

Assessment of Fluconazole Utilization: A Prospective Observational Study of Prescribing Patterns, Resistance Trends, and Empirical Therapy Outcomes in Hospitalized Patients at a Tertiary Care Hospital

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ABSTRACT

Background: Fluconazole is a triazole antifungal extensively indicated for the treatment of Candida infections, particularly in hospitalized and immunocompromised patients. It exerts its action by inhibiting lanosterol 14-demethylase, thereby disrupting ergosterol synthesis and fungal cell membrane integrity. However, its widespread and prolonged use has contributed to the emergence of resistance, especially among non-albicans Candida species. **Objectives:** This underscores the importance of rational drug utilization and continuous evaluation of prescribing patterns. **Materials and Methods:** This study is designed to systematically evaluate the utilization patterns of fluconazole in a tertiary care hospital setting. It focuses on assessing prescribing patterns, dose optimization and adherence to evidence-based guidelines. Additionally, the study aims to analyze antifungal resistance trends among Candida isolates and to correlate these findings with clinical outcomes. The results are intended to support optimized clinical decision-making and promote rational antifungal therapy. This study aimed to evaluate the prescribing patterns of fluconazole in a tertiary care hospital, assess resistance trends among Candida isolates in invasive candidiasis, and determine the clinical effectiveness of empiric therapy, including treatment outcomes, and breakthrough infections. A drug utilization study of fluconazole was conducted by using prospective observational design from November 2024 to July 2025 at Deenanath Mangeshkar Hospital, Maharashtra. **Results:** A total of 180 hospitalized patients undergoing antifungal therapy were enrolled. The collected variables included demographic characteristics, clinical indications, antifungal treatment modality (empirical or targeted), dosage regimen, formulation, duration of therapy, renal function assessment via creatinine clearance, site of fungal isolation, and antifungal susceptibility profiles. Data was analyzed using Microsoft excel software. Prescribing patterns were evaluated using standard Drug Utilization Review (DUR) indicators to assess therapeutic appropriateness and adherence to evidence-based clinical practices. Among 180 patients receiving fluconazole, *Candida tropicalis* (30%) and *Candida glabrata* (16.67%) were prominent resistant species. Male patients (59.4%) and age ≥ 60 years (52.8%) were most affected. Empirical therapy accounted for 50% with 14.4% resistance. *Candida tropicalis* (30%) and *Candida auris* (20%) were frequent isolates, mainly from urine (57%) Fluconazole use was highest in immunocompromised patients (84%), minimal in those with invasive devices (1%) and withheld in (15%) due to resistance. **Conclusion:** Early and accurate mycological diagnosis, in conjunction with routine antifungal susceptibility testing, is fundamental for optimizing the clinical use of fluconazole. Timely identification of fungal pathogens and their susceptibility profiles enable precise selection of antifungal therapy and supports early de-escalation to targeted treatment approaches. This strategy reduces unnecessary empirical exposure to antifungal agents, minimizes the risk of adverse drug reactions, and enhances therapeutic efficacy. In addition, continuous monitoring of antifungal prescribing patterns and resistance trends is crucial to ensure judicious fluconazole utilization in healthcare settings. Implementation of evidence-based treatment protocols and microbiological surveillance may further aid in reducing the emergence and spread of fluconazole-resistant fungal isolates. Collectively, these measures contribute to improved patient outcomes and the preservation of antifungal effectiveness in clinical practice.

Keywords: Antifungal resistance, Candida species, Drug utilization review, Fluconazole.

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INTRODUCTION

Fluconazole, a structurally refined bis-triazole antifungal agent, remains a cornerstone in the management of invasive and mucocutaneous candidiasis, cryptococcal meningitis, and other systemic fungal infections because of its favorable pharmacokinetic profile, good oral bioavailability, and broad



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antifungal activity. It is widely prescribed in both oral and parenteral formulations for conditions such as vulvovaginal candidiasis, oropharyngeal and esophageal candidiasis, candidemia, and fungal meningitis. Depending on the severity and type of infection, fluconazole therapy may range from a single 150 mg oral dose to prolonged high-dose regimens administered over several weeks (Akbar *et al.*, 2024; Govindarajan *et al.*, 2024; Pfizer, 2024). Additionally, long-term maintenance therapy with fluconazole following amphotericin B treatment is commonly employed in immunocompromised patients, particularly those with AIDS, to prevent relapse of cryptococcal meningitis (Rex *et al.*, 1994).

Despite its clinical utility, the extensive and often empirical use of fluconazole has contributed to the emergence of antifungal resistance, particularly among non-albicans *Candida* species such as *Candida glabrata*, *Candida krusei*, and *Candida auris*. Resistance mechanisms are primarily associated with alterations in efflux pump expression and mutations in the ERG11 gene, which encodes the fungal cytochrome P450-dependent enzyme lanosterol 14- α -demethylase, the primary target of fluconazole (Whaley *et al.*, 2016). Recent epidemiological evidence has highlighted the growing burden of resistance worldwide. A single-center Indian study reported *Candida auris* as the predominant isolate, with all isolates demonstrating resistance to fluconazole (Chowdhary *et al.*, 2017). Similarly, the National Centre for Disease Control (NCDC) annual report up to 2024 documented tentative fluconazole resistance in 66% of *Candida auris* isolates with Minimum Inhibitory Concentration (MIC) values >32 mg/L. Furthermore, a 10-year surveillance analysis of *Candida parapsilosis* bloodstream isolates in the United States demonstrated a significant increase in fluconazole resistance from 8.2% to 20.3% (Pfaller *et al.*, 2019).

In addition to resistance concerns, optimization of fluconazole dosing remains clinically important. Studies comparing high-dose and low-dose fluconazole therapy in intensive care unit patients with invasive candidiasis have suggested that higher-dose regimens may improve outcomes and reduce mortality in selected high-risk populations while remaining cost-effective under certain clinical thresholds (Pappas *et al.*, 2016; Andes *et al.*, 2012). However, inappropriate prescribing practices, prolonged empirical therapy, inadequate dose adjustments, and irrational antifungal use may contribute to therapeutic failure, adverse drug reactions, and increased healthcare costs. Common adverse effects associated with fluconazole include nausea, vomiting, epigastric discomfort, and hypersensitivity reactions (Rex *et al.*, 1994).

Considering the increasing prevalence of antifungal resistance and the widespread use of fluconazole in hospital settings, periodic evaluation of its utilization pattern has become essential. Drug Utilization Review (DUR) serves as an effective tool to assess the appropriateness, safety, and rationality of medication

use. Therefore, the present prospective observational study was conducted among hospitalized patients at a tertiary care hospital to evaluate the utilization pattern of fluconazole, assess prescribing practices, identify resistance trends among *Candida* species, and promote the rational use of antifungal therapy (Denning *et al.*, 2022; Hossain *et al.*, 2022; Matthew *et al.*, 2023).

The findings of this study may help optimize fluconazole prescribing, minimize resistance development, and improve overall patient outcomes.

MATERIALS AND METHODS

Study Population

Data for this prospective observational study were collected from the hospital's electronic medical records over six months, enrolling 180 patients who met predefined fluconazole-treatment eligibility criteria. Ethics committee approval was obtained prior to the commencement of the study.

Study Design and Setting

This prospective observational study was conducted at Deenanath Mangeshkar Hospital and Research Center (DMHRC) to comprehensively characterize fluconazole utilization among hospitalized patients with microbiologically confirmed or empirically suspected *Candida* infections.

The primary objectives were to delineate prescribing patterns, evaluate dose optimization strategies, assess treatment duration metrics, and analyze local resistance epidemiology. Evaluation criteria were developed in accordance with evidence-based antifungal stewardship principles and established *Candida* susceptibility frameworks, focusing on the appropriateness of indications, renal function-adjusted dosing accuracy, formulation suitability, adherence to guideline-recommended duration of therapy, and concordance with institutional resistance surveillance data.

Data Collection

Prospective data were collected from 1 November 2024 to 30 April 2025 using hospital electronic medical records and antifungal susceptibility databases. Detailed variables included patient demographics, diagnostic classification, and site of infection, isolated *Candida* species, therapeutic approach (empirical or targeted), formulation type, dose and duration profile, renal function parameters, resistance phenotype. Prescription patterns were systematically evaluated using real-time hospital informatics systems and antifungal susceptibility reports to assess rational pharmacotherapy, alignment of treatment duration with clinical response, and trends in resistance patterns over time. As the study followed a non-interventional observational design, no modifications to prescribing practices or clinical management were implemented. Outcome measures focused on evaluating the appropriateness of fluconazole use, distribution and frequency

of resistance phenotypes, and overall prescribing trends within the study population. All collected data were compiled into a standardized analytical framework and analyzed using descriptive statistical methods, with results presented through structured tables, bar charts, and graphical representations for comprehensive interpretation.

RESULTS

Table 1 indicated that elderly patients aged >60 years constituted the majority of the study population (52.8%), followed by patients aged 40-59 years (30%). Male patients predominated (59.4%) compared to females (40.6%), suggesting increased susceptibility and hospitalization among elderly male patients with fungal infections.

Table 2 demonstrated that oral tablet formulation was the most commonly prescribed route of administration (65%), followed by intravenous therapy (20%). Fluconazole was not administered in 14% of cases due to documented resistance. Treatment duration analysis showed that most patients received therapy for 1-5 days

Table 1: Demographic distribution of study population (n=180).

Demographic details	Number of patients	Percentage (%)
Age Group (Years)		
0-18	7	3.9%
18-39	24	13.3%
40-59	54	30.0%
>60	95	52.8%
Gender		
Male	107	59.4%
Female	73	40.6%

(50%), while 32.8% received treatment for 6-14 days, indicating preference for short-course therapy in most hospitalized patients.

Figure 1 illustrated the dosage profile of fluconazole, showing that standard-dose regimens were predominantly utilized, while higher doses were reserved for severe invasive fungal infections and critically ill patients. Dose adjustments were also performed according to renal function and clinical condition. Table 3 indicated that empirical antifungal therapy accounted for 50% of total prescriptions, including cases where cultures were not sent or yielded no growth. Culture-guided continuation of fluconazole therapy was observed in 35.56% of patients, whereas therapy was discontinued in 14.44% of cases due to antifungal resistance, emphasizing the importance of susceptibility-based treatment modification.

Figure 2 demonstrated that non-albicans *Candida* species predominated among isolates. *Candida tropicalis* was the most frequently isolated species (30%), followed by *Candida auris* (20%), reflecting the growing epidemiological shift toward resistant non-albicans *Candida* infections in hospitalized patients.

Table 4 showed that urine was the most common site of fungal isolation (57.78%), followed by bloodstream infections (24.44%). Gastrointestinal, dermatological, central nervous system, and bone isolates were comparatively less common, indicating a high prevalence of candiduria among hospitalized and immunocompromised individuals.

Figure 3 demonstrated the resistance pattern of *Candida* isolates, where fluconazole resistance was observed in 14.4% of cases. *Candida tropicalis* and *Candida glabrata* emerged as the predominant resistant species, highlighting the increasing challenge of azole resistance and the necessity for routine antifungal susceptibility testing.

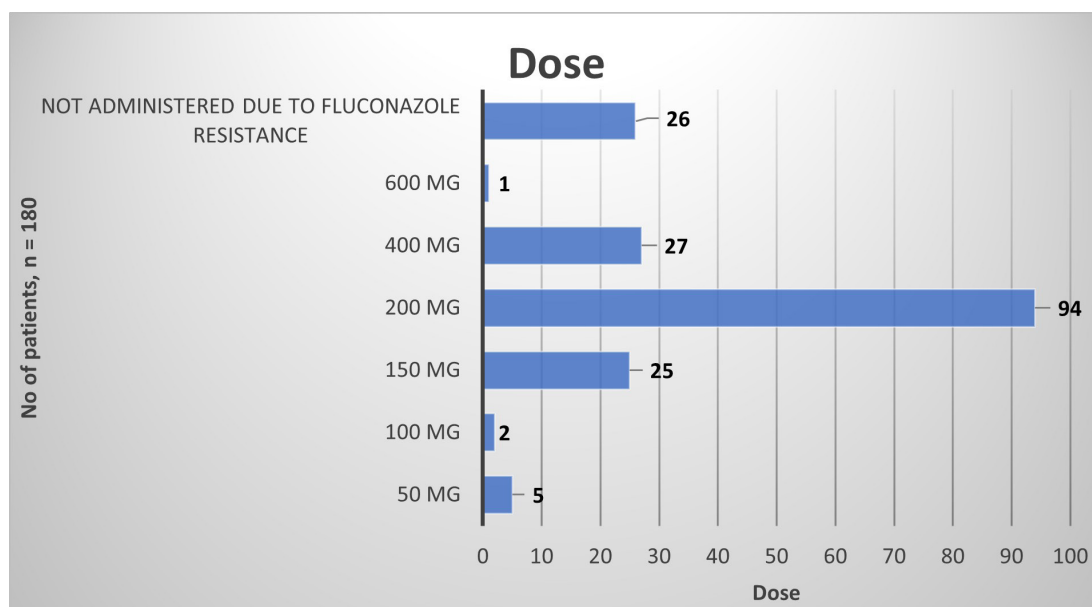


Figure 1: Dosage profile of Fluconazole.

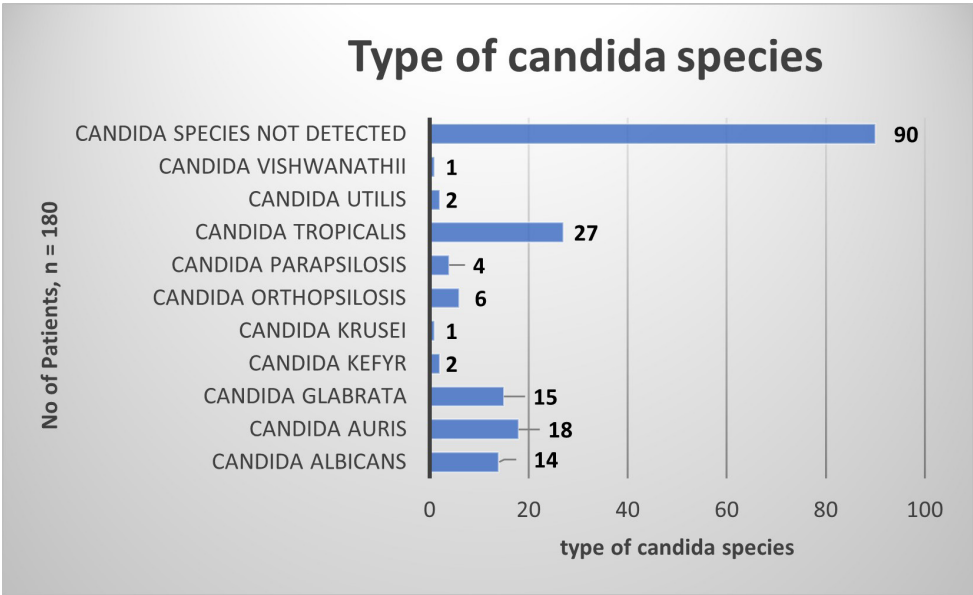


Figure 2: Comprehensive analysis of Candida species.

Table 2: Evaluation of drug administration routes and Treatment Span (n=180).

Route of administration	No of patients	Percentage (%)
Tablet	117	65%
IV	37	20%
Not administered due to fluconazole resistance	26	14%
Treatment Span	No of patients	Percentage
1-5 days	90	50%
6-14 days	59	32.8%
Above 14 days	5	2.8%
Not administered due to fluconazole resistance	26	14.4%

Figure 4 illustrated the specificity of fluconazole utilization, showing that most recipients were immunocompromised patients (84%). Only a small proportion received fluconazole in association with invasive medical devices (1%), while fluconazole was withheld in 15% of cases because of confirmed resistance, reflecting rational and evidence-based prescribing practices

DISCUSSION

The present study provides a clinically relevant overview of fluconazole utilization patterns, resistance trends, and Candida species distribution in a critical care-oriented patient population, with findings that highlights significant implications for antifungal stewardship in Indian healthcare settings.

In the comprehensive systematic review by Verma et al. (2021), encompassing 106 studies spanning 20 Indian states and comprising over 11,429 isolates, *C. albicans* was identified as the most prevalent species at 37.95% of total isolates, followed by (29.40%) *C. tropicalis*, (11.68%).

C. glabrata and (8.36%) *C. parapsilosis*. These proportions underscore the continued clinical relevance of *C. albicans*, while also highlighting the substantial representation of NAC species. The prominence of *C. tropicalis* and *C. glabrata* parallels findings from other Indian tertiary care studies, where regional surveillance has repeatedly demonstrated elevated prevalence of NAC species, particularly in bloodstream and urinary isolates (Guinea et al., 2014).

In our cohort, *Candida tropicalis* and *Candida glabrata* emerged as the predominant fluconazole- resistant species, accounting for 30% and 16.67% of resistant isolates, respectively. This observation is of particular concern, as both species are increasingly implicated in invasive candidiasis in India and are well recognized for their reduced susceptibility to azole antifungals.

The prominence of *C. glabrata* aligns with its intrinsic tendency toward dose-dependent susceptibility and acquired resistance, especially following prior azole exposure. Similarly, the rising burden of *C. tropicalis* reflects a shifting epidemiological landscape in which non-albicans *Candida* species are progressively replacing *Candida albicans*, particularly in critically ill and immunocompromised patients. These findings reinforce the critical importance of species-level identification and susceptibility testing to guide antifungal therapy rather than reliance on empirical azole use.

The demographic profile of patients receiving fluconazole demonstrated a male predominance (59.4%), a trend commonly

reported in hospital-based fungal infection studies. This may reflect higher healthcare-seeking behavior, increased occupational exposure, or a higher prevalence of underlying comorbid conditions, including diabetes, chronic organ disease, and smoking-related comorbidities among males. Additionally, more than half of the study population comprised elderly patients aged ≥ 60 years (52.8%), underscoring the heightened vulnerability of this age group to fungal infections. Age-associated immune senescence, coexisting comorbid conditions, frequent hospitalizations, and exposure to invasive procedures collectively predispose elderly patients to opportunistic *Candida* infections, making antifungal optimization particularly crucial in this population.

Prescription pattern analysis revealed a predominant use of oral fluconazole formulations, reflecting the drug's excellent oral bioavailability, favorable pharmacokinetic profile. This prescribing preference suggests rational clinical decision-making, especially in clinically stable patients where oral therapy offers

therapeutic equivalence to intravenous administration while reducing hospital costs and catheter-related complications. Such practice is especially relevant in resource-limited settings, where optimizing cost without compromising efficacy is essential.

Empirical antifungal therapy accounted for 50% of fluconazole use in this study. While early empirical initiation is often justified in critically ill patients to reduce morbidity and mortality associated with delayed treatment, it also poses the risk of unnecessary antifungal exposure when cultures are negative or non-fungal etiologies are present. The remaining patients received culture guided therapy, enabling targeted treatment based on microbiological evidence. This balanced approach highlights the ongoing clinical challenge of initiating timely therapy while minimizing inappropriate antifungal use. The observed fluconazole resistance rate of 14.4% is clinically significant and emphasizes the urgent need to strengthen antifungal stewardship programs, promote early diagnostic testing, and encourage timely de-escalation or modification of therapy based on culture and susceptibility results.

Table 3: Types of Therapy Administered (n=180).

Type of therapy	No of patients	Percentage (%)
Empirical (culture not sent)	30	16.67%
Empirical (culture sent-no growth)	60	33.33%
Culture guided (fluconazole continued)	64	35.56%
Culture guided (fluconazole discontinued due to resistance)	26	14.44%

Species distribution analysis further demonstrated *Candida tropicalis* as the most frequently isolated organism (30%), followed by *Candida auris* (20%). The emergence of *C. auris* is particularly alarming, given its association with multidrug resistance, nosocomial outbreaks, and high mortality in critically ill patients. Its presence in a substantial proportion of isolates highlights the growing threat posed by this pathogen in Indian hospitals and underscores the need for stringent infection control measures alongside judicious antifungal use.

Urine was the most common site of *Candida* isolation (57%), reflecting a high prevalence of *candiduria*, especially among elderly, hospitalized, and immunocompromised individuals. While *candiduria* may often represent colonization rather than true infection, inappropriate treatment can contribute to

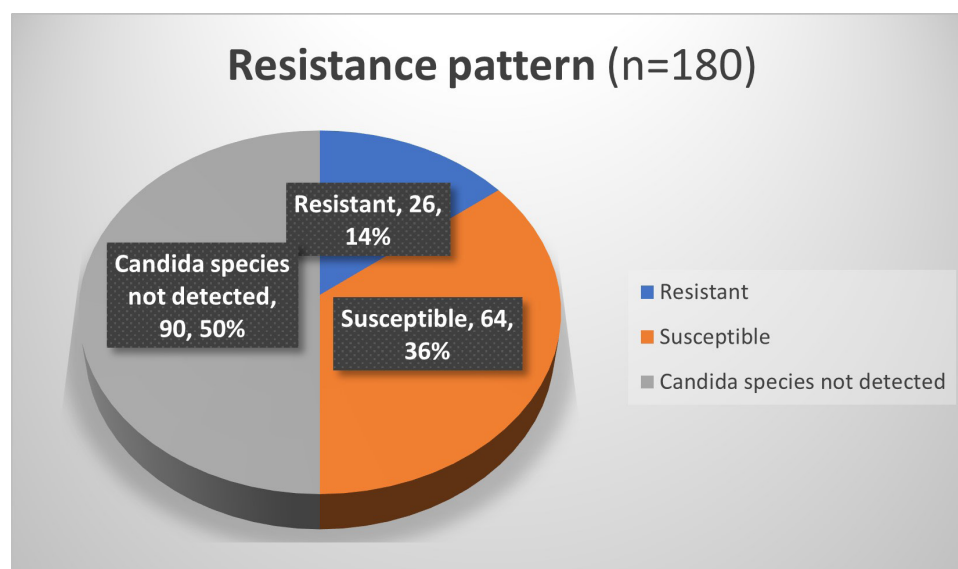


Figure 3: Resistance pattern.

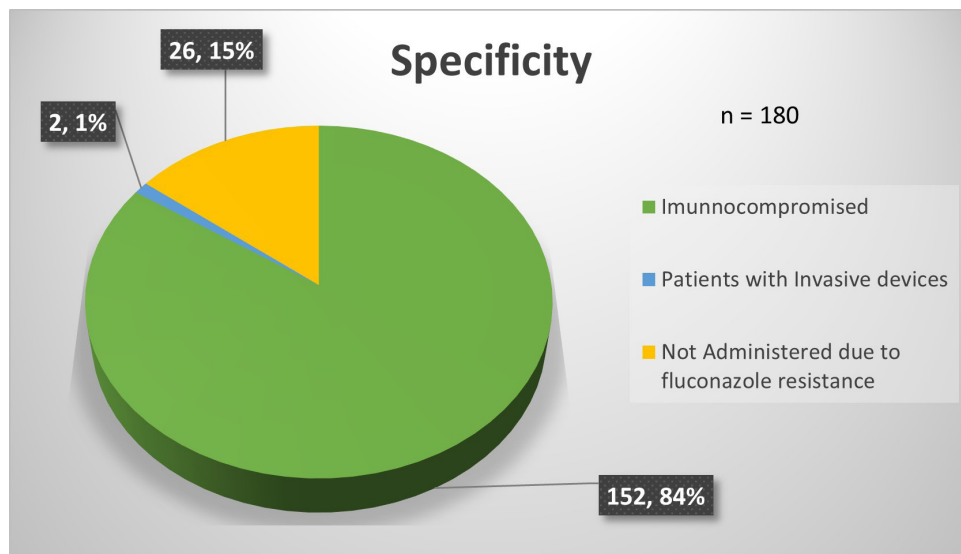


Figure 4: Specificity.

Table 4: Site of isolation (n=180).

Site of isolation	No of patients	Percentage (%)
GI Tract	7	7.78%
Dermatological	6	6.67%
Bloodstream	22	24.44%
CNS	2	2.22%
Urine	52	57.78%
Bones	1	1.11%
Not administered due to fluconazole resistance	90	50%

antifungal resistance. These findings emphasize the importance of correlating microbiological results with clinical features and adhering to evidence-based guidelines when deciding on antifungal therapy.

Fluconazole utilization patterns depicted, further support rational prescribing practices, with most recipients being immunocompromised patients (84%). This aligns with current clinical understanding that such patients are at heightened risk for invasive fungal infections and often warrant antifungal prophylaxis or therapy. The minimal use of fluconazole in patients with invasive medical devices (1%) suggests cautious and selective prescribing, likely influenced by awareness of device-associated biofilms and reduced azole efficacy in such settings. Importantly, fluconazole was withheld in 15% of patients due to documented resistance, indicating appropriate therapeutic restraint and responsiveness to microbiological data.

Overall, this study highlights the evolving epidemiology of *Candida* infections, the growing challenge of fluconazole resistance, and the critical importance of integrating clinical

judgment with microbiological evidence. A human-centered approach balancing early treatment for vulnerable patients while safeguarding antifungal efficacy through stewardship is essential. Strengthening routine surveillance, promoting culture-guided therapy, and implementing robust antifungal stewardship programs are imperative to optimize patient outcomes and curb the further emergence of resistant *Candida* species in critical care settings

CONCLUSION

This Drug Utilization Review (DUR) of Fluconazole conducted in a tertiary care hospital highlights important trends in antifungal prescribing practices, patient demographics, and emerging resistance patterns. Fluconazole use was observed predominantly among elderly male patients, likely due to comorbidities, prolonged hospitalization, immunosuppression, and increased exposure to invasive procedures that predispose them to fungal infections. Oral fluconazole was commonly prescribed because of its high oral bioavailability and suitability for clinically stable patients. Empirical therapy was frequently initiated in high-risk and immunocompromised patients before microbiological confirmation, emphasizing the need for timely culture and susceptibility reports to optimize therapy and prevent unnecessary antifungal exposure. The study also demonstrated a shift toward non-albicans *Candida* species, particularly *Candida tropicalis* infection, along with increasing fluconazole resistance, underlining the importance of species identification, antifungal susceptibility testing, and continuous microbiological surveillance. These findings support the implementation of robust antifungal stewardship strategies to promote rational prescribing, limit resistance development, reduce adverse effects, and improve clinical outcomes. Further multicenter studies with larger populations and long-term monitoring are recommended

to strengthen evidence-based antifungal prescribing policies and infection management practices.

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ABBREVIATIONS

AIDS: Acquired Immunodeficiency Syndrome; **AMB:** Amphotericin B; **CDC:** Centers for Disease Control and Prevention; **GI:** Gastrointestinal; **DUE:** Drug Utilization Evaluation; **MIC:** Minimum Inhibitory Concentration; **NAC:** Non-albicans Candida; **NCDC:** National Center for Disease Control; **SP:** Study Population.

CONFLICT OF INTEREST

The authors declare that there is no conflict of interest.

ETHICAL APPROVAL

This study received approval from the Institutional Ethics Committee of Deenanath Mangeshkar Hospital & Research Center (Approval No. PharmD_2024_Oct_SP_25).

PATIENT CONSENT

The authors hereby affirm that informed consent was duly obtained from all participants prior to their inclusion in the study, in accordance with established ethical standards.

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