A clinical study to assess efficacy of rasapachaka kashaya in rasapradoshaja vyadhi - panduroga (iron deficiency anaemia) in females in reproductive age

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Abstract:

**Background:** Pandu is a Rasa Pradoshaja Vyadhi described by Acharya Charaka. Pandu causes extreme debility as it is dominated by the symptoms like Palpitation, Fatigue, Dyspnoea on exertion etc, due to the vitiation of Rasa and Rakta Dhatu, which are the essential factors for nourishment of body. There is a correlation of Pandu with Anaemia of Modern science. Females in reproductive age are more susceptible for Iron Deficiency Anaemia due to regular menstrual flow and dietary inadequacies and ultimately suffer complications in pregnancy as well in delivery. The present clinical study was conducted to assess efficacy of Rasapachaka Kashaya in Rasapradoshaja Vyadhi - Panduroga (Iron Deficiency Anaemia) in females in reproductive age.

**Methods:** Total 30 female patients of Panduroga in the age group 18-45 years were selected randomly. The study subjects were given Rasapachaka Kashaya in the dose of 1 gm twice a day after meals. Total study duration was of 90 days and assessment was done before initiation of study and at the end of every month.

**Results:** The relief in symptom scores such as Panduta (Pallor), Hrutspandan (Palpititation), Shunakshikut (Periorbital oedema), Daurbalya (Weakness), Hatanal (Loss of Appetite), Arohanayas (Exhaustion during climbing), Pindikodveshta (Calf muscle cramp), Aruchi (Anorexia), Shrama (fatigue), Bhrama (giddiness) and Nidralu (Sleepiness) symptom was statistically significant (p < 0.01).

Statistically significant difference was observed in objective parameters such as Haemoglobin level and RBC count (p < 0.05 and < 0.001 respectively) also in PCV and MCMC after 3 months of treatment.
No significant improvement was noticed in blood indices such as MCV and MCH. WBC count found to be improved to significant level whereas ESR showed decline to statistically significant level. No significant change in Platelet count was seen over a period of three months, i.e. completion of treatment.

**Conclusion:** The Rasapachaka Kashaya is found to be effective in the management of Rasapradoshaja Vyadhi– Panduroga in females in reproductive age.

**Key-words:** Rasapradoshaja Vyadhi, Panduroga, Rasapachaka Kashaya

**Introduction:**

Dhatu are the vital elements of body. Dhatu Pradoshaja Vikara is a condition in which the Dhatu are in vitiated state. Acharya Charaka has devoted a special chapter on the concept of DhatuPradoshajaVikaras in Sutrasthana. Among these Dhatu Pradoshaja Vyadhi, Pandu is a Rasa Pradoshaja Vyadhi described by Acharya Charaka.\(^1\) It is characterized by pallor of the body. Pandu causes extreme debility as it is dominated by the symptoms like Palpitation, Fatigue, Dyspnoea on exertion etc, due to the vitiation of Rasa and Rakta Dhatu, which are the essential factors for nourishment of body.\(^2\)

Rasa Dhatu is considered as Tarpankarka&Pushtikarka for RaktaDhatu.\(^3\) It is clear that Pandu occurs due to improper functioning of Rasa leading to malnourishment of the body and deterioration of other Dhatus like Rakta, Mamsa, Meda etc. In Ayurvedic classics Rakta has been considered as the key factor for Jeevana, Prinana, Dharana, & Poshana Karma of the Body.\(^4\)

This description avails the correlation of Pandu with Anaemia of Modern science. Anaemia is considered as a blood disorder characterized by low Haemoglobin (Hb gm\%) level. Hb is Iron bearing protein in Red Blood Cells, which delivers oxygen to tissues throughout the Body. Iron is a mineral that is essential for proper growth & for performing various vital function of the body.

As per the World Health Organization’s (WHO’s) report, there are about two billion anemia cases globally, of which half of them are IDA. It is a serious health problem as it causes general debility, lethargy, lassitude, suboptimal work performance and in certain situations mental retardation, poor intelligence and abnormal immune response.\(^5\)

Anemia is the late indicator of iron deficiency in the human body, hence the prevalence of iron deficiency is estimated 2.5 times higher than that of anemia. IDA during pregnancy is associated with maternal mortality, preterm labor, low birth weight, and infant mortality.\(^6\) IDA among children affects their cognitive and
motor development and increases the susceptibility of infections. Females in reproductive age are more susceptible for Iron Deficiency Anaemia due to regular menstrual flow and dietary inadequacies. Due to Anaemia, these females suffer complications in pregnancy as well in delivery. Modern Medicine can effectively treat Acute Anemia, but still the pitfall for management of chronic deficiency anemia exists. This type of chronic disease can be managed by Ayurveda successfully. As evident from the research studies undertaken on this topic.

Signs and Symptoms of Pandu and Iron deficiency anemia are comparable to a great extent. Iron and nutritional therapy is but one aspect of its treatment. The Samprapti of Pandu lays a great emphasis upon involvement of Rasa Dhatu and Dhatwagni. Its Samyavastha is crucial in treatment of Pandu. Acharya Charaka has mentioned Dhatupachaka Kashaya in Jwarachikitsa Adhayaya of Chikitsa Sthana for all the DhatugatJwara, wherein Rasapachaka Kashaya for the treatment of Rasagata Jwara zai.e. SantatJwara. Pandu is counted as Rasapradoshaja Vyadhi by Acharya Charaka. As per extension of reasoning, Rasapachaka Kashaya can be used for treatment of the same. For better patient compliance, Rasapachaka Kashaya was converted to tablet form and used as study drug.

In the study, Total 30 female patients of Panduroga were selected randomly in the age group 18-45 years irrespective of their socio-economic status. The patients were given Rasapachaka Kashaya in the dose of 1 gm twice a day after meals. Total study duration was of 90 days and assessment was done before initiation of study and at the end of every month (Day 0, Day 30, Day 60 and Day 90).

Thus, the present study entitled “A Clinical Study to Assess Efficacy of Rasapachaka Kashaya in Rasapradoshaja Vyadhi - Panduroga (Iron Deficiency Anaemia)”; emphasizes on conceptual aspects of Pandu Vyadhi (Iron Deficiency Anemia) as well as clinical study of Rasapachaka Kashaya in its treatment.

Materials and Methods:
The present study was Single Arm, Prospective, and Interventional Study. 30 female patients showing signs and symptoms of Pandu, between the age group of 18 to 50 years were selected, irrespective of sex and religion from OPD & IPD of concerned Ayurvedic Hospital.

Selection of patients-
Inclusion Criteria: Females in the age group between 18-45 yrs, having Blood Haemoglobin levels between 8 to 10 gm% and without any other acute or chronic major illness.
Exclusion Criteria: Females having any major illness like Cancer, Tuberculosis and such others and Any bleeding disorders such as Internal bleeding, Haemorrhoid, Menorrhagia, pregnant ladies and lactating mothers were excluded from the study.

Ingredients of Rasapachak Kashay i.e. Kalingaka, PatolPatra, Katurohini were sourced from local drug vendor. Authentication and identification of drugs were done in Department of Dravyaguna Vigyan of concerned Ayurvedic College. For the sake of patient compliance, Preparation of Rasapachak Kashaya has been done as per scientific and authentic method according to Sharangdhar Samhita. Dried seeds of Kutaja, Dried leaves of Patola, Dried rhizomes of Kutaki were collected. The Rasapachak Kashay was prepared by using equal quantity of ingredients in the form of bharad powder. Then this bharad powder was added into 16 times of water. The whole preparation was boiled till ¼th part of the decoction remains. After making it lukewarm, the decoction was filtered. Thus, Rasapachak Kashay was prepared. Rasapachak Kashaya was converted to tablet form in teaching pharmacy of Ayurvedic college by API approved methods. Standardization of tablets was done in authentic laboratory.

Diagnostic Criteria for Pandu-Roga:

For the diagnosis of Pandu-Roga whole importance was given to the pathological investigation and symptoms of Panduroga.

Laboratory Investigations-
- RBC
- Haemoglobin level
- WBC
- RBC Indices: PCV, MCV, MCH, MCHC
- Platelet Count
- ESR

Symptoms of Pandu-Roga like Panduta (pallor), Hrutspandan (palpitation), Shunakshikut (periorbital oedema), Durbal (weakness), Hatanal (Loss of Appetite), Arohanayas (exhaustion during climbing), Pindikodvesht (calf muscle cramp), Aruchi (Anorexia), Shrama (fatigue), Bhrama (giddiness), Nidralu (always want to sleep)

Ethical committee clearance was taken from the institutional Ethics Committee. Written informed consent of the subject was taken prior to the study. The assessment of study subjects was done by specially designed case record form.

Plan of Study: The total number of subjects was 30 and RasapachakaKashaya was given in a dose of 1 gm (4 tablets of 250 mg of active ingredients) twice a day for 3 months. Pathological Investigations were done to assess the effect of Rasapachak Kashay before and after the
administration of RasapachakaKashay. Follow up was carried out after every month i.e. 2 times in three months.

Criteria of Assessment:
The assessment of result was based on subjective and clinical improvement which includes the observation of patients and assessment of physician during the trial. According the signs and symptoms the parameters were as follows:

Symptomatic Assessment of Study Subjects of Pandu-Roga (Iron Deficiency Anaemia) Panduta (pallor), Hrutspandan (palpitation), Shunakshikut (peri orbital oedema), Durbal (weakness), Hatanal (Loss of Appetite), Arohanayas (exhaustion during climbing), Pindikodvesht (calf muscle cramp), Aruchi (Anorexia), Shrama (fatigue), Bhrama (giddiness), Nidralu (always want to sleep)

Grades- 0 – Absent, 1 – Mild, 2 – Moderate, 3- Severe

Assessment of Haematological Parameters of Study Subjects of Pandu-Roga (Iron Deficiency Anaemia): RBC, Haemoglobin level, WBC, RBC Indices: PCV, MCV, MCH, MCHC, Platelet Count and ESR

Plan for Statistical Analysis:
The study data generated and collected was put to statistical analysis to reach to the final results and conclusions. The demographic data were presented in tables and graphs. The data obtained in the studies were subjected to tests of significance. GraphPad InStat (www.graphpad.com) software was used for statistical analysis of data.

Results:

A) Demographic Details:

Age: Out of the 30 subjects of Pandu, 12 study subjects (40%) were in the age group of 30- 40 years,10 study subjects (33.33%) were in 40-45 years age group. Whereas, 08 study subjects (26.67%) were in the age group of 18- 30 years. Religion: Out of 30 study subjects enrolled in the study, 27 (90%) study subjects belonged to Hindu religion, 01 (3.33%) to Muslim religion whereas 02 (6.67%) individuals belonged to Baudha religion. Occupation: Out of 30 study subjects enrolled in the study, 11 (36.67%) subjects were doing labour work, 11 (36.67%) subjects were housewives whereas 04 (13.33%) study subjects were shopkeepers. 02 (6.67%) were teachers whereas 01 (3.33%) study subject was factory worker. In India, housewives have more physical work and inadequate diet. Also, laborers may be included in lower socio economic category and they are more prone to this disease due to malnutrition.

Diet: Out of 30 study subjects enrolled in the study, 24 (80%) subjects were having mixed diet whereas only 06 (20%) individuals were habituated to vegetarian
diet. Due to small sample size, no conclusion can be drawn. **Prakriti:** Out of 30 study subjects enrolled in the study, maximum study subjects i. e. 17 (56.67%) were of Vata-Pittaprakriti, 08 (26.67%) study subjects were of Pitta-Kaphaprakriti. whereas; only 05 (16.67%) study subjects were of Vata-Kaphaprakriti. This observation has a clinical significance as the persons with Vata-Pittaprakriti are naturally more prone to the vitiation of Vata and Pitta. **Agni:** Out of 30 study subjects enrolled in the study, maximum study subjects i. e. 20 (66.67%) had Mandagni whereas 10 (26.67%) study subjects had Vishamagni. No study subject had Teekshnagni. Mandagni and Vishamagni create Ama production and improper Rasadhatu formation which is the foremost step in development of Pandu. **Koshtha:** Out of 30 study subjects enrolled in the study, maximum study subjects i. e. 15 (50%) had KrooraKoshtha, 08 (26.67%) study subjects had Mridu Koshtha. Whereas only 07 (16.67%) study subjects had Madhyama Koshtha. Kroarakoshtha has dominancy of Vatadosha in Mahasrotas and improper digestion which leads to Pandu.

**B) Clinical Assessment-**

Clinical assessment was done at every follow up of one week for assessment of the improvement in signs & symptoms. For the assessment of study subjects, the specific criteria were used. On the basis of those criteria the statistical analysis of improvement in symptoms & signs was done. 90.14% relief was observed in Panduta (Pallor) symptom which was statistically significant too (p < 0.001). 78.33% relief was observed in Hrutspadan (Palpitation) symptom which was statistically significant too (p < 0.001). 88.98% relief was observed in Shunakshikut (Periorbital oedema) symptom which was statistically significant too (p < 0.001). 75.86% relief was observed in Daurbalya (Weakness) symptom which was statistically significant too (p < 0.001). 69.23% relief was observed in Hatanal (Loss of Appetite) symptom which was statistically significant too (p < 0.01). 84% relief was observed in Arohanayas (Exhaustion during climbing) symptom which was statistically significant too (p < 0.001). 84% relief was observed in Pindikodveshta (Calf muscle cramp) symptom which was statistically significant too (p < 0.001). 68.29% relief was observed in Aruchi (Anorexia) symptom which was statistically significant too (p < 0.001). 84.91% relief was observed in Shrama (fatigue) symptom which was statistically significant too (p < 0.001). 63.14% relief was observed in Bhrama (giddiness).
symptom which was statistically significant too (p < 0.001). 61.11% relief was observed in Nidralu (Sleepiness) symptom which was statistically significant too (p < 0.001).

In the assessment of objective criteria, after the intervention for 3 months in 30 study subjects suffering from Panduroga (Iron Deficiency Anaemia), statistically significant difference was observed in objective parameters such as haemoglobin level and RBC count (p < 0.05 and < 0.001 respectively). Statistically significant improvement was observed in blood indices such as PCV and MCMC after 3 months of treatment. No significant improvement was noticed in blood indices such as MCV and MCH. WBC count found to be improved to significant level whereas ESR showed decline to statistically significant level. No significant change in Platelet count was seen over a period of three months, i.e. completion of treatment.

C) **Overall Assessment of Therapy:**

From the statistical analysis, it was concluded that the Rasapachaka Kashaya was found to improve subjective and objective criteria of assessment for treatment of Pandu significantly. Not a single adverse event reported in any of the study subjects during or after the study.

**Discussion:**

*Pandu Roga* can be effectively compared with Anaemia on the ground of its similar signs & symptoms. The term Anaemia can be taken under the broad umbrella of Pandu. Also, *Pandu* is considered as a Rasapradosha Vikara. Due to vitiated *Kapha*, there is Aamotpatti and Mandagni leading to malabsorption of essential nutrients which leads to manifestation of Anaemia.

The existing protocol for management of Anemia solely depends on Iron supplementation. But the non optimal results achieved call for the review of some basic considerations. Formulations mentioned in the context of *Pandu* contain herbal ingredients that are known correctors of the metabolism and enhancers of bioavailability of nutrients irrespective of the factor whether they contain metallic Iron or not. 102 formulations are mentioned in the treatment of Pandu in Ayurvedic Formulary of India among which 72 does not contain metallic Iron. All these indicate that more emphasis was given in the text books of Ayurveda for factors affecting metabolism, perhaps including that than Iron supplementation in the management of Pandu.

Considering all these facts, *Rasapachaka Kashaya* was selected, which can improve
the metabolism & Agni & thus improve the Pandu. Acharya Charaka has mentioned Dhatupachaka Kashaya in Jwarachikitsa Adhayay of Chikitsa-Sthana for all the Dhatugata Jwara, wherein Rasapachaka Kashaya for the treatment of Rasagata Jwara i.e. Santat Jwara. As per extension of reasoning, RasaPachaka Kashaya was considered for treatment of the Pandu. For better patient compliance, Rasapachaka Kashaya was converted to tablet form and used as study drug. Rasapachaka Kashaya was found to be effective in Panduroga as significant improvement was noted in haematological parameters such as – Haemoglobin, RBCs, PCV, MCHC and WBCs which statistically significant too. Rasapachaka Kashaya having with predominance of Tiktarasa and Ushnaveerya improves the Rasa-Dhatvagni thus improves the quality of Rasa-Dhatu and improves the quantity of Rakta-Dhatu. RasapachakaKashaya improves the Dhatvagni, and thus relieves the symptoms of Panduroga. No complications were observed in this study.

Probable mode of action of Rasapachaka Kashaya-

DhatuPachaka Yoga are polyherbal formulations mentioned in the Charaka Samhita and Ashtanga Hridaya in the Jvara Adhikara. However, the importance of the five Dhatupachaka Yoga is not only confined to Vishama Jvara, but is used widely by physicians all over in the form of Churna- Vati-Kwath to treat various other diseases. The main action of Rasa Dhatu is to provide nourishment to the body. Due to vitiation of Rasa Dhatu in Santata Jwara this action is hampered. Improperly formed Rasa Dhatu is also a chief etiological factor in Samprapti of Pandu. Thus, Rasapachaka Kashaya consisting of Kalingaka, Patola Patra, Katrohini is considered for treatment of Pandu. Here, Kalingaka is Agnideepana, pachana, and useful in digestion ofRasagataAma. Patola is useful in Pitta and Kapha Vyadhi to digest Doshas. While, Katrohini is especially useful as Pachana because of its Tikta Rasa. Together, they show a synergistic action as Jatharagni Deepaka, Dhatvagni Deepakaand Ama Pachaka. Rasapachaka Kashaya has predominance of Tikta rasa and Ushnaveerya which improves the Rasa-Dhatvagni thus improves the quality of Rasa-Dhatu and improves the quality and quantity of Rakta-Dhatu. This probably results in better absorption of nutrients from diet and thus proved to be beneficial in treatment of Pandu Vyadhi occurred as a Rasapradoshaja Vikara in females in reproductive age.
Conclusion:
The Rasapachaka Kashaya is found to be effective in the management of Rasapradoshaja Vyadhi– Panduroga in females in reproductive age. Not a single adverse event reported in any of the study subjects during or after the study. The study should be conducted in a large sample to get a convenient result. Rasapachaka Kashaya along-with or followed by Iron supplements may give better results. The study should be conducted for a longer duration so as to to explore the efficacy of Dhatupachaka Kashaya.

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Conflict of Interest: Non  
Source of funding: Nil

Cite this article:

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