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.
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) were included.
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 Tyaktadravtva dominant symptoms).
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.

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. Student’s paired “t” test was 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

Table 1: Drug, dose, duration

| Details | Group A (treatment group) | Group B (placebo group) |
|---------|---------------------------|-------------------------|
| Drug    | Bhringaraja [Eclipta alba (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) |
| Sevana Kala | Pragbhakta | Pragbhakta |
| Anupana | Jala | Jala |
| 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 to75% 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 Viruddhahana [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 Viruddhahana 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 Anuvahasrotas 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. 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. 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 Atisnigdhahara [Table 11]. This % of Aharaja Nidanas [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 Kasa Dhatu as the main Dushya in Amlapitta.

### Table 4: Age wise distribution of the 42 patients

| Age (years) | Group A | Group B | Total | % |
|-------------|---------|---------|-------|---|
| 20–30       | 8       | 9       | 17    | 40.48 |
| 31–40       | 9       | 9       | 18    | 42.86 |
| 41–60       | 7       | 0       | 7     | 16.66 |

### Table 5: Gunatmaka dominance in diet of the 42 patients

| Pradhan Guna                  | Group A | Group B | Total | %   |
|------------------------------|---------|---------|-------|-----|
| Guru, Sheeta, Snigdha        | 3       | 4       | 7     | 16.67 |
| Snigdha, Ushna, Guru, Drava   | 15      | 14      | 29    | 69.04 |
| Ushna, Ruksa, Guru           | 6       | 0       | 6     | 14.29 |

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

| Diet type (provocation)      | Group A | Group B | Total | %   |
|------------------------------|---------|---------|-------|-----|
| 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, Viruddhahana

| Habits – Samashana, Vishamashana, etc. | Group A | Group B | Total | %   |
|---------------------------------------|---------|---------|-------|-----|
| Positive                              | 18      | 16      | 34    | 80.95 |
| Negative                              | 06      | 02      | 08    | 19.05 |

### Table 8: Deha Prakriti wise distribution of the 42 patients

| Deha Prakriti | Group A | Group B | Total | %   |
|---------------|---------|---------|-------|-----|
| 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 | Group A | Group B | Total | %   |
|---------------|---------|---------|-------|-----|
| Pravara       | 0       | 0       | 0     | 0   |
| Madhyama      | 3       | 2       | 5     | 11.91 |
| Avara         | 21      | 16      | 37    | 88.09 |
and 66.67% in Aruchi were observed. Placebo (Group B) drug showed maximum 52.94% improvement in Amlodgara and 50% improvement in Chhhardi. It also showed improvement in Amlodgara 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 Koshithata, Aruchi, Angusada, 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 Koshithata, Aruchi, Angusada, Klama, Vid Bheda in Group B, while statistically significant results (P<0.05) were observed in Utklesha, Amlodgara, and 52.94% in Amlodgara by 42.11% [Figure 2].

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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 Koshithata, Aruchi, Angusada, 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 Koshithata, Aruchi, Angusada, Klama, Vid Bheda in Group B, while statistically significant results (P<0.05) were observed in Utklesha, Amlodgara, and 52.94% in Amlodgara 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 Koshithata, Aruchi, Angusada, 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 Koshithata, Aruchi, Angusada, Klama, Vid Bheda in Group B, while statistically significant results (P<0.05) were observed in Utklesha, Amlodgara, and 52.94% in Amlodgara 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.
Table 13: Effect of Bhringaraja on symptoms of Amlapitta in Group A (paired “t” test applied to symptoms)

| Chief complaints | n  | B.T. mean | A.T. mean | Mean difference | ±SD | ±SE | t   | P    |
|------------------|----|-----------|-----------|-----------------|-----|-----|-----|------|
| Utklesha         | 15 | 1.93      | 0.40      | 1.53            | 0.92| 0.24| 6.49| <0.001|
| Amlodgara        | 15 | 2.40      | 0.47      | 1.93            | 0.79| 0.20| 9.37| <0.001|
| Avipaka          | 15 | 1.73      | 0.40      | 1.33            | 0.72| 0.19| 7.14| <0.001|
| Guru Koshthata   | 15 | 2.07      | 0.60      | 1.47            | 0.74| 0.19| 7.64| <0.001|
| Gaurava          | 12 | 1.17      | 0.50      | 0.67            | 0.78| 0.23| 2.76| <0.05 |
| Chhardi          | 7  | 1.00      | 0         | 1.00            | -   | -   | -   | -    |
| Aruchi           | 9  | 1.33      | 0.44      | 0.89            | 0.60| 0.2  | 4.44| <0.01 |
| Angasada         | 9  | 1.33      | 0.22      | 1.11            | 0.78| 0.26| 4.26| <0.01 |
| Klama            | 14 | 1.64      | 0.36      | 1.29            | 0.73| 0.19| 6.62| <0.001|
| Kandu/Kotha, etc.| 5  | 1.40      | 0.25      | 1.20            | 0.45| 0.20| 6    | <0.01 |
| Vid Bheda        | 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    |
|------------------|----|-----------|-----------|-----------------|-----|-----|-----|------|
| Utklesha         | 7  | 2.71      | 1.57      | 1.14            | 0.90| 0.34| 3.36| <0.05|
| Amlodgara        | 7  | 2.43      | 1.14      | 1.29            | 1.11| 0.42| 3.06| <0.05|
| Avipaka          | 7  | 2         | 1         | 1               | 1.15| 0.44| 2.29| NS    |
| Guru Koshthata   | 7  | 1.71      | 1.57      | 0.14            | 0.38| 0.14| 0.99| NS    |
| Gaurava          | 4  | 0.57      | 0.57      | 0               | -   | -   | -   | -     |
| Chhardi          | 1  | 2         | 1         | 1               | -   | -   | -   | -     |
| Aruchi           | 3  | 0.43      | 0.43      | 0               | -   | -   | -   | -     |
| Angasada         | 5  | 1.4       | 1.20      | 0.20            | 0.45| 0.20| 1.0 | NS    |
| Klama            | 6  | 1.43      | 1.14      | 0.29            | 0.52| 0.21| 1.36| NS    |
| Kandu/Kotha, etc.| 0  | -         | -         | -               | -   | -   | -   | -     |
| Vid Bheda        | 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    |
|---------------------------|-------------------|------|
| Utklesha (nausea)         | 0.51              | NS   |
| Amlodgara (sour belching) | 0.35              | -    |
| Avipaka (indigestion)     | 0.07              | -    |
| Guru Koshthata (feeling of heaviness in the abdomen) | 0.99 | NS   |
| Gaurava (feeling of heaviness of body) | 0.00 | -    |
| Chhardi (vomiting)        | -                 | -    |
| Aruchi (anorexia)         | 0.36              | -    |
| Angasada (body ache)      | 0.60              | NS   |
| Klama (fatigue without any physical work) | 2.19 | NS   |
| Kandu/Kotha, etc. (itching, eruption, etc.) | - | -    |
| Vid Bheda (unformed/liquid stool) | - | -  |

P: 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-Vishesha Siddhanta). Bhringaraja, the selected drug, has opposite properties (like Ruksha–Ushna) 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, Raksha Dravya (like Bhringaraja) can reduce Dravata. Ushna Virya Dravya (like Bhringaraja) can reduce Dravata of Grahaniyata Sama Pitta. Bhringaraja has both these properties, i.e. Raksha and Ushna Virya. That is why Bhringaraja is capable of reducing Drava Guna of

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

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516
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 (UI/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 (×10¹²/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                | 2            | 3            | 42.86        | 42.86        |
| Mild improvement         | 2            | 3            | 42.86        | 42.86        |
| Moderate improvement     | 4            | 1            | 14.29        | 14.29        |
| Marked improvement       | 8            | -            | -            | -            |
| Complete remission       | 1            | -            | -            | -            |

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        |
| 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 Dosha. 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 oesophagus 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., Raksha-Ushna, can be a choice of remedy for the physician while treating diseases of Pitta Drava Guna Vrddhi like Amlapitta.

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