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

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Summary:
Background: 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 tablet at bed time for 6days (51patients) or oral metronidazole 500mg twice daily for 7days (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.

Introduction:

The vaginal flora plays an important role in female health, and, when the naturally dominant Doderlein’s bacillus (a Lactobacillus 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 deters mental 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 homogenous 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].

An 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 aspeal 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 malodours 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 PH≥4.7 were included in this study, 10% KOH were added...
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Table No 1: Epidemiological features of patients in vagi-C, metrotridazole treated groups at baseline visit.

<table>
<thead>
<tr>
<th>Character</th>
<th>Vitamin C</th>
<th>Metronidazole</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years)</td>
<td>29.5±4.67</td>
<td>28.82±4.92</td>
<td>P=0.6</td>
</tr>
<tr>
<td>Height (cm)</td>
<td>163.4±2.97</td>
<td>164.8±3.49</td>
<td>P=0.27</td>
</tr>
<tr>
<td>Weight (kg)</td>
<td>67.5±5.37</td>
<td>69.6±5.25</td>
<td>P=0.8</td>
</tr>
<tr>
<td>Presence (%)</td>
<td>Discharge</td>
<td>51 (100%)</td>
<td>45 (100%)</td>
</tr>
<tr>
<td>KOH 10% +ve test</td>
<td>45 (88.3%)</td>
<td>38 (95%)</td>
<td>P=0.8</td>
</tr>
<tr>
<td>-20% clue cell +ve test</td>
<td>41 (80.3%)</td>
<td>36 (80%)</td>
<td>P=0.8</td>
</tr>
<tr>
<td>PH &gt; 4.7</td>
<td>51 (100%)</td>
<td>45 (100%)</td>
<td>/</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Character</th>
<th>Vagi C</th>
<th>Metrotridazole</th>
<th>Odd Ratio</th>
<th>CI 95%</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Discharge</td>
<td>13 (25.5%)</td>
<td>14 (31.1%)</td>
<td>0.1</td>
<td>0.4-2.4</td>
<td>P=0.9</td>
</tr>
<tr>
<td>KOH 10%</td>
<td>4 (7.3%)</td>
<td>6 (13.3%)</td>
<td>0.2</td>
<td>0.1-2.1</td>
<td>P=38</td>
</tr>
<tr>
<td>Clue cell</td>
<td>10 (19.6%)</td>
<td>12 (26.7%)</td>
<td>0.6</td>
<td>0.2-1.7</td>
<td>P=0.41</td>
</tr>
<tr>
<td>PH 4.7</td>
<td>10 (19.6%)</td>
<td>11 (24.4%)</td>
<td>0.7</td>
<td>0.2-1.9</td>
<td>P=0.5</td>
</tr>
<tr>
<td>Bacterial vaginosis</td>
<td>8 (15.9%)</td>
<td>12 (26.7%)</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Character</th>
<th>Vagi C</th>
<th>Metrotridazole</th>
<th>Odd Ratio</th>
<th>CI 95%</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Vag discharge</td>
<td>14 (27.5%)</td>
<td>16 (35.6%)</td>
<td>0.6</td>
<td>0.2-1.6</td>
<td>P=0.3</td>
</tr>
<tr>
<td>KOH 10%</td>
<td>2 (3.9%)</td>
<td>6 (22.2%)</td>
<td>0.2</td>
<td>0.05-1.5</td>
<td>P=0.1</td>
</tr>
<tr>
<td>Clue cell</td>
<td>10 (19.6%)</td>
<td>15 (33.3%)</td>
<td>0.4</td>
<td>0.1-1.2</td>
<td>P=0.1</td>
</tr>
<tr>
<td>PH 4.7</td>
<td>10 (19.6%)</td>
<td>16 (35.6%)</td>
<td>0.4</td>
<td>0.1-1.1</td>
<td>P=0.08</td>
</tr>
<tr>
<td>Bacterial vaginosis</td>
<td>10 (19.6%)</td>
<td>15 (33.3%)</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

The patients in both groups showed 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.

Results:

One hundred and one women included in this study, fifty one patients received vitamin C, vaginal tablet contain 250 mg for 6 days applied at bed time, 50 patients received oral metronidazole 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 course.

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.
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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 was 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 = 0.715 [5].

Our result disagree with other author claim 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, burning 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 form 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 inflammatory disease and Post surgery infection.

References:
15-Comparison effect vitamin C vaginal tablet with Metronidazole vaginal gel treatment and relapse bacterial vaginosis 19th European congress of clinical microbiology and infectious Disease helsinki, Finland16-19may 2009 12 9 09.