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An Evaluation of the Efficacy of *Tapyadi Loha* in *Garavishajanit Pandu*

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Abstract

The frequent and consistent intake of Viruddhahar also correlated as Garavisha by Vagbhatacharya causes vitiation of the Dosha especially Pitta Dosha further resulting in vitiation of Dhatu and the inappropriate formation of Aahar Rasa. This ultimately leads to Dhatukshaya especially Raktakshaya and subsequently manifests as Pandu showing symptoms of Agnimandya, Aruchi, Daurbalya, Shvasa, Jvara, Gaurav etc.

Forty patients were diagnosed with Garavishajanit Pandu on the basis of a special questionnaire and case report form. They were subjected to clinical trials conducted at Bharati Vidyapeeth Medical Foundation's Ayurved Hospital and Research Center, Pune. They were randomly allotted by lottery method to Control or Trial group of 20 patients each. IEC clearance and Informed consent were taken prior to commencement of study. Both groups were administered Avipattikar Churna as Mridu shodhan for the first 7 days as premedication. Trial group was administered the Tapyadi Loha at Vyanodan Kala whereas Control group received Tab.Raricap once daily for 30 days each. Appropriately graded Subjective and objective parameters were assessed on a weekly basis.

Significant results were noted in Agnimandya, Aruchi, Jvara, Gaurava, Angamarda, Shvasa, Akshikuta Shotha in both groups as also Hb% and RBC count using appropriate tests for statistical analysis.

Keywords

Viruddhahar, Garavisha, Pandu, Tapyadi Loha, Avipattikar Churna

Greentree Group

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INTRODUCTION

The current lifestyle invariably includes the consumption of fast food, variations in traditional recipes and irregular and untimely eating habits that can be collectively categorized under the aegis of *'Viruddhahar'*. Such trends can be further subjugated as *Matra Viruddha; Kala Viruddha; Sanskar Viruddha*[1] and the like.

Vagbhatacharya correlates this with *'Garavisha'*[2]. He states it as an aetiological factor of a variety of diseases, *Pandu* being one of them[3]. This disease has also been re-iterated by *Charakacharya.*

The frequent and consistent intake of such *Viruddhahar* causes vitiation of the *Pitta Pradhan Doshadushti* further resulting in vitiation of *Rasa-Raktadi Dhatu* and the inappropriate formation of *Aahar Rasa*. This ultimately leads to *Bala-Varna-Ojakshaya* and subsequently manifests as *Agnimandya, Aruchi, Daurbalya, Shvasa, Jvara, Gaurav* etc[4].

A survey conducted to study the prevalence of consumption of *Viruddhahar* with *Pandu* as its outcome revealed the former to be a prime aetiological factor of *Pandu* and symptoms produced thereof simulated those of *Pandu Vyadhi*. *Viruddhahar being* synonymous with *Garavisha*, the condition was termed as *Garavishajanit Pandu*. So for *Shodhan* of *GaraVisha, Avipattikar Churna* was used as *Mridu Virechan* and *Tapyadi Loha* was used as *Rakta Vardhan*. *Avipattikar Churna* is *KatuRasapradhan, Laghu, Ushna,Katuvipak, Deepana, Pachana* and *Mridu Rechan*. *Tapyadi Loha,* which is indicated in both *Pandu* and *Visha*[5] seemed to be an appropriate *Rakta Vardhan Dravya* with *Svarna Makshika, Shilajita, Rajat Bhasma, Mandura* and *Triphala* and an appropriate *Deepana-Pachana Dravya* with *Chitraka, Shunthi, Maricha, Pippali* and *Vidanga.*It is also an appropriate *Vishahara Dravya* with *Svarna Makshika* and *Rajat Bhasma*.

The treatment of *Garavisha* as *Hetuviparit Chikitsa* and the manifestations of *Pandu* as *Vyadhiviparit Chikitsa* become components of management. Thus in *Viruddhaharjanit Pandu*, the treatment protocol should comprise removal of *Viruddhaharjanit Garavisha* and vitiated *Dosha* involved, thus indicating the administration of *Vamana* (emesis) and *Virechana*(purgation) and then administration of *Shaman Dravya*[6].

Tapyadi Loha is also used in *Pandu* and *Visha*. Among the *Dravya* of *Tapyadi Loha,*

Rasaushadhi have *Rakta Prasadana* and *Rasayana* qualities. *Triphala* is *Deepana-Pachana* whereas *Chitrak, Shunthi, Marich, Pippali* and *Vidanga* are *Ushna Virya.* Besides *Svarna Makshika* and *Rajat Bhasma* show *Vishahara* properties. Hence, this was the apt choice as the Trial Drug or *Vyadhi Viparit Dravya.*

Raricap tablets, used as the Standard Control Drug have a greater iron absorbance due to Ferrous Calcium Citrate (FCC) as its key constituent. It also has no GI disturbances as side effects since it has a Multilayered Delivery System (MDS) enabling duodenal release of iron for better absorption[7].

Avipattikar Churna as per *Vagbhatacharya*, is used in *Pandu* and all types of *Visha. Gunakarmadi* of the *Avipattikar Churna* can be summarised as a *Katurasapradhan, Laghu, Ushna ,Katuvipak, Deepana, Pachana* and *Mridu Rechan Dravya,* thus chosen as premedication to aid *Shodhan* i.e. *Hetu Viparit Chikitsa*[8].

A careful study of the previous work done showed that many *Ayurvedic* formulations have been tested for their efficacy in *Pandu*. Eg.*Tapyadi Loha, Mandur Vatak, Nishaloha Vati, Navayas Loha, Triphala-Mandur, Darvyadi Churna, Punarnavadi Mandur, Dadimadi Ghrita* etc. Studies on *Garavisha* and other *Vyadhi* arising thereof have also been done. However, no study has been conducted so far to evaluate the efficacy of *Tapyadi Loha* in *Garavishajanit Pandu.*

AIM AND OBJECTIVES

Aim:

- To study the efficacy of *Tapyadi Loha* in *Garavishajanit Pandu*.

Objectives:

- Identification of a traditional formulation as a cure for *Garavishajanit Pandu*.
- Evaluation of clinical efficacy of *Hetu* and *Vyadhiviparit Chikitsa* in *Garavishajanit Pandu*.
- Observation of side effects (if any) during treatment.

HYPOTHESIS:

- **H0:** Use of *Tapyadi Loha* is not an effective treatment for *Garavishajanit Pandu.*
- **H1:** Use of *Tapyadi Loha* is an effective treatment for *Garavishajanit Pandu.*

MATERIALS AND METHODS

Avipattikar Churna and Tapyadi Loha raw material were purchased from Manakarnika Aushadhalaya, Pune; authenticated and mixed together following the Standard Operating Procedures (SOP) to prepare the final product as per GMP standards. They were then standardized and found to comply with the API norms.

Randomized Clinical Trial (RCT) was conducted at Bharati Vidyaeeth Medical Foundation's Ayurved Hospital & Research Centre, Katraj- Dhankawadi, Pune-411043following permission of the Institutional Ethics Committee (IEC No. BVDU/COA/40/2014-15, dated 24/04/2014).

1)Patients consuming *Viruddhahara* as per questionnaire and showing symptoms of *Pandu* as stated in the subjective parameters of assessment, irrespective of gender and with a low Haemoglobin concentration of 8-12 gm% in Males and 6-10 gm% in females were included in the study.

2) However, an Hb<8 gm% in Males and Hb<6 gm% in Female or those with a history of other systemic diseases like diabetes mellitus, hypertension, tuberculosis, cardiac diseases etc, those having *Panduroga* as an *Upadrava* of other diseases and known cases of congenital anaemia like thalassaemia, sickle cell anaemia, leukaemia, aplastic anaemia, anaemia due to bleeding piles, haemophilia, menorrhagia, pregnancy etc. were excluded from the study.

3) Patients diagnosed with *Garvishajanit Pandu* in accordance with questionnaire and Case proforma were randomly divided in to two groups by lottery method viz. Group A/Control Group and Group B/ Trial Group of 20 patients each.

4) Informed Consent was taken from each enrolled patient.

5) Both groups received *Avipattikar Churna* for the first 7 days as pre-medication drug for *Shodhan* in *Koshthaanurupa Matra* with *Koshnajala* at *Nisha Kala.*

6) The patients of Group A were administered Tab. Raricap once daily from Day 8 to Day 35.

7) The patients of Group B were administered *Tapyadi Loha* 250 mg with *Madhu* at *Vyanodan Kala* from Day 8 to Day 35.

8) *Agnimandya, Aruchi, Daurbalya, Jvara, Gaurava, Angamarda, GatraSaithilya, Shvasa, Akshikuta Sotha, Shabda Asahishnuta* formed the Subjective Parameters of assessment based on the

survey study and references from the classics.

9) Weekly follow-ups were taken on Day 7, 14, 21, 28 and 35 to assess Subjective Parameters.

10)Pre and post-trial laboratory investigations of Hb% and RBC count were done in accordance with objective parameters i.e. Day 0 and Day 35.

RESULTS AND DISCUSSION

1] General Observations:

✓ A total of 217 Patients were screened for the study out of which 89 fulfilled the criteria of assessment as per the questionnaire and case proforma. A total of 48 patients were enrolled in the study but a dropout of 8 patients was seen.

✓ In Control Group 55%, while 45% of Trial Group patients belonged to 18-23 years age group which is the age when consumption of *Viruddhahar* is frequent.[Fig 1] [Table 1]

✓ Both Control and Trial groups, showed a female predominance of 70% and 80% respectively indicating them to be more prone to be the condition.[Fig 2] [Table 2]

Table 1"Comparison of Age Distribution"

Age Group	Control Group		Trial Group	
	Frequency	%	Frequency	%
18-23	11	**55**	9	**45**
24-29	6	30	7	35
30-35	2	10	2	10
36-41	0	0	1	5
42-47	1	5	1	5
TOTAL	20	100	20	100

Table 2"Comparison of Gender"

Gender	Control Group		Trial Group	
	Frequency	%	Frequency	%
Male	6	30	4	20
Female	14	**70**	16	**80**
TOTAL	20	100	20	100

Fig 1 "Comparison of Age Distribution"

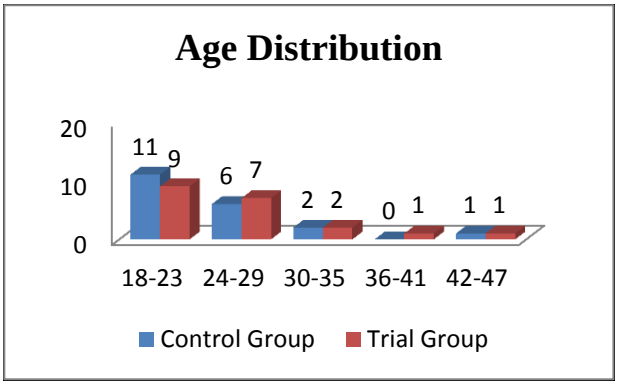
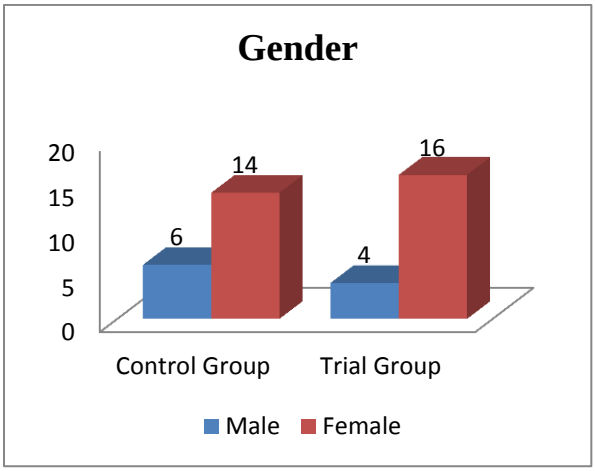


Fig 2 "Comparison of Gender"



2] Parameters of Assessment:

✓ Out of the 10 subjective parameters, **9 except *Shabda Ashishnuta*** showed **significant** result in **Trial group.**

✓ Out of the 10 subjective parameters, **7 except *Shabda Ashishnuta* ,*Gatra Shaithilya*** and ***Daurbalya*** showed **significant** result in **Control group.**

✓ The objective parameters compared before and after trial in both groups showed **significant** result. In **Control group** Hb rise from 0.5 to 2.4gm% and in **Trial group** Hb increase in a range of 0 to 2.8gm%.

✓ A conversion from **Hypochromic Microcytic to Normocytic Normochromic** in blood pictures of RBCs.

The Wilcoxon Signed Rank test was used to analyse drug efficacy of the Subjective parameters while T-test was applied for Objective parameters. Mann-Whitney U-test was used for inter-group comparison subjective parameters whereas Unpaired t-test analysed the Objective parameters.

Subjective Parameters:-

➢ *Agnimandya:-*

- A maximum of 14 patients in Control Group showed a severity of grade 3 in *Lakshan Agnimandya* on day 0 which was reduced to grade 0 in 9 patients by day 35.[Fig 3]
- A maximum of 17 patients in Trial Group showed a severity of grade 3 in *Lakshan Agnimandya* on day 0 which was reduced to grade 0 in 13 patients by day 35.[Fig 3]
- For comparison between Trial Group and Control Group the Mann Whitney U test, was used. Here, P-Value is greater than 0.05, hence **no significant difference** is noted in Trial and Control Groups i.e. both are **equally effective**. [Table 3]

Agnimandya was more effectively reduced in Trial group due to *Deepana-Pachana Dravya* of *Tapyadi Loha* viz. *Mandura, Chitraka, Vidanga, Shunthi, Pippali* as well as *Shodhan* effect of *Avipattikar Churna.*

Table 3"Comparison of *Agnimandya*"

Agnimandya	Median Improvement	Mann Whitney U Test	P-Value
Control Group	3.0	150.000	.114
Trial Group	3.0		

Table 4"Comparison of *Aruchi*"

Aruchi	Median Improvement	Mann Whitney U Test	P-Value
Control Group	2.0	30.000	.000

Trial Group	3.0

Fig 3 "Comparison of *Agnimandya*"

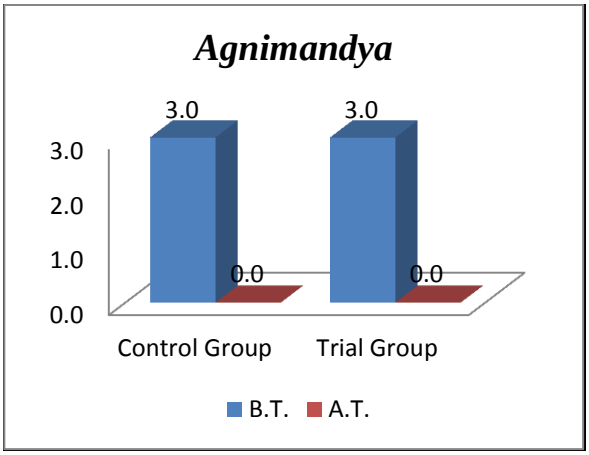
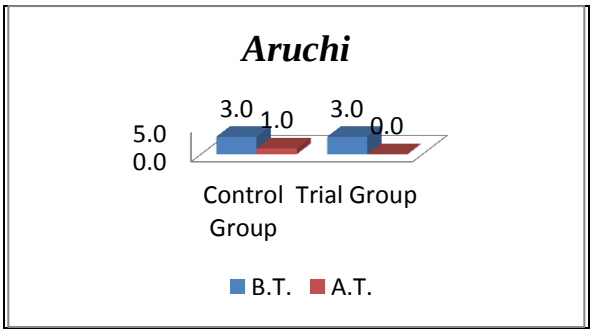


Fig 4 "Comparison of *Aruchi*"



➢ *Aruchi :-*

- A maximum of 15 patients in Control Group showed a severity of grade 3 in *Lakshan Aruchi* on day 0 which was reduced to grade 0 in 8 patients by day 35.[Fig 4]
- A maximum of 17 patients in Trial Group showed a severity of grade 3 in *Lakshan Aruchi* on day 0 which was reduced to grade 0 in 15 patients by day 35.[Fig 4]
- For comparison between Trial Group and Control Group Mann Whitney U test was used. From the above table it can be observed that P-Value is less than 0.05. Hence, there is significant difference in Trial Group and Control Group. Also **Trial Group is more effective** than Control Group as median improvement observed is more in Trial Group.[Table 4]
- The symptom of *Aruchi* was alleviated to a greater extent in Trial group due to *Ruchikar Dravya* in *Tapyadi Loha* viz. *Raupya, Mandura, Shunthi*.

➢ Similar results were noted in the symptoms of *Jvara, Gaurava, Shvasa, Akshikuta Shotha and Gatra Shaithilya.*

➢ *Jvara* was cured due to *Katu-Mahur Rasatmaka and Jvaraghan* property of *Tapyadi Loha.* Similar reduction in Control group was also seen which may be due to nutritional diet and *Nidan Parivarjan*.

➢ The overall relief in *Gaurava* is seen because of *Yathauchit Vegotsarg* achieved by *Jirna Ahar Rasa* causing *Sharir Laghav.*

➢ A reduction in *Shvasa* can be due to the *Shavasahara* properties of *Pippali, Ushna, Deepana, Pachana, Vatanuloman* properties of *Haritaki* and *Marich* and the *Rasayan Karma* of *Shilajeet*.

➢ *Akshikuta Shotha* is an important symptom noted in *Pandu* which alleviated due to the *Rakta Vardhak ,Rasayan,* and *Shothahara properties* of *Svarnamakshik,Shilajatu, Mandur, Chitraka, Haritaki, Shunthi* .

➢ The *Ushna, Deepana, Pachana, Rasayan* and *Dhatuvardhan* properties of the Trial drug can lead to reduction in *Gatra Shaithilya*.

➢ *Daurbalya* was reduced faster and more effectively in Trial group due to *Dhatuvardhan* especially *Raktadhatu* due to contents like *Shilajeet, Raupya* and *Svarnamakshik* and *Mandur*. These caused *Dhatuposhan* and *Dhatuvardhan* of all *Saptadhatus* in turn.

➢ However, better results in Control Group were observed in *Angamarda* that may be attributed to the rise in Hb% and RBC count by the haematinic supplement.

➢ *Shabda Asahishnuta,* a *Lakshan* seen as a results of *Rasadi Dhatukshaya* but was not alleviated inspite of the *Raktavardhak* and *Rasayan Karma* of the ingredients of the Trial drug. This non significance may be because of the short duration of the trial drug administration.

Objective Parameters:-

➢ Haemoglobin

- After the treatment with Tab.Raricap mean difference of Haemoglobin (gm%) was increased by 8.6950 to 10.1650 .[Fig 5]
- After the treatment with *Tapyadi Loha* mean difference of Haemoglobin (gm%) was increased by 8.8750 to 10.3050 .[Fig 5]
- For Comparison between Trial Group and Control Group we have used Unpaired t-Test. Here, P-Value is greater than 0.05 showing that there is **no significant difference** in Trial Group and Control Group i.e. they are **equally significant**.[Table 5]
- A rise in the Hb% in both groups, equally significant is indicative of the *Raktavardhan,Rasayan* and *Deepana-Pachana Karma* as also the haematinic property of the Trial and Standard Control drugs respectively.

➢ Red Blood Cells Count

- After the treatment with Tab.Raricap mean difference of RBC was increased by 3.3200 to 3.8950.[Fig 6]
- After the treatment with *Tapyadi Loha* mean difference of RBC was increased by 3.4050 to 3.9750.[Fig 6]

- For Comparison between Trial Group and Control Group we have used Unpaired t-Test. Hence, it can be said that P-Value is greater than 0.05 and that there is **no significant difference** in Trial Group and Control Group.[Table 6]
- The same applies to the RBC count that showed a conversion from Hypochromic microcytic to Normocytic normochromic in blood pictures of RBCs.

The probable action of *Tapyadi Loha* in *Garavishajanit Pandu* is because of *Katu-Madhur Rasatmaka, Deepana, Pachana,Rakta Prasadana, Rasayan* and *Vishahara* properties.

Besides this *Madhu (Anupan Dravya)* too assisted in *Samprapti Bhanga*, due to its *Laghu,Ruksha, Sukshma, Vishaghna* and *Yogavahi Guna.*

Table 5"Comparison of HB%"

HB %	Mean Change	t-Value	P-Value
Control Group	1.5	.191	.849
Trial Group	1.4		

Table 6 Comparison of Red Blood Cells Count

RBC	Mean Change	t-Value	P-Value
Control Group	0.6	.062	.951
Trial Group	0.6		

Fig 5 "Comparison of HB%"

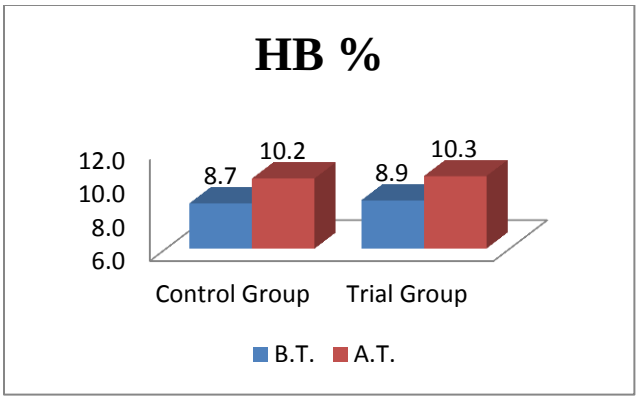
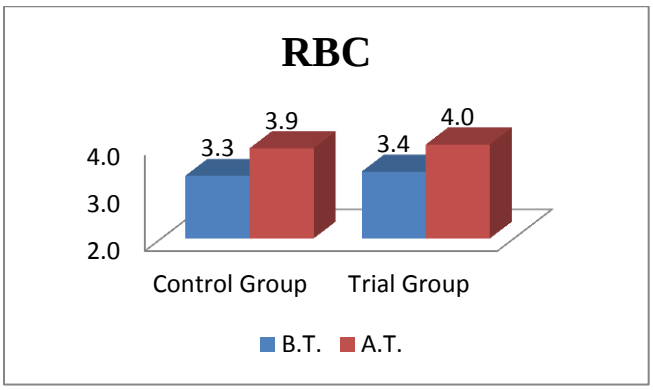


Fig 6 "Comparison of Red Blood Cells Count"



CONCLUSION

Tapyadi Loha is an effective treatment in *Garavishajanit Pandu Agnimandya, Aruchi* and *Daurbalya* as also Objective Parameters of Hb% and RBCs.

Symptoms of *Jvara, Gaurava, Angamarda, Shvasa, Akshikuta Shotha* showed equivalent significance while non-significant results were noted in *Shabda Asahishnuta* in both groups.

However, *Gatra Shaithilya* and *Daurbalya Lakhshan* showed non-significant results in Control Group.

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