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Original Article

Compliance and effectiveness of syndromic approach in females with reproductive tract infections

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Abstract

Background: India has strengthened its fight against sexually transmitted infections (STIs) and reproductive tract infections (RTIs) by implementing syndromic approach at peripheral health centres. However, effective control of STIs and RTIs still remains a huge challenge. One of the biggest hurdles could be patient compliance towards the complete course of treatment. Yet, little is known about its association with the effectiveness of syndromic management of STIs and RTIs.

Aim: This study aimed to assess the patient compliance with syndromic management and its effectiveness.

Methods: A prospective, analytic study was conducted at a tertiary care hospital in Haryana, India, from March to November 2016. One hundred female patients suffering from any of the following complaints, (a) vaginal discharge; (b) cervical discharge; (c) lower abdominal pain; (d) burning micturition and (e) itching, were screened for RTIs. All eligible patients were interviewed in depth, and treatment was given to them according to syndromic management guidelines of National AIDS Control Organization (NACO). Patients were assessed in terms of clinical cure at the end of the treatment. Assessment of compliance to treatment regimen was made by using modified Morisky scale. Data were entered into excel sheet and analysed by SPSS software version 20 by IBM, Chicago, IL, USA. Chi-square and Fisher's exact test were applied. $P < 0.05$ was considered statistically significant.

Results: Out of the 100 patients, 68 were cured. Of the 68 cured patients, 66 (97.1%) participants had high motivation, whereas 57 (83.8%) patients had high knowledge. Of the 32 patients who were not cured, 29 (90.6%) participants had low motivation and 30 (93.8%) participants had low knowledge. *P* values of motivation (<0.001) and knowledge (<0.001) between cured (66) and uncured (32) patients were highly statistically significant.

Conclusion: This study showed the effect of compliance on the effectiveness of syndromic management but did not find the array of factors which could affect the compliance.

Keywords: Compliance, reproductive tract infections, sexually transmitted infections, syndromic management

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INTRODUCTION

Sexually transmitted diseases are one of the major health problems of adult population. In women of childbearing age, sexually transmitted infections (STIs) and reproductive tract infections (RTIs) are next to pregnancy-related issues in terms of morbidity and mortality.[1] Early and effective treatment of STI not only reduces the morbidity and

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complications in individuals suffering from it, but also reduces its transmission in the community.[2] There are a number of pathogens responsible for these sexually transmitted RTIs, which can be managed by effective antimicrobial treatment. In spite of this, STIs still pose a major public health concern. To overcome the various challenges in the treatment of STIs, the World Health Organization (WHO) came up with syndromic management of STIs and RTIs.[3] The syndromic management classifies STIs/RTIs into various syndromes based on symptoms/signs, and the patient is treated for the most common pathogens responsible for these syndromes.[3] India has also adopted syndromic management under the NACO guidelines.[4]

For effective management of STIs/RTIs, full curative course of antimicrobials must be taken. In this regard, four Cs act as the pillar apart from diagnosis and treatment. These four Cs include compliance with treatment, counselling, condom promotion and contacting partners for treatment.[5] Healthcare providers must explain the importance of completing the drug regimen even after all symptoms have disappeared. Concerns have been raised, from time to time, about the use of syndromic approach in STIs such as overdiagnosis of STIs and its possible risks such as relationship problems, partner management and compliance to treatment regimen.[6,7] Very limited data are available regarding these; therefore, this study was planned to assess the patient compliance with syndromic management and its effectiveness.

METHODS

A prospective, analytical study was conducted in association with the Obstetrics and Gynaecology Department at a tertiary care hospital (MMIMSR) from March 2016 to November 2016. The study protocol was approved by the Institutional Ethics Committee (IEC), IEC approval no. IEC/MMIMSR/16/207. The target population consisted of women visiting the gynaecology outpatient department for the first time with the following complaints: (a) vaginal discharge, (b) cervical discharge, (c) lower abdominal pain, (d) burning micturition, (e) itching and were screened for RTIs.

Sample size

The sample size was calculated as per the WHO algorithm. Assuming 30% clinical failure of syndromic management in STIs and keeping confidence level of 95% with precision *d* 10%, the sample size was calculated as 81. Expected withdrawal was assumed to be 20%, so the sample size was adjusted after it reached 96. We recruited 100 female patients of 18–65 years of age. Pregnant females and patients with other illness, i.e., diabetes, hypertension, tuberculosis, other terminal illness and allergic to drugs being used in the study, were excluded from the study.

Procedure

After obtaining informed consent, patients were interviewed in depth, and their present complaint, sexual history and partner history were noted. After doing per-speculum examination, syndromic diagnosis as per the National AIDS Control Organisation (NACO) guidelines was made.[8] Patients were screened by Treponema pallidum haemagglutination assay for syphilis and 4th-generation enzyme-linked immunosorbent assay for HIV.

They were managed as per the NACO guidelines,[8] and the assessment of compliance to treatment regimen was made by using modified Morisky scale.[9]

Various factors including demographic factors, i.e., age groups, religion, area of residence and occupation, treatment duration and syndromic diagnosis, were studied in relation to compliance.

Statistical analysis

Data were entered into excel sheet and analysed by SPSS software version 20 by IBM Chicago, IL, USA. The categorical data were used to provide a descriptive summary (%), comparing each categorical variable, i.e., age, occupation, syndromic diagnosis knowledge and motivation. Chi-square and Fisher's exact tests were applied. $P < 0.05$ was considered statistically significant.

RESULTS

Out of the 100 patients, RTI was most common in patients aged between 26 and 35 years (52%); percentage of SITs reduces as the age advances [Table 1]. Majority (95%) of the females were homemakers, and most of them resided in the rural area (59%) [Table 1]. Apart from vaginal discharge (78%), lower abdominal pain (62%), foul-smelling discharge (29%), burning micturition (17%) and itching in the perineal region (13%) were the common complaints of the participants [Table 2]. Based on syndromic diagnosis, the most common syndrome was vaginitis (39%), followed by lower abdominal pain (37%) and cervicitis (24%) [Table 3].

The most common drugs used in 63 (63%) patients was a combination of ciprofloxacin + doxycycline + metronidazole 2 g stat, followed by clotrimazole + doxycycline + ceftriaxone + metronidazole in 55 (55%) patients [Table 4]. After treatment, as per the NACO guidelines, 68 (68%) patients were cured and 32 (32%) patients were not cured

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Table 1: Sociodemographic profile of the study population

Sociodemographic characteristics	*n*, frequency (%)
Age group (years)	
15-25	13 (13.0)
26-35	52 (52.0)
36-45	31 (31.0)
>45	4 (4.0)
Occupation	
Homemaker	95 (95.0)
Working	5 (5.0)
Location	
Urban	41 (41.0)
Rural	59 (59.0)
Marital status	
Married	100 (100.0)
Divorcee	0
Widow	0

Table 2: Symptomatic distribution of reproductive tract infections (*n*=100)

Symptoms	*n* (%)
White discharge	78 (78)
Lower abdominal pain	62 (62)
Foul-smelling discharge	29 (29)
Burning micturition	17 (17)
Itching on perineal region	13 (13)

Table 3: Distribution of syndromic diagnosis as per the National AIDS Control Organisation guidelines (*n*=100)

Syndromic diagnosis	*n* (%)
Vaginal discharge syndrome	
Vaginitis	39 (39)
Cervicitis	24 (24)
Lower abdomen pain syndrome (PID)	37 (37)
Inguinal bubo	0
Genital ulcer	0

PID: Pelvic inflammatory disease

Table 4: Percentage distribution of various drugs used in management of patients

Treatment	*n* (%)
Ciprofloxacin+ Doxycycline+ Metronidazole 2g stat	63 (63)
Clotrimazole +Doxycycline +cefitriaxone+metronidazole	55 (55)
Clotrimazole + ciprofloxacin +Doxycycline+Metronidazole	8 (8)
Ciprofloxacin+ Doxycycline+ Metronidazole 400 mg	37 (37)
Ceftriaxone	3 (3)
Doxycycline + Metronidazole	34 (34)

at the end of treatment. In 11 (11%) cases, the treatment was changed, whereas in 89 (89%), no change in treatment was required.

While using the modified Morris scale of compliance, it was found that 69% of participants had high motivation, whereas 31% had low motivation, and the knowledge about RTI symptoms was high in 59% and low in 41% of participants. Overall 58% of participants had high motivation and high knowledge [Table 5]. Data for compliance were analysed to find any association with demographic factors, i.e., age groups, religion, area of residence and occupation. There was no statistically significant difference towards compliance in relation to any of the following demographic factors: motivation ($P = 0.712$) and knowledge ($P = 0.912$) in relation to age, motivation ($P = 0.729$) and knowledge ($P = 0.588$) in relation to religion, motivation ($P = 0.899$) and knowledge ($P = 0.623$) in relation to area of residence and motivation ($P = 1.000$) and knowledge ($P = 1.000$) in relation to occupation. Compliance in relation to treatment duration, i.e., <7 or >7 days, also showed statistically insignificant *P* value (0.573) of motivation and *P* value (0.286) of knowledge. There was no statistical difference for the compliance with different syndromic diagnosis, i.e., motivation ($P = 0.473$) and knowledge ($P = 0.767$).

When compliance was analysed in relation to final treatment outcome, of the 68 cured patients, 66 (97.1%) participants had high motivation, whereas 57 (83.8%) patients had high knowledge. Of the 32 patients who were not cured, 29 (90.6%) participants had low motivation and 30 (93.8%) participants had low knowledge. *P* values of difference in motivation (<0.001) and knowledge (<0.001) with outcome were highly statistically significant [Table 6].

DISCUSSION

The study was designed to gather the sociodemographic data and data related to various factors, i.e., duration of treatment, syndromic diagnosis that could affect the compliance of the patients suffering from STIs and compliance and association of various factors with compliance in relation to treatment outcome in patients suffering from STIs. After treatment, as per the NACO guidelines, 68% of patients were cured. We found that patients who got cured were more compliant to treatment regimen than those who were not cured. In spite of the well-known problem of non-compliance and adverse health outcome, this issue is still a major contributor of effective healthcare.[10] In this study, most of the participants were of 26–35 years age, but there was no statistically significant relation between age and treatment compliance. Although few researchers have found relationship between age and compliance,[11] majority of the studies have not found any relation between demographic factors and compliance as these might not be true independent factors for compliance as shown in this study. Our study showed no significant relationship between other sociodemographic parameters such as religion, area of residence and occupation to treatment compliance. As per syndromic diagnosis, the most common syndrome in this study was vaginitis (39 [39%]), but we could not find any significant relation between type of syndromic diagnosis and treatment compliance.

Table 5: Compliance of the study patients towards full treatment as per the Modified Morisky Scale

Compliance	*n* (%)
Motivation	
Low (0-1)	31 (31.0)
High (2-3)	69 (69.0)
Knowledge	
Low (0-1)	41 (41.0)
High (2-3)	59 (59.0)
Combined	
Low motivation, low knowledge	30 (30.0)
Low motivation, high knowledge	1 (1.0)
High motivation, low knowledge	11 (11.0)
High motivation, high knowledge	58 (58.0)

Table 6: Compliance in the association of outcome

Compliance	Outcome, *n* (%)		*P*
	Cured	Not cured	
Motivation			
Low	2 (2.9)	29 (90.6)	<0.001
High	66 (97.1)	3 (9.4)	
Knowledge			
Low	11 (16.2)	30 (93.8)	<0.001
High	57 (83.8)	2 (6.3)	

Disease type and disease severity have been found to affect treatment compliance,[12] but this study failed to find any such relationship, which might be due to the short course of treatment in the majority of STIs.

Non-compliance in STI patients to drug regimen not only leads to treatment failure, but also increases the drug resistance, which, as of now, is a major challenge.[7]

Conclusion

In our study, compliance was found to play a role in the success of syndromic approach, so we concluded that syndromic approach can help in rapid cure in STI patients, but healthcare professionals need to make sure that patients imply to their directions. However, this study failed to show the factors which might be affecting compliance; hence, we need to study other factors which could affect compliance so that effective measures can be taken to increase compliance.

Limitations

Although our methods showed the association between compliance and treatment outcome, they did not show any factor affecting the compliance. It could be because of the small sample size and failure in identifying the factors which might have relation to compliance. More studies of factors influencing compliance in STI patients should be conducted to fill the gap in knowledge.

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Conflicts of interest

There are no conflicts of interest.

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