



**A SAFETY EVALUATION AND EFFICACY OF FEMOHILLS CAPSULE AN
AYURVEDIC FORMULATION IN MENORRHAGIA SUBJECTS**

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ABSTRACT

Background: Menorrhagia i.e. heavy menstrual bleeding (HMB), is an excessive menstrual bleeding, either excessive in amount or duration or both which interfere a women's physical, mental, emotional and also social quality of life. In different *Ayurved Samhitas*, abnormal & excessive uterine bleeding is explained under the term of *Raktapradar* and *Asrukadara* which can be correlated with menorrhagia. Ayurvedic herbal medicines provide significantly better results in menorrhagia than any medication in other pathies. **Objectives:** The aim of the study was to evaluate safety and efficacy of Femohills capsule on amount and duration of abnormal uterine bleeding, and menstrual pain in menorrhagia subjects. **Materials and methods:** It was an interventional, prospective, clinical study conducted on 56 subjects of Menorrhagia. The data was assessed on clinical symptoms. **Results:** during final assessment 51.79% subjects shows relief by 2 grades i.e. good relief in symptom of amount of bleeding; whereas 14.29% subjects shows relief by 3 grades (complete relief) and 28.57% subjects shows relief by 1 grade. Statistically significant ($p < 0.001$) results are seen in the study. Thus all clinical symptoms were reduced significantly from baseline to end of the treatment. **Conclusions:** Femohills capsule is effective in the management of menorrhagia and found to be devoid of any adverse effects.

KEYWORDS: Femohills Capsule, Menorrhagia, Heavy Menstrual Bleeding (HMB), Raktapradar, Asrukadara.

1. INTRODUCTION

Abnormal Uterine Bleeding (AUB) and its sub group, menorrhagia i.e. heavy menstrual bleeding (HMB), is a common condition affecting 14–25% of women of reproductive age^[1] and may have a significant impact on their physical, social, emotional and material quality of life,^[2] along with the direct impact on the woman and her family. HMB is define as 'excessive menstrual blood loss which interferes with a woman's physical, social, emotional and/or material quality of life'^[3] Chronic AUB is defined as 'bleeding from the uterine corpus that is abnormal in volume, regularity and/or timing that has been present for the majority of the last 6 months'^[4] The uterine and ovarian arteries supply blood to the uterus. These arteries become the arcuate arteries; then the arcuate arteries send off radial branches which supply blood to the two layers of the endometrium, the functionalis and basalis layers. Progesterone levels fall at the end of the menstrual cycle, leading to enzymatic breakdown of the functionalis layer of the endometrium. This breakdown leads to blood loss and sloughing, which makes up menstruation. Functioning platelets, thrombin, and vasoconstriction of the arteries to the endometrium control blood loss. Any derangement in the structure of

the uterus (such as leiomyoma, polyps, adenomyosis, malignancy, or hyperplasia), derangements to the clotting pathways (coagulopathies or iatrogenically), or disruption of the hypothalamic-pituitary-ovarian axis (through ovulatory/endocrine disorders or iatrogenically) can affect menstruation and lead to abnormal uterine bleeding.^[5]

The bleeding may be abnormal in frequency, duration or amount or combination of all three. Shows sign and symptoms like- Menstrual flow that soaks one or more tampons and more pads for every hour; Need to double up pads to control flow and need to change pads during night; Menstrual periods for more than 7 days; Menstrual flow with blood clots of large size; Having constant pain in lower abdomen.^[6]

In *Ayurved Samhitas* menorrhagia have been described under the headings of *Raktapradar* and *Asrukadara*. According to *Acharya Charaka*, vitiated *doshas* increase in quantity of blood and came into *Rajovaha sira* which increases the quantity of *aartava* also and leads to *Raktpradar*.^[7] *Acharya Sushrut* mentioned term '*Asrugdara*'^[8] for HMB. In *Asrugdara* there is

excessive & prolonged bleeding during menstruation or in intermenstrual period. Vitiating *Pitta dosha* increases quantity of *Rakta dhatu* and *Vata* increases its flow which further increases *Rajas (Artava)* in quantity. *Charak* has enumerated *Asrukadaraa* among *Apanaavritta Vyan Vayu lakshanas* and *Pittaavrita Apan Vayu lakshanas*.^[9] According to *Madhavnidana* abortion is also cause of *Asrugdara*. *Brihatrayee* describes *Asrukadaraa* complication should be treated on the line of *Adhogarakatapitta chikitsa*.

Heavy menstrual bleeding is assessed by number of pads used, passage of clots (size, and number) and duration of bleeding. Hysteroscopy and biopsy are the best to evaluate the endometrial pathology in Dysfunctional uterine bleeding. Modern medicine suggests hormones therapy, anti-prostaglandin and anti-fibrinolytic agent, NSAID's etc. are not much effective and having more complications. If medical therapy fails to treat these conditions in a child bearing woman, hysterectomy may be considered as a last option to correct this condition.

In ayurveda there are many herbal drugs prescribed to treat these conditions, there are many effective remedies to reduce abnormal uterine bleeding along with other symptoms like pain, weakness, low backache associated with menstruation. Cap Femohills contains combination of different ayurvedic herbal drugs which are useful in different gynecological conditions and also have possess rejuvenating properties. Primary objective of this study was to evaluate safety and efficacy of Femohills capsule on subjects complaining of abnormal heavy menstrual blood flow

2. MATERIALS AND METHODS

It was an interventional, non-comparative, prospective trial. The trial protocol and related documents were reviewed and approved by the Institutional Ethics Committee. The study was conducted in accordance with Schedule Y of Drugs and Cosmetics Act, India, amended in 2005 and Indian Council of Medical Research (ICMR) ethical guidelines for biomedical research on human participants, adopted from World Medical Association (WMA) - Declaration of Helsinki.

Each Capsule Contains- Femohills Ghruta - 500 Mg- processed with following herbs.

Table-1.

Sr. No.	Drug	Latin Name	Weight
1	<i>Shatavari</i> Root ^[10,11]	<i>Asparagus racemosus</i>	38.45 Mg
2	<i>Ashoka</i> Bark ^[12,13]	<i>Saraca indica</i>	76.90 Mg
3	<i>Kumari</i> Leaves ^[14,15]	<i>Aloe barbadensis</i>	38.45 Mg
4	<i>Nagkeshar</i> Stamen ^[16,17]	<i>Messua ferrea</i>	38.45 Mg
5	<i>Lodhra</i> Stembark ^[18,19]	<i>Symplocos racemosus</i>	115.40 Mg
6	<i>Yashtimadhu</i> Root ^[20,21]	<i>Glycerrhiza glabra</i>	38.45 Mg
7	<i>Dashamoola</i> Root ^[22]	Generic preparation	76.90 Mg
8	<i>Mudgaparnee</i> whole plant ^[23,24]	<i>Phaseolus trilobus</i>	38.45 Mg
9	<i>Mashparnee</i> whole plant ^[25,26]	<i>Teramnus labialis</i>	38.45 Mg
10	<i>Go Ghril</i> ^[27]	Cow Ghee	500 Mg
11	<i>GO Dugdha</i> ^[28]	Cow Milk	500 Mg

2.1. Primary and secondary outcome measures

- Primary outcome measure of study was to evaluate efficacy of Femohills capsule in subjects complaining of abnormal uterine bleeding by assessing symptoms like amount and duration of uterine bleeding, abdominal pain, clots and other related symptoms before and after the intervention
- To check, whether any adverse effects were observed in any of the cases.

2.2. Trial interventions

Femohills 2 capsules (500 mg) twice in a day with warm water as a anupan; before meal for 90 days were used in this study and follow up were done after every one month. The trial drugs were procured from the Ayurvedic Pharmacopoeia of India complied GMP (Good manufacturing practice) certified company.

Sample size:- Total 56 patients includes in this study.

2.4. Inclusion criteria

- Age ranging between 15-45yrs.
- Excessive vaginal bleeding during menstruation.
- Vaginal bleeding during two menstrual cycles
- Increased duration of the menstruation, (More than 5 days.)
- Painful vaginal bleeding during menstruation (Dysmenorrhea)
- Clots in menstrual flow.
- Duration of illness 6-24 months.

2.5. Exclusion criteria

- Pelvic inflammatory disease
- Ovarian cyst; uterine fibroid
- Endometrial carcinoma
- Cervical carcinoma
- Endometrial polyp
- Endometriosis
- Hypothyroidism & Hyperthyroidism
- Genital tuberculosis
- IUCD
- Hypertension

- Coagulatory defects
- Adenomyosis

2.6. Withdrawal criteria

- Patients who develop any side effect or illness during treatment
- Aggravation of symptoms if any
- Patients who will not follow prescription & instructions.

2.7. Study procedures

Total 56 out of 64 subjects aged between 15 to 45 years complaining of menorrhagia were included in this study. Each subject underwent through physical examination

Assessment Criteria

Table 2.

Grades	Amount of bleeding	Duration of bleeding	Pain
0	1-3 Pads	3-4 Days	No Pain
1	4-5 Pads	5-7 Days	Can manage routine work
2	6-7 Pads	8-10 Days	Unable to work
3	>7 Pads	>10 days	Bed ridden

2.8. Follow-up assessment

End point evaluation visits were made at baseline and at visits on 0, 30, 60, and 90th day. Assessments of all symptoms were recorded during every follow-up of subjects.

2.9. Statistical analysis

In the present study observations like amount and duration of uterine bleeding, abdominal pain is a type of ordinal data and is not precisely measurable by any scale or device or instrument. Hence observations measured on ordinal scale. They are expressed from range (grades) of 0 to 3. Grade 0 is lowest grade- no symptoms and grade 3 is highest grade for symptoms.

As the data is ordinal, mean will be poor marker of central tendency. So, difference of observations in pairs i.e. before and after will give value indicative of whether the observation is increased or decreased. So, highest grade difference will indicate highest level of increase or decrease in symptoms; lowest grade difference will indicate lowest level of increase or decrease in symptoms and no grade difference will indicate no changes in symptoms after treatment.

So in the present study, for this qualitative data of ordinal scale 'grade difference' is used as indicator of relief in symptoms, calculation were done and then data analysis was done with appropriate test of significance. (Wilcoxans sign rank test)

3. OBSERVATIONS AND RESULTS

The study was conducted on 64 subjects, out of these, 56 have completed the study and 8 were dropped out. All 56 subjects complied well during the trial period. Physical examination and subjective feelings did not reveal any abnormalities in any of the subjects throughout the study.

for fitness, they were assigned a number and inform written consents were obtained. After checking the baseline parameters (pulse rate and blood pressure), initial assessments of all symptoms were recorded on day '0' as per the assessment criteria. Femohills 2 capsules (500 mg) twice a day was given to the subjects for 90 days. The subjects were followed up every 30th day to check if there were any adverse effects or intolerance during the treatment period. Symptoms like amount of bleeding, duration of bleeding, abdominal pain, blood clots were assessed with the help of gradation as per following assessment criteria. Case report forms in all respects were completed under the supervision of qualified medical professional.

The scores of the subjective and objective parameters were recorded initially, during follow up and at the end of the study at monthly interval up to 3 subsequent assessments. Main parameters adopted for the assessment of result were amount of bleeding, duration of flow and abdominal pain. No adverse effects were observed in any of the cases.

3.1 Effect of therapy

➤ On amount of bleeding

Before treatment, 6 cases (10.71%) complained severe bleeding; 27cases (48.21%) complained with moderate bleeding and 23cases (41.07%) were with mild amount of bleeding. After treatment, 37 cases (66.07%) shows normal amount of bleeding and 13 cases (23.21%) were come under the criteria of mild bleeding, 5 cases (8.93%) showed moderate amount of bleeding and 1case (1.79%) still complained severe bleeding. (Table-3.A)

As per observations, there was reduction in amount of bleeding with respect to gradation. All the 56 patients had this symptom and at the end of treatment, relief by 2 grade (good relief) observed in 20 cases i.e. 35.71%; relief by 1 grade (mild relief) observed in 29 cases i.e. 51.79%; and no relief (i.e. 0 grade difference) observed in 7 cases i.e.12.5% in amount of bleeding with respect to gradation. (Table-3.B)

➤ Duration of bleeding

Before treatment, 23 cases (41.07%) were with more than 10 days duration of bleeding; 20 cases (35.71%) were with 8-9 days duration of bleeding & 13 cases (23.21%) were with 5-7 days duration of bleeding. After treatment, normal duration was found in 36 cases (64.28%), 17 cases (30.36%) were come under the criteria of 5-7 days duration of bleeding; 2 cases (3.57%) were remain with 8-9 days of duration, And 1 cases

(1.79%) had more than 10 days duration of bleeding. (Table-4.A)

As per observations, there was reduction in duration of bleeding with respect to gradation. All the 56 patients shows this symptom and at the end of treatment, relief by 3 grade (complete relief) observed in 8 cases i.e. 14.29%; relief by 2 grade (good relief) observed in 29 cases i.e. 51.79%; relief by 1 grade observed in 16 cases i.e. 28.57%; and no relief observed in 3 cases i.e. 5.36% in duration of bleeding with respect to gradation. (Table-4.B)

➤ Menstrual pain

Before treatment, 16 cases (28.57%) reported to no pain, 24 cases (42.85%) were with mild pain but can manage to routine work and 16 cases were having severe pain out of that 10 (17.86%) patients were unable to any work during bleeding & 6 (10.71%) were bed ridden. After treatment, 39 cases (69.64%) came under no pain group, 14 cases (25%) in mild pain, and 3 cases (5.36%) remain in severe pain group, (Table-5.A)

As per observations, there was reduction in abdominal pain with respect to gradation. 40 out of 56 patients had this symptom and at the end of treatment, relief by 2 grade observed in 7 cases i.e. 17.5%; relief by 1 grade observed in 28 cases i.e. 70% and no relief observed in 5 cases i.e. 12.5% in abdominal pain with respect to gradation. (Table-5.B)

Table 3.A

Amount of bleeding	Grades	No. of cases	
		Before treatment	After treatment
1-3 Pads	0	0	37
4-5 Pads	1	23	12
6-7 Pads	2	27	4
> 7 Pads	3	6	1

Table 3.B

Reduction in amount of bleeding after treatment			
	Grade difference	No. of cases	%
No relief	0	7	12.5%
Mild relief	1	29	51.79%
Good relief	2	20	35.71%
Complete relief	3	0	00%

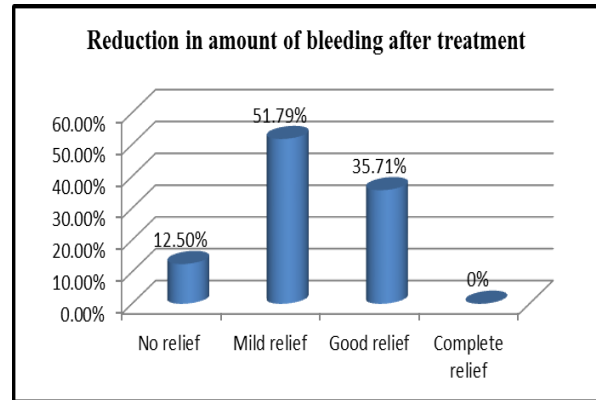


Fig-1

Table 4.A

Duration of bleeding	Grades	No. of cases	
		Before treatment	After treatment
3-4 Days	0	0	36
5-7 Days	1	13	17
8-9 Days	2	20	2
> 10 Days	3	23	1

Table 4.B

Reduction in duration of bleeding after treatment			
	Grade difference	No. of cases	%
No relief	0	3	5.36%
Mild relief	1	16	28.57%
Good relief	2	29	51.79%
Complete relief	3	8	14.29%

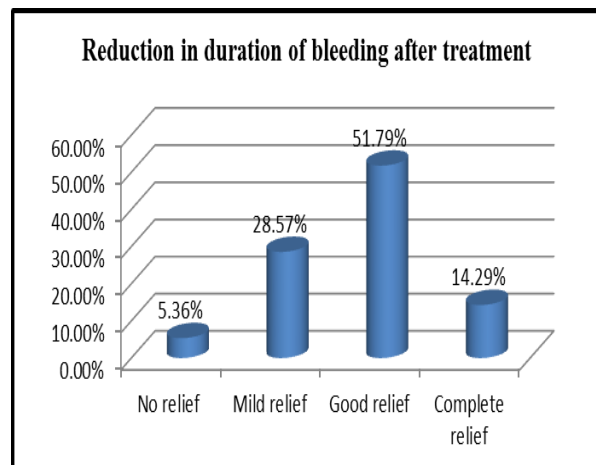


Fig-2

Table 5.A

Menstrual (abd.) pain	Grades	No. of cases	
		B.T.	A.T.
No Pain	0	16	39
Can manage to work	1	24	14
Unable to work	2	10	3
Bed ridden	3	6	0

Table 5.B

Reduction in duration of bleeding after treatment			
	Grade difference	No. of cases	%
No relief	0	5	12.5%
Mild relief	1	28	70%
Good relief	2	07	17.5%
Complete relief	3	0	00%

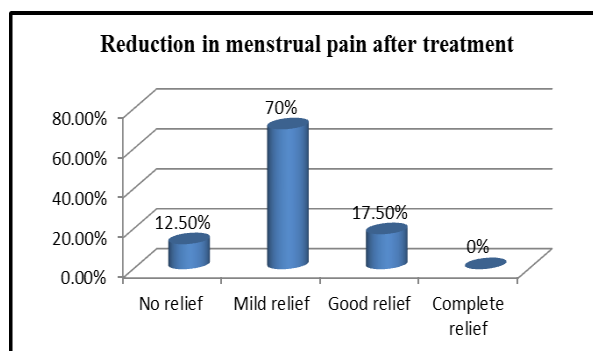


Fig-3.

Table 6.

	Duration	Number of positive differences	Number of negative differences	P value	Significance at (P< 0.05)
Amount of bleeding	B.T.-A.T.	0	49	<0.0001	Yes
Duration of bleeding	B.T.-A.T.	0	53	<0.0001	Yes
Abdominal pain	B.T.-A.T.	0	35	<0.0001	Yes

4. DISCUSSION

Primary outcome measure of study was to evaluate efficacy of Femohills capsule in subjects complaining of abnormal uterine bleeding by assessing symptoms like amount and duration of uterine bleeding, abdominal pain, clots, and other related symptoms before and after the intervention. The subjects were selected as per the selection criteria and the total effect of therapy was assessed by observing grade differences found in symptoms before and after the treatment.

Results of this study showed that, during final assessment after the completion of treatment, relief in symptom - amount of bleeding by 2 grades i.e. good relief is observed in 51.79% subjects; whereas 14.29% subjects shows complete relief and 28.57% subjects shows mild relief in symptom in duration of bleeding. Statistically significant ($p < 0.001$) results are seen in the study. Findings show that Femohill Capsule an Ayurvedic proprietary drugs reduced amount & duration of abnormal uterine bleeding as well as abdominal pain associated with menstruation and there is also improvement in other symptoms like weakness, giddiness, low back pain, pain associated with abnormal uterine bleeding.

As in the pathogenesis of *Asrugdara*, *chala guna* of *vaata*, *Sara* and *dravya guna* of *pitta* increase the amount of blood and mixed along with *raja* which increases uterine blood flow. To stop this excessive blood flow, the treatment like *Raktstambhan* with the help of, *Tikta-Kashay rasa* is require to reduce *chala guna* of *vaata*, *Sara* and *dravya guna* of *pitta* as well as *sheet* and *madhur rasa* drugs might also have affect on vitiated *pitta*.

Composition of Femohills Capsule is collectively having *Vata* and *Pittashamaka* as well as *raktastambhan*, *rasayana*, and *vedanasthapana* properties. Chief ingredient *Lodhra* (*Symplocus racemosus*) and *Ashoka*

(*Saraca indica*) along with *Nagkeshar* (*Messua ferrea*) reduces excessive quantity of abnormal uterine blood flow by its *raktstambhan* property and *Dashmula* a polyherbal formulation reduces abdominal pain during menstruation and low backache by its *ushna virya* and *Vatahar*, *Vednasthapan* properties. The *pitta shamaka* properties of *Shatavari* (*Asparagus racemosus*), *Kumari* (*Aloe barbadensis*), *Yashtimadhu* (*Glycyrrhiza glabra*), *Mudgaparni* (*Phaseolus trilobus*) and *Mashparni* (*Teramnus labialis*) by its *sheeta* (cold) & *snigdha* (unctuous) *gunas*; they also reduce weakness, giddiness by their *balya* and *brumhan* properties. No any adverse reaction was noted during the study.

5. CONCLUSION

It is concluded that the effect is of the treatment of Femohill capsule is effective in the management of menorrhagia i.e. heavy menstrual bleeding HMB. This study provides the evidence in support of the potential efficacy of Femohill capsule an proprietary Ayurvedic medicines. It is a safe and effective in the treatment of menorrhagia

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