Original article

Syndromic management of vaginal discharge among women in a reproductive health clinic in India

Snehalata Vishwanath, Vibha Talwar, Rajendra Prasad, Kurus Coyaji, Christopher J Elias, Isabelle de Zoysa

Objectives: To examine the performance of the syndromic approach in the management of vaginal discharge among women attending a reproductive health clinic in New Delhi, India.
Methods: Women who sought services from the clinic and who had a complaint of vaginal discharge were interviewed, underwent a pelvic examination, and provided samples for laboratory investigations of bacterial vaginosis, candidiasis, syphilis, trichomoniasis, and *Chlamydia trachomatis* and *Neisseria gonorrhoeae* infections. Data analysis focused on the prevalence of infection and on the performance of the algorithm recommended by the national authorities for the management of vaginal discharge.
Results: The most common infection among 319 women was bacterial vaginosis (26%). At least one sexually transmitted infection was detected in 21.9% of women. The prevalence of *C trachomatis* infection was 12.2%; trichomoniasis 10%; syphilis 2.2%; *N gonorrhoeae* was not isolated. An algorithm based on risk assessment and speculum assisted clinical evaluation was not helpful in predicting cervical infections associated with *C trachomatis* (sensitivity 5% and PPV 9%). This algorithm was sensitive (95%) though not specific (22%) in selecting women for metronidazole therapy effective against bacterial vaginosis or trichomoniasis, and overtreatment was a problem (PPV 38%). The sensitivity, specificity, and PPV of this algorithm for the treatment of candidiasis were 46%, 98%, and 88% respectively. The cost per case assessed using the algorithm was $2 and the cost per infection correctly treated was $4.25.
Conclusions: The prevalence of cervical infection associated with *C trachomatis* was high among these "low risk" women. The syndromic approach is not an efficient tool for detecting this condition, and alternative approaches to evaluation and intervention are required. The syndromic management of vaginal discharge among women seeking family planning and other reproductive health services should focus on vaginal infections, thus enhancing quality of care and addressing women's concerns about their health.
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Keywords: syndromic approach; vaginal discharge; *Chlamydia trachomatis*; reproductive health; India

Parivar Seva Sanstha, New Delhi, India
S Vishwanath

Department of Microbiology, University College of Medical Sciences, New Delhi, India
V Talwar

Population Council, New Delhi, India
R Prasad
I de Zoysa

Division of Obstetrics and Gynaecology, KEM Hospital, Pune, India
K Coyaji

Population Council, Bangkok, Thailand
C J Elias

Correspondence to:
Dr Isabelle de Zoysa, Population Council, 53 Lodi Estate, New Delhi 110003, India
isabelle@pcindia.org

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Introduction

Reproductive tract infections (RTI), including sexually transmitted infections (STI), represent a major public health problem in many developing countries. In India, there is an effort to extend RTI treatment services through the formal healthcare system to women seeking family planning and other reproductive health services. Syndromic management of symptomatic individuals is recommended. Concerns have been raised, however, about the use of the syndromic approach, especially among populations with a low prevalence of STI.[1] We conducted a study to assess the performance of the syndromic management of vaginal discharge in a reproductive health clinic in New Delhi, India.

Methods

Women who sought services from the clinic and who had a complaint of vaginal discharge were interviewed, underwent a pelvic examination, and provided vaginal and cervical samples for laboratory investigations.

Trichomonas vaginalis was identified through microscopy of a wet mount or Giemsa stain of a vaginal smear. Candidiasis was diagnosed when budding yeasts or pseudohyphae were seen on a wet mount or Gram stain of a vaginal smear. Bacterial vaginosis was defined by Amsel's criteria (presence of at least three of the following: homogeneous vaginal discharge, positive whiff test, pH >4.5, and clue cells observed on a Gram stained vaginal smear). *Neisseria gonorrhoeae* was detected through examination of a Gram stain of a cervical smear and culture of another by inoculation on modified Thayer–Martin medium followed by incubation at 37°C in 10% carbon dioxide. Chlamydial antigen was detected in cervical swabs using a direct immunofluorescence (DIF) assay (MicroTrak, Syva Corporation, Palo Alto, CA, USA). Syphilis was identified through screening of sera by a Venereal Disease Research Laboratory Test (VDRL) and considered positive when the titre was >1:8. External quality control was provided through repeat DIF tests on a sample of slides at the Chlamydia National Reference Laboratory of the All India Institute of Medical Sciences, New Delhi.

The algorithm recommended by the National AIDS Control Organisation (NACO) for the management of vaginal discharge was used

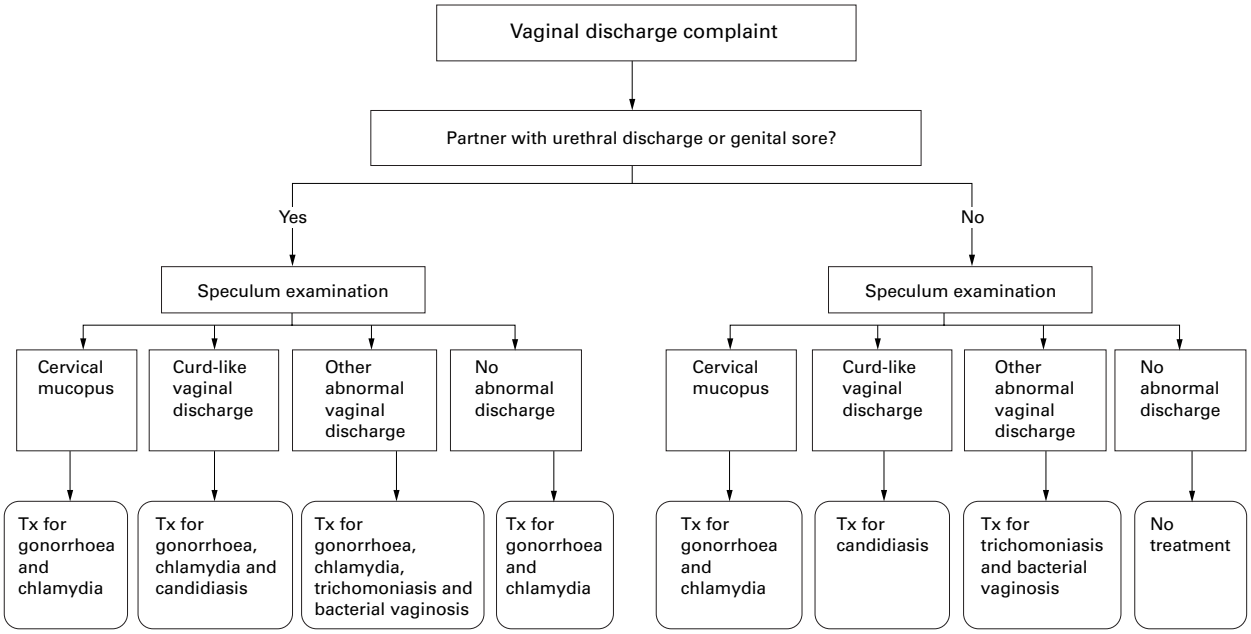

Figure 1 NACD algorithm for the management of vaginal discharge.

Table 1 Aetiological diagnosis (n=319)

Condition	*No*	*%*
None detected	128	40.1
Bacterial vaginosis	83	26.0
Candidiasis	81	25.4
Chlamydia trachomatis	39	12.2
Trichomoniasis	32	10.0
Syphilis	7	2.2
Neisseria gonorrhoeae	0	0.0

Note: 44 women (13.8%) had multiple infections.

(fig 1) and the results compared with laboratory diagnosis of infection.

Results

Table 1 gives the prevalence of laboratory identified infections. No infections were detected in 40.1% of 319 women. The most common infection was bacterial vaginosis (26%). At least one STI (*Chlamydia trachomatis* infection, trichomoniasis, or syphilis) was detected in 21.9% of women. Cervical infections were common: *N gonorrhoeae* was not isolated but the prevalence of *C trachomatis* infection was 12.2%.

The algorithm based on risk assessment and speculum assisted clinical evaluation was not helpful, however, in predicting cervical infections. Using this algorithm, 21 women (6.6%) were treated for both *C trachomatis* and *N gonorrhoeae* infections as they reported a symptomatic partner (6.0%) or were found to have cervical mucopus on examination (0.6%). All of the treatment for gonorrhoea was unnecessary as no laboratory evidence of *N gonorrhoeae* was found. Only two *C trachomatis* infections were correctly managed (sensitivity 5%), and the majority of women treated for this condition did not have laboratory evidence of infection (positive predictive value, or PPV 9%) (table 2). Specificity, however, was high (93%).

On the other hand, the algorithm led to the correct management of most cases of bacterial vaginosis and trichomoniasis (sensitivity 94% and 100% respectively). As the algorithm does not distinguish between bacterial vaginosis and trichomoniasis, and both infections are treated with a single dose of oral metronidazole (the NACO guidelines advise that sexual partners also be treated with a single dose of metronidazole in cases of suspected trichomoniasis), we assessed the performance of the algorithm in the management of these two infections considered together. The algorithm was sensitive (95%), though not specific (22%), in identifying women requiring metronidazole therapy, and overtreatment was a problem (PPV 38%). Using this approach a total of 268 (84%) women were selected for metronidazole treatment, but the PPV remained only marginally higher than the actual prevalence of infection associated with either bacterial vaginosis or trichomoniasis (33.9%).

Nearly half the women with candidiasis were correctly treated (sensitivity 46%), and the specificity and PPV of the algorithm for this condition were high (98% and 88% respectively).

Table 2 Performance of NACO algorithm

Diagnosis	*Number (%) of infected women*	*Number of cases detected*	*Sensitivity (%)*	*Specificity (%)*	*PPV (%)*
Chlamydia trachomatis	39 (12.2)	2	5	93	9
Bacterial vaginosis	83 (26.0)	78	94	19	29
Trichomoniasis	32 (10.0)	32	100	18	12
Bacterial vaginosis or trichomoniasis	108 (33.9)	103	95	22	38
Candidiasis	81 (25.4)	37	46	98	88

We assessed whether or not the management of vaginal infections could be improved through the use of microscopy, which can be conducted at the bedside. Use of microscopy for the diagnosis of trichomoniasis did not have an impact on sensitivity (which was already 100%), but it improved specificity (from 18% to 100%) and PPV (from 12% to 100%), thereby ensuring that no woman was inappropriately treated for this condition.

On the other hand, the use of microscopy increased somewhat the sensitivity of the diagnosis of candidiasis (from 46% to 57%) but had little impact on specificity and PPV, which were already high at 98% and 88% respectively.

The cost of the drugs used in applying the algorithm amounted to $635 (cost of bulk order in the local market at the August 1998 exchange rate of Rs 40 to the US$) and the cost per case assessed was $2 per case. The number of infections correctly treated in applying the algorithm was 149 and the cost per infection correctly treated was $4.25.

Discussion

These results are a reminder that the syndromic management of vaginal discharge is not an efficient approach for identifying women with cervical infections. The prevalence of *C trachomatis* infections was high in this "low risk" population, but the performance of the NACO algorithm in predicting these infections was unacceptably poor. The algorithm had low sensitivity, missing most true infections, and low PPV, leading to overtreatment and erroneous labelling of women as having a serious STI. The PPV was lower than the prevalence of cervical infections in the women studied, and the application of the algorithm was no better than random treatment. These results are consistent with those of other validation studies, which have found that sociodemographic and behavioural risk assessment and clinical assessment are rarely sufficient for identifying cervical infections (case finding) in most settings,[2] though they may be helpful in selecting women for further diagnostic tests in settings where these are available (selective screening).[3–6]

In most instances, the syndromic management of vaginal discharge should focus on vaginal infections, especially bacterial vaginosis and trichomoniasis, in recognition of the fact that vaginal discharge is primarily a manifestation of these conditions.[2] In this study, the algorithm usefully selected most women requiring metronidazole treatment, which is effective against bacterial vaginosis and trichomoniasis, if we accept high levels of overtreatment. The low cost and minimal side effects of metronidazole may temper concerns about the overuse of this antimicrobial. In fact, presumptive metronidazole treatment of all women with vaginal discharge has been advocated,[2] and should be considered in case it is not possible to conduct a speculum examination of women with vaginal discharge.

On the other hand, the sensitivity of the algorithm was low for the identification of candidiasis, though specificity and PPV were both high. The low sensitivity of the algorithm may be related to the fact that overgrowth of *C albicans* in the vagina is not always associated with discharge, and that other symptoms, such as pruritus, may be more appropriate entry points for an algorithm seeking to address vaginal candidiasis.

The use of simple bedside microscopy only marginally increased the proportion of vaginal infections that were correctly managed. Their value was not so much in increasing sensitivity, but in improving specificity and PPV, so that the use of microscopy for the specific diagnosis of candidiasis and trichomoniasis would ensure that no woman is inappropriately treated for these conditions. The additional costs involved may be offset by the savings on treatment costs associated with more precise diagnoses, and reduced wastage of drugs.

In family planning and other reproductive healthcare settings, a broader concern about RTIs is preferable to a more narrow focus on STIs, because if reflects a more comprehensive and less stigmatising vision of women's need for reproductive health services.[7] In such settings, algorithms can be constructed that adequately manage most common vaginal infections such as bacterial vaginosis or trichomoniasis, through empirical treatment with metronidazole (100% sensitivity) or the use of specific tests to increase specificity and PPV and make more precise diagnoses. The principal benefits of treating vaginal infections are the relief of symptoms of these conditions, thereby meeting a major expectation of clients of reproductive health services, as well as the prevention of gynaecological,[8] and obstetric complications[9–11] (and possibly HIV transmission),[12 13] associated with bacterial vaginosis.

At the same time, other approaches for the control of cervical infections are required to ensure quality of care in antenatal and family planning clinics serving populations with moderate to high prevalence, given the potentially severe consequences of these infections for women's health. The control of STIs in resource-poor settings remains a major challenge. The development of simple and affordable diagnostic tests that can be used for case finding is of highest priority. However, an overly narrow focus on the case management of vaginal discharge in reproductive healthcare settings is clearly inadequate as a public health strategy for reducing the prevalence of STIs among women.[13] Other approaches, such as more aggressive treatment of these infections in men, with effective partner management, are required.

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Contributors: SV contributed to the design, execution, analysis, and interpretation of the study; VT contributed to the design of the study and supervised all the laboratory analyses; RP carried out the statistical analysis and contributed to the interpretation of the results; KC contributed to the design,

analysis, and interpretation of the study; CE contributed to the design, analysis, and interpretation of the study and helped write the paper; IdZ contributed to the design, execution, analysis, and interpretation of the study and took the lead in writing the paper.

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