European Journal of Molecular & Clinical Medicine (EJMCM)
ISSN: 2515-8260 Volume 09, Issue 02, 2022

Original research article

Study of Current Role of Syndromic Management in Vaginal Discharge and the Non-Responders

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Abstract

Background: Vaginal discharge is one of the commonest problems faced by women. Syndromic management is a benchmark in management of vaginal discharge.

Objectives:

1. To evaluate the efficacy and tolerance of one day combination kit therapy in syndromic management of vaginal discharge in present scenario.
2. To find etiological cause in patients who do not resolve from vaginal discharge after 14 days.

Material and Methods: It was a prospective study done on 100 women in gynaecological opd of a tertiary hospital for a period of 3 months. Patients were evaluated before and after single day AFS kit therapy.

Results: There was excellent response in vaginal discharge(90%). Urinary symptoms and pruritus vulva improved by 80% and 50% respectively. 84% patients had good tolerance and only 2% patients had bad tolerance. 19% patients had Persistent vaginal discharge(PVD) which were due to infectious(42.1%) and non-infectious(57.9%) etiology. Out of these 31.5% had candida albicans, 10.5% had bacterial vaginosis, 15.7% had cervical erosion, 5.2% had cervical polyp and in 37.1% cases no etiology was found.

Conclusion: Combination kits are effective, well tolerable and given in single dose orally in reducing vaginal discharge, pruritus vulva and even urinary symptoms. Persistent vaginal discharge is due to candida and bacterial vaginosis (infectious) and cervical erosion, polyps and unknown cause(non-infectious).

Keywords: Vaginal discharge, syndromic management

Introduction

About 20-25% of women who attend gynecology out-patient department complain of vaginal discharge. Though, in a few cases, discharge may be physiological increase in normal vaginal secretion, in more than 60% of cases, it is because of the infection of the vagina and/or the cervix. Often, these infections are sexually transmitted. Untreated STI is more prone to disease spread and risk of contracting HIV.

The individual and national expenditure on STI care can be substantial. To overcome this problem, a syndrome-based approach was developed and promoted in a large number of developing countries, based on the identification of consistent groups of symptoms and easily recognized signs (syndromes) and the provision of treatment that dealt with the majority and the most serious organisms responsible for the syndrome. WHO had developed a simplified

tool (a flowchart or algorithm) to guide health workers in the implementation of syndromic management of STIs.[1] These guidelines have been revised in 2021 world congress .[2]
In this era too underdeveloped countries we still rely on immediate treatment with three drug therapy due to economic and other constraints where laboratory tools are not available. Numerous studies have been conducted since the introduction of syndromic management to evaluate its efficacy to diagnose specific STIs. Syndromic algorithms have some shortcomings, and they need to be periodically reviewed and adapted to the epidemiological patterns of STI in a given setting.[3]

In this study one day combination therapy for vaginal discharge was studied in a low resource setting. Since, some patients often revisit with persistence of discharge etiology of persistent vaginal discharge was also assessed.

MATERIAL AND METHODS:

Study design: Hospital based prospective study .

Study place: Department of Obstetrics and Gynecology out-patient department, P.M.C.H, Bihar.

Study Period: 3 months, 1 July 2021 to 31 September 2021.
Sample size: 100 women

INCLUSION CRITERIA: Women with chief complaints of vaginal discharge with or without features of chronic cervicitis were included.

EXCLUSION CRITERIA:
1. Pregnant, lactating and menopausal women.
2. Patients with history of drug allergy.
3. Those who had received any type of medication for vaginal discharge in the last two weeks were
excluded.
4. Patients who did not follow up or who did not take the prescribed treatment were excluded.

DATA COLLECTION:
Written informed consent was subsequently obtained, and a detailed questionnaire administered in the local language. Information was collected on the participant's socio-demographic characteristics, sexual behaviour, and medical history, followed by physical examination with sample collection.
The couple (husband and wife) were given one day combination kit, containing Fluconazole (150 mg) - 1 tablet Azithromycin (1 gram) - 1 tablet Secnidazole (2 grams) - 2 tablet.
These patients (husband and wife) were asked to take these tablets after meals on the same day. The couple were advised abstinence for fourteen days.
The couple were asked to follow up after seven and fourteen days, with empty packets of the tablets to confirm the compliance of the patient. On follow up visits, women were asked and examined about the improvement from the symptoms (in percentage). Also tolerance of tablets in the form of adverse effects; observed after the consumption of tablets, were noted. Overall assessment were done regarding the efficacy and tolerance of the combination. On day 14th patients who suffered from persistant vaginal discharge by per speculum examination were

identified and etiology of persistant vaginal discharge by per speculum examination and vaginal swab culture was determined.

ETHICAL APPROVAL: Study approved by Institutional Ethical Committee.

DATA ANALYSIS: Data collected in questionnaries were analysed by Microsoft excel.

RESULTS

Table 1: AGE DISTRIBUTION

AGE (yrs)	NO. OF PATIENTS
20-25	12
26-30	**30**
31-35	**25**
36-40	17
41-45	10
46-50	06

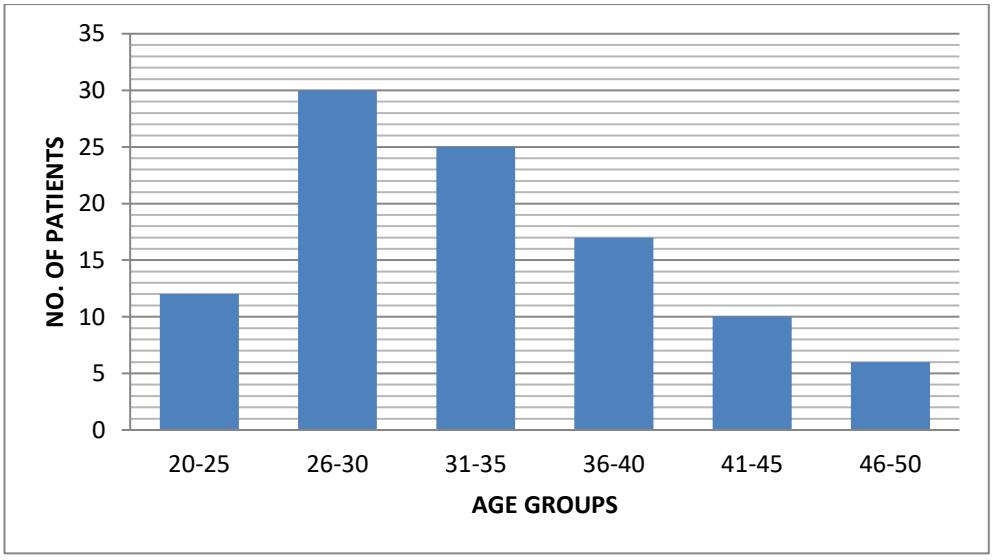


Figure-1:

A total of 100 women coming with the complaint of vaginal discharge were taken for this study. These patients were between 21 and 50 years of age. All patients were married.

Table 2: SOCIO ECONOMIC CLASS

SOCIO ECONOMIC CLASS	NO. OF PATIENTS
UPPER	07
MIDDLE	33
LOWER	**60**

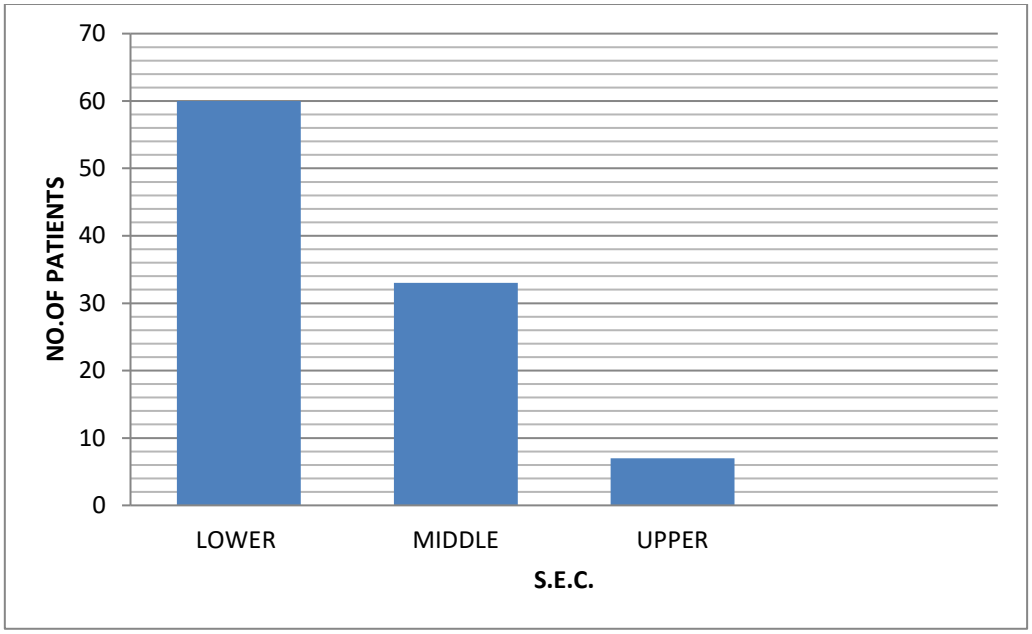


Figure 2:

Majority of patients were from the lower socio economic class(60%).

Table 3: SYMPTOMS OF PATIENTS

SYMPTOMS	NO.OF PATIENTS
1.Vaginal discharge	100
2.Pruritus vulva	32
3.Urinary symptoms	30
4.Pain abdomen	10

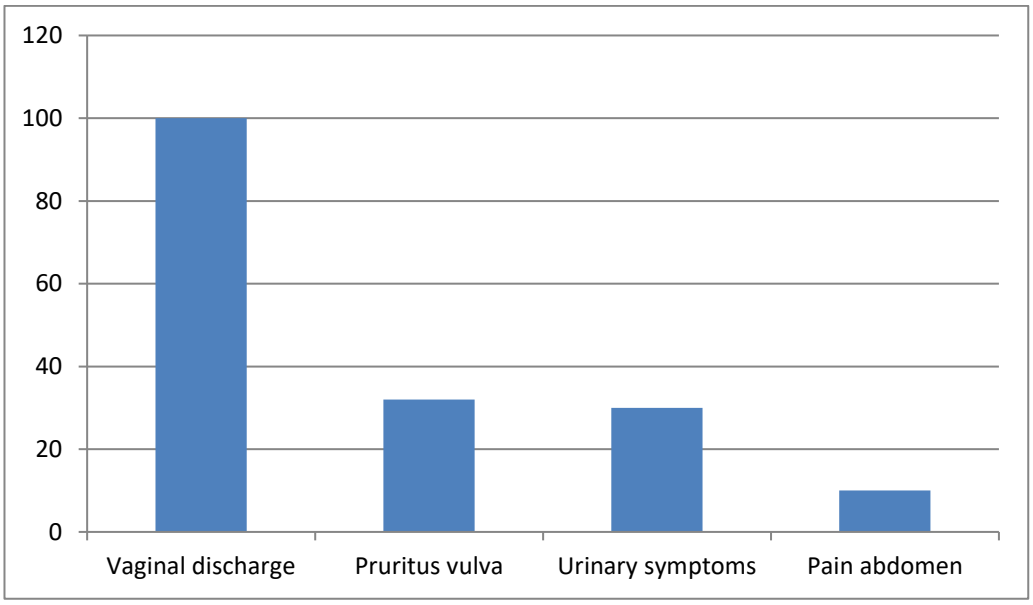


Figure 3:

Apart from the chief complaints of vaginal discharge, 30 women complained of urinary symptoms, like burning micturition, dysuria or frequency of micturition. 32 had pruritus vulvae and 10 women had complaints of pain in lower abdomen.

Table 4: CLINICAL FINDINGS

CLINICAL FINDINGS	NO.OF PATIENTS
Cervical erythma	20
Cervical hypertrophy	15
Cervical erosion	12
Polyp	01
Cervical tenderness	08
Forniceal tenderness	02

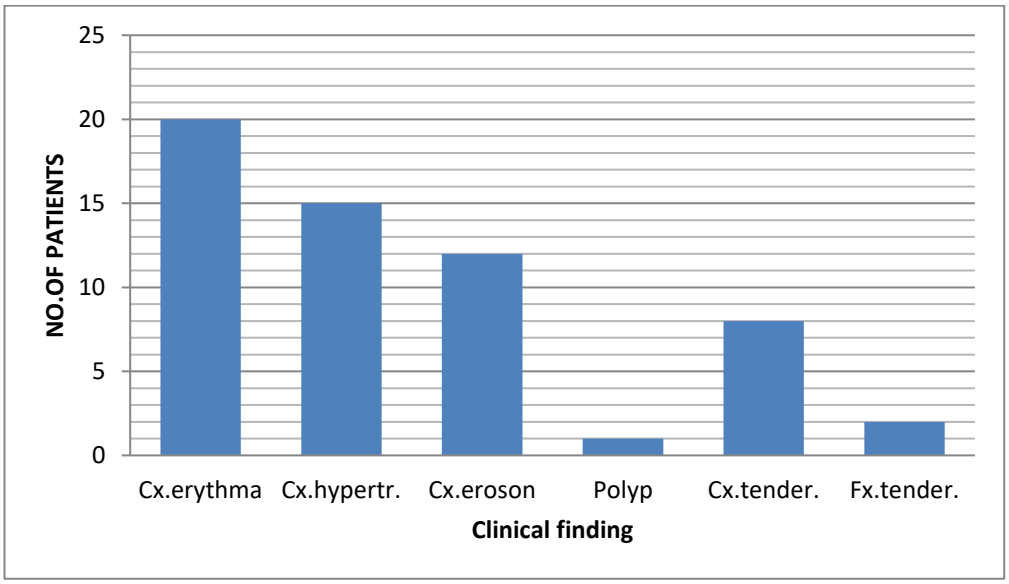


Figure 4:

Table 5(A): PAP SMEAR FINDING

PAP SMEAR FINDING	NO.OF PATIENTS
1.Normal	28
2.Inflammatory	72

Pap smear showed **inflammatory smears** in 72 patients and in 28 patients the smear was normal. All the cervical smears were negative for squamous intraepithelial lesion (SIL).

Table 5(B): HIV Status

HIV FINDING	NO.OF PATIENTS
NEGATIVE	100
POSITIVE	00

100 patients who consented to HIV testing, None of the patients were HIV positive.

Table 6: RELIEF FROM VAGINAL DISCHARGE
(n =100)

Response (% decrease in vaginal discharge)	**No. of patients on day 7th**	**No. of patients on day 14th**
Excellent(Good) >75%	50(50%)	90(90%)
Moderate 51% -75%	38(38%)	06(06%)
Minimal 25% -50%	10(10%)	02(02%)
No response <25%	2(2%)	02(02%)

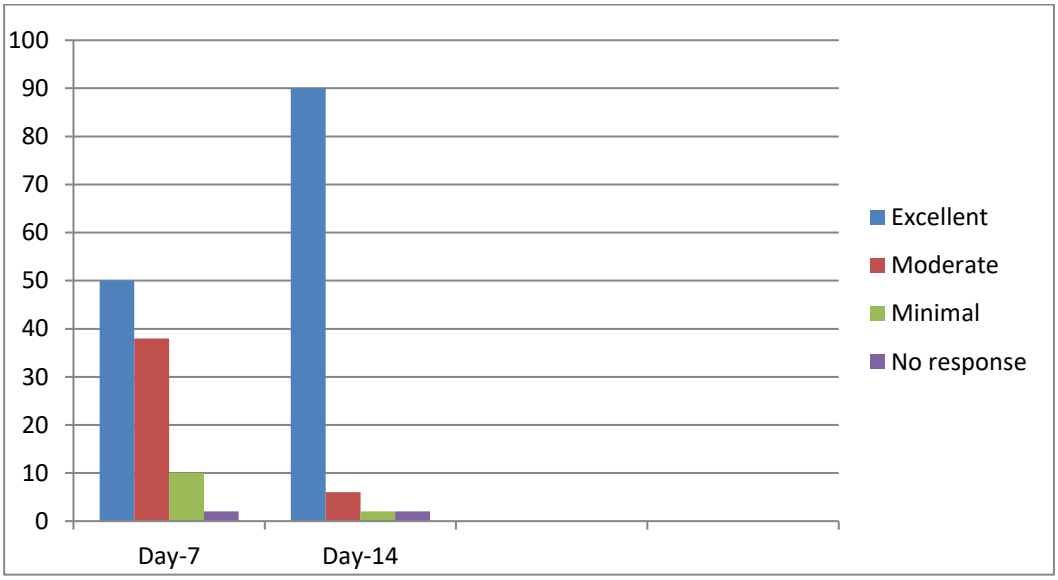


Figure 5:

All the 100 women and their husbands took the prescribed treatment. Womens were followed up on day-7th and day-14th and treatment response were recorded. Only 50% women had excellent - good response (i.e. 75% - 100% relief from vaginal discharge) by day seven, the number increased to 90% by day fourteen. Only two woman had no relief (< 25% decrease) from the vaginal discharge by day fourteen .(table-6)

Table 7:RELIEF FROM PRURITUS VULVA

Response(n =32)	**No. of patients on day 7th**	**No. of patients on day 14th**
Excellent(Good) >75%	12(37.5%)	16(50%)
Moderate 51% -75%	15(46.9%)	12(37.5%)
Minimal 25% -50%	03(9.3%)	03(9.3%)
No response <25%	02(6.3%)	01(3.2%)

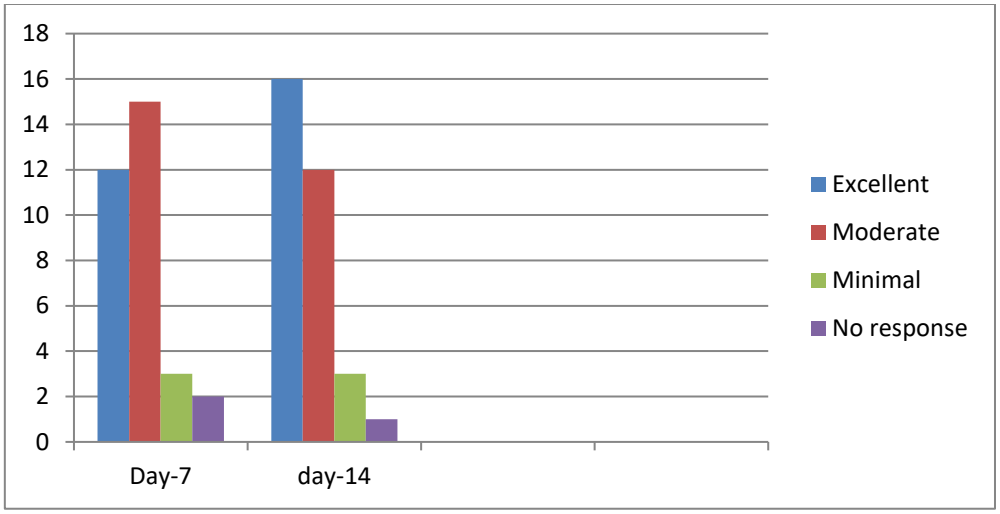


Figure 6:

On day 7th response in pruritus vulva was excellent in 37.5% , moderate in 46.9%, minimal in 9.3% and no response in 6.3%. On day 14th response excellent in 50% , moderate in 37.5%, minimal in 9.3% and no response in 3.2%. (table no.7)

TABLE 8: RELIEF FROM URINARY SYMPTOMS

Response(n =30)	No. of patients on day 7th	No. of patients on day 14th
Excellent(Good) >75%	15(50%)	24(80%)
Moderate 51% -75%	08(26.7%)	03(10%)
Minimal 25% -50%	05(16.7%)	02(6.6%)
No response <25%	02(6.6%)	01(3.4%)

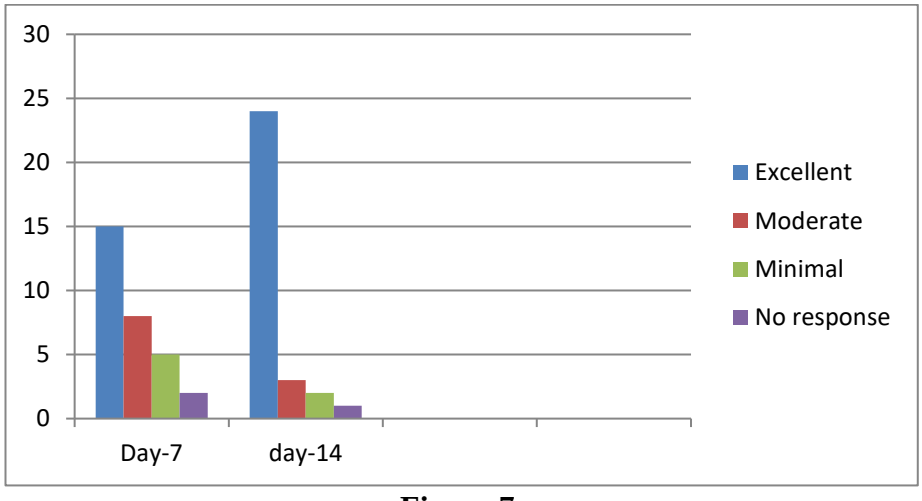


Figure 7:

On day 7th response in urinary symptoms was excellent in 50% , moderate in 26.7%, minimal in 16.7% and no response in 6.6%. On day14th response excellent in 80%, moderate in 10%, minimal in 6.6% and no response in 3.4%. (table no.8)

Table 9: PERCENTAGE REDUCTION IN SYMPTOMS

symptoms	No.of patients on day one	% Reduction on 7th day	% Reduction on 14th day
Vaginal discharge	100	50	90
Pruritus vulva	32	37.5	50
Urinary symptoms	30	50	80

Table-9 shows the percentage reduction in the symptomatic patients. The patient with significant degree of improvement i.e. excellent to good response to drugs, in vaginal discharge on day 7th 50% and on day 14th 90%, in pruritus vulva on day 7th 37.5% and day 14th 50%, in urinary symptoms on day 7th 30% and on day 14th 80 %. The overall evaluation was mainly based on the efficacy of drugs in reducing vaginal discharge - (subjective symptoms). As per overall evaluation 90% of patients showed clinical cure, 6% had improvement, 2% had minimal response while 2% had failure in vaginal discharge. So we conclude that one day combination kit had excellent efficacy in treatment of vaginal discharge.

Table 10: NUMBER OF PATIENTS WITH INFECTIOUS AND NON INFECTIOUS ETIOLOGY OF PERSISTANT VAGINAL DISCHARGE

After 14 days clinical examination done and out of 100 patients 19 patients had PVD. These 19 patient's vaginal discharge specimen was sent for laboratory examination and classified into infectious and non-infectious etiology

Etiology	No. Of patients
Infectious	08
Non infectious	11

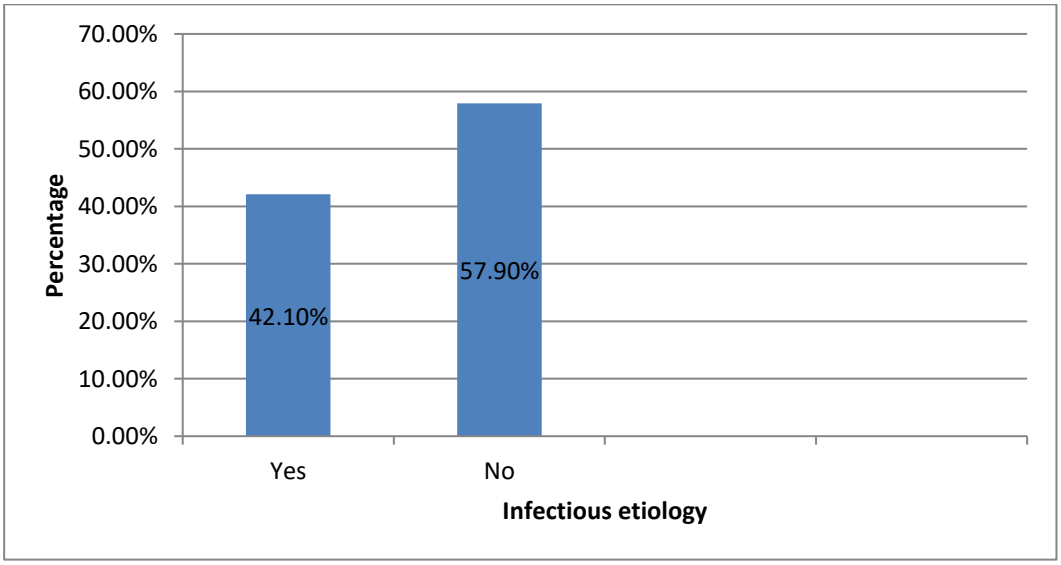


Figure 8:

On day 14th, out of 100 women 19 had persistant vaginal discharge, out of which 08(42.1%) had infectious etiology and 11(57.9%) had non-infectious etiology.

Table 11(A): Laboratory reports of patients who had persistant vaginal discharge on Day -14

(n-19)

INVESTIGATION	POSITIVE	NEGATIVE
1.Candida culture	06	13
2.Bacterial vaginosis gram stain	02	17
3.Trichomonas vaginosis culture	00	19
4.Gonococcal culture	00	19
5.Chlamydia	00	19

Out of 19 patients had PVD 08 had an identified infectious etiology. (table 11 A). 06 patients had candidiasis, 02 patients had Bacterial vaginosis (BV) and no patients had Trichomonas Vaginosis. None of the patients had a mixed infectious etiology.

Table 11(B): clinical examination reports of patients who had persistant vaginal discharge on Day -14.

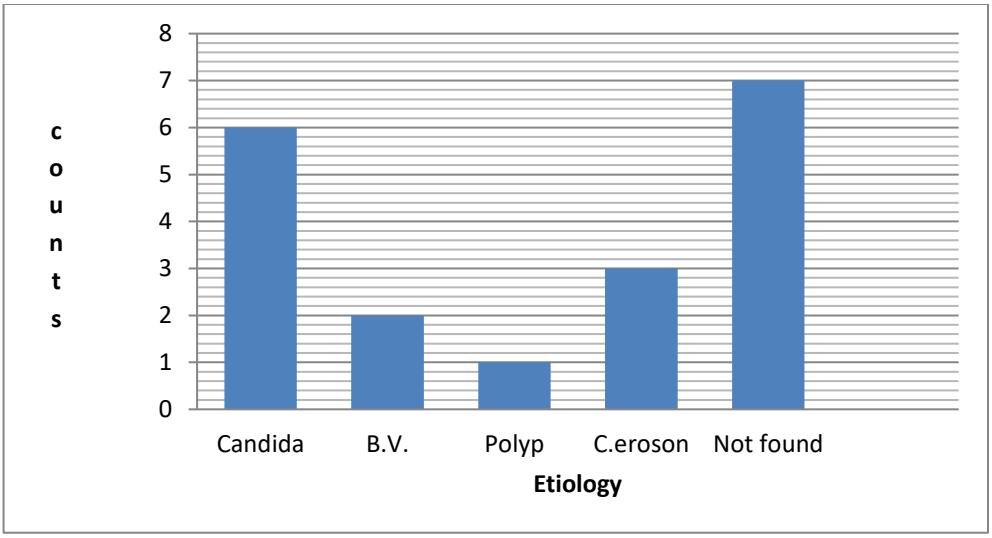
(n=19)

Clinical findings	positive	negative
1.Cervical erosion	03	16
2.Polyp	01	18
3. Cervical erythema	00	19
4. Cervical hypertrophy	00	19
5. atrophic vaginitis	00	19

Out of 19 patients had PVD, 04 had positive clinical findings ,3 patients had cervical erosion and 1 patient had polyp.

Table 11(c): DISTRIBUTION OF ETIOLOGY IN PERSISTANT VAGINAL DISCHARGE

Etiology	No. of patients
Candida	06
Bacteroids vaginosis	02
Polyp	01
Cervical erosion	03
Not found	07



(figure 9)

The etiology identified included candidiasis in 06, BV in 02, cervical erosion in 03 and cervical polyp in 01 patient. No etiology was identified in 07 patients.

Table 12: ADVERSE EFFECTS

Category	Side effects	No. of patients
Mild	Anorexia	15
	Metalic taste	20
	Nausea	24
Moderate	Minimal vomiting	04
	Epigastric discomfort	09
	Headache	02
Severe	Abdominal cramps	01
	Severe vomiting	00
	Skin rash	00
	Stomatitis	01

Adverse effects observed after consumption of drugs are summarized in Table 12. 24 patients had nausea ,20 patients had metallic taste and 15 patients had anorexia. Only two patients had severe type of adverse effects. Patients who had no or mild type of adverse effects were categorized as excellent or good tolerance, while woman who had severe type of side effects were categorized as bad tolerance.

DISCUSSION

100 sexually active women were enrolled in the study. All of them were in reproductive age group and most patients were between 26-35 years. The mean age being 33 years. This period has maximum sexual activity, the chances of exposure are also likely to be increased, and hence more prevalence is found in this age group.[4]

The mean age in a meta analysis done in 2016 was 27 years.[5]

Most of the cases belonged to lower and middle class according to kuppuswamy index. This may be attributed to poor hygiene and poor nutritional status of these women.
In present study 100 % patients had vaginal discharge,32% had pruritis vulvae,30% had urinary symptoms, 10% had pain abdomen. However vaginal discharge reported by
Philips et al was 24.4%,pruritis vulvae in 22.2% ,urinary symptoms in 57.8% and dyspareunia in 26.7% cases which were non comparable.[6]

Apart from vaginal discharge, lower abdominal pain (35%) followed by burning micturition (23.9%) were the most common associated complaints among participants by Chauhan et al.[7]
Pap smear was done in this study to identify cervical cancer cases which can be a cause of persistent vaginal discharge. It was negative for SIL in all cases.

The study also proved that 50% women after AFS regimen had excellent response(75-100%) relief from vaginal discharge on day 7 which increased to 90% by day 14. Only 2 % women had no relief at end of day14. Hence complete relief in 90% cases, partial in 8% and no relief in 2%. Shailesh Kore et al in 2006 showed 88% complete relief after AFS single day kit, 11% partial relief and 2% no relief which was comparable to my study.[8] His study also showed 62% had excellent response in prurutis vulvae which is slightly greater than my study(50%) and 91% relief from urinary symptoms which is also greater than my study(80%). The comparative low relief from pruritis was probably from secondary fungal infection.

The tolerability was 84% good tolerance,14% intermediate and only 2% bad tolerance in my study. This can allow supervised or directly observed therapy for both partners with almost 100 % cure rate with single day regimen only.
In present study 19% cases had persistent vaginal discharge identified by per speculum examination on day 14.Out of these 31.5% had candida albicans, 10.5% had bacterial vaginosis, 15.7% had cervical erosion, 5.2% had cervical polyp and in 37.1% cases no etiology was found.

The prevalence of various organisms in vaginal discharge was candidiasis 39 %, bacterial vaginosis 28 %, trichomoniasis 5 %, *N. gonorrhoeae* 5 % and chlamydia 2 % among the 100 women in a study by Meena V et al before treatment.[9] In a systematic review the majority of cases of vaginal discharge the cause was either TV or BV. [5]

This shows that majority of infectious causes are covered by AFS kit except few cases of candidiasis. The targeted drug therapy has been shown to be more effective than syndromic management.[9] But, the economic contraints of sample collection, transportation and evaluation in low resource settings makes syndromic management the mainstay of treatment.
Among non infectious causes it was found that 12 women before treatment had cervical erosion out of which 3 had persistent vaginal discharge after treatment. Crowly T et al(1997) showed that ocps and cervical ectopy were risk factors for c. trachomatis, but in our study none was found.[10]

Endocervical polyp was is common in women in 40s and 50s however in our study it was found as a cause of persistent vaginal discharge in a 27 year old.
Atrophic vaginitis should be considered as cause of persistent vaginal discharge in postmenopausal women.

There are a few limitations of this study. Only symptomatic females coming to gynecology outpatient department of a district hospital were included. Thus, our study population is not

representative of whole population and there can be selection bias. It was not possible to recruit patients as controls due to lack of resources to conduct laboratory investigations in clinically asymptomatic females. Therefore, prevalence could also not be calculated from our study.

CONCLUSIONS

The **mean age** of women for vaginal discharge was **33 yrs** with range between **21-50 years**. Low socio economic status is a risk factor for vaginal discharge. Efficacy of AFS drugs regime in vaginal discharge was 90% and was cost effective. Majority had good tolerance, only 2 patients had bad tolerance. Hence, syndromic management of vaginal discharge allows simple, fast and assured therapy with a high cure rate. The most important benefit of syndromic management is that treatment begins immediately. Patient acceptance and compliance is good. Immediate treatment dramatically increases the chance of successful care and reduces the time interval during which the infection can spread. Candidiasis is the most common(31.5%) infectious etiology in patients with persistent vaginal discharge, followed by Bacterial vaginosis (10.5%). Gynaecological causes like cervical erosion, cervical polyp and atrophic vaginitis can also lead to the persistence of the vaginal discharge.

Conflict of interest: None
Acknowledgement: None
Funding: Nil.

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