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EFFICACY AND SAFETY OF "SACHI SAHELI" POLYHERBAL FORMULATIONS IN GYNAECOLOGICAL DISORDERS: A PROSPECTIVE, NON-RANDOMISED, OPEN-LABEL STUDY

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ABSTRACT

Background and aim: Symptoms of gynaecological disorders, including dysmenorrhea, leukorrhea, and premenopausal syndrome (PMS), are a common health concern, particularly among women of reproductive age. Due to the adverse effects of conventional treatments, the use of herbal remedies to treat various gynaecological disorders has increased. This study aimed to assess the efficacy and safety of Sachi Saheli formulations in subjects suffering from dysmenorrhea, leucorrhoea, and PMS. Methods: This was a single-arm, open-label, non-randomised prospective study. Female participants were recruited based on the inclusion and exclusion criteria. Study interventions were given to all participants for 90 days. Changes in blood haemoglobin levels were assessed from the baseline to the end of the study. Subjective symptoms and the investigators' severity assessment on 27 questionnaires were evaluated at baseline and the end of the study. Safety was also assessed by measuring liver and kidney function's haematological and biochemical markers. Results: A total of 120 female subjects were enrolled. After treatment with Sachi Saheli syrup and tablets, blood haemoglobin levels increased significantly compared to baseline ($p < 0.0001$). All subjects showed significant improvement in anxiety, menstrual pain, depression, and vaginal discharge symptoms. A significant improvement in the severity of physical and affective symptoms across 27 parameters was also observed. There were no significant changes observed in laboratory safety parameters. None of the subjects reported any adverse events during the treatment period. Conclusions: Sachi Saheli syrup and tablet may improve the symptoms of dysmenorrhea, leukorrhea and PMS.

Keywords: Sachi Saheli, Dysmenorrhea, Irregular Period, Anaemia, Clinical Trial

INTRODUCTION

Primary dysmenorrhea (PD) is a generalised gynaecological disorder in reproductive women characterised by stomach or pelvic pain and discomfort before or during menstruation in the absence of other pelvic pathologies.[1] PD affects 45–95% of women of reproductive age, with 10–18% experiencing severe dysmenorrhea.[2,3] The most common symptoms of PD are pain or cramps in the lower abdomen, which back pain, leg pain, muscle cramps, fatigue, dizziness, headaches, nausea, diarrhoea, chills, and vomiting may accompany.[4,5] The aetiology of PD is associated with an abnormal increase in prostaglandin (PG) secretion, particularly PGE2 during menstruation, which is synthesised from arachidonic acid via the cyclooxygenase (COX) pathway.[6] Nonsteroidal anti-inflammatory drugs (NSAIDs) or contraceptives are frequently used to treat PD.[7,8] However, these treatments are known to have several adverse effects.[8,9]

Leukorrhea or vaginal discharge is also a common problem in females and is characterised by a whitish, yellowish, or greenish vaginal discharge.[10] The causes of leucorrhoea include oestrogen imbalance, malnutrition, unhygienic conditions, atrophic vaginitis, malignancy, vulval dermatitis, infections such as bacterial vaginosis and vulvovaginal candidiasis, and sexually transmitted infections (*Chlamydia trachomatis*, *Neisseria gonorrhoeae*, and *Trichomonas vaginalis*).[11] The common symptoms of leucorrhoea include vaginal discharge associated with abdominal pain, backache, vulval itching, and loss of appetite.[12] Depending on its cause, corticosteroids and antibiotics such as nystatin, gentamicin, metronidazole, and povidone are most commonly prescribed.[13]

Another prevalent condition in women of reproductive age is premenstrual syndrome (PMS). PSM is a set of physical, behavioural, and emotional signs and symptoms in the last week of the luteal phase.[14] PMS symptoms include irritability, mood swings, anxiety, depression, abdominal cramps, breast tenderness, headaches, generalised pain, abdominal bloating, and appetite changes.[14,15] Abnormal functions or productions of steroidal hormones (progesterone, allopregnanolone, and estrogen) and central neurotransmitters (serotonin, gamma-aminobutyric acid, glutamate, and beta-endorphins) are the primary causes of PMS.[16,17] Many traditional therapies for PMS are commonly prescribed, including selective serotonin reuptake inhibitors (SSRIs), progesterone, oral contraceptives, and gonadotropin-releasing hormone (GnRH) agonists.[18]

Despite the availability of several pharmacotherapies for dysmenorrhea, leucorrhoea, and PMS, these are also associated with numerous adverse effects. Therefore, there is an urgent need for alternative treatments or therapies that can be effective and safe for clinical uses against such gynaecological disorders. Recently, there has been an increase in the use of herbal medicines. However, all herbal medicines are not free from adverse effects, and their self-administration and unrecognisable side effects are increasing.[19] In light of these facts, traditional Indian medicines, particularly Ayurvedic medicines, have been used since ancient times and are considered safe and effective by

Ayurvedic practitioners based on clinical experience. However, confidence in the treatment is primarily based on practice that has not been scientifically evaluated. Many medicinal plants have been used in ayurvedic formulations to treat gynaecological disorders such as leukorrhea, menorrhagia, dysmenorrhea, amenorrhea, painful menstruation, excessive menstrual flow, and others.[20] These plants are expected to improve the quality of life of patients with gynaecological complaints. Therefore, the current study sought to evaluate the efficacy and safety of Sachi Saheli syrup and tablets in improving the gynaecological symptoms associated with dysmenorrhea, leukorrhea, and PMS.

MATERIALS AND METHODS

Trial Design

This was a prospective, single-arm, non-randomised, open-label study in 120 female subjects with dysmenorrhea, leukorrhea and PMS. Considering the prevalence of these disorders and the adverse effects of NSAIDs and steroidal drugs, we evaluated the efficacy and safety of "Sachi Saheli" syrup and tablets. The 90-day study consisted of 3 site visits and a telephone follow-up visit. The study was conducted at the SARV Advanced Multispeciality Clinic and Diagnostic Centre (Bangalore, India) between July 2021 and December 2021 in strict conformity with the Declaration of Helsinki, ICMR ethical standards for biomedical research, and ICH recommendations for good clinical practise (GCP). The independent medical ethical committee of the institution approved the study protocol (Protocol No.: SBS/DIV/003/2021) and was prospectively registered with the Clinical Trials Registry-India (ID: CTRI/2021/07/034539) dated July 2, 2021. The study's purpose and procedure were explained to all the participants. At the screening visit, signed informed consent was collected from all participants, and participants were evaluated for eligibility based on inclusion and exclusion criteria. At the outset, all subjects were given a Sachi Saheli syrup and tablet and told to take 10 ml syrup and one tablet twice daily after meals, preferably in the morning and at night. On day 45, a telephone follow-up was made to monitor the subject's general well-being, concomitant medications, and adverse effects. At the end of the study period (day 90), a final assessment of the subjects was made.

Participants and selection criteria

Potential subjects were recruited through the outpatient department at SARV Advanced Multispeciality Clinic and Diagnostic Centre. No statistical consideration has been made for selecting the subject size. Based on the eligibility criteria, 120 subjects were recruited in this study voluntarily.

Patient inclusion criteria include female subjects aged between 13-45 years who voluntarily sign a consent form; subjects with primary dysmenorrhea and/or leukorrhea, loss of appetite, anaemia, general weakness and irregular menstrual cycle and an individual who was self-motivated and willing to participate in this study were included. Pregnant and breast-feeding women, subjects who had undergone any surgery, taken part in any clinical trial in the last three months, and subjects who refused to sign the informed consent form were excluded from the study.

Intervention

Sachi Saheli syrup and tablet are polyherbal formulations of various medicinal plants of Ayurvedic origin. Sachi Saheli Syrup is an aqua-based liquid oral formulation of 50 Ayurvedic herbs, while the Sachi Saheli Tablet comprises 17 Ayurvedic herbs. Both products are marketed in India for treating dysmenorrhea, leukorrhea, PMS and other gynaecological symptoms.

Primary Outcome Measures

The study's primary outcomes were to assess the change in blood haemoglobin levels and subjective symptoms on a self-rating scale questionnaire on anxiety, depression, vaginal discharge, and pain at the start and end of the study. The following anxiety levels were assigned to subjects: 0 means no symptoms; 1-2 means slight fear and worry; 3-4 means mild fear and worry; 5 means moderate worry and physical agitation; 6-7 means strong agitation and pacing; and 8-10 means out of control behaviour, hitting, and rhyming voices. The depression rating scale and the ZUNG self-rating depression scale questionnaire were used to determine the level of depression. On a depression rating scale, subjects were rated according to their depression levels as follows: 0: no symptoms; 1-2: a minorly depressed mood; 3-4: slightly stronger depression; 5: a definite malaise and insomnia; 6-7: feeling bad, at the edge; and 8-10: deeper, suicidal feelings. The Zung Self-Rating Depression Scale (SDS) contains 20 items, each rated on a 4-point scale. The total scale score ranges from 20 to 80 points, and the depression severity is classified on SDS scores as 25–49: no depression, 50–59: mild to moderate depression, 60–69: moderate to severe depression, and above 70: severe depression.[21] The vaginal discharge symptom was evaluated by the mean change in the number of days subjects had experienced vaginal discharge from baseline to the end of the study. The visual analogue scale (VAS) was used to measure the intensity of menstrual pain. VAS is represented by a straight line, with the left endpoint being the minimum pain score of zero and the right endpoint being the maximum pain score of 10. The pain score was used to classify pain severity by scoring no pain as 0, mild pain as 1–3, moderate pain as 4–7, and severe pain as 8–10. The severity of PMS symptoms was also assessed by asking participants in an investigator assessment questionnaire if they experienced any of 27 different symptoms before or after their menstrual period and the severity of each symptom. The severity of each symptom was individually scored from 1–4 (none = 1, mild = 2, moderate = 3, severe = 4) and summed across symptoms to derive sub-scores for affective symptoms (n = 6 symptoms; the range of possible scores = 6–24), physical symptoms (n = 21 symptoms; the range of possible scores = 21–84), and a total symptom score (range of possible scores = 27–108).

Secondary Outcome Measures

The secondary outcomes of this study were the evaluation of laboratory safety parameters assessed at the baseline and the final visits. The laboratory safety parameters included the complete blood count (CBC), erythrocyte sedimentation rate (ESR), and serum levels of creatinine and alanine transaminase (ALT). The incidence of adverse events was also examined at the end of the study as part of the safety study.

Statistical Analysis

SSPS software was used for statistical analysis. A descriptive statistic was used for the continuous variable, and the data were provided as means, standard deviations, numbers, and percentages. A sample t-test was used to compare differences in subjective symptom scores and investigator evaluation scores at two assessment points. The significance value was set at $P \leq 0.05$.

RESULTS

Demographic and Baseline Data

A total of 124 women were screened, of whom 120 completed the study. During the study, four individuals withdrew their consent. The participants' average age was 28.58 ± 7.37 years. At the baseline visit, most patients had lower abdominal pain with other symptoms such as anxiety, depression, vaginal discharge, abdominal cramp, menstrual backache, weakness, fatigue, forgetfulness, etc.

Primary Outcomes

Blood Haemoglobin (Hb) Level

Blood haemoglobin levels were measured at the start and end of the study. After 90 days of treatment with Sachi Saheli syrup and tablet, the mean Hb level increased to 12.43 ± 1.001 compared to day 0 (11.97 ± 1.62) with a mean difference of -0.4588; 95% CI -0.6614 to -0.2563; and a p-value < 0.0001.

Subjective Symptom Scores

Subjective symptom scores on the levels of anxiety, depression, menstrual pain, and the duration of vaginal discharge were assessed before and after treatment. After 90 days of treatment, the means of anxiety, depression, vaginal discharge, menstrual pain, and SDS scores were statistically significantly ($p < 0.0001$) lower than on day 0 (Table 1).

Table 1: Subjective symptom severity before and after treatment

Symptoms	Symptom score, n = 120 (mean ± SD)		Mean diff.	95% CI	P-value
	Day 0	Day 90			
Anxiety	4.55 ± 2.13	1.82 ± 1.29	2.73	2.510 - 2.957	< 0.0001
Depression	3.98 ± 1.88	1.23 ± 1.04	2.74	2.488 - 2.996	< 0.0001
Vaginal discharge	5.98 ± 7.80	3.30 ± 2.76	2.67	1.613 - 3.737	< 0.0001
Pain	6.05 ± 1.66	3.08 ± 1.28	2.97	2.751 - 3.183	< 0.0001
SDS	61.41 ± 7.37	23.69 ± 3.31	37.72	36.39 - 39.05	< 0.0001

Table 2: Frequency and severity of PMS symptoms of all study participants (n = 120)

Symptoms	Frequency n (%)		Symptom score (mean ± SD)		Mean diff.	95% CI	P-value
	Day 0	Day 90	Day 0	Day 90			
Physical Symptoms							
Abdominal bloating	96 (80.0)	61 (50.83)	1.27 ± 0.91	0.65 ± 0.72	1.08	0.986 to 1.172	< 0.0001
Abdominal cramp	120 (100.0)	100 (83.33)	2.09 ± 0.65	1.12 ± 0.66	0.98	0.857 to 1.108	< 0.0001
Menstrual backache	102 (85.0)	77 (64.17)	1.68 ± 1.01	0.75 ± 0.64	0.94	0.782 to 1.095	< 0.0001
Acne	77 (64.17)	24 (20.0)	0.85 ± 0.77	0.20 ± 0.40	0.64	0.486 to 0.795	< 0.0001
Weakness	116 (96.67)	78 (65.0)	2.45 ± 0.71	0.75 ± 0.63	1.70	1.564 to 1.836	< 0.0001
Breast tenderness	109 (90.83)	70 (58.33)	1.41 ± 0.73	0.72 ± 0.69	0.69	0.564 to 0.820	< 0.0001
Confusion	113 (94.17)	75 (62.50)	1.86 ± 0.96	0.69 ± 0.59	0.69	0.553 to 0.830	< 0.0001
Diarrhoea	30 (25.0)	17 (14.170	0.53 ± 1.0	0.14 ± 0.35	0.39	0.256 to 0.527	< 0.0001
Constipation	64 (53.33)	49 (40.83)	1.30 ± 1.31	0.42 ± 0.51	0.88	0.717 to 1.049	< 0.0001
Dizziness	45 (37.50)	32 (26.67)	0.57 ± 0.80	0.28 ± 0.47	0.29	0.186 to 0.398	< 0.0001
Fatigue	118 (98.33)	78 (65.0)	2.49 ± 0.66	0.75 ± 0.63	1.74	1.608 to 1.875	< 0.0001
Weight gain	102 (85.0)	82 (68.33)	1.34 ± 0.85	0.58 ± 0.62	0.77	0.650 to 0.883	< 0.0001
Forgetfulness	115 (95.83)	72 (60,0)	1.53 ± 0.69	0.73 ± 0.69	0.81	0.682 to 0.935	< 0.0001
Headache	94 (78.33)	89 (74.17)	1.86 ± 1.12	0.88 ± 0.62	0.98	0.857 to 1.110	< 0.0001
Oily skin	82 (68.33)	44 (36.67)	1.03 ± 0.84	0.38 ± 0.52	0.65	0.526 to 0.775	< 0.0001
Hives	37 (30.83)	6 (5.0)	0.33 ± 0.50	0.05 ± 0.22	0.28	0.194 to 0.356	< 0.0001
Increased appetite	107 (89.17)	55 (45.83)	1.33 ± 0.87	0.48 ± 0.55	0.84	0.697 to 0.986	< 0.0001
Insomnia	92 (76.67)	44 (36.67)	1.45 ± 1.04	0.43 ± 0.62	1.02	0.870 to 1.163	< 0.0001
Nausea	68 (56.67)	35 (29.17)	0.60 ± 0.56	0.29 ± 0.45	0.32	0.220 to 0.413	< 0.0001
Palpitations	100 (83.33)	78 (65.0)	1.87 ± 0.67	0.78 ± 0.66	1.08	0.994 to 1.173	< 0.0001
Swelling extremities	108 (90.0)	65 (54.17)	1.70 ± 0.93	0.64 ± 0.66	1.06	0.925 to 1.192	< 0.0001
Total physical score (sum of symptoms)			29.06 ± 4.69	11.69 ± 2.98	17.37	16.66 to 18.07	< 0.0001
Affective Symptoms							
Anxiety	120 (100)	78 (65.0)	1.87 ± 0.67	0.78 ± 0.66	1.08	0.994 to 1.173	< 0.0001
Nervousness	80 (66.67)	44 (36.67)	1.21 ± 0.96	0.43 ± 0.60	0.74	0.621 to 0.862	< 0.0001
Depression	113 (94.17)	56 (46.67)	1.83 ± 0.71	0.60 ± 0.71	1.23	1.108 to 1.359	< 0.0001
Irritability	113 (94.17)	87 (72.50)	1.94 ± 0.89	0.97 ± 0.72	0.98	0.866 to 1.084	< 0.0001
Mood swings	107 (89.17)	74 (61.67)	1.74 ± 0.96	0.77 ± 0.69	0.98	0.857 to 1.093	< 0.0001
Tendency to cry easily	116 (96.67)	49 (40.83)	2.08 ± 0.95	0.50 ± 0.66	1.58	1.422 to 1.745	< 0.0001
Total effective score (sum of symptoms)			10.63 ± 3.93	4.04 ± 2.85	6.59	6.161 to 7.022	< 0.0001
Total symptom score (sum of all symptoms)			39.69 ± 7.11	15.73 ± 4.58	23.96	23.05 to 24.87	< 0.0001
Point values are assigned to each symptom where none = 1; mild = 2; moderate = 3; severe = 4. Participants report symptoms during menstruation as being experienced in numbers and percentages. PMS symptom severity scores were expressed as mean ± SD before and after treatment.							

Table 3: Haematological, liver and kidney function parameters before and after treatment

Parameter	Day 0 (mean ± SD)	Day 90 (mean ± SD)	P-value
Total leukocytes (× 10^9/L)	88.33 ± 26.05	83.76 ± 14.39	0.02*
Neutrophils (%)	58.08 ± 9.04	56.77 ± 8.45	0.11
Lymphocytes (%)	33.75 ± 8.61	33.28 ± 7.29	0.55
Eosinophils (%)	3.22 ± 2.16	4.22 ± 2.05	< 0.0001***
Monocytes (%)	4.73 ± 1.97	5.52 ± 1.95	< 0.0001***
Basophils (%)	0.22 ± 0.42	0.29 ± 0.52	0.12
RBC (x 10*12/L)	4.47 ± 0.51	4.49 ± 0.40	0.62
Platelet (lakh)	2.81 ± 0.80	2.80 ± 0.52	0.90
ESR (mm/hr)	15.40 ± 8.90	14.46 ± 4.10	0.16
Creatinine (mg/dL)	0.75 ± 0.15	0.82 ± 0.16	< 0.0001***
ALT (U/L)	22.07 ± 12.53	20.64 ± 7.63	0.09

Investigator's PD symptoms assessment

The investigator's PMS symptom frequencies and severities are presented in Table 2. More than 90% of participants reported mild to moderate symptoms, including abdominal cramps (100.0%), weakness (96.67%), breast tenderness (90.83%), confusion (94.17%), fatigue (98.33%), forgetfulness (95.83%), swelling extremities (90.0%), anxiety (100.0%), depression (94.17%), irritability (94.17%), and a tendency to cry easily (96.67%). All 27 physical and affective symptoms among the participants had mild to moderate severity scores at the baseline (day 0). After 90 days of treatment, all physical and affective symptom scores were statistically significantly reduced ($p < 0.0001$). The total physical symptom and affective symptom scores were significantly reduced from 29.06 ± 4.69 to 11.69 ± 2.98 ($p < 0.0001$) and 10.63 ± 3.93 to 4.04 ± 2.85 ($p < 0.0001$), respectively. The overall PMS symptom score was also significantly ($p < 0.0001$) reduced from 39.69 ± 7.11 to 15.73 ± 4.58.

Secondary Outcomes

At the beginning and end of the study, haematological parameters and biochemical markers of liver and kidney function were assessed. Table 3 displays the results of the haematological parameters and liver and kidney function test biomarkers. No significant changes were observed in the studied parameters, and all parameters were within the normal range. None of the subjects reported any study drug-related adverse events.

DISCUSSION

Herbal products are often used as an alternative therapy for various gynaecological disorders such as premenstrual syndrome and dysmenorrhea because of the serious adverse effects of modern pharmacotherapies.[22] However, there is no consistent evidence regarding the safety and efficacy of herbal products. Hence, the safety and efficacy of herbal products need to be evaluated through pre-clinical and clinical studies. Several factors, such as hormonal imbalances, malnutrition, stress, incorrect lifestyles, the use of contraceptives, and genetics, cause gynaecological problems.[23] In the classical texts of Ayurveda, several formulations or plants have been described for the management of different kinds of gynaecological disorders.[24]

This study evaluated a combination therapy of Sachi Saheli syrup and tablet, proprietary polyherbal formulations containing various medicinal plants of ayurvedic origin, for its effectiveness in treating gynaecological disorders, particularly dysmenorrhea, leukorrhea, PMS and other gynaecological symptoms. This study showed that this combination therapy of Sachi Saheli syrup and tablet significantly ($p<0.0001$) increased blood haemoglobin levels compared to the baseline. In addition, subjective symptom scores on menstrual pain, anxiety, depression, and duration of vaginal discharge were also reduced after 90 days of treatment. Besides, the results showed a significant ($p<0.0001$) reduction in the severity of 27 physical and affective PMS symptoms and the overall PMS score. No adverse events were observed among the participants during the treatment period. Although the precise underlying mechanism of action was known, extensive pharmacological research has revealed that these plants exhibit antidepressant, anti-oxytocic, anxiolytic, sedative, GABA receptor antagonist, immunoregulatory, uterine stimulant and relaxant, antioxidant, anti-inflammatory, and analgesic properties.[20,25] Therefore, it can be hypothesised that the ingredients of Sachi Saheli syrup and tablet act by regulating multidirectional pathways of the endocrine, nervous, and immune systems.

CONCLUSION

Taken together, the results of this study demonstrated that the combined intake of Sachi Saheli syrup and tablet is a productive and safe alternative treatment for reducing the severity of physical as well as psychologic symptoms of various gynaecological disorders, particularly anaemia, dysmenorrhea, leukorrhea and PMS. It was also found to be safe for human consumption.

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