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Original Research Article

Efficacy of conventional pharmacotherapy of syndromic management of STIs: a two year cross-sectional prospective study

Beenu Kushwah[1], Devendra Singh Kushwah[2]*

[1]Department of Gynecology, S.S. Medical College, Rewa, Madhya Pradesh, India
[2]Department of Pharmacology, Gajra Raja Medical College, Gwalior, Madhya Pradesh, India

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***Correspondence to:**
Dr. Devendra Singh Kushwah, Email: dev_singh433@yahoo.com

ABSTRACT

Background: Syndromic management has been the centre for treating STIs in a resource constraint facility since its introduction by WHO and CDC more than a decade back. Recently there has been lots of debate on its empirical use in an era of antibiotics resistance and ever-changing varieties of microorganisms causing these infections. Present study evaluated the efficacy of pharmacotherapy of syndromic management measured by symptomatic improvement in females presenting with STIs.
Methods: It was a two year cross-sectional prospective study including all the females of STI syndromes, attending Gynecology OPD of Sanjay Gandhi Memorial Hospital and results were assessed in pharmacology department, Gajra Raja medical college Gwalior from Jan 2015 to December 2016.
Results: During the study period total of 24,556 patients attended the Gynecology OPD out of which 8562 patients presented with different STI syndromes. Lower abdomen pain with vaginal discharge was the most common symptom while Ulcerative lesions were the least common complaint. Maximum recurrence was seen in patients of vaginal discharge and itching followed by PID syndrome which responded to second line of drugs.
Conclusions: Syndromic Management of STIs is an old approach to deal with a very common gynecological problem and needs to be reviewed in an era of wide spread antibiotics resistance.

Keywords: Antibiotics resistance, Lower Abdomen Pain (LAP), Vaginal Discharge (Vag Ds)

INTRODUCTION

Sexually Transmitted infections (STIs) are among the most common infectious diseases which affect a female of reproductive age group, 75-80% of the total burden of which is being carried by developing world.[1] STIs are an important cause of morbidity due to their consequences such as Chronic Pelvic Pain, Infertility, Ectopic pregnancy, Miscarriages, Congenital infections, Cervical cancer, Emotional distress, Marital discord, Social rejection etc.[2-4] It is a known fact that presence of any of the STIs predisposes to catch HIV infection to a great extent.[5] Therefore controlling STIs effectively is an unavoidable step towards achieving Millennium Development Goals (MDGs) for not only those which involve maternal health but child health and HIV transmission prevention as well. Various studies done on the prevalence of gynecological morbidities caused by STIs, conducted at different Indian states show a common pattern of presentation. A study carried out in urban slums of Baroda city, Gujarat, and the other carried out in the rural areas of three selected districts of the state found a very high prevalence (76 to 85%) of symptoms suggestive of STIs.[6,7] In one more study of urban slum population in the two cities of Gujarat, India, 42% of the women reported that they had ever experienced any symptom of STI.[8] Because of this high burden, STIs rank second as the

cause of healthy life lost among women of reproductive age group, after maternal morbidity and mortality.[9]

More than a decade back World Health Organization introduced a simplified tool in the form of a flowchart/algorithm to guide resource poor settings in the form of syndromic management of STIs.[10]

Syndromic management removes the need for laboratory testing and extra clinic visits for follow-up, which may result in treatment delays and to some extent the need for a physical examination.

This approach is viewed as a practical strategy for use in resource-limited settings as it provides prompt treatment and helps avoid potential loss to follow-up. Despite being a very useful tool, Syndromic algorithms seem to have some shortcomings too, and they need to be periodically reviewed and adapted to the epidemiological patterns of STI in a given setting.[11] Over-diagnosis and over-treatment are major disadvantages of the syndromic approach.[12-14] As per one study, the performance of the algorithm in predicting these infections was unacceptably poor.[12]

As a general practice, all the women who come to our Gynecological OPD are managed by Syndromic approach which has been recommended by National Aids Control Organization (NACO), India.[15]

Author's own experience shows that there is an increasing trend of recurrences of STIs especially Vaginal Discharge Syndrome and Urinary symptoms despite of receiving complete course of antibiotics as suggested by syndromic approach. Therefore, the present study was conducted with an aim to evaluate the efficacy of syndromic management of STIs at our setup.

METHODS

It was a cross-sectional prospective study which was done over a period of two year. The study was carried out at the Gandhi Memorial Hospital, Associated with Shyam Shah Medical College, Rewa, MP, and results were assessed in pharmacology department, Gajra Raja medical college Gwalior, over a period of two year from 1st Jan 2015 to 31st December 2016. Institutional Ethics Committee approval was obtained prior to the commencement of the study. A total of 8562 cases of STIs residing mainly in rural area, attending STI clinic of our OPD, who were willing and able to provide informed consent to take part in the study were included.

Inclusion criteria

All females of reproductive age group presenting with STI symptoms as per syndromic management algorithm, were included.

Exclusion criteria

Any female with any major medical or surgical illness and any female having allergy to the drugs included in syndromic management of STIs.

Study protocol

Details including Demographic characteristics, sexual history, contraception history, and relevant social, personal, medical and surgical history were recorded as per the performa and examination was done. Physical examination (Vaginal, per speculum and bimanual) was carried out, to assess which category of syndromes a woman belonged to and were categorized in four main classes viz. Vagina discharge syndrome (VD), Urinary symptoms, Lower Abdominal Pain (LAP)-suggestive of Pelvic Inflammatory disease (PID) and Genital Ulcer Disease (GUD). All the patients were treated as per Syndromic management guidelines of NACO (Details of which mentioned in Table 1).[15] Patients were then followed after completion of treatment. A VDRL, HBsAg, HIV testing was performed on all the cases. A follow up visit was conducted at 48 hours if needed and on 7th and 14th day as a routine. Improvement in symptoms was noted on a 0 to 3 scale; 0-No improvement, 1- Minimal improvement, 2-Moderate improvement, 3- Complete improvement.

In case of failure/recurrence (Treatment Failure/drug resistance defined as inability of a particular antibiotics kit to treat a syndrome, as observed during follow up visits or resurgence of same syndromic symptoms within 3 months of the first line of treatment and a simple relapse if recurrence of the symptoms took place after 3 months of initial treatment), A woman of Vaginal discharge syndrome along with itching was treated with Clotrimazole pessary of 100mg vaginally for 7 days and in case of only discharge and presence of cervicitis and urethritis with Tablet Doxycycline 100mg twice a day for 7 days, A case of LAP with Moxifloxacin 400mg once a day for 14 days (as suggested by Centre for Disease Control and prevention-CDC).[16]

The completed proformas were entered in the computer for analysis after checking. The data was analysed and tabulated using the SPSS software (version 7.5). The diagnosis and treatment of various STIs by syndromic approach based on symptoms and clinical examination was evaluated.

RESULTS

Demographic characteristics

During the study period total of 24,556 females attended the Gynecology OPD out of which 8562 females had presented with symptoms of any of the STIs. With a Median age of 28 years and maximum (62%) belonged to the age group between 21-35 years; women who had never

been married were only 7%, 74% were from rural background and 47% belonged to lower middle-class category with only 15% educated above primary level; Maximum of females were multipara (64%) while 26% were nullipara.

Sexual and contraceptive history

Only 5% of the study population who had any of the STI symptoms used condoms while 30% females reported that their husbands were residing outside and they did not use any contraceptive method ever. Among others 31% have been permanently ligated, 15% had Copper T inserted, 2% using natural methods and rest (17%) were reluctant to give right information.

Table 1: Depicting various drug kits used in syndromic management of STIs.

Clinical condition	Kit to be prescribed	Drugs included
Urethral or anorectal or cervical discharge	Kit 1: gray	Tab azithromycin 1g (1 tab) Tab cefixime 400mg (1 tab)
Vaginal discharge (vaginitis)	Kit 2: green	Tab secnidazole 2g (1 tab) Tab fluconazole 150mg (1 tab)
Genital ulcer disease (non herpitic)	Kit 3: white	Inj. Benzathine penicillin 2.4mu (1 vial) + tab azithromycin 1g (kit also contains 10ml disposable syringe + 21 gauge needle + 1 vial of 10 ml sterile water)
Genital ulcer disease (nonherpetic) in patient allergic to penicillin	Kit 4: blue	Tab doxycycline 100mg (1 tab bd for 14 days) Tab azithromycin 1g (1 tab)
Genital ulcer disease (herpetic)	Kit 5: red	Tab acyclovir 400mg x 1 tab tds x 7 days
Lower abdominal pain (pelvic inflammatory disease)	Kit 6: yellow	Tab cefixime 400mg (1 tab) Tab metronidazole 400mg x (1 bd 14 days) Tab doxycycline 100mg (1 tab bd for 14 days)
Inguinal bubo	Kit 7: black	Tab doxycycline 100mg (1 tab bd for 21 days) Tab azithromycin 1g (1 tab)

STI prevalence

Overall, 26% of TOTAL Gynecology OPD patients were diagnosed with an STI through the clinician-based syndromic diagnosis (Figure 1). Vaginal discharge syndrome was the most common group (48%), followed by Lower abdominal pain (33%) and urinary symptoms group (18.5%) while GUD was reported by only .03% of the females who presented with STI symptoms (Figure 1 and Figure 2).

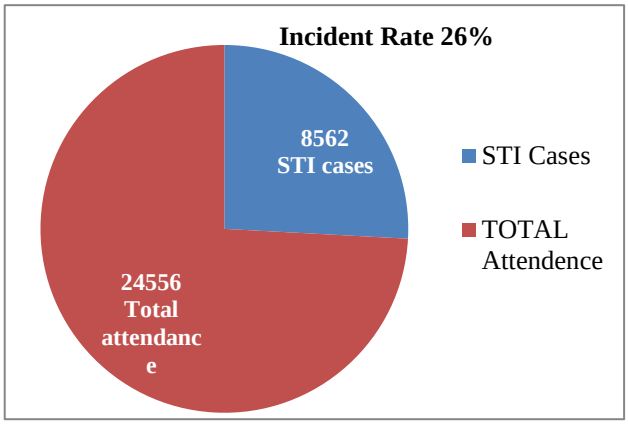

Figure 1: Incidence rate of STI in gynecological patients.

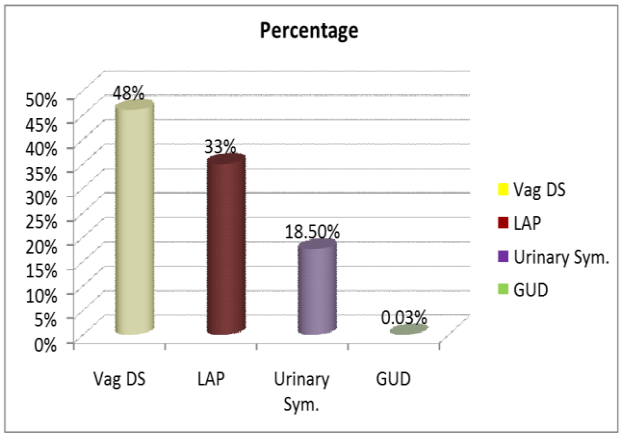

Figure 2: Percentage contribution of different STIs.

Performance of syndromic management

As it is evident from Figure 3 that syndromic management proved to be most efficacious in GUD (100%) and least effective in Urinary symptoms (51%) while Vagina discharge syndrome responded in 87% cases and LAP in 67% cases.

Response to second line treatment

In present study, LAP and VD syndromes responded well to second line treatment viz. 90 and 95% respectively, while urinary symptoms did not respond well to second

line treatment too in up to 55% cases which is almost one forth of total cases.

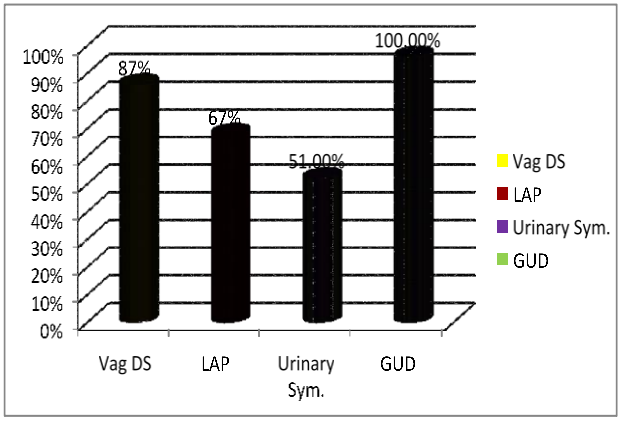

Figure 3: Response to first line treatment as per syndromic management.

DISCUSSION

The prevalence of STI based on syndromic approach was found to be 26% in this study. This finding is quite similar to other studies done across the country.[17,18] Similar results were obtained in studies from other developing world, where prevalence ranged between 30%-40%.[19,20] The most common syndrome diagnosed in this study was vaginal discharge (48%), followed by lower abdominal pain (33%). In other studies, also, done in India, Vaginal discharge was the commonest symptom.[21-23]

In this study prevalence of STI was highest in the age group 21-35 years (62%), followed by 35-50 years (30%). Studies done by Kosambiya et al, Sharma et al and Rathore et al also reported that there was a high prevalence in sexually active reproductive age group which is comparable to this study.[24-26] Women in reproductive age group constitute 22.2% of population in India.[23] Maximum burden of the disease was found to be in this age group in this study resulting in huge burden on the socio economic and health status of the community. 74% of this study population was from rural background and 47% belonged to lower middle class category with only 15% educated above primary level. Substandard hygiene, promiscuity, lack of awareness and traditional taboos against these diseases are the usual factors responsible for this high prevalence in lower socio economic and illiterate group. Only 5% of the study population used condoms, this confirms the well-known fact that contraceptive methods like condoms have a protective role in prevention of most STI. 0.5% of all STI patients were found to be HIV positive in present study.

In present study we found that 87% of clinically diagnosed cases of Vaginal discharge, 67% cases of LAP, 51% cases of Urinary symptoms and 96% cases of GUD had complete improvement, while 9% cases of VD, 4% cases of LAP, 16% cases of urinary symptoms and none of the cases in GUD group were such who didn't show any improvement, rest showed minimal-moderate improvement. According to a study conducted in a slum area in Chandigarh, follow-up done after 1 month showed effectiveness in terms of symptomatic relief in 72.7% while 13.6% had no effect, 9.1% discontinued treatment, and 4.5% did not comply with the medications.[27] Another study conducted in Chandigarh showed 83.4% patients were cured after 1 month while 11.6% were partially cured and 5% had no relief.[28]

As it shows that VD syndrome didn't respond completely to the syndromic approach in present study which may be a result of over diagnosis i.e. giving treatment to a woman with physiological discharge, another reason may be that single oral tablet of Fluconazole may not be as effective as local insertion of Clotrimazole vaginal pessaries which has been emphasized in recent report of CDC[16]. Therefore, the sensitivity of the syndromic approach for VDS may be high, but the specificity of this method in diagnosing VD was low, as reported in other study as well.[29] In a Chinese study, which attempted to validate diagnostic algorithms for syndromic management of STIs with laboratory diagnostic support, reported that the specificity and positive predictive value of syndromic management of VD were not satisfactory.[30] In contrast to this report, a community-based study in India[31] in 812 women revealed that 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%). 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.

In present study a high rate of non response (32%) was found in cases of LAP which may either be a result of overtreatment (treated as PID patients but were not cases of PID in reality) as observed in previous studies or is a reflection of the fact that these cases may have been caused by Mycoplasma Genitalium which remains unresponsive to standard PID regimen and responds to Moxifloxacin therapy which has been observed in present study as well as 92% of failure cases of LAP responded to Moxifloxacin regimen in present study.[16,31]

The highest failure rate of syndromic management in present study, is reported in females with Urinary symptoms, recent emergence of resistance to Azithromycin or M. Genitalium being the main causative organism are the two possible causes which should be taken into consideration and a repeat course of Doxycycline 100Mmg twice a day for 7 days or Moxifloxacin 400mg once a day for 7 days should be considered as per recent CDC guidelines.[16]

In present study GUD was the only category which showed highest sensitivity and specificity of syndromic approach in diagnosing and treatment as there were no relapses seen

in this group, this finding is corroboratory with other studies.[32-34] This study is done at a place where STI clinic is running successfully and there is fair rate of follow up, therefore these results can be adopted as a representation of most of the population of this area which has high incidence of STIs. Taking these results in consideration, at a larger scale we need a frequent review of drugs used in syndromic management at in order to make the regimen more efficacious.

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