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Research Article

A Randomized Comparative Trial to Evaluate the Role of Bala Beeja Granules and Jeevanti Granules in Fetal and Maternal Wellbeing W.S.R To Garbhini Paricharya in the Second Trimester

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Abstract

Ayurveda emphasizes comprehensive antenatal care through the concept of Garbhini Paricharya, which advocates month-wise dietary and lifestyle regimens to promote optimal fetal and maternal wellbeing. The present randomized comparative clinical trial was conducted to evaluate the role of Bala Beeja Granules and Jeevanti Granules both described under Madhura Skandha by Acharya Charak in supporting fetal and maternal wellbeing during the second trimester of pregnancy. Sixty uncomplicated pregnant women aged 21– 40 years were randomly allocated into two groups, with Group A receiving Bala Beeja Granules and Group B receiving Jeevanti Granules in a dose of 10 g twice daily with milk for 16 weeks. Assessment was carried out using fetal biometry parameters, estimated fetal weight, amniotic fluid index, Doppler indices, maternal anthropometric measures, biochemical parameters and relief of minor pregnancy ailments.

Both interventions demonstrated encouraging outcomes in maintaining fetal growth parameters within Indian and international reference standards. However, Group B showed comparatively higher mean values for abdominal circumference, femur length, biparietal diameter, and estimated fetal weight at 28 weeks, suggesting a modest advantage in fetal growth promotion. Doppler studies in both groups remained within normal physiological limits, with Group B showing values closer to reference standards, indicating better uteroplacental adaptation. Maternal parameters such as Symphysio fundal height, abdominal girth, weight gain and BMI showed improvement in both groups, with slightly better trends in Group B. Relief in minor ailments differed between groups, with Group A showing greater improvement in constipation and general debility, while Group B showed better relief in pallor and palpitations. No adverse drug reactions were observed.

The study concludes that both Bala Beeja Granules and Jeevanti Granules are safe and effective formulations for supporting fetal and maternal wellbeing during the second trimester with Jeevanti Granules demonstrating a marginal clinical advantage in enhancing fetal growth and maternal nutritional status.

Keywords: Ayurveda, Garbhini Paricharya, Antenatal Care, Fetal Growth; Maternal Health, Pregnancy, Second Trimester, Randomized Controlled Trial, Herbal Medicine, Bala (Sida cordifolia), Jeevanti (Leptadenia reticulata), Fetal Biometry, Estimated Fetal Weight.

INTRODUCTION:

Maternal and child health remains a major public health priority and receives significant emphasis in Ayurveda through the concept of Garbhini Paricharya, a comprehensive antenatal care regimen. Pregnancy is associated with profound physiological and psychological changes¹ that directly influence maternal health and fetal development. ²Ayurveda extends beyond preventive and curative healthcare by emphasizing maternal wellbeing, improved quality of life and the attainment of a healthy progeny.^{3 4}

Classical Ayurveda texts, particularly Charaka Samhita, advocate meticulous care of the pregnant woman, comparing her to a vessel filled with oil, wherein even

minimal physical or emotional disturbance may lead to adverse outcomes. This analogy highlights the vulnerability of the gravid state and the necessity for cautious management throughout pregnancy. Accordingly, Acharyas have elaborated a systematic, month-wise antenatal regimen comprising Ahara (dietary guidelines), Vihara (appropriate daily activities) and Vichara (psychological and emotional discipline)⁵ to ensure normal pregnancy progression and favorable maternal and fetal outcomes.⁶

The primary objective of Garbhini Paricharya is to ensure adequate nourishment, psychological stability and safety of both mother and fetus throughout gestation and childbirth. Ayurveda scholars emphasize

that fetal Wellbeing is intrinsically dependent on maternal health; hence, maintaining the wellness of the Garbhini forms the cornerstone of healthy fetal growth and development.⁷ The principal goals of Garbhini Paricharya include Paripurnatva (optimal nourishment of the mother and fetus)⁸, Anupaghata (uncomplicated pregnancy), Sukha Prasava (normal labor) and the birth of a healthy child endowed with desirable attributes and longevity.⁹

Maternal nutrition is a critical determinant of fetal growth, neonatal survival and long-term health outcomes. Nutritional inadequacy during the second trimester, a crucial phase for fetal organ development and rapid growth, may lead to altered fetal growth patterns.¹⁰ Evidence indicates that structured maternal nutrition interventions, including dietary counselling and micronutrient supplementation, significantly reduce pregnancy-related complications and improve perinatal outcomes.^{11,12}

According to recent World Health Organization reports, India remains among the leading contributors to global preterm births, which constitute a major cause of neonatal mortality. Recent estimates indicate a neonatal mortality rate of 26.62 per 1,000 live births,¹³ while the maternal mortality ratio has declined to 97 per 100,000 live births.¹⁴ Despite this progress, nearly 80% of fetal deaths occur during the antepartum period, primarily due to chronic fetal hypoxia, maternal complications, congenital anomalies and unexplained causes. Intrauterine growth restriction accounts for a substantial proportion of antepartum fetal deaths, underscoring the importance of effective antenatal care.¹⁵ Strengthening maternal awareness and antenatal healthcare services remains essential for improving maternal and neonatal health outcomes.

AIM

To evaluate the efficacy of Bala Beeja Granules and Jeevanti Granules in promoting maternal and fetal wellbeing during the second trimester of pregnancy.

OBJECTIVES

Primary Objective

To assess and compare the efficacy of Bala Beeja Granules and Jeevanti Granules in improving maternal and fetal wellbeing during the second trimester of pregnancy.

Secondary Objectives

1. To evaluate and compare the efficacy of Bala Beeja Granules and Jeevanti Granules in alleviating minor ailments and preventing common complications associated with the second trimester of pregnancy.
2. To assess and compare the effect of Bala Beeja Granules and Jeevanti Granules on fetal growth and overall fetal wellbeing during the second trimester of pregnancy.

MATERIALS AND METHODS

Literary Review

A comprehensive literary review was conducted by consulting classical Ayurveda texts along with their authoritative commentaries. Relevant information was also collected from modern medical literature and previously published research articles available in institutional and departmental libraries. In addition, electronic databases such as PubMed, AYUSH Research Portal, Google Scholar were systematically searched to obtain contemporary scientific evidence related to maternal and fetal health and antenatal care.

Clinical Study

The present study was conducted as a clinical trial following a predefined research protocol. A total of sixty registered antenatal cases fulfilling the inclusion criteria were randomly selected from the Outpatient and Inpatient Departments of the Arogyashala, Postgraduate Department of Prasuti Tantra evum Stri Roga, National Institute of Ayurveda, Jaipur. Participants were enrolled irrespective of caste, religion, nationality or socioeconomic status.

Pregnant women between the 13th & 14th weeks of gestation, aged between 21-40 years, with a history of recurrent abortion, previous bad obstetric history, or conception following infertility were included in the study. Patients with haemoglobin levels below 9gm/dl, multiple pregnancy, uterine fibroid or carcinoma, cardiovascular disorders, severe systemic illnesses, congenital uterine anomalies, preexisting diabetes mellitus or hypertension were excluded from the study.

The study was designed as a prospective, single-blind, randomized comparative clinical trial with a total duration of sixteen weeks. Participants were advised to report for follow-up at an interval of four weeks. Randomization was carried out using a computer-generated random sequence, and allocation concealment was ensured using the SNOSE (Sequentially Numbered, Opaque, Sealed, Envelope) method. Single blinding was maintained throughout the study period. The participants were divided into two groups with thirty subjects allocated to each group. Data were collected from both OPD and IPD of the National Institute of Ayurveda, Jaipur. The primary endpoint of the study was the evaluation of therapeutic efficacy of the interventions on maternal and fetal wellbeing.

Details of Drugs and Intervention:

For the present clinical study, Bala Beeja Granules and Jeevanti Granules were selected as the trial drugs. Both formulations were prepared under standardized conditions in the GMP-certified Nageshwar Pharmacy of the National Institute of Ayurveda, Jaipur, ensuring quality, safety and uniformity of the formulations used for clinical administration.

Drug Review:

Bala (*Sida cordifolia* Linn.), belonging to the family Malvaceae, with seeds as the useful part, is a well-recognized drug described in the Madhura Skandha of

Charaka Samhita. The nomenclature “Bala” is traditionally associated with Parvati, the goddess symbolizing strength and beauty, reflecting the inherent pharmacological attributes of the drug.¹⁶ Bala is endowed with Jeevaniya, Brumhana, Balya, Medhya, Rasayana, Prajasthapana and Shothaghna properties, which collectively contribute to nourishment and strength of both the Garbha and the Garbhini.¹⁷ It is especially known for its Balya action. The drug possesses Madhura Rasa and Madhura Vipaka, Sheeta Virya, and exhibits Vataghna, Brumhaniya, Balya, and Garbhaposhaka properties, making it highly suitable for promoting maternal strength and fetal nourishment during pregnancy.¹⁸

Jeevanti (*Leptadenia reticulata*), belonging to the family Apocynaceae, with root as the useful part, is also described under the Madhura Skandha of Charaka Samhita. In addition, Jeevanti is classified under Snehopaga Gana, Swashar Gana, and Vayasthapana Gana in classical Ayurveda literature.¹⁹ The drug is well known for its Jeevaniya (vitalizing) and Vayasthapana properties. It also exhibits Vrishya, Stanyajanana, Balya, Rasayana and Anulomana actions, which support maternal vitality, fetal growth and overall pregnancy wellbeing.²⁰ Pharmacodynamically, Jeevanti possesses Madhura Rasa and Madhura Vipaka with Sheeta Virya and is characterized by Sheeta, Snigdha and Laghu Guna, making it beneficial for nourishment and maintenance of physiological balance during gestation.^{21,22}

Godugdha (cow's milk) is traditionally advised in Garbhini Paricharya throughout pregnancy for Garbhapusti and Garbha Dhardhyatva. It is Madhura in taste and promotes Saumanasyam (mental wellbeing) in the Garbhini. Milk is recommended daily in almost all months of pregnancy, as it is considered a complete food containing essential proteins, carbohydrates, vitamins and calcium, thereby fulfilling the nutritional requirements of both mother and fetus. From the fourth month onwards, fetal muscular and skeletal development becomes prominent, and milk, being rich in high-quality proteins, plays a vital role in supporting this growth. Acharya Charaka has described milk as Swadu, Sheeta, Mridu, Snigdha, Bahala, Shlakshna, Picchhila, Guru, Manda and Prasanna in nature and has attributed Jeevaniya and Rasayana properties to it. Milk is known to enhance longevity and alleviate disorders of Vata and Pitta, thereby contributing to a healthy pregnancy and optimal fetal development.²³

Methods of Administration of Therapy

Prior to initiation of the study, all eligible pregnant women were informed in detail about the nature, objectives, and procedure of the clinical trial. After preliminary screening, written informed consent was obtained from those fulfilling the inclusion and exclusion criteria. Baseline demographic and clinical data were recorded before the commencement of therapy. The enrolled participants were randomly allocated into two groups, each comprising thirty subjects. Participants in Group A received Bala Beeja Granules, while those in Group B received Jeevanti Granules. In both groups, the trial drugs were

administered in a dose of ten grams twice daily, thirty minutes after meals, at approximately 9:00 AM and 9:00 PM through the oral route. Godugdha was used as Anupana in both groups. The intervention was continued throughout the second trimester for a total duration of sixteen weeks. Routine antenatal care was continued in accordance with standard Ayurveda protocols. All participants were advised to report for follow-up at intervals of four weeks.

Laboratory Investigations

Baseline laboratory investigations were carried out prior to initiation of treatment to assess maternal and fetal status. These included complete blood count, total leukocyte count, fasting blood sugar, liver function test, renal function test, screening for human immunodeficiency virus, venereal disease research laboratory test, hepatitis B surface antigen, routine and microscopic urine examination, ultrasonography for fetal wellbeing, and DIPSI test.²⁴ During the course of treatment, a detailed anomaly scan was performed at the 20th week of gestation to evaluate fetal biometry parameters, including biparietal diameter, head circumference, abdominal circumference and femur length, along with assessment of amniotic fluid and estimated fetal weight.²⁵ After completion of the treatment period, haemoglobin percentage, fasting blood sugar, liver function test, renal function test, ultrasonography for fetal biometry and color Doppler evaluation were repeated.²⁶

Withdrawal Criteria and Safety Monitoring

Participants were withdrawn from the study if any serious pregnancy-related condition such as gestational diabetes mellitus, severe pregnancy-induced hypertension, eclampsia or any other medical emergency requiring urgent intervention developed during the trial period.²⁷ Subjects were also withdrawn if they voluntarily chose to discontinue participation or demonstrated irregular follow-up and non-compliance with the treatment protocol. Any adverse drug reaction observed during the treatment or follow-up period was carefully documented using the adverse drug reaction reporting form, and appropriate medical management was provided in consultation with the attending physician.²⁸ All adverse events were promptly reported to the Institutional Ethics Committee. In case of any intercurrent illness during the study period, participants were advised to consult the concerned specialist and receive appropriate treatment for a short duration without discontinuation from the study unless clinically indicated.²⁹

Outcomes and Outcome Measurement

The primary outcome of the study was assessment of fetal well-being, which was evaluated through ultrasonographic fetal biometry parameters including biparietal diameter, head circumference, abdominal circumference, femur length, amniotic fluid index, and estimated fetal weight.³⁰ Color Doppler studies were performed to assess fetal circulation by measuring pulsatility index, resistive index and umbilical artery systolic-to-diastolic ratio.³¹ Secondary outcomes

included evaluation of prevention of major pregnancy-related disorders such as pregnancy-induced hypertension and gestational diabetes mellitus, along with assessment of the frequency and severity of minor maternal ailments. Maternal Wellbeing was assessed through parameters such as pregnancy weight gain, mid upper arm circumference, blood pressure and maternal blood glucose levels.³²

Assessment Criteria

Fetal Wellbeing was assessed using ultrasonography, which included measurement of fetal biometry parameters, assessment of amniotic fluid volume, estimation of fetal body weight, and evaluation of color Doppler indices including pulsatility index, resistive index and umbilical artery systolic-to-diastolic ratio.³³ All measured parameters were compared with standard fetal growth percentile charts and estimated fetal weight reference charts. Maternal assessment included evaluation of pregnancy weight gain, mid-upper arm circumference, month-wise abdominal girth, and symphysis-fundal height measurements after twenty-four weeks of gestation.³⁴ Maternal ailments commonly encountered during pregnancy, such as Malabandha (constipation), Kati Shoola (low backache), Dourbalya (general debility), Panduta (pallor), Anga Gaurava (heaviness of body), Pada Shotha (pedal edema), Hrida Drava (palpitations) and Aruchi (anorexia), were also assessed and recorded.^{35,36}

Ethical Considerations and Statistical Analysis

The study was conducted in accordance with the prevailing standards of Good Clinical Practice and ethical principles for biomedical research. The study protocol and any subsequent amendments were submitted to the Institutional Ethics Committee for approval prior to implementation. The trial was registered with the Clinical Trials Registry of India. Standardized proformas and assessment scales were adopted for data collection.³⁷ Statistical analysis was carried out using appropriate parametric or non-parametric tests based on the nature and distribution of the data.³⁸

Observations:

A total of 61 pregnant women were screened for eligibility in the present randomized comparative clinical trial. Of these, 60 pregnant women fulfilling the inclusion and exclusion criteria were enrolled and randomly allocated into two equal groups, Group A and Group B, with 30 participants in each group. All enrolled participants completed the trial, and no dropouts were reported, indicating good compliance and follow-up.

The demographic analysis revealed that the majority of the pregnant women belonged to the age group of 26–30 years (55.00%), followed by 21–25 years (23.30%), 31–35 years (15.00%), and 36–40 years (6.70%). Most participants had a height between 151–161 cm (63.30%), while 20.00% measured 140–150 cm and 16.70% were between 162–172 cm. With respect to body weight, the majority of women weighed between 51–61 kg (41.70%), followed by 62–72 kg (36.70%).

Religion-wise distribution showed that most participants belonged to the Hindu religion (90.00%), while a smaller proportion were Muslim (8.30%) or Christian (1.70%). Slightly more than half of the participants were from joint families (51.70%), and the remaining were from nuclear families (48.30%). A predominantly urban population was observed, with 75.00% residing in urban areas. Occupational distribution revealed that 53.33% were housewives, while 46.67% were working women. Socioeconomic assessment showed that the majority belonged to the upper middle class (51.70%), followed by lower middle class (26.70%).

Educational status analysis demonstrated that most participants were postgraduates (73.30%), followed by senior secondary (13.30%) and secondary education levels (11.70%). Diet-wise distribution revealed that the majority of pregnant women were vegetarian (88.30%), while a small proportion consumed a mixed diet (11.70%). Assessment of dietary patterns showed that Katu rasa–dominant intake was most prevalent (38.30%), followed by Madhura rasa (28.30%) and Amla rasa (20.00%). Regarding Aharavidhi, Samashana was the most commonly observed dietary habit (50.00%).

Agni assessment indicated that most women had Manda Agni (41.70%), followed by Sama Agni (31.70%) and Vishama Agni (24.90%). Addiction history revealed that tea consumption was common (45.00%), while 36.70% reported no addiction. Bowel habit assessment showed that 68.30% of women had irregular bowel habits, and normal micturition was observed in 58.30% of participants. Sleep assessment revealed that 60.00% of women had normal sleep patterns.

Dashavidha Pariksha findings demonstrated that dual-dosha Prakriti predominated, with Vata–Pitta (36.70%) and Pitta–Kapha (30.00%) being most common. Most participants had Madhyama Sara (53.30%), Madhyama Samhanana (58.40%), and Madhyama Pramana (43.30%). Sarvarasa Satmya was observed in 55.00% of women, and Madhyama Satva predominated (53.30%). Similarly, Madhyama Vyayamashakti (55.00%), Madhyama Abhyavaharana Shakti (61.70%), and Madhyama Jarana Shakti (63.30%) were most frequently noted.

Menstrual history analysis revealed that the majority of women had regular menstrual cycles prior to conception (86.70%), with normal menstrual duration of 3–7 days in 83.30% and normal intermenstrual intervals in 88.30%. Obstetric history showed an almost equal distribution between primigravida (48.30%) and multigravida (51.70%) women. Most participants had normal vaginal deliveries (80.60%), while 19.40% underwent LSCS.

General physical examination indicated that 51.67% of participants had a normal BMI, while 38.33% were overweight. Most women had normal blood pressure values, with 63.33% having systolic blood pressure below 120 mmHg. The assessment of minor ailments revealed that constipation (58.33%), general debility

(56.67%), heaviness of the body (55.00%), and low backache (53.33%) were the most commonly reported complaints during pregnancy.

RESULTS:

Comparative Analysis of Mean Parameter Values

(n = 60; Group A = 30, Group B = 30)

1. Individual Parameter Comparison: A set of four charts showing the growth from "During Treatment" (DT) to "After Treatment" (AT) for each specific parameter (HC, AC, FL, BPD). This highlights how Group A and Group B performed side-by-side at each stage.

2. Overall Comparative Analysis: A single grouped bar chart that places all parameters together, allowing you

to see the relative scale differences between measurements (e.g., how much larger HC/AC are compared to FL/BPD).

Observations from the Graphs:

Parallel Growth: Both Group A and Group B show a consistent upward trend across all biometric markers.

AC Catch-up: While Group A had a higher mean Abdominal Circumference (AC) during treatment (156.03 vs. 147.47), Group B showed a slightly higher mean value after treatment (253.11 vs. 249.48).

Consistency in FL & BPD: The Femur Length and Biparietal Diameter measurements remain very close between the two groups, with Group B showing a marginally higher final mean in both.

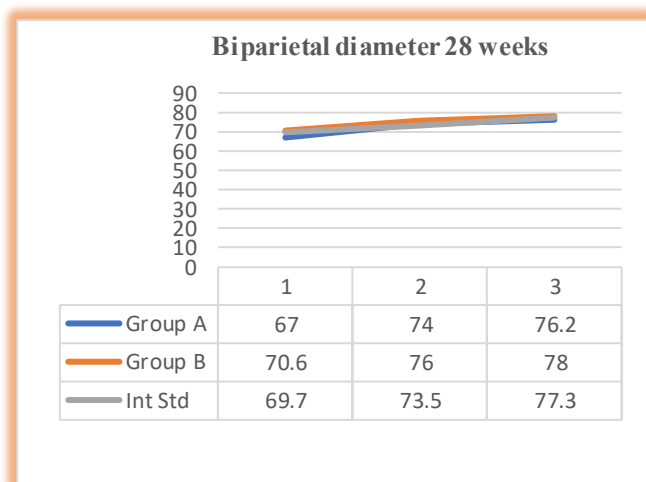
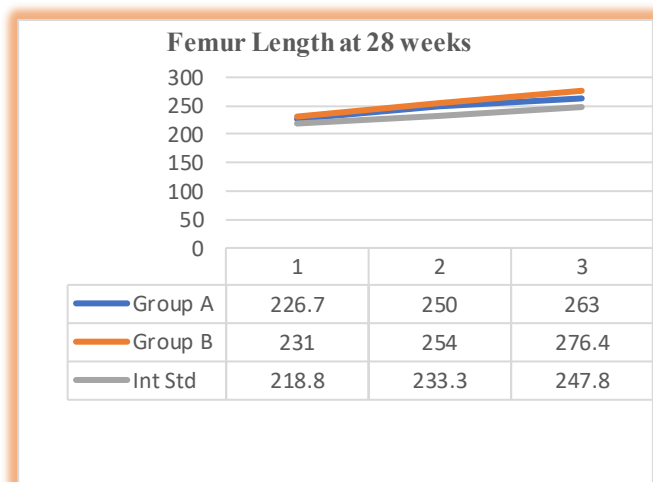
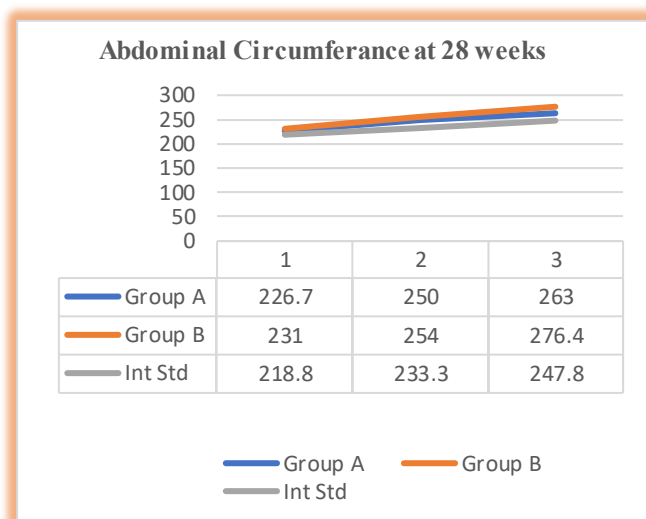
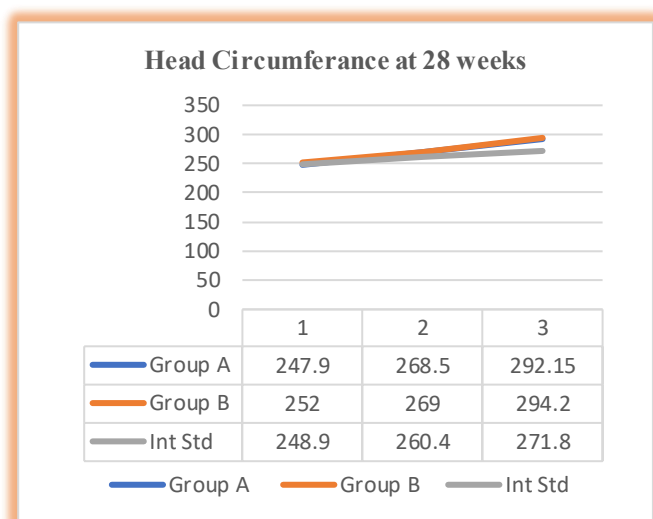


Figure 1: Comparison of mean values of parameters between Group A and Group B with Indian standards and the International Standard Percentile at 28 weeks.

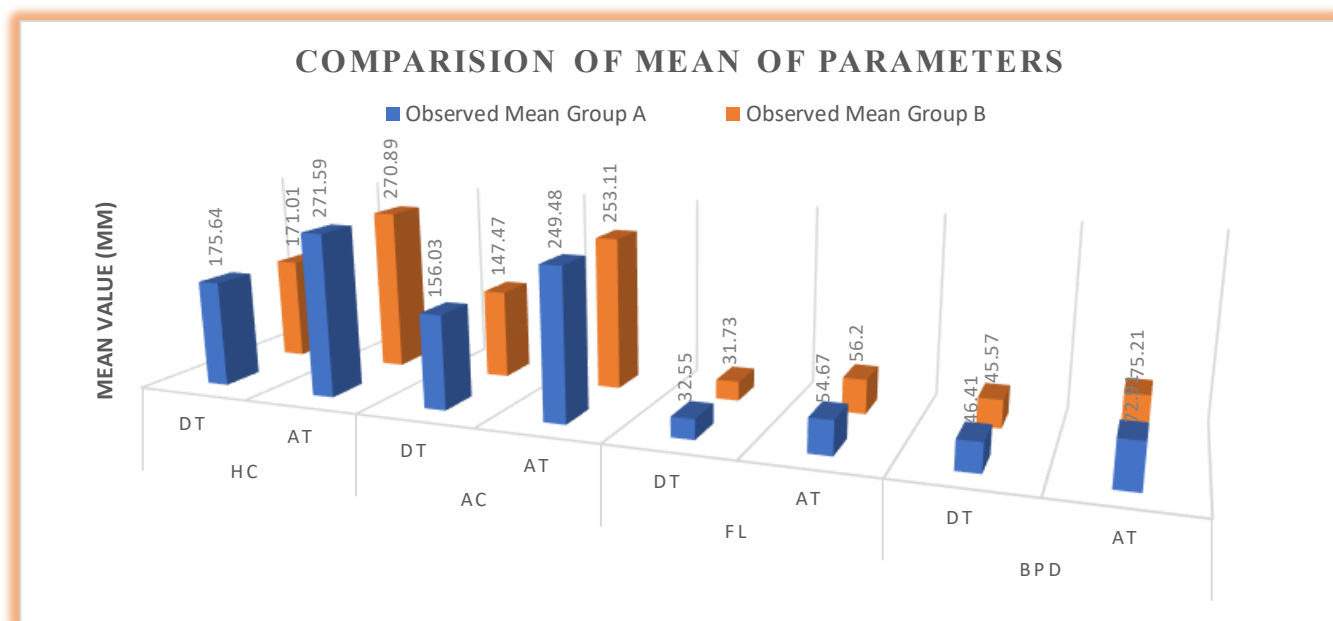


Figure 2: Comparison of mean of parameters in Group A and Group B

Comparison of EFW and AFI with Standard Mean (One-Sample t-Test)

At 20 Weeks: There was no statistically significant difference between the study groups and the international standard. Both Group A ($P=0.30$) and Group B ($P=0.72$) were well-aligned with the reference mean of 330 g.

At 28 Weeks: A dramatic shift occurred. Both groups showed EFW values significantly higher than the standard mean of 1189 g. Group A (1327g) showed significant growth ($P=0.0016$), while Group B (1412 g) showed extremely significant growth ($P < 0.0001$). This

indicates that the trial intervention or cohort characteristics led to fetal weights that notably exceeded global averages by the third trimester.

Amniotic Fluid Index (AFI)

At 28 Weeks: When compared to the international standard mean (approx. 14.6), the observed means for Group A (14.05) and Group B (14.43) showed no statistically significant deviation. With P -values of 0.84 and 0.31 respectively, the amniotic fluid levels in both groups are considered to be perfectly within the expected standard range.

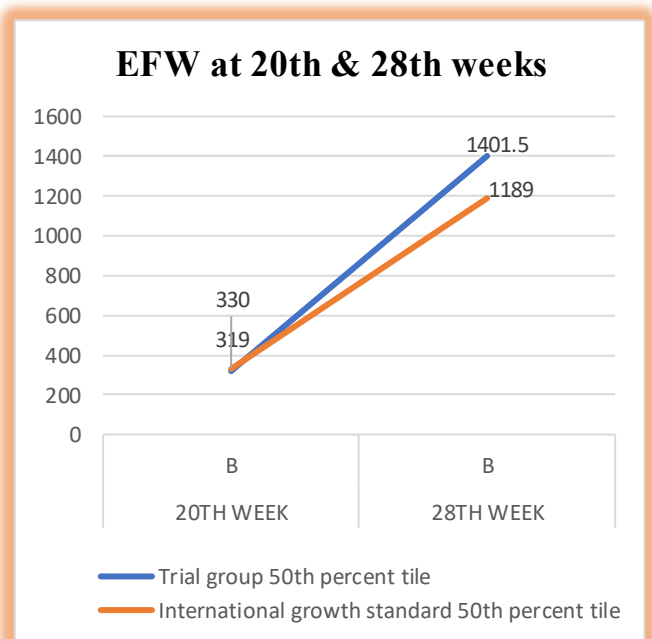
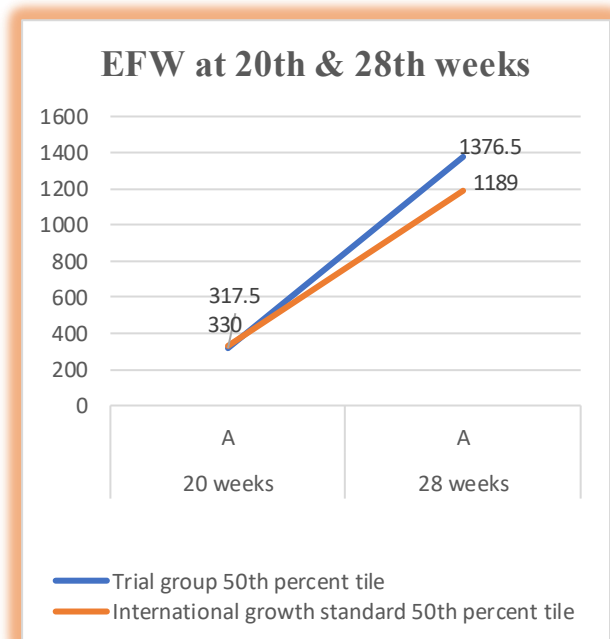


Figure 3: Comparison of EFW with international growth standard at 20th & 28th week

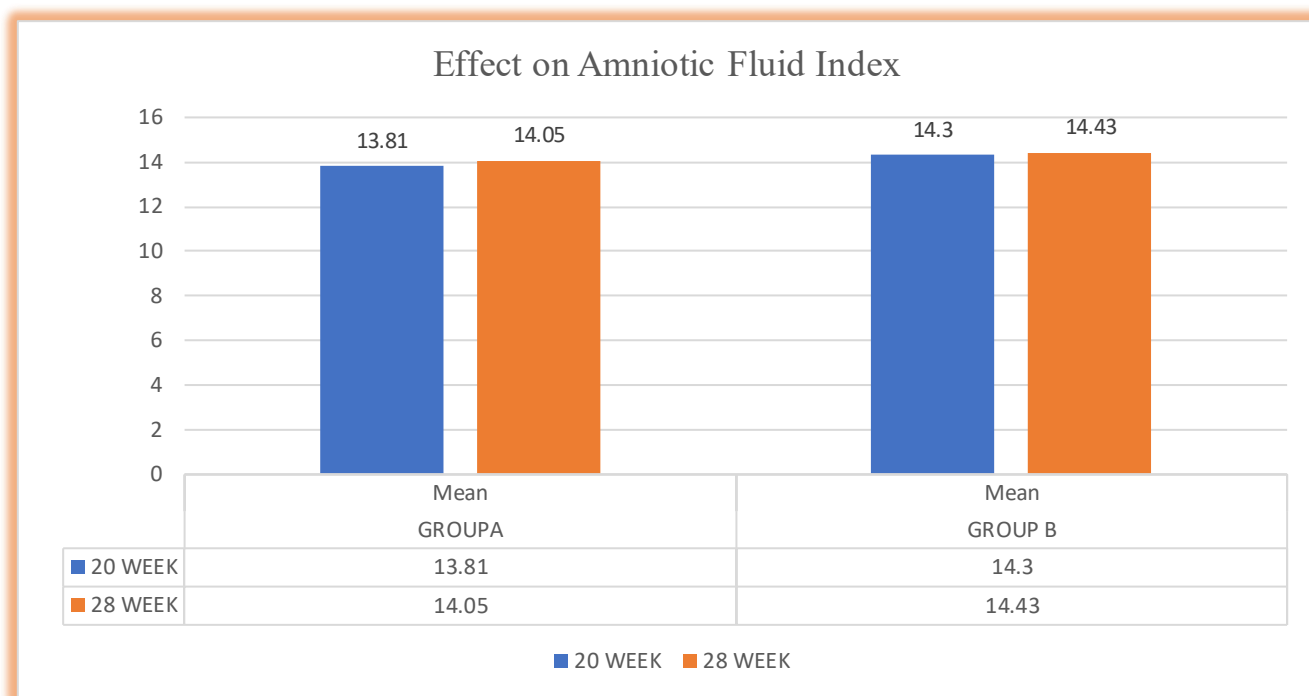


Figure 4: Mean AFI of Group A & Group B at 20th and 28th weeks

1. Comparison with Indian Standards

During Treatment (20 Weeks): Both Group A and Group B mean values were very close to the Indian Standard Mean. Notably, Group A's HC (175.64 mm) and BPD (46.41 mm) almost perfectly mirrored the Indian standard benchmarks (176.7 mm and 46.4 mm).

After Treatment (28 Weeks): Both study groups slightly exceeded the Indian Standard Mean across all parameters. For instance, Group A and Group B recorded AC values of 249.48 mm and 253.11 mm respectively, which were higher than the Indian standard of 236.2 mm.

2. Comparison with International Growth Standards (50th Percentile)

Head Circumference (HC): At 20 weeks, both groups were aligned with the 50th percentile (172.5 mm). By 28 weeks, both groups (271.59 and 270.89 mm) performed slightly better than the International 50th percentile (260.4 mm) and stayed within the 90th percentile range.

Abdominal Circumference (AC): This parameter showed significant growth. While the groups started near the 50th percentile (147.7 mm) at 20 weeks, by 28 weeks, Group B (253.11 mm) actually exceeded the International 90th percentile (247.8 mm), indicating robust abdominal growth.

Femur Length (FL): Both groups followed the international trend closely. At 28 weeks, Group A (54.67 mm) and Group B (56.20 mm) were both above the 50th percentile (51.3 mm), with Group B approaching the upper limit of the international growth chart.

Biparietal Diameter (BPD): At 20 weeks, the groups were slightly below the International 50th percentile (48.4 mm) but remained well above the 10th percentile.

By 28 weeks, both groups caught up, with Group B (75.21 mm) performing above the 50th percentile (73.5 mm).

Results of the Therapeutic Trial

In the present randomized comparative clinical study, a total of 61 pregnant women were screened, of whom 60 fulfilling the eligibility criteria were enrolled. All enrolled participants completed the study, resulting in a completion rate of 100%. The participants were randomly allocated into two equal groups, with 30 pregnant women in Group A and 30 in Group B. Statistical analysis of the data was carried out using GraphPad Prism software.

Intra-group Comparison

To evaluate the efficacy of the respective interventions within each group, intra-group analysis was performed. Parametric variables were analyzed using the paired t-test, while non-parametric variables were assessed using the Wilcoxon matched-pair signed-rank test, based on the distribution of the data.³⁹ Both groups demonstrated statistically significant improvements in fetal growth parameters, maternal anthropometric measures, and selected clinical outcomes over the course of the intervention period.⁴⁰

Inter-group Comparison

Inter-group comparison was carried out to assess the comparative effectiveness of the two trial regimens. For normally distributed data, the unpaired t-test was applied, whereas the Mann-Whitney U test was used for non-parametric variables. Overall, both groups showed comparable therapeutic outcomes across most fetal and maternal parameters, with only selective parameters demonstrating statistically significant differences between the groups.⁴¹

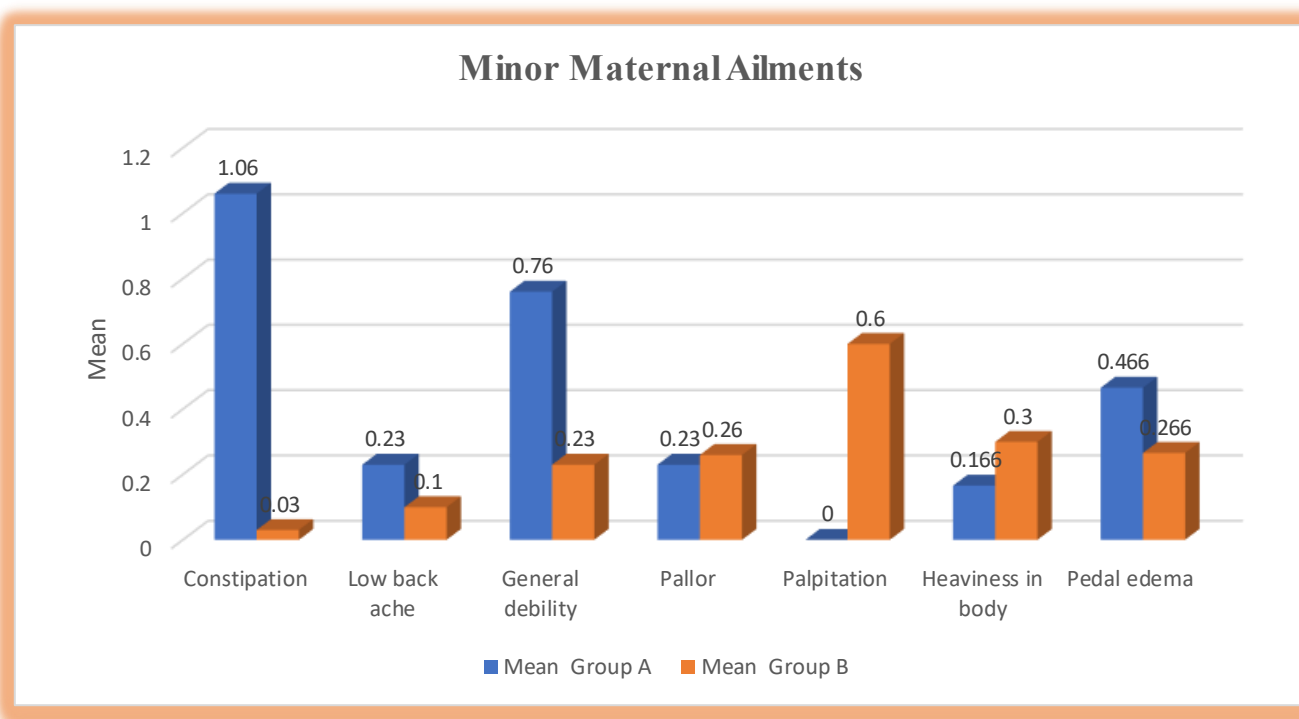


Figure 5: Intergroup comparison of minor ailments using Mann Whitney test

The Mann-Whitney U test highlights that the primary differences between the groups lie in Constipation, General Debility and Palpitation. For other physical discomforts like back ache and edema, both groups

showed similar clinical presentations, suggesting that these common pregnancy-related minor ailments were distributed evenly across the study population.

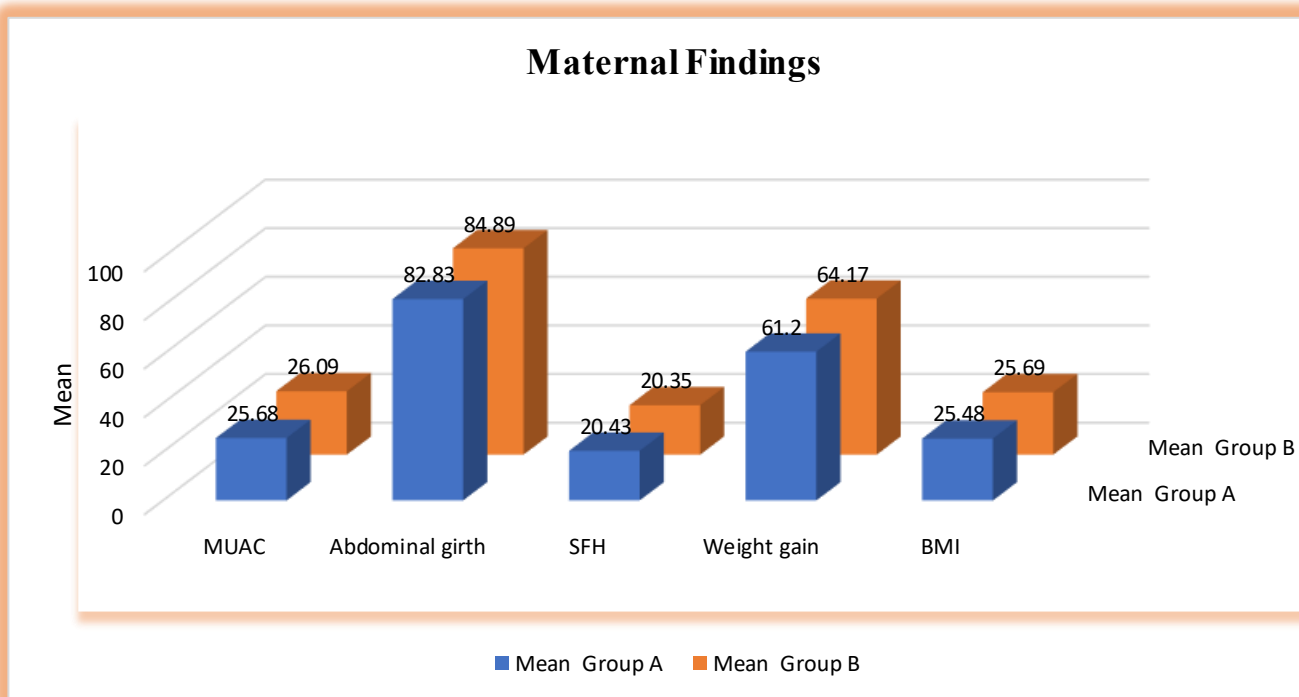


Figure 6: Statistical Comparison of Maternal Findings Between Groups

All analyzed maternal parameters yielded P-values well above the 0.05 significance threshold. Therefore, the differences observed are considered to be due to chance, confirming that both groups are statistically similar in terms of maternal physical findings.

Comparison with International Standards

Maternal and fetal wellbeing parameters were evaluated against established international growth standards using percentile charts. Where reference

mean values were available, a one-sample t-test was employed. The observed values in both groups were largely consistent with international standards, indicating physiological and appropriate fetal growth and maternal adaptation during the second trimester.^{42,43}

Observation-Based Results on Parameters

Effect on Fetal Wellbeing Indicators

Assessment of fetal biometric parameters, including head circumference, abdominal circumference, femur length, and biparietal diameter, was carried out at 20 and 28 weeks of gestation. At 20 weeks, the mean fetal biometric values in both groups were found to lie between the 10th and 90th percentiles of international growth standards, closely approximating the 50th percentile, thereby indicating normal fetal growth.

At 28 weeks of gestation, a further increase in all fetal biometric parameters was observed in both groups. The post-treatment values continued to align closely with international reference standards. Comparative analysis revealed no statistically significant difference between Group A and Group B for head circumference, abdominal circumference, and femur length at 28 weeks. However, biparietal diameter showed a statistically significant difference favoring Group B ($p = 0.02$). Despite this, overall fetal growth patterns were comparable between the two groups.⁴²

Effect of Trial Regimen on Estimated Fetal Weight

Estimated fetal weight assessed at 20 and 28 weeks showed a progressive increase in both groups. At 20 weeks, no statistically significant difference was observed between Group A and Group B. At 28 weeks, although Group B demonstrated a marginally higher mean estimated fetal weight compared to Group A, inter-group comparison revealed no statistically significant difference. When compared with international growth standards, estimated fetal weight at 28 weeks was found to be significantly higher than the reference mean in both groups, whereas values at 20 weeks were comparable with standard norms.⁴³

Effect on Amniotic Fluid Index

Amniotic fluid index measured at 20 and 28 weeks showed normal values in both groups throughout the study period. Inter-group comparison revealed no statistically significant difference at either time point, indicating that both trial regimens maintained adequate amniotic fluid volume within physiological limits.⁴⁴

Utero-placental and Feto-placental Circulation

Color Doppler evaluation at 28 weeks demonstrated that most uterine and umbilical artery Doppler indices were comparable between the two groups. A statistically significant reduction in uterine artery resistance index was observed in Group A, suggesting relatively better uteroplacental perfusion.⁴⁵ Conversely, umbilical artery pulsatility index showed a statistically significant difference in Group B, indicating favorable fetoplacental circulation. Both groups exhibited a significant

reduction in umbilical artery systolic/diastolic ratio, reflecting improved placental blood flow.

Maternal Haematological and Biochemical Parameters

Haemoglobin levels and fasting blood sugar values assessed before and after treatment remained within normal physiological ranges in both groups. Statistical analysis revealed no significant intra-group or inter-group differences, indicating that the interventions did not adversely affect maternal haematological or glycemic status. DIPSI values at 28 weeks were within normal limits in both groups, showing extremely significant deviation from the diagnostic threshold for gestational diabetes, thereby confirming metabolic safety of both regimens.⁴⁸

Maternal Anthropometric Parameters

Maternal parameters including mid-upper arm circumference, abdominal girth, symphysis-fundal height, body weight, and body mass index showed a consistent and statistically significant increase over successive follow-up visits in both groups.⁴⁹ Repeated measures analysis demonstrated that improvements became highly significant from mid-treatment onwards and continued progressively until the end of the study. Inter-group comparison of maternal anthropometric outcomes revealed no statistically significant difference between Group A and Group B, suggesting comparable efficacy of both interventions in improving maternal nutritional and physiological status.

The Unpaired t-test results across all five maternal parameters yielded P-values significantly higher than the 0.05 threshold. This confirms that Group A and Group B are homogenous regarding maternal physical findings, which strengthens the validity of the trial by reducing the likelihood of maternal physical bias.

The analysis reveals that while MUAC and Weight Gain are significantly lower than established research standards in this cohort, the SFH is actually performing slightly above standard benchmarks as the pregnancy enters the third trimester.

Effect on Minor Ailments

Evaluation of minor ailments revealed a statistically significant reduction in constipation scores in Group A, whereas no significant improvement was observed in Group B. Low backache showed a mild reduction in both groups; however, the changes were not statistically significant.⁵⁰

DISCUSSION:

The discussion is a critical component of clinical research, as it interprets results in light of existing knowledge and theoretical frameworks. In Ayurveda-based studies, interpretation gains strength when classical concepts are rationally integrated with contemporary biomedical understanding. The present randomized, single-blind comparative clinical study evaluated the effect of two Ayurvedic formulations on maternal and fetal wellbeing during the second trimester of pregnancy.

Among the 61 enrolled participants, 60 completed the study, with equal distribution between the two groups. Randomization by sealed envelope ensured allocation concealment and reduced selection bias. The second trimester represents a phase of rapid fetal growth and increased maternal nutritional demand. Classical Ayurvedic texts describe this period as crucial for Garbha Vriddhi, development of Manas, Mamsa, and Shonita, and maintenance of maternal Bala and Ojas. Hence, Balya, Brimhana, Snigdha, and Rasayana drugs are recommended during this phase.^{51,52}

Both Bala Beeja and Jeevanti possess Madhura Rasa, Snigdha and Guru Guna, Sheeta Veerya, and Madhura Vipaka, making them suitable for second-trimester Garbhini Paricharya. Madhura Rasa, dominated by Prithvi and Jala Mahabhuta, supports anabolic activity, tissue nourishment, and fetal stability. The Rasayana effect contributes to preservation of maternal Ojas, which is directly associated with fetal vitality.⁵³

Bala (*Sida cordifolia* Linn.) is classically described as Balya, Brimhana, and Prajastapana. Its reported anti-inflammatory, antioxidant, vasorelaxant, and immunomodulatory actions may help in maintaining uteroplacental circulation and preventing maternal debility. Analytical findings showed higher extractive values and richer phytochemical profiles in Bala Beeja granules, supporting their classical attributes.⁵⁴

Jeevanti is described as Jeevaniya, Rasayana, Balya, Stanyajanana, and Hridya. Experimental studies suggest anti abortifacient, estrogenic, and antioxidant properties, attributed to flavonoids such as quercetin and luteolin. These actions may enhance placental function and fetal growth through reduction of oxidative stress and metabolic support.

Milk (Ksheera), used as Anupana, is described as Rasayana and Jeevaniya. From a biomedical perspective, it provides high-quality proteins, calcium, vitamin B12, iodine, and choline, essential for fetal skeletal and neurodevelopment. Activation of anabolic pathways such as mTORC1 may explain its growth-promoting effects, supporting classical Ayurvedic claims.⁵⁵

Analytical evaluation confirmed the identity, purity, and safety of both formulations, with acceptable physicochemical parameters and microbial limits. Clinically, both groups demonstrated maintenance of fetal growth parameters within standard reference ranges. Group B (Jeevanti) showed comparatively higher mean values of BPD, AC, FL, and EFW at 28 weeks, with statistically significant improvement observed in BPD. Doppler studies indicated favorable uteroplacental and fetoplacental circulation in both groups.

Both formulations were effective in improving maternal wellbeing and reducing minor pregnancy-related complaints such as fatigue and constipation. Overall, the study validates the classical Ayurvedic concept of trimester-specific Garbhini Paricharya and supports the safe and effective use of Bala Beeja and Jeevanti during the second trimester.

CONCLUSION

The present randomized, single-blind comparative clinical study was conducted to evaluate the role of Bala Beeja Granules and Jeevanti Granules in promoting fetal and maternal wellbeing during the second trimester of pregnancy, with reference to the principles of Garbhini Paricharya. The findings of the study support the relevance of trimester-specific Ayurvedic interventions as a complementary approach to contemporary antenatal care.

Both trial formulations, administered at a dose of 10 g twice daily with milk throughout the second trimester, were found to be safe, well tolerated and effective in maintaining normal maternal physiological parameters and supporting fetal growth. The observed fetal biometric indices including head circumference, abdominal circumference, femur length, biparietal diameter, and estimated fetal weight—remained within established Indian and international reference standards in both groups, indicating healthy and appropriate fetal development.

Comparative analysis revealed that Jeevanti Granules demonstrated marginally higher mean values for several fetal growth parameters, particularly abdominal circumference, femur length, biparietal diameter, and estimated fetal weight at 28 weeks of gestation. Doppler indices in both groups remained within normal physiological limits, suggesting satisfactory uteroplacental and fetoplacental circulation, with Jeevanti showing values slightly closer to standard reference ranges, indicating comparatively better vascular adaptation.

Assessment of maternal wellbeing parameters including symphysio-fundal height, abdominal girth, weight gain, BMI, haemoglobin, and fasting blood sugar showed that both regimens effectively supported normal gestational adaptations. Although intergroup differences were not statistically significant, the Jeevanti group consistently exhibited slightly higher mean values, suggesting a modest clinical advantage in improving maternal nutritional and physiological status.

Evaluation of minor pregnancy-related ailments revealed differential therapeutic responses. Bala Beeja Granules showed greater relief in constipation, general debility, pedal edema, and low backache, whereas Jeevanti Granules demonstrated better improvement in pallor, palpitations, and heaviness of the body. No adverse drug reactions were reported in either group, confirming the safety of both formulations during the second trimester.

Overall, the study validates classical Ayurvedic concepts of Madhura Skandha drugs possessing Balya, Brimhana, and Rasayana properties in supporting maternal strength and fetal growth. While both formulations were effective, Jeevanti Granules exhibited a slight comparative advantage in enhancing fetal growth parameters and maternal nutritional indices, whereas Bala Beeja Granules were more effective in alleviating specific minor ailments. These findings support the rational use of both drugs as part of trimester-specific

Garbhini Paricharya and provide a foundation for further integrative and evidence-based research in Ayurvedic antenatal care.

Clinical Implications: The findings of the present study highlight the clinical relevance of incorporating trimester-specific Ayurvedic interventions into routine antenatal care. Both Bala Beeja Granules and Jeevanti Granules were found to be safe and effective in supporting maternal physiological adaptation and maintaining fetal growth within normal reference standards during the second trimester. Jeevanti Granules demonstrated a modest advantage in enhancing fetal growth parameters and maternal nutritional indices, whereas Bala Beeja Granules showed greater efficacy in alleviating certain minor pregnancy-related ailments such as constipation and general debility. These observations suggest that individualized selection of formulations based on maternal symptoms and clinical priorities may optimize outcomes. The study supports the integrative application of Garbhini Paricharya as an adjunct to conventional antenatal monitoring for improving overall maternal fetal wellbeing.

Future Directions: Future studies with larger, multicentric samples and longer follow-up periods are recommended to evaluate long-term maternal and neonatal outcomes. Exploration of combined or sequential use of Bala and Jeevanti formulations, along with lifestyle-based interventions such as yoga and dietary counselling, may further strengthen evidence for integrative antenatal care models.

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