

Clinical Evaluation of Sahasraveeryadi Granules on General and Reproductive Health of Females

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Abstract

Within the framework of WHO definition of health as a state of complete physical, mental and social well-being & not merely the absence of disease or infirmity. Reproductive health addresses reproductive processes, functions and system at all stages of life. The reproductive axis is closely linked to nutritional status especially under nutrition in females. Women life is associated with drastic physiological, anatomical & psychological changes during menarche, reproductive period, menopause and post menopause. Deficient food intake, inadequate alimentary regimens, strong dietary restrictions and a general lack of nutrients result in loss of both body weight and physical performance as well as delayed puberty, lengthening of postpartum interval to conception, lower gonadotropin secretion level with alteration of physiological ovarian cyclicity, increase infertility and can worsen the effect of menopausal syndrome. Sahasraveeryadi Granules work as general nutritive tonic for females. The entire reproductive period of females when divided into two gives a first half with better reproductive potential and a second half where reproductive system functions to help women in leading a healthy personal and family life by providing proper hormonal support. The HPO axis is base of normal reproductive function.

Objectives: To evaluate the efficacy of Sahasraveeryadi Granules in improving the general and reproductive health of females and providing a conventional health drink for females.

Conclusion: drug gives optimistic results on these patients. The BMI of all patients increase with moderate to complete relief in all gynaecological symptoms caused because of nutritional deficiency. During study it was observed that there were no side effects of drug and most of the patients feel happy, relaxed and energetic with improvement in their functional capacity which gave an add on boost to the study. The drug is giving very promising result in a competitive market to conventional health drink.

Keywords: Reproductive; Health; Conventional

Introduction

The continuum of an individual life can be divided into several life stages each characterised by certain features. Having knowledge of framework of life stages can bring deeper empathic understanding. Accompanied by considerable hormonal changes the life stages of women are generally divided into infancy, puberty, reproductive age, climacteric period and elderly. Health status in a particular stage then influences the next stage. It is important to pay attention to psychological aspects of women's health and reflect such understanding in clinical practice. Within the framework of WHO definition of health as a state of complete physical, mental and social well-being & not merely the absence of disease or infirmity. Reproductive health addresses reproductive processes, functions and system at all stages of life [1]. The reproductive axis is closely linked to nutritional status especially under nutrition in females. food intake, inadequate alimentary regimens, strong dietary restrictions and a general lack of nutrients result in loss of both body weight and physical performance as well as delayed puberty, lengthening of postpartum interval to conception, lower gonadotropin secretion level with alteration of physiological ovarian cyclicity, increase infertility and can worsen the effect of menopausal syndrome [2].

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Various Life Stages

Puberty /adolescence: The first half of this period may specifically

be called puberty and second half adolescence [3]. One's sense of values developed during this stage. When a girl changes into women, her nutritional need changes to support growth and development [4]. Approx. 1-5% of women suffer from weight related amenorrhea because many girls with delayed puberty are relatively thin during adolescence it has been suggested that a certain critical body weight is required for onset of cyclical ovarian activity.¹

Reproductive age: From late teens to perimenopause in late 40s is a period of sexual maturity also called reproductive age. In this maturation period the psychological changes unique to women are menstruation related disorders and uterine or ovarian diseases [5]. Nutritional needs undergo enormous shift when a woman is in reproductive age to improve quality of their life and to increase survival & healthy development of their child. Menstrual periods often cease after a 10-15% decrease in normal body weight. Menstruation becomes irregular when BMI <19 Kg/m².

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Menopausal age: During this age women tends to loss bone strength, connective tissues, muscle mass & generalised body strength, so they need nutritional support [6]. Up to 100% of circulating oestrogen comes from fat in post- menopausal women (Figure 1).

Posology

Drug Name : Sahasraveeryadi Granules

Constituents : Ashwagandha, Shatavari, Bala, Lodhra For the purpose of

For the purpose of granulation sita was taken

Dosage : 6 gm – 12 gm depending on Bala, desh, kala, prakriti, aging of Patient

Aushadh Sewana Kala : Antrabhakta and Nishakala.

Anupana of drug : Gau dugdh

Route of administration: Orally

Duration of trial : 3 months

Follow up : 15 days

Collection of Data

Patient suffering from general debility and ill reproductive health attending OPD & IPD of Prasuti Tantra & Stree Roga Department of Government Ayurveda College & Hospital, Varanasi will be selected randomly for this clinical study.

The patient will also be selected from special camps organised time to time by PTSR Department.

Material and Methods

Materials

Drug was prepared in the pharmacy of Govt. Ayurveda College & Hospital Varanasi with the help of Ras Shastra Dept.

Selection of cases

The pilot study included twenty female patients with the complaints of generalised weakness, reduced weight and associated gynaecological

symptoms coming under inclusion criteria from the O.P.D, Dept. of prasuti tantra and strirog, Government Ayurveda PG College and hospital, Varanasi [7]. Total 20 patients of three age groups (adolescent, reproductive and menopausal age group) were taken randomly for the study and effect of the drug was evaluated on them. Duration of trial was approx. 3 months.

Study Design

Pilot study was done on 20 patients. It was a single arm prospective study done on three age groups of females (adolescents, reproductive, menopausal) selected randomly.

Advices

Patients will be advised some life style modifications: -

Having a healthier, wholesome, fresh, warm & balanced diet.

Sound sleep for 7-8 hours.

Avoid alcohol, smoking and caffeine.

Set aside time for activities that makes you happy.

Yoganasanas to improve digestion like Paschimottanasana, Balasana, and Pavanmuktasana etc.

Follow up

Treatment is continued for a period of 3 months. The patient will come for follow up on every 15th day up to 90 days.

Inclusion Criteria

- Patients willing & able to participate in study.
- Female patients of 10-55 years age group.
- Patients whose BMI is from 16.0 to 19.0 kg/m².
- Patients suffering from mild to moderate nutritional deficiency.
- Patient suffering from any kind of menstrual abnormalities and vaginal discharges because of general debility.
- Patient with peri-menopausal and post-menopausal symptoms.

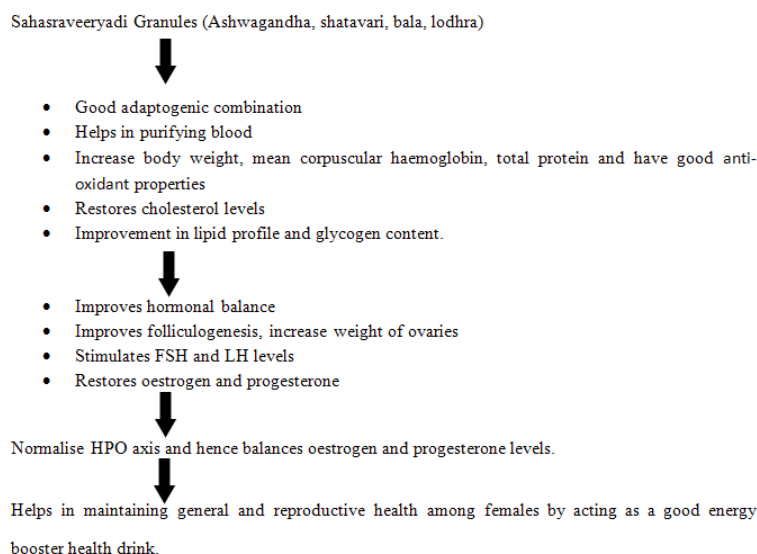


Figure 1: Effect of Sahasraveeryadi Granules on Females.

- Patient with delayed menarche and secondary sexual characters.

Exclusion Criteria

- Patient not willing & not able to participate in study.
- Female patients <10 years & >55 years of age.
- Severe acute malnutrition (SAM).
- Patients having BMI <16.0 Kg/m² & >19.0 Kg/m².
- High clinical suspicion of acute & chronic disease like TB, HTN, DM etc.
- Patient suffering from structural abnormalities, systemic, endocrinal, metabolic, chromosomal disorders and any abnormal growth.
- Pregnant and lactating females.

Informed Consent

The purpose of the study, nature of study and potential risks and benefits were explained in non-technical terms. There after their written consent was taken before starting the procedure.

Drug formulation

Churna kalpana of ashwagandha mula, shatavari mula, lodhra twaka and bala panchang were taken in equal quantity. Decoction of these four drugs according to classics was made and sita (mishri)1/3 of total drug) was added in it [8]. Then churna prepared was well mixed with this decoction and granulation of drug was done.

Investigations

1. Haematological Studies- CBC, BT, CT, ESR.
 2. Serology- VDRL, HBsAg, HCV, HIV1&2
 3. Measure Serum LH, FSH, Prolactin.
 4. CMP test – Comprehensive Metabolic Panel (LFT, KFT, Blood sugar etc.)*
 5. Lipid Panel.
 6. Thyroid Profile.
 7. USG*
 8. Endometrial Biopsy*
 9. Urine Analysis- R/M and (C/S)*
- (* - As needed)

Examination

- General Examination.
- Systemic Examination.

Gynaecological Examination.

Criteria to be followed during study

Subjective criteria

To assess general health of females

Before Treatment

Nutrient intake

- o Adequate
- o Inadequate

After Treatment

Nutrient intake in past 2 weeks

- o Adequate
- o Improved but not adequate
- o No improvement

Before Treatment

Functional capacity

(Assessed by level of Fatigue and progressive loss of function)

- o No dysfunction
- o Reduced capacity

After Treatment

Functional capacity in the past two weeks (Tables 1-3).

- o Improved
- o No change
- o Decrease

Final Assessment

- Cured - >90% relief
- Markedly improved- >75-90%
- Moderately improved- >50-75%
- Mild improvement- >

Case Study

Total 20 patients of three age groups from 10 -55 years were taken for study. All of the females are lean and thin with BMI ranging from 16.0 to 19 kg/m². Also with that they all were suffering from some kind of gynaecological disorder like delayed puberty, menstrual irregularities, scanty menses, white discharge, menopausal symptoms etc (Table 4).

Table 1: Happiness Scale.

Criteria	Yes/No
I feel happy & relaxed	
I feel calm & relaxed	
I feel energetic	
When I woke up I felt refreshed and I had enough rest	
My daily me is full of interesting things	

Table 2: BMI (Weight /height²).

Above 19.0 kg/m ²	0
From 17.5- 18.9 kg/m ²	1
From 16-17.4 kg/m ²	2
Less than 16.0 kg/m ²	3

Table 3: Gynaecological Symptoms.

Relief in symptoms	Grading
No relief	0
Mild relief	1
Moderate relief	2
Complete relief	3

Table 4: Case study on 20 patients of their age groups ranges between 10-55.

S.no	Patient's Age	Symptoms	BMI before treatment	BMI after treatment	Relief
1	22	Generalised weakness, white thin discharge from 2 months, backache	18.2	19.2	Got relief
2	28 years	Generalised weakness, scanty menses from 3 cycles , loss of appetite, incomplete bowel clearance	17.5	18.6	Moderately improved
3	22 years	White thin discharge from 4 months, lower backache, generalised weakness	17.8	19	Got relief
4	12 years	Pain just before and during menses since menarche, generalised weakness	16.9	18	Got relief
5	31 years	Heavy bleeding during menses from 6 months, generalised weakness	16	16.8	Mildly improved
6	26 years	Thick white discharge from 2months, wants to conceive child from 1 year,	17.6	19.2	Moderately improved
7	13 years	Pain during menses since menarche, generalised weakness	18.3	19.4	Got relief
8	15 years	Thick white discharge per vagina from 3 and half months, generalised weakness	18.1	19.6	Markedly improved
9	17 years	White thin discharge per vagina from 1 month associated with pain in lower abdomen, backache, loss of appetite	16.4	18.2	Markedly improved
10	24 years	Absence of menses from 2 months , history of delayed menses, generalised menses	17.4	19	Moderately improved
11	18 years	Menstruation has not start yet, ill developed secondary sexual characters, generalised weakness	16.1	18	Moderately improved
12	48 years	Sleeplessness, lower backache, hot flushes associated with generalised weakness from 1 year	18.2	19.6	Got relief
13	42 years	Irregular menstruation with delayed interval of 40-42 days from 1 years, pain in legs, generalised weakness	16.9	18	Moderately improved
14	16 years	Excessive pain during menses with scanty flow from 6 months, generalised weakness	17.3	19.2	Markedly improved
15	50 years	Hot flushes, sleeplessness, lower backache, generalised weakness from 4 months	18.2	19.4	Moderately improved
16	53 years	Pain in all joints and lower back, generalised weakness from 3 years	18	19.5	Moderately improved
17	35 years	Mood swings associated with anxiety and headache, irregular menses with reduced interval of 21-23 days from 3 months	18.4	19.6	Markedly improved
18	28 years	White thick discharge per vagina from 6 months, loss of appetite, reduced functional capacity	17.2	18.8	Moderately improved
19	21 years	Delayed menstrual cycle with interval of 36-38 days from 2 years, pain during menses White thin discharge per	17.7	19	Moderately improved
20	30 years	vagina from 15 days , pain in lower back, generalised weakness	16.4	18	Markedly relief

Results

- Cured – 25 percent
- Markedly improved – 50 percent
- Moderately improved- 95 percent
- Mild relief - 100 percent

Discussion

The significance of the women health cannot be over emphasized as it is very basic for good family life. Females pay very less attention toward their health and many of them are under nourished. Decreased BMI in females leads to various reproductive health issues like delayed puberty, leucorrhoea, disturbance in menstrual cycles, abnormal uterine bleeding, increased peri menopausal symptoms and reduced pain tolerance etc. Good nutritional supports plays an important role in maintaining the basic reproductive health and increasing functional capacity among females by increasing their weight, providing energy and making them feel more relaxed and happy (Figure 2).

Sahasraveeryadi Granules were taken for study containing ashwagandha, shatavari, bala, lodhra and sita to see their combined effect on reproductive as well as general health of females. Granulation is done so that the patient can take the medicine easily with milk. Granules were given twice in a day for three months. The drug works optimistically in improving and maintaining health among females [9].

Ashtavidha and dwividha veerya & panchbhautik gunna Yukta aahar

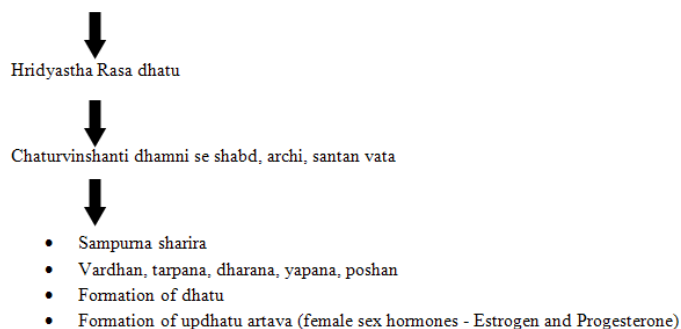


Figure 2: Relation of good nutrition and artava (female sex hormones).

It reduces all gynaecological symptoms happened because of reduced weight. The patients feel very happy, energetic and relaxed. By using the drug continuously for 3 months the weight of patient increases with the average of 1 kg every fortnight which automatically increase their immunity and pain tolerance.

Conclusion

The study was done on 20 patients between the age group between 10-55 years and whose BMI ranges from 16 to 19 kg/m² suffering from mild to moderate nutritional deficiency. Sahasraveeryadi granules were given to patients for 3 months. The drug gives optimistic results on

these patients [10]. The BMI of all patients increase with moderate to complete relief in all gynaecological symptoms caused because of nutritional deficiency. During study it was observed that there were no side effects of drug and most of the patients feel happy, relaxed and energetic with improvement in their functional capacity which gave an add on boost to the study. The drug is giving very promising result in a competitive market to conventional health drink.

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