



## Drug utilization study in patients with acute respiratory tract infections at a tertiary care hospital in Bhimavaram, India

Gogineni Vinutna<sup>1</sup>, Mallela Babji<sup>2</sup>, Reshma Namburi<sup>3</sup>, Raj Kumari<sup>4</sup>

<sup>1</sup>Assistant Professor, Hillside College of Pharmacy, Bengaluru, Karnataka

<sup>2,3,4</sup>Student, Shri Vishnu College of Pharmacy, Kovvada, Andhra Pradesh

### ABSTRACT

*Our study was aimed to focus on the trends in the drug utilization in acute respiratory tract infections and also to analyze the current prescription patterns of drugs used in the treatment of acute respiratory tract infections. A prospective observational study conducted in both in-patient and out-patient department of tertiary care hospitals. The institutional ethical committee of Shri Vishnu College of Pharmacy authorized this observational study. After obtaining verbal consent, patient demographics and drugs prescribed data were collected and analyzed. Along with this interaction with the patient was also done whenever required. Data obtained was analyzed using Sigma Graphed prism and Microsoft Excel. A total of 150 patients were observed in our study. Of which, males were 54.6% and females were 45.4%. When the patients were classified according to age, children contributed for 4%, adolescents were 15.3, adults were 69.3%, the elderly were 11.3% of the total population. Drug utilization of antibiotics can be observed by determining the PDD values of those drugs. PDD is greater than DDD for drugs Levofloxacin, Ofloxacin, Cefpodoximeproxetil, and Linezolid. PDD is less than DDD for drugs Amoxicillin and Azithromycin. PDD is equal to DDD for drugs Moxifloxacin, Ciprofloxacin and Cefixime. Drug consumption value is determined by DDD/1000 inhabitants/day value. The value of DDD/1000 inhabitants/day is high (0.805) for Levofloxacin, followed by Cefpodoximeproxetil (0.177) and is low for Ofloxacin (0.007). In this project, we observed how the drugs are utilized by the physician. Antibiotics are most commonly prescribed for these ARTI's. Symptomatic relief is preferred in these patients by prescribing antihistamines, antipyretics and analgesics, bronchodilators, Cold and Cough combinations. From this study, it is evident that antibiotics were commonly prescribed in the patients of URTI and is a matter of concern. The highest value of 0.805 DDD/1000 inhabitants/day was accounted for Levofloxacin indicating that it was the popular drug of choice as a broad spectrum antibiotic, followed by Cefpodoximeproxetil with the value of 0.177 DDD/1000 inhabitants /day. Most commonly used antibiotic was Levofloxacin followed by Cefpodoximeproxetil. Prescribing by generic names has to be encouraged.*

**Keywords**— Drug utilization review, Respiratory tract infections, Prescribed daily dose, Defined daily dose, Antibiotics

### 1. INTRODUCTION

Acute respiratory infection is a serious infection which prevents the person to breathe properly. The infection usually starts as a viral infection in the nose, trachea (windpipe), or lungs. If the infection is not treated, it may spread to the entire respiratory system.

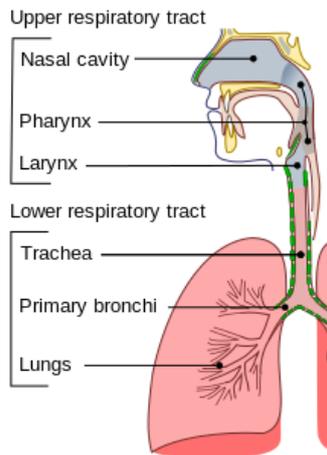
Acute respiratory infections are infectious, which means they can spread from one person to another. The disease is quite widespread. It is particularly dangerous for children, older adults, and people with immune system disorders. Early symptoms appear in the nose and upper lungs like congestion. Acute respiratory infections account for 20 to 40% of out-patient and 12 to 35% of in-patient attendance in a general hospital.

Respiratory tract infections are one of the main reasons for the people to visit the general physician or pharmacist. Children tend to get more upper RTIs than adults because they have not yet built up immunity (resistance) to the many viruses that can cause these infections. Respiratory tract infections refer to the number of infectious diseases involving the respiratory tract. Acute respiratory infection is a serious infection that prevents normal breathing function [1].

Acute respiratory tract infections are infectious, which means they are spread from person to person. RTIs are also the commonest acute problem dealt with in primary care – the 'bread and butter' of daily practice [2].

An infection of the respiratory tract is classified into two types:

- 1. Upper respiratory tract infection:** Constitute Common Cold, Influenza, Laryngitis, Otitis media, Pharyngitis, Sinusitis, and Tonsillitis
- 2. Lower respiratory tract infection:** Constitute Asthma, Bronchitis, COPD, Emphysema Pneumonia, and Tuberculosis.



**Fig. 1: Respiratory tract infection classification**

- **Bronchitis:** Inflammation of the mucous membrane in the bronchial tubes, which carry air to and from lungs. Peoples having bronchitis often cough up thickened mucous, which can be disclosed. It may be either acute or chronic.
- **Otitis media:** Inflammation of the middle ear characterized by the accumulation of infected fluid in the middle ear, burging of the eardrum, pain in the ear and if the eardrum is perforated, drainage of purulent material (pus) into the ear canal is seen.
- **Pharyngitis:** Inflammation of the pharynx (the back side of the throat) which causes a sore throat, as well as scratchiness in the throat and difficulty in swallowing. In many cases, it is quite painful.
- **Pneumonia:** It is a lung inflammation caused by a bacterial or viral infection in which the air sacs fill with pus and may become solid, causing cough with phlegm or pus, fever, chills, and difficulty in breathing. It affects both the lungs (double pneumonia) and the single lung (single pneumonia).
- **Rhinitis:** It is the inflammation of the mucous membrane of the nose, caused by viral infection (common cold) or by an allergic reaction (hay fever). It is also defined as an allergic reaction that mimics the chronic cold.
- **Sinusitis:** Inflammation of the cavities around nasal passages (sinuses) air spaces within the bones of the face resulting in symptoms like thick nasal mucous, plugged nose and pain in the nose.
- **Tonsillitis:** Inflammation of the tonsils, which are the two oval-shaped pads of tissue at the back of the throat, one tonsil on each side, most commonly caused by viral or bacterial infection. Tonsillitis is typically referred to as strep throat.

The most common signs and symptoms observed in respiratory tract infections are coughing, sneezing, congestion, runny nose, low-grade fever, anorexia and myalgia, and the advanced symptoms are difficulty in breathing, dizziness, and loss of consciousness.

According to the World Health Organization (WHO), acute respiratory infections kill an estimated 2.6 million children annually every year worldwide.

In its World Health Report of 2004, the World Health Organization (WHO 2004) estimated that respiratory infections generated 94.6 disability-adjusted life years lost worldwide and were the fourth major cause of mortality, responsible for 4 million deaths or 6.9% of a global number of deaths in 2002 [3].

**Table 1: International classification of diseases (ICD 10 version)**

Disease	Classification
Bronchitis	J 20
Otitis media	H 65.0
Pharyngitis	J 02
Pneumonia	J 16
Rhinitis	J 00
Sinusitis	J 01
Tonsillitis	J 03
Unspecified RTI	J 06

Rational use of drug aims to minimize the drug-related adverse events, development of resistant strains of microorganisms, patient non-compliance and increased the cost of treatment [4].

Drug use evaluation is an ongoing, authorized and systematic quantity process, which is designed to:

- Review drug use and/or prescribing patterns
- Provide feedback of results to clinicians and other relevant groups
- Develop criteria and standards which describe optimal drug use
- Promote appropriate drug use through education and other interventions

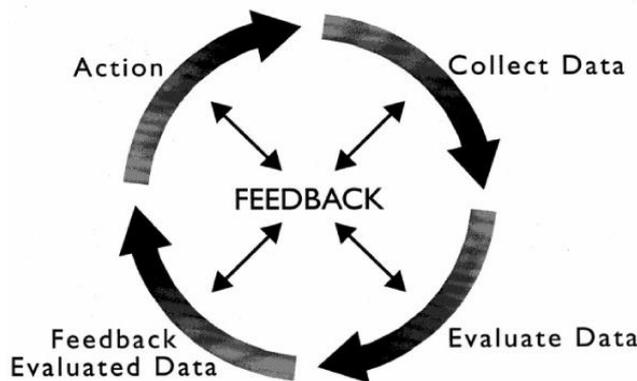


Fig. 2: Drug use evaluation

Drug utilization can be measured by using the defined daily dose and prescribed daily dose.

**Defined Daily Dose:** WHO defined that DDD is the assumed average maintenance dose per day for a drug used for its main indication. Formula:

$$DDD = \text{Items issued} \times \text{Amount of drug per item} / \text{DDD}$$

**Prescribed Daily Dose:** WHO defined that PDD is the average dose prescribed according to a representative sample of prescriptions. Formula:

$$PDD = \text{Total dose prescribed} / \text{Number of days prescribed}$$

DUE may be applied to drug, therapeutic class, disease state or condition, a drug use process or specific outcomes. It may be applied in various practice settings, including hospitals, other facilities, and community practice environments.

## 2. MATERIALS AND METHODS

The present study was conducted in a Tertiary care hospital in Bhimavaram. Institutional ethical committee approval was obtained before initiating the study. Oral consent was obtained from patients who are willing to participate in the study.

A prospective study was conducted in both out-patient and in-patient departments of the ENT Department at a tertiary care hospital for a period of 6 months (December 2014 to May 2015). Patient demographics and drugs prescribed data were collected and analyzed. Along with this interaction with the patient was also done whenever required.

This was an observational study involving all the patients with both genders and all the ages who are suffering from respiratory tract infections. The study was conducted for six months in both in patients and out patients. The patients who were not willing to participate and pregnant women were excluded from the study.

The present study was initiated with an enrollment of patients based on inclusion and exclusion criteria. The patients who were visiting the ENT department and Pulmonology department were monitored in the study. The patient background information like Age, Gender, Height, Weight, BMI, and Reason for hospital visit were collected. The patient’s Diagnosis and prescribed medicines were noted. All the patients were categorized according to age, gender and diagnosis. All the antibiotics prescribed for the patients were noted and monitored. The prescribed daily dose for all the antibiotics was calculated and noted. The number of DDDs for all the antibiotics was calculated using the standard Defined daily doses. The prescribed daily doses which were calculated earlier were compared against the number of DDDs for the same drug and the results were noted.

## 3. RESULTS

Acute respiratory tract infections are a most common condition for the patients to visit a hospital in moist and humid climate. Acute respiratory infections are infectious, which means they can spread from one person to another. The disease is quiet widespread and the prevalence is high in winter seasons. According to WHO, ARTI kills an estimated 2.6 million children annually worldwide. In this project, we observed how the drugs are utilized by the physician. Antibiotics are most commonly prescribed for these ARTI’s. Symptomatic relief is preferred in these patients by prescribing antihistamines, antipyretics and analgesics, bronchodilators, Cold and Cough combinations.

Table 1: Showing the drug utilization of the antibiotics prescribed by a physician for ARTIs during the study period

Drug Name	ATC Code	DDD	PDD	DDD/1000/Day
<b>Quinolones</b>				
Levofloxacin	J01MA12	500mg	517mg	0.805
Moxifloxacin	J01MA14	400mg	400mg	0.022
Ofloxacin	J01MA01	400mg	800mg	0.007
Ciprofloxacin	J01MA02	1000mg	1000mg	0.018
<b>Cephalosporin</b>				
Cefpodoxime proxetil	J01DD13	400mg	498mg	0.177
Cefixime	J01DD08	400mg	400mg	0.022

Penicillin				
Amoxicillin	J01CA04	1000mg	867mg	0.150
Macrolides				
Azithromycin	J01FA10	500mg	487mg	0.101
Oxazolidinone				
Linezolid	J01XX08	1200mg	2400mg	0.022

Table 2: Showing the comparison of PDD and DDD values of antibiotics prescribed by a physician during the study period

PDD > DDD	PDD < DDD	PDD = DDD
Levofloxacin	Amoxicillin	Moxifloxacin
Ofloxacin	Azithromycin	Ciprofloxacin
Cefpodoxime Proxetil		Cefixime
Linezolid		

Drug utilization of antibiotics can be observed by determining the PDD values of those drugs. PDD is greater than DDD for drugs Levofloxacin, Ofloxacin, Cefpodoxime proxetil, Linezolid. PDD is less than DDD for drugs Amoxicillin and Azithromycin. PDD is equal to DDD for drugs Moxifloxacin, Ciprofloxacin and Cefixime. Drug consumption value is determined by DDD/1000 inhabitants/day value. The value of DDD/1000 inhabitants/day is high (0.805) for Levofloxacin, followed by Cefpodoxime proxetil (0.177) and is low for Ofloxacin (0.007).

Table 3: Showing the distribution of various types of ARTIs in males and females and a total number of cases of each disease observed in the study period

Disease	Male	Percentage of males	Female	Percentage of females	Total	Percentage
Bronchitis	27	18	23	15.3	50	33.3
Otitis media	7	4.6	3	2	10	6.6
Pharyngitis	26	17.3	25	16.6	51	34
Pneumonia	8	5.3	4	2.6	12	8
Rhinitis	3	2	5	3.3	8	5.3
Sinusitis	2	1.3	4	2.6	6	4
Tonsillitis	4	2.66	2	1.3	6	4
Unspecified RTI	5	3.33	2	1.3	7	4.6
<b>Total</b>	<b>82</b>	<b>54.6</b>	<b>68</b>	<b>45.4</b>	<b>150</b>	

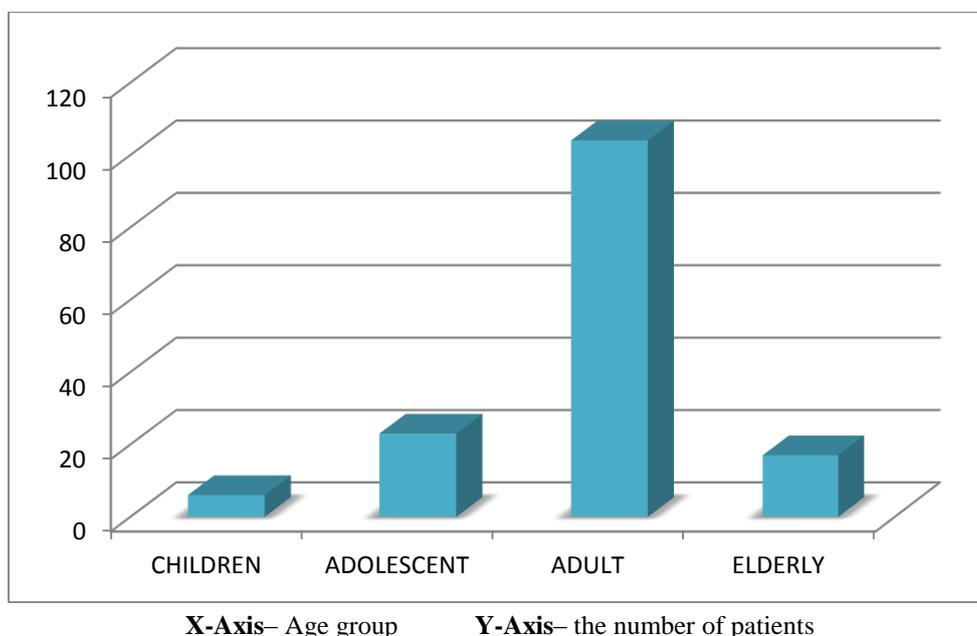
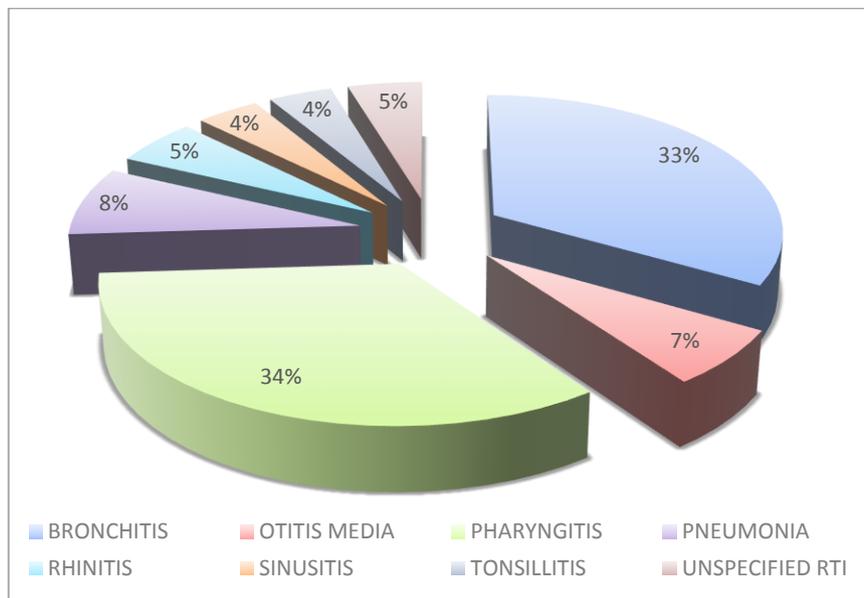


Fig. 3: Showing the distribution of ARTIs among different age groups

In our study, out of 150 cases collected, males were 54.6% and females were 45.4%. When the patients were classified according to age, children contributed for 4%, adolescents were 15.3, adults were 69.3%, and the elderly were 11.3% of the total population. Out of all ages, patients with age among 21-30(30.6%), followed by age between 31-40 (16.6%) and the least were children with age among 1-10 (4%).

**Table 4: Showing the total number of each type of ARTIs obtained in the study period**

Disease	Total number
Bronchitis	50
Otitis media	10
Pharyngitis	51
Pneumonia	12
Rhinitis	8
Sinusitis	6
Tonsillitis	6
Unspecified RTI	7



**Fig. 4: Showing the percentages of each type of ARTI obtained in the study period**

The above pie chart shows seven different types of ARTI’s and unspecified RTIs prescribed in our study. Out of 150 cases, 50 bronchitis, 10 otitis media, 51 pharyngitides, 12 pneumonia, 8rhinitis, 6 sinusitis, 6 tonsillitis, and 7 unspecified RTI. From the above data, we observed that pharyngitis and bronchitis contributed the most of the cases with 33.3% and 34% of the total population respectively.

**Table 5: Showing the WHO prescribing indicators of drugs of acute respiratory tract infections**

Parameter	Total number and percentage
Total number of prescriptions	150
Total number of drugs prescribed	765
Average number of drugs per prescription	5.1
Total number of antibiotics	157 (20%)
Total number of FDC drugs	97 (12%)
Number of encounters with an antibiotic prescribed	131(87%)
Number of encounters with an injection prescribed	28(18%)

From all the prescriptions, we observed that there were 765 medicines prescribed in 150 prescriptions with an average of 5.1 medicines per prescription. There were 157 antibiotics prescribed by a physician in 150 prescriptions contributing about 20% of total population. Fixed-dose combinations are the medications with a combination of 2 or more drugs with fixed doses. The physician has prescribed 97 FDC drugs in total.

There are cases which contain at least one antibiotic prescribed. This indicates that there are patients who are not prescribed with at least one antibiotic.

**Table 7: Showing the number of FDC drugs prescribed for ARTIs during the study period**

FDC Drug	Total number
Amoxicillin+ clavulanic acid	13
Cefpodoxime+ clavulanic acid	1
Cefoperazone+ sulbactam	6
Cetirizine+ phenylephrine	3
Levocetirizine+ monteleukast	3

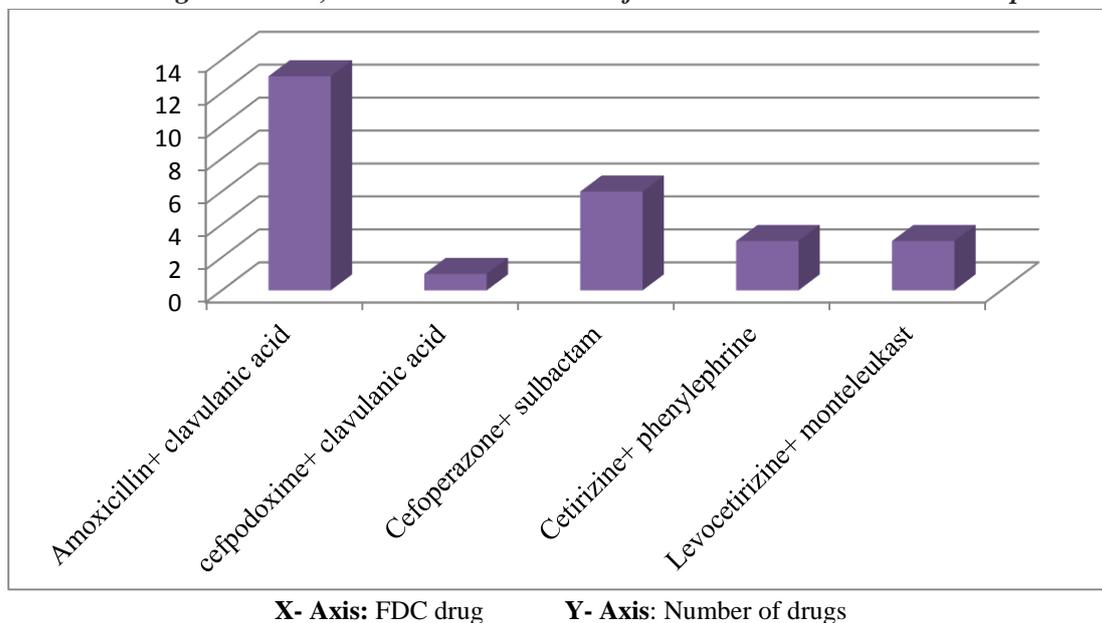


Fig. 5: Showing the total number of FDC drugs prescribed during the study period

The above table shows the FDC drugs used in the present study that is approved by the WHO. From the table, we observed that Amoxicillin + Clavulanic acid is a most preferred combination and is used more. The other combination drugs that are used in the study are Multivitamins which are prescribed for 71 times in 150 prescriptions.

Table 8: Showing the total number of different classes of drugs prescribed by a physician during the study period

Classification	Total number
Antibiotics	157
H2 blockers	101
Multi vitamins	71
C & C Combinations	70
Bronchodilators	67
Antihistamines	48
Antipyretics and Analgesics	42
Throat gargles	30
Nasal sprays	27

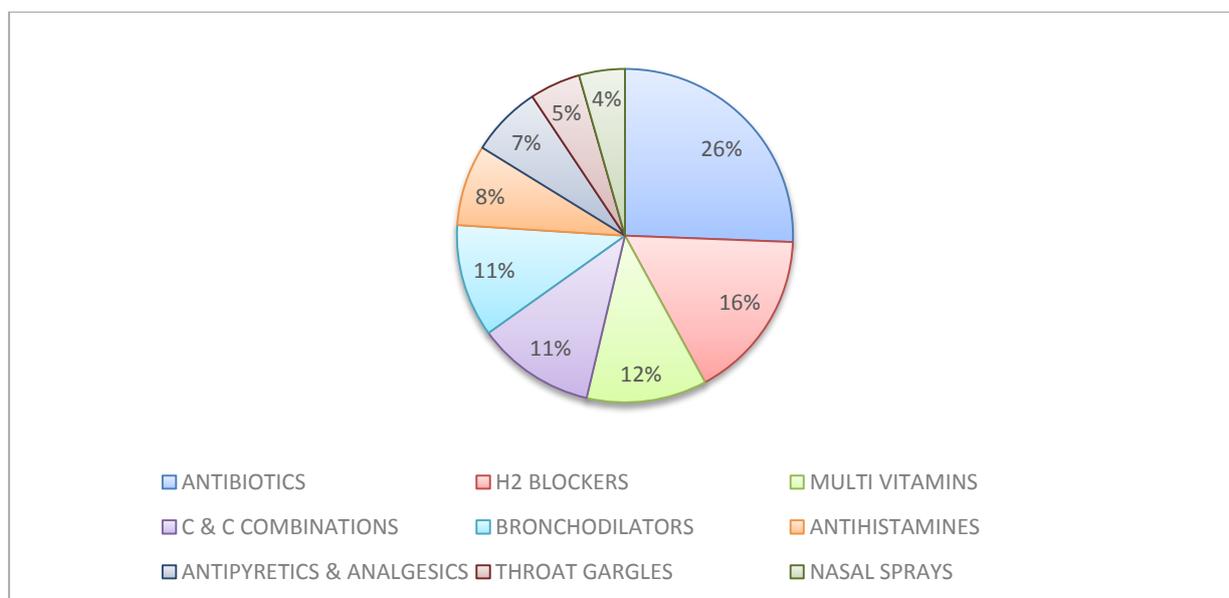


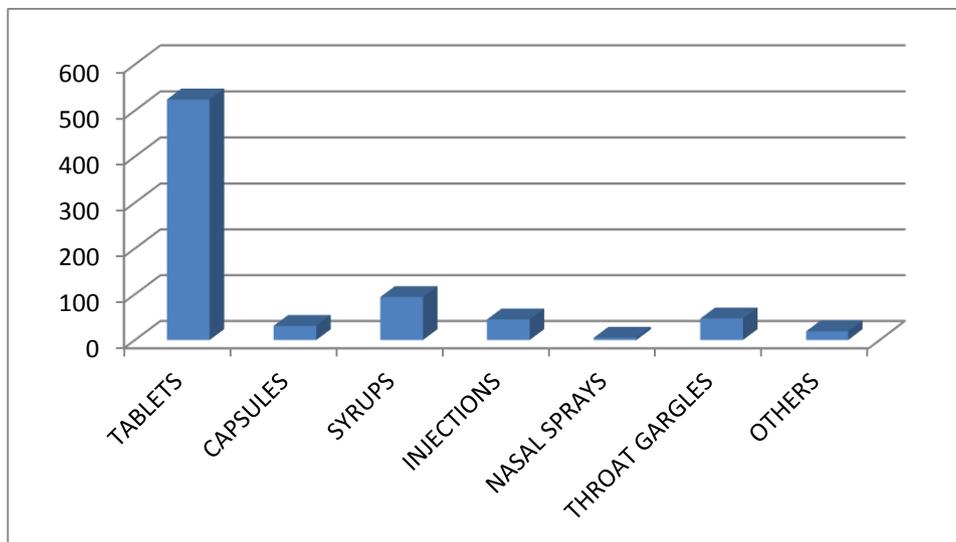
Fig. 6: Showing the percentages of different classes of drugs prescribed during the study period

Different classes of drugs like Antibiotics, Antihistamines, Antipyretics, Analgesics, Cough and cold combinations, Bronchodilators, Throat gargles, Nasal sprays, Multivitamins, and H2 blockers were prescribed. Out of all different types of drugs prescribed, Antibiotics (26%) are more prescribed followed by H2 blockers (16%) and least were Nasal sprays (4%).

Bronchodilators (n=44) were highly prescribed for Bronchitis followed by Pneumonia (n=10). No Bronchodilators were prescribed for Sinusitis and Otitis media.

**Table 9: Showing the total number of different types of dosage forms used by a physician during the study period**

Dosage form	Total number
Tablets	524(68%)
Capsules	31(4%)
Syrups	94(12%)
Injections	45(5.8%)
Nasal sprays	5(0.65%)
Throat gargles	47(6.1%)
Others	19(2.4%)



**Fig. 7: Showing the total number of different dosage forms used during the study period**

Different routes of administration like Oral, Intravenous and Nasal sprays were used in the present study. A few rotahalers were also prescribed in some prescriptions. The oral route of administration was more preferred to other routes. 84.8% (n=649) of total medicines were prescribed by the oral route, followed by intravenous route 5.8% (n=45) of and was nasal route least preferred. Throat gargles were prescribed in cases of tonsillitis or pharyngitis. We observed that rotahalers were prescribed for patients only with bronchitis or pneumonia.

In this study, most of the drugs are prescribed by oral route in the form of tablets and syrups. Prescribing drugs by tablets is more preferred to other types. Out of all 765 medicines 524 were prescribed in the form of tablets, capsules were 31, syrups were 94, injections were 45, nasal sprays were 5, throat gargles were 47 and other forms were 19.

**Table 10: Showing the generic names and their class of antibiotics used by the prescriber during the study period.**

Drug class	Drug Name
<b>Quinolones</b>	Levofloxacin
	Maxifloxacin
	Ofloxacin
	Ciprofloxacin
<b>Cephalosporin</b>	Cefpodoxime proxetil
	Cefoperazone
	Cefixime
<b>Penicillin</b>	Ampicillin
<b>Macrolides</b>	Azithromycin
<b>Aminoglycosides</b>	Amikacin
<b>Oxazolidinone</b>	Linezolid

In this study, Quinolones, Cephalosporin, Penicillin, Macrolides, Aminoglycosides, and Oxazolidinone are the types of antibiotics prescribed. Levofloxacin, Ciprofloxacin, Ofloxacin, and Moxifloxacin are Quinolones. Cephalosporins include Cefpodoxime proxetil, Cefoperazone, Cefixime. Macrolides include azithromycin. Aminoglycosides include Amikacin. Oxazolidinone includes linezolid.

**Table 11: Showing the total number and percentage of each class of antibiotic used by a physician during the study period**

Antibiotic Class	Total number
Quinolones	94(59%)
Cephalosporins	37(23%)
Penicillins	13(8%)
Macrolides	11(7%)
Aminoglycosides	1(0.6%)
Oxazolidinone	1(0.6%)

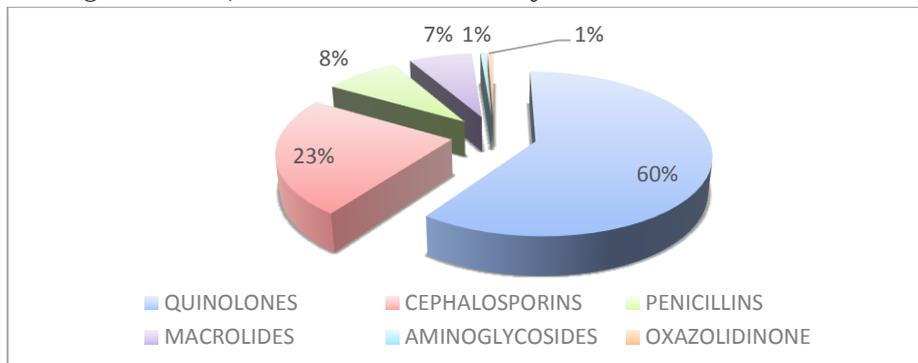


Fig. 8: Showing the percentages of different classes of antibiotics used by a physician during the study period.

Quinolones are the more preferred class of antibiotic which contributes to 59% of total prescribed antibiotics. 23% were cephalosporins, 13% were penicillins, 11% were macrolides. Aminoglycosides and Oxazolidinones were prescribed once each. Out of all 157 antibiotics, levofloxacin is highly prescribed with 55.4% (n=87).

Table 12: Shows the number of drugs prescribed for each type of ARTI during the study period

Parameter	Bronchitis	Otitismedia	Pharyngitis	Pneumonia	Rhinitis	Sinusitis	Tonsillitis	Uruti
Antibiotics	55	12	51	17	5	4	6	7
H2 blockers	35	3	42	9	5	1	3	3
Multi vitamins	21	5	30	4	3	2	2	4
C & c combinations	45	0	14	7	1	0	0	3
Bronchodilators	44	0	7	10	2	0	2	2
Antihistamines	0	4	25	0	7	6	0	6
Analgesics and antipyretics	3	5	15	3	4	4	5	3
Throat gargles	0	0	27	0	0	0	3	0
Nasal sprays	0	5	16	0	2	3	0	2
Rota halers	29	0	0	6	0	0	0	0

The above table shows all the classes of drugs prescribed for each disease in the present study. From the above table, antibiotics are highly prescribed compared to all other drugs, followed by H2 blockers and multivitamins. H2 blockers are highly prescribed in the case of pharyngitis, rota halers and throat gargles are very less used. In very few cases, oral paints are used.

Table 13: Showing the total number of antibiotics prescribed for different types of ARTIs during the study period

Disease	Number of antibiotics
Bronchitis	55
Otitis media	12
Pharyngitis	51
Pneumonia	17
Rhinitis	5
Sinusitis	4
Tonsillitis	6
Unspecified RTI	7

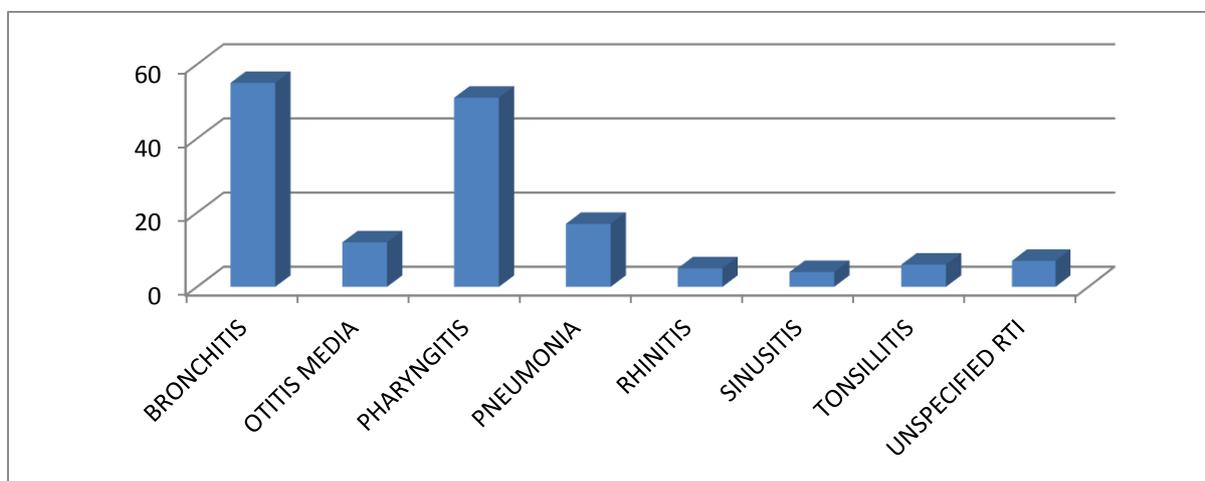


Fig. 9: Showing the number of each type of ARTIs during the study period

The above table shows the total number of antibiotics prescribed for patients suffering from each type of ARTIs. Bronchitis and Pneumonia have the highest number of antibiotic usage with 55 and 51 number of antibiotics respectively. The least number of antibiotics were given for patients suffering from Sinusitis.

#### **4. DISCUSSION**

A prospective observational study was conducted among out-patients as well as in-patients those who visit tertiary care hospital in Bhimavaram for the management of ARTIs. Drugs play an important role in improving human health and in promoting well-being. To produce the desired effect, they have to be safe and efficacious.

##### **Age, gender distribution in ARTI patients**

In our study, when the patients were classified according to age, children contributed for 4%, adolescents 15.3%, adults 69.3%, elderly 11.3% of total population. From the above data, ARTI's are more prevalent in adults, with age between 21-30 years.

When the gender is taken into consideration from the collection 150 cases, males 54.6% (82) and females 45.4% (68). From this data, we observed that males are more prone to ARTI's when compared to females.

##### **Drug utilization study in ARTI patients**

Drug consumption data were expressed as defined daily doses (DDD) per 1000 inhabitants per day. The highest value of 0.8054 DDD/1000inhabitants/day was accounted for Levofloxacin indicating that it was the popular drug of choice as a broad-spectrum antibiotic, followed by Cefpodoxim epoxetil with the value of 0.1777 DDD/1000 inhabitants /day.

In our study, much higher doses were used and this must be considered when using the DDD as a unit of measurement. From the data, Levofloxacin, Cefpodoximeproxetil, Ofloxacin, and Linezolid were prescribed in higher doses, Amoxicillin and Azithromycin were prescribed in lower doses when compared to defined daily doses. The drugs for which both PDD and DDD equal were Cefexime, Moxifloxacin, Ciprofloxacin.

##### **Prescribing patterns in ARTI patients**

Drug prescriptions form a very important point of contact between the doctor and the patients. In total 765 drugs prescribed for 150 patients, among those 157 were antibiotics, and others include histamine blockers, multi-vitamins, Cold and Cough combinations, bronchodilators, analgesics and antipyretics, drops, sprays, inhalers, and gargles.

Drugs were prescribed as per indicated symptoms, and antibiotics were prescribed as per symptoms of patients.

Our study shows antibiotics (20.5%) are the most prescribed drugs for ARTIs followed by histamine blockers (13.3%), multi-vitamins (9.2%) and Cold and Cough combinations (9.0%).

Among the 150 cases, 101 cases were with bronchitis and pharyngitis. Remaining 49 cases were with otitis media, pneumonia, rhinitis, sinusitis, tonsillitis and unspecified RTIs. Antibiotics were more prescribed in pharyngitis and bronchitis. Combination therapy of antibiotics prescribed in ARTIs was amoxicillin with clavulanic acid and cefpodoximeproxetil with clavulanic acid. Followed by antihistamines like phenylephrine with cetirizine and montelukast with cetirizine and multi-vitamins. Overall prescribing patterns suggested that monotherapy (82.6) is most frequently used than combination therapy (17.4%).

#### **5. CONCLUSION**

When prescriptions were screened thoroughly, antibiotics were not prescribed in the percentage of cases. Rest of the cases received antibiotics. Almost % of adults and % of children with ARTI are prescribed antibiotics by physicians. Most of the drugs are prescribed by brand names. Prescribing by generic drugs helps the hospital pharmacy to have better inventory control. Drug consumption data is expressed as DDD/1000 inhabitants/day. The highest value of 0.805 DDD/1000 inhabitants/day was accounted for Levofloxacin indicating that it was the popular drug of choice as a broad spectrum antibiotic, followed by Cefpodoxim epoxetil with the value of 0.177 DDD/1000 inhabitants /day. From our study, males were 54.6% (82) and females were 45.4% (68). We observed that males are more prone to ARTI's when compared to females. Based on age, children contributed for 4%, adolescents 15.3%, adults 69.3%, elderly 11.3% of total population. ARTI's are more prevalent in adults, with age between 21-30 years.

To conclude, it is evident from the present study that, antibiotics were commonly prescribed in the patients of URTI and is a matter of concern. Most commonly used antibiotic was Levofloxacin followed by Cefpodoxim epoxetil. Prescribing by generic names has to be encouraged.

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