The Professional Medical Journal
www.theprofesional.com

ORIGINAL PROF-3668

DOI: 10.17957/TPMJ/17.3668

BACTERIAL VAGINOSIS;

COMPARISON BETWEEN METRONIDAZOLE VAGINAL GEL AND CLINDAMYCIN VAGINAL CREAM FOR TREATMENT OF BACTERIAL VAGINOSIS

Dr. Faiqa Saleem[1], Dr. Munazza Malik[2], Dr. Muhammad Shahid[3], Prof. Muhammad Tayyab[4]

1. MBBS, MCPS, MRCOG
   Assistant Professor
   Obstetrics & Gynaecology
   King Edward Medical University
   Lady Willingdon Hospital, Lahore
2. MBBS, MCPS
   Senior Registrar
   Jinnah Hospital, Lahore
3. MBBS, MCPS, FCPS
   Associate Professor
   Services Institute of Medical Sciences
4. MBBS, MCPS, FRCOG, FRCP, DCPS
   Jinnah Hospital Lahore

Correspondence Address:
Dr. Faiqa Saleem
339-Overseas Enclave -A,
Sector-B, Bahria Town, Lahore
drfaiqabaig@hotmail.com

Article received on:
10/10/2016
Accepted for publication:
14/12/2016
Received after proof reading:
14/02/2017

ABSTRACT… In women of reproductive age bacterial vaginosis is a most common polymicrobial disease and is the leading reason for vaginal discharge in this age group. Additionally it is further linked with sizeable disease burden of community problem in terms of infectious complications. Clindamycin vaginal cream and metronidazole vaginal gel are effective in the management of vaginal infections caused by multi bacteria. **Objectives:** To compare the therapeutic efficacy of Metronidazole vaginal gel and clindamycin vaginal cream as modality of treatment for bacterial vaginosis. **Study Design:** Randomized control trial. **Setting:** Department of Obstetrics and Gynaecology, Unit-3 Jinnah Hospital Lahore. **Period:** Six months from 02-05-2011 to 01-11-2011. **Material & Methods:** A total of 300 patients were included in this study. They were divided into two groups. Group A received metronidazole vaginal gel (5 g daily for 7 days) while group B administered with clindamycin vaginal cream (5g daily for 7 days). **Results:** Mean age of the patient was observed 34.3+3.5 and 32.9+ 2.1 years in group –A and B respectively. Vaginal discharge was absent in 104 patients (69.3%) from group A and 127 (84.7%) from group-B. Absence of clue cells on microscopy revealed in 112 patients (74.7%) from group A and 137 patients (91.3%) from group B. Absence of amine odour found in 116 patients (77.3%) of group A and 134 patients (89.3%) of group B. Significant difference was found between two groups with p value of 0.006 in respect of efficacy. **Conclusion:** Clindamycin vaginal cream is more effective in comparison to Metronidazole vaginal gel for the treatment of bacterial vaginosis.

Key words: Bacterial vaginosis, Clindamycin vaginal cream, Metronidazole vaginal cream.

Article Citation: Saleem F, Malik M, Shahid M, Tayyab M. Bacterial vaginosis; comparison between metronidazole vaginal gel and clindamycin vaginal cream for treatment of bacterial vaginosis. Professional Med J 2017;24(2):252-257.
DOI: 10.17957/TPMJ/17.3668

INTRODUCTION

Bacterial vaginosis is a common and polymicrobial disease and is the leading reason for vaginal complaints.[1] Additionally it is further linked with reasonable disease burden of community problem in terms of infectious complication in sexually active women.[2] Bacterial vaginosis is associated with increased risk of sexually transmitted diseases. Another risk of bacterial vaginosis that it can adversely affect the outcome of pregnancy. In literature incidence of bacterial vaginosis was reported as 36%.[3] Disturbance of vaginal flora is a common cause of symptoms in vaginal infection and that increased the risk of acquisition super added infections.[4] Risk of preterm delivery is increased if infection is acquired during pregnancy.[5] Prevalence of bacterial vaginosis is higher (10-20%) during pregnancy as compared to non- pregnant ladies.[6]

Obstetric and gynaecological complications are higher with bacterial vaginosis and increased risk of HIV-1 transmission.[7] Hydrogen peroxide producing Lactobacilli deficiency disturbs the ecosystem resulting in abundance of Gardenella vaginalis, anaerobes and mycoplasma. Vaginal discharge, pruritus and malodour are common presentation but 50% of patients remain asymptomatic.[8] For rapid diagnosis gram staining and Amsel`s clinical criteria are helpful while conventional culture technique is sometimes unreliable and not cost effective.[9] In a study done by Ferris et al, efficacy of metronidazole vaginal gel in a dose of 5 g applied twice daily

for 5 days was associated with cure rate of 75% in comparison to clindamycin vaginal cream 5 g once daily for 7 days cure rate was 86.2%.[10] Community can be saved by timely diagnosis and proper treatment to avoid gynaecological and prenatal complications.[11]

OBJECTIVE

Objective of the study were to

To compare the efficacy of Metronidazole vaginal gel and clindamycin vaginal cream for treatment of bacterial vaginosis.

Operational definitions

Efficacy

It was measured in terms of resolution of vaginal discharge and odour, on examination absence of clue cells on microscopy on high vaginal swab. Absence of above-mentioned findings were considered effective (when they will have resolution of vaginal discharge, amine odour and clue cells on microscopy at follow - up visit) was assessed after 14 days.

Hypothesis

Clindamycin vaginal cream is effective in more number of patients as compared to Metronidazole vaginal gel for the treatment of bacterial vaginosis.

MATERIAL AND METHODS

Study design

Randomized controlled trial.

Setting

Department of Obstetrics and Gynaecology, Unit-III, Jinnah Hospital, Lahore.

Duration of study

Study was carried out over a period of six months from 02-05-2011 to 01-11-2011.

Sample size

The calculated sample size was 150 cases in each group with 5% level of significance, 80% power of test, taking expected percentage of effectiveness of Metronidazole and clindamycin in the treatment of bacterial vaginosis i.e. 75% and 86%.2%, respectively.

Sampling technique

Non-probability purposive sampling.

Sample selection

Inclusion criteria

- Age 18 -45 years
- Non- pregnant
- Patients with bacterial vaginosis
- Cases diagnosed for bacterial vaginosis by history and laboratory test (presence of clue cells under microscopy with vaginal discharge having amine odour is diagnostic sign of bacterial vaginosis.
- Non – diabetic patients (assessed on BSL fasting <126 mg/dl and not on any hypoglycaemic agents)

Exclusion Criteria

- Lactating mothers.
- Anticipated menstruating during treatment.
- Patients who are not compliant to the prescribed treatment.

Data collection procedure

Three hundred women fulfilling inclusion and exclusion criteria in whom standard criteria was applied to diagnose bacterial vaginosis (vaginal discharge, amine odour and clue cells) reporting to outpatient department were included in this study. Informed consent was obtained from each subject. Demographic history of patients was recorded.

Three hundred cases were divided into two group (A and B) 150 in each group by using lottery method. Single blind technique was used. Group-A was given Metronidazole vaginal gel (5g) for 7 days as single application and group-B had clindamycin vaginal cream (5g) given once daily for total of 7 days as treatment of bacterial vaginal infections.

Woman returned for follow –up examination 14 days post treatment. Women were considered cured when they had resolution of vaginal

discharge, amine odour & clue cells on microscopy at follow-up visit. All this information recorded in study Performa (attached). Data were collected by researcher herself.

Data analysis procedure

All the data were entered and analysed using SPSS version 11.0. The variables like age presented by calculating mean and standard deviation. Frequency and percentages were calculated for efficacy, (absence of vaginal discharge (Yes, No), odour (Yes, No) and absence of clue cells (Yes, No). Comparison of two groups in terms of efficacy was determined by Chi square test and significance was measured as P value < 0.05.

RESULTS

A total of 300 cases were divided into two groups (A and B) 150 cases in each group were included in this study during the study period of six months from 02-05-2011 to 01-11-2011.

Regarding age distribution, 11 patients (7.3%) from group-A and 14 patients (9.3%) from group-B were <20 years old. 36 patients (24.0%) form group-A and 34 patients (22.7%) from group-B were between 20-25 years of age. 43 patients (28.7%) from Group-A and 48 patients (32.0%) from group-B were 26-35 years old. 60 patients (40.0%) from group-A and 54 patients (36.0%) from group-B were 36-45 years old. Mean age of the patients was observed 34.3+3.5 and 32.9+2.1 years in group-A and B, respectively (Table-I).

Vaginal discharge was absent in 104 patients (69.3%) from group-A and 127 patients (84.7%) from group-B (Table-II).

Absence of clue cells on microscopy revealed in 112 patients (74.7%) from group-A and 137 patients (91.3%) from group-B (Table-III).

Absence of amine odour found in 116 patients (77.3%) of group-7 and 134 patients (89.3%) of group-B (Table-IV).

When group-A and B were compared in terms of efficacy, Metronidazole vaginal gel was efficacious in 115 patients (76.6%) as compared to clindamycin vaginal cream efficacious in 133 patients (88.7%). Significant difference was found between two groups with p value of 0.006 (Table-V).

Age (year)	Group-A (Metronidazole vaginal gel)		Group-B (Clindamycin vaginal cream)	
	No.	%	No.	%
< 20	11	7.3	14	09.3
20-25	36	24.0	34	22.7
26-35	43	28.7	48	32.0
36-45	60	40.0	54	36.0
Total	**150**	**100.00**	**150**	**100.0**
Mean +SD	**34.3+3.5**		**32.9+2.1**	

Table-I. Distribution of cases by age (N=300)

Absence of vaginal	Group-A (Metronidazole	vaginal gel)	Group-B (Clindamycin	vaginal cream)
Discharge	**No.**	**%**	**No.**	**%**
Yes	104	69.3	127	84.7
No	46	30.7	23	15.3
Total	**150**	**100.00**	**150**	**100.0**

Table-II. Absence of vaginal discharge (N=300)

Chi Square = 9.96 df = 1 P value = 0.001

Absence of clue cells on	Group-A (Metronidazole	vaginal gel)	Group-B (Clindamycin	vaginal cream)
microscopy	**No.**	**%**	**No.**	**%**
Yes	112	74.7	137	91.3
No	38	25.3	13	08.7
Total	**150**	**100.00**	**150**	**100.0**

Table-III. Absence of clue cells on microscopy (N=300)

Chi Square = 14.76 df = 1 P value = 0.0001

Absence of Amine odour	Group-A (Metronidazole	vaginal gel)	Group-B (Clindamycin	vaginal cream)
	No.	**%**	**No.**	**%**
Yes	116	77.3	134	89.3
No	34	22.7	16	10.7
Total	**150**	**100.00**	**150**	**100.0**

Table-IV. Absence of amine odour (N=300)

Chi Square = 7.78 df = 1 P value = 0.005

Efficacy	Group-A (Metronidazole	vaginal gel)	Group-B (Clindamycin	vaginal cream)
	No.	**%**	**No.**	**%**
Yes	115	76.6	133	88.7
No	35	23.4	17	11.3
Total	**150**	**100.00**	**150**	**100.0**

Table-V. Distribution of cases by efficacy (N=300)

Chi Square = 7.54 df = 1 P value = 0.006

DISCUSSION

Bacterial vaginosis is the most common reason of vaginal discharge in females in the age of childbearing and the figure is as high as 40 to 50 percent of cases.[12]

Major risk factor for bacterial vaginosis is sexual activity and it is believed by most experts that bacterial vaginosis does occur in those females only who had vaginal intercourse.[13]

Sexual transmission of bacterial vaginosis pathogens is strongly supported by epidemiologic studies. In women who have sex with other females, there is a high incidence of bacterial vaginosis along with concordance of micro flora that further suggested sexual transmission is an important risk factor in this situation.[14]

Bacterial vaginosis may resolve spontaneously in up to one-third of non-pregnant and 50% of those with pregnancy.[15] For relief in symptomatic women with infection, treatment is indicated and also in those with asymptomatic infection to prevent postoperative infection before abortion or hysterectomy.

Risk of acquiring STDs, including HIV may also be reduced by the treatment of bacterial vaginosis.[16] Experts support the idea of treating the idea of symptomatic and asymptomatic women with bacterial vaginal infections. Pregnant women with history of preterm delivery in previous pregnancy may get benefited by treatment of bacterial vaginosis. Treatment and screening of these females is not supported by evidence in literature.[17]

Clindamycin or Metronidazole given orally or administered intravaginally result in significant clinical recovery rate of about 70 to 80 % at follow-up after four weeks.[18] Even oral medications are easy to take, but side effects are too much. Tinidazole as alternative can be good option.

Metronidazole 0.75 % gel (5 g topical vaginal therapy for five days administered as single application) is having similar results in term of

effectiveness as compared to oral Metronidazole. Patient preference will decide the choice of oral versus topical therapy. Single dose of 2 g oral therapy is less effective.[19]

Side effects of metronidazole are nausea and metallic taste, a disulfiram-like effect with alcohol, transient neutropenia (7.5 percent), Peripheral neuropathy is a well-known side effect and it may interact with warfarin, Pruritis and urticaria may be manifestation of allergy to the drug.[20]

Multiple randomized trials has proved that clindamycin is an effective drug for the above mentioned problem.[21]Vaginal administration of 5 g clindamycin as 2 % preparation used for seven days is effective alternate therapy.[22]

300mg Clindamycin oral preparation prescribed twice a day for seven is an alternate regime. It can be prescribed as Alternative options include once daily clindamycin 100 mg ovule or bio-adhesive therapy.[23]

Present study is designed to compare the therapeutic efficacy of clindamycin vaginal cream and Metronidazole vaginal gel as a choice of better treatment option for bacterial vaginosis. In group-A, 150 patients after administration of Metronidazole vaginal gel and in group-B, 150 patients administered clindamycin vaginal cream.

Both the drugs i.e. Clindamycin and Metronidazole are effective options for the treatment of bacterial vaginal infections.[24] All the symptomatic females must be treated. Those with multiple relapses shows response to this treatment.

In current study comparison of group-A (Metronidazole vaginal gel) and B (clindamycin vaginal cream) showed that Metronidazole vaginal gel was efficacious in 115 patients (76.6%) as compared to clindamycin vaginal cream efficacious in 133 patients (88.7%). Significant difference was found between two groups with p value of 0.006. These results are comparable with the findings of Ferris et al.[10]

CONCLUSION

This 7-day therapy of 5g clindamycin vaginal cream as once a day application was found to be significantly better and effective than Metronidazole 5g vaginal gel as single daily application for seven days used for the treatment of bacterial vaginal infections. The use of clindamycin vaginal cream is better option and results are better in terms of cure and symptomatic relief.

REFERENCES

1. Kalra A, Palcu CT, Sobel JD, Akins RA. **Bacterial Vaginosis: Culture- and PCR – based Characterizations of a Complex Polymicrobial Disease's pathobiology.** Curr infect Dis Rep 2007;9:485-500.

2. Verstraelen H, Verhelst R. **Bacterial vaginosis: an update on diagnosis and treatment.** Expert Rev Anti infect Ther 2009;7:1109-24.

3. Cherpes TL, Hillier SL, Meyn LA, Busch JL, Krohn MA. **A delicate balance: risk factors for acquisition of bacterial vaginosis include sexual activity, absence of hydrogen peroxide-producing lactobacilli, black race, and positive herpes simplex virus type 2 serology.** Sex Transm Dis 2008;35:78-83.

4. Koumans EH, Sternberg M, Bruce C, McQuillan G, Kendrick J, Sutton M, et al. **The prevalence of bacterial vaginosis in the United states, 2001-2004; associations with symptoms, sexual behaviors, and reproductive health.** Sex Transm Dis 2007;34:864-9.

5. Handler I, Andrews WW, Carey CJ, Klebanoff MA, Noble WD, Sibai BM, et al. **The relationship between resolution of asymptomatic bacterial vaginosis and spontaneous preterm birth in fetal fibronectin-positive women.** Am J Obstet Gynecol 2007;197:488. el-5.

6. Larsson PG, Fahreaus L, Carlesson B, Jakobsson T, forsum U. **Predisposing factors for bacterial vaginosis, treatment efficacy and pregnancy outcome among term deliveries; results from a preterm delivery study.** BMC Women's Health 2007;7:20.

7. Oduyebo OO, Anorlu RI, Ogunsola FT. **The effects of antimicrobial therapy on bacterial vaginosis in non-pregnant women.** Cochrane Database Syst Rev 2009;8:CD006055.

8. Romanik MK, Ekiel AM, Tomana L, Martirosian G. **The bacterial vaginosis –treatment problems.** Wiad Lek 2007;60:64-7.

9. Rizvi S, Khan MS, Khaskheli QA, Agha ZA, Sabir M.

Frequency of bacterial vaginosis and its rapid diagnosis in married females of child bearing age. Med Channel 2006;12:62-3.

10. Ferris DG, Litaker MS, Woodward L, Mathis D, Hendrich J. **Treatment of bacterial vaginosis: a comparison of oral Metronidazole, Metronidazole vaginal gel, and clindamycin vaginal cream.** J Fam pract 1995,41:443-9.

11. Azaz S, Chaudry A, Kareem F. **Bacterial vaginosis in patients at MH Rawalpindi.** Pak Armed Forces Med J 2005;55:24-8.

12. Hauth JC, Macpherson C, Carey JC. **Early pregnancy threshold vaginal PH and Gram stain scores predictive of subsequent preterm birth in asymptomatic women.** Am J Obstet Gynecol 2003;188:831.

13. Marrazzo JM, Antonio M, Agnew K, Hillier SL. **Distribution of genital Lactobacillus strains shared by female sex partners.** J Infect Dis 2009;199:680.

14. Thomson JL, Gelbartsm D, Broekhuizen FF. **Advances in the understanding of Bacterial Vaginosis.** J Repord Med 1989;34:581-7.

15. Gardner HC, Dukes CD. **Haemophilus vaginitis.** Am J Obstet Gynecol 1955; 69:962-76.

16. Amsel R, Lotten PA, Spiegel CA. **Nonspecific vaginitis: diagnostic criteria and microbial and epidemiologic associations.** Am J Med 1983;74:14.

17. Owen J, Jr. **Physiology of the menstrual cycle.** Am J Clin Nutr 1975;28:333-8.

18. Eschenbach DA, Thwin SS. **Influence of the normal menstrual cycle on vaginal tissue, discharge, and microflora.** Clin Infect Dis 2000;30:901-7.

19. Shi Y, Chen L. **Preliminary characterization of vaginal micro biota in healthy Chinese women using cultivation-independent methods.** J Obstet Gynecol Res 2009;35:525-32.

20. Zhou X, Bent SJ. **Characterization of vaginal microbial communities in adult healthy women using cultivation-independent methods.** Microbiology 2004;150:2565-73.

21. Otero CM, Nader-Macias EM. **Lactobacillus adhesion to epithelial cells from bovine vagina.** Communicating Current Research and Educational Topics and Trends in Applied Microbiology 2007; 2:749-57.

22. Farage M, Maibach H. **Lifetime changes in the vulva and vagina.** Archives of Gynaecology and Obstetrics 2006;273:195-202.

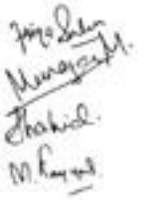
23. Kararashev JA, Vassileva SG. **Dermatologic diseases of the vulva.** Clinics in Dermatology 1997;15:53-65.

24. Castelo-Branco C, Cancelo MJ, Villero J, Nohales F, Julia MD. **Management of post-menopausal vaginal atrophy and atrophic vaginitis.** Maturitas 2005;52:S46-S52.

PREVIOUS RELATED STUDY

Rubina Sohail, Ghazala Agha, Farrukh Zaman. BACTERIAL VAGINOSIS; FREQUENCY IN GYNAECOLOGICAL POPULATION (Original) Prof Med Jour 11(2) 176-180 Apr, May, Jun, 2004.

AUTHORSHIP AND CONTRIBUTION DECLARATION

Sr. #	Author-s Full Name	Contribution to the paper	Author=s Signature
1	Dr. Faiqa Saleem	All original contributions in writing this paper from order of priority	
2	Dr. Munazza Malik		
3	Dr. Muhammad Shahid		
4	Prof. Muhammad Tayyab		