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TO STUDY THE EFFICACY OF SHUNTIKHANDIN THE MANAGEMENT OF AMLAPITTA

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ABSTRACT

In recent years there has been an unprecedented increase of incidences related to GI system due to changing in life style, Diet pattern, behavioral pattern and mental stress and strain. *Amlapitta* is such type of GI disorder due to same causative factor as, closely resembles with Gastritis in modern science also and in chronic stage it may lead to ulceration condition. In this study *Shunthikhand* Ayurvedic preparation with cap Omeprazole allopathic medicine compares and observed the result. *Shuntikh* and preparation was taken from *bhaishajyaratnavati*. *ShunthiKhanda'* constitutes with *Shunthi* as the main ingredient i.e. 16 time more than other drugs, along with other prakshepadravyas (1/16th part) and *Ghrita, Dugdha, Madhu* and *Sharkara*. Cap omeprazole is the worldwide accepted drug for hyperacidity but it has some limitations. This study was done to study the efficacy of *shuntikhand* in comparison with cap omeprazole.

Keyword: gastritis, *amlapitta*, *shuntikhand*, cap omeprazole

INTRODUCTION

Amlapitta is one of the most common diseases seen in society. In modern era's changing life style along with changing food culture, behavioral pattern; Hurry, Worry and Curry are three main reasons for this disease. *Amlapitta* is a disease of *Annavahasrotas*. In present time most of the people suffering from *Ajirna* and *Amlapitta* due to mental stress and bad food habit. Acid Peptic Disease is vast terminology it cannot be correlated with Amlapitta but the etiology and symptoms of non ulcer Acid Peptic diseases like gastritis is similar to *Amlapitta* so it can be compared with *Amlapitta.* In this study chronic and those having recurrent symptoms of *Amlapitta* patient was selected. Patients were equally distributed in two different groups and observed the result of *Shunthikhand Ayurvedic* preparation and cap Omeprazole allopathic medicine. Omeprazole is the Worldwide accepted drug for Acid peptic disorder but this drug has some side effect. In this study how *Shunthikhand* gave result in comparison with Cap Omeprazole was discussed.

Aims and objective:

1. To study efficacy of *Shunthikhand* in the management of *Amlapitta.*
2. To study efficacy of cap Omeprazole in the management of *Amlapitta.*
3. To evaluate the efficacy of *Shunthikhand* in comparison with cap Omeprazole in the management of *Amlapitta.*

Material and method

GROUP – A

Shunthikhand: All drugs of *Shunthikhand* were identified and authentified by respected guide and the *churnadravyas* were added as per *Bhaishajyaratnavali* refer-

ence. *Shunthikhand* was standardized from Qualichem laboratory.

GROUP – B

Cap Omeprazole: Cap Omeprazole is the standard drug for Acid Peptic Disorder. This drug was used for comparison in this clinical study

INCLUSIVE CRITERIA:

a) Age : >20 to <60years
b) Sex : No barrier
c) Race & Religion : No barrier
d) Economic status : No barrier
e) Chronicity : >1yr to <5yr
f) Patients presenting classical features of *Amlapitta* described in *shastra.*
g) Patients willing to give informed written consent.

5. EXCLUSIVE CRITERIA:

a) Age below 20 and above 60 years.
b) Patient with history of Haemetmesis, Maleana and Anaemia.
c) Patient with drug induced Amlapittas.
d) Patient who are known case of peptic ulcer, T.B, ca oesophagus & other diseases
e) Patient having major cardiac disorder, diabetes mellitus.
f) Patients suffering from infectious diseases, pregnant women.

6. INFORMED CONSENT: Patient fulfilling criteria for selection will be included under the study after receiving their written consent.

7. WITHDRAWAL FROM STUDY: withdrawal of patient will be done on ethical ground after discussion with respected guide.

9. GROUPING:

GROUP A (TRIAL GROUP)

Number of Patients: 30 (including LAMA) well diagnosed patients of *Amlapitta* presenting with classical symptoms of *Amlapitta.*

Treatment: *Shunthikhand* for 1 month (4 week) 3gm in divided dose Follow up was taken at 1 week interval

GROUP B (CONTROL GROUP)

Number of Patients: 30 (including LAMA) well diagnosed patient's of *Amlapitta* presenting with classical symptoms of *Amlapitta*

Treatment: Cap Omeprazole 20mg BD for 1 month follow up was taken at 1 week interval

Table no.1 Scoring pattern:

Sr. No	Symptoms	Grade	Lakshana
1	*Amloudgara*	0	No amloudgara
		1	Sometime during a day
		2	Amloudgara of modrate severity upto next meal but not disturb the patient
		3	Severe amloudgara disturbing the patient
		4	Small amount of fluid regurgitate to patient mouth
2	*Urdaha*	0	No *Urdaha*
		1	Mild degree of *Daha*
		2	Modrate degree of *daha* that subside after taking sweet /cold food /milk/antacid
		3	Severe degree of *daha* involving two or three region relieved after vomiting.
3	*Amlaprachiti*	0	No *Amlaprachiti*
		1	Mild *Amlaprachiti* during day
		2	IntermitantAmlaprachiti
		3	Persistant*Amlaprachiti*
4	*Kantdaha*	0	No *kantadaha*

		1	Mild degree of *daha* in kantaPradesh
		2	Moderate degree of *daha*
		3	Severe degree of *daha* relived after vomiting
5;	Constipation	0	Occurs easily in routine time
		1	Some time difficulty in defecation
		2	Difficulty in defecation but *malpravruti* daily with discomfort in abdomen
		3	Can't pass stool daily and heaviness in abdomen
6;	***Shirshool***	**0**	**No *shirshool***
		1	Mild *shirshool* after lunch
		2	Intermitantshirshool
		3	Persistantshirshool
7	*Hrulas*	0	No *Hrullas*
		1	Frequency of salivation on every day
		2	Feel sense of nauseating and vomit occasionally
		3	Frequency of vomiting is two or three time or more per week
8	*Adhman*	0	No *Adhman*
		1	Occasionally feeling distention of abdomen
		2	Daily after intake of food upto 1hr with mild distention abdomen
		3	Distention of abdomen upto 1-3 hr after intake of food
9;	*Udargaurav*	0	No *Udargaurav*
		1	Occasionally *udargaurav* due to indigestion
		2	Daily *Udargaurav* with *udgarbahuly*a which subside within hour
		3	*Udargavarav* and *udgarbahuly*a disturb the routine life
10	*Angasad*	0	No *Angasad*
		1	Occasionally feeling of heaviness for sometime in hand and feet
		2	Feeling of heaviness in hand and feet
		3	Daily feeling of heaviness over body which lead to *akarmanyata*
11	*Netradaha*	0	No *netradaha*
		1	*Mild netradaha*
		2	*Intermitant netradaha*
		3	Persistant *netradaha*

Observation and Result:

In the present study patients were diagnosed with the help of clinical features. All these patients were randomly distributed into two equal groups, namely Trial Group and Control Group. Out of total 60 patients, 4 nos and 5nos of patients from Trial and Control Group respectively left the treatment without prior intimatimation. Theywere labeled as LAMA (Left against Medical Advice). Therefore their observations were not included in this study. Remaining 51 patients from both the groups were examined clinically according to the specially prepared proforma (CRF).

Effect of therapy on *PramukhLakshan:*

Table no. 2 Showing Effect of Therapy on General Symptoms Score of 51 Patients of Amlapitta

Sr.No	Symptoms	Group	Symptoms Score			% of Relief (Diff/BT)
			BT	AT	Diff	
1	*Amloudgara*	Trial Group Control Group	31 34	08 07	23 27	74% 72%
2	*Urodaha*	Trial Group Control Group	45 44	13 09	32 35	71% 79%
3	*Amlaprachiti*	Trial Group Control Group	37 36	08 06	29 30	78% 83%
4	*Kantadaha*	Trial Group Control Group	28 24	09 07	19 17	68% 70%
5	*Constipation*	Trial Group Control Group	25 21	05 11	20 10	80% 48%
6	*Shirshool*	Trial Group Control Group	12 11	03 02	09 09	75% 81%
7	*Hrullas*	Trial Group Control Group	16 17	03 08	13 09	81% 52%
8	*Adhman*	Trial Group Control Group	20 25	04 14	16 11	80% 44%
9	*Udargaurav*	Trial Group Control Group	13 14	04 08	09 06	80% 42%
10	*Angasad*	Trial Group Control Group	09 09	04 05	05 04	55% 44%
11	*Netradaha*	Trial Group Control Group	06 08	02 04	04 04	66% 50%
	Total	Trial Group Control Group	242 243	63 81	179 162	73.96% 66.66%

RESULT: It could be comprehended that percentage of relief was more in the *Urodaha, Amlaprachiti, Kantadaha, shirashool* of Control Group than Trial Group but the Percentage of relief in *Adhaman, Malabadhata* (constipation), *Hrullas, Udargavrav* was found more in Trial Group than control Group.

STATISTICAL ANALYSIS:

Table no. 3 Showing Effect of Therapy on Symptoms of 51 Patients of *Amlapitta* by Wilcoxon- Ranked Singed Test

S. N	Symptoms	Groups	W	T+	T_	Mean ± SD		P	Result
						BT	AT		
1	*Amloudgara*	TG	105	105	0.0	1.19±1.167	0.30±0.47	0.0001	E.S
		CG	120	120	0.0	1.36±1.25	0.28±0.54	<0.0001	E.S
2	*Urdaha*	TG	210	210	0.0	1.73±1.002	0.5±0.509	<0.0001	E.S
		CG	171	171	0.0	1.76±1.09	0.36±0.56	<0.0001	E.S
3	*Amlaprachiti*	TG	120	120	0.0	1.42±1.33	0.307±0.47	<0.0001	E.S
		CG	136	136	0.0	1.44±1.08	0.24±0.52	<0.0001	E.S
4	*Kantadaha*	TG	78	78	0.0	1.07±0.97	0.34±0.62	0.0005	E.S
		CG	91	91	0.0	0.96±0.93	0.28±0.45	0.0002	E.S

5	*Constipation*	TG	78	78	0.0	0.96±0.99	0.23±0.51	0.0005	E.S
		CG	55	55	0.0	0.84±0.98	0.44±0.58	0.0020	V.S
6	*Shirshool*	TG	25	25	0.0	0.46±0.76	0.11±0.32	0.0156	S
		CG	28	28	0.0	0.44±0.70	0.08±0.27	0.0156	S
7	*Hrullas*	TG	55	55	0.0	0.61±0.80	0.11±0.32	0.0020	V.S
		CG	28	28	0.0	0.68±0.98	0.32±0.55	0.0156	S
8	*Adhman*	TG	66	66	0.0	0.76±0.99	0.15±0.36	0.0010	V.S
		CG	55	55	0.0	1±1.11	0.56±0.65	0.0020	V.S
9	*Udargaurav*	TG	36	36	0.0	0.5±0.76	0.15±0.36	0.0078	V.S
		CG	21	21	0.0	0.56±0.76	0.32±0.47	0.0313	S
10	*Angasad*	TG	15	15	0.0	0.34±0.69	0.15±0.36	0.0625	NOT Q.S
		CG	10	10	0.0	0.36±0.56	0.2±0.40	0.1250	N.S
11	*Netradaha*	TG	6	6	0.0	0.23±0.65	0.076±0.27	0.2500	N.S
		CG	10	10	0.0	0.32±0.69	0.16±0.37	0.1250	N.S

W=sum of all rank

T+=sum of all positive rank

T-=sum of all negative rank

S.D. =Standard Deviation

- P>0.05 - N.S. (Non Significant)
- P=0.01-0.05 - S (Significant)
- P=0.001-0.01 - V.S. (Very Significant)
- P<0.0001 - E.S. (Extremely Significant)

MANN WHITNEY TEST

Difference between the summation of before treatment and after treatment results of all the subjective parameters was calculated separately for both the groups.

Null hypothesis: There is no significant difference between two groups.

Alternative hypothesis: There is significant difference between two groups. Two tailed test was applied to find out the P value. As P value <0.001 then null hypothesis rejected and if P value >0.001 then null hypothesis accepted.

Table no.4 showing patient wise difference between before treatment and after treatment of symptoms of both groups

SR. NO.	Difference of Group A	Difference of group B
1	10	6
2	6	6
3	13	10
4	8	5
5	7	8
6	8	5
7	6	8
8	6	7
9	11	4
10	9	8
11	8	7
12	7	7

13	7	7
14	8	8
15	4	7
16	6	8
17	9	5
18	3	5
19	5	0
20	6	8
21	5	5
22	6	7
23	6	7
24	2	7
25	5	7
26	6	
Mean	**6.808**	**6.480**
S.D.	**2.384**	**1.917**
S.E.	**0.4675**	**0.3835**
Median		
Passed Normality	**No**	**No**
Mann-Whitney U statistics = 322 P(two tailed)= 0.4812, considered not significant		

In above table p value is >0.001 then null hypotheses accepted i.e. there was no significant difference between two groups

D) Total effect of therapy

Table no.5 Showing Total Effect of Therapy on Total Patients of *Amlapitta*

Sr. No	Criteria For Total Effect of Therapy	Groups	Total No. of Patients	%
1	Complete remission	TG	03	10%
		CG	03	10%
2	Markedly Relieved	TG	20	66%
		CG	19	63%
3	Moderately Relieved	TG	03	10%
		CG	02	06%
4	Unchanged	TG	00	00%
		CG	01	03%
5	LAMA	TG	04	13%
		CG	05	16%

In this study 3 patients (10%) had complete remission in both Trial and control group. 20 Patient from Trial group and 19 Patients (63%) from control group had markedly relieved. However 3 patients from Trial group and 2 patients from Control group had moderately relieved. There was no Patient unchanged in Trial group but 1 Patient was unchanged in Control group.

DISCUSSION

Mode of action of *Shunthikhand*

'ShunthiKhand' constitutes *Shunthi* as the main ingredient i.e. 16 time more than other durgs, along with other *prak-*

shepadravyas (1/16th part) and *Ghrita, Dugdha, Madhuand Sharkara*. Most of the ingredients of *shunthikhand* having *Katu, Tikta* and *Madhura* predominant *Rasa, Laghu, Ruksha, Tikshna Guna, Ushna Sheeta Virya. Katu, MadhuraVipaka* having *Agnideepan* property

Shunthi having *ushnvirya, katu rasa guru rukshatikshnaguna* and *madhurvipak* so it is useful in *sampitta*. Hence *Shunthi* being *MadhuraVipaka* subsides *Ama* but does not provoke *Pitta.* Also *Shunthi* is the best medicine for *Amapachaka* and alleviates the *Srotorodha* by *UshnaTikshna Guna.*

In *Shunthikhand Dugdha, Sharkara, Goghrit*a are more in quantity than that of *Shunthi.* This increased quantity reduces the *Ushna, Tikshna* property of *shunti* to some extent. So *Shunthikhand* shows both *Pittashaman* as well as *Agnideepaniya* property.

All the drugs in *Shunthikhand* having *Deepana Pachana* property which improves the status of Agni subsequently prevent the *Ama* formation and vitiation of *Doshas. Laghu, Ruksha, Tikshnaguna, Katuvipaka* and *Ushnavirya* drug having opposite to that of *Kapha* which helps in alleviation of *Kapha*. Once this *Kapha* is alleviated *Avarana* of *Vayu* gets removed and *vayu* traverses through its own path leading to relief in symptoms.

Ghrita having *pittaghn*a property. *Dugdha* has *Rasayana, Medhya* and *Anulomana* action. Due to *madhur rasa* and *madhurvipaka* it has *pittaghna* property and *Madhu* is the best *Yogavahi*, possesses nutritive properties, and improves general metabolism.

Mode action of Omeprazole:

Omeprazole is a selective and irreversible proton pump inhibitor. It suppresses stomach acid secretion by specific inhibition of the H +/K + ATPase system found at the secretory surface of gastric parietal cells. Omeprazole will inhibit the final step of acid production. Omeprazole will also inhibit both basal and stimulated acid secretion irrespective of the stimulus.

According modern point of view *Amlapitta* (Hyperacidity) means accumulation of extra acid in stomach. It can't differentiate *sama pitta, pittavrudhi* & *Acccha-pitta. Acchapitta* is useful in digestion of food and sepration of *sar*a from *kitta*. However *sama pitta* and *Piitavrudh*i is pathological.

Table no. 6Effect of therapy

SYMPTOMS	GROUP A			GROUP B		
	n	% Relief	Significance P value	n	% Relief	Significance P value
Amloudgara	14	74%	0.0001	15	72%	<0.0001
Urdaha	21	71%	<0.0001	19	79%	<0.0001
Amlaprachiti	15	78%	<0.0001	17	83%	<0.0001
Katadaha	16	68%	0.0005	17	70%	0.0002
Constipation	13	80%	0.0005	12	48%	0.0020
Shirshool	08	75%	0.0156	07	81%	0.0156
Hrullas	11	81%	0.0020	09	52%	0.0156
Adhman	11	80%	0.0010	12	44%	0.0020
Udargaurav	09	80%	0.0078	10	42%	0.0313
Angasad	06	55%	0.0625	08	44%	0.1250
Netradaha	03	66%	0.2500	05	50%	0.1250

Above data stated that there was extremely significant result in the symptoms *Amloudgara, Urdaha, Amlaprachiti, Kantadaha* of both group but the Percentage of relief was more in *Uradaha, Amlaprachiti, Kantadaha, Shirshool* of Group B (control group) than Group A (Trial group).

Percentage of relief in *Amloudgara, Constipation, Hrullas, Adhman, Udargaurav, Angasad* and *Netradaha* of Group A (Trial group) was more than Group B (control group) and level of significance also better than control group. In *Angasad* and *Netradaha* Non significant result were found in both the group because these symptoms were less in number in the patients. Total percentage of relief in Trial group 78.93% was more than total percentage of relief in control group was 66.66%.

Comparison between the effects of two drugs:

Cap Omeprazole is worldwide accepted drug for *Amlapitta* (Gastritis). In comparison with this standard drug, the drug *Shunthikhand* also gave significant result, both the drugs were not significantly different become statistically proved.

Though cap Omeprazole is the standard drug for Amlapitta it has some limitation. It can't cure all symptoms of *Amlapitta* because main cause of *Amlapitta* is *Agnidushti* but it was not relieved by cap Omeprazole. *Shunthikhand* first of all relived the *Agnidushti* so it was given better result in all symptoms of *Amlapitta.*

CONCLUSION

- *Amlapitta* is the burning problem in society due to changing lifestyle.
- Conclusions drawn from the various aspects of clinical study are as: All the 60 patients of present study were taking *Vishamashana, Katu-Amla rasa Pradhna* diet, tea and tobacco. *Mandagni* is the main cause of *Amlapitta.* Constipated peoples are more prone to disease *Amlapitta.*
- In the present study both the Groups showed equal result, but the total percentage of relief was more in the Trial group than Control group.
- Cap Omeprazole is the standard drug for *Amlapitta*. In comparision with this standard drug, the drug *Shunthi khand* also gave significant result.
- Cap Omeprazole has some limitation.
- *Shunthikhand* were giving relief from all the symptoms of *Amlapitta* by relieving *Agnidushti.*

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STANDARDIZATION OF SHUNTHI KHAND

Standardization of shunthikhand was done in Qualichem laboratories

Test report is as follow

no	Test	Remarks
1)	PH(1% Aqueous solution) Method: A.P	2.74
2)	Loss on drying at 105 degc	3.27
3)	Total ASH	2.42
4)	Acid insoluble ASH	0.58
5)	Water soluble extractive	57.61
6)	Alcohol soluble extractive	24.04

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