


# Study to Evaluate Targeted Management and Syndromic Management in Women Presenting with Abnormal Vaginal Discharge

Veena Meena<sup>1</sup>  Charu Lata Bansal<sup>2</sup>

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## About the Author



**Veena Meena** is acting as corresponding author for this original article. She completed her graduation examination from Maulana Azad Medical College, New Delhi in 2009 and postgraduation (M.S.) in Obstetrics and Gynaecology from Lady Hardinge Medical College & Associated Smt. Sucheta Kriplani Hospital and Kalawati Saran Children's Hospital, New Delhi in year 2014.

## Abstract

**Introduction** Vaginal discharge is a commonest complaint among women in reproductive age group. Infective vaginal discharge can be broadly categorized into vaginitis or mucopurulent cervicitis. Vaginitis is predominantly

caused by bacterial vaginosis, vaginal candidiasis, vaginal trichomoniasis, etc. Mucopurulent cervicitis is due to chlamydia or gonococcal infection. The targeted management is based on identification of causative organism and targeting the therapy against it, while syndromic management is based on high risk factors's presence.

**Aims and Objectives** To study the effect of targeted management as compared to syndromic management in achieving a complete cure for abnormal vaginal discharge and to study the microbial flora of women presenting with abnormal vaginal discharge.

**Method** The study is a randomized control trial conducted at tertiary health care on 200 women who presented with abnormal vaginal discharge, distributed in two groups A and B each consisted of 100 women. Group A underwent laboratory investigations, and treatment was started as soon as reports were available. Group B was given syndromic management based on high risk factors's presence. Both groups were followed up after 2 weeks.

Dr. Veena Meena, MS, is working as senior resident in Department of Obstetrics and Gynaecology at Smt. Sucheta Kriplani Hospital and Kalawati Saran Children's Hospital, Lady Hardinge Medical College, New Delhi, India; Dr. Charu Lata Bansal is working as an assistant professor in Department of Obstetrics and Gynaecology at Gangori Hospital, SMS Medical College Jaipur, Rajasthan, India.

✉ Veena Meena  
veenadobbal@gmail.com

<sup>1</sup> Department of Obstetrics and Gynaecology, Smt. Sucheta Kriplani Hospital and Kalawati Saran Children's Hospital, Lady Hardinge Medical College, New Delhi, India

<sup>2</sup> Department of Obstetrics and Gynaecology, Gangori Hospital, SMS Medical College, Jaipur, Rajasthan, India

**Results** The prevalence of various organisms in vaginal discharge was candidiasis 39 %, bacterial vaginosis 28 %, trichomoniasis 5 %, *N. gonorrhoeae* 5 % and chlamydia 2 % among the 100 women in group A. Response to treatment for vaginitis was 76.3 % in group A, whereas it was 41 % in group B. With cervicitis, 71.4 % women responded to treatment in targeted group as compared to 54 % in syndromic management group.

**Conclusion** There is a potential disadvantage of syndromic management because of its total reliability on a subjective clinical assessment.

**Keywords** Abnormal vaginal discharge · Syndromic management · Targeted management

## Introduction

Vaginal discharge is a commonest complaint among women in reproductive age group which may be physiological or pathological. Normal vaginal flora mostly consists of aerobic organisms, most common of which is hydrogen peroxide producing lactobacilli. Abnormal vaginal discharge may be of non-infective or infective origin. Non-infective vaginal discharge may be associated with endocervical polyps, tumors, vesicovaginal or uterovaginal fistulae, chemical irritants and medications, and infective vaginal discharge can be broadly categorized into vaginitis or mucopurulent cervicitis. Vaginitis is predominantly caused by bacterial vaginosis, vaginal candidiasis, vaginal trichomoniasis and sometimes due to bacterial infection. Mucopurulent cervicitis is caused by chlamydia or gonococcal infection. Vaginal discharge is considered to be abnormal if it is yellowish, greenish or curdy white in color, mixed with blood and is malodorous. It may be associated with pruritis, vulvar pain or pelvic discomfort, soreness, swelling, dyspareunia and dysuria [1]. Bacterial vaginosis characterized by the replacement of normal hydrogen peroxide producing lactobacilli with anaerobic bacteria like *Gardnerella Vaginalis*, *Mobiluncus Hominis*, *Bacteroides* and *Peptostreptococcus*. For diagnosis at least 3 out of 4, Amsel [2] criteria should be present for diagnosis which includes: (1) Homogenous gray or white adherent discharge on the vaginal wall, (2) Vaginal pH > 4.5, (3) Positive whiff test and (4) Presence of clue cells on microscopic examination of saline wet mount or gram stain of vaginal discharge [3]. Vaginal candidiasis caused by *Candida Albicans*, *Candida Parapsilosis*, *Candida Tropicalis* or *Candida Glabrata* [4]. Vaginal trichomoniasis caused by *Trichomonas Vaginalis*. Diagnosis is confirmed by demonstration of actively motile organism with jerky movements on wet mount [5]. Mucopurulent cervicitis caused by *C. trachomatis* or *N. gonorrhoeae*

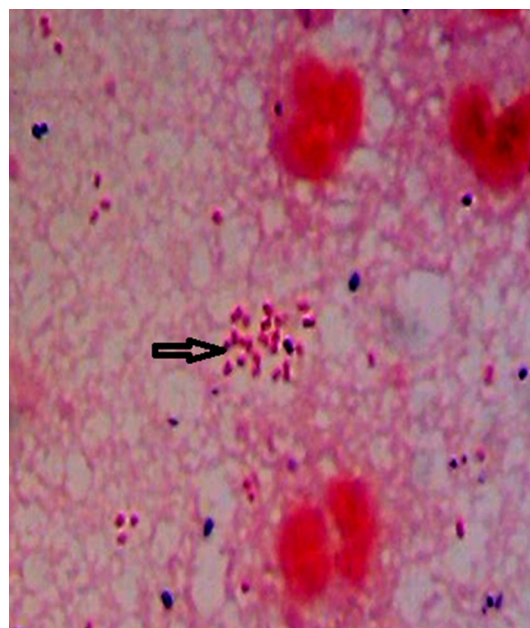
which typically produces yellowish discharge. The presence of gram-negative intracellular diplococci on gram stain gives a presumptive diagnosis of gonorrhoeae.

The targeted management is based on identification of causative organism and targeting the therapy against it [6]. Syndromic management is based on high risk factors's presence. If high risk factors are present, then treatment for both cervicitis and vaginitis is initiated. In the absence of endocervical discharge and high risk factors, treatment for vaginitis only is initiated.

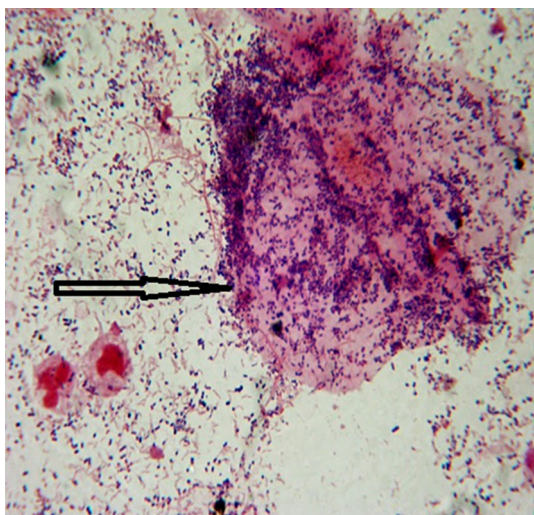
## Materials and Methods

This randomized control trial was conducted at tertiary care hospital over 19 months on 200 women after fulfilling the inclusion and exclusion criteria. After obtaining written consent, detailed history and examination, they were divided into two groups A and B by computer-generated randomization, each consisting of 100 women. Group A were subjected to OPD procedures (pH of vagina using standard pH paper; wet saline mount for *Trichomonas*, KOH mount for budding hyphae) and laboratory procedures which includes gram staining, cultures (*Candida* and *N. gonorrhoeae*), antigen detection test for chlamydia and Pap smear by conventional method (Figs. 1, 2).

Treatment initiated according to the organism detected on investigation. For bacterial vaginosis, tab tinidazole 2 gm single dose was given, for candidiasis, tab fluconazole 150 mg single dose was given and for trichomoniasis, tab tinidazole 2 gm single dose was given. For gonorrhoea



**Fig. 1** Showing gram-negative diplococci on gram staining



**Fig. 2** Arrow showing clue cell in bacterial vaginosis in gram stain (1000× enlarged) coated with gram variable bacilli

and chlamydia, tab azithromycin 2 gm single dose was given. Group B was given syndromic management on the same day of examination which was based on whether vaginal discharge alone was present or there was endocervical discharge or high risk factors also present along with vaginal discharge. If endocervical discharge or high risk factors were present, then tab azithromycin 2 gm single dose plus tab tinidazole 2 gm single dose plus tab fluconazole 150 mg single dose was given. If only vaginal

discharge was seen, then tab tinidazole 2 gm single dose and tab fluconazole 150 mg were given. Both groups were followed after 2 weeks, and a repeat per speculum examination was done for the presence of same type of discharge.

## Main Outcome Measures and Results

This randomized controlled trial was done on 200 women and divided into two groups A and B. Group A were subjected to laboratory procedures and treatment initiated based on the organism detected on investigation. Group B was given syndromic management based on WHO criteria. All the outcome parameters were expressed as number and percentages or mean  $\pm$  standard deviation by computer-based Statistical Product and Service Solutions (SPSS) latest version. Comparison of outcome parameters between the two groups was done using students *t* test and Chi-square test (Table 1).

The prevalence of infection in group A based on laboratory tests was as follows: candidiasis 39 %, bacterial vaginosis 28 %, *N. gonorrhoeae* and trichomoniasis 5 % each and chlamydia in 2 % of women. With candidiasis, 52 % of women had white color of discharge. With bacterial vaginosis, 89.2 % women had whitish or grayish-white color discharge. Forty % women with gonorrhoeae and 60 % with trichomoniasis had greenish discharge,

**Table 1** Demographic details, color of discharge, odor, associated symptoms and respond to treatment in group A patients

	Bacterial vaginosis	Candidiasis	Gonorrhoea	Trichomoniasis	Chlamydia	No organism
Number ( <i>N</i> = 100)	28	39	5	5	2	21
Percentage (%)	28	39	5	5	2	21
<i>Color of discharge</i>						
White (%)	13 (26)	26 (52)	0	0	0	11 (22)
Grayish-white	12 (60)	3 (15)	2 (10)	0	0	11 (22)
Yellowish (%)	0	6 (43)	1 (7.1)	2 (14.2)	2 (14.2)	3 (2.1)
Greenish (%)	3 (12.5)	4 (25)	2 (12.5)	3 (19)	0	4 (25)
<i>Odor</i>						
Fishy (%)	19 (79.2)	2 (8.3)	1 (4.2)	1 (4.2)	0	1 (4.2)
Non-specific (%)	3 (5.4)	26 (47.3)	3 (5.4)	4 (7.3)	2 (3.6)	17 (31)
Non-foul smelling (%)	6 (28.6)	8 (38)	0	0	0	7 (33)
<i>Symptoms</i>						
Ithcing	22 (78.6)	30 (76.9)	4 (80)	5 (100)	1 (50)	
Dysuria <i>N</i> (%)	22 (78.6)	23 (59)	4 (80)	5 (100)	0	
Dyspareunia <i>N</i> (%)	7 (25)	9 (23.1)	4 (80)	3 (60)	0	
Pelvic discomfort <i>N</i> (%)	6 (21.4)	3 (7.7)	3 (60)	2 (40)	0	
<i>Respond to treatment</i>						
Cured <i>N</i> (%)	22 (78)	31 (79)	3(60)	3 (60)	2 (100)	
Not cured <i>N</i> (%)	4 (14)	7 (18)	2 (40)	2 (40)	0	
Lost to follow up <i>N</i> (%)	2 (7)	1 (3)	0	0	0	

**Table 2** Associated symptoms with abnormal vaginal discharge in both the groups

Associated symptom	Group A		Group B		<i>p</i> value
	Number of patients	Group A (%)	Number of patients	Group B (%)	
Fever	0	0	0	0	
Itching	79	79	88	88	0.060
Menorrhagia	1	1	0	0	1.000
Pelvic discomfort	16	16	8	8	0.082
Dysuria	71	71	83	83	0.165
Dyspareunia	26	26	8	8	0.001

**Table 3** Prevalence of vaginitis, vaginitis plus cervicitis and cervicitis based on per speculum examination in both groups

Diagnosis	Group A	Percentage (%)	Group B	Percentage (%)	<i>p</i> value
Vaginitis	72	72	73	73	0.234
Vaginitis and cervicitis	17	17	1	1	<0.001
Cervicitis alone	11	11	26	26	<0.001
Total	100	100	100	100	

**Table 4** Response to treatment of vaginitis in both groups

Result	Group A (targeted management)	Cured	Percentage (%)	Group B (syndromic management)	Cured	Percentage (%)	<i>p</i> value
Vaginitis	72/72	45	62.5	73	30	41	<0.001
Vaginitis plus cervicitis	14/17	10	71.4	1	0	0	<0.001
Cervicitis	7/11	5	71.4	26	14	54	<0.001

whereas all women with chlamydial infection had yellowish discharge. Bacterial vaginosis was diagnosed in 79.2 % of women who had fishy odor of vaginal discharge. Twenty-one women had non-foul smelling discharge out of which 28.6 % had bacterial vaginosis, 38 % had candidiasis, and 33 % did not have any organism. In group A, 79 out of 100 women had organism detected on laboratory tests. On the basis of laboratory investigation in group A, 78 % of women with bacterial vaginosis were cured, 79 % of women with candidiasis were cured, 60 % women with trichomoniasis and gonorrhoea were cured, and all patient with chlamydia were cured (Table 2).

Maximum number of women in both groups presented with moderate amount of vaginal discharge. The most common complaint along with vaginal discharge was itching (79 % in group A, 88 % in group B) and dysuria (71 and 83 % in group A and B, respectively) as compared to other complaints (Table 3).

In both groups, vaginitis was diagnosed on per speculum examination in 72 and 73 % of women. In comparison with per speculum diagnosis of vaginitis, vaginitis plus cervicitis and cervicitis alone, it was found that out of 72 women with vaginitis on per speculum 57 (77.1 %) were

vaginitis on laboratory test, 14 (19.4 %) were physiological and 1 (1.3 %) was cervicitis (Table 4).

In group A, 72 % of women were diagnosed with vaginitis on per speculum examination out of which 57 were confirmed as vaginitis on laboratory test and out of which 62.5 % (45 out of 72 women) were cured. In addition, 14 women who were diagnosed as vaginitis plus cervicitis on per speculum had vaginitis only on laboratory evaluation and were treated accordingly, and 10 from them cured; hence, in total, 55 (76.3 %) women with vaginitis diagnosed on laboratory test were cured. In group B, 41 % women with vaginitis were cured. In group A, 11 cases were diagnosed as cervicitis on per speculum and 7 women were confirmed to have cervicitis on laboratory test. In total, 71.4 % (5 out of 7) were cured. In group B, 54 % (14 out of 26) with cervicitis were cured.

## Discussion

Group A underwent laboratory investigations, and treatment was started as soon as reports were available. Recommended treatment for bacterial vaginosis is tab

tinidazole 2 gm single dose, for candidiasis tab fluconazole 150 mg single dose and for trichomoniasis tab tinidazole 2 gm single dose and for gonorrhoea and chlamydia, tab azithromycin 2 gm single dose or oral doxycycline 100 mg twice daily for 7 days or oral ofloxacin 300 mg twice daily for 7 days [6].

Group B was given syndromic management on the same day of examination. For cervicitis, recommended regimen is azithromycin 2 gm orally single dose and for vaginitis tab tinidazole 2 gm or metronidazole 2 gm single dose plus oral fluconazole 150 mg as single dose. Both groups were followed up after 2 weeks.

The pattern of distribution and follow-up of enrolled cases in this study were similar to the study done by Chandey et al. [6]. Enrolled cases in both the groups had their age ranging between 18 and 45 years, and maximum numbers of women were in the age range of 20–29 years (reproductive age group). This finding shows that vaginal infection commonly occurs in reproductive age group which was comparable to that reported by Thulkar et al. [7], Ryan et al. [8], Rao et al. [9], Sanchez et al. [10] and Sharma et al. [11]. Most common complaint along with vaginal discharge was itching (79 % in group A, 88 % in group B) and dysuria (71 and 83 % in group A and B, respectively) as compared to other complaints. Lower abdominal pain was the most common complaint in a study conducted by Rizvi et al. [12]. Lower abdomen pain is commonly found in patients of pelvic inflammatory disease; however, in present study, these patients were not included in the study group, and this may be the reason for difference between the two studies. Vaginitis was present in 72 and 73 % in group A and B, respectively. Cervicitis alone was present in 11 and 26 % in group A and B, respectively. Cervicitis was more commonly seen in group B as compared to group A, and vaginitis plus cervicitis was more common in group A as compared to group B. Seventy-one percentage of women with abnormal vaginal discharge had pH of more than 4.5, and 29 % of women had pH of less than 4.5. Out of 79 women with infection 51 (64.5 %) had pH > 4.5, and out of 21 women without infection, 20 (98 %) had pH > 4.5. Hence, pH was not very specific for the presence of infection. In a study conducted by Chandey et al. [6], 120 women were recruited and 68 % of women had pH > 4.5 and 32 % of women had pH of <4.5. This result was in accordance with the present study. Pap smear was done in all women with abnormal vaginal discharge to screen for presence of malignancy and detection of organism. Twenty-three percentage of women had hyphae, 20 % of women had clue cells, and 1 woman had trichomoniasis. In addition, inflammatory cellular reaction was seen in 56 %. This finding was similar to that reported by Barouti et al. [13] who observed pathogenic organisms in Papanicolaou

vaginal smears. Seventeen percentage of women were positive for bacterial vaginosis, 10.6 % for candidiasis, and only 0.4 % for trichomoniasis. Etiological cause of abnormal vaginal discharge in group A was obtained in 79 (79 %) patients, and in the remaining 21 % of the patients, no etiological cause was found. Similarly, in the study of Ryan et al. [8], Moherdaul et al. [14] and Nugent et al. [15], the same prevalence was observed. Vaginitis was diagnosed in 72 % women based on laboratory investigations which corresponded with the per speculum diagnosis of vaginitis. Vaginitis was predominantly due to candidiasis followed by bacterial vaginosis and trichomoniasis which was 39, 28 and 5 %, respectively. This was similar to that reported by Rizvi et al. [12]. In the study done by Chandey et al. [6], the prevalence of bacterial vaginosis was high as compared to candidiasis and trichomoniasis. Prevalence of cervicitis was 7 % by laboratory test as compared to 11 % on per speculum examination. These results were in accordance with a study by Tann et al. [16] who found a prevalence of 4.3 and 5 % for *N. gonorrhoeae* and chlamydia, respectively. In a study conducted by Chandey et al. [8], the prevalence of *N. gonorrhoeae* and chlamydia (0.4 and 4 %, respectively) was similar to this study. Vaginitis plus cervicitis was not detected in any women following laboratory evaluation in group A, whereas it was detected in 17 % women on per speculum examination. This shows a poor correlation between clinical and laboratory findings for diagnosis of cervicitis. The reason behind this could be an over diagnosis on clinical examination due to observer error or an under diagnosis by laboratory test. Further studies are needed to develop recommendations for diagnosis of cervicitis based on clinical and laboratory tests which have high sensitivity, specificity and predictive value similar to that of Amsel's criteria for diagnosis of bacterial vaginosis. In women with white discharge, 52 % of women had candidiasis, 26 % had bacterial vaginosis, and in 22 % of women had no organism detected. In women with grayish-white discharge, 60 % of women had bacterial vaginosis, 15 % had candidiasis, and 10 % women had gonorrhoeae. In women with yellowish discharge, 43 % had candidiasis, 7.2 % had gonorrhoeae, and 14.2 % had trichomoniasis and chlamydia. In women with greenish discharge, 12.5 % each had bacterial vaginosis and gonorrhoeae, 25 % had candidiasis, and 19 % had trichomoniasis. In group A, 72 women had vaginitis by per speculum examination and by laboratory test also. Out of 72 women with vaginitis on per speculum, 57 were confirmed vaginitis on laboratory tests, 14 were physiological, and 1 had cervicitis. In group A, 62.5 % (45 out of 72 women) were cured, 27.7 % of women were not cured, and 2.7 % were lost to follow up. In this group, 14 women who were diagnosed as vaginitis plus cervicitis on per speculum had vaginitis only or laboratory evaluation.

They were given treatment of vaginitis alone based on laboratory test. Ten out of these 14 women were cured. So in total 76.3 % (55 out of 72), women with vaginitis on laboratory test were cured. In group B, 73 of women were diagnosed with vaginitis on per speculum examination out of which 41 % women were cured and 2.7 % were lost to follow up and 56.3 % were not cured. The difference was statistically significant with a  $p$  value of  $<0.001$ . In group B, the reason for a significant percentage (56.3 %) of women not being cured could be due to presence of physiological discharge in some of them which did not need any treatment and hence persisted despite treatment. In the present study, in group A, 11 cases were diagnosed as cervicitis by per speculum examination, 6 out of 11 (54.5 %) were cervicitis, 4 were physiological (36.3 %), and 1 (9 %) was vaginitis on laboratory investigation. One woman who was diagnosed as vaginitis on per speculum had cervicitis on laboratory investigation. In total, 71.4 % (5 out of 7) women with laboratory diagnosis of cervicitis were cured in group A, whereas 54 % (14 out of 56) women of patient with cervicitis were cured in group B. The difference was significant with a  $p$  value of 0.001. The difference in cure rates in both groups could be because of over diagnosis of physiological discharge as cervicitis.

This was similar to that reported by Chandeying et al. [6]. In this study, in group A, organism was detected in 79 women on investigation and treatment was given accordingly. In 21 women, no organism was detected on investigation and no treatment was given to them. Seventy-eight percentage (21) women with bacterial vaginosis were cured, 6 were not cured, and 1 was lost to follow up. Seventy-nine percentage with candidiasis were cured, 7 not cured, and 1 was lost to follow up. *N. gonorrhoeae* and trichomoniasis were diagnosed in 5 women each, and in both groups, 3 were cured and 2 were not cured. All cases of chlamydia were cured.

## Conclusion

Response to treatment for vaginitis was 76.3 % in targeted management group, whereas it was 41 % in syndromic management group. With cervicitis, 71.4 % women responded to treatment in targeted group as compared to 54 % in syndromic management group. This difference was statistically significant. Low response to treatment in syndromic management group is due to low sensitivity of clinical examination in diagnosing the nature of vaginal discharge. Thus, in clinics where laboratory facilities are available, they should be used to confirm the diagnosis for targeted management.

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**Authors Contribution** Veena Meena involved in study design, data collection, data analysis and manuscript writing, and she will act as a guarantor for the study. Charu Lata Bansal involved in data analysis and manuscript writing.

## Compliance with Ethical Standards

**Conflict of interest** None.

**Ethical approval** This study included human subjects and all participants signed informed consent. Study had been approved by the ethical committee of Delhi University (session 2011–2014).

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