

CLINICAL EFFICACY OF AN AYURVEDA POLY HERBAL FORMULATION IN MENSTRUAL MORBIDITIES – AN OPEN CLINICAL TRIAL

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ABSTRACT

Objectives: To formulate and evaluate the clinical efficacy of Rajasree Avaleha (RA), a Poly Herbal Formulation in menstrual morbidities. **Methods:** In a prospective, multicentred, open clinical trial, with a specially designed and validated Proforma, 30 women patients, age range between 15-45 years, suffering from different sorts of menstrual morbidities were selected and subjected to 10 grams of RA for a period of 3 months and assessments were done. **Results:** The poly herbal formulation RA was found to be statistically significant in women suffering from menstrual irregularities like dysmenorrhea (P 0.01), menorrhagia (P 0.01), and leucorrhea (P 0.005) however it was not found to bring any significant changes in oligomenorrhea (P 0.15). **Conclusion:** The formulated RA compound was found to be effective in relieving the symptoms of common gynecological problems like dysmenorrhea, menorrhagia and leucorrhea etc how so ever in cases of oligomenorrhea, RA has failed to achieve its therapeutic efficacy.

Keywords: Ayurveda, Poly Herbal Compound, Rajasree Avaleha, Menstrual Morbidities,

INTRODUCTION

Menstrual morbidities are common and often distressing complaints that frequently affect the quality of life of females in the current scenario¹. Of these major problems are dysmenorrhea, menorrhagia, oligomenorrhea and leucorrhea². These are broad notions that comprehend the woman's health status and are alarmingly immense³. It also encompasses the reproductive morbidity of the individual including obstetric⁴, gynecological⁵ and reproductive morbidity⁶ that adds upon results to limit fertility, compromising regular cycles and even other health problems related to the physiological imbalance of reproductive and endocrine functions⁷. Although the magnitude of menstrual morbidities is highly prevalent globally, little attention is paid in ameliorating women's menstrual morbidities⁸.

Half of India's population is constituted by women and girls⁹ and yet a majority of women population across the nation still faces reasonable impediments in safe and poised experiences with menstrual health¹⁰. Thus, in the long run, the prevalence of menstrual morbidities are becoming more and more common among the females and are of great concern since they could even deteriorate the day to day activities of women by detonating many medical repercussions. Although menstrual morbidities are often attributed to an immature HPG axis, certain other factors like PCOS, other Endocrine dysfunctions, Obesity, Anemia, Sedentary lifestyles, impaired food habits, disturbed sleep-wake cycle, and even increased levels of stress in the present day to day scenario adds to this sequelae¹¹. With a broad peak of affective and somatic complaints, menstrual morbidities are now a common picture

portraying an adverse mortality and morbidity rates, questioning the public health domains shortly.

The global burden of disease approach that accesses to the mortality and morbidity indicators of various disease has not even estimated these complex reproductive and endocrine disorders¹². Though the western medical research has evolved to be profound and widespread, the most up to date research findings have not unprecedented any impressive advances in the line of management of menstrual morbidities in an array of treatment sphere¹³. At this crisis, it's the need of the hour in expanding to focus on the increased prevalence of menstrual morbidities and suggest prompt evaluation and treatment of menstrual morbidities, with the highest priority in primary health programs to have an impact on women's health status as well as the quality of life. Ayurveda being one of the traditional medicinal systems of India, encompasses the concept of poly herbal combination to achieve greater therapeutic efficacy. Works of literatures like '*Sarangadar Samhita*' reviews the enhanced therapeutic efficacy of polyherbal formulations synergistically wherein the idea of the multiplicity of factors and complications are the root causes of diseases in most of the cases and so the applicability of a poly herbal formulation with distinct properties will have a significant impact on uprooting the pathological changes¹⁴.

The clinical study presented in this article evaluates the clinical efficacy of a poly herbal formulation '*Rajasree Avaleha*' (RA) in women suffering from different sorts of menstrual morbidities like dysmenorrhea, oligomenorrhea, menorrhagia, leucorrhea, etc. Several Ayurveda formulations have proved to be effective in treating such illnesses and RA being a poly herbal Ayurvedic formulation with an empirical and traditional background, practically followed by an ethno population with a semisolid (avaleha) consistency of classically used Ayurvedic drugs, possesses the qualities like *Pitta Samana*, *Kaphahara*, *RaktaPrasada*, *Sitavirya*, anti-inflammatory, anti-septic, antimicrobial, anti-fungal properties and even capable of arresting the bleeding pathologies.

Aim and Objectives:

To evaluate the clinical efficacy *Rajasree Avaleha* (RA) in menstrual morbidities.

To discuss, evaluate and develop a poly herbal formulation RA capable of treating diverse conditions of menstrual morbidities like dysmenorrhea, oligomenorrhea, menorrhagia and leucorrhea.

MATERIALS AND METHODS:

In a prospective multicentred study, an open clinical trial was done for a period of 3 months with 30 patients age range between 15-40 years diagnosed with different sorts of menstrual morbidities like dysmenorrhea, menorrhagia, oligomenorrhea and leucorrhea were selected. The selection was based on screening criteria and subjects were enrolled from 'Karayil Center for Ayurveda Therapies' and from jeevaneeyam Ayurveda Research Center, Ernakulam for the study. A project specific code was given to the participants and this was used for further data analysis. The assessment was done towards the end of the trial period.

Written informed consent was sought from every participant before inclusion in the study. The open clinical trial was also approved by an independent ethical committee. During the enrolment procedure, the general physical and systemic examination of the patient was carried out in a specially designed and validated Proforma for the clinical trial.

INCLUSION CRITERIA:

- Women between the age group 15-40 years
- Women with heavy and prolonged bleeding, scanty bleeding and having vaginal discharge
- Patients with an open consent willing to undergo treatment

EXCLUSION CRITERIA:

- Complicated cases of menstrual morbidities with other serious systemic ailments
- Women with diabetes mellitus and those who are contraindicated for Avaleha kalpana
- Women undergoing hormonal therapy

The selected groups of patients were given 10 grams of RA thrice daily for a period of three months. The poly herbal formulation was prepared and each 100 mg contains

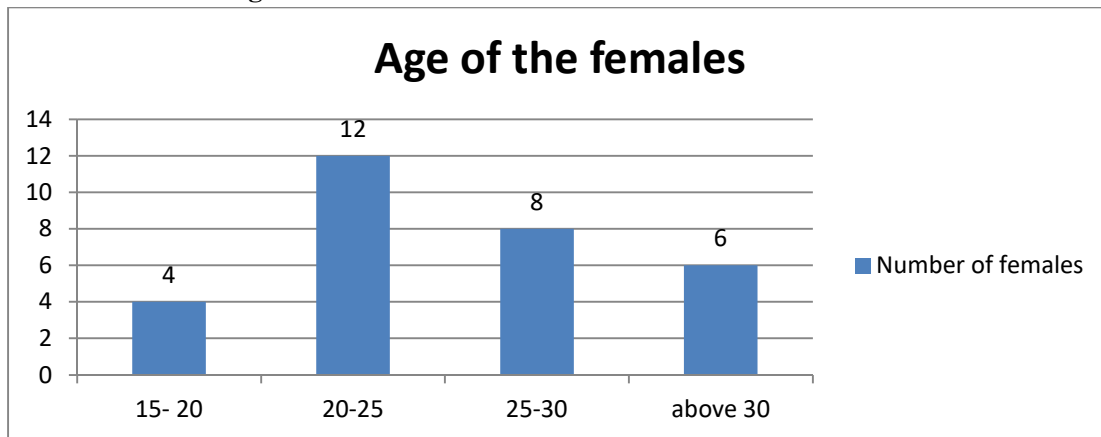
Table 1:

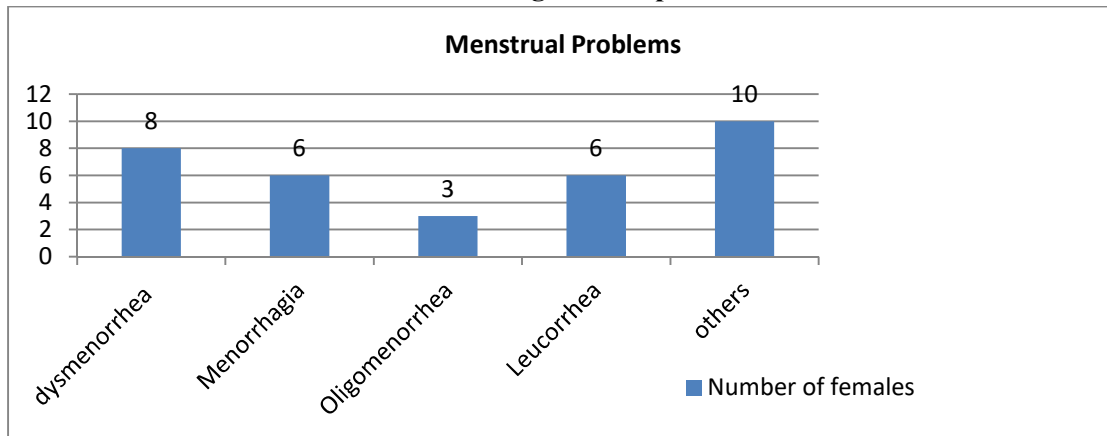
No	Sanskrit name	Scientific name	Amount in 100 gms
1	Kadali	Musa acuminata	4gm
2	Vari	Asparagus racemosus	3gm
3	Thavakshiri	Maranta arundinacea	3 gm
4	Aswagandha	Withania somnifera	3 gm
5	Eala	Elettaria cardamomum	0.5 gm
6	Devapushpam	Eugenia caryophyllata	0.5 gm
7	Kesara	Crocus sativus	0.5 gm
8	Ajaali	Lepidium sativum	0.5 gm
9	Dhatri	Embllica officinalis	0.5 gm
10	Nagara	Zingibe rofficinale	0.5 gm
11	Mustha	Cyperusrotundus	0.5 gm
12	Methi	Trigonella foenum	0.5 gm
13	Dhanyaka	Coriandrum sativum	0.5 gm
14	Ajamoda	Trachysper mumammi	0.5 gm
15	Vidanga	Embeli aribes	0.5 gm
16	Krishnajeeraka	Carum carvi	0.5 gm
17	Maricha	Piper nigrum	0.5 gm
18	Sadi	Kaempfera galangal	0.5 gm
19	Ghrita	Purified butter	4 gm
20	Madhu	Honey	6 gm
21	Guda	Jaggery	70 gm

Statistical analysis of the pre-treatment and post-treatment variables has been recorded and the mean score was charted out with relief percentage.

OBSERVATIONS

Age wise distribution of the females who received RA



Menstrual irregularities presented**RESULTS:**

Effect of RA in dysmenorrhea

	Mean Score	n	SD	SEM	t	p
BT	0.533	30	0.702	0.128	2.340	0.01
AT	0.233	30				

RA has significantly reduced the symptoms of dysmenorrhea in the selected population.

Effect of RA in menorrhagia

	Mean Score	n	SD	SEM	t	p
BT	0.433	30	0.850	0.155	2.362	0.01
AT	0.066	30				

RA has significantly reduced the symptoms of menorrhagia in the studied population.

Effect of RA in oligomenorrhea

	Mean Score	n	SD	SEM	t	p
BT	0.066	30	0.182	0.033	1.0	0.15
AT	0.033	30				

RA couldn't produce any significant changes in oligomenorrhea in the studied population.

Effect of RA in leucorrhoea

	Mean Score	n	SD	SEM	t	p
BT	0.400	30	0.711	0.129	2.56	0.005
AT	0.066	30				

RA has significantly reduced the symptoms of leucorrhoea in the studied population.

The mean score after the treatment in individual cases were analysed and the resultant SD, SEM value, and 't' value was capitulated to obtain respective 'P' values after 3 months of clinical trial therapy. Thus in the trial study population, RA was found to be significantly effective in dysmenorrhea (P 0.01), menorrhagia (P 0.01), and leucorrhoea (P 0.005). However the statistical significance of RA in oligomenorrhea (P 0.15) was not found to be effective. The trial duration was limited to a study of single follow up after the treatment. The variations like improvements or worsening on their symptoms were assessed and recorded. The trial protocol period has also

ensured the exclusion of any sorts of concomitant treatment. After 3 months of protocol period, 30 patients have successfully completed the therapeutic criteria's and assessment schedules without any dropouts.

DISCUSSION

According to the clinical trial findings, the women around the age group 20-25 years were more, when compared to other age groups who were subjected for the study. From the study, it was noted that number of subjects suffering from dysmenorrhea symptoms were 26.6% and 20% of women had complaints on menorrhagia and leucorrhoea

while 10% of the study population complained about oligomenorrhea. Now considering the effect of RA in menstrual morbidities, the mean score before and after the treatment in dysmenorrhea capitulated a standard deviation of 0.702 with a SEM value of 0.128 and brought significant results in subjective parameters of the studied population (P 0.01). The probable reason to this outcome could be the effect of the drugs possessing *vatanulomana* and *raktaprasadaka* nature that shows an invariable relation in reducing the dysmenorrheal symptoms. The RA treatment in menorrhagia and leucorrhea yielded a standard deviation of 0.850 and 0.711 respectively with negligible SEM values contributing significantly in reducing the symptoms (P 0.01 and P 0.005 respectively) in both conditions. In leucorrhea, caused due to *kapha pitta dushti*, most of the *pitta samana* drugs and *kaphasamana* drugs like *ela*, *methi*, *ajamoda*, *vidanga* might have taken its role in reducing the symptoms. Similarly in menorrhagia like conditions drugs like *kadali*, *twakshiri* and *satavari*, significantly having *pitta samana* and *raktaprasada* nature that are capable of arresting *paittika* conditions whereas the results were highly contradicting in subjects who had oligomenorrhea. The mean score before and after treatment in oligomenorrhea yielded a standard deviation of 0.182 with an SEM value of 0.033 (P 0.15), adding to the adverse effect of RA in treating oligomenorrhea and since majority of drugs in RA were having *sita* property contradicting to the *rajapravartaka* action it is found to be one of the probable reason.

The strength of this study itself is a multicentred, prospective open clinical trial. Taken into consideration the limitations, the data collected on the nature and characteristics of subjective menstrual complaints, were retrospectively judged. The results of the study also point towards the fact that the existing differences between different ethno populations may also have a significant influence towards the better interpretation of the findings.

CONCLUSION

In a multicentred open clinical trial, Rajasree Avaleha was found to be effective in treating menstrual morbidities like dysmenorrhea, menorrhagia and leucorrhea whereas it was found to be less significant in oligomenorrhea. Hence for treating diverse gynecological condition this poly herbal formulation was found to be very significant.

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