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ORIGINAL ARTICLE

Effectiveness and safety of gemifloxacin versus cefpodoxime in acute exacerbation of chronic bronchitis

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ABSTRACT:

Background: Acute exacerbation of chronic bronchitis (AECB) refers to a sudden worsening of symptoms in individuals with chronic bronchitis, which is characterized by inflammation and irritation of the bronchial tubes. The present study was conducted to evaluate effectiveness and safety of gemifloxacin versus cefpodoxime in acute exacerbation of chronic bronchitis. **Materials & Methods:**80 patients with acute exacerbation of chronic bronchitis of both genderswere divided into 2 groups of 40 each. Group I received either gemifloxacin 320 mg once daily and group II received cefpodoxime 200 mg twice daily orally for 7 days. Clinical success rate at day 14 visit and the changes in clinical global impression (CGI) scales and incidence of adverse events (AEs) were recorded. **Results:** Group I had 22 males and 18 females and group II had 17 males and 23 females. The mean respiratory symptoms score in group I and II at baseline was 8.5 and 9.3, at first follow up was 7.9 and 8.2 and at second follow up was 6.8 and 7.2 respectively. The difference was significant (P< 0.05). Clinical cure was seen in 23 in group I and 21 in group II, clinical improvement was seen in 12 in group I and 13 in group II and treatment failure was seen in 5 in group I and 6 in group II. The difference was non- significant (P> 0.05). **Conclusion:** For the treatment of AECB, a 7-day course of gemifloxacin is similar to cefpodoxime in terms of safety and clinical efficacy.

Keywords: chronic bronchitis, Gemifloxacin, Clinical cure

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INTRODUCTION

Acute exacerbation of chronic bronchitis (AECB) refers to a sudden worsening of symptoms in individuals with chronic bronchitis, which is characterized by inflammation and irritation of the bronchial tubes (the airways that carry air to the lungs).[1] AECB is a common complication of chronic bronchitis and is typically triggered by bacterial or viral infections, environmental factors, or other respiratory irritants.[2]

Bacterial or viral respiratory infections, such as the flu (influenza), common cold viruses, or bacterial pneumonia, are common triggers of AECB.Exposure to air pollution, tobacco smoke, dust, fumes, or other respiratory irritants can exacerbate symptoms of chronic bronchitis and trigger acute flare-ups.Allergens such as pollen, mold, pet dander, or certain foods may exacerbate symptoms in individuals with allergic bronchitis.Cold weather, humidity changes, or sudden temperature changes can trigger AECB in susceptible individuals.Failure to adhere to treatment, non-compliance with medications, or inadequate management of underlying chronic bronchitis can increase the risk of acute exacerbations.[3]

A more recent generation of fluoroquinolone, gemifloxacin, shares pharmacokinetic and pharmacodynamic characteristics with other members of the class, but it has outperformed the other respiratory fluoroquinolones in vitro, exhibiting lower minimal inhibitory concentrations (MIC) against S. pneumoniae.[4] However, there is a comparable level of antimicrobial action against atypical pathogens such Chlamydia pneumoniae, Legionella pneumophila, and Mycoplasma pneumoniae as well as gram-negative respiratory pathogens like H. influenzae and M. catarrhalis.[5]An oral third-generation cephalosporin called cefpodoxime exhibits modest activity against anaerobic organisms in addition to having good antibacterial activity against aerobic gram-positive and gram-negative bacteria such as S. pneumoniae, H. influenzae, and M. catarrhalis.[6] AECB can be effectively treated with cefpodoxime, according to the findings of a few trials that assessed the drug's efficacy for treating different respiratory tract infections.[7,8]The present study was conducted to evaluate effectiveness and safety of gemifloxacin versus cefpodoxime in acute exacerbation of chronic bronchitis.

MATERIALS & METHODS

The present study consisted of 80 patients with acute exacerbation of chronic bronchitisof both genders. All gave their written consent to participate in the study.

Data such as name, age, gender etc. was recorded. Patients were divided into 2 groups of 40 each. Group I received either gemifloxacin 320 mg once daily and group II received cefpodoxime 200 mg twice daily orally for 7 days. Clinical success rate at day 14 visit and the changes in clinical global impression (CGI)

scales and incidence of adverse events (AEs) were recorded. Data thus obtained were subjected to statistical analysis. P value < 0.05 was considered significant.

RESULTS

Table I Distribution of patients

Groups	Group I	Group II
Drug	320 mggemifloxacin	200 mgcefpodoxime
M:F	22:18	17:23

Table I shows that group I had 22 males and 18 females and group II had 17 males and 23 females.

Table II Respiratory symptom scores

Period	Group I	Group II	P value
Baseline	8.5	9.3	0.02
First follow up	7.9	8.2	0.05
Second follow up	6.8	7.2	0.04

Table II, graph I shows that mean respiratory symptoms score in group I and II at baseline was 8.5 and 9.3, at first follow up was 7.9 and 8.2 and at second follow up was 6.8 and 7.2 respectively. The difference was significant (P< 0.05).

Graph I Respiratory symptom scores

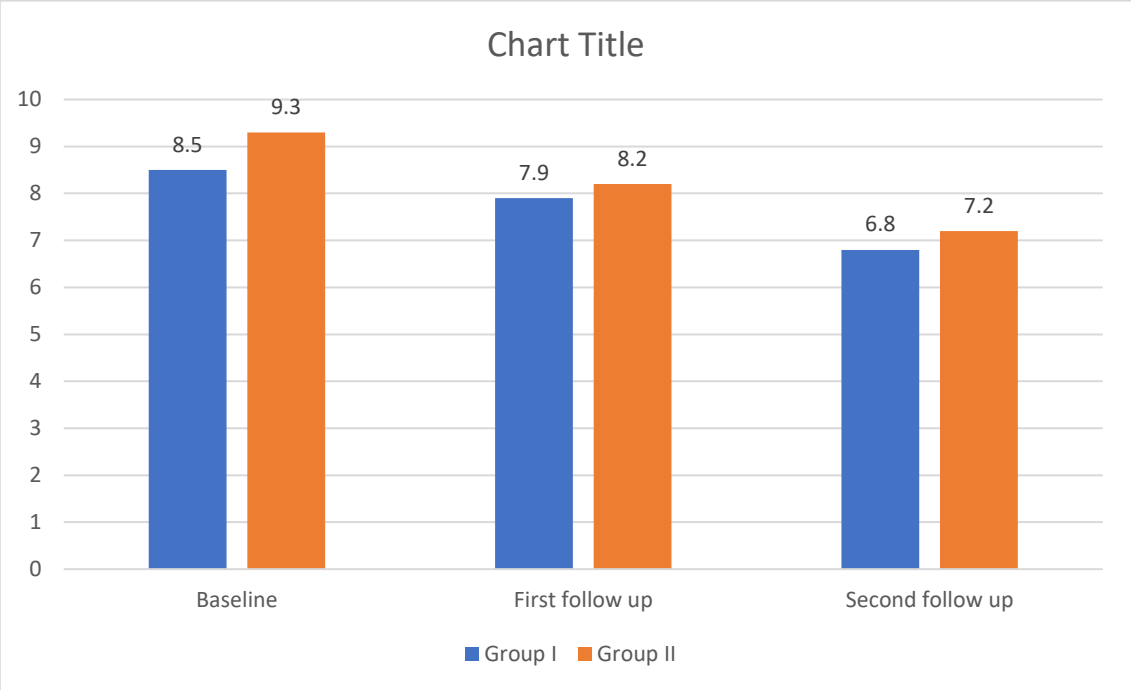

Table III Comparison of treatment success rates

Success rates	Group I	Group II	P value
Clinical cure	23	21	0.92
Clinical improvement	12	13	
Treatment failure	5	6	

Table III shows that clinical cure was seen in 23 in group I and 21 in group II, clinical improvement was seen in 12 in group I and 13 in group II and treatment failure was seen in 5 in group I and 6 in group II. The difference was non- significant (P> 0.05).

DISCUSSION

Persistent or worsening cough, often producing thick, discolored mucus (sputum), difficulty breathing, especially with exertion or during physical activity, high-pitched whistling sound during breathing, indicating airway narrowing or obstruction, discomfort or pressure in the chest, often described as a feeling of heaviness or squeezing, generalized tiredness, weakness, or malaise, elevated body temperature, especially if the exacerbation is due to an underlying infection, excessive production of mucus or changes in the color or consistency of sputum are symptoms and signs in patients with acute exacerbation of chronic bronchitis.[9,10]The present

study was conducted to evaluate effectiveness and safety of gemifloxacin versus cefpodoxime in acute exacerbation of chronic bronchitis.

We found that group I had 22 males and 18 females and group II had 17 males and 23 females.Chatterjee et al[11]evaluated the effectiveness and safety of gemifloxacin, a new fluoroquinolone, versus cefpodoxime, an oral third-generation cephalosporin, for the treatment of mild to moderately severe cases of AECB.Adult subjects diagnosed with chronic bronchitis with clinical symptoms suggestive of an Anthonisen type II acute exacerbation (any two of the following criteria – increased dyspnea, cough, sputum purulence) were eligible and those fulfilling the subject selection criteria were randomized to receive either gemifloxacin 320 mg once daily or cefpodoxime 200 mg twice daily orally for 7 days. The primary outcome measure was clinical success rate at day 14 visit and the secondary outcome measures were changes in Clinical Global impression (CGI) scales and incidence of adverse events (AEs). Fifty-two subjects were enrolled: 26 in gemifloxacin group and 24 in the other and 2 were lost to follow-up.The clinical success rates were comparable (84.6% in gemifloxacin group versus 83.3% in cefpodoxime group) and no statistically significant difference was observed between the groups. AEs were mild, self-limiting and few (two in gemifloxacin and three in cefpodoxime arm) and tolerability was also good.

We found that mean respiratory symptoms score in group I and II at baseline was 8.5 and 9.3, at first follow up was 7.9 and 8.2 and at second follow up was 6.8 and 7.2 respectively. We found that clinical cure was seen in 23 in group I and 21 in group II, clinical improvement was seen in 12 in group I and 13 in group II and treatment failure was seen in 5 in group I and 6 in group II. Wilson et al[12] evaluated efficacy and safety of a 5-day course of gemifloxacin were compared with those of a standard 7-day regimen of clarithromycin in patients with an acute exacerbation of chronic bronchitis (AECB)in 93 centers in 7 countries. Adult patients (age >40 years) with a history of chronic bronchitis and an Anthonisen type 1 acute exacerbation (increased dyspnea, cough, and sputum purulence) were eligible. Patients were randomized to receive gemifloxacin 320 mg once daily for 5 days or clarithromycin 500 mg twice daily for 7 days. Clinical and bacteriologic response rates were assessed at the end-of-therapy visit (days 8-12), the week 2-3 follow-up visit (days 13-24), and the week 4-5 follow-up visit (days 25-38). Seven hundred twelve patients were randomized to treatment, 351 to gemifloxacin and 361 to clarithromycin. The long-term study included 438 patients, 214 receiving gemifloxacin and 224 receiving clarithromycin. Clinical success rates at the 2-3 weeks follow-up visit were 85.4% for gemifloxacin and 84.6% for clarithromycin. Bacteriologic success rates were 86.7% for gemifloxacin and 73.1% for clarithromycin. Significantly more patients receiving gemifloxacin than clarithromycin remained free of AECB recurrences (71.0% vs 58.5%, respectively; P = 0.016). Both treatments were well tolerated.

The limitation of the study is the small sample size.

CONCLUSION

Authors found that for the treatment of AECB, a 7-day course of gemifloxacin is similar to cefpodoxime in terms of safety and clinical efficacy.

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