

**ORIGINAL RESEARCH**

# Azithromycin vs Levofloxacin: An empirical use for the respiratory tract infection at the out patient department of medicine in a tertiary care hospital

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**ABSTRACT**

**Background:** Patients with Respiratory tract infections were one of the most common infectious cases presents to the Out Patient Department of Medicine in any Health Institutions. **Objective of the study:** To assess the efficacy and tolerability of Azithromycin and Levofloxacin for Respiratory Tract Infections. **Materials and methods:** This is a prospective observational study where 100 patients attending Medicine OPD at GIMS, Kalaburagi with Respiratory Tract Infections were taken in the study. Their demographic details, clinical assessment details, prescription details and any lab investigation details (optional) were recorded in the Case Record Form (CRF). **Results:** In this study, 54 female participated compared to 46 male patients. More number of patients were from 18-49 years age group (n=46). On day 3, azithromycin (n=14) and Levofloxacin (n=19) had cough whereas 22 patients had fever in azithromycin compared to levofloxacin (n=27). Azithromycin (n=32), levofloxacin (n=42) still had sore throat. On day 3, azithromycin group (n=18) and levofloxacin group (n=29) patients still had one or more symptoms (cough, fever, sore throat, running nose or breathlessness), significantly more in levofloxacin group. **Conclusion:** In this study, Azithromycin showed slightly better efficacy and tolerability than Levofloxacin for Respiratory Tract Infections in out-patients.

**Keywords:** Azithromycin, Levofloxacin, Respiratory tract infections

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**INTRODUCTION**

Patients with Respiratory tract infections were one of the most common infectious cases presents to the Out Patient Department of Medicine in any Health Institutions. Respiratory tract infections were one of the most common public health problems occurring in day to day life at all age groups and in all seasons. It causes huge economic losses to the public health in terms of cost and man labour. Respiratory tract infections were divided into upper respiratory tract infections (URTI) and lower respiratory tract infections (LRTI). URTI include common cold pharyngitis, sinusitis, and tracheobronchitis. LRTI include bronchitis, pneumonia, and various viral lower respiratory track inspections. Many groups of antibiotics were used for Respiratory tract infections in different hospitals even different physicians uses different class of antibiotics for the same Respiratory tract infection. Respiratory Tract Infections include

Upper Respiratory Tract Infections & Lower Respiratory Tract Infections. Patients commonly present with cough that may be productive or non productive, fever, breathlessness, sore throat, running nose, headache and altered sensorium.<sup>1</sup> Some of the classes of antibiotics used were Macrolides, Fluoroquinolones, Penicillins, Cephalosporins, Glycopeptide Antibiotics, Tetracyclines, Monobactams, Carbapenems etc. Azithromycin belongs to Macrolide group of antibiotics and it acts by inhibiting protein synthesis by binding to 50s Ribosomal Subunit. They were bacteriostatic agents effective against *S. pneumoniae*, *H. influenzae* & atypical pathogens. Levofloxacin is a Fluoroquinolone antibiotic acts by inhibiting Bacterial DNA Gyrase and Topoisomerase IV. They were effective against *S. pneumoniae*, *H. influenzae* & *M. catarrhalis*. Fluoroquinolones were now commonly being used as single agents in Community Acquired Pneumonia. So

either a newer Fluoroquinolone like Levofloxacin or a Macrolide like Azithromycin is the antibiotic of choice for Respiratory tract infections.<sup>2,3,4</sup>

Usually Prescribers do not follow any standard antibiotic guidelines for Respiratory Tract Infections. Many health professionals were overprescribing for Upper Respiratory Tract Infections as well as Lower Respiratory Tract Infections.<sup>5, 6</sup> These antibiotics were many a times used inappropriately and irrationally, leading to antibiotic resistance, increased health cost, increased adverse effects and patient non-compliance.<sup>7-9</sup> Rational use of selective antibiotic is essential in upper Respiratory tract infections for shorter visit duration of patients to health setups, decreasing health expenses.<sup>10,11</sup> In some self limiting Respiratory Tract Infections like viral, there is no need to prescribe antibiotics but then also it is commonly prescribed.<sup>12-14</sup> By increasing the clinical data on commonly used antibiotics like Azithromycin and Levofloxacin in Respiratory tract infections we can guide and recommend antibiotics in the use of Respiratory tract infections for rational use.<sup>15</sup> In many studies efficacy of Azithromycin is seems to be equivalent to Levofloxacin or Moxifloxacin for chronic bronchitis and community acquired pneumonia.<sup>16-18</sup>

Azithromycin & Levofloxacin were one of the commonly prescribed antibiotics for the Respiratory tract infections as prophylactic or therapeutics purposes. But we don't have much clinical data regarding the efficacy of these two antibiotics in Respiratory tract infections in India. Hence, the study to assess the empirical use of Azithromycin v/s Levofloxacin in Respiratory tract infections for out-patients in Medicine OPD was undertaken.

#### AIMS AND OBJECTIVE

To assess the efficacy and tolerability of Azithromycin and Levofloxacin for Respiratory Tract Infections in the out-patients of Medicine Department in a tertiary care hospital.

#### MATERIALS AND METHODS

**Source of Data:** OPD Patients attending Medicine Department, GIMS, Kalaburagi

**Study Design:** Prospective observational based study.

**Study Period:** Study will be conducted over a period of One Month.

#### INCLUSION CRITERIA

1. Patients with respiratory tract infections diagnosed by physicians.
2. Out-Patients willing to participate in study and giving informed consent.
3. Patients above 18 years of age.

#### EXCLUSION CRITERIA

1. Patients admitted in the Hospital (In-Patients)
2. Patients on Anti Tubercular Drugs and Anti Retroviral Drugs

3. Patients with other systemic infections
4. Patients receiving any parenteral medications.

#### METHODS OF COLLECTION OF DATA

After taking Institutional Ethics Committee (IEC) approval on 12/10/2023, a total number of 100 patients attending Medicine OPD at GIMS, Kalaburagi with Respiratory Tract Infections and giving informed consent were taken in the study.

Their demographic details, clinical assessment details, prescription details and any lab investigation details (optional) were recorded in the Case Record Form (CRF). Follow-up of the patients were done for evaluation according to the course of the treatment. Method of follow up of patients was done by asking patients to visit on the respective days ( 3, 5 and 7th) or by calling the patients over phone and recording information. Medicine were provided in our college pharmacy, free of cost. If medicine not available, researcher will bear the cost of the treatment.

#### STATISTICAL ANALYSIS

Descriptive statistics and other suitable statistical tests were used for analysis of data.

#### RESULTS

A total of 100 patients attending medicine OPD were taken for the study. Table 1 shows the demographic details of the study. In this study, 54 female participated compared to 46 male patients. More number of patients were from 18-49 years age group (n=46). Patients in both the antibiotics group shows nearly equal distribution in age group and gender except in age group 65-79, which shows 16 patients in azithromycin and 11 patients in levofloxacin.

**Figures 1-5** shows bar charts describing effects of study drugs on various symptoms (cough, fever, sore throat, running nose, breathlessness) from the time of initiation of therapy (day-1) to the end of treatment.

**Figure 1** shows decrease in incidence of cough from day-3 in both the group. On day 5, Only 7 patients had cough in levofloxacin group and 2 patients in azithromycin group. **Figure 2** shows 22 patients had fever in azithromycin compared to levofloxacin (n=27) at day 3. Till day 5, almost all patients got relieved of fever in both the groups. **Figure 3** shows the incidence of sore throat. All patients had sore throat on day1, which persist in azithromycin (n=32) but less, comparatively than levofloxacin (n=42) on day 3. On day 7, 5 patients in azithromycin and 9 patients in levofloxacin still complained of sore throat. **Figure 4** shows azithromycin group (n=28) and levofloxacin group (n=31) patients having running nose on day 3. On day 5, higher number of patients in levofloxacin group (n=19) still had running nose, which got resolved till day 7. **Figure 5** shows the effect of both the study drugs on breathlessness of the patients which was present in all subjects on day 1, but shows significant decrease in incidence,

azithromycin group (n=12) and levofloxacin group (n=14) at day 3 itself.

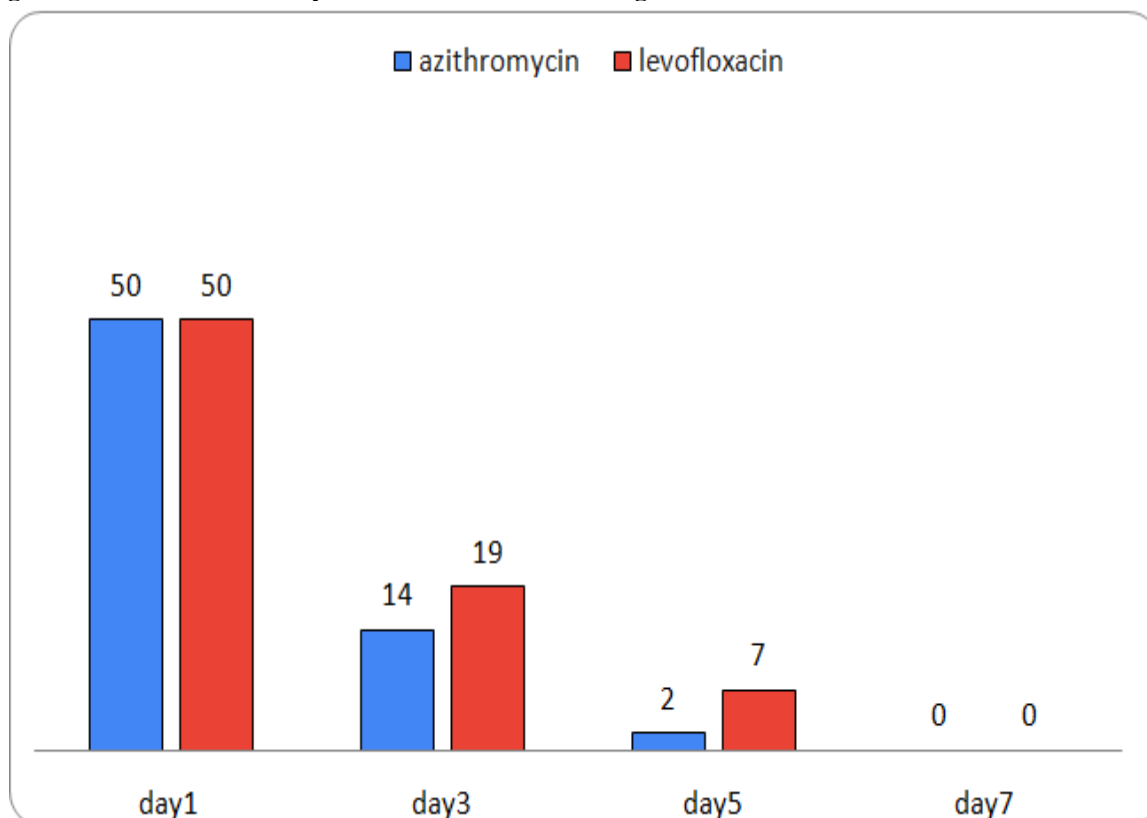
**Figure 6** shows overall patients left with symptoms after treatment on respective day. On day 3, azithromycin group (n=18) and levofloxacin group (n=29) patients still had one or more symptoms (cough, fever, sore throat, running nose or

breathlessness), significantly more in levofloxacin group. But till day 5, only 6 patients in azithromycin group and 9 patients in levofloxacin group had one or more symptoms. On day 7, all the study subjects were free of any symptoms in both the azithromycin and levofloxacin groups except few patients (5 in azithromycin, 9 in levofloxacin) still had sore throat.

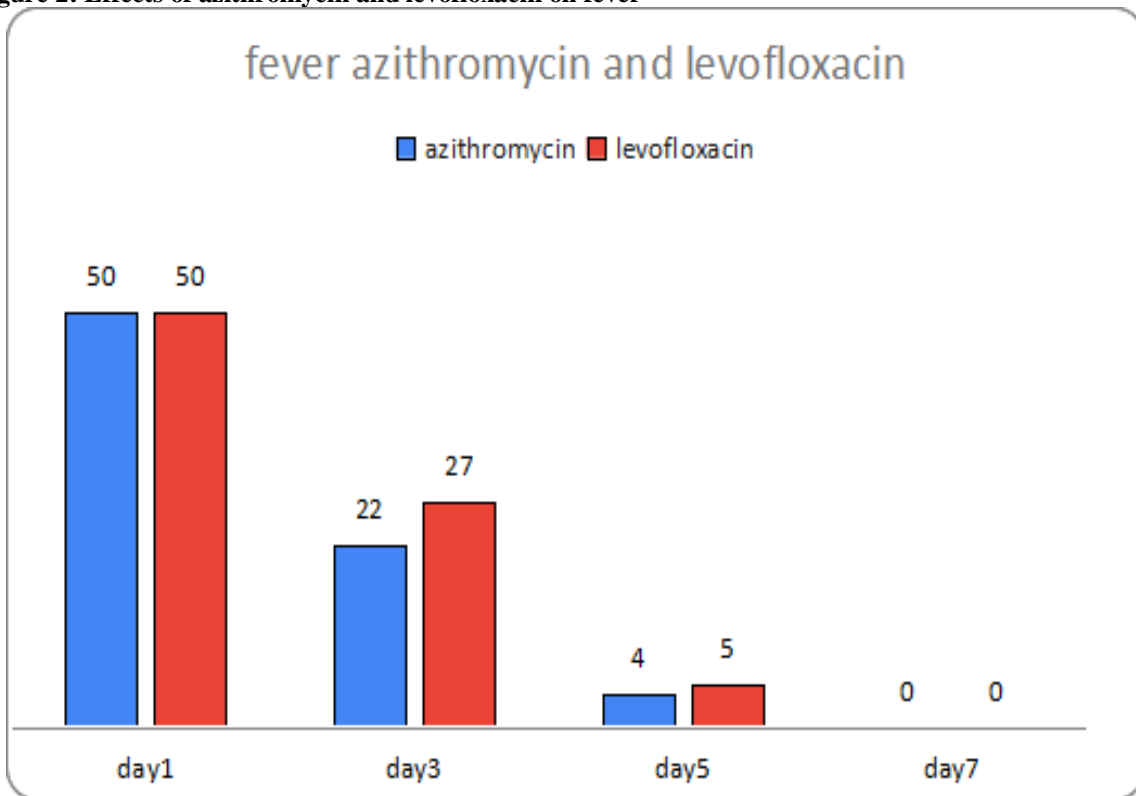
**Table 1: Age and Gender distribution**

AGE GROUP	NUMBER OF PATIENTS	GENDER (M-46, F-54)	AZITHROMYCIN	LEVOFLOXACIN
AGE 18- 49	46	MALE – 18 FEMALE- 28	23 (M –10, F-13)	23 (M –8, F-15)
AGE 50-64	23	MALE –9 FEMALE-14	10 (M –4, F-6)	13(M –5, F-8)
AGE 65-79	27	MALE –16 FEMALE-11	16 (M –11, F-5)	11 (M –5, F-6)
AGE > 80	4	MALE –3 FEMALE-1	1 (M –0, F-1)	3 (M –3, F-0)
TOTAL	100	100	50	50

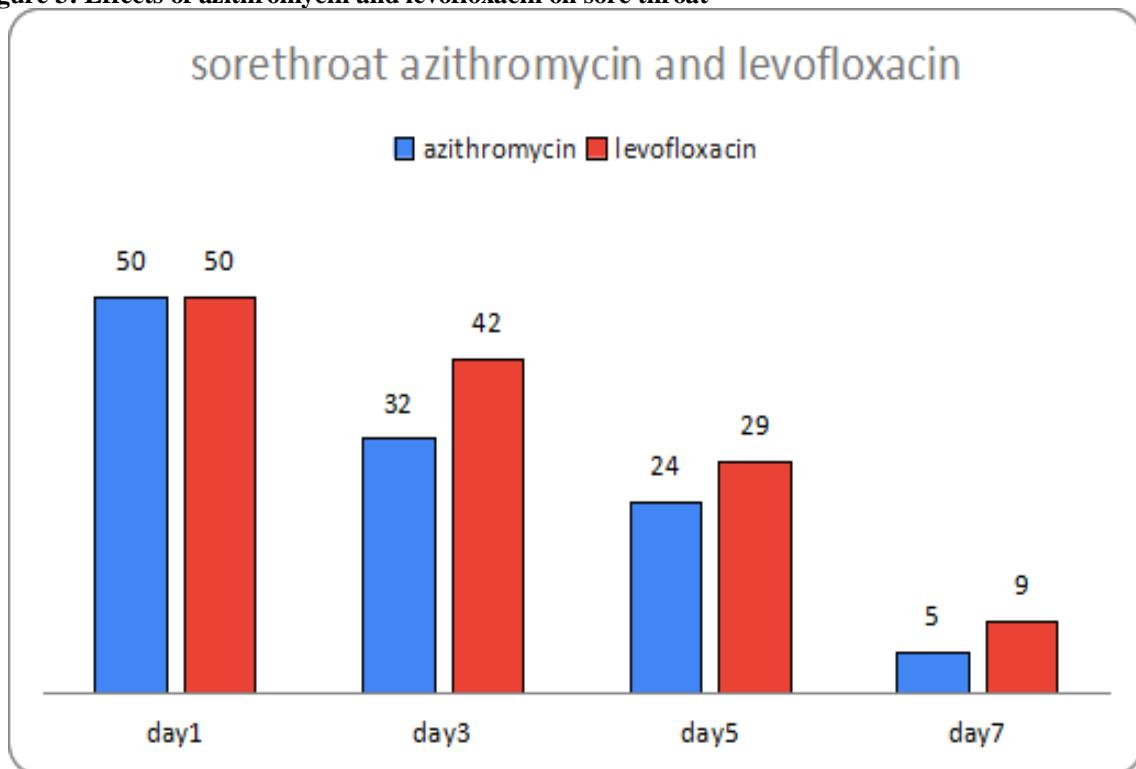
**Figure 1: Effects of azithromycin and levofloxacin on cough**



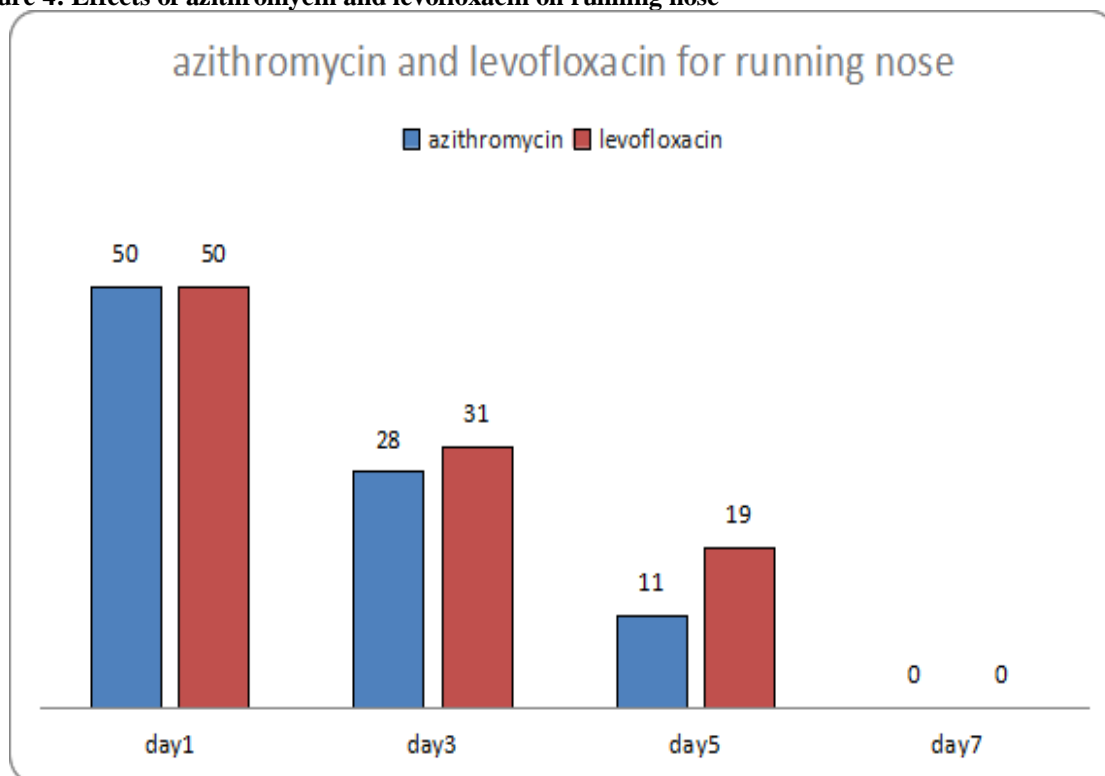
**Figure 2: Effects of azithromycin and levofloxacin on fever**



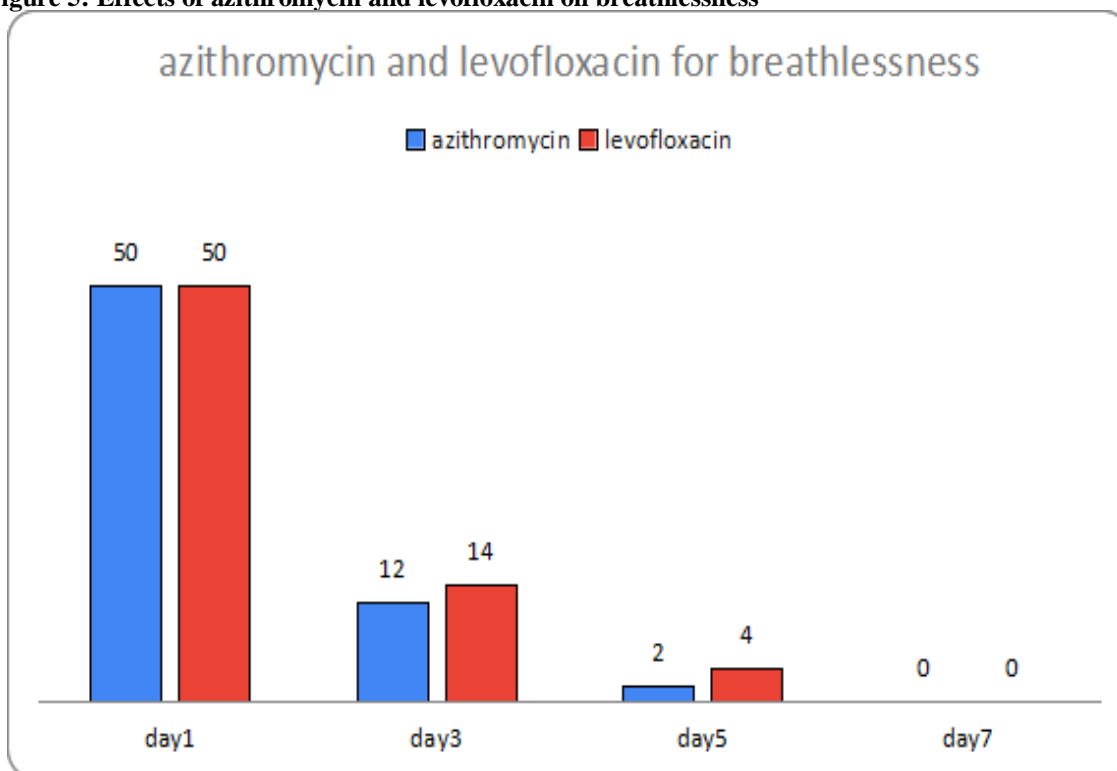
**Figure 3: Effects of azithromycin and levofloxacin on sore throat**

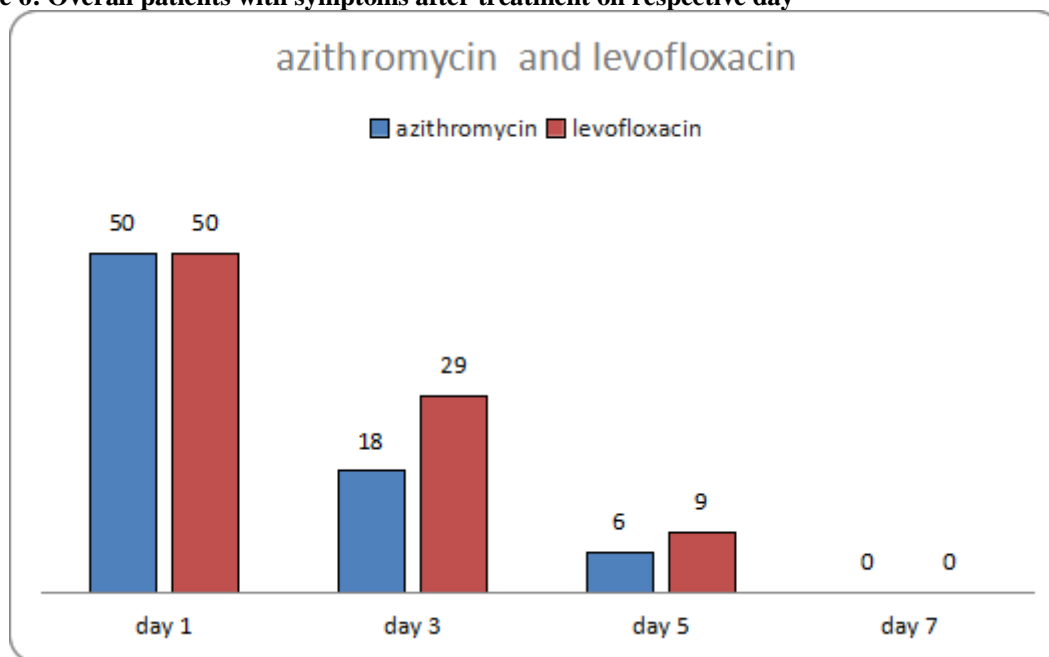


**Figure 4: Effects of azithromycin and levofloxacin on running nose**



**Figure 5: Effects of azithromycin and levofloxacin on breathlessness**



**Figure 6: Overall patients with symptoms after treatment on respective day****DISCUSSION**

Azithromycin and levofloxacin were one of the commonly prescribed medicine for mostly upper respiratory tract infection, where as pencillin group of drugs were common in the study by Kokani VR.et al<sup>7</sup>. In our study, azithromycin 200mg BD for 5 days and levofloxacin 500mg BD for 7 days is used as in the similar study by Amsden GW et al<sup>17</sup>. In our study cough, fever, sore throat, running nose and breathlessness symptoms were taken into consideration to assess the effectiveness of the study drugs. Patients were given instructions about the dosing of drugs and asked to report about the symptoms present and severity on day 3, 5 and 7 by person or call. Patients were also told to report adverse effects if any.

In this study, female participants were more in number. Age group wise patients distribution is nearly equal in both azithromycin and levofloxacin study groups. In this study, cough and breathlessness subsides on day 3 itself in maximum patients while fever, sore throat and running nose persist in both the study groups but more in levofloxacin group. On day 5, many patients were left with sore throat (more in levofloxacin group), few with running nose (more in levofloxacin group) and nearly all were cleared of rest of symptoms. On day 7, few subjects had only sore throat without other symptoms, again more in levofloxacin group.

In this study, azithromycin shows significant decrease in various symptoms of the respiratory tract infection than levofloxacin starting from day 3 itself as shown in Fig:6 as in contrast to the study by . Martinez FJ et al.<sup>19</sup>On day 5, azithromycin cleared symptoms of almost all the patients of respiratory tract infections compared to levofloxacin, showing better efficacy, similar to the study by Amsden GW et al.<sup>17</sup>

In this study, few patients reported adverse effects, which were more in number in levofloxacin group compared to azithromycin group. Anoxeria and itching were the common adverse effects reported in azithromycin group while headache, nausea and vomiting were common adverse effects with levofloxacin group.

The limitations of our study were 1. Small sample size, 2. Short data collection period (1 month), 3. complete micro organisms testing by culture and antibiotic spectrum analysis is not done in all subjects.

**CONCLUSION**

In this study, Azithromycin showed slightly better efficacy and tolerability than Levofloxacin for Respiratory Tract Infections in out-patients.

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**Conflict of interest:** none declared

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