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Levofloxacin versus Cefpodoxime for Antibacterial Prophylaxis in Allogeneic Stem Cell Transplantation



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National guidelines recommend antimicrobial prophylaxis for allogeneic stem cell transplant patients during the pre-engraftment period because of increased infection risk during neutropenia. Fluoroquinolones have demonstrated lower rates of bacteremias and incidence of neutropenic fever, but there is limited evidence in the use of alternative antibacterials such as cefpodoxime. The primary objective of this study is to compare the rates of antibiotic prophylaxis failure between levofloxacin and cefpodoxime in allogeneic stem cell transplant recipients. Secondary objectives include comparing and characterizing number and type of infections, mortality at day 100 post-transplant, and hospitalizations for infectious causes in the first 100 days of transplant. This is a single-center, retrospective chart review of adult patients who received an allogeneic stem cell transplant from matched related and matched unrelated donors and antibacterial prophylaxis with levofloxacin or cefpodoxime from January 1, 2011, to October 1, 2014. A total of 142 patients were evaluated (71 levofloxacin, 71 cefpodoxime). Both levofloxacin and cefpodoxime groups had similar rates of neutropenic fever and antibiotic prophylaxis failure (58% versus 58%, $P=NS$). There were similar incidences of *Clostridioides difficile* and Multi-drug resistant (MDR) infections among both levofloxacin and cefpodoxime groups. Rates of infections, hospitalizations, and mortality in the first 100 days were similar among both groups. Cefpodoxime can be used as an alternative to levofloxacin for antibiotic prophylaxis in allogeneic stem cell transplant patients.

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Allogeneic hematopoietic stem cell transplant (HSCT) patients are at considerable risk for infection because of prolonged neutropenia caused by myeloablative and immunosuppressive conditioning regimens. Both the National Comprehensive Cancer Network and the American Society of Blood and Marrow Transplantation recommend that prophylaxis with antibiotics should be considered in patients at high risk for neutropenia, including those receiving a stem cell transplant [1,2]. According to guidelines from the American Society of Clinical Oncology, Infectious Diseases Society of America, and American Society of Blood and Marrow Transplantation, antibacterial prophylaxis with fluoroquinolones should be considered for high-risk patients who are expected to have a prolonged and profound neutropenia duration (absolute neutrophil count [ANC] ≤ 100 cells/m³ for at least 7 days) and/or at the time of transplant and continuing until recovery of neutrophils [3,4].

Because of their broad spectrum of activity against gram-positive and gram-negative pathogens, fluoroquinolones are the most widely used antibacterial agent to prevent infection in patients who are neutropenic or expected to be neutropenic and receiving myelosuppressive chemotherapy. Several studies have demonstrated the effective use of fluoroquinolones for the prevention of neutropenic fever and other infectious-related outcomes in patients receiving conventional chemotherapy [5,6]. A meta-analysis performed concluded that fluoroquinolone prophylaxis reduced the incidence of fever, infection, and all-cause mortality in patients at high risk for febrile neutropenia [5]. However, concerns over the rise in fluoroquinolone-resistant organisms and increased appreciation of uncommon adverse events associated with fluoroquinolones have led some to question the continued benefit of fluoroquinolone prophylaxis [7,8]. In addition, patient-level contraindications, such as allergy or QT prolongation, may preclude the use of fluoroquinolones. Therefore, there is increasing interest in effective alternatives to fluoroquinolones as prophylaxis in patients at high risk for febrile neutropenia but little data to guide any alternative strategies.

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At MD Anderson Cancer Center, patients undergoing HSCT have received fluoroquinolone prophylaxis for over a decade. Cefpodoxime, an oral third-generation cephalosporin, has been used for several years as an alternative to levofloxacin at our institution in patients who have an allergy, intolerance, or other contraindication to levofloxacin. Cefpodoxime is generally well tolerated with both gram-positive and gram-negative activity; however, it lacks activity against *Pseudomonas aeruginosa*. To our knowledge, only 1 single-center case series has evaluated the use of cefpodoxime for antibacterial prophylaxis in patients with hematologic malignancies [9]. To more specifically describe the use of cefpodoxime as a potential alternative agent in HSCT patients, we conducted a retrospective analysis comparing rates of prophylaxis failure and outcomes between cefpodoxime and levofloxacin.

METHODS

This single-center retrospective cohort study included patients who received an allogeneic HSCT from matched related or unrelated donors and who received levofloxacin or cefpodoxime for antibacterial prophylaxis during transplant from January 1, 2011, to October 1, 2014. Patients who received a haploidentical or cord blood HSCT or a second allogeneic HSCT were excluded. Patients with active infections or receiving intravenous antimicrobials prior to transplant were also excluded. After obtaining approval from the Investigational Review Board at MD Anderson Cancer Center, patients were identified through our institutional HSCT and pharmacy databases. Adult patients (18 years old or older) who received a matched related donor, matched unrelated donor, or 1-antigen mismatched unrelated donor HSCT at MD Anderson Cancer Center and received levofloxacin or cefpodoxime for antibiotic prophylaxis for a minimum of 3 days were included in this study. Antibacterial prophylaxis was started when ANC was <1000 cells/mm³ or by day -1 , the day before stem cell infusion, and continued until neutrophil engraftment (ANC ≥ 500 cells/mm³). To control for relevant confounding variables related to infection risk, patients who received cefpodoxime were matched to levofloxacin patients in a 1:1 ratio. Matching criteria included the following: age ± 10 years, stem cell source, transplant type, underlying disease, and conditioning regimen.

The primary objective of the study was to compare the rates of antibiotic prophylaxis failure between levofloxacin and cefpodoxime in allogeneic HSCT recipients, defined as the incidence and time to development of neutropenic fever (temperature $\geq 38.2^{\circ}\text{C}$ and ANC <500 cells/mm³). When patients met the criteria for neutropenic fever, a fever workup was performed (2 sets of blood cultures, urinalysis, urine culture, chest x-ray), antibiotics were escalated (ie, antipseudomonal beta-lactam and vancomycin), and the prophylactic agent was discontinued. In addition to neutropenic fever, the number of neutropenic fever episodes and need for antibiotic escalation independent of neutropenic fever (eg, other signs and/or symptoms of infection) were also captured. Secondary objectives were to compare and characterize the number and type of pathogens causing bloodstream infections, *Clostridioides difficile* infections (on the basis of 1 or more unformed stools and a positive enzyme immunoassay for *C. difficile* toxin A and/or toxin B), hospitalizations for infectious causes, antibiotic use, and mortality within the first 100 days post-HSCT.

STATISTICAL ANALYSIS

To account for the paired nature of the data, demographic categorical variables were assessed using the McNemar chi-square test for matched pairs. As all continuous variables were non-normally distributed, distribution of these variables was compared using the Wilcoxon matched pairs signed-rank test. Outcome analyses were compared using an identical analysis strategy. The primary outcome, time to development of neutropenic fever, was assessed visually with Kaplan-Meier curves and using an unadjusted Cox proportional hazards model with shared frailty to account for the paired nature of the data. Patients were right-censored at the time of neutrophil engraftment. Other outcomes (ie, antibiotic escalation, isolation of a multidrug-resistant pathogen, *C. difficile* infection, rehospitalization, additional antibiotic use, and death, all within 100 days) were assessed using univariate conditional logistic regression analysis to account for matched pairs. No adjusted analyses were performed as exact matching was used to

account for key confounding variables. All statistical analyses were performed using Stata v14.1 (StataCorp LP, College Station, TX).

RESULTS

During the study period, 71 patients received cefpodoxime for antibacterial prophylaxis after HSCT, and 71 patients who received levofloxacin were matched for further analysis. As expected based on matching criteria, the study population in both levofloxacin and cefpodoxime arms was similar in age, sex, underlying disease, conditioning regimen intensity, stem cell type, and stem cell source (Table 1). Notably, most patients had acute myeloid leukemia and/or myelodysplastic syndrome as the underlying disease. Most patients received a myeloablative conditioning regimen. Five patients in the cefpodoxime arm and 2 patients in the levofloxacin group received a 1-antigen mismatched matched unrelated donor. Peripheral blood stem cells were the primary source of donor stem cells. The median number of antibiotic prophylactic days was 11 days among both the levofloxacin and cefpodoxime groups. Prophylactic antibiotics were typically started on day -1 , or the day before transplant, and continued until engraftment (ANC ≥ 500 cells/mm³). The median time to engraftment was 12 days among both groups.

With regard to the primary endpoint, there was no difference in the incidence of neutropenic fever for recipients of cefpodoxime versus levofloxacin (58% versus 58%; hazard ratio, 1.01; 95% confidence interval, 0.63 to 1.62; $P = .96$) after excluding 2 pairs who had developed fever on or immediately before initiation of antibiotic prophylaxis (Figure 1). The median number of neutropenic fever episodes and incidence of escalation of antibiotics were also similar among both groups (Table 2). Escalation of antibiotics was documented in 68% of patients receiving either levofloxacin or cefpodoxime.

In the first 100 days post-transplant, 7 (9.9%) patients in the cefpodoxime group and 4 (5.6%) patients in the levofloxacin group experienced a *C. difficile* infection. There were similar rates of multidrug-resistant pathogens, antibiotic usage, hospitalizations for infections, and deaths within the first 100 days of transplant among both treatment groups, as summarized in Tables 2 and 3.

A total of 12 pathogens were isolated from positive cultures in the levofloxacin group, and 9 pathogens were isolated from patients in the cefpodoxime group (Table 4). Most notably, a significantly higher number of gram-positive bloodstream infections, particularly *Rothia* spp., occurred in patients receiving levofloxacin compared with those patients receiving cefpodoxime (12.7% versus 2.8%, $P = .03$).

DISCUSSION

Antibacterial prophylaxis with fluoroquinolones is recommended in patients undergoing allogeneic HSCT [2]. Because many allogeneic HSCT patients may have an allergy, an intolerance, or a contraindication to fluoroquinolones, we sought to determine if cefpodoxime might be a suitable alternative to our standard prophylaxis with levofloxacin. Similar rates of antibiotic prophylaxis failure were demonstrated with levofloxacin and cefpodoxime. These rates in our study are similar to neutropenic fever rates reported in other studies [6,10]. There was also a similar incidence of *C. difficile* and multidrug-resistant infections among both levofloxacin and cefpodoxime groups, but rates of gram-positive bloodstream infections in the levofloxacin group were higher in comparison to the cefpodoxime group. In particular, both *Rothia* spp. and *Staphylococcus aureus* were numerically more common in recipients

Table 1
Baseline Characteristics

Variable	Cefpodoxime	Levofloxacin	P Value
Male sex	33 (47)	30 (42)	.60
Antifungal prophylaxis			1.00
Fluconazole	24 (34)	24 (34)	
Voriconazole	21 (30)	22 (31)	
Posaconazole	2 (3)	5 (7)	
Caspofungin	19 (27)	18 (25)	
Antiviral prophylaxis			.65
Valacyclovir	69 (97)	68 (96)	
Acyclovir	2 (3)	3 (4)	
Underlying disease			1.00
AML	29 (41)	30 (42)	
MDS	12 (17)	10 (14)	
AML/MDS	7 (10)	8 (11)	
ALL	5 (7)	5 (7)	
Myeloablative conditioning regimen	58 (82)	56 (79)	.16
Transplant type			.32
MUD	31 (44)	33 (46)	
MRD	35 (49)	36 (51)	
MUD (1-antigen mismatch)	5 (7)	2 (3)	
Stem cell source			1.00
Peripheral blood	49 (69)	49 (69)	
Marrow	22 (31)	22 (31)	
Age, y*	59 (51-65)	58 (50-64)	.07
Time to engraft, mean, d*	12 (11-13)	12 (11-15)	.22
Antibiotic prophylaxis time, mean, d*	11 (7-14)	11 (7-17)	.06

All values reported as n (%) and compared using the McNemar chi-square test unless otherwise specified.

AML indicates acute myelogenous leukemia; MDS, myelodysplastic syndrome; ALL, acute lymphoblastic leukemia; MUD, matched unrelated donor; MRD, matched related donor.

* Median (interquartile range), compared using Wilcoxon matched pairs signed-rank test.

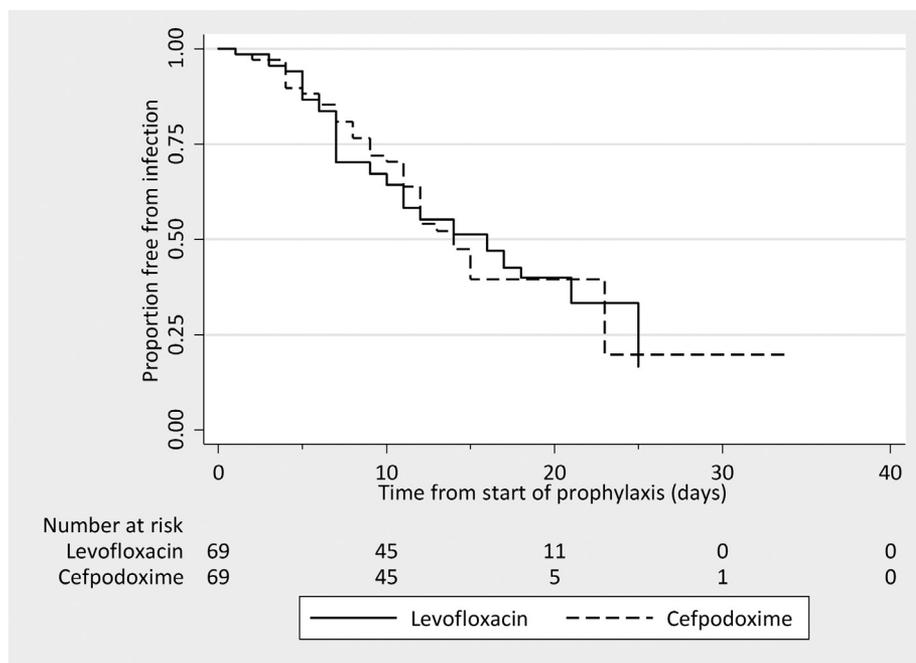


Figure 1. Kaplan-Meier curves comparing time with neutropenic fever among patients receiving levofloxacin and cefpodoxime prophylaxis. Hazard ratio, 1.01; 95% confidence interval, 0.63 to 1.62; $P = .96$. Two pairs were excluded because of the development of fever on or immediately before the initiation of antibiotic prophylaxis.

Table 2
Outcomes of Interest

Outcome	Cefpodoxime	Levofloxacin	P Value
Any fever	41 (58)	41 (58)	1.00
Antibiotic escalation	48 (68)	48 (68)	1.00
MDR pathogen within 100 days	9 (13)	7 (10)	.59
<i>Clostridioides difficile</i>	7 (10)	4 (6)	.32
Rehospitalized within 100 days	17 (24)	23 (32)	.29
Antibiotic use within 100 days	60 (85)	66 (93)	.13
Death in 100 days	10 (14)	5 (7)	.13

MDR, multidrug-resistant.

All values reported as n (%) and compared using the McNemar chi-square test.

Table 3
Unadjusted Conditional Logistic Regression Models (Levofloxacin as Reference Group) for Secondary Outcomes

Outcome	Odds Ratio	95% Confidence Interval	P Value
Antibiotic escalation	1.00	0.45-2.23	1.00
MDR in 100 days	1.33	0.46-3.84	.59
<i>Clostridioides difficile</i> infection	2.00	0.50-8.00	.33
Rehospitalized within 100 days	0.68	0.34-1.39	.29
Antibiotics within 100 days	0.45	0.16-1.31	.14
Death in 100 days	2.33	0.60-9.02	.22

MDR, Multidrug-resistance pathogen.

of levofloxacin. *Rothia* spp. are normal oral and respiratory flora, but they have been seen increasingly in immunocompromised HSCT patients and can cause serious infectious complications [11]. In contrast, levofloxacin is active against *Pseudomonas* whereas cefpodoxime is not, perhaps explaining why *Pseudomonas* was observed only in recipients of cefpodoxime. It is important to note that this study is not powered to detect true differences in organism distribution among the 2 prophylactic strategies, and these observations must be validated in larger cohorts.

The results of our study were comparable to the results of another single-center, retrospective cohort study conducted by Guthrie et al. [10] that compared ceftazidime prophylaxis and levofloxacin. In this study, a similar rate of nonblood-stream infections during the first 100 days after transplant was observed. Our study demonstrated comparable rates of neutropenic fever, mortality, emergence of antibiotic resistance, and occurrence of *C. difficile* as the Guthrie et al. [10] study.

Although the results are similar to our study, it is difficult to compare because of the difference in spectrum of activity, particularly activity against *P. aeruginosa*, between the 2 cephalosporins (ceftazidime and cefpodoxime) used. Ceftazidime is advantageous over cefpodoxime as it has antibacterial activity against *Pseudomonas* spp., whereas cefpodoxime does not. However, unlike ceftazidime, which is available only for intravenous administration, cefpodoxime is available for oral administration and is less expensive. In addition, standards of care and practices also varied among both institutions. The practice at Fred Hutchinson Cancer Research Center/Seattle Cancer Care Alliance (FHCR/SCCA) has transitioned from using ceftazidime to levofloxacin, whereas at our institution, levofloxacin remains been the standard of care.

Recently, the Mayo Clinic group conducted a study comparing antibacterial prophylaxis between levofloxacin and two oral third-generation cephalosporins, cefpodoxime and cefdinir, in patients with acute leukemia with neutropenia matched

Table 4
Pathogens Causing Bloodstream Infection by Prophylaxis Choice

Organism	Levofloxacin (n = 71)	Cefpodoxime (n = 71)	P Value
Any gram negative	3 (4)	7 (10)	.21
<i>Escherichia coli</i>	2	1	
<i>Citrobacter</i> spp.	1	1	
<i>Klebsiella pneumoniae</i>	0	2	
<i>Pseudomonas aeruginosa</i>	0	2	
<i>Stenotrophomonas maltophilia</i>	0	1	
Any gram positive	10 (13)	2 (3)	.03
Alpha-hemolytic <i>Streptococcus</i>	2	2	
<i>Leuconostoc</i> spp.	1	0	
<i>Rothia</i> spp.	3	0	
<i>Staphylococcus aureus</i>	2	0	
<i>Staphylococcus epidermidis</i>	2	0	
Yeast	1	1	

All values reported as n (%) and compared using the McNemar chi-square test. Statistical analysis performed only for bacterial categorical groupings because of small numbers of individual organism types.

by age and the Charlson comorbidity index. Similar to our study, they reported comparable rates of febrile neutropenia and positive cultures between the levofloxacin and the cephalosporin groups [12]. Although they included patients who received both cefpodoxime and cefdinir, both cephalosporins have a similar spectrum of activity. The same group previously reported a case series of patients with hematologic malignancies who received cefpodoxime as antibacterial prophylaxis during neutropenia [9]. The rate of febrile neutropenia was 85%, with positive cultures in 60% of patients. Although these rates are higher than the rates in our study, their study defined fever as a single temperature $\geq 38.3^{\circ}\text{C}$ or a temperature $\geq 38^{\circ}\text{C}$ sustained for 1 hour. Importantly, the authors did find a similar rate of *Pseudomonas* spp. in culture-positive infections among the third-generation cephalosporin and levofloxacin groups, which does contrast with our findings [12].

In addition, the European Conference on Infections in Leukemia performed a systematic literature review that included 2 randomized controlled trials and 12 observational studies from 2006 to 2014, which overall concluded that fluoroquinolone prophylaxis was associated with a lower rate of bloodstream infections and neutropenic fever episodes but had no impact on mortality [7]. In a survey conducted by Rashidi et al. [13], antibiotic prescribing patterns were described across various Blood and Marrow Transplant Clinical Trials Network centers. Of the 41 centers that responded to the survey, approximately 75% prescribed fluoroquinolone prophylaxis with levofloxacin (~80%) or ciprofloxacin (~20%). The remaining 15% of centers did not use any antibacterial prophylaxis. Most centers initiated antibacterial prophylaxis based on date (~55% before day 0), whereas others started prophylaxis at the onset of neutropenia. Ninety-five percent of centers discontinued antimicrobial prophylaxis at the time of neutropenic fever or neutrophil recovery, whichever was sooner.

From an antimicrobial stewardship perspective, drug resistance is an increasing concern. Bock et al. [14] described in their single-center study that there was greater resistance to levofloxacin among isolates in patients undergoing HSCT when comparing antibiotic sensitivities with hospital-wide isolates, especially in *Escherichia coli*, *Klebsiella pneumoniae*, and *P. aeruginosa*. Institutional antibiotic resistance patterns should be considered to determine effective infection prophylaxis and treatment strategies for HSCT patients. Because of the emergence of fluoroquinolone resistance, alternative antibacterial agents are warranted in both prophylaxis and treatment settings.

The limitations of our study include its retrospective study design and the small sample size, making it underpowered to detect statistical noninferiority of cefpodoxime to levofloxacin. The small sample size may have not been able to fully represent our patient population as well as the variety and number of infections that we encounter. Also, our study looked at only allogeneic HSCT patients from related and unrelated donors and did not include haploidentical and cord blood HSCT patients. Therefore, the findings of our study must be recapitulated in other institutions and other patient populations before being viewed as broadly applicable. In addition, the escalation of prophylactic antibiotics was not always as a result of infectious causes. For example, escalation of antibiotics may occur in patients who experienced fever caused by a reaction to conditioning regimens containing antithymocyte globulin or in patients without fever who had a decline in their clinical status based on physician discretion. Our study was also limited by reviewing only the incidence of infections from the day of

transplant to day 100. It is important to note that many infections can occur and affect HSCT recipients after this time. Furthermore, our results reported escalation of antibiotics during the incidence of neutropenic fever and also included incidences when physicians escalated antibiotics based on their subjective judgment for low-grade fevers, certain clinical situations, and when positive blood and/or urine cultures occurred in the absence of fever.

CONCLUSION

Cefpodoxime appears to be a potentially acceptable alternative to levofloxacin as antibacterial prophylaxis for patients receiving an allogeneic HSCT, especially in patients with contraindications to fluoroquinolones. There were similar rates of antibiotic prophylaxis failure, multidrug-resistant infections, *C. difficile* infections, hospitalizations for infection, infectious complications, and mortality between the levofloxacin and cefpodoxime groups. To confirm the results of the study, future directions may include prospective evaluation of cefpodoxime or alternative agents, such as cefdinir or azithromycin, for antibacterial prophylaxis for HSCT patients with fluoroquinolone allergy, adverse effects, or resistance. In addition, an integrated pharmacoeconomic analysis should be considered in future studies to determine the economic impact of antibacterial prophylaxis using alternative agents and the outcomes when prophylactic treatment fails.

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