e-ISSN: 0975-9506, p-ISSN: 2961-6093

Available online on www.ijpqa.com doi: 10.25258/ijpqa.16.8.60

International Journal of Pharmaceutical Quality Assurance 2025; 16(8); 348-357

Original Research Article

An Observational Clinical Study on Antibiotic Utilization Pattern among Patients Undergoing Elective Laparoscopic Cholecystectomy at a Tertiary Care Medical Training Institution in Kolkata

Ghosh S.[1], Chatterje S.[2], Banerjee P.[3], Sarkar S.[4]

[1]Senior Resident, Department of Clinical and Experimental Pharmacology, School of Tropical Medicine, Kolkata, India

[2]Associate Professor, Department of Pharmacology, North Bengal Medical College and Hospital, Siliguri, West Bengal, India

[3]Associate Professor, Department of Pharmacology, Prafulla Chandra Sen Government Medical College and Hospital, Arambagh, West Bengal, India

[4]Assistant Professor, Department of General Surgery, College of Medicine and Sagore Dutta Hospital, Kamarhati, Kolkata, India

Received: 25-06-2025 / Revised: 10-07-2025 / Accepted: 26-07-2025

Corresponding Author: Dr. Somdatta Ghosh

Conflict of interest: Nil

Abstract:

Background: Drug Utilization Study is the "marketing, distribution, prescription and the use of drugs in a society with special emphasis on the resulting medical, social and economic consequences". The current study was conducted to observe the antibiotic utilization pattern in patients undergoing elective laparoscopic cholecystectomy in College of Medicine and Sagore Dutta Hospital.

Methods: This observational, cross-sectional study was conducted for a year to study the antibiotic utilization pattern in patients, during the post-operative period. Data was collected from the bedside treatment records of the patients.

Results: A total of 384 patients were recruited and it was observed that the most commonly used antibiotics used for post-operative prophylaxis in patients undergoing elective laparoscopic cholecystectomy were a monotherapy with intravenous ceftriaxone (43.23%) followed by a dual therapy with intravenous ceftriaxone and metronidazole (22.14%). Among patients who were switched over to oral antibiotics the most commonly used regimen was a dual therapy with oral ciprofloxacin and metronidazole (21.16%) followed by a monotherapy with oral cefuroxime axetil (18.67%).

Conclusion: The results of this study, provide baseline data for conducting future research work in the area of Antibiotic Utilization Studies, to improve the prescription patterns of antibiotics used for surgical prophylaxis and to combat the rising threat of antimicrobial resistance.

Keywords: Drug Utilization Study; Antibiotic Utilization Study; Post-operative Prophylaxis.

Introduction

Drug Utilization Study is the "marketing, distribution, prescription and the use of drugs in a society with special emphasis on the resulting medical, social and economic consequences". [1]

Different antibiotic regimes are prescribed prophylactically, during the post-operative period, to patients undergoing elective laparoscopic cholecystectomy, to prevent surgical site infections (SSIs).

Constant surveys are carried out in order to study the changed regimes of antimicrobial agents and to ensure their optimum use. Current study was conducted to observe the antibiotic utilization pattern in patients undergoing elective laparoscopic cholecystectomy in College of Medicine and Sagore Dutta Hospital.

Aims & Objectives

Primary Objective: To observe the post-operative antibiotic utilisation pattern among the patients undergoing elective laparoscopic cholecystectomy at a tertiary care medical college in Kolkata.

Secondary Objective: To study the WHO/INRUD core drug use indicators and prescribing trends of antibiotics during the post-operative period

Materials & Methods

Study type & design: Observational, descriptive, cross-sectional

Study setting: The study was conducted in the Department of Pharmacology in collaboration with the Department of General Surgery, College of Medicine and Sagore Dutta Hospital, Kamarhati, Kolkata

Study population: All adult patients, between the ages of 18–65 years, of either sex, who underwent elective laparoscopic cholecystectomy in the Department of General Surgery, during the stipulated time period were recruited for this study. Written informed consent was obtained from each patient, prior to recruitment in the study.

Inclusion Criteria: Adult patients, between the ages of 18–65 years, both males and females, who underwent elective laparoscopic cholecystectomy, during the stipulated time period were recruited for this study.

Exclusion Criteria:

- Patients presenting with surgical emergencies
- Patients who refused to give written consent
- Pregnant and lactating women

Sample Size: Drug Utilization Study is a pharmaco-epidemiological study and utilises descriptive statistics.

To calculate the sample size, we used the following formula [2]:

$N = Z2 \times p (1-p) / d2$

Where, 'N' is the sample size; 'Z' is the standard normal value of confidence interval of 95% that is equal to 1.96; 'd' is the margin of sampling error tolerated, 0.05 and 'p' is the estimated proportion of inappropriate prescription pattern as per WHO core indicators. Since we did not have the prevalence rate for antibiotic utilisation study in College of Medicine and Sagore Dutta Hospital, 'p' value was taken to be 0.5 as that allowed us to calculate the maximum sample size required.

Thus, $N= 1.962 \times 0.5(1-0.5) / 0.052 = 384.16$

Therefore, the sample size was taken to be 384[3] .

Study Duration: Total duration of study was 12 months (8 months for data collection and 4 months for data analysis and writing of the thesis), subject to satisfactory recruitment as per the study requirements.

- Data collection started from 01/03/2023 (8 months)
- Analysis of data and calculation 01/11/2023 to 31/12/2023 (2 months)
- Write up of the study from 01/01/2024 to 29/02/2024 (2 months)

Tools and Procedures: Data regarding antibiotic utilisation was collected from the bedside treatment records of patients, admitted in the General Surgery wards. The study tools included:

- Patient information sheet in English, Bengali and Hindi
- Written consent form in English, Bengali and Hindi
- Pre-designed Case Record Form to interview the patients and to note the drug and prescription details
- Drug Utilization Report Form
- National List of Essential Medicine (NLEM) [Published in 2022] [4]
- ATC-DDD toolkit [5]

Outcome Variables: Data is represented in the form of mean, standard deviation, total count and percentages and depicted in the form of pie diagrams and bar graphs. The WHO/INRUD core prescribing indicators include [6]:

- The average number of drugs prescribed per encounter
- The percentage of drugs prescribed by generic name
- The percentage of encounters where an antibiotic was prescribed
- The percentage of encounters where an injection was the route of drug administration
- The percentage of drugs prescribed from the Essential Drugs List (EDL) or any other recognised formulary

The Patient care indicators include [7]:

- Average consultation time
- Average dispensing time
- Percentage of drugs actually dispensed
- Percentage of drugs adequately labelled
- Patient's knowledge of correct dosing

Facility care indicators include [7]:

- Availability of copy of essential drug list
- Availability of key drugs

Demographic data of the individual patients were also documented.

Data Collection: The study commenced after the approval of the Institutional Ethics Committee at College of Medicine and Sagore Dutta Hospital, Kamarhati. The data was collected from the bedside treatment records of the patients admitted in the male and female General Surgery indoor wards

Statistical Analysis Plan: The collected data was compiled in the form of excel sheet. A descriptive analysis of the antibiotic utilisation pattern, was performed. The data was then compiled in the form of excel sheet. The analysis was done primarily using Microsoft Excel (version 2021). The results are displayed in the form of appropriate diagrams and tables.

Ethical Considerations: The study was conducted in accordance to ICMR Guidelines (2000) of Biomedical Research involving human subjects [8]. All efforts were made to adhere to Good Clinical Practice Guidelines of Government of India [9]. Informed Consent was mandatory for recruitment of the study subjects.

Subject recruitment started only after approval from Institutional Ethics Committee (IEC) was obtained.

Results

The current study was conducted on a total of 384 prescriptions obtained from indoor patients in the male and female wards of the Department of General Surgery. Gender stratification is shown in figure 1.

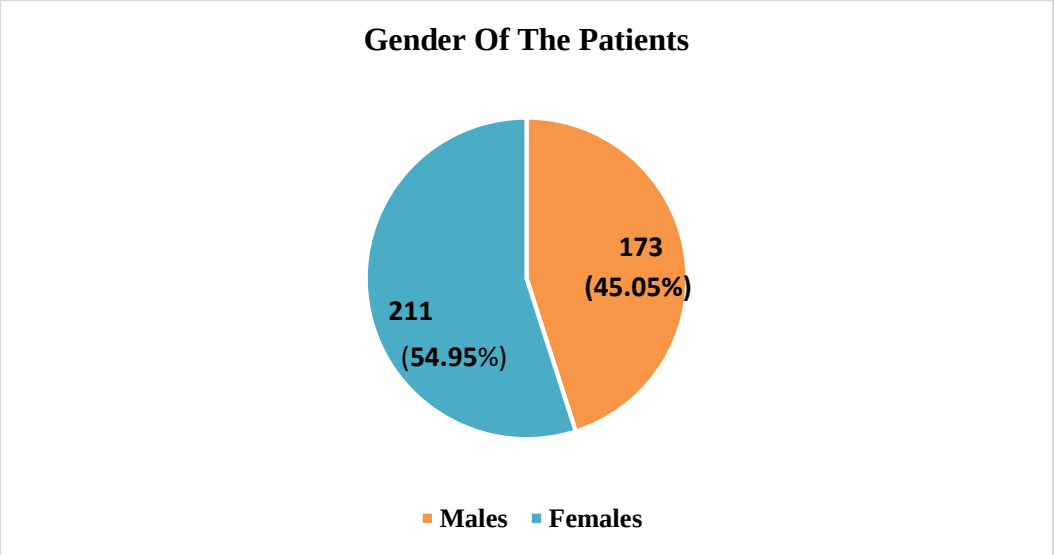

Figure 1: Gender of the Patients

The age of the patients ranged from 18 – 63 years with mean age being 38.83 + 12.31 years, as shown in figure 2.

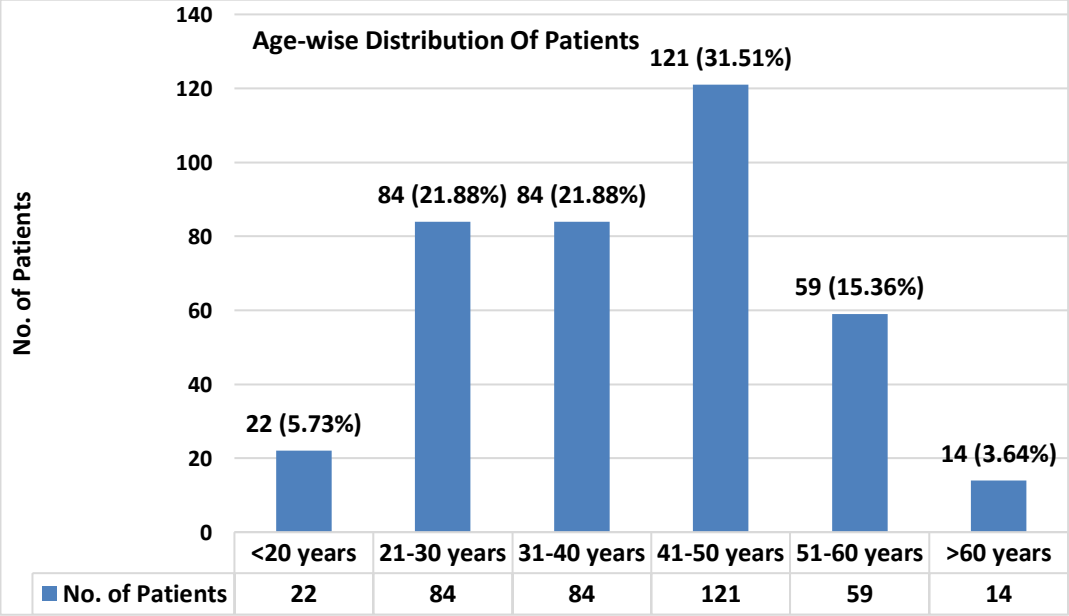

Figure 2: Age-wise Distribution of Patients

The mean age of female patients was found to be 40.22 + 12.76 years and the mean age of male patients was found to be 37.13 + 11.58 years.

A total of 30 patients (7.81%) were smokers or addicted to tobacco, 28 (7.29%) were found to consume alcohol on a regular basis and 37 (9.64%) consumed both tobacco and alcohol. It was ob-

served that 289 patients (75.26%) refrained from consuming either tobacco or alcohol which comprised of 53.18% of the male population and 93.37% of the female population.

Of the total 384 patients, it was found that 3 (0.78%) of them were allergic to sulfa drugs and 5 (1.30%) were allergic to penicillin antibiotics. The demographic profile of all the patients is shown in table 1.

Table 1: Demographic Profile of Patients

Parameters	Mean + Standard Deviation (SD)	Range
Age	38.33+12.31 years	18-63 years
Height	1.66+0.09 metres	1.50-1.92 metres
Weight	69.40+10.80 kg	45-115 kg
Body mass index (BMI)	25.20+3.16 kg/m^2	16.53-35.16 kg/m^2

Of the 384 patients, 299 of them or 77.86% were without any pre-existing comorbidities. The remaining 85 or 22.14% were found to have pre-existing comorbidities, which are listed in figure 3.

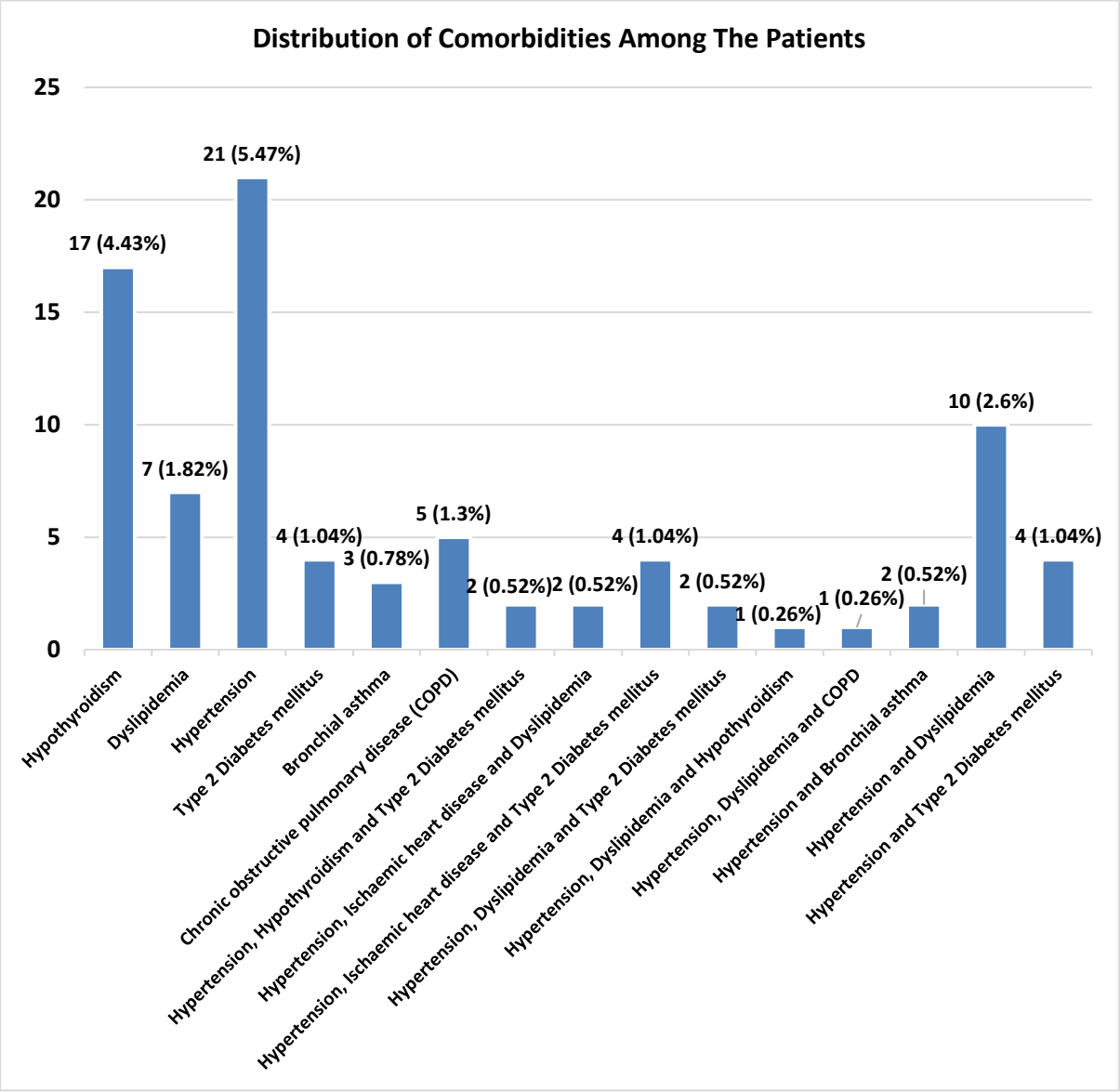

Figure 4: Distribution of Comorbidities Among The Patients

Figure 4 illustrates the distribution of the various gall bladder pathologies observed in the study participants, for which they underwent elective laparoscopic cholecystectomy.

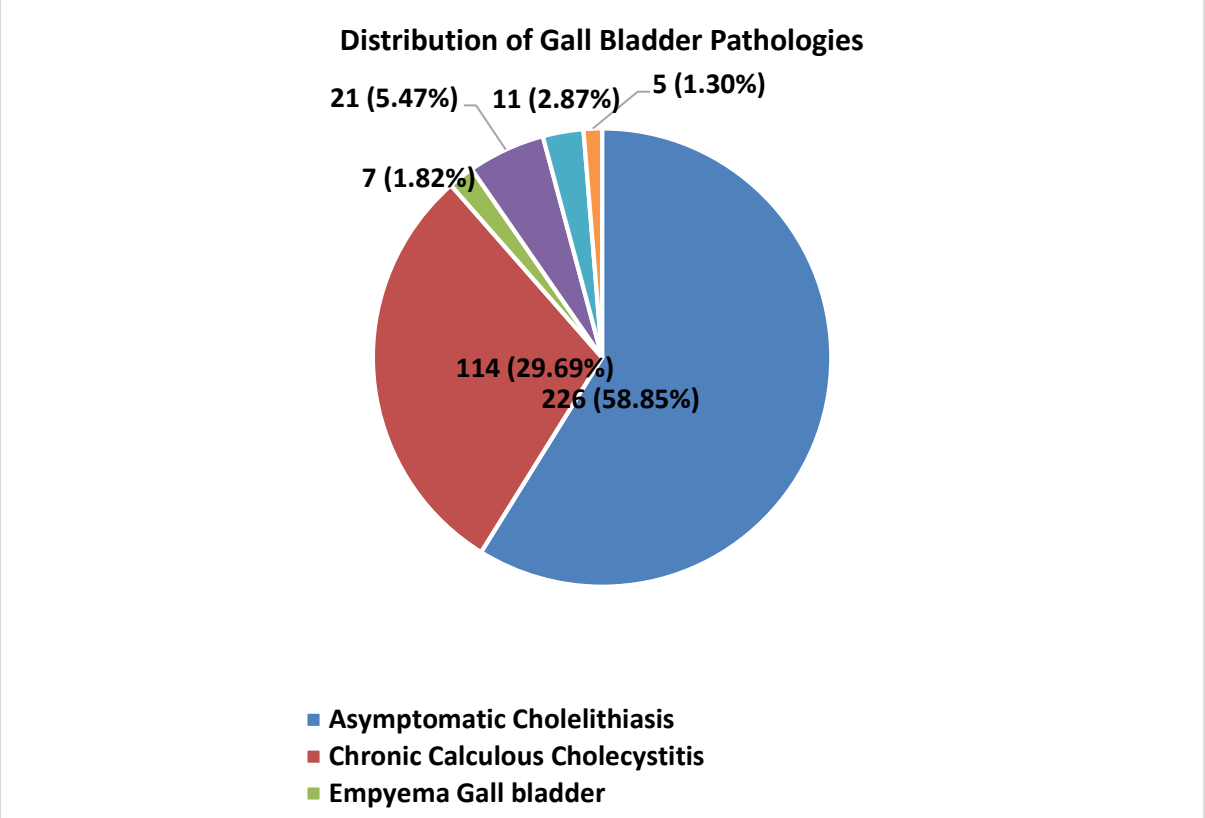

Figure 5: Distribution of gall bladder pathologies

After analysing the antibiotic use in patients, it was observed that all the patients received antibiotic prophylaxis during the post-operative period. The initial parenteral antibiotic therapy was restricted to the use of either one or two antibiotics.

Antibiotic prophylaxis started on the day of the surgery and continued for 1-2 days post-operatively, which was then subsequently switched over to the appropriate oral antibiotics. As this was a cross-sectional observational study, the presence or absence of oral antibiotics in the treatment records relied on the timing of patient interview and data collection.

The antibiotics used both intravenously and orally, along with their doses, formulations, routes of administration, frequency of administration, DDD (as per WHO) and their respective ATC codes are enumerated in Table 2.

Table 2: List of Frequently Prescribed Antibiotics

Sl. No.	Name of Drug	Dose	Frequency	Formulation	ATC code	WHO DDD
Intravenous Antibiotics						
1.	Ceftriaxone	1000mg	Twice daily	Injection	J01DD04	2gm
2.	Amoxicillin/Clavulanate	1200mg	Thrice daily	Injection	J01CR02	3gm
3.	Piperacillin/Tazobactam	4500mg	Thrice daily	Injection	J01CR05	14gm
4.	Metronidazole	500mg/100ml	Thrice daily	Injection	P01AB01	2gm
Oral Antibiotics						
1.	Cefuroxime axetil	500mg	Twice daily	Tablet	J01DC02	0.5gm
2.	Cefixime	200mg	Twice daily	Tablet	J01DD08	0.4gm
3.	Ciprofloxacin	500mg	Twice daily	Tablet	J01MA02	1gm
4.	Amoxicillin/Clavulanate	625mg	Thrice daily	Tablet	J01CR02	1.5gm
5.	Metronidazole	400mg	Thrice daily	Tablet	P01AB01	2gm

The intravenous antibiotics use pattern is summarised in Figure 5.

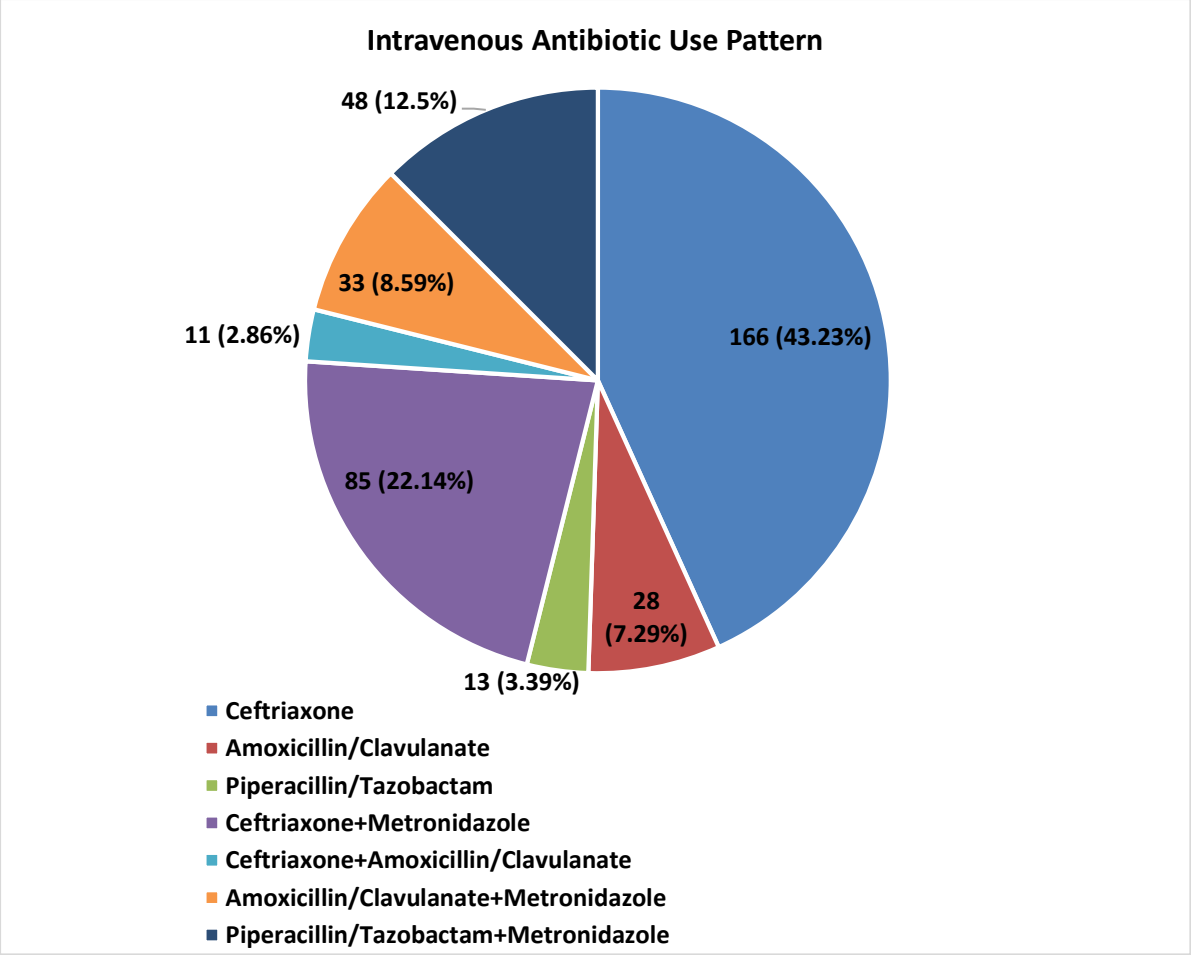

Figure 6: Intravenous antibiotic use pattern

It was observed that 241 patients (62.76%) were switched over to oral antibiotics from intravenous, at the time of interview and data collection and 143 patients (37.24%) were still offered intravenous antibiotics, as depicted in Figure 6.

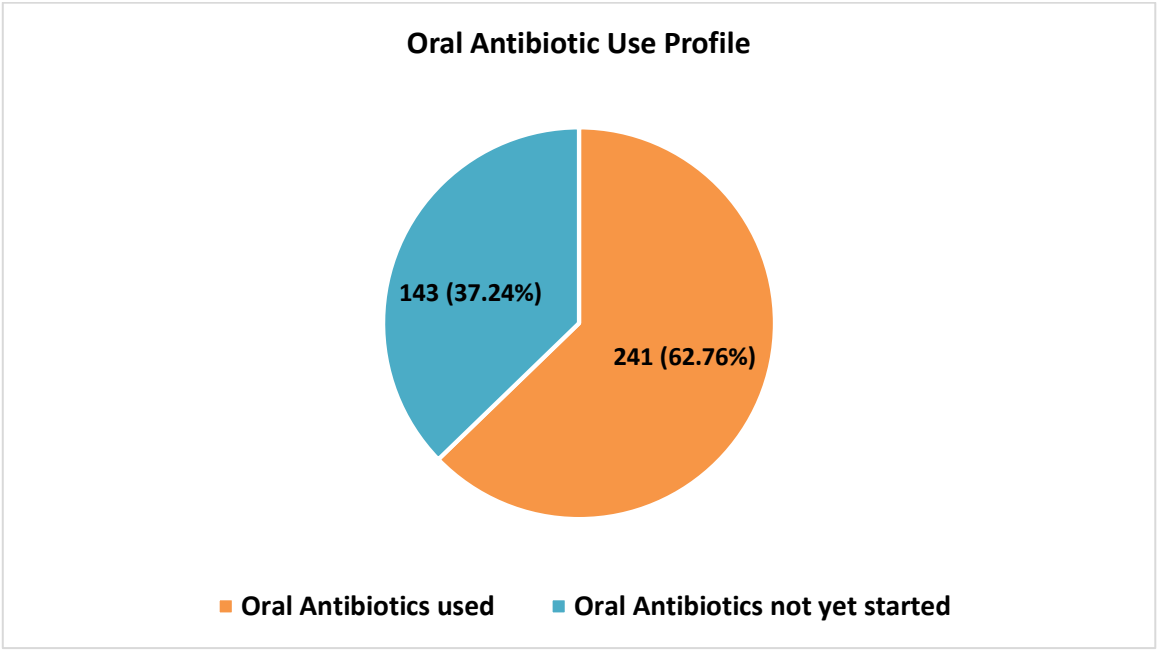

Figure 6: Oral Antibiotic Use Profile

Of the 241 patients, who were already started on oral antibiotics, 92 (38.17%) received only a single oral antibiotic whereas 149 (61.83%) received dual oral antibiotic prophylaxis. The oral antibiotic use pattern is shown in Table 3.

Table 3: Oral Antibiotic Use Pattern

SL. No.	Name of Drug	No. of patients	Total
Single Oral Antibiotic Used			
1.	Cefixime	11 (4.56%)	92 (38.17%)
2.	Cefuroxime axetil	45 (18.67%)	
3.	Ciprofloxacin	16 (6.64%)	
4.	Amoxicillin/Clavulanate	20 (8.3%)	
Dual Oral Antibiotics Used			
1.	Cefixime + Metronidazole	24 (9.96%)	149 (61.83%)
2.	Cefuroxime axetil + Metronidazole	38 (15.77%)	
3.	Cefuroxime axetil + Amoxicillin/Clavulanate	6 (2.49%)	
4.	Ciprofloxacin + Metronidazole	51 (21.16%)	
5.	Ciprofloxacin + Amoxicillin/Clavulanate	2 (0.83%)	
6.	Amoxicillin/Clavulanate + Metronidazole	28 (11.62%)	

Table 4 depicts the pattern of transition from intravenous to oral antibiotics.

Table 4: Transition Pattern of Antibiotics from Intravenous to Oral Route

Name of IV antibiotic used	Oral Antibiotic used	No. of Patients
Ceftriaxone		
	Cefixime	10 (4.15%)
	Cefuroxime Axetil	43 (17.84%)
	Ciprofloxacin	16 (6.64%)
Amoxicillin/Clavulanate		
	Amoxicillin/Clavulanate	18 (7.47%)
Piperacillin/Tazobactam		
	Cefixime	1 (0.42%)
	Cefuroxime Axetil	2 (0.83%)
	Amoxicillin/Clavulanate	2 (0.83%)
Ceftriaxone + Metronidazole		
	Cefixime + Metronidazole	20 (8.3%)
	Cefuroxime Axetil + Metronidazole	15 (6.22%)
	Ciprofloxacin + Metronidazole	37 (15.35%)
Ceftriaxone + Amoxicillin/Clavulanate		
	Cefuroxime Axetil + Amoxicillin/Clavulanate	6 (2.49%)
	Ciprofloxacin + Amoxicillin/Clavulanate	2 (0.83%)
Amoxicillin/Clavulanate + Metronidazole		
	Cefuroxime Axetil + Amoxicillin/Clavulanate	5 (2.08%)
	Amoxicillin/Clavulanate + Metronidazole	26 (10.79%)
Piperacillin/Tazobactam		
	Cefuroxime Axetil + Metronidazole	18 (7.47%)
	Cefixime + Metronidazole	4 (1.66%)
	Ciprofloxacin + Metronidazole	14 (5.8%)
	Amoxicillin/Clavulanate + Metronidazole	2 (0.83%)

All the drugs prescribed were readily available at no cost, in the hospital pharmacy, through government-funded healthcare provision. The WHO/INRUD core drug use indicators are shown in Table 5.

Table 5: Who/Inrud Core Drug Use Indicators

Core Indicators		Outcome
Prescribing Indicators		
	Average number of drugs per prescription	6.95+2.12
	Percentage of drugs prescribed by generic name	100%
	Percentage of encounter with an antibiotic prescribed	100%
	Percentage of encounter with an injection prescribed	100%
	Percentage of drugs prescribed from National List of Essential Medicines, 2022	76.47%
Patient Care Indicators		
	Average consultation time	5 mins
	Average dispensing time	42 mins
	Percentage of drugs actually dispensed	100%
	Percentage of drugs adequately labelled	100%
	Patient's knowledge of correct dosing	42%
Facility Indicators		
	Availability of copy of essential drug list	YES
	Availability of key drugs	YES

The average hospital stay ranged from 2-4 days with a mean duration of 2.8 + 0.67 days. Table 6 notes few additional observations during the course of our study.

Table 6: Some Additional Observations

Sl. No.	Parameter	Number	Mean	Range
1.	Hospital stay	-	2.8+0.67 days	2-4 days
2.	Total drugs used	2665	6.95+2.12 drugs per prescription	4-17 drugs per prescription
3.	Total antibiotics used	759 (28.48%)	1.98+0.82 antibiotics per prescription	1-3 antibiotics per prescription
4.	Total injections prescribed	1950 (73.17%)	5.08+0.79 injections per prescription	4-8 injections per prescription

Discussion

The present study observed a female preponderance for the development of gall bladder pathology, with 54.95% patients being female and 45.05% being male. A similar result showing female preponderance for the development of cholelithiasis, was observed in a study conducted by Bansal A et al., with 65% of the patient population being female and 35% male [10]. The male to female ratio was found to be 1 : 9.725 for patients undergoing cholecystectomy in a study conducted in Babol, Iran between March 2012 and March 2015.[11]

The traditional risk factors for gallstone disease are the four "F's: female, fat, forty, and fertile," with some older studies suggesting "fair skinned" as being the fifth risk factor[12] and in our study a majority of the patients were aged between 41-50 years.

In a study conducted by Sajid MS et al., it was concluded that antibiotic prophylaxis during induction in elective cholecystectomy has proved to significantly reduce the chances of developing post-operative infective complications [13]. The success rate in preventing surgical site infections, observed with antibiotic prophylaxis of 1gm cefotetan, 2gm cefotetan and 2gm cefoxitin was about 97%, 98% and 97%, respectively.[14] In the current study, it was observed that a majority of the patients received monotherapy with intravenous ceftriaxone (2gm/day), a third-generation cephalosporin, during the post-operative period. Our study also observed that the most common oral antibiotic administered, was a combination of ciprofloxacin and metronidazole. In a study conducted by Salim S et al., it was observed that the tissue and serum concentrations of ceftriaxone were significant at a test value of 4 mg/L and a single prophylactic dose of 1 gm intravenous ceftriaxone administered immediately prior to skin incision in laparoscopic cholecystectomy can prevent SSIs in Indian population.[15]

Harvey et al., found that the most popular timing for a review of a possible switch to oral antibiotic therapy was 48-72 hours from the initiation of intravenous therapy. This is at par with the findings of our study.[16]

Limitations

- The study was observational and cross-sectional in nature.
- Since this was a monocentric study, the patient population was mostly homogenous in nature, with little scope to study the prescribing trend

of antibiotics across diverse demographic groups.
- Sample size was relatively small since the duration of the study period was kept short. Thus, the analysis might not be generalizable.
- Antibiotic utilization in case of surgical emergencies could not be studied.
- Correlation between the prescribing pattern of antibiotics and associated comorbidities were not studied.
- Adverse Drug Reactions due to antibiotics were not observed.

Conclusion

In the present study we found a female preponderance for patients undergoing elective laparoscopic cholecystectomy. Age-wise distribution showed that most patients were aged between 41-50 years. Hypertension followed by hypothyroidism and dyslipidaemia were the most commonly observed comorbidities.

Asymptomatic cholelithiasis followed by chronic calculous cholecystitis were the most commonly observed gall bladder pathologies, for which patients underwent elective laparoscopic cholecystectomy.

A majority of patients received a monotherapy with intravenous ceftriaxone followed by a dual therapy with intravenous ceftriaxone and metronidazole. Among patients who received oral antibiotics the most commonly used antibiotic regimen was a dual therapy with oral ciprofloxacin and metronidazole followed by a monotherapy with oral cefuroxime. Antibiotic utilization studies promote the judicial use of antibiotics and the data can be used as feedback for the purpose of spreading awareness and training healthcare professionals regarding the need for rational prescriptions to curtail the rising issue of antimicrobial resistance. However, further studies on a larger patient population and for a longer duration are required to establish the rational use of antibiotics and to utilise the result for policy implementation. Follow-up of patients must be done to observe any adverse drug reactions that may occur due to antibiotic usage.

The results of this study, provide a baseline data for conducting future research work in this area that help in improving the prescription patterns of antibiotics used for surgical prophylaxis. This in turn, will ensure the safer use of antibiotics, improve the quality of patient care and help in controlling antibiotic resistance.

References

1. World Health Organisation, WHO International Working Group for Drug Statistics Methodology, WHO Collaborating Centre for Drug Statistics Methodology, WHO Collaborating Centre for Drug Utilisation Research and Clinical Pharmacological Services. Introduction to Drug Utilisation Research; ISBN 92 4 156234 X; Oslo, Norway, 2003: 08.
2. Naing L., Nordin R.B., Rahman A. H. et al. Sample size calculation for prevalence studies using Scalex and ScalaR calculators. BMC Med Res Methodol.2022;22: 209.
3. Demeke B., Molla F., Assen A., Melkam W., Abrha S., Masresha B., et al. Evaluation of drugs utilization pattern using WHO prescribing indicators in Ayder Referral Hospital, Northern Ethiopia. International Journal of Pharma Sciences and Research. 2015; 6(2): 343-347.
4. National List of Essential Medicines, 2022. https://main.mohfw.gov.in/?q=newshighlights-104 – Site accessed on 4th February, 2024.
5. WHO newsletter DDD-ATC. https://www.who.int/tools/atc-ddd-toolkit/methodology#:~:text=The%20ATC%20classification%20system%20groups,linked%20to%20the%20ATC%20code – Site accessed on 12th February, 2024.
6. Kilipamwambu A., Bwire G.M., Myemba D.T., Njiro B.J., Majigo M.V. WHO/INRUD core prescribing indicators and antibiotic utilization patterns among primary health care facilities in Ilala district, Tanzania. JAC Antimicrob Resist. 2021 May 20; 3(2):dlab049. doi: 10.1093/jacamr/dlab049. PMID: 34223117; PMCID: PMC8210294.
7. Goruntla N., Ssesanga J., Bommireddy B.R., Thammisetty D.P., Kasturi Vishwanathasetty V., Ezeonwumelu J.O.C., Bukke SPN. Evaluation of Rational Drug Use Based on WHO/INRUD Core Drug Use Indicators in a Secondary Care Hospital: A Cross-Sectional Study in Western Uganda. Drug Healthc Patient Saf. 2023;15: 125-135.
8. National Ethical Guidelines for Biomedical Research involving human participants. https://ethics.ncdirindia.org/asset/pdf/ICMR_National_Ethical_Guidelines.pdf - Site accessed on 12th February, 2024.
9. Good Clinical Practice guidelines, Government of India. https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=MzM5NQ== - Site accessed on 21st January, 2024.
10. Bansal A, Akhtar M, Bansal AK. A clinical study: prevalence and management of cholelithiasis. Int Surg J. 2014; 1:134-9.
11. Darzi A.A., Nikmanesh A., Bagherian F. "The Effect of Prophylactic Antibiotics on Post Laparoscopic Cholecystectomy Infectious Complications: A Double-Blinded Clinical Trial; PMID 27382438; Iran, May 2016.
12. Sherlock S., Dooley J., Iber F. Diseases of the liver and biliary system. Oxford: Blackwell science; Jan 2002.

13. Sajid M.S., Bovis J., Rehman S., Singh K.K. Prophylactic antibiotics at the time of elective cholecystectomy are effective in reducing the post- operative infective complications: a systematic review and meta- analysis. Transl Gastroenterol Hepatol 2018; 3:22.
14. Fabian T. C., Zellner S. R., Gazzaniga A., Hanna C, Nichols R L, Waxman K. Multicenter open trial of cefotetan and cefoxitin in elective biliary surgery.; Am J Surg. 1988;155:77–80.
15. Salim S., Kumar M.N., Tripathi C.D., Arya SV, Verma V., Ahmed K.B., Meshram G.G. Pharmacological evaluation of prophylactic anti- microbial use in laparoscopic cholecystectomy; an open labelled study evaluating the concentrations of single dose intravenous ceftriaxone at serum and tissue level. Eur J Clin Pharmacol. 2021 Jul; 77(7):1011-1016.
16. Harvey E.J., McLeod M., De Brún .C, Ashiru-Oredope D. Criteria to achieve safe antimicrobial intravenous-to-oral switch in hospitalised adult populations: a systematic rapid review. BMJ Open. 2023 Jul 7; 13(7).