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RESEARCH ARTICLE

# Clinical Efficacy and Safety of *Navayasa Churna* in the Management of Iron Deficiency Anemia

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## ABSTRACT

**Introduction:** Iron deficiency anemia (IDA) is a condition where deficiency of iron in the body leads to reduction in the number of red blood cells (RBC). Even though IDA is an easily manageable condition with excellent outcome, it is observed that modern iron preparation often irritates gastric mucosa and causes adverse effects. In Ayurveda, IDA can be correlated with pandu based on symptomatic similarity. *Navayasa Churna* is an iron containing herbomineral preparation used for the management of *Pandu*. In this study, clinical efficacy and safety of *Navayasa Churna* has been evaluated in IDA.

**Aims and objectives:** To evaluate clinical efficacy and safety of *Navayasa Churna* in IDA.

**Materials and methods:** An open-labeled multicenter prospective clinical trial was conducted at Ayurveda Regional Research Institute, Mandi; M.S. Regional Ayurveda Central Research Institute, Jaipur; and the National Institute of Ayurvedic Pharmaceutical Research, Patiala. Patients with IDA (n = 150) belonging to either sex, with hemoglobin in the range of 8 to 10%, aged between 18 and 50 years and with serum ferritin <30 mg/dL, and blood smear depicting microcytic, hypochromic state were selected. *Navayasa Churna* was given 1 gm (2 capsules of 500 mg each) twice daily with water for 90 days with a follow-up period of 1 month without drug. Assessment was done based on the relief in clinical symptoms of IDA and hematological parameters. Safety assessment was done through analysis of liver function tests (LFTs) and kidney function tests (KFTs) before and after the trial period.

**Results:** The formulation showed significant relief in cardinal symptoms of anemia and also in hemoglobin level. No adverse events/effects were was noted during trial period. The values of LFT and KFT were observed to be within limits during the entire period.

**Conclusion:** *Navayasa Churna* in the above-mentioned dose and duration was found effective and safe in patients suffering from IDA.

**Keywords:** Hemoglobin, Iron deficiency anemia, *Navayasa Churna*, Pandu.

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## INTRODUCTION

Anemia is the most common nutritional deficiency disorder in the world.[1] Iron deficiency anemia is the most significant contributor of all types of anemia[2] and around 30 to 52% of non-industrialised population has anemia in general and iron deficiency in particular. Iron deficiency anemia was considered as one among the top 10 risks globally and regionally.[3] It causes 8.4 lakh deaths and 35 million cases of disability adjusted life years.[4,5] Anemia is defined as qualitative and quantitative reduction of circulating RBC and/or the percentage of hemoglobin concentration in relation to standard age and sex.[6] The prevalence of anemia in all the age groups is higher in India as compared with other developing countries. The main reasons for IDA have been determined to be inadequate intake of iron, low bioavailability of dietary iron from plant foods due to inhibitory factors, low levels of absorption enhancers in the diet, and increased needs during growth and development among children and adolescents.[7] Anemia and iron deficiency are known to have several functional consequences. In children, IDA adversely affects cognitive performance, behavior, and

physical growth.[8,9] Preventive strategies are through food-based approaches that cause multinutritional benefit. Conventional approach for IDA is through iron supplements, such as ferrous sulfate. Adherence to this type of medication is difficult due to various side effects, such as epigastric discomfort, nausea, diarrhea, or constipation.[5] Side effects can be minimized by drug intake along with food; however, doing this reduces the iron absorption by 40%.[10] Iron preparations inhibit the absorption of other drugs, such as tetracyclines, sulfonamides, and trimethoprim.[11] Hence, there is a need to look for newer agents that have better therapeutic utility and less adverse effects. Complementary and alternative medicine or traditional medicines, which are widely used by the ailing community, need to be explored. Empirical use of different preparations of iron in the treatment of anemia from ancient times is evident. *Lauha* (iron) preparations are said to be effective in IDA.[12,13] Based on Ayurveda classics and previous studies conducted on IDA, *Lauha* preparations, such as *Navayasa Churna* are observed to be effective in IDA, due to its *Pandughna* (antianemic), *Prinana* (nourishing and replenishing), and *Raktaprasadana* (providing qualitative and quantitative excellence) properties. Traditionally, *Navayasa Churna* is successfully used by Ayurvedic physicians for the management of *Pandu*. Hence, *Navayasa Churna* was selected for this trial.

## OBJECTIVE

To evaluate the clinical efficacy and safety of *Navayasa Churna* in the management of IDA.

## MATERIALS AND METHODS

### Selection of Patients

An open-labeled prospective multicenter clinical trial was conducted at three peripheral institutes, viz.; Regional Ayurveda Research Institute for Nutritional Disorders, Mandi; M.S. Regional Ayurveda Research Institute for Endocrine Disorders, Jaipur; and Central Ayurveda Research Institute for Respiratory Disorders Patiala of Central Council for Research in Ayurvedic Sciences (CCRAS) under infant mortality rate annual action plan 2012 to 2013. The study was approved by Institutional Ethics Committee of all the three participating centers and was done in accordance with World Health Organization (WHO) Good Clinical Practice Guidelines.

### Study Participants

A total of 198 patients were screened (Table 1) in accordance with the inclusion and exclusion criteria mentioned in the protocol, out of which 150 participants fulfilled the criteria were enrolled in the trial, 50 from each of the three centers.

**Table 1:** Status of the screened patients

| *Name of the center* | *Total screened* |
|---|---|
| Mandi | 65 |
| Jaipur | 59 |
| Patiala | 74 |
| Total | 198 |

### Inclusion Criteria

Patients of either sex aged between 18 and 50 years, with hemoglobin level ranging from 8 to 10 gm% and serum ferritin level <30 µg/L were included in the study.

### Exclusion Criteria

Patients suffering from other types of anemia, those diagnosed with cardiovascular disorders of any type, those under medication for major systemic illnesses necessitating long-term drug therapy, patients with uncontrolled hypertension and/or diabetes mellitus, those with history of stroke and such other neurological diseases, those under medications, such as corticosteroids, antidepressants, etc., which may influence the outcome of the study were excluded. Patients with concurrent serious hepatic, renal, or pulmonary diseases were excluded. Patients with worm infestation were also excluded from the study and patients who have the past record of hypersensitivity to any of the ingredients of trial medications were also excluded. Patients who have participated in any other clinical trial during past 6 months were also excluded from the study.

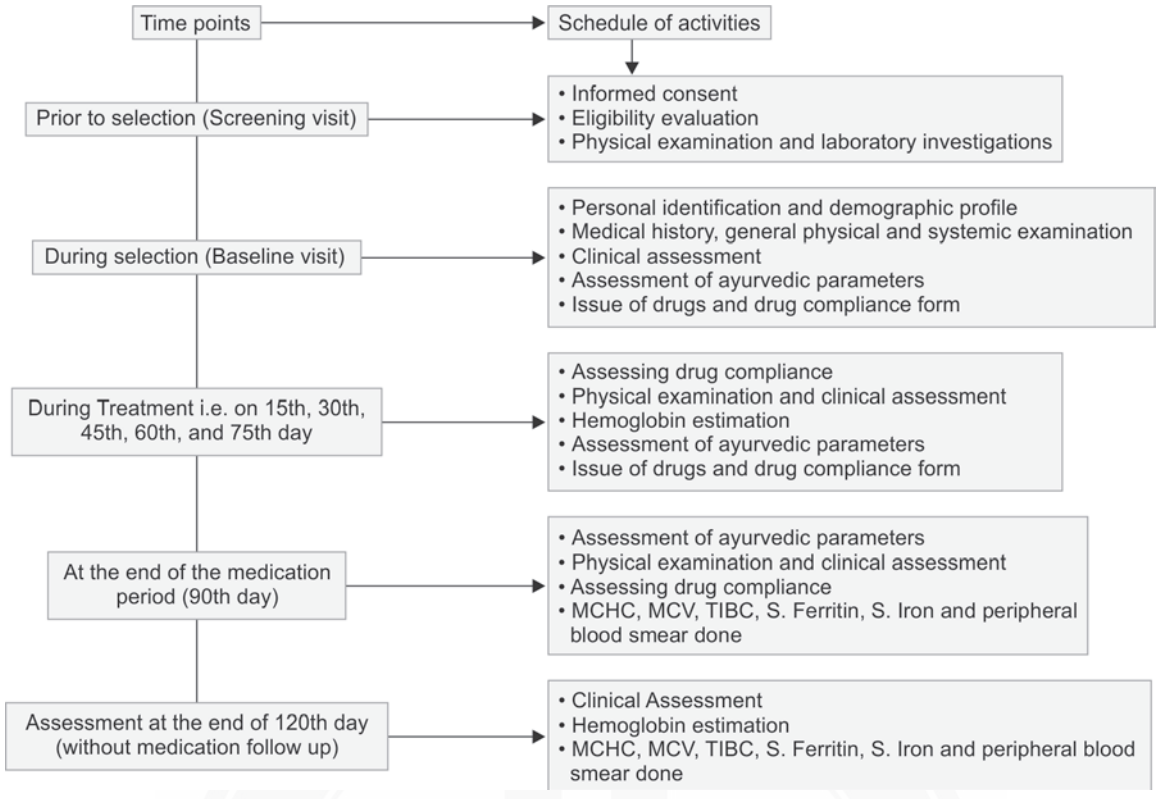
### Study Intervention

The trial drug (*Navayasa Churna*) in capsule form was administered to selected patients in the dose of 1 gm (2 capsules of 500 mg each) twice daily after food along with water as *anupana* for a period of 90 days. Patients were guided regarding *pathya/apathya* regimen during every follow-up visit and at the next follow-up, the patients were asked about the kind of food they have taken with since the last follow-up. Periodic assessment was done every 15 days for the first 90 days and then after 30 days without medication.

### Ingredients of Trial Drug

Contents of the trial drug *Navayasa Churna* (API-Part-II-Vol.-I, Page-49) includes Amalaki (*Emblica officinalis Gaertn*), Haritaki (*Terminalia chebula Retz.*), Bibhitaki (*Terminalia bellerica Roxb.*), Shunthi (*Zingiber officinale Roxb.*), Pippali (*Piper longum Linn.*), Maricha (*Piper nigrum Linn.*),

**Flow Chart 1:** Study schedule




Chitraka (*Plumbago zeylanica Linn.*), Musta (*Cyperus rotundus Linn.*), Vidanga (*Embelia ribes*), and Lauha Bhasma (incinerated iron).

## Study Procedure

Patients were enrolled in the study from May 2014 to May 2016. On the enrolment day at baseline (Visit 1), patient's demographic profile, medical history, family history particularly related to IDA, *Sharirik Prakriti*, and vital parameters were recorded. Subsequent visits were planned at an interval of 15 days [15th day (Visit 2), 30th day (Visit 3), 45th day (Visit 4), 60th day (Visit 5), 75th day (Visit 6). and 90th day (Visit 7)]. Patients were assessed and given study medications at each subsequent visit till 90th day. There was also without medication follow-up after 15 days of the 90th day visit. Details of clinical assessment and study schedule are given in Flow Chart 1.

At the study site, data of all the patients 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 laboratory investigations reports of the patients were sent by the participating centers to the Council's headquarters on weekly basis for the purpose of clinical trial monitoring.

Out of 198 screened patients, a total of 150 patients were enrolled in the study, 6 dropped out during the course of the study. The reason for dropout is: 2 patients had migrated from their residence place, patient lost to follow up with no contact. This data is evident from Table 2.

**Table 2:** Number of patients who dropped out with any reason

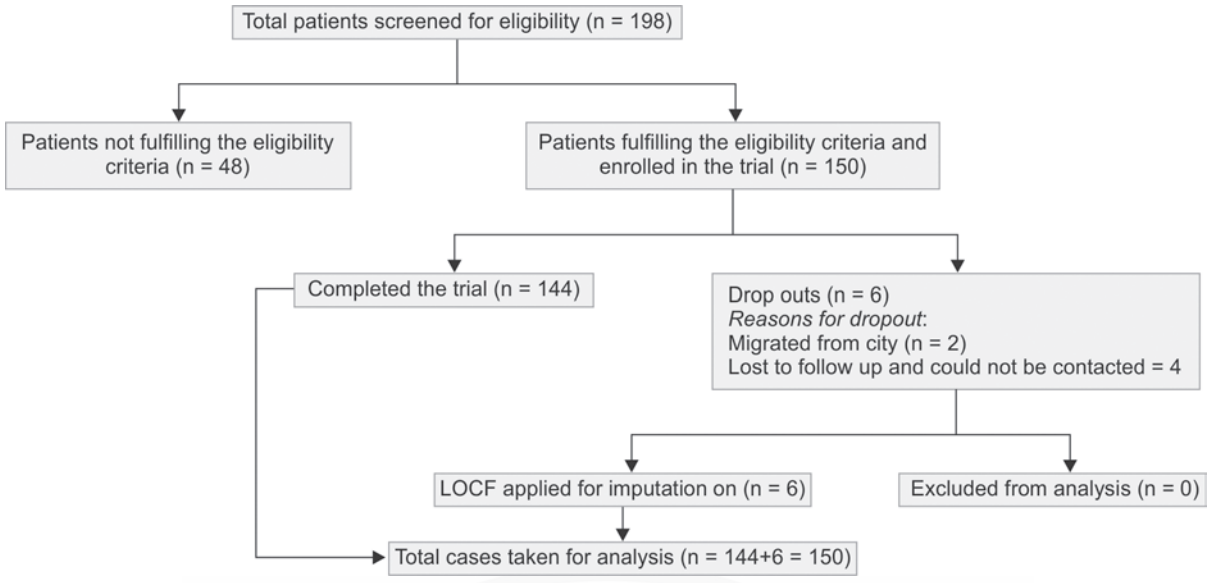
| *Study center* | *No. of patients dropped out* | *Stage at which dropped out* | *Reason for drop out* |
|---|---|---|---|
| Mandi | 1 | 60th day | Migrated due to husband's transfer |
| Patiala | 1 | 45th day | Patient had nausea and loss of appetite |
| Patiala | 1 | 75th day | Lost to follow-up, could not be contacted |
| Patiala | 1 | 90th day | Migrated from India |
| Patiala | 1 | 60th day | Lost to follow-up |
| Jaipur | 1 | 60th day | Lost to follow-up |

Intention-to-treat analysis was done and the data of all those patients who have completed at least 15th day visit were imputed by last observation carried forward method. Patients who dropped out after baseline visit only were excluded from analysis. Hence, data of a total 150 patients were used for statistical analysis. Flow Chart 2 shows the outflow of the patients in the study.

## Outcomes

Primary outcome measure was mean change in hemoglobin level at 90th day from baseline. The secondary

**Flow Chart 2:** Outflow of the patients in the study




outcome measures were mean change in serum ferritin level, change in peripheral blood smear, and relief in symptoms like weakness, fatigue, dizziness, headache, palpitation, shortness of breath, irritability, taste disturbances, etc. at 90th day as compared with baseline.

### Statistical Analysis

Primary outcome and secondary outcome measures, viz., hemoglobin and serum ferritin were analyzed as mean change in the response from baseline to 90th day by using paired t-test. A *P*-value of <0.05 was considered significant. Symptomatic relief was assessed as percentage change in terms of presence of any symptom at baseline and at 90th day. All statistical analysis was performed using Statistical Package for Social Sciences version 15.0

## RESULTS

Patients were selected in the age range of 18 to 50 years. Highest incidence of patients were observed in the ages of 32 to 38 years, i.e., 39 (26.0%), and majority of the patients were females, 144 (96%). Moreover, 126 (84%) of the patients were from above the poverty line, which attributes to the fact that IDA is not restricted to economically backward society; 74% of patients were having vegetarian diet habit. Demographic data of the patients are given in Table 3. In *Sharirik Prakriti* (physical body constitution), majority of the patients were of *Vata-Pittaja Prakriti*, 114 (76%), followed by *Pitta-Kaphaja Prakriti*, i.e., 22%. In regards to *Sara Pareeksha*, maximum were of *Rasa* and *Rakta Sara*. *Ahara Shakti (digestive capacity)* was *madhyama* in majority of cases (90%) during the initial stage and *Agni* was observed to have increased in 12% of cases.

Weakness, fatigue, dizziness, headache, palpitation, shortness of breath, irritability, and pallor were the major

**Table 3:** Demographic profile of the patients

| *Demographic profile (n = 150)* | |
|---|---|
| ***Age Group*** | |
| 18–24 | 31 (20.7) |
| 25–31 | 26 (17.3) |
| 32–38 | 39 (26.0) |
| 39–45 | 34 (22.7) |
| 46–50 | 20 (13.3) |
| ***Sex*** | |
| Male | 6 (4.0) |
| Female | 144 (96.0) |
| ***Socioeconomic status*** | |
| Above poverty line | 126 (84.0) |
| Below poverty line | 24 (16.0) |
| ***Dietary habits*** | |
| Vegetarian | 111 (74.0) |
| Nonvegetarian | 39 (26.0) |
| ***Sharirik Prakriti*** | |
| Pittaja | 01 (0.7) |
| Vata-Pittaja | 114 (76.0) |
| Vata-Kaphaja | 2 (1.3) |
| Pitta-Kaphaja | 33 (22.0) |

Values are expressed as n (%)

symptoms recorded and it was observed that there was significant relief in these symptoms by the end of the trial period. Weakness was observed in 97.3% patients initially and was completely absent in 46.7% of cases by the end of 120 days. Symptoms, such as fatigue, dizziness, headache, palpitation, shortness of breath got completely relieved in 66.0, 44.7, 44.7, 42.0, and 43.3% respectively. These data are evident from Table 4 and Graph 1.

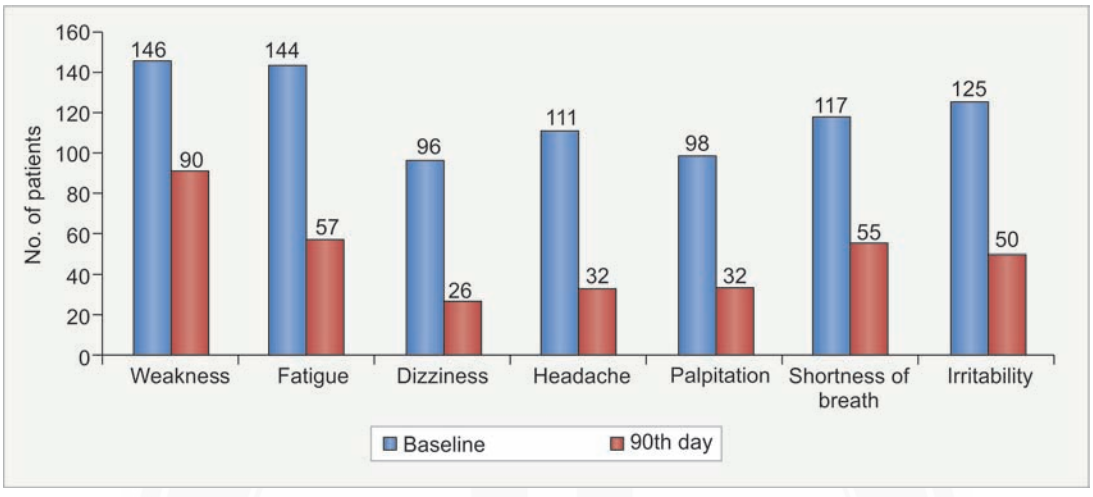
*Navayasa Churna* provided highly significant statistical results in hemoglobin level at every follow-up period (p-value < 0.001) and there was significant increase in the level of serum ferritin also. By the 90th day, 18%

**Table 4:** Effect of the treatment on chief complaints

| *Presence of chief complaints (n = 150)* | *Baseline* | *90th day* | *120th day* |
|---|---|---|---|
| Weakness | 146 (97.3) | 90 (60.0) | 80 (53.3) |
| Fatigue | 144 (96.0) | 57 (38.0) | 45 (30.0) |
| Dizziness | 96 (64.0) | 26 (17.3) | 29 (19.3) |
| Headache | 111 (74.0) | 32 (21.3) | 44 (29.3) |
| Palpitation | 98 (65.3) | 32 (21.3) | 35 (23.3) |
| Shortness of breath | 117 (78.0) | 55 (36.7) | 52 (34.7) |
| Irritability | 125 (83.3) | 50 (33.3) | 44 (29.3) |
| Pallor | 111 (74.0) | 82 (54.7) | 67 (44.7) |

Values are expressed as n (%)

of patients achieved normocytic normochromic blood smear picture, while 24% of patients achieved it in 120 days. There is no any significant change in the total leukocyte count, differential leukocyte count, and erythrocyte sedimentation rate with baseline. No significant change in mean corpuscular hemoglobin concentration (MCHC), mean corpuscular volume (MCV), reticulocyte count, and serum iron levels were witnessed after the trial. Significant change was observed in packed cell volume (PCV) percentage and total iron binding capacity (Table 5 and Graph 2).

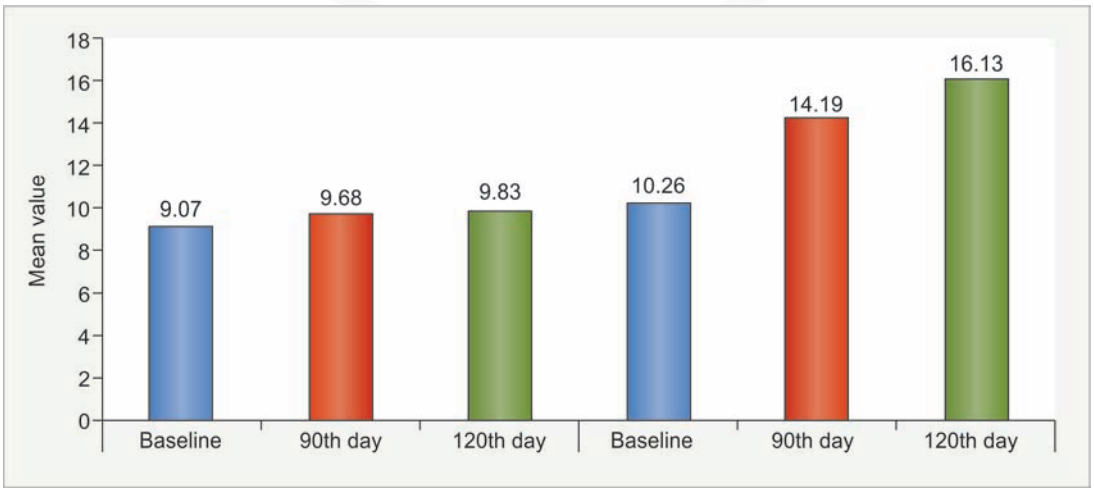



**Graph 1:** Effect of therapy on subjective symptoms

**Table 5:** Effect of the treatment on hematological parameters

| *Parameters (n = 150)* | *Baseline* | *90th day* | *t-value$* | *p-value** |
|---|---|---|---|---|
| Hemoglobin (gm/dL) | 9.07 (0.655) | 9.68 (1.010) | 9.366 | <0.001 |
| MCHC (g/dL) | 29.35 (2.219) | 29.30 (2.300) | 0.305 | 0.761 |
| MCV (fL) | 80.20 (11.119) | 80.52 (11.668) | 0.407 | 0.685 |
| PCV (%) | 31.58 (3.936) | 32.56 (4.854) | 2.632 | 0.009 |
| Serum ferritin (ng/mL) | 10.26 (7.530) | 14.19 (12.102) | 5.781 | <0.001 |
| Serum iron (µg/dL) | 39.52 (28.742) | 42.78 (26.895) | 1.604 | 0.111 |
| Total iron-binding capacity | 437.63 (68.882) | 424.00 (73.804) | 2.388 | 0.018 |

Values are expressed as mean (standard deviation), $Compared using paired t-test at baseline and 84th day, *p-value of <0.05 has been considered as significant




**Graph 2:** Effect of treatment on hematological parameters

**Table 6:** Effect of treatment on LFT and KFT

| *Parameters* | *Baseline* | *90th day* | *t-value*[$] | *p-value** |
|---|---|---|---|---|
| Blood urea (mg/dL) | 21.92 (4.572) | 23.07 (7.894) | 1.997 | 0.048 |
| Serum creatinine (mg/dL) | 1.00 (1.896) | 0.81 (0.415) | 0.745 | 0.457 |
| Serum uric acid (mg/dL) | 4.25 (1.034) | 4.55 (2.573) | 1.602 | 0.111 |
| SGOT (AST) (IU/L) | 22.62 (6.186) | 22.23 (5.821) | 0.673 | 0.502 |
| SGPT (ALT) (IU/L) | 21.86 (7.503) | 21.57 (6.665) | 0.550 | 0.583 |
| Total protein (gm/dL) | 7.42 (0.559) | 7.48 (1.379) | 0.529 | 0.598 |
| Serum albumin (gm/dL) | 4.27 (0.366) | 4.29 (0.383) | 0.515 | 0.607 |
| Serum globulin (gm/dL) | 3.14 (0.421) | 3.10 (0.406) | 1.586 | 0.115 |
| Conjugated bilirubin (mg/dL) | 0.36 (0.282) | 0.34 (0.288) | 2.089 | 0.038 |
| Unconjugated bilirubin (mg/dL) | 0.36 (0,235) | 0.39 (0.273) | 1.813 | 0.072 |
| Serum alkaline phosphatase (IU/L) | 163.35 (87.068) | 154.89 (77.336) | 1.962 | 0.052 |

Values are expressed as mean (standard deviation), [$]Compared using paired t-test at baseline and 84th day, *p-value of <0.05 has been considered as significant

### Safety Profile

Effect of *Navayasa Churna* on parameters of kidney and liver was assessed based on blood urea, serum uric acid, serum creatinine, serum glutamic oxaloacetic transaminase (SGOT), serum glutamic pyruvic transaminase (SGPT), total protein, serum albumin, serum globulin, conjugated bilirubin, unconjugated bilirubin, and serum alkaline phosphatase, before and after the trial period, and all parameters were found to be within normal limits, as given in Table 6.

## DISCUSSION

It has been observed in the study that prevalence of IDA in females is higher than that in males, which may be due to social inattention, inadequate dietary habits, less education, and unawareness about receiving extra iron containing diet to compensate loss during menstrual periods, lactation etc. During child-bearing years, women have high incidence for IDA, because of uncompensated iron loss sustained due to menstruation, lactation, and pregnancy. Middle age is the perfect age for aggravation of *Pitta* and hence, diseases owing to *Pitta* vitiation will be present in this age group. Perhaps these patients had suitable *hetu* (cause) in the form of excessive exercise, improper diet, and psychological stress due to their day-to-day jobs. Majority of patients were of age group 32 to 38 years, which is an ideal age for manifestation of IDA, due to pregnancy, lactation, and maximum stress in females. Maximum patients were vegetarians and it might be because of vegetarian predominant area and iron is present in fewer amounts in vegetables compared with nonvegetarian products and it contains mainly nonheme iron, which is less absorbable. It is observed that most of the patients (84%) belong to economically forward section and it shows that anemia is not a condition, i.e., restricted to the economically backward. Majority of cases were belonging to *Vata Pittaja Prakrti* and we can assume that such *Prakrti* persons have a tendency to get *Raktadhatu ksaya janya* rogas, such as *Pandu*. *Navayasa Churna* was found highly effective in reducing the clinical symptoms of IDA. Changes in hematological parameters occur much later than the clinical symptoms which manifest earlier, since the average lifespan of RBC is about 120 days. The symptoms of *Rasadhatu* and *Rakta dhatu ksaya* will be present initially and these symptoms will respond earlier to therapy as *Navayasa Churna* is capable of producing *Rasadhatu Prinana* and *Raktadhatu Prasadana*. Weakness, fatigue, dizziness, headache, palpitation, shortness of breath, and improved physical activity were noticed at the end of trial period.

### Probable Mode of Action of Therapy

*Navayasa Churna* relieves mentioned clinical features by raising hemoglobin and serum ferritin levels and bringing down total iron binding capacity. Iron (Lauha) is also present in Amalaki and Musta. It has been reported that presence of ascorbic acid (vitamin C) in Amalaki has a significant effect on iron bioavailability from cereals and pulses *in vitro*.[14] Musta contain copper and manganese, which might play an important role in increasing iron metabolism and hemoglobin synthesis in the body.[15] Therefore, iron absorption is enhanced. Lauha bhasma possesses significant hematinic and cytoprotective activity.[12] Lauha bhasma also has hemoglobin regeneration efficacy. As per Ayurveda, Triphala is antianemic and antioxidant. Haritaki has ferric-reducing antioxidant activity which is ideal in IDA.[16] Bibhitaki fruit contains essential vitamins, minerals, and protein and is a rich source of vitamin C and minerals like selenium, manganese, potassium, iron, and copper. It also contains Amalaki that has *rochana, deepana, and anulomana* properties and is also having a significant role in the digestion, absorption, and motility of digestive materials in the gut. As it is *hridya* (cardioprotective), *yakrututtejaka* (liver stimulant), and *shonitasthapana* (hemostatics), it has a direct action on

*Rasavaha* (lymphatic channels) and *Raktavahasrotas* (circulatory systems). It has been considered as a potent *rasayana* enhancing the essence of all the *dhatus* (basic body tissues). Amalaki is a rich source of iron and vitamin C. Trikatu is a known bioavailability enhancer.[17] Vidanga also has krimighna (deworming) property,[18] which enables it to indirectly eradicate one major cause of anemia.

## CONCLUSION

*Navayasa Churna* was successful in producing significant symptomatic improvement in subjective parameters like weakness, fatigue, dizziness, headache, palpitations, and shortness of breath and also in objective parameters, such as hemoglobin percentage, serum iron, serum ferritin, and total iron binding capacity.

Keeping in view the overall effect of the trial, it can be concluded that *Navayasa Churna* is effective for the management of IDA with continuation of medication for 90 days and it may be believed to produce even better results if the medication is continued for a period of 120 days. During the study and follow-up period, no untoward adverse effect was observed, and the treatment was well tolerated by all patients. *Navayasa Churna* is effective and safe in the management of IDA.

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# हिन्दी सारांश

## लौहक्षयजन्य एनीमिया में नवायस चूर्ण की आतुरीय प्रभावकारिता एवं सुरक्षा– एक प्रत्याशित बहुकेन्द्रीय ओपन लेबल अध्ययन

[1]बबीता यादव, [2]बनी आर मीणा, [3]ओमराज शर्मा, [4]हरबंस सिंह, [5]सुरेन्द्र के शर्मा, [6]विनोद बी कुमावत, [7]राजेश संड, [8]गुरु सी भुयान, [9]राकेश राणा, [10]रिचा सिंहल, [11]श्रुति खंडूरी, [12]भगवान एस शर्मा [13]सोफिया जमीला, [14]आदर्श कुमार, [15]नारायणम श्रीकांत

**भूमिका:** एनीमिया वह व्याधि हैं जहा लाल रक्त कोशिकाओं या उनकी ऑक्सीजन परिवहन क्षमता शरीर की अवश्यकताओ को पूरा करने के लिए अपर्याप्त है। लौहक्षयजन्य एनीमिया सामान्यतः शारीर में लौह तत्व की कमी के कारण होता है। इसकी लक्षणों के आधार पर पांडु रोग से तुलना कर सकते है।

**उद्देश्य:** नवायस चूर्ण के प्रभाव एवं सुरक्षा को पांडुरोगियों में अध्ययन करना।

**साधन एवं विधि:** यह एक बहु केन्द्रीय अध्ययन है जो की केन्द्रीय आयुर्वेदीय अनुसंधान परिषद् के ३ केन्द्रों पर १५० रोगियों में चयन प्रक्रिया के अनुसार किया गया। इन रोगियों को नवायस चूर्ण १ ग्रां (२ कैप्सूल प्रत्येक ५०० मिलीग्राम) दिन में दो बार जल के साथ ९० दिन तक दिया गया। साथ ही रोगियों को बिना औषधि दिए ९० दिनों के पश्चात ३० दिनों तक और निरीक्षण किया गया। इस अध्ययन में १५० रोगियों के आंकडों का आंकलन किया गया है। इन रोगियों का एच. बी, एम. सी एच, टी. एई. बी.सी, सीरम फरीटिन, सीरम आयरन आदि को पहले दिन एवं ९० दिन पर जांच किया गया तथा इसमें महत्त्वपूर्ण परिणाम प्राप्त हुआ।

**परिणाम:** ९० दिन के समाप्त होने पर सीरम फेरीटिन, हीमोग्लोबिन, पी. सी. वी में वृद्धि पाई गयी। एनीमिया के लक्षणों में भी लाभ प्राप्त हुआ। इस अध्ययन के तहत ३ माह के बाद भी एल. एफ.टी एवं के. एफ. टी की मूल्यांकन में कोई वृद्धि नही हुई जिससे यह ज्ञात होता है की यह ओषधि सुरक्षित है।