

# A Prospective Study of Antibiotics Uses for Lower Respiratory Tract Infections in A Tertiary Care Hospital

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## Abstract

Drug utilization study plays an important role in identifying the prescription pattern among the patients which helps in providing useful information for improvement of the appropriate and effective use of antibiotics and also developing the proper protocols for the use of antibiotic in hospitals. Thus, a prospective study was conducted to analyze the antibiotics use for lower respiratory tract infections in department of general medicine at Integral Institute of Medical Science and Research. A prospective observational study was carried out in general medicine department over a period of 6 months enrolling 100 patients which included the evaluation of the patient's medical records of antibiotics and physician records. A majority of patients with the lower respiratory tract infections (70%) were in the age group of 41-60 years with higher number of male patients as compared to female patients. Azithromycin (33.16%) was the mostly prescribed antibiotic followed by combination of amoxicillin plus clavulanic acid (25.91%). Several adverse drug reactions were reported. The present study gives an overview of antibiotics use and complications involved in the patient with lower respiratory tract infections. It will be helpful to future clinical pharmacists and clinicians for the rational use of antimicrobials and also minimizing the antibiotic resistance.

**Keywords:** Lower Respiratory Tract Infections; Drug Utilization; Antibiotics; Prospective Observational Study.

## Introduction

Lower respiratory tract infections (LRTIs) are infections in the lungs or below the voice box. These include pneumonia, bronchitis, chronic obstructive pulmonary disease and tuberculosis [1]. LRTIs are the leading infectious disease and cause of death in the world and also the fifth cause of death. Old people have an increased risk of developing LRTIs compared to young adults [2]. Acute bronchitis is usually caused by a viral infection where chronic bronchitis is more serious. It keeps coming back or doesn't go away. Both viral and bacterial pneumonia are contagious [3]. Smoking, chronic medical illness, previous antibacterial therapy, physical decline, asthma, chronic obstructive pulmonary disease or other breathing conditions and long-term bedridden conditions are risk factors for LRTIs in this popula-

tion [4,5]. One of the major causes of the growing LRTIs burden is increasing antimicrobial resistance. Streptococcus pneumonia, Clamidia pneumonia, Staphylococcus aureus and other bacterial pathogens remain the common causes of LRTIs [6]. Antibiotics are the oldest class of drugs that fight against specific micro-organisms like bacteria and fungi. Most commonly used types of antibiotics are penicillin, cephalosporins, fluoroquinolones, tetracycline and macrolide.

Antibiotics used in LRTIs can treat or prevent some types of bacterial infections which enhance the effectiveness of treatment of LRTIs. There is also need of study because over-prescribing of antibiotics in primary care has major impact on the development of antibiotics resistance as well as increase in the total

cost of treatment. It is necessary to conduct drug utilization of antibiotics which helps in better understanding about errors and risks involved in prescriptions and also helps to know about if a bacterium is resistance to some antibiotics then which antibiotics or combination of antibiotics are used to treat infection [7]. There are more effective drugs today on the market than ever before. Patients are better educated, have greater expectations from health care, and they use multiple sources of health care. Still, drugs are not frequently used to their full potential or according to the generally accepted criteria. Consequently, there is as much concern about inappropriate and expensive prescribing, as about under-prescribing which increases burden of cost of therapy and also causes loss of working hours [8].

In the recent years, studies on drug utilization have become a potential tool to be used in the evaluation of health systems. Drug utilization among outpatient is frequently monitored in many countries but the studies on in-patients are rare and incomplete. Studies of drug utilization in respiratory tract infections are also low. The development of drug utilization as a research area made it possible to study drug prescribing and drug usage in a scientific and formal manner. Thus, aim of the study was designed to analyze the antibiotics use for lower respiratory tract infections in department of general medicine at Integral Institute of Medical Science and Research.

## Materials and Methods

The study was designed to analyze the antibiotics use for lower respiratory tract infections in department of general medicine at Integral Institute of Medical Science and Research with the

### objectives

- To identify the adverse drug reactions (ADRs) for patients suffering from lower respiratory tract infection in tertiary care
- To assess the cost analysis of antibiotics
- To assess the most commonly prescribed antibiotics in general practices of LRTIs in medicine department at Integral institute of medical sciences and research, Integral University.
- To provide effective management suggestions based on the study results for improved health care in LRTIs patients.

A Prospective observational based study was performed at Integral Institute of Medical Sciences and Research, Lucknow, Uttar Pradesh, India. 100 patients were participated in the study which was carried out for a period of 6 months. Oral and written consents were obtained on consent forms from parents before the participation of the subjects in the study.

### Patients Were Selected on The Basis of Set Criteria Mentioned Below-

#### Inclusion criteria

- All the patients, irrespective of the age, sex attending the pediatric and medicine OPD and IPD were included in the study.
- Patients who were diagnosed with LRTIs.

#### Exclusion criteria

- Patients who were not treated with antibiotics.
- Patient who were unable to comply.

- Patients who were mentally challenged and unconscious.
- Pregnant and lactating women.

## Sources of Data and Data Collection

Physicians prescribing records and Patient's medication profile were the sources of data. The data collection form was designed as per the requirements of the study. The data collection form included age, weight, sex, patient address, drug (generic/brand name) received by patients, their dosage, frequency of drugs, ADR related to antibiotics prescribed, and open-ended questions to gather additional information. Data was collected through a review of case sheets in the inpatients/outpatients of the general medicine department at Integral institute of medical sciences and research [9-11].

## Evaluation of set parameters

The data was compiled and analyzed as per need of the study. The parameters which were evaluated were –

Gender distribution of the study subjects, age wise distribution, commonly prescribed antibiotics, average number of antibiotics prescribed per prescription, most commonly prescribed category of antibiotics, mode of administration, percent encounters with an injection prescribed, percentage medicines prescribed by generic name, cost analysis, mono therapy versus combined therapy, and suspected adverse drug reaction due to antibiotics [12].

## Data analysis

Results are expressed in percentage. Descriptive statistics was applied to the collected data using Microsoft Excel 365 software. The sample size was calculated using a single population proportion formula as follows-

$$N = \frac{Z^2 a / 2 p (1-p)}{d^2}$$

$$N = 1.96^2 * 0.07 (1-0.07) / 0.05^2 = 100.$$

Where N = is desired sample size;  $Z_{a/2}$  = is standard normal distribution at 95% confidence level usually 1.96, p=proportion [13].

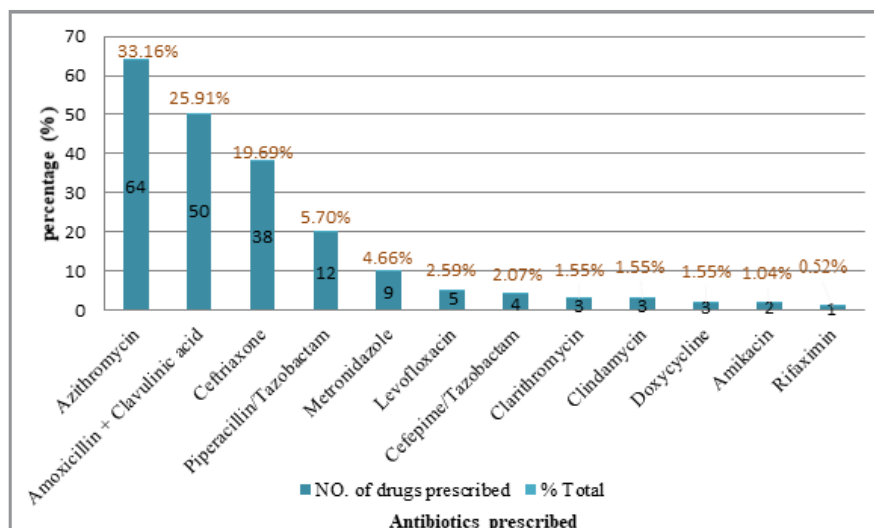
## Ethical Approval

The study was complied fully with the WHO guidelines and was done after obtaining approval from Institutional Research and Ethics Committee (IEC/IIMS&R/2023/49).

## Results

A prospective observational study was conducted over a period of 6 months at Integral Institute of Medical Science and Research Hospital (IIMS&R), Lucknow. During the study, 100 patients were enrolled and diagnosed with lower respiratory tract infections (LRTIs). 76% of the patients who participated in the study were male and 24% were females. It was found that 70% of the prescriptions were in the age group of 41-60 years, followed by 14% in the age group of 20-40 years, 10% in the age group of 61-80 years, 4% in the age group of less than 20 years and 2% in the age group above 80 years.

The study reports that 33.16% of the prescriptions were prescribed with azithromycin, 25.91% with amoxicillin+clavulanic acid, 19.69% with ceftriaxone, 5.70% with piperacillin/tazobactam and 4.66% of the prescriptions were prescribed with metronidazole (Figure 1).



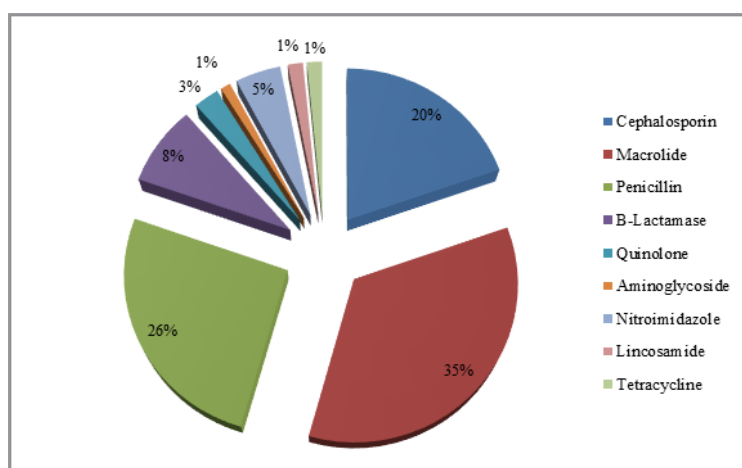
**Figure 1:** Commonly Prescribed Antibiotics.

Among 100 patients, 193 antibiotics were prescribed to the patients of LRTIs. Average number of antibiotics prescribed per prescription was found to be 1.93.

The study reports that the most commonly prescribed category of antibiotics were macrolide about 35.26%, followed by penicillin (26.32%), and cephalosporin (20.00%) in the patients (Table 1; Figure 2).

**Table 1: Most Commonly Prescribed Category of Antibiotics.**

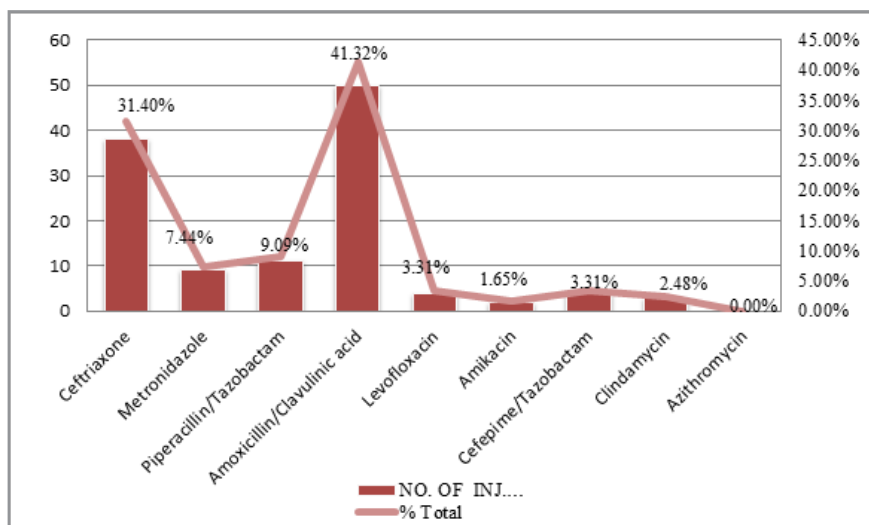
Sl. No.	Antibiotics category	No. of prescription (n=100)	Percentage
1.	Macrolide	67	35.26%
2.	Penicillin	50	26.32%
3.	Cephalosporin	38	20.00%
4.	B-Lactamase	16	8.42%
5.	Nitroimidazole	9	4.74%
6.	Quinolone	5	2.63%
7.	Lincosamides	3	1.58%
8.	Tetracycline	3	1.58%
9.	Aminoglycosides	2	1.05%



**Figure 2:** Most Commonly Prescribed Category of Antibiotics.

The study reports that out of 193 antibiotics prescribed, 36% were oral formulations and 64% were parenteral preparations.

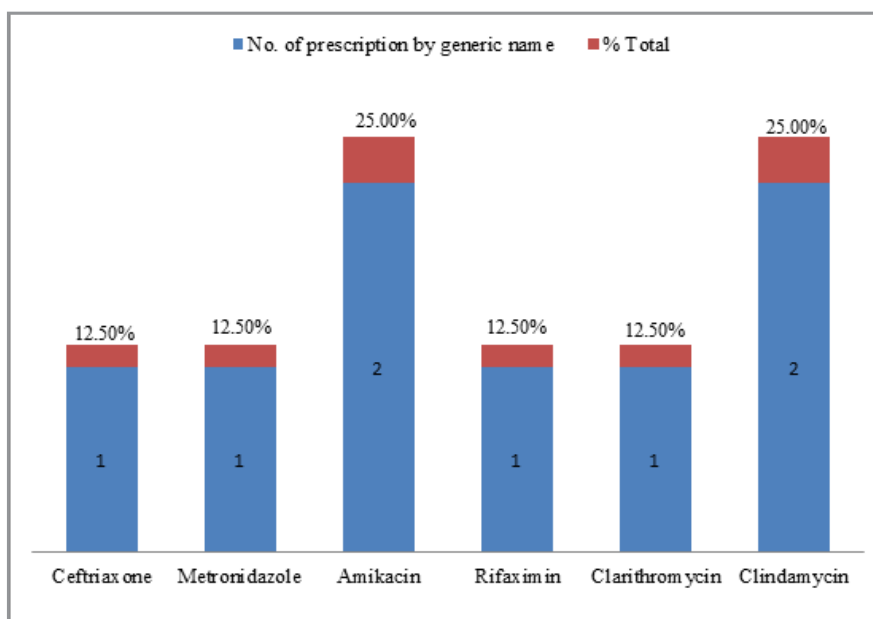
Most of the antibiotics were prescribed in injection form. The most commonly prescribed antibiotics with an injection form was amoxicillin/clavulinic acid about 41.32% followed by ceftriaxone (31.40%) and piperacillin/tazobactam (9.09%) (Figure 3).



**Figure 3:** Percent Encounters with an Injection Prescribed.

Most of the drugs were prescribed by brand name. Amikacin was mostly prescribed antibiotics with generic name accounted

for 25% followed by clindamycin which is also 25%, ceftriaxone (12.50%) and metronidazole (12.50%) (Figure 4).



**Figure 4:** Percentage Medicine Prescribed by Generic Name.

Amoxicillin/Clavulinic acid was mostly prescribed as mono therapy (about 43%), followed by ceftriaxone (35%) and piperacillin/tazobactam (22%) in the patients (Table 2).

**Table 2: Mono Therapy of Antibiotics in Lrtis.**

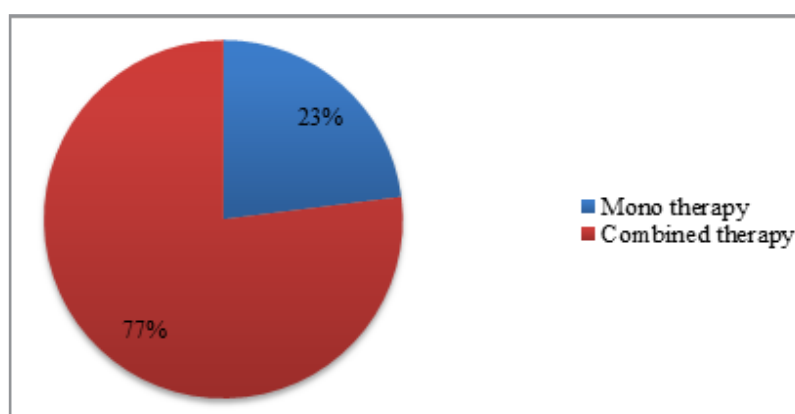
Sl. No.	Antibiotics	No. of prescription (n=100)	Percentage
1.	Amoxicillin / Clavulanic acid	10	43.00%
2.	Ceftriaxone	8	35.00%
3.	Piperacillin / Tazobactam	5	22.00%

Amoxicillin/clavulanic acid + azithromycin was mostly prescribed as combined therapy (about 38.90%) followed by ceftriaxone + azithromycin (23.30%) and piperacillin/tazobactam + azithromycin (12.90%) in the patients with LRTIs (Table 3).

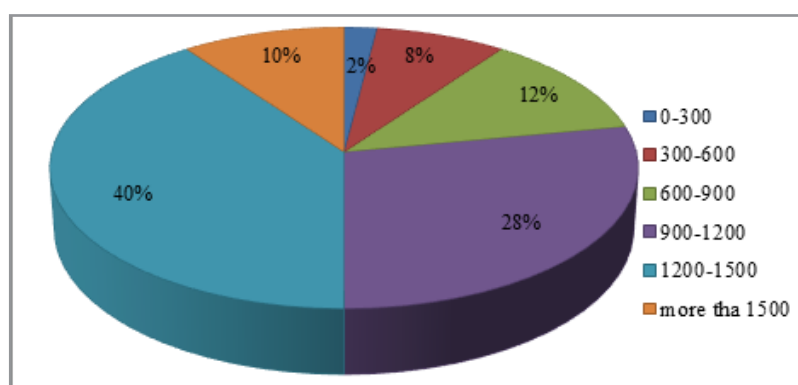
**Table 3: Combined therapy of antibiotics in LRTIs.**

Sl. No.	Antibiotics	No. of prescription (n=100)	Percentage
1.	Amoxicillin/Clavulanic acid + Azithromycin	30	38.90%
2.	Ceftriaxone + Azithromycin	18	23.30%
3.	Piperacillin/Tazobactam + Azithromycin	10	12.90%
4.	Amoxicillin/Clavulanic acid + Levofloxacin	8	10.30%
5.	Ceftriaxone + Azithromycin + Amoxicillin/Clavulanic acid	5	6.40%
6.	Ceftriaxone + Azithromycin + Metronidazole	6	7.70%

The study reports that most of the antibiotics were prescribed as combined therapy about (77%), whereas mono therapy was about 23% prescribed in the patients with LRTIs (Figure 5).

**Figure 5: Mono Therapy Versus Combined Therapy.**

Average cost of antibiotics per prescription was found to be in the range of Rs.1200-1500 INR followed by 900-1200 INR (Figure 6).

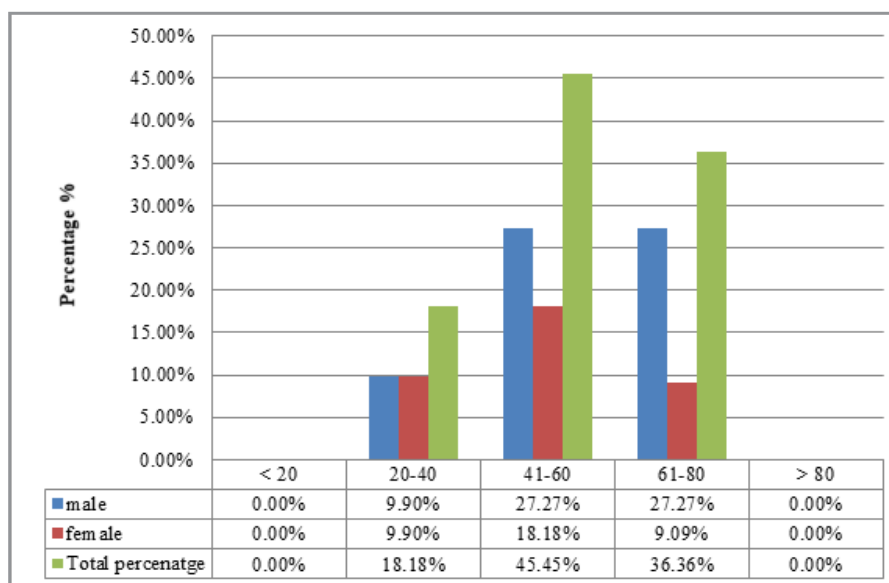
**Figure 6: Cost Analysis in INR.**

The study revealed that the number of ADRs reported was 11. The ADRs were found to be more prone among males constituting to about 63.63% of the patients and to about 36.36% in female patients with LRTIs.

ADRs based on age group showed that the patients who were at an age group of 41-60 years were mostly affected to about 45.4% followed by 61-80 years at 36.3% and patients at an age group 20-

40 years were least affected by the adverse reactions to antibiotics which constituted to only about 18.18%.

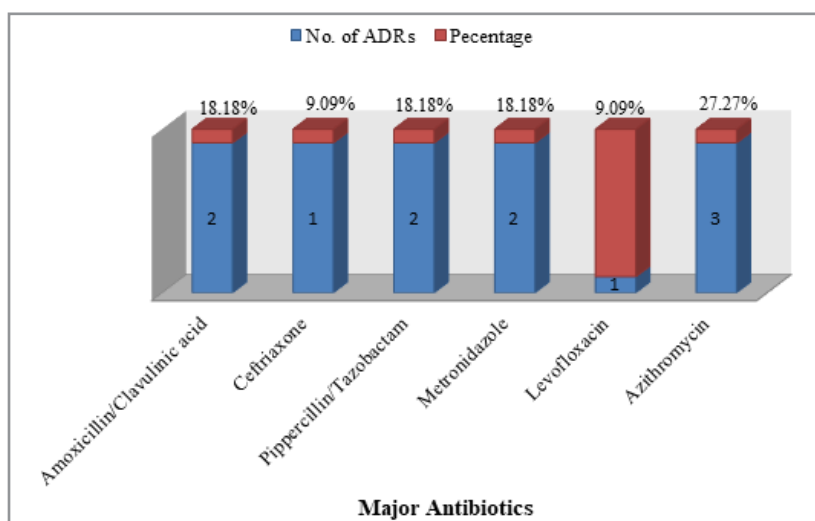
The age and gender wise distribution of ADRs showed that 27.27% of male patients in the age group of 41-60 were more affected followed by 27.27% of male patients in the age group of 61-80 were affected. In the age group of 20-40 both male and female were equally prone to the reaction to about 9.90% (Figure 7).



**Figure 7:** Age Wise and Gender Wise Distribution of ADRs.

The major antibiotics causing ADRs in the patients with LRTIs were found to be azithromycin in 27.27% followed by piperacillin / tazobactam in 18.18%, amoxicillin / clavulanic acid in 18.18%,

metronidazole in 18.18%, levofloxacin in 9.09% and ceftriaxone in 9.09% of the patients were being reported in the study (Figure 8).



**Figure 8:** Antibiotics Causing ADRs.

The adverse drug reactions assessment by Naranjo's causality assessment scale showed that around possible ADRs were counted

for 63.63% and probable ADRs were counted for 36.36% among the patients with LRTIs (Table 4).



Based on the level of severity, mild ADRs constituted to about 45.45%, moderate ADRs to about 54.54% and severe ADRs were not observed or reported in the patients with LRTIs.

In the study, all the eleven ADRs which were observed among the patients with LRTIs during the use of antibiotics were fully recovered during the hospital stay.

**Table 4: Naranjo's Causality Assessment Scale.**

Assessment score	No. of ADRs	ADRs (%)
Unlikely; $\leq 0$	0	0
Possible; 1-4	7	63.63%
Probable; 5-8	4	36.36%
Highly probable; $\geq 9$	0	0
Total	11	100%

## Discussion

The drug utilization study of antibiotics used for LRTIs was conducted based on the prospective observational study. A total of 100 patients were included according to inclusion and exclusion criteria. Out of the total 100 patients, 76 were males and 24 females. This observation reports that majority of the patients with LRTIs were males [14,15].

Most of the prescriptions were in the age group of 41-60 years followed by 61-80 years. Similar study also found that most of the prescriptions were in age group of 46-60 years which indicates this age groups are more sensitive to LRTIs [16].

The current study reports the most commonly prescribed antibiotic among patients were azithromycin (33.16%) followed by amoxicillin / clavulanic acid (25.91%) during the hospital stay. This study was similar to a study who also found that the antibiotics that were commonly prescribed were azithromycin (122), followed by doxycycline (84), ciprofloxacin (82) [17]. During the study among 100 patients, 193 antibiotics are prescribed so average number of antibiotics prescribed per prescription was 1.93 which was similar to a study which found that the average number of antibiotics per prescription was about 1.36 [18]. The most commonly prescribed category of antibiotic was macrolide (35.26%) followed by penicillin (26.32%) during the hospital stay which could be compared to a similar study which found that the major class of antibiotics prescribed among patients were cephalosporins constituting about 55.3% followed by penicillins (46.6%) [19].

The current study reports that out of 193 antibiotics prescribed, 124 (64%) were parenteral preparations and oral formulations were 69 (36 %) which is similar to a study which found that 91.01% antibiotics were prescribed in injectable form and 9.09% were in oral form [18,20].

The reports on the most commonly prescribed antibiotics with an injection form is Amoxicillin/Clavulanic acid about 41.32% followed by ceftriaxone (31.40%), Piperacillin/Tazobactam (9.09%) and metronidazole (7.44%) which is similar to study which found that the most commonly prescribed injections were ampicillin (21.4%), cloxacillin (13.4%), penicillin (12.4%) and ceftriaxone (9.8%) [21]. During the study, most of the drugs are prescribed by brand name. Amikacin is mostly prescribed antibiotics with generic name accounted for 2 (25.00%) followed by

Clindamycin which is also 2 (25.00%), ceftriaxone 1 (12.50%) and metronidazole 1 (12.50%). A similar study also compared percentage medicine prescribed by generic name and found that only 22.5% of the antibiotics were prescribed by generic name. Hence, prescription of drugs by generic name needs improvement [22].

The comparison of monotherapy versus combined therapy seen in the study were mono therapy (23.0%) and combined therapy (77.0%) with the mostly prescribed antibiotics as monotherapy were Amoxicillin/Clavulanic acid (43.0%), Ceftriaxone (35.0%) and mostly prescribed antibiotics as combined therapy were Amoxicillin/Clavulanic acid + Azithromycin (38.90%), Ceftriaxone + Azithromycin (23.30%) which were similar to the study which found that when prescriptions were screened thoroughly, the number of prescriptions of mono-antibiotics were 33 (34.37%) where prescriptions containing combined-antibiotic therapy were 63 (65.62%) [7].

In the present study, cost of the most common antibiotics was calculated. The Average cost of Antibiotics per prescription was found to be in the range of Rs.1200-1500 (40.0%) which was low when compared to study which analysed that the average cost of antibiotic in per prescription according to disease was found as follows, antibiotic prescription in bronchopneumonia cost INR 1681.94, bronchiolitis INR 355.68. This cost can be reduced by prescribing alternate antibiotics at a lower cost which help in minimizing the patient's expenditure [23].

In the present study, 11 ADRs were observed. On gender wise distribution the study revealed that the adverse drug reactions are found to be more prone among male patients. In study which found males were more predominant than females in ADR occurrence [24]. In the present study, most of adverse drug reactions (ADR) were at an age group of 41-60 years 5 (45.45%) followed by 61-80 years 4 (36.36%). A similar study also found that most of ADRs were reported in age group of 61-80 years [25].

The current study showed that majority of ADR were reported by azithromycin (27.27%) in antibiotic class of macrolide which is similar to a study which also noted that most ADRs were reported by ceftriaxone and therapeutic class of antibiotics implicated to cause ADRs were  $\beta$ -lactams [26]. An assessment of ADR by Naranjo's causality assessment scale showed both possible and

probable ADR among the patients which is similar to a study which also showed that majority of ADRs were probable and possible commonly seen ADRs in the study were rashes, loss of appetite and nausea/vomiting [26,27]. These ADRs can be prevented by proper monitoring during drug administration and through educating the healthcare professionals regarding commonly occurring ADRs. It is similar to a study who observed rashes and urticaria as most commonly seen ADR pattern in their study. In the present study, most ADRs were moderate (54.54%) and all ADR among the patients were fully recovered during the hospital stay. It is similar to a study who also noted that most patients were recovered [28-30].

## Conclusions

The present study gives an overview of antibiotics use and complications involved in the patients with lower respiratory tract infections. The documentation of pharmacist observation on prescription in the patient folder will certainly help for the safe drug monitoring and rational therapeutic use of antibiotics in minimizing the antibiotic problems. It will be helpful to future clinical pharmacists and clinicians for the rational use of antimicrobials and also minimizing the antibiotic resistance.

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## Declaration of Conflicting Interests

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