



Original Article

Development of a Personal Formulary for Uncomplicated Vaginal Candidiasis by Residents of Pharmacology and Gynaecology

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ABSTRACT

Background: Vaginal candidiasis is one of the most common causes of vulvovaginal complaints among women of reproductive age, with nearly 75% of women experiencing at least one episode during their lifetime. Although multiple azole antifungals are available for treatment, prescribing practices often vary and may not always be guided by systematic evaluation of efficacy, safety, cost, and convenience. The P-drug concept promotes rational and evidence-based selection of medicines through structured comparison.

Aim: To develop a personal formulary for uncomplicated vaginal candidiasis using the P-drug concept among residents of Pharmacology and Gynaecology.

Materials and Methods: This study was conducted in the Department of Pharmacology, IGIMS, Patna. The P-drug for uncomplicated vaginal candidiasis in adult non-pregnant women was selected using the WHO 6-step approach. Four azole antifungals available under the Janaushadhi scheme, Clotrimazole vaginal tablet, Clotrimazole 2% vaginal gel, Fluconazole tablet, and Itraconazole capsule, were evaluated. Drugs were compared based on four parameters: efficacy, safety, cost, and convenience according to the P-drug concept of Joshi and Jayawick Ramarajah. Each parameter was scored from 1 to 10 and assigned weighted values of 0.4, 0.3, 0.2, and 0.1, respectively. The total weighted score was calculated for each drug, and the highest-scoring drug was selected as the personal formulary drug.

Results: Among the evaluated drugs, Fluconazole 150 mg single-dose tablet achieved the highest total score (9.0), followed by Clotrimazole vaginal tablet (8.4), Clotrimazole vaginal gel (7.5), and Itraconazole capsule (7.3). Fluconazole demonstrated superior efficacy, lowest cost, and maximum convenience with an acceptable safety profile, making it the preferred P-drug for uncomplicated vaginal candidiasis.

Conclusion: By applying rational drug selection principles with greater emphasis on efficacy and safety, Fluconazole 150 mg single oral dose was selected as the personal formulary drug for uncomplicated vaginal candidiasis. The structured evaluation enhanced critical appraisal skills among residents and promoted safe, effective, and economical prescribing practices in routine gynaecological care.

Keywords: Vaginal candidiasis, P-drug, Fluconazole, Rational drug use, Azole antifungals, Personal formulary.

INTRODUCTION

Vaginal candidiasis, also referred to as vulvovaginal candidiasis, is a fungal infection of the vulva and vagina caused predominantly by *Candida albicans* [1]. It is characterised by inflammation of the vaginal mucosa resulting from overgrowth of *Candida* organisms, which are otherwise commensals of the normal vaginal flora. The condition may present as an uncomplicated or complicated disease depending on severity, recurrence, host factors, and species involved. The

infection typically manifests with symptoms such as intense pruritus, vulvar burning, dysuria, dyspareunia, and a characteristic thick, curdy white vaginal discharge [2]. Vaginal candidiasis is one of the most common causes of vulvovaginal complaints among women of reproductive age and constitutes a significant public health burden worldwide. It is estimated that nearly 75% of women experience at least one episode during their lifetime, and about 40–50% have recurrent episodes [3]. Globally, recurrent vulvovaginal candidiasis affects millions of women annually, leading to considerable morbidity, impaired quality of life, loss of productivity, and increased healthcare expenditure. In the Indian context, vaginal candidiasis is frequently encountered in both outpatient and inpatient gynaecological practice, particularly among women with diabetes, pregnancy, antibiotic exposure, and immunocompromised states. The warm and humid climate in many parts of India, along with socio-cultural and hygienic factors, further contributes to its high prevalence, making it a common reason for gynaecological consultations. The diagnosis of vaginal candidiasis is primarily clinical but should ideally be supported by laboratory confirmation. A detailed history and thorough pelvic examination remain the cornerstone of diagnosis. Typical findings include vulvar erythema, oedema, fissures, and adherent white plaques over the vaginal walls. Microscopic examination of vaginal discharge using saline or 10% potassium hydroxide (KOH) mount may demonstrate budding yeast cells or pseudohyphae [4]. Vaginal pH is usually normal (≤ 4.5), which helps differentiate it from bacterial vaginosis and trichomoniasis [5]. In recurrent or complicated cases, culture and species identification are recommended to guide appropriate therapy, especially in the setting of antifungal resistance [6]. The most common causative organism of vaginal candidiasis is *Candida albicans*, accounting for the majority of cases worldwide. However, non-*albicans* species such as *Candida glabrata*, *Candida tropicalis*, *Candida krusei*, and *Candida parapsilosis* are increasingly being reported, particularly in recurrent infections and among immunocompromised individuals. The rising incidence of non-*albicans* species is clinically significant because these organisms may exhibit reduced susceptibility to commonly used azole antifungals, thereby complicating management and increasing the risk of treatment failure [7]. The treatment of uncomplicated vaginal candidiasis primarily focuses on azole antifungal agents, which are highly effective at clearing the infection by inhibiting the synthesis of ergosterol in the fungal cell membrane. These medications are available in various formulations, including topical creams, ointments, and vaginal suppositories (such as Clotrimazole, Miconazole, or Tioconazole) that range from single-dose to seven-day regimens. However, the drug of choice for most patients is a single oral dose of Fluconazole (150 mg) [8]. It is widely preferred due to its high clinical cure rate, convenience, and superior patient compliance compared to multi-day vaginal applications. While topical azoles are safer during pregnancy, oral Fluconazole remains the gold standard for non-pregnant individuals with uncomplicated cases. In recurrent or complicated cases, prolonged or maintenance therapy may be required. Selection of therapy depends on severity, patient preference, pregnancy status, cost considerations, and local resistance patterns. Although multiple effective antifungal agents are available in the market, prescribing practices may vary widely due to differences in clinician preference, pharmaceutical promotion, availability, and cost. In this context, the concept of developing a personal formulary becomes highly relevant. The choice of antifungal therapy is not always based on a systematic evaluation of efficacy, safety, cost, and convenience, which are the core principles of rational drug use advocated by the World Health Organisation. A personal formulary encourages clinicians to critically analyse available drug options and select the most appropriate agent based on objective criteria rather than habit or external influence. Developing a personal formulary for vaginal candidiasis by residents of Pharmacology and Gynaecology can promote evidence-based, safe, effective, and economical prescribing practices, ultimately contributing to improved patient care and rational use of antifungal agents.

METHODOLOGY

This study was carried out in the Department of Pharmacology, Indira Gandhi Institute of Medical Sciences, Patna, Bihar (India), among the residents of the Department of Pharmacology and Gynaecology. A personal formulary for antimicrobial therapy of vaginal candidiasis was developed after thorough discussion among the residents. In case of disagreements or doubt, senior faculty members were consulted.

P-drug for vaginal candidiasis was selected using the WHO 6-step approach.

Step 1: Define the Diagnosis: Uncomplicated vaginal candidiasis in adult, non-pregnant women, diagnosed clinically with or without microscopic confirmation.

Step 2: Specify the Therapeutic Objective

- Eradication of *Candida* infection
- Relief of symptoms such as itching and discharge
- Prevention of recurrence
- Minimisation of adverse effects
- Improvement in patient comfort and quality of life

Step 3: Identify Effective Drug Groups

Topical and oral azole antifungals.

Step 4: Compare Drugs Using P-Drug Selection Criteria

Residents were taught how to analyse and give scores (α) to drugs used for vaginal candidiasis available in the market. Four parameters, according to the P-drug concept of Joshi and Jayawick Ramarajah [9], efficacy, safety, cost and convenience were taken into consideration for each group and their drugs.

1. Efficacy was derived according to the efficacy profile as per the published literature. Drugs with more efficacy were given a higher score.
2. Safety of a drug was described according to the side effect profile as per the published literature. Drugs with more side effects were given a lower score.
3. Janaushadhi[10] was used to determine the cost of drugs. The Pradhan Mantri Bhartiya Janaushadhi Pariyojana (PMBJP) is a flagship campaign launched by the Department of Pharmaceuticals, Government of India, to provide quality generic medicines at affordable prices to all citizens. Originally introduced in 2008 and revamped in 2015, the scheme operates through dedicated outlets known as Janaushadhi Kendras, which offer drugs and surgical items at prices 50% to 90% lower than their branded counterparts. By procuring medicines from WHO-GMP certified suppliers and ensuring quality through NABL-accredited laboratory testing, the initiative dispels the myth that low-priced generic drugs are inferior in efficacy. As of 2026, the scheme has expanded significantly with a target of 20,000 functional Kendras across the country, saving citizens billions in out-of-pocket healthcare expenses while simultaneously promoting entrepreneurship and self-employment for pharmacists and NGOs [10, 11]. A lower score was given to drugs with a higher cost. Drugs not available under the Janaushadhi scheme were excluded from the study.
4. Convenience was compared according to the patient compliance, dosage form, dosage schedule and route of administration.

Scores were given to each four parameters from 1 to 10 for each drug. Each parameter was given a fractional numerical rating (β) according to the importance, i.e. 0.4 for efficacy, 0.3 for safety, 0.2 for cost and 0.1 for convenience. Score (α) was multiplied by fractional numerical rating (β) to get the total score ($\gamma = \alpha \times \beta$). A higher total score indicates a better value.

Step 5: Select the P-Drug

Based on the total weighted score, the drug with the maximum score was selected as the personal formulary drug for uncomplicated vaginal candidiasis.

Step 6: Prescribe the P-Drug

A personal formulary having details of Sample Prescription, Patient Counselling, Monitoring and Follow-up was made. Then the senior residents and postgraduate students kept a copy of the personal drug formulary.

RESULTS

Azoles (both topical and oral) form the mainstay of the treatment of uncomplicated vaginal candidiasis. Below is the price comparison of the available azoles on Janaushadhi.

Table 1: Azole Antifungals Used in Uncomplicated Vaginal Candidiasis

Drug	Dosage Form	Dose	Frequency	Route	Duration of Treatment	Price per unit	Total Cost
Clotrimazole	Vaginal tablet	100 mg	Once daily (at bedtime)	Intravaginal	6 days	1.407/tablet	8.442
	Vaginal gel (2%)	5 g applicatorful	Once daily (at bedtime)	Intravaginal	7 days	42.19/30g	42.19
Fluconazole	Tablet	150 mg	Single dose	Oral	Single day	5.16/tablet	5.16
Itraconazole	Capsule	200 mg	Once daily	Oral	3 days	8.25/capsule	24.75

(Cost: in rupees)

Accordingly, the following scores were given to each drug.

Table 2: Selection of Personal Drugs for Vaginal Candidiasis

Drug	Efficacy (0.4)	Safety (0.3)	Cost (0.2)	Convenience (0.1)	Total Score
Clotrimazole (Vaginal Tablet)	8 (3.2)	9 (2.7)	9 (1.8)	7 (0.7)	8.4
Clotrimazole	8 (3.2)	9 (2.7)	5 (1.0)	6 (0.6)	7.5

(Vaginal Gel 2%)					
Fluconazole (Tablet)	9 (3.6)	8 (2.4)	10 (2.0)	10 (1.0)	9
Itraconazole (Capsule)	8 (3.2)	7 (2.1)	6 (1.2)	8 (0.8)	7.3

Since Fluconazole (Tablet 150 mg single dose) has the highest total score (9.0), it is selected as the P-drug for uncomplicated vaginal candidiasis. Accordingly, the following personal formulary was prepared.

Table 3: Personal Formulary of Fluconazole Tablet 150 mg for Vaginal Candidiasis	
DOSAGE	Uncomplicated Vaginal Candidiasis: 150 mg single oral dose.
WHAT TO TELL THE PATIENT	
Information:	Fluconazole is an antifungal medicine effective against <i>Candida</i> species causing vaginal infection. It works by inhibiting fungal cell membrane synthesis and helps relieve itching, discharge and discomfort.
Side Effects:	Nausea, abdominal pain, headache, dizziness; rarely elevated liver enzymes or allergic reaction.
Contraindications:	Hypersensitivity to azole antifungals; caution in hepatic impairment and in patients taking interacting drugs (e.g., warfarin, certain antiarrhythmics). Avoid in pregnancy unless clearly indicated.
Instructions:	Take one tablet of Fluconazole 150 mg orally as a single dose. Swallow with water. It can be taken with or without food.
Next Appointment:	Review if symptoms persist beyond 3–5 days or worsen.
Follow-up:	If symptoms recur within 2 months, further evaluation for recurrent vulvovaginal candidiasis is advised.

DISCUSSION

Rational drug use requires that patients receive medications appropriate to their clinical needs, in adequate doses, for an appropriate duration, and at the lowest possible cost [12]. The concept of personal formulary development encourages residents to critically analyse available therapeutic options using objective criteria rather than relying solely on habit, promotional influence, or anecdotal experience. In the present exercise, four azole antifungals commonly used in uncomplicated vaginal candidiasis were evaluated using the weighted criteria of efficacy (0.4), safety (0.3), cost (0.2), and convenience (0.1), consistent with the WHO Guide to Good Prescribing [13] and the P-drug concept described by Joshi and Jayawickramarajah [9]. This structured approach allows systematic comparison and promotes evidence-based prescribing. Clotrimazole vaginal tablet/pessary was assigned an efficacy score of 8/10 because topical azoles are well established to achieve clinical and mycological cure rates of approximately 80–90% in uncomplicated vulvovaginal candidiasis [14]. However, its efficacy was considered slightly lower than systemic therapy in terms of uniform tissue penetration. Safety was scored 9/10 because clotrimazole has minimal systemic absorption when administered intravaginally, and adverse effects are usually limited to mild local irritation or burning. It is considered safe even during pregnancy, which further strengthens its safety profile. The cost score was 9/10 based on the value derived from the cost sheet in Table 1 (₹8,442), indicating that it is an economical option. Convenience was scored 7/10, as intravaginal insertion for 6 days may cause discomfort, embarrassment, and compliance issues, particularly in working women or those with limited privacy. Clotrimazole 2% vaginal gel demonstrated efficacy comparable to the vaginal tablet formulation and was therefore also assigned 8/10 for efficacy. Its safety profile remains favourable due to minimal systemic exposure, and thus it received 9/10 for safety. However, its cost (₹42,190) was higher relative to other selected options, resulting in a lower cost score of 5/10. Convenience was scored 6/10 because gel formulations require applicator use, may be messy, and can cause leakage, particularly when administered for multiple days. These practical issues reduce patient acceptability and adherence despite adequate therapeutic efficacy.

Fluconazole 150 mg single-dose oral therapy received the highest efficacy score of 9/10. Multiple randomised controlled trials and international guidelines, including CDC and widely accepted gynaecological references, report high clinical and mycological cure rates with single-dose fluconazole in uncomplicated cases. Its systemic action ensures effective eradication of *Candida* species, contributing to reliable outcomes. Safety was scored 8/10 because fluconazole is generally well tolerated, with adverse effects such as nausea, abdominal discomfort, and headache being mild and transient. Rare hepatotoxicity and drug interactions have been reported, as documented in standard pharmacology texts such as Goodman & Gilman's and other authoritative sources, which justifies a slightly lower safety score compared to topical azoles. The

cost score was 10/10, as per the cost (₹5.160), making it the cheapest among the evaluated drugs. Convenience was assigned the maximum score of 10/10 due to its single oral dose regimen, absence of local discomfort, and excellent patient compliance, which are significant advantages in routine clinical practice.

Itraconazole capsule was assigned an efficacy score of 8/10, as it is effective in uncomplicated vaginal candidiasis but has not consistently demonstrated superiority over fluconazole in this setting. Its safety was scored 7/10 because, as a systemic azole, it carries potential risks of hepatotoxicity, significant drug–drug interactions due to CYP3A4 inhibition, and possible negative inotropic effects, as described in standard pharmacology literature [15]. These considerations reduce its safety margin compared to fluconazole and topical azoles. The cost score of 6/10 was based on the cost of ₹24.750, reflecting a moderate expense relative to other options. Convenience was rated 8/10 because it is administered orally and typically for a short duration, but may require more than a single dose, thereby reducing compliance compared to single-dose fluconazole.

When all four parameters were weighted and total scores calculated, fluconazole achieved the highest overall score, followed by clotrimazole vaginal tablet, clotrimazole gel, and itraconazole. The higher weightage given to efficacy and safety appropriately reflects their clinical importance, while cost and convenience ensure practical applicability in real-world Indian settings. This structured evaluation demonstrates that although topical azoles remain highly safe and effective, single-dose oral fluconazole offers superior convenience and cost-effectiveness without significant compromise in safety, thereby emerging as the preferred P-drug for uncomplicated vaginal candidiasis. The exercise highlights how objective scoring and critical appraisal can guide rational prescribing and strengthen clinical decision-making among residents in pharmacology and gynaecology.

CONCLUSION

By applying the principles of rational drug use and the P-drug concept with greater weightage to efficacy and safety, followed by cost and convenience, fluconazole 150 mg single oral dose emerged as the most suitable personal drug for the treatment of uncomplicated vaginal candidiasis among the evaluated azole antifungals. Although topical clotrimazole preparations demonstrated excellent safety and good efficacy, fluconazole provided superior convenience and cost-effectiveness without significant compromise in safety, resulting in the highest overall score. This structured exercise enabled residents of Pharmacology and Gynaecology to critically appraise therapeutic options using objective criteria and evidence-based literature rather than routine prescribing habits. The development of a personal formulary through systematic evaluation promotes rational, safe, effective, and economical prescribing practices and is expected to enhance clinical decision-making and patient care in routine gynaecological practice.

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