IAMJ

INTERNATIONAL
AYURVEDIC
MEDICAL JOURNAL

Research Article | ISSN: 2320-5091 | Impact Factor: 6.719

A STANDARD COMPARATIVE CLINICAL STUDY ON PANDUROGA W.S.R TO IRON DEFICIENCY ANAEMIA WITH SAMMOHA LOHA OVER FERROUS SULPHATE

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https://doi.org/10.46607/iamj06p5062021

(Published online: September 2021)

Open Access

Article Received: 29/08/2021 - **Peer Reviewed:** 12/09/2021 - **Accepted for Publication:** 15/09/2021

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ABSTRACT

Context: Anemia is the most common and intractable nutritional problem in the world today. Anaemia due to iron deficiency is the most prevalent type of Anemia. As the name denotes the main feature of *Panduroga* (Anemia) is *Pandutva* (pallor). *Panduroga* as mentioned in classics is a *Pitta PradanaVyadhi*. The side effects of oral allopathic drugs are very common, therefore a study on *Ayurvedic* formulation *SammohaLoha* was chosen in the study. **Aim:** Evaluation of the efficacy of *SammohaLoha* over Ferrous Sulphate in *Panduroga*. **Materials and Methods:** Randomized, single-blind standard comparative clinical study. The study was conducted on 40 patients, and they were divided into 2 groups each with 20. One group was treated with trail drug *SammohaLoha* and the other group with standard drug Ferrous Sulphate. Clinical parameters were documented before and after treatment. **Results:** After statistically assessment of subjective and objective parameters results were drawn.

Keywords: *Panduroga*, Iron Deficiency Anaemia, *SammohaLoha*, Ferrous Sulphate

INTRODUCTION

The world's population is increasing at a rapid rate, due to which most of the people are living in unhygienic, under-nourishing conditions. Adaption of people towards western culture like fast foods intake like pizza, chips, burgers, carbonated drinks etc are considered as low nutrient foods and as well they impair the digestion and affect the absorption of various nutrients including iron and also varies stress and strain factors affects the health. This disease was chosen for the study due to its high incidence.

Globally 50% of anaemia is attributable to iron deficiency[1]. Generally, symptoms like fatigue, headache, giddiness, breathlessness and palpitations are seen in anaemia[2]. Oral iron salts are the most readily available way of replacing iron, Ferrous Sulphate is the most effective and economical oral preparation. But about 10 – 20% of patients will develop gastrointestinal side effects related to Ferrous Sulphate these range from nausea, epigastric discomfort, vomiting, constipation and diarrhoea[3]. Hence an attempt was made to compare the effect of *SammohaLoha* over Ferrous Sulphate.

Aim and Objectives:

- To evaluate the effect of *SammohaLoha* in *Panduroga*.
- To compare the efficacy of *SammohaLoha* over Ferrous Sulphate in *Panduroga*.

Materials and Methods:

Study Design: Randomized control single-blind comparative clinical study. It was conducted on subjects suffering from IDA. A computer-based randomized technique was adopted[4].

Sample Size and Grouping: A minimum of 40 patients suffering from *Panduroga* were selected and made into two groups randomly, Group A-20 patients and Group B-20 patients.

Selection of Cases: Patients suffering from the Signs and Symptoms of *Panduroga* (IDA) were selected from O.P.D. and I.P.D. of D.G.M.A.M.C. & Hospital Gadag, and medical camps were conducted after fulfilling the inclusion and exclusion criteria.

Inclusion Criteria:

1. *Panduta* in *Twak*, *Nakha*, *Netra*, *Jihwa*, *Hasthapadatala* (pallor in nails, conjunctiva, tongue, palm and sole), *Shrama* (fatigue), *Brama* (giddiness), *Dourbalya* (weakness), *Arohanaayasa* (exertional dysponea), *Aruchi* (anorexia), *Pindakodwestana* (muscle cramps) and *Gatrashoola* (body ache).
2. Patients of *Panduroga* between the age group of 10 – 60 years.
3. Hb% between 6 gm/dl - 10gm/dl.

Exclusion Criteria:

1. Known cases of Thalassemia, Sickle Cell Anemia, Pernicious Anemia.
2. Anemia associated with any malignancy.
3. Patients under chemotherapy and radiation treatment etc.
4. Patients suffering from DM and HTN.
5. Anemia due to hookworm infestation.

Selection of drug:

Background of drug selection: With the reference of Rasendra Sara Sangraha *SammohaLoha*[5] was chosen for the study. This is indicated in *Panduroga* and it contains drugs like *Pippali*, *Maricha*, *Shunti*, *Chitraka*, *Amalaki*, *Vibhitaki*, *Hritaki*, *Vidanga*, *Lohabhasma*, *Abhrakabhasma* and *Ghrita*. This has properties like *Balaya*, *Varnaya*, *Agnivardhana*, *Kamala*, *Pandurogahara*, *Hridroga*, *Shotahara*, *Krimighna*, hence the drug was chosen for the trial. Ferrous Sulphate was taken as a standard drug for comparison.

Table 1: Ingredients, parts used and proportion of trail drug

SL.NO	DRUG	BOTANICAL NAME	PART USED	PROPORTION
1	*Pippali*	*Piper longum*	Fruit	1 part
2	*Marica*	*Piper nigrum*	Fruit	1 part
3	*Sunthi*	*Zingiber Officinalis*	Rhizome	1 part
4	*Amalaki*	*Embelica officinalis*	Fruit pulp	1 part

5	*Vibhitaki*	*Terminalia belerica*	Fruit pulp	1 part
6	*Haritaki*	*Terminalia chebula*	Fruit pulp	1 part
7	*Vahni*	*Plumbago zeyalanica*	Root	1 part
8	*Vidanga*	*Embilicaribes*	Fruit	1 part
9	*Loha*	*Iron*	Incinerated iron	1 part
10	*Abhraka*	*Biotite*	Incinerated mica	1 part
11	*Ghrita*	*Ghee*	Ghee	q.s

Schedule of treatment: cases registered for the study were randomly grouped into two.

Group A- the patient was treated with a trial drug i.e. *SammohaLoha*, 250mg TID

Group B- the patient was treated with standard drug i.e. Ferrous Sulphate, 150mg TID

Form of drug – trial drug in the form of a capsule, standard drug in the form of a tablet.

Time – after food

Duration – 30days

The patient was assessed on the 0^{th}, 15^{th}, 30^{th}, 45^{th} and 60^{th} days.

Follow up – 30 days

Total study duration – 60 days

Approval of institutional ethical committee: Institutional ethical committee's approval has been taken for this comparative, randomized study.

Subjective Parameters: *Panduta* in *Twak*, *Nakha*, *Netra*, *Jihwa*, *Hasthapadatala*, *Shrama*, *Brama*, *Dourbalya*, *Arohanaayasa*, *Aruchi*, *Pindakodwestana* and *Gatrashoola*.

Objective Parameters: In this study CBC (red cell indices i.e. Haemoglobin levels, RBC, PCV/HCT, MCV, MCH, MCHC) and Serum Ferritin were the objective parameters undertaken.

Laboratory investigations:

- Complete blood count (CBC)
- RBS
- Serum Ferritin
- Stool examination (if necessary)
- Urine routine

Criteria for Assessment: assessment was done by considering the baseline of data, subjective and objective parameters to pre and post medication. All the results were analyzed statistically using the unpaired 't'-test.

Table 2: Grading of subjective parameters

Grades	***Panduta***	***Shrama***	***Bhrama***	***Arohanaayasa***
0	Absent	Absent except hard work	Absent	Absent after climbing the stairs
1	In any 2 of them	After moderate work for a certain time	Occasionally present	Exertion after climbing the stairs
2	In any 3 of these	After little work for a certain time	Frequently present	Exertion during climbing the stairs
3	In any 4 and more	After routine activities for a certain time	Persistent throughout the year	Unable to climb stairs

Grades	***Dourbalya***	***Aruchi***	***Pindakodwestana***	***Gatrashoola***
0	No feeling of Dourbalya during daily activities	Normal desire to take food	Absent	Absent except hard work
1	Sometimes felt but performs work	Most of the tines dislikes food	Occasionally present	After moderate work
2	Often the feeling of Dourbalya hampers daily activities	Dislikes food even though hungry but takes food	Frequently present	After light work
3	Always feeling of Dourbalya, unable to perform daily activities	Dislikes the food and takes a little or doesn't take food	Persistent (throughout the day)	After routine activities, needs medication

Objective Criteria Assessment: The following laboratory assessment was assessed pre and post-treatment - Hb%, PCV, RBC, MCV, MCH, MCHC and Serum Ferritin.

Observations and Results:

Table 3: Statistical analysis

	Group A				Group B			
Parameters	**Mean BT**	**Mean AT**	**% relief**	**P-value**	**Mean BT**	**Mean AT**	**% relief**	**P-value**
Panduta	2.1	0.65	60.97%	<0.0001	2.45	0.4	85.83%	<0.0001
Dourbalya	1.5	1.5	92.5%	<0.0001	1.8	0.1	95%	<0.0001
Shrama	1.4	0.3	74.16%	<0.0001	1.25	0	85%	<0.0001
Bharama	0.8	0.5	62.5%	<0.0001	0.7	0	60%	<0.0001
Pindakodwestana	1.1	0	85%	<0.0001	0.05	0.95	87.5%	<0.0001
Arohanaayasa	1.6	0.1	95%	<0.0001	1.75	0.05	97.5%	<0.0001
Aruchi	1.2	0	80%	<0.0001	0.6	0	90%	0.0004
Gatrashoola	0.95	0.05	82.5%	<0.0001	0.0	0.66	55%	0.0001
Shirashoola	0.65	0	95%	<0.0001	0.35	0.05	30%	0.01
Hb	9.12	9.67	5.36%	0.0002	8.85	10.87	18.76%	<0.0001
Rbc	4.31	4.24	-0.48%	0.33	4.13	4.35	5.07%	0.01
PCV	28.79	28.7	1.63%	0.97	28.33	32.93	13.25%	0.0005
MCV	64.8	68.24	4.45%	0.012	65.1	74.75	16.8%	<0.0001
MCH	21.35	22.59	9.57%	0.001	21.05	25.96	18.32%	<0.0001
MCHC	21.35	22.59	1.08%	0.001	31.7	32.9	2.45%	0.25
Sr. Ferritin	3.58	4.29	10.46%	0.06	6.29	29.31	86.36%	<0.0001

Table 4: Showing the comparative efficacy of the therapies in Group A and Group B by using unpaired 't' test

Sl.No.	Parameters of Assessment	Noof Pts	Group A			Group B			T value	P-value	Remark
			Mean	SD	SE	Mean	SD	SE			
1	*Panduta*	40	1.45	0.60	0.13	2.05	0.68	0.15	-2.93	0.005	S
2	*Dourbalya*	40	1.35	0.58	0.13	1.7	0.47	0.10	-2.08	0.04	S
3	*Shrama*	40	1.1	0.64	0.14	1.25	0.78	0.17	-0.66	0.51	N.S
4	*Brama*	40	0.75	0.63	0.14	0	0.65	0.14	0.24	0.80	N.S
5	*Pindakodvestana*	40	1.1	0.64	0.14	0.95	0.39	0.08	0.89	0.3	N.S
6	*Arohanaayasa*	40	1.5	0.60	0.13	1.7	0.47	0.10	-1.16	0.25	N.S
7	*Aruchi*	40	1.2	0.83	0.18	0.6	0.82	0.18	2.29	0.02	S
8	*Gatrashoola*	40	0.9	0.44	0.1	0.43	0.65	0.14	1.33	0.19	N.S
9	*Shirashoola*	40	0.65	0.48	0.10	0.3	0.47	0.10	2.30	0.02	S
10	Hb%	40	-0.55	0.54	0.12	-2.02	0.67	0.15	7.50	<0.0001	H.S
11	PCV/HCT	40	0.03	4.21	0.94	-4.6	4.94	1.10	3.18	0.002	S
12	RBC	40	0.06	0.30	0.06	-0.22	0.36	0.08	2.76	0.008	S
13	MCV	40	-3.36	5.48	1.22	-9.65	7.13	1.59	3.12	0.003	S
14	MCH	40	-1.24	1.44	0.32	-4.93	3.91	0.87	3.95	0.0005	H.S
15	MCHC	40	-1.24	1.44	0.32	-1.17	4.50	1	-0.061	0.95	N.S
16	Sr.Ferritin	40	-0.70	1.58	0.35	-23.01	8.47	1.89	11.56	<0.0001	H.S

Group A

Markedly improved – 4(20%)
Moderate improvement – 10(50%)
Mild improvement – 3(15%)
Unchanged – 3(15%)

Group B

Cured – 7(35%)
Markedly improved – 8(40%)
Moderate improvement – 3(15%)
Unchanged – 2(10%)

DISCUSSION

Panduroga is *Varnoplakshitavyadhi* (disease of dis-colouration) where *Panduta* looks like *Ketakidula*[6] mixture of white and yellow colour like pollen grains of *Ketaki* flower. Acharya Charaka tells *Pandu* as *Rasapradoshaja vyadhi*[7], Acharya Sushruta tells it as

Raktapradoshajavyadhi and here we must consider nutritional deficiency as *Rasapradoshaja* and lack of blood as *Raktapradoshaja*.

In this study 27(67.5%) of the patients belonged to the 20-30 age group, 6(15%) patients belonged to the 40-50 age group, 5(12.5%) patients belonged to the 30-40 age group and 1(2.5%) patient belonged to 10-20 and 50-60age group each. This shows that all the age group people get affected by *Panduroga*.

The study shows 34(85%) patients were middle class, 3(7.5%) were rich and 3(7.5%) were poor of socio-economic background. This shows all of them need to be educated about the disease.

The study showed 20(50%) of patients belonged to *the Vatapitta* type of *Shariraparkruti*, 18(45%) patients belonged to *Pittakaphaja* and 2(5%) patients belonged to *Vatakaphaja prakruti*. This shows *Vatapitta* are more prone *to Pittajavyadhi* followed by *Pittakaphaja prakruti* persons.

In this study, all of the 40(100%) patients had *Pandu-ta*, *Dourbalya* and *Arohanaayasa*. *Panduroga* itself tells *Pandu Varna* as cardinal feature. *Dourbalya* due to malnourishment of *Dhatus* leads to *Dhatukshaya* (depletion of tissues) which leads to debility. *Aroha-naayasa* be due to less amount of blood leads to less oxygen supply to the body tissues, hence body demands more oxygen causing exertional dysponea.

In this study, 35 (87.5%) of the subjects had *Shrama*, which may be due to *Dhatukshaya*, *Raktaalpata* (less amount of blood), as well as *Ojakshaya* (suppression of immunity) and 25 (62.5%) of the subjects, had *Bhrama*, may be due to *Rasakshaya*. In this study 25 (62.5%) of the patients had *Aruchi*. In *Panduroga*, there is *Dravarupa pitta vruddhi*, which leads to *mandagni* (decreased *Agni*) then the formation of *Ama* (undigested food particle), due to *Ama* there will be *Aruchi*.

In this study 34 (85%) of the subjects had *Pindako-dvestana*. This may be due to *Dhatukshaya* which leads to *Vatavruddhi* causes *Pindakodvestana*. In this study 26 (65%) of the patients had *Gatrashoola*. This may be due to *Vatavruddhi* and 22 (55%) of the patients had *Shirashoola*, which may be due to lack of blood supply and oxygen supply to the body tissues.

SammohaLoha contains drugs like *Pipali*, *Maricha*, *Shunti*, *Chitraka*, *Amalaki*, *Vibitaki*, *Haritaki*, *Vidanga*, *Lohabhasma*, *Abrakabhasma*. This has properties like *Balaya*, *Varnaya*, *Agnivardhaka*, *Pandu*, *Kamala Rogahara*, *Shotahara*, *Hridrogahara*, *Krimighana*, hence the drug is chosen for the trail. Trial medicine was prepared according to the classical reference.

In this yoga *Trikatu* i.e. *Pipali*, *Maricha*, *Shunti*, these are the *Ushna dravyas* which does *Amapachana*, *Agnideepana*, removes *Ama*, *Aruchi* and gives *Ruchikara*.

Tripahala i.e. *Amalaki*, *Vibhitaka*, *Haritaki* these are *Tridoshaghana*. *Haritaki* initiates *Anulomana* (regulation) effect and prevents the probable chances of constipation resulted due to *Loha* and *Abhrakabhasma*. *Amalaki* is a rich source of natural vitamin C which helps in the better absorption of iron. *Vibhitaki* has *Ushnaveerya* (hot potency) which does *Amapachana*(digests the *Ama*).

Vidanga the main karma is *Krimighana* (antihelmintic), as hookworm infestation is one of the causes for *Panduroga* it acts on *Krimi*(worm). *Chitraka* and *Vidanga* both are *Ushana dravyas* so does *Amapachana* and *Srotoshodhana*. *Lohabhasma* and *Abhrakabhasma* are the main iron contents in the drug, and they are *Ruchya*, *Ayushya*, *Balya*, *Rasayana* etc. Here the herbal ingredient corrects the metabolism and enhances the bioavailability of nutrients to the body.

Ferrous Sulphate is a Standard drug that was chosen for comparative study. Ferrous Sulphate is directly indicated in Iron Deficiency Anaemia, so it is chosen as a standard drug for comparison, and this was bought from the registered pharmacy.

Discussion on subjective parameters: Pallor, weakness, fatigue, giddiness, exertional dysponea, muscle cramps, anorexia, body ache and headache have been relived after treatment in a complaint to before treatment is 60.97%, 92.5%, 74.16%, 62.5%, 95%, 85%, 80%, 82.5% and 65% respectively where the p-value for all the above parameters is <0.0001which is highly significant with *SammohaLoha*.

Discussion on objective parameters: Hb%, RBC, PCV, MCV, MCH, MCHC and Serum Ferritin are the objective parameters, and their relief factor is 5.36%, -0.48%, 1.63%, 4.45%, 9.57%, 1.08% and 10.46% respectively and p values is 0.00002 (highly significant), 0.33 (not significant),0.97 (not significant), 0.012 (significant), 0.001(significant), 0.001(significant) and 0.06 (not significant) these were the statistical analysis noted in the trail group.

SammohaLoha has given highly significant results in subjective parameters, which shows that it corrects the basic pathophysiology. All the ingredients are in a combination of *Ushnaveerya*, *Deepana*, *Pachana* action which clears the undigested food particles and clears the channels, then helps in better absorption of nutrients to the body.

Patients under the Ferrous Sulphate group had highly significant results in both subjective and objective parameters. Among 20 patients 5 of them had side effects, two of them had constipation, two of them had nausea and one had epigastric discomfort. These were the common side effects of this drug which were noted during the ferrous sulphate medication intake.

CONCLUSION

Without a conclusion always a study is incomplete. *Panduroga* is one of the leading nutritional deficiencies in the world affecting all the age groups of people, mainly females than males.

Group A was given trial drug *SammohaLoha* and Group B was given standard drug Ferrous Sulphate. Among them, Group A has shown highly significant results in subjective parameters and Group B has shown highly significant results in both subjective and objective parameters.

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Source of Support: Nil
Conflict of Interest: None Declared

How to cite this URL: Rajeshwari M S & R V Shettar: A Standard Comparative Clinical Study On Panduroga W.S.R To Iron Defi-Ciency Anaemia With Sammoha Loha Over Ferrous Sulphate. International Ayurvedic Medical Journal {online} 2021 {cited September 2021} Available from: http://www.iamj.in/posts/images/upload/3090_3095.pdf