

## A Randomized Controlled Clinical Evaluation of Night-Time Draksha Infusion Water in the Management of Acid-Peptic Symptoms

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### ABSTRACT

Acid-peptic disorders correlate with Amla Pitta in Ayurveda, arising from Pitta prakopa along with vishama ahara, raatri jagarana and mental stress. Draksha (*Vitis vinifera*) is described as Sheetala, Mridu, Pitta-shamaka and Raktaprasadana, beneficial in Amlapitta and hyperacidity. Although Draksha is widely used, its therapeutic effect as night-soaked infusion water has not been clinically evaluated. This study aimed to assess the efficacy of night-time Draksha infusion water, intake in morning for reducing acid-peptic symptoms.

### METHODS

A randomized controlled clinical study was conducted on 20 adults (18–50 years)

fulfilling inclusion criteria for functional acid-peptic symptoms (non-ulcer dyspepsia) with classical Amlapitta lakshanas. Subjects were randomized into two groups (n=10 each):

- Intervention Group: Night-time Draksha Infusion Water (10–12 raisins) soaked overnight in 100 ml water; infusion consumed on empty stomach in morning.
- Control Group: 100 ml plain water on empty stomach in morning.

### RESULTS

The Draksha infusion group showed a significant reduction in epigastric burning, reflux episodes and Amlapitta symptoms compared to the control group. Improvement in Agni and decreased need

for antacids were observed. No adverse events occurred.

## DISCUSSION

Draksha's Sheetala, Pittashamaka, Mridu Rechana and Vata-Anulomana properties help pacify aggravated Pitta and soothe the upper GI tract. The infusion format enhances bio-availability and mild Anulomana without heaviness.

## CONCLUSION

Night-time Draksha infusion water is a safe, novel and effective Ayurvedic intervention for acid-peptic symptoms, showing promising results for future large-scale RCTs.

## KEYWORDS

Draksha, Acid Peptic Symptoms, Amlapitta.

## INTRODUCTION

Acid-peptic symptoms such as heartburn and epigastric burning are common functional gastrointestinal complaints. In Ayurveda, these symptoms correlate with Amlapitta, caused by Pitta aggravation and impaired Agni. Conventional treatment mainly relies on antacids and PPIs, which have limitations with long-term use. Draksha, described as Sheetala and Pittashamaka in classical texts, is traditionally used in Pitta disorders. However, its clinical efficacy in the form of night-soaked infusion needs scientific evaluation.

## NEED OF STUDY –

1. Rising prevalence of acid-peptic symptoms due to lifestyle and dietary factors
2. Limitations and recurrence associated with long-term conventional therapy.

3. Need to scientifically validate Draksha infusion water as a safe, cost-effective management option for Amlapitta.

4. No such study has been done earlier in this form, hence it is a NOVEL study.

**AIM** - To Evaluate the efficacy of Night-Time Draksha Infusion Water in the Management of Acid-Peptic Symptoms

**OBJECTIVE** - Evaluation of the efficacy of Night-Time Draksha Infusion Water in the Management of Acid-Peptic Symptoms

**RESEARCH QUESTION** - Is Night-Time Draksha Infusion Water effective in the Management of Acid-Peptic Symptoms ?

**NULL HYPOTHESIS** - Night-Time Draksha Infusion Water is not effective in the Management of Acid-Peptic Symptoms

**ALTERNATE HYPOTHESIS** - Night-Time Draksha Infusion Water is effective in the Management of Acid-Peptic Symptoms

## METHODOLOGY –

**STUDY TYPE** – Prospective, Randomized, Controlled, Parallel-Group Clinical Trial

**SAMPLE SIZE** – 20 Participants (10 per arm)

**GROUP A – (Draksha Infusion)** – 10-12 clean, dried raisins (draksha) soaked in 100 ml water overnight. The Infusion is consumed early morning empty stomach daily for 7 days.

**GROUP B – (Control)** – 100 ml plain portable water consumed at same time daily for 7 days.

**RANDOMIZATION & BLINDING** – Simple Randomization (computer-generated) into Group A (Draksha Infusion) or GROUP B (Plain Water), Open Labelled.

## INCLUSION CRITERIA

1. Age 18–50 years; either sex.

2. Clinical diagnosis of functional acid-peptic symptoms (heartburn, regurgitation, sour eructation)  $\geq 3$  days/week for past month.

3. Ayurvedic signs consistent with Amlapitta (Daha, Utklesha, Avipaka).

4. Willing to provide informed consent and adhere to protocol.

### EXCLUSION CRITERIA

1. Peptic ulcer disease, erosive esophagitis, GI bleeding, severe GERD, prior GI surgery.

2. Chronic NSAID, steroid, or proton-pump inhibitor (PPI) use within 2 weeks.

3. Pregnant or lactating women.

4. Serious systemic illness (uncontrolled diabetes, hepatic/renal disease).

5. Allergy to grapes/raisins.

### ASSESSMENT CRITERIA

#### Primary outcome -

Change in weekly heartburn episodes (GSRS reflux domain score) from baseline to Day 7.

#### Secondary outcomes

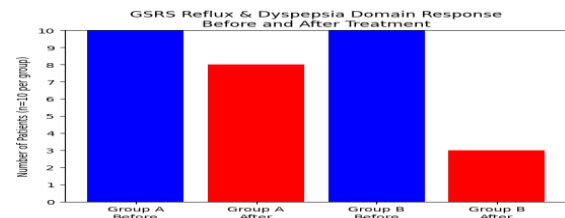
1. VAS for epigastric burning (0–10).
2. Ayurvedic Amlapitta Symptom Score (Daha, Tikta-Amla Udgara, Utklesha, Avipaka).
3. Agni Bala assessment (Mandagni vs Vishamagni).
4. Frequency of rescue antacid use.
5. Sleep disturbance due to nocturnal acidity.

#### What are GSRS domains ?

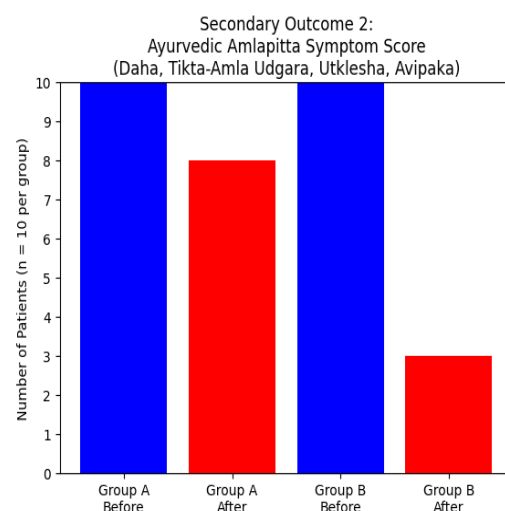
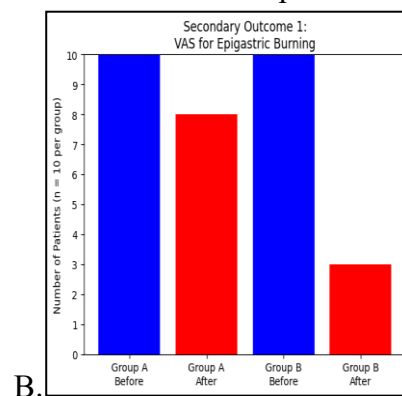
There are 5 domains in GSRS. In my study, only Reflux and Dyspepsia domains were used, which are appropriate for Amlapitta / acid-peptic symptoms. Reflux Domain measures heartburn, acid regurgitation & Dyspepsia domain measures upper

abdominal discomfort, pain and bloating. It is calculated on a 7 point Likert Scale where 1 shows no symptoms and 7 shows very severe symptoms.

### STATISTICAL ANALYSIS –

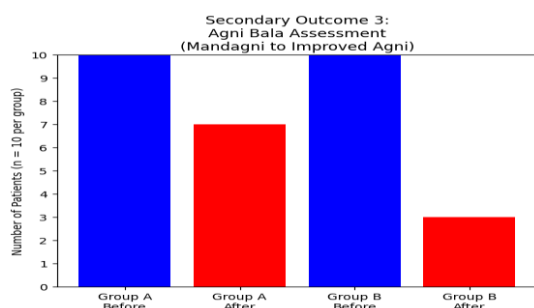


This shows that, in Group A – 8 patients got relieved from GSRS R&D Domain after 7 days & in Group B – 3 patients got relieved from GSRS R&D Domain after 7 days. This shows that, highly significant results were seen in Group A than Group



Similarly, when VAS for Epigastric burning was seen 8 patients got relieved in group A

& 3 patients in Group B. Also the Amlapitta score show highly significant results in Group A than Group B.



Also, In Agni Bala Assessment, it was seen that Agni Improved in Group A in 7 patients and in Group B in 3 patients, which showed significant results in Group A than Group B.

**OBSERVATION** – It was seen that there were highly significant results seen in Group A than Group B.

Hence, Null Hypothesis was Rejected & Alternate Hypothesis was ACCEPTED.

#### MODE OF ACTION –

##### AYURVEDIC PERSPECTIVE

Draksha - Sheetal (cooling), Madhura (sweet), Pittashamaka and Mridu Virechana. Night-soaked infusion is thought to extract cooling and pacifying constituents that reduce Pitta prakopa & Amlodhana, restore Agni & produce mild Anulomana (downward movement) to relieve Urdhwaga Amlapitta symptoms.

##### MODERN PERSPECTIVE

Raisins contain polyphenols, tannins, flavonoids and natural sugars that may:

1. Provide a mild mucosal coating/buffer effect, reducing acid irritation of the esophagus/stomach.
2. Have anti-inflammatory and antioxidant properties that calm mucosal inflammation.
3. Modulate gastric emptying and vagal tone via nutrients and

osmolality, reducing reflux episodes.

4. Improve sleep quality via mild carbohydrate load at night, indirectly reducing nocturnal acid secretion and arousals that provoke reflux.

#### FURTHER SCOPE OF STUDY

1. A Multicentric Randomized Controlled Trial of Draksha Infusion in Amlapitta
2. Comparative Study of Draksha Infusion vs Standard Antacids in Functional Dyspepsia
3. Long-Term Evaluation of Night-Time Draksha Infusion in Chronic Amlapitta
4. Dose-Response Study of Draksha Infusion in Acid-Peptic Disorders
5. Effect of Draksha Infusion on Recurrent Amlapitta with Lifestyle Modification

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