

Original Research

A comparative study to evaluate Efficacy of levofloxacin and moxifloxacin on outcome of multidrug-resistant tuberculosis treatment

Jitendra Kumar

Associate Professor, Department of T.B. & Chest, Saraswathi Institute of Medical Sciences, Hapur, Uttar Pradesh, India

ABSTRACT:

Background: Although several studies have compared levofloxacin with other FQNs, such as ciprofloxacin or ofloxacin, studies comparing levofloxacin and moxifloxacin are lacking. So, Present study aimed to evaluate Efficacy of levofloxacin and moxifloxacin on outcome of multidrug-resistant tuberculosis treatment. **Materials & methods:** A total of 100 patients with MDR-TB were included in the present study. All the patients were broadly divided into two study groups with 50 patients in each group. Group A comprised of patients who were given levofloxacin as a part of treatment therapy, and Group B included patients who were given moxifloxacin as a part of treatment therapy. Treatment outcome was assessed in terms of success of treatment and presence and incidence of adverse effects. All the results were summarized in SPSS software. **Results:** Non-significant results were obtained while comparing the treatment outcome and associated adverse drug effects in between both the study groups. **Conclusion:** Both the drugs can be used with equal efficacy in MDR-TB patients.

Key words: Levofloxacin, Moxifloxacin.

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Corresponding author: Dr. Jitendra Kumar, Associate Professor Department of T.B. & Chest, Saraswathi Institute of Medical Sciences, Hapur, Uttar Pradesh, India

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INTRODUCTION

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 (95% confidence interval [CI], 390,000 to 510,000) cases of MDR-TB, which is 3.6% of all incident TB cases, emerge each year, causing 150,000 deaths worldwide.

The treatment of multidrug-resistant tuberculosis (MDR-TB) remains difficult because of the high cost, need for prolonged treatment, and frequent adverse events. With such obstacles, the success rate for treating MDR-TB is less than 70%. 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. Present study aimed to evaluate Efficacy of levofloxacin and moxifloxacin on outcome of multidrug-resistant tuberculosis treatment

MATERIALS & METHODS

The present study was conducted in the department of pulmonary medicine with the aim of assessing and comparing the efficacy of levofloxacin and moxifloxacin on the outcome of MDR-TB. For the present study, ethical approval obtained from the institutional ethical committee and written consent was obtained after explaining in detail the entire research protocol. A total of 100 patients with MDR-TB were included in the present study. All the patients were broadly divided into two study groups with 50 patients in each group. Group A comprised of patients who were given levofloxacin as a part of treatment therapy, and Group B included patients who were given moxifloxacin as a part of treatment therapy. According to data records, a minimum of isoniazid and rifampicin resistance was shown by all the patients during in-vitro drug susceptibility testing. Complete demographic details of all the subjects were obtained. For assessing the outcome of treatment, Laserson et al. criteria were used. Treatment outcome

was assessed in terms of success of treatment and presence and incidence of adverse effects. All the results were summarized in SPSS software. Chi-square test was used for assessment of level of significance. P-value of less than 0.05 was taken as significant.

RESULTS

In the present study, a total of 100 patients were analyzed. Among these 100 patients, 50 were given levofloxacin as

a part of treatment, while the remaining 50 were given moxifloxacin as a part of treatment. Mean age of the patients of the levofloxacin group and moxifloxacin group was 43.5 and 44.8 years respectively. Non-significant results were obtained while comparing the treatment outcome and associated adverse drug effects in between both the study groups.

Table 1: Comparison of demographic data

Parameter		Levofloxacin group	Moxifloxacin group
Age group (years)	Less than 30	15	16
	30 to 40	13	15
	More than 40	22	19
Gender	Males	28	27
	Females	22	23

Table 2: Comparison of Treatment modalities and adverse effect in patients of both the study groups

Parameter	Levofloxacin group	Moxifloxacin group	p-value
Surgical resection (no. of subjects)	1	1	0.42
Number of resistant drugs	1	4	0.00*
Adverse drug effects (no. of subjects)	5	6	0.46

*: Significant

Table 3: Outcome of treatment among patients of both the study groups

Parameter	Levofloxacin group	Moxifloxacin group	P-value
Treatment success	47	45	0.25
Treatment failure	2	3	0.41
Others (cases transferred)	1	2	0.86

DISCUSSION

It is universally acknowledged by those treating patients with tuberculosis (TB) that the current recommended regimen requires improvement. Treatment takes too long, many patients are unable to tolerate the combination, and there is a growing threat from multidrug-resistant (MDR)- and extremely drug-resistant (XDR)-TB. All of the current components of the standard anti-TB regimen were discovered between 1946 and 1967, yet it was not until the early 1980s following a series of clinical trials in the UK and USA that the current 6-month regimen was settled.⁶⁻⁸

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 (95% confidence interval [CI], 390,000 to 510,000) cases of MDR-TB, which is 3.6% of all incident TB cases, emerge each year, causing 150,000 deaths worldwide.⁹

In the present study, a total of 100 patients were analyzed. Among these 100 patients, 50 were given levofloxacin as a part of treatment, while the remaining 50 were given moxifloxacin as a part of treatment. Mean age of the patients of the levofloxacin group and moxifloxacin group was 43.5 and 44.8 years respectively. Lee J et al compared the effect of levofloxacin and moxifloxacin on treatment outcomes among patients with multidrug-resistant tuberculosis (MDR-TB). A retrospective analysis of 171 patients with MDR-TB receiving either levofloxacin or moxifloxacin was performed. Treatment responses were categorized into treatment success (cured and treatment completed) or adverse treatment outcome (death, failure, and relapsed). Approximately 56% of the patients were male. Seventeen patients had extensively drug-resistant tuberculosis, and 20 had a surgical resection. A total of 123 patients (71.9%) received levofloxacin for a median 594 days, and 48 patients (28.1%) received moxifloxacin for a median 673 days. Other baseline demographic, clinical, and radiographic characteristics were similar between the two groups. The moxifloxacin group had a significantly higher number of resistant drugs (p < 0.001) and a higher incidence of resistance to ofloxacin (p = 0.005) in the drug sensitivity test. The treatment success rate was 78.9% in the levofloxacin group and 83.3% in the moxifloxacin group (p = 0.42). Adverse reactions occurred at similar rates in the groups. Patients in the moxifloxacin group were not more likely to have treatment success than those in the levofloxacin group. Both levofloxacin and moxifloxacin showed equivalent efficacy for treating MDR-TB.⁹

Fluoroquinolones (FQs) are the cornerstone of MDR-TB treatment. Levofloxacin (LFX) has a high in vitro and in vivo bactericidal activity against *Mycobacterium tuberculosis* and is more affordable and available in high-burden and resource-limited countries than is moxifloxacin (MXF). The safety profile of LFX is considered excellent. The efficacy of LFX has been shown to be predicted by ratio of the free area under the concentration time curve (fAUC) to MIC with a target of fAUC/MIC ≥ 100 .¹⁰

In the present study, non-significant results were obtained while comparing the treatment outcome and associated adverse drug effects in between both the study groups. Kang YA et al compared final treatment outcomes between patients with MDR-TB randomized to levofloxacin or moxifloxacin. 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 not different between the two groups, based on 2008 World Health Organization definitions as well as 2013 definitions. With 2008 definitions, cure was achieved in 54 patients (70.1%) in the levofloxacin group and 54 (73.0%) in the moxifloxacin group ($P=0.72$). Treatment success rates, including cure and treatment completed, were not different between the two groups (87.0 vs. 81.1%, $P=0.38$). With 2013 definitions, cure rates (83.1 vs. 78.4%, $P=0.54$) and treatment success rates (84.4 vs. 79.7%, $P=0.53$) were also similar between the levofloxacin and moxifloxacin groups. Time to culture conversion was also not different between the two groups (27.0 vs. 45.0 d, $P=0.11$ on liquid media; 17.0 vs. 42.0 d, $P=0.14$ on solid media). Patients in the levofloxacin group had more adverse events than those in the moxifloxacin group (79.2 vs. 63.5%, $P=0.03$), especially musculoskeletal ones (37.7 vs. 14.9%, $P=0.001$). The choice of levofloxacin or moxifloxacin made no difference to the final treatment outcome among patients with fluoroquinolone-sensitive MDR-TB.¹⁰

CONCLUSION

From the above results, the authors concluded that both the drugs can be used with equal efficacy in MDR-TB patients. However; further studies are recommended.

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