

# Efficacy of syndromic management measured as symptomatic improvement in females with vaginal discharge syndrome

Vidyalaxmi Chauhan, Maitri C. Shah, Sangita V. Patel<sup>1</sup>, Yogesh S. Marfatia<sup>2</sup>, Dhara Zalavadiya<sup>1</sup>  
Departments of Obstetrics and Gynecology, <sup>1</sup>Community Medicine and <sup>2</sup>Skin and VD, Government Medical College,  
Baroda, Gujarat, India

## Address for correspondence:

Dr. Maitri C. Shah, 30, Gulabchand Park, Opposite Ambalal Park, Kareli Baug, Baroda - 390 018, Gujarat, India.  
E-mail: maitrishah.gynec@gmail.com

## Abstract

**Background:** In spite of a few shortcomings such as over diagnosis and over treatment, syndromic management is a recommended practice in India for sexually transmitted infections (STIs). This study tries to find out the efficacy of syndromic management measured as symptomatic improvement in females with vaginal discharge syndrome. **Objective:** The objective of the study is to find out the effectiveness of syndromic management in terms of symptomatic improvement among females with vaginal discharge syndrome. **Materials and Methods:** A longitudinal study was conducted in Gynecology Department of Tertiary Care Hospital including 180 symptomatic females having vaginal discharge syndrome. Demographic profile, presenting complaints, menstrual history, obstetric history, partner history, and contraceptive history were noted. This was followed by clinical examination and specimen collection for laboratory tests and blood tests to find out type of STI including viral STI such as human immunodeficiency virus (HIV), herpes simplex virus (HSV), and hepatitis B surface antigen (HBsAg). Treatment was given according to syndromic management on the same day. All the participants were asked to come for follow-up after 15 days and their improvement in symptoms was noted as complete improvement, some improvement or no improvement on a five point scale. **Results:** 63.9% cases showed complete improvement, while 36.1% showed some improvement. None of the patients was without any improvement. Vaginal discharge syndrome was most common between 20 and 30 years (43.4%), and 67.8% of symptomatic females with vaginal discharge syndrome belonged to the lower socioeconomic group. HSV infection was the most common (15%) associated viral infection with vaginal discharge syndrome, while hepatitis B infection was the least common (0.5%). HIV was reactive in 2.8% cases only. **Conclusion:** Syndromic management was found to be effective in relieving symptoms in most of the cases of vaginal discharge syndrome.

**Key words:** Symptomatic improvement, syndromic management, vaginal discharge syndrome

## INTRODUCTION

The incidence and prevalence of sexually transmitted infections (STIs) are very high in developing countries, where the STI treatment is

less accessible.<sup>[1]</sup> STIs rank second as the cause of healthy life lost among women of reproductive age group, after maternal morbidity and mortality.<sup>[2]</sup> Human papillomavirus, herpes simplex virus (HSV),

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and both hepatitis A and B are some of the most common viral STIs worldwide. They are preventable, but unlike bacterial STIs the person may harbor the virus in her or his body for life with periodic recurrences of active infection. Viral STIs have long-term health consequences, some of which are serious and life-threatening.<sup>[3]</sup> Presence of STIs increases the risk of human immunodeficiency virus (HIV) transmission 2-fold to 20-fold.<sup>[4]</sup> World Health Organization has developed a simplified tool (a flowchart or algorithm) to guide health workers in the implementation of syndromic management of STIs.<sup>[5]</sup> Numerous studies have been conducted since the introduction of syndromic management to evaluate its efficacy to diagnose specific STIs. Syndromic algorithms have some shortcomings, and they need to be periodically reviewed and adapted to the epidemiological patterns of STI in a given setting.<sup>[6]</sup> Over-diagnosis and over-treatment are major disadvantages of the syndromic approach.<sup>[7-9]</sup> A study showed that the syndromic approach might not be a very effective way to identify STI patients. The performance of the algorithm in predicting these infections was unacceptably poor.<sup>[7]</sup>

### Objective

Current study was conducted to find out the effectiveness of syndromic management in terms of symptomatic improvement among females with vaginal discharge syndrome.

### MATERIALS AND METHODS

The present longitudinal study was conducted in the Department of Obstetrics and Gynecology in a Tertiary Care Hospital over a period of 2 years from May 1, 2010, to April 30, 2012. The study protocols were approved by the Institutional Ethical Committee Human Rights. Assuming 40% prevalence of STIs among females,<sup>[2]</sup> 20% as allowable error and adding 10% nonresponse rate, our sample size was calculated as 165. We recruited 190 females  $\geq$  20 years with vaginal discharge, attending gynecology outpatient department. Pregnant females, cases with medical illnesses such as diabetes, hypertension, tuberculosis, and jaundice and terminally ill cases were excluded. Six females who refused for the blood testing and another four females who did not turn up for the follow-up were also excluded. Finally, 180 cases with vaginal discharge were recruited in the study. After obtaining written informed consent, all females were interviewed in depth and their presenting complaints, menstrual history, obstetric history, partner history, and contraceptive history were noted. All the presenting symptoms

mainly vaginal discharge, lower abdominal pain, and burning micturition were noted.<sup>[9]</sup> After doing a per speculum examination of each participant, a clinical diagnosis of vaginal discharge syndrome was made.<sup>[2,5,10]</sup> This was followed by clinical examination and specimen collection for laboratory tests. They were screened for bacterial vaginosis, trichomoniasis, and candidiasis. Detail methodology and results of this part is discussed elsewhere.<sup>[9]</sup> Serological tests for HIV (ELISA), hepatitis B virus serum hepatitis B surface antigen (HBsAg), syphilis (rapid plasma regain test and treponema pallidum hemagglutination test), HSV-2 (immunoglobulin M ELISA) were performed. During the first visit, treatment was given according to the guidelines of syndromic approach for management of vaginal discharge syndrome i.e., kit 2 containing tablet secnidazole 2 g stat + capsules fluconazole 150 mg was given.<sup>[11]</sup> All the participants were asked to come for follow-up after 15 days and their improvement in all symptoms with which they had presented were noted as complete improvement, some improvement or no improvement. Each participant was asked to evaluate all symptoms on a scale of 0–5 where 0 means no improvement, five means complete improvement and score anywhere between 0 and 5 was labeled as some improvement. The process of data collection did not pose any potential risk or harm to the participants. Privacy was ensured while taking the interview and sample collection. To maintain confidentiality, all the participants were given a unique identification number and the study instrument and laboratory requisition form were given the same identification number for each participant. Data safety and confidentiality were also given due consideration by keeping the file containing identity related details password protected. All the data were entered into a Microsoft Excel sheet and analyzed by using Epi-info software version 7. (Centers for Disease control and prevention, Atlanta, Georgia, USA).

### RESULTS

#### Sociodemographic profile

Vaginal discharge syndrome was most common between 20 and 30 years (43.4%). Percentage of STIs reduces as the age advances. It was the least in peri-menopausal females; 7.2% in 45 to 49 years age group and only 2.8% after 50 years of age. 32.2% of symptomatic females were illiterate. 67.8% of symptomatic females with vaginal discharge syndrome belonged to the lower socioeconomic group earning < Rs. 5000 per month.

### Viral infection

In the cases of vaginal discharge syndrome,  $n = 180$ , associated viral infections were also noted. HSV infection was the most common (15%) associated viral infection with vaginal discharge syndrome, while hepatitis B infection was the least common (0.5%). HIV was reactive in 2.8% cases only.

### Follow-up of patients treated according to syndromic management (on the basis of symptomatic improvement)

Apart from vaginal discharge, lower abdominal pain (35%) followed by burning micturition (23.9%) were the most common associated complaints among participants. After giving treatment on the basis of syndromic management, they were called for follow-up after 15 days and their symptomatic improvement (on a scale of 1–5) was noted. 63.9% cases showed complete improvement, while 36.1% showed some improvement. None of the patients was without any improvement.

### DISCUSSION

STIs and reproductive tract infections (RTIs) are an important public health problem in India.<sup>[12]</sup> Provision of STI/RTI care services is a very important strategy to prevent HIV transmission and promote sexual and reproductive health under the National AIDS Control Programme and Reproductive and Child Health Programme of the National Rural Health Mission. Syndromic case management with appropriate laboratory tests is the cornerstone of STI/RTI management.<sup>[13]</sup> This study tries to evaluate the performance and effectiveness of syndromic management in terms of clinical improvement of cases with vaginal discharge syndrome. Association of viral markers such as HIV, serum HBsAg, and

HSV with vaginal discharge syndrome was also found out during the study. The result of this study [Table 1] correspond to that obtained by Shendre and Tiwari, where majority (53.72%) of the study subjects belonged to 20–30 years age group.<sup>[14]</sup> There were 44.1% cases of STIs in the same age group according to the study conducted at Puducherry.<sup>[15]</sup> A similar pattern has been observed in numerous other studies.<sup>[16-18]</sup> This period has maximum sexual activity, the chances of exposure are also likely to be increased, and hence more prevalence is found in this age group.<sup>[19]</sup> Being the economically productive group, there is a great loss of manpower at work due to STI morbidity, measured as disability adjusted life years lost.<sup>[20]</sup> In our study, majority of females with vaginal discharge syndrome belonged to the lower socioeconomic group and most of them had education less than primary level. These data were comparable to a study conducted in Punjab.<sup>[21]</sup> This can be explained

**Table 1: Sociodemographic profile of participants**

Sociodemographic parameters	Cervicitis (n=50) (%)	Vaginal discharge (n=130) (%)	Total (n=180) (%)
Age groups, n (%)			
20-24 years	13 (26)	26 (20)	39 (21.7)
25-29 years	12 (24)	27 (20.8)	39 (21.7)
30-34 years	7 (14)	27 (20.8)	34 (18.9)
35-39 years	10 (20)	21 (16.1)	31 (17.2)
40-44 years	6 (12)	13 (10)	19 (10.5)
45-49 years	2 (4)	11 (8.5)	13 (7.2)
≥50 years	0	5 (3.8)	5 (2.8)
Education, n (%)			
Illiterate	16 (32)	42 (32.3)	58 (32.2)
Up to 10 <sup>th</sup> standard	28 (56)	73 (56.2)	101 (56.1)
Beyond 10 <sup>th</sup> standard	6 (12)	15 (11.5)	21 (11.7)
Income, n (%)			
<Rs. 5000	32 (64)	90 (69.2)	122 (67.8)
Rs. 5000-Rs. 10,000	14 (28)	38 (29.2)	52 (28.9)
≥Rs. 10,000	4 (8)	2 (1.6)	6 (3.3)

**Table 2: Association of viral markers with STIs**

Viral markers	Cervicitis (n=50) (%)	Vaginal discharge			Total (n=180) (%)
		Bacterial vaginosis (n=76) (%)	Trichomoniasis (n=18) (%)	Candidiasis (n=36) (%)	
HIV reactive	0	3 (3.9)	2 (11.1)	0	5 (2.8)
Serum HBsAg positive	1 (2)	0	0	0	1 (0.5)
HSV 2 ELISA reactive	7 (14)	13 (17.1)	4 (22.2)	3 (8.3)	27 (15)

HIV=Human immunodeficiency virus; HBsAg=Hepatitis B surface antigen; HSV=Herpes simplex virus; STIs=Sexually transmitted infections

**Table 3: Symptomatic improvement after treatment according to syndromic management (on the scale of 0-5)**

Follow-up	Cervicitis (n=50) (%)	Vaginal discharge			Total (n=180) (%)
		Bacterial vaginosis (n=76) (%)	Trichomoniasis (n=18) (%)	Candidiasis (n=36) (%)	
Complete improvement	33 (66)	40 (56.6)	16 (88.9)	26 (72.2)	115 (63.9)
Some improvement	17 (34)	36 (47.4)	2 (11.1)	10 (27.8)	65 (36.1)

by lack of knowledge about mode of spread of STIs, importance of personal hygiene and role of barrier contraception in prevention of STIs. According to a study conducted by Choudhry *et al.*, 45% females were positive for HSV-2. Seroprevalence of HIV was 10% and HBsAg was 6%.<sup>[6]</sup> These results were higher than those obtained from our study [Table 2]. We have observed that 63.9% of clinically diagnosed cases had complete improvement, while 36.1% showed some improvement after treatment according to syndromic approach [Table 3]. According to a study conducted in a slum area in Chandigarh, follow-up done after 1 month showed effectiveness in terms of symptomatic relief in 72.7% while 13.6% had no effect, 9.1% discontinued treatment, and 4.5% did not comply with the medications.<sup>[22]</sup> Another study conducted in Chandigarh showed 83.4% patients were cured after 1 month while 11.6% were partially cured and 5% had no relief.<sup>[23]</sup> There are a few limitations of the present study. Here, only symptomatic females coming to gynecology outpatient department of a tertiary care hospital were included. There will be many more symptomatic females not attending the hospital. Thus, our study population is not representative of whole population. As this was an observational longitudinal study without control group odds ratio could not be generated. It was not possible to enroll patients as controls due to lack of resources to conduct laboratory investigations in clinically asymptomatic females. Therefore, prevalence could also not be calculated from our data. We recommend to conduct a similar study, but with a larger sample size which can be representative of the whole population.

## CONCLUSIONS

Syndromic management was found to be effective for symptomatic improvement in females with vaginal discharge syndrome.

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## Conflicts of interest

There are no conflicts of interest.

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