

Original Research Article

A comparative interventional study on the efficacy of single and multiple dose combination drug regimen of leucorrhea among women in reproductive age group

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ABSTRACT

Background: Reproductive tract infections (RTIs) in women are becoming major public health problem not only in India but also over the world. Syndromic approach is advocated by World Health Organization (WHO) to manage common RTIs using clinical flow charts based on identifying a syndrome that cause the symptoms reported by patients. The most commonly reported among the women with RTIs is abnormal vaginal discharge or Leucorrhea. Single dose regimen is not preventing the recurrence of infections. A second course of treatment is required followed by standard single dose regimen for achieving better cure rate in chronic vaginal discharge. Objective of the study was to compare the efficacy of single dose drug combination regimen with multiple dose regimens in the treatment of leucorrhoea.

Methods: Quasi-experimental study was done in Urban field service area, RMMCH – Chidambaram among Married women in the reproductive age group (15-49 years) with complaints of abnormal vaginal discharge for ≥15 days coupled with any one of the symptoms suggestive of RTI. The study subjects were categorized into two groups – one with single dose regimen and the other with multiple dose regimen. Follow up was done on day 7, 15 and after 6 months of therapy.

Results: A total of 113 subjects were recruited with 57 participants in single dose group and 56 in multiple dose groups. The subjects who received single dose had a better cure rate as compared to multiple dose group on day 7 (87.7% & 85.7%), day 15 (94.7% & 89.3%) and after six months (84.2% & 76.8%) assessment respectively. Recurrence rate was found to be equal in both the groups. Our study indicates that variables such as age of the study subjects and type of flow had significant association with the outcome.

Conclusions: Single-dose therapy is as effective as multiple- dose in the management of vaginal discharge based solely on symptoms. The multiple drug regimens can be given if the symptoms persist after single drug regimen as the chances of developing complications due to chronic vaginal discharge are high.

Keywords: RTI, Reproductive age group, Syndromic approach

INTRODUCTION

Reproductive tract infections (RTIs) in women are becoming major public health problem not only in India but also over the world. Almost two decades after the call

for universal access to reproductive health at the fourth International Conference on Population and Development in Cairo (1994) and twenty years after the introduction of Reproductive and Child Health Program (RCH) by the Government of India (1997), reproductive tract infections

(RTIs) continue to be a major cause of acute illness, cancer, infertility, long-term disability, and death with severe medical and psychological consequences for millions of men, women, and infants.^{1,2}

The Reproductive and Child Health Rapid Household Survey (RCH-RHS – 1 and 2) report shows the reproductive health is poor all over the country. This is confirmed by a systematic review done in 2015 which showed prevalence of all RTIs ranged from 11% to 72% in the self-reported community-based studies. The most commonly reported among the women with RTIs is abnormal vaginal discharge or Leucorrhea. Globally, Leucorrhea occurs in 1-14% of all the women in the reproductive age group and is responsible for 5-10 million OPD visits per year.^{3,4} The prevalence of excessive vaginal discharge in India is estimated to be 30%.³ The NFHS -3 results show that 11% of women in India report at least one reproductive health problem related to vaginal discharge.^{5,6}

World Health Organization (WHO) has advocated a simpler and more cost-effective method for detection and management of RTI/STI cases through a syndromic approach.⁷ This approach is to manage common RTIs using clinical flowcharts based on identifying a syndrome - a group of symptoms and signs associated with a number of well-defined aetiological pathogens that cause the symptoms reported by patients. Treatment is generally given for most of the diseases that could cause that syndrome. This emphasizes mostly on single dose regimen and directly observed therapy (DOT) for better treatment adherence and outcomes.⁸ Still, current recommended treatment is not preventing the recurrence of infections like Bacterial Vaginosis and Chlamydia.^{9,10} The reason for recurrence may be resistant organisms, reinfection from the source of infection or abnormal vaginal flora. This proposes the hypothesis that a second course of treatment is required followed by standard single dose regimen for achieving better cure rate in chronic vaginal discharge.^{11,12} In this context, this study was aimed to compare the cure and relapse rates of oral single dose & multiple dose regimen consist of Fluconazole (150 mg), Azithromycin (1 g) and Secnidazole (2 g) (i.e.) empirical treatment recommended by WHO as syndromic management.

Objectives

1. To compare the efficacy of single dose drug combination regimen with multiple dose regimen in the treatment of leucorrhoea.
2. To analyze the influence of selected variables such as age, age at marriage, educational status, annual family income, duration of leucorrhoea, amount of flow and nature of discharge on the outcome.

METHODS

Study design: Intervention study – Quasi-experimental study

Study area: Urban field service area, RMMCH - Chidambaram

Study population: Married women in the reproductive age group (15-49 years) with complaints of abnormal vaginal discharge for ≥ 15 days coupled with any one of the symptoms suggestive of RTI such as lower abdominal pain, low back ache, pruritus vulva, post-coital bleeding, burning micturition or genital ulceration.

Study tool: Pretested interview schedule / Clinical history of symptom profile.

Study setting: Field practice area of Urban Health Center, Division of Community medicine, Rajah Muthiah Medical College Hospital (RMMCH), Chidambaram.

Exclusion criteria

- Pregnant or Lactating women
- Women who had used prescribed medications for vaginal complaints in the past 3 weeks.
- Not given consent and not willing to participate in the study.

Data collection: Ethical clearance for this study was obtained from institutional ethical committee, RMMCH, Annamalai University. The details regarding socio-demographic data including age, marital status, educational status, occupation, annual family income were collected using pretested proforma. Further information regarding obstetric history, menstrual history, history of leucorrhoea, associated symptoms, current contraceptive status and history of genital infection in husband were also collected. No clinical examination and laboratory investigation was done.

The study subjects were categorized into two groups – one with single dose regimen and the other with multiple dose regimen. Every alternate study subjects with the complaints of abnormal vaginal discharge and symptoms suggestive of RTI was included in each arm. Single dose of Azithromycin 1gm, Secnidazole 2 gm and Fluconazole 150 mg was administered to one group (i.e.) empirical treatment recommended by WHO as syndromic management. Two doses of same drugs, with 1week interval, were given to the other group. A stat dose of 2 gm Secnidazole was given to the husbands of the study subjects. The subjects were followed up after 7 days, one month and 6 months for estimating the cure rate and recurrence rate. Compliance among study subjects and spouses were assessed subjectively. The drugs were given free; the reported compliance was highly reliable.

Data analysis: Data collected were entered in Microsoft 2007 excel spread sheet, compiled and analysed using SYSTAT 12 statistical package. Statistical analysis

included descriptive statistics and Pearson Chi-square test, performed to compare both intervention group in terms of their basic attributes, cure rate and recurrence.

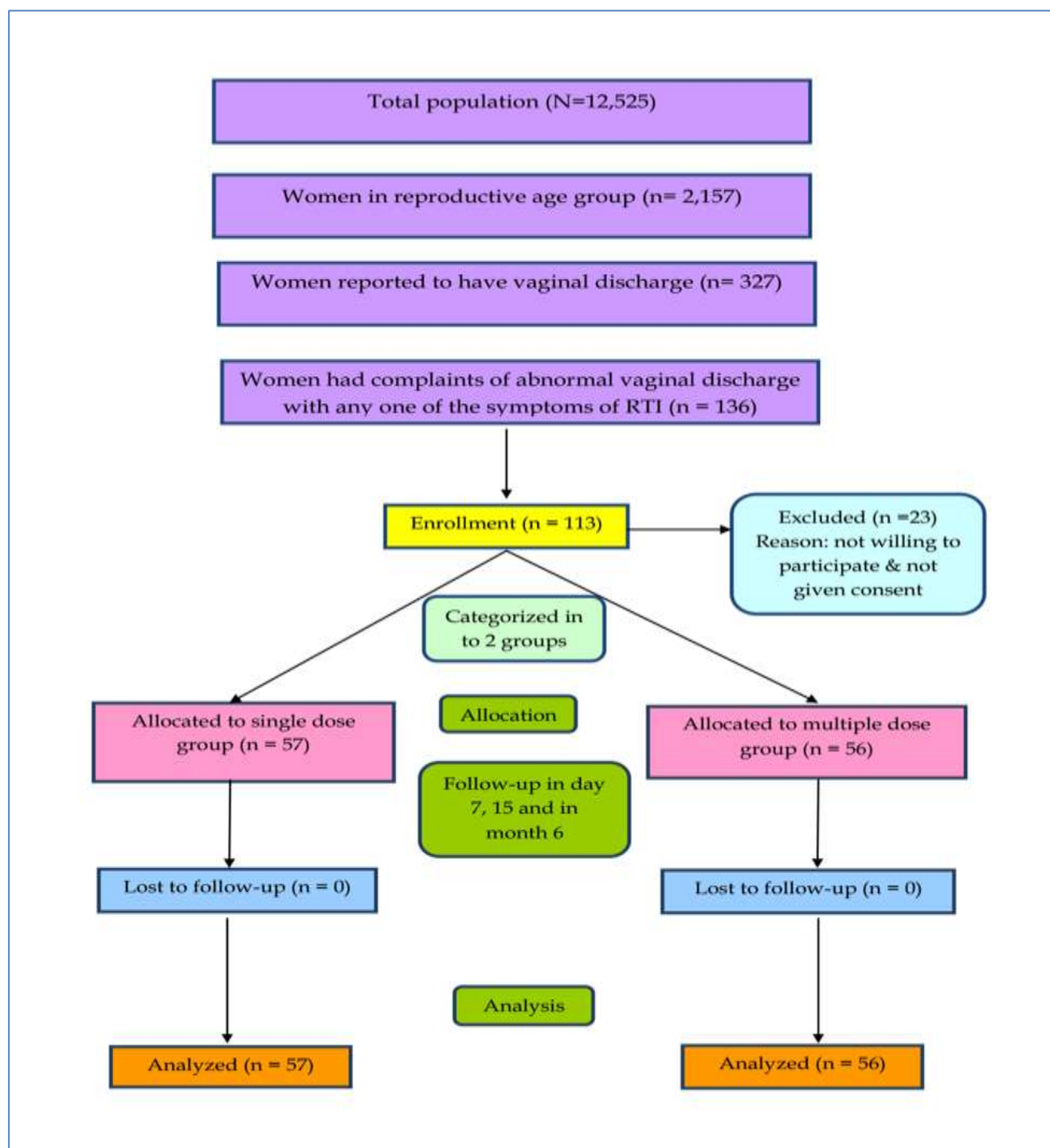


Figure 1: Recruitment of study subjects and allocation.

RESULTS

All Married women in the reproductive age group (15-49 years) with complaints of abnormal vaginal discharge for ≥ 15 days coupled with any one of the symptoms suggestive of RTI were included for the study. Of the

total 113 participants with Leucorrhea, 57 were allocated into the single dose regimen and 56 to the multiple dose regimen group. The collected information was categorized into socio – demographic details, information on leucorrhea and cure after the single and multiple – dose regimen. Socio-demographic details included age,

marital status, education, age at menarche, duration of married life and parity was depicted in Table 1. Majority of the participants are of 31 – 40 years age (42.5%), married (94.7%) and had attended middle school (38.6%). Mean age menarche was found to be 14 years and mean age of marriage was 23 years.

Menstrual history was taken in detail for all the participants. Majority of the participants were having regular menstrual cycle except for 15.8% of single dose group and 19.6% of multiple – dose group. Pain during menstruation was present in 52.6% single dose group and 66.1% of multiple – dose group. Inter-menstrual bleeding was observed in 2 participants. Only 40.5% of the participants were using Sanitary napkin which is indirectly associated with increased leucorrhoea.

Table 1: Comparison of participants in both intervention groups in terms of their socio – demographic.

Variable	Single Dose Group No. (%)	Multiple Dose Group No. (%)
Age (in years)		
15-30	27(47.4)	18(32.1)
31-40	24(42.1)	24(42.9)
41-49	6(10.5)	14(25)
Marital status		
Married	56(98.2)	51(91.1)
Divorced / Widow	1(1.8)	5(8.9)
Educational qualification		
Illiterate	7(12.3)	16(28.6)
Primary	6(10.5)	8(14.3)
Middle	23(40.4)	18(32.1)
Secondary	13(22.8)	10(17.9)
H.sec / Degree	8(14)	4(7.1)
Age at menarche (in years)		
≤12	10(17.5)	13(23.2)
13-15	37(65)	32(57.1)
>15	10(17.5)	11(19.7)
Age at marriage (in years)		
≤18	23(40.4)	23(41.1)
>18	34(59.6)	33(58.9)
Duration of married life (in years)		
<5	13(22.8)	10(17.9)
6-10	10(17.5)	8(14.3)
11-20	26(45.6)	22(39.3)
>20	8(14.1)	16(28.5)
Parity		
0	0(0)	3(5.4)
1	13(22.8)	7(12.5)
2	32(56.1)	26(46.4)
≥3	12(21.1)	20(35.7)

Table 2 explains in detail about the history of leucorrhoea. In both intervention groups, leucorrhoea was present for more than 2 years in a total of 63 (55.7%) participants. Majority of the respondents were found to have mucopurulent discharge in both the groups (52.7% and 48.2% respectively). Profuse flow was found among 37.16% of participants of whom 15 (13.27%) were using sanitary napkins regularly. Symptoms associated with leucorrhoea were Lower abdominal pain, Low back ache, Pruritus vulva, Genital ulcers and Burning micturition. Of the currently married women about 98.2% and 91.8% were living with their husband from single and multiple – dose groups respectively. Genital infection in husbands was found for 2 participants. A stat dose of 2 gm Secnidazole was given to the husbands of the study subjects.

Table 2: Comparison of participants in both intervention groups in terms of their history of leucorrhoea.

Variable	Single Dose Group No. (%)	Multiple Dose Group No. (%)
Duration of leucorrhoea (in months)		
<6	5(8.8)	9(16.1)
6-12	9(15.8)	4(7.1)
13-24	12(21)	11(19.6)
25-60	17(29.8)	16(28.6)
>60	14(24.6)	16(28.6)
Flow		
Scanty	17(29.8)	14(25)
Moderate	23(40.4)	17(30.4)
Profuse	17(29.8)	25(44.6)
Nature of discharge		
Muco- purulent	30(52.7)	27(48.2)
Frothy	8(14)	4(7.1)
Curdy white	8(14)	13(23.2)
Watery	11(19.3)	12(21.5)
Associated Symptoms		
Itching	21(36.8)	28(50)
Foul smell	17(29.8)	19(33.9)
Wetting of garments	9(15.8)	9(16.1)
Lower abdominal pain	48(84.2)	47(83.9)
Low back ache	52(91.2)	53(94.6)
Pruritus vulva	18(31.6)	27(48.2)
Genital ulceration	1(1.8)	3(5.4)
Burning micturition	29(50.9)	23(41.1)

The study participants were followed after 7 days, 15 days and 6 months of administering the drugs. On day 7, immediate outcome was assessed using relieved of symptoms. On day 15, cure rate and recurrence rate of leucorrhoea were estimated. After 6 months, long term cure rate and recurrence rate of both single dose regimen and multiple dose regimens were estimated. The results

are shown in Table 3. The difference between the cure rate and recurrence rate in 15 days and 6 months was statically assessed using chi – square for trend which was found to be not significant (p-value=0.2).

The influence of selected variables such as age, age at marriage, educational status, annual family income, duration of leucorrhoea, amount of flow and nature of

discharge on the outcome was analysed at the end of six months follow-up. The cure rate was higher among subjects in the age group of 41 - 49 years (90%) and as age increases cure rate also increases (p value = 0.038). The cure rate was better in literates (82.2%) and the subjects who married at >18 years (82.1%) compared to those married at ≤18 years (78.3%).

Table 3: Distribution of participants showing treatment outcome over the period of time.

Outcome	On day 7	On day 15		After 6 months	
	Relieved of Symptoms	Cured	Recurrence	Long term cure	Recurrence
Single Dose Group	50 (87.7)	54(94.7)	1(1.8)	48(84.2)	7(12.3)
Multiple Dose Group	48 (85.7)	50(89.3)	0(0)	43(76.8)	7(12.5)

Table 4: Association between outcome and bio-social characteristics.

Variable	Cured N (%)	Not cured N (%)	Total N (%)	Chi – Square Value	P-Value
Age (in years)					
15 – 30	31 (68.9)	14 (31.1)	45(100)	6.521	0.038
31 – 40	42 (87.5)	6 (12.5)	48(100)		
41 – 49	18 (90)	2 (10)	20 (100)		
Educational Status					
Illiterate	17 (73.9)	6 (26.1)	23 (100)	2.196	0.700
Primary	12 (85.7)	2 (14.3)	14 (100)		
Middle	35 (85.4)	6 (14.6)	41 (100)		
Secondary	17 (73.9)	6 (26.1)	23 (100)		
H.sec & others	10 (83.3)	2 (16.7)	12 (100)		
Annual Family Income (Rs)					
≤ 60000	53 (82.8)	11 (17.2)	64 (100)	0.490	0.484
> 60000	38 (77.5)	11 (22.5)	49 (100)		
Age at Marriage					
≤ 18 years	36 (78.3)	10 (21.7)	46 (100)	0.255	0.614
> 18 years	55 (82.1)	12 (17.9)	67 (100)		
Duration of Leucorrhoea					
< 1 year	24 (88.8)	3 (11.2)	27 (100)	3.793	0.285
1 – 2 years	18 (78.2)	5 (21.8)	23 (100)		
3 – 5 years	28 (84.8)	5 (15.2)	33 (100)		
> 5 years	21 (70)	9 (30)	30 (100)		
Flow of Discharge					
Scanty	28 (90.3)	3 (9.7)	31 (100)	5.938	0.05
Moderate	34 (85)	6 (15)	40 (100)		
Profuse	29 (69.1)	13 (30.9)	42 (100)		
Nature of Discharge					
Mucopurulent	49 (85.9)	8 (14.1)	57 (100)	2.493	0.477
Frothy	9 (75)	3 (25)	12 (100)		
Curdy white	15 (71.5)	6 (28.5)	21 (100)		
Watery	18 (78.3)	5 (21.7)	23 (100)		

At the end of six months follow up, subjects with duration of leucorrhoea for < 1 year had better (88.8%) cure rate compared to others with more than 1 year of duration. The cure rate was higher (90.3%) in subjects with scanty flow compared to subjects with medium (85%) and profuse (69.1%) flow in follow up. As flow of discharge increases, cure rate tends to decrease (p value = 0.05). There was a significant association between flow of discharge and cure rate in the study subjects. Long term cure rate was higher (85.9%) in subjects with mucopurulent discharge compared to subjects with frothy (75%), curdy white (71.5%) and watery (78.3%) discharge respectively and there was no significant association between nature of discharge and cure rate. Our study indicates that variables such as age of the study subjects and type of flow had significant association with the outcome as shown in Table 4.

DISCUSSION

Though reproductive tract infections (RTIs)/ sexually transmitted infections (STIs) are treated effectively with existing treatment regimens like syndromic management, a second course of treatment is required followed by standard single dose regimen for achieving better cure rate in chronic vaginal discharge.^{13,14}

Studies conducted to assess the efficacy of one day - oral combination kit therapy containing fluconazole 150 mg, azithromycin 1 gm and secnidazole 2 gm in treating vaginal discharge revealed that 55% - 65% women showed excellent response to treatment by day seven.^{15,16}

The present study showed that the number of subjects who had reported the presence of symptoms was reduced on day fifteen (3.5% & 10.7%) compared to (12.3% & 14.3%) day seven by the single and multiple dose group respectively. Similar outcome was observed by Shailesh Kore et al in their study on assessing the efficacy of one day - oral combination kit therapy containing fluconazole 150 mg, azithromycin 1 gm and secnidazole 2 gm in treating vaginal discharge.¹⁷ The study revealed that the women showed excellent response to treatment by day fourteen (88%) compared to (55%) day seven.

The long term follow-up on month 6 reveals better and less recurrence rate (i.e. 12.3% and 12.5% in single and multiple dose group respectively) compared to other intervention studies.^{9,10}

At the end of six months follow up, the present study showed the cure rate was higher (90 %) in subjects belonged to the age group of 41 - 49 years, followed by 87.5% in 31 - 40 and 68.9% in 15 - 30 years of age group respectively. Significant association was found between age and cure rate in the study subjects (p value = 0.038). As age increases cure rate also increases in the study subjects. The reason for this may be that the younger age group are sexually active compared to other age groups

and this might have facilitated the chance of reinfection¹⁸. Although endogenous infections are usually not sexually transmitted, they may be sexually associated possibly because sexual intercourse affects the vaginal flora (e.g. by increasing vaginal pH) and may influence and affect the cure rate.¹⁹

The subjects who had married at >18 years had better cure rate (82.1%) compared to those married at ≤ 18 years (78.3%), even though the difference is non-significant statistically. As regards the educational qualification, the cure rate was better among literates (82.2%) compared to illiterates (73.9%), even though the difference is non-significant. The reason could be that awareness about the disease and treatment is better in literates compared to illiterates.

The subjects with leucorrhoea for <1 year had better (88.8%) cure rate compared to others with more than 1 year of duration, even though the difference is non-significant statistically. Chronicity of the disease and resistant organisms in subjects with the duration of more than one year may be the reasons for poor outcome.

The cure rate was higher (90.3%) in subjects with scanty flow compared to subjects with moderate (85%) and profuse (69.1%) flow respectively. There is a significant association between flow of discharge and cure rate in the study subjects (p value = 0.05). As flow of discharge increases, cure rate tends to decrease in the study subjects. The reason could be that flow indicates the degree of severity and subjects with scanty flow may have less infection compared to subjects with moderate and profuse flow.

The cure rate was higher (85.9%) in subjects with mucopurulent discharge compared to subjects with frothy (75%), curdy white (71.5%) and watery (78.3%) discharge respectively. Usually mucopurulent discharge will be present in cervicitis with chlamydial or gonorrhoeal infections, curdy white discharge in fungal candidiasis, frothy discharge in trichomoniasis and watery discharge may be due to bacterial vaginosis or physiological. So the outcome may be influenced by type of infection and organisms responsible for the discharge. It was observed that age of the study subjects and type of flow had influenced the cure rate.

At the end of six months follow-up, the reported cure rate was 84.2% and 76.8% in single and multiple dose groups respectively and the recurrence rate was 12.3% and 12.5%. The subjects who have reported presence of symptoms were 3.5% and 10.7% in single and multiple dose group respectively. There was no significant difference between single dose and multiple dose drug regimen in terms of cure, recurrence and unrelieved in women with the complaints of Leucorrhoea. Chi square for trend done showed non-significant difference between both the intervention groups.

CONCLUSION

A systematic approach to the control of infectious diseases like RTIs/STIs is crucial to protect the health of the women in the reproductive age group. Single-dose therapy is as effective as multiple-dose in the management of vaginal discharge based solely on symptoms. Given its low price and easier adherence, single dose should be considered as a first-line treatment for vaginal discharge syndrome. The multiple drug regimens can be given if the symptoms persist after single drug regimen as the chances of developing complications due to chronic vaginal discharge are high. Investigations like High Vaginal Swabs should be performed when syndromic management fails.

Limitations

Randomization was not done, because of the constraints in the field. Assessment of cure was done based on the reported version; the influence of subjective element could not be ruled out.

Recommendations

1. At resource poor settings, where speculum examination is not possible and no laboratory facilities are available, single dose therapy with Azithromycin 1 gm, Secnidazole 2 gm and Fluconazole 150 mg (i.e. empirical treatment recommended by WHO as syndromic management) can be recommended as sound management for vaginal infections.
2. In vaginal discharge, clinical diagnosis is often inaccurate and has limited value in final diagnosis and treatment. Speculum examination may be uncomfortable for the patient. Laboratory diagnosis is time consuming, expensive and many a times unavailable. So it is better to treat vaginal discharge as a 'Syndrome' rather than an individual disease.
3. Results of this study can be further confirmed by conducting large scale trials.

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Conflict of interest: None declared

Ethical approval: The study was approved by the Institutional Ethics Committee, Rajah Muthiah Medical College, Annamalai University, Chidambaram, Tamilnadu

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