Sexually transmitted infections in women: A correlation of clinical and laboratory diagnosis in cases of vaginal discharge syndrome

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ABSTRACT

Aims: This study compares the clinical and laboratory diagnosis of vaginal discharge syndrome. **Settings and Design:** This cross-sectional study was carried out at the gynaecology outpatient department of a tertiary care hospital in Gujarat, India. **Material and Methods:** Total of 180 females diagnosed as vaginal discharge or cervicitis based on syndromic approach and were recruited for the study. Their clinical profile was noted and they were investigated for bacterial vaginosis, trichomoniasis, candidiasis, gonorrhoea and chlamydia infection. **Results:** Lower abdominal pain (35%) followed by burning micturition (23.9%) were the common associated complaints. Bacterial vaginosis was the most common clinical diagnosis, while trichomoniasis was least common. Upon laboratory investigation, 35.6% of cases of vaginal discharge and 12% of cases of cervicitis tested positive. Percentage of cases confirmed by laboratory investigation was 50, 27.8 and 41.7 for bacterial vaginosis, trichomoniasis and candidiasis respectively. **Conclusion:** Among all the females diagnosed as vaginal discharge syndrome, a very small percentage actually turned out to be positive upon laboratory testing.

Key words: Clinical diagnosis, laboratory diagnosis, sexually transmitted infections, vaginal discharge syndrome, women

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INTRODUCTION

Sexually transmitted diseases (STD) are a major public health problem in both developed and developing countries, but prevalence rates are apparently far higher in developing countries where STD treatment is less accessible.[1] The consequences of sexually transmitted infections (STIs) in female include pelvic inflammatory disease, infertility, ectopic pregnancy, post-abortal and puerperal sepsis, cervical cancer, chronic physical pain and emotional distress.[2-4]

A syndrome-based approach to the management of STI patients has been developed by World Health Organization to guide health workers using simple flowcharts or algorithms.[5] Although syndromic management has been promoted as a practical means to treat infections, there is still no universal consensus on its effectiveness, especially regarding the diagnosis of vaginal and cervical infections.

Providing comprehensive laboratory services for the etiological diagnosis of STIs has been conceptualized during National AIDS Control Program (NACP) III.[6] In order to strengthen laboratory support for reproductive tract infections (RTI)/STI throughout India, a network of seven Regional RTI/STI Centers has been established by National AIDS Control Organization. As a part of this, a study was undertaken at a tertiary care hospital to compare the clinical and laboratory parameters in cases of vaginal discharge syndrome to find out the accuracy of syndromic management approach.

MATERIALS AND METHODS

This cross-sectional study was carried out at the gynaecology outpatient department (OPD)

of a tertiary care hospital over a period of two years from May 2010 to April 2012.

All sexually active females in the age group of 20 years or more with the complaint of vaginal discharge were enrolled in the study. Pregnant females, post-menopausal females, those having medical illnesses such as diabetes, hypertension, tuberculosis, jaundice and terminally ill cases were excluded. Assuming 40% prevalence of STIs/RTIs among females[7] and 20% as allowable error, the recommended sample size comes to 150; adding 10% as non-responders, it comes to 165.[8] A total of 186 females were included, out of which six females refused for the blood testing and were excluded. Finally, 180 cases were recruited for the study. Necessary clearances and permissions were obtained from the Institutional Ethics Committee for Human Research before starting the study.

After obtaining a written informed consent, all females were interviewed in depth and their presenting complaints, menstrual history, obstetric history and sexual history were noted. A provisional clinical diagnosis was made based on the history, the color, consistency, quantity and odor of the discharge and associated symptomatology, if any. Further, each patient underwent a per speculum examination to know whether the discharge was from the vagina or the cervix. They were labelled as vaginal discharge or cervicitis for the purpose syndromic management approach.[5,7,9]

Three vaginal swabs were drawn from each patient for *Trichomonas*, *Candida* and bacterial vaginosis (BV) testing. In cases of cervical discharge, two more swabs were drawn from the cervix for *Neisseria gonorrheae* and *Chlamydia* testing. A serological test for chlamydia was also performed in all cases of cervical discharge.

Vaginal discharge samples were tested for *Candida* by potassium hydroxide (KOH), BV by Gram stain and trichomoniasis by wet mount. The cervical samples were tested for gonococcus by Gram stain and chlamydia by Giemsa stain.

For detection of BV, specimens of vaginal exudates were collected with a swab from the posterior fornix of the vagina. A standardized 0-10 scoring system (Nugent's criteria) was used to evaluate BV on the basis of the presence of large Gram-positive rods (*Lactobacilli*), small Gram-negative rods (*Gardnerella*) and *Mobiluncus*. A Nugent's score of ≥7 was considered as positive for BV.[10]

High vaginal specimens were examined under a microscope after adding normal saline *solution* for detecting motile *Trichomonas vaginalis* (wet mount preparation). Culture was done in Modified *Trichomonas* cysteine, peptone digest, liver digest, maltose medium.

For detection of *Candida albicans* infection, 20% KOH preparation was carried out. This was followed by Gram stain preparation from vaginal swabs, which were screened for the presence of Gram-positive yeast cells and pseudo-hyphae. One swab taken from the posterior fornix was also inoculated on Sabouraud's dextrose agar.

For the detection of *Neisseria gonorrhoeae*, a direct smear was prepared from the endocervical sample and Gram's staining was performed. The slide was viewed under the oil immersion lens. The presence of intracellular Gram-negative diplococci within the polymorphonuclear leucocytes was considered suggestive of gonorrhea. Culture was done in Modified GC Agar.

Serological test for *Chlamydia* (immunoglobulin M enzyme-linked immunosorbent assay) were also performed in patients with cervicitis.

Treatment was given according to the guidelines of syndromic approach to management of STI in all cases.[5,7,9]

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 digital file containing identity-related details password protected.

All the data was entered into a Microsoft Excel Sheet and analyzed by using Epi-info Centres for Disease Control and Prevention, Atlanta, Georgia, USA software version 7.

RESULTS

Common clinical presentations in cases of vaginal discharge syndrome were lower abdominal pain (35%) followed by burning micturition (23.9%). Dyspareunia was present in 5% cases. Three cases had a history of infertility. Cervical motion tenderness and nabothian follicles were observed in cases of cervicitis, BV and trichomoniasis, while none of these signs were present in candidiasis [Table 1].

Correlation of clinical diagnosis with laboratory diagnosis

BV was detected in 18% patients with cervicitis and 29.2% patients with vaginal discharge. *T vaginalis* was detected in 3.8% and *C albicans* in 11.5% patients with vaginal discharge. *N gonorrhoeae* and *Chlamydia* was detected in 6% patients each with cervicitis [Table 2].

BV was the most common clinical diagnosis, while trichomoniasis was the least common. Half of the cases of BV were found

Table 1: Clinical features in cases of vaginal discharge syndrome

Clinical features	Cervicitis* (*n*=50) (%)	Vaginal discharge BV* (*n*=76) (%)	Trichomoniasis (*n*=18) (%)	Candidiasis (*n*=36) (%)	Total* (*n*=180) (%)
Discharge per vaginum	50 (100)	76 (100)	18 (100)	36 (100)	180 (100)
Lower abdominal pain	22 (44)	28 (36.8)	5 (27.8)	8 (22.2)	63 (35)
Burning micturition	13 (26)	13 (17.1)	12 (66.7)	5 (13.9)	43 (23.9)
Dyspareunia	4 (8)	5 (6.6)	0	0	9 (5)
Post-coital bleeding	1 (2)	0	0	0	1 (0.6)
Secondary infertility	1 (2)	2 (2.6)	0	0	3 (1.7)
Recurrent pregnancy loss	1 (2)	0	0	0	1 (0.6)
Cervical motion tenderness	6 (12)	8 (10.5)	1 (5.6)	0	15 (8.3)
Nabothian follicle	6 (12)	5 (6.6)	1 (5.6)	0	12 (6.7)
Endocervical polyp	1 (2)	0	0	0	1 (0.6)

*Multiple responses possible, BV: Bacterial vaginosis

positive on investigation. Upon investigation, 35.6% of cases of vaginal discharge and 12% of cases of cervicitis tested laboratory positive. About 27.8% cases of trichomoniasis were confirmed by laboratory test. 41.7% cases of candidiasis tested positive [Table 3].

DISCUSSION

STIs are dynamic in nature. The clinical pattern of various STIs is a result of the interaction among pathogens, the behaviors that transmit them and the effectiveness of preventive and control interventions. On evaluating clinical profile, abdominal pain and burning micturition were the most common complaints in cases of vaginal discharge. Similar to this study, lower abdominal pain (42%) and urinary complaints (20%) were few of the most common complaints associated with STIs, in a study conducted in an urban slum of New Delhi.[4]

According to a study conducted by Choudhry *et al*., 24% females accounted for laboratory positive syphilis, 19% had gonorrhea and chlamydia each, 13% had trichomoniasis and only 5% had candidiasis.[11] Vishwanath *et al*. concluded in their study that the prevalence of BV was 26%, candidiasis 25.4%, chlamydia infection 12.2%, trichomoniasis 10% and syphilis 2.2% in a reproductive health clinic in New Delhi.[12] The present study showed laboratory positivity in 26.1%, 2.8%, 8.3% in BV, trichomoniasis and candidiasis patients respectively; while syphilis, gonorrhea and chlamydia were diagnosed in 1.7% each.

STIs rank second as the cause of healthy life lost among women of reproductive age group, after maternal morbidity and mortality. As per STI prevalence study (2003), about 40% of women have RTI/STI at any given point of time.[7] In India, provision of STI/RTI care services is a very important strategy to prevent human immunodeficiency virus transmission and promote sexual and reproductive health under the NACP and Reproductive and Child Health Program of the National

Table 2: Laboratory diagnosis in cases of vaginal discharge syndrome

Lab diagnosis	Cervicitis* (*n*=50) (%)	Vaginal discharge* (*n*=130) (%)	Total* (*n*=180) (%)
BV	9 (18)	38 (29.2)	47 (26.1)
Trichomoniasis	0	5 (3.8)	5 (2.8)
Candidiasis	-	15 (11.5)	15 (8.3)
Gonorrhea	3 (6)	-	3 (1.7)
Chlamydia	3 (6)	-	3 (1.7)
VDRL positivity	0	3 (2.3)	3 (1.7)

*Multiple responses possible. BV: Bacterial vaginosis, VDRL: Venereal Disease Research Laboratory

Table 3: Correlation of clinical diagnosis with laboratory diagnosis

Clinical diagnosis (180)	Laboratory positive (64) (%)	Laboratory negative (116) (%)
Cervicitis (*n*=50)	6 (12)	44 (88)
BV (*n*=76)	38 (50)	38 (50)
Trichomoniasis (*n*=18)	5 (27.8)	13 (72.2)
Candidiasis (*n*=36)	15 (41.7)	21 (58.3)

BV: Bacterial vaginosis

Rural Health Mission. Timely diagnosis and treatment are critical components in the prevention of the spread of STIs. Accordingly, syndromic case management (SCM) with appropriate laboratory tests is the cornerstone of STI/RTI management.[6]

In a study conducted in an urban slum of New Delhi, 72% of females were diagnosed as laboratory positive cases of STIs.[4] Ray *et al*. in Delhi, have observed that among symptomatic females, 94.6% had some syndrome while only 37.5% had a confirmed etiological diagnosis.[13] In the present study, only 35.6% of symptomatic females tested positive for various STIs in the laboratory. This disparity can be explained by the fact that many cases with physiological

vaginal discharge are being over-diagnosed with SCM approach. In a study conducted in Goa, psychosocial factors instead of etiological agents of RTIs/STIs were found to have the strongest association with the complaint of vaginal discharge. It was recommended that syndromic management algorithms should be refined so that women with complaints that are non-infectious in etiology can be offered psychosocial interventions.[14]

Laboratory positive vaginal discharge cases outnumbered cases of cervicitis, which may reflect that flowcharts for vaginal discharge particularly for diagnosis of cervicitis are not satisfactory. Vaginal discharge is indicative of the presence of vaginal infection, but it is poorly predictive of cervical infection (gonococcal and/or chlamydial).[5] Several studies, including the present study has shown that the complaint of vaginal discharge does not correlate well with cervical infection.[15-17] Further, among patients presenting with cervicitis, only 6% each tested positive for gonococcal and chlamydial infection in our study. This suggests that neither the presenting symptom of vaginal discharge nor the clinical diagnosis of cervicitis is a reliable indicator of infection with *Neisseria gonorrhea or Chlamydia trachomatis*.

Given the high rates of BV, trichomoniasis and candidiasis among women with vaginal discharge, they should receive syndromic treatment for these infections, as is currently the practice in India. Concurrent treatment of women for *N. gonorrhea* and *C. trachomatis* is likely to result in over-treatment of many women, with potential adverse effects to drugs, high cost and antibiotic resistance.[18]

In this study, only symptomatic females reporting to the gynaecology OPD of a tertiary care hospital were included. There would be many more symptomatic females not attending the hospital. Thus, our study population was not representative of the whole population. It was not possible to enrol patients as controls due to lack of resources to conduct laboratory investigations in clinically asymptomatic females. Therefore prevalence could not be calculated from our data. For validation of syndromic management, specificity, sensitivity, positive predictive value and negative predictive value could also not be calculated.

Although a high proportion of women were diagnosed by the syndromic approach, their total infection load as determined by laboratory diagnosis was quite low. This could mean that STIs are being over-diagnosed and even that physiological discharge was misinterpreted as pathological. It might have also been due to faulty technique of specimen collection. There might be loss of organisms during the time duration between collection of specimen and performance of laboratory tests as transport media were not always available during the collection of every specimen due to technical difficulties. Availability of accurate, more sensitive and standardized laboratory facilities can be helpful in improving the performance of syndromic approach.

We recommend conducting a similar study, but with a control group as well as larger sample size which can be representative of the whole population.

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