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Original Research Article

Evaluation of prescription pattern of antifungal drugs in the dermatology department of a tertiary care teaching hospital

Abhishek S. Kalola*, Shreya M. Shah, Chirag B. Mistry

Department of Pharmacology, Government Medical College Baroda, Gujarat, India

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***Correspondence:**

Dr. Abhishek S. Kalola,

Email: abhi.kalola@gmail.com

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ABSTRACT

Background: In general, fungal infections are one of the contributors of disease burden in the community, but irrational use of antifungal drugs can result in unwanted adverse events or antifungal drugs resistance. The present study was designed to analyze the prescription pattern of antifungal drugs prescribed in the dermatology department of a tertiary care teaching hospital.

Methods: After getting permission from the ethics committee, this prospective observational cross-sectional study was conducted by analysis of prescriptions of 900 voluntary participant patients over a period of seven months in the dermatology outpatient department of a tertiary care teaching hospital in western India. Prescribed medicines' parameters were analyzed as per WHO/INRUD prescription indicators.

Results: Overall 900 prescriptions were analyzed, and among them around 50% patients were having tinea corporis and tinea cruris, making it the most common fungal infection. The most commonly prescribed antifungals were Clotrimazole (34.59%), followed by Fluconazole (31.61%) and Luliconazole (23.52%). Percentage of drugs prescribed from the WHO model list of essential medicines was 71.22%. Average number of antifungal drugs per prescription was $2.83 \pm 0.57\%$.

Conclusions: This study indicates prescribing practices of anti-fungal drugs and supportive medicines at tertiary care hospital that can be further improved by promoting prescribing by generic names. Overall final list of essential medicines at district level, state level and national level may vary as compared to the WHO list for anti-fungal drugs and doctors can consider alternative drugs as per domestic resistant pattern.

Keywords: Antifungal drugs, Prescription pattern, Drug utilization, Essential medicine

INTRODUCTION

In tropical countries like India, fungal infections are more common as compared to the cold weather countries. Overall fungal infections have increased in the last four decades due to environmental factors, increased use of broad-spectrum antifungal agents and an increasing prevalence of patients with immune deficiency states where there is a decrease in natural host defence.¹

Moreover, frequency of invasive fungal infections with the emergence of new species of pathogenic fungi have increased vastly, so, incorporation of new antifungal drugs in clinical practice has important implications for patient care as it can facilitate the use of prophylactic, empirical, pre-emptive and targeted treatment.²

In general, dermatological conditions account for almost 5% of antibiotic prescriptions worldwide and most of the conditions require prolonged treatment. Over a period of

time during follow up with multiple doctors, the skin conditions can be wrongly diagnosed and treated due to alteration of original morphology by topical steroids. Thus, continuous monitoring is required to evaluate the pattern of drug use to detect any changes from contemporary practices, local resistance pattern and latest treatment guidelines.³

Identification and understanding of prescription pattern as well as the quality of prescription in terms of rationality, drug interactions and financial burden of disease to the individual can be possible by drug utilization studies and these studies can have a favourable impact on improving the standards of treatment and identifying the problems related to polypharmacy, as well as drug-drug interactions. Periodic auditing of prescriptions in the form of drug utilization studies is an important tool to enhance the therapeutic efficacy, to optimize the cost of the treatment and to provide useful feedback to the clinician.² Aim of facilitating the rational use of drugs in population can be achieved by drug utilization research by analysis of prescription of a well-documented drug at an optimal dose, together with the correct information, at an affordable price and suggesting measures to improve prescribing habits.¹ According to WHO, the rational use of drugs helps in evolving standard treatment guidelines, averting inappropriate drug use, adoption of local essential list of drugs, and preventing irrational prescriptions. The study of prescription pattern is a component of medical audit that helps doctors to provide rational and cost effective medical care which can be beneficial to patients.¹ Region wise list of essential medicines can vary nation to nation as compared to global WHO suggested essential medicines list for anti-fungal drugs as per domestic resistant pattern. So, this study was carried out for analysis of pattern of dermatological diseases in this locality and to study the prescription pattern of antifungals in this institution. This study will help to understand antifungal prescription practices and also to develop local policies for appropriate use of antifungal drugs.

Aim and objectives

The aim of the present study was to analyse the prescription pattern of antifungal drugs in the dermatology outpatient department of a Tertiary care teaching hospital. Objectives of current study were to analyse the use of antifungal drugs in the dermatology outpatient department, to analyse prescriptions as per WHO/INRUD prescription indicators and to use ATC/DDD methodology to determine overuse/underuse of drug.

METHODS

After getting permission from the ethics committee, present hospital based prospective, observational, cross-sectional study was carried out in the dermatology outpatient department of Sir Sayajirao General Hospital, a tertiary care teaching hospital in western India. The study

was carried out for seven months from April 2021 to October 2021.

Sampling and sample size

Based on the data from the dermatology department, minimum 864 prescriptions with antifungal drugs were to be included to estimate 10% lowest prescribed antifungal drug with 20% relative precision and 95% confidence. Considering drop outs, we included the data from 900 prescriptions selected randomly and the data was entered in the pre checked case record form (CRF). A total of 900 patients were selected randomly from the outpatient department of dermatology who fulfilled the following inclusion and exclusion criteria.

Inclusion criteria

Inclusion criteria for current study were; patients who were prescribed at least one antifungal drug, either newly diagnosed or follow-up patients of either gender and of any age and patients who were willing to give written consent or assent.

Exclusion criteria

Exclusion criteria for current study were; patient/parent not willing to give consent for participation in study and psychiatric patients with skin disorder and unable to give informed written consent.

Data collection procedure

Patients attending the outpatient department of dermatology who were prescribed at least one antifungal drug were included in the study. Patients' demographic data, detailed medical history including drugs prescribed, it's dosage forms, route of administration, frequency of administration, indication and duration of therapy were recorded from the case papers in the case record form. Confidentiality and data safety were maintained throughout the study.

Data analysis

Data of overall 900 patients who fulfilled the inclusion and exclusion criteria was recorded in the Case Record Form. Analysis of demographic characteristics, diagnosis of the present condition and detailed treatment history was carried out. The recorded data was entered in excel spreadsheet and presented in the form of frequency distribution and mean \pm SD and percentage with the help of Microsoft Excel software.

RESULTS

Overall analysis of data was done for prescriptions of total 900 patients attending outpatient dermatology department who were prescribed antifungal drug/s.

Demographic profile

Age and gender wise distribution: Out of 900 patients, 524 (58.22%) were male and 376 (41.78%) were female. In this study, the youngest patient was of 1.5 years of age while the oldest patient was 82-year-old. Mean±SD of age of all patients was 36.07±12.96 (Table 1, Figure 1).

Table 1: Age and gender wise distribution.

Age groups (years)	Male	Female	N (%)
Upto 10	10	2	12 (1.33)
11-20	66	39	105 (11.67)
21-30	161	61	222 (24.67)
31-40	137	133	270 (30.00)
41-50	91	83	174 (19.33)
51-60	40	42	82 (9.11)
61-70	16	15	31(3.44)
71-80	2	1	3 (0.33)
81-90	1	0	1 (0.11)
Total	524	376	900 (100)

Table 2: Different fungal infections observed.

Diagnosis	N	%
Tinea Corporis+Tinea Cruris	440	48.89
Tinea Corporis	175	19.44
Steroid Modified Tinea	82	9.11
Tinea Cruris	72	8.00
Tinea Faciei	36	4.00
Tinea Pedis	25	2.78
Intertrigo Groin	16	1.78
Tinea Capitis	16	1.78
Onychomycosis	12	1.33
Candidial Intertrigo	5	0.56
Onychomycosis+Tinea Cruris+Tinea Corporis	3	0.33
Seborrheic Dermatitis	3	0.33
Tinea Mannum+Tinea Corporis	3	0.33
Tinea Versicolor	3	0.33
Onychomycosis+Paronychia	2	0.22
Tinea Intertrigo	2	0.22
Oral Candidiasis	1	0.11
Vulval Candidiasis	1	0.11
Tinea Cruris+Seborrheic Dermatitis	1	0.11
Tinea Barbae	1	0.11
Tinea Cruris+Tinea Corporis with Contact Irritant Dermatitis	1	0.11
Total	900	100

Different fungal infections encountered and antifungals prescribed

Fungal infections observed in patients: Most common fungal infection observed during this study was tinea corporis+ tinea cruris. There were 440 (48.89%) patients who had both tinea corporis+tinea cruris. tinea corporis

and steroid modified tinea were present in 175 (19.44%) and 82 (9.11%) patients respectively.

Table 3: Various antifungal drugs prescription pattern.

Antifungal drugs	N	%
Clotrimazole	881	34.59
Fluconazole	805	31.61
Luliconazole	599	23.52
Itraconazole	114	4.48
Ketoconazole	44	1.73
Oxiconazole	42	1.65
Terbinafine	29	1.14
Griseofulvin	14	0.55
Amorolfine	12	0.47
Miconazole	4	0.16
Ciclopirox	3	0.12
Total	2547	100

Table 4: Oral antifungal drugs.

Oral antifungal drugs	N	%
Fluconazole	805	83.94
Itraconazole	114	11.89
Terbinafine	26	2.71
Griseofulvin	14	1.46
Total	959	100

Table 5: Topical antifungal drugs.

Topical antifungal drugs	N	%
Clotrimazole	881	55.48
Luliconazole	599	37.72
Ketoconazole	44	2.77
Oxiconazole	42	2.64
Terbinafine	3	0.19
Amorolfine	12	0.76
Miconazole	4	0.25
Ciclopirox	3	0.19
Total	1588	100

Table 6: Treatment modalities.

Treatment modalities	N	%
Combined therapy (oral+topical)	895	99.44
Monotherapy (topical)	5	0.56
Total	900	100

Tinea cruris and tinea faciei accounted for 72 (8%) and 36 (4%) patients respectively. Other fungal infections observed in our study were tinea pedis, intertrigo groin, tinea capitis, onychomycosis, candidial intertrigo, onychomycosis+ tinea cruris+tinea corporis, seborrheic dermatitis, tinea mannum+tinea corporis, tinea versicolor, onychomycosis+paronychia, tinea intertrigo, oral candidiasis, vulval candidiasis, tinea cruris+seborrheic dermatitis, tinea barbae, tinea cruris+tinea corporis with contact irritant dermatitis accounting to 10.55% (Table 2).

Table 7: Other medications prescribed.

Group	N	%	Drugs
Antihistaminics	886	92.87	Chlorpheniramine maleate, Levocetirizine, Hydroxyzine
Analgesics	2	0.21	Ibuprofen
Antimicrobials	17	1.78	Soframycin, Doxycycline, Amoxicillin, Amoxicillin+Clavulanic, Azithromycin, Neomycin Cefadroxil, Clindamycin
Glucocorticoids	8	0.84	Clobetasol, Betamethasone
Retinoids	5	0.52	Adapalene, Benzoyl peroxide
Others	36	3.77	White soft paraffin Whitfield ointment, Lignocaine, Multivitamin

Table 8: WHO/INRUD prescribing indicators for this study.

Drug use Indicators	Result of analysis
Total number of prescriptions	900
Total number of drugs	3501
Total number of Antifungal drugs	2547
Average number of drugs per prescription	3.89±0.61%
Average number of the antifungal drugs per prescription	2.83±0.57%
Percentage of the Antifungal prescribed by generic name	73%
Percentage of Injectable drugs prescribed	0.00%
Percentage of the antifungal drugs prescribed from Gujarat essential drug list	71.80%
Percentage of the Antifungal drugs prescribed from WHO model list of essential medicines 22nd List (2021)	72.51%

Table 9: ATC-DDD classification of antifungal prescribed with calculated prescribed daily dose.

Drug	ATC Code	DDD (mg)	PDD (mg)	PDD/DDD
Fluconazole	J02AC01	200	70	0.35
Itraconazole	J02AC02	200	200	1
Griseofulvin	D01BA01	500	500	1
Terbinafine	D01BA02	250	500	2

Associated dermatological conditions: Apart from fungal infections, other associated dermatological conditions were eczema and acne vulgaris in 7 and 4 patients respectively.

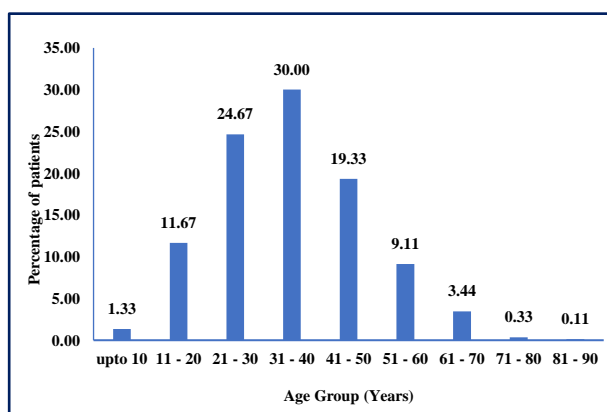


Figure 1: Age wise distribution of patients.

Antifungal drugs prescribing pattern: Among 900 patients, for 3501 times, different medicines were prescribed, out of which 2547 were antifungals. Among antifungal drugs

clotrimazole was prescribed for highest time (34.59%) followed by fluconazole (31.61%) and luliconazole (23.52%) (Table 3). Out of 2547 antifungals, 1588 were topical antifungal drugs and 959 were oral antifungal drugs. Most common topical antifungal was clotrimazole followed by luliconazole and ketoconazole. Most common oral antifungal was Fluconazole followed by itraconazole, terbinafine and griseofulvin (Table 4-5). Treatment modalities: Regarding treatment pattern, only five patients were prescribed topical agents. All other patients were prescribed combination therapy i.e., oral as well as topical antifungal agents (Table 6). Among 3501 prescribed medicines, only 0.17% were FDCs, which included amoxicillin+clavulanic acid in three patients and terbinafine+mometasone, adapalene+clindamycin as well as adapalene+benzoyl peroxide in one patient each. Accompanying medications prescribed: Apart from antifungal drugs, other drugs prescribed to these patients were antihistaminics, analgesics, antibiotics, corticosteroids etc. for associated dermatological or other conditions (Table 7). WHO/INRUD prescribing indicators: In the present study, total 3501 medicines were prescribed including antifungal and other drugs. So average number of drugs per prescription was 3.89±0.61%. Out of 3501 total medicines, 2547 were antifungal drugs

making it 2.83 ± 0.57 antifungal drugs per prescription. As all the patients included in the study were from OPD set up, all the medicines were prescribed by oral or topical route. Route of administration: Out of 3501 drugs 1857 (53.04%) drugs were prescribed by oral route while 1644 (46.96%) drugs were prescribed by topical route.

Analysis of prescribed antifungals from different list of essential medicine

Among eleven different antifungals prescribed, clotrimazole, fluconazole, itraconazole, griseofulvin, terbinafine and miconazole are from WHO model list of essential medicines-22nd List (2021) making it 72.51% of total antifungals prescribed. If we consider national list of essential medicines 2022, clotrimazole, fluconazole, itraconazole and griseofulvin and terbinafine are from the list making it 72.35% of total antifungal drugs. On the other hand analysis by looking into essential list of Gujarat State-Drug formulary, clotrimazole, fluconazole, itraconazole and terbinafine are from 2022 Gujarat State Drug formulary which accounted for 71.80% (Table 8). Anatomical therapeutic chemical-defined daily dose (ATC-DDD) classification of antifungal prescribed: Defined daily dose for the antifungal drugs prescribed by oral route was obtained from the WHO website. Prescribed Daily Dose was calculated by taking mean of different doses of a particular drug prescribed in all patients. Overall ratio of prescribed daily dose and defined daily dose of fluconazole and terbinafine was 0.35 and 2 respectively. For itraconazole and griseofulvin, PDD/DDD ratio was 1 (Table 9).

DISCUSSION

In India, dermatological diseases are one of the commonly encountered medical conditions in the outpatient department of dermatology and untreated dermatological diseases can have serious impact on people's quality of life in developing countries, where climate, socioeconomic status, religions are widely varied in different parts of country.¹ Dermatophytoses, commonly known as tinea or ring worm is a superficial fungal infection of keratinised structures such as skin, hair and nails. About 25% of the world population is affected by this disease and an individual person is likely to have a 10 to 20% life-time risk of acquiring dermatophytoses. It is also estimated that 30 to 70% of adults remain as asymptomatic carriers.⁴ The widespread use of antibiotics has contributed to alteration of normal flora of skin and the growing infection rate as fungal infections are known to occur after antibiotic therapy, which has the effect of killing the beneficial bacteria that normally suppress fungi.⁵ To identify medicinal factors, drug utilization studies emphasis on factors related to prescribing, dispensing, administering and taking of medication and its associated events like covering the medical and non-medical determinants.⁶ As per findings of the present study, prescriptions of 900 patients who were prescribed at least one antifungal drug were analyzed. Out of 900 patients, 58.22% were male and

41.78% were female. In the similar study conducted in northern India, total 1000 prescriptions with antifungals were analyzed, of which 43% were of male and 57% were of female patients.⁶ Gopimohan et al in their study observed similar result showing 59.6% male and 40.4% female.¹ Male predominance for fungal infections seen in majority of the studies can be due to more outdoor activities, less strong immune response compared to female and enhanced activity of macrophage and dendritic cell and associated inflammatory response in female compared with male.⁹

In the present study, more than half of the patients were between 21-40 years of age group 54.67%, followed by 41-50 years of age 19.33%. Mean age of all patients was 36.07 ± 12.96 years. This shows that majority of the patients were in their 3rd and 4th decade of life which represents the most active population in the society. Similar findings were seen in the study by Gopimohan et al and he observed highest cases in 18-35 years of age group.⁴ Similar study done by Vegada et al. reported maximum cases between 16-30 and 31-45 years of age group.⁷ In different other studies also most of the cases were from age group 16-30 year of age and 18-30 years of age.^{2,5} In the present study, most common fungal infection observed was tinea corporis with tinea cruris 48.89% followed by tinea corporis 19.44% and steroid modified tinea 9.11%. Other cases for which antifungals were prescribed were tinea corporis, tinea cruris, tinea pedis, intertrigo groin, tinea capitis, onychomycosis, seborrheic dermatitis and candidiasis. As per findings of study done by Bansal P et al. 2021 tinea cruris was reported in 41.50% patients followed by tinea corporis in 38.20% patients.⁶ Another study conducted by Shetty et al observed that tinea corporis constituted highest number of cases 50.27% followed by a combination of tinea corporis and tinea cruris. similarly, Yadav C K et al. in their study reported highest number of fungal infection cases of tinea cruris accounting to 41.5% of total patients.^{4,2}

Most of the fungal infections can be managed by combination of oral and topical antifungal therapy in an attempt to increase cure rate. In our study, 99.44% of patients received combination of topical and oral therapy during entire period. As per study of Vegada et al most of the patients 95.92% were treated with a combination of oral as well as topical antifungal drugs.⁷ In a study conducted by Gopimohan et al it was observed that majority of the patients received combination therapy.⁴ Among 900 prescriptions analyzed in the present study, clotrimazole 55.48% was most commonly prescribed topical antifungal drug followed by luliconazole 37.72% and ketoconazole 2.77%. Most commonly prescribed oral antifungal drugs in the present study were fluconazole 83.94%, followed by itraconazole 11.89%, terbinafine 2.71% and griseofulvin 1.46%. In the study done by Vegada et al 2015, clotrimazole was reported to be prescribed in 91.93% patients and fluconazole prescribed in 97.20% of patients. Fluconazole is most commonly prescribed oral antifungal drug because it's once-a-week dose schedule results in cost effective treatment and lower propensity of adverse effects.⁷ Similar utilization pattern was also seen in the

study done by Gopimohan et al.⁴ In the study done by Deb et al most frequently prescribed oral and topical antifungal drugs were terbinafine 64.81% and eberconazole 58.49% respectively.⁵ Apart from antifungal drugs, other drugs which were prescribed in our study patients were antihistaminics, analgesics, antibiotics, corticosteroids etc. for another dermatological or associated conditions. As per prescription pattern analysis based on WHO/INRUD, Average number of drugs in a prescription audit is an important factor. Polypharmacy increases the risk of drug interactions, ADRs, medication error, patients' poor compliance, under use of effective treatment and increased cost of therapy.⁷ Total 3501 different drugs were prescribed to 900 patients. Average number of drugs per encounter was $3.89 \pm 0.61\%$ and average number of antifungal drugs per prescription was $2.83 \pm 0.57\%$. In the study done by Gopimohan et al average number of drugs and antifungals prescribed were 3.12 and 2 respectively.⁴ In a study done in northern India also, similar result 3.68 and 2.33 was observed.⁶ In the study done by, Vegada et al average number of drugs and antifungals were 3.39 and 2.08.⁷ Similar utilization pattern was also seen in the study done by Yadav et al 3.18 and 2.02.² WHO model list of essential medicines represents minimum medicines need for basic health care system, listing the most efficacious, safe and cost-effective medicines for priority conditions.¹⁰

In the present study, percentage of antifungals prescribed from WHO Model list of essential medicine WHO - EML was 72.51% and from National list of essential medicines 2022 was 72.35%, while it was 71.80% from the state drug formulary. In a study conducted by Gopimohan et al the percentage of drug prescribed from WHO-EML was 33.08% and from National list of essential medicines was 66.92%.⁴ In a study conducted by Vegada et al the percentage of drugs prescribed from WHO-EML and NLEM were 43.14% and 56.86%.⁷ Out of 11 different Antifungal prescribed in present study, only 5 are from NLEM 2022. This indicates the need for a better synchronization between clinicians' prescribing and recommendations in NLEM. In the present study, commonest route of treatment was oral 53.04% followed by topical 46.96%. This finding is comparable with that of study done by Patil et al and Pathak et al.^{3,8} In the present study, only 0.17% out of total antifungal drugs prescribed were fixed drug combinations. The trend in the present study showed that physicians preferred prescribing monotherapy compared to fixed dose combination drugs. Same findings were seen in the study done by Vegada et al and Deb et al where FDC prescribed were 13.66% and 5.16%.^{5,7} Analysis done as per anatomical therapeutic chemical ATC/DDD classification of antifungal prescribed, the defined daily dose DDD is the assumed average maintenance dose per day for a drug used for its main indication in adults. The DDD is a unit of measurement and does not necessarily agree with the recommended or prescribed daily dose. The prescribed daily dose PDD is defined as the average dose prescribed according to representative sample of prescriptions. When the PDD/DDD ratio is either less than or greater than one,

it may indicate either under or over utilization of drugs. But it is important to note that the PDD can vary according to 'patient' and 'disease' related factors.⁶ The purpose of the ATC/DDD system is to serve as a tool for drug utilization monitoring and research to improve quality of drug use. One component of this is to present and compare drug consumption statistics. The ATC classification system and the defined daily dose DDD as a measuring unit have become the gold standard for drug utilization monitoring and research.¹¹

The DDD for fluconazole is 200 mg/day and PDD of fluconazole in present study was 70 mg/day. So, PDD/DDD ratio of fluconazole was 0.35, which suggest that the drug was underutilized in present study. DDD for Terbinafine is 250 mg/day, while PDD in present study was 500 mg/day. so, PDD/DDD ratio for terbinafine was 2. This may suggest that terbinafine was overutilized in this study. This statement can be a misinterpreted because PDD depends on many factors like condition for which the drug is used, severity and duration of the condition etc. For example, Dose of fluconazole for tinea corporis and tinea pedis is 150 mg bi weekly. Some authors suggest 100 mg daily for 2-4 weeks. In some conditions, it is given in the dose of 150 mg-450 mg once a week for 6 to 12 months. For some indication it is given 150 mg three times a day.¹² So, if DDD is not based on indication or severity, the PDD/DDD ratio for that particular drug is of little value. For other systemic antifungal drugs the PDD/DDD ratio was one. Similarly in a study conducted by Vegada et al calculated PDD for fluconazole was 270/7 mg/day and PDD/DDD ratio of was more than one.⁷ Overall final list of essential medicines at district level, state level and national level can very as compare to WHO list for anti-fungal drugs and doctors can consider alternative drugs as per local resistant pattern.

CONCLUSION

Most common fungal infection observed during this study was Tinea corporis with Tinea cruris. Most commonly prescribed topical antifungal was clotrimazole and oral antifungal was Fluconazole. Overall current study has managed to contribute substantial information regarding the drug utilization and pattern of various antifungal drugs prescribed in a tertiary care teaching hospital. The present study indicates that prescribing practices of drugs in tertiary care hospital can be improved by promoting generic name drug prescribing and drug from NLEM.

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