

Original Article

COMPARISON OF 2% VAGINAL CLINDAMYCIN WITH ORAL METRONIDAZOLE FOR TREATMENT OF BACTERIAL VAGINOSIS AT SERVICES HOSPITAL LAHORE

Tayyaba Tahira, Robina Tariq, Misbah Javaid, Farah Shabaz and Huma Tehseen

Objective: To compare the efficacy and safety of local application of 2% vaginal clindamycin with oral metronidazole for treatment of bacterial vaginosis.

Methods: Two hundred married women were included in the study in which bacterial vaginosis was diagnosed by standard criteria. Patients were randomized to two group with 100 patients in each group. One group (A) were treated with oral metronidazole, 400mg, three time daily for seven days, while group (B) patients were treated with intravaginal clindamycin 2% cream for seven days. The symptomatic response of the both groups was checked by follow up after one week, 3 month and then 6 months after completion of treatment.

Results: In group A 14 (14%) patients were free of symptoms with in seven days 68 (68%) patients after seven days and 18 patients (18%) had no alleviation, while in group B 20 (20%) patients were free of symptoms within seven days, 74 (74%) patients after seven days and 6(6%) patients had no alleviation of problem. In group A 10 patients (10%) had vomiting and diarrhea, 14 (14%) patients had abdominal pain. In group B, 2 (2%) patient had abdominal pain and 10 (10%) patients had local irritation and swelling. There were 18 (18%) patients who had failure of response of treatment in group A and 6 (6%) patients in group B had failure. In group A 16 (16%) patients had recurrence after three months and 12 (12%) patients in group B.

Conclusion: It is concluded from our study that 2% intravaginal clindamycin; is better than oral metronidazole in the treatment of bacterial vaginosis in term of improvement / cure rate, side effect, failure rate and recurrence rate.

Keywords: Bacterial vaginosis, Anti-infective agents, Metronidazole, Clindamycin, Vaginal Gel.

Introduction

Bacterial vaginosis is the commonest cause of vaginal discharge in women of child bearing age, almost 40-59% of cases of vaginal discharge.^{1,3} In United states, the National Health and Nutrition Examination survey (NHANES) which includes vaginal swabs from over 3700 women, estimated that the prevalence of bacterial vaginosis was 29% in general population of women aged 14-49 years and 50% in African-American women.⁴ This included both symptomatic and asymptomatic infection. World wide bacterial vaginosis is common among women of reproductive age, with variations according to population studied.⁵ The basic pathology is the growth of anaerobic bacteria replacing the normal flora, lactobacillous, resulting into the alkaline pH of the vagina (from 4.5 to 7). Anaerobic bacteria include, *G. vaginillis* (50%) *provotella*, *mycoplasma* and *mobiluncus* species.⁶ The commonest symptom is vaginal discharge which is ivory to grey in colour, having pH of 5-6.5 with distinctive fishy odour, without itching.⁷ Diagnosis is confirmed, when at least three of following criteria are present (AMSEL

CRITERIA): thin homogenous discharge, pH more than 5, positive amine test, presence of clue cells in a saline wet drop. A variety of complications have been associated with bacterial vaginosis, post abortion sepsis, preterm labour⁸, preterm premature rupture of membranes,⁹ chorioamnitis, post partum endometriosis, post hysterectomy cuff infection, post operative wound infection.¹⁰ The recent randomized controlled studies preferred local clindamycin with better results.¹⁵

Methods

This experimental study was carried out in the department of Obstetrics and Gynaecology unit 1, SIMS/Services Hospital, Lahore from 01.01.2014 to 30.06.2014 for 6 months. The sampling technique was purposive non probability sampling. Two hundred married woman with vaginal discharge and fulfilling the inclusion criteria were selected from out patient department of Obstetrics and Gynaecology. An informed consent was taken, detailed history of the patient was taken regarding duration vaginal after discharge, its colour, odour, association with itching and gynaecological history (abortion, contraception

and surgical procedure). General physical as well as systemic examination was performed to exclude general illness. Pelvic examination included sterile per speculum examination top look for colour, odour and consistency of discharge. Investigations performed were urine analysis, complete blood count and blood glucose level to exclude systemic disease. Patients were counselled about personal hygiene and managed as OPD cases. The response of both groups was checked by:-

- I) Alleviation of symptoms after full therapy.
- ii) Side effect of therapy like nausea, vomiting, diarrhea.
- iii) Failure (after 7 days by P/s examination).
- iv) Recurrence at follow up visits at 3 months and 6 months.

All these observations were recorded on predesigned proforma.

Statistical Analysis

All the collected information was transferred to computer soft ware SPSS version 12 and analyzed accordingly. The quantitative variable like, duration of marriage and monthly income were presented as mean and standard deviation. The qualitative variable, like age, parity, occupation, history of vaginal discharge, history of contraception, history of abortion, history of STD, symptoms alleviation, side effects (vomiting, diarrhea, abdominal pain, local irritation / swelling) failure and recurrence were presented as frequency and percentage. The outcome variables like response of treatment, i.e symptoms free, side effect of therapy and vomiting, diarrhea, abdominal pain, local irritation/swelling and success or failure of therapy was analysed by applying chi square test, P. value < 0.05 was considered as significant.

Results

A total of two hundred patients were included in the study. The mean age of the patient in group A was 30 + 5 years and was 29 + 5.3 years in group B. In the distribution of occupation, in group A, 8% (8 patients) were working women and 92% (92 patients) were house wives. While in group B 4% (4 patients) were working women and 96% (96 patients) house wives. Regarding parity, 16% (16 patients) were primipara, 28% (28 patients) para 1-2 and 54% (54 patients) were para 3-6. In the distribution of gynaecological history, in group A, 40% (40 patients) had history of contraception 38% (38 patients) had history of abortion and 14% (14 patients) had history of sexually transmitted disease

while in group B 14 (14%) had history of contraception, 20 (20%) had history of surgical procedure and 10 (10%) had history of STDs.

Table-1: Descriptive Analysis for cases of Bacterial Vaginosis

Variables	Group-A n=100	Group-B n=100
Age	Mean±SD30.4±5.0	Mean±SD29.0±5.3
20 - 25 Years	22 (22%)	32 (32%)
26 - 30 Years	34 (34%)	36 (36%)
31 - 35 Years	28 (28%)	20 (20%)
36 - 40 Years	16 (16%)	10 (10%)
Parity	Mean±SD31± 2.4	Mean±SD 2.1± 1.9
0	16 (16%)	32 (32%)
1 - 2	30 (30%)	28 (28%)
3 - 4	28 (28%)	26 (26%)
5 - 6	26 (26%)	14 (14%)
Occupation		
Working Women	8 (6%)	4 (4%)
House Wife	92 (92%)	96 (96%)
Duration of Vaginal Discharge (Months)	Mean±SD7.2±4.5	Mean±SD6.4±3.6
1 - 3	20 (20%)	24 (24%)
4 - 6	42 (42%)	46 (46%)
7 - 9	8 (8%)	6 (6%)
10 -12	30 (30%)	24 (24%)

Response of treatment In group A, 14% (14 patients) were free of symptoms with in 7 days, 68% (68 patients) after 7 days. While 18% (18 patients) had no alleviation of symptoms. In group B 20% (20 patients) were free of symptoms within 7 days, 74% (74 patients) after 7 days and 6% (6 patients) had no alleviation of symptoms. Side effect of treatment in group A 10% (10 patients) had diarrhea and vomiting and 14% (14 patients) also had abdominal pain, while in group B fewer patient had abdominal pain 2% (2 patients) and 10% of (10 patients) had local irritation and swelling.

Table-2: Comparison of two groups by gynaecological history

Variables	Group-A n=100	Group-B n=100
History of Contraception	40 (40%)	14 (14%)
History of Abortion/Gynae surg. Procedures	38(38%)	20 (20%)
History of sexual transmitted disease	14 (14%)	10 (10%)

Table-1: Comparison of response of therapy between two study groups.

Variables	Group-A n=100	Group-B n=100	P-value
Symptoms Alleviation			
With 7 days	14 (14%)	20 (20%)	0.4
After 7 days	68 (68%)	74 (74%)	0.6
No alleviation	18 (18%)	6 (6%)	0.05
Recurrence of sym.			
3 months	16 (16%)	12(12%)	0.02
6 months	0	0	
Side effects			
Vomiting &		0	0.01
Diarrhoea	10 (10%)	0	0.01
Abdominal Pain	14 (14%)	2 (2%)	0.03
Perineal irritation	(0%)	10 (10%)	0.01

In the distribution of failure rate, there were 18% (18 patients) failures in group A and 6% (6 patients) in group B with significant P value of 0.05. Recurrence of symptoms after 3 months was 16% (16 patients) in group A, while it was 12% (12 patients) in group B. At six month, there were no such symptoms in either group.

Discussion

Bacterial vaginosis is challenging problem for clinicians throughout the world. It is troublesome and common problem among women in reproductive age^{11,12} BV if not properly treated in early phase, may lead to secondary complications. In pregnant women it may either cause preterm delivery or chorioamnionitis. The risk of contacting sexually transmitted diseases e.g HIV, syphilis, gonorrhoea, and trichomoniasis¹³ is higher in patients of Bacterial Vaginosis, when compared with healthy individuals.¹⁴

The preferred drugs for the treatment are oral metronidazole, oral clindamycin or topical agent like metronidazole intravaginally or 2% clindamycin vaginal cream.¹⁵ The oral use of metronidazole is associated with diarrhea, nausea, vomiting, abdominal pain while local use rarely cause local burning, itching, rash, redness and swelling.

Demographic analysis of all patients showed no significant difference between the two treatment groups. In our study, the mean age of the patients in group A was 30±5 years and in group B was 29±5 years. As compared with the study of Mahakit et al

the mean age of the patients was 28 years which is comparable to our study.¹⁴ Improvement response

after one week of therapy was 94% in the clindamycin group versus 82% in the metronidazole group. Andres et al¹⁸ evaluated that 97% of the patient treated with clindamycin vaginal cream had improvement or cure at the first following visit versus 83% of those taking oral metronidazole. However there was no statistically significant difference between the two results.

The adverse side effect after treatment was 24% in group A and 12% in group B. The side effect in the metronidazole group of our study showed vomiting and diarrhea in 10% patients and abdominal pain in 14% patients. In clindamycin group 2% patients had abdominal pain and 10% patients had local irritation swelling. As compared with the study of Paavonen et al.¹⁵ treatment related adverse effects were reported more frequently in the metronidazole treatment group. Systemic symptoms, such as nausea and taste perversion accounted for most of the difference between groups. In our study, the failure rate was 18% patients in metronidazole group and 6% in clindamycin group, with significant p-value of 0.05. As compared with the study of Luis Arredondo et al¹⁶, the failure rate in metronidazole group was in 15% patients as compared to 3% patients in clindamycin group, which is comparable with our study.¹⁰

In our study, the recurrence after three months in metronidazole group was 16% while in clindamycin group was 12%. In a similar study by Fishbach et al¹⁷ the recurrence rate was 9% in the clindamycin group and 10% in the metronidazole groups which is comparable with our study.

Clinidmycin vaginal cream offers similar efficacy and safety to standard oral metronidazole therapy for bacterial vaginosis). However it has lesser side effects, failure rate and recurrence rate.

Conclusion

It is conducted from our study, that 2% intravaginal clindamycin is better than oral metronidazole in the treatment of bacterial vaginosis in term of improvements / cure rate, side effect, failure rate and recurrence rate.

Department of Obst & Gyne
Services Hospital Lahore
www.esculapio.pk

References

1. Joesoef, G, Schmid, G, Bacterial vaginosis clinical evidence *BMJ* 2001, P 887
2. Morris M, Nicoll, Simms et al Bacterial vaginosis, a public health review *BJOG* 2001, 108:439
3. Tolosa JE, Chai wong wathana s, Daly s et al *Am J Obstetrics Gynaecol* 2006, 195:1198
4. Allsworth JE, Peipest J, prevalence of Bacterial vaginosis 2001-2004, National & Nutritional examination survey data, *Obstet Gynecol* 2007, 109:114
5. Kenyon C, Colebunders R, crutti , The global epidemiology of bacterial vaginosis , a systemic review *Am. J. obstet Gynecol*, 2013, 209:50 ,
6. McGregor, Joesef M, Schmid L Bacterial vaginosis, *Clin Evid* 2001; 6 1208-15
7. Siddiq NB ,Malik N ,Faruqi JN ,Ali ss, Bacterial vaginosis in pregnant women with history of preterm labor or late miscarriages, *Pak. J. obstet Gynecol* 2005 13:69
8. Demba E ,Morris L, *BMC infection disease* (2005) available from URL- <http://www.biomedcentral.com/1471-2334/5/2012>
9. Siddiq NB ,Malik N ,Faruqi JN ,Ali ss, Bacterial vaginosis in pregnant women with history of preterm labor or late miscarriages, *Pak. J. obstet Gynecol* 2005 13:6
10. Centre of disease control (CDC) sexually transmitted disease treatment guideline (online) Oct 2002 cited 2005 Dec 12 Available from <http://www.cdc.gov/std/treatment>.
11. Spiegel CG, Bacterial vaginosis *Clin Microbiol REV.* 1991, 4:485-502.
12. Fredrick DN, Fiedler TL, Marrazzo JM, molecular identification of bacteria associated bacterial vaginosis, *N-England J. Med.* 2005 ;353;1899-1911 (pubmed)
13. Hillier SC, Nugent RP, Eschenbach DA, Krohn MA, Gibbs RS, Martin DH et al association between bacterial vaginosis and preterm delivery of a low birth infant *N . E n g l a n d . J M e d* ;1995;333:1737-42 Pubmed
14. Mahakit P, vicente JG, Butt DI, Angeli G, Bansal S, Zambrano D. Oral Clindamycin 300mg BID , compared with oral Amoxicillin/clavulanic acid igm BID in the outpatients. *International multicentre randomized control trial-blinded prospective trial in patients. Clin Ther* 2006; 28:99-109
15. Paavonen, Mangioni C, Martin MA, Wajs Zeuk CP, vaginal clindamycin and oral metronidazole for bacterial vaginosis, a randomized trial *Obstet Gynecol* 2000; 96: 256-60
16. Luis Arrendondo J, Higura F, Narcio MC, Casanova G, Bertin M, New alternative in the treatment of Bacterial vaginosis *Gynecol Obstet* 1994; 62:226-34
17. Fishbach F, Peterson EE, Weissenbacher ER, Efficacy of clindamycin vaginal cream versus oral metronidazole for bacterial vaginosis *OBstet Gynecol* 1993; 82: 405-10.
18. Andres FJ, Parker R, Hosien I , Benrubi GI, Clindamycin vaginal cream versus oral metronidazole in the treatment of bacterial vaginosis , prospective double blind clinical trial. *South Med J* 2002; 85:1077-80.