Efficacy of metronidazole and lactobacillus in the treatment of bacterial vaginosis- A comparative study

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Abstract

Introduction: Bacterial vaginosis (BV) is a well-known lower reproductive tract disorder occurred due to the replacement of normal vaginal flora such as lactobacillus species with another anaerobic microbial flora. Metronidazole is the primary therapeutic choice with 70% recovery rate.

Aim: To assess the efficacy of Metronidazole and lactobacillus in the management of bacterial vaginosis.

Materials and Methods: A total 140 cases diagnosed with bacterial vaginosis, following Nugent's scoring system and Amsel's criteria were recruited. Based on the drug administered, cases were divided in to 2 groups i.e. group 1 medicated with lactobacillus 1 bd capsule for one month then 1 od for preceding month and group 2 medicated orally with metronidazole 400mg bd for one week.

Results: Vaginal pH was recorded <5 in 20 cases, 5-5.5 in 98 cases and > 5.5 in 22 cases. Saline mount examination showed clue cells in 88.5% cases, complete absence of clue cells in 7.8% cases and clue cells in combination with pus cells in 3.5% cases. Positive whiff-amine test was observed in 95.7% cases.

Conclusion: Comparison based on Amsel criteria showed good therapeutic benefits was noted at the end of 1st week, 1st month. At the end of 3rd month and 6th month benefits were gradually decreased. Comparison by Nugent's scoring system showed good response rate was gradually decreased at the end of 1st week, 1st month and 3rd month in both the study groups. Whereas at the end of 6th month, therapeutic response was gradually decreased in both groups. Recurrence was seen in 8.5% cases of group 1 at the end of 6th month, no recurrence was seen in group2.

Keywords: Bacterial vaginosis (BV), Metronidazole, Lactobacillus, Amsel criteria, Nugent's scoring system.

Introduction

Bacterial vaginosis (BV) is a disorder of reproductive age women which commonly affects distal genital tract and leads to vaginal discharge.[1] BV has a prevalence varies from 5% in college people to >60% in women with STDs and it is always associated with elevated levels of pH (pH>4.5).[2] In bacterial vaginosis, normal vaginal flora such as lactobacillus is replaced by other microbialflora i.e. Gardnerella vaginalis, peptostreptcocci, Mycoplasma hominis, Ureaplasma urealyticum and mobiluncus species.[3]

In bacterial vaginosis, wet smear findings shows appearance of clue cells (vaginal epithelial cells) which are coated externally with clumps of bacteria.[4] The diagnosis of bacterial vaginosis based on Amsel criteria usually depends on homogeneous vaginal discharge, pH of vaginal discharge, when vaginal discharge is mixed with KOH produce amine like odor and clue cells 20% more than vaginal epithelial cells.[5] Another diagnostic tool for bacterial vaginosis is Nugent score system also called as gram staining score system which showed sensitivity 97% and specificity 98%.[6]

Metronidazole is currently the therapeutic choice for bacterial vaginosis with success rate of 80-90%.[7] Studies suggest that after successful treatment recurrence was seen in 50-70% cases within 4-6 weeks, in 70% cases within 3 months and in 80% cases recurrence was seen within a year.[8,9] Lactobacillus is a Probiotic alternative drug and with a research interest this study was designed to assess the efficacy of Metronidazole and lactobacillus in the management of bacterial vaginosis.

Materials and Methods

The present prospective study was conducted in Department of DVL, MNR Medical College and Hospital, Sangareddy during April 2016 to June 2018. A total 140 cases attending outpatient wing of department of DVL diagnosed with bacterial vaginosis, following Nugent's scoring system and Amsel's criteria were recruited.

Inclusion Criteria: cases fulfilled Nugent's scoring system and Amsel's criteria, cases in the study age group are included.

Exclusion criteria: Women under pregnancy, lactation and with other associated complication for vaginal discharge were excluded from the study.

Study protocol and methodology was clearly explained to all the cases and Informed consent was obtained. Study protocol was approved by institutional ethics committee. Based on the drug administered, cases were divided in to 2 groups i.e. group 1 medicated with lactobacillus 1 bd capsule for one month then 1 od for preceding month and group 2 medicated orally with metronidazole 400mg bd for one week.

All the cases were subjected to detailed clinical examination, Genital examination and microbial examination for vaginal and endo cervical smears. All the participants were followed up to assess the outcome at the end of 1st week, 1st month, 3rd month and 6th month. At every visits routine genial examinations was performed to assess the treatment outcome. Outcome data was extracted in to datasheet and percentages was performed by using Microsoft excel sheet.

Results

A total 140 cases between age group 21-50 years with mean age of 34.1 years were included. Regular menstrual cycle was seen in 115 cases, irregular menstrual cycle in 20 and menopause was attained by 5 cases. Among the total cases, 98 cases had complaint of genital discharge, 24 cases had complaints of genital itching, 5 cases had complaint of severe genital odour and 13 cases did not specified any complaints.

Among 140 cases, 126 cases were married and 14 cases were un-married. Among total cases, 34.2% cases were primiparous, 50% cases were multi parous (>2 pregnancies) and 15.71% cases had no pregnancies including unmarried participants (Table 1).

Table 1: Obstetric history of the participants in both groups.

Obstetric history	Cases	
	Number	Percentage
Details of parity		
Primi	48	34.28%
Multi	70	50%
No pregnancy	22	15.71%
Mode of Delivery		
Normal delivery	89	70.6%
LSCS	20	15.8%
Normal + LSCS	03	2.3%
Abortion	05	3.9%
Normal + abortion	09	7.1%

Table 2: Clinical features observed in bacterial vaginosis cases.

Clinical feature	Group 1	Group 2	Percentage
Saline mount examination	68	56	88.5%
KOH mount (Whiff test)	71	63	95.7%

Vaginal pH was recorded <5 in 20 cases, 5-5.5 in 98 cases and > 5.5 in 22 cases. Saline mount examination showed clue cells in 88.5% cases, complete absence of clue cells in 7.8% cases and clue cells in combination with pus cells in 3.5% cases. Vaginal discharge with a drop of 10% KOH produced rotten fishy odour which is positive whiff-amine test was observed in 95.7% cases (Table 2).

Table 3: Values of Amsel's criteria among two study groups.

Time period	Amsel's criteria	Group 1		Group 2	
		Number	Percentage	Number	Percentage
End of 1st week	Responded	66	94.2%	68	97.1%
	Not Responded	04	5.7%	02	2.8%
End of 1st Month	Responded	67	95.7%	66	94.2%
	Not Responded	03	4.2%	02	2.8%
End of 3rd month	Responded	61	87.1%	69	98.5%
	Not Responded	03	4.2%	-	-
End of 6th month	Responded	54	77.1%	70	100%
	Not Responded	08	11.4%	-	-

*Grade 1&2: Responded, Grade 3, 4 &5: Not responded.

Table 4: Values of Nugent's criteria among two study groups.

Time period	Nugent's criteria	Group 1		Group 2	
		Number	Percentage	Number	Percentage
End of 1st week	1st Grade	36	51.4%	51	72.8%
	2nd Grade	26	37.1%	14	20%
	3rd Grade	08	11.4%	05	7.1%
End of 1st Month	1st Grade	47	67.1%	57	81.4%
	2nd Grade	14	20%	12	17.1%
	3rd Grade	09	12.8%	01	1.4%
End of 3rd month	1st Grade	31	44.2%	65	92.8%
	2nd Grade	14	20%	05	7.1%

	3rd Grade	0	-	0	-
End of 6th month	1st Grade	18	25.7%	60	85.7%
	2nd Grade	32	45.7%	10	14.2%
	3rd Grade	06	8.5%	0	-

*Scores of Nugent's criteria - 1st grade: 0-3, 2nd grade: 4-6, 3rd grade: 7-1.

Discussion

Bacterial vaginosis is a common cause of vaginal discharge in reproductive age women. BV is associated with the loss of the lactobacilli colonies with a subsequent overgrowth of anaerobic polymicrobials consisting of anaerobes and Gardnerella vaginalis, and an increase in the vaginal pH over 4.5 within the vaginal lumen. The present study was designed to assess the management of bacterial vaginosis with metronidazole and lactobacillus. A total 140 cases between age group 21-50 years with mean age of 34.1 years were included. Morris et al, in his study stated that incidence of bacterial vaginosis is more in sexually active reproductive age people.[10] Among the total cases, 98 cases had complaint of genital discharge, 24 cases had complaints of genital itching, 5 cases had complaint of severe genital odour and 13 cases did not specified any complaints.

Vaginal discharge with a drop of 10% KOH produced rotten fishy odour which is positive whiff-amine test was observed in 95.7% cases (Table 2). Amines like putrescine and cadaverine composed in the secretion of bacterial vaginosis leads to the rotten fishy odor and decreases candida albicans existence.[11] Vaginal pH was recorded <5 in 20 cases, 5-55 in 98 cases and > 5.5 in 22 cases. pH>4.5 in bacterial vaginosis is considered as abnormal.[7] Saline mount examination showed clue cells in 88.5% cases, complete absence of clue cells in 7.8% cases and clue cells in combination with pus cells in 3.5% cases.

Efficacy of medication was assessed based on Amsel's criteria and Nugent's scoring system and was observed at the end of 1st week, 1st month, 3rd month and 6th month of after treatment. In this study, the comparison based on Amsel's criteria observed therapeutic benefits at the end of 1st week and 1st month, but at end of 3rd month slight difference between the response group 1 (87.1%) and group 2 (98.5%). Whereas at the end of 6th month observed much difference between both groups i.e. group 1 showed good response in 77.1% cases and group 2 showed good response in all 100% cases (Table 3). Results of Selvaraj N et al., showed results were compatible between both groups at end of 1st week, 1st, 2nd month whereas at 6th months metronidazole group showed good response in 76.2% cases and Lactobacillus group showed good response in 94% cases.[12]

Therapeutic effect assessment based on Nugent's scoring system between both groups showed that in group 1, at the end of 1st week (51.4%), 1st month (67.1%) high response rate was gradually increased thereafter response rate was gradually decreased at the end of 3rd month (44.2%) and 6th month (25.7%). In group 2, at the end of 1st week (72.8%), 1st month (81.4%) and 3rd month (92.8%) high response rate was gradually increased thereafter response rate was slightly decreased at the end of and 6th month (85.7%) (Table 4). The results of this study was compatible with the study of Selvaraj N et al.[12]

Study by Kingsley C et al., stated that at the end of 1st month good response was seen in 90% cases of lactobacillus group and in 55 % cases of metronidazole group.[13] Study by Reid G et al., on comparison between lactobacillus and placebo found reappearance of lactobacillus colonies in 37% lactobacillus group cases and 13% in placebo group cases.[14] Nausea and fatty changes in the liver was observed in few cases.

Conclusion

The results of this study concludes that, Metronidazole is effective in the management of bacterial vaginosis than lactobacillus. The comparison based on Amsel criteria observed therapeutic benefits at the end of 1st week and 1st month, while at end of 3rd month slight difference was observed between group 1 (87.1%) and group 2 (98.5%). Whereas at the end of 6th month, good response was seen in 77.1% of group 1 cases and 100% of group 2 cases. Comparison by Nugent's scoring system showed good response rate was gradually decreased at the end of 1st week, 1st month and 3rd month in both the study groups. Whereas at the end of 6th month, therapeutic response was gradually decreased in both groups. Recurrence was seen in 8.5% cases of group 1 at the end of 6th month, no recurrence was seen in group 2. Further studies are required to assess efficacy of study drugs on fungal isolates and with more sample size.

Conflicts of Interest: None.

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