Journal of Rare Cardiovascular Diseases
ISSN: 2299-3711 (Print) | e-ISSN: 2300-5505 (Online)
www.jrcd.eu

RESEARCH ARTICLE

A Study on Consumption of WHO Reserve Antibiotics In Inpatients Admitting At Tertiary Care Hospital

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Received: 16/09/2025
Revised: 25/10/2025
Accepted: 11/11/2025
Published: 19/11/2025

ABSTRACT:- **Background**: Antibiotic resistance is a global health threat. In order to prevent this, WHO classifies antibiotics into Access, Watch, and Reserve groups for rational prescribing. The reserve group antibiotics are last resort options for treating infections. Irrational usage leads to resistance and development of adverse drug reactions. So, the aim of our study is to assess Defined Daily Dose (DDD) and consumption of reserve antibiotics in a tertiary care hospital. **Methodology**: This was a cross-sectional study conducted on patients prescribed reserve antibiotics for treating various infections admitted at SMCRI. Ethical approval was obtained, and 80 cases were enrolled based on the inclusion criteria over a period of 6 months. Demographics, medical and medication details were obtained and subjected to statistical analysis. Results: Among 80 subjects, 56 (70%) subjects were found to be males, and they were in the age group between 41-60 years. About 55 (68.7%) prescription were prescribed with Feropenem. Only 27 (33.75%) subjects were prescribed reserve antibiotics based on the culture sensitivity report, and post-operative prophylaxis (68.75%) was the main indication. About 85.2% of organisms were gram negative, and Pseudomonas aeruginosa accounted for 37%. We observed a significant increase in the DDD of Feropenem 3.84 times, Linezolid 3.52 times, and Tigecycline 2.53 times. **Conclusion**: Our study concludes that, gram-negative organisms and Pseudomonas aeruginosa now showing resistance to access and watch antibiotics. Reserve antibiotics were the last resort to treat bacterial infections, and irrational usage leads to bacterial resistance. Therefore, care should be taken while prescribing reserve antibiotics.

Keywords: Reserve antibiotics, Defined daily dose, Antimicrobial resistance, WHO, AWaRe classification.

INTRODUCTION

Antibiotics are the medications that can destroy or inhibit the growth of bacteria by either killing or inhibiting them[1]. The clinical use of antibiotics was arguably the greatest medical breakthrough of the 20th century. In addition to treating infectious diseases, antibiotics made many modern medical procedures possible, including cancer treatment, organ transplants, and open-heart surgery[2]. According to a Lancet study, the world could see more than 39 million deaths directly related to antimicrobial resistance between 2025 and 2050 due to superbugs[3]. By 2050, a total of two million people in India are expected to be affected due to antibiotic resistance[4].

Various drug prescription problems have been identified in health sectors especially in developing countries. Mainly, irrational antibiotics usage can lead to increased healthcare utilization, morbidity, mortality, adverse drug events, and drug resistance[5].Irrational use of medicines occurs when medications are not prescribed in accordance with guidelines for correct dosage, duration, and indication. The antibiotics treatment regimens given to most of the patients were without culture sensitivity testing before prescribing, which lead to irrational prescribing[6]. Irrational use of medicines is present in all countries but mostly in developing countries due to the fragile or fragmented health system. Major driving forces for irrational use of antibiotics include lack of adequate knowledge on the behalf of the patients or prescriber, easy access to antimicrobials without prescriptions, and pharmaceutical promotions[7].

According to the World Health Organization (WHO), the standard method for quantitatively evaluating the use of antibiotics is Anatomical Therapeutic Classification (ATC) / Defined Daily Dosage (DDD). DDD is the assumed average maintenance dose per day for a drug when used for its main indication in adults. A DDD value higher than the WHO standard indicates the likelihood of irrational use of antibiotics, whereas a smaller DDD value indicates a more judicious use of antibiotics[8]. Infection Prevention and Control Committee (IPC) and Antibiotic Stewardship Programs play a key role in preventing antibiotic resistance[7].The World Health Organization's (WHO) expert committee developed the 'AWaRe' classification on using the Essential Medicine List (EML) in 2017 and has classified the antibiotics into 3 major groups: Access, Watch, and Reserve. This classification helps to support, strengthen, and monitor the antibiotic stewardship program and was further updated in 2021[9].

Access group antibiotics are generally narrow-spectrum agents with minimal adverse effects. They are recommended for the treatment of twenty-one different diseases and pathological conditions. Examples are Amikacin, Ampicillin +sulbactum, Cefodroxil, Nitrofurrantoin, ornidazole, Metronidazole, Penamecillin, and sulfadiazine. Watch group antibiotics are those that have a higher potential for adverse effects and are more likely to develop resistance compared to Access group antibiotics. These antibiotics are classified separately by the WHO expert committee to ensure careful monitoring and rational use[10]. Examples are Azithromycin, Cefdinir, Cefoprazone, Erythromycin, Kanamycin, Meropenem, Vancomycin, cefuroxime, Piperacillin, Sisomycin.

The Reserve group antibiotics are last-resort options and are used for specific patients and clinical settings in case of failure of other alternatives[11]. The reserve class of antibiotics such as, tigecycline, aztreonam, cefiderocol, ceftazidime + avibactam, fosfomycin, Meropenem + vaborbactam, plazomicin, Feropenem, polymyxin B and colistin, covers different serious clinical infections. These antibiotics helps to treat carbapenem-resistant organisms, Pseudomonas spp and Acinetobacter spp.

Currently, the carbapenems, colistin, and tigecycline, alone or in combinations, are used as reserve antibiotics to treat fatal bacterial infections[12]. Colistin is commonly used against extensively drug-resistant (XDR), pan-drug-resistant (PDR), and multidrug-resistant (MDR) bacterial infections, which are normally left untreated by other classes of antibiotics. The emergence of colistin resistance complicates treatment options, emphasizing the urgent need for prudent antibiotic use and the development of new antimicrobial agents[13]. Evidence from recent hospital-based studies shows an increasing trend in the use of last-line reserve antibiotics, reflecting an erosion of the antibiotic hierarchy and growing dependence on high-end agents for empirical therapy[14]. They are often prescribed without adequate microbiological justification, leading to inappropriate use and increased risk of adverse clinical outcomes[15].

The irrational use of antibiotics could be minimized in hospital settings through the implementation of antimicrobial stewardship programs where health professionals work together to give patients the appropriate antibiotics in the correct dose and for the correct duration based on rapid microbial testing[16].Ensuring the optimal use of reserve antibiotics is complex and difficult at both a patient and country level, but control of the use of reserve antibiotics is critical to maintaining their future effectiveness[17]. So the aim of the study is to assess DDD and consumption of reserve antibiotics in tertiary care hospital for treating of infection.

METHODOLOGY

This was a hospital based Prospective cross-sectional study. This study was conducted in the departments of intensive care unit, general medicine and, surgery among patients receiving reserve antibiotics for the treatment of various infections at SMCRI.

The patients who were admitted at a tertiary care hospital and prescribed with reserve group of antibiotics, such as feropenem, colistin, linezolid, fosfomycin, tigecycline and polymyxin were, included.

Ethical approval:
The study was undertaken after obtaining permission from the Institutional Ethics Committee [IEC] at Siddaganga Medical College and Research Institute, bearing approval letter Ref

No: SMCRI/IEC/2025-26/116.

Sample size:

Formula: $n = (Z^2_{(1-\alpha)} \times P(1-P))/d^2$

(n = sample size, z = 1.96, d = 95%, p = 5% = 0.055)

Calculation: $n = ((1.96)^2 \times 0.055(1-0.055))/(0.05)^2 = 79.68 \approx 80$

The sample size is calculated by considering prevalence rate of Reserve Antibiotics 5% and for margin of error 5% and 95% confidence interval, the minimum number of subjects required for the present study is 80.[18]

Inclusion criteria:

- Both male and female patients aged >18 years.
- Patients those who are receiving Reserve antibiotics for their infection.
- The patients having with or without microbial culture sensitivity test report.

Exclusion criteria:

- Incomplete data.

Method of collection of data:

Data will be collected by using predesigned profile form. The patients who are admitted to SMCRI for their illness are on reserve antibiotics for their infection.

The following information will be collected:

- Socio-demographic details like name, age, sex, IP number, and occupation.
- Details on reserve antibiotics prescribed for patients with diagnosis will be obtained from inpatient case records.
- The data on drug utilization will be collected from in patient case sheets. The consumption of medications will be measured using the Defined Daily Dose (DDD) methodology, as per the WHO DDD classification system. The total quantity of each drug consumed will be calculated and expressed in DDD per 100 bed-days (for inpatient settings) or DDD per 1,000 inhabitants per day (for outpatient settings) to ensure standardized comparison. The Defined daily dose can be calculated by using formula[19].

$$\text{DDD/100 bed-days} = \frac{\text{No. of units administered in a given period} \times 10}{\text{DDD} \times \text{number of days} \times \text{number of beds} \times \text{occupancy index}}$$

$$\text{Where Occupancy index} = \frac{\text{Total inpatient service days for a period} \times 100}{\text{Total inpatient bed count} \times \text{number of days in the period}}$$

Study procedure:

A cross -sectional study was conducted for a duration of 6 months with the recruitment of 80 study subjects based on inclusion and exclusion criteria. This was a six-month observational study that involve data collection from inpatient case sheets. The study population included are subjects prescribed with reserve antibiotics such as, tigecycline, colistin, linezolid, feropenem, and polymyxin. The following data was collected, such as demographic details, antibiotic names, dosages, duration of therapy, and routes of administration. The collected data will then be analyzed for reserve antibiotics usage patterns and WHO Anatomical Therapeutic Chemical (ATC)/DDD classification system. The collected information was subjected to statistical analysis for trends in antibiotic usage, prescribing patterns, and adherence to antimicrobial stewardship guidelines.

RESULTS:

A cross -sectional study was conducted in SMCRI, Tumakuru. A total of 80 subjects were actively participated in the study who fulfilled the criteria for inclusion. The demographic details, such as name, age, gender, diagnosis and, treatment details from inpatients' case sheets, were collected using a suitable designed profile form.

Age, Gender and Clinical department distribution:

A total of 80 subjects were included during the study period. Among them, 56 (70%) subjects were found to be males and 24 (30%) subjects were females. It shows that males were more prevalent than females. In our study 9 (11.25%) subjects belonged to the age group between 18-40years, followed by 41–60 years 34 (11.25 %) subjects, 61 – 80 years 33 (41.2 %) subjects, and a minimum number of subjects were found to be 4 (5%) in the age group of above 80 years. Reserve antibiotics were commonly prescribed in three departments. Among them , 12 (15%) patients were prescribed in the intensive care unit, followed by 25 (31.2%) subjects in general medicine and 43 (53.7%) subjects in the surgery department. (Table -1)

CHARACTERISTICS	CATEGORY	NUMBER OF PATIENTS	IN PERCENTAGE
Gender	Male	56	70%
	Female	24	30%
Age	18-40	9	11.25 %
	41-60	34	42.5 %
	61-80	33	41.2 %
	>80	4	5 %
Departments	ICU	12	15%
	General medicine	25	31.2%
	Surgery	43	53.7%

Table 1: Age, Gender and Clinical Department Distribution.

Individualization usage of Reserve Antibiotics

Among 80 study subjects, 95 reserve antibiotics were prescribed. In that 10 (10.5%) reserve antibiotics were found to be colistin, 16 (16.8%) were found to be tigecycline, 32(33.6%) were found to be linezolid and 37(38.9%) were found to be feropenem. (Table -2)

Table 2: Individualization usage of Reserve Antibiotics Indications for Usage of Reserve Antibiotics

DRUG NAME	NUMBER OF DRUGS	IN PERCENTAGE (%)
Colistin	10	10.5 %
Tigecycline	16	16.8 %
Linezolid	32	33.6 %
Feropenem	37	38.9 %

Among 80 subjects, 55 (68.75%) subjects prescribed with reserve antibiotics for post -Operative prophylaxis, followed by 15 (18.75%) subjects for respiratory tract infections, 8 (10%) subjects for urinary tract infections, and 2(2.5%) subjects for meningo encephalitis. (Table -3)

Table 3: Indications for Usage of Reserve Antibiotics

INDICATIONS	NUMBER OF PATIENTS	IN PERCENTAGE
Meningo encephalitis	2	2.5 %
Urinary Tract Infection	8	10 %
Respiratory Tract Infections	15	18.75 %
Post- Operative Prophylaxis	55	68.75 %

Usage Based on Culture Sensitivity Report

Among the subjects, 27 (33.75%) subjects were prescribed with reserve antibiotics based on the culture sensitivity reports and 53 (66.25%) subjects prescribed with reserve antibiotics without culture sensitivity reports. (Figure -1)

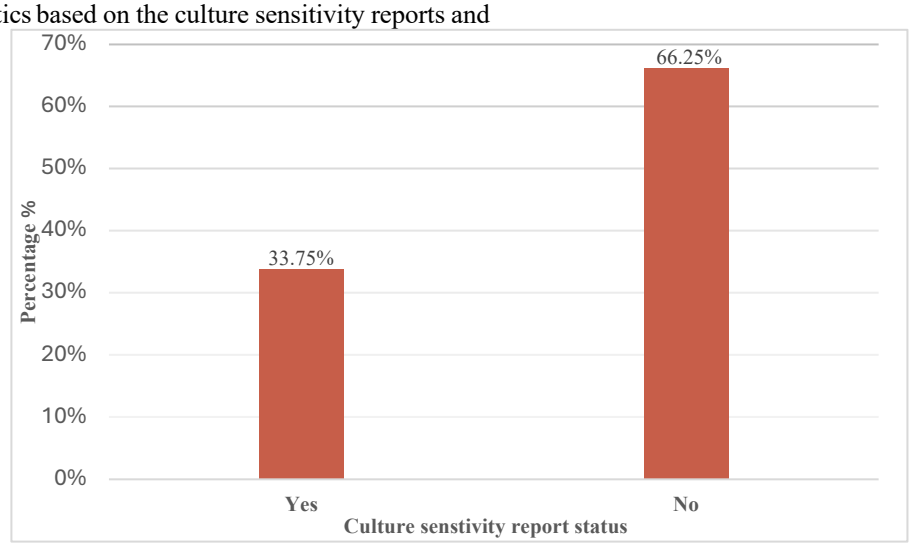

Figure 1: Usage Based on Culture Sensitivity Report

Profile of Bacterial Isolates from Various Clinical Specimens

Among the 27 subjects, 6 (22.2%) subjects were infected with Escherichia. coli, followed by 10 (37%) subjects with Pseudomonas aeruginosa, 3 (11.1%) subjects with Klebseilla pneumonia, 3 (11.1) subjects with Acinetobacter baumannii, 1 (3.7%) subject with Citrobacter freundii, 1 (3.7%) subject with Streptococcus species, 1 (3.7%) subject with Enterococcus faecium, and 2 (7.4%) subjects with Enterococcus faecalis. (Table - 4)

BACTERIA'S	CLINICAL SPECIMENS				NUMBER OF PATIENTS	IN PERCENTAGE
➢ Gram negative Bacteria	Sputum	Urine	Pus	ET		
Escherichia. Coli		2	4		6	22.2 %
Pseudomonas Aeruginosa			10		10	37 %
Klebseilla Pneumonia				3	3	11.1 %
Acinetobacter Baumannii	2			1	3	11.1 %
Citrobacter Freundii				1	1	3.7 %
➢ Gram positive Bacteria						
Streptococcus Species			1		1	3.7 %
Enterococcus Faecium		1			1	3.7 %
Enterococcus Faecalis		2			2	7.4 %

Table 4: Profile of Bacterial Isolates from Various Clinical Specimens

Defined Daily Dose (DDD) of Reserve Antibiotics

The calculated DDD for Feropenem was found to be 3.84g compared with WHO DDD reference of 0.75g followed by linezolid 3.52g (WHO DDD: 1.2g), and tigecycline 2.53g (WHO DDD: 0.1g). These antibiotics were prescribed to the subjects due to disease severity and based on the culture sensitivity report. In contrast colistin, the calculated DDD (1.56 million IU) was lower than the WHO reference value (9 million IU), which may reflect cautious and individualized prescribing in view of its toxicity profile and the need for tailored dosing in critically ill patients. (Table -5)

ANTIBIOTICS	WHO DDD	CALCULATED DDD
Feropenem	0.75g	3.84g
Linezolid	1.2g	3.52g
Tigecycline	0.1g	2.53g
Colistin	9Milli.IU	1.56Milli.IU

Table 5: Defined Daily Dose of Reserve Antibiotics

DISCUSSION

A total of 80 subjects were included in our study. The number of male subjects, 56 (70%) were prescribed with reserve antibiotics for their treatment was higher compared to female subjects, 24 (30%). This result shows that both adults and geriatric male populations have more chances of getting infections compared to female populations. These results are similar to the study conducted by Subash Senthil Kumar et al[20]., the maximum number of subjects were found in the age group of 41-60 years (42.5%) and 61-80 years (41.2%). These results are similar to the study conducted by Jones C et al[21].
Among the study subjects, most of the subjects receiving reserve antibiotics in surgery department 43 (53.7%) due to the various pre- and post-surgical conditions such as hernia, diabetic foot, and gangrene. A *majority of 50 (52.7%) subjects received antibiotic therapy through the intravenous route of administration.* These results are similar to the study conducted by Viviana Hodosan et al[22]. This suggests that parenteral administration is preferred for achieving rapid drug action and effectively treating serious infections where oral therapy may not be adequate**.**

Feropenem was the most frequently prescribed drug in the surgery department, accounting for 37 (38.9%). Post-operative prophylaxis was the main reason for prescribing reserve antibiotics, particularly in conditions such as hernia, diabetic foot, and gangrene, where the risk of infection after surgical procedures is high. In the general medicine department, Linezolid and Tigecycline were more commonly used for subjects infected with gram-negative microorganisms that were sensitive only to reserve antibiotics, as the watch group drugs were ineffective in these cases. These results are similar to the study conducted by Khilnani and Wilson et al[23].

A diverse range of microorganisms was identified in culture sensitivity, among which Gram -negative microorganisms were the most prevalent, accounting for 85.2% in patient

infections. These results are similar to the study conducted by Khilnani and Wilson et al[24].

Based on the culture sensitivity report, we found that Pseudomonas aeruginosa, E coli, Klebseilla pneumoniae, Acinetobacter baumannii species, and Enterococcus species are predominant pathogens responsible for causing infections. These results are similar to the study conducted by Julie Birdie Wahlang et al[25]. This result shows that populations have more chances of getting infected with Pseudomonas aeruginosa, accounting for 37%, and E coli (22.2%) compare to the other organisms. A majority of the subjects were prescribed reserve antibiotics without culture sensitivity reports, accounting for 53 (66.25%) of the cases. Only 27 (33.75%) subjects received reserve antibiotics based on culture and sensitivity reports. It reveals that the majority of reserve antibiotics were prescribed empirically without culture sensitivity support. This practice may contribute to inappropriate antibiotic use and increased antimicrobial resistance. Strengthening antibiotic stewardship and promoting culture-based prescribing are essential to ensure rational antibiotic use.

During our 6 -months study, we observed a significant increase in the DDD of antibiotics: Feropenem 3.84 times, Linezolid 3.52 times, and Tigecycline 2.53 times for DDD 100 bed days. The variation in the DDD of drugs was observed compared to the WHO DDD. Feropenem was frequently used due to critical care in surgical units where severe infections are encountered. Linezolid and Tigecycline associated with its role in treating complicated Gram-positive infections and multidrug-resistant organisms where therapeutic options are limited.

Higher use of the reserved class of antibiotics which may leads to multidrug resistance, results in fewer therapeutic options for future infections. So, strictly adhere to the antibiotic stewardship program, clinical audits, hospital formulary policies, procedures, and guidelines for rational usage of reserve antibiotics which helps to reduce or prevent the antimicrobial resistance.

CONCLUSION

Our study concludes that one third of the Feropenem, Linezolid, Tigecycline antibiotics were prescribed based on the culture sensitivity test, remaining were prescribed based on disease severity. The gram -negative organisms are more observed among the patients, and the bacteria's such as, Pseudomonas aeruginosa, E coli, and Klebseilla pneumonia were confirmed by cultural sensitivity tests. Post-surgical prophylaxis and severe infections are the main indications for prescribing reserve antibiotics. The calculated DDD of reserve drugs was higher compared to the WHO DDD, it shows that hospital response to patient needs particularly in departments managing severe resistant infections. These agents are considered as last resort options; higher use may lead to resistance to these drugs. Strengthening antimicrobial stewardship practices, optimizing infection control measures, and ensuring timely de-escalation of reserve antibiotics based on culture sensitivity findings collectively play a vital role in curbing antimicrobial resistance and safeguarding the effectiveness of these critical drugs.

FUNDING

This study was not financially funded by any organization.

CONFLICT OF INTEREST

The authors declare no conflict of interest.

ACKNOWLEDGEMENT

We would like to express our gratitude to our principal Dr. Suresh V Kulkarni, Sree Siddaganga College of Pharmacy, Tumkur, for allowing us to conduct this work. And we express our profound gratitude to our Professor and Head of Department Dr. P. Ashok Kumar, Sree Siddaganga College of Pharmacy, Tumkur, and Dr. Renushri B V, Professor and Head of Microbiology Department, SMCRI, Tumkur, for their invaluable support and guidance.

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