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Comparative Study on Efficacy of *Murvadya Churna* with *Lauha Bhasma and Navayas Churna* in *Pandu Roga* (Iron Deficiency Anemia)

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Authors' contributions

This work was carried out in collaboration between both authors. Both authors read and approved the final manuscript.

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Study Protocol

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ABSTRACT

Pandu Roga is mainly the *Rasapradoshaj Vyadhi* which vitiates the *Pitta.* Whereas Shushruta described it as *Raktapradoshaj Vyadhi*. In *Pandu Roga* due to *Alpa Rakta Twaka Vivarnata* (discoloration of skin) occurs.So according to name Panduta is the main feature of Pandu Roga.Due to lack of dietary intake & improper absorption of iron are the causes of Iron deficiency Anemia.

Aim: Efficacy of *Murvadya Churna* with *Lauha Bhasma* in the management of *Pandu Roga* (Iron Deficiency Anemia).

Material and Methods: Study was contained 60 patients of *Pandu* were divided into two groups (each group contain 30). In Group A (Experimental group)- *Murvadya Churna* with *Lauha Bhasma* 500 mg two times a day after meal with warm water for 30 days & In Group B 500 mg *Navayas Lauha was* administered two times a day after meal with honey. Assessment was recorded every 15^{th} day (15^{th} & 30^{th} day)

Result: Subjective and Objectives outcomes were assessed; both the groups were given equal effects on both the parameters subjective & objective.

Conclusion: *Murvadya churna* with *Lauha Bhasma* was equally effective as *Navayas Lauha.*

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Keywords: Lauha bhasma; Murvadya churna; Navayas churna; Pandu roga.

1. INTRODUCTION

1.1 Background and Rationale

According to Ayurveda, body comprises of seven *Dhatus*, which are responsible for sustenance of the being. Amongst them the first *Dhatu* i.e., *Rasa* has given more importance. According to Charaka, *Pandu Roga* is a *Rasapradoshaja Vyadhi* which is a *Pitta* dominant *Tridoshaja* disease. [1] Whereas, Sushruta described it as *Raktapradoshaja Vyadhi*. [2] It is a disease in which *Vivarnata of Twaka* (discoloration of skin) is mainly *Pandu* (pallor/ yellowish-whitish) due to *Alpa Rakta* (reduced blood). [3] Other signs of *Pandu Roga* are *Agnimandya* (diminished appetite), *Aruchi* (tastelessness in food*)*, *Daurbalya* (general debility), *Bhrama* (giddiness) etc. [4] The nearest correlation of *Pandu Roga* can be made with Iron deficiency Anemia, because of *Panduta* or pallor in the whole body.

Anemia means deficiency of Hemoglobin in the blood which can be caused by either too few RBCs or too little hemoglobin in the cells. [5] Anemia can be caused by innumerable factors, the most common being deficiency of essential elements for hemoglobin synthesis (Iron, Vit. B12 and folic acid), blood loss, repeated pregnancies in female of reproductive age, worm infestation, hemolysis due to known/ unknown causes and bone marrow conditions causing suppression of red cell synthesis. Anemia is a serious global public health problem & its prevalence is in young children & women. As per the National Family Health Survey, 53.2% of non-pregnant women and 50.4% of pregnant women of age 15-49 years were found to be anemic in 2016, whereas only 22.7% men were anemic in this age group. [6]

Ayurvedic Herbo-mineral iron preparations being devoid of hazards need to be evaluated to know their efficacy in treatment of *Pandu Roga*. Since ancient times, different these iron preparations are empirically used for treatment of *Pandu Roga*. *Murvadya Churna* is one of such ayurvedic preparations. [7] On looking at the ingredients of *Murvadya Churna*, it works by effect on *Srotasas* (micro channels) and *Agni* (digestive fire mechanism). [8] In literature, there is no studies regarding usefulness of *Murvadya Churna with Lauha Bhasma* in treatment of *Pandu Roga*. Therefore, we were planned a study to analyze the effect of *Murvadya Churna* with *Lauha Bhasma* [9] in treatment of *Pandu Roga* (Iron Deficiency Anemia)

1.2 Trial plan

Block randomization criteria were fulfilled by participants and they were randomly selected for the experimental as well as controlled group with 1:1 ratio.

2. Methodology

2.1 Type of Trial

This was the parallel group, single- blind, randomized, standard – controlled trial. The trial was including, a 30 days treatment period and 15th day follow up period.

Allocation ratio – total 60 patients were selected for the study which will be divided into two equal groups. Group A is experimental group whereas Group B is standard controlled.

2.2 Study Setting

Selection was done from OPD and IPD of Dept. of Kayachikitsa, Mahatma Gandhi Ayurvedic College & Research Centre, Salod (H), Wardha. Also, patients were selected from various specialized peripheral camps.

- **Trial Registration number** -This trial registered under CTRI with trial number
- **Ref. MGACHRC/IEC/August – 2020/93**
- **Diagnostic criteria:** The patients were having cardinal features like *Agnimandya* (loss of apetite), *Aruchi* (tastelessness), *Panduta* (pallor), *Dourbalya* (general debility) as *Pandu Roga*
- **Eligibility criteria:** Patients were taken between the age group 18-45 years of females.
- Patients who were having Hb % in the range of 7 to 11gm/dl
- Patients were having the symptoms of *Pandu Roga* like *Agnimadya, Daurbalya, Aruchi, Twakavaivarnya.*

2.3 Interventions

Group A- *Murvadya Churna* with *Lauha Bhasma 500*mg two times a day with warm water after meal

Group B – *Navayas Churna* 500 mg two times a day after meal with honey.

Pathya & Apathya ahar Vihar for both groups.

Vihara:

Diwaswapa, Atapasewana, Ativyayama, Vegavidharana, Chinta, Shoka, Krodha

2.4 Randomization

Block randomization criteria were fulfilled by participants and they were randomly selected for the experimental as well as control group with 1:1 ratio. Researchers were access the treatment allocation for each eligible participant through a remote and web-based randomization system. Total 60 patients were selected for the study which were then be divided into two groups. Group A is experimental group whereas Group B is standard controlled.

2.5 Blinding

Treatment allocations was blinded to the participants, clinicians, research assistants, drug managers, statisticians, and other staff members, and we're not be revealed until the study was completed. The clinicians were assessed all the participants throughout the study period.. For each eligible patient, the clinician was applied for a randomized assignment by logging into the web-based randomization system, and prescription for "*Murvadya Churna with Lauha Bhasma* after meal with warm water two times a day" Then, accompanied with a research assistant, the patients were taken to the appointed drug managers at the Dattatraya Rasa Shala. During the trial periods, clinicians, research assistants, and drug managers are forbidden from discussing the assignment possibilities with the participants. All drugs are packaged in an identical manner. The blinding codes will be kept strictly confidential, and was not broken during the trial unless serious adverse events occur.

Screening investigations (base line): CBC

Investigation during treatment: Hb%

Investigation (end line): CBC

2.6 Criteria for Discontinuing or Modifying Allocated Interventions

From the study if any untoward incidence, features of drug sensitivity or any other disease or problem arises, Subject was withdrawn and free treatment will be offered to the subject till the difficulty subsides. We will measure quantity of *Churna* for the consumption of appropriate dose for assessment and to check drug adherence, during treatment the subject will be followed up.

- **After treatment follow up:** 15th day during treatment and on 30th day at the end of treatment. Patient will be advised to take normal routine diet for food intake which is advised.

- **Primary Outcomes:** We will see the effect of Interventional drug on *Agnimandya* (diminution of Agni)*, Aruchi* (tastelessness)*, Panduta* (pallor in the various body parts like nails, palm, icterus*), Daurbalya* (general debility) & will see changes in values of Hb%, TIBC

- **Secondary Outcomes**: The secondary outcome of the trial is to check for reoccurrence of the disease and to monitor adverse effects (if any) of the trial drug and to compare the effects of experimental group to that of the control group.

- **Relief and relapse incidents-** The definition of relapse is the recurrence of *Panduta (*pallor in various body parts), *Agnimandya (*diminution of *Agni), Daurbalya* (general debility*),Aruchi (*tastelessness) in the patients of *Pandu Roga* who have achieved treatment success. Achieving treatment success means that *Pandu Roga* symptoms have been relieved. Relief and relapse incident outcomes include time until relief, time until first relapse, and total relapse times. Time until relief is defined as the time from patients receiving treatment to achieving treatment success. Time until first relapse is defined as the time from patients achieving treatment success to the recurrence of *Panduta (*pallor in various body parts), *Agnimandya (*diminution of *Agni), Daurbalya* (general debility*), Aruchi (*tastelessness). Total relapse times refer to the sum of relapse times during both the treatment period and the follow-up period.

- **Long-term effectiveness-** Participants who will be weekly adequate relief responders for at least 30 days during the follow-up period will be considered long-term effectiveness responders.

2.7 Statistical Analysis

A level of 5% (two-sided) type I error will be considered as statistically significant. Analysis will be based on both intention-to-treat and per-protocol populations. Baseline characteristics, which also include predictive factors, will be presented for each group. From baseline to each time point, discrete variables will be described with frequencies and percentages, and continuous variables will be described with either mean and standard deviation for data with normal distribution or median and interquartile range for non-normally distributed data. For comparisons between experiment and control group at each time point, Wilcoxon test. Paired as well as Unpaired t test will be used to analyze the data having objective criteria. The McNamara's test will be used to analyze the data with subjective criteria.

Chart 1. Formulations

Sr. No.	Ingredients	Botanical Name	Part Used	Quantity
1	*Murva*	*Marsdenia tenacissima*	Stem	1 part
2	*Chitrak*	*Plumbago zeylanic*	Root bark	1 part
3	*Bala*	*Sida cardifolia*	Stem, Seed	1 part

Chart 2. *Lauha Bhasma*

Sr. No.	**Ingredient**	**Botanical Name**	**Part Used**	**Quantity**
1	*Lauha Bhasma*	Iron	Powder	125mg

Chart 3. *Navayas Churna*

Sr.no.	**Content**	**Botanical name**	**Part used**	**Quantity**
1	*Shunthi*	*Zingiber officinale*	Rhizome	1 part
2	*Maricha*	*Piper nigrum*	Fruit	1 part
3	*Pippali*	*Piper longum*	Fruit	1 part
4	*Haritaki*	*Terminaliya chebula*	Fruit	1 part
5	*Amalaki*	*Emblica officinalis*	Fruit	1 part
6	*Bibhitaki*	*Terminaliya belerica*	Fruit	1 part
7	*Musta*	*Cyperus rotundus*	Rhizome	1 part
8	*Vidanga*	*Embelia ribes*	Fruit	1 part
9	*Chitraka*	*Plumbago zeylanika*	Root bark	1 part
10	*Lohabhasma*	Iron	Powder	1 part

Chart 4. *Pathya Ahara* [10]

Food	Old wheat, rice (*Shashtik*), barley, jowar, green gram and pea
Vegetables	Patola, Palak, Dudhi, *Punarnava, Haridra, Jeevanti*, all green vegetables
Non veg	Fish, goat meat, jungle meat
Fruits	Amla, grapes, Anjeera, Chikoo, banana, mango, Kharjura, papaya, pomegranate
Milk products	Cow milk, ghee*, Navaneeta takra*
Liquids	*Gomutra, Laja Manada, Koshna Jala, Laghu Panchamula Siddha Jala*
Kshara varga	*Yavaka Kshara*
Madya varga	*Sauvira, Tushodaka*

Vihara: light exercise

Chart 5. *Apathya ahara* [11]

Shaka Varga	Except the above mentioned *Sahaka Varga*
Shimbi Varga	*Masha, Pinyaka*
Dal	*Tila, Sarshapa*
Tail Varga	*Bijowar tail*
Drava Varga	*Atyambupana, Madyapana*

The analyses of predictive factors will be performed in two steps as follows: The first step is univariate analysis. The adequate relief follow-up (day 30) responder rates will be used as dependent variables, and predict factors, such as demographic and clinical characteristics, and key elements of *Murvadya Churna with Lauha Bhasma*, will be used as independent variables. A logistic regression analysis will be conducted. The selection criteria for the independent variable are defined as $\alpha = 0.1$. The second step is multivariate analysis. Those predictive factors selected through the first step will be entered into two multiple regression models, taking the follow-up (day 45) adequate relief responder rates as the dependent variable.

Sensitivity analyses was planned. Firstly, the main and safety outcomes between all randomized patients and exposed patients were compared and then impact of missing data on primary outcome was evaluated.

Planned subgroup analyses will be carried out in relation to the primary outcome— adequate relief. The main analysis for each subgroup will be an unadjusted test of interaction in a logistic model.

- **Statistical analysis:** Data having Normal Distribution will be done by paired & unpaired t test Data having non normal distribution will be done by Wilcoxon signed rank test & Mann Whitney u test

- **Total follow up:** At 0-day, 15th day & 30th day the patient will be followed up

- **Follow up Period**: At 15$^{th\ day}$ during the treatment & at 30th day on the completion of the treatment

- **Enrolment and interventions time schedule:** The intervention period was from 0 to 30 days and the patients were followed up on 15th and 30th day.

- **Recruitment:** By computerized simple random sampling method 60 patient will be recruited (30 in each group)

- **Implementation:** Principal Investigator will enroll and allocate the patient.

- **Methods:** Data collection, analysis and management

- **Data collection method: Assessment criteria**

- **Subjective** -*Panduta (*pallor)*, Aruchi* (tastelessness)*, Agnimandya* (anorexia)*, Daurbalya (*generalised weakness)

- **Objectives** -CBC, KFT (before and after treatment)

  The assessment will be done according to the gradations on 0th (before treatment), 15th (during treatment), on 30th day (at the end of treatment)

  The intervention protocol was supervised by Principal Investigator by contacting the patients and follow up data of patients were stored in documentation with reason.

- **Plan to promote participants retention and complete follow up:** We will stay in touch with patient by taking contact no. and timely advise them for medication and follow up and data of follow up will be stored in documentation with reason.

- **Data management:** The data will be collected from patients by doing clinical evaluation. Data will be collected using planned questionnaire filled during interview of the patient. Data will be entered in master sheet and analysed by using suitable statistical technique and data coding will be done by principal investigator.

Table 1. Gradation of Symptoms with validation (Symptoms will see before, during and after treatment using gradation of symptoms for clinical research methodology)

Duration	Symptoms
0, 15th & 30th days	*Panduta* *Agnimandya* *Aruchi* *Daurbalya*

Duration	Investigation
0,15th & 30th day	• Hb% • MCV • MCH • MCHC • KFT

Table 1A. *Panduta* (pallor): In *Twaka, Nakha, Netravarnata, Karnapali, Jiwha, Hastapadatala*

Sr.no.	Symptoms	Gradation
1	Absent	0
2	Present in one site	1
3	Present in 2-3 sites	2
4	Present in all sites	3

Table 1B. *Agnimandya* (Diminution of *Agni*)

Sr.no.	Symptoms	Gradation
1.	*Matravaha Ahara*, feels comfortable proper digestion	0
2.	*Matravaha Ahara*,discomfort, proper digestion	1
3.	Less than *Matravaha Ahara*, feels more discomfort	2
4.	Not able to digest even little food feels more discomfort	3

Table 1C. *Aruchi* (Tastelessness in Food)

Sr.no.	Symptoms	Gradation
1.	Normal taste in food, feeling to eat food in time	0
2.	*Aruchi*- feeling to take food but not having taste	1
3.	*Ananabhilasha*- not feeling to take food even if hungry	2
4.	*Bhaktadwesha*- aversion to food	3
5.	*Abhaktachchanda*	4

Table 1D. *Daurbalya* (General debility)

Sr.no.	Symptoms	Gradation
1.	No *Daurbalya*	0
2.	Not able to perform strenuous activity	1
3.	Not able to perform moderate activity	2
4.	Cannot perform moderate activity but can perform moderate activity without any difficulty	3
5.	Even mild activities cannot be performed	4

- Outcome will be compared using paired and unpaired student 't' test.
- **Dissemination policy:** The data will be circulated by paper publication.
- Any intended use and authorship eligibility guidelines of professional writers

3. RESULT

Expected outcome result in control group with intervention *Murvadya Churna with Laha Bhasma was* effective in subsiding the symptom of *Panduta* (pallor)*, Aruchi (*tastelessness)*, Agnimandya* (diminution of *Agni), Daurbalya* (general debility) as well as it is effective in increasing Hb% level. By following *Pathya* and *Apathya* , during treatment patient who was taken all follow up had a reduced amount of chance of recurrence of symptoms as compared with standard *Navayas Churna.*

4. DISCUSSION

This study was conducted with the aim to compare clinical efficacy of *Murvadya Churna* with *Llauha Bhasma* & *Navayas Churna* in *Pandu Roga* (Iron deficiency anaemia). According to ayurvedic literature *Deepana, Pachana, Krumighna, Raktavardhaka* treatment is given to cure the *Pandu Roga.* We observed that both *Murvadya Churna* with *Lauha Bhasma* & *Navayas Churna* were effectively reduce signs & symptoms of *Pandu Roga* (Iron deficiency anaemia) with reference to improve Hb%, MCH, MCHC, MCV. *Murvadya Churna* with *Lauha Bhasma* contains *Murva (Marsdenia tenacissima), Chitraka (Plumbago zeylanica), Bala (Sida cordifolia)* with *Lauha Bhasma.* In these *Murva* is having *Raktashodhaka & Krimighna* properties, while *Chitraka* having *Deepana, Pachana* properties. *Bala* is *Sheeta* in *Veerya* & *Madhura Rasa* which is effective in *Pittaja Vikaras. Lauha Bhasma* is also an important component which is the iron preparation it is having the haematitic activity & Haemoglobin regeneration efficacy. *Navayas Churna* is having the contents like *Triplala (Haritaki, Amalaki, Bibhitaki), Trikatu (Shunthi, Maricha, Pippali), Vidanga (Embelia ribes), Musta (Cyperus rotundus), Chitraka (Plumbago zeylanica), Lauha bhasma* (Iron). These all ingredients having the properties like *Deepana, Pacahana, Raktavardhaka & Balya* which are helpful in *Samprapti Vighatana* (breaking the pathogenesis) so helpful in reducing the symptoms of *Pandu Roga.* But in this study, we analysed the comparison in between both the formulations & effects on subjective as well as objective parameters. Total effects were show which formulation is highly effective in *Pandu Roga.*

5. CONCLUSION

From the above study, it is concluded that, the interventional drug *Murvadya Churna with Lauha Bhasma* is 10% further more effective in *Pandu Roga* patient as compared to *Navayas Churna* with minimum side effects.

CONSENT

The written consent has been taken before starting the study from the patient. During the study, privacy should be maintained of each & every patient. Model consent form and other related documentation with all information has been given to participant.

ETHICAL APPROVAL

The study was approved by Institutional Ethics Committee Letter no. MGACHRC/IEC/AUG2020/93

COMPETING INTERESTS

Authors have declared that no competing interests exist.

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