International Journal of Community Medicine and Public Health
Prameeladevi K et al. Int J Community Med Public Health. 2026 Aug;13(8):4205-4213
https://www.ijcmph.com
pISSN 2394-6032 | eISSN 2394-6040

DOI: https://dx.doi.org/10.18203/2394-6040.ijcmph20262692

Original Research Article

Evaluation of the efficacy of Saubhagyashunthi Paka and Dashamularishta in Sutika Paricharya (postnatal care): a prospective, single-arm clinical study

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Received: 30 July 2025
Revised: 07 July 2026
Accepted: 08 July 2026

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ABSTRACT

Background: The postnatal period, also known as the puerperium, starts as soon as the placenta separates and lasts up to 6 weeks. In Ayurveda, the treatment provided at this time is known as sutika-paricharya (postnatal care) emphasizes restoration of balance within the body, particularly the restoration of Vata dosha, which is believed to be aggravated during childbirth and aims to rejuvenate and strengthen the body, promote lactation, and enhance overall maternal well-being. The Ayurvedic formulations, saubhagyashunthi paka and dashmularishta, have long been recognized for their therapeutic benefits in managing postnatal recovery. This clinical study aimed to assess the effect of selected Ayurveda formulations in the management of post-natal care.
Methods: A single-center, single-arm prospective clinical study was conducted during 30th May 2020-30th November 2021 to evaluate the therapeutic efficacy of saubhagyashunthi paka and dashmularishta in sutika-paricharya. The study included 40 puerperal women, all of whom received the trial medications for a duration of eight weeks.
Results: The results of the study indicated significant improvements in various clinical measures. Lochial discharges were notably reduced; uterine involution was observed in all 37 patients (100%). Optimum lactation was reported in 32 cases (86.5%) and in all 37 cases (100%) by the 70th day. Improvements were seen in urogenital symptoms. Safety parameters, including liver and kidney function tests, remained within normal limits throughout the study period. No adverse events were reported.
Conclusions: The study provides preliminary evidence supporting the efficacy of saubagyashunti paka and dasmoolaarista in managing sutika-paricharya and lays the foundation for designing a randomized controlled trial to further evaluate their efficacy.

Keywords: Sutika Paricharya, Postnatal care, Saubhagya Shuntipaka, Dashamularishta

INTRODUCTION

Postnatal care is regarded as one of the most essential maternal healthcare services for the prevention of impairment and disability resulting from childbirth. Postnatal care includes a systematic examination of the mother and baby and appropriate advice given to the mother during the postpartum period. The World Health Organization (WHO) describes postnatal care as the most critical and most neglected phase of the life of mothers and babies as most of the death occurs during the postnatal period.[1] Ayurveda gives importance to the

mother's care at every phase of her life especially when it comes to postnatal care. A woman who has just given birth to a baby along with the placenta is assigned the term sutika in Ayurveda and the care given during this period is called Sutika Paricharya.[2] Puerperium begins as soon as the placenta is expelled and lasts for approximately 6 weeks when the uterus becomes regressed almost to the non-pregnant size.[3] The sutika phase lasts for 6 weeks from the day of delivery of the baby. During and after the delivery of the baby, various anatomical and physiological changes occur, and it is a critical period for the health of the mother and the newborn. In this postpartum phase, the mother may experience physical and psychological issues that may affect their quality of life, future health, and children's health. In Ayurvedic literature, various stages of puerperium are described under the aegis of sutika paricharya (postnatal care)wherein details of do's and don'ts for the dietary regimen, activities and the care required during this period are discussed.[4,5] During puerperium, the woman faces many problems like fever, diarrhoea, edema, colic, abdominal distension, weakness, drowsiness, anorexia and delirium The modern system of medicine primarily focuses on physical recovery during the postpartum period, while Ayurveda offers a comprehensive approach that also addresses common discomforts, emotional well-being, and challenges related to role fulfillment. Thus, the adoption of Ayurvedic formulations effectively supports the diverse needs of the puerperium.[6] Prevention of these complications depends mainly on the maintenance of the tone of the uterus and urinary bladder, supporting the general health of the mother, and ensuring optimum lactation.[7] In the modern system of medicine, supplementation with hematinic, calcium, and vitamins is done during the puerperal period to address the issues of anemia, deficiency in calcium and vitamins due to lactation, etc.[8] In the postnatal phase, Ayurveda emphasizes the holistic care of the mother, addressing key aspects such as strengthening the uterus and urinary bladder, promoting adequate lactation, improving appetite, and enhancing general well-being. Ayurvedic formulations, such as saubagyashunti paka and dasmoolaarista, are specifically designed to support these vital functions, ensuring a balanced recovery process. By targeting the root causes of postpartum discomforts and imbalances, Ayurveda offers a comprehensive approach to nurturing the mother's physical and emotional health during the puerperium.

The present study was conducted to validate the efficacy of two Ayurvedic formulations, viz., saubhagyashunthi paka and dashamularishta.[9,10] Both the formulations are having ingredients that may aid in restoring the normal muscle tone of the uterus and urinary bladder. Saubhagyashunthi paka is helpful in catering to the demands of the postnatal phase like the involution of the uterus, achievement of optimum lactation, regaining the tone of the urinary bladder, intestines, etc.[11] Ingredients of this formulation like pippali (*Piper longum L.*), shatavari (*Asparagus racemosus Willd.*), and shatapushpa (*Anethum sowa Kurz.*) are having lactogenic properties and thereby ensure optimum lactation.[12] These ingredients further help in the proper expulsion of lochial discharges and prevent early or late postpartum haemorrhage too.[13] Dashamularishta is a frontline arishta formulation used in the management of vata disorders. Key ingredients of dasmoolaarista, such as chitraka (*Plumbago zeylanica L.*), devadaru (*Cedrus deodara*), and lodhra (*Symplocos racemosa*), possess Shothaghna (anti-inflammatory) and krimighna (anthelmintic) properties, which help in preventing postnatal infections.[14] Additionally, ingredients like Devadaru (*Cedrus deodara*) and Shatapushpa (*Anethum sowa Kurz.*) have vataghna (vata-reducing) and shoolaghna (pain-relieving) properties, which can effectively address postnatal pain and spasms.[15]

METHODS

Study design

This was a single-center, single-arm prospective clinical study was conducted during May 2020-November 2021 to evaluate the therapeutic efficacy of saubhagyashunthi paka and dashmularishta in sutika-paricharya in accordance with the principles set out in the Good Clinical Practice (GCP) guidelines that guides the appropriate use of traditional medicines in clinical practice. The study protocol was approved by the Institutional Ethics Committee (IEC), and the study was registered in the Clinical Trial Registry of India (CTRI/2020/01/022935).

Study participants

The study included 40 puerperal women, all of whom received the trial medications for a duration of eight weeks were recruited from the OPD of Dr. Achanta Lakshmipathi Regional Research Institute for Ayurveda, Chennai and also, from Anganvadi and PHC in the vicinity of the study center.

Inclusion criteria

Primipara /multipara age between 20-35 years with full-term vaginal delivery, by cesarean section or forceps delivery/vacuum application, delivered on the 3rd to 10th postnatal day, having a live baby and those who were willing and able to participate in the study were included.

Exclusion criteria

Women after the 11th postnatal day; puerperium associated with complications like severe postpartum haemorrhage, acute inversion of the uterus, puerperal eclampsia, psychosis, and postnatal gestational diabetes; With uncontrolled hypertension (>160/100 mmHg) and diabetes mellitus (HbA1c>8.0%); evidence of malignancy; mothers with active herpes breast/breast abscess/retracted nipple/severely cracked nipples, having

a history of HbsAg, HIV, tuberculosis, chronic medical conditions and any other condition which investigator thinks may jeopardize the study were excluded from the trial.

Withdrawal criteria

If the participant became ineligible to continue in the study or developed any serious adverse effect (necessitating hospitalization) or noncompliance to the treatment regimen (minimum 80% compliance is essential to analyze the data) were withdrawn from the trial. The participants were free to withdraw anytime from the study. Further, those who were not formally withdrawn from the study but ceased to take medicine and came for examination were also withdrawn from the study.

Study interventions

Both the quality assured trial formulations were procured from Good Manufacturing Practice (GMP)-certified Indian Medicines Pharmaceutical Corporation Ltd. (IMPCL), Mohan, Uttarakhand, India. All the safety parameters like heavy metals, pesticide residue, and aflatoxin were within the permissible limit.

Table 1: Detailed posology of the selected interventions.

Details	Saubhagyashunthi paka	Dashamularishta
Dose	10 gm twice daily	20 ml twice daily in a day
Dosage form	Granules	Liquid
Route of administration	Oral	Oral
Time of administration	Before 30 minutes of meals	After 30 minutes of meals
Anupana (vehicle)	50 ml of milk	Water
Duration of therapy	8 weeks	8 weeks
Packing form	180 g granules	600 ml liquid
After treatment	Follow-up 2 weeks after treatment	Follow-up 2 weeks after treatment

All participants in the group were administered orally saubhagyashunthi paka (10 gm twice daily before 30 minutes of meals with 50 ml milk) in the form of granules and Dashamularishta (20 ml twice in a day after 30 minutes of meals with water) for two months (Table 1).

Outcome measures

Primary outcome measures

The primary outcome of the study was to assess the clinical efficacy of saubhagyashunthi paka and dasamularishta as part of sutika paricharya (postnatal care). This evaluation focused on their role in promoting postnatal recovery and maternal health.

Secondary outcome measures

The secondary outcome of the study was to evaluate the improvement in the quality of life of postnatal mothers due to the sustained effect of saubhagyashunthi paka and dashamularishta.

This was assessed using a specially designed questionnaire titled: “assessment of quality of life in postnatal care by mother generated index”.

The assessment was conducted at baseline (day 0) and on the 70th day of the intervention. The scoring system was structured such that higher scores indicated a better quality of life.

Sample size

To date, no studies have investigated sutika paricharya with both of the proposed drugs to generate evidence of their efficacy and safety. The aim of this study was to provide data on the effectiveness of these drugs. Based on the data generated from a pilot study with 30 participants and considering a potential 20% dropout rate (i.e.6), the total sample size was adjusted to 36. To account for any further loss, the sample size has been rounded up to 40. Therefore, the final sample size for this study was 40 participants.

Study procedures

On the screening visit the subject’s voluntary written informed consent was taken. On the enrollment day at baseline (visit 1), the patient’s demographic profile, medical history, general physical and systemic examination, and assessment of clinical parameters were recorded. Trial drugs and drug compliance report form was also given to the participants, and the subsequent visits were planned at an interval of 02 weeks [14th day (visit 2), 28th day (visit 3), 42nd day (visit 4), 56th day (visit 5), 70th day (visit 6)]. Participants were assessed and study medications were given at each subsequent visit till 56th day, without intervention follow-up at 70th day was also scheduled. All visits were home visits done by the Investigator and the study team The details of the study procedure for each visit are given in Figure 1.

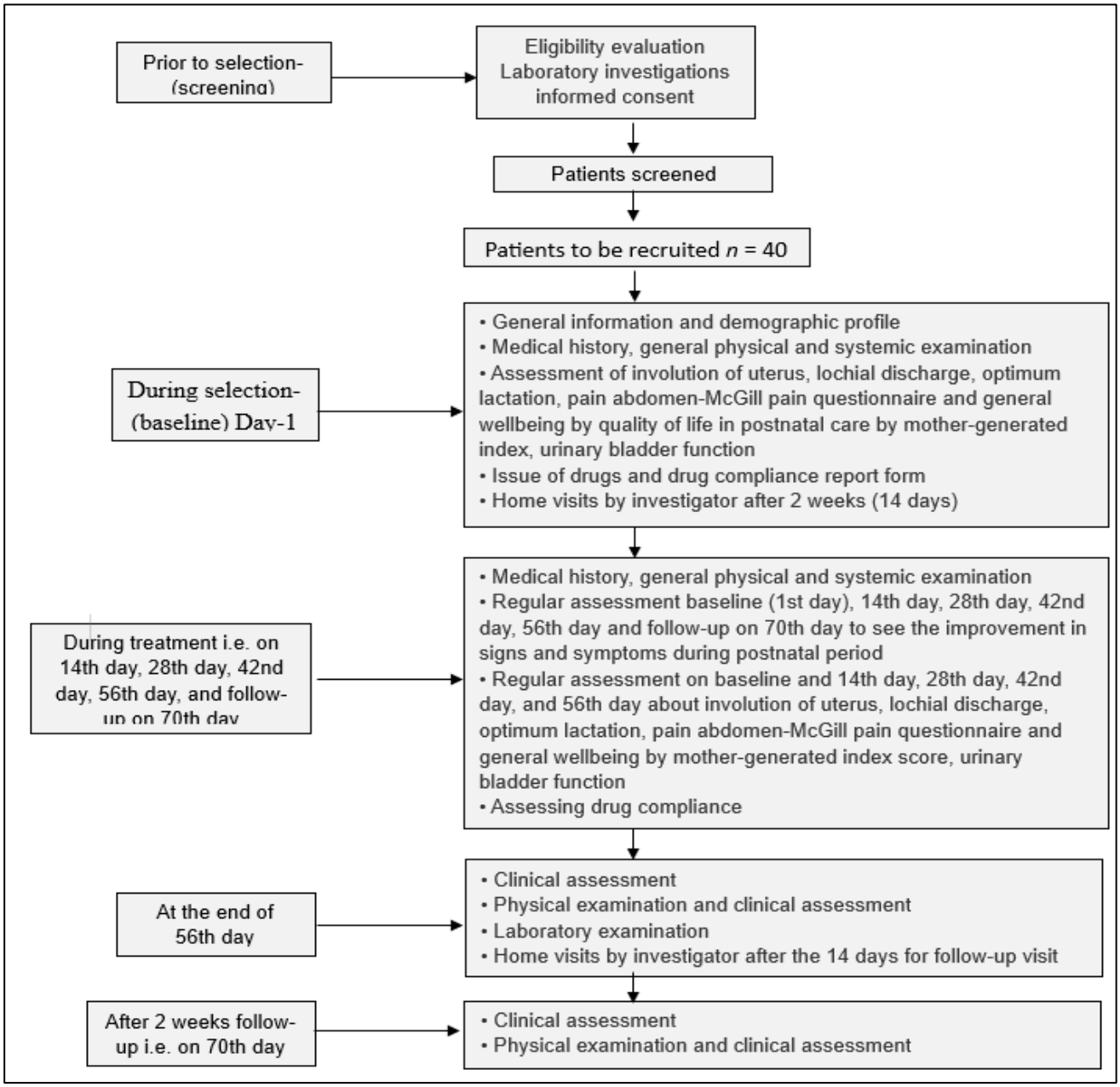

Figure 1: Study procedure.

Number of the patients screened n=40.

Data of all the participants were recorded in predesigned case report forms (CRFs) and were also entered in electronic formats (e-formats) designed in MS Excel with many data validation checks to ensure correct data entry. The e-formats and xerox of the CRFs along with the scorings and laboratory investigation reports of each participant were sent to the CCRAS headquarters on a weekly basis for the purpose of clinical study monitoring.

Statistical analysis

The collected data was entered in Ms-excel to check the discrepancies and accuracy. The quantitative data was reported in mean (SD). The qualitative data was reported in N (%). The quantitative data was compared with paired t-test/Wilcoxon sign rank test for pre-post analysis. The level of significance was taken at 5%. All the analysis has been done through the SPSS.

RESULTS

Out of the total 40 research participants enrolled in the study, 3 dropped out during the course of the study for various reasons like a patient not being available for follow-ups, going out of town, and issues related to palatability. A total of 37 cases were taken for analysis.

Demographic profile of study participants

It was observed from the demographic data that 18 participants were (48.6%) graduates and above, 17 (45.9%) had high school education and 2 (5.4%) had primary school education. A maximum number of subjects, 35 (94.6%) were housewives and were indulged in domestic work. It was also noticed that 37 (100.0%) subjects had mixed diets and none of the participants had any addiction (Table 2).

Table 2: Demographic profile of the participants (n=37).

Variables	N (%)/ mean±SD
Age (in years)	26.0±3.7
Educational status	
Primary school	2 (5.4)
High School	17(45.9)
Graduate and above	18 (48.6)
Occupation	
Employee	2 (5.4)
Housewife	35(94.6)
Religion	
Hindu	31 (83.8)
Muslim	1 (2.7)
Christian	5 (1.85)
Diet	
Mixed	37 (100.0)
Built	
Lean	14 (37.8)
Medium	23 (62.2)
Addiction	
No	37 (100.0)
Body Weight (kg)	57.99±11.73
Height(cm)	152.2±5.07
Blood pressure	
Systolic (mm Hg)	110.6±11.4
Diastolic (mm Hg)	75.7±7.72
Pulse Rate (Per minute)	84.68±10.09

Effect of the trial interventions on assessment parameters

The clinical effectiveness of trial interventions was assessed through improvement in clinical parameters like lochial discharges, early involution of the uterus, improvement in lactation, urogenital problems, constipation, and sleep at the baseline, 56th day, and on the 70th day.

Assessment of lochia discharge was done based upon inspection with respect to quantity and the number of sanitary pads used, an inspection of the perineum for the normal variation in color of the lochia depending upon its duration, and data gathered from the subject. 12 cases (32.4%) showed a scanty amount at baseline,18 cases showed (48.6%) a light amount, less than a 4-inch stain on the peripad, 6 cases showed (16.2%) moderate amount, less than 6- inch stain on the peripad and 1 case (2.7%) showed heavy amount, saturated peripad within 1 hour. On the 56th day and follow-up, i.e. 70th day 37 cases showed (100%) scanty discharges without any odour (Figure 2).

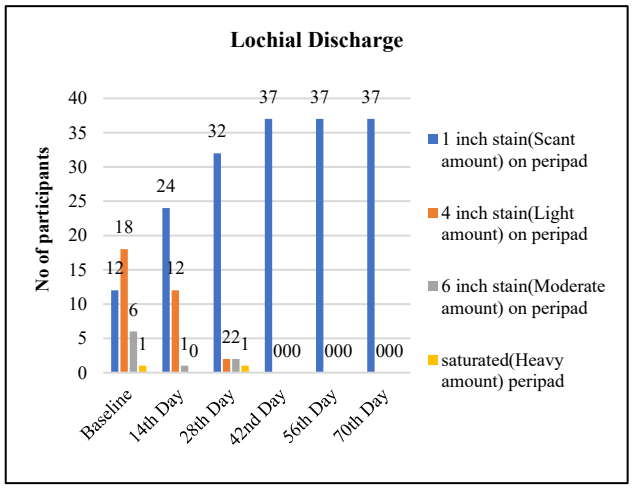

Figure 2: Lochial discharge.

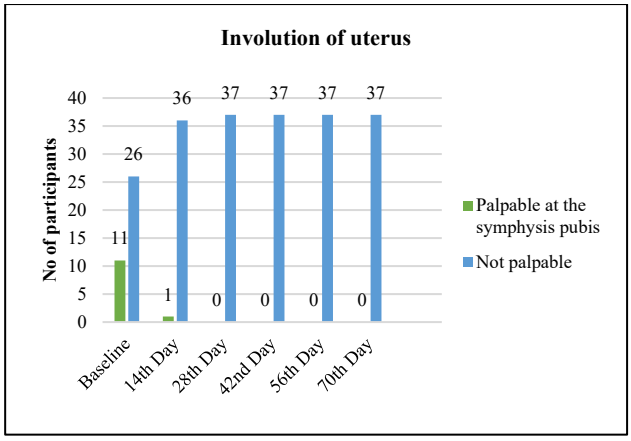

Figure 3: Involution of uterus.

Involution of the uterus was assessed by measuring the height of the fundus. In 11 cases (29. of 7%) fundus of the uterus was palpable at the symphysis pubis and in 26 cases (70.3%) not palpable at baseline and on 14th day 1 case (2.7%) showed fundus of the uterus was palpable at the symphysis pubis and 36 cases (97.3%) not palpable and on 28th day, and on follow up i.e. 70th day 37 cases showed (100%) the uterus not palpable which indicates that involution of the uterus has been improved. All postnatal mothers experience pain in some form or another. It is common that women experience cramping pain and discomfort following the birth of baby as the uterus contracts and returns to its pre-pregnancy size (Figure 3).

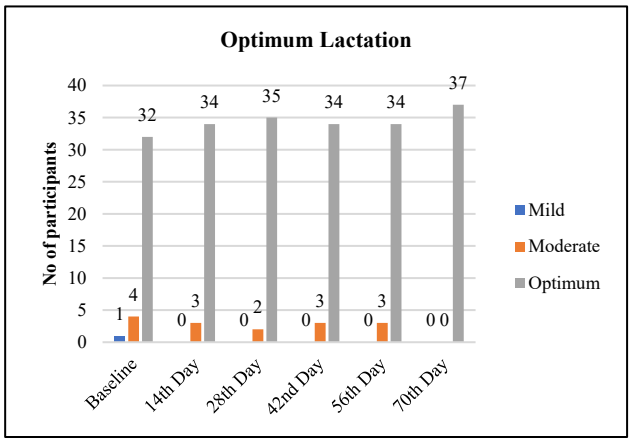

Figure 4: Optimum lactation.

Pain in abdomen was assessed by Mc Gill Pain Questionnaire. It has been observed that 19 mothers (51.4%) perceived mild pain, 2 mothers (5.4%) perceived moderate pain and 16 mothers (43.2%) perceived pain rarely at baseline. At 14th, 21 cases (56.8%) experienced rare pain, 14 cases (37.8%) showed mild pain and 2 cases (5.4%) perceived moderate pain. On 28th day 29 cases (78.4%) observed pain rarely and 8 cases (21.6%) observed mild pain. On 42nd day and on 56th day and follow up i.e. 70th day 37 cases showed (100%) perceived minimum pain.

Optimum lactation was observed in 32 cases (86.5%) at baseline, 34 cases (91.9%) on 14th day 35 cases (94.6%) on 28th day, 34 cases (91.9%) on 42nd day and 56th day 34 cases (91.9%) have optimum lactation and 37 (100%) cases on 70th day respectively (Figure 4).

In Urogenital assessment scale 34 participants (91.9%) have reported no problems like the). The feeling of urgency, leakage of urine related to activity, coughing or sneezing pain or discomfort in the lower abdomen or genital area. 3 participants (8.1%) have a slight problem like facing difficulty in emptying the bladder at base line. On 14th day 33 cases (89.2%) have no urogenital problems, only 3 cases (8.1%) have moderate problems. On 42nd day, on the 56th day and follow up i.e. 70th day 37 cases showed (100%) no urogenital problems.

At baseline 27 cases (73.0%) had no sleep disturbances and 9 (24.3%) cases had moderate sleep disturbances. On 14th day 29 cases (78.4%) cases had no sleep disturbance, 8 cases showed moderate sleep disturbances and on 42nd day 33 cases (89.2%) had no sleep disturbances, 4 cases (10.8%) showed moderate sleep disturbances. 34 cases (91.9%) had no sleep disturbances, 3 cases (8.1%) had moderate sleep disturbances on the 56th day and on the 70th day 37 (100%) cases had no sleep disturbances. 31 cases (83.8%) had no constipation, 4 cases (10.8%) had mild constipation and 2 cases (5.4%) had moderate constipation at baseline, on 14th day 33 cases (89.2%) had no constipation, 3 cases (8.1%) had mild constipation, 1 case (2.7%) showed moderate constipation. on 28th day 35 cases (94.6%) had no constipation, 2 cases (5.4%) had mild constipation, on 42nd day 37 cases (100%) had no constipation. On the 56th day, 36 cases (97.3%) had no constipation 1 case (2.7%) showed mild constipation. On 70th day) 37 cases (100%) had no constipation. 23 (62.2%) cases at baseline had mild low backache, and 7 cases (18.9%) had severe low backache. On 14th day 23 cases (62.2%) had mild low backache, 12 cases (32.4%) had no low back ache and 2 cases (5.4%) showed severe backache. On 28th day 22 cases (59.5%) had mild low backache, 12 cases (32.4%) had no low back ache and 2 cases (5.4%) showed severe backache. On the 56th day, 32 cases (86.5%) had no low back ache, 5 cases (13.5%) had mild low back ache and 37 (100%) cases had no low back ache on the 70th day.

At baseline 31 cases were moderately satisfied, and 5 cases were very satisfied. On 14th day 29 cases were moderately satisfied and 08 cases were very satisfied. On 42nd day 24 cases showed moderate satisfaction and 13 cases were very satisfied. On 56th-day survey, 33 cases were very satisfied and 04 cases were moderately satisfied. 34 cases were very satisfied on the 70th (follow-up) day and only 03 cases were moderately satisfied.

Table 3: Baby's birth weight in kg.

	Baseline	14th Day	28th Day	42nd Day	56th Day	70th Day
Mean	2.9	3.26	3.7	4.17	4.54	4.83
Std. deviation	0.37	0.34	0.617	0.73	0.79	0.76

Table 4: Effect of the treatment on hematological parameters (n=37).

Parameters	Baseline (Mean±SD)	56th day (Mean±SD)	P value
Hemoglobin (gm/dl)	11.66 (1.4)	12.19 (1.17)	0.013
TLC/mm^3	9187.16 (2256.75)	7893.02 (2127.5)	0.021
Polymorphs	66.88 (7.79)	56.80 (10.04)	<0.001
Lymphocytes	24.49 (6.59)	34.401 (7.94)	<0.001
Eosinophils	4.23 (2.06)	5.23 (3.37)	0.087
Monocytes	3.29 (1.01)	3.11 (1.05)	0.359
Basophils	0.11 (0.06)	0.16 (0.17)	0.055
ESR	67.13 (34.56)	35.21 (21.61)	<0.001
RBS	98.48 (16.7)	103.08 (19.3)	0.274

Table 5: Effect of the treatment on safety parameters (n=37).

Parameters	Baseline (Mean±SD)	56th day (Mean±SD)	P value
Total bilirubin	0.44 (0.11)	0.53 (0.15)	0.001
SGOT	23.005(8.05)	30.82 (13.07)	0.004
SGPT	17.74 (6.92)	34.31 (20.41)	<0.001
Total protein	6.50 (0.46)	7.26 (0.56)	<0.001
S. albumin	3.30 (.376)	4.10 (0.35)	<0.001
S. alkaline phosphatase	137.41 (37.2)	103.34 (25.11)	<0.001
Blood urea nitrogen	10.24 (2.73)	9.31 (2.62)	0.080
S. creatinine	0.57 (0.13)	0.60 (0.10)	0.015

Effect of the interventions on laboratory parameters for safety evaluation

The effect of these treatments on hematological parameters, liver function tests, and renal function tests was assessed at baseline and on the 56th day. The values of all the laboratory parameters were within range during the entire period. These observations validate that these classical drugs are safe for post-natal mothers to use. Further, no adverse events were reported during the treatment period.

DISCUSSION

From the statistical analysis of the results, it was observed that most of the study participants were between the age group of 20 and 34 years. The aim of the study was to restore the strength of the mother and minimize the complications and establishment of sufficient lactation as the primary outcome and the secondary outcomes are improvement in the quality of life and clinical safety of the trial drugs.

Clinical effectiveness saubhagyashunthi paka and dashamoolarishta were assessed on lochial discharges, involution of the uterus, improvement in lactation, pain abdomen, urogenital problems, sleep, etc. At baseline 18 cases (48.6%) showed a light amount, 6 cases (16.2%) showed a moderate amount and only one case (2.7%) showed a heavy amount. On the 56th day and following i.e. 70th day 37 cases (100%) showed scanty discharges without odor. In 11 cases (29. of 7%) fundus of the uterus was palpable at the symphysis pubis and in 26 cases (70.3%) not palpable at baseline and on the 56th day and follow up i.e. 70th day 37 cases showed (100%) the uterus not palpable which indicates that involution of the uterus has been improved. All postnatal mothers experience pain in some form or another. It is common that women to experience cramping pain and discomfort following the birth of a baby as the uterus contracts and returns to its pre-pregnancy size. Optimum lactation was observed in 32 cases (86.5%) at baseline, 34 cases (91.9%) and 37 (100%) cases on the 54th day and 70th day respectively. Only 3 participants (8.1%) have slight difficulty in emptying the bladder at baseline. No urogenital problems were observed in 37 cases (100%) on the 56th day and follow up i.e. 70th day. 9 cases (24.3%) showed moderate sleep disturbances at baseline, on the 56th day 34 cases (91.9%) had no sleep disturbances, and on the 70th day, 37 cases (100%) had no sleep disturbances. 23 (62.2%) cases at baseline presented with mild low backache, and 7 cases (18.9%) had severe low backache. On the 56th day,

32 cases (86.5%) had no low back ache, 5 cases (13.5%) had mild low back ache, and 37 (100%) cases had no low back ache on the 70th day. Statistical analysis reveals the body weight of the baby is improved well.

At baseline, 31 cases reported moderate satisfaction, and 5 cases reported very high satisfaction. On the 56th day of the survey, 33 cases reported being very satisfied, and by the 70th (follow-up) day, 34 cases reported being very satisfied. Regarding clinical safety, the results of safety laboratory parameters indicate that all the trial drugs are safe for use, with no adverse events reported by the study participants during the study period. These trial drugs are classical Ayurvedic formulations that have been used for centuries, which further supports their safety profile.

During puerperium, women often experience a range of issues, including fever, diarrhea, edema, colic pain, abdominal distension, loss of strength, drowsiness, anorexia, delirium, and other disorders caused by the vitiation of Kapha and Vata. These issues typically appear during the postpartum period. Saubhagyashunthi paka is an Ayurvedic compound formulation designed to alleviate puerperal disorders, anxiety, stress, and common post-delivery problems such as impaired lactation, body pain, arthritis, and fever. It acts as a postnatal tonic that facilitates the normal involution of the uterus and promotes milk production.[11] Estimation of nutritive value of saubhagyashunthi paka (delivery/per gram): iron 10.5 mg, protein 6.8 gm, fat 25.70 mg, carbohydrate 42.5 gm, calcium 212.02 mg, vitamin B_{12} 0.5 µg. Dashmularishta has also been used for centuries to treat various diseases, including the management of puerperium. It is known for its beneficial effects in managing dhatukshaya (weakness or depletion of body tissues) and acting as a uterine cleanser (garbhasayshodhaka). A study conducted on 40 puerperal women showed that dashmularishta was effective in improving health and quality of life during the postpartum period.

The combined use of saubhagyashunthi paka and dashmularishta in managing postpartal issues is a common practice in India and has proven to be both effective and safe. However, there is currently no documented evidence supporting their combined use. Although this study was not a randomized controlled trial- a limitation- it offers valuable insights and written evidence regarding the clinical safety and efficacy of both trial drugs.

CONCLUSION

Saubhagyashunthi paka and dashamoolarishta are effective in the management of sutika paricharya associated symptoms and promoting the quality of life of postnatal mothers and help in improving Breast milk production which supports gaining baby weight. Hence, these Ayurvedic formulations can be used effectively and safely for the management of postnatal care. Further, it is suggested that a randomized clinical trial (RCT) may be conducted to corroborate the result of this study.

ACKNOWLEDGEMENTS

The authors are thankful to all the study participants for their participation in the study and to the in-charge of the Institute for providing technical support and guidance. The authors are also thankful to Dr. Manjula, senior research fellow, and Dr. Nalini, senior research fellow of the project for providing logistic and technical support for data collection. It is a pleasure to acknowledge Prof. Kumaramangalam Bharathi, HOD, PTSR department, NIA, Jaipur for giving suggestions. The authors are highly grateful to Director General , CCRAS and Deputy Director General, CCRAS, New Delhi for providing financial and technical support to conduct the study.

Funding: The study was funded by Central Council for Research in Ayurvedic Sciences (CCRAS), M/O of AYUSH, Government of India
Conflict of interest: None declared
Ethical approval: The study was approved by the Institutional Ethics Committee Trial Registration: Clinical Trials registry – India [CTRI/2020/01/022935]

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Cite this article as: Prameeladevi K, Saradaota, Asha, Maheswar T, Tripathi A, Srinivas P, et al. Evaluation of the efficacy of Saubhagyashunthi Paka and Dashamularishta in Sutika Paricharya (postnatal care): a prospective, single-arm clinical study. Int J Community Med Public Health 2026;13:4205-13.