

Comparison Effect Of Vitamin C Vaginal Tablet Versus Oral Metronidazole For Treatment Of Bacterial Vaginosis

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Summary:

Back ground: Bacterial vaginosis is an important gynecological problem, during reproductive age group with high relapse rate, it is associated with high vaginal PH, vaginal vitamin C recently tried to decreased vaginal PH and treat bacterial vaginosis.

Patients & Methods: One hundred and one women with Bacterial vaginosis their age range from 18-40 years enrolled in this study, the Diagnosis is confirmed by at least 3 out of 4 of (Amsel criteria) which include a thin homogenous vaginal discharge, vaginal PH of ≥ 4.7 , a characteristic "amine odour" release when alkali (10% KOH) is added to a specimen of vaginal fluid, and at least 20% of epithelial cells having the appearance of clue cell in a wet mount of vaginal fluid or on gram stain. All women were randomly assigned to receive either 250mg vitamin C vaginal table at bed time for 6 days (51 patients) or oral metronidazole 500mg twice daily for 7 days (50 patients) the patients were evaluated at two follow up visit 1st after treatment completed and 2nd one week later. Therapeutic success was defined as the presence of less than 3 Amsel criteria.

Results: Regarding the infection with bacterial vaginosis no significant difference between two groups, (15.9%) of patients still infected with bacterial vaginosis at 1st follow up visit in (vagi-C) treated group. Compare to 26.7% of metronidazole group $P=0.5$, this confirmed at 2nd follow up visit $P=0.1$. Regarding vaginal PH there is significant reduction of vaginal PH in both groups at end of treatment $P=0.0032$ in Vagi-C, and $P=0.0001$ in metronidazole treated group.

Conclusion: Vitamin C vaginal table 250mg has effective as oral metronidazole for treatment of bacterial vaginosis.

Key Words: vaginal vitamin C, bacterial vaginosis.

*Fac Med Baghdad
2010; Vol. 52, No.4
Received May.2010
Accepted Sept. 2010*

Introduction:

The vaginal flora plays an important role in female health, and, when the naturally dominant Doderlein's bacillus (a Lacto bacillus sp.) is displaced, bacterial vaginosis (BV) occurs [1,2,3], which is the most common cause of vaginal discharge occurring in women during their reproductive years [4].

Doderlein's bacilli are capable of fermenting the glycogen, deriving from the decline of the eutrophic vaginal mucosa, to lactic acid, with the release of hydrogen ions, the final result of this metabolic pathway is an acidic PH with values between 4-4.5 [3].

Increased vaginal PH is detrimental for this pathogenic Micro organisms whose replication, in contrast, is favored by the absence of counter action exerted by Doderlein's bacillus [5].

The diagnosis established by detecting at least three of four compound criteria (Amsel criteria): a thin homogeneous vaginal discharge; a vaginal PH of ≥ 4.7 ; a characteristic 'amine' odour released when alkali: (10% KOH wt/vol) is added to a specimen of vaginal fluid, and at least 20% of epithelial cells having the appearance of (clue cells) in a wet mount of vaginal fluid. Alternative Laboratory based test include the use of Gram stain or gas liquid chromatography. [6,7].

Traditionally metronidazole use for treatment of this disease in different regimens [8,9]. Recently increase research interest in the host factors that control the PH of the vaginal environment. [3]

Acidification of the vagina has been tried by local application of products containing lactobacilli [10], lactic acid [11], hydrogen peroxid [12] and acetic acid [13].

A modern approach to decrease the PH, and consequently to get along lasting normalization of the vaginal flora consists in the vaginal application of vitamin C 250mg [4,14]. Ascorbic acid is characterized by a special galenic formulation that release the vitamin over hours to allow efficient action and at the same time local vitamin C. release [3].

Patients and Methods:

One hundred and one women included in this study their age range 18-40 years with chief complain malodorous vaginal discharge, were able to return for at least 2 follow up visits (at end of treatment, one week after discontinuation of treatment), had no antibiotic or used vaginal suppositories in the last 14 days, were not known to be immune compromised or have diabetes.

Vaginal fluid was collected and PH was measured, a vaginal Fluid $\text{PH} \geq 4.7$ were included in this study, 10% KOH were added to vaginal fluid (whiff test),

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release of fishy odor (considered as positive test), vaginal fluid examine for presence of clue cell if more than > 20% of cell in the vaginal fluid had clue cell appearance the sample considered positive on fresh smears, or by using gram stain.

Wet mount microscopy mixing with saline solution to exclude candidal, Trichomonas infection.

A systematic random sampling technique by given either A or B medication to every other patient.

A- Tablet of vitamin C 250mg at bed time for 6 days.

B- Oral metronidazole 500mg twice daily for 7 days Vagi-C manufactured by Global pharm company Dubi-UAE under licence from Polichem-Switzerland, tablets in pack of 6 vaginal tablets are available which usually sufficient.

Patients instructed to record any persistence or recurrence of symptoms, any side effect of treatment, again fluid collected after end of treatment and one week later same test applied therapeutic success was define as the presence of less than three Amsel criteria.

Statistical Analysis:

Categorical variable was compared with chi-square, while continuous variable were compared with student T.test, odd ratios with a confidence interval (CI) was used to compare the out come of two groups. P value less than 0.05 considered to be significant.

Results:

One hundred and one women included in this study, fifty one patients received vitamin C. vaginal table contain 250 mg for 6 days applied at bed time, 50 patients receive oral metonidazole 500 mg twice daily for 7 days. 96 patients completed the study one patient in vitamin C group dropped out prematurely, 4 patients in metronidazole group were not complete the treatment coarse.

The epidemiological feature of patients in two groups at baseline visit are reported in table no. 1

--There is no statistical significant difference between 2 type of treatment regarding the presence of bacterial vaginosis at end of the treatment (visit no 1), as shown in figure no.1 .

Depend on Amsel criteria, Bacterial vaginosis was still present in (15.9%) in vagi C. treated group compared to (26.7%) of metronidazole treated group. P=0.5 as shown in table no.2

This result confirmed at 2nd follow up visit were bacterial vaginosis still present in 19.6% of patients treated with vagi-C and in 33.3% in patients treated with Metronidazole P=0.1 as shown in table no.3

Positive amine test present in 7.9% of patients in vagi C treated group and 13.3% in Metronidazole treated group at 1st follow up visit, In 3.9% in vagi C. treated group and 22.2% of Metronidazole treated group 2nd follow up visit, there is no statistical significant difference between two groups at both visits as shown in tables no.2,3 respectively.

No significant difference were found between two group at 1st and 2nd follow up visit regarding the

presence of clue cells, as shown in tables no.2,3 respectively.

The patients in both groups shown significant reduction of vaginal PH, P=0.0032 in vagi-C treated group and P=0.0001 in Metronidazole treated group again no statistical significant difference between two groups as shown in figure no.2.

The safety was good in both groups, patients developed occasional itching and burning sensation in vagi-C group and gastrointestinal side effect in Metronidazole group.

Table No 1: Epidemiological features, of patients in vagi-C, metronidazole treated groups at baseline visit.

Character	Vitamin C. N=51	metronidazole N=45	P value
Age (years)	29.5± 4.67	28.82±4.92	P=0.6
Height (cm)	163.4± 2.97	164.8±3.49	P=0.27
Weight (kg).	67.5± 5.37	69.6±5.25	P=0.8
Presence of (%)			
Discharge	51 (100%)	45 (100%)	/
KOH 10% (+ve test)	45 (88.3%)	38 (95%)	P=0.8
>20% clue cell(+ve test)	41(80.3%)	36 (80%)	P=0.8
PH ≥ 4.7	51 (100%)	45(100%)	/

Table no. 2: First follow up visit characteristics features of patients in two groups.

Character	Vagi C	Metronidazole	Odd ratio	C.I 95 %	P value
Discharge	13 (25.5%)	14(31.1%)	0.1	0.4-2.4	P=0.9
KOH 10%	4 (7.8%)	6 (13.3%)	0.2	0.1-2.1	P=38
Clue cell	10 (19.6%)	12 (26.7%)	0.6	0.2-1.7	P=0.41
PH≥ 4.7	10 (19.6%)	11(24.4)	0.7	0.2-1.9	P=0.5
Bacterial vaginosis	8(15.9%)	12(26.7%)			

Table no. 3: 2nd follow up visit characteristic features of patients two groups

Character	Vagi C	Metronidazole	Odd ratio	C.I 95%	P value
Vag.discharge	14 (27.5%)	16 (35.6%)	0.6	0.2-1.6	P=0.3
KOH 10%	2(3.9%)	6 (22.2%)	0.2	0.05-1.3	P=0.1
Clue cell	10 (19.6%)	15 (33.3%)	0.4	0.1-1.2	P=0.1
PH≥ 4.7	10 (19.6%)	16 (35.6%)	0.4	0.1-1.1	P=0.08
Bacterial vaginosis	10(19.6%)	15(33.3%)			

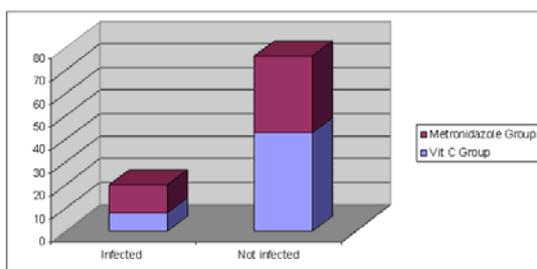


Figure no.1: Infected patients versus non infected patients with (BV) at first follow up visit in two treatment groups.

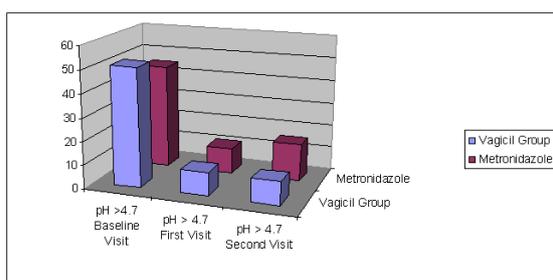


Figure no.2:changes in vaginal PH in both groups

Discussion:

In the present study, at 1st follow up visit : bacterial vaginosis was still present in significantly lower percentage of patients 15.9% in vagi-C treated group, p=0.0001 This result comparable with Petersen et al where 14% of patients still infected at 1st follow up visit [4]. No significant difference were found when compared with Metronidazole treated group P=0.5 in agreement with a study compared vagi C versus Metronidazole vaginal gel where 76.7% cured by vagi C compared to 80% cured by Metronidazole vaginal gel at first follow up visit P=0.7[15]

Our result disagree with other author clam poor result in the treatment of bacterial vaginosis with intra vaginal acid preparation (acetic acid based vaginal gel) [5,13] this could be due to the nature of its ingredients result in quick absorption and metabolism by vaginal mucosa, and poor adhesiveness of the gel to the vaginal mucosa and clearance of the product by vaginal discharge.

Regarding Vaginal PH : There is statistical significant reduction in vaginal PH in both groups was obtained in this study, same result obtained by Petersen[4]. Franco pollatti et al found that local application of vitamin C vaginally has significant lowering effect on high vaginal PH in agreement with our study [3]. Three out of 51 patients on vagi-C treated group developed occasional itching, burring sensation, during course of treatment in agreement with other author were Three out of thirty were reported occasional burning and itching during product use [16]. So this product is safe and very low risk for systemic adverse effect. This study

confirm that the local application of a vaginal tablet containing 250mg of vitamin C has effectiveness as oral Metronidazole for treatment of bacterial vaginosis this effect persist for one week after discontinuation of treatment, this product safe with very low risk of systemic adverse effect can use in situation were systemic adverse effect unwanted like pregnancy, DM. Another study should be per found to evaluate the possible benefit and vagi C in treatment of bacterial vaginosis associated complication like:- low birth weight, preterm labour ,chorioamnionitis, post partum endometritis, pelvic in flamatory disease and Post surgery infection.

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