads used during menstruation with the baseline numbers to different therapeutic follow-ups, there was a significant decrease of 25.87% (p<0.0001) on the first follow-up (14th days) and 35.32% (p<0.0001) on the fourth follow-up (90 days) (Table 6 & Fig. 1). Similar conclusion had been noticed by other author[37].

**Pallor**

Comparing the pallor observed during menstruation to the values at baseline to various therapy follow-ups, there was a significant decrease of 21.19% ($p<0.0001$) on the first follow-up ($14^{th}$ days) and 22.52% ($p<0.0001$) on the fourth follow-up (90 days) (Table 6 & Fig. 1). Assessment of pallor of the conjunctiva, the palms and nailbeds was done using semi quantitative scale (0= no pallor, 1=possible pallor, 2= definite pallor, 3= definite severe pallor).

**Intermenstrual bleeding**

Patients with heavy menstrual bleeding had not shown signs of intermenstrual hemorrhage (Table 3 & Fig. 2).

**The menstrual blood volume assessment-based pictorial blood loss assessment chart (PBAC)**

A total of 77 patients had their menstrual blood volume measured by PBAC; of them, PBAC ≥ 100 accounted for 24.68% (19/77), PBAC = 101-199; 67.53% (52/77), and PBAC = 200-280; 7.79 % (06/77) (Table 7 & Fig. 2). PBAC of patients (n=77) is according to self-assessed menstrual blood volume. The other authors had also made similar interventions[38].

The goal of this study carried out during 2016-2022 was scientifically validate the efficacy and safety of the compound Unani medicine *Safoof Habis ud dam* in treating (HMB). The results are based on clinical, biochemical and haematological parameters carried out on 128 registered patients of HMB, out of which 77 cases were completed successfully and results recorded.

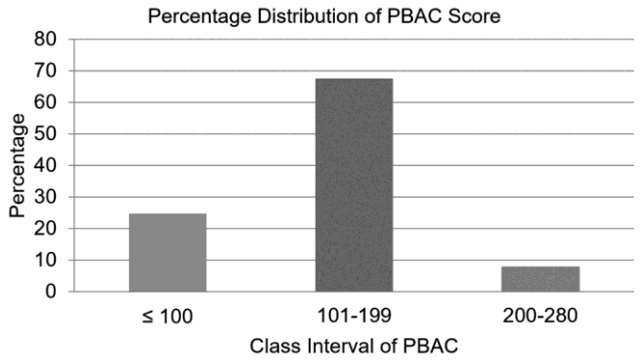



Fig. 2 — Pictorial blood loss chart (PBAC): assessment of menstrual blood volume in heavy menstrual bleeding (HMB) patients

Table 7 — Pictorial blood assessment chart (PBAC) in heavy menstrual bleeding patients

| Group → / Parameter ↓ | Number of patients and % n=77 |
|---|---|
| PBAC ≤ 100 | 19 (24.68%) |
| PBAC 101-199 | 52 (67.53%) |
| PBAC 200-280 | 06 (7.79%) |

**Main findings**

The investigated Unani test drug *Safoof Habis ud dam* has been found non toxic, safe and effective in the therapeutic treatment of HMB patients with significant improvement. The drug being belonging to Indian Medicine System (ISM) has no adverse effect even in prolonged use unlike drugs of allopathic medicines.

**Strength**

It is a potential treatment option for heavy menstrual bleeding with high efficacy, cost-effective and no adverse effect unlike allopathic drugs.

**Limitations**

The present study has been conducted on a small population of sample size (n=77). Therefore, there is a need for investigations with larger population. Because participants were required to recall and respond to questions about the length of bleeding, the number of pads, the passage of clots, and their impact on physical, social, emotional, and familial life, and general well-being recall bias was the study's main weakness. Another issue was the lack of a control group.

While corroborating the results of the drug *Safoof Habis ud dam* with earlier studies done on a number of Unani drugs in the treatment of HMB, namely Gulnar (*Punica granatum* L.)[39], Ginger: *Zingiber officinale* Rosc. (Zinzabeel)[40] and Persian Gulnar (*Punica granatum* L.)[41], it transpires that these studies are lacking in safety parameters *viz.*, SGOT, SGPT, alkaline phosphatase, urea and creatinine) besides having series of adverse side-effects *viz.*, abdominal pain, gastrointestinal reflex, constipation, dryness of skin, excessive appetite, leucorrhea bloating, heartburn, dryness of mouth, nausea, vomiting, diarrhea, headache, vertigo and breast tenderness. Furthermore, the studies on two compound drugs, namely, Unani formulation: (Khurma (*Phoenix dactylifera* Linn), Rasaut (*Berberis aristata*), Tal makhana (*Asteracantha longifolia* Linn), Lodh pathani (*Symplocos racemosa* Roxb)[42] and *Safoof Habis-ud-dam*[43] lacks most of the essential subjective parameters for efficacy of drug *viz.*, associated pain, total number of pads used during menstruation and intermenstrual bleeding. However, The drug 'vaginal suppository' formulation (*Acacia Arabica* (Lam.) Willd. gum and *Cinnamomum camphora* (L.)[44] have been completely studied for all safety and efficacy

Table 8 — Showing Unani medicines previously studied in the treatment of HMB, providing abstract information on safety, toxicity, adverse side-effects and efficacy etc. on scientific lines (2013-2024)

| S NO | Name of Unani drugs investigated. | Parameters | | |
|---|---|---|---|---|
| | | Safety | Subjective parameters for efficacy | Adverse effects, if any |
| | | S.G.O.T., S.G.P.T., Alkaline phosphatise, Urea, and creatinine. | A significant reduction in PBAC score, (MQ), and length of bleeding, intermenstrual bleeding, total number of pad used during menstruation and Pallor. | Abdominal pain, gastrointestinal reflex, constipation, bloating, heartburn, dry mouth, dry skin, excessive appetite, nausea, vomiting, vertigo and leucorrhoea. |
| 1 | Gulnar (*Punica granatum* L.)[39] | Not done | A significant reduction in PBAC scores, MQ, and length of bleeding, and increase in haemoglobin level. | Adverse side-effects reported. |
| 2 | Ginger (*Zingiber officinale*)[40] | Not done | Those who received ginger have significant reduction in blood loss than those who received a placebo. | Adverse side-effects reported. |
| 3 | *Punica granatum* L. flower (Persian Gulnar)[41] | Not done | A significant reduction in TA and PG both have remarkable decreased in PBAC score and blood loss. Additionally, there was a significant rise in mean hemoglobin in both the PG and TA groups. | Adverse side-effects reported. |
| 4 | Unani Formulations[42] | ALT and AST, two safety parameter,were within normal range. | A significant reduction in MBL, MIQ, PBAC, DOB, and haemoglobin levels were reported in HMB patients. However, QOL and hemoglobin levels had improved. | No adverse side- effect reported. |
| 5 | *Safoof Habis-ud-dam*[43] | SGOT and SGPT were found to be within normal limits. | A significant reduction in DOF, PBAC score had been reported. | No adverse side- effects reported. |
| 6 | vaginal suppository formulation[44] | ALT and AST were within normal range. | The mean PBLAC score declined statistically significantly in both the SG and TG group, espectively. | No adverse side- effects reported. |

(PBAC score) Pictorial blood loss assessment chart, Menstrual blood loss (MBL), (DOB) The duration of bleeding, (DOF) Duration of flow (MIQ) Menorrhagia impact questionnaire (MQ) Menorrhagia questionnaire,(QOL) The quality of life, Alanine aminotransferase (ALT), (AST) Aspartate aminotransferase, (TA) Tranexamic, (PG) Persian Gulnar (SG) Suppository group, (TG) Transexamic group

parameters and reportedly without any side-effects. This drug is indeed safe for use by HMB patients; but, this is not oral like previous drugs (Table 8).

## Conclusions

The results of our test drug *Safoof Habis ud dam* to combat HMB are quite encouraging and meet all requisite safety, toxicity and efficacy standards. Our studies also corroborate the results of earlier investigations on such Unani drugs as discussed above. Nevertheless, we suggest more studies on larger population of this test drug for better understanding its efficacy and safety before inclusion in wider medical use.

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## Conflict of Interest

Authors declare that there is no conflict of interest financial or otherwise.

## Author Contributions

All the authors contributed equally.

## Ethics Approval

Every participant in the study provided written, informed consent. The RRIUM, Aligarh on December 28, 2016, received approval for this investigation from its institutional ethics committee (Ref: 8-22/2014-15/RRI-ALG/Misc./169).

## Data Availability

Deidentified participant data and a data dictionary will be made available upon publication. Requests for data can be made via email to the corresponding author.

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