P-1958

Efficacy and Safety of Rezafungin, A Long-Acting Echinocandin

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KEY FINDINGS

- **Rezafungin is demonstrated to be safe, well-tolerated and effective for treatment of candidemia, invasive candidiasis and mucosal candidiasis in the real-world.**
- **Outcomes were successful in all diagnostic areas, including mucosal candidiasis, which has not been studied in depth.**
- **The cohort was at high risk for Candida infections, comorbid and heavily treatment experienced.**
- **As a long-acting weekly echinocandin, rezafungin is favorable for outpatient treatment of patients with fungal infections.**

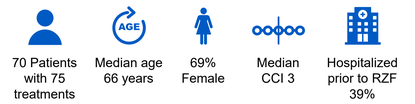
Introduction

- Rezafungin (RZF) is a novel, next generation, long-acting intravenous echinocandin that was approved by the FDA in March 2023 for adult patients with candidemia and invasive candidiasis with safety established for up to 4 weekly doses.
- The once weekly dosing regimen is advantageous in outpatient settings, eliminating the requirement for central venous catheters and daily medication administration.
- This real-world study evaluates the use of rezafungin in Infectious Disease outpatient infusion centers, both as community initiation therapy and continuation therapy following hospitalization.

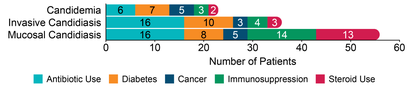
Methods

- A retrospective, cohort study was conducted in Infectious Disease physician infusion centers of patients who received ≥ 1 dose of rezafungin for treatment of any fungal infection, which included candidemia, invasive candidiasis and mucosal candidiasis.
- Patients with multiple episodes of fungal infections and treatments with rezafungin were included.
- Data collected included demographics, medical history, risk factors for fungal infections, prior therapy, and reasons for use of rezafungin.
- Disease course and treatment details were evaluated including infection types, pathogens, drug dose and frequencies and adverse events.
- Outcomes were assessed for type of fungal infections and by pathogen as success, non-success or non-evaluable.
- Clinical success was defined as a complete or partial resolution of symptoms of infection and no need for change of regimen for completion of therapy.
- Non-success was defined as relapse or persistent infection at the end of therapy or required discontinuation of rezafungin.
- Patients were non-evaluable if clinical response was indeterminate.
- Adverse events occurring during therapy were noted, including therapy discontinuations.
- Continuous data were reported as medians with interquartile ranges, and categorical data as counts and percentages.

Study Cohort

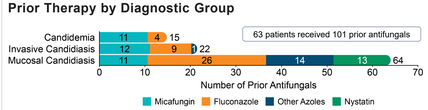


Risk Factors for Fungal Infection*



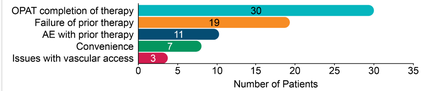
- Median number of risk factors for fungal infections was 2 (IQR 1-3) per patient
- Other comorbidities included cardiovascular disease 50%,and chronic renal disease 11%

Prior Therapy by Diagnostic Group

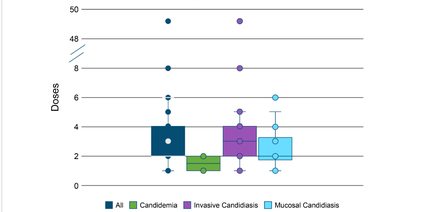


63 patients received 101 prior antifungals

Prescriber Reasons for Use of Rezafungin



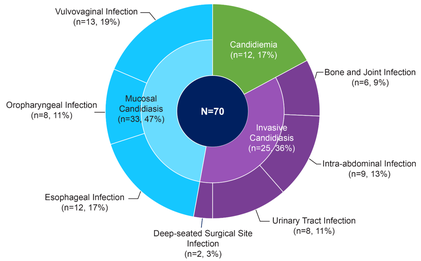
Median Duration of Rezafungin Therapy



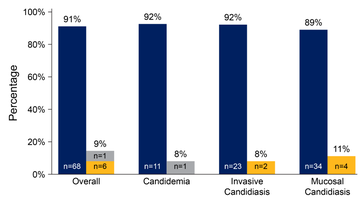
- Median doses for all 75 treatment courses were 2 (IQR 2-4) with longer term therapy in invasive candidiasis (BJI) in 2 patients, both with successful outcomes.
- 9 patients received > 4 weekly doses.
- All patients received loading doses of 400mg, including those transitioning from the hospital.

Results

Infection by Diagnostic Group

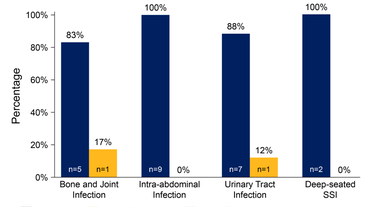


Outcome by Diagnosis (n=75 treatment courses)



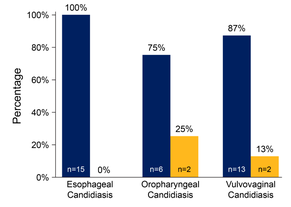
Overall Success 91%

Outcome by Infection Type for Invasive Candidiasis



- Invasive Candidiasis 92% Success
  - 100% in IAI and Deep-seated SSI
  - 83% in Bone and Joint Infections

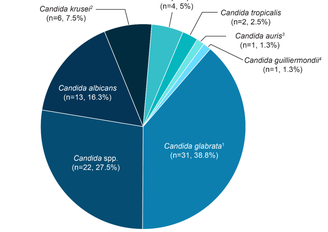
Outcome by Infection Type for Mucosal Candidiasis



- Mucosal Candidiasis 89% Success
- 100% in Esophageal Candidiasis
- 3 pts had 5 new infections –all successful outcomes
  - 2 VVC due to long-term broad-spectrum ABX for MDR UTI
  - 3 EC due to biologic therapy for RA, other infections and ABX

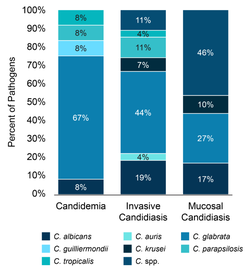
Microbiologic Results

Pathogens**

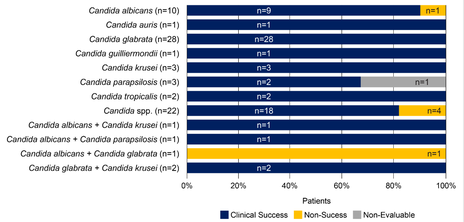


- 80 pathogens were isolated in 75 treatment courses, with cultures representing baseline targeted pathogens.
- *C. glabrata* was the most frequently isolated.

Pathogens by Diagnostic Group

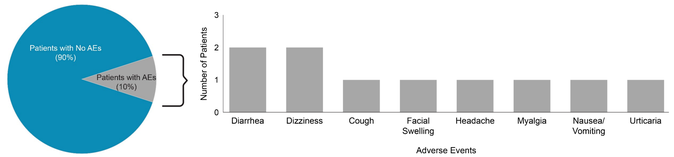


Outcomes by Pathogen



- Treatment success was seen with 90.6% of treatments by pathogen. Two non-successes (*Candida* spp.(1) and *C.albicans* + *C. glabrata* (1) were due to AEs with discontinuation.

Safety



- 10 AEs were reported in 7 patients (see figure).
- 8 were mild and did not require discontinuation of therapy.
- 2 patients had moderate AEs with discontinuation of therapy: one for exacerbation of diarrhea (BJI) and one for urticaria (VVC).
- None of the AEs were reported as severe.

Discussion

This study provides a very large real-world database on outpatient use of rezafungin.

- The cohort was co-morbid with a high number of risk factors for fungal infections, with antibiotic use the most predominant.
- Prior antifungals were utilized in 90% of patients.
- The primary reason for use of rezafungin was continuation of therapy in the OPAT setting following hospitalization.
- Rezafungin was successful in eradication of disease in numerous *Candida* pathogens, including organisms with high rates of resistance to azoles.
- Successful outcomes were high over all diagnoses.
  - Candidemia success was 92%.
  - Invasive candidiasis success was 92%, with 100% success in intra-abdominal and deep-seated SSI.
  - These data report first use of rezafungin for treatment of mucosal candida infections, which was 100% successful in treatment of esophageal candidiasis. Oropharyngeal was the least effective, most likely due to persistence of high-risk factors in this population.
- Rezafungin was a safe, well tolerated, and effective treatment for candidemia, invasive and mucosal candidiasis in this treatment experienced comorbid population.
- These real-world data establish the successful use of a long-acting weekly echinocandin in the outpatient treatment of patients with fungal infections.

Abbreviations and Footnotes

Abbreviations: ABX, antibiotic; AE, adverse event; BJI, bone and joint infection; CCI, Charlson Comorbidity Index; EC, esophageal candidiasis; FDA, Food and Drug Administration; IAI, intra-abdominal; IQR, interquartile range; ID, Infectious Disease; MDR, multi-drug resistant; OPAT, Outpatient parenteral antimicrobial therapy; SSI, surgical site infection; RA, rheumatoid arthritis; RZF, rezafungin, VVC, vulvovaginal candidiasis.

*Risk factors associated with CDC guidelines for fungal infections included: antibiotic use, diabetes, cancer, HIV/AIDS, immunosuppression/immunomodulatory drugs, including chemotherapy and steroid use, both systemic and inhaled.

**Current naming convention for pathogens: [1]*Candida glabrata* is *Nakaseomyces glabrata*, [2]*Candida krusei* is *Pichia kudriavzevii*, [3]*Candida auris* is *Candidozyma auris* and [4]*Candida guilliermondii* is *Meyerozyma guilliermondii*.

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