Original Article

A clinical study to evaluate the role of *Doshik* predominance in the management of *Amlapitta*

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Abstract

Background: *Amlapitta* is a lifestyle disorder caused due to vitiation of *Pitta* and *Kapha* by *Ama*. **Objective:** The objective was to assess the role of *Doshik* predominance in the management of *Amlapitta*. **Materials and Methods:** Patients who had fulfilled the inclusion criteria were registered primarily for this study. Out of them, those who were selected only by the presence of cardinal features of *Amlapitta* were allotted randomly in Group C-1 and Group C-2 and rest of them were allotted in Group A and B after diagnosed by typical features of *Kapha* and *Pitta Dosha* predominant *Amlapitta* and had been treated with *Shunthikhanda* and *Vasakhanda Kushmandaka* granules, respectively. **Results:** Regarding overall effect of therapy, marked positive improvement in Group A was 35.29%, in Group B, 26.47%, in Group C-1, 23.08%, and Group C-2, 16.67%. No improvement was observed only in Group C-1 (4.76%) and C-2 (5.56%). Complete remission (2.56%) was observed only in Group C-2 (5.56%) **Discussion:** Out of 112 registered patients with a mean age of 42 years, 107 had completed their treatment. Maximum patients were male (66.96%), Hindu (83.93%), married (94.64%), middle class (43.75%), and educated (93.75%) from *Jangala Desha* (96.43%) and used to take *Viruddha Ahara* (83.04%). Patients of Group A and Group B, who were diagnosed and treated according to the *Doshik* predominance, showed better improvement than of Group C-1 and Group C-2 where patients were diagnosed and treated as per the cardinal features of *Amlapitta* only. **Conclusion:** Treatment of disease according to *Doshik* predominance is more effective than of only cardinal features.

Keywords: *Amlapitta*, *Doshik* predominance, *Shunthikhanda*, *Vasakhanda Kushmandaka* granules

Introduction

According to Ayurvedic classics, *Agni* is responsible for *Ayu* (age), *Varna* (colour), *Bala* (power), *Swasthya* (health), *Utsaha* (excitement), *Upachaya* (digestion), *Prabha, Oja* and *Teja*[1] and *Agni* takes a pivot role in the etiopathogenesis of all human ailments.[2,3] According to *Acharya Charaka,* indulging in *Ajirna*, *Atibhojana* (over eating), *Vishama Bhojana* (irregular diet), *Asatmya* (incompatible diet) and *Sandushta Bhojana* produces *Shuktata* due to *Agni Dushti* (impairment of *Agni*) followed by *Ama* and *Amavisha* which further develops *Ajirna* (indigestion) by vitiating *Dosha*.[4] Continuous indulgence in improper diet and erratic lifestyle basically aggravates *Pitta Dosha* which leads the disease into acute condition of *Vidagdhajirna* (indigestion) which due to ignorance inturn converts into *Amlapitta* in long run.

It is better to consider *Amlapitta* as a syndrome (acid reflux syndrome)[5] rather than a particular gastrointestinal disease due to the same causative factors with similar signs and symptoms as in Ayurvedic parlance closely resembles with gastritis,[6] non-ulcer dyspepsia,[7] hyperchlorhydria,[8] as well as hypochlorhydria[9] and in chronic stage, it may lead to gastric ulcer. Gastrointestinal disorders become lifestyle maladies when people shift their eating pattern toward ready-to-eat commercial junk meals from homemade food and adopt erratic lifestyles. According to the National Digestive Diseases Information Clearinghouse, the prevalence rate of gastritis in India is 10,572,391 and that of peptic ulcer is 5 million (1987).[10]

Knowledge of etiological factors, responsible for genesis of a particular disease, is essential in the selection of appropriate

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therapies which are opposite to disease as well as etiological factors (*Vyadhi-Hetu Pratidwandwi*) because the attributes of *Dosha* resembles the etiological factors which vitiate the *Dosha*.

Various types of *Avarana* (layer) should be considered into the pathogenesis. *Avarana* is mainly of three types, viz., 1. *Sama-Vata Avrita* by *Vriddha-Pitta* and *Kapha*, 2. *Vriddha-Vata Avrita* by *Sama-Pitta* and *Kapha*, 3. *Vriddha-Vata Avrita* by *Vriddha-Pitta* and *Kapha*. In the disease *Amlapitta,* third pathogenesis is rare. Hence, the first two are commonly considered in which clinical conditions such as *Kapholvana* and *Pittolvana* type of *Amlapitta* have been found.

Increased *Drava* and *Amla Guna* of *Pachaka Pitta* plays an important role in the pathogenesis of *Amlapitta*. *Sneha* is one of the special qualities of both *Kapha* and *Pitta,* but *Sneha* is present in *Pitta* in feeble quantity. *Dravya* which have the property of *Kleda* are *Snigdha*. *Sneha* performs the function of *Mardava* (softens the food stuff). Hence, it can be declared that *Sneha* is the common property of *Kledaka Kapha* and *Pachaka Pitta*. Hence, both of them are responsible for the pathogenesis of *Amlapitta* which is a *Pathya Asadhya, Bheshaj Asadhya* and *Kashtasadhya Vyadhi*. Hence, *Nidana Parivarjana*, *Hetu Viparita*, *Vyadhi* and *Dosha Pratyanika* (*Kapha-Pittahara*) therapies would be beneficial in *Amlapitta* [Figures 1 and 2].

Aims and objectives

1. To assess the role of *Doshik* predominance in the management of *Amlapitta*.

Materials and Methods

This clinical study is registered in the Clinical Trial Registry of India, ICMR, New Delhi (CTRI; www.ctri.nic.in) vide CTRI/2011/09/002003 and explained as per the Consolidated Standards of Reporting Trials statement 2010.[11] A total of 112 clinically diagnosed patients of *Amlapitta* attending outpatient and inpatient department of PG Hospital, Kayachikitsa at IPGT and RA, Gujarat Ayurved University, Jamnagar, were registered for this study. Out of 112, five patients were dropped out for several reasons.

Criteria for diagnosis

Subjective criteria

A total of 112 patients were diagnosed and confirmed by the presence of *Pratyatma Niyata Lakshana* (cardinal features)[12] of *Amlapitta* (*Avipaka* [indigestion], *Klama* [exhaustion], *Utklesha* [nausea], *Tikta-Amla Udgara* [eructation with bitter and sour taste], *Gaurava* [feeling of heaviness of the body], *Hrit-Kantha-Daha* [burning sensation in the chest and throat], and *Aruchi* [loss of appetite]) in general.

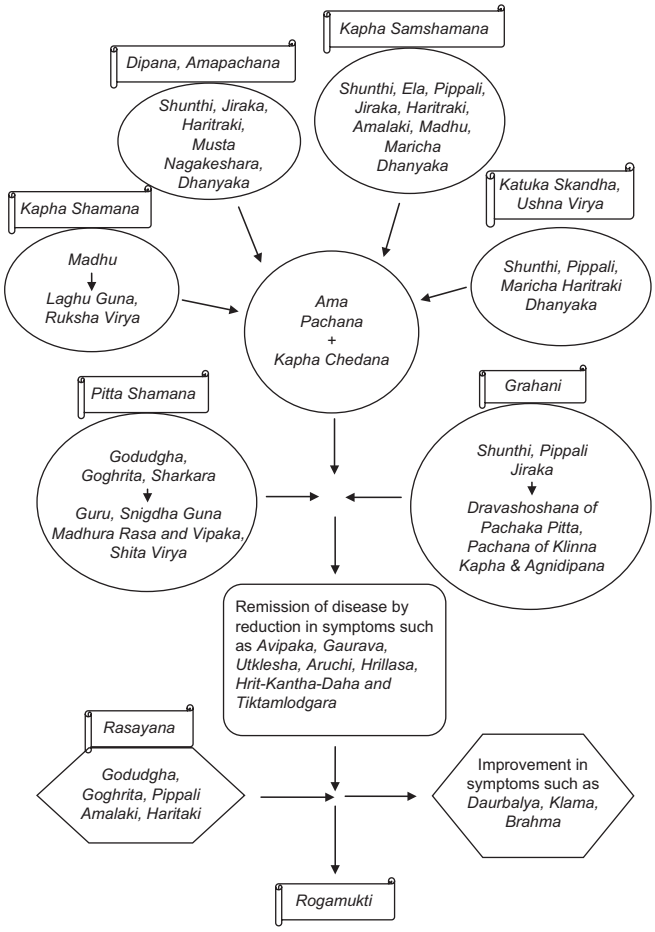


Figure 1: Probable mode of action of *Shunthikhanda* granules

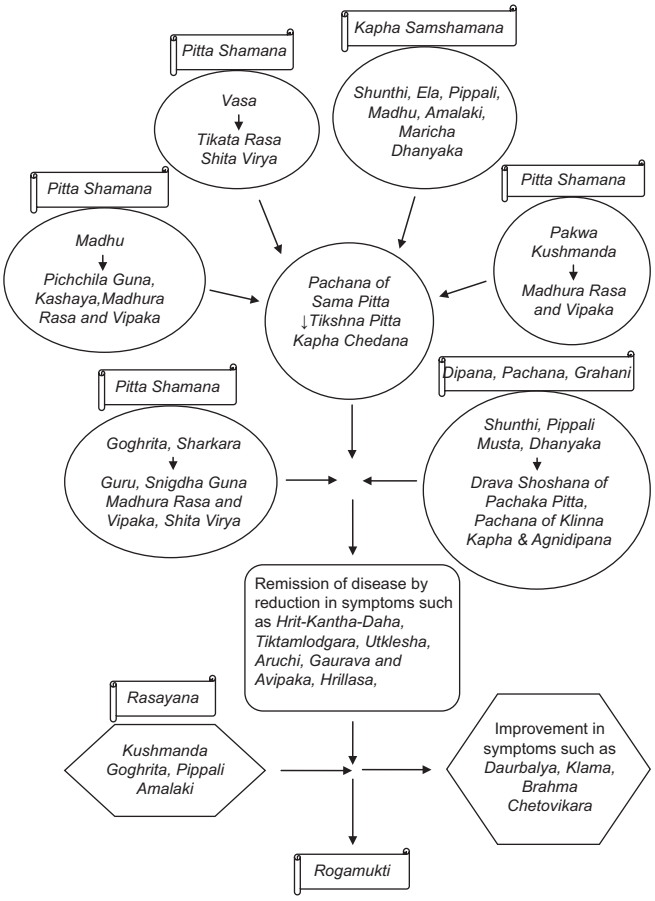


Figure 2: Probable mode of action of *Vasakhanda Kushmandaka* granules

Patients of *Kaphaja Amlapitta* will be diagnosed by the presence of the symptoms[13,14] such as *Aruchi, Gaurava, Jadyata, Kaphanisthivana* (expectoration of thick phlegm), *Lepa* (coating of tongue), *Sada* (Lassitude), *Sheeta* (coldness), *Vami* (vomiting) and *Kandu* (itching sensation) whereas *Pittaja Amlapitta* will be diagnosed by the presence of the symptoms[14,15] such as *Nanavidha Pravritti* (fluids eliminated through rectum with different colors), *Trishna* (excessive thirst), *Hrit-Kantha-Kukshi Daha* (burning sensation in chest, throat, and abdomen), *Murccha* (fainting), *Bhrama* (giddiness), *Moha* (delusion), *Anala Sada* (poor digestive power), *Hrillasa* (nausea), *Sweda* (excessive sweating) and *Anga Peetata* (yellowish discoloration of the skin).

Objective criteria

Out of 112, five patients were dropped out for several reasons. The objective criteria were taken; however, to exclude other pathological conditions, the following investigations were carried out (a) blood: total leukocyte count (TLC), differential leukocyte count (DLC), hemoglobin percentage (HB%), erythrocyte sedimentation rate (ESR), fasting blood sugar (FBS), liver function tests (LFT), lipid profile (b) stool: routine microscopic examination of the stool and (c) urine: routine examination.

Criteria for selection of patients

Inclusion criteria

(1) Age: Patients between 21 and 60 years of age. (2) Sex: Patients of both sex. (3) Presence of cardinal features of *Amlapitta* as well as typical features of *Kapha* and *Pitta Dosha*-predominant *Amlapitta*. (4) Patients not taking any other medicines for *Amlapitta*. (5) Chronicity of >3 months.

Exclusion criteria

(1) Patients with peptic ulcer, duodenal ulcer, carcinoma stomach, cardiac disorders. (2) Taking medicines for any other diseases such as hypertension, diabetes mellitus, ischemic heart diseases and chronic renal failure.

Plan of study

Clinically diagnosed 34 cases of *Kapha* predominant *Amlapitta* were allocated in Group A and 39 patients of *Pitta* predominant *Amlapitta* were allocated in Group B whereas 39 patients were allocated in Group C irrespective of their *Doshik* predominance. *Shunthikhanda* granules was administered to the patients of Group A, *Vasakhanda Kushmandaka* granules were given to the patients of Group B and one of these two drugs was administered randomly to the patients of Group C.

Further, the patients who were randomly treated with *Shunthikhanda* granules, allocated in Group C-1 and the patients who were randomly treated with *Vasakhanda Kushmandaka* granules were allocated in Group C-2 to observe the comparative effectiveness of drugs in between the groups where patients were treated according to *Doshik* predominance and without *Doshik* predominance, respectively. All patients of three groups were administered their recommended drug in a dose of 5 g, orally, twice a day, in between food with water for a period of 30 days. Computer-generated randomization[16] from www.randomization.com vide seed 18,135 created on Tuesday; January 03, 2012, at 2:12:18 PM was used for the clinical study.

Criteria for assessment

In this study, an effort has been made to follow the guidelines laid down by *Acharya Charaka* for the assessment of results. Having close acquaintance with the various states of the disease, such therapies should be prescribed which may help attainment of the four-fold blessings (*Chatuhshreya*).[17] *Amlapitta* symptoms rating scale (ASRS) was adopted to assess the relief in each symptom in *Amlapitta* patients. The ASRS is 20 items based on *Rogabala, Agnibala, Dehabala,* and *Chetasabala*; a disease-specific instrument used to evaluate symptoms of *Amlapitta*. The items are measured on a 5-point Likert-type scale[18] ranging from 0 = "no discomfort" to 4 = "very severe discomfort." The ASRS was administered at baseline and after the end of 30 days' clinical trial.

Total 100 scores were divided into *Rogabala*, *Dehabala*, *Agnibala* and *Chetasabala*. Thirty-five scores allotted for "*Rogabala*" were subdivided into seven items such as *Hrit-Kantha-Daha*, *Tiktamlodgara*, *Vami*, *Gaurava*, *Utklesha*, *Shula* and *Brahma* for the assessment of the severity of symptoms of *Amlapitta*. Twenty-five scores allotted for "*Agnibala*" were subdivided into five items such as *Abhyavaharana Shakti* (capacity of ingestion of food), *Jarana Shakti* (power of digestion), *Avipaka* and *Aruchi* for the assessment of power of digestion in *Amlapitta*. Twenty scores allotted for "*Dehabala*" were distributed into four items, viz., *Balavriddhi* (strength), *Klama*, *Swara-Varna Yoga* (clarity in voice and luster) and *Sharira Upachaya* (weight gain) for the assessment of bodily strength in *Amlapitta*. Twenty scores allotted for "*Chetasabala*" were subdivided into four items such as *Nidra Labho Yathakalam* (regularity in sleep), "*Sukhena Cha Pratibodhanam"* (feeling of well-being), "*Vaikarikanam Cha Swapnana Darshanam*"(uncomfortable dreams) and "*Mano Buddhi Indriya Avyapatti"* for the assessment of strength of mental faculties in *Amlapitta*.

Statistical analysis

The data obtained on the basis of observations were subjected to statistical analysis by applying Sigmastat 3.5 software (Software is now based in San Jose, California) in terms of mean, percentage, standard deviation, and standard error. The *t*-test and *P* values were calculated by using paired *t*-test and unpaired *t*-test considered at the level of $P \geq 0.05$ (insignificant), $P \geq 0.002$ to ≤ 0.04 (significant), and $P \leq 0.001$ (highly significant).

Assessment of overall effect of therapy

For the overall assessment of the therapy, following five categories were taken into consideration:

- Complete remission- 100% relief in the clinical signs and symptoms
- Marked improvement- 76%–99% relief in the clinical signs and symptoms

- Moderate improvement- 51%–75% relief in the clinical signs and symptoms
- Mild improvement- 26–50% relief in the clinical signs and symptoms
- Unchanged- Below 25% relief in the clinical signs and symptoms.

Follow-up study

After completion of due course of treatment, all the patients were requested to report for follow-up study for 1 week. During this period, no medicine was provided to the patients and recurrence of any symptoms regarding *Rogabala, Dehabala, Agnibala* and *Chetasabala* as well as impact of therapies on quality of life were observed.

Observations

Epidemiological data observed among 112 patients of *Amlapitta* was exhibited in Graph 1. However, features of *Pitta Prakriti* were observed in 51 (45.54%) patients, *Kapha Prakriti* was observed in 33 (29.46%) patients and *Vata Prakriti* was in 28 (25%) patients. Different types of dietary habits such as *Viruddhashana* (intake of contraditory food combination), *Atiguru Bhojana* (excessive heavy diet), *Atiruksha Bhojana* (excessive ununctous diet), *Vidahi Bhojana* (spicy food), intake of *Katu Rasa* and *Lavana Rasa* dominant diet, *Bhuktamatrasya Swapna* (going to sleep just after lunch and dinner), *Atidaryta* (intake diet hurriedly) and *Ativilambita Bhojana* (intake of in a diet very slowl pattern) were observed among 112 patients of *Amlapitta* [Graph 2].

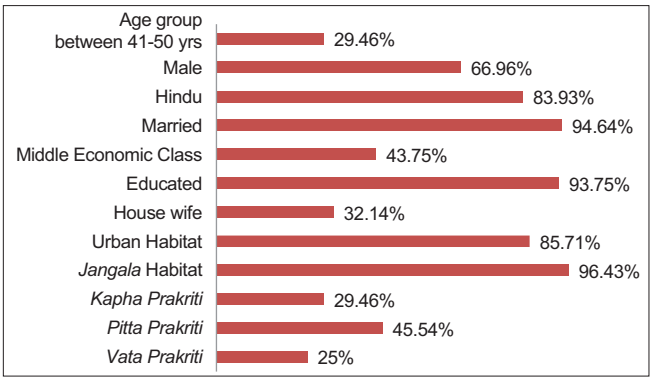
26.79% of patients were not doing exercise at all, 52.68% were habituated of *Vegavidharana* (suppression of their natural urges) and 40.18% had the habit of *Prajagarana* (night vigilance). Maximum patients were addicted with tea (97.32%) followed by tobacco (51.79%) observed in this study.

Most of patients were afflicted with *Krodha* (anger – 54.46%) followed by *Avasada* (depression – 35.71%), *Chinta* (tension – 31.25%), and *Lobha* (greedy – 21.43%).

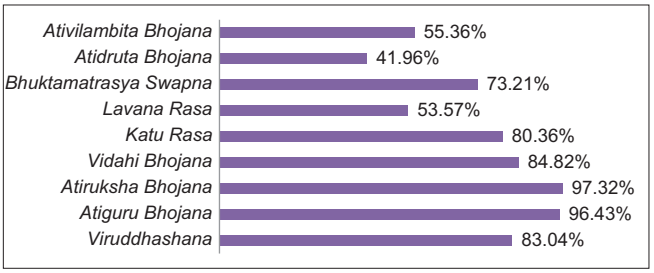
In this study, all the patients had the cardinal symptoms such as *Avipaka*, *Tiktamlodgara*, *Hrit-daha*, *Kantha-daha*, *Utklesha*, *Gaurava*, *Aruchi* and *Klama*. Other signs and symptoms observed were *Adhmana* (flatulence), *Udara shula* (abdominal pain), *Nidralpata* (insomnia), *Vibandha* (constipation), *Atipipasa* (excessive thirst), *Bhrama* (giddiness), *Kampa* (tremor) and *Angasada* (lethargy) [Graph 3].

Maximum patients had the previous history of *Ajirna* (49.11%) followed by *Amlapitta* (47.32%) and had the chronicity of 3 months to 1 year (45.54%).

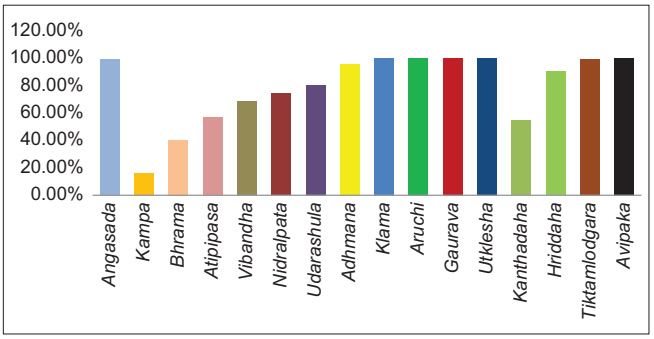
Strotodushti observed in 112 of patients in this study were *Purishavaha* (100%), *Rasavaha* (72.31%), *Annavaha* (62.89%), *Raktavaha* (39.30%) and *Swedavaha Strotas* (25.50%). Of the total observed 1117 frequency of symptoms of involvement of *Dosha*, majority represented *Kapha* (55.68%) followed by *Pitta* (47.36%) and *Vata* (32.77%).



Graph 1: Observed data collected from 112 patients of *Amlapitta*



Graph 2: Dietary habits of 112 patients of *Amlapitta*



Graph 3: Cardinal symptoms observed in 112 patients of *Amlapitta*

Effect of therapy

Rogabala

Shunthikhanda granules in Group A and C-1 and *Vasakhanda Kushmandaka* granules in Group B and C-2 provided highly significant relief ($P < 0.001$) in the symptoms of *Utklesha*, *Tiktamlodgara*, *Gaurava* and *Angasada*, *Hrit-Kantha Daha*, *Chardi* and *Shula*. On *Brahma, Shunthikhanda* granules in Group A provided highly significant relief ($P < 0.001$) and in Group C-1 provided significant relief ($P < 0.05$) whereas *Vasakhanda Kushmandaka* granules provided significant relief in Group B ($P = 0.002$) and Group C-2 ($P < 0.05$) [Graph 4].

Agnibala

Shunthikhanda granules in Group A and *Vasakhanda Kushmandaka* granules in Group B provided highly significant relief ($P < 0.001$) in the symptoms of *Abhyavaharana Shakti*, *Jarana Shakti*, *Aruchi*, *Avipaka* and *Vata-Mutra-Retasam Mukti*. *Shunthikhanda* granules in Group C-1 and *Vasakhanda*

Kushmandaka granules in Group C-2 provided highly significant relief ($P < 0.001$) in the symptoms of *Abhyavaharana Shakti*, *Jarana Shakti*, *Aruchi* and *Avipaka* but insignificant relief ($P > 0.05$) in *Vata-Mutra-Retasam Mukti* [Graph 5].

Dehabala

Shunthikhanda granules in Group A and *Vasakhanda Kushmandaka* granules in Group B provided highly significant relief ($P < 0.001$) in the symptoms of *Bala Vriddhi*, *Swara-Varna Yoga*, *Klama* and *Sharira Upachaya*. *Shunthikhanda* granules in Group C-1 and *Vasakhanda Kushmandaka* granules in Group C-2 provided highly significant relief ($P < 0.001$) in the symptoms of *Balavriddhi*, *Swara-Varna Yoga* and *Klama* and insignificant relief ($P > 0.05$) in *Sharira Upachaya* [Graph 6].

Chetasabala

Shunthikhanda granules in Group A and *Vasakhanda Kushmandaka* granules in Group B showed highly significant relief ($P < 0.001$) in the symptoms of *Nidra Labho Yathakalam*, *Sukhena Cha Pratibodhanam*, *Vaikarikanam Cha Swapnana Darshanam* and *Mano Buddhi Indriya Avyapatti*. *Shunthikhanda* granules in Group C-1 showed highly significant relief ($P < 0.001$) in the symptoms such as *Sukhena Cha Pratibodhanam*, *Vaikarikanam Cha Swapnana Darshanam* and *Mano Buddhi Indriya Avyapatti* and significant relief ($P < 0.05$) in *Nidra Labho Yathakalam*. *Vasakhanda Kushmandaka* granules in Group C-2 showed statistically highly significant improvement ($P < 0.001$) in *Sukhena Cha Pratibodhanam*, *Vaikarikanam Cha Swapnana Darshanam*, *Nidra Labho Yathakalam* ($P = 0.001$) and significant relief in *Mano Buddhi Indriya Avyapatti* ($P < 0.01$) [Graph 7].

Comparative effect of therapy

Rogabala

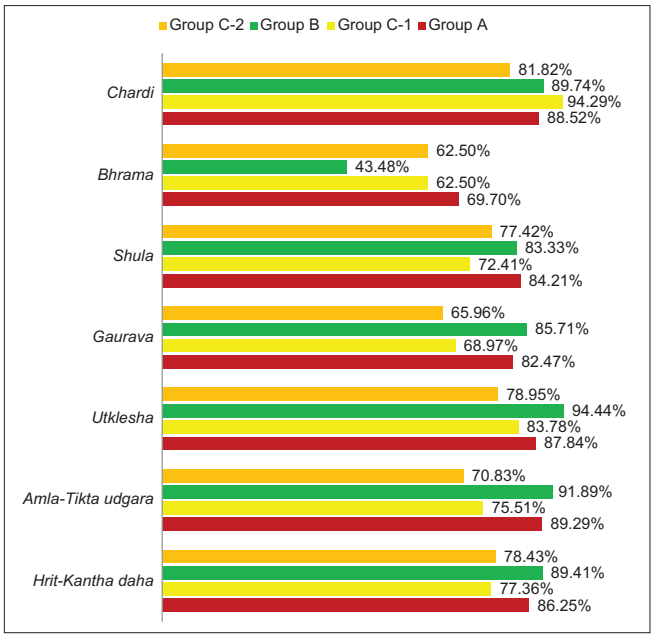
In comparison between Group A and Group C-1 [Table 1], both showed statistically insignificant improvements with $P > 0.05$, except in *Gaurava* and *Shula*; therapeutic effect was statistically significant with $P < 0.05$. In comparison between Group B and Group C-2 [Table 2], both showed statistically insignificant improvements with $P > 0.05$. In comparison between Group C-1 and Group C-2 [Table 3], both showed statistically insignificant improvements with $P > 0.05$.

Agnibala

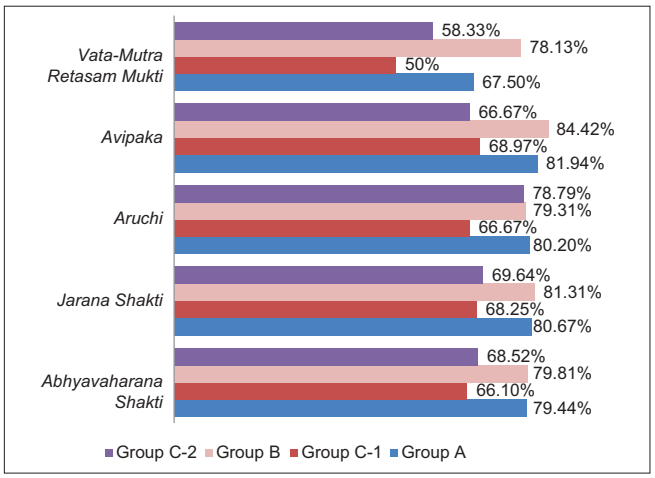
In comparison between Group A and Group C-1 [Table 4], both showed improvements which were statistically highly significant with $P < 0.001$ in *Abhyavaharana Shakti*, *Jarana Shakti* and *Aruchi*. The effect was statistically insignificant on *Avipaka* and *Vata-Mutra Retasam Mukti* with $P > 0.05$. In comparison between Group B and Group C-2 [Table 5], both showed statistically insignificant improvement with $P > 0.05$.

Dehabala

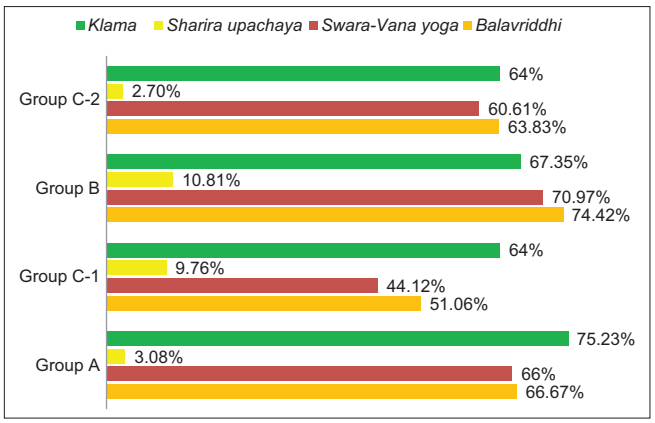
In comparison between Group A and Group C-1 [Table 6], both showed statistically insignificant improvements in *Swara-Varna Yoga* and *Sharia Upachaya* with $P > 0.05$, highly significant ($P < 0.001$) in *Balavriddhi* and statistically significant ($P < 0.05$) in *Klama*. In comparison between Group B and Group C-2 [Table 3], both showed statistically insignificant improvements with $P > 0.05$.



Graph 4: Effect of therapy on *Rogabala* in Group A, C-1, B and C-2



Graph 5: Effect of therapy on *Agnibala* in Group A, C-1, B and C-2



Graph 6: Effect of therapy on *Dehabala* in Group A, C-1, B and C-2

Table 1: Comparison of the effect of therapy on *Rogabala* between Group A and Group C-1 (unpaired *t*-test)

Symptom	Group A (*n*=34)			Group C-1 (*n*=21)			*t*	*P*
	n	Mean±SEM	Relief (%)	*n*	Mean±SEM	Relief (%)		
Hrid-Kantha Daha	34	2.029±0.143	86.25↓	21	1.952±0.109	77.36↓	−0.382	0.704
Amla-Tikta Udgara	34	2.206±0.157	89.29↓	21	1.762±0.181	75.51↓	−1.811	0.076
Utklesha	32	1.688±0.145	87.84↓	20	1.550±0.114	83.78↓	0.671	0.505
Gaurava	34	2.353±0.157	82.47↓	21	1.905±0.118	68.97↓	−2.029	0.048
Shula	26	1.846±0.154	84.21↓	16	1.313±0.120	72.41↓	2.448	0.019
Brahma	20	1.150±0.254	69.70↓	6	0.833±0.307	62.5↓	−0.317	0.530
Chardi	32	1.688±0.145	88.52↓	21	1.571±0.111	94.29↓	0.579	0.565

Data (mean±SEM). *P<0.05, **P<0.02, ***P<0.01. ↓: Decrease, SEM: Standard error of mean, * : Not significant; ** : Significant; *** : Highly significant, SEM : Standard Error of Mean

Table 2: Comparison of the effect of therapy on *Rogabala* between Group B and Group C-2 (unpaired *t*-test)

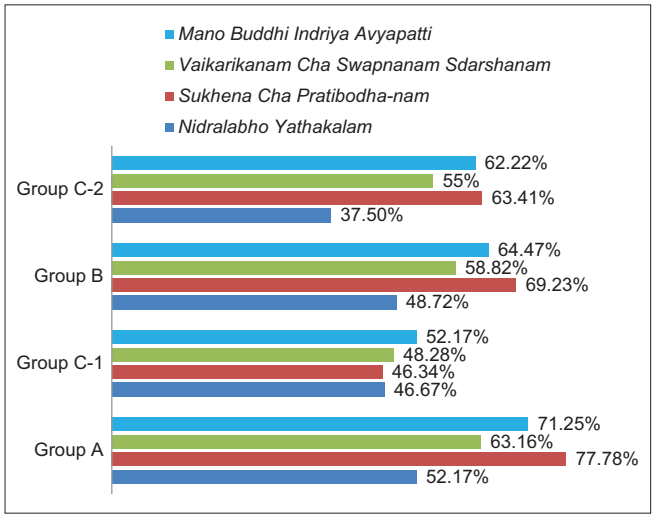
Symptom	Group B (*n*=34)			Group C-2 (*n*=18)			*t*	*P*
	n	Mean±SEM	Relief (%)	*n*	Mean±SEM	Relief (%)		
Hrid-Kantha Daha	34	2.235±0.104	89.41↓	18	2.222±0.129	78.43↓	0.076	0.939
Amla-Tikta Udgara	34	2.000±0.127	91.89↓	18	1.889±0.179	70.83↓	0.511	0.611
Utklesha	34	1.500±0.087	94.44↓	18	1.667±0.140	78.95↓	−1.062	0.293
Gaurava	33	2.182±0.165	85.71↓	18	1.722±0.226	65.96↓	1.646	0.106
Shula	25	1.400±0.129	83.33↓	15	1.714±0.163	77.42↓	−1.486	0.146
Brahma	11	0.909±0.211	43.48↓	10	1.000±0.298	62.5↓	0.252	0.803
Hrillasa/Praseka/Chardi	27	1.296±0.129	89.74↓	18	1.500±0.167	81.82↓	−0.978	0.333

Data (mean±SEM). *P<0.05, **P<0.02, ***P<0.01. ↓: Decrease, SEM: Standard error of mean, * : Not significant; ** : Significant; *** : Highly significant, SEM : Standard Error of Mean

Table 3: Comparison of the effect of therapy on *Dehabala* between Group B and Group C-2 (unpaired *t*-test)

Symptom	Group B (*n*=34)			Group C-2 (*n*=18)			*t*	*P*
	n	Mean±SEM	Relief (%)	*n*	Mean±SEM	Relief (%)		
Balavriddhi	33	1.882±0.132	74.42↑	18	1.667±0.181	63.83↑	0.963	0.340
Swara-Varna Yoga	34	1.294±0.108	70.97↑	18	1.111±0.137	60.61↑	−1.023	0.311
Sharira Upachaya	33	0.235±0.120	10.81↑	18	−0.056±0.151	2.70↑	1.469	0.148
Klama	34	1.941±0.158	67.35↓	18	1.778±0.207	64↓	−0.619	0.539

Data (mean±SEM). *P<0.05, **P<0.02, ***P<0.01. ↓: Decrease, ↑: Increase, SEM: Standard error of mean, * : Not significant; ** : Significant; *** : Highly significant, SEM : Standard Error of Mean



Graph 7: Effect of therapy on *Chetasabala* in Group A, C-1, B and C-2

Chetasabala

Comparative effect of therapy on *Nidra Labho Yathakalam* and *Vaikarikanam Cha Swapnana Darshanam* in between Group A and Group C-1 was statistically insignificant with $P > 0.05$ [Table 7] but significant on *Mano Buddhi Indriya Avyapatti* with $P < 0.05$ and highly significant on *Sukhena Cha Pratibodhanam* ($P < 0.001$). In comparison between Group B and Group C-2 [Table 8], both showed statistically insignificant improvements with $P > 0.05$.

Comparison of overall effects as well as average relief of therapies

Regarding overall effect of therapy, marked positive improvement in Group A was 35.29%, in Group B, 26.47%, in Group C-1, 23.08% and Group C-2, 16.67%. Moderate improvement in Group A was 52.94%, in Group B, 58.82%, in Group C-1, 42.86% and in C-2, 61.11% whereas mild

Table 4: Comparison of the effect of therapy on *Agnibala* between Group A and Group C-1 (unpaired *t*-test)

Symptom	Group A (*n*=34)			Group C-1 (*n*=21)			*t*	*P*
	n	Mean±SEM	Relief (%)	*n*	Mean±SEM	Relief (%)		
Abhyavaharana Shakti	34	2.588±0.120	79.44↑	21	1.857±0.159	66.10↑	3.704	<0.001
Jarana Shakti	34	2.912±0.115	80.67↑	21	2.048±0.201	68.25↑	4.027	<0.001
Aruchi	34	2.441±0.212	80.2↓	21	1.333±0.187	66.67↓	3.603	<0.001
Avipaka	34	1.794±0.125	81.94↓	21	1.905±0.168	68.97↓	0.536	0.595
Vata-Mutra Retasam Mukti	30	0.900±0.100	67.5↑	11	0.636±0.152	50↑	1.393	0.172

Data (mean±SEM). *P<0.05, **P<0.02, ***P<0.01. ↓: Decrease, ↑: Increase, SEM: Standard error of mean, * : Not significant; ** : Significant; *** : Highly significant, SEM : Standard Error of Mean

Table 5: Comparison of the effect of therapy on *Agnibala* between Group B and Group C-2 (unpaired *t*-test)

Symptom	Group B (*n*=34)			Group C-2 (*n*=18)			*t*	*P*
	n	Mean±SEM	Relief (%)	*n*	Mean±SEM	Relief (%)		
Abhyavaharana Shakti	34	2.441±0.128	79.81↑	18	2.056±0.171	68.52↑	−1.789	0.080
Jarana Shakti	34	2.559±0.105	81.31↑	18	2.167±0.185	69.64↑	1.989	0.052
Aruchi	33	2.091±0.181	79.31↓	17	1.412±0.243	78.79↓	1.943	0.058
Avipaka	34	1.912±0.122	84.42↓	18	1.778±0.173	66.67↓	0.639	0.526
Vata-Mutra Retasam Mukti	26	0.962±0.117	78.13↑	10	0.700±0.153	58.33↑	1.232	0.226

Data (mean±SEM). *P<0.05, **P<0.02, ***P<0.01. ↓: Decrease, ↑: Increase, SEM: Standard error of mean, * : Not significant; ** : Significant; *** : Highly significant, SEM : Standard Error of Mean

Table 6: Comparison of the effect of therapy on *Dehabala* between Group A and Group C-1 (unpaired *t*-test)

Symptom	Group A (*n*=34)			Group C-1 (*n*=21)			*t*	*P*
	n	Mean±SEM	Relief (%)	*n*	Mean±SEM	Relief (%)		
Balavriddhi	32	1.875±0.108	66.67↑	21	1.143±0.173	51.06↑	3.795	<0.001
Swara Varna Yoga	34	1.031±0.105	66↑	21	0.714±0.156	44.12↑	1.748	0.086
Sharira Upachaya	34	0.059±0.111	3.08↑	21	−0.190±0.112	9.76↑	1.495	0.141
Klama	34	2.412±0.153	75.23↓	19	1.684±0.217	64↓	−2.788	0.007

Data (mean±SEM). *P<0.05, **P<0.02, ***P<0.01. ↓: Decrease, ↑: Increase, SEM: Standard error of mean, * : Not significant; ** : Significant; *** : Highly significant, SEM : Standard Error of Mean

Table 7: Comparison of the effect of therapy on *Chetasabala* between Group A and Group C-1 (unpaired *t*-test)

Symptom	Group A (*n*=34)			Group C-1 (*n*=21)			*t*	*P*
	n	Mean±SEM	Relief (%)	*n*	Mean±SEM	Relief (%)		
Nidra Labho Yathakalam	28	0.964±0.196	52.17↑	17	1.059±0.201	46.67↑	−0.319	0.751
Sukhena Cha Pratibodhanam	34	1.941±0.119	77.78↑	21	0.905±0.168	46.34↑	−5.166	<0.001
Vaikarikanam Cha Swapnana Darshanam	24	1.083±0.158	63.16↑	18	0.778±0.191	48.28↑	1.241	0.222
Mano Buddhi Indriya Avyapatti	34	1.765±0.127	71.25↑	21	1.143±0.159	52.17↑	−3.045	0.004

Data (mean±SEM). *P<0.05, **P<0.02, ***P<0.01. ↑: Increase, SEM: Standard error of mean, * : Not significant; ** : Significant; *** : Highly significant, SEM : Standard Error of Mean

Table 8: Comparison of the effect of therapy on *Chetasabala* between Group B and Group C-2 (unpaired *t*-test)

Symptom	Group B (*n*=34)			Group C-2 (*n*=18)			*t*	*P*
	n	Mean±SEM	Relief (%)	*n*	Mean±SEM	Relief (%)		
Nidra Labho Yathakalam	22	0.864±0.136	48.72↑	11	0.818±0.182	37.5↑	−0.196	0.846
Sukhena Cha Pratibodhanam	32	1.688±0.122	69.23↑	18	1.444±0.185	63.41↑	1.136	0.262
Vaikarikanam Cha Swapnana Darshanam	22	0.864±0.190	58.82↑	11	1.000±0.234	55↑	0.293	0.771
Mano Buddhi Indriya Avyapatti	33	1.485±0.116	64.47↑	18	1.556±0.185	62.22↑	−0.340	0.735

Data (mean±SEM). *P<0.05, **P<0.02, ***P<0.01. ↑: Increase, SEM: Standard error of mean, * : Not significant; ** : Significant; *** : Highly significant, SEM : Standard Error of Mean

improvement observed in Group A was 11.76%, in Group B, 14.71%, in Group C-1, 23.81%, and in Group C-2, 11.11%. No improvement was observed only in Group C-1 (4.76%) and C-2 (5.56%). Complete remission (2.56%) was observed only in Group C-2 (5.56%) [Table 9].

Average relief of Group A and Group B where *Shunthikhanda* and *Vasakhanda Kushmandaka* granules were given according to *Doshik* predominance was far better (68.78% and 65.4%, respectively) than that of Group C-1 and C-2 (60.40% and 64.46%) where *Shunthikhanda* and *Vasakhanda Kushmandaka* granules were given randomly without any *doshik* predominance [Table 10].

After 1 week of follow-up, lesser incidence of recurrence of disease was reported in Group A (14.71%) and Group B (20.59%) rather than Group C-1 (33.33%) and Group C-2 (22.22%). *Shunthikhanda* granules in Group A exert a more sustained effect than *Vasakhanda Kushmandaka* granules in Group B on patients of *Amlapitta* even after discontinuation of the drug for 1-week follow-up [Table 11].

Discussion

Manifestation of a disease depends upon the intensity of conjunction of *Nidana*, *Dosha* and *Dushya*. *Amlapitta* is one of the most prevalent lifestyle disorder caused by *Mandagni* due to vitiation of *Vata* (32.77%), *Pitta* (47.36%) and *Kapha* (55.68%) as well as *Purishavaha* (100%), *Rasavaha* (72.31%), *Annavaha* (62.89%), *Raktavaha* (39.30%) and *Swedavaha* (25.50%) *Strotasa*. *Amashaya* is the seat of *Samana Vayu*, *Pachaka Pitta*, *Kledaka Kapha* and also the root of *Annavaha Strotasa* whereas *Grahani* is the seat of *Agni*. *Samana Vayu*, *Pachaka Pitta* and *Kledaka Kapha* may involve in the *Sthanasamshraya* at *Amashaya* including *Grahani* where simultaneously *Khavaigunya* takes place. When *Vata* gets vitiated by *Ama*, there is the possibility of *Marga Avarana* by *Vriddha Pitta* and *Kapha*. Hence, *Amlapitta* is the disease condition produced by *Pitta-Kapha Avrita Vata*.

A patient constitutes the *Karyadesha* or the site for administration of therapies with a view to bringing about equilibrium of *Dhatu*. Manifestation of disease depends on resemblance of the afflicted *Dosha-Dushya-Prakriti-Desa-Kala-Bala* of individual with that of the *Hetubala* and *Vyadhibala*. The dosage in which a therapy is to be administered depends on the intensity of morbidity as well as the strength of the patients.

Maximum patients (29.46%) were in the age group of 41–50 years (*Pitta*-predominant state). *Pitta Prakriti* (45.54%), afflicted with *Krodha* (54.46%), habituated in taking of *Viruddhashana* (83.04%); *Vidahi* (84.82%), *Katu* (80.36%) and *Lavana Rasa* (53.57%) predominant diet as well as intake of *Guru Ahara* (heavy in quantity and quality – 96.43%), *Shita Ahara* (32.14%) and habits of *Bhuktamatrasya Swapna* (73.21%) cause *Agninirvapana* by increasing *Dravatva* of *Pachaka Pitta* and *Snigdhata* of *Kledaka Kapha* because basically *Drava* and *Snigdha Guna* procreate *Klinnata* in our body. This excessive *Kleda* causes *Agnimandya* and produces *Ama*. Due to *Shuktapaka*, *Ama* gets vitiated and produces *Amavisha* which again comes in contact with *Vidagdha Pachaka Pitta* which is evolve as *Vidagdhajirna*. If the disease is neglected, establishing their affinity in *Amashaya* and *Grahani*, the vitiated *Doshas* lead the condition into *Amlapitta*.

In *Shamana* therapy, *Kapha-Pittahara Chikitsa* is the principle of treatment for *Amlapitta*. Due to *Kapha*-pacifying ingredients in *Shunthikhanda* granules and *Pitta*-pacifying ingredients in *Vasakhanda Kushmandaka* granules, the drugs were advocated to the patients of *Kapha*-predominant and *Pitta*-predominant *Amlapitta,* respectively [Figures 1 and 2].

Average relief of the patients (in Group A and B) whom medicines were given according to *Doshik* predominance was far better (68.78% and 65.4%) than the patients (in Group C-1

Table 9: Overall effect of therapy

Criteria	Effect of therapy			
	Group A, number of patients (%)	Group B, number of patients (%)	Group C-1, number of patients (%)	Group C-2, number of patients (%)
Unchanged	0	0	1 (4.76)	1 (5.56)
Mild improvement	4 (11.77)	5 (14.71)	5 (23.81)	2 (11.11)
Moderate improvement	18 (52.94)	20 (58.82)	9 (42.86)	11 (61.11)
Marked improvement	12 (35.29)	9 (26.47)	6 (28.57)	3 (16.67)
Complete remission	0	0	0	1 (5.56)

Table 10: Comparison on average relief of the effect of therapy between Group A, Group B, Group C-1, and Group C-2

Group	Rogabala (%)	Agnibala (%)	Dehabala (%)	Cetasabala (%)	Average relief (%)
Group A	77.80	77.95	57.11	62.27	68.78
Group C-1	80.03	65.13	42.36	54.10	60.40
Group B	74.97	77.74	58.52	50.37	65.4
Group C-2	74.59	71.76	51.62	59.88	64.46

Table 11: Recurrence of *Amlapitta* during follow-up

Recurrence			
Group A, number of patients (%)	Group B, number of patients (%)	Group C-1, number of patients (%)	Group C-2, number of patients (%)
5 (14.71)	7 (20.59)	7 (33.33)	4 (22.22)

and C-2) where medicines were given randomly without any *doshik* predominance (60.40% and 64.46%, respectively).

The *Phalashruti* is that the vitiated *Dosha*, alleviated by *Langhana* and *Pachana*, may be aggravated at any time, but those who are eliminated by proper *Samshodhana* therapies do not recur further.[19] However, in this study, we knowingly had to ignore *Aptopadesha* to compromise on patients' preference and it was reflected on recurrence of the disease which was observed more in the patients of Group C-1 (33.33%) and C-2 (22.22%) than of Group A (14.71%) and Group B (20.59%).

Conclusion

In the era of rapid civilization, *Amlapitta* evolves as the most developing lifestyle disorder where *Pitta* and *Kapha* take pivot role associated with *Vata* in etiopathogenesis of *Amlapitta*. *Amlapitta* adversely affects the quality of life of patients, making it difficult to make dietary choices and causing sleep loss even hampering social life and contributes to a higher medical cost. The long-term effects can also lead to poorer quality of life. Diagnosis of the disease and treatment (*Dosha-Dushya Vighatana*) on the basis of *Doshik* predominance proved beneficial in this study.

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Conflicts of interest

There are no conflicts of interest.

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