

EFFECTIVE MANAGEMENT OF MENORRHAGIA WITH AN AYURVEDIC NON-HORMONAL FORMULATION 'VEERHA'- A CLINICAL STUDY

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ABSTRACT

Menstruation is a crucial factor in determining women's health. Worldwide, menstrual disturbances and associated problems are rising rapidly. Menorrhagia is a common symptom in women referring to heavy or prolonged bleeding, which arises due to various underlying disease conditions. Although various approaches to management are available, irrational selection of treatment is prevalent. The present study is an open-label, single center, non-comparative, retrospective clinical study. This study was aimed to evaluate the efficacy of a non-hormonal Ayurvedic proprietary formulation 'Veerha' containing ingredients like Ashoka (*Saraca asoca*), Lodhra (*Symplocos racemosa*), Musta (*Cyperus rotundus*), Kramuka (*Areca catechu*), Mocharasa (*Bombax ceiba*), Shatavari (*Asparagus racemosus*), etc. in menorrhagia. A total of 90 patients suffering from heavy, prolonged or heavy and prolonged menses falling in the age group of 21-50 years and fulfilling all the inclusion criteria were considered for the study. Patients diagnosed with serious gynecological conditions like endometriosis, adenomyosis, etc. were excluded from the study. Four tablets of Veerha (1g each) were administered daily with water for three consecutive months. The patients were followed up after completion of three months to assess amount of bleeding, period of bleeding, etc. 75.94% patients reported reduced bleeding and 55.17% patients reported shortened period length. Associated complaints like dysmenorrhea, passage of blood clots also showed significant improvement. The p value was found to be less than 0.05. The results were statistically as well as clinically significant. No adverse events or adverse drug reactions were noted during the study. All the patients tolerated the medicine well and none experienced worsening of the condition.

KEYWORDS: Menorrhagia, ayurvedic formulation, *veerha*.

INTRODUCTION

Menstruation is a prime determinant of a woman's reproductive health. Deviation in diet and lifestyle habits in the current times have led to the advent of various non-communicable diseases and menstrual disturbances in women. Menorrhagia is a common complaint in women which refers to heavy or prolonged cyclical bleeding at normal intervals. Menstrual blood loss exceeding 80ml per cycle or bleeding prolonged beyond 7 days is considered as menorrhagia.^[1] Causes of menorrhagia range from trivial to serious underlying disease conditions like uterine fibroids (leiomyomata), uterine polyps, adenomyosis, endometriosis, hormonal imbalances, cancers, bleeding disorders, dysfunctional uterine bleeding, etc. Menorrhagia can be associated with both ovulatory and anovulatory cycles. Certain

medications like anticoagulants, estrogen and progestins, antipsychotics, corticosteroids, etc. are also reported to cause menorrhagia. The conventional management of menorrhagia includes two approaches viz. medical and surgical, depending upon the severity, chronicity and the underlying cause. The medical management involves non-hormonal and hormonal medication. The non-hormonal treatment includes administration of NSAIDs like mefenamic acid, reducers of capillary fragility like ethamsylate and antifibrinolytics like tranexamic acid. While the hormonal treatment includes the administration of oral progestogens, androgens, combined OCPs and gonadotropin releasing hormone antagonists. The surgical interventions include dilation and curettage, endometrial ablation, etc. While in severe unmanageable cases, hysterectomy is advised. Hormone-

releasing intrauterine system is another approach in the management of menorrhagia.^[2,3] Although various treatment approaches are available, none of these treatments address the root cause. Therefore, the patients either get temporary relief or the condition might even worsen leading to the need for surgical interventions like Hysterectomy. Considering the substantial load of menorrhagia on the healthcare system, there is an ardent need to scout for effective and safe alternatives for the currently available treatment options. Ayurveda has an ocean full of wisdom to offer in the treatment of gynecological disorders. The relatively safe herbal and herbal-mineral formulations exhibit tremendous results

in menstruation-related problems. The present in-clinic response study intends to evaluate the efficacy of a non-hormonal proprietary Ayurvedic formulation 'Veerha' in patients suffering from menorrhagia.

MATERIALS AND METHODS

- 1. Study design-** Single-centric, open-label, non-comparative clinical study.
- 2. Sample size-** A total of 90 eligible patients suffering from menorrhagia were prescribed *Veerha* for a period of 3 months (90 days)

Age- wise distribution of participants is mentioned in the table below.

Table 1: (Age-wise distribution of participants).

Age Group (in years)	Number of participants
21-30	26
31-40	32
41-50	30
Below 20/ Above 50	2
Total participants	90

A) Inclusion criteria

1. Pelvic inflammatory disease.
2. Endometrial hyperplasia - Endometrial thickness below 10mm.
3. PCOD.
4. Hormonal imbalance.
5. Mild and moderate endometriosis.
6. Small fibroids of size below 2cm and up to 3 in number.

B) Exclusion criteria

1. Severe endometriosis.
2. Adenomyosis
3. Multiple fibroids (more than 3) and fibroids larger than 2cm in size.
4. Bleeding/ blood clotting disorders like Von Willebrand disease, anti-phospholipid syndrome,

disseminated intravascular coagulation, congenital hypo or afibrinogenemia, etc.

5. Cancers- Cervical, ovarian, uterine, etc.
6. Endometrial hyperplasia- Endometrial thickness more than 10mm.

C) Study site- An Ayurveda gynecology clinic in Mumbai.

D) Details of the study product

1. Name of the product- *Veerha* Ayurvedic tablets manufactured and marketed by Gynoveda Pvt. Ltd.
2. Composition- *Lodhra*, *Ashoka*, *Kutaja*, *Triphala*, *Kutki* are some of the ingredients. The detailed composition is given in table 2.
3. Dosage- 2 tablets of 1g each twice a day with water. Total dose per day was 4g.

Table-2: (Composition of *Veerha* tablet with properties of each ingredient).

Ingredient	Rasa	Vipak	Veerya	Guna	Karma
<i>Lodhra</i> (<i>Symplocos racemosa</i>)	<i>Kashay</i>	<i>Katu</i>	<i>Sheeta</i>	<i>Laghu</i>	<i>Grahi, Raktastambhak, Balya, Shothaghna</i>
<i>Ashoka</i> (<i>Saraca asoca</i>)	<i>Kashay, tikta</i>	<i>Katu</i>	<i>Sheeta</i>	<i>Laghu</i>	<i>Raktasangrahi, Vedanasthapak</i>
<i>Kutaja</i> (<i>Holarrhena antidyenterica</i>)	<i>Katu, kashay, tikta</i>	<i>Katu</i>	<i>Sheeta</i>	<i>Ruksha</i>	<i>Sangrahi, Paachak, Raktasangrahi</i>
<i>Haritaki</i> (<i>Terminalia chebula</i>)	<i>Pancharasa (except lavana)</i>	<i>Madhur</i>	<i>Ushna</i>	<i>Ruksha, laghu</i>	<i>Deepana, Paachana, Anulomana, Vayahsthaapana</i>
<i>Amalaki</i> (<i>Emblica officinalis</i>)	<i>Pancharasa (except lavana)</i>	<i>Madhur</i>	<i>Sheeta</i>	<i>Laghu, grahi</i>	<i>Rasayana, Mruduvirechana, Vrushya</i>
<i>Bibhitaki</i> (<i>Terminalia</i>)	<i>Katu, tikta</i>	<i>Madhur</i>	<i>Ushna</i>	<i>Laghu, sara, ruksha</i>	<i>Bhedana</i>

<i>bellirica)</i>					
<i>Kutaki (Picrorrhiza kurroa)</i>	<i>Tikta, katu</i>	<i>Katu</i>	<i>Sheeta</i>	<i>Ruksha, laghu</i>	<i>Deepana, Rechana</i>
<i>Patanga (Caesalpinia sappan)</i>	<i>Tikta, kashay, Madhur</i>	<i>Katu</i>	<i>Sheeta</i>	<i>Ruksha</i>	<i>Vranaropana, raktastambhana, Shonitasthaapana, Daahaprashamana</i>
<i>Aamra beeja (Mangifera indica)</i>	<i>Kashay, Madhur, amla</i>	<i>Katu</i>	<i>Sheeta</i>	<i>Ruksha</i>	<i>Sangrahi, daahaghna</i>
<i>Kramuka (Areca catechu)</i>	<i>Kashay</i>	<i>Katu</i>	<i>Sheeta</i>	<i>Sara, guru, ruksha</i>	<i>Deepana, paachana, rechana</i>
<i>Musta (Cyperus rotundus)</i>	<i>Tikta, katu, kashay</i>	<i>Katu</i>	<i>Sheeta</i>	<i>Laghu, ruksha</i>	<i>Deepana, paachana, sangraahi</i>
<i>Daruharidra (Berberis aristata)</i>	<i>Tikta, kashay</i>	<i>Katu</i>	<i>Ushna</i>	<i>Ruksha, laghu</i>	<i>Paachana, grahi, rasayana, pittavirechaka</i>
<i>Patha (Cissampelos pareira)</i>	<i>Katu, tikta</i>	<i>Katu</i>	<i>Ushna</i>	<i>Laghu</i>	<i>Vrushya, tridoshaghna, shoolahghna</i>
<i>Jambu (Syzygium cumini)</i>	<i>Kashay, Madhur</i>	<i>Katu</i>	<i>Sheeta</i>	<i>Guru</i>	<i>Grahi, Rochana, Paachana, Vishtambhi</i>
<i>Lajjalu (Mimosa pudica)</i>	<i>Kashay, tikta</i>	<i>Katu</i>	<i>Sheeta</i>	<i>Laghu</i>	<i>Yonirogahara, grahi</i>
<i>Mocharasa (Bombax ceiba)</i>	<i>Kashay</i>	<i>Katu</i>	<i>Sheeta</i>	<i>Laghu</i>	<i>Stambhana, vranaropana</i>
<i>Jeeraka (Cuminum cyminum)</i>	<i>Katu</i>	<i>Katu</i>	<i>Ushna</i>	<i>Laghu, ruksha</i>	<i>Deepana, paachana, vatanulomana, grahi</i>
<i>Khadira (Acacia catechu)</i>	<i>Tikta, katu</i>	<i>Katu</i>	<i>Sheeta</i>	<i>Laghu, ruksha</i>	<i>Stambhana, krimighna</i>
<i>Guduchi (Tinospora cordifolia)</i>	<i>Tikta, kashay</i>	<i>Madhur</i>	<i>Ushna</i>	<i>Guru, snigdha</i>	<i>Vedanasthaapana, anulomana, tridoshaghna, vrushya, daahaprashamana, rasayana</i>
<i>Gokshura (Tribulus terrestris)</i>	<i>Madhur</i>	<i>Madhur</i>	<i>Sheeta</i>	<i>Guru, snigdha</i>	<i>Vedanasthaapana, anulomana, balya</i>
<i>Utpala (Nelumbo nucifera)</i>	<i>Kashay, Madhur, tikta</i>	<i>Madhur</i>	<i>Sheeta</i>	<i>Laghu, snigdha, picchhila</i>	<i>Shonitasthaapana, stambhana, daahaprashamana, prajasthaapana, rasayana</i>
<i>Shatavari (Asparagus racemosus)</i>	<i>Madhur, tikta</i>	<i>Madhur</i>	<i>Sheeta</i>	<i>Guru, snigdha</i>	<i>Grahi, vedanasthaapana, shoolahara, rasayana</i>
<i>Shweta musali (Asparagus adscendens)</i>	<i>Madhur</i>	<i>Madhur</i>	<i>Sheeta</i>	<i>Guru, snigdha</i>	<i>Balya, rasayana, bruhana</i>
<i>Vasa (Adhatoda vasica)</i>	<i>Tikta, kashay</i>	<i>Katu</i>	<i>Sheeta</i>	<i>Ruksha, laghu</i>	<i>Shothahara, vedanasthaapana, raktastambhaka</i>
<i>Godanti bhasma</i>	<i>Lavana</i>	<i>Madhur</i>	<i>Sheeta</i>	-	<i>Deepana, balya</i>
<i>Shuddha gairika</i>	<i>Madhur, kashay</i>	<i>Madhur</i>	<i>Sheeta</i>	<i>Snigdha</i>	<i>Raktastambhana</i>
<i>Lauha bhasma</i>	<i>Tikta, kashay, Madhur</i>	<i>Madhur</i>	<i>Sheeta</i>	<i>Ruksha, guru</i>	<i>Shoolahara, vrushya, lekhana</i>

RESULTS

A) Baseline Demography

A total of 90 subjects between the age group of 21 to 50 years participated in the study. At baseline 2 participants had menstrual cycle at a frequency of 22-28 days, 39 had

a menstrual cycle frequency of 25-28 day, while 49 subjects had a frequency of 28-35 days.

Table-3: (Length of menstrual cycle in days).

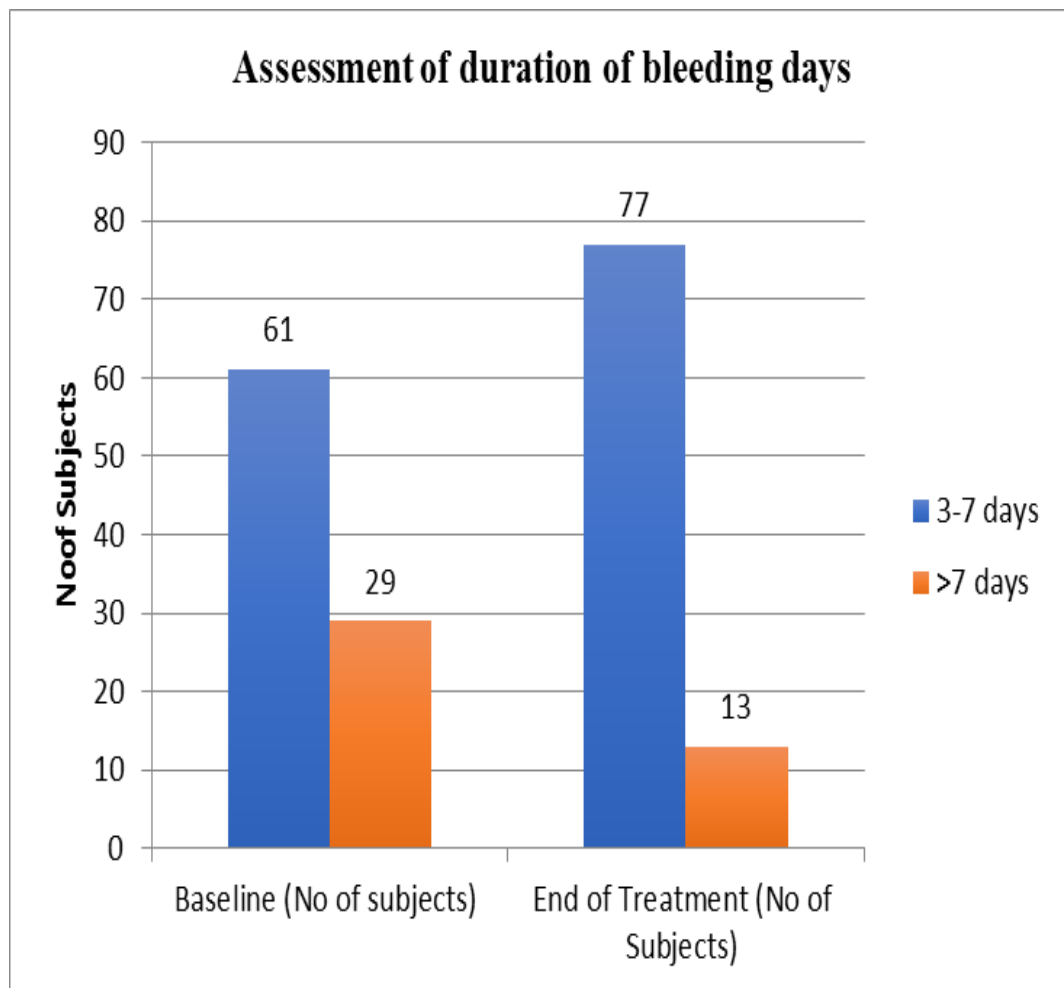
Cycle length	Number of participants
22-28	2
25-28	39
28-35	49
Total	90

B) Efficacy Parameter assessment

Parameter 1 - Assessment of Number of bleeding days per Menstrual cycle (Duration)

Table-4: (Period length).

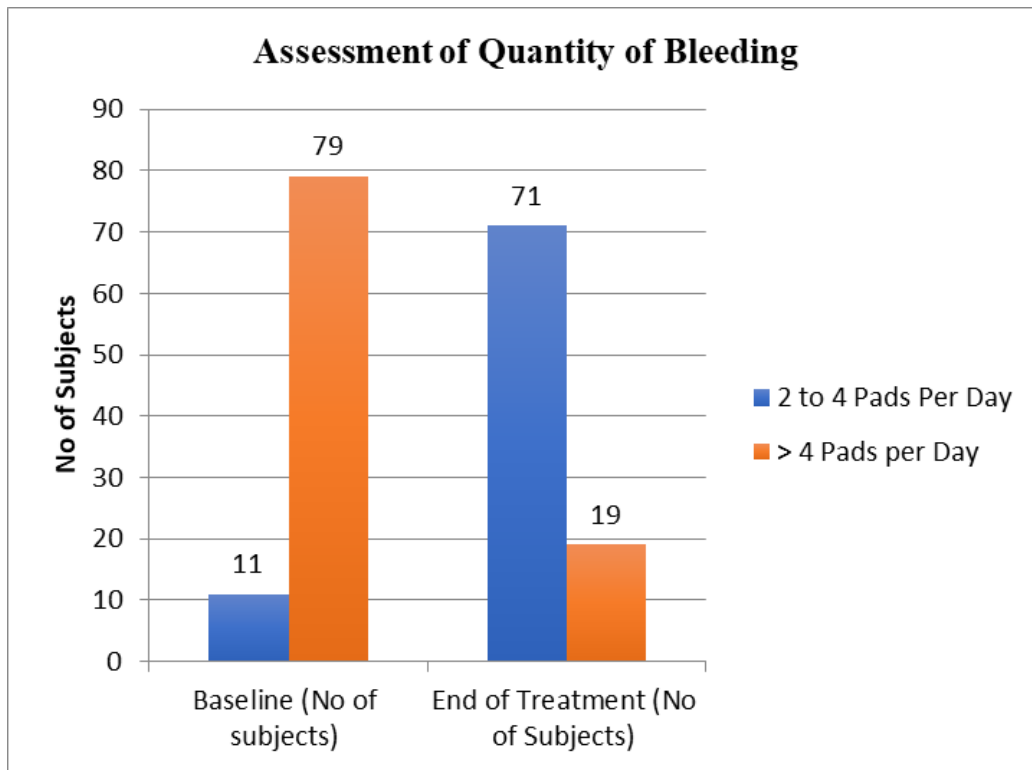
Duration of period	Baseline (No. of subjects)	End of Treatment (No. of Subjects)
3-7 days	61 (67.77%)	77 (85.55%)
>7 days	29 (32.22%)	13 (14.44%)
p value	p<0.05 (S)	



Parameter 2 - Assessment of Quantity of Bleeding Per Menstrual Cycle

Table-5: (Quantity of blood per cycle).

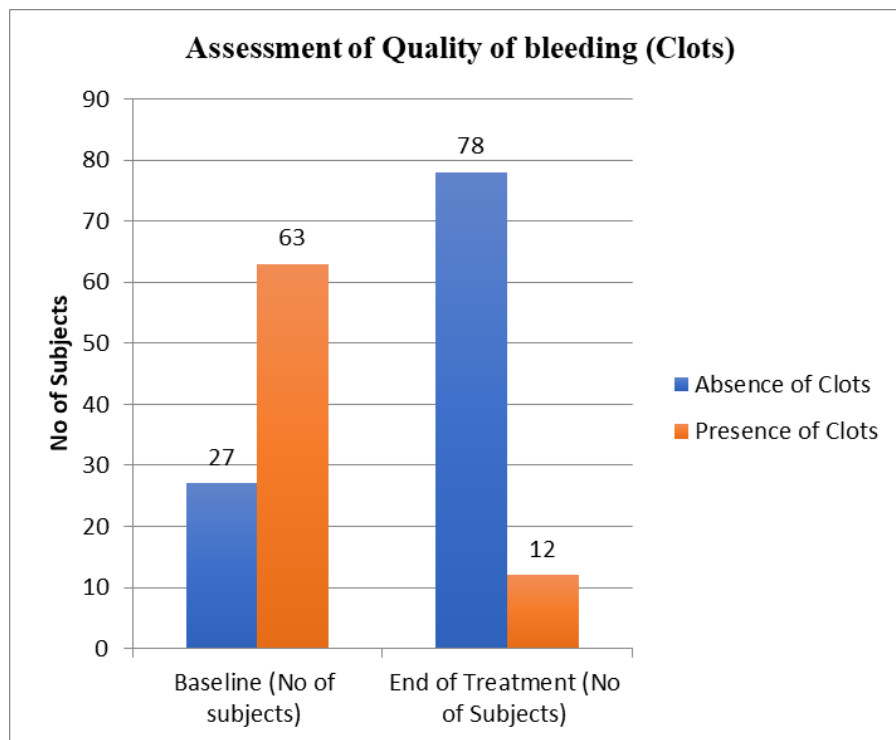
Average no. of pads changed per day	Baseline (No. of subjects)	End of Treatment (No. of Subjects)
2 to 4 Pads Per Day	11 (12.22%)	71 (78.88%)
> 4 Pads per Day	79 (87.77%)	19 (21.11%)
p value	p<0.05 (S)	



Parameter 3: Assessment of Quantity of Blood Clots.

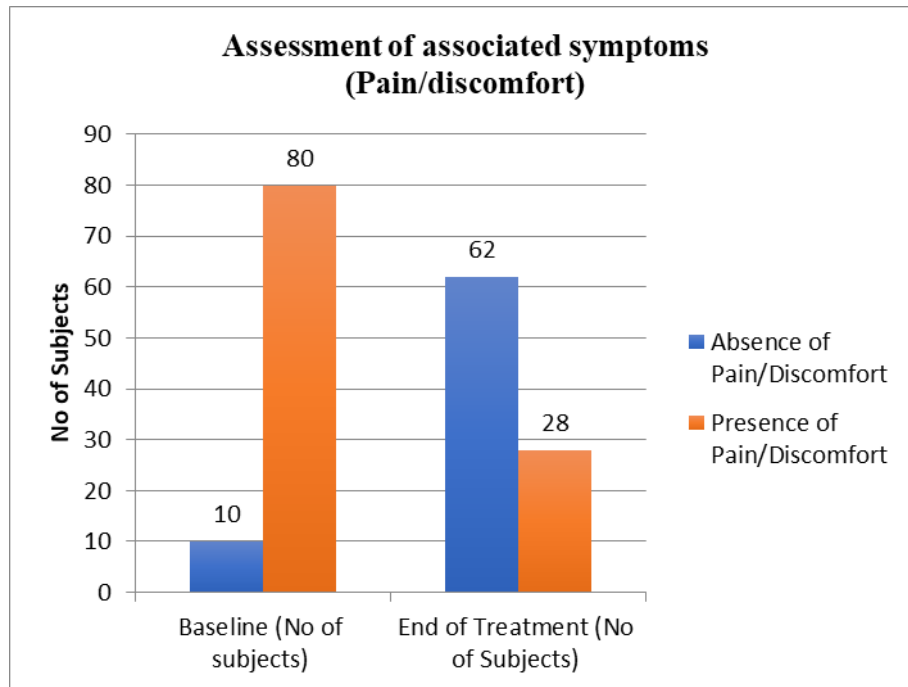
Table-6 (Blood clots).

Presence/Absence of Clots in Menstrual Bleeding	Baseline (No. of subjects)	End of Treatment (No. of Subjects)
Absence of Clots	27 (30%)	78 (86.66%)
Presence of Clots	63 (70%)	12 (13.33%)
p value	p<0.05 (S)	



Parameter 4: Assessment of associated symptoms (Pain/discomfort).**Table-7: (Pain assessment).**

Presence/absence of pain/discomfort	Baseline (No. of subjects)	End of Treatment (No. of Subjects)
Absence of pain/discomfort	10 (11.11%)	62 (68.88%)
Presence of pain/discomfort	80 (88.88%)	28 (31.11%)
p value	p<0.05 (S)	

**DISCUSSION**

According to modern medicine, menorrhagia is known to be a symptom in many mild to severe disease conditions. Similarly, Ayurveda scholars have explained *Aartava vriddhi* (excessive menstrual bleeding) as a symptom in various conditions like '*Raktapradara (Asrugdara)*', '*Asruja*' or '*Raktayoni yonivyapada*', etc. Vitiating of *Pitta dosha* and increase in the quantity of *Rakta dhatu* are known to cause *Aartava vriddhi*.^[4] The pathophysiology of menorrhagia comprises events like inflammation, increase in the endometrial thickness, any gynecological condition leading to increased surface area of uterus, anovulatory menstrual cycles, uterine atonicity and hormonal imbalance. One or more of these events occur in different gynecological disorders which eventually present in the form of menorrhagia. If we closely examine the conventional treatment modalities opted for managing menorrhagia, we can understand most of the cases are subjected to hormonal treatment which provide temporary relief by suppression of the symptoms. Whereas the herbs mentioned in Ayurveda are known to arrest the pathophysiology significantly. The herbs in *Veerha* like *Guduchi*, *Triphala*, *Gokshura*, *Shatavari*, etc. have anti-inflammatory action. Herbs like *Shatavari*, *Ashoka*, *Ashwagandha* and *Shweta musali* are known to improve the tonicity of the uterine musculature thus strengthening and causing tonic contractions for expulsion of endometrium in controlled manner. The astringent effect of *Lodhra*, *Khadira*, *Mocharasa*, etc.

helps in the capillary contraction which controls excess bleeding. The herbs in *Veerha* are also known to induce ovulation by maintaining hormonal balance. Due to the corrective effects of all the ingredients in *Veerha*, excellent results were observed in a significant number of participants in the study. Not only the amount of bleeding and the period length has decreased, but associated symptoms like passage of clots and dysmenorrhea have also shown significant improvement in the study subjects. Paired t-test was applied for the statistical analysis of all the parameters. The p value obtained was less than 0.05 which clearly indicate that the results obtained are statistically significant. No adverse event or adverse drug reaction was reported during the study. All the patients tolerated the medicine well. No worsening of symptoms was noted.

CONCLUSION

Considering the clinical as well as the statistically significant results obtained in the present study, we can clearly state that the non-hormonal, proprietary Ayurvedic formulation *Veerha* is an efficacious and safe medicine in menorrhagia and can be established as a potential alternative to the conventional medicines or as an adjuvant to the multiple treatment modalities prescribed in modern medicine. However, there is a huge scope for research, in order to establish Ayurvedic medicines like *Veerha* as the drug of choice for the holistic management of menorrhagia.

Declaration

Informed consent was obtained from all the study participants prior to study initiation. The authors declare that no competing interests exist.

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