



Effectiveness of Hygiene Intervention with Everteen Natural Intimate wash to Control Recurrence of Vaginal Yeast Infection and Bacterial Vaginosis

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Abstract

Objective: To study the role and effectiveness of Everteen natural intimate wash in reducing the recurrence of vaginal yeast infection and bacterial vaginosis in patients after treatment with medical therapy.

Methods: Women diagnosed with vaginal yeast infection and bacterial vaginosis were taken into the study and two groups were formed as 1 group of women with vaginal yeast infection and 1 group of women with bacterial vaginosis. A total 200 women were recruited for the study whereas 100 women were diagnosed with vaginal yeast infection (Group 1) and 100 women were belonged to the group of bacterial vaginosis (Group 2). All 200 women were treated with respective antifungal and antibiotic therapy for yeast infection and bacterial vaginosis and followed by the application of everteen natural intimate wash and placebo wash during and after the treatment. In both the group, half of the women were given everteen intimate wash to wash their vagina and other half with placebo wash during 3 menstrual cycles (post treatment) in a double-blind, randomized, placebo-controlled trial.

Results: The medical therapy provided to the women of both groups resulting into the cure rate of 82% in Group-1 (Vaginal Yeast Infection) and 78% in Group-2 (Bacterial Vaginosis). After the one menstrual cycle (covered during treatment regimen), the uncured patients with infection in Group-1 (18 Patients) and in Group-2 (22 Patients) were further treated with recommended medical therapy and these women patients were excluded out of the study. Rest of the women (cured both in Group-1 and Group-2) were followed with everteen natural intimate wash and placebo wash for 3 menstrual cycles. In the Group-1 (Vaginal Yeast Infection), 89% of women, who used everteen natural intimate wash, reported no recurrence of vaginal yeast infection whereas 67% of women in Group-1 using placebo wash reported recurrence of vaginal yeast infection. The analysis of Group-2 showcased, 76% of women using everteen natural intimate wash have no sign of bacterial vaginosis while in the sub group of women using placebo wash, 54% has bacterial vaginosis recurrence problem.

Conclusion: The study shows that everteen natural intimate wash is significantly effective in preventing vaginal infection – vaginal yeast infection and bacterial vaginosis. The regular use of everteen natural intimate wash reduced the chances of vaginal infection and it lengthens the time to relapse for women experiencing vaginal infection.

Background

Vaginal yeast infection is a common problem with women as it is found that 75% of women suffer with vaginal yeast infection at some point of time. It is an infection which causes vaginal discomforts

like vaginal itching, and burning around vagina. Vaginal yeast infection is caused due to overgrowth of the fungus candida. Vaginal yeast infection is treated with antifungal medicine.

Bacterial vaginosis, a disease not with unknown etiology is not uncommon among women. It leads to reduction of commensal and over growth of other bacteria. It presents with a common sign, malodour discharge. It may lead to pre-term delivery if it happens during pregnancy¹.

The recommended treatment regimes for BV are oral or vaginal Metronidazole and vaginal clindamycine².

The primary objective of this study was to investigate if adjunct Everteen natural intimate wash application could improve the initial cure rate after antifungal and antibacterial therapy, and secondly, if Everteen natural intimate as repeated after treatment during 3 menstrual cycles could lengthen the time to relapse after initial cure.

Scenario:

Vaginal infection is a commonly rising problem amongst women causing vaginal discomforts and affecting quality of life of women. Numerous women do adopt several methods to prevent these infection, however a low awareness in the segment lead to unhygienic practice of feminine hygiene. Feminine hygiene wash are also used by women as one of the method to maintain vaginal hygiene. Feminine hygiene wash is growing to be daily cleansing process for women to maintain vaginal hygiene. It is important to know if feminine hygiene wash helps in maintaining the vaginal pH of ~4.5 and it does not disturb vaginal environment. It is therefore to understand whether the feminine hygiene wash helps in preventing vaginal infection without disturbing vaginal pH ~4.5.

Methods

The study was conducted at an out-patient private gynaecological clinic, New Delhi from August 2016 until December 2016. All women with symptomatic vaginal yeast infection and bacterial vaginosis who visited the clinic and fulfilled the inclusion criteria were consecutively invited to participate in a prospective, double-blind, placebo-controlled study of Everteen natural intimate wash. The women patients in respect to the treated infection (vaginal yeast infection and

bacterial vaginosis) were given medical therapy in terms of antifungal and antibacterial. The patients who were fully treated after medical therapy were continued in the study with application of everteen natural intimate wash for 3 menstrual cycles.

Selection criteria were: regularly menstruating women 25 years of age or older, with normal gynaecological status, not pregnant or breast feeding, and without signs of other genital tract infections.

Exclusion criteria were: patients with hormonal IUD without regular menstruation; women with clinical Candida infection or Trichomonas vaginalis infection.

Study Sample

All 200 patients were randomized into two major groups of Group-1 for vaginal yeast infection and Group-2 for bacterial vaginosis with each of 100 patients. The major groups (Group-1 & Group-2) were further divided in four sub-groups dedicated to application with everteen natural intimate wash and placebo wash.

Group-1 (Vaginal yeast Infection)

100 Patients	
Everteen Sub-group	Placebo Sub-group
50 patients	50 patients

Group-2 (Bacterial Vaginosis)

100 Patients	
Everteen Sub-group	Placebo Sub-group
50 patients	50 patients

The mean age was 34.3 years with a total range of 25–52 yrs. The main complains were 90% malodorous discharge, 70% excessive discharge, 14% itching, and 11% burning. The diagnosis of BV based on Amsel criteria were 94% fulfilling the criteria: typical discharge, 95% positive whiff test, 97% had presence of clue cells (one missing data), and 100% had a pH > 4.5.

Clinical Methods

At inclusion in the study, women underwent a routine gynaecological examination. Vaginal secretion of all were analysed for pH using special

pH strips (range 3.8–5.0). The patients fulfil at least 3 out of 4 criteria: vaginal itching & burning, thin homogenous discharge, vaginal pH above 4.5, positive amine test, presence of clue cells⁴.

Management

The participants were given the recommended medical therapy for respective vaginal infection and everteen natural intimate wash and placebo wash for vaginal application. After each menstruation, the treatment with everteen wash or placebo wash was repeated during 10 days for three cycles. Thus the treatment regime included one treatment course followed by regular everteen Intimate wash application courses, one within the same menstrual cycle and the other during the next three consecutively cycles.

Follow up

After each menstruation, the patient self-swabbed a specimen of vaginal fluid and stroked the cotton tip on a glass slide: the sample was then air dried and submitted in a sealed envelope to the clinic according to a previously described method. The vaginal sample was collected after cessation of bleeding and before starting of the treatment. Women who were considered still to be infected with vaginal yeast infection and bacterial vaginosis in respective groups after the first menstruation were re-treated with medical therapy and were excluded from the study. The remaining participants were asked to continue to swab vaginal samples and continued with everteen wash and placebo wash. The nurse affiliated with the study conducted a telephone interview with each participant to document treatment complications and concomitant medication. If the patient had failed to submit a sample of vaginal fluid at the right time, the sample was recorded as missing and she was reminded to send in a new sample after the next menstruation. After four menstrual cycles, the participant was scheduled for a follow up visit to the clinic. Normally the vaginal samples were taken once every 28 days and the follow up time of 3 menstrual cycles thus would be 3 and half months but for some women, 3

menstrual cycles exceeded 3 months. Therefore, we report these 4-months follow up as number of vaginal infection free days between cured and relapse, as well as menstrual cycles.

Study Design

The initial part of the study was open, whereby patients were treated with antifungal and antibacterial therapy; it continued thereafter as a double-blind, randomized, placebo-controlled trial with parallel group design. The patients were equally allocated 1:1 to either Everteen natural intimate wash or placebo cleansing wash of identical appearance by block randomization.

Statistical Methods

Not all patients collected a vaginal fluid sample every month, but all who sampled at least once were included in the analysis. In case of missing data during the follow up, the procedure "last observation carried forward" (LOCF) was used. In case of missing data from a visit for a relapsed patient, the observation from the following visit was transferred back. This procedure was used in order not to over-estimate the effect. The variable "days from cured to relapse" has been calculated in days and is given by Kaplan-Meier plot. All comparisons between and within groups were performed two-tailed with a significance level of 5%.

All study personnel were blinded to the treatment throughout the study and all the data were collected and recorded in data sheets before the code of the active or placebo treatment was added. Thereafter no changes in the data sheet were allowed.

A difference in relapse rate between the Everteen wash group and the placebo group of at least 20% was considered clinically relevant. All the analysis in this study was performed in accordance with the principal of intent to treat

Result

The initial cure after the first menstruation was 82% (82/100) in the Group-1 (vaginal yeast infection) and 78% (78/100) in Group-2 (bacterial

vaginosis). In the vaginal yeast infection Group-1, 89% (37/42) using everteen natural intimate wash group versus 33% (13/40) in the placebo group reported no recurrence of vaginal yeast infection during the study. In the bacterial vaginosis Group-2, 76% (30/40) using everteen natural intimate wash has no relapse with bacterial vaginosis while 54% (21/38) in placebo wash group reported relapse in bacterial vaginosis.

Group-1 (Vaginal yeast Infection)	
100 Patients	
Everteen Sub-group	Placebo Sub-group
50	50
After medical therapy follow up (excluding the untreated)	
42 patients continued	40 patients continued
37 reported no recurrence	13 reported no recurrence

Group-2 (Bacterial Vaginosis)	
100 Patients	
Everteen Sub-group	Placebo Sub-group
50	50
After medical therapy follow up (excluding the untreated)	
40 patients continued	38 patients continued
30 reported no relapse	17 reported no relapse

However any patient with missing or unclassified smears at the initial visit who continued the study and whose next smear indicated a cure was included in the cured group. The patients were continuously advised and reminded of appropriate way of maintaining hygiene and follow up a healthy lifestyle. The change in pH of the vagina was regularly checked during every visit of the subjects in all groups of the study.

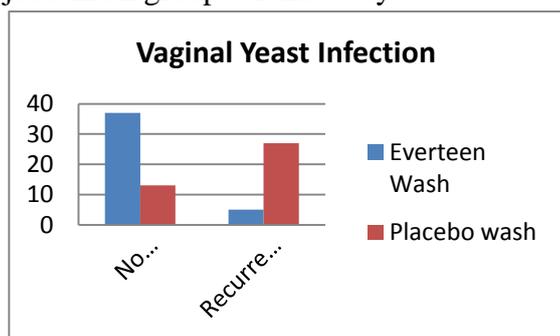


Figure 1

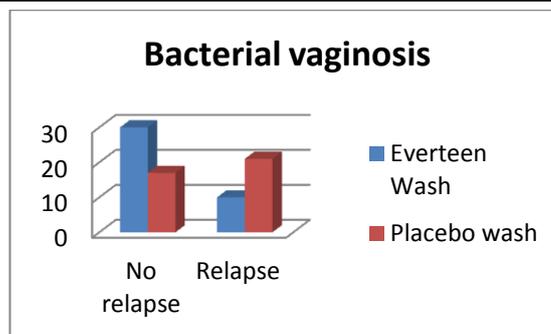


Figure 2

Discussion

This study shows that supplement therapy with Everteen Natural Intimate Wash could help in preventing the recurrence of vaginal yeast infection and bacterial vaginosis. The cure rate improved at the 2nd menstrual cycle from 56% to 80% in Group-1 and 44% to 85% in Group-2, an over 20% difference that may be of clinical importance.

We had a dropout rate of 5% in this 3-months follow up study which is statistically considered to be an acceptable. The strength of our study is that all patients were recruited at the same clinic and that all patients were recruited by the same investigator and that all smears and all follow up were done by one investigator. Drawbacks are that we recruited women with recurrent vaginal yeast infection and bacterial vaginosis as well as women with initial infections and we had no knowledge of the number of sex partners.

The reported adverse events are mild and transient and no difference between placebo or everteen intimate wash groups is indicated. Some patients had been treated for symptomatic candida infections and bacterial vaginosis and accordingly divided in the group. As most other treatment studies for bacterial vaginosis report that 10% of the patients have a symptomatic candida infection, our results are in concordance with other studies⁵.

Conclusion

In conclusion, this study shows that adjunct treatment with everteen natural intimate wash significantly reduces the chances of vaginal yeast infection and bacterial vaginosis. After Everteen natural intimate wash was given during three

menstrual cycles, there is a marked improvement in "time to relapse" so more women remain cured, i.e. vaginal infection-free, after 4 months. Everteen natural intimate wash is effective feminine hygiene wash in preventing vaginal infection and it minimizes the recurrence vaginal infection frequently experienced by women.

References

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