

## Original Research Article



# Outcome of Oral Moxifloxacin as Monotherapy in Treating Mild to Moderate Diabetic Foot Infections

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**Abstract: Objectives:** Diabetic patients frequently suffer from foot infections. These infections are often associated with multiple organisms that require a broad-spectrum or a combination of antibiotic therapy. Moxifloxacin is a broad-spectrum antibiotic and used orally for foot infection. This study was designed to evaluate the suitability of moxifloxacin as a monotherapy in terms of efficacy, safety and costing. **Methods:** In this prospective study, 120 patients with age range between 18-60 years suffering from mild to moderate diabetic foot infections and were treated as OPD patients were included. All patients were given moxifloxacin (400 mg/day orally for 10 days). Clinical responses and any adverse effects were recorded at 3-5 days and at 10 days post therapy for evaluation. **Results:** 41.66%-foot infections occurred in 51-60 age group and average duration of infections at presentation of DFI was 4.4 days. Overall success rate was 80% at 3-5 days and 88.75% at 10 days. There was no response in 10% cases and 2.5% case in fact deteriorated. There was no severe adverse effect and no discontinuation of drug. Commonest adverse effect was anorexia (2.5%). Total treatment cost of antibiotic was 400.00 BDT for 10 days. **Conclusions:** Moxifloxacin can be given as a single antibiotic for the treatment of diabetic foot infection. It is effective, free from severe adverse effect, tolerable and reasonably cheap.

**Keywords:** Diabetic Foot Infections, Moxifloxacin, Monotherapy.

## Introduction

Treatment of foot infections is a challenging job for all health professionals. It is more complicated if it occurs in diabetic patients. Indeed, foot infection is a common complication of diabetes mellitus. Any foot infection occurring in diabetic patients is known as diabetic foot infection (DFI). In many studies<sup>1</sup>, it was established that about 15% of diabetic patients will develop foot infection in their

life time. So DFI not only exploits a significant portion of national health budget but also causes major morbidity and decreases the quality of patient's life<sup>2,3</sup> and thereby, DFI reduces the productivity of diabetic people. If DFI is not treated early and properly, patients often need hospitalization for further treatment and sometimes end in amputation. Foot infections have a high recurrence rate and common within 3 years<sup>2</sup>.

DFI is also a major cause of non-traumatic amputation<sup>2</sup>.

As diabetes is a chronic disease it needs a long course of treatment with different options of treatment. To treat any complication, diabetic patients require an optimum glycemic control and it is a must. If foot infection occurs, in addition to glycemic control patient needs an appropriate course of antibiotic, local wound care and may require surgical intervention according to severity<sup>3</sup>. Clinicians may select antibiotic from a long list. Though the list of antibiotics is long, no one is proven superior to others<sup>3</sup>. So, to select an antibiotic clinicians must take in consideration of the severity of infection, causative organism, efficacy of the antibiotic, cost and adverse effects of the drug<sup>4</sup>. Initially DFI is caused by Gram-positive cocci (GPC) and most isolates are staphylococci. But in recurrent and long-standing cases, DFI is complicated by Gram-negative and obligate anaerobic organisms in addition to GPC<sup>5</sup>. However, at first presentation of DFI the common practice is to start an antibiotic initially and to revise the treatment after having the sensitivity report as is in other types of infections. Almost all mild to moderate DFI patients usually attend the outpatient department (OPD) for treatment and treated as OPD patients. But severe and some special cases of moderate DFI need hospitalization for proper treatment and sometimes for surgical interventions.

Regarding the treatment at OPD, clinicians usually select an antibiotic considering the route of administration, less frequent dosing, cheap and minimum side effects. Though many studies have been done to show the efficacy of different antibiotics, no single antibiotic is declared as the best one<sup>6</sup>. So, choice varies according to local pattern of antibiotic resistance, prices, availability of drugs, patient's compliance and above all spectrum of activity. Moxifloxacin is one of the fluoroquinolones and is approved for treatment of DFI<sup>7,8</sup>. It has a broad spectrum of activity against common organisms causing DFI. It is effective against both gram positive and gram negative organism<sup>9</sup>. It can also be taken orally with or without meal, has minimum adverse effects, once daily dose and above all very cheap<sup>7,10</sup>. This study aimed at to explore these facts about moxifloxacin

in treating mild to moderate DFIs in patients who were treated at OPD with only oral moxifloxacin as antibiotics.

## Methods

This study was done on 120 patients who were suffering from mild to moderate diabetic foot infections and all these patients were treated as OPD patients at 250 Bedded General Hospital, Naogaon, Bangladesh from June 2023 to May 2024. Cases were selected randomly at OPD from both sexes and ages between 18 to 60 years. Younger and older patients and patients with severe DFIs were excluded from this study. Cases were defined as patients who had documented evidence of diabetes mellitus and had clinically detectable foot infection. The severity of DFI was identified according to the guidelines and recommendations of International Working Group on the Diabetic Foot (IWGDF)<sup>11</sup>. To define infection, we searched the features of infection like-local swelling or induration, erythema or redness, local pain or tenderness, local rise of temperature and pus discharge from the wound. Non infected ulcers in foot were excluded in this study, but infected ulcers were included. We also excluded other causes of non-infective inflammation like trauma or fracture, arthritis, venous disorders etc.

Mild DFI includes infection of skin and the subcutaneous tissue without involving the deeper tissues and without any systemic signs. Here the erythema was limited within 2 cm beyond the ulcer margin. Whereas, moderate DFI was characterized by involvement of deeper structures like, abscess formation, bone infection, septic arthritis, fasciitis and without any systemic signs. Here erythema extended more than 2 cm from the margin. But if DFI patients had systemic symptoms and signs of infection like fever, tachycardia etc., the cases were regarded as severe infection and excluded from the study. These patients required hospitalization for intravenous antibiotics and often needed surgical interventions. Moreover, these patients had neurological or vascular complications and not suitable for management at OPD. We also excluded patients with tendinitis, polyneuropathy and myasthenia gravis as these were contraindications for moxifloxacin therapy<sup>7</sup>.

Moxifloxacin has a wider spectrum of activity and excellent bioavailability following oral administration. All patients in this study were given moxifloxacin 400 mg orally, once daily for 10 days. Along with moxifloxacin, other supportive treatment and appropriate drugs to achieve optimum glycemic control were given as advised by endocrinologist.

The objective of this study was to analyze the outcome of treatment with moxifloxacin. To do this, we evaluated the patient clinically before starting the antibiotic therapy, at 3-5 days after therapy and at the end of the therapy. During the therapy period we also recorded if there were any clinically evident adverse effects like anorexia, nausea, diarrhea, dizziness, tendinitis, arrhythmias, allergy etc. and also recorded patient's compliance. We assess the DFI only clinically and no microbiological study was considered. We also record the cost of moxifloxacin used for the treatment of DFI.

### Statistical Analysis

All related data were collected and recorded. The compiled data were analyzed by using computer software. We considered the demographic profile of the cases. We analyzed the outcome of treatment with attention to the response of DFI, adverse effects and compliance of the patients. We also compare the cost of treatment with other commonly used oral antibiotics. Before starting the study, ethical clearance was taken from the ethical committee of the 250 Bedded General Hospital, Naogaon.

### Results

In 250 Bedded General Hospital, Naogaon, Bangladesh, this study was done from July 2023 to June 2024 and included 120 patients who were suffering from both foot infections and diabetes mellitus. The cases were selected randomly and all were treated with moxifloxacin and other supporting drugs. As shown in Table-1, the mean age of the patients was 48.35 years with standard deviation 8.67 years. Maximum patients (41.66%) were in the age group 51-60 years. 54.17% patients were male and rest were female. Among the patients, most were middle and low social status groups with only 12.50% from high class. Table-2 showed that majority of patients were being treated with insulin and 47.50% were getting both insulin

and oral drugs for glycemic control. Only 21.67% were treated with oral drugs. Regarding the severity of DFI, 61.67% had mild and 38.33% had moderate infections.

Regarding the clinical features at presentations, 90.83% patients had pain at the site of infections and majority of patients had other signs of inflammation like redness (86.67%), raised temperature (95.00%), swelling (90.00%) and discharge (67.50%). But only 55.83% had foot ulcers. At follow up on 3-5 days after starting of treatment, general conditions of 80.00% patients showed improvement though only 3 patient (2.50%) deteriorated and 21 patients (17.50%) remained as before. Table-4 showed most of the features of inflammation were improved except discharge and ulceration. Only 66.67% patients showed improvement of discharge and no significant ulcer healing was seen. But at follow up on 10 th day, overall improvement was satisfactory. Improvements in pain, redness, temperature and swelling were more than that of first follow up. Notably, 86.42% patient showed improvement in discharge and 53.73% ulcers showed healing progress. However, 87.50% patients showed improvement in general conditions and 3 patients (2.50%) deteriorated.

During the study period no serious adverse effect was recorded. Table-6 showed the common adverse effects following moxifloxacin administration. Anorexia, nausea, vomiting, diarrhea and vertigo were noted at follow up visits. No cases of drug intolerance or discontinuation of moxifloxacin was noted. A comparative price of commonly used and available antibiotics in Bangladesh were shown in Table-7. Average price of moxifloxacin is 40/- per tablet and cheapest drug is levofloxacin (15/- per tablet). However, total cost of 10 days treatment with moxifloxacin was only 400/- taka and highest in case of tedizolid (5000/-).

**Table 1: Demographic Profile of the study patients (n=120)**

Baseline Characteristics		(n=120)
Age (years)	Mean±SD	48.35 ± 8.67
	20-30	4.17% (n=5)

<b>Age distribution (10 Years interval)</b>	31-40	20.00%(n=24)
	41-50	34.17%(n=41)
	51-60	41.66%(n=50)
<b>Sex</b>	Male	54.17% (n=65)
	Female	45.83% (n=55)
<b>Social status</b>	Low	38.33% (n=46)
	Middle	49.17 (n=59)
	High	12.50% (n=15)

<b>Duration of DM (Months)</b>	Mean±SD	43.6 ± 20.54
<b>Treatment of DM</b>	Oral	21.67% (n=26)
	Insulin	30.83% (n=37)
	Insulin+Oral	47.50% (n=57)
<b>Duration of DFI (days)</b>	Mean±SD	4.4 ± 1.35
<b>Severity of DFI</b>	Mild	61.67 (n=74)
	Moderate	38.33 (n=46)

Clinical Features	(n=120)	(%)
<b>Pain</b>	109	90.83%
<b>Redness</b>	104	86.67%
<b>Raised temperature</b>	114	95.00%
<b>Swelling/edema</b>	108	90.00%
<b>Discharge</b>	81	67.50%
<b>Ulceration</b>	67	55.83%

Clinical Features	(n)	(%)
<b>Pain</b>	(n=109)	(% of n)
	Improved	106 97.25%
	Deteriorated	0 0%
Static	3 2.75%	
<b>Redness</b>	(n=104)	(% of n)
	Improved	81 77.88%
	Deteriorated	1 0.97%
Static	22 21.15%	
<b>Raised temperature</b>	(n=114)	(% of n)
	Improved	102 89.47%

Deteriorated	2	1.75%
Static	10	8.78%
<b>Swelling/edema</b>	(n=108)	(% of n)
	Improved	85 78.70%
	Deteriorated	0 0%
Static	2 21.30%	
<b>Discharge</b>	(n=81)	(% of n)
	Improved	54 66.67%
	Deteriorated	1 1.23%
Static	26 32.10%	
<b>Ulceration</b>	(n=67)	(% of n)
	Improved	0 0%
	Deteriorated	0 0%
Static	100 100%	
<b>General condition</b>	(n=120)	(% of n)
	Improved	79 80.00%
	Deteriorated	3 2.50%
Static	21 17.50%	

Clinical Features	(n)	(%)
<b>Pain</b>	(n=109)	(% of n)
	Improved	108 99.08%
	Deteriorated	0 0%
Static	1 0.92%	
<b>Redness</b>	(n=104)	(% of n)
	Improved	100 96.16%
	Deteriorated	2 1.92%
Static	2 1.92%	
<b>Raised temperature</b>	(n=114)	(% of n)
	Improved	112 98.24%
	Deteriorated	1 0.88%
Static	1 0.88%	
<b>Swelling/edema</b>	(n=108)	(% of n)
	Improved	98 90.74%
	Deteriorated	2 1.85%
Static	8 7.41%	
<b>Discharge</b>	(n=81)	(% of n)
	Improved	70 86.42%
	Deteriorated	2 2.47%
Static	9 11.11%	
<b>Ulceration</b>	(n=67)	(% of n)
	Improved	36 53.73%
	Deteriorated	1 1.49%
Static	30 44.78%	
<b>General condition</b>	(n=120)	(% of n)
	Improved	105 87.50%
	Deteriorated	3 2.50%
Static	12 10.00%	



**Table 6: Adverse effects of moxifloxacin: (n=120)**

	(n=120)	(%)
Anorexia	3	2.50%
Nausea	2	1.67%
Vomiting	1	0.83%
Diarrhea	1	0.83%
Vertigo	1	0.83%
Tendinitis	0	0%
Allergy	0	0%
Arrhythmia	0	0%

**Table 7: Costing of Moxifloxacin and some other antibiotics: (n=120)**

Antibiotics	Price/Unit *	Total antibiotic cost* (10 days)
Moxifloxacin (1 tab, BID)	40.00	400.00
Linezolid (1 tab, BID)	85.00	1700.00
Cefuroxime (1 cap, BID)	45.00	900.00
Levofloxacin (1 tab, OD)	15.00	150.00
Cefixime (1 cap, BID)	45.00	900.00
Faropenem (1 tab, TID)	95.00	2850.00
Flucloxacillin (1 tab, QID)	14.00	560.00
Tedizolid (1 tab, OD)	500.00	5000.00
*All costs are in Taka		

## Discussion

Diabetes is the leading endocrine and metabolic disease that has an increasingly high incidence and prevalence. As a result, the number of complications is also increasing. This increasing demand of health care exploits a major portion of national health care budget. One of the most common complications of diabetes mellitus is foot infection. Approximately 15% of diabetic patient will suffer from foot infections at any time in their life<sup>1</sup>. Treatment of foot infection is a specialist job and needs multisectoral approach. Patients usually need antibiotic for bacterial infection. A rational use of antibiotic is necessary for effective treatment, to reduce treatment cost and also to combat antibiotic

resistance. In this study we elicited the suitability of moxifloxacin as a single antibiotic to treat mild and moderate DFI as OPD patient.

The study showed, the average age of diabetic patients was 48.35 years with a standard deviation of 8.67 years. Though this finding is nearer to many studies<sup>27</sup>, the age of onset of diabetes or foot infections is becoming lower as compared to other studies<sup>28</sup>. It is due to increase of risk factors worldwide. Sex distribution was also like other studies with slight male preponderance<sup>14</sup>, though Jawed Mohammad Akther et al showed more incidence in male specially who works in outdoor and smoker<sup>12</sup>. This study showed an increasing incidence of DFI with advancing age with maximum patients were in the age group 41-50 and 51-60 years. This type of finding is compatible with many studies<sup>13,14</sup>. Regarding the social status, the study revealed that like other studies, DFI is more common in lower and middle social class<sup>14</sup>. Poor socio-economic status is regarded as a risk factor for DFI<sup>15</sup>.

Mean duration of diabetes was 43.6 months with SD 20.54 months. It was showed in some studies<sup>16,17</sup> that 5.8% diabetic patients developed DFI within 3 years of onset of diabetes though lifetime risk was 15% to 20%<sup>1,16</sup>. The earlier age of diabetes and development of complications are due to less controlled life style. As healthy lifestyle choices, such as a healthy diet, moderate weight loss, and regular exercise, can maintain normal blood sugar levels and minimize or delay diabetes-related complications<sup>17</sup>. However, longer the duration of diabetes, more severe will be the complications<sup>18,19</sup> with involvement of multiple organs. In this study only 21.67% patients were treated with oral hypoglycemic drugs and rest were treated with either insulin or in combination with oral drugs. Insulin is the best drug for glycemic control and we can expect best result in these patients<sup>20</sup>.

In this study only mild and moderate DFI patients that were treated at OPD were included and no severe case or admitted patients were included. As shown, mild cases were 61.67% and moderate cases were 38.33%. As we set different inclusion criteria, this ratio may not be same as in other studies. However, due to increasing awareness, DFI are being diagnosed at an early stage. As a result, we

found more DFIs in mild stage<sup>21</sup>. In spite of this, patients presented 4.4±1.35 days after the onset of DFI and this is somewhat less than that described in literatures of some western countries<sup>22</sup>. Regarding the clinical features of DFI, though majority of cases in this study showed features of inflammation, patient may not show any features of infection. In a study by Magnus Eneroth *et al*, 50% of patients showed no features of infection<sup>23</sup>. However, in this study all the major features of infection like pain, redness, temperature and swelling were present in most of the cases. But discharge and swelling were not so common as other features.

Follow up of patients 3-5 days after administration of oral moxifloxacin, showed that most of the clinical features improved except discharge from the wound and ulceration. Pain and temperature improved most satisfactorily. Redness and edema also improved upto the mark. But there was no improvement of ulceration and discharge from the wound was reduced only in 66.67% cases. Overall improvement of general conditions was noticed in 80% cases, though 2.50% cases deteriorated and no change was noticed in 17.50% cases. At the end of 10 days of treatment, the results were more surprising. Overall improvement in general conditions were 87.50% and deterioration in 2.50%. So, the success rate is 87.50% and most of these was achieved within 3-5 days. Unfortunately 10% cases remained as before without any change.

Now, if we review other studies, we will find near similar results. In a study by Inge C. Gyssens *et al*. the overall success rate was 89.6% and it was not inferior to intravenous piperacillin/tazobactam therapy<sup>24</sup>. Culley CM *et al*. also showed 88-97% success rate<sup>25</sup>. We found most of the adverse effects were gastro-intestinal related. The commonest was anorexia and others were mild. This study did not show other recognized adverse effects like tendinitis, arrhythmia, severe allergic reactions etc. these findings were also supported by other study<sup>24</sup>. Regarding the cost of treatment, we found that in Bangladesh a wide range of antibiotics with different price were used for infection<sup>26</sup>. In this study we used one of the cheap antibiotics with wide spectrum efficacy and acceptable adverse effects. Moxifloxacin has an affordable price with once daily dose and thereby has a very reasonable total treatment cost. So, we can say that moxifloxacin is not inferior to other standard antibiotics in respect to efficacy, price and safety<sup>24</sup>.

## Conclusion

Among the complications of diabetes mellitus, diabetic foot infections are a major group. Mild and

moderate foot infections can be treated as OPD patient and usually needs no hospitalization for treatment. Moxifloxacin is one of the most suitable antibiotics for OPD treatment as a single antibiotic, as it is cheap, once daily dose, can be taken orally, well tolerated and above all has a good response. This study was done with data from clinical observations only and no microbiological data were included. So, for better understanding, a large scale multicentric study with microbiological investigations is recommended.

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## Conflict of interest

None declared

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## Ethical considerations

Proper ethical clearance was taken from appropriate authority before stating the study.

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