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original article

**Comparative study in patients of vaginal and cervical discharge:
SYNDROMIC VS. EVIDANCE BASED MANAGEMENT**

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Abstract:

IntroductionThe syndromic management has been the cornerstone of management of sexually transmitted infections (STIs) over the last few decades especially in developing countries. But due to its inability to treat asymptomatic cases leading to undesirable sequelae, it has received a lot of criticism recently. On the other hand, Evidence based management of patients of vaginal and cervical discharge has lead to effective and timely management of these patient but has increased the financial burden.

Objective:The goal of the study is to compare syndromic vs. Evidence based approach in the management of vaginal and cervical discharge.

Method:The present study was conducted in the outpatient department of dermatology, venereology & leprology of a tertiary care teaching hospital. 354 patients of clinical impression of vaginal and cervical discharge were included in the study. Detailed history and examination was recorded. Patients selected for syndromic management were managed as per NACO guidelines. For evidence based management special investigations were carried out and patients were managed accordingly.

Result:Out of total 342 cases of VD, treated with syndromic and evidence based approach, p value is significant for 7,14 and 21 days follow-up which means evidence based approach is better than syndromic approach. Similar findings were observed in patients of cervical discharge. Also, among CVV patients managed on lines of syndromic approach only 10% showed improvement by end of one week.

Conclusion:The control of STIs in resource-poor settings remains a major challenge. Focus is now shifting towards a diagnostic model of STI care, given the improving economic status of developing countries and availability of affordable point-of care testing. Also, various changes in the syndromic approach are needed immediately for it to still remain relevant.

KEYWORDS: vaginal, cervical, National AIDS Control Organization (NACO)

INTRODUCTION:

Vaginal discharge is one of the most common problems faced by women. It may be physiological or pathological. Normal vaginal discharge is white, becoming yellowish on contact with air due to oxidation. Physiological discharge arises due to increased mucous production from the cervix in mid cycle pregnancy and women on oral contraceptive.¹ A pathological vaginal discharge may originate either from vagina or the cervix. Discharge of vaginal origin may be associated with Bacterial Vaginosis (BV), and infection with Candida and Trichomonas Vaginalis (TV), while discharge of cervical origin is usually due to infection with Neisseria Gonorrhoeae (NG), Chlamydia trachomatis (CT), and Mycoplasma Genitalium (MG).³ Untreated STDs are more prone to disease spread, development of complications like infertility and ectopic pregnancies and runs a greater risk of contracting HIV. Aetiological diagnosis of STI is difficult in many settings. It places constraints on time, resources, costs and access to treatment especially in developing countries. To overcome this, a syndrome-based approach to the management of STI patients was developed. It is based on

the identification of consistent groups of symptoms and easily recognized signs (syndromes), and the provision of treatment that will deal with the majority of organisms responsible for producing a syndrome.² In India, the flowcharts recommended by the National AIDS Control Organization (NACO) are available for use at primary health centres as well as designated STI/RTI clinics (Suraksha clinics) at district hospitals. Also, the NACO provides prepacked colour-coded treatment kits under the NACP for syndromic management of STI's and are available free of cost at various public facilities offering STI services.⁴ Evidence based management mainly relies on laboratory tests like microscopy, serology, culture, antigen and antibody detection etc. So, it can easily pick up asymptomatic patients. After clinically suspecting particular condition, investigations are done accordingly. By identifying correct causative organism, disease specific treatment can be done. Various guidelines for management of STIs exist like CDC, NACO, European guidelines for STI management, Australian guidelines for STI management, British Columbia treatment guidelines for STI in adolescents and adults (2014) and Canadian guidelines for STIs. The syndromic flowcharts are simple and easy to use for healthcare providers and, once trained, even non-STI specialists can use them at primary health centres in rural or remote areas.⁵ However, it is important to recognize the limitations of the vaginal discharge algorithms, particularly in the management of cervical (gonococcal and chlamydial) infections. There are very few studies which compares syndromic approach against evidence-based approach in management of STIs. Attempts should be made to increase the sensitivity and specificity of the vaginal discharge algorithm and mandate use of microscopy, culture or other diagnostic modalities to correctly identify and manage patients.

Aims and objectives:

1. To evaluate validity of syndromic approach in patients of vaginal and cervical discharge.
2. To evaluate validity of evidence-based management in patients of vaginal and cervical discharge.
3. To compare validity of syndromic approach against evidence-based approach in patients of vaginal and cervical discharge.

Material and method:

The present study was conducted in the outpatient department of dermatology, venereology & leprology of a tertiary care teaching hospital. 354 patients of clinical impression of vaginal and cervical discharge were included in the study.

In all the patients, detailed clinical history in form of name, age, sex, marital status, exposure history and duration of disease was recorded. Also detailed clinical examination and relevant basic laboratory tests were carried out and findings were recorded.

Patients selected for syndromic management, were categorized in different syndromes as depicted by NACO. The syndromes depicted by NACO are cervicitis, vaginal discharge and others. Patients selected for evidence-based management were undergone for disease wise special investigations (10% KOH, Gram stain, Wet mount, Whiff test, Giemsa stain and PAP smear) were done and treated accordingly. For these, we followed CDC guidelines 2015.

INCLUSION CRITERIA:

All the patients of sexually transmitted infections giving consent and attending the outpatient department diagnosed either clinically (syndromic) or by laboratory tests (evidence based) will be included in the study.

EXCLUSION CRITERIA:

Other STI's (other than cervical and vaginal discharge) were excluded from study.

STATISTICAL ANALYSIS:

All data entry was done in EXCEL 2016 and analysis was done using Z test of difference between two proportions.

Results:

TABLE 1: Out of the total 354 cases, 342 cases were of vaginal discharge syndrome and 12 cases were of cervical discharge syndrome with division as follows:

Sr. No.	Syndromic Diagnosis	Evidence Based Diagnosis	No Of Patients
1.	Vaginal Discharge Syndrome	CVV	227
		BV	66
		TV	8
		Mixed VD	41
2.	Cervical Discharge Syndrome	Candidial Cervicitis	6
		Chlamydial Cervicitis	3
		Trichomonal vaginitis	1
		Unknown etiology	2

TABLE2: Peak incidence of vaginal discharge was in 18- 30-year age group. Maximum being the cases of CVV as demonstrated by table below:

Sr. No.	Syndromic Diagnosis	Evidence Based Diagnosis	Age(years)/Sex							
			<18		18-30		31-50		>50	
			M	F	M	F	M	F	M	F
1.	Vaginal Discharge	CVV	-	2	-	114	-	111	-	0
		BV	-	0	-	32	-	34	-	0
		TV	-	1	-	5	-	2	-	0
		Mixed VD	-	2	-	18	-	21	-	0
2.	Cervical Discharge	Candidial Cervicitis	-	1	-	4	-	1	-	0
		Chlamydial	-	-	-	3	-	-	-	0

		Cervicitis								
		Trichomonal vaginitis	-	-	-	1	-	-	-	0
		Unknown etiology	-	-	-	-	-	2	-	0

TABLE 3: NUMBER OF PATIENTS TREATED BY SYNDROMIC & EVIDENCE BASED APPROACH

Sr. No.	Syndromic Diagnosis	Evidence Based Diagnosis	Evidence Based Approach	Syndromic Approach
1.	Vaginal Discharge Syndrome	CVV (227)	124	103
		BV (66)	31	35
		TV (8)	4	4
		Mixed VD (41)	21	20
2.	Cervical Discharge Syndrome	Candidial Cervicitis (6)	3	3
		Chlamydial Cervicitis (3)	2	1
		Trichomonal vaginitis (1)	0	1
		Unknown etiology (2)	2	0

TABLE 4: INVESTIGATIONS DONE IN VAGINAL DSCHARGE:

Syndromic Diagnosis	Etiological Diagnosis	Laboratory Tests									
		A	B	pH		C	D	E	F	HIV	RPR
				>4.5	<4.5					+ve	+ve
Vaginal Discharge Syndrome	CVV (227)	190	91	0	227	19	-	-	-	0	0
	BV (66)	-	55	29	0	-	45	-	55	0	0
	TV (8)	-	-	6	0	6	-	-	-	0	0
	Mixed VD (41)	19	12	3	38	-	13	11	-	0	0

[A-10% KOH positive, B-gram's stain positive showing clue cells, gram positive and variable bacilli/yeast cells, C-wet mount positive, D-whiff test positive, E-Giemsa stain positive, F- Nugent score > 7]

84% of CVV patients were positive on KOH staining; rest had evidence of gram positivity.

Maximum variability was seen in mixed vaginal discharge patients with 47% showing fungal hyphae on 10% KOH and 30% having positive gram stain results.

TABLE 5: INVESTIGATIONS DONE IN CERVICAL DISCHARGE:

Syndromic Diagnosis	Etiological Diagnosis	Laboratory Tests					
		A	B	C	D	HIV (+)	RPR (+)
Cervical Discharge	Candidial Cervicitis	1	6	6	-	0	0
	Chlamydial Cervicitis	-	3	-	-	0	0
	Trichomonal vaginitis	1	-	-	-	0	0

[A-WET MOUNT, B-GRAM'S STAIN, C- 10% KOH, D- PAP SMEAR]

Maximum patients of cervical discharge had positive gram staining with few having evidence of fungal hyphae on 10% KOH.

TABLE 6: NUMBER OF PATIENTS TREATED WITH EVIDENCE BASED APPROACH

Sr. No	Syndromic Diagnosis	Evidence Based Diagnosis	No Of Patients Treated With Evidence Based Approach	Improvement On F'up				
				F'up On 7 Days	F'up On 14 Days	F'up On 21 Days	Not Improved	Lost to f'up
1.	VAGINAL DISCHARGE	CVV	124	78	30	11	3	2
		BV	31	15	7	4	3	2
		TV	4	1	2	-	-	1
		Mixed VD	21	6	8	5	2	-
2.	CERVICAL DISCHARGE	Candidial Cervicitis	3	-	2	1	-	-
		Chlamydial Cervicitis	2	-	1	-	1	-
		Trichomonal vaginitis	0	-	-	-	-	-
		Unknown etiology	2	0	0	1	-	1

As shown in above table, 50% of CVV and BV patients showed evidence of improvement within 7 days. Late response i.e. at 14 weeks was observed in mixed VD and Candidial Cervicitis.

TABLE 7: NUMBER OF PATIENTS TREATED WITH SYNDROMIC APPROACH

Sr.	Syndromic	Evidence	No Of
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No.	Diagnosis	Based Diagnosis	Patients Treated With Syndromic Approach	F'up On 7 Days	F'up On 14 Days	F'up On 21 Days	Not Improved	Lost to F'up
1.	Vaginal Discharge	CVV	103	10	54	31	2	6
		BV	35	3	14	11	3	4
		TV	4	0	2	1	-	1
		Mixed VD	20	1	8	7	-	4
2.	Cervical Discharge	Candidial Cervicitis	3	0	2	-	-	1
		Chlamydial Cervicitis	1	0	1	-	-	-
		Trichomonal vaginitis	1	0	0	1	-	-
		Unknown etiology	0	-	-	-	-	-

As shown in above table, among CVV patients managed on lines of syndromic approach only 10% showed improvement by end of one week. 50% of CVV and BV patients had evidence of improvement only by end of 2 weeks. Patients of candidial cervicitis also had late improve.

TABLE 8: COMPARISON OF IMPROVEMENT SEEN IN PATIENTS OF VAGINAL DISCHARGE

	NO OF PATIENTS IMPROVED			No of patients not improved	No of patients lost to follow-up
	F'UP ON 7 DAYS	F'UP ON 14 DAYS	F'UP ON 21 DAYS		
No of patients treated by Evidence Based Approach(n=180)	100(55.55%)	47(26.11%)	20(11.11%)	8(4.44%)	5(2.78%)
No of patients treated via Syndromic Approach(n=162)	14(8.64%)	78(48.14%)	50(30.86%)	5(3.08%)	15(9.25%)
P value	<0.00001	0.00866	0.00210	-	-

Out of total 342 cases of VD, treated with syndromic and evidence-based approach, p value is significant for 7,14- and 21-days follow-up which means evidence-based approach is

better than syndromic approach. Evidence based approach is ideal being scientifically proven and treatment is specifically targeted towards causative organism.

TABLE 9: COMPARISON OF IMPROVEMENT SEEN IN PATIENTS OF CERVICAL DISCHARGE

	NO OF PATIENTS IMPROVED			No of patients not improved	No of patients lost to follow-up
	F'UP ON 7 DAYS	F'UP ON 14 DAYS	F'UP ON 21 DAYS		
No of patients treated with Evidence Based Approach(n=7)	0 (0%)	3 (42.85%)	2 (28.57%)	1(14.28%)	1(14.28%)
No of pts treated with Syndromic Approach(n=5)	0 (0%)	1(20%)	3 (60%)	0 (0%)	1 (20%)
P value	<0.00001	0.00011	0.02001	-	-

Out of 12 patients of cervical discharge treated with syndromic and evidence-based approach, p value is significant for 7,14 and 21 days follow up which means evidence-based approach is better than syndromic approach. There is a wide list of causes of cervicitis, so there are high chances of missing the correct etiology if we go through syndromic approach. Thus, evidence-based approach picks up the true etiology and treatment is directed towards the same.

Discussion:

Abnormal vaginal discharge can both be the cause as well as the effect of pelvic inflammatory disease. Vaginal discharge was found to be most commonly associated with use of intra- uterine device, poor menstrual hygiene and low socio-economic class. Early management is of prime importance to prevent the possible complications. Syndromic management has many advantages over conventional methods. It decreases dependence on laboratory tests in resource-limited countries like India where laboratory testing may be too expensive and are often unavailable. Even where laboratory diagnosis is available, it is time consuming and often does not correlate with clinical findings.⁴Other advantages include simultaneous treatment of mixed infections, an opportunity to educate and counsel patients regarding safe sex practices, contact tracing, partner management and a return visit to ensure treatment compliance. Syndromic approach greatly simplifies complete administrative process with advanced medical -skills or experience. The most important benefit of syndromic management is that treatment begins immediately thus reducing the spread of infection. However, studies have suggested poor agreement of syndromic diagnosis with aetiological diagnosis and poor operational efficacy, especially in areas with high HIV-prevalence.⁶ Also, the sensitivity of the algorithm was low for the identification of candidiasis and cervical infections, though specificity was high. The low sensitivity of the algorithm may

be related to the fact that overgrowth of *Candida albicans* in the vagina is not always associated with discharge, and that other symptoms, such as pruritus, may be more appropriate entry points for an algorithm seeking to address vaginal candidiasis especially in low prevalence settings. Also, there are no clear guidelines on reporting patients with STIs who visit health facilities other than the designated STI centres, such as other departments of a government hospital (e.g., gynaecology), private practitioners or alternative systems of medicine. Therefore, information on STI epidemiology in India is largely incomplete and inaccurate, and cannot be used to validate the syndromic approach. The use of microscopy and other investigations can increase the specificity and positive predictive value of the syndromic approach, while decreasing its sensitivity marginally thus preventing overtreatment. Additional costs involved may be offset by the savings on treatment costs associated with more precise diagnoses, and reduced wastage of drugs. Other approaches for the control of cervical infections are required to ensure quality of care in antenatal and family planning clinics serving populations with moderate to high prevalence, given the potentially severe consequences of these infections for women's health.⁵

CONCLUSION:

The control of STIs in resource-poor settings remains a major challenge. Symptomatic cases of STIs represent only the tip of the iceberg as most of the cervical STIs are asymptomatic and thus syndromic management will not prove to be effective for such asymptomatic cases as it is primarily based on signs and symptoms. The algorithm has low sensitivity, missing most true infections, and low PPV, leading to overtreatment and erroneous labelling of women as having a serious STI. The sensitivity is especially low for cervical infections, and the application of the algorithm was no better than random treatment.

In addition to this, social and economic empowerment of women must be stressed upon to bring about a positive change in the reproductive health of women. Also, education and increasing awareness about personal and menstrual hygiene along with use of barrier contraceptives plays an important role in alleviating the problem of vaginal discharge.

Focus is now shifting towards a diagnostic model of STI care, given the improving economic status of developing countries and availability of affordable point-of care tests. . The development of simple and affordable diagnostic tests that can be used for case finding is of highest priority. Till such time, there is need to train healthcare professionals in providing the STI/RTI services, so that the syndromes are not misdiagnosed and correct treatment is offered.

The following changes in the syndromic approach are needed immediately for it to still remain relevant: (i) a separate strategy to detect and treat asymptomatic cases for overall control of STI burden in the community; (ii) revision of syndromic algorithms as per the current STI trends and drug susceptibility patterns; (iii) widespread use of the 'enhanced' syndromic approach wherever possible; and (iv) regular training and monitoring of medical and paramedical staff, with a focus on examination and counselling in addition to providing treatment kits.

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