Original Article

Efficacy and safety of oral gemifloxacin for the empirical treatment of pneumonia

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ABSTRACT

Context: Respiratory tract infections (RTI) are common causes of morbidity and mortality worldwide. Initial antibiotic therapy in upper and lower respiratory tract infections is usually empirical. The increasing evidence of antibacterial resistance in the pathogens commonly associated with pneumonia has raised concerns about the efficacy of currently available therapies and poses a challenge to clinicians. Gemifloxacin is a synthetic fluoroquinolone antimicrobial agent exhibiting potent activity against most Gram negative and Gram positive organisms. Hence, this study was planned to evaluate the efficacy of gemifloxacin as an empirical therapy in pneumonia. **Materials and Methods:** This was an open labelled, single-arm study. Patients with clinical features of community acquired pneumonia (CAP) who fulfilled the inclusion criteria received treatment with oral gemifloxacin 320 mg once daily for 5-7 days. Once enrolled in the study, patients were treated as outpatient or as inpatient depending on clinical need. The primary efficacy was to evaluate the clinical response at the end of therapy, i.e., day 9-11 for CAP. Secondary efficacy parameters included radiological and bacteriological response at the end of therapy. Patients were evaluated three times during the entire course of treatment (Visit 1, Day 0; Visit 2, Day 2-4; Visit 3, Day 9-11) for their clinical, radiological and/or bacteriological response, as well as for safety assessment. **Results:** A total of 105 patients received the study medication (gemifloxacin 320 mg orally). Two patients were "lost to follow-up" and one patient had to discontinue medication due to insufficient therapeutic effects. Clinical response at the end of therapy was successful in 99 (96.1%) while clinical failure was reported in 4 (3.9%) patient. As per the radiological response, 77.1% of the total cases showed improvement, 8.6% had no change, and 2.9% cases had deterioration in radiological findings. Gemifloxacin is an effective drug in the management of CAP. **Conclusions:** Gemifloxacin with coverage against both Gram positive and Gram negative organisms as well as atypical pathogens, with once daily oral dosing and minimum side effect is a very effective and economical choice for treating CAP empirically.

KEY WORDS: Community acquired pneumonia, gemifloxacin, outcomes

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INTRODUCTION

Community acquired pneumonia (CAP) is a common cause of morbidity and mortality worldwide. In India, approximately 9.5% of the total population suffers from respiratory tract infections.[1] Initial antibiotic therapy in upper and lower respiratory tract infections in usually empirical, focused towards the most common etiologic agents, which include *Streptococcus pneumoniae*, *Klebsiella pneumonia*, *Hemophilus influenza*, and *Moraxella catarrhalis*.[2] The decreasing susceptibility pattern of these pathogens, particularly *S. pneumoniae*, to antibacterials has raised concerns about the decreasing efficacy of currently available therapies.[3] In the US, almost 100% of clinical *M. catarrhalis* isolates produce beta-lactamase and upto 50% of *H. influenzae* isolates produce beta-lactamase. Penicillin resistant strains have been identified worldwide[4] and resistance to other antibacterials such as cephalosporins and macrolides is increasing among isolates of *S. Pneumonia*.[5-7] Thus, the efficacy of therapy with antibacterials such as the penicillins, cephalosporins, and macrolides may be compromised.

The increasing evidence of antibacterial resistance in the pathogens commonly associated with Respiratory

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tract infections (RTI) has therefore raised concerns about the efficacy of currently available therapies in CAP. New agents with broad spectrum of activity against the range of organisms implicated in CAP are therefore needed.

Gemifloxacin is a novel synthetic broad-spectrum fluoroquinolone that exhibits bactericidal activity primarily by inhibiting bacterial DNA gyrase.[8] Topoisomerases IV of the bacteria is another target of the drug. Gemifloxacin has excellent activity against both gram-negative and gram-positive organisms including potent antibacterial activity against *Streptococcus* species and *Staphylococcal* species. Hence, this study was planned to evaluate the efficacy of gemifloxacin as empirical therapy in pneumonia.

MATERIALS AND METHODS

This was an open labelled, single-arm study. Patients with clinical features of CAP who fulfilled the inclusion criteria received treatment with oral gemifloxacin 320 mg once daily for 7-10 days. Once enrolled in the study, patients were treated as outpatients or as inpatients depending on clinical need.

Inclusion criteria

1. Male or female patients aged 18-70 years having given their informed consent.
2. Clinically and radiological confirmed cases of community acquired pneumonia (CAP).
3. Patients who had at least one respiratory sign or symptoms like cough, throat irritation, purulent sputum production, dyspnoea.
4. Female patients of child bearing potential having a negative urine pregnancy test prior to enrolment (including those who were practicing birth control, those with tube ligation and those less than 1 year post menopausal).
5. Patients having given written consent to participate in the study.

Exclusion criteria

1. Females who were pregnant, lactating, planning a pregnancy or of childbearing potential and not using an accepted method of contraception.
2. Hypersensitivity to quinolone or any member of quinolone class of antibacterials.
3. Patients with other chronic pulmonary disease like cystic fibrosis, active tuberculosis, bronchiectasis, or active pulmonary malignancies.
4. Patient with a life threatening or serious underlying disease, which is unstable, e.g. Myocardial infarction
5. Patients with known or suspected renal impairment and/or known creatinine clearance < 40 ml/min.
6. Patients with ALT, AST, or alkaline phosphatase levels greater than 3 times the upper limit of normal.
7. Patients who were immunocompromised including HIV positive patients.
8. Patients with history of epilepsy, myasthenia gravis, alcohol abuse, heavy smoking (> 40 cigarettes a day), drug addiction.
9. Patients with a clinical history or evidence of hemolytic crisis, G6PD deficiency, tendonitis, prolongation of QTc interval.
10. Patients receiving Class IA or Class III anti-arrhythmic agents or steroids.
11. Patient requiring parenteral antibacterial therapy for any other condition other than CAP.

Duration of therapy

CAP: Seven to ten days treatment

Patients were evaluated three times during the entire course of treatment (Visit 1, Day 0; Visit 2, Day 2-4; Visit 3, Day 7-9 and Visit 4, Day 9-11) for their clinical, radiological and/or bacteriological response, as well as for safety assessment.

RESULTS

Efficacy and safety parameter

The primary efficacy was to evaluate the clinical response at the end of therapy, i.e., day 9-11 for community acquired pneumonia (CAP). Secondary efficacy parameters included 1) radiological response at the end of therapy 2) bacteriological response at the end of therapy.

The safety end point was to evaluate the incidence of adverse effects and laboratory parameters.

Data on a continuous scale was expressed as a mean along with standard deviation. Categorical data was expressed as percentage. Comparative statistical analysis was carried out using ANOVA in respect of data measured on a continuous scale and using non parametric ANOVA in respect of data measured on ranking scale. All differences with *P* value below 0.05 were labelled as statistically significant.

Key demographic data

A total of 105 patients received the study medication (gemifloxacin 320 mg orally). All the subjects received at least one dose and were therefore included for safety analysis. Two patients were lost to follow-up and one patient had to discontinue medication due to insufficient therapeutic effects. The age of patients ranged from 18-70 years with an average of 48.21 years. Mean weight and height of subjects were within normal limits. Of the total subjects treated 58% were male and remaining 42% were female subjects [Table 1].

Data analysis and efficacy results

Clinical response among 103 patients at the end of therapy was successful in 99 (96.1%), while clinical failure was reported in 4 (3.9%) patient. A detailed account of primary efficacy parameters used to analyze the overall clinical outcome is shown in Table 2.

Results reveal that mean respiratory rate was 23.31 at baseline level, which after treatment at 2-4 days had

significantly fallen by 12.1% and at end of treatment by 25.8% from baseline level. Mean temperature was 100.08°F at baseline level which after treatment at 2-4 days was 98.55°F, which was a significant reduction and at end of treatment average temperature was 98.27°F. There was no significant change in mean diastolic blood pressure. Analysis shows that 82.8% of the total cases had fever and 48.6% had chills at baseline level. After the treatment at the end of 2-4 days only 8.6% of the cases had fever and 11.4% had chills, which was significant reduction from baseline level.

Of the total, 74.0% and 92.0% had rales and cough, respectively, at baseline level. After the treatment at the end of 2-4 days, only 2.8% of cases had cough and 20.0% had rales, which was significant reduction from base line level. Of the total, 60.0% and 63.0% had dyspnoea and tachypnoea at baseline level. After the treatment at the end of 2-4 days, tachypnoea had a significant fall, i.e., 51.4% and dyspnoea showed a significant fall, i.e., 42.8% from baseline level. In the study group, 21.2% cases had hypoxemia and 48.6% had chest pain at baseline level. After the treatment at the end of 2-4 days, significant fall was observed in chest pain and significant reduction in hypoxemia at the end of 9-11 days. In the study group, 80.0% and 86.0% had pulmonary consolidation and sputum respectively at baseline level. After the treatment at the end of 2-4 days, both signs had significant fall from baseline level.

Secondary efficacy parameters

According to the bacteriological outcome in Table 3, 84.5% cases were clinically cured and hence could not expectorate sputum, required for bacteriological analysis at the end of therapy. They were classified under 'unable to determine'. About 13.5% of the patients had eradication and in 2% there was a bacteriological persistence.

As per the radiological finding in Table 4, 77.1% of the total cases showed improvement, 8.6% had no change; 2.9% cases had deterioration in radiological findings. In 11.4% outcome was "unable to determine".

SAFETY RESULTS

Laboratory investigations

None of the patients experienced vital signs of potential clinical concern or reported any adverse events during the course of study. Only one patient had increase in the value of alkaline phosphatase, which was considered unrelated to study medication. The drug was found to be safe and well tolerated in all treated patients [Table 5].

DISCUSSION

Community-acquired pneumonia (CAP) is the cause of substantial morbidity, mortality, and resource utilization worldwide. Despite substantial progress in therapeutic options, CAP remains a significant cause of morbidity and death, and there continues to be a major controversy concerning the antimicrobial management of this infection.[9] The mixed etiology and the changing susceptibility of pathogens causing CAP, in particular that of *Streptococcus pneumoniae*, has created a challenge, in some circumstances, to clinicians as to which therapeutic approaches may be the most appropriate in terms of optimal patient outcome.[10] Initial antimicrobial therapy is normally given empirically, before the bacterial cause of the infection can be determined in the laboratory, and in many cases treatment is empirical throughout due to the lack of reliable microbiological data. An understanding of the possible pathogens and resistance patterns is helpful in guiding antibiotic choice, and a detailed knowledge of the local susceptibility of the potential pathogens would ensure

Table 1: Key demographic data

Parameter	Mean	S.D.	Range
Age (yrs)	48.21	17.26	18-70 yrs
Weight (kg)	58.19	10.75	30-83 kg
Height (cm)	162.22	7.22	140-177 cm

No. of patients (105)

Table 2: Primary efficacy parameters

Parameters	Baseline level	2-4 Days	9-11 Days
Change in mean respiratory rate	23.31 ± 3.23	20.51 ± 7.65	17.29 ± 2.86
Change in mean temperature	100.08 ± 1.44	98.55 ± 0.77	98.27 ± 0.45
Change in mean diastolic pressure	79.51 ± 10.54	78.37 ± 8.08	77.89 ± 7.28
Change in fever and chills	29	03	01
	17	04	02
Change in signs of cough	32	01	01
and rales	26	07	04
Change in signs of dyspnoea	22	16	07
and tachypnoea	21	03	03
Change in signs of	14	03	0
hypoxemia and chest pain	17	01	0
Change in signs of sputum	30	14	03
and pulmonary consolidation	28	07	08

Table 3: Secondary efficacy parameters

Bacteriological response at the end of the therapy	No. of subjects, *n*	Percentage
Eradication	02	01.9
Presumed bacteriological eradication	12	11.6
Bacteriological persistence	01	01.0
Presumed bacteriological persistence	01	01.0
Unable to determine in clinically cured subjects	87	84.5

Table 4: Radiological outcomeassessment

Overall evaluation of radiological outcomeassessment	No. of subjects, *n*	Percentage
Improved	81	77.1
Unchanged	09	08.6
Worsened	03	02.9
Unable to determine in clinically cure subjects	12	11.4
Total	*n* = 103	100.0

Table 5: Laboratory investigations

Parameters (Units)	Baseline level	End of Rx
Hematology		
Hemoglobin(g/dl)	12.84 ± 2.07	12.90 ± 1.97
Haematocrit (%)	33.45 ± 14.64	35.27 ± 13.16
Platelet Count ($\times 10^3$ /mm^3)	237.10 ± 95.76	247.84 ± 77.03
WBC ($\times 10^3$ /mm^3)	10.05 ± 4.49	9.49 ± 2.79
Neutrophils (%)	67.13 ± 13.20	64.13 ± 11.56
Lymphocytes (%)	22.48 ± 10.14	25.11 ± 7.55
Monocytes (%)	7.39 ± 9.24	7.21 ± 10.11
Eosinophils (%)	3.96 ± 6.96	4.91 ± 9.21
Basophils (%)	0.38 ± 0.84	0.45 ± 0.70
Clinical Chemistry		
Alkaline Phosphatase (U/L)	212.74 ± 121.55	203.80 ± 126.4
AST (U/L)	28.96 ± 11.09	27.95 ± 14.88
ALT (U/L)	29.11 ± 9.27	28.07 ± 10.40
BUN (mg/dl)	30.51 ± 15.45	28.33 ± 10.46
Albumin (g/dl)	4.33 ± 0.72	4.32 ± 0.56
Serum Bilirubin (mg/dl)	0.81 ± 0.71	0.74 ± 0.69
Serum Protein (g/dl)	7.34 ± 0.80	7.28 ± 0.65
Creatinine (mg/dl)	0.96 ± 0.27	0.93 ± 0.23
Glucose (mg/dl)	111.09 ± 48.6	108.8 ± 52.3

a more appropriate selection of the antimicrobial agent to be used. Although CAP may be caused by many possible pathogens, a limited number of common pathogens are responsible for most cases.[11] In fact, no etiologic agent is found in as many as 50% of cases, even when extensive diagnostic testing is performed.[12] In those cases in which an etiologic agent is identified, *S. pneumoniae* accounts for the majority of bacterial pneumonia.[13] *Mycoplasma pneumoniae*, Chlamydia *pneumoniae*, *Hemophilus influenzae*, *Legionella pneumophila*, and respiratory viruses are the other common causes.

Almost all of the major decisions regarding management of CAP, including diagnostic and treatment issues, revolves around the initial assessment of severity. Site-of-care decisions (e.g., hospital vs. outpatient, intensive care unit [ICU] vs. general ward), choice and route of antibiotic administration are based on the assessment of the patient through PORTS/CURRB-65/PSI criteria. Severity-of-illness scores, such as the CURB-65 criteria (confusion, uremia, respiratory rate, low blood pressure, age 65 years or greater), or prognostic models, such as The Pneumonia Severity Index (PSI) or PORTS scoring, can be used to identify patients with CAP who may be candidates for outpatient treatment. Infectious Diseases Society of America/American Thoracic Society Consensus Guidelines on the Management of CAP in adults suggests that patients with a CURB-65 score of 0-1 be treated as outpatients and similarly patient with PSI risk class I and II. The oral route is recommended in these non-severe pneumonia.

Recommended empirical antibiotics for community acquired pneumonia is on the basis of guidelines of IDSA (Infectious Disease Society of America)/ATS (American thoracic society)/Canadian guidelines (CIDS, CTS).

1. Previously healthy and no use of antimicrobials within the previous 3 months:
   A Macrolide (strong recommendation; level I evidence); OR
   Doxycyline (weak recommendation; level III evidence)
2. Presence of co morbidities such as chronic heart, lung, liver or renal disease; diabetes mellitus; alcoholism; malignancies; asplenia; immunosuppressing conditions or use of immunosuppressing drugs; or use of antimicrobials within the previous 3 months (in which case an alternative from a different class should be selected)
   A respiratory fluoroquinolone (moxifloxacin, gemifloxacin, or levofloxacin [750 mg]) (strong recommendation; level I evidence)
   OR
   A β-lactam plus a macrolide (strong recommendation; level I evidence)
   OR
   Cefpodoxime or Cefuroxime or ceftrioxone plus macrolide.
3. In regions with a high rate (125%) of infection with high-level (MIC, 16 mg/ml) macrolide-resistant *Streptococcus pneumoniae,* consider use of alternative agents listed above in (2) for patients without comorbidities (moderate recommendation; level III evidence).

Penicillin-resistant *S. pneumoniae* (PRSP) has become a great problem. PRSP is a widespread problem, with rates of resistance ranging from 5% to 80% in various parts of the world. Risk factors for infection with PRSP strains include young age, day-care center attendance, prior administration of antimicrobial agents, and severe underlying diseases. It is likely that, in cases in which isolates have intermediate or low-level resistance to penicillin, the drug concentrations achieved in serum and in the lungs are adequate to eradicate these strains. However, strains for which the minimum inhibitory concentrations (MICs) of penicillin are higher (≥ 4 mg/L) may affect outcomes, and therapeutic failures are more likely to be seen as more strains with high-level penicillin resistance emerge.

As the use of non-penicillin antimicrobials has increased, so has the development of resistance to these agents among *S. pneumoniae*. Worldwide rate of macrolide resistance has risen dramatically in recent years. The prevalence of resistance is highly variable between countries, ranging from < 3% to > 70%.

The new fluoroquinolones[14] (clinfloxacin, gatifloxacin, gemifloxacin, grepafloxacin, levofloxacin, moxifloxacin, sitafloxacin, sparfloxacin and trovafloxacin) offer excellent activity against Gram-negative bacilli and improved Gram-positive activity (e.g., against *Streptococcus pneumoniae* and *Staphylococcus aureus*) over ciprofloxacin. All of the new fluoroquinolones display excellent bioavailability and have longer serum half-lives than ciprofloxacin allowing for once daily dose administration. Clinical trials comparing the new fluoroquinolones to each other or to standard

therapy have demonstrated good efficacy in a variety of community-acquired respiratory infections. Gemifloxacin is a antimicrobial agent that is used for treatment of community-acquired pneumonia and acute exacerbation of chronic bronchitis.[15-17] Gemifloxacin, in contrast to other quinolones, demonstrated improved activity against Streptococcus pneumoniae and similar activity against gram-negative respiratory pathogens (*Hemophilus influenzae, Moraxella catarrhalis*) and atypical pathogens such as *Chlamydia pneumoniae, Legionella pneumophila,* and *Mycoplasma pneumoniae*. It has insufficient activity against methicillin-resistant *S. aureus* and cannot be used for such infections. It can be used as a once-daily dose drug as a result of its long half life.

Our study has shown excellent result in CAP patients treated with gemifloxacin (320 mg). Clinical response among 103 patients at the end of therapy was successful in 99 (96.1%) while failure was reported in 4 (3.9%). Analysis of secondary efficacy parameter reveals 84.5% were clinically cured and hence could not expectorate sputum required for bacteriological analysis at the end of therapy. These were classified as "unable to determine". Another 13.5% of the patients had eradication and in 2% there was bacteriological persistence. As per radiological outcome 77.1% of the total cases showed improvement, 8.6% had no change and 2.9% had deterioration in radiological findings.

Several fluoroquinolones have either been withdrawn from the market or had their use severely restricted because of adverse effects [Table 6].

The remaining fluoroquinolones such as gatifloxacin, gemifloxacin, levofloxacin, and moxifloxacin have adverse effect profiles similar to ciprofloxacin Gemifloxacin is well tolerated; the frequency of adverse events with this agent is low. In this study none of the patients experienced any significant adverse drug reaction. Blood biochemical parameters were largely unaffected except statistically insignificant rise in the value of alkaline phosphatase. In other studies also most adverse events are mild-to-moderate in severity, with diarrhoea, nausea and rash (< 3%), and headache (< 2%) most commonly reported. Drug interactions with gemifloxacin are not common, although absorption is greatly reduced when given with divalent and trivalent cation-containing compounds, such as antacids.

CONCLUSIONS

Gemifloxacin is effective in patient showing resistance to macrolides, B-lactam, 3rd generation cephalosporins and quinolones like Levofloxacin, Ciprofloxacin, and Ofloxacin. Amongst quinolones also it scored over equipotent trovafloxaciveis due to no hepatotoxicity like the latter. Rightly it has been termed as respiratory floroquinolone and it is considered the only agent effective against multidrug resistant *S. pneumonia* (DRSP, i.e., resistant to two or more of the following antibiotics – penicillin, 2nd generation cephalosporin, macrolides, tetracycline, and co-trimoxazoloe). Besides, gemifloxacin is effective against atypical pathogens like *M. pneumonia*, *E. pneumonia* and *L. pneumophilia*. Gemiflox is therefore the true broad spectrum agent most suited for empiric therapy of CAP. It has no major side effects and drug-drug interaction with commonly co-prescribed drugs like Digoxin, theophylline antacids, etc are negligible. Clinical response among 103 patients at the end of therapy was successful in 99 (96.1%), while failure was reported in 4 (3.9%). It was not associated with any drop out of patient due to adverse effect. Gemifloxacin is a good efficacious, well tolerated economical drug for empirical treatment of CAP.

Table 6: Toxicity with fluoroquinolones leading to their discontinuation

Name	Adverse effects
Clinfloxacin	Photo toxicity and hypoglycemia
Grepafloxacin	Prolongation of the QTc interval and resultant torsades de pointes
Sparfloxacin	Phototoxicity
Trovafloxacin	Hepatotoxicity

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