

**COMPARATIVE STUDY ON FORMULATION OF MICONAZOLE AND
NYSTATIN IN THE TREATMENT OF VAGINAL CANDIDIASIS****K. Gajalakshmi*, M. Praveen Kumar, M. Vijayalakshmi, V. Krishnan**

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ABSTRACT

Vaginal candidiasis is one of the most common fungal infections affecting women, mainly caused by *Candida albicans*. It is often associated with symptoms such as vaginal itching, irritation, burning sensation, and abnormal discharge, which can significantly affect a woman's comfort and quality of life. Effective antifungal therapy is therefore important for both symptom relief and prevention of recurrence. The present study focuses on the comparative evaluation of two commonly used antifungal drugs, miconazole and nystatin, formulated for the treatment of vaginal candidiasis. Miconazole is an imidazole antifungal agent that acts by inhibiting the synthesis of ergosterol, an essential component of the fungal cell membrane. This disruption weakens the membrane and ultimately leads to

the death of the fungal cells. Nystatin, on the other hand, is a polyene antifungal antibiotic that binds directly to ergosterol in the fungal membrane, creating pores that cause leakage of intracellular components and fungal cell destruction. Both drugs are widely available in vaginal dosage forms such as creams, tablets, and suppositories for local administration. This comparative study evaluates the effectiveness of the formulations based on parameters such as antifungal activity, symptom relief, patient tolerance, and recurrence of infection. Previous clinical observations indicate that both medications are effective in managing vaginal candidiasis. However, miconazole formulations may provide faster symptom relief and slightly higher cure rates, while nystatin remains a safe and reliable option with minimal systemic absorption and good patient tolerance. In conclusion, both miconazole and nystatin formulations are effective in the treatment of vaginal candidiasis. A comparative

understanding of their formulation characteristics and therapeutic outcomes can help healthcare professionals select the most appropriate treatment option for better patient care.

KEYWORDS: Miconazole is an imidazole antifungal agent that acts by inhibiting the synthesis of ergosterol, an essential component of the fungal cell membrane.

INTRODUCTION

Vaginal candidiasis is a common fungal infection affecting a large number of women worldwide, primarily caused by *Candida albicans*. It is characterized by symptoms such as itching, irritation, burning sensation, and abnormal vaginal discharge, which can significantly affect a woman's quality of life. Factors such as antibiotic use, hormonal changes, weakened immunity, and poor hygiene can increase the risk of developing this condition.

Antifungal therapy plays a crucial role in the management of vaginal candidiasis, with topical formulations being widely preferred due to their targeted action and reduced systemic side effects. Among the commonly used antifungal agents, miconazole and nystatin have been extensively employed in clinical practice. Miconazole, an imidazole antifungal, works by inhibiting the synthesis of ergosterol, an essential component of the fungal cell membrane, thereby disrupting cell integrity. In contrast, nystatin, a polyene antifungal, binds directly to ergosterol in the fungal cell membrane, leading to increased permeability and eventual cell death.

The formulation of these drugs into suitable dosage forms, such as creams, gels, or suppositories, plays a vital role in determining their effectiveness, stability, and patient compliance. Differences in drug release, absorption, and retention at the site of infection can influence therapeutic outcomes.

This comparative study focuses on evaluating the formulation aspects of miconazole and nystatin in the treatment of vaginal candidiasis. It aims to analyze their effectiveness, formulation characteristics, and overall performance to identify the most suitable option for better patient outcomes.

CAUSES OF VAGINAL CANDIDIASIS

Vaginal candidiasis is primarily caused by the overgrowth of *Candida* species, especially *Candida albicans*, which is normally present in small amounts in the vaginal flora. Under

certain conditions, this harmless organism can multiply rapidly and lead to infection. The following factors contribute to the development of vaginal candidiasis.

Antibiotic Use

The use of broad-spectrum antibiotics can disturb the natural balance of vaginal microorganisms by reducing beneficial bacteria such as *Lactobacillus*. This creates a favorable environment for fungal overgrowth.

Hormonal Changes

Fluctuations in hormone levels during pregnancy, menstruation, or due to the use of oral contraceptives can alter the vaginal environment, making it more susceptible to fungal infections.

Weakened Immune System

Individuals with reduced immunity, such as those with chronic illnesses or undergoing immunosuppressive therapy, are at a higher risk of developing candidiasis due to decreased resistance to infections.

Uncontrolled Diabetes Mellitus

High blood glucose levels can promote the growth of fungi, as excess sugar in vaginal secretions provides an ideal medium for *Candida* proliferation.

Poor Personal Hygiene

Inadequate or improper hygiene practices can contribute to microbial imbalance and increase the risk of infection.

Tight or Non-Breathable Clothing

Wearing tight-fitting clothes or synthetic underwear can create a warm and moist environment, which supports fungal growth.

Excess Moisture in the Genital Area

Prolonged dampness due to sweating or not drying properly after bathing can encourage fungal multiplication.

Use of Irritating Products

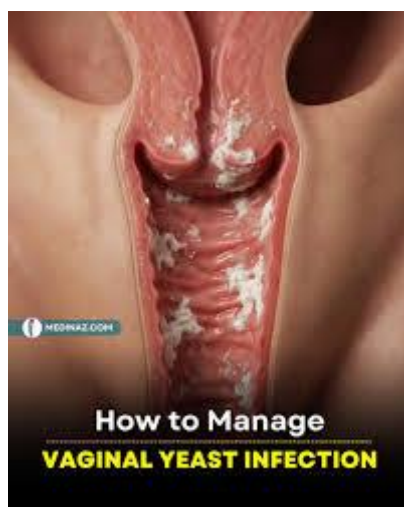
Products such as scented soaps, vaginal sprays, or douches can disrupt the natural pH and protective flora of the vagina.

Relevance to Comparative Study

Understanding these causes is essential in the comparative study of miconazole and nystatin formulations, as the effectiveness of these antifungal agents depends not only on their pharmacological action but also on how well the formulation can counteract the conditions that promote fungal growth. Proper formulation can enhance drug delivery, improve retention at the site of infection, and ultimately provide better therapeutic outcomes.

DIAGNOSIS OF VAGINAL CANDIDIASIS

(for miconazole and nystatin treatment)



Vaginal candidiasis, commonly known as a yeast infection, is mainly caused by the overgrowth of *Candida* species, especially *Candida albicans*. Proper diagnosis is important before starting treatment with antifungal drugs like miconazole or nystatin.

1. Clinical Symptoms (Initial Diagnosis)

The first step in diagnosis is based on the patient's symptoms. Common signs include.

Thick, white vaginal discharge (often described as “curd-like”)

Itching and irritation in the vaginal area

Burning sensation, especially during urination or intercourse

Redness and swelling of the vaginal tissues

These symptoms usually guide healthcare professionals to suspect a fungal infection.

2. Physical Examination

A healthcare provider may perform a pelvic examination to observe.

Red and inflamed vaginal walls

Presence of white discharge adhering to the vaginal lining

This helps confirm the likelihood of candidiasis.

3. Microscopic Examination

A sample of vaginal discharge is taken and examined under a microscope using a potassium hydroxide (KOH) preparation. This test helps to.

Detect yeast cells or budding forms of *Candida*

Confirm fungal infection

This is a quick and commonly used diagnostic method.

4. Culture Test

In some cases, the vaginal sample is cultured in a laboratory to.

Identify the exact species of *Candida*

Determine sensitivity to antifungal drugs like miconazole and nystatin

This step is especially useful in recurrent or resistant infections.

5. pH Testing

Vaginal pH is usually normal (around 4–4.5) in candidiasis.

A normal pH helps differentiate it from other infections like bacterial vaginosis.

Relation to Miconazole and Nystatin

Once vaginal candidiasis is confirmed.

Miconazole is often preferred due to its broad antifungal activity and faster symptom relief.

Nystatin is also effective but may act slightly slower and is mainly used when patients cannot tolerate azole drugs.

PATHOPHYSIOLOGY OF VAGINAL CANDIDIASIS

Vaginal candidiasis is a fungal infection mainly caused by the overgrowth of *Candida albicans*, a microorganism that normally lives harmlessly in the vaginal environment. Under healthy conditions, its growth is controlled by beneficial bacteria (especially *Lactobacillus* species) and the body's immune defenses. However, when this natural balance is disturbed, *Candida* begins to multiply excessively, leading to infection.

1. Disruption of Normal Vaginal Flora

The vagina normally maintains an acidic environment (pH around 4–4.5), which prevents harmful microbial growth. Factors such as.

Antibiotic use

Hormonal changes (pregnancy, oral contraceptives)

Diabetes

Poor hygiene or tight clothing

can reduce protective bacteria. This allows *Candida* to grow unchecked.

2. Overgrowth of *Candida*

Once the balance is disturbed, *Candida albicans* rapidly multiplies. It changes from a harmless yeast form into an invasive filamentous (hyphal) form. This transformation increases its ability to.

Adhere to vaginal epithelial cells

Invade deeper tissues

Resist host immune responses

3. Adhesion and Tissue Invasion

The fungal cells attach to the vaginal lining using surface proteins. After attachment, they penetrate the epithelial layer and release enzymes such as proteases and phospholipases. These enzymes.

Damage host cells

Break down tissue barriers

Promote further fungal spread

4. Host Immune Response

The body reacts to this invasion by activating the immune system. This leads to.

Release of inflammatory mediators

Recruitment of white blood cells

As a result, symptoms like itching, redness, swelling, and irritation occur. The thick white discharge is formed due to the accumulation of fungal cells, dead epithelial cells, and immune components.

5. Biofilm Formation (in some cases)

In recurrent infections, *Candida* can form a biofilm on vaginal surfaces. This biofilm.

Protects the fungus from antifungal drugs

Makes treatment more difficult

Increases the chances of recurrence

Relation to Miconazole and Nystatin

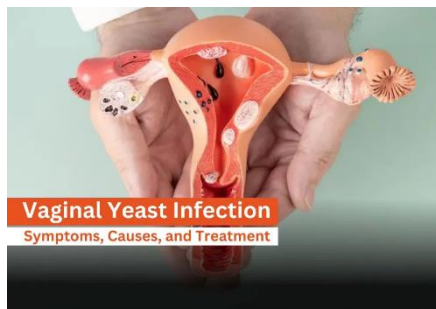
Understanding the pathophysiology helps explain how these antifungal drugs work.

Miconazole (an azole antifungal) inhibits the synthesis of ergosterol, an essential component of the fungal cell membrane. This weakens the membrane, causing leakage of cell contents and fungal death. It is effective against both yeast and filamentous forms.

Nystatin (a polyene antifungal) binds directly to ergosterol in the fungal cell membrane, creating pores. This leads to loss of essential intracellular components and ultimately kills the fungus.

Both drugs target the fungal cell membrane but act through different mechanisms, which is important in comparative formulation studies.

INTRODUCTION - (MICONAZOLE) IN THE TREATMENT OF VAGINAL



CANDIDIASIS

Vaginal candidiasis is a common fungal infection that affects many women, mainly caused by the overgrowth of *Candida albicans*. It is usually associated with symptoms such as itching, irritation, burning sensation, and thick white discharge. Effective treatment requires antifungal agents that can act directly at the site of infection and provide quick relief from discomfort.

Miconazole is a widely used antifungal drug belonging to the imidazole class. It is commonly prescribed for the treatment of vaginal candidiasis due to its broad-spectrum antifungal activity. Miconazole works by inhibiting the synthesis of ergosterol, an essential component

of the fungal cell membrane. This disruption weakens the cell membrane, leading to leakage of cellular contents and ultimately causing the death of the fungal cells.

One of the major advantages of miconazole is its ability to provide rapid symptom relief compared to many other antifungal agents. It is effective against both the yeast and filamentous forms of *Candida*, making it suitable for different stages of infection. Miconazole is available in various pharmaceutical formulations such as creams, gels, and vaginal suppositories, allowing flexibility in treatment and improving patient compliance.

In pharmaceutical research, the formulation of miconazole plays a crucial role in determining its effectiveness. Factors such as drug release rate, retention time in the vaginal cavity, and ease of application can significantly influence therapeutic outcomes. Therefore, optimizing its formulation is important for enhancing its antifungal activity and patient acceptability.

In the context of this comparative study, miconazole is evaluated alongside nystatin to understand differences in formulation performance, drug release, and clinical effectiveness in the treatment of vaginal candidiasis. This comparison helps in identifying VAGINAL CANDIDIASIS the most suitable formulation for achieving better therapeutic results.

INTRODUCTION-NYSTATIN IN THE TREATMENT OF VAGINAL CANDIDIASIS

Vaginal candidiasis is a common fungal infection that primarily affects women of reproductive age. It is most often caused by the overgrowth of *Candida* species, especially *Candida albicans*, leading to symptoms such as itching, irritation, burning sensation, and abnormal vaginal discharge. Effective antifungal therapy plays a crucial role in managing this condition and improving the quality of life of affected individuals.

Nystatin is a well-established antifungal agent that belongs to the polyene class of antibiotics. It has been widely used for decades in the treatment of fungal infections, particularly those caused by *Candida* species. Nystatin works by binding to sterols in the fungal cell membrane, especially ergosterol, which results in increased membrane permeability. This leads to leakage of essential intracellular components and ultimately causes the death of the fungal cells.

One of the key advantages of Nystatin is its safety profile. Since it is minimally absorbed from mucosal surfaces, it primarily exerts its effect locally, making it suitable for topical and intravaginal use. This property reduces the risk of systemic side effects, which is particularly

beneficial in the treatment of vaginal candidiasis. Nystatin is commonly formulated as creams, pessaries, and vaginal tablets, allowing flexibility in administration based on patient preference and clinical condition.

In comparative studies involving antifungal agents such as miconazole, Nystatin is often evaluated for its effectiveness, duration of treatment, and patient tolerability. Although it may require a slightly longer duration of therapy compared to some azole antifungals, it remains a reliable and cost-effective option, especially in cases where resistance or intolerance to azole drugs is observed.

Overall, Nystatin continues to be an important therapeutic agent in the management of vaginal candidiasis. Its long-standing clinical use, safety, and efficacy make it a valuable component in comparative studies aimed at optimizing antifungal treatment strategies.

ADVANTAGES OF MICONAZOLE VS NYSTATIN

S NO:	PARAMETER	MICONAZOLE	NYSTATIN
1.	Antifungal spectrum	Broad-spectrum; Effective against various Fungi including candida	Narrow spectrum; Mainly effective against Candida species
2.	Speed of relief	Faster relief from itching, burning ,and irritation	Slower relief compared to miconazole.
3.	Treatment duration	Shorter course (1-7 days)	Longer treatment duration required
4.	Tissue penetration	Good penetration into vaginal tissues	Limited penetration ; acts mainly on surface
5.	Anti-inflammatory action	Has additional anti-inflammatory effect	No significant anti-inflammatory effect
6.	Systemic adsorption	Minimal absorption ,but slightly more than nystatin	Negligible absorption remains localized
7.	Safety profile	Generally safe, but may cause mild irritation in some cases	Very safe with minimal effects
8.	Use in sensitive patients	May cause irritation in sensitive individuals	Preferred for sensitive or intolerant patients
9.	Use in recurrent infection	Effective, but repeated use may cause resistance in rare cases.	Safe for repeated and long term uses
10.	Patient compliance	Better due to shorter treatment duration.	Slightly lower due to longer course.

AVAILABILITY OF DOSAGE FORM BEST FORMULATION

Availability and Optimal Dosage Forms of Miconazole and Nystatin for Vaginal Candidiasis

Vaginal candidiasis is a common fungal infection usually caused by *Candida* species. Among the widely used antifungal treatments are miconazole and nystatin, both of which are available in several dosage forms designed for effective local action.

Miconazole is considered one of the preferred treatments due to its broad antifungal activity and higher efficacy. It is commonly available as.

- Vaginal creams (2% and 4%)
- Vaginal suppositories or pessaries (100 mg, 200 mg, 1200 mg)

The best formulation of miconazole depends on patient convenience and severity of infection. Short-course therapies, such as a single-dose 1200 mg suppository or 3-day regimens, are often preferred because they improve patient compliance while maintaining effectiveness.

Nystatin, although effective, has a narrower antifungal spectrum compared to miconazole. It is usually available as.

- Vaginal tablets (100,000 units)
- Vaginal creams

Nystatin typically requires longer treatment durations (usually 7–14 days), which may reduce patient adherence. However, it remains a good option for patients who cannot tolerate azole antifungals.

COMPARATIVE STUDY FOR FORMULATION

Study of Formulations: Miconazole and Nystatin in Vaginal Candidiasis

1. Introduction

Vaginal candidiasis is a common fungal infection primarily caused by *Candida albicans*. It affects a large number of women worldwide and is associated with symptoms such as itching, irritation, and abnormal discharge. Antifungal therapy plays a key role in management, and among the commonly used agents are Miconazole and Nystatin.

These two drugs differ significantly in their formulation approaches, availability, and clinical effectiveness, especially in vaginal drug delivery systems.

2. Availability of Formulations

Miconazole

Miconazole is widely available in multiple vaginal dosage forms, making it highly adaptable for patient use. These include.

Vaginal creams (usually 2%)

Vaginal suppositories (100 mg, 200 mg)

Vaginal tablets (pessaries)

Combination packs (cream + applicator)

Its broad availability allows flexibility in dosing duration, ranging from single-dose therapy to 7-day regimens.

Nystatin

Nystatin is comparatively limited in vaginal formulations. Commonly available forms include.

Vaginal tablets (100,000 units)

Vaginal creams (less commonly used)

Unlike miconazole, nystatin formulations are fewer and less diverse, which may affect patient convenience and treatment adherence.

3. Formulation Design and Characteristics

Miconazole Formulation

Miconazole is lipophilic and poorly soluble in water, so its formulations are carefully designed to improve drug release and absorption.

Typically formulated in **oil-in-water emulsions** or **gel bases**

Uses excipients such as.

Surfactants

Co-solvents (e.g., polyethylene glycol)

Designed to enhance **mucoadhesion and retention time** in the vaginal cavity

Provides better penetration into infected tissues

These properties contribute to its higher therapeutic effectiveness.

Nystatin Formulation

Nystatin presents different challenges due to its physicochemical nature:

Practically insoluble in water

Usually formulated as a **suspension** rather than a solution

Incorporated into.

Vaginal tablets

Ointment bases

Key formulation limitations:

Poor drug release

Limited mucosal penetration

Stability issues (sensitive to heat and light)

As a result, its action remains mostly localized.

4. Mechanism of Drug Delivery in Vaginal Candidiasis

Miconazole works by inhibiting ergosterol synthesis, disrupting fungal cell membrane formation.

Nystatin binds directly to ergosterol, forming pores that lead to cell death.

From a formulation perspective.

Miconazole ensures -**better distribution and retention**

Nystatin provides- **surface-level antifungal action**

5. Comparative Effectiveness in Vaginal Use

Clinical observations suggest.

Miconazole provides.

Faster symptom relief

Higher cure rates

Shorter treatment duration

Nystatin.

Requires longer therapy

May show slower response

Higher chances of recurrence

This difference is largely due to **formulation efficiency and drug penetration** rather than just pharmacological activity.

6. Patient Compliance and Acceptability

Miconazole formulations are.

Easier to apply

Available in short-course therapies

More convenient

Nystatin formulations:

Require multiple doses over longer periods

May be less comfortable due to formulation texture

Better formulation design in miconazole improves patient adherence.

7. CONCLUSION

In the treatment of vaginal candidiasis, both drugs are effective, but their formulation characteristics significantly influence their performance.

Miconazole stands out due to

Wider availability of dosage forms

Better formulation design

Improved drug delivery and efficacy

Nystatin, while safe and effective for localized infections, is limited by

Poor solubility

Restricted formulation options

Lower patient compliance

Overall, modern pharmaceutical approaches favor miconazole formulations for vaginal candidiasis due to their enhanced therapeutic outcomes and user-friendly design.

DISCUSSION

The comparative evaluation of Miconazole and Nystatin formulations in the treatment of vaginal candidiasis highlights how formulation design plays a crucial role in therapeutic outcomes, beyond just the pharmacological action of the drug.

One of the most important differences between the two drugs lies in their physicochemical properties, which directly influence formulation strategies. Miconazole, being lipophilic and poorly water-soluble, is typically incorporated into well-designed emulsion or gel systems that enhance its solubility, retention, and penetration into vaginal tissues. These formulations often include surfactants and co-solvents that improve drug dispersion and allow for sustained contact with the infected mucosa. As a result, miconazole is able to achieve deeper and more effective antifungal action.

In contrast, nystatin presents significant formulation challenges due to its large molecular size, poor solubility, and instability under environmental conditions such as heat and light. It is commonly formulated as a suspension or incorporated into simple vaginal tablets. While these formulations are effective in delivering the drug locally, they lack the ability to ensure uniform distribution and prolonged retention in the vaginal cavity. Consequently, the antifungal activity of nystatin is largely confined to the surface of the mucosa.

Another key aspect of this comparison is the availability and versatility of dosage forms. Miconazole is available in a wide range of formulations, including creams, suppositories, and vaginal tablets, allowing for flexible dosing regimens such as single-dose or short-course therapies. This variety improves patient convenience and compliance. On the other hand, nystatin has more limited formulation options, which may restrict its clinical use and reduce adherence to treatment, especially when longer therapy durations are required.

The differences in formulation also translate into variations in clinical effectiveness. Miconazole formulations generally provide faster symptom relief and higher cure rates, primarily due to better drug penetration and retention. In contrast, nystatin often requires prolonged use and may be associated with slower clinical improvement. Although both drugs are effective against *Candida* species, the superior formulation design of miconazole enhances its overall therapeutic performance.

Patient acceptability is another factor influenced by formulation. Miconazole products are often designed to be more user-friendly, with smoother textures and shorter treatment durations, which can significantly improve compliance. Nystatin formulations, particularly suspensions or less refined vaginal tablets, may be less convenient and sometimes uncomfortable for patients, potentially affecting consistent use.

Overall, this comparative study demonstrates that while both drugs are valuable in the treatment of vaginal candidiasis, formulation plays a decisive role in determining their success. Miconazole, with its advanced formulation approaches, offers clear advantages in terms of efficacy, patient compliance, and flexibility. Nystatin, although safe and effective for localized infections, is limited by its formulation constraints.

In conclusion, the findings emphasize that the development of optimized drug delivery systems is essential for improving antifungal therapy. Future research may focus on

enhancing nystatin formulations or developing novel delivery systems that can match the efficiency and patient acceptability seen with miconazole.

ADVERSE EFFECT

Both miconazole and nystatin are commonly used antifungal agents for the treatment of vaginal candidiasis and are generally well tolerated. However, some adverse effects may occur, which can influence patient compliance and overall treatment outcomes.

Miconazole, an imidazole antifungal, may cause local side effects such as mild burning, itching, or irritation in the vaginal area. In some cases, patients report abdominal cramps or headache, although these are less common. Prolonged use may occasionally lead to increased sensitivity or allergic reactions, but such occurrences are rare.

Nystatin, a polyene antifungal, is also associated with local irritation, including itching and burning sensations. Compared to miconazole, these effects are usually milder and less frequently reported. Systemic side effects are extremely rare with nystatin due to its minimal absorption through mucosal surfaces. However, hypersensitivity reactions, though uncommon, may still occur in certain individuals.

Overall, both drugs exhibit a favorable safety profile. Miconazole may produce slightly more noticeable local irritation in some patients, while nystatin is often considered gentler but may require longer treatment duration. The choice between the two should therefore consider not only efficacy but also patient tolerance and comfort.

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