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Case report

Rezafungin for suppressive therapy of *Candida auris* in a patient with a left ventricular assist device (LVAD)

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ABSTRACT

Introduction: Invasive candidiasis is a common healthcare-associated infection with significant morbidity and mortality. *Candida auris* in particular has emerged as a problematic and challenging healthcare-associated infection, especially with regards to infections involving left ventricular assist devices (LVADs). There is a paucity of evidence on the best management of these particular types of infections. Rezafungin is a newly-approved echinocandin and an important new tool in the management of invasive candidiasis. We report the novel use of rezafungin for suppressive therapy in a patient with an LVAD-associated *C. auris* infection.

Case: The patient is a 57-year-old male with a past medical history most notable for heart failure with ischemic cardiomyopathy. The patient underwent LVAD placement and his post-LVAD placement clinical course was notable for recurrent *C. auris* fungemia. The patient was originally on indefinite micafungin therapy, but was eventually switched to once-weekly rezafungin as this was felt to be safer, easier, and more convenient for the patient. He did well on weekly rezafungin for about 4 months but did eventually develop breakthrough *C. auris* fungemia.

Conclusions: Rezafungin is a promising new antifungal in the armamentarium of drugs for treatment of invasive candidiasis, notably *C. auris*. Though the patient did develop a breakthrough *C. auris* bloodstream infection while on rezafungin therapy, his infection was well-controlled for a little over 4 months, which prevented any *C. auris*-related hospital admissions during that time period. This case represents the first example of rezafungin being used for an LVAD-associated *C. auris* infection.

Introduction

Invasive candidiasis is a common and serious healthcare-associated infection with substantial morbidity and mortality [1]. In addition, they are associated with increased hospital costs and substantial economic burden [2,3]. Hospitalizations for *Candida* infections totaled about $1.4 billion in 2017 in the United States [2]. The armamentarium of drugs against invasive candidiasis is relatively sparse; echinocandins are first-line treatment with azoles being used as step-down or alternate therapy but azoles are hampered by potential drug interactions and increasing resistance [4–6]. Rezafungin is a newly-approved echinocandin that is structurally similar to the other existing echinocandins and offers the added advantage of pharmacokinetics that allow for once-weekly administration [7]. Rezafungin was recently shown to be non-inferior to caspofungin in candidemia and invasive candidiasis for the primary endpoints of day-14 global cure and 30-day all-cause mortality in the ReSTORE clinical trial [8]. Though patients with indwelling prosthetic devices, such as left ventricular assist devices (LVADs), were excluded in the ReSTORE clinical trial, rezafungin has a potential use in these instances, particularly *Candida auris* LVAD-associated infections.

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Though *C. auris* is a relatively rare infection in the LVAD population, it is nonetheless still a serious infection that is becoming increasingly implicated in LVAD-associated infections [9].

As invasive candidiasis becomes more prevalent due to the increased complexity, advanced age, more immunocompromised state, and presence of multiple comorbidities in affected patients [10], additional antifungal therapy will be needed. Furthermore, shifts from *Candida albicans* to non-*albicans* species, which are often more resistance, highlight the need for alternate treatments [11,12]. A potential niche for rezafungin is prosthetic and device-related *Candida* infections, but of course this requires further study and real-world, clinical experience. We report the use of rezafungin for suppressive therapy in a patient with an LVAD-specific *C. auris* infection. To the best of our knowledge, this is the first case of rezafungin being used for an LVAD-specific *C. auris* infection.

Patient case

The patient is a 57-year-old male with a past medical history most notable for heart failure with ischemic cardiomyopathy. His other medical comorbidities included hypertension, hyperlipidemia, obesity (body mass index: 33), gout, and chronic kidney disease stage III. He underwent LVAD placement 30 months prior to index presentation due to progressive heart failure symptoms despite adherence to goal-directed medical therapy (see Fig. 1a for timeline of patient's post-LVAD course). After LVAD placement, his clinical course was complicated by a deep driveline infection due to methicillin-sensitive *Staphylococcus aureus*, managed with PO (by mouth) minocycline suppressive therapy. He also experienced several non-infectious complications, including right ventricular dysfunction, requiring a right ventricular assist device implant 4 days after LVAD placement, LVAD pump exchange about a week after initial placement due to fibrous clots affecting flow, subdural hematoma, gastrointestinal bleeding, ascending aortic hematoma, and prolonged respiratory failure requiring a tracheostomy. Most notably, he developed *C. auris* fungemia about 2 years after LVAD placement; it was not hospital-onset nor associated with a known outbreak at that time. Given unclear source for the *C. auris* fungemia and also concern that the *C. auris* could have seeded the LVAD, a PET-CT was obtained that showed FDG uptake surrounding the driveline exit site, the outflow tract tubing, within the mesentery, and involving the posterior paraspinal musculature (though unclear if mesentery and paraspinal musculature were truly involved vs just an artifact on PET-CT). A culture was taken from the patient's driveline site, which also grew *C. auris*. The patient was placed on IV micafungin 100 mg daily and continued on PO minocycline 100 mg twice daily. He was admitted again about a month later due to recurrent *C. auris* bloodstream infection. A repeat PET-CT showed persistent FDG uptake surrounding the outflow tract tubing (Fig. 2). Table 1 lists the MIC values for the *C. auris* isolate over the patient's three *C. auris*-related hospital admissions. It remained susceptible to micafungin on both the initial and second hospital admission. Thus, the plan was for indefinite micafungin and minocycline therapy because his LVAD was considered as destination therapy, meaning it will remain in place permanently.

The patient was seen in the combined LVAD/Transplant Infectious Disease clinic about 4.5 months following the initial episode of *C. auris*. He was doing well on IV micafungin 100 mg daily and PO minocycline 100 mg twice daily, but requested alternate options to indefinite daily IV antifungal therapy. He and his caregiver also endorsed concerns regarding the risks of a long-term PICC line (i.e., infection and deep vein thrombosis), even though the patient fortunately did not have previous PICC line-related complications. Though the *C. auris* isolate was resistant to fluconazole, other oral azole therapy was still considered, but

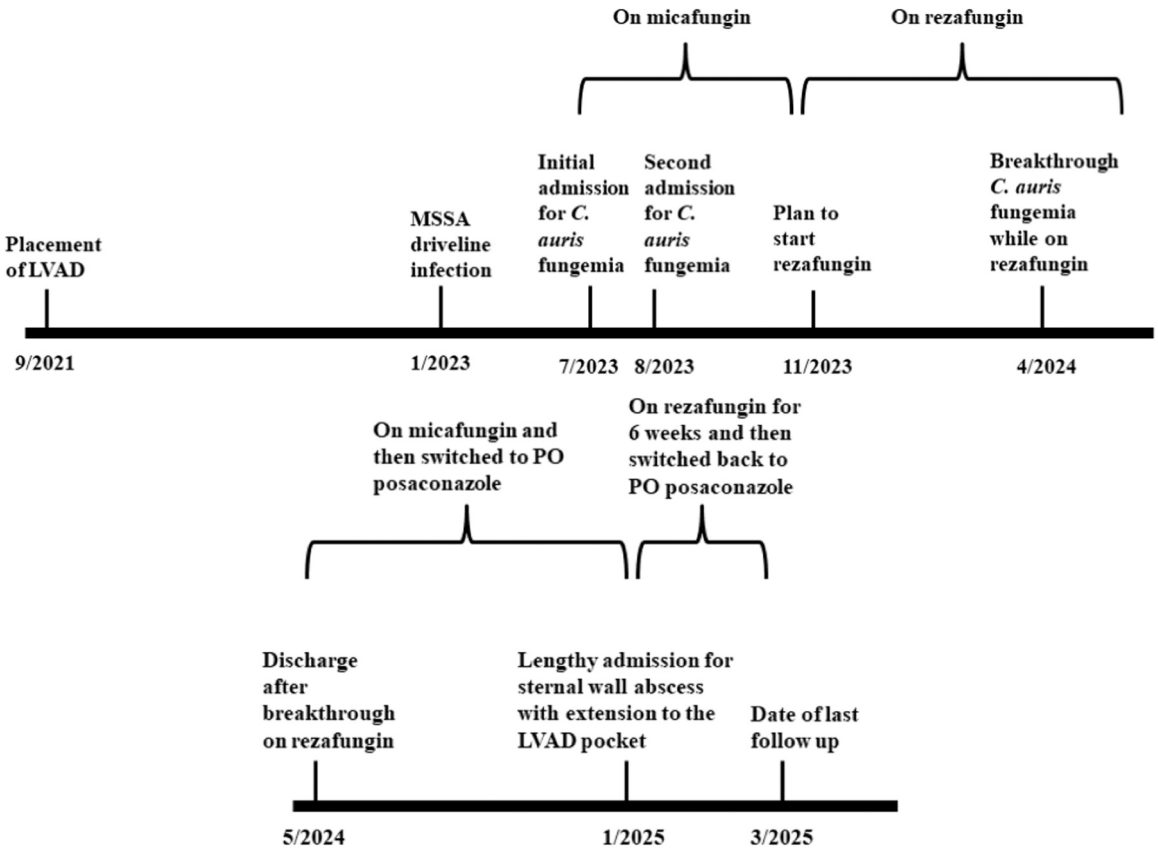

Fig. 1. a: Timeline of key events after patient's LVAD placement. For the sake of brevity, note that there were multiple non-infectious complications in the period immediately after LVAD placement that are not specifically listed on the timeline. Fig. 1b: Timeline of key events after the patient's admission for breakthrough *C. auris* fungemia while on rezafungin.

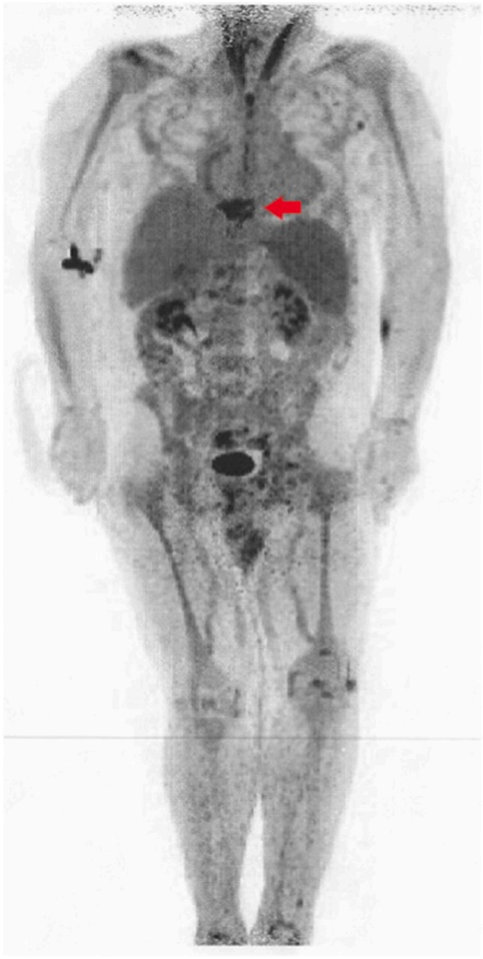

Fig. 2. PET-CT showing persistent FDG uptake surrounding the outflow tract tubing (red arrow).

decided against due to multiple drug interactions with his other medications such as warfarin and sildenafil. A decision was made to transition the patient from daily micafungin to once-weekly rezafungin. He was started on IV rezafungin with a dosing of 400 mg IV loading dose, followed by 200 mg IV weekly. The patient had 2 heart failure-related hospital admissions in the initial 4-month period that he was on outpatient IV rezafungin; neither admission was related to a worsening/relapsed infection. The patient tolerated rezafungin well without any apparent side effects.

After about 4 months of therapy with IV rezafungin 200 mg weekly, the patient was re-admitted to the hospital with sepsis and found to have recurrent *C. auris* fungemia. A PET-CT on that admission showed FDG uptake along the distal outflow tract and new sternal bone uptake. During this admission, empiric high dose micafungin was begun at 200 mg daily, along with amphotericin, while susceptibilities for micafungin, rezafungin, and amphotericin were pending. The susceptibilities for both micafungin and amphotericin did return before discharge showing that the *C. auris* isolate retained susceptibility to both micafungin and amphotericin, with MICs of 0.064 μg/mL and 0.5 μg/mL, respectively (Table 1). No genotypic testing to look for *FKS* or other mutations of the *C. auris* isolate was done. Debridement of the suspected sternal osteomyelitis was not considered after evaluation by the cardiothoracic surgery team as they felt as though risks outweighed benefits for the procedure given the patient's multiple medical comorbidities and concern for seeding other parts of the LVAD during the debridement procedure. Given clinical breakthrough with rezafungin and the fact that the rezafungin susceptibility was not immediately available at the time of discharge, the patient was switched back to micafungin, but at a dose of 150 mg daily, with a new PICC line in place. The susceptibility to rezafungin did eventually come back after discharge showing that the *C. auris* isolate was likewise still susceptible to rezafungin as well, with a MIC of 0.5 μg/mL (Table 1).

The patient remained stable on IV micafungin 150 mg daily for about 3 months but was eventually transitioned to PO posaconazole at the request of the patient and his caregiver, as daily IV micafungin therapy was too taxing for them. Although there were initial concerns about potential drug interactions, particularly with warfarin and sildenafil, the Advanced Heart Failure Team approved the use of posaconazole in his case given the patient's close outpatient monitoring and the presence of an implantable cardioverter-defibrillator. While on PO posaconazole therapy, he developed a sternal wall abscess with extension to the LVAD

Table 1
MIC values for the *C. auris* isolate over the patient's three *C. auris*-related hospital admissions. Note that amphotericin and rezafungin susceptibilities were not obtained during the patient's first two hospital admissions for *C. auris*.

Hospital admission #1		
Fluconazole	>32 μg/mL	Resistant
Micafungin	0.19 μg/mL	Susceptible

Hospital admission #2		
Fluconazole	>32 μg/mL	Resistant
Micafungin	0.125 μg/mL	Susceptible

Hospital admission #3		
Fluconazole	>32 μg/mL	Resistant
Micafungin	0.064 μg/mL	Susceptible
Rezafungin	0.5 μg/mL	Susceptible
Amphotericin	0.5 μg/mL	Susceptible

pocket, which required a lengthy admission for management of the new infection. The patient was able to be placed back on rezafungin for 6 weeks, with initial plans to again use rezafungin on a longer-term basis for suppressive therapy, but the patient again requested PO therapy only for management of his chronic LVAD infection (see Fig. 1b).

Of particular importance, heart transplant candidacy was discussed several times, but the patient was not considered an optimal candidate because of his multiple medical comorbidities, declining functional status, and persistent infection. As a result, he will remain with the LVAD in place for life unless his overall medical condition improves enough that he qualifies for a heart transplant.

Discussion

Rezafungin is a promising new antifungal for treatment of invasive candidiasis. Though rezafungin was shown to be non-inferior to caspofungin in the treatment of candidemia and invasive candidiasis in the ReSTORE trial, there were some key exclusion criteria (i.e. prosthetic joint infections, osteomyelitis, endocarditis, presence of an indwelling catheter or device that could not be removed, and chronic disseminated candidiasis) [8]. The types of *Candida* infections that were excluded in the ReSTORE clinic trial are often the most challenging ones, requiring the most priority and aggressive management. Three other recent studies have explored novel, "off-label" uses for rezafungin. Pechacek et al. used rezafungin to treat a case of refractory *Pichia kudriavzevii* (formerly *Candida krusei*) peritonitis in a liver transplant recipient [13]. In another case, Mori et al. used rezafungin as suppressive therapy for a case of *Candida* endocarditis [14]. And lastly, Viceconte et al. used rezafungin for a case of *Candida parapsilosis* spondylodiscitis that had reduced susceptibility to azoles [15].

Similar to the cases mentioned above, our case demonstrated the novel application of rezafungin for suppressive therapy in an LVAD patient for chronic invasive candidiasis. In our case, rezafungin was an attractive option for several reasons. First, once-weekly administration was more convenient for the patient and caregiver as opposed to daily dosing. Secondly, once-weekly administration of rezafungin obviated the need for a PICC line and its associated potential complications, such as infection or deep vein thrombosis. Thirdly, the use of IV rezafungin in the place of an azole prevented potential drug interactions and long-term adverse effects related to azole therapy. Fourth, rezafungin was appealing since azoles can be problematic due to unreliable susceptibilities for *C. auris* [16] and that fact that only rezafungin currently has Clinical and Laboratory Standards Institute-established breakpoints for *C. auris*. And lastly, there are possible cost savings for patients whose insurance programs fully cover the cost of once weekly treatment at an outpatient infusion center. Those patients may save on the costs associated with a daily IV antifungal, PICC line insertion, home health nursing visits, and supplies. However, we acknowledge that the possibility of potential cost savings is purely speculative and would require further cost analysis studies. Due to difficulties in obtaining accurate monetary data, we could not calculate any potential cost savings with rezafungin in our patient.

Since rezafungin is a relatively new antifungal, there are not yet any studies looking at potential cost savings from once-weekly rezafungin. One recent study looking at healthcare resource utilization and discharge readiness in adults hospitalized with candidemia or invasive candidiasis found that almost half (42.9 %) were potentially dischargeable prior to their actual discharge date [17]. Given the considerable economic burden associated with candidemia and invasive candidiasis, rezafungin could be used in the instances described in the study by Lodise et al. to reduce hospital-associated costs. Possible healthcare cost savings for other types of invasive *Candida* infections is speculative at this point; therefore, more data is needed to determine if rezafungin may contribute to significant healthcare cost reduction for select patients with other invasive *Candida* infections.

Although our patient did eventually develop a relapsing *C. auris* bloodstream infection while on rezafungin therapy, he previously had a breakthrough infection while on micafungin as well. Moreover, when he was initially placed on micafungin, he had recurrent *C. auris* fungemia after about 1.5 months on micafungin, but remained infection-free for just over 4 months while on rezafungin therapy. During that 4 month time period on rezafungin, the patient was able to avoid any infection-related hospital admissions. This fact should not be understated given not only the staggering healthcare costs associated with LVAD-specific and LVAD-related infections, but also the overall hospital costs of frequent readmissions in patients with LVADs [18–20].

We do acknowledge that our patient had a breakthrough *C. auris* infection and that the patient ultimately had a failure of rezafungin suppressive therapy. However, there were several variables obfuscating the conclusion of whether the patient truly failed rezafungin therapy or not. First, given the patient's adherence to therapy and the *C. auris* remaining susceptible to rezafungin, it was felt that the recurrence of the *C. auris* fungemia may not have been a fault of rezafungin per se, but rather due to a lack of source control in the setting of a chronically infected LVAD (with infection not limited to just the driveline site). The LVAD cannot practically be removed/exchanged given that the patient is destination therapy and that the procedure itself would be prohibitively morbid due to the patient's multiple medical comorbidities and declining functional status. Secondly, it is possible that our patient may have had an unfavorable outcome despite appropriate treatment given his extreme comorbidity burden and acuity of illness. Indeed, there may exist a niche role for rezafungin in cases similar to ours and rezafungin may demonstrate more success if the correct patient population is chosen. For example, rezafungin may have a role in patients who are able to get better source control or in patients who are less acutely ill/with less medical comorbidities wherein it could be used for shorter-term suppressive therapy as a bridge to transplant. However, this would require further study, and it is our hope that our manuscript will spark further research in this area.

Another potential complicating variable as to why our patient had breakthrough *C. auris* fungemia despite seemingly appropriate treatment with rezafungin is that there is still much to learn about the pharmacokinetics and pharmacodynamics (PK/PD) of rezafungin, especially with *C. auris* and in patients with LVADs. The PK/PD of rezafungin can be variable, but overall higher doses lead to higher % probability of PK-PD target attainment [21,22]. Indeed, our patient may have benefited from 400 mg weekly for maintenance dosing as opposed to 200 mg weekly. In addition, rezafungin appears to have lower tissue penetration into the heart compared to other tissues, which is another potential reason for the breakthrough *C. auris* fungemia despite ostensibly adequate treatment [23]. Moreover, relatively little is known about the PK/PD of medications in patients with LVADs. The few studies that have been done on the PK/PD of medications in patients with LVADs have shown widely variable drug levels in the serum [24,25], and virtually no PK/PD data exists for antimicrobials. Further studies exploring PK/PD data in patients with LVADs for not only rezafungin, but also other antimicrobials, will help inform optimal dosing in this very challenging cohort of patients.

Lastly, other therapeutic options for this patient's challenging *C. auris* infection were considered, including both ibrexafungerp and oral encochleated amphotericin B, but were logistically difficult to obtain. In addition, when the patient was admitted with breakthrough *C. auris* fungemia while on rezafungin, combination therapy with flucytosine was pursued at the time of discharge, but flucytosine was unfortunately not covered by the patient's insurance.

Rezafungin offers a unique treatment in the fight against invasive fungal infections. Our case report describes a potential novel use of rezafungin for suppressive therapy in a patient with an LVAD infection with *C. auris*. Rezafungin can serve as an alternative to other echinocandins, with comparable efficacy but with the advantage of once-weekly dosing, in selected patients. In closing, we hope that this manuscript will help augment the literature on the treatment of

challenging *C. auris* infections, which is an area where more evidence is urgently needed.

CRediT authorship contribution statement

Kapadia Mona: Writing – review & editing, Writing – original draft, Visualization, Data curation, Conceptualization. **Hasbun Rodrigo:** Writing – review & editing. **Ostrosky-Zeichner Luis:** Writing – review & editing, Validation, Supervision, Resources. **Babic Jessica:** Writing – review & editing. **Park Sun O:** Writing – review & editing. **Stack Matthew Alexander:** Writing – review & editing, Writing – original draft, Visualization, Supervision, Resources, Project administration, Methodology, Data curation, Conceptualization.

Author Contributions

MS, LO, RH, SP, JB, and MK jointly conceived the study. MS performed the chart review, material preparation, and data collection. MS wrote the first draft of the manuscript in addition to subsequent versions of the manuscript and all authors commented and gave feedback on previous versions of the manuscript. All authors read and approved the final manuscript.

Consent

We obtained written consent from the patient for publication of this case report.

Patient Consent

We obtained written consent from the patient for publication of this case report. The study was approved by our institution's IRB.

Ethical approval

The study was approved by our institution's IRB.

Transparency Declarations

Authors MS, RH, SP, JB, and MK declare they have no financial interests or associations that might pose a conflict of interest. LO has received consulting honoraria from Cidara and Melinta.

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Declaration of Competing Interest

LO has received consulting honoraria from Cidara and Melinta. Authors MS, RH, SP, JB, and MK declare they have no financial interests or associations that might pose a conflict of interest.

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