Original Article

Prescription auditing of griseofulvin in a tertiary care teaching hospital

M. Hepsi Bai Kirubha

Department of Pharmacy Practice, Sri Ramachandra College of Pharmacy, Sri Ramachandra University, Chennai, India

Address for correspondence:
M. Hepsi Bai Kirubha, Department of Pharmacy Practice, Sri Ramachandra College of Pharmacy, Sri Ramachandra University, Chennai - 600116, India.
E-mail: hkirubha@gmail.com

ABSTRACT

Background: Griseofulvin has been the mainstay of treatment for dermatophytosis since many years. Since it is a penicillium antibiotic and used commonly in the outpatient department, the prescription should be audited for its safety and quality. Clinical pharmacists being an important member of the healthcare system have an immense responsibility in delivering pharmaceutical care by auditing prescriptions in order to achieve rational and cost-effective medical care thereby improving patient's Quality of Life (QOL). **Aims:** To study the utilization of griseofulvin by auditing prescriptions, to assess the impact of griseofulvin on the QOL of patients and to emphasize role and responsibilities of a clinical pharmacist in the treatment outcome of dermatophytosis. **Methods:** 120 patients prescribed with griseofulvin in the dermatology outpatient department were included in the study. On the basis of therapeutic response, improvement was graded at the end of the treatment regimen. Adverse drug reactions (ADRs) during the treatment period were recorded. Laboratory investigations were performed at baseline and at the end of treatment. Quality of Life was measured at baseline and at the end of therapy. **Results:** 56.7% were females and 43.3% were males. The most common diagnosis was tinea corporis (44.17%) followed by tinea cruris (14.17%) and onychomycosis (9.17%). The most common ADR due to griseofulvin was headache (5.83%). 64.20% patients had complete cure following treatment with griseofulvin. The overall QOL score improved significantly following treatment with griseofulvin ($P < 0.0001$). **Conclusion:** Griseofulvin can be used extensively for the treatment of dermatophytosis as it has no serious adverse effects and has higher cure rates. Treatment with griseofulvin significantly improves the QOL in patients with dermatophytosis.

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INTRODUCTION

Dermatophytes are fungi that invade and multiply within keratinized tissues causing infection called dermatophytosis or Tinea or ringworm. Dermatophytosis contributes to a large extent in any skin clinic in India. Griseofulvin which was first discovered in 1939 was the first orally effective antifungal agent used against dermatophytes. It inhibits the fungal cell division by disruption of the mitotic spindle structure.[1-8] Absorption of griseofulvin can be increased by the administration of a fatty meal or by reducing the drug particle size.[9]

The role of pharmacist has changed dramatically over the past years. Recently, the profession of pharmacy has adopted pharmaceutical care as its mission and thereby extended the responsibility of the pharmacist. Clinical pharmacists, providers of pharmaceutical care have the responsibility to identify, prevent and resolve medication-related problems. The ultimate goal is to achieve optimal outcomes that improve the patient's Quality of Life (QOL). Pharmaceutical care provided by clinical pharmacists adds value to the care of patients. This added value includes improvement in patient outcomes, enhanced patient compliance and reduced healthcare costs.[10]

The word prescription audit focuses on 'evaluation of healthcare'. The aim of the present study is focused

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to study the utilization of griseofulvin by auditing prescriptions, to assess the impact of griseofulvin on the QOL of patients with dermatophytosis and to emphasize role and responsibilities of a clinical pharmacist in the treatment outcome of dermatophytosis.

METHODS

The study was performed between August 2006 and March 2007 in the dermatology outpatient department of Sri Ramachandra Hospital, Chennai. Patients of both sexes, all age groups and who were prescribed with micronized griseofulvin for the treatment of dermatophytosis were included in the study. Exclusion criteria were: 1) All other skin conditions other than dermatophytosis; 2) Patients who did not visit for follow up from the second week of treatment and 3) Patients with dermatophytosis but not prescribed with griseofulvin due to clinical conditions.

Clinical assessment and diagnosis was made by dermatologists and confirmed by direct mycologic microscopic examination of skin scrapings (in potassium hydroxide). Prior to initiation of treatment and during the treatment period, patients were subjected to laboratory monitoring including complete blood count and liver function test. Before initiating the therapy, patients were educated on: 1) Compliance; 2) Regular follow up; 3) Possible adverse drug reactions (ADRs) and 4) Precautions to be taken while taking griseofulvin. Griseofulvin was prescribed for 26 weeks for fingernail onychomycosis, 52 weeks for toenail onychomycosis and 6 weeks for other tinea infections.

Patient information leaflet on griseofulvin [Table 1] was prepared and oral counseling was given to patients for better compliance. Each patient was reviewed weekly or on alternative weeks. The ADRs were recorded as 'Yes' or 'No' in the ADR assessment form. Improvement was graded at the end of the treatment regimen by dermatologists as:

Grade 0: No improvement - No improvement
Grade I: Persistence of few papular lesions or erythema with mild-to-moderate itching. - Partial cure
Grade II: scaly lesion with or without itching
Grade III: disappearance of original lesion(s) with or without residual pigmentation.[11] - Complete cure

Table 1: Griseofulvin patient information leaflet[18]

- Griseofulvin is an antifungal medication used to treat fungal infections of the skin, hair and nails.
- Take the tablet with a fatty meal to increase absorption or with food or milk to avoid GI upset.
- Avoid taking alcohol.
- Use sunscreen, wear protective clothing and eye wear, and avoid excessive exposure to direct sunlight.
- Frequent blood tests may be required with prolonged therapy.
- Do not take this medication without first talking to your doctor if you are pregnant or breast-feeding.
- Men should avoid fathering a child during treatment with griseofulvin and for 6 months following treatment.
- Take the missed dose as soon as you remember.
- Take full course of medication.
- Do not discontinue the medication without consulting the prescriber.
- Less serious side effects may be more likely to occur. Continue to take the tablet and notify your doctor if you experience confusion, dizziness, drowsiness, nausea, vomiting or diarrhea; or increased sensitivity to sun.
- Practice good hygiene measures to prevent re-infection.
- Store in a cool dry place. Protect from light. Keep medicine away from reach of children.

The patients QOL was assessed at baseline and during the final visit with the questionnaire, 'Dermatology Life Quality Index' (DLQI) for adults and 'Children's Dermatology Life Quality Index-cartoon' (CDLQI) version for children. The questionnaire comprised 10 questions and applied for every patient. The questions were scored and summed up. The scoring was 0 to 30. The higher the score, the more QOL is impaired.[12] Formal permission was obtained from the authors of the questionnaire.

Statistical analysis

Data were entered into a software spreadsheet (Excel, Microsoft) and the age, gender, duration of the disease and QOL scores were summarized by mean ± SD and clinical variants of dermatophytosis, co-morbid diseases, scrapings for fungus test, ADRs and therapeutic response were summarized by percentage. Assessment of the patient's QOL at baseline and after treatment was analysed using paired sample *t*-test. The data were analyzed by the Graph Pad Instat version 3.05 statistical package.

RESULTS

Altogether 120 patients were enrolled in the study. In the study population there were 52 males (43.3%) with a mean age of 33.8 ± 16.04 years and 68 females (56.7%) with a mean age of 41.82 ± 15.32 years. It was

found that dermatophytosis were more common in the age group of 11–20 for males (17 patients) and 31–50 for females (16 patients in 31–40 and 16 patients in 41–50 age group). The mean duration of the disease was 11.82 ± 4.57 months.

Table 2 shows the clinical variants of dermatophytosis. Approximately 95% of patients had positive result for scraping for fungus test; 27 patients (22.5%) had past history of dermatophytosis. The co-morbid conditions seen in the study population were: 11 patients (9.2%) had diabetes mellitus, 10 patients (8.3%) had hypertension and one patient (0.8%) had bronchial asthma.

Ten patients out of 120 discontinued the therapy due to severity in the clinical conditions and adverse drug reactions. One hundred and ten patients (91.66%) completed the therapy with griseofulvin. Figure 1 shows the ADRs of griseofulvin during the study period. Seventeen patients (14.17%) reported ADR with griseofulvin. Clinical cure rate was good on treatment with griseofulvin. Seventy seven patients (64.2%) had complete cure with griseofulvin and 40 patients (33.3%) had partial cure with the drug. Only three patients (2.5%) showed no improvement in the cure rate. Using paired sample *t*-test the QOL scores were analysed. The CDLQI and DLQI scores before and after treatment were analysed under six subscales.

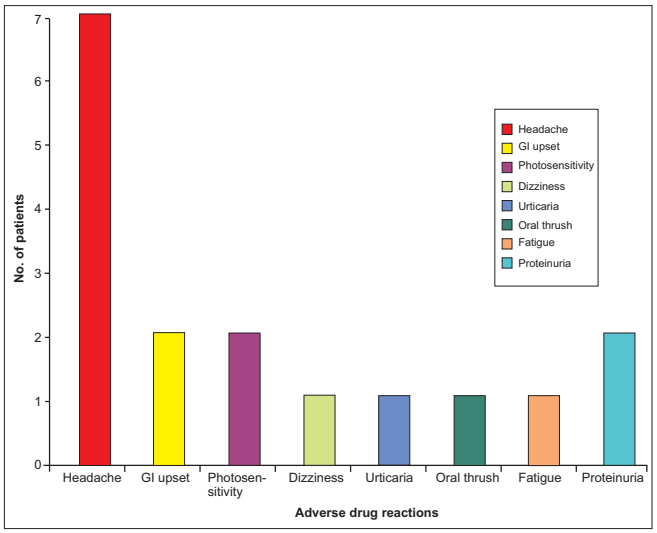

Figure 1: ADRs of griseofulvin during treatment

Tables 3 and 4 show that the overall mean CDLQI score was 9.14 ± 4.94 (SD) before treatment which decreased significantly ($P < 0.0001$) with a mean of 1.71 ± 1.36 (SD) after treatment. The overall DLQI score was found to be increased with a mean of 7.62 ± 4.27 (SD) which decreased significantly ($P < 0.0001$) with a mean of 1.49 ± 1.70 (SD) after treatment. The QOL in diabetic patients was also observed before and after treatment. The mean score before treatment was found to be 6.64 ± 5.43 (SD) which decreased significantly ($P < 0.0031$) after treatment with a mean of 1.00 ± 1.18 (SD).

Table 2: Clinical variants of dermatophytosis

Clinical types	Male (n = 52)	Female (n = 68)	Total (n = 120)
Tinea capitis	2 (1.66)	2 (1.66)	4 (3.33)
Tinea corporis	14 (11.66)	39 (32.5)	53 (44.16)
Tinea barbae	1 (0.83)	0 (0)	1 (0.83)
Tinea faciei	2 (1.66)	0 (0)	2 (1.66)
Tinea axillae	0 (0)	4 (3.33)	4 (3.33)
Tinea manuum	1 (0.83)	2 (1.66)	3 (2.5)
Tinea pedis	1 (0.83)	0 (0)	1 (0.83)
Tinea cruris	16 (13.33)	1 (0.83)	17 (14.16)
Tinea glutei	1 (0.83)	0 (0)	1 (0.83)
Tinea incognito	2 (1.66)	2 (1.66)	4 (3.33)
Onychomycosis	0 (0)	11 (9.16)	11 (9.16)
Tinea corporis and tinea faciei	0 (0)	2 (1.66)	2 (1.66)
Tinea corporis and tinea axillae	1 (0.83)	0 (0)	1 (0.83)
Tinea corporis and tinea cruris	5 (4.16)	2 (1.66)	7 (5.83)
Tinea corporis and tinea glutei	2 (1.66)	1 (0.83)	3 (2.5)
Tinea corporis and onychomycosis	1 (0.83)	1 (0.83)	2 (1.66)
Tinea faciei and tinea incognito	1 (0.83)	0 (0)	1 (0.83)
Tinea cruris and tinea incognito	0 (0)	1 (0.83)	1 (0.83)
Tinea cruris and tinea glutei	2 (1.66)	0 (0)	2 (1.66)

Figures in parentheses are in percentage

Table 3: Distribution of subscale scores of CDLQI (n = 28)

Subscales	Before treatment Mean ± SD	After treatment Mean ± SD	Two-tailed *P* value
Symptoms and feelings (items 1 and 2)	3.29 ± 1.69	0.68 ± 0.72	<0.0001‡
Leisure (items 4, 5 and 6)	1.86 ± 1.86	0.21 ± 0.49	<0.0001‡
School or holidays (item 7)	0.54 ± 0.74	0.07 ± 0.26	0.0045†
Personal relationships (items 3 and 8)	1.39 ± 1.62	0.32 ± 0.61	0.0003‡
Sleep (item 9)	1.46 ± 1.14	0.14 ± 0.36	<0.0001‡
Treatment (item 10)	0.57 ± 0.84	0.29 ± 0.53	0.0432*
Overall score	9.14 ± 4.94	1.71 ± 1.36	<0.0001‡

‡Extremely significant, †Very significant, *Significant

Table 4: Distribution of subscale scores of DLQI (*n* = 92)

Subscales	Before treatment Mean ± SD	After treatment Mean ± SD	2 tailed *P* value
Symptoms and feelings (items 1 and 2)	3.53 ± 1.52	0.78 ± 0.81	<0.0001‡
Daily activities (items 3 and 4)	1.34 ± 1.56	0.19 ± 0.45	<0.0001‡
Leisure (item 5 and 6)	0.36 ± 1.07	0.00 ± 0.00	0.0017†
Work and school (item 7)	1.47 ± 0.99	0.30 ± 0.53	<0.0001‡
Personal relationships (items 8and 9)	0.53 ± 0.93	0.04 ± 0.21	<0.0001‡
Treatment (item 10)	0.34 ± 0.62	0.14 ± 0.35	0.0039†
Overall score	7.62 ± 4.27	1.49 ± 1.70	<0.0001‡

‡Extremely significant, †Very significant, *Significant

DISCUSSION

This study on the prescription auditing of griseofulvin in a population of 120 patients showed a clear clinical improvement in patients treated with griseofulvin. This study shows several interesting epidemiologic features. In this study, dermatophytosis was more prevalent in females than in males. The most common diagnosis was tinea corporis (52.47%) followed by tinea cruris (14.16%) and onychomycosis (9.16%), which was similar to the report by Chee-leok *et al*..[5] Tinea corporis was seen more commonly in females (39 patients) than in males (14 patients).

Human contact (family members and friends) such as sharing combs, hats, towels, socks, shoes and clothes and close personal contact with playmates was observed to be greater source of infection than animal contact. Lack of personal hygiene and direct animal contact were found to be the causative factors. The majority of patients who were enrolled in the study were from low socioeconomic status. Hence these patients were counseled more on hygienic measures. The prevalence of onychomycosis and tinea corporis were seen among diabetic patients. The significance of onychomycosis, tinea pedis and tinea corporis in diabetic patients should be looked into because diabetics have impaired sensation that is often associated with trauma that can initiate infection. Additionally, these patients have altered resistance to infections resulting in widespread and recurring fungal and bacterial infection.[13-15] Hence, diabetic patients should be counseled on proper footcare to prevent the fungal infection of feet. No interactions were seen with the antidiabetic drugs.

Almost all patients completed the therapy with griseofulvin except 10 patients who were prescribed with newer antifungals because of severity in the clinical condition and adverse reactions due to griseofulvin. Headache, gastrointestinal upset, photosensitivity and proteinuria were the common ADRs observed in the study population. The side effects subsided after withdrawal of griseofulvin.

The overall mean QOL score of patients improved after treatment with griseofulvin. Although the newer oral antifungal agents have largely superseded griseofulvin, it still remains the safe and cost-effective drug for the treatment of dermatophytosis.[11,14,16] However the disadvantages of griseofulvin are that it requires prolonged treatment thereby leading to noncompliance; contraindicated in pregnancy, hepatic impairment and porphyria and has side effects such as headache, photosensitivity and gastrointestinal disturbances.[5-20]

CONCLUSION

From this study, it can be concluded that griseofulvin can be used extensively for the treatment of dermatophytosis as it has no serious adverse effects and also the clinical cure rates are higher. Dermatophytosis significantly lowers the QOL of patients. Treatment with griseofulvin has a significant improvement in the QOL in these patients indicating that griseofulvin has a good treatment outcome in tinea infections. Proper education on personal hygiene to patients plays a key role in the prevention of spreading the infection to others. Clinical pharmacist key responsibility of providing proper counseling on the use of medication improves the treatment outcome of dermatophytosis.

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