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Case Study

CLINICAL EVALUATION ON EFFECT OF ROOT OF *AMLEEKA* (*TAMARINDUS INDICA* LINN.) IN *NASTARTHAVA* (AMENORRHOEA) - A CASE SERIES STUDY

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ABSTRACT

Menstrual abnormalities are common in women nowadays due to lifestyle modifications, changes in dietary habits and lack of excercise. Of these menstrual disorders, amenorrhoea or absence of menstruation is a common clinical presentation for abnormalities of hypothalamo pituitory ovarian axis. Ayurvedic treatise, Vaidya Manorama and Chikitsamanjary mentions the use of root of *Amleeka* in treating *Nastarthava* (Amenorrhoea) – which is absence or abnormal cessation of menstruation. Amenorrhoea causes much physical and psychological problems to affected women. Considering the disease scenario, drawbacks of existing treatment modalities in modern medicine (which advocates greater use of steroids, hormones or surgery), effectiveness of the drug used by traditional practitioners and its easy availability, it seems ideal to investigate the effect of root of *Amleeka* in *Nashtartava* so as to provide a safe and affordable treatment. The clinical trial was undertaken as a before and after trial with 30 patients for a period of 3 months with the test drug and three months follow up. The assessment criteria were the amount and duration of menstrual bleeding, interval of menstrual cycle and associated symptoms before trial, after trial and after follow up. The trial drug was found to be effective in improving amount of menstrual bleeding from scanty to moderate and duration of bleeding from short to moderate level (P<0.001***). Thus it can be concluded that study drug is effective in inducing menstruation.

KEYWORDS: *Amleeka*, *Tamarindus indica* Linn., *Nastarthava*, Amenorrhoea.

INTRODUCTION

Ayurveda – the life science, a traditional documented system of health care, provides a number of useful and harmless medicaments including single drug therapies which were shown effective through prior experiences. *Amleeka* (*Tamarindus indica* Linn.) is one such a common and useful drug described under *Amla varga* (group of sour drugs) belonging to family – Caesalpiniaceae. Ayurvedic treatise like Chikitsa manjary and Vaidya Manorama prescribes the use of root of *Amleeka* in treating *Nastarthava* (Amenorrhoea)[1,2].

Nastarthava (amenorrhoea) can be defined as absence or abnormal cessation of menstruation, which is a common clinical presentation for abnormalities of hypothalamo pituitary ovarian axis. Amenorrhoea causes much physical and psychological problems to affected women. It has become a leading cause of infertility today which lead to an unhealthy family life. Due to changes in lifestyle, dietary habits, lack of exercise and various environmental factors the prevalence of amenorrhoea is higher now a days[3,4]. Ethno botanical surveys revealed that *Amleeka* is being used by many rural traditional practitioners to induce menstruation in amenorrhoea as being a common and easily available drug and so far no toxicity reported[5]. As evidence based medicine is the need of the hour, this study was an attempt to develop a scientific rationale regarding the use of root of *Amleeka* in *Nashtartava.*

Objective of the study

To clinically evaluate the effect of root of *Amleeka* (*Tamarindus indica* Linn.) in *Nastarthava* (amenorrhoea) by orally administering drug for three consecutive months and clinically assessing signs and symptoms before treatment, after treatment and after follow up.

MATERIALS AND METHODS

Study design - interventional study.

Selection of patients – Women of age group 18-45 years complaining of absence of menstruation for last 3 or more months consecutively were selected from OPD of Department of Dravyagunavijnan, Govt.Ayurveda College Trivandrum.

Exclusion criteria

- Patients with primary amenorrhoea.
- Patients with gross structural abnormalities of uterus, thyroid disease
- Patients taking steroid medications or under long term medication for chronic illness.
- Subjects who are not co-operative.

Collection of data

The data was collected as per a case proforma. History of all cases including their age, occupation, socio economic status, educational status, personal history, history of present and past illness, menstrual history,

obstetric and treatment history were collected. General and systemic examination were done to find and rule out other systemic or structural abnormalities.

Investigations

- Haematological examination, Abdominal ultrasonography done before study to find out any ovarian or uterine pathology for amenorrhoea, Hormonal assay (FSH, LH and Prolactin) done before study to find out hormonal imbalance.

Assessment criteria

a) Amount of blood loss :

Since the exact amount of blood loss was very difficult to measure, the number of pads used by the patient with the area of soaking was considered to assess the amount of bleeding and were graded as

Scanty (0) - 1- 2 pads per day with minimum soaking.

Moderate (1)- 2 - 4 pads per day with complete soaking.

Excessive (2)- More than 4 pads per day with complete soaking

b) Duration of graded as

- Short (0) - 1-2 days.
- Moderate (1)- 3-7 days.
- Excess (2) - greater than 7 days.

c) Interval of menstruation d) Clots – Present or absent.

- Frequent (0) - less than 21 days.
- Normal (1) - 21-35 days.
- Delayed (2) - more than 35 days.

Associated symptoms like Anaemia, Body weight, General body weakness, Pain during menstruation, Abdominal distension, Appetite, Hyper pigmentation of skin were also assessed

Treatment procedure

Selected 30 patients were given 6g of powdered drug mixed with 48 ml of milk morning and evening before food twice daily. Drug was administered consecutively for three months, stopped during menstruation, then again continued with strict diet control and exercise. Amount and duration of menstrual bleeding, interval of menstrual cycle, and associated symptoms was assessed before treatment, after treatment and after follow up. During the follow up period no drug was administrated.

Statistical analysis - Values obtained were statistically evaluated using paired t test, Friedman's test and Wilcoxon's signed rank test. In datas related to clinical picture, anova test is not used. As non- parametric methods are used for analysing the data, normality assumption has been violated in the case of all parameters (by Colmogorov-Smirnov test, $P < 0.001^{***}$).

Ethical consideration - Every patient was selected after getting an informed consent from them. Before starting study consent from the authorities was also obtained.

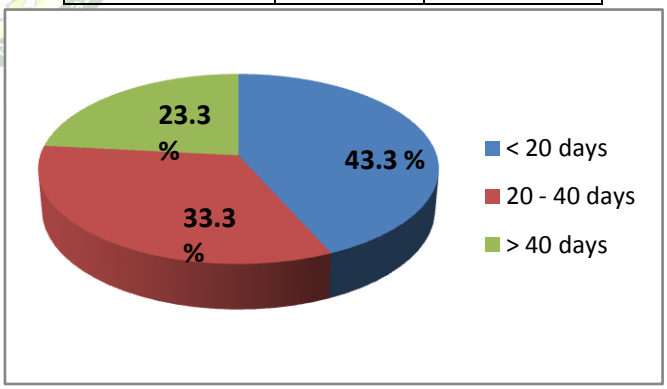
OBSERVATION AND RESULTS

Out of 30 patients majority belongs to age group 20-39 having a medium body built taking mixed diet mainly nonvegetarian. The complaints of menstrual irregularity is more with people taking non vegetarian diet consisting mostly poultry items which were grown using hormones. About 57% of the patients had moderate nature of work, but the duration of amenorrhoea was seen increased in patients who followed a sedentary mode of life. Lack of exercise and sedentary mode of life may cause obesity, insulin resistance and anovulation which may lead to amenorrhoea. Most of the patients had their body mass index (BMI) around 25 and beyond 25, indicating a relationship between amenorrhoea and BMI. Also patients with high BMI had increased body weight.

Majority of the patients had the duration of illness above 2 years. About 43.3% of the patients required less than 20 days for induction of menstruation with treatment and 23.3% required greater than 40 days. Analyzing the character of menstruation it was observed that, 80 % of the patients had scanty bleeding requiring only one or two pads, 67% of the patients were having short duration of bleeding lasting for about 1 or 2 days. All patients had delayed intervals of menstruation. About 67% of patients had clots along with menstrual bleeding and 10% had severe pain. Among the associated symptoms, the most prominent one was abdominal distension (63.3%), then decrease in appetite (37%), general body weakness (40%), hyper pigmentation of skin (37%), increased body weight (13.3%) etc.

Table and graph no.1 showing no: of days required for induction of menstruation

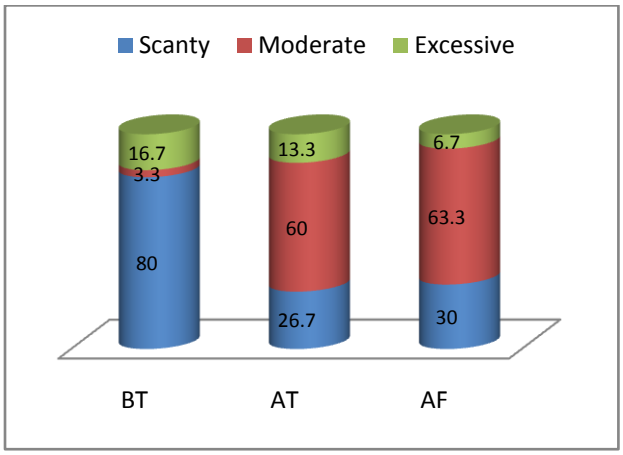
No of days	Count	percentage
< 20 days	13	43.3
20–40 days	10	33.3
>40 days	7	23.3
Total	30	100



About 43.3% of the patients required only less than 20 days for induction of menstruation with the medicine, 33.3% required 20 -40 days and 23.3% required greater than 40 days.

Table and graph no.2 showing data of effectiveness of treatment on amount of bleeding

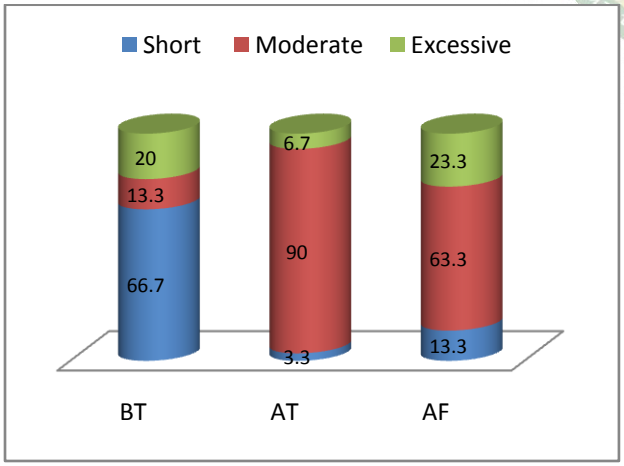
	BT		AT		AF	
Bleeding	F	%	F	%	F	%
0	24	80	8	26.7	9	30
1	1	3.3	18	60	19	63.3
2	5	16.7	4	13.3	2	6.7



From the table, it is seen that before the treatment majority (80%) of the patients were in scanty bleeding category. After treatment the percentage improved to 60%. But with the withdrawal of medicine, i.e., during follow up – 30% patients retrieved to scanty bleeding pattern. Wilcoxon's Signed Rank test showed that the treatment had significant effect before treatment and after treatment, (P< 0.001), before treatment and after follow up (P< 0.01), but after treatment and after follow up it is not significant (P>0.05).

Table and graph no.3 showing data of effectiveness of treatment on duration of bleeding

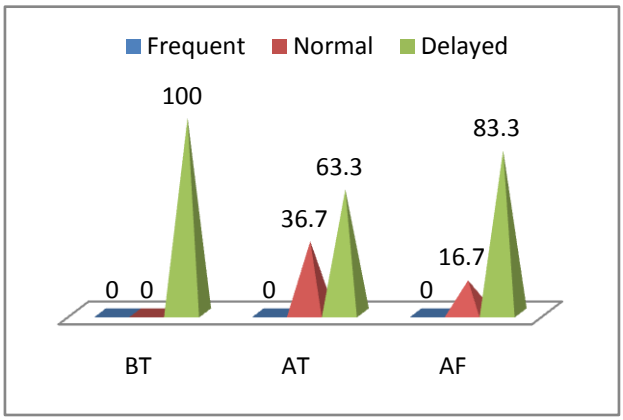
	BT		AT		AF	
Duration	**F**	**%**	**F**	**%**	**F**	**%**
0	20	66.7	1	3.3	4	13.3
1	4	13.3	27	90	19	63.3
2	6	20	2	6.7	7	23.3



From table, it is seen that before the treatment majority (66.7%) of the patients had less duration of bleeding, after treatment it reduced to 3.3% and 90% of patients came to moderate or normal bleeding category but after follow up 13.3% of patients retrieved to less bleeding category. Wilcoxon's Signed Rank test showed that the treatment has significant effect before treatment and after treatment (P< 0.001), before treatment and after follow up (P<0.001) and after treatment and after follow up it is not significant (P>0.05).

Table showing data of effectiveness of treatment on interval of bleeding

	BT		AT		AF	
Interval	**F**	**%**	**F**	**%**	**F**	**%**
0	0	66.7	1	3.3	4	13.3
1	0	13.3	27	90	19	63.3
2	30	20	2	6.7	7	23.3



From table it is seen that, all patients had delayed menstrual interval before treatment. After treatment 36.7% came to normal interval and after follow up it became 16.7% Wilcoxon's Signed Rank test showed that the treatment has significant effect before treatment and after treatment (P<0.001), before treatment and after follow up (P<0.05), and after treatment - after follow up (P>0.05) it is not significant.

On analysis of clot during menstruation**,** majority (66.7%) of the patients had clots, but after treatment it reduced to 26.7% and after follow up it retrieved to 33.3%. Wilcoxon's Signed Rank test showed that the treatment has significant effect before treatment and after treatment (P<0.001). On analysis of pain during menstruation, before treatment 10% of the patients had severe pain. But after treatment none of the patients had severe pain. Wilcoxon's Signed Rank test showed that the treatment has significant effect before treatment and after treatment (P<0.001).

DISCUSSION

Most of the patients with hirsuitism and hyper pigmentation of skin has polycystic ovarian disease. Considering *Dosha* predominance in patients, most of them (70%) were of *Vata kapha prakriti*. In addition to *Prakriti*, mode of life including food - junk foods, bakery items, sedentary nature of work etc may lead to vitiation of *Kapha*, psychological stress and anxiety may causes a *Vata* vitiation. All these may leads to *Srothorodha* and *Amavastha* which inturn added to the pathogenesis of disease. In hormonal assay done before study, no significant hormonal imbalance was seen. However serum prolactin of some patients seems to be raised. In abdominal ultrasound done to find out ovarian or uterine pathology for amenorrhoea, 66% of the patients had polycystic appearance of ovaries. While analysing the blood investigation, about 50% of patients had Hb% less than 12 gms% before treatment and after treatment there was only slight improvement observed. It was also

observed that many patients with general body weakness has less haemoglobin percentage.

After treatment, the duration and amount of menstrual bleeding of most patients showed significant improvement from the short and scanty grade to moderate(P<0.001***).Clots reduced from 66.7% before treatment to 33.3% after follow up (P< 0.001***). Pain also reduced from severe grade to moderate or mild.

In case of interval between menstrual cycle, only 36.7% came to normal interval after treatment(P<0. 05). The effect of drug was found to be more just after treatment than after follow up showing drug has action mainly during the time of medicine intake. Considering the associated symptoms, it was observed that they generally decreased with resolving of chief complaints. Most remarkable changes were noticed in case of abdominal distension (P< 0.001***) and body weight which decreased from increasing nature (P< 0.001***). In the follow up, it was noticed that most of the symptoms reappeared, but was not as severe as before.

From the study it was observed that, effect of the drug was more in patients having amenorrhoea for short duration. The amount and duration bleeding improved from scanty and short grade to moderate level in most patients. But the interval of menstrual cycle seems to be extended in almost all cases. Thus it can be concluded that the drug is effective in inducing menstruation but is not able to regularize it. The drug was found to be more effective with strict diet control and exercise.

CONCLUSION

- The root bark of *Amleeka (Tamarindus indica* Linn.) has significant effect in improving the amount of menstrual bleeding from scanty to moderate and duration from short to moderate.
- The study drug is effective in reducing clots, menstrual pain and abdominal distention. General body weakness and appetite showed slight improvement.
- The study drug was found to be effective in inducing menstruation but not able to regularize menstrual cycle.
- The medicine was found to be more effective in amenorrhoea of recent onset.
- The study drug appears to be a safe combination in the management of *Nastarthava* as no adverse effects were observed during the study.

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