Introduction

The multicenter, randomized, parallel-group, double-blind, placebo-controlled study evaluated the efficacy and safety of Mucinex® D (guaifenesin 600 mg and pseudoephedrine hydrochloride 60 mg extended-release bi-layer tablets) in providing relief of respiratory symptoms when used as adjunctive therapy to antibiotics in patients with acute respiratory infections (ARI).

Methods

Adult patients 18-75 years, considered by the treating physician as having an ARI, were enrolled in this study. Patients with a diagnosis of ARI were randomized into the treatment regimens determined by the treating physician, and received Mucinex® D or a matching placebo 600 mg twice daily for 7 days. As per protocol, patients were taking no prior or concomitant medications for ARI. Approval was obtained from the IRB Quorum Review Inc., and written informed consent was obtained from all patients. Patients completed symptom diaries and treatment assessments twice daily for Days 4 and 8. Efficacy was assessed in intent-to-treat (ITT) and per-protocol analyses. Safety was assessed throughout the study.

Results

Data from the 30-center ITT population (n=601; Mucinex® D, 303; placebo, 298) showed lower mean symptom scores with Mucinex® D vs placebo starting on Day 3 in every symptom assessed, with statistically significant improvements in total symptom score (p=0.004). Significantly more patients felt the “medication was helping during the day” on Day 2 (p=0.003) in the Mucinex® D group, and patient-off-treatment assessments of treatment effectiveness showed a significant preference for Mucinex® D (p=0.021), as compared with placebo. The time to overall relief (no symptom worse than mild) was shorter for Mucinex® D than for placebo (4.6 days vs 5.5 days). Study medication was not withdrawn in the Mucinex® D treatment group were insomnia (4.0%), nausea (3.5%), and headache (3.3%).

Discussion

When used in combination with antibiotic therapy in patients with ARI, Mucinex® D was well tolerated, short-term to relief and improved respiratory symptoms better than placebo.

INTRODUCTION

• Acute respiratory infection (ARI) is one of the most common reasons why patients visit a physician in the United States and accounts for about 75% of all antibiotic prescriptions.

• Excessive mucus and congestion are frequent symptoms of ARI.

• The evaluation of an antibiotic, expectorant and decongestant is quite common in the treatment of ARI1 with recent clinical practice guidelines published in the United States and Europe.2 The most common antibiotic for respiratory treatments for symptomatic relief.

• Mucinex® D (Guaifenesin + Pseudoephedrine; Therapeutics, Chester, NJ, USA) is a combination of an expectorant (guaifenesin 600 mg) and a nasal decongestant (pseudoephedrine hydrochloride 60 mg) extended-release bi-layer tablet form, used to help lessen mucus (phlegm) and thin bronchial secretions, and to temporarily relief nasal congestion, and sinus congestion and pressure.

• The study was undertaken to assess the efficacy and safety of Mucinex® D compared with placebo when used for symptom relief in combination with antibiotics in patients with ARI.

METHODS

• This was a multicenter, randomized, parallel-group, double-blind, placebo-controlled study.

• Adult patients aged 18-75 years with symptoms of ARI that began within 7 days of screening and a total symptom score of ≥15 based on a 0-5 to 3 severity rating of 10 respiratory symptoms (cough, congestion, runny, nose, facial pressure/pain, post-nasal drip, sore throat) were enrolled. The study protocol, patients were taking no prior or concomitant medications for ARI. Approval was obtained from the IRB Quorum Review Inc., and written informed consent was obtained from all patients before study entry.

• Adult patients aged 18-75 years with symptoms of ARI that began within 7 days of screening and a total symptom score of ≥15 based on a 0-5 to 3 severity rating of 10 respiratory symptoms (cough, congestion, runny, nose, facial pressure/pain, post-nasal drip, sore throat) were enrolled. The study protocol, patients were taking no prior or concomitant medications for ARI. Approval was obtained from the IRB Quorum Review Inc., and written informed consent was obtained from all patients before study entry.

• Patients provided a medical history and informed consent from all patients before study entry.

• Patients completed symptom diaries and treatment assessments twice daily and attended doctor visits on Days 4 and 8. Efficacy was assessed in intent-to-treat (ITT) and per-protocol analyses. Safety was assessed throughout the study.

RESULTS

Demographics

A total of 605 patients were enrolled and randomized to study treatment (302 in the Mucinex® D group and 303 in the placebo group). Four patients did not take study medication and were not included in the safety/ITT population (2 in each group).

• The two groups were well matched with regard to baseline demographic and clinical characteristics (Table 1). Smallest was the most frequent diagnosis at baseline.

• Mean total symptom scores at baseline were comparable for the Mucinex® D and placebo groups (Table 1).

• Treatment with Mucinex® D was well tolerated (Table 2). The most common adverse events (AEs) in the Mucinex® D group were insomnia (4.0%), nausea (3.5%), and headache (3.3%).

• The incidence of AEs considered to be related to study medication was 9.0% in the Mucinex® D group and 5.7% in the placebo group.

• AEs resulting in treatment discontinuation in 15 patients in the Mucinex® D group (5.0%) and 8 patients in the placebo group (2.7%). The most frequently reported AE leading to treatment discontinuation was insomnia (7 patients in the Mucinex® D group (2.3%) and 2 patients in the placebo group (0.7%).

• No serious AEs or deaths were reported in either treatment group during this study.

CONCLUSIONS

• Treatment with Mucinex® D for 7 days as adjunctive therapy to antibiotics in patients with ARI shortened the time to relief and improved respiratory symptoms better than placebo, with most marked effects seen for nasal congestion and sinus headache.

• Patient and investigator global assessments of treatment efficacy significantly favored Mucinex® D over placebo.

• Treatment with Mucinex® D was well tolerated and there were no unexpected safety findings in this study.

• Mucinex® D as an adjunct to antibiotics addresses the importance of managing symptoms in the acute treatment of ARI.