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Original Research Article

Comparison of targeted management versus syndromatic management for abnormal vaginal discharge and the common micro-organisms sensitivity associated with it

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ABSTRACT

Background: Abnormal vaginal discharge usually occurs in women of reproductive age group. There are many etiologies related to abnormal vaginal discharge. Abnormal vaginal discharge is second most frequent issue, behind menstrual problem in women. The main aims and objectives of this study were to compare the targeted management to syndromic management in achieving the complete cure for vaginal discharge; and to find out the common organism in vaginal discharge, in high vaginal swab culture and sensitivity.

Methods: The study was a randomized control trial, where 200 patients were enrolled. The study participants were divided into 2 groups, A and B. Group A was given treatment according to the lab results. Group B was treated according to the syndromic management of vaginal discharge.

Results: In group A, 88% patients having bacterial infection were cured, 10 patients were partially cured by antibiotics. 40% patients in sub group B1 were cured, 40% patients with their partners cured in subgroup B2, 37% in sub group B3 were cured. In group A, 94 patients out of 100 had organism detected on lab test. 14 patients on per speculum examination had vaginitis with cervicitis, but in lab test only vaginitis was present.

Conclusions: We can conclude that syndromic management of vaginal discharge is not an efficient approach for treatment. Low response in syndromic management is due to low sensitivity of clinical examination in diagnosing the nature of vaginal discharge. Development of simple and affordable diagnostic tests that can be used is of highest priority.

Keywords: Abnormal vaginal discharge, Vaginal swab, Syndromic management of vaginal discharge, Sensitivity

INTRODUCTION

Women in reproductive age group frequently have abnormal vaginal discharge, which has a variety of etiologies. Abnormal vaginal discharge is second most frequent issue, behind menstrual problem.¹ Physiological vaginal discharge alters with menstrual cycle day, the discharge being clearly pliable in consistency around ovulation then being heavy and mild yellow during the luteal phase. Increased amount of vaginal discharge is seen during increased estrogen states such as ovulation, the luteal phase, puberty and pregnancy. Oestrogen based therapies also play a major role.

Depending on the type of epithelium and other element in microenvironment, the vaginal, ectoderm and endodermal susceptible to a variety of infection (viral bacterial and protozoan).

Both *Candida* and *Trichomonas vaginalis* can infect the stratified squamous epithelium of vagina and ectocervix. *Chlamydia trachomatis* and *Neisseria gonorrhoea* can infect the endocervical columnar epithelium. Both type of epithelium is susceptible for *Herpes simplex* virus. Multiple illness might present in same person, making it difficult to pinpoint the exact cause.⁵

Symptom brought on by pathological discharge include dyspareunia, a burning feeling, itching and aberrant odour. The treatment of vaginal discharge frequently employs a syndromic management. Primary drawback of this syndromic case management is an incorrect diagnosis and irrational use of numerous antimicrobials, which result in emergence of drug resistance strains that places a financial burden on the patient.⁶

Bacterial vaginosis, trichomoniasis and vulvovaginal candidiasis are the 3 main etiological factors causing abnormal vaginal discharge.⁷ On infective causes of vaginal discharge include atrophic vaginitis, foreign body, malignancy, contact dermatitis or there mechanical or chemical irritation.⁹ An intrauterine contraceptive device can also because vaginal discharge related to chronic irritant cervicitis or endometritis.

Main signs of bacterial vaginosis are an offensive malodorous discharge. A significant amount of yellowish or greenish, occasionally foamy discharge is a symptom of vaginal trichomoniasis.

Aims and objectives

The aims and objectives of the study were to compare the targeted management to syndromic management in achieving the complete cure for vaginal discharge; and to find out the common organism in vaginal discharge, in high vaginal swab culture and sensitivity.

METHODS

Study type

The study was a randomized control trial.

Study period

Duration of the study was from 01 July 2022 to 28 February 2023 (7 months).

Study place

The study was done in Sparsh Hospital, Kannauj, Uttar Pradesh.

Inclusion criteria

Women between the age of 18 to 45 years, sexually active, attending the gynae OPD with the chief complain of vaginal discharge were included in the study.

Exclusion criteria

Pregnant women, adolescent girls, women having any polyp or mass in cervix, any endometrial pathology and PID patients were excluded.

Procedure

200 women patients attending the gynae OPD with chief complaint of vaginal discharge were enrolled. The patients were divided into two groups A and B with 100 patients in each group. In group A, patients with consent were subjected to per speculum examination. Colour, consistency, smell of discharge was noted. High vaginal swab was taken for culture and sensitivity and microscopy. For patients with history for STIs and clinically suspected for STIs, samples were sent for real time PCR for *Chlamydia* and *Gonorrhoea*.

Vaginal swab was carried out with good light and in clean condition by a health care professional. Clean sterilized speculum was inserted into the vagina to see the cervix and vagina, whilst also protecting the swab from being contaminated by organisms on the vulva. After insertion of the swab to the top of the vagina, it was rotated to obtain a sample of the discharge. Then the speculum was removed and sample was sent for culture and sensitivity, in charcoal-based transport medium. If the sample was not to be sent to the laboratory immediately, it was stored in fridge.

In group B, treatment according to syndromic management was started on the same day of enrolment, on the basis of whether vaginal discharge alone was present or present with any high-risk factors. Group B was further divided into sub-groups B1, B2, and B3.

Sub-group B1

In 20 patients (suspected for chlamydia or gonorrhea infection), tablet azithromycin 1 gm, tablet cefixime 400 mg (kit grey) was given. Partners were also treated.

Sub-group B2

In 10 patients (vaginal discharge with abdominal pain), tablet doxycycline 100 mg, tablet cefixime 400 mg, tablet metronidazole 400 mg was given for 14 days (kit 5 yellow). 4 partners were treated with grey kit (kit 1).

Sub-group B3

In 70 patients (only vaginal discharge), tablet secnidazole 2 gm, fluconazole 150 mg (kit 2 green kit) was given. 10 partners treated in this group. Both the groups were followed up after 2 weeks.

Statistical analysis was done and data was analysed in numbers and percentages.

RESULTS

In group A, the culture of 6 patients were sterile. Bacterial infection was diagnosed in 86 patients out of 100. In group A, 86% patients had white greyish discharge.

In group B, 8 (40%) patients in sub group B1 were cured, 4 (40%) patients with their partners cured in subgroup B2, 6 (37%) patients in sub group B3 was cured. 76 (88%) patients having bacterial infection were cured, 6 patients had full courses of antibiotics. 10 patients (who were partially relieved by antibiotic) had cervical erosion on repeat per speculum examination, thermal cautery was done for erosion and patients were cured completely. All patients of chlamydia and candida were cured.

Treatment in group A was initiated based on organism detected in investigation. For specific bacteria diagnosed in culture, targeted antibiotic was started. For *Candida*, tablet fluconazole 150 mg or other anti-fungal according to report was given. For *Chlamydia*, tablet doxycycline 100 mg bd for 14 days was prescribed.

With bacterial infection, 90% women had whitish or greyish white discharge. 50% of women of *Chlamydia* had yellowish discharge. 11% women of bacterial infection had foul smelling vaginal discharge. 79% women of bacterial infection had fishy smell in vaginal discharge. In group A, 94 patients out of 100 had organism detected on lab test. Most common complaint along with vaginal discharge was itching and dysuria. In group A, 80 women with vaginitis on per speculum against the 64 were vaginitis on lab test. 10 were physiological and 6 had cervicitis. 14 patients per speculum examination had vaginitis with cervicitis, but in lab test only vaginitis present.

Table 1: Prevalence of organisms in vaginal swab culture report of group A.

| Name of organisms | No. of patients |
|-------------------------------|-----------------|
| <i>E. coli</i> | 50 |
| <i>Klebsiella pneumoniae</i> | 4 |
| <i>Enterococcus faecalis</i> | 10 |
| <i>Candida</i> | 4 |
| <i>Pseudomonas aeruginosa</i> | 6 |
| <i>Streptochloramphenicol</i> | 6 |
| <i>Streptococcus anginaus</i> | 6 |
| <i>Nissaria gonorrhea</i> | 0 |
| <i>Trichomoniasis</i> | 4 |
| <i>Chlamydia</i> | 4 |

Table 2: Associated symptoms with abnormal vaginal discharge in both the groups.

| Associated symptoms | Group A | | Group B | |
|---------------------|-----------------|----|-----------------|----|
| | No. of patients | % | No. of patients | % |
| Fever | 0 | 0 | 0 | 0 |
| Itching | 80 | 80 | 90 | 90 |
| Menorrhagia | 0 | 0 | 0 | 0 |
| Pelvic pain | 50 | 50 | 56 | 56 |
| Dysuria | 76 | 76 | 70 | 70 |
| Dyspareunia | 36 | 30 | 40 | 40 |

In B1 treatment given for chlamydia and gonorrhea only 8 patients cured, in group B2 syndromic treatment given for lower abdominal pain with discharge, only 4 patients cured. In group 3 patients treated for bacterial vaginosis on the basis of symptoms but only 26 patients were cured.

Rest of the patient continue to come for treatment.

Table 3: Incidence of vaginitis, vaginitis with cervicitis based on per speculum examination in group A.

| Diagnosis | No. of patients | % |
|---------------------------------|-----------------|----|
| Vaginitis | 80 | 80 |
| Vaginitis and cervicitis | 14 | 14 |
| Cervicitis | 6 | 6 |
| Total | 100 | |

Table 4: Group B with subgroups.

| Subgroups | Total |
|-----------|-------|
| B1 | 20 |
| B2 | 10 |
| B3 | 70 |

Table 5: Follow-up results.

| Subgroups | Cured, N (%) |
|-----------|--------------|
| B1 | 8 (40) |
| B2 | 4 (40) |
| B3 | 26 (37) |

DISCUSSION

These results are a reminder that the syndromic management is not an efficient approach for identifying women with vaginal discharge. These results were consistent with those of other validation studies, which had found that sociodemographic and behaviour risk assessment were rarely sufficient for identifying cervical infection in most setting.¹¹ Though they may be helpful in selecting women for further diagnostic tests in settings where these were available (selective screening).¹²⁻¹⁵

In most instances, the syndromic management of vaginal discharge should focus on vaginal infection, especially bacterial vaginosis and trichomoniasis, in recognition of the fact that vaginal discharge is primarily a manifestation of these condition.¹¹ In this study, also, most cases were diagnosed as bacterial vaginosis in group B, most women required metronidazole treatment which was effective against bacterial vaginosis and trichomoniasis, and only few patients were cured completely in this group. It offered high level of over treatment by metronidazole. In fact, metronidazole presumptive treatment of all women with vaginal discharge had been advocated.¹¹

The use of bed side simple microscopy only marginally increased the correct diagnosis of vaginal infection. In family planning and other reproductive health care

settings, a broader concern about RTIS was preferred to a more narrow focus on STIs, because it reflected a more comprehensive and less stigmatizing vision of women need for reproductive health services.¹⁶ The principal benefits of treating vaginal infections are the relief of symptoms of these condition, there by meeting a major expectation of clients of reproductive health services, as well as the prevention of gynaecological, and obstetric complications, and possibly HIV transmission, associated with bacterial vaginosis.¹⁷⁻²¹

Group A underwent laboratory investigations and treatment was started as soon as reports were available. Recommended treatment for bacterial vaginosis was tablet tinidazole 2 gm single dose, for candidiasis tablet fluconazole 150 mg single dose and for trichomoniasis tablet tinidazole 2 gm single dose and for Gonorrhoea and Chlamydia tablet azithromycin 2 gm single dose or oral doxycycline 100 mg twice daily for 7 days or oral ofloxacin 300 mg twice daily for 7 days.²⁷ Antibiotics were started on the basis of swab culture report.

Group B was given syndromic management on the same day of examination. Both groups were followed up after 2 weeks.

Pattern of distribution and follow-up of enrolled cases in this study were similar to the study done by Eying et al.⁶ Enrolled cases in both the groups had their age ranges between 1 to 45 years and maximum numbers of women were in the age of 20 to 29 years. This finding suggested that vaginal infection commonly occurred in reproductive age group, which was comparable to that report by Thulkar et al, Ryan et al, Rao et al, Sanchez et al and Sharma et al.²⁸⁻³² Most common complaint along with vaginal discharge was itching and dysuria as compared to other complaints. Lower abdominal pain was the most common complaint in a study conducted by Rizvi et al.³³ Lower abdominal pain was commonly found in patient of pelvic inflammatory disease, however in present study these patients were not included in this study, and this may be the difference in the two studies etiological cause of abnormal vaginal discharge in group A was found in patients and in remaining no cause was found. Similarly, in the study of Ryan et al, Moherdaul et al and Nugent et al same prevalence was observed.^{29,35,36}

Undoubtedly, syndromic case management had numerous advantages in terms of early initiation of treatment on the first visit of patient, better compliance, lower laboratory cost and higher cure rate. WHO had also noted that the etiological diagnosis of STI may be problematic in many settings as a result of time, resource, costs and access to treatment.³⁹

As seen in our study, adhering to strictly to syndromic case management while not consulting laboratory reports can do more harm than good. Treatment of all cases presenting with a particular syndrome result in receiving antimicrobial drugs against organisms which might not be

responsible of the present condition, thus resulting in exposure to unnecessary side effects, development of drug resistance, and increased treatment cost, more over large numbers of asymptomatic or subclinical infections were likely to be missed.³⁸ Distinction of STIs and endogenous RTIs is also important from social point of view, as has been noted previously, labelling all vaginal discharge as STIs may cause domestic and social issues in a women's life thus emphasizing the importance of etiological diagnosis.⁴⁰

In present study, in group A, almost 86% patients were cured in group B, 38% were cured and rest of the patients continued to come for treatment. Syndromic approach management of vaginal discharge is not a significant approach for identifying women for STIs as shown in result of group B. Syndromic approach management is also poor in treating bacterial vaginosis (due to bacterial infection) as shown in result of group B (only 14 patients cured out of 35).

Limitations

This study showed a poor correlation between clinical and laboratory findings for final diagnosis. The reason behind this could be an over diagnosis on clinical examination due to observer error or an under diagnosis by laboratory test. Pregnant women, adolescent girls, women having any polyp or mass in cervix, any endometrial pathology and PID patients were excluded. So, this was the limiting factor in the study. Other limitation was that the study was a single-centre study, so therefore, the sample size was considerably small. As the study duration was also less (7 months), therefore the long-term effects were also not observed.

CONCLUSION

It is concluded that syndromic management of vaginal discharge is not an efficient approach for treatment. There is mismatch in the final diagnosis by laboratory tests and diagnosis made by clinical examination and history. The principal benefits of treating vaginal infections by syndromic approach are relief of symptoms for some time, there by meeting a major expectation of clients of reproductive health services, as well as reduces the rate of gynecological and obstetric complications (possible HIV transmission) associated with bacterial vaginosis. Low response in syndromic management is due to low sensitivity of clinical examination in diagnosing the nature of vaginal discharge.

Recommendations

Development of simple and affordable diagnostic tests that can be used is of highest priority. High vaginal swab culture and sensitivity and microscopy can be used as diagnostic test in vaginal discharge patients, as it gives report of accurate organism and drug to be used against it. Sample collection of this test is easily collected in low

resource setting, and not very expensive, in comparison to cost and side effect of repeated course of medicine. Real time PCR for Chlamydia and Neisseria gonorrhoea can be used in high-risk patients, showing mucopurulent discharge from cervix, to prevent complication by these organisms to genital organs, by using these tests we can prevent over treatment and mis diagnosis of patients.

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Ethical approval: The study was approved by the Institutional Ethics Committee

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