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ASSESSMENT OF THE EFFICACY AND TOLERABILITY OF A TINIDAZOLE, CLINDAMYCIN, AND CLOTRIMAZOLE VAGINAL CAPSULE IN MIXED VAGINA AND CERVIX INFECTIONS

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ABSTRACT

Background: Mixed vaginitis, involving two or more pathogens, presents overlapping symptoms that hinder diagnosis and treatment. Clingen Forte pessaries, combining clindamycin, clotrimazole, and tinidazole, provide broad-spectrum coverage against bacterial, fungal, and protozoal infections. This study evaluated healthcare professionals (HCPs) real-world experience with the efficacy, safety, and tolerability of Clingen Forte in managing mixed vaginal and cervical infections in India. **Methods:** This retrospective, multicentre, questionnaire-based observational study was conducted among 85 HCPs from January to March 2025. Data on the last 10 patients treated with Clingen Forte for mixed vaginal and cervical infections were collected. The 22-item survey focused on patient demographics, comorbidities, clinical presentation, treatment patterns, symptom resolution, recurrence, adverse effects, and quality-of-life improvements. Descriptive statistical analysis was performed. **Results:** Most affected women were aged 20–30 years, with diabetes (49.41%) and obesity (36.47%) reported as the most common comorbidities. The predominant symptoms were vaginal discharge, itching, and burning (75.29%), with 34.12% of HCPs noting a severity score of 4 on a 1-5 scale prior to treatment initiation. Complete symptom resolution was achieved in 90% of cases, with 43.53% of HCPs observing relief within 3 days of treatment. Recurrence occurred in 40% of cases, most often attributed to partner reinfection (45.88%). Adverse effects were reported in 56.47% of patients, generally mild in nature, and included irritation (47.06%), burning sensation (28.24%), and vaginal dryness (24.71%). Quality of life improved in 96.47% of patients, and overall treatment satisfaction was rated as excellent or good by 95.29% of HCPs. **Conclusion:** Clingen Forte pessaries showed high efficacy, rapid symptom relief, good tolerability, and improved quality of life in mixed vaginal and cervical infections, supporting their use as an effective treatment, with emphasis on recurrence prevention.

KEYWORDS : Mixed vaginitis, Clindamycin, Clotrimazole, Tinidazole, Combination therapy

INTRODUCTION:

Vaginitis is a highly prevalent condition affecting approximately 75% of women worldwide at some point in their lives [1]. Mixed vaginitis refers to the simultaneous presence of at least two types of vaginitis, which together disrupt the normal vaginal environment and produce characteristic symptoms and signs. However, individual symptoms often have limited diagnostic value in clinical settings [2, 3]. Approximately 30% of vaginitis cases are caused by simultaneous infections involving two or more pathogens [1]. The majority of infections in the female reproductive tract occur in the vagina and cervix [3].

Bacterial vaginosis is the most common cause, accounting for 40% to 50% of cases, followed by yeast infections, which affect about 20% to 25% of women at least once in their lifetime [4]. Cervicitis, often resulting from infection, triggers an immune response characterized by the release of proinflammatory cytokines, infiltration of neutrophils, and epithelial damage. This immune activity disrupts the cervical mucus barrier, diminishing its protective function against ascending infections [5]. Trichomonas vaginalis, Neisseria gonorrhoeae, herpes simplex virus, Candida species, and other potential vaginal pathogens may act as concomitant agents contributing to vaginitis [2].

The clinical presentation of mixed vaginitis is often atypical and may not align with the classic symptoms associated with a single pathogen. It may manifest with features typical of one form of vaginitis or present overlapping signs and symptoms of multiple types simultaneously, which complicates both diagnosis and management [6]. Vaginal infections are typically diagnosed through clinical examination, vaginal pH measurement, and microscopic evaluation of vaginal discharge. An elevated vaginal pH (>4.5) is commonly observed in cases of bacterial vaginosis and trichomoniasis [1].

Combination therapy can offer prompt and effective treatment for vaginal infections, regardless of whether they are caused by single or multiple pathogens, and even when an exact diagnosis is uncertain [1]. A fixed-dose combination of Clindamycin, Clotrimazole, and Tinidazole provides broad-spectrum antimicrobial coverage and has been shown to deliver rapid and substantial symptomatic relief in patients with mixed vaginitis of bacterial, fungal, and protozoal origin [7]. The present study evaluated the intravaginal efficacy and safety of this fixed-dose combination (Clingen Forte pessaries) for the treatment of mixed infections involving the vagina and cervix.

METHODS:

Study Design

This questionnaire-based retrospective multicenter observational study was conducted among Indian healthcare practitioners (HCPs) from January 2025 to March 2025. Participation in the study was completely voluntary, and the study process, along with the data analysis, ensured the confidentiality and anonymity of the HCPs. All study-related information, including the questionnaire, was thoroughly explained to participants and verbal consent was obtained before participation. The study protocol was approved by the independent ethics committee (ACEAS-Independent Ethics Committee, Ahmedabad, Date of approval: 26 November

2024).

Study Questionnaire

The study questionnaire was designed based on existing literature, guidelines, and expert opinions. It consisted a total of 22 questions focused on clinical effectiveness, safety, tolerability, and patient satisfaction associated with the use of a combination capsule of tinidazole, clindamycin, and clotrimazole (Clingen Forte) for management of mixed vaginal and cervical infections. The questionnaire focused on last 10 patients with mixed vaginal and cervical infections.

Data Collection

Participants in the study were provided with a concise overview of the study's nature and the process for completing the questionnaire. The questionnaire was given to the HCP either in person, via phone calls, or through online platforms, as per the HCP's convenience.

Data Analysis

The responses of HCPs were entered into Microsoft excel and descriptive statistics, such as frequencies and percentages, were employed to present data.

RESULTS:

A total of 85 HCP were included in this study. Majority of HCPs (40%) reported women aged between 20-30 years were most commonly affected with the vaginal infections. Most of the HCPs (49.41%) reported diabetes as common comorbidity, followed by obesity (36.47%), thyroid disorders (8.24%), hypertension (5.88%).

The most predominant symptoms observed by HCPs (75.29%) were vaginal discharge, itching, and burning sensation, before using the pessary in these 10 patients. Among all 85 HCPs, 34.12% HCPs observed severity of scale 4 of these symptoms on a scale of 1-5 before initiating treatment. The majority of HCPs prescribed Clingen Forte for 7 days in these 10 patients. Nine out of ten HCPs (45.88%) observed complete resolution of symptoms after treatment. Of all, 43.53% HCPs reported onset of symptom relief three days after treatment, while 40% HCPs observed recurrence of symptoms in one out of 10 patients after treatment.

According to 49.41% HCPs, women report recurrence of symptoms after three months. Transmission of infection from sexual partner was most common reasons for recurrence of symptoms observed by 45.88% HCPs. One out of ten patients required retreatment for recurrence of symptoms after treatment with Clingen Forte as reported by 43.53%. Majority of HCPs (56.47%) observed women reported any adverse effects while using the pessary, Clingen Forte.

The most commonly observed adverse effects reported HCPs among 10 women treated with Clingen Forte was irritation (47.06%), followed by burning sensation (28.24%) and vaginal dryness (24.71%). Most of the HCPs (56.47%) reported no history of intolerance to vaginal pessaries. The 91.76% HCPs observed that, the pessary tolerated, particularly by patients with sensitive vaginal mucosa.

Treatment adherence was complete in nearly half of the cases, though only 45.88% of HCPs reported checking baseline vaginal pH before prescribing. The majority of HCPs (50.59%) agreed that alkaline vaginal pH increases infection risk, and a considerable number of patients had associated risk factors. Routine follow-ups were conducted by most of HCPs, and 96.47% of HCPs reported improved quality of life. The HCPs reported overall satisfaction with the treatment was high, with most rating (95.29%) as excellent and good.

DISCUSSION

Vaginal infection is a common polymicrobial syndrome affecting women across various age groups [8]. However, it most frequently occurs in women between the ages of 20 and 45 years [7]. Obesity may serve as an independent risk factor for recurrent vulvovaginal and bacterial infections in women of reproductive age, potentially through mechanisms involving altered vaginal immunity [9]. In the current study, 40% of patients were in the 20–30 years age group, followed by 34.12% in the 30–35 years group. The most commonly observed comorbidity by HCPs was diabetes (49.41%), followed by obesity, reported by 36.47% of HCPs.

The predominant symptoms before treatment were vaginal discharge, itching, and burning sensation, with 75.29% of HCPs reporting all of these symptoms. The severity of symptoms was rated as 3 or 4 on a scale of 1–5 by 69.41% of HCPs. Similarly, a study by Yano et al., the observed most common symptoms were itching (91.2%), burning (68.3%), and redness (58.1%) [10]. The majority of HCPs (83.53%) prescribed a seven-day course of Clingen Forte. Complete resolution of symptoms was achieved in 45.88% of patients, while 28.24% had partial resolution. The onset of symptom relief reported by 43.53% of HCPs within was three days. These outcomes were comparable to the study by Maladkar M, et al. reported that, the combination therapy offers broad antimicrobial coverage and fast, effective symptom relief in patients with mixed vaginosis caused by bacteria, fungi, and protozoa [7].

A study by Clarke MA, et al. suggested that elevated vaginal pH is associated with the detection of human papillomavirus infection, particularly multiple-type infections and low-grade squamous intraepithelial lesions in certain age groups, with the detection of Chlamydia trachomatis DNA in women under 25 years of age [11]. In present study, the majority of HCPs (50.59%) identified that, an alkaline vaginal pH as increasing the risk of infections. However, only 28.24% of patients had risk factors associated with changes in vaginal pH, which highlights the importance of considering both clinical symptoms and laboratory findings in the management of vaginal infections.

Recurrence was observed by 80% of HCPs, primarily after two and three months, with key contributing factors being poor treatment adherence, partner-related reinfection, and uncontrolled diabetes. More than half of the HCPs (56.47%) reported no adverse effects, others HCPs reported irritation (47.06%), burning (28.24%), and dryness (24.71%). These findings align with a study of Maladkar et al., who noted similar adverse effects such as abdominal cramps, burning, diarrhea, frequent urination, headache, itching, rash, and vaginal discomfort linked to combination therapy [7].

Routine follow-up after treatment was conducted by 78.82% of HCPs, and 96.47% of HCPs reported an improvement in their quality-of-life post-treatment. Patient satisfaction was high, with 95.29% of HCPs rating the treatment as excellent and good, which underscores the effectiveness of the combination therapy in managing vaginal infections and improving patient outcomes.

CONCLUSION

Early diagnosis, appropriate treatment, and patient education are the key factors play major role in effective management of vaginal infections. The combination therapy offers broad-spectrum antimicrobial coverage and demonstrated substantial symptomatic relief, supporting its use as an effective treatment option in vaginal infection.

Conflict Of Interest: All authors have no conflict of interest to declare.

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Table 1: Responses Of Physicians For The Questions Related To Combination Therapy

Question	Options	Response of HCPs (N=85)
Out of these 10 patients, what was the most common age group of these patients with vaginal infections?	Less than 20 years	4 (4.71)
	20-30 years	34 (40.00)
	30-35 years	29 (34.12)
	35-40 years	14 (16.47)
	Greater than 40 years	4 (4.71)
What were the most common comorbid diseases in these patients?	Diabetes	42 (49.41)
	Obesity	7 (36.47)
	Thyroid disorders	5 (8.24)
	Hypertension	31 (5.88)
What are the predominant symptoms patients present before using the pessary in these 10 patients?	Vaginal discharge	13 (15.29)
	Itching	7 (8.24)
	Burning sensation	1 (1.18)
	All of the above	64 (75.29)
How would you rate the severity of these symptoms on a scale of 1-5 before initiating treatment?	1	8 (9.41)
	2	4 (4.71)
	3	30 (35.29)
	4	29 (34.12)
	5	14 (16.47)
What was the duration of treatment for Clingen Forte you prescribed in these 10 patients?	3 days	7 (8.24)
	5 days	7 (8.24)
	7 days	71 (83.53)
How many of these patients had complete resolution of symptoms after treatment?	10/10	15 (17.65)
	9/10	39 (45.88)
	8/10	24 (28.24)
	Less than 8/10 patients	7 (8.24)
What was the reported onset of symptom relief experienced by these 10 patients?	1 day after treatment	10 (11.76)
	2 days after treatment	21 (24.71)
	3 days after treatment	37 (43.53)
	Greater than 3 days after treatment	17 (20.00)
How many of these patients had recurrence of symptoms after treatment?	None	12 (14.12)
	1/10	34 (40.00)
	2/10	26 (30.59)
	Greater than 2/10 patients	13 (15.29)
When did the women report recurrence of symptoms?	After 1 month	17 (20.00)
	After 2 months	26 (30.59)
	After 3 months	42 (49.41)
What could have been the reasons for recurrence of symptoms?	Non adherence to treatment duration	32 (37.65)
	Transmission of infection from sexual partner	39 (45.88)
	Uncontrolled diabetes	14 (16.47)
How many of these patients required retreatment for recurrence of symptoms after treatment with Clingen Forte?	None	13 (15.29)
	1/10	37 (43.53)
	2/10	29 (34.12)
	Greater than 2/10 patients	6 (7.06)
How many of these women reported any adverse effects while using the pessary, Clingen Forte?	None	48 (56.47)
	1/10 women	21 (24.71)
	2/10 women	13 (15.29)
	Greater than 2/10 women	3 (3.53)
Which were the most commonly reported adverse effects reported by these 10 women treated with Clingen Forte?	Irritation	40 (47.06)
	Burning sensation	24 (28.24)
	Vaginal dryness	21 (24.71)
How many of these women had a past history of intolerance to vaginal pessaries?	None	48 (56.47)
	1/10 women	14 (16.47)
	2/10 women	17 (20.00)
	Greater than 2/10 women	6 (7.06)
How well is the pessary tolerated, particularly by patients with sensitive vaginal mucosa?	Well tolerated	78 (91.76)
	Not well tolerated	7 (8.24)
How many of these 10 patients adhered to the prescribed treatment with Clingen Forte?	All	41 (48.24)
	9/10	22 (25.88)
	8/10	16 (18.82)
	Less than 8/10 patients	6 (7.06)
What vaginal pH increases the risk of infections?	Acidic pH	35 (41.18)
	Alkaline pH	43 (50.59)
	Neutral pH	7 (8.24)
How many of these10 women had risk factors associated with change in vaginal pH?	All	24 (28.24)
	9/10	11 (12.94)
	8/10	19 (22.35)
	Less than 8/10 patients	31 (36.47)
Did you check the baseline vaginal pH levels before prescribing the pessary?	Yes	39 (45.88)
	No	46 (54.12)
Did you call these women for a routine follow up after treatment?	Yes	67 (78.82)
	No, women come back only if they have a recurrence of symptoms	18 (21.18)
Did patients report an improvement in their quality of life after using the pessary?	Yes	82 (96.47)
	No	3 (3.53)
How satisfied are they with the treatment outcomes on a scale of 1-5?	Excellent	51 (60.00)
	Good	30 (35.29)
	Fair	3 (3.53)
	Poor	-
	Not satisfied at all	1 (1.18)

REFERENCES

1. Mixed vaginal infections. Fertility Blaze. 2011;1 (8). Available from: https://wbhf.walterbushnell.com/publications/fertility-blaze/item/339-mixed-vaginal-infections. Last accessed on: 06.06.2025.
2. Sobel JD, Subramanian C, Foxman B, Fairfax M, Gygax SE. Mixed vaginitis-more than coinfection and with therapeutic implications. Curr Infect Dis Rep. 2013;15(2):104-108.
3. Qi W, Li H, Wang C, Li H, Zhang B, Dong M, Fan A, Han C, Xue F. Recent Advances in Presentation, Diagnosis and Treatment for Mixed Vaginitis. Front Cell Infect Microbiol. 2021;11:759795.
4. Hildebrand JP, Carlson K, Kansagor AT. Vaginitis. [Updated 2025 Jan 19]. In: StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2025 Jan-. Available from: https://www.ncbi.nlm.nih.gov/books/NBK470302/. Last accessed on: 06.06.2025.
5. Iqbal U, Carlson K, Wills C. Cervicitis. [Updated 2025 Jan 21]. In: StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2025 Jan-. Available from: https://www.ncbi.nlm.nih.gov/books/NBK562193/. Last accessed on: 06.06.2025.
6. Wenhui Qi, huanrong li, Chen Wang, et al. Mixed vaginitis: clinical recommendations regarding presentation, diagnosis and treatment. Authorea. 2024.
7. Manish Maladkar, Chitra Tekchandani, Urja Dave. Clindamycin, Clotrimazole and Tinidazole in Mixed Vaginosis- A "Real World" Clinical Experience. Journal of Gynecology and Obstetrics. 2015;3(3): 49-54.
8. Regassa BT, Kumsa C, Wondimu F. et al. Prevalence of bacterial vaginosis and its associated factors among pregnant women attending antenatal care clinics at public hospitals in West Shoa Zone, Oromia, Ethiopia. Sci Rep.2024;14:21474.
9. Ventolini G, Khandelwal N, Hutton K, Lugo J, Gygax SE, Schlabritz-

Loutsevitch N. Obesity and recurrent vulvovaginal bacterial infections in women of reproductive age. Postgrad Med J. 2017;93(1099):297.
10. Yano J, Sobel JD, Nyirjesy P, Sobel R, Williams VL, Yu Q, Noverr MC, Fidel PL. Current Patient Perspectives of Vulvovaginal Candidiasis: Incidence, Symptoms, Management and Post-Treatment Outcomes. BMC Womens Health. 2019;19:48.
11. Clarke MA, Rodriguez AC, Gage JC, Herrero R, Hildesheim A, Wacholder S, Burk R, Schiffman M. A large, population-based study of age-related associations between vaginal pH and human papillomavirus infection. BMC Infect Dis. 2012;12:33.