RESEARCH PAPER

RANDOMISED OPEN CONTROLLED CLINICAL TRIAL TO EVALUATE THE EFFICACY OF BILVA PHAL MAJJA CHURNA IN SUTIKA PANDU W.S.R. TO IRON DEFICIENCY ANEMIA-A STUDY PROTOCOL

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ABSTRACT

Background

Ayurved described the mostly occurring Prasavvyapad in Sutika kal (Postpartum period) is Sutika pandu (Iron Deficiency Anemia). Due to increasing demand of newbie and need of body of mother the circulating red cell mass increases by 20-30%, rise in both cell number and size. It rises more in women with multiple pregnancies. The increase in plasma volume causes haemodilution. In postpartum phase, woman has already low immunity. Diminution and vitiation of Rasa dhatu continued from ante partum phase leading to sutika pandu. Ayurvedic regime of health care and medicinal treatment for this condition is significant called the sutika paricharya, is thoroughly explained in Ayurved Samhita. This study will illustrate the burden of PPA in women and highlights the recent state of the art of PPA management by Ayurvedic holistic approach.

Methodology

By pilot study drug dose and sample size obtained. IEC approval is taken. CTRI registration done for the trial. Then random sampling will decide the study and control group participants. Both group will receive their decided interventions. Group A will have study drug Bilva fal majja churn 3gm twice after meals with water and Group B control group will have drug Tab. FS once after meals with water for 21 days. Blood sample will be collected before study and after 21 days of treatment for testing the previous and after study value of Hemoglobin and Serum Ferritin. Statistical analysis will be done after completion of treatment to compare the changes in assessment parameters from the baseline.

Expected Outcome

Study intervention and results will be observed and recorded in terms of value changes in objective and relief of symptoms as per subjective Criteria decided. Results and conclusion will be drawn according to data obtained by statistical analysis.

Keywords: sutikapandu, prasavvyapad, raktalpata, garbhopdrava, avastha, paricharya.

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Introduction:

Motherhood is the best gift of universe for a woman in her life. This transformation is the choicest, it's like a boon of happiness. Perhaps this pretty journey has some controversies too. The physical and mental health issue occurs often in this joyful journey. Anaemia is the most common issue on a big scale found in developing countries. This is because there is lacuna of basic fundamental facilities and awareness at the tertiary level. Though government runs many health programmes for every stage but the conveying and execution of those is lacking, negligence and illiteracy play a key role. Antenatal period is crucial for health of a mother. According to Ayurveda Garbhini Avastha and its paricharya is thoroughly described. But to follow that properly is a big task. Aacharyas described many diseases in this Garbhini Avastha (ANC period). They are called as

Garbhopdrava. Pandu (Anaemia) is the most common Garbhopdrava (1). Due to increasing demand of Garbha (foetus) and need of the body of a pregnant woman, this condition occurs. During pregnancy, there is 20-30% increase in the mass of circulating red blood cells. It increases significantly more with iron supplementation and higher in women who have had several pregnancies(2). Haemodilution results from an increase in plasma volume. Mother typically develops anemia due to the fetus's high iron requirements. That is accentuated because of the stages of labor, especially if the third stage is compromised. Prasavvyapad is an additional problem caused by these disorders. Woman's immunity is already low in the postnatal phase, and her rasa dhatu has continued to diminish and been vitiated from the antenatal phase. She suffers and develops chronic illnesses as a result. Garbhini Pandu should therefore receive prompt medical attention (3).The most common Prasav vyapad is Pandu / Raktalpata (anaemia) in Sutika kal (postnatal period). This condition is described as Sutika rog in Ayurveda. Sutika avastha and its hazards are described as Sutika rog in Kashyap Samhita. The health condition of a mother in postnatal period is crucial because of loss of power of vitality, care of new born and unawareness. Most common symptoms are fatigue and weakness. Gradually, anorexia and loss of appetite surplus it. And then cumulatively results in postnatal anaemia called Sutika Pandu. In count of 64 Sutika rog, Sutika Pandu (4) is most important. Detailed description is not given in classics. But by the severity and impact of condition this can be understand by literary review. By taking reference of the samanya Pandu vyadhi and its relation to Garbha vastha ANC period. We can understand and elaborate Pathophysiology of Sutika Pandu. During Antenatal period many physiological and pathological changes occur from conception to labour. The physical and mental conditions of a woman play a big role in her good and bad prognosis of disease. She has to face many challenges during this period. In Ayurved Samhita these are explained as Garbha Dhan, Garbhvridhi, Garbhopghatkar Bhav, Garbhopdrav, and Garbhini Vyapada (4) in post natal period "Shoonyasharir (5,6) Avastha is mainly responsible for this critical scenario. Exhausted mother bleeding in third stage of labour, discharges in 10 days of postpartum the Lochia (7) exaggerate this condition. Vat vridhi, raktakshaya, dourbalya, agnimandya, aahar, vihar, dincharya all these are inextricably related to each other. Evacuation of foetus from womb causes sarva dhatukshaya, the efforts (shram) during labour make her (weak) kshin, durbal (shoonya). Agni becomes mand (less digestive power). Ras and rakta kshaya occurs. According to Charak Samhita Pandu is raspradoshaj vyadhi. Galitgatra Avastha (fatigue) is due to rasdhatu kshinata and dhatwagni kshaya is there. To overcome this situation body seeks extra nourishment but due to pathyaapathya and breast feeding this kshinata get worsened. This is surplused by newbie care. More attention is paid towards the newbie by every member in family including mother herself.

Justification: Anaemia is hazardous disease.According to WHO anaemia in antenatal or postnatal period is a commonest Hematological disorder and said to be when Hb% is lower than 11gm/dl7 .The Prevalence of anemia varies greatly, ranging from 10–20% in developed nations to 40–80% in tropical regions(8) The prevalence rate of anaemia in India is 65-75%. In India 80% of maternal death occurs due to anaemia. Inspite of all facilities given in antenatal Period the labour hazards and carelessness are the factors responsible for anaemia in Post-natal period (9,10). Guidelines by WHO are given to central and state government till tertiary care center time by time. But the problem still persists, so to tackle this situation with Ayurvedic approach and blend of treatment this study is proposed. The restoration of health including post-partum complications for everyone is possible by following proper Sutika paricharya.(11) One can adopt this easily for wellbeing of patients and can contribute to society. This is possible by traditional way and the cheapest formulation advised in ayurveda. Iron tablets, commonly used in form of sulphate (FS-325mg) having elemental iron 60mg evidenced nausea, vomiting, epigastric pain, constipation. The antacids, oxalates, phosphates used in treatment reduce intestinal absorption. While amino acids, ascorbic acid and lactate increase absorption. These properties are present in the drug which I have chosen for study. Bilva with its gun virya vipak properties efficiently overcome the above said symptoms.(12-13)

RESEARCH QUESTION

PRIMARY- Is Bilva Phal Majja Churna effective in raising the serum ferritin level in Sutika Pandu (Iron deficiency anaemia)?

SECONDARY – Is Bilva Phal Majja Churna effective to increase the Hb% in Sutika Pandu (Iron deficiency anaemia)?

HYPOTHESIS

NULL HYOPTHESIS H0 - Bilva Phal Majja Churna is not significantly useful in raising serum ferritin level and Hb% in Sutika Pandu (Iron deficiency anaemia)

PRIMARY HYPOTHESIS H1 - Bilva Phal Majja Churna is significantly useful in raising serum ferritin level in Sutika Pandu (Iron deficiency anaemia).

ALTERNATIVE HYPOTHESIS H2 - Bilva phal majja churna is useful to increase the Hb level in Sutika Pandu (Iron deficiency anemia)

AIM : To study and evaluate the efficacy of Bilva Phal Majja Churna on serum ferritin level and Hb% in the management of Sutika Pandu.

OBJECTIVES

PRIMARY- To evaluate the efficacy of Bilva Phal Majja Churna on serum ferritin level and Hb% in Sutika Pandu.

SECONDARY – • To replenish Dhatu. • To improve the Pandu vyadhi lakshana like dourbalya, Panduta, shramaj glani, shramaj shwas. • To support health status of patient during puerperal period. • To prevent post-partum complications.

Material and Methods:

Trial Drug: Bilva Phal Majja Churna i.e dried pulp powder of ripened Aegle marmelos Linn., Material will be purchased from GMP Standard Ayurvedic Pharmaceutical Company.

Control Drug: Tablet Ferrous Sulphate 325mg purchased from market.

Study Design: - Randomized open Controlled clinical Trial

Additional points for RCT:

Randomisation: Simple Random Technique.

Allocation: Simple random (lottery Method).

Blinding: No Blinding.

Study setting: -IPD of Prasutitantra –Strirog Dept.

Study Population: All full term delivered cases according to Inclusion criteria.

Duration of Study: 3 Weeks

Follow up: After 21 days of treatment on 22nd day

Sample Size : Sample size calculated with help of G power v.3.1. T test – Mean: Difference between two independent means (two groups) The following sample size calculated for mean differences of two independent group as study design is open labelled randomized controlled clinical trial. Two tailed, (d) Effect size Probability of α-error = 0.05 Power = 0.5 = 0.80 i.e (1-β error probability) Allocation ratio for groups i.e. N2 : N1 = 1 Output: Non centrally parameter δ = 2.83 Critical t Degree of freedom Sample size

Study Group = 126 = 64 Sample size Control Group = 64 = 1.9790 37 Total sample size = 128 Actual power = 0.80

Here hypothesis testing will be done at 0.05 alpha with 80% power. (14)

As an outcome variable that is Hb% is a continuous variable and mean and standard deviation of this Hb% from prior study, particularly related with Sutika Pandu is not available. Hence to put value for effect size is not possible, so as per Cohen`s guideline 0.5 (medium effect size) consider for input value for two tail test sample size generated is 64 sample in each arm.

Study Design

Method of Selection of study Subject: Screening of patients will be done in OPD of Prasutitantra and Streerog of our institute. Random selection will be done. By applying diagnostic criteria, full filling patients will be included and other shall be excluded. Included patients will be explained about the treatment and written consent shall be taken. According to sample size trial group and control group will be decided and accordingly treatment will be advised.

Study group : Bilva fal majja churna

Control group : ferrous sulphate tablets.

Diet and behavioral modification will be advised to all patients.

Follow up : on 22nd day of treatment done

Base Line assessment: This included, Family history, personal History.

CRITERIA OF SELECTION:

Inclusion criteria

1. Women with 15th to 42th day of post-partum.
2. Puerperal women of age between 25-35 years will be selected.
3. Both Primi para and Multi para full term delivered patients will be selected.
4. Women having Hb above 7gm % will be considered for the study.

Exclusion criteria

1. Women which are known case of HIV, VDRL and HbsAg.
2. Women suffering from disease like aplastic anaemia, thalassemia, haemolytic sickle cell disease and haemorrhagic disorders.
3. Women suffering with puerperal infection will be excluded from the study
4. Preterm delivered patients
5. History of anaemia due to bleeding piles, menorrhagia, gastric ulcers
6. Coagulation defects, renal insufficiency, CHD, HTN, DM, TB etc.

Withdrawal criteria

1. Any hypersensitivity reaction seen after ingestion of the trial or control drug.
2. Patients unable to complete the full duration of trial

Study End Point: If the value of hemoglobin decreased progressively.

Ethical consideration: During preparation of drug and treatment if any adverse reaction seen in patient, treatment will be stopped and proper care of the patient will be taken with essential treatment and patient shall be withdrawn from the research Project.

MODE OF DRUG ADMINISTRATION

Particulars	Group A Trial	Group B Control
Drug	Bilva Phal Majja Churna	Tablet Ferrous Sulphate
Dose	3 gm	325 mg
Frequency	2 times a day after meal	Once a day
Anupan	Water	Water
Route	Per oral	Per oral
Duration	3 weeks, increase duration of treatment according to need of patient	3 weeks
Sample size	64	64

ASSESSMENT CRITERIA:

Subjective criteria:

Criteria	Grading
Pallor	0 No 1 Pallor seen only in conjunctiva 2 Pallor at conjunctiva, tongue, nails 3 Palmer crease and skin also affected
Fatigue	0 No fatigue 1 Fatigue after a physical work 2 Fatigue on routine work 3 Fatigue even during rest
Breathlessness (Shwas)	0 Breathlessness Absent 1 Breathlessness after heavy work relieve soon 2 Breathlessness after moderate work relieved later 3 Breathlessness after light work relieved later, intolerable
Weakness (Dourbalya)	0 No feeling of weakness during daily activity 1 Sometimes feeling of weakness but perform daily activity. 2 Often feel weakness, hampers daily activity 3 Always feel weakness, can't perform daily activity even routine and postural movements.

SUBJECTIVE PARAMETERS: - 1. Complete Cure: - 100% Relief in symptoms.
2. Marked Improvement : - 75 to 99% Relief in symptoms.
3. Moderate Improvement : - 50 to 74% Relief in symptoms.
4. Mild Improvement : - 25 to 49% Relief in symptoms.
5. No Improvement : - 0 to 24% Relief in symptoms.

OBJECTIVE PARAMETERS: - 1. Good improvement in Hb% : more than 1gm %.
2. Mild improvement in Hb% : by 0.5 to 1gm %.
3. No improvements in Hb% : less than 0.5 gm %.
4. Good improvement in serum ferritin level by 10µg /dl.
5. Mild improvement in serum ferritin level by ≥5µg/dl.
6. No improvement in serum ferritin level by < 5 µg/dl.

Statistical analysis:

The prevalence of Iron Deficiency Anemia will be calculated as per proportion and the categorical outcomes will be assessed by Paired T-test. In regards to all the Parameters other tests like Wilcoxon Signed Rank test and Mann Whitney U test for in and inter group comparison will be used.

Trial status:

The recruitment of study participants has been started in March
2024. The study is in progress. The trial results will be published
through national/ international peer-reviewed journals after the
completion of the study.

Outcomes:

Primary: Increase in both the objective parameters Hb and Serum Ferritin.

Secondary: Reduction in symptoms of Anemia (the said subjective criteria). Restore and replenish dhatu,support health status and prevent postpartum complications.

Participant Timeline: Day 1 to 21 days of treatment and follow-up on the 22nd day for the lab investigation. Report will be collected.

Consent:

Proper information about disease and its treatment information sheet will be provided.
Written informed consent will be taken from the patient before starting
the study.

During the study, the confidentiality of each patient will be maintained.

Data Collection, Management, And Analysis Methods:

Observations will be taken and results shall be obtained by statistical analysis after completion of the study.

The data will be collected with the help of the following:

I. Case Registration Form with detailed history and examination

II. Follow Up Assessment Proforma.

Ethics and dissemination:

The trial will be conducted as per ICMR guidelines involving human participants (2017) and in accordance with the ethical principles of the Declaration of Helsinki for biomedical research. IEC certificate, obtained vide Ref No. PMT/AYU-Obs/IEC-04/STR/15dated 08.12.2021. The trial is also registered in CTRI with registration number CTRI/2023/07/054645.

Discussion: Bilva Pakwa Phal majja with its Gun : Guru, Snigdha, Grahi Ras : Madhur, Kashay Virya : Ushna vipak : Katu,Tikta and constituents like vit c b and folic acid with iron ,magnesium,phosphorus have excellent results on duodenum for absorption of iron in digested food. On the basis of observation results will be obtained after the study.Thorough explaination will be given. Statistical Analysis for overall assessment will be done to draw the outcome of treatment. Results obtained will definitely provide safety and effectiveness of drug with better therapeutic option to avoid hazards of FS. The holistic approach of Ayurvedic postnatal care will definitely be the excellent option.

Future plan: Trial will be uploaded. Result drawn from study after completion shall be published in national and international peer reviewed journals

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