

The Efficacy of Chlorhexidine Gel in Managing Vaginal Infections

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Abstract

Introduction: Vaginal infections are prevalent among the population. It complicates pregnancy, lactation and also deteriorates the quality of life. There are antifungal and antimicrobial medications, which are more precise in their therapy, are already available for such infections. A novel bio-adhesive vaginal gel with % chlorhexidine gluconate was recently developed using a patented technique. This formulation provides for a longer release of Chlorhexidine throughout time because of its bio-adhesive properties it is important to investigate this medication in vaginal infections.

Aims and Objectives: To find the efficacy of chlorhexidine gel as compared to the existing treatment protocols in managing vaginal infections

Materials and Methods: This prospective study was conducted with the patients of vaginal infections, namely, Vulvovaginal candidiasis (VC), bacterial vaginosis (BV) and non-specific vaginitis (NSV). The confirmed diagnosis of the conditions was done by the suspected clinical features and laboratory results. The patients were given Chlorhexidine vaginal gel along with Oral metronidazole for VC, Vaginal clotrimazole gel or combination of these two for NSV. The outcomes were assessed by observing the side effects, improvement of the condition and Visual Analog Scale (VAS) score. The statistical analysis was conducted.

Results: The mean score of VAS for Chlorhexidine vaginal gel and Oral metronidazole in Bacterial Vaginosis were found to be 8.85 ± 1.15 and 8.89 ± 1.12 , respectively. In Non-Specific Vaginitis, the mean score of VAS for Chlorhexidine vaginal gel and combination therapy were found to be 8.63 ± 1.25 and 8.85 ± 1.22 , respectively. The significance test revealed that each group treated with Chlorhexidine vaginal gel and other drugs for each of the condition, was found to be statistically insignificant ($P > 0.05$).

Conclusion: The study has shown that there is a satisfactory outcome in each of the conditions considered for this study and it suggests that Chlorhexidine vaginal gel can be used as an adjuvant drug for these conditions which should be made as a guideline to the treatment of these conditions.

Keywords: chlorhexidine, visual analog scale, vaginitis, candidiasis, vaginal infection

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Introduction

The occurrence of urinary tract infections (UTIs) as well as sexually transmitted illnesses has increased (STDs); vaginal illnesses caused by bacteria have gotten a lot of attention [1]. During the reproductive years, as one of the most main sources of vaginal secretions are bacterial infections [2]. Women visit gynecological clinics for a variety of reasons, including vaginitis. Antiseptics have been suggested as one of several alternative treatments. Since the turn of the century, antiseptics were being used to manage vaginal infections. Antiseptics, like antibiotics, kill vaginal anaerobic bacteria, allowing native lactobacilli to regenerate. Antiseptics have a wide range of effects in most cases. They eliminate germs by breaking down their cell walls. As a result, resistance to these variables has only been reported infrequently [3].

Infection is one of the primary drivers of complications of pregnancy, accounting for 15% of all maternal fatalities. During labor, every woman is vulnerable to infection, but women who have had a cesarean section are at a higher risk. Postoperative infection morbidity has been reduced thanks to advancements in aseptic surgical methods and antibiotic administration [4]. As an illness progresses from the lowest to the highest vaginal canal, on the other hand, is a prevalent but underappreciated cause of infection. Before a caesarean section, washing the vagina through an antiseptic solution of chlorhexidine can be an inexpensive as well as easy way to prevent infection [5].

Aerobic illnesses are another likely consequence of altered vaginal flora, which is one of the leading causes of pregnancy issues such as increased amniotic fluid infections, early membrane rupture, and preterm labor [6]. Treatment with a single medicine is inefficient in combination infections, although broad-spectrum anti-bacterial in addition to anti-fungal drugs, like chlorhexidine

digluconate, show promise for fast treatment [7].

To treat vaginal infections, many drug delivery techniques are used [8]. Physiological secretions wash out the vaginal fluid, causing it to dry up; the longstanding vaginal preparations like suspensions, pills, creams, as well as solutions remain in one spot for a while. Mucosal-adherent vaginal medication delivery methods, like drugs plus gels, attach in the direction of the mucus in the vaginal cavity as well as avoid the medicine since being flushed. Drugs plus other vaginal delivery methods, like creams and suspensions, have been linked to formulation flaws and leaks, resulting in consumer dissatisfaction [9, 10].

Antifungal and antimicrobial medications, which are more precise in their therapy, are already available for such infections. Of course, their specificity stems from the fact that these drugs are methodically specified, thus pharmacological side effects should be minimal, which isn't an issue with topical drugs. Local toxicity is the only negative effect of a topical medication. Chlorhexidine is an oral antibiotic that has no local effects. As a result, it outperforms comparable preparations when it comes to output, cost, besides lateral special effects. Furthermore, Chlorhexidine is an OTC drug that is used as a topical antiseptic and that is widely accessible toward patients. In addition, investigations have demonstrated that chlorhexidine digluconate is beneficial in lowering *E. coli* and *Candida albicans* microbial loads [11].

Chlorhexidine is an anti-bacterial and anti-fungal agent with a broad spectrum of activity that is utilized to prevent plus treat infections of the oral mucosa. Vaginal showers using 0.25-0.5 % chlorhexidine may help to prevent bacterial and fungal vaginitis. The formulation's small

interaction period through the vaginal mucosa, however, could limit its effectiveness. For the purpose of diagnosis of vaginal infections, a novel bio-adhesive vaginal gel with % chlorhexidine gluconate was recently developed using a patented technique. This formulation provides for a longer release of Chlorhexidine throughout time because of its bio-adhesive properties [12].

Considering the paucity of research on vaginal chlorhexidine gel in India and the wide range of species for which it can be used, it is important to investigate this medication in vaginal infections. As a result, the goal of this investigation was towards equate the effectiveness of vaginal chlorhexidine gel in treating various vaginal infections (VVC, BV and nonspecific vaginitis).

Materials and Methods

This prospective study was conducted during the period of one year two months. The patients who visited the outpatient department of our hospital were considered. The included patients had chief complaint of abnormal vaginal discharge, followed our hospital's treatment protocol and also appeared during the follow-up study. The patients who were excluded are those who did not cooperate, those who had other underlying gynaecological disorders and patients who did not visit for follow-up study. Finally, the study considered 60 patients. The patients were given Chlorhexidine vaginal gel and any one of the three drugs (Oral metronidazole, Vaginal clotrimazole gel or combination of these two). The study considered 3 conditions of vaginal infections, namely, Vulvovaginal candidiasis, bacterial vaginosis and non-specific vaginitis.

For those patients who were suspected to have vulvovaginal candidiasis ($n = 20$), they had clinical features like burning sensation, pruritis and vaginal discharge. Some patients also had dyspareunia,

dysuria and most of them had erythematous vagina and vulvar edema. The patients were also observed with sticky secretion and papular or pustular lesions. For those patients with bacterial vaginosis ($n = 20$), they had burning sensation around vagina, discharge, abnormal odour from vagina. Whiff test was done and clue cells were observed. Those patients whom the identification was not confirmed and cannot be classified as the diagnosis of vulvovaginal candidiasis (VC) or bacterial vaginosis (BV), they were considered as non-specific vaginitis (NSV) ($n = 20$). So, for each group of diagnosis (VC, BV and NSV), there were 20 patients. In each group, 10 patients were given Chlorhexidine vaginal gel and other 10 patients were given Oral metronidazole, Vaginal clotrimazole gel or combination of these two, respectively for bacterial vaginosis, Vulvovaginal candidiasis and non-specific vaginitis.

To keep the whole study double-blinded, the drugs were prescribed on random basis, assuring that the investigators and the physicians did not know each other or there is no transmission of information between them. The patients also visited the outpatient department for follow-up study and further evaluation.

Statistical analysis

The study has collected data and analyzed using SPSS 25 and excel software. The study used Mann-Whitney U test for comparing ordinal data while Chi-Square or Fischer's exact test was employed for analyzing qualitative data. The level of significance was considered as $\alpha=0.05$.

Results

The study found that the age of the patients with VC, BV and NSV were found to be 34.25 ± 5.25 years, 33.65 ± 4.58 years and 34.12 ± 5.21 years old, respectively. The study considered the outcomes (including side effects and improvements) of the various treatment

protocols used (Table 1). The Visual Analog Score (VAS) has been used in this

study to assess the efficacy of the treatment (Table 2).

Table 1: The outcomes of various treatment protocol at the end of each treatment

Group/Diagnosis	Vulvovaginal Candidiasis (n = 20)		Bacterial Vaginosis (n = 20)		Non-Specific Vaginitis (n = 20)	
	Clorhexidine vaginal gel	Vaginal clotrimazole gel	Clorhexidine vaginal gel	Oral metronidazole	Clorhexidine vaginal gel	Combinations
Vaginal burning	3 (30%)	3 (30%)	2 (20%)	2 (20%)	2 (20%)	3 (30%)
Nausea	0	0	0	1 (10%)	1 (10%)	1 (10%)
Vomiting	0	0	0	1 (10%)	0	1 (10%)
Cutaneous lesions	0	1 (10%)	0	0	1 (10%)	1 (10%)
Improvement	9 (90%)	10 (100%)	10 (100%)	10 (100%)	10 (100%)	10 (100%)

The study found that the mean score of VAS for Clorhexidine vaginal gel and Vaginal clotrimazole gel in Vulvovaginal Candidiasis were 9.08 ± 1.23 and 8.11 ± 1.12 , respectively. The mean score of VAS for Clorhexidine vaginal gel and Oral metronidazole in Bacterial Vaginosis were found to be 8.85 ± 1.15 and 8.89 ± 1.12 , respectively. In Non-Specific Vaginitis,

the mean score of VAS for Clorhexidine vaginal gel and combination therapy were found to be 8.63 ± 1.25 and 8.85 ± 1.22 , respectively. The significance test revealed that each group treated with Clorhexidine vaginal gel and other drugs for each of the condition, was found to be statistically insignificant ($P > 0.05$). The details are given in Table 2.

Table 2: Satisfaction scores of Visual Analog Scale (VAS) for each diagnosis

Treatment Protocol	Statistical Parameters	Vulvovaginal Candidiasis (n = 20)	Bacterial Vaginosis (n = 20)	Non-Specific Vaginitis (n = 20)
Clorhexidine vaginal gel	Mean \pm SD	9.08 ± 1.23	8.85 ± 1.15	8.63 ± 1.25
Vaginal clotrimazole gel	Mean \pm SD	8.11 ± 1.12		
	P-value	> 0.05		
Oral metronidazole	Mean \pm SD		8.89 ± 1.12	
	P-value		> 0.05	
Combination of the above two	Mean \pm SD			8.85 ± 1.22
	P-value			> 0.05

Discussion

There was no substantial modification amongst patients in the two sets of vaginal

chlorhexidine in relationships of cheese-like secretions, vulvar burning sensations, negative Whiff test, and observation of

fungus under microscopy ($P > 0.05$). There were no significant differences between the chlorhexidine vaginal gel groups in the Whiff test ($P = 0.30$), Nitrazine test ($pH > 4.5$) ($P = 0.573$), malodorous discharge ($P = 0.618$), and clue cells ($P = 1.000$) [13].

Vaginal burning was the furthestmost collective lateral consequence in both the chlorhexidine vaginal gel groups, but only a few patients in each group had it. There were no reports of nausea and vomiting. Symptoms improved for the vast majority of people. Simply a pair of patients in the chlorhexidine vaginal gel groups reported no improvement in symptoms. Between chlorhexidine vaginal gels, there was furthestmost collective lateral consequence vaginal burning [13].

The chlorhexidine vaginal gel group had more vaginal burning than the oral metronidazole group in BV patients; $P < 0.05$. The oral metronidazole group suffered from nausea and vomiting. There were no skin lesions recorded in either group, and all patients improved.

Patients who administered chlorhexidine vaginal gel or oral metronidazole reported vaginal burning in the nonspecific vaginitis group. There were no reports of nausea or vomiting. The chlorhexidine vaginal gel group had three patients develop skin lesions. Patients who got chlorhexidine vaginal gel had the highest rates of recovery and satisfaction, according to this study. Compared to previous therapies, such as Clotrimazole and oral metronidazole [13], no further side effects were observed other vaginal burning.

Transmission rates in injuries was considerably poorer in the chlorhexidine arm than in the povidone-iodine arm (0.6% vs 2.0%; $P = 0.039$), according to Lakhi et al. Various vaginal infections, such as cesarean beforehand, were also explained in several studies. Vaginal washing with 1.0% chlorhexidine gluconate solution reduced the proportion

of women in the intervention group who had a composite outcome of post-cesarean endometritis and wound infection when compared to the control group. At our center, we provide CS to at-risk women; we urge the use of chlorhexidine vaginal washing. In the research area, it is utilized as a supplement to the SSI control intervention, particularly in parturients that are in the vigorous stage of labor those who have a prolonged rupture of membranes prior to CS [14].

Antiseptic vaginal douches containing CHX 0.25-0.5% is routinely used in obstetrics. CHX douches (every 4-6 hours) have been found to minimize peripartum infections and the risk of Group B Streptococcus transmission from mother to child during labor. However, the efficacy of CHX douches may be limited due to the formulation's brief contact time with the vaginal mucosa. CHX's effectiveness in addition to acceptability in the management of vaginal infections remains unknown. For the first time, our findings showed that using a chlorhexidine-based bioadhesive vaginal gel to treat together bacterial in addition to fungal vaginal infections is an effective treatment. This gel's effectiveness and tolerance profile are comparable to established treatments for these diseases [14].

This study only had a four-week follow-up period. As a result, extended follow-up periods are not possible to assess CHX-VG efficacy (i.e. the effectiveness of this novel vaginal gel on recurrence frequency of vaginal reinfections). Antibiotics are commonly used to treat vaginal infections, but they have side effects, vaginal chlorhexidine has no effect on the vaginal flora, which is dominated by lactobacilli. This action might be important in lowering the re-infection rate following therapy with chlorhexidine. Though, more clinical trials are needed towards assess the effectiveness as well as acceptability of this novel chlorhexidine vaginal gel over

time and in terms of lowering vaginal infection recurrence rates [14, 15].

Chlorhexidine digluconate inhibited *Candida albicans* vaginal isolates, according to Alvendal et al. In patients with RVVC, biofilm is an issue, decreasing the effectiveness of antifungal therapy. To lower the high risk of recurrences, new treatment options must be developed as quickly as possible. Chlorhexidine digluconate was more successful in eradicating candida than fluconazole at dispersing an established biofilm. Future therapy techniques could include a combination of chlorhexidine digluconate and fluconazole to prevent relapses, as well as preventive chlorhexidine digluconate use to prevent biofilm formation and infections [15].

C. albicans planktonic growth was inhibited by fluconazole. Fluconazole, on the other hand, had no effect on candida cells in a formed biofilm and was unable to disperse and diminish it. *C. albicans* growing planktonically and in biofilms, on the other hand, were killed directly by chlorhexidine digluconate. Chlorhexidine digluconate also dispersed existing biofilm as well as reduced novel biofilm development. Following chlorhexidine digluconate treatment, no significant changes in biofilm or development were seen amongst commensal isolates as well as candida producing recurrent vulvovaginitis [15]. The efficiency of chlorhexidine gel in addressing numerous vaginal infections was shown to be optimal in all linked and published studies. [16]

Conclusion

The study has shown that there is satisfactory outcome in each of the condition considered for this study. The findings of side effects and improvement for each of the condition with each Chlorhexidine vaginal gel compared to another drug prescribed, have revealed that Chlorhexidine vaginal gel is well tolerated

while it gives significant clinical outcomes. Moreover, in BV, nausea and vomiting occurred with oral metronidazole while Chlorhexidine vaginal gel did not cause nausea and vomiting. Again, in NSV, vomiting was not found among the patients treated with Chlorhexidine vaginal gel but there was 1 patient with vomiting treated with combination therapy. However, 90% patients showed improvement treated with Chlorhexidine vaginal gel in VC while treatment with clotrimazole led to 100% outcome, although this is not significant. In other cases, Chlorhexidine vaginal gel proved to be same with the prescribed drugs. In case of VAS, it was found that the treatment with Chlorhexidine vaginal gel and with other drugs in each case, showed that there is no significant finding ($P > 0.05$), which implies that Chlorhexidine vaginal gel can be used in these conditions. However, there are certain limitations of this study. There is a need to conduct studies with larger and varied population and in more different severity. Therefore, the study suggests that Chlorhexidine vaginal gel can be used as an adjuvant drug for these conditions which should be made as guideline to the treatment of these conditions.

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