ORIGINAL ARTICLE

Comparison of Intravaginal Versus Oral Metronidazole in the Treatment of Bacterial Vaginosis in Obstetrical Patients

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ABSTRACT

Aim: To compare intravaginal route of metronidazole and oral dosage of metronidazole for treatment in bacterial vaginosis (BV) of obstetrical patients.

Methods: In this randomized controlled trial, A total of 150 cases (75 in each group) were included in present study. The study was done at outpatient department of obstetrics and gynaecology, unit-ii, sir Ganga ram hospital, Lahore. Group-A participants were given an adequate treatment of oral metronidazole 400mg two times per day for a whole week and those in group-B were treated with intravaginal metronidazole gel 0.75% 5gms once daily for 5 days.

Results: Mean age was 31.9±1.8 and 32.7±3.1 year in group-A and B, respectively. Mean gestational age was 36.1±2.5 weeks in group-A while 35.9±1.9 weeks in group-B. Majority of the patients had parity between 0-2 in both groups. Oral metronidazole (Group-A) was effective in 64 patients (85.3%) and metronidazole intravaginal gel (group-B) in 67 patients (89.3%). Difference between two groups was not significant (P=0.461) (P=0.461).

Conclusion: It is concluded from present study, that metronidazole vaginal gel is more effective than oral dosage form of metronidazole required for proper treatment and cure of bacterial vaginosis, but apparently, there was no critical distinction seen among two groups. Its use is associated with good results and relief of symptoms of BV.

Keywords: Bacterial vaginosis, Intravaginal metronidazole gel, Oral metronidazole

INTRODUCTION

A polymicrobial clinical condition depicted by substitution of normally dominant lactobacilli by an overabundance of anaerobic life frames in the vagina is called Bacterial vaginosis (BV)[1,2]. It is the most surely understood usage of uncommon vaginal release in the regenerative of conceptive/regenerative age gathering[3,4]. General prevalance ranges from 11-48%[5]. Event/occurrence of BV in patients going to obstetrical focuses is 10-25%[2]. The causative living creatures consolidate Gardnerella vaginalis, Mycoplasma hominis and diverse anaerobes[6,7]. Atopobium vaginae is as of now seen as a pathogen related with BV[8].

Gardnerella vaginalis has for quite a while been the most broadly perceived pathogen related with BV. It has been represented to occur in upto 100% of women with signs and signs of BV and in upto 70% of women with no signs and reactions[2]. Every now and again women with BV are asymptomatic yet can have vaginal release, pruritis and rottenness (4). The perceived fishy smell is relied upon to trimethylamine. The investigation of BV relies on upon Amsel's criteria by finding 3 out of 4 of the going with: Homogenous white vaginal release, pH < 4.5, Whiff test, Clue cells[9]. The use of research office test in conjunction with clinical revelations is essential for the finish of BV. The Amsel's criteria for the assurance of BV is quick, strong and modest[10]. BV is regarded with antibacterial pharmaceuticals as metronidazole coordinated by oral or intravaginal highway[4].

A couple explore audits have differentiated oral and vaginal course of the metronidazole association and have gathered that there is no refinement between the relative feasibility of the two dosage forms as oral doses of metronidazole and intravaginal route of metronidazole for the cure of BV[4]. Nevertheless, as shown by one close-by audit intravaginal metronidazole is more fruitful for the treatment of BV and is connected with better consistence and less responses. Sufficiency of oral metronidazole for the treatment of BV has been represented to be 77% and that of intravaginal metronidazole 85%[11] in non-pregnant people. As shown by one research audit treatment with intravaginal metronidazole gel achieves 91% cure of ladies with bacterial vaginosis[12]. Another survey demonstrated assurance of bacterial vaginosis in 70% women after treatment with oral metronidazole[13].

There is a high transcendence of iron

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inadequacy[14], malnourishment and contamination in our obstetrical populace out of which bacterial vaginosis is a typical event.. There is no local study done in obstetrical patients for the treatment of bacterial vaginosis by different routes of metronidazole. Therefore, my study will help in establishing the better route of metronidazole in the treatment of bacterial vaginosis among our obstetrical patients.

MATERIALS AND METHODS

Using Randomized controlled trial the study was designed at Outpatient Department of Obstetrics and Gynaecology, Unit-II, Sir Ganga Ram Hospital, Lahore. Sample size of 150 cases (75 in each group) with 80% of test, 5% level of significance and taking expected percentage of efficacy in both groups i.e. 91% intravaginal metronidazole group versus 70% in oral group in the medication and cure of bacterial vaginosis in obstetrical patients. We used non-probability purposive sampling in our research study. Among all the pregnant women with gestational age 14-39 weeks assessed by ultrasound having 3 out of 4 of Amsel's criteria were included. Females with history of drug allergy to metronidazole and low-lying placenta as seen by ultrasound were excluded. After approval from hospital ethical committee, 150 patients attending the gynaecology outpatient department of Sir Ganga Ram Hospital fulfilling the inclusion criteria were included in the study. Informed consent was taken. They were divided into two groups of 75 patients each randomly by lottery method. One group was labeled as group-A and the other group was labeled as group-B. Demographic data i.e. patients name, age, parity, address was recorded. Group-A participants were given regimen with oral dose of metronidazole 400mg two times per day for a week and those belonging with group-B were treated with intravaginal route of metronidazole gel with dosage 0.75% 5gms onetime per day for five days. Follow-up was done after 2 weeks and outcome was measured in terms of clinical absence of homogenous white vaginal discharge. Measured in terms of absence of homogenous white vaginal discharge assessed clinically after 2 weeks of metronidazole treatment. Data was entered into SPSS version 20 and analyzed. The quantitative variables of study, i.e., age, gestational age was presented as mean and standard deviation The qualitative variable, i.e., efficacy was presented as frequency and percentages. The difference among qualitative variables (efficacy) in both sections was tested using Chi-square test. Probability of $P<0.05$ was being taken as significant in this procedure.

RESULTS

A total 150 cases were divided into two groups (A and B) 75 cases in each group were included in this study. Majority of the patients 27 (36.0%) in group-A and 26 patients (34.6%) in group-B were between 36-45 years of age. In group-A, minimum number of patients 8 (10.7%) and in group-B 11 patients (14.7%) were < 20 years old with Mean age was 31.9±1.8 and 32.7±3.1 year in group-A and B, respectively. Mean gestational age was 36.1±2.5 weeks in group-A while 35.9±1.9 weeks in group-B (Table-2). Majority of the patients had parity between 0-2 in both groups. Oral metronidazole was effective in 64 patients (85.3%) and metronidazole intravaginal gel (group-B) in 67 patients (89.3%). Difference between two groups was not significant (P=0.461).

Table-1: Distribution of patients by age

	Group-A (Oral Metronidazole)	**Group-B (Metronidazole gel)**
Age (years)	31.9±1.8	32.7±3.1
Gestational age (weeks)	36.1±2.5	**35.9±1.9**

Table 2: Comparison of intravaginal versus oral metronidazole in the treatment of bacterial vaginosis in obstetrical patients

Efficacy	**Group-A (Oral Metronidazole)**	**Group-B (Metronidazole gel)**
Yes	64(85.3%)	67(89.3%)
No	11(14.7%)	**8(10.7%)**
Total	75(100%)	**75(100%)**

Chi Square = 0.54 (p-value = 0.461)

DISCUSSION

Transmission of HIV and some other STDs is related to various obstetrical and gynaecological complications. Various factors for STD acquisition are hypothesized to be production of vaginal flore of women with BV due to lack of hydrogen peroxide, raised level of pH in vagina and also locally production of cytokine[15]. It has been found out in a cross-sectional research study that there is a quite certain link among seropositivity of Bacterial Vaginosis and HIV [16]. Seroconversion of HIV related with vaginal flora changes as found by planned researches. [17]. HIV transmission risk factors were shown, Cu-Uvin et al exhibited ladies infected with HIV and with BV were in a general sense more slanted to have strange measures of infections in genital tract specially lower part ,than ladies not with BV[18]. Cervical and vaginal diseases are sometimes found to be present with BV. Specially women

suffering from trichomoniasis are essentially at danger to be contaminated or infected with bacterial vaginosis[19]. An arranged audit shows, vaginal flora that was anamolous was linked with acquirement of trichomoniasis on gram's stain. Anamolous vaginal flora are related to some diseases of Neisseria gonorrhoeae and Chlamydia. In a cross-sectional research study of women setting off to a STD focus, lactobacilli were accessible in a general sense less women were affected with gonorrhea than uneffected women[20].

Antimicrobial drugs like metronidazole and clindamycin are at present most acceptable for cure of BV having therapeutic effects upto in up to 94%[21], however 40-80% announced reccurrence rates in preceding 6 months after treatment[22]. Oral and intravaginal routes can help regulate dosage of metronidazole and also clindamycin inquisitively. But in some cases anaerobic gram –ve and gram +ve cocci have shown resistance after intavaginal route[23].

According to the Center for Disease Control and Prevention (CDC) and the Guideline of Bacterial Vaginosis of the German Association for Gynecology and Obstetrics oral metronidazole should be taken 500 mg twice a day consistently for over a week. It may be applied intravaginally as a gel 0.75%. (5g) for consecutive five days [24]. Althought in some countries like Germany this Gel is not authenticated but still intravaginal utilization of metronidazole 500mg i9s prescribed mostly. In Germany a dosage of 2 g is prescribed by government opposed to CDC[25]. In present trail, metronidazole vaginal gel was convincing in 89.3% and oral metronidazole was practical in 85.3% of the patients. Hanson et al evaluated the reasonability and security of 0.75% metronidazole vaginal gel with oral metronidazole for the treatment of bacterial vaginosis (BV). As shown by their audit, the ampleness of 0.75% metronidazole vaginal gel in treating BV resembled that of oral metronidazole treatment. They reported that BV was clinically discarded in 83.7% of the intravaginal gathering and 85.1% of the oral gathering [26]. Results of Hanson et al[26] are comparable with our findings**.**

Hillier SL finished an exploration audit in the Department of Obstetrics and Gynecology, University of Washington, Seattle. In their survey, 87% of the women who got intravaginal 0.75% metronidazole were free of bacterial vaginosis[27]. This survey in like manner agree with our results.Ferris et al reported that there were no authentically basic differentiations in cure rates for oral metronidazole (84.2%), metronidazole vaginal gel (75%) in the treatment of bacterial vaginosis[28]. In a multicenter, pending, twofold blinded trial Livengood et al uncovered that after metronidazole treatment, 38 (78%) of 49 patients were cured at to start with, differentiated and 11(27%) of 41 fake treatment beneficiaries ($p < 0.001$). They suggested that intravaginal metronidazole is effective, secured, effortlessly endured, strong treatment for bacterial vaginosis[29]. Another inescapable audit was directed to take a gander at the cost-practicality of metronidazole versus Metrogel Vaginal in the treatment of bacterial vaginosis. The survey revealed that the most monetarily wise treatment for bacterial vaginosis was non particular metronidazole. While the usage of the all the more exorbitant Metrogel Vaginal may be sensible for patients experiencing side effects of oral metronidazole, most patients should be treated with the less expensive flat metronidazole[30]. Orally treated patients included 129 women (mean 36.2 years age) with dosage of 2g metronidazole compared with 134 patients (mean age =35.5 years) intravaginally 1 g metronidazole for 2 consecutive days. Following intravaginal application the treatment rate was 92.5%, for eight days ensuing to start the treatment, when appeared differently in relation to 89.9% after oral association. The engineers contemplated that the intravaginal dosage and treatment was as effective as the oral management of metronidazole in treating BV. Regardless, inside and out less negative events were represented after at this very moment intravaginal when stood out from oral dosage with probability =0.023 ($p = 0.023$)[31] all the above refered to studies are in simultaneousness with our discoveries.

CONCLUSION

It is concluded from present study, that metronidazole vaginal gel is more effective than oral metronidazole for the treatment of bacterial vaginosis, but no significant difference was observed between two groups. Its use is associated with good results and relief of symptoms of bacterial vaginosis. Hence it can be concluded from our study that vaginal gel for the drug metronidazole was found to be more therapeutically effective for cure of BV, but no critical distinction was noted between these groups. To achieve better treatment and relieve symptoms it is frequently used in clinical practices.

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