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The Syndromic Management of Vaginal Discharge Using One-Day Combination Kit Therapy: A Randomized Controlled Trial

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Abstract

Background: Reproductive tract infections (RTIs) and sexually transmitted infections (STIs) are major public health problems in developing countries. **Aim**: To observe the responses of improvement symptoms and to reduce the risk of complication. **Methods**: This randomized study was conducted at Department of obstetrics and Gynaecology OPD in Shaheed M. Monsur Ali Medical college and Hospital, Sirajganj, Bangladesh during January 2019 to June 2019. A total of 219 patients were included for the study. Couple was given one day kit containing: Fluconazole (150 mg) 1 tablet, Azithromycin (1 gm) 1 tablet, Secnidazole (2 gm) 2 tablets. The database so prepared was analyzed with the help of SPSS statistical software. **Results:** About two third (70.3%) of the women were in age group 16-30 years, one third of them were illiterate (37.4%), 80.4% of them were homemakers. The History of abortion-MR was present 83 (37.9%) and two third (77.2%) of the women were happen home delivery. Moderate to copious 88 (40.2%), Profuse 71 (32.4%) and Scanty 60 (27.4%). Responses for symptoms of vaginal discharge 121 (55.3%), 60 (27.4%), 17 (7.8%) and 21 (9.6%) had excellent, moderate, minimal and no responses, respectively. Pain abdomen was completely 8(28.57%), partially 18(64.29%) relieved in women. Adverse effects of kit therapy were anorexia 53(44.54%) metallic taste 39(32.77%), nausea 46(38.66%), vomiting 30(25.21%) epigastric pain 42(35.29%). The Response rate of the age group 16-30 years is higher than the age group 31-45 years for all gynecological symptoms. **Conclusions:** Combination kit therapy in syndromic management of vaginal discharge is cheaper, effective and is given in single doses, with excellent efficacy.

Keywords:- *Vaginal Discharge*, *Syndromic Management*, *Combination Kit Therapy*, *STD*, *SAF*.

INTRODUCTION

Reproductive tract infections (RTIs) and sexually transmitted infections (STIs) are major public health problems in developing countries. In 1994, the International Conference on Population and Development (ICPD) in Cairo recommended that control of RTIs/STIs be considered as one of the essential components of reproductive health.[1]

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Syndromic management implies the simultaneous treatment of two or more infections. The higher cost of drugs is more than compensated by saving on diagnosis assays, but adverse effects are more frequent and adherence to multiple-dose regimens can be suboptimal.[2,3] In the majority of cases, this syndrome is caused by either Bacterial vaginosis (BV), Trichomonas vaginosis (TV), Vulvovaginal Candidiasis (CA) or any combination thereof. Reproductive tract infection account for the second most important cause for morbidity and mortality in women of reproductive age due to the lack of medical facilities available. Untreated diseases lead to long-term complications; chronic abdominal pain (PID), ectopic pregnancy infertility and cervical cancer.[4] About 20-25% of women who attended the Department of Gynecology's outdoor (OPD) complain of vaginal discharge and leucorrhea. Although in some cases the discharge may be physiological, increasing the normal discharge of the vagina, in more than 60% of cases it is due to a vaginal or uterine infection caused by bacteria, fungi or parasitic agents.[5] Many times these infections are sexually transmitted. Vaginal discharge is often polymicrobial, and treatment of only one or most of the objectionable factors may lead to stimulation and clinical manifestations of other factors. The World Health Organization (WHO) has suggested a simpler and more expensive method for identifying and managing RTI / STI cases through a syndrome approach.[6] The benefits of Syndromic management include simple immediate care, first aid treatment and cost savings without the need for expensive laboratory tests. Treatment first seen before the start of treatment results in the patient not being lost for follow-up and results in a reduction in the need for return visits to reduce further infections and complications before the start of treatment and to collect laboratory test results. The use of flowcharts in RTI / STI management standardizes diagnosis, treatment, referrals and reporting.[2] However, the main disadvantages of Syndromic management are: (a) additional diagnostics and additional treatment costs when multiple antimicrobials are given to a patient with one or more infections and (b) excessive use of antimicrobials that increase selective stress for community-resistant pathogens. (c) It is not as effective for women became of low sensitivity and specificity for gonococcal and chlamydial infections. (d) Even with risk scores, it is not highly sensitive or specific for asymptomatic infection.

MATERIAL AND METHODS

This randomized study was conducted at Department of obstetrics and Gynaecology OPD in Shaheed M. Monsur Ali Medical college and Hospital, Sirajganj, Bangladesh during January 2019 to June 2019. A total of 219 patients were included for the study according to following inclusion and exclusion criteria. The aim of this study is to observe the responses of improvement symptoms and to reduce the risk of complication. Couple was given one day kit containing: Fluconazole (150 mg) 1 tablet, Azithromycin (1 gm) 1 tablet, Secnidazole (2 gm) 2 tablets. The couple was advised abstinence from intercourse for fifteen days. On follow-up visits after two weeks, patients were asked about improvement of the symptoms in the percentage; tolerance of tablets in the form of adverse effect observed after the consumption. The Chi-square or Fisher's exact test as applicable was applied for

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analysis of categorical variables. The data thus collected was computerized in a specific programme developed on Microsoft excel 2010 software. The database so prepared was analyzed with the help of SPSS statistical software.

- **Inclusion Criteria**
  - Women of reproductive ages (16 to 45 yes)
  - Women presenting with vaginal discharge and various signs and symptoms of RTIs (Pruritus vulvae, lower abdominal pain, urinary symptoms etc.)
- **Exclusion Criteria**
  - Patients not given valid consent
  - Unmarried women
  - Women with pregnancy & lactating and any uterine pathology.
  - Patient with per vaginal bleeding
  - Diagnosed genital malignancy.
  - History of drug allergy or those who had received any type of medication for vaginal discharge for last two weeks.

RESULTS

About two third (70.3%) of the women were in age group 16-30 years, one third of them were illiterate (37.4%), 80.4% of them were housewives and rest were Job holders or students, almost half of Husband Occupation were Farmers/Labors /Drivers (54.35%) and only 15 of them belongs to Exposure History (6.8%). The History of abortion-MR was present 83 (37.9%) and two third (77.2%) of the women were happen home delivery, 41.6% of them were used OCP as a Contraceptive method [Table 1]. The color of the discharge was White 56 (25.57%) followed by Grayish White 51 (23.29 %), Greenish Yellow 48 (21.92%), Yellow 20 (9.13%), Mucopurulent 36 (16.44 %) and Purulent 8 (3.65%). The Quantity of the discharge was Moderate to copious 88 (40.2%), Profuse 71 (32.4%) and Scanty 60 (27.4%).The consistency of the discharge was thick watery 120 (54.8%). Total 62 (28.3%) of the women reported their discharge to be Malodorous and Foul-smelling discharge 22 (10.05%) among them. Genital itching was 169 (77.17%), Wet garments was 204 (93.15%) and Dyspareunia was 101 (46.12%) [Table 2]. Out of 219 women, responses for symptoms of vaginal discharge 121 (55.3%), 60 (27.4%), 17 (7.8%) and 21 (9.6%) had excellent, moderate, minimal and no responses, respectively. Out of 122 women, 76 (62.3%) women had excellent responses for Pruritus vulva. Twenty-three (18.9%), three (2.5%) and Twenty (16.4%) women showed moderate minimal and no response for Pruritus vulva, respectively. The response rate of Urinary Symptoms had 44 (46.8%), 21 (22.3%), 6 (6.4%) and 23 (24.5%) for excellent, moderate, minimal and no responses, respectively [Table 3]. Pain abdomen was completely 8 (28.57%), partially 18 (64.29%) relieved in women (out of 28) [Table 4]. Most common adverse effects of kit therapy were anorexia 53 (44.54%) metallic taste 39 (32.77%), nausea 46 (38.66%), vomiting 30 (25.21%) epigastric pain 42 (35.29%), headache (12.61%) and burning sensation with vagina 8 (6.72%). Eight (6.72%) women's husbands discontinued the therapy due to not agreeing to take medicine [Table 5]. The Response rate of the age group 16-30 years is higher than the age group 31-45 years for all gynecological symptoms. Among the all symptoms Pruritus vulva, Dyspareunia and Post coital Bleeding are statistically significant (P-value <0.05) [Table 6].

Table 1: Baseline characteristics of the treatment groups

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Variables	Category	n(%)
Age Group	16-30	154 (70.3)
	31-45	65 (29.7)
Education Status	illiterate	82 (37.4)
	Primary School	89 (40.6)
	Secondary school or more	48 (21.9)
Patient Occupation	Housewife	176 (80.4)
	Job holder	32 (14.6)
	Student	11 (5.0)
Husband Occupation	Businessman	49 (22.4)
	Farmer/Labour /Driver	119 (54.3)
	Service holder	48 (21.9)
	Student	3 (1.4)
Exposure History of Patient	Absent	219 (100.0)
Exposure History of Husband	No	204 (93.2)
	Yes	15 (6.8)
Children	0	8 (3.7)
	1-2	167 (76.3)
	2+	44 (20.1)
History of abortion-MR	No	136 (62.1)
	Yes	83 (37.9)
Contraceptive use	Condom	43 (19.6)
	Implant	8 (3.7)
	Injection	22 (10.0)
	IUCD	11 (5.0)
	Not Using	36 (16.4)
	OCP	91 (41.6)
	Tubectomy	8 (3.7)
Place of delivery	Home	169 (77.2)
	Institutional	50 (22.8)

Table 2: Symptoms and signs presented by women

Symptoms/sign	n (%)
Symptoms	
Vaginal discharge	219 (100)
Thin watery	120 (54.8)
Thick white	99 (45.2)
Curd-like	70 (31.96)
Others	28 (12.79)
Foul-smelling discharge	105 (47.95)
Genital itching	169 (77.17)
Wet garments	204 (93.15)
Dysuria	85 (38.81)

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Dysperunia	101 (46.12)
Signs on inspection	
Vulval soreness	15 (6.85)
Oozing of discharge	215 (98.17)
Reddish and swollen vulva	44 (20.09)
Foul smell	22 (10.05)
Signs on speculum examination(Vagina)	
Discharge present	219 (100)
Colour	
Curdy White	56 (25.57)
Greyish White	51 (23.29)
Greenish Yellow	48 (21.92)
Yellow	20 (9.13)
Type	
Watery	48 (21.92)
Curd-like	20 (9.13)
Forthy	36 (16.44)
Quantity	
Moderate to copious	88 (40.2)
Scanty	71 (32.4)
Profuse	60 (27.4)
Smell	
Malodorous	62 (28.3)
Signs on speculum examination (cervix)	
Endocervical mucopus	37 (16.89)
Friable cervix	16 (7.31)

Table 3: Response in percentage for efficacy.

Symptoms	**Number**	**Excellent**	**Moderate**	**Minimal**	**No Response**
Vaginal discharge	219	121 (55.3)	60 (27.4)	17 (7.8)	21 (9.6)
Pruritis vulva	122	76 (62.3)	23 (18.9)	3 (2.5)	20 (16.4)
Urinary Symptoms	94	44 (46.8)	21 (22.3)	6 (6.4)	23 (24.5)
Backache	20	7 (35.0)	3 (15.0)	4 (20.0)	6 (30.0)
Dyspareunia	65	30 (46.2)	22 (33.8)	4 (6.2)	9 (13.8)
Sores/Blister in Genitalia	14	3 (21.4)	4 (28.6)	0 (0)	7 (50.0)
Post coital Bleeding	10	1 (10.0)	3 (30.0)	1 (10.0)	5 (50.0)

Table 4: Relief of pain abdomen.

Symptom	**Number**	**Complete Relief %**	**Partial relief %**	**No Response %**
Complete Relief	28	8(28.57)	18(64.29)	2(7.14)

Table 5: Adverse Effects for taking treatment

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Symptoms	Number of patient	N(%)
Anorexia	53	44.54
Metalic Taste	39	32.77
Nausea	46	38.66
Vomiting	30	25.21
Epigastric Pain	42	35.29
Headache	15	12.61
Burning sensation with vagina	18	15.13
Discontinuation of Medicine (Husband Only)	8	6.72

Table 6: Response Outcome percentage according to Age Group

Symptoms	Symptoms	Age Group		
	Outcome	16-30	31-45	p-value
Vaginal discharge (%)	Excellent	87 (56.5)	34 (52.3)	0.364
	Moderate	41 (26.6)	19 (29.2)	
	Minimal	14 (9.1)	3 (4.6)	
	No Response	12 (7.8)	9 (13.8)	
Pruritis vulva (%)	Excellent	55 (66.3)	21 (53.8)	0.008
	Moderate	19 (22.9)	4 (10.3)	
	Minimal	1 (1.2)	2 (5.1)	
	No Response	8 (9.6)	12 (30.8)	
Urinary Symptoms (%)	Excellent	26 (41.3)	18 (58.1)	0.092
	Moderate	17 (27.0)	4 (12.9)	
	Minimal	6 (9.5)	0 (0.0)	
	No Response	14 (22.2)	9 (29.0)	
Backache (%)	Excellent	3 (50.0)	4 (28.6)	0.272
	Moderate	1 (16.7)	2 (14.3)	
	Minimal	2 (33.3)	2 (14.3)	
	No Response	0 (0.0)	6 (42.9)	
Dyspareunia (%)	Excellent	22 (51.2)	8 (36.4)	<0.001
	Moderate	19 (44.2)	3 (13.6)	
	Minimal	1 (2.3)	3 (13.6)	
	No Response	1 (2.3)	8 (36.4)	
Sores/Blister in Genitalia (%)	Excellent	2 (40.0)	1 (11.1)	0.222
	Moderate	2 (40.0)	2 (22.2)	
	No Response	1 (20.0)	6 (66.7)	
Post coital Bleeding (%)	Excellent	1 (100.0)	0 (0.0)	0.019
	Moderate	0 (0.0)	3 (33.3)	
	Minimal	0 (0.0)	1 (11.1)	
	No Response	0 (0.0)	5 (55.6)	

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DISCUSSION

The WHO has recommended syndromic management guidelines for women with vaginal discharge.[7] All enrolled women come to hospital with vaginal discharge, but the findings showed that a large proportion of them did not have any common vaginal and cervical infection. The other causes of vaginal discharge might include side effect of contraceptive use,[8] or misconceptions about normal physiological discharge.[9] Our study had almost half of Husband Occupation where Farmers/Labours /Drivers (54.35%) and 15 Husbands belonged to Exposure History (6.8%). There is a common belief that most women in Bangladesh do not have sex before or outside of marriage as compared to men.[10] A study has found that unmarried marital sex is prevalent among Bangladeshi men and most of them have sex with sex workers with less use of condoms.[11] A recently completed study found that women's uterine infections were not associated with husbands at home, unfaithful husbands and polygamous marriages.[12] In present study analysis of patients according to findings of per speculum examination out of 219 patients 56 (25.57%) had Curdy White vaginal discharge 120 (54.8%) presented with thin watery discharge. 48 (21.92%) patient had Greenish Yellow discharge with foul smell (10.05%). The Quantity of the discharge was Moderate to copious 88 (40.2%) and total 62 (28.3%) of the women reported their discharge to be Malodorous. It is showed in their study that most of patients presented with homogenous white discharge 43(28.7%) cases, 42(28%) presented with curdy white discharge.[13] It is observed that 195 patients of vaginal symptoms and found 36% relief by single day therapy.[14] In our study, we found excellent response in combination kit in 55.3% of cases for vaginal discharge syndrome along with lower abdominal pain syndrome (28.57%). In our study, a few women experienced some side effects but no women stopped therapy. The most common facing etiologies of vaginal discharge are trichomoniasis, moniliasis, bacterial vaginosis, chlamydial infection and gonorrhea. Metronidazole was the first treatment in the last five decades. Now that the resistance to metronidazole for trichomoniasis has increased, the second dose of seconidazole 2g has better tolerability and patient compliance. It has a longer half-life and a longer duration of activity with fewer side effects. A single dose of 2 g is very effective in bacterial vaginosis and trichomoniasis.[15] The effect of combination therapy versus cotrimazole therapy on vaginitis.[16] They enrolled 161 patients out of which 84 were given combination therapy and 81 were on cotrimazole therapy. They found more effective response in combination therapy (99%).[16] The effect of combination therapy to chronic vaginal discharge with 56% improvement after first course and 84% improvement after second course.[17] Another study effect of single versus 7 days dose of metronidazole for treatment of Trichomonas vaginalis among 270 HIV positive patients. They found 7 days treatment is more effective in HIV positive patients.[18]

Limitations of the study

The sample size of participants was relatively small. The present study was conducted at a short period.

CONCLUSIONS

Combination kit therapy in syndromic management of vaginal discharge is cheaper,

effective and is given in single doses, with excellent efficacy. It allows good compliance, complete treatment at first onset, thus prevent STD transmission and HIV transmission. To make more conclusive results similar type of study should be done with large sample size and long period of follow-up.

REFERENCES

1. Roseman MJ, Reichenbach L. International Conference on Population and Development at 15 years: achieving sexual and reproductive health and rights for all?. Am J Public Health. 2010;100(3):403-406. doi:10.2105/AJPH.2009.177873
2. Dallabetta GA, Gerbase AC, Holmes KK. Problems, solutions, and challenges in syndromic management of sexually transmitted diseases. Sex Transm Infect. 1998;74 Suppl 1:S1-11.
3. Ingersoll KS, Cohen J. The impact of medication regimen factors on adherence to chronic treatment: a review of literature. J Behav Med. 2008;31(3):213-224. doi:10.1007/s10865-007-9147-y
4. Rabiu KA, Adewunmi AA, Akinlusi FM, Akinola OI. Female reproductive tract infections: understandings and care seeking behaviour among women of reproductive age in Lagos, Nigeria. BMC Womens Health. 2010;10:8. doi: 10.1186/1472-6874-10-8.
5. Crum-Cianflone NF. Bacterial, fungal, parasitic, and viral myositis. Clin Microbiol Rev. 2008;21(3):473-494. doi:10.1128/CMR.00001-08
6. Muula A, Geubbels E. Epidemiology of Reproductive Tract Infections (RTIs) in Malawi. Malawi Med J. 2006;18(4):175-188.
7. Spence D, Melville C. Vaginal discharge. BMJ. 2007;335(7630):1147-1151. doi:10.1136/bmj.39378.633287.80
8. Bhatia S, Mosley WH, Faruque AS, Chakraborty J. The Matlab family planning-health services project. Stud Fam Plann. 1980;11(6):202-12.
9. Hawkes S, Morison L, Foster S, Gausia K, Chakraborty J, Peeling RW, et al. Reproductive-tract infections in women in low-income, low-prevalence situations: assessment of syndromic management in Matlab, Bangladesh. Lancet. 1999;354(9192):1776-81. doi: 10.1016/s0140-6736(99)02463-0.
10. Vlassoff C. Gender differences in determinants and consequences of health and illness. J Health Popul Nutr. 2007;25(1):47-61.
11. Caldwell B, Pieris I, Barkat-e-Khuda, Caldwell J, Caldwell P. Sexual regimes and sexual networking: the risk of an HIV/AIDS epidemic in Bangladesh. Soc Sci Med. 1999;48(8):1103-16. doi: 10.1016/s0277-9536(98)00417-1.
12. Bogaerts J, Ahmed J, Akhter N, et al. Sexually transmitted infections among married women in Dhaka, Bangladesh: unexpected high prevalence of herpes simplex type 2 infection. Sex Transm Infect. 2001;77(2):114-119. doi:10.1136/sti.77.2.114
13. Shethwala N, Mulla S. Study on reproductive tract infection among the female patients attending the gynecology OPD in a teaching hospitals of Gujarat India. Int J Med Sci Public Health. 2014;3(2):123. http://dx.doi.org/10.5455/ijmsph.2013.161020131
14. Onyekonwu CL, Olumide YM, Oresanya FA, Onyekonwu GC. Vaginal discharge: aetiological agents and evaluation of syndromic management in Lagos. Niger J Med. 2011;20(1):155-62.
15. Rossignol JF, Maisonneuve H, Cho YW. Nitroimidazoles in the treatment of trichomoniasis, giardiasis, and amebiasis. Int J Clin Pharmacol Ther Toxicol. 1984;22(2):63-72.
16. Bornstein J, Zarfati D. A universal combination treatment for vaginitis. Gynecol Obstet Invest. 2008;65(3):195-200. doi: 10.1159/000111946.
17. Sabir S. Hussan L. Outcome of syndromic management in case of chronic vaginal discharge. JPM. 2010; 24(03):234-8.
18. Kissinger P, Mena L, Levison J, Clark RA, Gatski M, Henderson H, et al. A randomized treatment trial: single versus 7-day dose of metronidazole for the treatment of Trichomonas vaginalis among HIV-infected women. J Acquir Immune Defic Syndr. 2010;55(5):565-71. doi: 10.1097/QAI.0b013e3181eda955.

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