International Journal of Research in Health and Allied Sciences
Journal home page: www.ijrhas.com
Official Publication of "Society for Scientific Research and Studies" [Regd.]
ISSN: 2455-7803

Original Research

Assessment of Efficacy of levofloxacin and moxifloxacin on outcome of multidrug resistant tuberculosis

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***ABSTRACT*:**
Background: Tuberculosis (TB) remains one of the major global health threats leading to morbidity and mortality. The present study was conducted to compare levofloxacin or moxifloxacin for the treatment of patients with fluoroquinolone-sensitive multidrug-resistant tuberculosis (MDR-TB). **Materials & Methods:** The present study comprised of 112 patients of multidrug-resistant tuberculosis (MDR-TB) of both genders. Patients were divided into 2 groups of 56 each. Group I patients were given 750 mg/d levofloxacin and group II patients were given 400 mg/d moxifloxacin. Treatment responses were categorized into treatment success (cured and treatment completed) or adverse treatment outcome (death, failure, and relapsed). **Results:** Group I patients were given 750 mg/d levofloxacin and group II patients were given 400 mg/d moxifloxacin. Duration of treatment in group I was 516 days and in group II was 617 days, number of drugs used in both groups was 5, resistant drugs were 4 in both groups, adverse drug reactions were eye toxicity seen in 6 in group I and 3 in group II, hepatotoxicity 4 in group I and 2 in group II, Hematologic abnormalities were 2 in group I and 1 in group II, dermatological abnormalities were 3 in group I and allergic reactions were 2 in group I and 1 in group II. 42 patients in group I and 38 in group II were cured and 14 in group I and 18 in group II had complete treatment, treatment failure was seen in 3 in group I and 4 in group II and death were seen in 2 in group I and 3 in group II. The difference was significant (P< 0.05). **Conclusion:** Authors found that patients on levofloxacin showed better treatment outcome as compared to moxifloxacin groups.
Key words: Levofloxacin, Moxifloxacin, Tuberculosis

Received: 20 July, 2019 Revised: 12 August, 2019 Accepted: 15 August, 2019

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This article may be cited as: Choudhary A, Raina K, Gupta BN, Singhai V, Kaur G, Bagaria A. Assessment of Efficacy of levofloxacin and moxifloxacin on outcome of multidrug resistant tuberculosis. Int J Res Health Allied Sci 2019;5(5):19-22.

INTRODUCTION

Tuberculosis (TB) remains one of the major global health threats leading to morbidity and mortality. One in three persons across the world representing 2–3 billion individuals are known to be infected with Mycobacterium Tuberculosis (M. Tuberculosis) of which 5–15% are likely to develop active TB disease during their lifetime.[1] Tuberculosis is a chronic granulomatous infectious disease. Infection occurs via aerosol, and inhalation of a few droplets containing M. tuberculosis bacilli. After infection, M. tuberculosis pathogenesis occurs in two stages. The first stage is an asymptomatic state that can persist for many years in the host, called latent TB.[2]

In the year 1993, World Health Organization (WHO) declared TB a global public health emergency. About one-third of the world's population (> 2 billion), are infected with TB bacilli. 10% of the people infected with TB bacilli will become sick with active TB in their lifetime.[3]

Multidrug-resistant tuberculosis (MDR-TB), defined as in vitro resistance to at least isoniazid and rifampicins, is a growing health concern. An estimated 440,000 cases of MDR-TB, which is 3.6% of all incident TB cases, emerge each year, causing 150,000 deaths worldwide.[4]

Only a few effective second-line anti-TB drugs are available, and those at the forefront are fluoroquinolones (FQNs). FQNs show an encouraging in vitro pharmacokinetic profile for treating TB, and current guidelines for managing MDR-TB recommend that all patients be treated with FQNs if the strain is susceptible or if the agent is thought to have efficacy.[5] The present study was conducted to compare levofloxacin or moxifloxacin for the treatment of patients with fluoroquinolone-sensitive multidrug- resistant tuberculosis (MDR-TB).

MATERIALS & METHODS

The present study comprised of 112 patients of multi drug-resistant tuberculosis (MDR-TB) of both genders. All were informed regarding the study and written consent was obtained. Ethical clearance was obtained prior to the study. Data such as name, age, gender etc. was recorded. Patients were divided into 2 groups of 56 each. Group I patients were given 750 mg/d levofloxacin and group II patients were given 400 mg/d moxifloxacin. Patients were recalled regularly and sputum samples were cultured in solid mycobacterial culture medium. Treatment responses were categorized into treatment success (cured and treatment completed) or adverse treatment outcome (death, failure, and relapsed). Results thus obtained were subjected to statistical analysis. P value less than 0.05 was considered significant.

RESULTS

Table I Distribution of patients

Groups	Group I	Group II
Drugs	750 mg/d levofloxacin	400 mg/d moxifloxacin
Number	56	56

Table I shows that group I patients were given 750 mg/d levofloxacin and group II patients were given 400 mg/d moxifloxacin.

Table II Comparison of parameters

Parameters	Group I	Group II	P value
Duration of treatment (Days)	516	617	0.05
No. of drugs used	5	5	1
Resistant drugs	4	4	1
Adverse reaction Eye toxicity	6	3	0.05
Hepatotoxicity	4	2	
Hematologic abnormalities	2	1	
Dermatological abnormalities	3	0	
Allergic reaction	2	1	

Table II, graph I shows that duration of treatment in group I was 516 days and in group II was 617 days, number of drugs used in both groups was 5, resistant drugs were 4 in both groups, adverse drug reactions were eye toxicity seen in 6 in group I and 3 in group II, hepatotoxicity 4 in group I and 2 in group II, Hematologic abnormalities were 2 in group I and 1 in group II, dermatological abnormalities were 3 in group I and allergic reactions were 2 in group I and 1 in group II.

Graph I Comparison of parameters

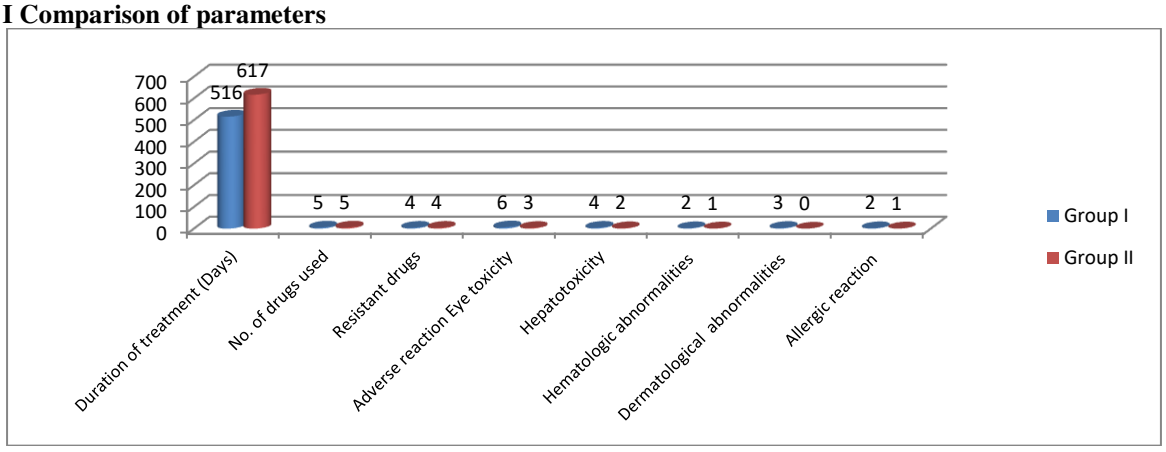
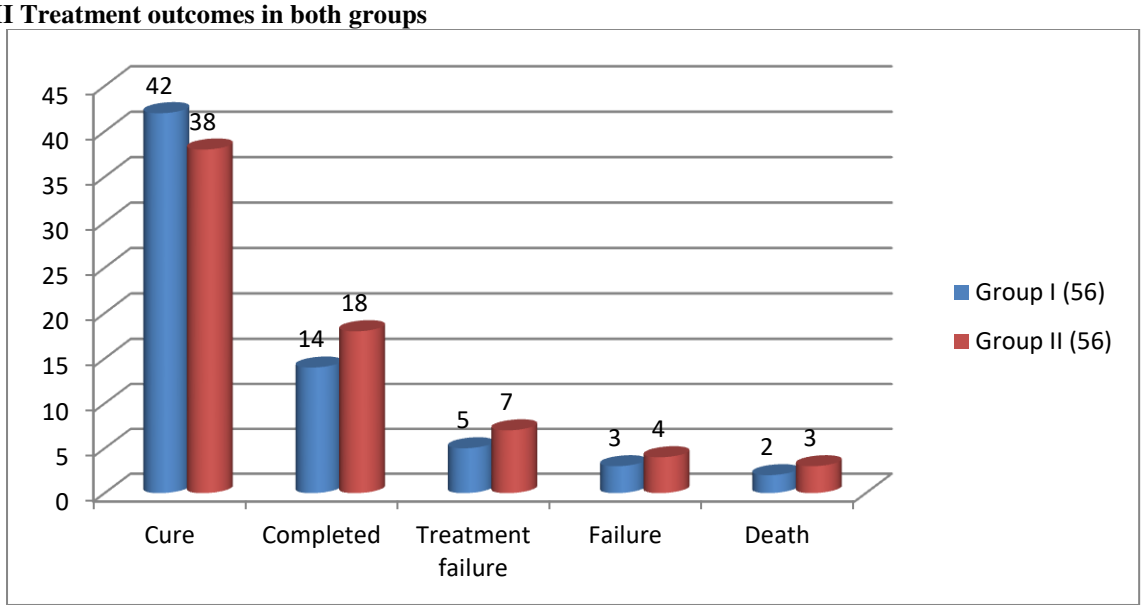


Table III Treatment outcomes in both groups

Treatment success	Group I (56)	Group II (56)	P value
Cure	42	38	0.05
Completed	14	18	
Treatment failure	5	7	0.02
Failure	3	4	
Death	2	3	

Table III, graph II shows that 42 patients in group I and 38 in group II were cured and 14 in group I and 18 in group II had complete treatment, treatment failure was seen in 3 in group I and 4 in group II and death were seen in 2 in group I and 3 in group II. The difference was significant (P< 0.05).

Graph II Treatment outcomes in both groups



DISCUSSION

Tuberculosis (TB) is an airborne bacterial infection caused by M. Tuberculosis which affects any part of the body and most commonly the lungs. M.[6] Tuberculosis is exposed to the air as droplet nuclei from coughing, sneezing, shouting or singing of individuals with pulmonary or laryngeal TB. Transmission occurs through inhalation of these droplet nuclei which passes through the mouth or nasal cavities, the upper respiratory tract, bronchi and finally reaches the alveoli of the lungs.[7] Once the M. Tuberculosis or the tubercle bacilli reaches the alveoli, they are ingested by alveolar macrophages resulting in the destruction or inhibition of a greater proportion of the inhaled tubercle bacilli. The small unaffected proportion multiplies within the macrophages and is released upon death of the macrophages.[8] The present study was conducted to compare levofloxacin or moxifloxacin for the treatment of patients with fluoroquinolone-sensitive multidrug-resistant tuberculosis (MDR-TB).

In present study, group I patients were given 750 mg/d levofloxacin and group II patients were given 400 mg/d moxifloxacin. Fluoroquinolones, which inhibit DNA supercoiling and disrupt DNA replication of Mycobacterium tuberculosis through interfering with DNA gyrase, are pivotal drugs for the treatment of MDR-TB.[9] Current guidelines recommend that later-generation fluoroquinolones should be used for all patients with MDR-TB. Among these, levofloxacin and moxifloxacin are the two most commonly prescribed to treat patients with MDR-TB.[10]

We found that duration of treatment in group I was 516 days and in group II was 617 days, number of drugs used in both groups was 5, resistant drugs were 4 in both groups, adverse drug reactions were eye toxicity seen in 6 in group I and 3 in group II, hepatotoxicity 4 in group I and 2 in group II, Hematologic abnormalities were 2 in group I and 1 in group II, dermatological abnormalities were 3 in group I and allergic reactions were 2 in group I and 1 in group II.

The use of at least four susceptible drugs has been recommended to cure patients with MDR-TB. Among the various drugs with antimycobacterial activities, injectables and FQNs, as well as ethambutol and pyrazinamide, are believed to be the most potent for patients with MDR-TB. Moreover, the impact of one of four or five drugs used to

treat patients with MDR-TB may not make much difference in terms of outcome.[11]

We observed that 42 patients in group I and 38 in group II were cured and 14 in group I and 18 in group II had complete treatment, treatment failure was seen in 3 in group I and 4 in group II and death were seen in 2 in group I and 3 in group II.

Koh et al[12] conducted a study in which a total of 151 participants with MDR-TB who were included for the final analysis in our previous trial were followed through the end of treatment. Treatment outcomes were compared between 77 patients in the levofloxacin group and 74 in the moxifloxacin group. Cure was achieved in 54 patients (70.1%) in the levofloxacin group and 54 (73.0%) in the moxifloxacin group. Treatment success rates, including cure and treatment completed, were not different between the two groups. It was found that cure rates and treatment success rates were also similar between the levofloxacin and moxifloxacin groups. Time to culture conversion was also not different between the two groups. Patients in the levofloxacin group had more adverse events than those in the moxifloxacin group, especially musculoskeletal ones.

CONCLUSION

Authors found that patients on levofloxacin showed better treatment outcome as compared to moxifloxacin groups.

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