Original Article

Comparative Study of Side Effects Associated with Different Oral Antifungal Regimens in Patients with Superficial Dermatophytosis

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Abstract

Background: Superficial dermatophytosis is among the commonest fungal infections found across the globe with rising incidences of chronicity, recurrences, and resistance to therapy, especially in India. Systemic antifungal medications like Itraconazole, Terbinafine, and Fluconazole are commonly prescribed for the treatment of extensive and recurrent cases of dermatophytosis; but long-term administration of these drugs can result in toxicities to the liver, kidneys, blood cells, electrolytes, and the heart. The aim is to conduct a comparative study on the toxicity profiles of systemic Itraconazole, Terbinafine, and Fluconazole for the management of superficial dermatophytosis. **Material and Methods:** In this prospective observational comparative study, patients were randomly distributed between 3 groups Itraconazole, Terbinafine, and Fluconazole in tertiary care hospital, at TMU Hospital and Research for 4 weeks. There biochemical and clinical profile was evaluated to understand the side effects of these oral antifungal drugs. **Results:** No differences were seen between the three medication groups at baseline regarding haematology, biochemistry, kidney function, and liver function parameters. The only differences that were noted were in baseline serum sodium ($p = 0.010$) and serum chloride ($p = 0.048$), which were within the physiological normal range. At follow up, there was no difference between the three drug groups in hemoglobin levels, white cell count, platelets count, renal function markers, liver enzymes, bilirubin, serum electrolytes, or blood pressure measures (all $p > 0.05$). A minimal increase in the mean diastolic blood pressure was seen in the itraconazole group at follow up but this was not statistically significant. **Conclusion:** All three antifungals were effective and safe in the treatment of patients with Superficial Dermatophytosis.

Keywords: Superficial dermatophytosis; itraconazole; terbinafine; fluconazole; adverse effects; safety profile.

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Introduction

Superficial dermatophytosis, previously viewed as a trivial and readily manageable superficial infection, has in recent years become an important dermatological and public health issue in India. The clinical profile of the disease has changed significantly, with growing intensity, unusual presentations, therapeutic unresponsiveness, and disturbingly high rates of relapse. This change has been linked to various factors, such as the abuse of antifungal drugs, improper prescribing habits, extensive self-medication, and increasing issue of antifungal resistance. All these tendencies not only compromise therapeutic outcomes but also make disease control more difficult, generating a critical demand for solid clinical research to evaluate the effects of prevailing curative practices. [1,2]

Oral antifungal drugs like griseofulvin, terbinafine, itraconazole, and fluconazole remain the key drugs for the treatment of superficial dermatophytosis, especially in extensive, chronic, recurrent, or nail and scalp infections. Their systemic nature allows better penetration into keratinized tissue, which is a must in severe infections. But with their growing use has arrived mounting awareness of harmful drug interactions, from minor gastrointestinal upset to possibly serious hepatotoxicity, hematological disorders, cardiovascular toxicity, and renal impairment. Although most physicians are knowledgeable about these risks, in clinical practice, monitoring is frequently inadequate, especially in ambulatory dermatologic practice. One of the most significant side effects associated with systemic antifungals is hepatotoxicity, which is especially true when used for extended durations. Cases of high levels of liver enzymes, cholestatic hepatitis, and rare occurrences of liver failure have been noted in patients who have used Itraconazole, Terbinafine, and Fluconazole. Blood disorders, such as neutropenia, thrombocytopenia, and anemia, have been observed on rare occasions.[3]

Itraconazole, Terbinafine, and Fluconazole are common orally administered antifungals prescribed in extensive and recurring dermatophytosis cases. Terbinafine, which is an allylamine type

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of antifungal, works by suppressing the enzyme known as squalene epoxidase. The end result is depletion of ergosterol followed by the death of the fungus. This antifungal is fungicidal in nature and is usually very efficient in dealing with dermatophytes. Itraconazole and fluconazole are classified under azole group of antifungals and work by inhibiting cytochrome P450-dependent lanosterol 14-α-demethylase enzymes, which inhibit ergosterol synthesis and development of fungal cell membranes. Itraconazole is generally broad-spectrum in action and has good cutaneous absorption; it is therefore extensively used in chronic and stubborn cases of dermatophytosis. On the other hand, although fluconazole is less lipophilic compared to itraconazole, it is more widely used because of its high oral availability, dosing, and better safety profile. [4–7]

Thus, this study was conducted with an aim to investigate and compare the safety profile of oral Itraconazole, Terbinafine, and Fluconazole in patients of superficial dermatophytosis. Parameters like hematological, biochemical, liver function test, renal function test, electrolytes, and blood pressure were analyzed in patients during treatment to detect any adverse effects of these commonly used antifungals.

Materials and Methods

This was a prospective observational comparative study conducted in the Department of Dermatology, Venereology and Leprology at TMU Hospital and Research Centre over a period of 18 months (August 2024 to January 2026). Adult patients diagnosed with superficial dermatophytosis and fulfilling the eligibility criteria were enrolled consecutively and followed during treatment with oral antifungal agents. Baseline clinical and laboratory assessments were performed, followed by scheduled follow-up visits to monitor adverse effects and laboratory parameters.

Sample Size and Sampling Method: Convenient sampling technique was used. Calculation of the sample size was done based on the formula to estimate single proportion for 95% confidence level and 7.5% margin of error. This was done using the formula.

$$N=Z^2_{\alpha}Pq/d^2$$

The sample size obtained was 136. Taking into account the loss of 20%, the sample size is 170.

Inclusion and Exclusion Criteria:

The study was conducted using patients clinically diagnosed as suffering from superficial dermatophytosis, visiting the Outpatient Department of Dermatology, Venereology and Leprology (DVL) of TMU Hospital and Research Centre, in the period under study. The eligible patients were those of both sexes, aged above 18 years, who were ready to take part in the study and signed informed consent form.

The patients having deranged liver function test results, electrolyte imbalance, preexisting cardiac ailments, or hypertension were excluded from the study. Pregnant ladies and patients under any other antifungal treatment other than the one under study were excluded from the study population.

Data Collection and Clinical Evaluation

Data collection involved the use of a structured questionnaire that had been designed beforehand and contained information about demographics, medical history, length of illness, therapy history, and information about the oral anti-fungal drugs that have been prescribed to the patients. Data regarding any adverse effect that has occurred during the period of therapy such as gastrointestinal adverse effects, skin adverse effects, neurological adverse effects, liver adverse effects, and other systemic adverse effects were also gathered. Clinical examination was done to diagnose the type, distribution, extent, and severity of dermatophytosis.

In patients suffering from superficial dermatophytosis, there was a follow-up visit carried out to look for any drug adverse effect in relation to the selected antifungal drugs. Causality and severity of the adverse effects were assessed using clinical methods using patient's history, examination results, and laboratory investigations where necessary. Baseline investigations such as liver function tests and serum electrolyte tests were done prior to commencement of therapy and followed up in patients suspected of experiencing adverse effects from the drugs.

Treatment and Follow-up

The patients were given appropriate antifungal drugs according to the nature and severity of superficial dermatophytosis as per recommended protocols for their treatment. Commonly used oral antifungal drugs in the treatment of such infections included terbinafine (250 mg), itraconazole (100 mg), and fluconazole (150 mg). Participants were instructed regarding drug dose, course of treatment, and side effects. The subjects were recalled to OPD for follow-up sessions on certain fixed dates as per schedule at OPD of the investigating dermatologist for conducting the study.

Statistical Analysis: Data was collected from a Microsoft Excel spreadsheet and further, statistical analysis was performed using IBM SPSS Statistics. Frequency, percentage, mean, and standard deviation were employed for describing the data set. The adverse effects frequency and pattern for various oral antifungal drugs were calculated. The association between categorical variables was analysed using Chi-square test and Fisher's Exact Test. Statistical significance was determined at $p < 0.05$.

Ethical Considerations: The ethical clearance for the experiment was received from the Institutional Ethics Committee of Teerthanker Mahaveer University, (Ref. No. TMU/IEC/PG 2024-25/065). Informed consent was taken from all participants, and participants were allowed to leave the experiment at any time.

Results

A total of 170 participants were randomly selected for different antifungals inc. Itraconazole (n=103, 60.5%), Terbinafine (n=37, 21.7%), and Fluconazole (n=30, 17.6%) for treatment of Superficial dermatophytosis. The type of drug and age distribution was also compared. It was observed that median age was highest in terbinafine group (38 years), followed by fluconazole (33 years) and itraconazole (32 years). [Table 1].

The socio-demographic study revealed that there was male preponderance among the participants with 53.6% male and 46.4% female participants with majority (32.4%) of participants in age group 18-28 years, followed by 29.4% in 29-39 years, 18.8% between 40-49 years, 10.5% between 50-59 years and

8.8% were >60 years. The mean age of study participants was 36.6 + 14.4 years. Further, it was observed that maximum number of participants (27.1%) were educated till senior secondary level, followed by high school (23.5%), primary (15.3%), secondary (14.7%), graduate (10.6%) and 8.8% were illiterate [Table 2].

The baseline levels of haematological, biochemical, renal, hepatic, and electrolytes were similar in Itraconazole, Terbinafine, and Fluconazole groups. Median haemoglobin concentrations were found to be 13.6 g/dL (IQR: 11-14.4) in itraconazole, 14 g/dL (IQR: 12.9-14.1) in terbinafine, and 13 g/dL (IQR: 11.1-14.8) in the fluconazole group without showing any significant difference among them (p = 0.60). In addition, total leukocyte count, platelet count, and random blood sugar levels were comparable among all three groups (p > 0.05 for all). [Table 3]

The liver function test parameters such as total bilirubin, direct bilirubin, indirect bilirubin, alkaline phosphatase, SGOT, and SGPT had no significant differences in the baseline values between the groups (p > 0.05 for all). Furthermore, renal function parameters such as blood urea and serum creatinine levels also did not differ significantly among the treatment groups (p = 0. p = 0.610 and p = 0.979, respectively). [Table 3]

In the case of serum electrolytes, serum sodium and chloride were the parameters that showed statistical significance in their results among the groups. Median values of serum sodium were found to be 141 mmol/L (IQR: 140-142.8), 140 mmol/L (IQR: 139-141), and 141 mmol/L (IQR: 140-143.5) in the Itraconazole, Terbinafine, and Fluconazole groups, respectively (p = 0.010). Similarly, median values of serum chloride were observed to be 102 mmol/L (IQR: 101-103), 101.5 mmol/L (IQR: 100-103), and 103 mmol/L (IQR: 101-104.5) in the respective groups (p = 0.048). The study reflected that the differences were in the normal range and were clinically non-significant. Serum potassium levels were also comparable between the tree groups (p=0.335). [Table 3]

During the 4th visit, there was similarity between the haematological, biochemical, renal, and liver function indices in the Itraconazole, Terbinafine, and Fluconazole groups. Statistically, there were no differences between the groups based on their p values (>0.05). The median value of haemoglobin for the Itraconazole, Terbinafine, and Fluconazole groups was 13.6 g/dL (IQR = 11.2–15.4), 13.9 g/dL (IQR = 12.4–15.3), and 13.3 g/dL (IQR = 11.4–15.2) (p = 0.68). Also, in terms of total leukocyte count and platelet count, similarity was observed (p=0.147 & p= 0.521, respectively). [Table 4]

No statistically significant difference in terms of blood glucose, serum electrolytes, or renal parameters was observed. The median random blood sugar in the itraconazole group was 96 mg/dL (86-104), while that of the terbinafine group was 95 mg/dL (86-103), and the fluconazole group was 101 mg/dL (85-105) (p = 0.458). Blood urea and serum creatinine levels were statistically not different among all groups (p = 0.745 and p=0.589, respectively). [Table 4]

Likewise, the parameters of liver function such as total, direct and indirect bilirubin, alkaline phosphatase, SGOT and SGPT were not significantly different among the treatment groups (all p > 0.05). Median SGOT values were 26 U/L (23–40), 28 U/L (25–45), and 25 U/L (22–43) in the Itraconazole, Terbinafine, and Fluconazole groups, respectively (p = 0.712) and median values of SGPT were 29 U/L (25–52), 27 U/L (21–50), and 30 U/L (23–54), respectively (p = 0.867). Serum sodium, potassium and chloride levels were also similar between groups with no statistically significant differences. In general, laboratory parameters at visit 4 did not reveal any significant hematologic, hepatic, renal, or electrolyte abnormalities attributable to any of the treatment regimens. [Table 4]

Blood pressure values of systole and diastole did not differ significantly across the three groups receiving either itraconazole, terbinafine, or fluconazole, and they were alike for all these groups. Median baseline systolic blood pressure (SBP) was 120 (IQR: 110-120) in itraconazole group, 115 (IQR: 110-127.5) in terbinafine group and 120 in fluconazole group (p = 0.11). Baseline diastolic blood pressure (DBP) was also similar between the groups: 80 mmHg (IQR: 72.5–90), 80 mmHg (IQR: 72.5–87.5) and 80 mmHg in the itraconazole, terbinafine and fluconazole groups, respectively (p = 0.939). [Table 5]

Follow-up in the 3rd week showed no statistically significant differences in the blood pressure parameters among the three treatment groups. Median SBP values at the 3rd week were 120 mmHg (IQR: 110–130) in the itraconazole group, 115 mmHg (IQR: 110–127) in the terbinafine group and 120 mmHg in the fluconazole group (p = 0.716). Median DBP values at 3rd week were 90 mmHg (IQR: 80-95), 80 mmHg (IQR: 75-85), and 80 mmHg (IQR: 75-90) in Itraconazole, Terbinafine, and Fluconazole groups, respectively (p = 0.487). Overall blood pressure parameters were comparable between the treatment groups throughout the study period. [Table 5]

Table 1: Distribution of study participants as per type of drug.

Type of drug	Frequency	Age distribution
Itraconazole	103	32 (24-45)
Terbinafine	37	38 (30-49)
Fluconazole	30	33 (23-44)
Total	170	170

Table 2: Sociodemographic profile of study of participants (n=170).

Socio-demographic Variable	N (%)
Gender	
Male	91 (53.6)
Female	79 (46.4)

Age	
18-28	55 (32.4)
29-39	50 (29.4)
40-49	32 (18.8)
50-59	18 (10.5)
>60	15 (8.8)
Educational status	
Secondary	25 (14.7)
Senior secondary	46 (27.1)
Primary	26 (15.3)
High school	40 (23.5)
Illiterate	15 (8.8)
Graduate	18 (10.6)

Table 3: Comparison of baseline lab investigation between type of drugs.

Baseline Lab parameter	Itraconazole Median (IQR)	Terbinafine Median (IQR)	Fluconazole Median (IQR)	p-value
Hb	13.6 (11-14.4)	14 (12.9-14.1)	13 (11.1-14.8)	0.60
TLC	7100 (6000-9000)	7475 (6250-9000)	7000 (5835-8200)	0.42
Platelets	279000(235000-385000)	287000 (242000-392000)	274000(230000-378000)	0.512
RBS	89 (80-100)	88 (80-97.75)	89 (80-100)	0.946
Total bilirubin	0.5 (0.4-0.7)	0.5 (0.4-0.8)	0.5 (0.35-0.7)	0.909
Direct Bilirubin	0.2 (0.12-0.3)	0.2 (0.1-0.3)	0.2 (0.15-0.4)	0.138
Indirect Bilirubin	0.2 (0.2-0.39)	0.25 (0.2-0.4)	0.3 (0.15-0.31)	0.249
ALP	80 (70-100)	84.5 (70.7-100.25)	85 (71-103)	0.820
Blood urea	28 (22-32)	28 (20-32.6)	28 (22-32)	0.610
Sr. Creatinine	0.6 (0.5-0.8)	0.66 (0.5-0.74)	0.7 (0.5-0.8)	0.979
SGOT	21 (18.25-22)	20 (18-22)	21 (18-22.5)	0.993
SGPT	22 (19-25)	20 (18.7-23.25)	20 (18-25.5)	0.470
Sr. Na	141 (140-142.8)	140 (139-141)	141 (140-143.5)	0.010*
Sr. K+	4.17 (4-4.3)	4.2 (4-4.3)	4.2 (4-4.35)	0.355
Sr. Cl-	102 (101-103)	101.5 (100-103)	103 (101-104.5)	0.048*

Table 4: Comparison of lab investigations at fourth visit between type of drugs.

Lab parameter at 4th visit	Itraconazole Median (IQR)	Terbinafine Median (IQR)	Fluconazole Median (IQR)	p-value
Hb	13.6 (11.2-15.4)	13.9 (12.4-15.3)	13.3 (11.4-15.2)	0.68
TLC	7100 (6300-8300)	6900 (6200-8800)	6500 (5900-7900)	0.147
Platelets	285000 (240000-380000)	292000 (245000-385000)	278000 (235000-375000)	0.521
RBS	96 (86-104)	95 (86-103)	101 (85-105)	0.458
Total bilirubin	0.55 (0.42-0.78)	0.52 (0.42-0.72)	0.58 (0.42-0.76)	0.645
Direct Bilirubin	0.25 (0.16-0.44)	0.20 (0.14-0.40)	0.30 (0.14-0.47)	0.734
Indirect Bilirubin	0.30 (0.24-0.38)	0.32 (0.26-0.44)	0.28 (0.20-0.34)	0.189
ALP	87 (76-122)	90 (79-112)	84 (73-107)	0.312
Blood urea	27 (24-32)	28 (23-34)	26.5 (24-32.5)	0.745
Sr. Creatinine	0.70 (0.56-0.84)	0.69 (0.53-0.82)	0.74 (0.56-0.80)	0.589
SGOT	26 (23-40)	28 (25-45)	25 (22-43)	0.712
SGPT	29 (25-52)	27 (21-50)	30 (23-54)	0.867
Sr. Na	142 (140-145)	141.5 (139.5-144.5)	142.5 (140.5-146)	0.789
Sr. K+	4.15 (4.05-4.35)	4.4 (4.2-4.6)	4.25 (4.15-4.65)	0.512
Sr. Cl-	102.5 (101-106)	102 (100.5-104.5)	103.5 (102-106)	0.105

Table 5: Comparison of blood pressure values across type of drug therapy.

Blood Pressure	Itraconazole Median (IQR)	Terbinafine Median (IQR)	Fluconazole Median (IQR)	p-value
SBP at baseline	120 (110-120)	115 (110-127.5)	120 (110-)	0.11
SBP at 3rd week	120 (110-130)	115 (110-127)	120 (110-)	0.716
DBP at baseline	80 (72.5-90)	80 (72.5-87.5)	80 (70-)	0.939
DBP at 3rd week	90 (80-95)	80 (75-85)	80 (75-90)	0.487

Discussion

This longitudinal observational study conducted at the Dermatology, Venereology, and Leprosy Department of Teerthanker Mahaveer Medical College and Research Centre evaluated the clinical and biochemical side effect profile of selected oral antifungals—Itraconazole, Terbinafine, and Fluconazole—in 170 adults diagnosed with superficial dermatophytosis. The primary aim was to document biochemical side effects of these agents. Following institutional ethics committee approval, patients aged over 18 years with confirmed diagnosis (via clinical examination and KOH mount), but without pre-existing derangements in liver function tests,

electrolytes, cardiac disease, or hypertension, were enrolled using convenient sampling over an 18-month period. Baseline and serial monthly follow-ups (up to four visits) involved comprehensive assessments including complete blood counts, liver enzymes (SGOT/SGPT), renal function (urea, creatinine), serum electrolytes (Na, K, Cl), total/direct/indirect bilirubin, ALP, random blood sugar, platelets, blood pressure monitoring, and treatment outcome evaluation. The findings revealed high treatment completion rates (86.6–89%) across all drugs, with no clinically significant toxicity; most laboratory parameters remained within normal reference ranges, though mild baseline anemia (37.5%) and transient elevations in bilirubin/ALP were noted, highlighting the overall safety of these antifungals in low-risk patients under structured monitoring.

Herein, it was observed that majority (33%) of participants were in age group 18-28 years, followed by 29% in 29-39 years, 19% between 40-49 years, 11% between 50-59 years and 9% were >60 years. The mean age of study participants was 36.6 years. This was comparable to study conducted by Thakare V et al,[8]8and Vishwanath V et al,[9] where mean age of participants was reported as 32.2 years and 35.68 ± 11.32 years respectively.

In study conducted by Hassan Z et al mean age of participants in itraconazole and terbinafine group was reported as 31.87+ 13.4 years and 39+ 14 years, which was in concurrence to present study. The findings of present study were also like study conducted by Amruthadevi TS et al,[10] where also similar mean age was reported among participants in itraconazole and fluconazole group i.e., 38.63±5.25 years and 37.23±6.78 years.

Regarding gender distribution, it was observed that there was male preponderance among the participants with 53.6% male and 46.4% female participants. The findings were similar to study conducted by Thakare V et al,[8] where also male preponderance was reported.

The findings of the present study were congruent with study conducted by Amruthadevi TS et al,[10] where also 58.5% of participants were females. In study conducted by Yadav P et al, male preponderance was reported, which was similar to the present study. The similar findings in various studies indicate that superficial dermatosis infection is prevalent n 20-30 years age group, with higher preponderance among males as compared to females.

Regarding occupation, it was observed that maximum number of participants (32.7%) were housewives, followed by student (20.2%), laborer (19.6%), farmer (15.5%), business (8.3%) and only 0.6% of participants were unemployed. The finding was similar to study conducted by Hassan Z et al,[11] where also maximum number of participants were housewife's, followed by students.

These similar finding indicates that housewives and students were more at risk of developing superficial dermatosis as compared to other occupations. In educational status, it was observed that maximum number of participants (27%) were educated till senior secondary level, followed by high school (24%), primary (15%), secondary (14.9%), graduate (10.7%) and 8.9% were illiterate.

In the present study, it was observed that maximum number of participants (60.2%) were on Itraconazole therapy, followed by Terbinafine (22%) and Fluconazole (17.8%). The findings were in contrast to study conducted by Swaroopa K et al, where equal number of participants were reported in each group. this difference could be accounted to the reason of different study design of both studies i.e., comparative study design for later study as compared to prospective observational study design of present study.

Regarding lab investigation at baseline, it was observed that in maximum number of patients (37.5%) hemoglobin levels were deranged, followed by 10.7% with deranged direct bilirubin level, 10.1% with deranged ALP levels and 1.8% each with deranged platelets and indirect bilirubin.

Regarding lab parameters, it was observed that mean values for all variables were within normal limits at baseline and during follow up visits. Regarding comparison of lab parameters among different drug therapy, it was observed that all the three drugs were comparable at baseline with no statistically significant difference in lab parameters. The similar findings were also observed at third visit, where also no statistically significant difference was observed in lab values. The findings of the present study were comparable to study conducted by Tyagi H et al,[12] where also statistically non-significant difference among three drugs was reported. The findings were also congruent with those reported in study by Silva H et al,[13] which compared fluconazole and Itraconazole, where also no significant difference in biochemical parameters was reported. The similar findings in different studies indicate that all the three drugs have similar biochemical profile at baseline and during follow up visits. In study conducted by Hassan Z et al,[11] it was reported that there was no statistically significant difference in terbinafine and itraconazole regarding elevation of liver enzymes, which was in concurrence to present study.

In the current study, there were no statistically significant differences in SBP and DBP between the Itraconazole, Terbinafine, and Fluconazole groups at baseline and during the 3rd week of administration. Although a higher median DBP was seen in the itraconazole group during the 3rd week, this did not reach statistical significance. This indicates that the use of these three drugs in the short term does not lead to significant changes in patients' blood pressure levels.

Our results correlate with those from previous studies in which the impact of these antifungals on the cardiovascular system is assessed. However, itraconazole has been linked to cardiovascular side effects like hypertension, edema, and heart failure in the long-term course of therapy and in sensitive subjects. For instance, it is found that the incidence of itraconazole-induced hypertension is quite high according to Kline et al. [14] Also, itraconazole can cause other cardiovascular adverse events including heart problems as described by Teaford et al. [15] Our study demonstrates no change in BP, possibly due to the short-term use of the drug and proper patient selection.

These results confirm that Itraconazole, Terbinafine, and Fluconazole can be considered as being safe in terms of cardiovascular effects on the short term, although monitoring is recommended for the sake of patients having some risk factors for cardiovascular complications.

Conclusion

The present research provides strong evidence in favour of the safety profile of systemic antifungals such as Itraconazole, Terbinafine, and Fluconazole, when they are prescribed to patients with superficial dermatophytosis cases. The clinical and biochemical profile of the drugs in question with regard to the above-mentioned laboratory and hemodynamic variables has proven to be clinically acceptable during the course of the study. There was no clinical significance for changes in any of the laboratory and hemodynamic parameters in the groups receiving different antifungal therapy. However, some variations in the serum level of sodium and chloride at baseline, although statistically significant, did not exceed physiological values. Likewise, there were no differences between blood pressure parameters in the three groups.

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Conflicts of interest

There are no conflicts of interest.

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