IOSR Journal of Pharmacy and Biological Sciences (IOSR-JPBS)
e-ISSN:2278-3008, p-ISSN:2319-7676. Volume 13, Issue 2 Ver. VI (Mar. – Apr. 2018), PP 60-71
www.iosrjournals.org

A Study on Rational Use of Fluoroquinolones Class Antibiotics and Meropenem Antibiotic at a Tertiary Care Hospital

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Abstract:*The inappropriate and unnecessary use of antibiotics is a common practice in health care system. It has been observed that the irrational use of antibiotics leads to an escalation in the both mortality and morbidity rate in community, increase healthcare cost and develop resistance against antibiotics. Data was retrieved from Patient Medical Record and stored in a data collection form for a period of 6 months. Rationality of the prescriptions was assessed by equating the obtained data with Antimicrobial policy GHG/BGSGH/HIC/02/ Version No. 5 issued on 20th December 2016 which was designed based on NABH standard reference: HIC/02(g) followed in our hospital setting for the prescription of antibiotics. A total of 150 prescriptions were collected in which 65 were females and 85 were males.56 prescriptions contain meropenem, in which 33 were rational and 23 were irrational followed by levofloxacin 35 prescriptions in which 28 were rational and 7 were irrational. Although most of the prescriptions out of 150 were rational but still, 47 prescriptions came out to be irrational, so measures to be taken in such a way to reduce the irrationality of the prescriptions.It is recommended to guide antibiotics utilization according to microbiology and discontinue empirical therapy as soon as possible.*

Key Words:*- Rational, Fluoroquinolones, Meropenem.*

Date of Submission: 20-04-2018 Date of acceptance: 07-05-2018

I. Introduction

Rational use of drugs is defined by WHO as 'rational use of drugs as one that requires the patients receive medications appropriate to their clinical needs, in doses that meet their own individual requirements for an adequate period of time, and at the lowest cost to them and to their community'. This means that the correct drug is chosen based on the efficacy, safety, suitable dosage form with appropriate information that the patient can understand and the right indication at the right cost.

The rationality of the antibiotics is the most controversial and debated issue in the today's clinical practice[1].

Irrational use of medicine results in serious morbidity & mortality as well as additional economic burden leading to reduction in the quality of drug and, thereby wastage of resources, increased treatment cost, increased risk for adverse drug reaction and emergence of resistance[2] It is estimated that up to 50% of all antibiotics use is inappropriate[3]

Meropenem is a broad spectrum restricted antibiotic effective against Gram positive and Gram-negative organism and also against anaerobes. Various researchers have proved that meropenem is equally or more effective than conventional choices in conditions like febrile neutropenia and urinary tract infections, thereby increasing the frequency of prescriptions. Meropenem use in ICU appears to be inconsistent with evidence based assessment criteria. The most evident inappropriateness was observed in empirical therapy[4].

In acute care hospitals, 20 to 30% of inpatients receive antibiotics every day and antibiotics constitute around 40% of the drug prescribed[5].

A study on rational use of fluoroquinolones was carried out among inpatients in a teaching hospital in Western Nepal, they found that there is an increased use of fluoroquinolones[5]. One more study conducted in NGSM Institute of Pharmaceutical Sciences, Mangalore, Karnataka, India shows that there is an irrational use of fluoroquinolones especially Ciprofloxacin followed by Levofloxacin10.

To our knowledge no study has been conducted in our hospital setting on rational use of fluoroquinolones and meropenem antibiotics, our main objective is to analyse the rational use of fluoroquinolones and meropenem antibiotics using NABH (National accreditation Board for Hospitals & Healthcare Providers) guidelines followed in our hospital formulary design.

COMMON TYPES OF IRRATIONAL USE OF DRUGS: -

1. Polypharmacy

2. Inappropriate use of antibiotics, often inadequate dosage or the in appropriate indication.
3. Over use of injections when the oral route would be more appropriate
4. Inappropriate self-medications
5. Failure to prescribe in accordance with the clinical guidelines.

STEPS TO IMPROVE RATIONAL USE OF DRUGS PRESCRIBING RECOMMENDATIONS OF WHO FOR RATIONAL USE OF DRUGS

1. Establishment of a multi-disciplinary national body to coordinate policies on medicine use.
2. Use of clinical guidelines.
3. Development and use of National Essential Medicines List
4. Establishment of Drugs and Therapeutics committees in hospitals
5. Inclusion of problem based pharmacotherapy training in undergraduate curricula
6. Continuing in-services medical education as a licensure requirement
7. Supervision, audit and feedback
8. Use of independent information on medicines
9. Patient education about medicines.
10. Avoidance of presence financial incentives.
11. Use of appropriate and enforced regulations'
12. Sufficient government expenditure to ensure availability of medicines and staff.

RATIONAL USE OF ANTIBIOTICS:

1. Use antibiotics only when required.
2. Before commencing antibiotic therapy, specimen for gram stain, culture sensitivity testing should be done.
3. Choice should be based on suspected causative organism, safety, previous clinical response, cost.
4. Adequate dose and duration of treatment.
5. History of allergy or ADR.
6. Prophylaxis use of antibiotic restricted.
7. Oral therapy preferred more than parenteral therapy
8. Antimicrobial combination should be used only when indicated.
9. More effective and least toxic drug should be used.

II. Material and Methods

Study Site: BGS global hospital, kengeri, Bengaluru, Karnataka**.**
Study Design: Prospective observational study.
Study Duration: Six months.
Inclusion Criteria:

1. Hospitalized patients.
2. Patients who are prescribed with fluoroquinolones and meropenem.
3. Patients who are willing to participate.
4. Either sex

Exclusion Criteria:

1. Patients who are not prescribed with fluoroquinolones and meropenem antibiotics.
2. Patients those who are not willing to participate in the study.

Source Of Data Collection:
The data necessary for the study was collected from:

1. Patient data collection form.
2. Patient case files.
3. Treatment charts.
4. Doctors notes.
5. Laboratory data.

Ethical Approval:
This study was approved by Institutional Ethical Committee of P.E.S College of Pharmacy, Bengaluru**.**

Data Collection Form:
The data collection form was developed by referring available literatures. It includes patient demographics, reasons for admission, provisional diagnosis, final diagnosis and medication chart.

Documentation:

The data collected from the patients was documented for further analysis.
Microsoft excel software is used for statistical analysis.

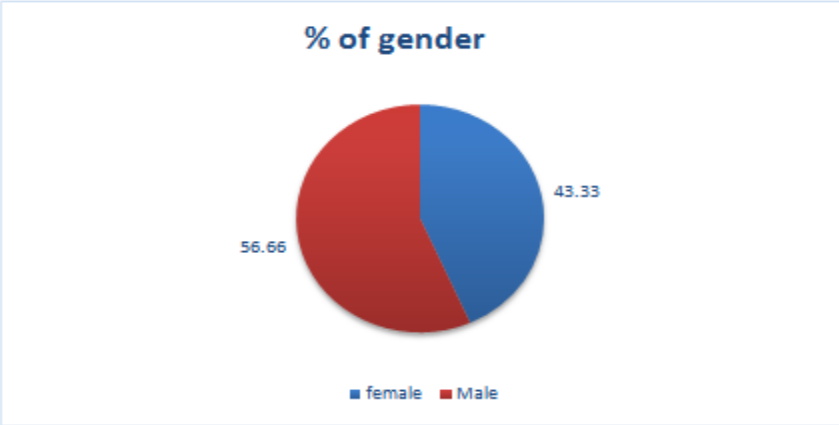
III. Result

1.This was a prospective observational study carried out for a period of six months in a tertiary care hospital. During the study a total of 150 patient's data were collected and analysed, patients who were prescribed with fluoroquinolones and meropenem antibiotics were taken into the study. Out of 150 patients, 65 **(43.33%)** were females and 85 **(56.66%)** were males.

Table No: 1 Distribution of patients based on Gender

Gender	No of patients (%)
Female	65 (43.33%)
Male	85 (56.66%)
Grand Total	**150 (100%)**

Figure No: 1 Percent Gender Distribution



2.Out of 150 patients, 4(2.66%) patients were < 14 years, 12 (8%) patients were between 15-24 years of age, 12 (8%) patients were between 25-44 years of age, 63 (42%) patients were between 45-64 years of age and 42(28%) patients were >65+ age.

A study conducted to assess the rationality of antibiotics in Coimbatore, under the category of age concluded many of the patients were hospitalized under te age group of 51-65, where as in the study we conducted we observed that many of the patients fall into age category of 65+

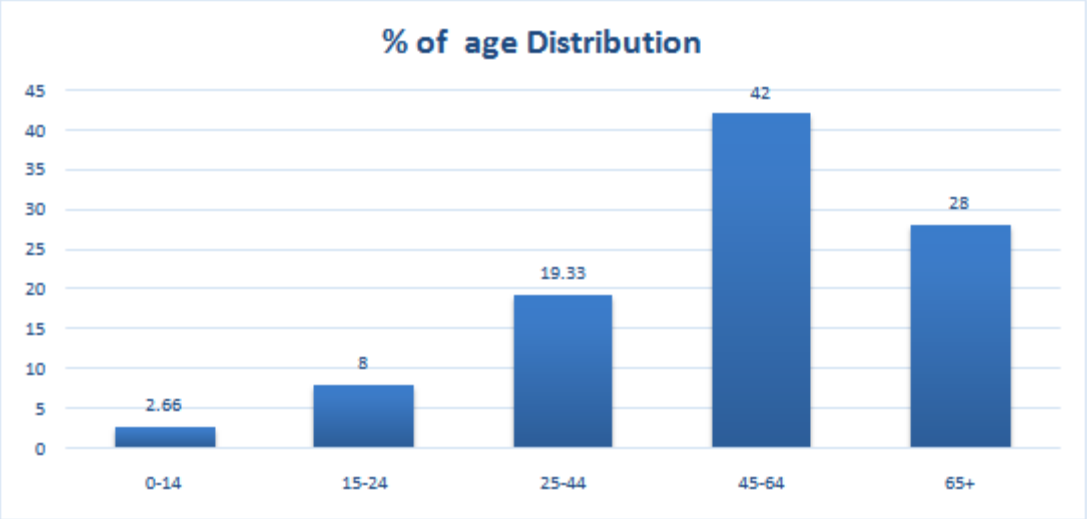
The study conducted in Coimbatore categorised the age group as follows:

1. Adolescent (13-18),
2. Early adulthood (19-35),
3. Adulthood (36-50),
4. Late adulthood (51-65),
5. Young old (66-74),
6. Old (75-84)
7. Old-old (>85), where as we categorized the age groups as shown in the Table 2

Table No: 2 Distribution of patients based on their age

Age category	No of patients (%)
0 - 14	4 (2.66%)
15 - 24	12 (8%)
25 - 44	29 (19.33%)
45 - 64	63 (42%)
65 +	42 (28%)
Grand Total	**150 (100%)**

Figure No: 2 Percent Age distribution

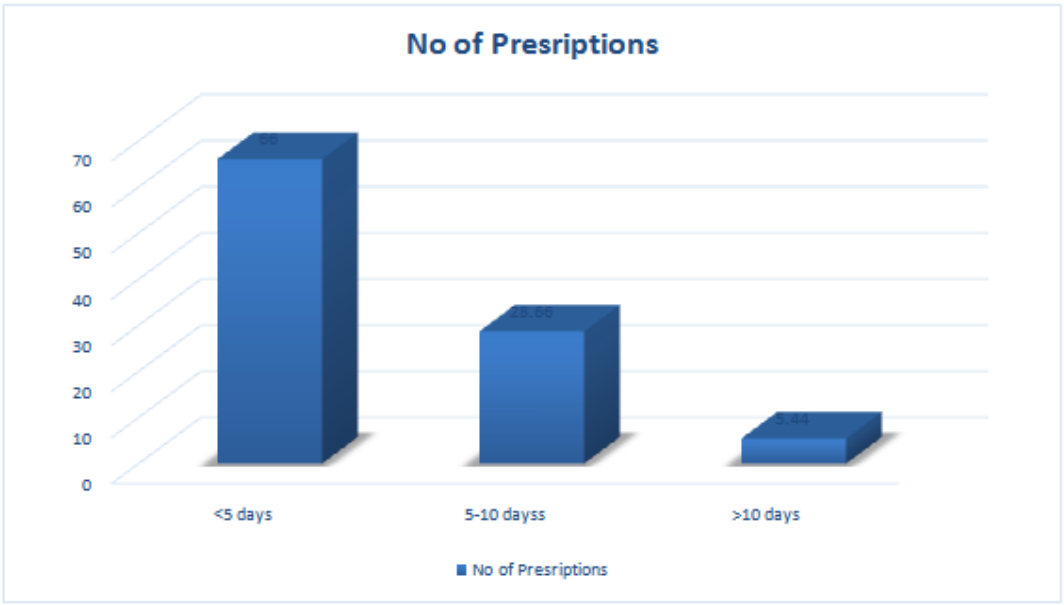


3.Out of 150 prescriptions, 99 medications were given for less than 5 days, 43 medications were between 5-10 days, 8 medications were given for >10 days. Duration of therapy in our project was referred from a study conducted by Osama M Sanhoury and Ahmed S Eldalo wherein they have collected data of 135 patients who have received only meropenem out of which 85 patients receive therapy in the duration of 5-10 days, but in our study we have included the patients who have received both meropenem and FLUOROQUINOLONES and observed that out of 150 patients 99 patients received therapy with in a duration of less than 5 days.

Table No: 3 Duration of therapy

Duration of therapy	**No of Presriptions (%)**
< 5 days	99 **(66%)**
5 - 10 days	43 **(28.66%)**
> 10 days	8 **(5.44%)**
Grand Total	**150 (100%)**

Figure No: 3 Percent Duration of Treatment



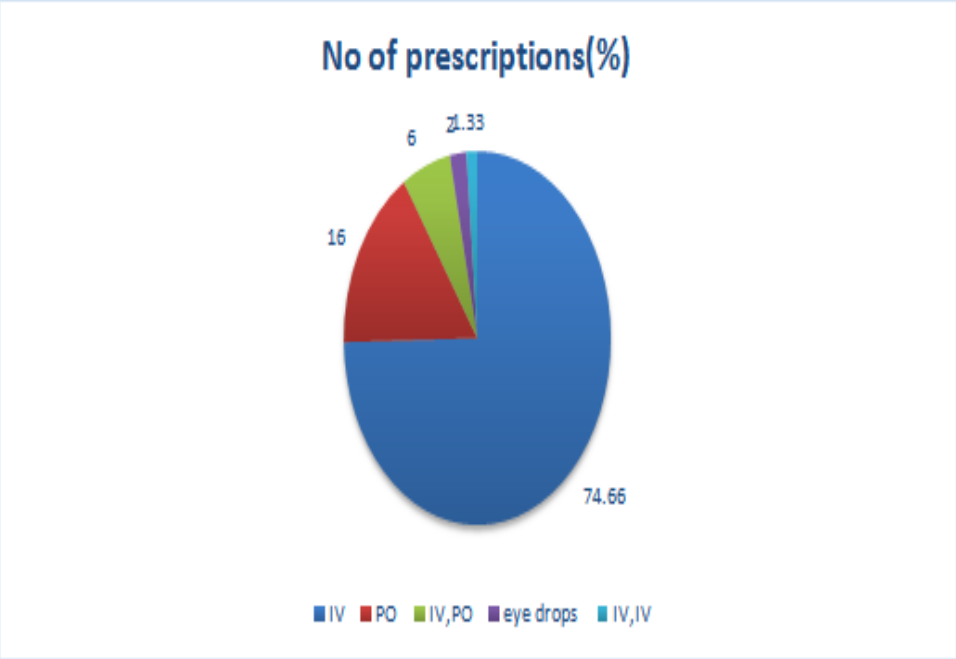
4.Out of 150 prescriptions 112(74.66%) prescriptions were given by intravenous route, 24(16%) prescriptions were given by oral route, 3(2%) prescriptions were given by ophthalmic route, 2(1.33%)

prescriptions contain two medications with intravenous route and 9(6%) prescriptions contain two medications with both intravenous and oral route

Table No: 4 Distribution of prescriptions based on the route of Administration

Route of admission	**No of prescriptions (%)**
IV	112 **(74.66%)**
PO	24 **(16%)**
IV, PO	9 **(6%)**
Eye Drops	3 **(2%)**
IV, IV	2 **(1.33%)**
Grand Total	**150 (100%)**

Figure No: 4 Percent of ROA classification

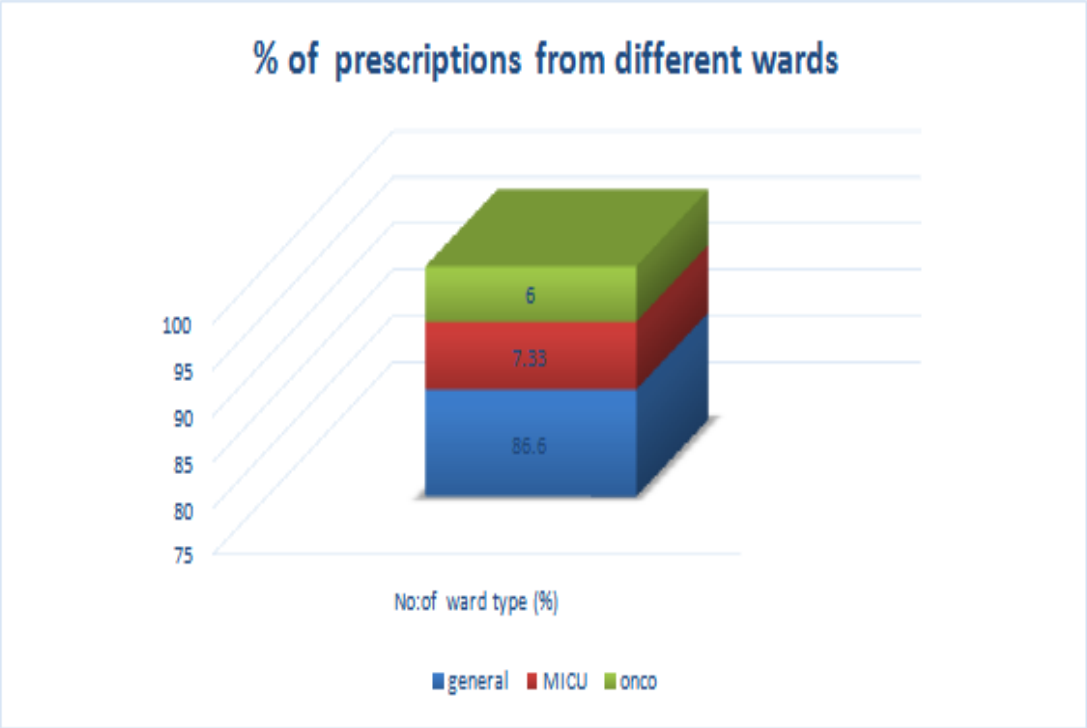


5.Departments wise categorization of collected data was done in which out of 150 prescriptions 130 (86.6%) prescriptions are from general ward, 11 (7.33%) prescriptions are from MICU, 9 (6%) prescriptions are from oncology department

Table No: 5 No of prescriptions from different wards

Department	**No of prescriptions (%)**
General	130 **(86.6%)**
MICU	11 **(7.33%)**
Oncology	9 **(6%)**
Grand total	**150 (100%)**

Figure No: 5 Prescription percent classification based on Wards

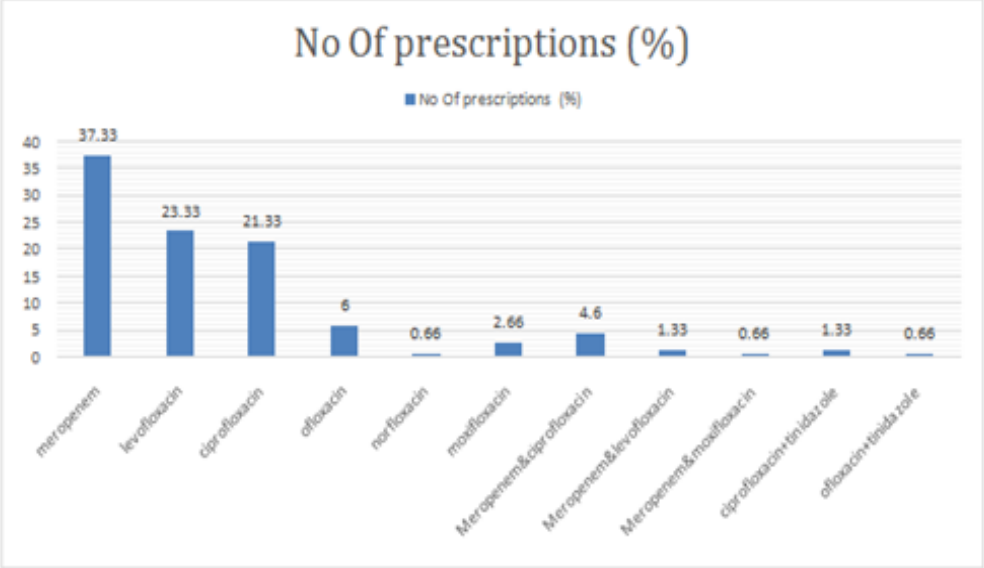


6.Out of 150 prescriptions Meropenem was the most commonly prescribed drug, constitutes around **56(37.33%)** prescriptions, followed by Levofloxacin **35 (23.33%)** prescriptions, Ciprofloxacin **32 (21.33%)** prescriptions, Ofloxacin**9(6%)** prescriptions, Moxiflioxacin**4(2.66%)** prescriptions, Norfoxacin**1(0.66%)** prescriptions. Then **7 (4.6%)** prescriptions contain both Meropenem and Ciprofloxacin, **2 (1.33%)** prescriptions contains both Meropenem and Levofloxacin, **1(0.66%)** prescriptions contains both Meropenem and Moxifloxacin. Then **2(1.33%)** prescriptions contain a combination of Ciprofloxacin+Tinidazole and **1(0.66%)** prescriptions contain a combination of Ofloxacin+Tinidazole.

Table No: 6 No of drugs prescribed

DRUG NAME	**No Of prescriptions (%)**
Meropenem	56 **(37.33%)**
Levofloxacin	35 **(23.33%)**
Ciprofloxacin	32 **(21.33%)**
Ofloxacin	9 **(6%)**
Norfloxacin	1 **(0.66%)**
Moxifloxacin	4 **(2.66%)**
Meropenem&Ciprofloxacin	7 **(4.6%)**
Meropenem&Levofloxacin	2 **(1.33%)**
Meropenem&Moxifloxacin	1 **(0.66%)**
Ciprofloxacin+Tinidazole	2 **(1.33%)**
Ofloxacin+Tinidazole	1 **(0.66%)**
Grand Total	**150 (100%)**

Figure No: 6 Percent of drugs prescribed

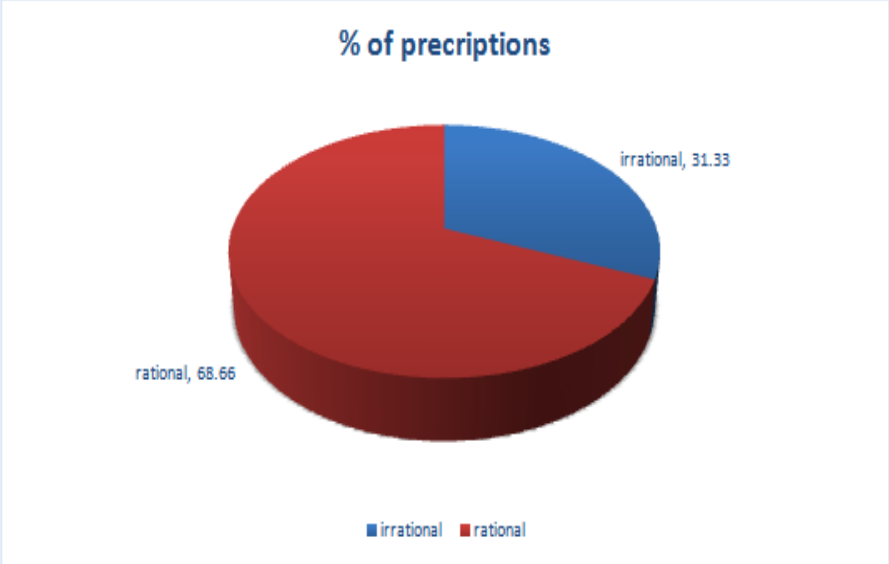


7.Rationality of the prescriptions was assessed based on Antimicrobial policy GHG/BGSGH/HIC/02/ Version No. 5 issued on 20th December 2016 which was designed based on NABH standard reference: HIC/02(g) followed in our hospital setting for the prescription of antibiotics, the purpose of these guidelines is to develop a system of monitoring drug susceptibility based on culture and sensitivity and accordingly develop an antimicrobial policy, by using these antimicrobial policy out of 150 prescriptions **47(31.33%)** prescriptions were Irrational and **103(68.66%)** prescriptions were Rational, whereas the study conducted by B. Rajalingam (*et al*) has categorised according to the guidelines of rational use of antibiotics that was developed after reviewing relevant literatures, electronic database (Micromedex) and by using the National Formulary of India 2011 (NFI) with respect to dose, indication, frequency and duration of antibiotics.

Table No: 7 Rationality of prescriptions classification

Rationality	**No of prescriptions**
Irrational	47 **(31.33%)**
Rational	103 **(68.66%)**
Grand Total	**150 (100%)**

Figure No: 7 Percent rationality of prescriptions

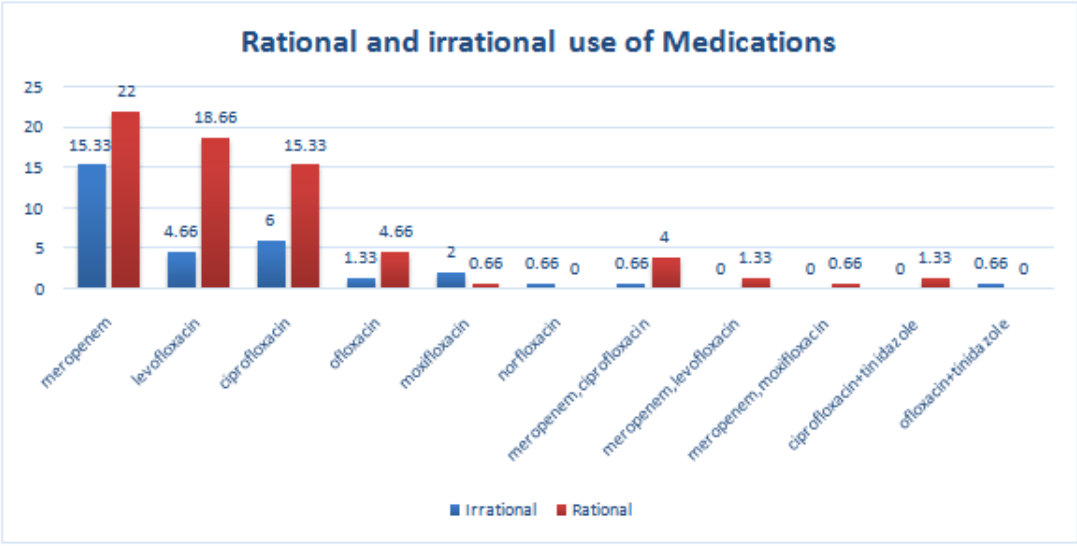


8.Rationality of each medication was analysed, out of 150 prescriptions, 56 prescriptions contain Meropenem in which **23(15.33%)** were irrational and **33(22%)** were rational, whereas a study conducted by Osama M Sanhoury and Ahmed S Eldalo in military hospital to evaluate the meropenem use in ICU in Sudan, in this study a total of 135 patients were encountered and the results showed that, no culture was done for any patient before meropenem used. Overall 80% of meropenem was prescribed empirically, their study concludes that the Meropenem use in ICU appears to be inconsistent with evidence based assessment criteria. The most evident inappropriateness was observed in empirical therapy.[4]**35 (23.33%)** prescriptions contains Levofloxacin in which **7(4.66%)** were irrational and **28(18.66%)** were rational, **32 (21.33%)** prescriptions contains Ciprofloxacin in which **9(6%)** were irrational and **23 (15.33%)** were rational, **9(6%)** prescriptions contains Ofloxacin in which **2(1.33%)** were irrational and **7(4.66%)** were rational, **4(2.66%)** prescriptions contains Moxifloxacin in which **3(2%)** were irrational and **1(0.66%)** was rational, **1(0.66%)** prescriptions contain Norfoxacin which was irrational. **7 (4.6%)** prescriptions contain both Meropenem and Ciprofloxacin in which **1(0.66%)** was irrational and **6(4%)** were irrational, **2 (1.33%)** prescriptions contains both Meropenem and Levofloxacin which were rational, **1(0.66%)** prescriptions contains both Meropenem and Moxifloxacin which was rational, **2(1.33%)** prescriptions contain a combination of Ciprofloxacin+Tinidazole which were rational and **1(0.66%)** prescriptions contain a combination of Ofloxacin+Tinidazole which was irrational

Table No: 8 Rationality of medications

Medications given	Irrational	Rational	Total no of prescriptions
Meropenem	23 (15.33%)	33 (22%)	56 (37.33%)
Levofloxacin	7 (4.66%)	28 (18.66%)	35 (23.33%)
Ciprofloxacin	9 (6%)	23 (15.33%)	32 (21.33%)
Ofloxacin	2 (1.33%)	7 (4.66%)	9 (6%)
Moxifloxacin	3 (2%)	1 (0.66%)	4 (2.66%)
Norfloxacin	1 (0.66%)	0 (0%)	1 (0.66%)
Meropenem&Ciprofloxacin	1 (0.66%)	6 (4%)	7 (4.66%)
Meropenem&Levofloxacin	0 (0%)	2 (1.33%)	2 (1.33%)
Meropenem&Moxifloxacin	0 (0%)	1 (0.66%)	1 (0.66%)
Ciprofloxacin+Tinidazole	0 (0%)	2 (1.33%)	2 (1.33%)
Ofloxacin+Tinidazole	1 (0.66%)	0 (0%)	1 (0.66%)
Grand Total	**47(31.33%)**	**103 (68.66%)**	**150 (100%)**

Figure No: 8 Percent of rationality of Medications



9.Out of 150 prescriptions, **36(24%)** prescriptions were prescribed for digestive system disorders like Acute Gastritis,IBD, Liver disorders, appendicitis in which 9(6%) were irrational and 27(18%) were rational , **34(22.6%**) prescriptions are prescribed for urinary system disorders like UTI and Renal disorders in which 7(4.66%) were irrational and 27(18%) were rational , **29(19.33%)** prescriptions were prescribed for Immune system disorders like carcinoma and fever in which 11(7.33%) were irrational and 18(12%) were rational, **15(10%)** prescriptions were prescribed for circulatory system disorders like sepsis, anemia in which 3(2%) were irrational and 12(8%) were rational, **13(8.66%)** prescriptions were prescribed for respiratory system disorders like Pneumonia, COPD, Respiratory Failure conditions, asthma in which 3(2%) were irrational and 10(6.66%)

were rational, **11(7.33%)** prescriptions were prescribed for CVS disorder IHD in which 6(4%)were irrational and 5(3.33%) were rational, **7(4.66%)** prescriptions were prescribed for CNS disorders like CVA and seizures in which 6(4%) were irrational and 1(0.66%) were rational **3(2%)** prescriptions were prescribed for skeletal system disorder like Steno clavicular abscess in which 1(0.66%) was irrational and 2(1.33%) were rational, **1(0.66%)** was prescribed for Endocrine system disorder Diabetic foot which was rational and **1(0.66%)** was prescribed for integumentary system disorder Burns was irrational.

We have categorized the prescriptions based on the systems involved where as a study conducted in sudan have categorized according to the disease. In the study conducted in sudan they witnessed that many of the patients were suffered by sepsis, but in our study we have observed that many of the patients have been suffering from Digestive System disorders like liver diseases, IBD, appendicitis and gastritis

Table No: 9 Systems Involved

SYSTEMS INVOLVED	No of Prescriptions (%)
DIGESTIVE	36 (24 %)
URINARY	34 (22.6 %)
IMMUNE	29 (19.33 %)
CIRCULATORY	15 (10 %)
RESPIRATORY	13 (8.66 %)
CVS	11 (7.33 %)
CNS	7 (4.66 %)
SKELETAL	3 (2 %)
ENDOCRINE	1 (0.66 %)
INTEGUMENTARY	1 (0.66 %)
Grand Total	**150 (100 %)**

Figure No: 9 Percent of prescribed classified based on systems involved

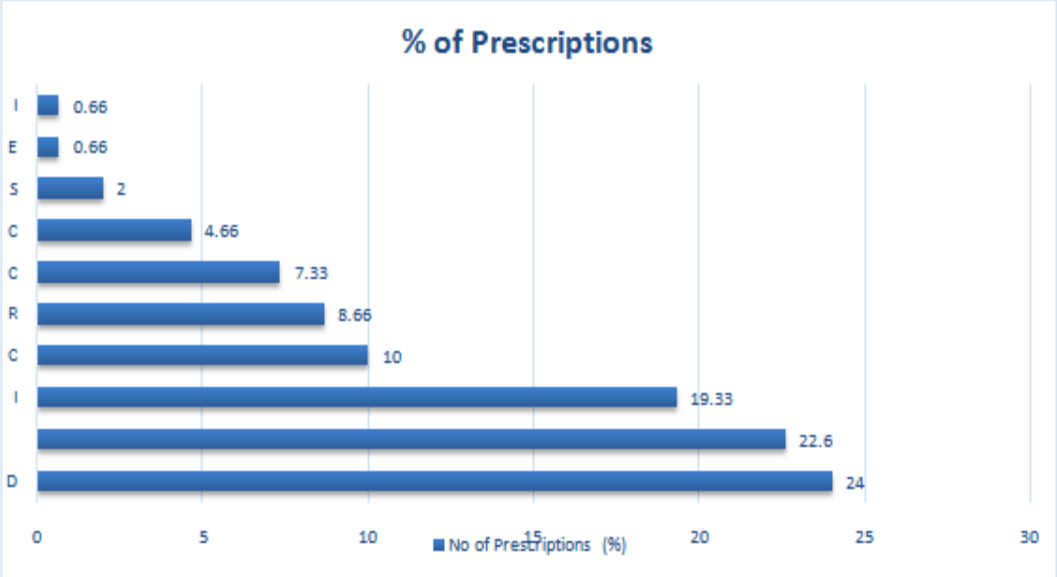
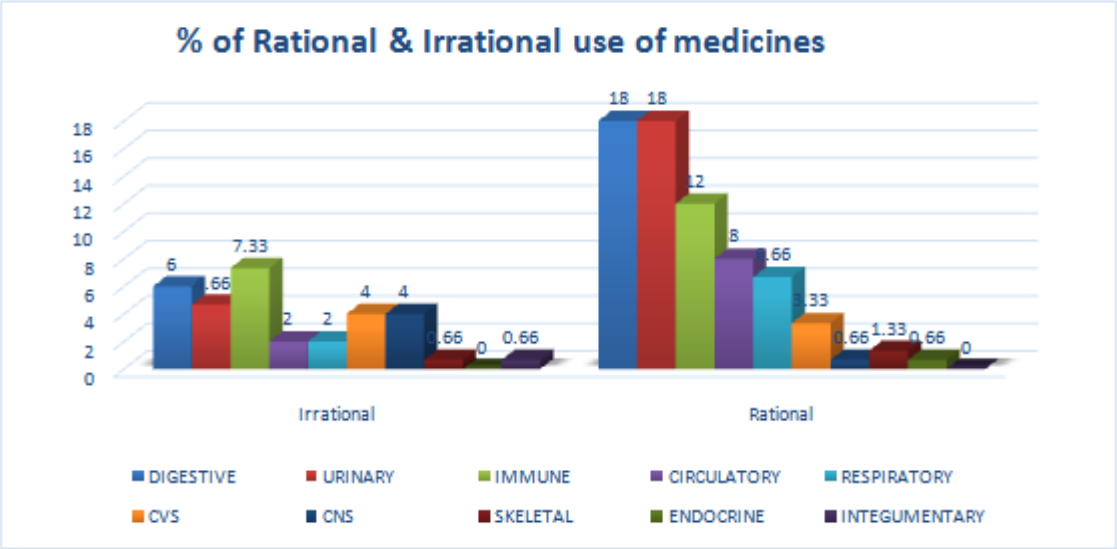


Table No: 10 Rationality of prescriptions based on systems involved

SYSTEMS INVOLVED	Irrational	Rational	No of Prescriptions (%)
DIGESTIVE	9 (6 %)	27 (18 %)	36 (24 %)
URINARY	7 (4.66 %)	27 (18 %)	34 (22.6 %)
IMMUNE	11 (7.33 %)	18 (12 %)	29 (19.33 %)
CIRCULATORY	3 (2 %)	12 (8 %)	15 (10 %)
RESPIRATORY	3 (2 %)	10 (6.66 %)	13 (8.66 %)
CVS	6 (4 %)	5 (3.33 %)	11 (7.33 %)
CNS	6 (4 %)	1 (0.66 %)	7 (4.66 %)
SKELETAL	1 (0.66 %)	2 (1.33 %)	3 (2 %)
ENDOCRINE	0 (0 %)	1 (0.66 %)	1 (0.66 %)
INTEGUMENTARY	1 (0.66 %)	0 (0 %)	1 (0.66 %)
Grand Total	**47 (31.33%)**	**103 (68.66%)**	**150 (100 %)**

Figure No: -10 Percent rationality of prescriptions based on systems involved.



Out of 150 prescriptions 75(50%) were prescribed with their brand name and 75(50%) were prescribed with their generic name, in these meropenem was prescribed with their generic name in all the prescriptions.
Due to the unavailability of the different brands of fluoroquinolones in our hospital, cost minimization analysis for these drugs was not carried out. Whereas for meropenem there is an availability of brands but they are prescribed with their generic name, so it wasn't possible for us to carry out the Cost- minimization analysis
In most of the cases medications were prescribed based on the patient's clinical conditions rather than the diagnosis.
In most of the cases microbial investigations were not done before prescribing the medications which actually plays a vital role in the prescription of antibiotics

IV. Discussion

This was a prospective observational study carried out for a period of six months in a tertiary care hospital. During the study a total of 150 patient's data were collected and analysed, patients who were prescribed with fluoroquinolones and meropenem antibiotics were taken into the study. Out of 150 patients, 65 **(43.33%)** were females and 85 **(56.66%)** were males
A study conducted to assess the rationality of antibiotics in Coimbatore, under the category of age concluded many of the patients were hospitalized under te age group of 51-65, where as in the study we conducted we observed that many of the patients fall into age category of 65+
The study conducted in Coimbatore categorised the age group as follows:

1. Adolescent (13-18),
2. Early adulthood (19-35),
3. Adulthood (36-50),
4. Late adulthood (51-65),
5. Young old (66-74),
6. Old (75-84)
7. Old-old (>85)

Duration of therapy in our project was referred from a study conducted by Osama M Sanhoury and Ahmed S Eldalo wherein they have collected data of 135 patients who have received only meropenem out of which 85 patients receive therapy in the duration of 5-10 days, but in our study we have included the patients who have received both meropenem and FLUOROQUINOLONES and observed that out of 150 patients 99 patients received therapy with in a duration of less than 5 days.

Rationality of the prescriptions was assessed based on Antimicrobial policy GHG/BGSGH/HIC/02/ Version No. 5 issued on 20th December 2016 which was designed based on NABH standard reference: HIC/02(g) followed in our hospital setting for the prescription of antibiotics, the purpose of these guidelines is to develop a system of monitoring drug susceptibility based on culture and sensitivity and accordingly develop an antimicrobial policy, by using these antimicrobial policy out of 150 prescriptions **47(31.33%)** prescriptions were Irrational and **103(68.66%)** prescriptions were Rational, whereas the study conducted by B. Rajalingam (*et al*) has categorised according to the guidelines of rational use of antibiotics that was developed after reviewing relevant literatures, electronic database (Micromedex) and by using the National Formulary of India 2011 (NFI) with respect to dose, indication, frequency and duration of antibiotics.

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We have categorized the prescriptions based on the systems involved where as a study conducted in sudan have categorized according to the disease. In the study conducted in sudan they witnessed that many of the patients were suffered by sepsis, but in our study we have observed that many of the patients have been suffering from Digestive System disorders like liver diseases, IBD, appendicitis and gastritis

V. Conclusion

In our study a total of 150 patients data was collected in which 47 prescriptions were irrational and 103 were rational, out of which meropenem was highly irrational followed by Ciprofloxacin, Levofloxacin, Moxifloxacin, Ofloxacin. Although most of the prescriptions out of 150 were rational but still, 47 prescriptions came out to be irrational, so measures need to be taken in such a way to reduce the irrationality of the prescriptions. In these study we found many of the antibiotics were prescribed without any appropriate microbial culture tests, therefore microbial culture test should be performed before prescribing the antibiotics for the better treatment of patients and also to minimize the resistance and adverse drug reactions.This study provides valuable insight to antibiotics usage in hospital settings. Our data points that overuse of antibiotics exists in our hospital. It is recommended to guide antibiotics utilization according to microbiology and hospital antibiotic policy.

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IOSR Journal of Pharmacy and Biological Sciences (IOSR-JPBS) is UGC approved Journal with Sl. No. 5012, Journal no. 49063.

Riya Teresa Joseph . "Study of Nebulization with Hypertonic Saline and Other Nebulizing Agents with or With Out Antibiotics in Bronchiolitis Patients Aged 2 Months to 2 Years Admitted In Rmmch." IOSR Journal of Pharmacy and Biological Sciences (IOSR-JPBS) 13.2 (2018): 60-71.