

Efficiency of Probiotic Vaginal Tampons versus Oral Metronidazole in the Treatment of Bacterial Vaginosis

Haitham A. Torky^{1*}, Asem A. Moussa²

¹Department of Obstetrics and Gynecology, October 6 University, Cairo, Egypt

²Department of Obstetrics and Gynecology, Al-Azhar University, Cairo, Egypt

*Corresponding author: Haitham A. Torky, Department of Obstetrics and Gynecology, October 6 University, Cairo, Egypt, Tel: +201001230161; Fax No: +20225240066; E-mail: haithamtorky@yahoo.com

Abstract

Introduction: Bacterial vaginosis is defined as change in the vaginal ecology characterized by replacement of lactobacilli by a variety of bacterial flora including anaerobes. The condition is diagnosed using Amsel Criteria. Ten to fifteen percent of cases do not improve on antibiotics, which encouraged the use of probiotics.

Aim: To compare between the efficiency of probiotic vaginal tampons and oral metronidazole in the treatment of bacterial vaginosis.

Patients & Methods: Three hundred and three qualified cases -of which 270 case continued- were subjected to history, general, abdominal, local examination including speculum examination and investigations in the form of pH strip indicator, vaginal swab from the discharge, 10% potassium hydroxide (KOH) added to perform Whiff test and finally vaginal smear, then the patients were divided into 2 groups Group 1 consisted of 151 patients receiving oral metronidazole for one week and Group 2 received oral placebo and probiotic vaginal tampons for one week. All patients had follow-up after 10 and 30 days from the start of treatment to assess the efficacy of treatment and assess persistence or recurrence respectively and data were collected.

Results: There was insignificant difference between both groups as regards age or the type of contraception used. Follow-up after 30 days showed a significant difference in the cure rate between both groups in favor of the probiotic vaginal tampons (91.8% vs 57.8%).

Conclusion: Probiotic vaginal tampons are superior to oral metronidazole in the treatment of bacterial vaginosis with the advantages of avoiding drug side effects and resistance.

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Introduction

Bacterial vaginosis is defined as change in the vaginal ecology characterized by replacement of lactobacilli by a variety of bacterial flora including anaerobes and Gardnerella vaginalis^[1]. Reproductive age women commonly have bacterial vaginosis with world-wide variations depending on the population studied^[2].

The condition is diagnosed using the criteria established by Amsel and co-workers^[3]. Untreated cases of bacterial

vaginosis are at increased risk of sexually transmitted diseases such as HIV, in addition to, complications of pregnancy^[4] such as miscarriage and preterm labor^[5] hence, the importance of treatment.

Metronidazole and clindamycin are the antibiotics usually used in treatment. They can be administered either orally or vaginally^[6]. However, between 10 and 15% of cases do not improve with the first course of antibiotics and high recurrence rates up to 80% have been reported^[7]. This encouraged the increased use of alternative medicine such as probiotics^[8] which

were shown to be safe, with lower cost and less side effects^[9].

Cochrane reviews had conflicting results as two reviews done in 2009^[10] and 2014^[11] found tentative, however, insufficient evidence for probiotics as a treatment for BV. Another review done in 2013 found benefit for the use of probiotics in pregnancy^[12].

Considering the conflicting results in the Cochrane reviews we decided to perform a randomized control trial to compare between the efficiency of probiotic vaginal tampons and oral metronidazole in the treatment of bacterial vaginosis.

Patients and Methods

The current study is a single blinded clinical interventional trial done in the outpatient clinic in both Al-Azhar and October 6th University hospitals from November 2014 to may 2015 on 303 patients between the age of 20 and 40 diagnosed with bacterial vaginosis according to Amsel's criteria^[3]. Those with evidence of other genital infection, pregnant, breast feeding, known hypersensitivity to metronidazole or probiotics, intercourse or vaginal douching within 24 hours or those with conditions predisposing to infection such as diabetes mellitus or intake of steroids were excluded from the study.

All cases were verbally consented then subjected to history, general, abdominal and local examination including speculum examination, in addition to, investigations in the form of pH strip indicator dipped in the posterior fornix, vaginal swab from the discharge and 10% potassium hydroxide (KOH) added to perform Whiff test and finally vaginal smear done and spread on clear serial slides.

Fixation and staining of the smears

All slides were left to dry in air then transferred to the microbiologist. Slides were fixed by heating and stained by gram stain.

Examination of smears

The slides were examined microscopically for the presence of clue cells.

The patients were divided into two groups: group 1 included 151 patients who received oral metronidazole tablets 500 mg twice daily for one week and group 2 included 152 patients who received probiotic vaginal tampons combined with oral placebo twice daily for one week. All patients had follow-up after 10 and 30 days from the start of treatment to assess the efficacy of treatment and assess persistence or recurrence respectively. All the information was collected in a questionnaire form filled by the examiner.

Data management and analysis

The collected data were revised, coded, tabulated and introduced to a PC using system software package (SAS, version 9.0). Data were presented and analysis was done according to the type of data obtained for each parameter.

Descriptive statistics

Numerical variables were presented as mean, standard deviation and range. Categorical variables were presented as numbers and percentages.

Analytical statistics

Independent-Samples T test was used for comparison of numerical variables between two groups, Chi-Square was used for comparison of categorical variables between two groups, paired T-test was used for comparison of numerical variable more than one time for the same study group, Mc Nemar test was used for comparison of categorical variables measured more than one time for the same study group. P-value was considered significant if < 0.05 , highly significant if < 0.01 and non-significant if > 0.05 .

Results

The three hundred and three women enrolled in the study were divided into 2 groups. Group 1 containing 151 patient receiving metronidazole for one week and group 2 containing 152 patients receiving oral placebo + probiotic vaginal tampons for one week. Sixteen cases in group 1 and seventeen cases in group 2 were lost during follow-up making the total number of cases 270 (135 in each group). Mean age in group 1 was 26.83 ± 4.34 SD while that of group 2 was 28.03 ± 4.66 SD, $t = 1.031$ and P-value was 0.307 which was not statistically significant.

The contraceptive methods used were as follows: 36 cases used intrauterine device (26.6%) in group 1 and 35 cases in group 2 (25.9%), 12 cases used oral contraceptive pills (8.9%) in group 1 and 11 cases in group 2 (8.1%), six cases used depo-medroxyprogesterone acetate in group 1 (4.4%) and 5 cases in group 2 (3.7%), four cases used implanon in group 1 (3.0%) and six cases in group 2 (4.4%), while the remaining cases in both groups which were 77 (57.0%) in group 1 and 78 (57.7%) in group 2 didn't use any form of contraception.

Clue cells in wet mount had a sensitivity of 90% and specificity of 97%, whereas vaginal pH > 4.5 had a sensitivity of 85% in the current study.

The follow-up of cases after 30 days revealed that 124 out of 135 cases were cured in group 2 representing 91.8% as compared to 78 out of 135 cases in group 1 representing 57.8%, there were 11 cases who were resistant to treatment in group 2 representing 8.2% to 39 cases in group 1 representing 28.9%, and no cases of relapse in group 2 0.0% as compared to 18 cases in group 1 representing 13.3%. Those results showed a significant difference between the two groups.

Discussion

Bacterial vaginosis is a condition characterized by the replacement of lactobacilli by Mycoplasma Hominis, Gardenella Vaginalis and anaerobic bacteria as Bacteroides Spp^[13]. It is the commonest cause of abnormal vaginal discharge in reproductive age women affecting between 27 and 31% of the population in a study done by^[14] and reaching up to 55.5% in an Egyptian study done by^[15].

Complications of bacterial vaginosis include post-operative infection and pelvic inflammatory disease^[16], in addition to, pregnancy related complications as miscarriage, preterm labor and low-birth weight^[17].

Treatment modalities as antibiotics have been tried but the results were not optimum, therefore, another treatment modality was used aiming at the restoration of lactobacilli using probiotic vaginal tampons to displace and kill the abnormal pathogens, in addition to, modulation of the immune response to

interfere with the inflammatory cascade with promising results^[18], however, Cochrane reviews provided conflicting results^[10-12].

The commonest symptom in the current study was vaginal discharge (Table 1), which showed a significant improvement after treatment and one month follow-up in the group treated by probiotic vaginal tampons group as compared to the metronidazole treated group similar to the results found in the study done by^[19].

Table 1: Comparison of the vaginal discharge between the two groups using t test.

Discharge	Probiotic vaginal	tampons	Metronidazole	Metronidazole	T	P
Discharge	No. of cases	%	No. of cases	%		
pretreatment	152	100	151	100	0.000	1.000
10 days post-treatment	71	47.3	121	80.1%	-3.009	0.004
30 days post-treatment	30	19.7	50	33.1%	-2.608	0.012

The current study showed that vaginal pH > 4.5 was a sensitive indicator of bacterial vaginosis, and although there was no significant improvement 10 days at the completion of the treatment course in both groups this was not the case after one month follow-up where there was a significant improvement in the probiotic vaginal tampon group (Table 2), a possible explanation for this finding is that lactobacilli reached their optimum level after some time. Dunne and co-workers^[20], found similar results to the current study.

Table 2: Comparison of vaginal pH between the two groups using t test.

Vaginal pH	Probiotic	Vaginal tampons	Metronidazole	Metronidazole	t	P
	Mean	SD	Mean	SD		
Pretreatment	5.13	0.73	5.23	0.78	0.511	0.611
10 days post-treatment	4.43	0.529	4.55	0.54	0.855	0.395
30 days post-treatment	3.90	0.490	4.29	0.57	2.68	0.010

The current study showed no significant difference in the Whiff test between both groups either in the pre-treatment phase or after follow-up (Table 3), however, the presence of clue cells in the wet mount which was found to be a specific criterion for the diagnosis of bacterial vaginosis in the current study (90% sensitivity and 97% specificity) showed a significant improvement in favor of the probiotic vaginal tampons group both at 10 and 30 days post treatment (Table 4).

Table 3: Comparison of Whiff test between the two groups using t test.

Whiff test	Probiotic	Vaginal tampons	Metronidazole	Metronidazole	t	p
	No. of cases	%	No. of cases	%		
Pretreatment	152	100	151	100	-1.79	0.078
10 days post-treatment	40	26.3	40	26.5	-0.071	0.943
30 days post-treatment	10	6.5	10	6.6	0.111	0.912

Table 4: Comparison of clue cells between the two groups using t test.

Clue cells	Probiotic	Vaginal tampons	Metronidazole	Metronidazole	t	P
	No. of cases	%	No. of cases	%		
Pretreatment	152	100	151	100	0.30	1.30
10 days post-treatment	30	19.7%	71	47%	-1.88	0.044
30 days post-treatment	10	6.6	80	53	-3.184	0.003

The current study defined cure rate as clinical improvement in Amsel's criteria^[3] and normal vaginal smear after one month of treatment the reason for choosing this time period is that an early study done by^[21] revealed persistence of symptomatic bacterial vaginosis to be between 11 and 29% one month after treatment. Using this definition 91.8% of the patients in the probiotic vaginal tampons group were cured as compared to 57.8% in the metronidazole group.

Anukam and co-workers^[22], compared metronidazole followed by oral probiotics versus oral metronidazole alone and found 88% cure rate in the first group as compared to 40% in the second with 96 % of cases showing high counts of lactobacilli in the former group as compared to 53% in the latter group

concluding the effectiveness of oral probiotic in the treatment of bacterial vaginosis.

Probiotic vaginal tampons were also shown to be superior to other forms of treatment as eating pasteurized yoghurt in the treatment of bacterial vaginosis in the study done by^[23].

The current study found a significant difference in the failure rate which was 8.2% in the probiotic vaginal tampon group as compared to 28.9% in the metronidazole group which may possibly be due to the development of metronidazole resistance, while there were no cases of relapse in the probiotic vaginal tampon group as compared to 13.3% in the metronidazole group.

Conclusion

Probiotic vaginal tampons are superior to oral metronidazole in the treatment of bacterial vaginosis, in addition to, having the advantages of avoiding the problems of drug therapy as side effects and the development of drug resistance.

Further studies are needed to test patient acceptability of using vaginal tampons in The Egyptian community.

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References

1. Tabrizi, S.N., Fairly, C.K., Bradshaw, C.S., et al. Prevalence of *Gardnerella vaginalis* and *Atopobium vaginae* in virginal women. (2006) *Sex Transm Dis* 33(11): 663-665.
2. Kenyon, C., Colebunders, R., Crucitti, T. The global epidemiology of bacterial vaginosis: a systemic review. (2013) *Am J Obstet Gynecol* 209(6): 505-523.
3. Amsel, R., Totten, P.A., Spiegel, C.A., et al. Nonspecific vaginitis. Diagnostic criteria and microbial and epidemiologic associations. (1983) *Am J Med* 74(1): 14-22.
4. Amaya-Guio, J., Martinez-Velasquez, M.Y., Viveros-Carreño, D.A., et al. Antibiotic treatment for the sexual partners of women with bacterial vaginosis. (2015) *Protocols* 1-15.
5. Bacterial vaginosis from National Health Service, Uk. Page last reviewed 3/10/2013.
6. Oduyebo, O.O., Anorlu, R.I., Oguniola, F.T. The effects of antimicrobial therapy on bacterial vaginosis in non-pregnant women. (2009) *Cochrane Database Syst Rev* (3).
7. Senok, A.C., Verstraelen, H., Temmerman, M., et al. Probiotics for the treatment of bacterial vaginosis. (2009) *Cochrane Database Syst Rev* (4).
8. Trutnovsky, G., Law, C., Simpson, J.M. et al. Use of complementary therapies in a sexual health clinic setting. (2001) *Int J STD AIDS* 12(9): 307-309.
9. Reid, G., Burton, J. Use of lactobacillus to prevent infection by pathogenic bacteria. (2002) *Microbes and infection* 4(3): 319-324.
10. Senok, A.C., Verstraelen, H., Temmerman, M., et al. Probiotics for the treatment of bacterial vaginosis. (2009) *Cochrane database of syst rev* (4).
11. Huang, H., Song, L., Zhao, W. Effects of probiotics for the treatment of bacterial vaginosis in adult women: a meta-analysis of randomized clinical trials. (2014) *Arch gynecol obstet* 289(6): 1225-1234.
12. VandeVusse, L., Hanson, L., Safdar, N. Perinatal outcomes of prenatal probiotic and prebiotic administration: an integrative review. (2013) *J perinatal neonatal nurs* 27(4): 288-301.
13. Spiegel, C.A. Bacterial vaginosis. (1991) *Clin Microbiol Rev* 4(4): 485-502.
14. Jenifer, E.A., Jeffrey, F., Peipert, L. Prevalence of Bacterial vaginosis: 2001-2004 National Health and nutrition Examination Survey Data. (2007) *Obstet Gynecol* 109(1): 114-120.
15. Ahmed, M., El Shourbagy, M., Kareem, S., et al. Bacterial vaginosis risk factors and assessment of prevalence in Ain Shams maternity hospital outpatient clinics. (2005).
16. Taylor, B.D., Darville, T., Haggerty, C.L. Does bacterial vaginosis cause pelvic inflammatory disease? (2013) *Sexually Transmitted Diseases* 40(2): 117-122.
17. Sangkomkham, U., Lumbiganon, P., Prasertcharoensook, W., et al. Antenatal lower genital tract infection screening and treatment programs for preventing preterm delivery. (2008) *Cochrane Database Syst Rev* (2).
18. Reid, G., Bocking, A. The potential for probiotics to prevent bacterial vaginosis and preterm labour. (2003) *Am J Obstet Gynecol* 189(4): 1202-1208.
19. Eriksson, K., Carlsson, B., Forsum, U., et al. A double-blind treatment study of bacterial vaginosis with normal vaginal lactobacilli after an open treatment with vaginal clindamycin ovules. (2005) *Acta Derm Venereol* 85(1): 42-46.
20. Dunne, C., O'Mahony, L., Murphy, L., et al. In vitro selection criteria for probiotic bacteria of human origin: correlation with in vivo findings. (2001) *Am J Clin Nutr* 73(2 suppl): 386S-392S.
21. Hanson, J.M., McGregor, J.A., Hillier, S.L., et al. Metronidazole for bacterial vaginosis. A comparison of vaginal gel vs oral therapy. (2000) *J Reprod Med* 45(11): 889-896.
22. Anukam, K.C., Osazuwa, E., Osemene, G.I., et al. Clinical study comparing probiotic Lactobacillus GR-1 and RC-14 with metronidazole vaginal gel to treat symptomatic bacterial vaginosis. (2006) *Microbes Infect* 8(12-13): 2772-2776.
23. Shalev, E., Battino, S., Weiner, E., et al. Ingestion of yogurt containing Lactobacillus acidophilus compared with pasteurized yogurt as prophylaxis for recurrent candida vaginitis and bacterial vaginosis. (2006) *Arch Fam Med* 5(10): 593-596.