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Research Article

A CLINICAL STUDY ON THE EFFICACY OF *SITAMANDOOR* ON *AMLAPITTA*

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ABSTRACT

Acharya Caraka & Kashyapa have explained that *Amlapitta* is mainly caused by dietetic pattern, mental stress and strain which are related to our digestion. The occurrence involves the GIT & chiefly *Kapha & Pitta Dosha*. The symptoms like Gastritis, peptic disorders, hyperacidity, hyperchlorhydria condition resemble that of *Amlapitta.*

Aim & Objective: To evaluate the efficacy of *Sitamandoor* in Specific patients of *Amlapitta*

Study Design: The study was conducted on total 18 patients of *Amlapitta* who completed the treatment all along the study period. The patients were selected from the OPD of DGMAMC & H, Gadag for respective clinical trial.

Assessment criteria: Criteria of assessment are set aside on the basis of relief in the signs and symptoms of *Amlapitta* both subjective and objective parameters.

Results: Among 18 patients 9 responded moderately, 3 markedly improved and 5 responded well to the treatment.

Interpretation & Conclusion: Though the criteria of assessment & statistical analysis reveal the effect of the study but the fact that the mode of action of the drug is the base of the relief in signs & symptoms cannot be ignored. Conclusively the treatment was satisfactorily effective in the patients.

KEY WORDS: *Amlapitta,* Gastric disorders, peptic ulcers, *Sitamandoor.*

INTRODUCTION

In *Samhitas, Amlapitta* is not mentioned as a separate disease entity but there are several references in *Charaka Samhita*[1] regarding *Amlapitta. Mad*havakara and *Kashyapa* have described this disease as a separate entity with detailed description. *Kashyapa*[2] has accepted the involvement of three *Doshas* in *Amlapitta* while *Madhavakara*[3] has accepted the dominance of *Pitta* in this disease. This disorder is the result of *Grahani Dosha* (Duodenal disease). *Charaka and Kashyapa* have clearly indicated that the *Grahani Dosha and Amlapitta* occur in the persons who fail to check the temptation of food. *Ajirna* (Indigestion) after encountering the specific *Doshas* and affinity with specific site may cause various diseases[4,5,6]. Gastritis and non-ulcer dyspepsia have been correlated with *Amlapitta*. Patients of gastritis often results into peptic ulcer. Purificatory therapy procedure has given been importance in this disease by *Sangraha Granthakara*. But it is opted less frequently in practice due to more time consumption and today's tedious lifestyle. *Acharyas* have mentioned usage of the drugs which are having *Tikta Madhura Rasa, Madhura Vipaka, Sheeta Virya and Laghu, Ruksha* property with *Kapha pittahara* action for the same.

A quick sneak into the pathology of the disease in GIT gives a brief information that on an average 500 ml of gastric juice is secreted per meal in the stomach which is acidic in reaction. Gastric acid hyper secretion occurs in Zollinger Ellison's Syndrome, Peptic ulcer, G-cell hyperplasia etc. The chronic acid hyper secretion may lead to several other complications, so it is essential to prevent it in prior stage only. In

modern science it is managed with antacids, anti-ulcers and anti-secretory drugs, being Ranitidine the most favorite and nowadays second generation drugs like omeprazole, H2 blockers can successfully control gastric irritation but these drugs are having several ill effects like skin rash, headache, constipation.[7, 8, 9]

There are innumerable herbal and herbo-mineral preparations available in market for *Amlapitta*. But effective drugs have not yet been developed properly for the complete cure of the disease. Also the modern medicines have many types of complications in this regard. Usually most of the cases treated with different formulations have the chances of recurrences and also patients may become addict to such medicine. In *Ayurveda* classic *Sitamandoor* is mentioned in *Bhaishajya Ratnawali* which is best indicated in *Amlapitta.* Thus considering the above factors in present scenario the clinical study was conducted to evaluate the anti-secretory effect of *Sitamandoor* which is easily consumable as it is in *Lehya* form.

Aims & Objectives

The main aim of the present study is to assess the anti-secretory action of *Sitamandoor in Amlapitta.*

Preparation of Trial Drug[10]

The author of *Bhaishajya ratnavali* has explained the *Sitamandoor* under *Amlapitta prakarana* to treat *Amlapitta* with same ingredients as explained in *Rasendra sara sangraha*. The formulation consists of *Madhu, Triphala, Trikatu, Sukshma Ela, Vayuvidanga, Duralabha, Kooth, Lavanga, Madhyashti* (all in ¼ part), *Mandoora Bhasma* (1part), *Sita* (5parts), *Ghrta* (8 parts), *Dugdha* (16 parts).

Methodology

CLINICAL STUDY

For the Clinical study *Sitamandoor* is administered empty stomach with cold milk as *Anupana* (vehicle) considering its effect on the GIT diseases.

Selection of patients

Method of collection of data

Present study is a prospective clinical study. The patients with *Amlapitta* w.s.r.to Hyperchlorhydria within the age group of 15 yrs to 60 yrs were selected randomly from O.P.D of D.G.M.A.M.C.H. & Research Center after fulfilling the inclusion and exclusion criteria irrespective of their sex, occupation and socio-economic status.

Sample size

A minimum of 18 patients were taken including the dropouts. Among which 17 patients completed the treatment. The present study is a single group study where in patients were assigned one group. It is a simple random sampling technique clinical trial.

Exclusion criteria

Following were the criteria to exclude the patients from the study:

1. Patient below 15 and above 60 years of the age.
2. Patients with complications like Peptic ulcers, Acute or Chronic Gastritis, any secondary infections or syndromes and Medical Emergencies.
3. Pregnant women and lactating mother.
4. Any other systemic disorders other than *Amlapitta.*
5. *Amlapitta* patients along with metabolic diseases, such as Diabetes and Hypertension.
6. Complication which intervenes the course of treatment.
7. Patients on chemo and radio therapy for malignancy.

Inclusion criteria

The selection of the patient for clinical study was done with following criteria

1. Age of patients between 15 to 60 years
2. No discriminations of chronicity and severity of disease
3. Patients of classical *Amlapitta* symptoms irrespective of gender, caste, occupation and economic status.
4. *Amlapitta* of any *Dosha anubandha* (associated *Doshas)*.
5. Cases of *Amlapitta* in whom treatment was interrupted are considered with a period of one week gap and then selected for treatment.

Criteria of Diagnosis

Diagnosis is made on the basis of classical symptoms and presence of prominent feature of *Amlapitta*.

Study design: Clinical observational study Simple random sampling techniques.

Posology: *Sitamandoor* started with 2gm and day to day increase 1-1 gm till 12gm.once in a day, empty stomach for 30 days with cold milk as *Anupana.*

Study duration: 45 days study

Follow up: 15 days.

Criteria for Assessment: The symptoms as per the classical norms and the investigations as per the modern norms are both considered subjective and objective parameters. They are mentioned in the table1.1 below.

Table 1: Showing the Various Criterion for Assessment of *Amlapitta*

The Symptoms of *Amlapitta* in classical text are as follows[11, 12]

- *Avipaka* (indigestion)
- *Aruchi* (anorexia)
- *Gourava* (feeling of heaviness in the body)
- *Hrudaha* (burning sensation in chest)
- *Utklesha*(nausea)
- *Chardi* (vomiting)
- *Amlodgara, Tiktodgara* (erectations of sour/bitter taste)
- *Klama* (exhaustion without exertion)
- *Daha* (burning sensation in throat)
- *Agnimandya* (loss of appetite)

Investigations

- Hb %
- Total RBC count
- Total WBC count
- ESR
- Stool analysis (if necessary)

The effect of the drug under trial was based mainly on the improvement in the cardinal signs and symptoms of disease as mentioned above. To give some objectivity, from the above given classical signs & symptoms the score was assigned to each of the major symptoms of the disease like *Daha, Amlodgara, Shula, Chhardi and Avipaka*. These 5 symptoms were taken for consideration for grading criteria, they were given scores & on the basis of before and after treatment score, the statistical analysis was done using paired 't' test and S.D., S.E. and P value were calculated.

GRADING CRITERIA

Table 1.2: showing the grading criteria of the assessment parameters

Daha	Absent	:	0
	Mild	:	1
	Moderate	:	2
	Severe	:	3
Chardi	Absent	:	0
	Mild	:	1
	Moderate	:	2
	Severe	:	3
Shoola	Absent	:	0
	Mild	:	1
	Moderate	:	2
	Severe	:	3
Avipaka	Absent	:	0
	Mild	:	1
	Moderate	:	2
	Severe	:	3
Amlodgara	Absent	:	0
	Mild	:	1
	Moderate	:	2
	Severe	:	3
Aruchi	Absent	:	0
	Mild	:	1
	Moderate	:	2
	Severe	:	3
Gaurava	Absent	:	0
	Mild	:	1
	Moderate	:	2
	Severe	:	3
Utklesha	Absent	:	0
	Mild	:	1
	Moderate	:	2
	Severe	:	3
Tiktodgar	Absent	:	0
	Mild	:	1
	Moderate	:	2
	Severe	:	3
Klama	Absent	:	0
	Mild	:	1
	Moderate	:	2
	Severe	:	3

Assessment of result: The subjective and objective parameters of base line data to post medication as mentioned above were compared for assessment of result. All the result were analyzed statistically.

Observation & Result

EFFECT OF THERAPY

Total 17 patients completed their treatment with *Shamana chikitsa* by administering *Sitamandoor* group. *Sitamandoor* was given for 1 month in a dose of 2 gm tds for 1 month.

Observations are being presented in different parts i.e. effect on cardinal symptoms, effect on associated symptom, effect on *Agnidushti and Kostha Vikriti.* Total effect of therapies was assessed on the basis of above effect which is also being presented in the tables below.

The cardinal symptoms and associated symptoms were exhibited in different percentage in the patients. Generally all the patients showed *Shirahshula* and *Gaurava*. 65.36% patients showed *Bhrama* and 51.60% patients showed *Klama* as associated symptoms.

Table 1.3: Showing the no. of patients presenting the cardinal + other signs & symptoms

Complaints	No. of patients	Percentage of patients
Avipaka	17	94.45
Aruchi	14	77.78
Gaurava	10	55.56
Hritdaha	15	83.34
Utklesha	12	66.67
Amlodgar	15	83.34
Tiktodgar	08	44.45
Kanthadaha	15	83.34
Klama	10	55.56
Chardi	08	44.45

Table 1.4 Showing the Assessment Parameters with Their Grading

S.No	Signs/Symptoms	Before treat	After treat	After follow up
1	*Daha*	15	10	8
2	*Shoola*	14	8	6
3	*Chardi*	08	4	4
4	*Avipaka*	17	7	6
5	*Amlodgar*	15	6	5

Table 1.5: Showing the Grading of Associated Symptoms

S.No	Signs/Symptoms	Before treat	After treat	After follow up
1	*Aruchi*	14	9	8
2	*Gaurava*	10	5	4
3	*Utklesha*	12	7	6
4	*Klama*	10	4	4
5	*Tiktodgar*	08	3	3

Table 1.6 Showing Effect of *Sitamandoor* on cardinal symptoms of 17 patients of *Amlapitta*

Data	*Daha*	*Amlodgara*	*Shula*	*Chhardi*	*Avipaka*
N	17	17	17	17	17
B.T.	2.58	2.88	2.35	1.58	2.64
A.T.	1.00	0.94	0.76	0.47	0.52
% Relief	61.24	67.36	67.65	70.25	80.30
S.D.	0.50	0.48	0.79	0.52	0.78
S.E.	0.12	0.11	0.19	0.12	0.12
't'	13.16	17.09	08.31	09.75	11.72
P	<0.001	<0.001	<0.001	<0.001	<0.001

Table 1.7 Showing Effect of *Sitamandoor* on Associated symptoms of 17 patients of *Amlapitta*

Data	*Klama*	*Shirahshula*	*Gaurava*	*Bhrama*
N	07	17	17	10
B.T.	02	02	02	02
A.T.	1.71	1.29	0.94	1.70
% Relief	14.50	35.50	53.00	15.00
S.D.	0.48	5.68	0.42	0.48
S.E.	0.18	0.16	0.10	0.15
't'	1.55	4.37	10.50	2.00
P	>0.05	<0.001	<0.001	>0.05

Table 1.8 Showing Effect of *Sita mandoor* on *Agnidushti* of 17 patients of *Amlapitta*

Data	*Aruchi*	*Agnimandya*
N	17	17
B.T.	02	02
A.T.	0.47	0.52
% Relief	76.50	74.00
S.D.	0.51	0.51
S.E.	0.12	0.12
't'	12.66	12.25
P	<0.001	<0.001

Table 1.9 Showing Overall effect of *Sitamandoor* in 17 patient of *Amlapitta*

Total Effect	No. of Patients	%
Complete remission	00	00
Markedly improved	03	17.62
Moderately improved	09	52.92
Improved	05	29.40
Unchanged	00	00.00

17.62% patients showed marked improvement, 52.92% patients showed moderate improvement while 29.40% patients showed slight improvement. There was no complete remission in any of these patients and also no side effects were observed during the entire study duration.

STATISTICAL ANALYSIS OF CRITERIAS FOR ASSESSMENT

Table 2.0: Showing the Subjective & Objective Statistical Gradings

Symptoms	BT	AS	AF
Daha	3.12	1	0.4
Amlodgara	3.145	0.94	0.3
Shula	2.67	0.76	0.5
Chardi	2.04	0.47	0.6
Avipaka	2.94	0.52	0.4
Klama	2	1.71	0.6
Shirahashula	2	1.29	0.3
Gaurava	2	0.94	0.4
Bhrama	2	1.7	0.8
Aruchi	2	0.47	0.9
Agnimandya	2	0.52	0.6

Table 2.1: Showing the Subjective & Objective Statistical Gradings

Sl. No.	OPD No.	HB%		RBC Count		WBC Count		ESR	
		BT	AT	BT	AT	BT	AT	BT	AT
1	355	11.5	12.6	4.2	4.6	9000	8300	14	12
2	477	10.5	12.5	4.1	4.7	8300	7900	16	14

3	1024	11.5	12.6	4.4	4.7	8600	7900	18	13
4	1038	10.5	11.6	4.1	4.7	8400	8100	23	16
5	1155	11.5	12.5	4.2	4.7	7900	7400	22	16
6	1167	09.5	11.6	4.1	4.3	9000	8600	14	12
7	1275	11.3	12.4	3.8	4.3	8100	7900	18	14
8	1391	11.5	12.0	4.1	4.9	7800	7300	20	16
9	1614	10.3	11.5	4.0	4.1	8900	8100	14	12
10	1893	11.6	12.5	3.8	4.4	8300	7600	16	12
11	1928	11.5	12.9	4.2	4.7	7400	7200	13	10
12	1943	10.3	12.1	4.2	4.7	8300	8100	16	13
13	1994	11.0	12.4	4.1	4.6	7200	6900	24	16
14	2328	11.5	12.5	4.0	4.2	8300	8100	25	18
15	2383	10.5	11.5	3.9	4.1	8900	8700	16	12
16	2330	11.2	12.4	4.1	4.2	8400	8100	14	12
17	2321	11.4	10.3	4.0	4.6	8700	8200	21	18

DISCUSSION

Statistical point of view: 17.62% patients showed marked improvement, 52.92% patients showed moderate improvement while 29.9% showed slight improvement and no patient remains unchanged.

Drug action point of view[13,14,15]: The contents of *Sitamandoor* are *Laghu* and *Ruksha* in property. There is increase of *Drava Guna* in *Amlapitta. Kledaka Kapha* and *Pachaka Pitta* are Drava in dominancy. So *Laghu-Ruksha Guna* performs the function of *Dravansha - Shoshana*. Other functions of *Laghu*, *Ruksha Guna* are *Lekhana*, *Stambhana* and *Ropana*. This formulation is *Tikta* dominant and it performs the functions of *Pachana* rather than *Deepana*. *Tikta* Rasa helps in *Shoshana* of *Jala* dominant substances which includes *Kleda, Meda, Vasa, Lasika*, *Pitta* and *Kapha*.

Tikta-Kashaya Rasa helps in pacifying the *Kapha-pitta* both.

In these two rasa *Tikta* is better as it is *Laghu* and it does not stagnate the *Ama*. It performs the function of *Pitta-Sleshma Shoshana* as described by *Charaka*. "*Tikta Vishadyati*" can be observed throughout gastrointestinal tract (G.I.T.)

All contents of this formulation balance the each others drawback. As *Tikta* is *Avrishya* and *Vatakaraka* but *Duralabha* and *Kooth* are opposite to it. Because of *Tikta rasa* and *Laghu- Ruksha* Property there are chances of constipation but '*Triphala'* is added so there is *Anulomana* property. *Ksheera* also plays an important role as it is *Pathya* for *Amlapitta*.

CONCLUSION

- *Amlapitta* a foremost disease can be understood as the normal functioning of the *Agni, Pachaka pitta* (the secreto enzymatic functioning of GIT) where diet plays a vital role. It is chronic in nature.
- The drug under trial *Sitamandoor* was effective in hyperacidity condition. It relieved hyperacidity in 3 patients remarkably, 9 moderately & 5 patients ended with improving well.
- It was observed that patients taking *Sitamandoor* were relieved of their symptoms after 15 - 21 days drug regimen. It was observed that the drug is specifically effective in early cases of *Amlapitta*. This beneficial effect of trial drug may be due to *Tikta Rasa, Laghu - Ruksha* property and *Kapha pittahara* action of the combined drug of this preparation.
- *Sitamandoor* exhibited specific role in relieving the cardinal signs & symptoms of *Amlapitta*.
- These findings have proved that *Sitamandoor* has got specific therapeutic activity in the treatment of *Amlapitta*.

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