



Original Article

A RANDOMIZED COMPARATIVE CLINICAL STUDY TO EVALUATE THE EFFICACY OF TRIPHALA MANDOORA OVER KAMDUGHYA RASA IN URDHWAGA AMLAPITTA WITH SPECIAL REFERENCE TO DYSPEPSIA

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Abstract

Introduction - *Amlapitta* is one of commonest *Annavaha Srotas Vyadhi*, depending on signs and symptoms classified into two types *Urdhwaga* and *Adhoga Amlapitta*. Among this, *Urdhwaga Amlapitta* is said to be most common type which can be clinically correlated with Dyspepsia. In Ayurvedic classics, various therapeutic procedures like *Vamana*, *Virechana*, *Snehapana*, *Raktamokshana*, *Shamana Chikitsa* and *Rasayana* therapy are mentioned. In this Study, *Kamdughya Rasa* and *Triphala Mandoora* are selected as Standard and Study drug respectively for *Shamana Chikitsa*. In standard group 72.23% improvement was seen while in the study group 69.01% improvement was found. However no significant difference was found in % improvement between the groups ($p=0.243$). Result observed showed *Triphala Mandoora* was as effective as *Kamdughya Rasa*. This study concludes that there is not much difference in *Kamdughya Rasa* and *Triphala Mandoora*.

Keywords- *Amlapitta*, *Urdhwaga Amlapitta*, Dyspepsia, *Kamdughya Rasa*, *Triphala Mandoora*.

INTRODUCTION

The lifestyle of today is absolutely altered or modified, within the last two decades. In the present day peoples have improper living style, faulty dietary habits and psychological imbalance which upset the digestion initially and lead to various digestive system disorders one among them is *Amlapitta*.¹

In Classics like *Charak*² and *Kashyapa*³ have clearly discussed that the *Grahani Dosha* and *Amlapitta* occur in person, who could not verify the temptation of food in their life. *Amlapitta* is one of commonest *Annavaha Srotas Vyadhi* classified into two types depending on the clinical presentation of sign and symptom as *Urdhwaga* and *Adhoga Amlapitta*. Among this, *Urdhwaga Amlapitta* said to be the most common type of *Amlapitta* which can be clinically correlated with Dyspepsia.⁴ *Urdhwaga Amlapitta* and Dyspepsia are having symptoms as *Avipaka* (Indigestion), *Utklesa* (Nausea),

Tiktamlodgara (Sour and bitter eructations), *Gauravta* (Heaviness), *Hrtkantha Daha* (Burning sensation), *Aruchi* (Anorexia) etc.

In *Ayurvedic* classics, various therapeutic procedures like *Vamana*, *Virechana*, *Snehapana*, *Raktamokshana*, *Shamana Chikitsa*, and *Rasayana* therapy are mentioned to manage *Amlapitta*. The *Shamana Chikitsa* helps in bringing *Doshas* to a normal state by subsiding *Prakupita Dosha* brings equilibrium in the body and maintain the health of the patient.

In *Urdhwaga Amlapitta*, increased *Drava*, *Ushna*, *Snigdha* and *Guru Guna Bhaava* of *Pachaka Pitta* and *Kledaka Kapha* produces *Amliya Bhavata* of *Amlapitta*.⁵ In this present study, *Triphala Mandoora*⁶ and *Kamadugha Rasa*⁷ selected as trial and standard drug respectively.

AIMS & OBJECTIVES OF THE STUDY:

- 1) To study the efficacy of *Triphala Mandoora* in *Urdhwaga Amlapitta* w. s. r. to Dyspepsia.
- 2) To compare the efficacy of *Triphala Mandoora* over *Kamdugha Rasa* in *Urdhwaga Amlapitta* w. s. r. to Dyspepsia.

METHODOLOGY

MATERIALS

Literary source:

Literary work is done by using the departmental library, central library, digital library and recent updates published in the journals.

Sample source:

Patients suffering from *Urdhwaga Amlapitta* were selected from outpatient & inpatient of Kayachikitsa Department of BVVS Ayurved Medical College and Hospital, Bagalkot by present inclusion and exclusion criteria.

Drug source:

The raw drugs needed for preparation of *Triphala Mandoora* were collected from a reliable source and authenticated from *Dravyaguna* Department. Then the medicine was prepared at BVVS Ayurved Pharmacy of B.V.V.S Ayurved Medical College Hospital, Bagalkot.

Study Design:

A Randomized Comparative Clinical Study

Sample size: 40

Grouping:

The 40 patients selected were divided into two Groups i.e. Standard group and Study group each having 20 patients on the basis of the selection criteria.

Hypothesis:

- H_0 -*Triphala Mandoora* is not as effective as *Kamdugha Rasa* in *Urdhwaga Amlapitta* with special reference to Dyspepsia.

- H_A- *Triphala Mandoora* is as effective as *Kamdugha Rasa* in *Urdhwaga Amlapitta* with special reference to Dyspepsia.

Selection criteria:

1. Diagnostic Criteria:

Diagnosis was made depending on the classical features of *Urdhwaga Amlapitta* (Dyspepsia) like *Tiktamloudgara* (Bitter and Sour Belching), *HrithDaha* (Heart-Burn), *KanthaDaha* (Throat burn), *Utklesha* (Nausea), *Chardi* (Vomiting), *Avipaka* (Indigestion), *Aruchi* (Anorexia).

2. Inclusion criteria:

1. Patients between the age group 18-60 years of either sex.
2. Patients having classical signs and symptoms of *Urdhwaga Amlapitta* like-*Avipaka*, *Utklesha*, *Tiktamlodgara*, *Hritdaha*, *Chardi*.
3. Patient having dyspepsia signs and symptoms.

3. Exclusion criteria:

1. Patients with systemic disorders and metabolic disorder like Hyperthyroidism, Diabetes Mellitus, Hypertension, Cardiac Disorders and Immunodeficiency disorders like AIDS.
2. Patients with a history of *Parinama Shula* (gastric ulcer, duodenal ulcer), *Annadrava Shula*, *Krimiroma*, *Arbuda*, Oesophagitis reflux, Cancer, Hiatus hernia, Inflammatory Bowel Syndrome, Gall stone etc.
3. Patients on medications like NSAID's, H₂ blockers, antacids, corticosteroids, antidepressants or any other drugs which are having an influence on the outcome of the study.
4. Pregnant and Lactating women.
5. Patient with Psychological disorder like Anxiety, Depression and other mood disorders.

POSOLOGY

The Study group was administered Trial Drug *Triphala Mandoora* 4 Ratti Pramana (500mg)⁸ with *Anupana* of *Jala* twice daily morning and evening before food for 30 days.

Standard group was administered Standard Drug *Kamdugha Rasa* 4 Ratti Pramana (500mg)⁹ with *Anupana* of *Jala* twice daily morning and evening before food for 30 days.

Observation period- During treatment duration patients were asked to come for assessment on the 15th day and 31st day.

Follow-up Duration -Patients were asked to come for an assessment on the 45th day.

Methodology for Assessment criteria

Assessment criteria:

The assessment of the therapy was done on the basis of change in signs and symptom of *Urdhwaga Amlapitta* and Dyspepsia. These were assessed on basis of detail proforma by adopting standard scoring methods¹⁰ as listed below.

- 1) *Avipaka* (Indigestion)
- 2) *Tiktodgara* (Bitter Belchings)
- 3) *Amlodgara* (Sour Belchings)
- 4) *Hritdaha* (Heart Burn)

- 5) *Kanthadaha* (Burning sensation at throat region)
- 6) *Utklesha* (Nausea)
- 7) *Chardi* (Vomiting)
- 8) *Aruchi* (Anorexia)
- 9) *Gaurava* (Heaviness in Epigastric region)

Statistical Analysis: The data obtained in both groups was recorded, tabulated and statistically analyzed using Unpaired Student‘t’ test.

OBSERVATION

In Standard Group, out of 20 patients 20(100%) were having symptom of *Tiktamloudgara* , 19(95%) were having *Hrid-Kantha Daha*, 18(90%) were having *Aruchi*, 16(80%) were having *Utklesha*, 11(55%) were having *Gaurava*, 10(50%) having *Avipaka* , 11(55%) having *Shiroruja* and 10(50%) having *Chardi*.

In Study Group, out of 20 patients 20(100%) were having symptom of *Tiktamloudgara* , 19(95%) were having *Hrid-Kantha Daha*, 18(90%) were having *Aruchi*, 16(80%) were having *Utklesha*, 12(60%) were having *Gaurava*, 13(65%) having *Avipaka* , 10(50%) having *Shiroruja* and 10(50%) having *Chardi*.

STATISTICAL ANALYSIS

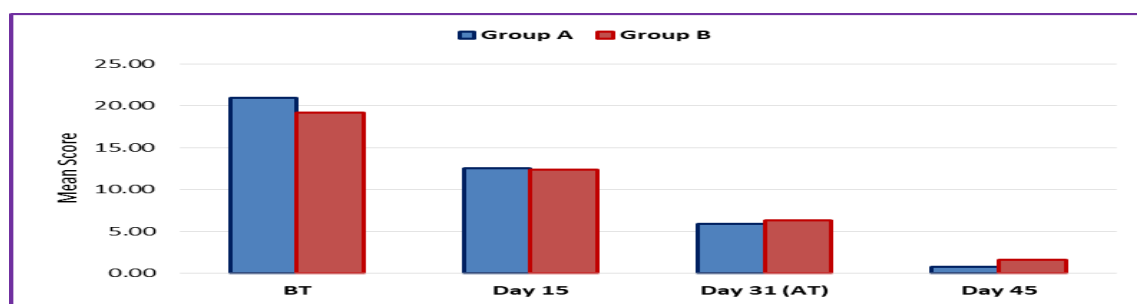
Table No. : 1: Shows the response of drugs in Standard and Study Groups on Overall Assessment

Time interval	Standard Group - Change from baseline					Study Group - Change from baseline				
	Mean	SD	% Impr	t-value	p-value!	Mean	SD	% Impr	t-value	p-value!
BT	-	-	-	-	-	-	-	-	-	-
Day 15	8.45	4.73	40.33	18.31	<0.001	6.80	4.71	35.42	15.29	<0.001
Day 31 (AT)	15.05	4.21	71.84	17.63	<0.001	12.90	4.22	67.19	18.25	<0.001
Day 45	20.20	3.94	96.42	16.96	<0.001	17.55	3.85	91.41	16.48	<0.001

Table shows overall response of drugs in the standard and study groups.

In standard group highly significant improvement was seen in any follow up and AT as well with 40.33% improvement at Day 15, 71.84% at Day 31(AT) and 96.42% at Day 45.

In study group highly significant improvement was seen in any follow up and AT as well with 35.42% improvement at Day 15, 67.19% at Day 31 (AT) and 91.41% at Day 45.



Graph No. 1: Shows the Intergroup & Intragroup Comparison of drugs between Standard and Study group on Overall Assessment

RESULT

Table No. : 2: Shows the Intergroup Comparison of drugs between Standard and Study groups for % overall Improvement

Group	% Overall Improvement		t-value	p-value
	Mean	SD		
Standard	72.23	6.25	1.185	0.243
Study	69.01	10.42		

Table shows % overall improvement of drugs in the standard and study groups.

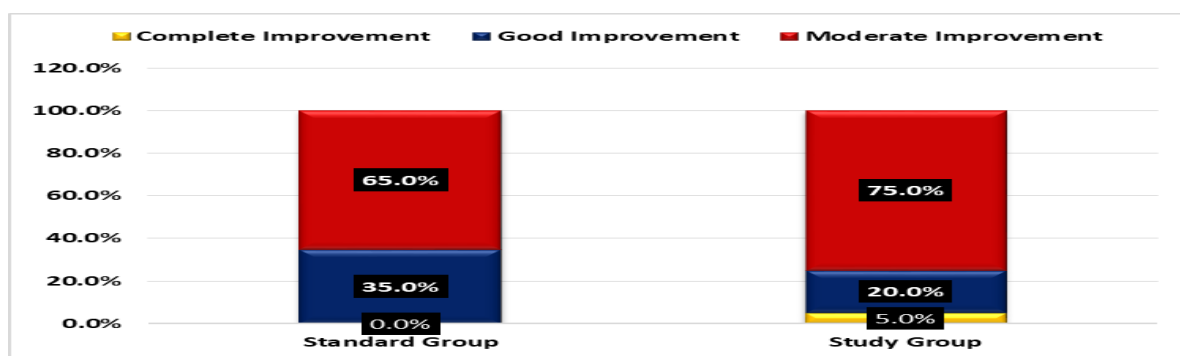
In standard group 72.23% improvement was seen while in the study group 69.01% improvement was found. However no significant difference was found in % improvement between the groups ($p=0.243$).

Table No. : 3: Shows the Intergroup Comparison of drugs between Standard and Study groups for Improvement Status

Status	Standard Group		Study Group		chi sq	p-value
	No.	%	No.	%		
Complete Improvement (90% - 100%)	0	0.0%	1	5.0%	1.961	0.375
Good Improvement (75% - 90%)	7	35.0%	4	20.0%		
Moderate Improvement (50% - 75%)	13	65.0%	15	75.0%		
Total	20	100.0%	20	100.0%		

Table shows final improvement status of drugs in the standard and study groups.

In standard group good improvement was seen in 35% cases, while moderate improvement was seen in 65% cases. In the study group good improvement was seen in 20% cases and moderate improvement was seen in 75% cases and one case showed complete improvement. No significant difference was found in various proportions of improvement levels between the groups.



Graph No.2: Showing Overall Improvement Status in %

DISCUSSION

The disease Urdhwaga Amlapitta caused by predominance of *Pitta dosha* and is an *Amashyothita vyadhi*. The ingredients of *Kamadugha Rasa* have *Madhura and Kashaya rasa* having *Tridoshara* property thus act on both *Pitta and Sthahanika Dosha* i.e. *Kapha Triphala Mandoora* has *rooksha and Laghu guna*, with *Madhura Vipaka* and *Tridoshahara* property acting on *drava guna* of *pitta* and *Sthanika Dosha*. Thus, both drugs shows their efficacy in treating disease by *Samprapti Vighatana Chikitsa* and help in relieving symptoms.

CONCLUSION

Depending on objectives and assessment of various parameters following conclusion were made.

- In this study, both drugs were highly significant in treating the assessment criteria *Tiktaudgara, Amloudgara, Avipaka, Aruchi, Hritdaha, Kanthadaha, Utklesha, Gaurava* after treatment ($p < 0.001$). *Kamadugha Rasa* was significantly effective in treating *Chardi* and *Triphala Mandoora* effective in treating it.
- Among 20 patients in standard group 7(35%) shows good improvement, 13(65%) shows Moderate improvement and no patients shows complete improvement.
- Among 20 patients in study group 4(20%) shows good improvement, 15(75%) shows Moderate improvement and 1(5%) shows complete improvement.
- In standard group 72.23% improvement was seen while in the study group 69.01% improvement was found. However no significant difference was found in % improvement between the groups ($p = 0.243$).

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