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Original Research Article

An audit of drug utilization patterns, rationality, and cost analysis of antimicrobial medicines in a tertiary care teaching hospital in central suburban India

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ABSTRACT

Background: Antimicrobial medicine (AMM) utilization patterns and rational drug use are important topics in today's world wrought with AMM resistance, irrational prescription of antibiotics, and lack of proper training such as stewardship programmes for medical graduates and general practitioners. Our objective was to perform an audit of the antimicrobial drug utilization pattern, evaluate the rationality of drug use, and perform a cost analysis of these drugs.
Methods: An observational cross-sectional study design was implemented. The study location was a tertiary care teaching hospital in suburban central India. Patients were recruited from the general medicine and general surgery departments.
Results: Out of 189 patients, the average age was 45.714 years and 67.725% were females. A total of 595 AMMs were prescribed to 189 patients with an average of 3.148±1.578 drugs per patient. 6.5% drugs prescribed were generic, 95% prescribed were included in the national essential medicine list, and 90% of patients' prescriptions were rational. The total expenditure on AMMs was ₹726043.610, with a median expenditure of ₹987.320.
Conclusions: Drug utilization patterns vary between medicine and surgery departments. They also vary between different institutions within the same country. Creating a structured standardized training program to uniformly train healthcare professionals in conservative antibiotic prescription practices is needed. This study hopefully paves the way for future studies to target critical areas in AMM prescription and to prospectively assess the impact of a structured antibiotic stewardship program on AMM utilization patterns.

Keywords: Antimicrobial drugs, Drug utilization, Cost analysis, Rational drug use, Tertiary care teaching hospital

INTRODUCTION

The extent of infections of bacterial etiology in India is ever growing.[1] People in this developing country suffer from bacterial infections which represent just a tip of the iceberg of the actual number of infections. Moreover, people are being given antimicrobial medicines (AMMs) without due consideration of the etiology of infection, with AMMs being prescribed indiscriminately even for viral infections.[2] Such use of antimicrobial agents leads to wide and acute development of antibiotic resistance, which is a serious hazard to the future of antibiotic development and treatment of bacterial infections.[3] Moreover, antimicrobial prescription leads to an increase in the overall cost of hospital stay of the patients, which many patients cannot afford in India. On 21st September 2016, India along with other global leaders adopted a political declaration at the high-level meeting at the 71st UN General Assembly, which calls for a collaborative, global response to the threat of antimicrobial resistance (AMR).[4] Optimization of antibiotic use is very important to curb development and transmission of multi-drug resistant pathogens.[5] Our audit aims to evaluate the prescription patterns of AMMs, the rationality for their use in patients, and the cost borne by the patients for these drugs. This study hopes to uncover the veil of AMM utilization patterns in a tertiary care teaching hospital in central India, where such a detailed study has not been done to the best of the authors' knowledge. This will help uncover the lacunae present in AMM prescription patterns and AMM utilization to help structure better training programs to target the shortcomings and reinforce strengths. Cost analysis will help hospitals to structure guidelines at an institutional level. This will enable practitioners to provide better patient care by understanding when and how to prescribe AMMs, thus reducing drug-resistant organism evolution and monetary strain especially in non-affording patients in India.

METHODS

This study was carried out in the departments of pharmacology at Smt. Kashibai Navale medical college and general hospital, Pune, Maharashtra in collaboration with the departments of medicine and surgery. Sample size was calculated with a descriptive study design in mind. Taking a population size of 20,000, an expected frequency of irrational antibiotic prescription of 12% based on results from another study, with an acceptable margin of error of 5%, the calculated sample size at a 95% confidence level was n=162.[6] Keeping in mind attrition and non-consent, n=200 patients were decided to be included in the study. Within the 6-month period between June 2021 to December 2021, 200 patients were enrolled who fulfilled the inclusion and exclusion criteria. Seven patients were dropped during the analysis due to non-fulfilment of the inclusion criteria and four patients did not provide consent for medical case record access (Figure 1).

Data collection and entry

We included all patients who were admitted in the medicine and surgery departments in our hospital, who were above 18 years of age, and were prescribed at least one antimicrobial drug. We excluded patients who were less than 18 years of age, were not prescribed even a single antimicrobial medicine, and who did not provide consent to access their medical records. Patient demographic data was collected manually from medical records after consent was taken.

It was entered in a pre-designed case sheet. Details about AMMs, their dosage, duration, frequency, route, their trade names as well as component names, whether they were generic or not, whether they were included in the national essential medicines or not, whether antibiotic susceptibility testing was done or not, and whether the AMM prescription was rational or not, was entered into the same case sheet. Antimicrobials were classified using the world health organization collaborative centre for drug statistics methodology's anatomical therapeutic chemical (ATC) classification system.[7] Rationality of drug use was calculated based on Kunin's criteria.[8] Classification of drugs as essential and non-essential was done on the basis of inclusion in the National list of essential medicines (NEML).[9] Individual as well as total expenditure on AMMs was calculated in Indian Rupees (INR) in the sheet using the hospital pharmacy medicine cost pricing. Data were entered into an MS Excel file for further cleaning and data analysis.

Statistical methods

Data on categorical variables are shown as n (% of cases) and the data on continuous variables is presented as Mean and Standard deviation (SD) or Median and Interquartile Range (IQR) as appropriate. The inter-group statistical comparison of categorical variables is done using the Chi-squared test while of continuous variables is done using the independent samples student's t-test; the Mann-Whitney U-test is applied for non-normally distributed data. The underlying normality and homogeneity of variance assumptions were tested before subjecting the study variables to the independent samples t-tests, $p<0.05$ are considered to be statistically significant, p values have not been corrected for multiplicity. All the hypotheses were formulated using two tailed alternatives against each null hypothesis (hypothesis of no difference). Sample size calculation is done using CDC's EpiInfo software, Version 7.2.5 for MS Windows. Statistical analysis is done using Stata Statistical Software: Release 17. College Station, TX: StataCorp LLC for MS Windows.

RESULTS

A total of 189 patients were included in the study from both medicine and surgery departments (Figure 1). Baseline characteristics of the study population are provided in (Table 1).

Table 1: Demographic data.

Variables	Overall (n=189)	Inter-departmental		
		Medicine (N=57)	Surgery (N=132)	P value
Median age (IQR) (years)	45 (30-59)	50 (37-65)	43 (28-56)	0.035[m]
Gender; N (%)				
Male	128 (67.7)	33 (57.9)	95 (72)	0.058[c]
Female	61 (32.3)	24 (42.1)	37 (28)	
Median duration of hospital stay (IQR) (days)	8 (5-12)	7 (5-11)	8 (5-13)	0.202[m]

[m]Mann-Whitney test, [c]Chi-squared test of independence

Table 2: Antimicrobial medicine utilization patterns.

Variables	Overall (n=189)	Inter-departmental		
		Medicine (N=57)	**Surgery (N=132)**	**P value**
Median AMMs prescribed per patient (IQR), number of drugs	3 (3-4)	2 (1-3)	4 (3-5)	<0.001[m] (S>M)
Monodrug therapy* N (%)**	85 (45)	38 (66.7)	47 (35.6)	<0.001[c] (M>S)
FDC therapy* N (%)**	106 (56.1)	18 (31.6)	88 (83)	<0.001[c] (S>M)
Generic AMMs N (%)	34 (18)	9 (15.8)	25 (18.9)	0.605[c]
Median number of generic AMMs prescribed per patient (IQR) number of drugs	1 (1-1)	1 (1-2)	1 (1-1)	0.004[m] (M>S)
Essential AMMs N (%)	182 (96.3)	54 (94.7)	128 (97)	0.456[c]
Median number of essential AMMs prescribed per patient (IQR) number of drugs	3 (2-4)	2 (1-2)	4 (3-4)	<0.001[m] (S>M)
Non-essential AMMs N (%)	18 (9.5)	7 (12.3)	11 (8.3)	0.396[c]
Number of non-essential drugs prescribed per patient N (%)	1 AMM: 12 (6.4)	1 AMM 7 (100)	1 AMM 5 (45.5)	0.057[c]
	2 AMMs: 4 (2.1)	2 AMMs 0 (0)	2 AMMs 4 (36.4)	
	3 AMMs: 2 (1.1)	3 AMMs 0 (0)	3 AMMs 2 (18.2)	
Rational drug therapy (Kunin's classes I and II)* N (%)	182 (96.3)	56 (98.3)	126 (95.5)	0.35[c]
Antibiotic susceptibility testing N (%)	17 (9)	2 (3.5)	15 (11.4)	0.083[c]
Frequency of AMM prescription per day N (%)	Once daily: 5 (2.7)	Once daily: 0 (0)	Once daily: 5 (3.8)	0.014[c]
	Twice daily: 112 (59.3)	Twice daily: 43 (75.4)	Twice daily: 69 (52.3)	
	Thrice daily: 70 (37)	Thrice daily: 13 (22.8)	Thrice daily: 57 (43.2)	
	Four times daily: 2 (1.1)	Four times daily: 1 (1.8)	Four times daily: 1 (0.8)	
Median frequency of AMM prescription per day (IQR) number of doses per day	2 (2-3)	2 (2-2)	2 (2-3)	0.044[m] (S>M)

[m]Mann-Whitney test, [c]Chi-squared test of independence, S: Surgery department, M: Medicine department, AMM: antimicrobial medicine, *p <0.05, **p <0.01, ***p <0.001

The median (IQR) age of the patients included in the study was 45 years (30-59 years). Our sample consisted of 128 (67.7%) males and 61 (32.3%) females. The median (IQR) duration of hospital stay of the patients was 8 days (5-12 days). The median (IQR) number of AMMs given to the patients were 3 drugs (2-4 drugs) (Table 2). In the entire study population, a total of 595 AMMs were prescribed, with 112 AMMs given in the medicine department, and 483 AMMs given in the surgery department. The total number of patients who received monodrug therapy were 85 (45%), while the total number of patients who received FDCs were 106 (56.1%). Out of a total of 595 AMMs prescribed, only 39 (6.5%) were generic drugs; further out of these 39 generic drugs, 13 drugs (33.3%) were prescribed in the medicine department while 26 (66.7%) were prescribed in the surgery department (Table 2). Out of 595 total AMMs prescribed, 228 (38.3%) were oral drugs, 364 (61.2%) were injectable drugs, and the remaining 3 (0.5%) drugs were local application drugs (Table 3). A total of 182 (96.3%) patients were prescribed at least one AMM from the National Essential Medicine List (NEML) (Table 2). Out of 595 drugs, 20 (3.4%) drugs prescribed were not from the NEML. Out of 189 patients, 171 (90.5%) were prescribed a drug therapy which fell in Kunin's criteria class I, 11 (5.8%) were class II, and 4 (2.1%) were class III. Antibiotic susceptibility testing (AST) was performed in 17 (8.995%) patients. The median frequency of AMM prescription was 2 times per day. The total expenditure by the 189 patients on a total of 595 AMMs was Rs. 726044, with a median (IQR) expenditure per patient of

Rs. 987 (Rs.512-Rs.1894). The total expenditure on oral AMMs alone was Rs.45708 with a median (IQR) expenditure per patient of Rs.147 (Rs.0-Rs.323).

Table 3: Route of antimicrobial medicine administration.

Variables	Overall (n=189)	Inter-Departmental		
		Medicine (N=57)	Surgery (N=132)	P value
Oral AMMs* N (%)**	136 (72)	31 (54.4)	105 (79.6)	<0.001^{c} (S>M)
Median number of oral AMMs prescribed per patient (IQR)***	2 (1-2)	1 (1-2)	2 (1-2)	<0.001^{m} (S>M)
Injectable AMMs (intravenous and intramuscular) N (%)**	162 (85.7)	42 (73.7)	120 (90.9)	0.002^{c} (S>M)
Median number of injectable (intravenous and intramuscular) AMMs prescribed per patient (IQR)	2 (2-3)	2 (1-2)	2 (2-3)	<0.001^{m} (S>M)
Local application N (%)	3 (1.6)	0 (0)	3 (2.3)	0.251^{c}

^{c}Chi-squared test of independence, S: Surgery department, M: Medicine department, *p <0.05, **p <0.01, ***p <0.001. The total does not add up to 100%, since patients were prescribed more than 1 AMMs.

Table 4: Cost analysis of antimicrobial medicines.

Expenditure (route)	Overall (n=189)	Inter-departmental		
		Medicine (N=57)	Surgery (N=132)	P value
Median overall expenditure per patient (IQR) Indian Rupees	987 (512-1894)	591 (245-1410)	1187 (720-2021)	<.001^{m} (S>M)
Median expenditure on oral drugs per patient (IQR) Indian Rupees	147 (0-323)	31.7 (0-229)	229 (91-370)	<.001^{m} (S>M)
Median expenditure on injectable drugs per patient (IQR) Indian Rupees	786 (336-1605)	549 (0-1410)	846 (472-1666)	.013^{m} (S>M)
Median expenditure on ointments per patient (IQR)# Indian Rupees	0 (0-0)	0 (0-0)	0 (0-0)	–

#Median expenditure on ointments per person equals zero, since only 3 patients visiting the surgery department in our study were prescribed ointments.

The total expenditure on injectable AMMs alone was approximately ₹1680219 with a median (IQR) expenditure per patient of ₹786 (₹336-₹1605). Only 3 patients from the surgery department were prescribed topical antimicrobials; their total expenditure amounted to ₹344 (Table 4). The commonest drug class prescribed were beta-lactamase inhibitors with 106 (23%) AMMs prescribed. The second and third most common drug classes prescribed were aminopenicillins with 91 (19.8%) being prescribed and cephalosporins with 79 (17.2%) being prescribed respectively (Figure 2). Out of a total of 20 non-essential drugs prescribed, rifaximin was the most commonly prescribed non-essential drug 6 times (30%) (Figure 3). The most common surgical indication for which AMMs were prescribed was bacterial cellulitis (19 patients; 24.359%), followed by acute appendicitis and inguinal hernias (both in 10 patients; 12.821% each) and obstructive uropathy (9 patients; 11.539%) (Figure 4). The most common medical condition for which antibiotics were prescribed was bacterial pneumonia (10 patients 27.027%), followed by chronic kidney disease (8 patients; 21.622%) and bacterial gastroenteritis (6 patients; 16.216%) (Figure 5).

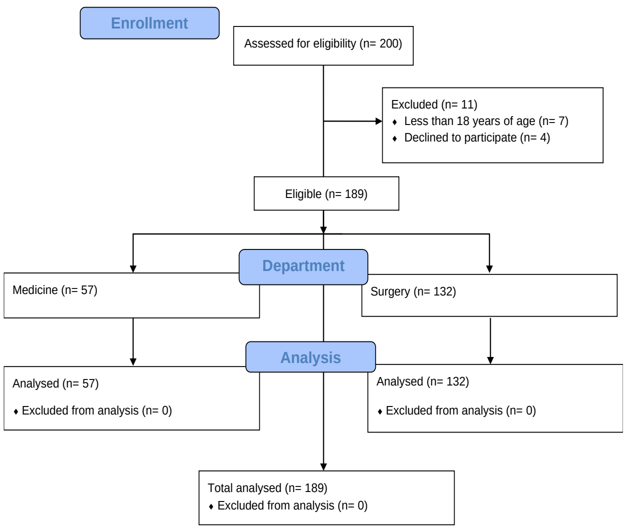


Figure 1: Patient disposition flow diagram.

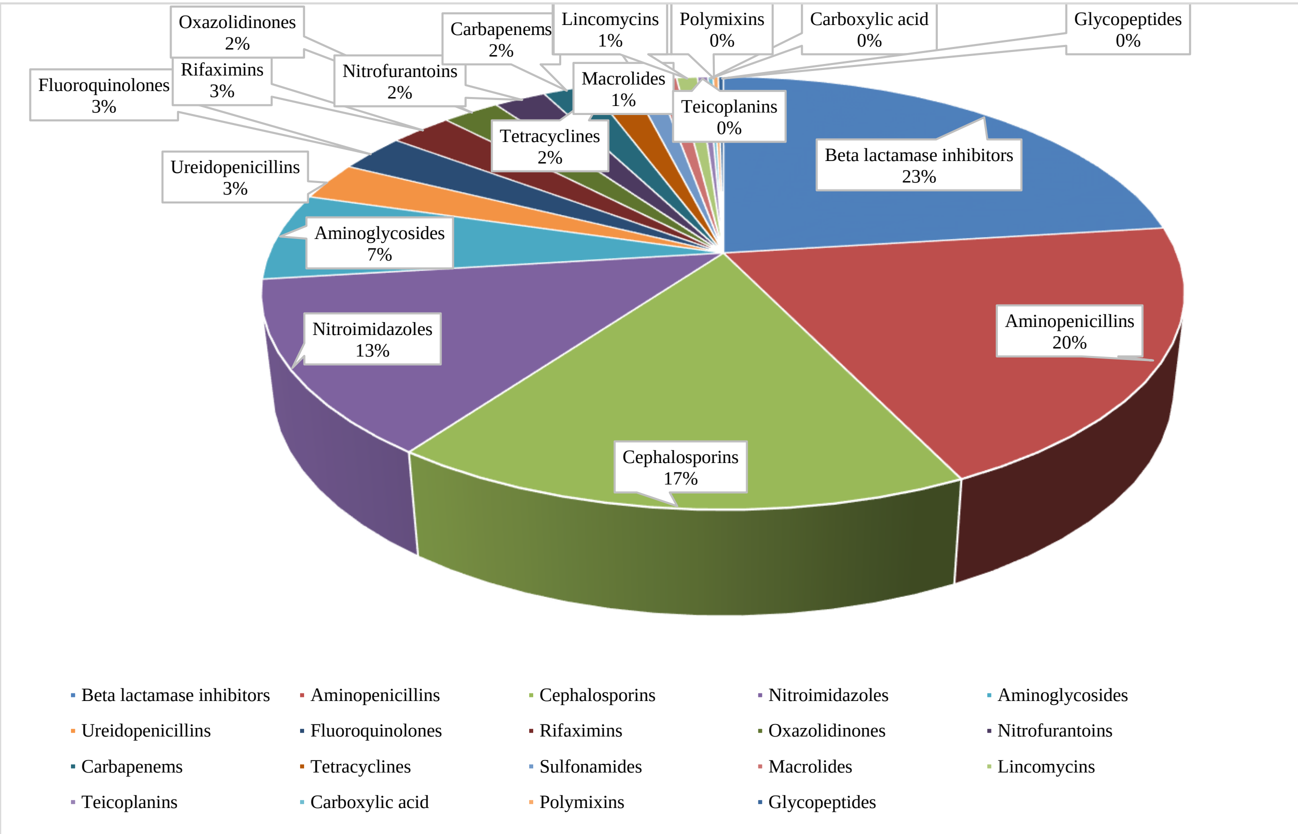


Figure 2: Frequency of prescription of antimicrobial medicines.

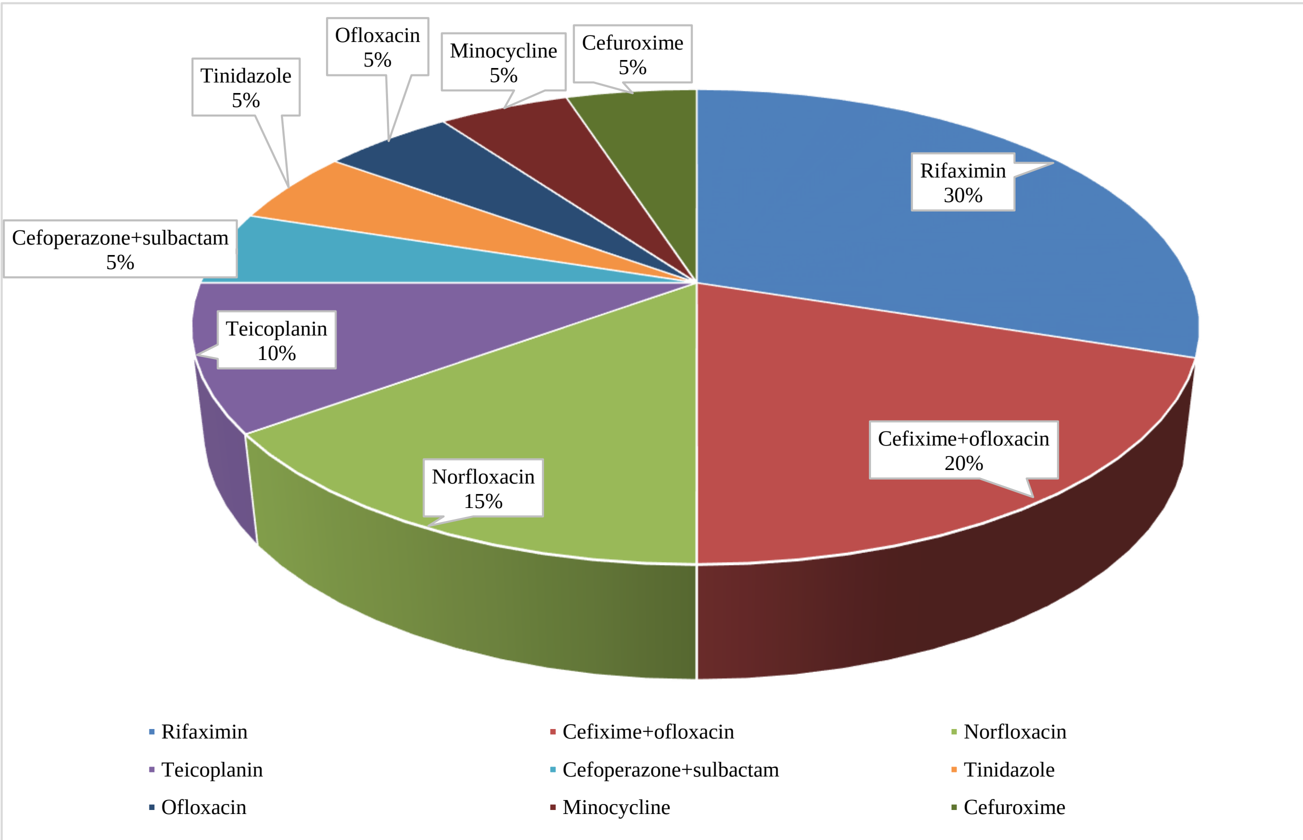


Figure 3: Frequency of prescription of non-essential drugs.

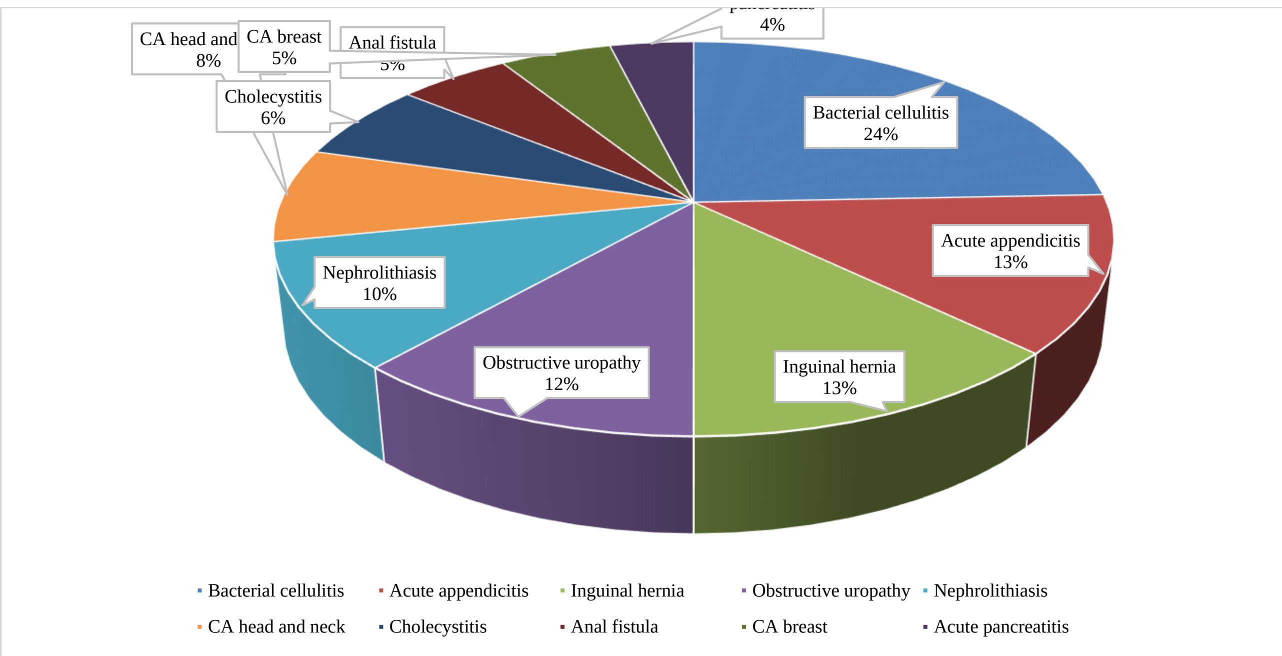
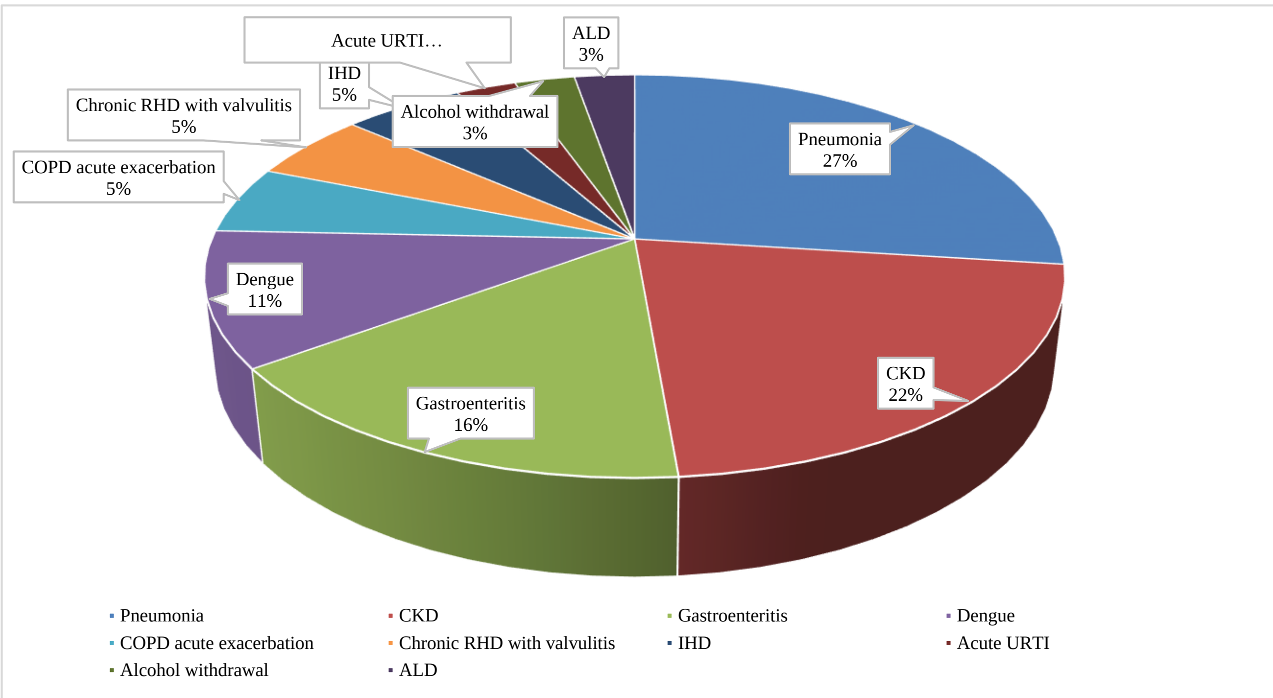


Figure 4: Ten most common surgical indications for antimicrobial medicine prescription.



IHD: ischemic heart disease, ALD: alcoholic liver disease, CKD: chronic kidney disease, COPD: chronic obstructive pulmonary disease, URTI: upper respiratory tract infection, RHD: rheumatic heart disease.

Figure 5: Ten most common medical indications for antimicrobial medicine prescription.

DISCUSSION

Antimicrobial use is a sensitive topic for most infectious disease specialists due to their extensive and near miss experiences with pathogen resistance.[10] Awareness of AMM utilization patterns are important to understand crucial sticking points in terms of prescribing AMMs to patients; this is of importance due to the fact that the patterns of antibiotic resistance are not the same everywhere.[11]

To aid with this everlasting problem of AMM resistance, the Government of India with the ministry of health and family welfare (MoHFW) has prepared a National essential medicine list which also includes essential

AMMs, to better guide healthcare professionals to prescribe only the most needful AMMs to their patients.[9] To address this growing concern for antibiotic resistance and the awareness to curb this problem, this study was performed to gauge the AMM utilization patterns and cost analysis for patient expenditure to be able to help train junior healthcare professionals better for improved patient care, increased awareness of this problem, and gain insight into the differences in AMM utilization patterns between different specialties as well as patient expenditure on AMMs. In this observational cross-sectional audit of antimicrobial utilization patterns in a tertiary care teaching hospital in suburban India, the median duration of hospital stay was found to be 8 days, which was higher in surgical patients; this was higher than a few related studies published earlier $\leq$5 days.[6,12] This is most likely attributable to patients coming in our tertiary care hospital referred by primary care centres.

In our study, department-wise AMM utilization patterns show significant variations. The median number of AMMs prescribed per patient were 2 and 4 respectively in medicine and surgery which is higher compared to earlier similar studies where it was 1-2 AMMs per patient.[6,13] This incidence of number of AMM drug prescriptions was twice more in surgery than in medicine ($p<0.001$) which was in stark contrast to earlier similar studies.[6,13] A prospective study, however, conducted in the United Kingdom, reported the frequency and duration of antibiotic prescription higher in surgical specialties than medicine specialties, which was in accordance with our study.[14]

This might be due to the fact that most surgeons are more wary of potential risks not directly associated with the actual surgery, and are willing to prescribe antibiotics more frequently to eliminate the risk of uncertainty; on the other hand, medicine allied specialties are well aware of the potential risks and side effects of prescribing antibiotics which may not always be essential for treating or preventing the problem. In a worldwide study, antibiotic usage was found to be the highest across central Europe, eastern Europe, and the central Asia super-region, with the median national antibiotic usage being 72%, and the lowest levels being in sub-Saharan Africa, with the median national usage being 42%.[15] In our present study, we also studied monotherapy and FDC utilization of AMMs and surprisingly, we found significant differences in their utilization patterns between medicine and surgical specialties. It was in the medicine department, where a significant number of patients i.e., 66.7% and 98.3% were prescribed single and rational AMM therapy respectively, while 35.6% and 95.5% in surgery were on single AMM therapy and rational AMM therapy respectively. Rational drug use constitutes the usage of a drug based on the diagnosis, defining effective and safe treatments, selecting appropriate drugs and dosages, writing clear prescriptions, giving patients adequate information and counselling, and evaluating treatment responses.[16] Rational drug use can also be practically defined when it falls into class I and II of Kunin's criteria for rationality of drug use.[8] When it comes to the use of FDCs, this percentage was higher in surgery (83%) compared to medicine (31.6%). These findings on rationality were accordance with earlier studies which found no such difference.[6,17] Moreover, the majority of the AMMs prescribed were not generic in both the specialties which might reflect doubt about the efficacy of these AMMs in the clinicians' mind. Achieving this needs a lot of motivation and making clinicians aware of the facts and myths of generic medicines for the patient's benefit, as many other countries now encourage the use of generic medicines due to their cost effectiveness.[18–20] This suggests a wide variance in prescription practices even within a single country, and between different continents too. This might be due to differing local guidelines, difference in the primary indications for AMMs, and awareness (or lack thereof) of local resistance patterns. An essential drug formulary helps to improve prescribing practices according to a country's specific needs and to satisfy the priority healthcare needs of the population.[21,22] The essential medicine concept is important for the economic use of medicines. It addresses several issues including good therapeutics and safe cost-effective medicines for the diseased.[22] A high rate of essential drugs prescription is always appreciable, however prescription of non-essential AMMs might not be completely avoidable due to rare infective diseases, resistant micro-organisms, or even unknown infective etiologies. Hence, even essential medicine lists require frequent corrections and local revisions over time.[23] In our study, the prescription rate for essential drugs was 96.3% which was higher compared to other studies.[6,24] A dosing frequency of 2 times a day, similar to what we found in our study, has been shown to improve patient adherence to taking medications; although our study was among inpatients, a lower frequency of daily doses is nevertheless desirable, as patients tend to become more compliant with taking their prescribed doses on time.[25,26] Antibiotic susceptibility testing is essential before prescribing antimicrobials, due to the emerging incidence of antibiotic resistance which is furthered by prescribing empiric therapies.[27] The antibiotic susceptibility testing rate in our study was 9%, which is indicative of a burning need for adopting antibiotic stewardship programs, improving prescribing practices, optimizing therapeutic regimens, improving diagnosis and diagnostic tools, and improving tracking methodologies at a hospital level. Such preventive measures can potentially render India immune to the accelerating surge of antimicrobial resistance. Our cost-analysis for AMMs in medicine and surgery revealed median expenditures per patient of ₹591 and ₹1187 respectively ($p<0.001$), with higher expenditures reported in surgery specialities. This might be explained by the fact that patients in the surgery department were prescribed a greater number of AMMs from the beginning - mostly injectables which are usually costlier than oral AMMs. However, the total expenditure reported in our study was much lesser than reported in similar studies, which might be due to the fact that these studies included only intensive care unit patients.[28,29] In our study, aminopenicillins and beta-lactamase inhibitors were the highest prescribed AMMs, followed by nitroimidazoles, aminoglycosides and fluoroquinolones, which was similar to what was reported in other studies.[15,30] Though the consumption of carbapenems, polymixins, glycopenptides, lincomycins and teicoplanin-like higher AMMs was the highest in high-income regions, our study reported significantly lower expenditure on these AMMs.[15] The most common surgical condition for which antibiotics were prescribed in our study were acute appendicitis and inguinal hernias wherein common medical conditions were bacterial pneumonia, bacterial gastroenteritis, chronic rheumatic heart disease, and alcoholic liver disease (Figures 4-5), which when studied in comparison with other worldwide studies suggest that the conditions for which AMMs are prescribed are fairly common throughout India as well as higher-income countries like the UK.[31] To the best of our knowledge, this is the first audit to study drug utilization patterns, rationality of drug use, and cost analysis and its variation between medicine and surgery specialties in suburban central India. One of the strengths of our study was a cross-sectional study design for our audit. This enabled us to enter the data without missing values and the need for statistical data imputation.

Limitations

Limitations of current study were; current study audit was restricted to the medicine and surgery departments without including other departments such as pediatrics and obstetrics and gynecology. Furthermore, we did not perform subgroup analyses according to subspecialties. We also excluded patients who visited the chest and TB department, thus eliminating prescriptions for anti-tubercular medicines.

CONCLUSION

In conclusion, our observational cross-sectional audit in a suburban tertiary care teaching hospital suggests that drug utilization patterns vary between the medicine and surgery specialties. However, rationality of drug use did not. Furthermore, drug utilization patterns also vary to a small extent between different institutions within the same country and vary considerably between low-income and high-income countries. The expenditure that patients have to incur on antibiotics was the highest for injectable drugs than for oral drugs. The indications for which the antimicrobials were prescribed were also quite similar to other studies, which indicate a loose homogeneity in rational drug use. Future prospective randomized controlled studies where a structured, standardized, and validated antibiotic stewardship training program is provided to the study group should help to address the inadequacies of current AMM prescription practices, and help to reduce hospital morbidities and patient costs as well.

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