

Comparison of two purification products of *shankha bhasma*: A prospective randomized control trial

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Abstract

Background: *Shankha bhasma* is widely used in the treatment of gastroesophageal reflux disease (GERD) patients. **Aim:** To compare the efficacy of two purification methods of *shankha bhasma* in relieving GERD symptoms. In method A, purification was done with lemon juice and method B with sour gruel. **Materials and Methods:** Patients with heartburn since at least four days/week but who did not undergo endoscopy to assess esophageal mucosa could participate. In this single-phase, single-center, prospective, randomized control trial, the patients were randomized to receive either *shankha bhasma* purified by method A or by method B. The primary efficacy variable was the proportion of patients with resolution of heartburn at week 4 and week 8. **Design:** Single-phase, single-center, prospective, randomized control trial in a hospital setting. **Results:** Of the total 70 patients who received samples A and B in a randomized double-blind manner, 65% of the patients showed resolution of symptoms in sample A and 28% in sample B at the end of four weeks, whereas, 71% of the patients showed resolution of symptoms in sample A and 31% in sample B at the end of eight weeks; *P* value was statistically significant for resolution of symptoms (*P* < 0.005). **Conclusion:** Purification of *shankha bhasma* by lemon juice method is better than sour gruel method in terms of clinical outcome in GERD patients and is hence recommended.

Key words: Gastroesophageal reflux disease, lemon juice, purification, *shankha bhasma*, sour gruel

INTRODUCTION

Gastroesophageal reflux disease (GERD) is a term used to describe symptoms of varying severity with or without endoscopically determined mucosal damage and histological changes resulting from episodes of gastroesophageal reflux. The most common symptom is heartburn, but acid regurgitation is also frequently seen.^[1-3] However, symptoms and severity do not match. The pathophysiology is multifactorial and includes transient lower esophageal sphincter (LES) relaxation, incompetence of LES, reduced esophageal clearance, and impaired resistance of the mucosa. Treatment of GERD

is important because it is a chronic recurring disease with many complications including stricture and bleeding.^[4-6]

Shankha bhasma is an Ayurvedic preparation commonly used in the treatment of GERD. It is the shell of a marine creature called *Turbinella rapha*. The chemical composition is CaCO₃. Two types of *shankha* are available. One is *vamavarta*, that is, opening onto the left side and *dakshinvarta*, that is, opening onto the right side. *Vamavarta* is used for the preparation of *shankha bhasma*.

There are two methods of preparation of *shankha bhasma* as per *rasatarangini*. In the first method (method A), the *shankha* is made into pieces of 1 to 2 inch size with iron mortar and pestle, tied into a poultice amidst lemon juice for three hours, taken out, and washed with warm water. In the second method (method B), the *shankha* is made into small pieces of 1 to 2 inches in size by pounding it with iron mortar and pestle, tied into a poultice, and subjected to boiling in *dolayantra* amidst sour gruel for three hours, taken out, and washed with warm water. After purification by either of these methods, the *shankha* is kept in an earthen

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plate, closed with another one, sealed, dried, and subjected to incineration in a *gajaputa*, following which the *shankha* becomes white *bhasma* after two sequential incineration steps.

Though *rasataranagini* describes two methods of purification of *shankha bhasma*, there is no study to address the superiority of either purification method in terms of clinical outcome. This study aims to determine the clinical outcome in GERD after treatment with two purified forms of *shankha bhasma* (*bhasma A* and *bhasma B*) as described above.

Criteria for patient selection

Patients aged 18 years or older with a history of heartburn for at least six months and having a current episode of moderate-to-severe heartburn for at least four days out of seven days prior to the commencement of the study were eligible to participate. The following were the exclusion criteria for the study: History of esophageal stricture/ulcer, evidence of gastroesophageal bleed within three days of entry into study, use of modern medication within the last one month, diabetes/hypertension/malabsorption syndrome, severe cardiopulmonary disease, renal disease, active malignancy, or cerebrovascular disease. Valid and informed written consent was obtained from the patients who satisfied the eligibility criteria.

Patients who satisfied the eligibility criteria were given sample A and sample B at a dose of 300 mg each^[7] with gooseberry twice daily. The patients were asked to report every week in the outpatient department and note down the symptoms of heartburn every time it occurred in a diary, and they were followed for eight weeks.

Design

This was a single-center, prospective, double-blind study in a hospital setting. Baseline evaluation was done with general medical history, use of alcohol, caffeine, review of past medications, and physical examination. The patients were not assessed endoscopically either at entry or during the study. Primary efficacy variable was proportion of patients with resolution of moderate-to-severe heartburn at weeks 4 and 8. Secondary efficacy variable was percentage of heartburn-free days, and any complication thereof.

Assessment of symptoms

Severity of heartburn was classified as None: No heartburn; Mild: Awareness but easily tolerated; Moderate: Discomforting heartburn causing interference with daily activities; Severe: Incapacitating heartburn preventing performance of normal daily activities.

Statistical analysis

Statistical analysis was done on SPSS software version 18.

RESULT

A total of 80 patients were included in the study over a six-month period in a medical college hospital that satisfied the inclusion criteria. Baseline characters of the patients were as shown in Table 1.

These patients were randomized to receive either sample A or sample B by a computer-generated double-blind technique. Of the 80 patients, 70 patients were available for follow-up. The reason for discontinuation of the study was due to not reporting in the outpatient department (8 patients) and adverse experience (2 patients). Adverse experience was in the form of nausea and vomiting immediately after taking the study medication. The patients did not require any other intervention except discontinuation of the study drug.

Resolution of symptoms

The proportion of patients who experienced no heartburn or only mild heartburn was significantly more in group A than group B. (65.71% *vs.* 28.57%) at four weeks and (71.42% *vs.* 31.42%) at eight weeks [Table 2].

Percentage of heartburn-free days

Of the total 56 days of study period (8 weeks), heartburn-free days were 48 in group A and 20 in group B [Figure 1].

Assessment of complication

Two patients out of a total of 70 patients described having adverse reactions to drugs and reported nausea and vomiting immediately after taking the medication (both in group A). However, the percentage for this complication is extremely low (2.8%).

DISCUSSION

In the treatment of GERD, symptomatic response to

Table 1: Baseline characters of the patients (n=80)

| Mean age (years) | 48.2 |
|------------------|-------------|
| Gender | |
| Male | 42 (52.5%) |
| Female | 38 (47.50%) |
| Weight (kg) | 74±8.2 |

Table 2: Number of patients with no heartburn or mild heartburn at 4 and 8 weeks in both groups (n=70)

| | Total patients | No heartburn or mild heart burn at 4 weeks (%) | No heartburn or mild heart burn at 8 weeks (%) |
|---------|----------------|--|--|
| Group A | 35 | 23 (65.71) | 25 (71.42) |
| Group B | 35 | 10 (28.57) | 11 (31.42) |

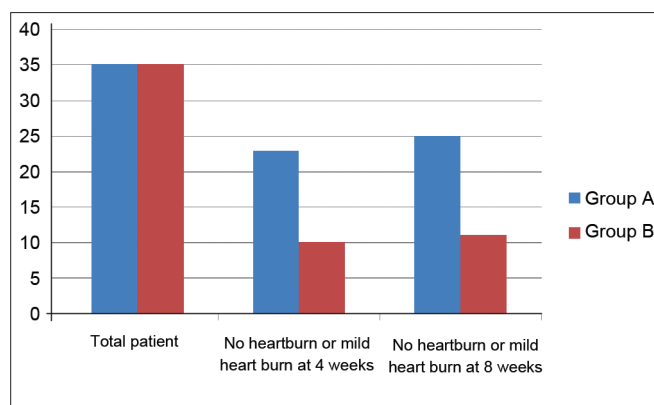


Figure 1: Incidence of heartburn at weeks 4 and 8 $P < 0.005$ between group A and group B patients. It is statistically significant. Group A: Purification of *shankha bhasma* by lemon juice method; group B: Purification of *shankha bhasma* by sour gruel method. Y axis: Number of patients

therapy is an important marker of clinical success because this factor is very troublesome for the patients. *Shankha bhasma* has been shown to be clinically effective in treating GERD in various studies, in rats,^[8] and also *in vitro*.^[9] Our study is the first of its kind to assess the clinical effectiveness in patients by two different purification methods. In the first method, *shankha bhasma* was purified by using lemon juice whereas in the second method, sour gruel in *dolayantra* was used. The patients were given 300 mg of *shankha bhasma*.

In our study, resolution of symptoms was statistically more significant ($P < 0.005$) in the lemon juice *shodhan* method than sour gruel method at four weeks (66 and 27%, respectively) and at eight weeks (71 and 31%, respectively). Although heartburn-free days were also higher in lemon juice *shodhan* compared to patients treated with *shankha bhasma* prepared by sour gruel method (48 vs. 20), adverse effects such as nausea and vomiting were reported by two patients administered *shankha bhasma* prepared by lemon juice *shodhan* method. In these patients, the adverse effects subsided following stoppage of the medication.

In previous studies evaluating the therapeutic efficacy of *shankha bhasma*, its neutralizing capacity was reported to be enhanced following coadministration of *amalki churna*.^[10] In another study, *shankha churna* when compared with

shavasana, did not improve clinical outcome.^[11] However, both these studies were not randomized, and hence results are difficult to interpret, although our study was randomized to eliminate any element of bias. There was a statistically significant clinical benefit by using *shankha bhasma* purified by lemon juice compared to sour gruel, and hence we recommend the use of lemon juice for purification process of *shankha bhasma* and suggest a twice-daily dose of 300 mg along with gooseberry as therapy for GERD.

REFERENCES

1. Spechler SJ. Epidemiology and natural history of gastro-oesophageal reflux disease. *Digestion* 1992;51:24-9.
2. Johnsson F, Joelsson B, Gudmundsson K, Greiff L. Symptoms and endoscopic findings in the diagnosis of gastroesophageal reflux disease. *Scand J Gastroenterol* 1987;22:714-8.
3. Joelsson B, Johnsson F. Heartburn—the acid test. *Gut* 1989;30:1523-5.
4. Kahrilas PJ. Gastroesophageal reflux disease. *J Am Med Assoc* 1996;276:983-8.
5. DeVault KR, Castell DO. Current diagnosis and treatment of gastroesophageal reflux disease. *Mayo Clin Proc* 1994;69:867-76.
6. DeVault KR, Castell DO. Guidelines for the diagnosis and treatment of gastroesophageal reflux disease. *Arch Intern Med* 1995;155:2165-73.
7. Richa A, Kadam HM, Kadam SS. Studies on *shankha bhasma*-I antacid activity evaluation of *Shankha Bhasma*. *Indian J Pharm Sci* 1997;59:254-6.
8. Pandit S, Sur TK, Jana U. Anti-ulcer effects of *shankha bhasma* in rats: A preliminary study. *Indian J Pharm* 2000;32:378-80.
9. Bagade S, Kadam HM, Kadam SS. Studies on *shankha bhasma*-II comparison of antacid activity of marketed *shankha bhasma* with chewable antacid tablet. Thesis Submitted to Institute of Postgraduate Teaching and Research in Ayurveda. Jamnagar, India: Gujarat Ayurved University; 1997;59:257-9.
10. Tank Zankhana GA. Pharmacological study of *shankha bhasma* alone and *shankha bhasma* along with amalaki churna in the management of amlapitta. Thesis Submitted to Institute of Postgraduate Teaching and Research in Ayurveda. Jamnagar, India: Gujarat Ayurved University; 2000.
11. Harinath J. A study of amlapitta with special reference to psychological manifestation. Thesis Submitted to Institute of Postgraduate Teaching and Research in Ayurveda. Jamnagar, India: Gujarat Ayurved University; 1986.

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