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Research Protocol

Urdwaga Amalpitta

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An Open Label Clinical Trial to Evaluate the Efficacy of Vamana Karma in the Management of Urdwaga Amalpitta

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Background: Amlapitta is one of the most common & familiar disease of Annavaha Srotas in present era described in various classical Ayurvedic text. The primary cause of Amlapitta is Agnidushti due to Pitta Dosha vitiation, often triggered by faulty dietary habits, stress, and sedentary lifestyle. Traditional management of Amlapitta primarily involves Shodhana along with the Shamana Chikitsa Shodhana Chikitsa (purificatory therapy) is considered more effective for long-term relief and prevention of recurrence. Among the Shodhana therapies, Vaman Karma (therapeutic emesis) is the prime treatment for Kapha and Pitta vitiated disorders.

Objective: To evaluate the efficacy of Vamana Karma in the management of Urdhwaga Amlapitta.

Methodology: The study was a single-arm open-label clinical trial. A total of 30 patients with cardinal symptoms of Urdhwaga Amlapitta who meet the Vaman Karma criteria, aged 25-50 years of either sex, willing to participate in the study was picked for a 15-day period.

Result: Change will be noted in the subjective parameter.

Conclusion: Vaman Karma will reduce the symptoms of Urdhwaga-Amlapitta.

Keywords: Annavahasrotas, Aahar-Vihar, Mandagni, Urdhwaga Amlapitta, Vamana, Gastritis, hyperacidity

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Introduction

Ayurveda is an ancient science of life since time immemorial. *Ayurveda* apart from providing various therapeutic measures for diseases, emphasizes on maintenance, promotion of health & prevention of disease through diet and lifestyle regimen.**[1]** In Ayurveda *Tridosha, Saptadhatu* and *Mala* forms the basic component of an individual.**[2]** There needs to be an equilibrium among these to lead a healthy life which can be maintained by following *Dincharya***[3]** (healthy day routine), *Ratricharya* (healthy night routine), *Ritucharya***[4]** (how should we live in whole year) and *Ashtavidhahar Visheshaytana***[5]** (Method of *Ahar Sevana*).

Any deviation from these can lead to various disease condition. *Amlapitta* is one of such examples which occurs due to imbalance of the *Pitta Dosha*. As we explore through the major Ayurvedic text *(Brihtryaee's)* such as *Charaka Samhita*, *Sushrut Samhita, Ashtang Hriidya, Amlapitta* is not mentioned as an independent disease but has been used in another context.

In *Charaka, Samhita* while illustrating the *Samprapti* of *Grahni Roga,* he states *Annavish* as a result of *Mandagni,* when combines with the *Pitta Dosha,* causes *Amlapitta.***[6]**

Asides *Brihtryaee's, Kashyap Samhita, Madhav Nidan, Bhaisajya Ratnavali, Bhavprakash* and *Gananath Sen* etc. present concept of disease has been discussed.

Acharya Madhava & *Acharya Kashyap* described the disease in detail & classified it on the basis of *Gati***[7]** i.e., (*Urdhwaga* and *Adhoga Amlapitta*) and *Sansarga* of the *Dosha's***[8]** (*Sanila Amlapitta, Sakapha Amlapitta & Sanila Kaphaja Amlapitta).*

Now days the life style toward which people are attracting is far away from the *Ayurvedic* way of living and most of the *Ahar & Vihar* followed by modernized society comes under the *Nidan* of *Annavaha Srotodusti* and *Amlapitta* such as intake of *Ahar* like junk food, salty, spicy & fried food, alcohol, frequent use of NSAIDs, antibiotics, steroids and aspirin like medicines.

Vihara like fasting,**[9]** eating between the meals (*Adhyasan*), having food in hurry & worry,**[10]** suppressing natural urges, etc. derange the *Pachaka Pitta* thus play a major role in developing *Amlapitta*.

Prakrita Rasa of *Pitta* is bitter *(Katu)* and *Amlapitta* is a condition where *Prakrita Rasa* of *Pitta* changes from bitter to sourer.**[11]**

The cardinal features of *Amlapitta* are *Avipaka* (indigestion), *Hritakantha Daha* (heart and throat burn) and *Tikta- Amlodgara***[12]** (sour and bitter belching).

Sign and symptoms of *Amlapitta* is very similar to some of modern diseases are hyperacidity as per namaste portal,**[13]** dyspepsia,**[14]** gastritis,**[15]** GERD,**[16]** etc. Whereas in *Ayurveda* all of these can be solely studied under concept of *Amlapitta.*

The incidence of GERD in India is approximately is, 7.6 to 30%,**[17]** and of gastritis is approximately 3 in 869 that is 12,25,614 people is suffering from gastritis out of total 106,50,70,607 population,**[18]** as we all are aware to the fact that many serious issues such as constipation, diarrhoea, nausea, anorexia,**[19]** anemia, gastric ulcer, gastric cancer, cardiovascular risk and various kidney diseases,**[20]** etc, are caused by the long-term usage Antacids, H-2 antagonists / proton pump Inhibitors etc. medications use to treat hyperacidity, dyspepsia gastritis, and GERD, which has some similarities to *Amlapitta.* is a real concern amongst the researcher? Hence there is a need to understand the concept, and line of treatment.

Ayurvedic line of treatment is mainly focus on *Shodhana* along with *Shamana Chikitsa*

Shodhana

Shodhana expels accumulated *Doshas* from their sites (*Shakha/Srotas*) and helps ***doshic* balance,** unlike *Shamana* which only pacifies them. *Shodhana* **targets the root cause,** offering **long-term and often permanent relief** from chronic or relapsing conditions.**[21]** By removing *Ama* (toxins) and clearing *Srotas* (channels), *Shodhana* **restore *Agni*,** leading to better digestion and nutrient assimilation.

Aim and Objective

Aim: To assess the efficacy of *Vamana* in the management of *Urdhwaga Amlapitta.*

Objective

Primary Objective:

1. To evaluate the efficacy of *Vamana Karma* in the management of *Urdhwaga Amlapitta.*

Secondary Objective:

2. To access clinical presentation of *Urdhwaga Amlapitta.*

3. To access changes in symptoms of *Urdhwaga Amlapitta.*

Case Definition

Patient having cardinal symptoms of *Urdhwaga Amlapitta*. Such as *Avipaka, Aruchi, Daha, Tiktamlaudgara, Shola, Utklesha* etc.

Research Question

Is *Vaman* effective in the management of *Urdhwaga Amlapitta*?

Hypothesis

Research Hypothesis(H_1):*Vamana* is effective in the management of *Urdhwaga Amlapitta.*

Null Hypothesis(H_0):*Vamana* is not effective in the management of *Urdhwaga Amlapitta.*

Experimental Source

It will be a pure Human Clinical trial; no animal experiment will be done

Materials and Methods

To fulfil the Aim and Objectives, the study plan is divided into 2 sections.

1. Literary review
2. Clinical study

Study design

Type of study: An Open Clinical Trial.
Type of trial: Interventional
Number of groups: 01
Sample size: 30
Health type: *Urdhwaga Amlapitta*
Estimated total duration of trial: 2 months (including follow-up).

Selection of patients: The patients fulfilling the criteria and attending *Panchkarma* OPD and IPD of *Panchkarma* department of the I.A.S.R Kurukshetra Haryana will be selected for research study.

Inclusion criteria

1. Patients having classical sign and symptoms of *Urdhwaga Amlapitta* as per Ayurvedic classics.
2. Patient having cardinal symptoms of gastritis and hyperacidity with the duration not more than one year.
3. Male or female between the age group 25- 50 year.
4. Patients who are fit for *Vaman Karma* as per ayurvedic classics.

Exclusion criteria

1. Patients below 25 years and above 50 years.
2. Patients of *Amlapitta* with any chronic system disease which interferes with the present study.
3. Patients suffering from any current acute illness.
4. Patients having associated complicated systemic disorders like cardiac diseases, diabetes, tuberculosis, bronchial asthma, autoimmune diseases etc.
5. Known case of gastric and duodenal ulcer.
6. Known case of gastric carcinoma.
7. Chronic gastritis (more than one year)
8. Hiatus hernia, Barrett's esophagus.
9. Patients with the previous history of hematemesis, hemoptysis or melena.
10. Patients having congenital physiological anomalies, surgical interventions, and any trauma.
11. Patients who are contraindicated for *Vamana Karma*.

Withdrawal criteria

1. During clinical trial, if any serious condition or serious adverse effect develops which require urgent treatment.
2. Irregulars follow up.
3. If patient wants to withdraw from the clinical trial.

Laboratory Investigations

For assessing the general condition of patient and exclusion of other pathogenesis the following investigation may be performed:

1. Blood and serological test
   - CBC
   - Hb%
   - ESR
   - RBS
   - CRP

2. Stool examination
   - Stool for occult blood test (if needed)

Materials:

Clinical study materials: Patients indicated and fit for trial were selected from outpatient & in patient Department of Panchakarma, I.A.S.R. Kurukshetra Haryana.

Conceptual study materials: Literary references are be collected from *Ayurvedic Samhitas* and their Commentaries, Modern literature, Research journals, online portal like PubMed, Ayush research portal, Google scholar are analyzed to frame the conceptual work

Trial Drugs

For Vamana Karma

Table 1: Name of drugs used in trial

Procedure	Drug Use
Snehpana	Go Ghrita
Sarwanga Abhyanga	Til Taila
Sarwanga Swedana	Dashmoola
Vamana Kalpa Preparation	Madana Phala Pippali Churna, Saindhav, Madhu
Vamnopaga	Yashthimadhu
Dhumpana	Dashmoola

Methods

Plan of study:

To follow the above objective, the research work has been planned as follow:

1. Review of literature

Literary references will be collected from Ayurvedic Samhitas and Commentaries, Modern literature, Research journals, online portal like PubMed, Ayush research portal, Google scholar and will be analyzed to frame conceptual work.

2. Clinical study

Clinical study will be done in patients under direct supervision, consider inclusion & exclusion criteria.

Group: 01

Intervention: *Vamana Karma*

Vamana Karma

After completing pre-clinical examination and the patients who comes under the inclusion criteria are subjected for *Vamana Karma* for 15 days.

Table 2: Showing 15 days Plan for *Vamana Karma*

Purva Karma	1st	Snehapana	Go-Ghrita		1st day 30ml OD (empty stomach) after that increase dose 30-50 ml/day for next six days (acc. to Kosthagi & Rogibala)	
	2nd	Snehapana	Go-Ghrita			
	3rd	Snehapana	Go-Ghrita			
	4th	Snehapana	Go-Ghrita			
	5th	Snehapana	Go-Ghrita			
	6th	Snehapana	Go-Ghrita			
	7th	Snehapana	Go-Ghrita			
	8th	Abhyanga	Til Tail			
	8th	Swedana	Nadi			
	9th morning	Abhyanga	Til Taila			
	9th morning	Swedana	Nadi			
Pradhan Karma	9th morning	Vaman	Madanphala Pippali Churna	5gm		Vamana Karma Patrak attached
			Saindhava Lavana	1gm		
			Honey	10gm		
		Akantha-Pana	Dugdha (Milk)			
		Vamnopaga	Mulethi Phanta			
Paschat Karma	9th	Dhumpana	Dasmula Varti			
	9th evening	Samsarjana Krama	Peya			
	10th morning	Samsarjana Krama	Peya			
	10th evening		Peya			
	11th morning	Samsarjana Krama	Vilepi			
	11th evening		Vilepi			
	12th morning	Samsarjana Krama	Vilepi			
	12th evening		Akrit Yush			
	13th morning	Samsarjana Krama	Akrit Yush			
	13th evening		Akrit Yush			
	14th morning	Samsarjana Krama	Krit Yush			
	14th evening		Krit Yush			
	15th morning	Samsarjana Krama	Krit Yush			
	15th evening		Normal diet			

Follow up

- The duration of trial will be of 15 days.
- The 1st follow-up will be done at 20th
- 2nd follow-up at 40th
- Last follow-up will be done on 60th

Criteria for Assessment

Subjective

Assessment is done based on improvement in the symptoms such as: - *Avipaka, Aruchi, Daha, Tiktamlaudgara, Shola, Utklesha* etc.

Assessment of Improvement

- Complete relief - One hundred percent relief in the complaints of patients,
- Marked improvement - More than 75% relief in the complaints as well as significant
- Moderate improvement - More than 50% relief in the complaints.
- Improvement - Twenty-five to fifty percent relief in the complaints.
- Unchanged - Patients with less than 25% relief in their complaints were regarded as unchanged.

Outcomes

Primary outcome

- Mild, Moderate or Complete relieve in the sign and symptoms of *Urdhwaga Amlapitta.*

Secondary outcome

- The lifestyle of patient improved after the treatment. Patient can perform daily routine activity without any trouble.
- He/she can enjoy the food and lifestyle of his/her choice.

Sample Size $n=Z^2P(1-P)/D^2$

P = percentage of prevalence of disease in India according to Indian council of medical research
Z = level of significance
D = margin of error

The sample size according to this formula comes out is too large.

Due to less duration of study time (1½ year), financial limitation the total number of patients taken for study will be 30.

Statistical Analysis

The observations and results will be analyzed and presented on the basis of respective and applicable statistical tests.

Ethical Clearance & CTRI Registration

Study was started after obtaining ethical clearance from the Institutional Ethics Committee, I.A.S.R. Kurukshetra. REF/2023/01/062848

Study was registered in CTRI: - CTRI/2023/03/050890

Observation and Result

The observation of patient will be carried out before, during and after the completion of treatment.

Some changes and exclusion can be done as per necessity of the study.

The parameters of criteria of assessment and laboratory finding, prior and after the clinical trial will be completed. Compounded statistically analyzed and conclusion will be drawn based on the results.

Discussion

The obtain results will be discussed on the basis of ayurvedic concept and modern parameters.

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