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Access this article online
Website: www.ayujournal.org
DOI: 10.4103/0974-8520.105241
Quick Response Code:

Clinical Research

Clinical evaluation of the efficacy of *Dashanga Kwatha Ghana Vati* in the management of *Urdhwaga Amlapitta* (Non-ulcer dyspepsia)

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Abstract

A study has been designed to evaluate the effectiveness of *Dashanga Kwatha Ghana Vati* in *Urdhwaga Amlapitta* (non-ulcer Dyspepsia). Randomized single blind, placebo controlled study was conducted in 138 patients attending O.P.D. of department of Basic Principles, I.P.G.T. and R.A., Gujarat Ayurved University, Jamnagar, and grouped into two. Both the groups consumed two tablets of either *Dashanga Kwatha Ghana Vati* or placebo, twice daily after food for a period of eight weeks. The patients were followed upto four weeks, 110 patients had completed the treatment and no adverse effects were reported during the treatment. Both groups had improved in the clinical symptoms and overall statistical significance was observed in the differences of scores between the two groups.

Key words: *Dashanga Kwatha Ghana Vati,* non-ulcer dyspepsia, *Urdhwaga Amlapitta*

Introduction

From stone-age to space age food pattern of people has undergone innumerable changes. These changes have been always for the better aspect of life, yet most of the diseases are firmly rooted in poor dietary habits and life style.[1] None of the existing systems of medicines are providing satisfactory answers for all the health problems as all these aim at symptomatic relief rather than a total cure. *Urdhwaga Amlapitta* (non-ulcer dyspepsia) is a burning problem with causative factors like improper diet and habits, stress, spicy irritant foods, etc.

Acharya Charaka has mentioned that if a person is under psychological stress; even the wholesome food taken in proper quantity will not get properly digested.[2] *Vagbhata* has described that all diseases are caused due to *Mandagni*.[3] Among the *Nidanas* of *Urdhwaga Amlapitta*, dietary factors, addiction to alcohol, tobacco chewing or smoking, drinking tea several times are chiefly associated and commonly found.[4]

Even with the advent of excellent techniques and advancement in science and technology; the humanity is left with innumerable health problems. Most of the diseases have direct or indirect link with the type of food habits and life style. 80% of the top ten life threatening diseases of the world are due to faults in dietary habits.[5]

There are only a few safe and effective remedies available for the management of *Urdhwaga Amlapitta*. Although, in Ayurveda *"Amlapittahara Dravyas"* are described in general, but in practice, it is seen that all of them are not equally effective against the *Urdhwaga Amlapitta*. Clinical efficacy and safety of *Dashanga Kwatha Ghana Vati* is one of such remedies, which has not been evaluated till date.

Hence, an attempt has been made to evaluate the comparative efficacy and safety of *Dashanga Kwatha Ghana Vati*[6] with that of placebo in the management of *Urdhwaga Amlapitta*.

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Materials and Methods

Study design and patient selection

This was a randomized single blind, placebo controlled trial. Patients attending O.P.D. of Department of Basic Principles, I.P.G.T. and R.A., Gujarat Ayurved University, Jamnagar, irrespective of sex, religion etc. who had presented the clinical symptoms of *Urdhwaga Amlapitta* were included into the study.

An elaborative case taking proforma was specially designed for the purpose of incorporating all aspects of the disease on Ayurvedic parlance. Informed consent was taken from the patient before including them in the trial.

Inclusion and exclusion criteria

Patients in between 15 to 65 years of age with classical signs and symptoms of *Urdhwaga Amlapitta* like *Avipaka*, *Vidaha*, *Klama*, *Tiktamlodgara*, *Hritdaha*, *Kanthadaha*, etc. were included in the trial. Patients who had chronicity for more than five years and suffering with diseases like gastric ulcer, duodenal ulcer, cancer of stomach and having major illness like cardiac diseases, diabetes, etc. were excluded from the trial.

Grouping

A total of 138 patients fulfilling the inclusion criteria were enrolled in the study. 110 patients completed study and 28 patients were discontinued. 82 patients were registered in Group A, among them 67 patients completed the treatment and 15 patients discontinued the treatment, whereas in Group B, total 56 patients were registered amongst them 43 patients completed the treatment and 13 patients discontinued.

Trial drug and posology

1. **Trial Group (Group A):** 82 selected patients of *Urdhwaga Amlapitta* were placed in this group and were administered with *Dashanga Kwatha Ghana Vati* [Table 1] in the dose of 250 mg twice a day after food along with water as *Anupana*.
2. **Placebo Group (Group B):** In this group, 56 selected patients of *Urdhwaga Amlapitta* were administered with Placebo tablet prepared with gram flour in the dose of 250 mg twice a day after food along with water as *Anupana*.

Duration of treatment: 8 weeks (56 days).

Diet: Patients were kept under normal diet with special restriction of Spicy diet.

Follow-up: The patients were followed-up once in seven days up to 28 days.

Laboratory Investigations:

1) Routine hematological investigations – Hb, TC, DC, E.S.R., P.C.V.
2) Urine examination – Routine and Microscopic.
3) Stool examination – Routine and Microscopic.
4) Biochemical examination – FBS, Sr. Cholesterol, Sr. Triglycerides, HDL, Blood Urea, Sr. Creatinine, S.G.P.T., S.G.O.T., Sr. Total Proteins, Albumin, Globulin, A/G Ratio, Sr. Alkaline Phosphate, Bilirubin (T), Bilirubin (D), Sr. Uric acid.

Table 1: Formulation composition of *dashanga kwatha ghana vati*

Drug - Sanskrit name (latin name)	Quantity
Vasa (*Adhatoda Vasica* Nees)	1 Part
Guduchi (*Tinospora cordifolia* (Willd.) Miers.)	1 Part
Parpata (*Fumaria parviflora* Lam.)	1 Part
Nimba (*Azadirachta indica* A. Juss.)	1 Part
Bhunimba (*Swertia chirata* Buch. Ham)	1 Part
Bhringaraja (*Eclipta alba* Hassk.)	1 Part
Haritaki (*Terminalia chebula* Retz)	1 Part
Bibhitaki (*Terminalia belerica* Roxb.)	1 Part
Amalaki (*Phyllanthus emblica* Linn.)	1 Part
Patola (*Trichosanthes dioica* Roxb)	1 Part

Above investigations were carried out before and after treatment to have a base line data, as well as to rule out any pathological conditions.

Criterion for assessment

The effect of the drug under trial was based mainly on the improvement in the cardinal signs and symptoms of the disease. To give some objectivity, the score was assigned as severe (3), moderate (2), mild (1), no symptom (0), to each of the major symptoms of the disease like *Amlodgara*, *Daha*, *Shula*, *Chhardi* and *Avipaka*. Similarly associated symptoms were also given scores, on the basis of before and after treatment score, the statistical analysis was done.

Statistical analysis

The obtained data was analyzed statistically and presented as mean ± SEM. The data generated during the study was subjected to student's "Unpaired 't' Test" for unpaired data to assess the statistical significance between the two groups. The change in signs and symptoms was analyzed by Paired't' test.

Observations and Results

Incidence of age and sex in 138 cases of *Urdhwaga Amlapitta*

There were 87 male and 51 female with a mean age of 37.98 years. Of which, 10.15% were belonging to an age group of 15-25 years, 33.33% to age group of 26-35 years, 35.5% to age group of 36-45 years, 17.4% of patients belonged to age group of 46-55 years, and 3.6% in 56-65 years of Age group.

Incidence of cardinal signs and symptoms in 138 cases of *Urdhwaga Amlapitta*

Amla Tikta Udgara and *Hrit Kantha Daha* was found in all (100%) registered patients, while *Avipaka* in 99.27% patients, *Udara shoola* in 91.30% patients and *Chhardi* was found in 68.11% patients [Table 2].

The incidence of associated signs and symptoms in 138 cases of *Urdhwaga Amlapitta*

Aruchi was found in all the registered patients (100%), while *Hrillasa* in 95.65%, *Gaurava* in 90.57%, *Agnimandya* in 80.43%, *Vibandha* in 78.26% and *Shira Shoola* in 74.63% of patients [Table 3].

Percentage-wise improvement in signs and symptoms of *Urdhwaga Amlapitta* in both groups

Maximum decrease in *Amla Tikta Udgara* after treatment was seen in Group A with 76.59% than Group B with 44.85%. Maximum decrease in *Hrit Kantha Daha* after treatment was seen in Group A with 81.62% than Group B with 48%. Maximum decrease in *Udara Shoola* after treatment was seen in Group A with 81.34% than Group B with 41.46%. Maximum decrease in *Avipaka* after treatment was seen in Group A with 91.13% than Group B with 50%. Maximum decrease in *Chhardi* after treatment was seen in Group A with 97.22% than Group B with 78.37%.

Comparative results of improvement in signs and symptoms of *Urdhwaga Amlapitta* in both groups

Statistically significant results of improvement in signs and

Table 2: Incidence of signs and symptoms in 138 cases of *Urdhwaga Amlapitta*

Signs and symptoms	No. of patients		Total	Percentage (%)
	Group A	Group B		
Amla Tikta Udgara	82	56	138	100
Hrit Kantha Daha	82	56	138	100
Udara Shoola	73	53	126	91.30
Avipaka	81	56	137	99.27
Chhardi	61	33	94	68.11

Table 3: Incidence of associated signs and symptoms in 138 cases of *Urdhwaga Amlapitta*

Associated signs and symptoms	No. of patients		Total	Percentage (%)
	Group A	Group B		
Aruchi	82	56	138	100
Hrillasa	78	54	132	95.65
Gourava	74	51	125	90.57
Shirashula	63	40	103	74.63
Vibandha	60	48	108	78.26
Agnimandya	70	41	111	80.43

Table 4: Effect of therapy on hematological and bio chemical measures

Laboratory parameters	Change (Mean±SEM)		t	*P*
	Group A	Group B		
Hb%	-0.04±0.058	-0.12±0.117	0.710	0.479
P.C.V.	0.070±0.165	-0.044±0.392	0.304	0.762
E.S.R.	2.02±1.40	1.76±0.951	0.137	0.891
F.B.S.	-1.2±1.71	0.88±1.617	-0.837	0.404
Sr. Ch	-3.31±3.07	1.34±4.467	-0.888	0.376
Sr. Tri	12.13±7.587	0.67±6.406	1.063	0.290
H.D.L.	-3.01±1.225	-0.23±1.821	-1.317	0.191
Blood Urea	-0.02±1.004	2.27±1.208	-1.458	0.148
Sr. Creatinine	0.022±0.019	0.023±0.031	-0.0247	0.980
S.G.P.T.	-2.08±1.68	0.674±1.822	-1.081	0.282
S.G.O.T.	-1.16±1.06	-0.744±0.854	-0.281	0.779
Tot. Protein	-0.08±0.04	0.069±0.057	-2.220	0.029
Albumin	0.011±0.033	0.032±0.032	-0.328	0.743
Globulin	-0.12±0.042	0.055±0.042	-2.786	0.006
Ak. Phosphate	-1.83±2.604	-6.72±5.419	0.902	0.369
Bilirubin (T)	0.067±0.092	0.079±0.048	-0.0972	0.923
Bilirubin (D)	-0.002±0.018	0.039±0.015	-1.590	0.115
Uric Acid	-0.13±0.13	0.167±0.258	-1.144	0.255

symptoms of *Urdhwaga Amlapitta* were observed in Group A when compared with Group B [Table 4].

Effect on hematological and bio chemical measures

No significant difference was observed in the mean change of hematological and bio chemical parameters after the drug administration [Table 5].

Overall effect of therapy

In group A, complete remission was observed in 2.44% of patients, while in group B complete remission was not found. Marked improvement was found in 59.7% in Group A, while in Group B 1.8%. Moderate improvement observed in Group A was 18.3% and in Group B it was 32.1%. Mild improvement observed in Group A was 1.22% and in Group B it was 39.3%. Only two patients (3.57%) in Group B were found to be unchanged [Table 6].

Adverse drug effects

Administration of trial drug did not associated with any clinically important adverse effects on blood pressure, pulse rate, body weight or laboratory assays.

Disucssion

The present study aimed to look for an effective, safe and affordable treatment of *Urdhwaga Amlapitta*. However, the herbal combination *Dashanga Kwatha Ghana Vati* used in this study showed better improvement in symptoms when compared to placebo. This trial drug was found to be well tolerated with no adverse effects.

Most of the etiological factors of *Urdhwaga Amlapitta* are related with the diet and life style. If one does not follow proper dietic habits, *Agni* will be diminished due to irregularities in the digestion and finally will lead to *Urdhwaga Amlapitta*. Maximum number of patients belonged to the age group between 26 to 45 years i.e. 68.83%. It is the most productive age in one's own life, since they struggle for upcoming in their economic status by which they suffer from stress and strain. Irregular food and drinking habits might have led to more incidences. This age is also of *Pitta* dominance.

Most of the individuals (99.3%) were taking *Katu Rasa* dominant food, followed by *Amla* (90.6%), and *Lavana* (53.6%). This observation proves the classical etiological factors in causing and aggravating the disease. 21.72% patients had a habit of *Adhyashana*. *Charaka* has advised to take food only after digestion of the previous meal. *Adhyashana* cause aggravation of *Doshas* and due to insufficient rest to the stomach the mucous membrane may undergo local damage. 43.47% patients were addicted to chewing tobacco which due to its *Ushna*, *Tikshna*, *Vyavayi Gunas* aggravate the *Amlapitta*. 28.26% patients were having *Krura Koshtha* which is due to *Vata Dosha*. These people were more prone to constipation which is also one of the symptoms of *Urdhwaga Amlapitta*. Stress is a known factor for disturbing the sleep. In this study more patients reported disturbed sleep followed by *Alpanidra*.

These beneficial actions of *Dashanga Kwatha Ghana Vati* might be due to the synergistic action of its ingredients, which possesses activities like anti-bacterial,[7] anti-inflammatory,[8] anti-spasmodic,[9] anti-ulcer[10] etc.

Probable mode of action of *Dashanga Kwatha Ghana Vati*

The chief *Dosha* involved in the *Urdhwaga Amlapita* is *Pitta* and *Kapha*.[11] Majority of the drugs of this formulation have

Table 5: Effect of therapy on cardinal and associated signs and symptoms

Symptoms	Group A		Group B		Difference between groups	t	*p*
	n	Change	n	Change			
Amla Tikta Udgara	67	2.14±0.085	43	1.11±0.068	1.03	9.80	<0.001
Hrut Kantha Daha	67	2.25±0.072	43	1.11±0.11	1.14	8.14	<0.001
Udara Shoola	58	1.87±0.098	42	0.81±0.109	1.07	6.604	<0.001
Avipaka	66	2.18±0.091	43	1.06±0.102	1.11	8.062	<0.001
Chhardi	49	1.46±0.0824	28	1.03±0.081	0.385	3.077	0.002
Aruchi	67	1.73±0.058	43	0.97±0.052	0.76	9.09	<0.001
Hrullasa	64	1.78±0.052	42	0.95±0.047	0.83	11.11	<0.001
Gaurava	65	1.44±0.062	43	0.81±0.060	0.636	7.01	<0.001
Shirashoola	52	1.73±0.062	30	0.866±0.079	0.87	8.58	<0.001
Vibandha	49	1.34±0.068	36	0.80±0.067	0.55	5.62	<0.001

Table 6: Overall effect of therapy

Result	No. of patients				Total	Percentage (%)
	Group A	%	Group B	%		
Complete remission	02	02.44	00	00.00	02	01.44
Marked improvement	49	59.70	01	01.80	50	36.23
Moderate improvement	15	18.30	18	32.10	33	23.90
Mild improvement	01	01.22	22	39.30	23	16.60
Un-Changed	00	00.00	02	03.57	02	01.44

Tikta and *Kashaya Rasa*, *Katu* and *Madhura Vipaka*, *Sheeta Virya*, *Pitta Kapha Shamaka* property. In *Urdhwaga Amlapitta*, *Rasa Dhatu* is affected. The property of *Deepana* and *Pachana Karma* and *Tikta Rasa* of the drugs will directly act on the vitiated *Rasa Dhatu*. Due to *Tikta Rasa* property, *Sama Pitta* will become *Nirama* and *Agni* will be increased. *Charaka* says that *Manadagni* and *Ajirna* creates *Annavisha*, when it gets mixed with *Pitta Dosha*, creates *Pittaja Vyadhis*[12] like *Amlapitta*. So, the *Tikta Rasa* property of the drugs purifies the *Pitta* by *Niramikarana*. *Acharyas* have also given the treatment of *Pittaja* disorders and says that first of all *Tikta Rasa Dravyas* have to be used for *Niramikarana* of *Pitta* and then after *Madhura Rasa* and *Kashaya Rasa* should be used to pacify *Paittika Vyadhis*.

Conclusion

Dashanga Kwatha Ghana Vati has shown significant relief in *Urdhwaga Amlapitta* in comparison to the placebo group. Encouraging results were also observed in the placebo group, which may be because of certain dietary restrictions advised to the enrolled patients during trial period. No clinically significant changes were observed in hematological or biochemical parameters after the study. No adverse drug reactions were noted with administration of the trial drug for 8 weeks of duration. Based on the results of the current study, it can be concluded that the trial drug can be used in cases of *Urdhwaga Amlapitta* (Non ulcer dyspepsia).

Acknowledgment

The authors would like to acknowledge the Dean and Director of I.P.G.T and R.A., Gujarat Ayurved University, Jamnagar.

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हिन्दी सारांश

उध्वांग अम्लपित्त में दशांग क्वाथ घनवटी के प्रभाव का चिकित्सकीय परीक्षण

उमापति सी. बारगी, महेश के. व्यास

आयुर्वेदिक औषधियों के प्रभाव का परीक्षण करने के लिए उचित वैज्ञानिक एवं चिकित्सकीय परीक्षणों की कमी है । इसलिए इस अध्ययन को उध्वांग अम्लपित्त में दशांग क्वाथ घनवटी की चिकित्सा क्षमता जाँचने के लिए एवं इस सामान्य स्थिति में सुरक्षित, प्रभावी, लेने योग्य और अल्पव्ययी वैकल्पिक चिकित्सा के परिप्रेक्ष्य में लिया गया । इस शोधकार्य में आई.पी.जी.टी.एण्ड आर.ए., मौलिक सिद्धांत विभाग के चिकित्सा बहिरंग विभाग में आने वाले १३८ रूग्णों को दो वर्गों में विभाजित कर दशांग क्वाथ घनवटी और प्लैसिबो का तुलनात्मक अध्ययन किया गया । व्याधि के आयुर्वेदिक दृष्टिकोण को ध्यान में रखते हुए एक विस्तृत परीक्षण पत्रक तैयार किया गया । इन अलग – अलग वर्गों में दशांग क्वाथ घन वटी, २ वटी दो बार भोजन के बाद; एवं प्लेसिबो ८ सप्ताह के लिए दिया गया । अध्ययन के बाद ४ सप्ताह तक रूग्णों को परीक्षण के लिए बुलाया गया । ११० रूग्णों ने चिकित्सा पूर्ण की । अध्ययन के दौरान कोई हानिकारक प्रभाव नहीं देखा गया । चिकित्सकीय परीक्षण के दौरान दोंनों वर्गों में लाभ मिला । अंकशास्त्र की दृष्टि से देखा जाय तो दोनों वर्गों के परिणामों के बीच अंतर पाया गया । अविपाक, हत्कण्ठदाह एवं अम्लतिक्तउद्गार इन लक्षणों में दशांगक्वाथधनवटी का प्रभाव प्लेसिबो की अपेक्षा अधिक सार्थक रहा ।