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"A PROSPECTIVE CLINICAL STUDY TO EVALUATE THE EFFICACY OF BIBHITAKADI MANDUR VATI IN COMPARISON WITH NAVAYAS LOHA IN THE MANAGEMENT OF PANDU W.S.R. TO IRON DEFFICIENCY ANAEMIA"

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ABSTRACT:

Pandu is one of the main medicinal disorder. A condition associated with a reduction in the haemoglobin concentration of the biood. *Ayurvedic* texts have described a variety of treatment options in the management of "*Pandu*". Despite of wide treatment options for its management which have multiplied over the recent years, yet considering the factors such as age, gender, education, religion, addiction, diet etc. is needed. *Bibhitakadi Mandur Vati* and *Navayas Loha* are mentioned in *Sushrut sanmhita and Sharangdhar sanmhita respectively.* in the management of *Pandu*. Both drugs are easily available, easy to consume and it is cost effective also. Therefore the present study was carried out for comparing clinical evaluation of the efficacy of *Bibhitakadi Mandur Vati* in comparison with *Navayas Loha.* Total 60 patients were selected by using purposive sampling method which was divided in 2 groups. The treatment conducted for 45 days. The responses to the treatment were recorded by parameters and therapeutic effects were evaluated by symptomatic relief. In the present study, according collected data, it is observed that both the drugs i.e. *Bibhitakadi Mandur Vati* and *Navayas Loha* has provided significant relief in all the symptoms of *Pandu.* .**As total comparison of both Group drugs mentioned that Group B drug (*Navayas Loha*) is Better effective than Group A drug (*Bibhitakadi Mandur***

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Vati).

Key words – *Pandu, Bibhitakadi Mandur Vati, Navayas Loha*.

INTRODUCTION

Nutritional deficiency anemia is very common in India and iron deficiency is the commonest nutritional deficiency all over the world. According to WHO, over one third of the world's population suffers from anemia, mostly it is due to iron deficiency.

Anemia affecting a large no. of women and children in developing countries. The no. are staggering: about 3 billian people i.e. over 30% of world's population are being anemic. It is genrally assumed that 50% of the cases of anemia are due to iron defficiency.

National Family Health Survey (NFHS-3) reveals the prevelence of anemia to be 80% in children, 68% in pregnent women and 24% in adult men.

Ayurveda mainly deals with maintenance & promotion of health of healthy person i.e. *dhatu-samya kriya*. As the name denotes the main feature of *Pandu Roga* is *Pandutwa*. According to *Charaka*, it is one among the *Rasavaha srotodushti*[1]. *Sushruta* has mentioned it as *Raktavaha Srotodushti*[2]. *Jeevana* is the Karma of *Raktha dhatu.*

The Sign and symptoms of *Pandu* include *daurbalya, bhrama, tandra, agnimandya,* breathlessness and palpitation, particularly with physical exertion and pallor of the skin and the mucous membrane.

Anaemia is one of the main medicinal disorder. A condition associated with a reduction in the haemoglobin concentration of the biood[3]. Commonly occurs in females. *Ayurvedic* texts have described a variety of treatment options in the management of "*Pandu*". Good numbers of researches have brought few recipes sufficiently efficacious; however the attempt to find new recipes or remedies never ends. *Bibhitakadi Mandur Vati*[4] and *Navayas Loha*[5] are mentioned in *Sushrut sanmhita and Sharangdhar sanmhita respectively,* in the management of *Pandu*. Both drugs are easily available, easy to consume and it is cost effective also. So this study has been selected.

AIM AND OBJECTIVES-

Aim-

To compare the effects of *Bibhitakadi Mandur Vati* & *Navayas*

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Loha in the management of *Pandu.*

Objectives-

1. To Study the efficacy of *Bibhitakadi mandur vati* on Pandu

2. To study the *pandu* and it's *chikitsa* with the help of *Bibhitakadi Mandur vati* and *Navayas Loha.*

3. To study the pathophysiology of Iron deficiency anaemia.

Methodology

MATERIALS AND METHODS

Randomly selected 60 patients of *Pandu* attending OPD and IPD department of *Kayachikitsa* were included in study and divided into 2 groups.

Group A and Group B

All the patients fulfilling inclusion and exclusion criteria were selected for the study with fully informed consent

	Group A	Group B
No of Patients	30	30
Drug	*Bibhitakadi Mandur Vati*	*Navayas Loha*
Matra (per day)	250 mg 2 tab BD	250 mg 2tab BD
Anupan	*Takra*	*Ghrita*
Duration	45 days	45 days
Sevankal	Twice a day	Twice a day
Follow-up	After 15 days	After 15 days
No of follow – ups	3	3

SELECTION CRITERIA

Inciusion Criteria

1) Patient with Hb% within the range of 7 to 12 gm%

2) Patients of either sex.

3) Age :- 16 to 60 years.

4) *Vataj, Pittaj, Kaphaj Pandu.*

5) Iron Deficiency anemia.

Exclusion Criteria

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1) Patient with Hb% below 7 gm% and above 12 gm%

2) Age below 16 years and above 60 years

3) All types of anemia except iron-deficiency anemia.

4) Pregnancy and lactation.

5) Patients with the history of other systemic diseases like diabetes mellitus and hypertension. Patients suffering from disorder associated with GIT, bleeding piles, malignancies.

Subjective Criteria:

The predominant signs and symptoms of *Pandu* According to *Ayurvedic* texts like, i. *e charak samhita, sartha vagbhat*[6]

1) Daurbalya

2) Shrama

3) Arohanaayasa

4) Hritspandan

5) Rukshata

6) Pandutwa

7) Bhrama

Clinical Study-

- A single blind randomize clinical trial was carried out.
- Selected patients were randomly divided into two groups.
- Group A & Group B
- A special case paper was prepared to note the history & clinical findings of the patients before during & after the treatment.
- The treatment started on day of counseling, for 45 days which were noted in the tabular form.
- During the course of treatment both groups were advised similar dietary & behavioral instructions

CRITERIA FOR ASSESMENT:

GRADATION OF SYMPTOMS:

A*) Daurbalya* (Weakness):

0: No weakness

1: Weakness not affecting the daily activities of the subject

2: Weakness affecting the daily activities of the subject

3: Activities reduced due to weakness of the subject.

B) *Shrama* (Fatigue):

0: No Fatigue

1: On prolonged physical activity

2: In the morning time and may increase during day time

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3: For longe duration, even at rest.

C)*Arohan-aayasa* (Breathlessness)[7]:

0: No Breathlessness

1: Troubled by shortness of breath on level or up-hill.

2: Walks slower than person of same age.

3: Stops after walking 100 yds (300ft).

4: Breathlessness at rest.

D) *Hrit-spandana* (Palpitation):

0: No Palpitation

1: Palpitation with routine physical work

2: Palpitation with normal activities like walking

3: Palpitation during rest.

E*) Rukshata* (Dryness of skin)

0: No dryness

1: Mild dryness all over the body

2: Dryness all over the body with cracking of lips, palms
and soles

3: Severe dryness of skin with cracking and bleeding.

F*) Pandutwa* (Pallor):

0: No Pallor

1: Conjunctiva slightly pale, nail and other mucus membrane not pale

2: Conjunctiva pale, nail and other mucus membrane slightly pale

3: Conjunctiva, nails and other mucus membrane pale.

G*) Bhrama* (Giddiness):

0: No *Bhrama*

1: Occuring while subject changing his position from supine to standing

2: Occuring while walking

3: subject falls down on ground.

INVESTIGATION

Complete Blood Count (Haemogram)

OBJECTIVE CRITERIA:

Haemoglobin (in gm/dl)

0: ≥ 12

1: 10 to 11.99

2: 8.6 to 10

3: 7 to 8.5

OBSERVATION AND RESULTS

Total 43 patients were taken in group A and 35 patients were taken in group B. Out of which 30 patients for each group were selected randomly for the project work. All the selected patients were thoroughly examined and diagnosed and selected, based on exclusive and

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inclusive criteria. The assignment revealed the following statistics.

Discussion on Observations –

Age:

In the present study, maximum no. of patients i.e. 50 % were from the age group of 18 to 30 year.

Gender:

In the present study, maximum numbers of patients i.e. 73.33% were females.

Education:

In present study, more patients i.e. 31.67 % had completed their education till high school followed by Graduate level.

Occupation:

In the present study maximum 31.67 % patients were accustomed to desk work type of occupation.

Economical Status:

In the present study, Patients belonging to the middle class i.e.35% were more affected by *Pandu* (Iron Deficiency Anemia).

Religion:

This Study records larger number of Hindus i.e.86.67 %.

Marital Status:

The present study shows that 80.00 % patients were married were the most sufferers of *Pandu*.

Diet:

Patients having pure vegetarian type of diet pattern were maximum i.e. 71.67%.

Addiction:

The present study revealed that majority of the patients i.e. 63.33 % were not having any type of addiction.

Dominance of *Rasa in aahara:*

In the present study, 63.33 % were having all type of *rasa in aahara* not specific.

Desh:

The present study reveals that 83.33 % patients were belonged to *sadharana* type of *desh*.

Locality:

61.67 % patients were belonged to the rural area

.Aakruti:

In the present study, 63.33 % patients were having *madhyama aakruti*.

Nidra:

The present study showed that majority i.e. 71.67 % patients were having *prakrut nidra.*

Agni:

The present study showed that majority i.e. 48.33 % of the patients were having *Mandagni.*

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Koshtha:

The present study showed that maximum i.e. 51.67 % patients were having *madhya Koshtha*

Prakruti:

Maximum no. of patients i.e. 28.33 % were having *Pitta-Kapha prakriti*.

COMPARATIVE ANALYSIS[8]:

Statistical Analysis:-

The null hypothesis, H_0:

The effect of treatment on all symptoms in *BIBHITAKADI MANDUR VATI* (Group A) is not significant than in *NAVAYAS LOHA* (Group B).

The alternative hypothesis H_a:

The effect of treatment on all symptoms in *BIBHITAKADI MANDUR VATI* (Group A) is significant than in *NAVAYAS LOHA* (Group B).

All the values in following tables are calculated by using Mann – Whiteny test for subjective criteria and Unpaired t test for the objective criteria. Let us see the statistical analysis for every symptom separately.

Symptom	*Daurbalya*
N	57
Mean of Group A	1.185
Mean of Group B	1.33
S.D. (±) of Group A	0.483
S.D. (±) of Group B	0.345

S.E.(±) of Group A	0.093
S.E.(±) of Group B	0.063
U	397
U ‘	4.3
P	>0.05

As the p value is greater than the significance level alpha = 0.05, we should accept the null hypothesis H_0 and reject the alternative hypothesis H_a, i.e. *BIBHITAKADI MANDUR VATI* (Group A) is not significant than in *NAVAYAS LOHA* (Group B) for *Daurbalya.*

Symptom	*Shrama*
N	51
Mean of Group A	1.043
Mean of Group B	1.143
S.D. (±), of Group A	0.208
S.D. (±), of Group B	0.356
S.E.(±), of Group A	0.043
S.E.(±), of Group B	0.067

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U	290
U ‘	354
P	>0.05

As the p value is greater than the significance level alpha = 0.05, we should accept the null hypothesis H_0 and reject the alternative hypothesis H_a, i.e. *BIBHITAKADI MANDUR VATI* (Group A) is not significant than in *NAVAYAS LOHA* (Group B) for *Shrama*

Symptom	*Aarohan-aayas*
N	51
Mean of Group A	1.042
Mean of Group B	1.037
S.D. (±), B.T.	0.204
S.D. (±), A.T.	0.192
S.E.(±), B.T.	0.041
S.E.(±), A.T.	0.037
U	322.5
U ‘	325.5
P	>0.05

As the p value is greater than the significance level alpha = 0.05, we should accept the null hypothesis H_0 and reject the alternative hypothesis H_a, i.e. *BIBHITAKADI MANDUR VATI* (Group A) is not significant than in *NAVAYAS LOHA* (Group B) for *Aarohan-aayas.*

Symptom	*Hrit-Spandan*
N	20
Mean of Group A	1.111
Mean of Group B	1.091
S.D. (±), B.T.	0.333
S.D. (±), A.T.	0.301
S.E.(±), B.T.	0.111
S.E.(±), A.T.	0.09
U	48.5
U ‘	50.5
P	>0.05

As the p value is greater than the significance level alpha = 0.05, we should accept the null hypothesis H_0 and reject the alternative hypothesis H_a, i.e. *BIBHITAKADI MANDUR VATI* (Group A) is not significant than in *NAVAYAS LOHA* (Group B) for *Hrit-spandan*.

Symptom	*Rukshata*
N	42
Mean of Group A	1.133
Mean of Group B	1.111
S.D. (±), B.T.	0.351
S.D. (±), A.T.	0.32
S.E.(±), B.T.	0.09
S.E.(±), A.T.	0.061

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U	198
U ‘	207
P	>0.05

As the p value is greater than the significance level alpha = 0.05, we should accept the null hypothesis H_0 and reject the alternative hypothesis H_a, i.e. *BIBHITAKADI MANDUR VATI* (Group A) is not significant than in *NAVAYAS LOHA* (Group B) for *Rukshata.*

Symptom	*Pandutva*
N	53
Mean of Group A	1.042
Mean of Group B	1.138
S.D. (±), B.T.	0.204
S.D. (±), A.T.	0.35
S.E.(±), B.T.	0.041
S.E.(±), A.T.	0.065
U	314.5
U ‘	381.5
P	>0.05

As the p value is greater than the significance level alpha = 0.05, we should accept the null hypothesis H_0 and reject the alternative hypothesis H_a, i.e. *BIBHITAKADI MANDUR VATI* (Group A) is not significant than in *NAVAYAS LOHA* (Group B) for *Pandutva.*

Symptom	*Bhrama*
N	34
Mean of Group A	1.06
Mean of Group B	1.111
S.D. (±), B.T.	0.25
S.D. (±), A.T.	0.323
S.E.(±), B.T.	0.062
S.E.(±), A.T.	0.076
U	137
U ‘	151
P	>0.05

As the p value is greater than the significance level alpha = 0.05, we should accept the null hypothesis H_0 and reject the alternative hypothesis H_a, i.e. *BIBHITAKADI MANDUR VATI* (Group A) is not significant than in *NAVAYAS LOHA* (Group B) for *Bhrama.*

Symptom	Haemoglobin
N	60
Mean Difference Score, Group A	0.837
Mean Difference Score, Group B	1.357
Combined S.D. (±)	0.459
S.E. (±)	0.118

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Unpaired t	4.38
P	>0.01
Result	Significant

As the t value calculated is greater than the t tabulated value at p>0.01, where df = 58, we should reject the null hypothesis H_0 and accept the alternative hypothesis H_a, i.e. *Navayas Loha* (Group B) is significant than *Bibhitakadi Mandur Vati* (Group A) for Haemoglobin.

Symptom	RBC
N	60
Mean Difference Score, Group A	0.552
Mean Difference Score, Group B	0.825
Combined S.D. (±)	0.431
S.E. (±)	0.111
Unpaired t	2.449
P	>0.02
Result	Significant

As the t value calculated is greater than the t tabulated value at p>0.02, where df = 58, we should reject the null hypothesis H_0 and accept the alternative hypothesis H_a, i.e. *Navayas Loha* (Group B) is significant than *Bibhitakadi Mandur Vati* (Group A) for RBC.

Symptom	HCT
N	60
Mean Difference Score, Group A	3.41
Mean Difference Score, Group B	4.42
Combined S.D. (±)	2.445
S.E. (±)	0.631
Unpaired t	2.09
P	>0.05
Result	Significant

As the t value calculated is greater than the t tabulated value at p>0.05, where df = 58, we should reject the null hypothesis H_0 and accept the alternative hypothesis H_a, i.e. *Navayas Loha* (Group B) is significant than *Bibhitakadi Mandur Vati* (Group A) for HCT.

Symptom	MCV
N	60
Mean Difference Score, Group A	8.917
Mean Difference	12.51

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Score, Group B	
Combined S.D. (±)	0.187
S.E. (±)	1.597
Unpaired t	2.247
P	>0.05
Result	Significant

As the t value calculated is greater than the t tabulated value at p>0.01, where df = 58, we should reject the null hypothesis H_0 and accept the alternative hypothesis H_a, i.e. *Navayas Loha* (Group B) is significant than *Bibhitakadi Mandur Vati* (Group A) for MCV.

Symptom	MCH
N	60
Mean Difference Score, Group A	3.53
Mean Difference Score, Group B	4.463
Combined S.D. (±)	1.76
S.E. (±)	0.454
Unpaired t	2.053
P	>0.05
Result	Significant

As the t value calculated is greater than ject the null hypothesis H_0 and accept the alternative hypothesis H_a, i.e. *Navayas Loha* (Group B) is significant than *Bibhitakadi Mandur Vati* (Group A) for MCH.

Symptom	MCHC
N	60
Mean Difference Score, Group A	0.607
Mean Difference Score, Group B	1.1
Combined S.D. (±)	0.904
S.E. (±)	0.233
Unpaired t	2.119
P	>0.05
Result	Significant

As the t value calculated is greater than the t tabulated value at p<0.01, where df = 58, we should reject the null hypothesis H_0 and accept the alternative hypothesis H_a, i.e. *Navayas Loha* (Group B) is significant than *Bibhitakadi Mandur Vati* (Group A) for MCHC.

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% RELIEF in OBSERVATIONS

Symptoms	% Relief	
	BIBHITAKADI MADUR VATI	*NAVAYAS LOHA*
Daurbalya	65.3%	68%
Shrama	54.54%	71.11%
Aarohan-aayas	58.13%	65.11%
Hrit-spandan	38.46%	42.85%
Rukshata	42.5%	76.92%
Pandutva	48%	61.11%
Bhrama	47.22%	56.75%

OVERALL EFFECT OF THERAPY on 60 patients of *Pandu*

Result	Group A		Group B	
	Number of patients	%	Number of patients	%
Complete remission (>80 %)	4	13.33%	8	26.66%
Marked improvement (60 – 80 %)	10	33.33%	9	30%
Moderate improvement (40 – 60 %)	8	26.66%	10	33.33%
Mild improvement (20-40 %)	6	20%	3	10%
N0 Relief or less than 20%	2	6.66	0	0

on all sign and symptoms of *Pandu.*

RESULT

Both *Bibhitakai Mandur Vati* and *Navayas Loha* are statistically effective But the *Navayas Loha* is comparatively

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much more effective than the *Bibhitakadi Mandur Vati* on all sign and symptoms of *Pandu.*

Discussion on probable action of *Bibhitakadi Mandur Vati-*[9]

Drug Name	*Rasa*	*Vipak*	*Virya*	*Karma* and *Rogaghnata*
Bibhitak	*Kashay*	*Madhur*	*Ushna*	*Shothahara, Dhatuvardhak.*
Shunthi	*Katu*	*Madhur*	*Ushna*	*Shothahara.*
Mandur	*Kashay*	*Katu*	*Sheeta*	*Raktavardhak,Pittashamak.*
Gud	*Madhur*	*Madhur*	*Ushna*	*Shothahara, Balya.*
Krushna Til	*Madhur, Kashay, Tikta,Katu*	*Madhur*	*Ushna*	*Balya*

Bibhitak has raktastambhan action due to *kashaya rasa,* therefore it is useful in *raktasravajanya Pandu*. Action of *Bibhitak* is *dhatuvardhak* due to *madhur vipak.*

-*Shunthi* has *agnidipana* and *amapachana* property, therefore it helps in *Agni vriddhi* and stimulates the heart and circulation.

and also *dhatuvardhak* by its *madhur vipak*.

-Action of *Mandur* is *Raktavardhak* and *Pittashamaka* due to *sheeta virya*.

-Due to *madhur,kashay,tikta,katu rasa* of *krushna til twakrukshata* in *pandu* is decreased.

-By *madhur vipak, Gud* is *shothahara* and *Raktavardhak* in *Pandu.*

CONCLUSION

Bibhitakadi Mandur Vati and *Navayas Loha* are beneficial in the treatment of *Pandu* .

Comparatively *Navayas Loha* (GroupB) provided better results as compared to *Bibhitakadi Mandur Vati* (Group A) in regarding improvement in signs and symptoms of *Pandu.*

Bibhitakadi Mandur Vati (Group A) is effective in *Daurbalya, Shrama, Arohan-*

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ayas, Hritspandan, Rukshata, Panduta, Bhrama. It also effective in increasing HB%, RBC, HCT, MCV, MCH, MCHC Values.

Comparatively, *Navayas Loha* (Group B) is more effective in *Daurbalya, Shrama, Arohan-ayas, Hritspandan, Rukshata, Panduta, Bhrama* and the HB%, RBC, HCT, MCV, MCH, MCHC Values than *Bibhitakadi Mandur Vati* (Group A)

45 days treatment of *Bibhitakadi Madur Vati* increases the Hb by 0.837 gm % and by taking treatment for same period, *Navayas Loha* increases Hb by 1.357 gm %.

Pandu is a *Tridoshaja vyadhi* with the main vitiated dosha *pitta.*

Indulgence of *katu, ruksha, laghu ahara, vegavidharana, vishamashana* indicates *apatarpanjanya* origin of the disease and *diwaswapna, Vyayama-varjana, madhura, guru ahara* indicates *Santarpanjanya* origin of the disease.

The *manas bhavas* like *Chinta, Krodha, Bhaya* and *Shoka* play an important role in vitiating the *sadhak pitta*, which is the root cause of the disease.

Females, more prone to the disease.

Change in life style, change in dietary habits, and faulty dietary habits leads to formation of *pitta*, leading to *Pandu*

This study provides the new *Shamana yoga* in the management of the

Contents of the *Bibhitakadi Madur Vati* are easily available and cheap compare to other formulation which are commonly used in *Pandu.* So physicians can use this drug onwards.

As total comparison of both Group *Navayas Loha* (Group B) is more effective in *Daurbalya, Shrama, Arohan-ayas, Hritspandan, Rukshata, Panduta, Bhrama* and the HB%, RBC, HCT, MCV, MCH, MCHC Values than *Bibhitakadi Mandur Vati.* (Group A)

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