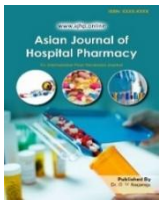
RESEARCH ARTICLE

Asian Jour Hosp Phar, Vol: 6, Issue: 2, 2026, 31-36

Asian Journal of Hospital Pharmacy

Content Available at www.ajhponline.com ISSN: 2583-0724



A PROSPECTIVE OBSERVATIONAL STUDY ON THERAPEUTIC EFFICACY AND SAFETY OF SIMETHICONE IN COMBINATION WITH ACTIVATED CHARCOAL IN PATIENTS WITH

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DOI: https://doi.org/10.38022/ajhp.v6i2.146

ARTICLE HISTORY: Received: 03 04 2026 Revised: 19 06 2026 Accepted: 09 07 2026

Abstract

Dyspepsia is a common gastrointestinal disorder characterized by upper abdominal discomfort, bloating, postprandial fullness, belching, nausea, and early satiety, leading to a considerable reduction in quality of life. The present prospective observational study was conducted to evaluate the therapeutic efficacy and safety of simethicone in combination with activated charcoal in patients with dyspepsia. The study was carried out over six months at a tertiary care hospital in Hyderabad, India, and included 60 adult patients diagnosed with dyspepsia who received simethicone (80 mg) and activated charcoal (250 mg) as part of routine clinical management. Demographic characteristics, clinical symptoms, comorbidities, treatment patterns, therapeutic outcomes, and adverse drug reactions were assessed. The majority of patients were males (60%), with the highest prevalence observed in the 31–40-year age group. Combination therapy was prescribed to 60% of patients and demonstrated greater improvement in dyspeptic symptoms, including bloating, abdominal discomfort, flatulence, and postprandial fullness, compared with monotherapy. Safety evaluation revealed that 78.33% of patients experienced no adverse effects, while only a small proportion reported mild gastrointestinal complaints such as bloating, abdominal distension, or upper abdominal burning, indicating excellent tolerability. Overall, the findings suggest that the combination of simethicone and activated charcoal is an effective, safe, and well-tolerated therapeutic option for the symptomatic management of dyspepsia and provides valuable real-world evidence supporting its routine clinical use.

Keywords: *Dyspepsia, Simethicone, Activated Charcoal, Therapeutic Efficacy, Safety, Prospective Observational Study, Gastrointestinal Symptoms.*

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INTRODUCTION

Dyspepsia is a common gastrointestinal disorder characterized by chronic or recurrent upper abdominal discomfort, bloating, nausea, belching, early satiety, and postprandial fullness, affecting nearly 20–30% of the general population worldwide [1,2]. It is one of the most frequent reasons for outpatient visits and significantly impacts patients' quality of life and healthcare expenditure [3]. Dyspepsia may be classified into functional dyspepsia and organic dyspepsia, based on the presence or absence of structural abnormalities [4].

The pathophysiology of dyspepsia is multifactorial and includes delayed gastric emptying, impaired gastric accommodation, visceral hypersensitivity, Helicobacter pylori infection, altered gut-brain interaction, and excessive gastrointestinal gas accumulation [5]. Gas-related symptoms such as bloating, abdominal fullness, and flatulence are highly prevalent and often troublesome, requiring effective symptomatic management [6].

Simethicone is an inert, non-systemic antifoaming agent that acts by decreasing the surface tension of gas bubbles, allowing them to coalesce and be expelled easily from the gastrointestinal tract [7]. It has been widely used for symptomatic relief of bloating, flatulence, and abdominal discomfort. Activated Charcoal, on the other hand, possesses

high adsorptive capacity and is known to bind gases, toxins, and fermentation products, thereby reducing intestinal gas and discomfort [8].

The combination of simethicone and activated charcoal is expected to provide synergistic benefits due to their complementary mechanisms of action. While simethicone facilitates gas dispersion, activated charcoal adsorbs excessive gases and irritants, potentially improving symptom relief in dyspeptic patients [9]. However, there is limited evidence regarding the combined therapeutic efficacy and safety of this regimen in clinical settings. Therefore, the present prospective observational study was undertaken to evaluate the therapeutic efficacy and safety of simethicone in combination with activated charcoal in patients with dyspepsia [10-13].

MATERIALS AND METHODS

Study Site

The present study was conducted at Gleneagles Hospital, Lakdikapul, Hyderabad, Telangana, India, a tertiary care multispecialty hospital providing comprehensive gastroenterology and general medicine services.

Study Design

A prospective observational study was carried out to evaluate the therapeutic efficacy and safety of Simethicone in combination with Activated Charcoal in patients diagnosed with dyspepsia.

Study Duration

The study was conducted over a period of six months.

Sample Size

A total of 60 patients who fulfilled the eligibility criteria were enrolled in the study.

Source of Data Collection

Data were collected from multiple sources to ensure comprehensive patient evaluation, including[14-16]:

- Inpatient and outpatient prescriptions
- Patient interviews
- Laboratory investigation reports
- Clinical case records
- Follow-up assessment reports

Eligibility Criteria

Inclusion Criteria

- Adults aged 18 years and above.
- Patients diagnosed with dyspepsia and prescribed Simethicone (80 mg) + Activated Charcoal (250 mg) combination therapy.
- Patients receiving the medication three times daily, one hour after meals, for a minimum duration of four weeks as part of standard treatment.
- Patients willing to participate and who provided written informed consent.

Exclusion Criteria

- Patients with a known history of hypersensitivity to simethicone or activated charcoal.
- Patients with conditions where short-term activated charcoal administration is contraindicated.
- Patients with a history of gastroduodenal obstruction.
- Patients with bowel perforation or gastrointestinal bleeding.
- Pregnant and lactating women.
- Patients unwilling to participate in the study.

Data Collection and Assessment

Demographic details such as age, gender, dietary habits, and medical history were recorded. Clinical symptoms of dyspepsia including bloating, abdominal discomfort, flatulence, belching, and fullness, were assessed at baseline and during follow-up. Therapeutic efficacy was evaluated based on symptom improvement and reduction in severity after treatment. Safety assessment was performed by documenting any adverse drug reactions or side effects during the study period [17,18].

Statistical Analysis

The collected data were analysed using appropriate statistical methods. Results were expressed as frequencies, percentages, and mean values. A comparative analysis was performed to assess the improvement in dyspeptic symptoms before and after treatment.

Ethical Approval

The study protocol was approved by the Institutional Ethics Committee of Gleneagles Hospital before initiation of the study, and all procedures were conducted according to ethical guidelines.

RESULTS AND DISCUSSION

Demographic Characteristics of the Study Population

A total of 60 patients diagnosed with dyspepsia were included in the present prospective observational study to evaluate the therapeutic efficacy and safety of Simethicone in combination with Activated Charcoal.

Gender-wise Distribution

The gender-wise distribution of study participants is represented in Table 01. Out of the total 60 patients, 36 (60%) were males, and 24 (40%) were females. The findings indicate that male patients were more frequently affected by dyspepsia compared to female patients. This higher prevalence among males may be attributed to increased exposure to risk factors such as smoking, alcohol consumption, stress, and irregular dietary habits. The results suggest that gender-related behavioural patterns may influence the occurrence of dyspeptic symptoms.

Table 01: Gender-wise distribution of study participants

Gender	Number of Patients	Percentage (%)
Male	36	60.0
Female	24	40.0

Age-wise Distribution

The age-wise distribution of individuals is depicted in Table 02 and Figure 01. Among the total study population, the majority of patients were in the age group of 31–40 years (24 individuals), followed by 41–50 years (17 individuals). No patients were found below the age of 30 years. This indicates that dyspepsia is more commonly observed in middle-aged individuals. Factors such as work pressure, unhealthy food habits, and stress could contribute to this age-related prevalence.

Table 02: Age-wise distribution of study participants

Age Group (Years)	Number of Patients	Percentage (%)
0–10	0	0
11–20	0	0
21–30	0	0
31–40	24	40.0
41–50	17	28.33
51–60	12	20.0
61–70	7	11.66

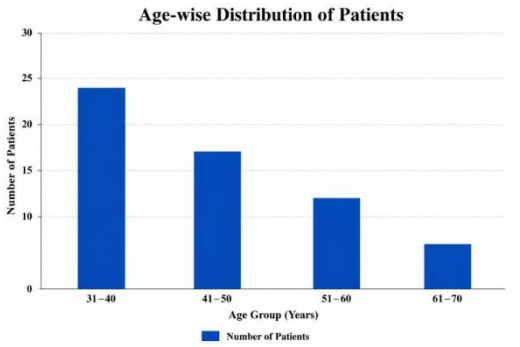


Figure 01: Age-wise distribution of study participants

Age and Gender Distribution

The age and gender distribution showed that males were predominantly affected in the 41–50 and 61–70 years age groups, while females were mainly distributed in the 31–40 and 51–60 years age groups (Table 03).

Table 03: Age and gender distribution of study participants

Age Group	Male	Female
31–40	12	12
41–50	11	6
51–60	6	6
61–70	7	0

Comorbidity Analysis

Out of 60 patients, 34 (56.66%) had associated comorbidities, while 26 (43.33%) had no comorbidities.

Types of Comorbidities

Functional dyspepsia was the most common associated condition (50%), followed by diabetes mellitus and constipation (20% each), as summarised in Table 04 and Figure 02.

Table 04: Distribution based on types of comorbidities

Comorbidity	Number of Patients
Hypertension	6
Diabetes Mellitus	12
Constipation	12
Functional Dyspepsia	30
Obesity	3
IBS	4
Others	1

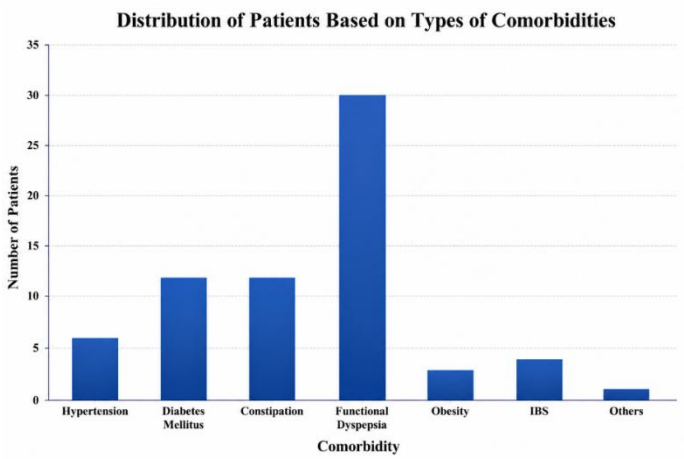


Figure 02: Distribution based on types of comorbidities

Social History

Social history analysis revealed that 36 patients (37.5%) had no social history, while smoking was reported in 24 patients (25%), as shown in Table 05 and Figure 03.

Table 06: Distribution based on social history

Social History	Number of Patients	Percentage (%)
No social history	36	37.5
Alcohol consumption	18	18.75
Smoking	24	25.0
Alcohol + Smoking	18	18.75

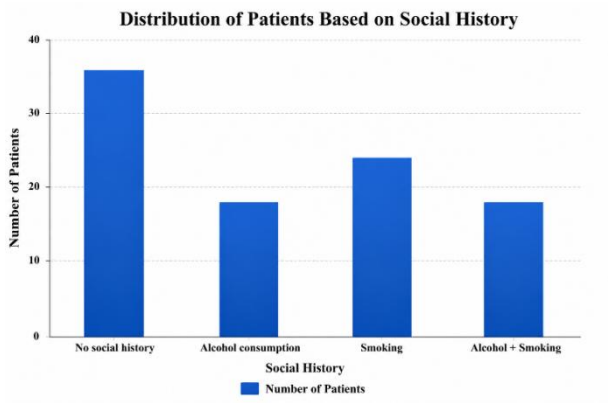


Figure 03: Bar graph representing the social history profile of dyspepsia patients included in the study.

Efficacy Assessment

Distribution Based on Therapy

Among the study population, 36 patients (60%) received combination therapy (Simethicone + Activated Charcoal), while 24 patients (40%) received individual therapy (Simethicone alone), as shown in Table 07.The results suggest that combination therapy demonstrated better therapeutic effectiveness and improved symptom relief compared to monotherapy.

Table 07: Distribution of patients based on therapy

Therapy	Number of Patients	Percentage (%)
Combination Therapy	36	60.0
Individual Therapy	24	40.0

Safety Assessment

Safety analysis revealed that 47 patients (78.33%) reported no adverse effects. Mild side effects such as abdominal distension, bloating, and upper abdominal burning were observed in a few patients, as shown in Table 08. The low incidence of adverse effects indicates that the therapy was generally safe and well tolerated. Combination therapy showed acceptable tolerability and improved clinical outcomes in dyspeptic patients.

Table 08: Safety profile of medications used in dyspepsia management

Side Effects	Number of Patients
No side effects	47
Bloating	3
Burning/discomfort	4
Abdominal distension	6

CONCLUSION

This prospective observational study demonstrated that the combination of simethicone and activated charcoal was effective and well tolerated in the management of dyspepsia. Patients receiving combination therapy experienced greater relief from symptoms such as bloating, upper abdominal discomfort, and difficulty in gas evacuation compared with individual therapy. The treatment also improved overall patient comfort and quality of life without significant safety concerns during the study period. These findings suggest that simethicone combined with activated charcoal is a useful therapeutic option for symptomatic dyspepsia. However, larger randomized controlled studies with longer follow-up are recommended to further confirm its efficacy and long-term safety.

FUNDING

Nil

CONFLICT OF INTEREST

The authors declare that there are no conflicts of interest regarding the publication of this paper.

ACKNOWLEDGMENT

We also thank the patients who consented to participate in this research.

AUTHOR CONTRIBUTIONS

M. Rama Krishna conceived and supervised the study and critically reviewed the manuscript. T. Vaishnavi, P. Manisha, and P. Sharvani contributed to data collection, data analysis, literature review, manuscript drafting, and revision. All authors read and approved the final version of the manuscript.

ETHICAL STATEMENT

The ethical committee clearance was obtained from Gleneagles Global Hospital before initiating the study. Reference number: AIPS/ 04/ IEC/05

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