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Comparative study of syndromic and etiological diagnosis of reproductive tract infections/sexually transmitted infections in women in Delhi

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KEYWORDS

Sexually transmitted infection (STI); Reproductive tract infection (RTI); Syndromic diagnosis; Etiological diagnosis; Asymptomatic carriers; Community-based study

Summary

Background: The adequacy of the World Health Organization's syndromic approach for the diagnosis and management of sexually transmitted diseases (STDs), especially at primary health centers (PHCs) and at other levels, is still debatable in different settings in India and requires validation.

Objectives: A cross-sectional study was carried out in women attending the peripheral government clinics of Delhi in order to (1) enumerate their self-reported reproductive tract infection (RTI)/sexually transmitted infection (STI) symptoms; (2) assess their clinical status; (3) determine the syndromic diagnosis of RTI/STI in symptomatic women and etiological diagnosis in both symptomatic and asymptomatic women; and (4) compare the level of agreement between self-reporting of morbidity and syndromic and etiological diagnosis.

Materials and methods: The study was conducted over 26 months in 4090 women attending peripheral government healthcare centers, both rural and urban, in four zones of Delhi. They were recruited into four different study groups: group I, non-pregnant, reporting with symptoms of RTI/STI; group II, with a bad obstetric history or infertility; group III, pregnant women in any trimester attending the antenatal clinic; and group IV, the control group. Gynecological examination, followed by the collection of genital specimens and blood, were performed after informed and written consent was obtained. Every symptomatic patient was managed on the basis of algorithms of the syndromic approach as recommended by the National AIDS Control Organisation (NACO), India. All specimens were transported to the STD Reference Laboratory, Safdarjung Hospital, New Delhi and processed by standard methods to diagnose the various STDs.

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Laboratory reports were sent to the clinicians and appropriate treatment was instituted. Data were analyzed by applying statistical methods.

Results: Overall, self-reporting of morbidity was 65.0%. However, the percentage of women with some STD-related syndrome was 71.4%. The rural women were observed to have significantly more STD syndromes than their urban counterparts. The etiological diagnosis could be established in only 32.2% of cases.

Conclusions: This study highlights the wide variation between self-reporting of morbidity and syndromic- and etiology-based diagnosis in women from both rural and urban settings. This has implications for the syndromic approach to STI case management. These observations call for a review of the diagnostic policy for RTIs/STIs by national authorities in order to avoid the overuse of antimicrobials. The study also highlights the need for the introduction and/or strengthening of facilities for simple diagnostic tests for RTIs/STIs, especially at the peripheral healthcare level. © 2009 International Society for Infectious Diseases. Published by Elsevier Ltd. All rights reserved.

Introduction

Globally, sexually transmitted infections (STIs) constitute a major public health problem. Over 300 million new cases are reported annually and 75–85% of them are in developing countries.¹ In India too, ulcerative and non-ulcerative STIs have emerged as important public health concerns,^{2–4} with increasing gynecological morbidity and mortality in women.⁴ Disability adjusted life years (DALYs) lost per annum are greater for women than men.⁵

This subject was not given its due importance until the advent of the HIV/AIDS era, when the spotlight shifted onto STIs due to their proven role in the facilitation of HIV infection.⁶ The main methods of prevention and control of HIV infection in the absence of a safe and effective vaccine, are the promotion of safe sex and the treatment of STIs.^{7,8} Recent data highlight the importance of bacterial vaginosis (BV) as a cofactor in HIV infection.⁹ In developing countries, like India, symptoms of STIs and reproductive tract infections (RTIs), like vaginal discharge and ulcers, should be reported by the women themselves. However, it is noticeable that very often they do not report to healthcare facilities due to various impediments such as their low status in society, illiteracy, ignorance, and rigid social norms. To compound this, there is the inherent problem of STIs remaining asymptomatic.¹⁰ The above factors have resulted in poor availability of data on RTIs/STIs, both symptomatic and asymptomatic, among women.

Women who do report to a healthcare facility for any RTI/ STI symptom are usually managed by the syndromic approach of the World Health Organization (WHO). This approach has been recommended by NACO, India,¹¹ at the primary health center (PHC) level,² as it is feasible, adaptable, and costeffective. Syndromic diagnosis is mostly carried out without offering any laboratory-based diagnosis, because of the high costs involved and the lack of facilities countrywide. However, a community study in women who self-reported morbidity, supported by laboratory diagnosis, could not establish consistency in the two methods.¹² Other studies have also been unable to fully validate the efficacy of this strategy.^{13,14} In addition, data on asymptomatic carriage of these infections by women are almost non-existent, thereby hindering treatment.

This study was carried out in women attending both rural and urban clinics in the outskirts of Delhi, India, with the objectives of: (1) enumerating their self-reported RTI/STI symptoms; (2) assessing the clinical status by vaginal, bimanual, and speculum examination; (3) determining the syndromic diagnosis of RTIs/STIs in symptomatic women and the microbiological diagnosis in both symptomatic and asymptomatic women; and (4) comparing the level of agreement between self-reporting of morbidity and syndromic and etiological diagnosis in the symptomatic women in the different groups.

Materials and methods

The study was carried out at the Regional STD Teaching, Training and Research Centre, Vardhman Mahavir Medical College and Safdarjung Hospital, New Delhi, over a period of 26 months, between March 2002 and April 2004. Institutional ethics committee approval was obtained prior to the commencement of the study.

Study population

The study population was recruited from different urban and rural health clinics in the National Capital Territory (NCT) of Delhi, having a population of approximately 10 million. Two government health set-ups, one urban and one rural, each from four zones — East, West, North, and South — were identified. A total of 4090 consecutive women (2079 from urban and 2011 from rural dispensaries), in the age range of 14–70 years, were recruited and assigned to one of the four study groups.

Women aged between 14 and 70 years, who were willing and able to provide informed consent to take part in the study, and who had symptoms unrelated to those of menstruation, either using/not using some method of contraception, were included. Group I consisted of a total of 1105 non-pregnant women (558 from urban and 547 from rural dispensaries), with symptoms of current vaginal discharge/ genital ulcer/other. Group II comprised 621 women (317 from urban and 304 from rural dispensaries), who were high-risk cases with a bad obstetric history (two or more abortions/ intrauterine growth retardation/stillbirth or neonatal death. and/or infertility (primary or secondary)). Group III consisted of 1563 pregnant women (790 from urban and 773 from rural areas) in any trimester, attending antenatal clinics. Group IV comprised 801 non-pregnant women (414 from urban and 387 from rural areas) recruited by consecutive sampling, with problems other than RTIs/STIs, attending gynecology (for uterine prolapse, fibroids), surgical, and medical clinics. This group was studied in order to determine the presence of syndromes as well as etiological agents of RTIs/STIs in asymptomatic women.

Women with other infections, such as urinary tract infections (UTIs), an irregular menstrual history, other menstrual problems, or gynecological surgeries were excluded from the study.

Data regarding literacy level, use of contraceptives, history of RTIs/STIs, knowledge and awareness of HIV/AIDS/ STIs, healthcare-seeking behavior, etc., were collected and collectively recorded in a proforma (questionnaire) designed for this purpose (details presented in a separate communication¹⁵). Before sending patients to the doctor, pre-test counseling and health education were imparted by a trained social worker using the conventional techniques. Informed written consent was obtained from all patients before participation in the study, and full confidentiality was assured. Each study recruit was assigned a code number for future reference.

Physical examination (vaginal, speculum, and bimanual) was carried out, to assess the presence of any abnormal discharge, genital ulcers, genital warts, cervicitis, cervical erosion, pelvic inflammatory diseases (PID), prolapse, etc. Cervical, vaginal, and urethral swabs and blood samples were collected for laboratory investigations. Swabs from ulcers (when present) were collected. Specimens were also collected from the asymptomatic patients included in the other study groups and the controls. All samples were transported immediately to the Regional STD Reference Laboratory of the Regional STD Teaching, Training and Research Centre, Vardhman Mahavir Medical College and Safdarjung Hospital, New Delhi in transport media, wherever applicable, and processed on the same day. Swabs for Chlamydia trachomatis antigen detection in special transport medium (supplied with the kit) were stored at -70 °C until use. The tests were carried out as per standard techniques as detailed below.¹⁶

Laboratory techniques

The following tests were carried out in all the study group subjects: (1) venereal disease research laboratory (VDRL; antigen from the Serologist to Kolkata, Government of India) and Treponema pallidum hemagglutination assay (TPHA; Plasmatec TPHA test kit, Hansard Diagnostics, UK) in VDRL reactive sera, for syphilis; (2) direct urethral/cervical smear and culture on chocolate agar and saponin-lysed blood agar with vancomycin, colistin, nystatin, trimethoprim (VCNT) supplement to detect Neisseria gonorrhoeae and confirmation of the isolates by standard methods;¹⁷ (3) ELISA (Bio-Rad Laboratories, WA, USA) for detection of chlamydial antigen (Chlamydia trachomatis); (4) direct wet mount examination and culture on Kupferberg broth with Trichomonas vaginalis supplement for the detection of T. vaginalis; (5) direct Gramstained smear examination and culture on Sabouraud's dextrose agar, followed by culture confirmation by germ tube test for the detection of Candida albicans and other Candida species; (6) examination and interpretation of vaginal Gramstained smear following Nugent's scoring¹⁸ for the diagnosis of BV; (7) herpes simplex virus-2 (HSV-2) IgM antibodies by ELISA (Equipar diagnostic kit, Italy) for detecting herpes progenitalis infection. Genital warts were clinically diagnosed. In addition to the above tests, only in patients with ulcers, Gram-stained smears and cultures from ulcer base specimens were examined for the presence of *Haemophilus ducreyi* and Giemsa-stained ulcer smears were examined for multinucleated giant cells for the detection of herpes progenitalis. (Detailed results of laboratory investigations, i.e., the presence of individual etiological agents, are presented in a separate communication.¹⁵)

Every symptomatic patient was managed on the basis of algorithms of the syndromic approach recommended by NACO, India, after carrying out risk assessment.¹¹ However, keeping in view the literacy status and lack of knowledge of the study groups, it was not always successful. The patients were offered specific treatment at their follow-up visits on the basis of their laboratory reports.

Statistical methods

Epi Info version 6.04d (January 2001) software, developed by the WHO, was used for data entry and analysis. The Chisquare test was applied to compare proportions in rural and urban women and also in the different groups, and *p*-values were calculated. The sensitivity and specificity of the different approaches of management were also calculated.

Results

Study population

The women ranged in age from 14 to 70 years and most of them (89.8%) belonged to the reproductive age group. The most predominant age group was 14-25 years (52.9%), followed by 26-35 years (36.9%), 36-45 years (7.8%), 46-55 years (1.9%), and 56-70 years (0.5%). All the groups had a similar distribution of ages, with the exception of group III, where 72% of the women were in the 14-25 years age group. In the rural clinics, there was higher representation of women in the 14-25 years age group than in the urban clinics.

Most of the patients were from the low-income group (51.5% urban, 49.3% rural) and were illiterate (38.9% urban, 30.8% rural); 77.4% were Hindu upper caste.

Many were not using any contraceptive method (63.3% urban, 59.8% rural), and knowledge about HIV/AIDS was nil in 49.8% urban and 51.9% rural women. Past history of RTIs/STIs was 63.4% in urban and 54.4% in rural women.

Presenting complaints

Overall, self-reporting of morbidity (Table 1) was 65.0%. Group I was 100% symptomatic. In group II, 72.9% (68.8% urban vs.77.3% rural, p < 0.02) had symptoms and in group III, 70.3% (74.3% urban vs. 66.2% rural, p < 0.001) had symptoms. Most of the women complained of vaginal discharge (VD), either singly or in combination with other symptoms like lower abdominal pain/low backache (LAP) not related to menstruation, redness and itching of the vulva, and dyspareunia. LAP was the only symptom in 5.8% cases. A total of 75.5% of women presented with more than one symptom, the most prominent combination being some type of VD and LAP (total 86.1%, urban 87.3%, rural 84.9%). Only 6.3% (4.9% urban, 7.7% rural) had redness and itching of the vulva in addition to this combination. A few women (1.6%; 1.0% urban

Complaints	Total			Group I			Group II			Group III			Group	IV	
	Urban	Rural	Total	Urban	Rural	Total	Urban	Rural	Total	Urban	Rural	Total	Urban	Rural	Total
VD only	246 (18.0)	213 (16.5)	459 (17.3)	104 (18.6)	96 (17.6)	200 (18.1)	40 (18.3)	29 (12.3)	69 (15.2)	102 (17.4)	88 (17.2)	190 (17.3)	-	-	-
LAP only	81 (5.9)	72 (5.6)	153 (5.8)	13 (2.3)	10 (1.8)	23 (2.1)	22 (10.1)	21 (8.9)	43 (9.5)	46 (7.8)	41 (8.0)	87 (7.9)	-	-	-
Other ^a	18 (1.3)	21 (1.6)	39 (1.5)	6 (1.1)	8 (1.5)	14 (1.3)	1 (0.5)	6 (2.6)	7 (1.5)	11 (1.9)	7 (1.4)	18 (1.6)	-	-	-
>1 ^b	1018 (74.7)	988 (76.3)	2006 (75.5)	435 (78.0)	433 (79.2)	868 (78.6)	155 (71.1)	179 (76.2)	334 (73.7)	428 (72.9)	376 (73.4)	804 (73.2)	-	-	-
Total	1363 (65.6)	1294 (64.3)	2657 (65.0)	558 (100)	547 (100)	1105 (100)	218 (68.8)	235 (77.3)	453 (72.9)	587 (74.3)	512 (66.2)	1099 (70.3)	-	-	-
No. tested	2079	2011	4090	558	547	1105	317	304	621	790	773	1563	414	387	801

Results are n (%). Group I, symptomatic; group II, bad obstetric history/infertility; group III, antenatal clinic attendees; group IV, control group; VD, vaginal discharge (mucoid/frothy yellowishgreen/curd-like/purulent); LAP, low abdominal pain/backache.

^a Other = redness and itching of the vulva or dyspareunia alone. ^b >1 = VD + LAP, or VD + redness and itching of the vulva, or VD + dyspareunia, or similar combinations with LAP.

 Table 2
 Clinical findings on vaginal examination in the study groups

Signs	Total			Group I			Group II			Group II	I		Group IV	/	
	Urban	Rural	Total	Urban	Rural	Total	Urban	Rural	Total	Urban	Rural	Total	Urban	Rural	Total
VD	1323	1405	2728	539	535	1074	166	195	361	499	549	1048	119	126 (32.6)	245
	(63.6)	(69.9)	(66.7)	(96.9)	(98.7)	(97.8)	(52.4)	(64.1)	(58.1)	(63.2)	(71.0)	(67.1)	(28.7)		(30.6)
GUD	8	10	18	5	2	7	0	2	2	2	4	6	1	2 (0.5)	3
	(0.4)	(0.5)	(0.4)	(0.9)	(0.4)	(0.6)		(0.7)	(0.3)	(0.2)	(0.5)	(0.4)	(0.2)		(0.4)
No signs	748	596	1344	12	5	17	151	107	258	289	220	509	294	259	553
	(36.0)	(29.6)	(32.9)	(2.2)	(0.9)	(1.5)	(47.6)	(35.2)	(41.5)	(36.6)	(28.5)	(32.6)	(71.0)	(66.9)	(69.0)
No. tested	2079	2011	4090	556	542	1098	317	304	621	790	773	1563	414	387	801

Results are n (%). Group I, symptomatic; group II, bad obstetric history/infertility; group III, antenatal clinic attendees; group IV, control group; VD, vaginal discharge (mucoid/frothy yellowishgreen/curd-like/purulent); GUD, genital ulcer disease.

and 2.3% rural) had only VD and redness and itching. The rest of the combinations (6.0%) were negligible and are not worth mentioning in detail. None of the women complained of genital ulcers or genital wart growths.

Clinical examination

Vaginal examination

A VD was observed in 2728 out of 4090 (66.7%) women, 63.6% in urban and 69.9% in rural women. The latter had significantly more VD in comparison to their urban counterparts in group II (p < 0.01) and in group III (p < 0.001). Overall, the type of discharge was mucoid in 51.4%, curd-like in 39.7%, yellowish-green in 7.4%, and purulent in 1.5%. No significant difference was observed in the type of discharge between urban and rural women. Genital ulcers were observed in only 18 women, eight urban (0.4%) and 10 (0.5%) rural (Table 2). Clinically, a diagnosis of chancroid was made in five patients, while a diagnosis of herpes progenitalis was made in 13.

Bimanual examination

Lower abdominal tenderness was observed in 13.5% of women as a whole, 8.1% urban and 19.1% rural. Tenderness in either or both fornices was observed in only 2.4% and pain on moving the cervix in 2.6% of women.

Speculum examination

The predominant finding was cervical discharge, either singly (52.4%) or in combination with a cervical growth like polyps (0.4%). Cervical discharge as a single finding was seen more often in rural women (58.9%) than in their urban counterparts (46.1%) and the difference was highly significant (p < 0.001). However, cervical discharge in association with other findings was observed in only 1.2% of urban and 5.1% of rural women. Cervical erosion was detected in a total of 2.3% of women (3.1% urban and 1.4% rural). Genital wart growths were present in only 18 out of 4090 women (0.3% rural and 0.5% urban). A total of 49.4% urban and 34.3% rural women had no findings.

Syndromic diagnosis

Overall, 71.4% (94.6% in group I, 65.5% in group II, 70.6% in group III, and 45.3% in group IV) had some STI syndrome, with

variations in rural and urban women. Genital ulcer disease (GUD) syndrome was observed alone in only four and in combination with vaginal discharge syndrome (VDS) in 14. VDS was predominantly observed, either singly or in combination with pelvic inflammatory disease (PID) syndrome and GUD syndrome. A total of 93.8% in group I, 63.4% in group II, 68.8% in group III, and 39.7% in group IV had VDS, singly or in combination with other syndromes. PID only was observed in 2.2% and in combination with VDS in 9.9%. The maximum prevalence of PID was in group I (19.7%). Rural women as a whole (74.8%) and in group II (73.0%) and group III (74.8%) had a significantly higher proportion of STI syndromes than the urban women (p < 0.001; Table 3).

Etiological diagnosis

Laboratory investigations of RTIs/STIs in the study groups revealed that overall 32.2% of women had some etiological diagnosis (Table 4). The common diseases encountered in etiological diagnosis included: (1) agents causing VDS: *C. albicans* and species (22.6% urban, 17.5% rural), BV (4.2% urban, 4.0% rural), *T. vaginalis* (2.0% urban, 2.3% rural), *C. trachomatis* antigen (1.1% urban, 1.6% rural), *N. gonorrhoeae* (0.6% urban, 0.7% rural); (2) agents causing GUD: HSV-2 (4.8% urban, 6.8% rural), VDRL and TPHA positivity (1.0% urban, 1.1% rural); (3) other: hepatitis B surface antigen positivity (1.1% urban, 1.6% rural), HIV seropositivity (0.2% urban, 0.1% rural).

Comparison of patient complaints, syndromic diagnosis, and etiological diagnosis in symptomatic women in urban and rural areas

A comparison of patient complaints, syndromic diagnosis of STIs, and etiological diagnosis (Figure 1) was made in the different study groups. It was observed that in groups I, II, III, and IV, respectively, 100%, 72.9% (68.8% urban and 77.3% rural), 70.3% (74.3% urban and 66.2% rural), and 0% had some STI symptoms, 94.6% (94.8% urban and 94.3% rural), 65.5% (58.3% urban and 73.0% rural), 70.6% (66.6% urban and 74.8% rural), and 45.3% (42.3% and 48.6%) had some syndrome, and 37.5% (42.6% urban and 32.2% rural), 32.2% (30.6% urban and 33.9% rural), 33.6% (36.1% urban and 31.0% rural), and 22.1% (18.6% and 25.8%) had an etiological diagnosis. The sensitivity

Syndrome	Group I		Group II		Group III		Group IV		Total with s	yndrome
	Urban	Rural	Urban	Rural	Urban	Rural	Urban	Rural	Urban	Rural
Only GUD	1 (0.2)	1 (0.2)	0	0	0	1 (0.1)	0	1 (0.2)	1 (0.05)	3 (0.2)
Only VD	380 (68.1)	440 (80.4)	146 (46.0)	194 (63.8)	443 (56.1)	532 (68.8)	107 (25.8)	163 (42.1)	1076 (51.8)	1329 (66.1)
Only PID	5 (0.9)	2 (0.4)	8 (2.5)	5 (1.6)	21 (2.7)	6 (0.8)	29 (7.0)	15 (3.9)	63 (3.0)	28 (1.4)
GUD + VD	4 (0.7)	1 (0.2)	0	2 (0.7)	2 (0.2)	3 (0.4)	1 (0.2)	1 (0.2)	7 (0.3)	7 (0.3)
VD + PID	139 (24.9)	72 (13.2)	31 (9.8)	21 (6.9)	60 (7.6)	36 (4.7)	38 (9.2)	8 (2.1)	268 (12.9)	137 (6.8)
Total	529 (94.8)	516 (94.3)	185 (58.3)	222 (73.0)	526 (66.6)	578 (74.8)	175 (42.3)	188 (48.6)	1415 (68.1)	1504 (74.8)
Total in group (<i>n</i>)	558	547	317	304	790	773	414	387	2079	2011

Results are n (%). Group I, symptomatic; group II, bad obstetric history/infertility; group III, antenatal clinic attendees; group IV, control group; STI, sexually transmitted infection; GUD, genital ulcer disease; VD, vaginal discharge (mucoid/frothy yellowish-green/curd-like/ purulent); PID, pelvic inflammatory disease.

 Table 3
 Syndromic diagnosis of STIs in the study groups

Table 4 Etiological diagnosis of STIs in the study groups	iological di	agnosis of S	TIs in the s	tudy groups											
Infection	Total			Group I			Group II			Group III			Group IV		
	Urban	Rural	Total	Urban	Rural	Total	Urban	Rural	Total	Urban	Rural	Total	Urban	Rural	Total
Single	593	524	1117	195	152	347	78	84	162	249	206	455	71	82	153
	(28.5)	(26.1)	(27.3)	(34.9)	(27.8)	(31.4)	(24.6)	(27.6)	(26.1)	(31.5)	(26.6)	(29.1)	(17.1)	(21.2)	(19.1)
Mixed	104	95	199	43	24	67	19	19	38	36	34	70	9	18	24
	(2.0)	(4.7)	(4.9)	(7.7)	(4.4)	(6.1)	(0.9)	(6.3)	(6.1)	(4.6)	(4.4)	(4.5)	(1.4)	(4.6)	(3.0)
Total	697	619	1316	238	176	414	76	103	200	285	240	525	77	100	177
	(33.5)	(30.8)	(32.2)	(42.6)	(32.2)	(37.5)	(30.6)	(33.9)	(32.2)	(36.1)	(31.0)	(33.6)	(18.6)	(25.8)	(22.1)
No. tested	2079	2011	4090	558	547	1105	317	304	621	290	773	1563	414	387	801
Results are $n~(\%).$ Group I, symptomatic; group II, bad obstetric	(%). Group I	, symptoma	tic; group II,	, bad obstet	history/i	nfertility; g	roup III, ant	enatal clinic	nfertility; group III, antenatal clinic attendees; group IV, control group.	group IV, c	ontrol group	Ċ			

of the syndromic approach for VDS in this study was 93.8%, but the specificity of this method in diagnosing vaginal discharge was low at 37.5%.

Discussion

The present study revealed that VD was the most common symptom reported by women, confirming previous studies.^{12–14} Overall, self-reporting of morbidity was 65.0%, with VD as the main complaint, either singly or in combination with low backache, abdominal pain, itching vulva, or dyspareunia. On clinical examination, VD was present in 66.7% of cases, confirming the data of a previous study.¹⁹ In this report, 12.7% of women complained of VD, up to 66.7% were found to have abnormal VD on vaginal examination, and 52.8% had a cervical discharge on speculum examination. In the present study, genital ulcers and genital warts were not reported by the study subjects. This is an indication that awareness of STIs and health-seeking behavior are inadequate in women, making them unable to relate their STI symptoms accurately.

While a high proportion of women were diagnosed by the syndromic approach, their total infection load as determined by etiological diagnosis was guite low. This could mean that RTIs/STIs are being over-diagnosed by the investigating physician and even that physiological discharge was misinterpreted as pathological. Therefore, the sensitivity of the syndromic approach for VDS in this study was high, but the specificity of this method in diagnosing VD was low, as reported previously.¹⁴ It is not possible to comment on the other minor syndromes as well as mixed syndromes from this data; this may be considered as one of the limitations of the study.

A community-based survey of 3000 women, randomly sampled from a population in Goa, India, was carried out in 2001–2003.²⁰ In this study, psychosocial factors instead of etiological agents of RTIs/STIs were found to have the strongest association with the complaint of VD. It was recommended that syndromic management algorithms be refined so that women with complaints that are non-infectious in etiology are offered psychosocial interventions. Another possibility for the disagreement between syndromic and laboratory diagnosis could be that the laboratory techniques for diagnosis are not available early enough.²¹ Also, there is a need for more sensitive techniques like PCR for the diagnosis of these infections.

The lower detection rate of RTIs/STIs by etiological approach than the syndromic approach in the present study could be real or could be due to self-medication, which is rampant in the community. This is due to the availability of 'over-the-counter' antimicrobials and requires further research in tertiary care health institutions to compare rates. Non-availability of nucleic acid-based tests like PCR, as mentioned above, could also have resulted in the lower detection by laboratory methods; this is another limitation of this study.

A Chinese study²² attempted to validate diagnostic algorithms for syndromic management of STIs with laboratory diagnostic support. The authors reported that the specificity and positive predictive value of syndromic management of VD were not satisfactory. In contrast to this report,²² a community-based study in India in 812 women revealed that

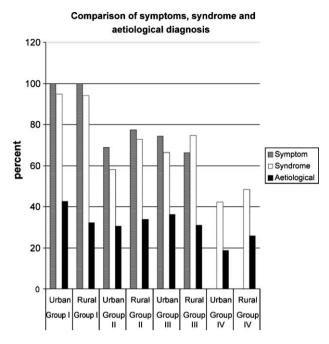


Figure 1 Comparison of symptoms, syndromic diagnosis, and etiological diagnosis.

compared to clinical diagnosis, history-based diagnosis had a high sensitivity (80.5%) and high positive predictive value (81.3%), but low specificity (48.6%) and low negative predictive value (47.5%).²³ The level of agreement was found to be fair (Kappa = 0.28, 95% confidence interval = 0.20-0.36). The authors recommended a revision of history-based syndromic protocols.

A study was undertaken in Entebbe, Uganda to measure the prevalence of RTIs during pregnancy and to evaluate the current syndromic diagnosis and management approach in effectively targeting BV and *T. vaginalis*.²⁴ It was observed that the sensitivity of syndromic management in detecting BV was 50.0% and for *T. vaginalis* was 66.7%.

STD syndromic treatment impacts very little in reducing genital HIV shedding, underscoring the need for appropriate validation of STD syndromic diagnosis and management to control heterosexual transmission of HIV.²⁵

The present study did not observe any association between the presenting symptoms, syndromic diagnosis, and etiological diagnosis, and thus the syndromic approach in VDS may not be effective, as reported earlier.^{12–14,26} A high rate of over-treatment was observed in the study groups, in contrast to a previous study reporting the chances of over-treatment for VD and PID as only 16% and 15%, respectively.²³ Over-treatment carries both financial and social costs, the latter in potentially exposing women misdiagnosed as having some STI to threats of domestic disruption or even violence.¹⁴

It is interesting to note that a higher proportion of rural women than urban women had some STI syndrome. This indicates that the urban women had a greater knowledge regarding STIs and that accessibility to medicines in the urban areas was better. However, the significantly higher etiological diagnosis in the urban women probably indicates improper and indiscriminate use of antimicrobials. A significant proportion of asymptomatic women in groups II, III, and IV harbored etiological agents of RTIs/STIs and were unfortunately not covered under syndromic management, as emphasized earlier.¹⁰ In a study in the red light area of Surat, India, the performance of the Indian recommended treatment guidelines for VDS and GUD against etiological diagnosis was observed to be poor.¹⁹ It was concluded that syndromic case management was missing a large number of the asymptomatic cases and was providing treatment in the absence of disease.

There remains an urgent need for the development of an affordable, rapid, and effective diagnostic technique to improve the detection of RTIs/STIs in women in resource-poor settings. This may prevent sequelae and reduce transmission of these infections.^{27–29}

Conclusions

This study highlights a wide variation between self-reporting of morbidity, syndromic-based diagnosis, and etiologicalbased diagnosis in women from rural and urban locations in different parts of Delhi. This may affect the assessment of the utility of the syndromic approach for STI case management countrywide. This data calls for an early appraisal and review of the diagnostic policy by national authorities, and the introduction and/or strengthening of laboratory facilities, especially at the peripheral level. Tertiary care centers can periodically assess the burden of STIs in the community and assess antimicrobial resistance patterns using laboratory tests to determine strategies. This may allow the overuse/ abuse of antimicrobials to be avoided and prevent the development of antimicrobial resistance.

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