Original Article

Validation of vaginal discharge syndrome among pregnant women attending obstetrics clinic, in the tertiary hospital of Western India

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Abstract

Introduction: Sexually transmitted infections (STIs) are major public health problem. The laboratory tests for diagnosing STI are often unavailable or too expensive. Therefore, World Health Organization has recommended a syndromic approach for diagnosis and management of STI/reproductive tract infections (RTIs). Very few studies so far had evaluated effectiveness of the syndromic approach in diagnosing STI/RTIs in pregnancy. **Aims and Objectives:** Validation of syndromic management for vaginal discharge syndrome in pregnancy. **Materials and Methods:** A cross-sectional study was carried out which included 233 pregnant females attending obstetric clinic. They were subjected to clinical examination, vaginal swab collection, and serological tests. **Results:** A total of 183 (78.54%) pregnant females had vaginal discharge on clinical examination and *Candida albicans* was the most common clinical diagnosis among them. Of 183 cases diagnosed clinically as vaginal discharge syndrome, 38 (20.7%) were tested positive in laboratory investigations. Out of 50 clinically negative cases, 9 (18%) were detected positive for one of the STIs on laboratory testing. **Conclusion:** Syndromic approach for management of vaginal discharge syndrome resulted in over-treatment of 78% (false positive) and under-diagnosis of 19.1% (false negative) pregnant females. Hence, integration of antenatal screening services in the form of laboratory tests for vaginal discharge is recommended.

Key words: India, pregnant women, screening, syndromic approach, vaginal discharge syndrome, validation

INTRODUCTION

More than 25 infectious organisms are transmitted primarily through sexual contacts, but the common ones include chlamydia, trichomonas vaginalis, *Neisseria gonorrhoeae*, herpes simplex, hepatitis B virus, HIV, and *Treponema pallidum* infections.[1,2]

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These infectious diseases have been recognized as major public and reproductive health challenges worldwide. The World Health Organization (WHO) estimates that about 340 million new cases of the four main curable sexually transmitted infections (STIs) (gonorrhea, chlamydial infection, syphilis, and trichomoniasis) occur every year, the majority of them in developing countries.[2]

Sexually transmitted infection/reproductive tract infections (RTIs), in nonpregnant females have tremendous adverse consequences and can lead to pain, organ damage, pelvic inflammatory diseases, infertility, and ectopic pregnancy.[3,4] A nationwide community-based study performed by the National

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AIDS Control Organization in 2001 reported high STI/RTI prevalence in pregnant women (32.5%), which indicates their vulnerability.[5] Even though, pregnant females are regarded as low-risk group for acquiring infections, the effect and consequences are of more serious nature compared with the nonpregnant counterpart.[6,7]

The impact of these infections on the obstetric outcome and management are well known.[1-3] STI/RTIs have been associated with conditions such as spontaneous miscarriages, stillbirth, prematurity, low birth weight, preterm labor, premature rupture of membranes, and postpartum endometritis. Other long-term morbidities such as cervical cancer, chronic hepatitis, and chronic pelvic infection are also observed in women who have acquired these infections during pregnancy.[8] The risk of infection is inversely related to gestational age at acquisition.[9]

Sexually transmitted infections are more dynamic than other diseases prevailing in the community.[10] Their epidemiological profile varies from country to country and from one region to another within a country. The clinical pattern of these infections also differs as a result of the interaction among pathogens, the behaviors that transmit them and the effectiveness of preventive and control interventions.

Effective control of STIs is a strong and most cost-effective strategy for reducing/preventing transmission of HIV. This is because both STIs and HIV have same routes of transmission and occur in individuals practicing similar type of high-risk behavior that is, unsafe sexual intercourse (with or without substance abuse, alcohol use). Since 1990, WHO has recommended a syndromic approach for diagnosis and management of STIs in patients presenting with consistently recognized signs and symptoms of particular STIs.[11]

There are many studies in India showing prevalence of various STI/RTIs in nonpregnant females. However, very few studies actually had evaluated effectiveness of the syndromic approach in diagnosing STIs in pregnancy. Hence, this study was undertaken with a specific objective of validating vaginal discharge syndrome among pregnant women.

MATERIALS AND METHODS

The present cross-sectional study was carried out over a period of 1½ years from 1st May 2011 to 31st August 2012 in apparently healthy, married, pregnant females aged 20-35 years, attending obstetrics clinic of tertiary care hospital.

Considering 32% prevalence of STI among pregnant females in India, sample size was calculated as 212, and adding 10% of refusal rate, 233 was the final sample size calculated.[5]

The study protocols were approved by the Scientific and Ethical Research Committee of the same institute.

Out of all pregnant females attending obstetrics clinic during study period in their first antenatal visit, total 235 females were selected by systematic random sampling, but two refused to give consent. Finally, 233 females were recruited for the study. All the patients were recruited during their first antenatal visit irrespective of gestational age.

After obtaining written informed consent, the participants underwent counseling, followed by an interview in clinic to collect information on sociodemographic variables, current and past STI symptoms. This was followed by clinical examination including per speculum examination and vaginal swab collection for laboratory tests. Representative samples were collected and processed in the standard manner as follows.

High vaginal swabs

Swab was taken from the posterior fornix with sterile swab sticks. The sample from the vagina was smeared on two separate glass slides. Normal saline and potassium hydroxide (KOH) was put on each of the slides respectively. Venous blood samples were also aseptically collected from the participants in a sterile container for processing. All samples were tested at Department of Microbiology, SSG Hospital, Baroda, in accordance with the standard operating procedure made by the Regional STI/RTI center. In vaginal swab, vaginal pH, KOH mount, grams stain, wet mount and Nugent scoring was done.

Direct examination

Wet mounts of all swab samples were made in sterile normal saline on clean slides and examined under a low power (×10) and high power (×40) magnifications for typical yeast cells with hyphae or pseudo-hyphae and trichomonas vaginalis. Gram stain was carried out on high vaginal swabs and examined with ×100 objective under oil immersion for Gram-negative diplococcic and clue cells. Bacterial vaginosis (BV) was defined according to the Nugent score as follows:

- 0–3 is considered negative for BV
- 4–6 is considered intermediate
- 7+ is considered indicative of BV.

Identification of isolates

Trichomoniasis was diagnosed using wet preparation, candidiasis by visual inspection of Candida species on KOH preparations or on gram-stained vaginal swabs. The pH of the saline preparation was found to vary between 5.0 and 5.6 when measured with a pH indicator paper and in a gram stain of positive cases, the normal lacto-bacilli flora was almost or completely replaced with masses of gram variable organisms. The specimens that were positive for pathogens were cultured.

They were also subjected for blood collection for serological markers. HIV antibody assay was carried out with determine HIV-1 and -2 rapid test strips. Syphilis antibodies were estimated by using syphilis ultra-rapid test strips. Hepatitis B surface antigen (HBsAg) test was done using HBsAg test strips.

All details related to participants were entered in separate register and patients were given separate ID number which was unique for each participant. The same unique ID number was used for study instrument and lab requisition form.

Pregnant female with symptoms or signs suggestive of vaginal discharge syndrome were treated on the spot following the syndromic STI case management guidelines.[12] All of them were asked to return for their HIV, HBsAG and Venereal Disease Research Laboratory results after 1 week. Those females found later to have infections, on laboratory testing, were treated for specific infections during the follow-up visit.

The process of data collection did not pose any potential risk or harm to the participants. Privacy was ensured while taking an interview and sample collection. Data safety and confidentiality was given due consideration by keeping the file containing the identity related details password protected.

All the data were entered into a Microsoft Excel Sheet and analyzed by using Epi-info software Version 6.04_d, Centers for Disease Control and Prevention., USA, 2001).[13]

RESULTS

Vaginal discharge was the most prevalent STI syndrome in pregnant females. Out of 233 females recruited in the study, 183 (78.5%) had vaginal discharge on clinical examination while 50 (21.4%) did not have any discharge. *Candida albicans* 92 (50.3%) was the most common clinical diagnosis in the pregnant females with vaginal discharge syndrome. This was followed by BV 54 (29.5%) and trichomonas vaginalis 37 (20.2%).

Vaginal discharge syndrome was most common between 20 and 24 years (53.5%). It was the least in 30-35 years (25%). Hence, prevalence of STIs reduced with advanced age but it was not statistically significant. With the highest sexual activity in the younger age group, chances of having STIs were high. The prevalence was also high in the females presented late (third trimester) for antenatal care [Table 1].

On laboratory diagnosis, candidiasis was seen in 8.5% of total study population. BV was seen in 8.1%, trichomoniasis in 3.4% cases while only one case of syphilis was seen [Table 2].

Out of 183 cases diagnosed clinically as vaginal discharge syndrome, 38 (20.7%) were tested positive in laboratory investigations. Only five cases tested positive among clinically diagnosed 37 cases of trichomoniasis. About 15% cases were laboratory positive out of 92 clinically diagnosed candidiasis. BV was diagnosed by laboratory in 35.1% cases [Figure 1].

Out of 183 clinically diagnosed cases of vaginal discharge syndrome, 38 were laboratory positive

Table 1: Sociodemographic profile of pregnant females with clinically diagnosed STIs

Cases	BV (*n*=54)	Trichomonas vaginalis (*n*=37)	Candida (*n*=92)	Total (*n*=183) (%)	χ^2 (*P* value)
Age (years)					
20-24	29	17	52	98 (53.5)	1.337 (0.85)
25-29	17	14	29	60 (32.7)	
30-35	8	6	11	25 (13.6)	
Gestational age (trimester)					
1st	14	10	21	45 (24.5)	4.134 (0.38)
2nd	20	12	24	56 (30.6)	
3rd	17	23	42	82 (44.8)	

BV=Bacterial vaginosis, STIs=Sexually transmitted infections

Table 2: Prevalence of STI in pregnant females according to clinical and laboratory diagnosis

STI	Clinical diagnosis (183)	Lab positive (47) (%)	Lab negative (136) (%)
BV	54	19 (35.1)	35 (64.8)
Trichomoniasis	37	5 (13.5)	32 (86)
Candidiasis	92	14 (15.2)	78 (85)

BV=Bacterial vaginosis, STI=Sexually transmitted infection

and 145 were laboratory negative. On clinical examination, 50 cases were negative for vaginal discharge syndrome. Out of those 50, 9 (18%) were detected positive for one of the STIs on laboratory testing. Out of those 9 cases, 6 turned out positive for candidiasis and 3 for trichomoniasis. There was no significant difference observed between clinical and laboratory diagnosis of STI [Table 3].

Table 4 depicts that HIV was reactive in eight cases only, and was associated in one case each of BV, trichomoniasis, and candidiasis. Total seven cases of hepatitis B infection was seen in the study and out of them one case was associated with *C. albicans*.

DISCUSSION

Sexually transmitted infections constitute a major public health problem for both developing and developed countries. The emergence of HIV infection has increased the importance of measures aimed at control of STIs. A proper understanding of the patterns of STIs prevailing in different geographic regions and community settings of a country is necessary for proper planning and implementation of STI control strategies. In the early 1990s, the WHO developed syndromic management guidelines as a case management of symptomatic STIs patients without laboratory support. Various studies have found this approach as a poor predictor of vaginal infections with a low sensitivity. Using them would lead to under-diagnosis of those with these infections and overtreatment of those without the infections.[14]

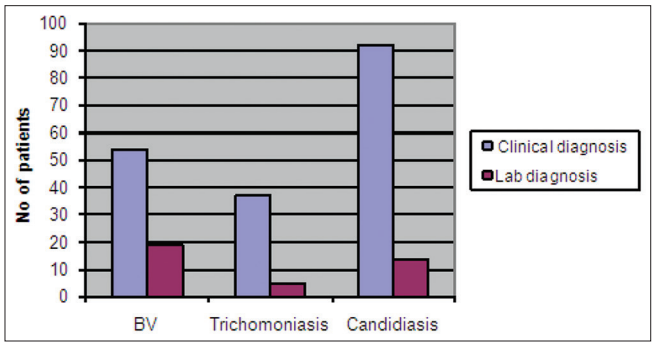

Figure 1: Comparison of clinical diagnosis with laboratory diagnosis

Table 3: Evaluation of clinical diagnosis (syndromic approach) as a screening test for vaginal discharge syndrome

Cases	Lab positive	Lab negative	Total	χ^2 (*P*)
Clinically positive	38	145	183	0.186 (0.66)
Clinically negative	9	41	50	
Total	47	186	*n*=233	

Out of the 9 cases who were clinically negative, 6 turned out positive for candidiasis and 3 for trichomoniasis

Table 4: Association of viral markers with STI

Viral markers	Discharge present			Discharge absent	Total
	BV	Trichomoniasis	Candida		
HIV reactive	1	1	1	5	8
HbsAg reactive	0	0	1	6	7

STI=Sexually transmitted infection, HIV=Human immunodeficiency virus, HbsAg=Hepatitis B surface antigen, BV=Bacterial vaginosis

High STI prevalence in pregnant females reported in several studies indicate risk of adverse consequences of STIs to the unborn fetus.[15] Management of STIs in pregnancy in many developing countries is complex with the lack of simple and affordable diagnostic tests. Only few community level studies showing the prevalence of STI were undertaken in India but the data are relatively patchy and incomplete.[16]

Majority (78%) of our total study population was having vaginal discharge syndrome. Similarly, in studies conducted at Tamil Nadu, India, vaginal discharge was the most common genital syndrome.[14,17] The most common prevalent STI was *C. albicans* (50%), followed by BV (29%) and trichomonas vaginalis (20%) on clinical examination in this study. On laboratory diagnosis, similar pattern was seen, candida had highest prevalence 20 (8.5%), followed by BV 19 (8.1%), and trichomoniasis 8 (3.4%). Similar results were observed in a study conducted by Ekanem *et al.* in Nigeria.[18] Pregnancy may modify the manifestations of many STIs. During pregnancy, suppressed maternal immune competence, increase in vaginal pH and alteration in vaginal flora increase their susceptibility for fungal infections.[19]

At least one STI was detected on investigation in 38 (21%) females with vaginal discharge syndrome in our study. One case (0.4%) of syphilis was observed in the present study while a study conducted in Vanuatu had observed 2.4% prevalence of syphilis and 40% women had one or more than one STI.[20] A constant decline in its prevalence in India has been observed in recent years.

A variety of social and demographic factors contribute to the high prevalence of STIs in developing countries. The results of this study shows the most common age group with vaginal discharge syndrome was 20-29 years (53%), similar pattern of age distribution was observed in studies conducted both in India and Nigeria.[16,18] This supports the current consensus that young adults should constitute a priority target group in the STI control program. Many females (44%) presented with

this syndrome in their third trimester of pregnancy which corresponds with the increase number of referral antenatal cases from peripheral health settings.

Moreover, it can be inferred that clinical diagnosis for vaginal discharge syndrome in pregnant females had 80.8% sensitivity and false negative rate of 19.1%. It means that out of 100 females actually having vaginal discharge syndrome, 81 can be detected by clinical examination, but 19 of them can be missed by clinical examination alone. This can be explained by the fact that many STIs are asymptomatic in nature.

The specificity of clinical diagnosis comes to 22% and false positive rate is 78%. It means that out of 100 females actually having vaginal discharge syndrome, only 22 females were correctly diagnosed negative for STIs on the clinical examination, but 78 of them were wrongly diagnosed as positive (false positives). That means that there is a possibility of over diagnosing vaginal discharge syndrome by clinical examination alone.

So if the treatment is given only on the basis of syndromic management for vaginal discharge syndrome, it would result in over-treatment of 78% (false positive) and under-diagnosis of 19.1% (false negative) of pregnant females with vaginal discharge. This approach is found to be less effective for the same in various other studies.[14,21-23]

As this was a hospital based study, the sample may not represent the general population.

CONCLUSION

The current symptom-directed treatment is likely to miss a substantial proportion of vaginal discharge cases because of the poor performance of the clinical examination as screening test, and because most infections are asymptomatic or unrecognized. Our study resulted in over-treatment of 78% (false positive) and under-diagnosis of 19.1% (false negative) pregnant females.

Recommendations

The introduction of simple, point of care laboratory screening tests for vaginal infections into routine antenatal care should be considered.

Further studies including large areas of population can be carried out before making new recommendations for management of vaginal discharge syndrome in pregnancy.

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