

A comparison of treatment outcomes for levofloxacin versus doxycycline plus metronidazole for first-line treatment of uncomplicated pelvic inflammatory disease



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ABSTRACT

Background: Pelvic inflammatory disease (PID), a common condition among women of reproductive age caused by various aerobic and anaerobic organisms, may sometimes lead to complications such as infertility, ectopic pregnancy, and chronic pelvic pain. Moxifloxacin is a broad-spectrum bactericidal acting against many Gram-positive, Gram-negative aerobic organisms and anaerobes. Rapid absorption and high bioavailability allow single daily dosing and improves compliance. **Aims and Objectives:** The present study was done to compare the treatment outcomes for levofloxacin versus doxycycline plus metronidazole for first-line treatment of uncomplicated in PID patients. **Materials and Methods:** This was hospital-based prospective, randomized, double-blind study conducted at gynecology outpatient department of Gouri Devi Institute of Medical Sciences and Hospital, Durgapur, West Bengal, from January 2019 to December 2019. The study group was divided into Group A 50 cases (receiving levofloxacin) and Group B 50 cases (receiving doxycycline plus metronidazole) were included in the study. Template was generated and analysis was done on SPSS software. **Results:** Among 50 patients of each group, mean age of the patients of Group A was 27.80 (± 3.58) and mean age of Group B was 27.57 (± 4.51). Mean parity of the patients of Group A was 1.93 (± 1.11) and mean parity of Group B was 2.07 (± 1.11). Past H/O PID in Group A was 17 and in Group B was 19. Visual analog scale (VAS) pain score of Group A was 3.80 (± 1.827) and VAS pain score of Group B was 3.97 (± 1.671). VAS pain score was 1.10 (± 0.960) in Group A and 2.63 (± 1.426) in Group B. VAS vaginal discharge was 1.40 (± 1.276) in Group A and 3.00 (± 1.619) in Group B. **Conclusion:** The management of uncomplicated PID requires broad-spectrum antibiotic regimens to cover all potential pathogens. This study confirmed that fluoroquinolones, specifically levofloxacin, are effective and well tolerated in the treatment of uncomplicated PID.

Key words: Doxycycline; Levofloxacin; Metronidazole; Pelvic inflammatory disease

INTRODUCTION

Pelvic inflammatory disease (PID) is a disease of the upper genital tract. It is a spectrum of infection and inflammation of the upper genital tract organs typically involving the uterus (endometrium), fallopian tubes, ovaries, pelvic peritoneum, and surrounding structures.¹

Despite better understanding of the etiology, pathogenesis, improved diagnostic tools such as sonar or laparoscopy and advent of wide range of antimicrobials, it still constitutes a health hazard both in the developed and more so in the developing countries.²⁻⁴ The incidence of pelvic infection is on the rise due to the rise in sexually transmitted diseases. The incidence varies from 1% to 2% per year among

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sexually active women. About 85% are spontaneous infection in sexually active females of reproductive age. The remaining 15% follow procedures, which favor the organisms to ascend up. Such iatrogenic procedures include endometrial biopsy, uterine curettage, insertion of intrauterine device (IUD), and hysterosalpingography.⁵

PID risk factors include douching single status substance abuse, multiple sexual partners, lower socioeconomic status, and recent new sexual partner(s) younger age (10–19 years). Other sexually transmitted infections with sexual partner are urethritis or gonorrhoea, previous diagnosis of PID, not using mechanical and/or chemical contraceptive barriers and endocervical testing positive for *Neisseria gonorrhoeae* or *Chlamydia trachomatis*.

Acute PID is usually a polymicrobial infection⁶ sexually transmitted and limited approximately to *N. gonorrhoeae* in 30%, *C. trachomatis* in 30%, and *Mycoplasma hominis* in 10%.⁷⁻¹⁰

Secondary organisms include aerobic organisms: Non-hemolytic *Streptococcus*, *Escherichia coli*, Group B *Streptococcus* and *Staphylococcus* and anaerobic organisms: *Bacteroides* species – fragilis and bivius, *Peptostreptococcus*, and *Peptococcus*.

Most cases of PID are presumed to occur in two stages. The first stage is acquisition of a vaginal or cervical infection. This infection is often sexually transmitted and may be asymptomatic. The second stage is direct ascent of microorganisms from the vagina or cervix to the upper genital tract, with infection and inflammation of these structures.

Although uncomplicated PID may be asymptomatic, if untreated it can lead to serious complications. Three principal complications of PID are chronic pelvic pain, infertility, and ectopic pregnancy.¹¹ Approximately 25% of patients with PID complain of chronic pelvic pain. Delayed diagnosis and treatment result in an incremental increase in the risks associated with PID, particularly for women with chlamydial infections. Repeated infections and inflammations may lead to adhesions and scarring of tubes, leading to infertility. Each successive episode of PID has been reported to 2-fold increased risk of tubal infertility. The risk of ectopic pregnancy is increased 15–50% in women with a history of PID.¹¹ Another serious complication of chronic PID is formation of tubo-ovarian abscess that may extend to produce pelvic peritonitis and Fitz-Hugh-Curtis syndrome (perihepatitis).^{12,13}

The current evidence suggests that adherence to clinical guidelines for PID diagnosis and management is less

than optimal. Interventions that make it easier to manage patients and provision of the entire treatment course to the patient at the time of evaluation improved compliance. Although outpatient treatment was described as being as effective as inpatient treatment in mild-to-moderate PID, compliance with antibiotic therapy for PID is poor, particularly in adolescents and in those receiving complex, prolonged treatment regimens.

The present study was done to compare treatment outcomes for levofloxacin versus doxycycline plus metronidazole for first-line treatment of uncomplicated PID.

Aims and objectives

The objective of the study is to compare treatment outcomes for levofloxacin versus doxycycline plus metronidazole for first-line treatment of uncomplicated PID and to compare the efficacy of tablet levofloxacin 500 mg OD PO for 14 days to that of tablet doxycycline 100 mg BD PO plus tablet metronidazole 500 mg BD PO for 14 days.

MATERIALS AND METHODS

Type of study

This was a prospective, randomized, and double-blind study.

Place of study

The study was conducted at the Department of Gynecology Gouri, Devi Institute of Medical Sciences and Hospital, Durgapur, West Bengal.

Period of study

The study period was from January 2019 to December 2019.

Study population

Subjects with an uncomplicated PID in the gynecology outpatient department of Gouri Devi Institute of Medical Sciences and Hospital, Durgapur, West Bengal.

Sample size

The sample size is calculated using proper statistical formula $n=4 pq/12$ p=prevalence of abnormal LFT in pregnancy 10% q=100-p.

After putting all this value in the above formula, my sample size was Group A 50 cases (receiving levofloxacin) and Group B 50 cases (receiving doxycycline plus metronidazole) after fulfilling the inclusion criteria were considered for the study. After collecting data, it was analysed with suitable statistical techniques and presented using different graphs, charts, and statistical tests (if any).

Inclusion criteria

Of the patients in the study group were based according to the CDC 2006 Clinical Diagnostic criteria of PID.

1. Lower abdominal tenderness. Adnexal tenderness
2. Cervical motion tenderness
3. Oral temperature $>38.3^{\circ}\text{C}$
4. Mucopurulent cervical or vaginal discharge. Raised C-reactive protein (CRP) and/or erythrocyte sedimentation rate (ESR)
5. Laboratory documentation of positive cervical infection with gonorrhoea or *C. trachomatis*.

Definitive criteria

1. Histopathologic evidence of endometritis on biopsy
2. Imaging study (transvaginal sonography/magnetic resonance imaging) evidence of thickened fluid filled tubes \pm tubo-ovarian complex.
3. Laparoscopic evidence of PID.

Exclusion criteria

The antenatal mother attending antenatal clinic in NRSMCH

1. Women who were pregnant or lactating
2. Those who had complicated PID (pelvic or tubo-ovarian abscess, diagnosed by pelvic)
3. Ultrasonography or by laparoscopic examination within 48 h before or 24 h after the start of therapy), those with any condition likely to require surgical intervention within 24 h of the start of treatment
4. Hypersensitivity to any study drug, related compound, or excipient
5. History of tendon disorders associated with quinolones
6. History of clinically relevant cardiovascular abnormalities
7. History of epilepsy
8. Defect in glucose-6-phosphate dehydrogenase
9. Patients who had received systemic antibacterial therapy 7 days before enrolment
10. History of uterine, pelvic, or abdominal surgery 30 days before treatment
11. Intolerance or inability to follow oral antibiotic regimen
12. Impaired liver function (Child-Pugh C) and/or transaminase levels more than 5 times the upper limit of normal
13. Impaired renal function (creatinine clearance 50 ml/min)
14. Neutropenia ($<1000/\text{mm}^3$)
15. Infection with human immunodeficiency virus.

Assessment period lasted for 6 weeks with the schedule of study visit as follows:

1. Pre-treatment (48 h preceding initiation of study drug)
2. During therapy (days 4–7)
3. Test of cure (TOC) (7–14 days after admission of study drug)
4. Follow-up (4–6 weeks after end of therapy).

Microbiological assessments were performed on endocervical, high vaginal swab specimens, and blood samples at the laboratory; culture and organism identification were performed 48 h after start of therapy and at TOC and follow-up visits. The clinical cure was assessed by visual analog score (VAS), temperature, white blood cell (WBC) count, ESR, and CRP. The bacteriological cure was assessed by high vaginal swab for organism identification by Gram stain, 10% KOH, and blood sample by ELISA.

Statistical analysis

The softwares used were Statistica version 6 (Tulsa, Oklahoma: StatSoft Inc., 2001) and GraphPad Prism version 5 [San Diego, California: GraphPad Software Inc., 2007]. Comparison of numerical variables between the two groups was done by Student's unpaired t-test and Mann-Whitney U-test and categorical variables was done using Fisher's exact test two-tailed test. $P \leq 0.05$ was considered to be statistically significant. $P \leq 0.05$ was considered for statistically significant.

Ethical clearance

The study was conducted after obtaining written approval from the Institutional Ethics Committee. Written informed consent will be taken from every study patient or their logical representative.

RESULTS

A hospital-based prospective, randomized, and double-blind study was undertaken comparing the efficacy of tablet levofloxacin 500 mg OD PO for 14 days to that of tablet doxycycline 100 mg BD PO plus tablet metronidazole 500 mg BD PO for 14 days in 100 subjects with an uncomplicated PID in the gynecology outpatient department of Gouri Devi Institute of Medical Sciences and Hospital, Durgapur, West Bengal, from January 2019 to December 2019 with due permission from the Institutional Ethical Committee and consent from the patient. The study group was divided into Group A 50 cases (receiving levofloxacin) and Group B 50 cases (receiving doxycycline plus metronidazole). A predesigned and pretested pro forma was used to collect all data.

Clinical response 14 days after completion of study was evaluated. Clinical cure was defined as: Reduction of pain score (Mankoski Pain Scale), a pyrexia (rectal/oral temperature value $<38.0^{\circ}\text{C}$), WBC count $<10,500/\text{cc}$, negative culture tests for *N. gonorrhoeae* and *C. trachomatis*, imaging evidence of reduction of size of tubo-ovarian complex.

Mean age of the patients of Group A was 27.80 (± 3.58) and mean age of Group B was 27.57 (± 4.51). Mean parity

of the patients of Group A was 1.93 (± 1.11) and mean parity of Group B was 2.07 (± 1.11). Past H/O PID in Group A was 17 and in Group B was 19 (Table 1).

VAS pain score of Group A was 3.80 (± 1.827) and VAS pain score of Group B was 3.97 (± 1.671). VAS vaginal discharge of Group A was 5.77 (± 1.331) and VAS vaginal discharge of Group B was 5.70 (± 1.264). VAS malaise in group was 1.90 (± 1.863) in Group A and 1.90 (± 1.863) in Group B. VAS dyspareunia was 0.80 (± 1.627) in Group A and 0.90 (± 1.539) in Group B. VAS backache was 0.87 (± 1.224) in Group A and 0.90 (± 1.155) in Group B (Table 2).

In the above table, VAS pain score was 1.10 (± 0.960) in Group A and 2.63 (± 1.426) in Group B. VAS vaginal discharge was 1.40 (± 1.276) in Group A and 3.00 (± 1.619) in Group B. VAS malaise was 0.27 (± 0.521) in Group A and 1.67 (± 1.561) in Group B. VAS dyspareunia was 0.30 (± 0.988) in Group A and 0.43 (± 0.898) in Group B. VAS

backache was 0.20 (± 0.484) in Group A and 0.57 (± 0.858) in Group B (Table 3).

Nausea in Group A was 5 (10%) and Group B, it was 22 (44%) which was statistically significant. Vomiting, flatulence, dyspepsia, and metallic taste Group A were not found and in Group B, it was 6 (12%), 3 (6%), 3 (6%), and 17 (34%), respectively. Diarrhea in Group A was 2 (4%) and in Group B was 14 (28%) which was statistically significant. Pain abdomen in Group A was 5 (10%) and in Group B was 7 (14%). Headache was found 3 (6%) in Group A and 10 (20%) in Group B (Table 4).

DISCUSSION

The aim of this study was to compare the efficacy and safety of levofloxacin, a new fluoroquinolone, used

Table 1: Baseline characteristics

Characteristics	Group A (n=50)	Group B (n=50)	P-value
Mean age (\pm SD) years	27.80 (± 3.58)	27.57 (± 4.51)	0.825
Mean parity (\pm SD)	1.93 (± 1.11)	2.07 (± 1.11)	0.644
BMI (\pm SD) kg/m ²	23.17 (± 4.12)	22.93 (± 3.96)	0.824
History of IUD use	7	7	1.000
Past H/O PID	17	19	0.792

PID: Pelvic inflammatory disease

Table 2: Baseline disease characteristics

Disease characteristics	Group A (n=50)	Group B (n=50)	P-value
VAS pain score	3.80 (± 1.827)	3.97 (± 1.671)	0.796
VAS vaginal discharge	5.77 (± 1.331)	5.70 (± 1.264)	0.894
VAS malaise	1.90 (± 1.863)	1.90 (± 1.863)	1.000
VAS dyspareunia	0.80 (± 1.627)	0.90 (± 1.539)	0.695
VAS backache	0.87 (± 1.224)	0.90 (± 1.155)	0.745
CRP value (\pm SD)	7.13 (± 1.74)	6.43 (± 1.22)	0.076
ESR (\pm SD)	15.97 (± 9.29)	14.37 (± 7.21)	0.459
Mean WBC \pm SD (10 ⁹ /L)	7.153 (± 2.339)	7.471 (± 2.091)	0.581
Presence of clue cell (%)	6 (12)	6 (12)	1.000
Positive Whiff test (%)	10 (20)	10 (20)	1.000
Pus cell	2.3 (± 2.103)	2.27 (± 2.033)	0.906
Bacterial infection*			
Gram positive			
Diplococci (%)	13 (26)	12 (24)	-
Gram-negative rods (%)	18 (36)	20 (40)	-
Gram negative Coccobacilli (%)	17 (34)	19 (38)	

*Bacterial infection proven by Gram stain, culture, or ELISA, CRP: C-reactive protein

Table 3: Therapeutic response between the two groups

Disease characteristics	Group A (n=50)	Group B (n=50)	P-value
VAS pain score	1.10 (± 0.960)	2.63 (± 1.426)	0.000
VAS vaginal discharge	1.40 (± 1.276)	3.00 (± 1.619)	0.000
VAS malaise	0.27 (± 0.521)	1.67 (± 1.561)	0.000
VAS dyspareunia	0.30 (± 0.988)	0.43 (± 0.898)	0.506
VAS backache	0.20 (± 0.484)	0.57 (± 0.858)	0.079
CRP value (\pm SD)	4.13 (± 0.973)	5.07 (± 0.980)	0.076
ESR (\pm SD)	11.50 (± 4.47)	11.83 (± 4.29)	0.459
Mean WBC \pm SD (10 ⁹ /L)	6.147 (± 1.814)	7.405 (± 2.139)	0.581
Presence of clue cell (%)	0	1 (2)	1.000
Positive Whiff test (%)	0	1 (2)	1.00
Pus cell	0.40 (± 0.675)	0.87 (± 1.008)	0.121
Bacterial infection*			
Gram positive			
Diplococci (%)	5 (10)	9 (18)	0.360
Gram-negative rods (%)	5 (10)	10 (20)	0.233
Gram negative Coccobacilli (%)	6 (12)	13 (26)	0.094

*Bacterial infection proven by Gram stain, culture, or ELISA, CRP: C-reactive protein

Table 4: Comparison of drug-related side effects between the groups

Drug side effects	Group A (n=50)	Group B (n=50)	P value
Nausea	5 (10)	22 (44)	<0.001
Vomiting	0	6 (12)	0.024
Flatulence	0	3 (6)	0.237
Dyspepsia	0	3 (6)	0.237
Metallic taste	0	17 (34)	<0.001
Diarrhea	2 (4)	14 (28)	<0.001
Pain abdomen	5 (10)	7 (14)	0.748
Headache	3 (6)	10 (20)	0.057

as monotherapy, with a first-line dual combination of doxycycline plus metronidazole. This is one of the few studies in women with PID to compare these two regimens. Only women with uncomplicated PID were recruited into this study. Diagnosis was based on clinical and laboratory criteria. There were no significant differences between treatment groups in demographic characteristics. The baseline disease characteristics including history of previous PID were similar between groups and indicated a population with signs and symptoms of relatively mild-to-moderate PID.

Mean age of the patients of Group A was 27.80 (± 3.58) and mean age of Group B was 27.57 (± 4.51). Mean parity of the patients of Group A was 1.93 (± 1.11) and mean parity of Group B was 2.07 (± 1.11). Past H/O PID in Group A was 17 and in Group B was 19.

The incidence of IUD usage between the two groups was also not significant between the groups.

Compliance in the treatment policy was 100% in both groups without any dropout. Baseline characteristics such as age, parity, and BMI were comparable between the two groups. A history of PID and history of IUD use were also similar.¹⁴

VAS pain score of Group A was 3.80 (± 1.827) and VAS pain score of Group B was 3.97 (± 1.671). VAS vaginal discharge of Group A was 5.77 (± 1.331) and VAS vaginal discharge of Group B was 5.70 (± 1.264). VAS malaise in group was 1.90 (± 1.863) in Group A and 1.90 (± 1.863) in Group B. VAS dyspareunia was 0.80 (± 1.627) in Group A and 0.90 (± 1.539) in Group B. VAS backache was 0.87 (± 1.224) in Group A and 0.90 (± 1.155) in Group B.

Heystek and Ross reported a clinical cure rate of 81.5% in women treated with moxifloxacin versus 83.2% in those treated with the comparator regimen.¹⁵

Nausea in Group A was 5 (10%) and Group B, it was 22 (44%) which was statistically significant. Vomiting, flatulence, dyspepsia, and metallic taste Group A were not found and in Group B, it was 6 (12%), 3 (6%), 3 (6%), and 17 (34%), respectively. Diarrhea in Group A was 2 (4%) and in Group B was 14 (28%) which was statistically significant. Pain abdomen in Group A was 5 (10%) and in Group B was 7 (14%). Headache was found 3 (6%) in Group A and 10 (20%) in Group B. Judlin et al., in MONALISA study, showed similar response.¹⁶

Although pathogens were isolated from a relatively low number of women, the absence of infection from the endocervix does not exclude a diagnosis of PID. Diagnosis

is based on clinical findings and all women included in the study met minimal criteria of the United States Centers for Disease Control for the diagnosis of PID (lower abdominal tenderness, bilateral adnexal tenderness, and cervical motion tenderness).^{14,17}

Hence, while the microbiological data did not confirm the presence of a causative organism, clinical signs were strongly suggestive of a diagnosis of PID.

Limitations of the study

The limitation of our present study is that the sample size was small. Only 50 cases are not sufficient for this kind of study. The study has been done in a single center. Therefore, further studies should be conducted with bigger sample sizes and hospitals in rural and urban area.

CONCLUSION

The management of uncomplicated PID requires broad-spectrum antibiotic regimens to cover all potential pathogens. The combination of doxycycline and metronidazole is often used as first-line therapy. However, the clinical response rate is not always satisfactory. There is always scope of more effective drug. This study confirmed that fluoroquinolones, specifically levofloxacin, are effective and well tolerated in the treatment of uncomplicated PID.

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ETHICAL APPROVAL

The study was approved by the Institutional Ethics Committee.

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Author's Contribution:

RD and SB- Involved in the diagnosis and management of the cases; **KKP and AG-** Did the literature search; **RD, KKP and BM-** Wrote the manuscript.

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