

Clinical Research

Fundamental approach in the management of *Drava Bahula Amlapitta* with *Bhringaraja (Eclipta alba)*

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Abstract

The disease *Amlapitta* has been selected for the clinical trials because it presents two type of manifestations depending upon the involvement of *Agni (Ushnagunadhikya)* and *Jala (Dravagunadhikya) Mahabhuta*. The present research work was focused at *Drava Guna*, with an aim to assess the efficacy of a drug with quality of *Ruksha* and *Ushna* predominance like *Bhringaraja* in treating *Amlapitta* with *Pitta Drava Guna Vriddhi*. Randomized open clinical trials were conducted on 22 patients of *Amlapitta* who were screened on the basis of clinical findings and allocated in to two groups. The criteria for selection were the signs and symptoms of *Dravagunadhikya Amlapitta*, irrespective of sex, religion, etc. Group A consisting of 15 cases received the trial drug *Bhringaraja* tablet (4 Tab. two times, 1 tablet=500 mg) and 7 cases in Group B received rice powder tablet as a placebo (4 Tab. two times, 1 tablet=500 mg) for 4 weeks. Special scoring pattern was adopted for the assessment of *Amlapitta*. Routine pathological tests such as blood, urine, stool, etc. were also carried out. In Group A, 55.33% patients showed marked improvement, whereas moderate improvement was observed in 26.67% patients. Complete cure was found in 06.67% of the patients and mild improvement in the chief complaints was observed in 13.33% patients. All the selected symptoms showed statistically significant results ($P<0.01$) except the *Vidbheda* in treated Group A, while in Group B, all symptoms showed statistically insignificant results except the *Utklesha* and *Amlodgara*. Total effect of the therapy showed statistically significant effect of the test drug. These results support the hypothesis.

Key words: *Amlapitta, Bhringaraja, Drava, Ruksha, Ushna Guna*

Introduction

Amlapitta is a very common disease in the society and is an abnormal pathological condition of *Pitta*. *Drava Guna* plays an important role in the pathogenesis of *Amlapitta*.^[1] On the basis of predominant *Rasa* and *Gunatmaka* diet consumed by the patient, one can visualize two types of *Amlapitta* (*Vikalpa Samprapti*) and thus can plan the therapeutic intervention [Figure 1]. If *Nidanas* (diet) are *Amla-Lavana-Drava-*

Snigdha-Ushna dominant in nature, then *Drava* property of *Pitta* increases, and if *Nidanas* are *Katu-Ushna-Ruksha* dominant in nature, *Ushna* and *Ruksha* properties of *Pitta* get increased.^[2]

The present study was carried out to evaluate clinically *Ruksha* and *Ushna* drug, i.e. *Bhringaraja*, in countering the *Drava Bahula Amlapitta*, thereby suggesting a fundamental approach based line of treatment for *Amlapitta*.

Aims and objectives

This study was carried out with the following aims and objectives:

1. To study the applied concept of *Drava Guna* particularly of *Pitta* in *Amlapitta* patients.
2. Evaluation of the efficacy of the selected drug *Bhringaraja* on *Drava Guna Vriddhi* of *Pitta* in comparison to placebo.

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Materials and Methods

Criteria of selection of patients

1. For the clinical study, the patients having the symptoms of *Amlapitta* (with *Drava Guna* dominant symptoms.^[31])
2. Age: 20–60 years.

Patients satisfying the above criteria were selected from the OPD/IPD of Department of Basic Principles, I.P.G.T. and R.A., G.A.U., Jamnagar.

Criteria of exclusion of patients

1. Patients below 20 years and above 60 years of age.
2. Patients having the symptoms of *Amlapitta* (with *Tyaktadravta* dominant symptoms^[31]).
3. Patients suffering from complications of *Amlapitta* like gastritis, duodenal ulcer, etc. and also having any endocrine disorder or chronic complicated disease.

Grouping

Patients were divided into two groups.

- I. Group A - Treatment group
- II. Group B - Placebo group

Drug and posology

The test drug and placebo used in this study were mentioned in Table 1 with their details.

Investigations

Laboratory investigations were carried out before and after treatment to rule out any other pathological conditions as well as to record any specific change brought about by the treatment.

- Routine hematological examinations: Total leukocyte count, differential count, hemoglobin percent, packed cell volume and erythrocyte sedimentation rate before and after treatment.
- Biochemical examination: Serum total proteins and A/G ratio, Blood urea level, serum creatinine, serum uric acid, serum alkaline phosphatase, total lipid profile and fasting blood glucose level before and after treatment.

Study design

Placebo-controlled randomized clinical trial was done. Informed written consent was taken from the patients before including them in the trial. An elaborative case taking proforma was specially designed for the purpose of incorporating the disease and *Drava Guna* concept.

Pathyapathya (wholesome–unwholesome diet): Patients were advised to take *Pathyahara* and to correct their dietary habits and avoid *Apathyahara* as per the classical guidelines.

Assessment of therapy

Relief in signs and symptoms of *Amlapitta* was assessed by B.T. and A.T. gradation of clinical features, on the basis of scoring pattern.

Criteria for overall assessment of therapy

The overall assessment based on relief from the symptoms is shown in Table 2.

Statistical analysis

The information gathered on the basis of observations was subjected to statistical analysis. Chi-square test and Student's

paired “t” test were carried out for all subjective parameter (symptoms). Student's paired “t” test was applied for the objective parameters like hematological and biochemical investigations. The results were interpreted at $P < 0.05$, $P < 0.01$ and $P < 0.001$ significance levels. Total effect of therapy was calculated with the help of Chi-square test.

Observations, Results and Discussion

In the present study, 42 patients of *Amlapitta* [Table 3] were evaluated. It was found that 42.86% patients were in the age group of 31–40 years [Table 4], which is *Pitta Dosha* dominance stage of life. This finding correlates with the findings of Iyer Shividya, Prof. R. R. Dwivedi *et al.* (2003) and Santosh

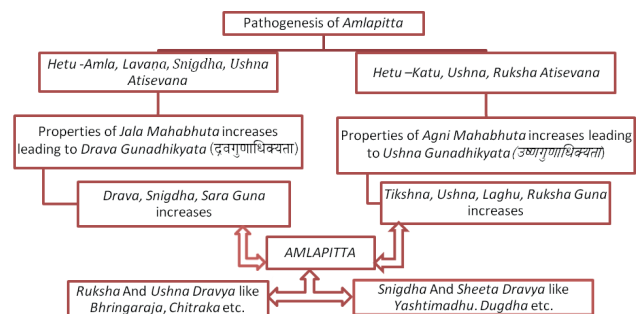


Figure 1: Pathogenesis of Amlapitta

Table 1: Drug, dose, duration

Details	Group A (treatment group)	Group B (placebo group)
Drug	<i>Bhringaraja</i> [<i>Eclipta alba</i> (L.) Hassk., F; Asteraceae]	Rice powder
Form	Tablet=500 mg	Tablet=500 mg
Dose	4 Tab. two times (4 g/day)	4 Tab. two times (4 g/day)
<i>Sevana Kala</i>	<i>Pragbhakta</i>	<i>Pragbhakta</i>
<i>Anupana</i>	<i>Jala</i>	<i>Jala</i>
Duration	28 days	28 days

Table 2: Criteria for overall assessment of therapy

Criteria for Assessment	Relief in percentage
Complete remission	100% relief
Marked improvement	>75% relief
Moderate improvement	>50 to 75% relief
Mild improvement	25 to 50% relief
Unchanged	<25% or No relief

Table 3: Status of the registered patients of Amlapitta

Patients	No. of patients		Total
	Group A	Group B	
Registered	24	18	42
Completed	15	7	22
Discontinued	9	11	20

Mane, Prof. R. R. Dwivedi *et al.* (2008). At this particular age, strenuous work, traveling, dietetic incompatibilities like Vishamashana, ignorance about Dinacarya, etc. are the other factors that set a solid foundation for Pitta disorders due to vitiation of Agni. Maximum (i.e. 69.04%) patients were taking Snigdha, Ushna, Guru, Drava diet like oily substance, spicy food which contains Snigdha as well as Ushna Guna [Table 5]. The symptoms exaggerated in 76.12% patients in relation to oily, spicy diet [Table 6]. These observations of the two tables indicate that Snigdha-Ushna Gunatmaka diet provokes the Drava Bahula Amlapitta which is in accordance with Madhukosha commentary view that Snigdha and Ushna are Hetu for Pitta Drava Vriddhi.

Maximum patients (80.95%) were habituated with improper diet styles like Samashana, Vishamashana and Viruddhashana [Table 7]. From this point of view, it can be said that for the manifestation of disease Amlapitta, all the above factors may be responsible collectively as well as individually. As per Acharya Sushruta, these are the most important factors in creating the Agnimandya. However, the role of these factors in increasing Pitta Dravata is still not clear. It can be inferred that Samashana, Vishamashana and Viruddhashana which includes Snigdha and Ushna Gunatmaka diet may be the reason for increase in Pitta Dravata.

On examining the Shareera Prakriti, it was observed that maximum (i.e. 35.72%) patients prone to this disease were of Kapha-Pittaja and Kapha-Vata Prakriti. This shows the tendency of Kapha Pitta predominance leading to Dushti of Annavahasrotas and ultimately producing its symptoms earlier than others [Table 8]. In Amlapitta, Pitta is the leading vitiated Dosha and Kapha is next to Pitta. Kapha and Pitta both have the Drava Guna.^[4] Hence, Pitta and Kapha Prakriti persons are more prone to the

disease, Amlapitta, as Drava Guna of Pitta increases in Amlapitta.

In this study 88.09% patients were having Avara Jarana Shakti [Table 9]. Pachaka Pitta is responsible for digestion. In normal condition, Pachaka Pitta is devoid (i.e. a smaller amount) of Drava Guna. If Drava Guna of Pachaka Pitta increases, then it decreases Ushna Guna of Pachaka Pitta which is the most essential Guna for digestion. In Amlapitta, due to increase in Drava Guna and decrease in Ushna Guna of Pitta, Avara Jarana Shakti was observed. This is in accordance with the classical view that if Drava Guna of Pitta increases, then it hampers digestion by creating Agnimandya.^[5]

Maximum patients (i.e. 57.14%) had been suffering from Amlapitta since more than a month [Table 10]. This indicates Chirakari Swabhava of Amlapitta. 83.33% and 9.05% of the patients were taking Guru Bhojana and Viruddhahara, respectively, while 38.10% of the patients were taking Atisnigdhabhara [Table 11]. This % of Ahara Nidan [Table 11] directly indicates their role in Amlapitta. Annavaha and Rasavaha Srotas involvement was seen in all of the patients (i.e. 100%) [Table 12]. This observation supports the classical view of Kashyapa which indicate Rasa Dhatu as the main Dushya in Amlapitta.^[6]

Percentage of improvement

In Group A (Bhringaraja treated), 100% relief was observed in Chhardi symptom. Next to Chhardi, maximum 85.71% relief was observed in Kandu/Kotha, followed by 83.33% in Angasada and 80.56% in Amlodgara. Utklesha was reduced by 79.31%, while Klama and Avipaka improved by 78.26% and 76.92%, respectively. 70.97% relief in Guru Koshtata

Table 4: Age wise distribution of the 42 patients

Age (years)	No. of patients		Total	%
	Group A	Group B		
20–30	8	9	17	40.48
31–40	9	9	18	42.86
41–60	7	0	7	16.66

Table 5: Gunatmaka dominancy in diet of the 42 patients

Pradhana Gunas	No. of patients		Total	%
	Group A	Group B		
Guru, Sheeta, Snigdha	3	4	7	16.67
Snigdha, Ushna, Guru, Drava	15	14	29	69.04
Ushna, Ruksha, Guru	6	0	6	14.29

Table 6: Anupashaya in relation to oily, spicy diet in 42 patients of Amlapitta

Diet type (provocation)	No. of patients		Total	%
	Group A	Group B		
Anupashaya in relation to oily, spicy diet	17	15	32	76.12
No relation with diet type	07	03	10	23.81

Table 7: Faulty dietary habits like Samashana, Vishamashana, Viruddhashana

Habits – Vishamashana, etc.	No. of patients		Total	%
	Group A	Group B		
Positive	18	16	34	80.95
Negative	06	02	08	19.05

Table 8: Deha Prakriti wise distribution of the 42 patients

Deha Prakriti	No. of patients		Total	%
	Group A	Group B		
Pitta–Vata	11	4	15	35.71
Kapha–Vata	4	5	9	21.43
Kapha–Pitta	6	9	15	35.72
Pittaja	3	0	3	07.14

Table 9: Jarana Shakti wise distribution of the 42 patients

Jarana Shakti	No. of patients		Total	%
	(Group A)	(Group B)		
Pravara	0	0	0	0
Madhyama	3	2	5	11.91
Avara	21	16	37	88.09

Table 10: Distribution of 42 patients according to the duration of the disease

Duration	No. of patients		Total	%
	Group A	Group B		
<30 days	03	00	03	07.14
>30 days up to 12 months	12	12	24	57.14
More than 1 year	09	06	15	35.72

Table 11: Nidanas (etiological factors) observed in 42 patients of Amlapitta

Nidanas	No. of patients		Total	%
	Group A	Group B		
<i>Viruddhahara</i> (incompatible diet)	16	13	29	69.05
<i>Adhyashana</i> (to eat before the previous food gets digested)	7	15	22	52.38
<i>Atyamlasevana</i> (excessive intake of sour substances)	10	9	19	45.24
<i>Atisnigdha Ahara</i> (oily, fatty diet)	7	9	16	38.10
<i>Ajeerna</i> (indigestion)	11	11	22	52.38
<i>Guru Bhojana</i> (heavy diet which takes a long duration to digest)	20	15	35	83.33
<i>Divaswapa</i> (day sleep)	17	12	29	69.05
<i>Atidravahara</i> (excess liquid)	9	2	11	26.19
<i>Gorasa</i> (milk product)	10	1	11	26.19
<i>Abhisyandi Bhojana</i> (food which blocks the channels, like curd)	5	6	11	26.19
<i>Antarodakapana</i> (drink too much water during eating)	1	0	1	2.38
<i>Ikshuvikara</i> (sugarcane products like <i>Guda</i> , etc.)	3	4	7	16.67

and 66.67% in *Aruchi* were observed. Placebo (Group B) drug showed maximum 52.94% improvement in *Amlodgara* and 50% improvement in *Chhardi*. It also showed improvement in *Utklesha* by 42.11% [Figure 2].

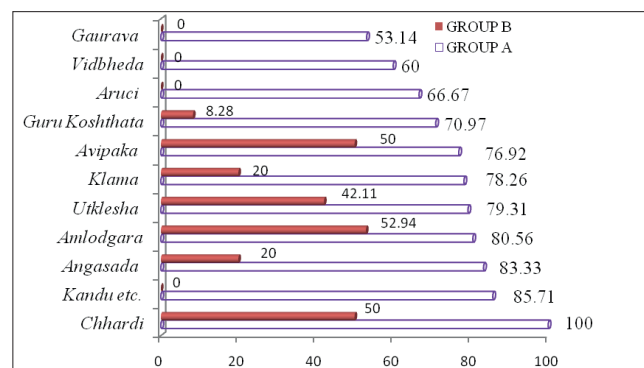
Use of placebo control excludes the psychological and environmental factors affecting the treatment efficacy. Hence, results obtained in Group A are due to the drug efficacy and not due to the effect of psychological and environmental factors.

Results of student's paired "t" test

Statistically highly significant result ($P < 0.01$) was obtained in symptoms like *Utklesha*, *Amlodgara*, *Avipaka*, *Guru Koshthata*, *Aruchi*, *Angasada*, *Klama*, *Kandu* under Group A. Significant result ($P < 0.05$) was obtained in *Gaurava* symptom, while nonsignificant result was obtained in *Vid Bheda* in Group A [Table 13]. Statistically nonsignificant result was obtained in symptoms like *Avipaka*, *Gaurava*, *Guru Koshthata*, *Aruchi*, *Angasada*, *Klama*, *Vid Bheda* in Group B, while statistically significant results ($P < 0.05$) were observed in *Utklesha*,

Table 12: Involvement of Srotas in 42 patients of Amlapitta

Srotas	No. of patients		Total	%
	Group A (24)	Group B (18)		
<i>Annava</i>	24	18	42	100
<i>Udakava</i>	1	0	1	02.38
<i>Rasava</i>	24	18	42	100
<i>Purishava</i>	18	14	32	76.10
<i>Mutrava</i>	3	4	7	16.67

**Figure 2: Percentage wise improvement in Groups A and B**

Amlodgara symptoms [Table 14]. This may be due to *Nidana Parivarjana* and *Pathya* followed by patients.

Result of Chi-square test on individual symptoms

This illustrates that test drug *Bhringaraja* is efficacious insignificantly in improving the above individual symptoms [Table 15]. Small sample size and variation of symptoms, i.e. all the symptoms not being present in each patient, may be the reason behind the insignificant results obtained with Chi-square test.

Result of paired "t" test applied to hematological data and biochemical parameters of Group A

It is evident that the *Bhringaraja* treated group showed statistically significant increase (paired "t" test) in four parameters: Hb (gm%) ($P < 0.001$), total red blood cell count (TRBC; $\times 10^{12}/l$), packed cell volume (PCV; %), and serum glutamate oxaloacetate transaminase (SGOT) [Table 16].

It can be inferred that statistically significant increase in Hb (gm%) ($P < 0.001$), TRBC ($\times 10^{12}/l$), PCV (%), and SGOT cannot be directly correlated with the *Drava Guna* concept. But as all these parameters can be included in *Pitta Varga*, it can be said that *Bhringaraja* has positive correlation with *Pitta*. Increase in these parameters can be taken as increase in *Agnimabhutatmaka* portion of *Pitta*. It is a hypothetical explanation which requires further logics to prove it. As there is no statistically significant increase or decrease in parameters like serum cholesterol, low density lipoprotein (LDL), and Total Leukocyte Count (TLC) which are considered as *Kapha Varga* parameters, it can be said that *Bhringaraja* has not that much effect on *Kapha Varga* parameters. The test drug did not cause abnormal deviation (out of normal physiological limit) in parameters but helped to maintain them within normal limits (e.g. statistically significant increase in SGOT was observed, but it was within normal range).

Table 13: Effect of *Bhringaraja* on symptoms of *Amlapitta* in Group A (paired “t” test applied to symptoms)

Chief complaints	n	B.T.	A.T.	Mean difference	±SD	±SE	t	P
<i>Utklesha</i>	15	1.93	0.40	1.53	0.92	0.24	6.49	<0.001
<i>Amlodgara</i>	15	2.40	0.47	1.93	0.79	0.20	9.37	<0.001
<i>Avipaka</i>	15	1.73	0.40	1.33	0.72	0.19	7.14	<0.001
<i>Guru Koshthata</i>	15	2.07	0.60	1.47	0.74	0.19	7.64	<0.001
<i>Gaurava</i>	12	1.17	0.50	0.67	0.78	0.23	2.76	<0.05
<i>Chhardi</i>	7	1.00	0	1.00	-	-	-	
<i>Aruchi</i>	9	1.33	0.44	0.89	0.60	0.2	4.44	<0.01
<i>Angasada</i>	9	1.33	0.22	1.11	0.78	0.26	4.26	<0.01
<i>Klama</i>	14	1.64	0.36	1.29	0.73	0.19	6.62	<0.001
<i>Kandu/Kotha, etc.</i>	5	1.40	0.25	1.20	0.45	0.20	6	<0.01
<i>Vid Bheda</i>	4	1.25	0.50	0.75	0.5	0.25	3	NS

N. S. - Non significant, B.T. - Before treatment, A.T. - After treatment

Table 14: Effect of placebo (rice powder tablet) on symptoms of *Amlapitta* in Group B (paired “t” test applied to symptoms)

Chief complaints	n	B.T. mean	A.T. mean	Difference mean	±SD	±SE	t	P
<i>Utklesha</i>	7	2.71	1.57	1.14	0.90	0.34	3.36	<0.05
<i>Amlodgara</i>	7	2.43	1.14	1.29	1.11	0.42	3.06	<0.05
<i>Avipaka</i>	7	2	1	1	1.15	0.44	2.29	NS
<i>Guru Koshthata</i>	7	1.71	1.57	0.14	0.38	0.14	0.99	NS
<i>Gaurava</i>	4	0.57	0.57	0	-	-	-	-
<i>Chhardi</i>	1	2	1	1	-	-	-	-
<i>Aruchi</i>	3	0.43	0.43	0	-	-	-	-
<i>Angasada</i>	5	1.4	1.20	0.20	0.45	0.20	1.0	NS
<i>Klama</i>	6	1.43	1.14	0.29	0.52	0.21	1.36	NS
<i>Kandu/Kotha, etc.</i>	0	-	-	-	-	-	-	-
<i>Vid Bheda</i>	2	0.29	0.29	0	-	-	-	-

N. S. - Non significant, B.T. - Before treatment, A.T. - After treatment

Table 15: Results obtained on applying Chi-square test on the symptoms of *Amlapitta*

Lakshana	Chi-square method	P
<i>Utklesha</i> (nausea)	0.51	NS
<i>Amlodgara</i> (sour belching)	0.35	-
<i>Avipaka</i> (indigestion)	0.07	-
<i>Guru Koshthata</i> (feeling of heaviness in the abdomen)	0.99	NS
<i>Gaurava</i> (feeling of heaviness of body)	0.00	-
<i>Chhardi</i> (vomiting)	-	-
<i>Aruchi</i> (anorexia)	0.36	-
<i>Angasada</i> (body ache)	0.60	NS
<i>Klama</i> (fatigue without any physical work)	2.19	NS
<i>Kandu/Kotha, etc.</i> (itching, eruption, etc.)	-	-
<i>Vid Bheda</i> (unformed/liquid stool)	-	-

Overall effect of therapy in percentage

Moderate to marked (summation of moderate+marked) improvement was observed in more than 80% and 14.29% of patients in groups A and B, respectively, when data were presented in percentage improvement method [Table 17]. 80%

and 14.29% values distinctly show the efficacy of *Bhringaraja* in contrast to placebo.

Overall effect of therapy with Chi-square test

Group A (*Bhringaraja* administered) showed statistically highly significant effects on chief complaints as compared to placebo [Table 18]. This indicates that though nonsignificant results were obtained when the symptoms were looked at separately, *Bhringaraja* showed increased efficacy when the overall effect was considered.

Probable mode of action of *Bhringaraja* in *Amlapitta*

In *Amlapitta*, *Drava Guna* of *Pitta* gets increased leading to pathogenesis. If *Drava Guna* increases, for reducing it one should use drugs which have opposite properties to that of *Drava Guna* (according to *Samanya-Vishesh Siddhanta*).^[7] *Bhringaraja*, the selected drug, has opposite properties (like *Ruksha-Ushna*)^[8] to that of *Drava Guna*, by means of which it is able to reduce increased *Drava Guna* and its actions. As per the classical view, *Ruksha Dravya* (like *Bhringaraja*) can reduce *Dravata*.^[9] *Ushna Virya Dravya* (like *Bhringaraja*) can reduce *Dravata* of *Grahanistha Sama Pitta*.^[10] *Bhringaraja* has both these properties, i.e. *Ruksha* and *Ushna Virya*. That is why *Bhringaraja* is capable of reducing *Drava Guna* of

Table 16: Statistically significant observations of Group A

Biochemical parameters (n=15)	B.T. mean	A.T. mean	Difference mean	% change	±SD	±SE	t	P
SGOT (U/l)	21.53	27.87	-6.33	29.41↑	10.99	2.84	2.23↑	<0.05
Hb (gm%)	12.53	12.73	-0.20	1.6↑	0.16	0.04	4.97↑	<0.001
PCV (%)	39.19	39.73	-0.54	1.38↑	0.61	0.16	3.43↑	<0.01
TRBC (×10 ¹² /l)	4.57	4.68	-0.11	2.33↑	0.12	0.03	3.53↑	<0.01

↑ - Increase, SGOT - Serum glutamic oxaloacetic transaminase, Hb - Haemoglobin, P.C.V. - Packed cell volume, T.R.B.C. - Total red blood cells

Table 17: Overall effect of therapy in percentage

Category	Group A (15)		Group B (07)	
	No. of patients	%	No. of patients	%
Unchanged	-	-	3	42.86
Mild improvement	2	13.33	3	42.86
Moderate improvement	4	26.67	1	14.29
Marked improvement	8	55.33	-	-
Complete remission	1	06.67	-	-

Overall effect of therapy calculated with Chi-square test

Table 18: Total effect of therapy (Chi-square test) wise distribution of 22 patients

Groups	NSI	GI	Row total		
A	2	13	15	$\chi^2=7.90$	$P<0.005$
B	6	1	7		
Column total	8	14	22		

NSI - Not sufficiently improved, GI - Good improvement

Pitta in *Amlapitta*. *Drava Guna* is a *Jalamahabhuta* property, while *Bhringaraja* is *Agnimahabhuta* dominant drug. Hence, *Bhringaraja* is supposed to decrease the *Drava Guna*, which has been verified clinically on *Drava Bahula Amlapitta* patients. The present research is helpful to study a different aspect of *Amlapitta* with emphasis on *Drava* property of *Pitta Dosh*. The data support the findings of previous research done at Tata Memorial Hospital, which suggest *Jeerna Amlapitta* as the predisposing disease factor responsible for Cancer of esophagus caused by consumption of excess *Amla* (sour), *Lavan* (salty), *Ushna* (hot), *Snigdha* (unctuous) dominant diet. These factors increase the *Drava* property of *Pitta* and may indeed lead to dreadful diseases.

Conclusion

The above explanation proves that *Bhringaraja* has efficacy in treating the *Drava Bahula Amlapitta* in comparison to placebo. *Bhringaraja* can give moderate to marked improvement in

Drava Bahula Amlapitta patients. Statistically significant results observed in Group A (*Bhringaraja*) specify that the applied concept of *Drava Guna* plays an important role in the pathogenesis of disease. Hence, *Bhringaraja* having *Drava* opposite properties, i.e. *Ruksha-Ushna*, can be a choice of remedy for the physician while treating diseases of *Pitta Drava Guna Vriddhi* like *Amlapitta*.

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