Comparison of syndromic diagnosis of reproductive tract infections with laboratory diagnosis among rural married women in Medak district, Andhra Pradesh, India

M. L. S. Prabha, G. Sasikala, Sudha Bala
Department of Community Medicine, ‘In charge Regional STD Centre, Department of Microbiology, Osmania Medical College, Hyderabad, Andhra Pradesh, India

Address for correspondence:
Dr. M. L. S. Prabha, Department of Community Medicine, Osmania medical College, Koti, Hyderabad, Andhra Pradesh, India.
E-mail: mlspspm@yahoo.com

Abstract

Introduction: In developing countries, reproductive tract infections (RTI) commonly affect the quality of life. Many reproductive tract infections including sexually transmitted infections (STI) and cervical cancers remain asymptomatic for long periods. Syndromic case management (SCM) is the mainstay in the control of RTI/STI, especially at primary level, where laboratory diagnosis is not possible. However, lab diagnosis should be used when it is available. Objective: To assess the consistency of syndromic diagnosis with laboratory diagnosis. Materials and Methods: A total of 407 women were screened. Women were categorized according to Syndromic Diagnosis of RTI/STI based on history and clinical examination. Microbiological tests and Pap smears were done to confirm the diagnosis and compared with Syndromic Diagnosis. Results: Microbiologically, 33.14% were positive for at least one organism. Bacterial vaginosis was the most common finding (14%). Pap smear showed 32.9% inflammatory changes and 0.25% low-grade squamous intraepithelial lesion. Sensitivity and specificity of syndromic diagnosis with laboratory findings: Vaginal discharge syndrome with microbiological tests- (Se 58.9; Sp55.1%) Lower abdominal pain syndrome with microbiological tests-(Se 14.4%; Sp76.6%) Conclusion: The findings of this study highlight the wide variation of syndromic and laboratory diagnosis.

Key words: Community based study, etiological diagnosis, reproductive tract infections, syndromic diagnosis, sexually transmitted infections

INTRODUCTION
Reproductive tract infections including sexually transmitted infections represent an urgent public health priority in developing countries. The 2002 ICMR community based prevalence study of STI/RTI has shown that 5% to 6% of sexually active adult population is suffering from some form of STI/RTI. The 2005 ICMR multicentre rapid assessment survey (RAS) indicates that 12% of female clients and 6% of male clients attend the out-patient departments for complaints related to STI/RTI. According to DLHS-3 18.3% women reported some symptom of reproductive tract infections/sexually transmitted infection.

Most are asymptomatic for long periods. Early diagnosis and treatment of these infections can
prevent serious complications and long term sequelae affecting the quality of life. Main barriers to the health seeking behavior among women are illiteracy, ignorance, low socioeconomic status, cultural norms and lack of privacy at the health care facilities. This results in poor availability of data on reproductive tract infections among symptomatic and asymptomatic women. In order to respond to situation of high prevalence and need for effective treatment for RTI/STI, especially in countries with limited resources, syndromic diagnostic approach was recommended by WHO and was adopted by NACO, India at the primary health center level.[3]

The approach of using simple laboratory tests in conjunction with syndromic approach is called enhanced syndromic management which can enhance the effectiveness i.e increase sensitivity, specificity and predictive values, and contribute to the epidemiological data in programming decision making.[4]

Much of the available data comes from hospital and clinic based studies. There are very few community based prevalence studies with laboratory support on reproductive tract infections/sexually transmitted infections studies among ever married women aged 15-49 years in rural India. To address this issue, this study was carried out among ever married rural women aged 15-49 years with the objective to assess the consistency of syndromic diagnosis with laboratory diagnosis.

MATERIALS AND METHODS
A community-based, cross-sectional study was undertaken in rural field practice area of Osmania medical college, Patancheru, Medak district, Andhra Pradesh between March 2010 and February 2011.

Study setting
Three subcenters under the rural health center with population of 19,081, women population of age group 15-49 years (5002), of this 25% were chosen ie 1250 women.

Sample size
Prevalence was taken as 50%, precision error as 10% 4pq/l2 = 400

Ethical considerations
Approval for the study was obtained from Osmania Medical College Ethics committee, Hyderabad and informed consent was taken from participants.

Study population recruitment
Inclusion criteria: ever married women of reproductive age group 15-49 years living in the particular village at the time of data collection.

Exclusion criteria: women with missed periods, undergone hysterectomy and unmarried women.

At Rural Health Center, convergence meeting was conducted which included medical officers, Auxillary Nurse Midwives, Health supervisors, ASHA workers, Anganwadi workers and other staff. And they were assessed on awareness on Reproductive tract infections. And the study aims and objectives with inclusion and exclusion criteria were explained. Household survey was conducted with the help of Asha workers, postgraduate students and assistant professors using interview schedule to collect demographic data. The participants were informed that they would be tested for RTIs and STIs and that they would be offered free treatment if found to be infected. Informed consent was obtained in all cases. Before being recruited the purpose of the study was explained to eligible women in their homes and to close family members, e.g. husbands, mothers-in-law. Each woman who agreed to participate attended clinic (Sub center building or Gram Panchayat office or Primary school or Rural health centre) and was interviewed in private about her socio demographic and reproductive history, current and past clinical symptoms affecting the reproductive tract, treatment-seeking behavior, and sexual behavior. Two gynecologists conducted a comprehensive physical examination that included a speculum-based examination of the cervix and vagina and bimanual examination.

Of the 751 women agreed to come for the study, only 536 women turned up to the camps, of whom 96 refused for examination and 33 were excluded due to menstruation and missed periods; so a total of 407 were taken up for the study.

Table 1: Criteria for diagnosis as per NACO guidelines

| Vaginal discharge syndrome | a. Vaginitis-presence of abnormal discharge described in terms of amount,smell,color, consistency and its association with itching. |
|---------------------------|-----------------------------------------------------------------------------------------------------------------|
|                           | b. Cervicitis-presence of cervical erythema, inflammation or bleeding with or without discharge. |
| Lower abdominal pain syndrome | Presence of lower abdominal pain and uterine tenderness with or without adnexal tenderness. |
| Genital ulcers             | Presence of vesicles, papules, ulcers at labia, vulva, cervix. |
| Genital growths            | Cauliflower lesions involving external genitals, perineum. |
Criteria for clinical diagnosis were standardized [Table 1] and findings recorded. During per speculum examination, papnicolaou smear, 3 vaginal, 3 cervical swabs, and a 5 ml blood sample were taken for microbiological investigations as per Standard Operating Procedures (SOP) Manual of Regional STD Reference Laboratory, Safdarjung Hospital, New Delhi and NACO guidelines [Table 2] and the samples were transported to Regional STI center at Osmania general hospital on the same day by the technician.

**Results**

**Study population characteristics**

Most of them were in the age group of 26-30 years comprising 29.2%, education was less than 5 years in 57.2%, most of them belonged to middle class(38%) followed by lower class(34%) as per BG Prasad’s socioeconomic status classification.

Prevalence of reproductive tract infections/sexually transmitted infections by syndromic diagnosis was 61.9% and by laboratory diagnosis was 33.1% [Figure 1]. Of the syndromes diagnosed, the most common is vaginal discharge syndrome (34%) followed by lower abdominal pain syndrome (28%). No cases of genital ulcers and genital warts were reported.

Results by microbiological investigations using gold standard procedures are shown in Figure 2 and via Papnicalaou smears shown in Table 3.

**Table 2: Criteria for laboratory diagnosis [11]**

| Reproductive tract Infections (Etiological agent) | Sample site | Laboratory methods | Diagnosis |
|--------------------------------------------------|-------------|--------------------|-----------|
| Bacterial vaginosis associated organisms          | Vagina      | 1) Direct microscopy for clue cells. 2) Gram’s stain examination and scoring | Nugent’s criteria |
| Trichomonas vaginalis                            | Vagina      | 1) Direct microscopy of saline wet mount 2) Transport on Amie’s transport media 3) Culture on Kupferberg trichomonas medium | Positive by either or two methods |
| Candidia species                                 | Vagina      | 1) Direct microscopy of KOH mount and Gram stained smear. 2) Culture on Sabouraud’s dextrose agar | Positive by either or two methods |
| Neisseria gonorrhoeae                            | Cervix      | 1) Direct microscopy of Gram’s stained smear. 2) Culture on Saponin lysed Blood Agar with VCNT inhibitors | Positive by either or two methods |
| Chlamydia trachomatis                            | Cervix      | Immunochromatography for antigen detection ELISA for antibody detection | Positive by either or two methods |
| Human papilloma virus infection                  | Cervix (transformation zone) | Papanicolaou stain | |
| Treponema pallidium                              | Blood(serum) | VDRL/TPHA | Positive by both |
| Hepatitis B                                      | Blood(serum) | Hepatitis B- for HBsAg | Positive |
| Hepatitis C                                      | Blood(serum) | Hepatitis C for anti HCV | Positive |
CONCLUSIONS

The results of this study provide wide variation between syndromic and laboratory diagnosis of reproductive tract infections in rural women, showing that enhanced syndromic management would be more effective. This study also demonstrated the feasibility of prevalence and early detection of precancerous and cancerous lesions.

ACKNOWLEDGMENTS

We are thankful to NACO, APSACS, Department of Microbiology (Regional STI Center) and Department of Pathology, Osmania medical college, our field staff and all study participants for their cooperation.

REFERENCES

1. National STI/RTI Control and Prevention Programme NACP, Phase-III, India, National AIDS Control Organisation, Department of AIDS Control, Ministry of Health and Family Welfare, Government of India.
2. District level household survey-3, 2007-2008; Ministry of health and family welfare, Mumbai, India: International Institute for Population Sciences.
3. National AIDS control organization. Simplified STI and RTI treatment guidelines, New Delhi: NACO, Ministry of Health and Family Welfare, Government of India; 1998.
4. National AIDS control programme. Resource material for trainers, Ministry of health and family welfare, Government of India, New Delhi; October 2008.
5. Prasad JH, Abraham S, George K, Lalitha MK, John R. Reproductive tract infections in rural women, India. Epidemiol Infect 2008;136:1432-40.
6. Dallabetta GA, Gerbase AC, Holmes KK. Problems, solutions and challenges in syndromic management of sexually transmitted diseases. Sex Transm Infect 1998;74(Suppl 1):S1-11.
7. Hawkes S, Morison L, Foster S, Gausia K, Chakraborty J, Peeling RW. Reproductive tract infections in women in low-income, low prevalence situations: Assessment of syndromic management in Matlab, Bangladesh. Lancer 1999;354:1776-81.
8. Prabha, et al.: Comparison of syndromic with laboratory diagnosis of reproductive tract infections
9. Patnaik L, Sahu T, Sahani NC. Syndromic diagnosis of RTI/STI among women of reproductive age group. Indian J Community Med 2008;4:1.
10. Ray K, Bala M, Bhattacharya M, Muralidhar S, Kumari M, Salhan S. Prevalence of RTI/STI agents and HIV infection in symptomatic and asymptomatic women attending peripheral health set-ups in Delhi, India. Epidemiol Infect 2008;136:1432-40.
11. Standard Operating Procedure manual for capacity building training programme on syndromic management of sexually transmitted diseases.

Source of Support: Nil. Conflict of Interest: None declared.