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A pilot study evaluating the therapeutic efficacy of Perumbadu Nivarani a Siddha herbal formulation in the management of Perumbadu (Menorrhagia).

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Abstract

Objective: To determine the effect of Perumbadu Nivarani, a Siddha herbal formulation in Menorrhagia patients.
Method: The pilot study was conducted at the Ayothidoss Pandithar Hospital, National Institute of Siddha, Tambaram Sanatorium, Chennai-47. Ten patients were recruited in the study those meeting with inclusion and exclusion criteria. Those patients were treated with 40 ml of Perumbadu Nivaran-twice a day for 5 – 7 days.
Result: There was a significant decrease in the bleeding volume as observed by the Pictorial Menstrual Bleeding Assessment Chart (PBAC) before and during treatment.
Conclusion: Perumbadu Nivarani has shown non-hormonal, safe and effective in the management of Menorrhagia and also did not cause any adverse reaction to any patients.

Keywords: Menorrhagia, Perumbadu, Excessive bleeding, Siddha medicine.

Introduction

Menorrhagia is defined as menstruation at regular cycle intervals but with excessive flow and duration and is one of the most common gynecological complaints in contemporary gynecology [1].

Clinically, menorrhagia is defined as total blood loss exceeding 80 ml per cycle or menses lasting longer than 7 days or both [2].

The World Health Organization reports that 18 million women aged 30-55 years perceive their menstrual bleeding to be exorbitant [3]. Reports show that only 10% of these women experience blood loss severe enough to cause anemia or be clinically defined as menorrhagia. In practice, measuring menstrual blood loss 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 4-5 days and flow measuring 20-80 ml [2].

Menorrhagia must be distinguished clinically from other common gynecological diagnoses. These include

metrorrhagia (uterine bleeding occurring at irregular but frequent interval), menometrorrhagia (prolonged uterine bleeding occurring at irregular intervals), polymenorrhea (bleeding at intervals < 21 days), and abnormal uterine bleeding (abnormal uterine bleeding that is unrelated to any anatomic lesion) [4].

Nearly 30% of all hysterectomies performed to alleviate heavy menstrual bleeding. Historically, definitive surgical correction has been the mainstay of treatment for menorrhagia. Modern Gynaecology has trended toward conservative therapy both for controlling costs and the desire of many women to preserve their uterus

According to the text of "YUGI VAITHIYA SINTHAMANI" Perumpadu is classified into 4 types. symptoms of Perumpadu are distended abdomen with reddish black menstrual bleeding, headache, abdominal pain, low back ache, hyperpigmentation of the body.

If the disease is left untreated, it will lead to the complication such as anemia, dropsy, shortness of breath, tiredness, poor concentration and depression.

In National Institute of Siddha outpatient department, a considerable number of female patients are recorded with symptoms of Perumpadu and due to this monthly or unpredictable issue they cannot do their daily duties and the entire family members are put in to trouble especially the kids. Their financial status also sounds bad since the working women are affected most.

In SIGICHARATNADEEPAM, PERUMBADU NIVAARANI is exclusively specified for Perumpadu which is in practice.

The ingredient of PERUMBADU NIVAARANI is only Naavalpattai (*Syzygium cumini*) and buffalo's buttermilk which is well known for its astringent property which is purely herbal and a single herbal preparation which is not taken in trial before. Hence the drug Perumbadu Nivaarani was selected as a drug for Perumbadu.

Naavalpattai (*Syzygium cumini*) is one of the widely used medicinal plants in the treatment of various diseases. The plant is rich in compounds containing anthocyanins, glucoside, isoquercetin, ellagic acid, myrecetin and kaemferol. The stem bark is rich in betulinic acid, β – sitosterol, gallic acid and ellagic acid, friedelin, quercetin kaempferol, myricetin, bergenins, tannins and flavonoids. The presence of gallo and ellagi-tannins may be responsible for the astringent property of stem bark. Also the plant has antioxidant, anti-inflammatory, neuropsycho-pharmacological, anti-microbial, anti-bacterial, anti-HIV, antileishmanial, antifungal, nitric oxide scavenging, free radical scavenging, anti-diarrheal, antifertility, anorexigenic, gastroproductive, anti-ulcerogenic, behavioural effects and radioproductive activities [5].

Aim of the study

To evaluate the clinical efficacy of Perumbadu Nivaarani in Perumbadu.

Objective of the study

- To study the clinical efficacy of drug Perumbadu Nivaarani by PBAC (Pictorial Blood Assessment Chart).
- To study the other related factors such as stress, anaemia, tiredness, etc.,

Materials and Methods

Ingredients:

1. Bark of *Syzygium cumini* -10g
2. Buffalo's butter milk - 40ml.

Identification and Collection of the Ingredients:

The bark of *Syzygium cumini* was collected from Syzygium tree. It is identified and authenticated by Department of Medicinal Botany, National Institute of siddha, Chennai. The buffalo's butter milk was prepared by self from Buffalo's curd.

Purification of Raw Drugs

The ingredients were purified by scraping the outer skin as mentioned in the text book of Marundu Sei Iyalum Kalaiyum.

Preparation of the trail drug:

The bark of *Syzygium cumini* is purified and crushed with 40 ml of buffalo's buttermilk and drained with the help of pure cotton cloth.

Drug Storage

- The bark of *Syzygium cumini* is purified and stored in air tight container.
- Buffalo's butter milk is prepared freshly whenever required.

Dosage: 40 ml twice a day after food.

Conduct of the Study:

This study was conducted in Sool and Magalir Maruthuvam Inpatient department of Ayothidoss Pandithar Hospital attached to National Institute of Siddha, Tambaram sanatorium, Chennai-47 with standard protocol which is approved by Institutional Ethical Committee of National Institute of Siddha (NIS/IEC/10/2016-17/25-20.5.2016). The trail has been registered in clinical trial registry India (CTRI/2017/07/008966).

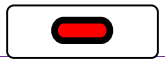
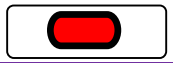
Before enrolment into the study the informed consent was obtained from the patients. A total of 10 patient's between 16 to 40 years of age with clinical features of distended abdomen with reddish black menstrual bleeding, headache, abdominal pain, low back ache, hyperpigmentation of the body are chosen for enrolment based on inclusion criteria.

After enrolling the patient in the study, the screening form was filled. A separate file for each patient is opened and all forms were arranged in the file. Study No. and Patient No. were entered on the top of file for easy identification. Patients who were all selected under the criteria were admitted in In Patient ward of Sool Magalir Maruthuvam and treated with the trial drug PerumbaduNivarani40 ml twice a day for 5 - 7 days.

Pictorial Blood Assessment Chart (PBAC) score:

It is a semi quantitative assessment of menstrual blood loss based on women filling in the number and appearances of their sanitary protection and size of blood clots on a pictorial chart. Scores of 100 or more equate to a menstrual blood loss of 80 mL or more[6].

Table 1: PBAC scoring system:

Pads		
1 point	For each lightly stained pad	
5 points	For each moderately stained pad	
20 points	For each completely saturated pad	
Clots/Flooding		
1 point	For each small clot	
5 points	for each large clot	
10 points	For each episode of flooding	

Results

The results observed during the study period were discussed below;

In AGE group, among 10 patients 3 patients were in the age group of 16-20 years, 2 patients were in the age group 21-25 years, 1 patient were in the age group 31-35 and 4 patients were in the age group 36-40. **(Table 2).**

In DIET, out of 10 patients 9 (90%) patients were mixed in diet and 1 (10%) patient is vegetarian.

In FAMILY HISTORY all the 10 patients recruited in the trial had negative history of Menorrhagia in their family.

PBAC score is calculated before treatment and on treatment. **(table 3)**

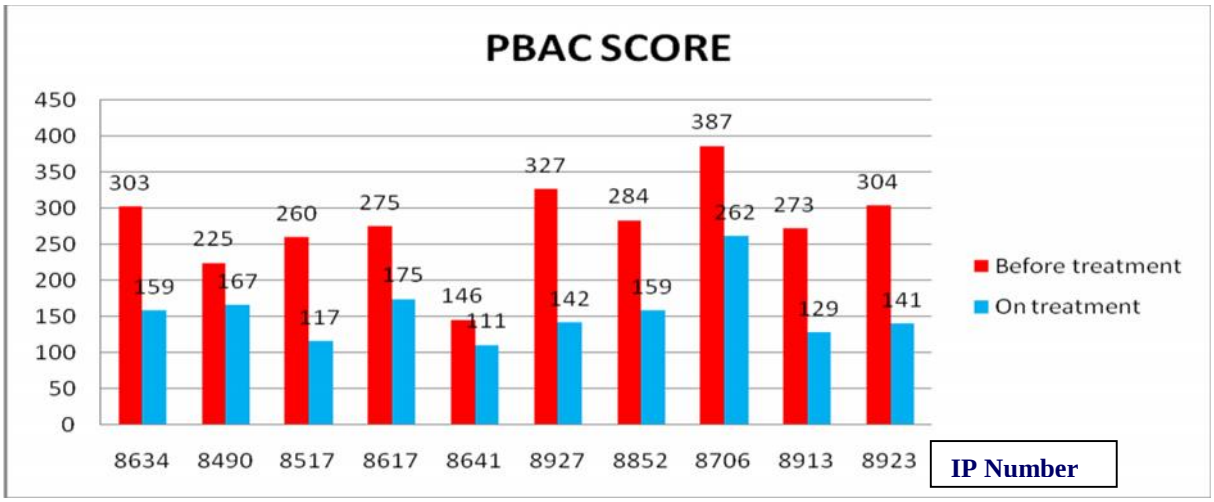
Table 2: Age wise distribution:

Sl.No	Age Group	No. of patients	Percentage
1	16-20	3	30%
2	21-25	2	20%
3	26-30	-	-
4	31-35	1	10%
5	36-40	4	40%

Bar diagram 1

Table 3: PBAC score assessment:

Sl.No	IP no	PBAC score	
		Before treatment	On treatment
1	8634	303	159
2	8490	225	167
3	8517	260	117
4	8617	275	175
5	8641	146	111
6	8927	327	142
7	8852	284	159
8	8706	387	262
9	8913	273	129
10	8923	304	141



Bar diagram 2

Table 4: PBAC score

Sl.No	PBAC score	Before treatment		On treatment	
		No. of patients	Percentage	No. of patients	Percentage
1	100-150	1	10%	5	50%
2	151-200	-	-	4	40%
3	201-250	1	10%	-	-
4	251-300	4	40%	1	10%
5	301-350	3	30%	-	-
6	351-400	1	10%	-	-

Discussion

Menorrhagia may happen,

If there is an any change in the normal fluctuations of progesterone and estrogen, the endometrium or inner lining of the uterus can build too much, which is then shed during menstruation.

If the ovary does not release an egg, no progesterone is produced, resulting in hormone imbalance.

10 patients with Menorrhagia are treated with the trail drug Perumbadu Nivarani. From the results it is noted that the trail drug reduces the excessive menstrual bleeding during the treatment.

In the present study the incidence is more common between 31 – 40 years.

All the 10 patients had a significant reduction in menstrual blood flow.

There was a significant decrease in the bleeding volume as observed by the Pictorial Menstrual Bleeding Assessment Chart before and during treatment.

Before treatment the PBAC score ranges from 100 to 390 and the mean value is 275.

On treatment the PBAC score ranges from 100 to 270 and the mean value become 142.

From the above results and discussion, it is assumed that the trail drug may have styptic action, so that there is

- Reduction in duration of flow
- Reduction in amount of flow
- Reduction in clots.

Conclusion

From the above outcome we can safely conclude that the trail drug taken in the present study is pure, gentle, non-hormonal, safe and effective in the management of Menorrhagia and hysterectomy should no longer be the only treatment option presented to women with abnormal uterine bleeding.

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