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# OBSERVATIONAL STUDY ON ANTIBIOTICS VS NO ANTIBIOTICS IN CASES OF LAPAROSCOPIC CHOLECYSTECTOMY IN A TERTIARY CARE HOSPITAL IN WEST BENGAL

Dr. Saurav Majumdar<sup>1</sup>, Dr. Akshita Khare<sup>2</sup>

<sup>1</sup>Senior Resident General surgery West Bengal University of Health Sciences.

<sup>2</sup>MBBS General Surgery West Bengal University of Health Sciences.

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Keywords	Abstract
Laparoscopic Cholecystectomy, SSI, Antibiotics, Biliary, Surgery	<b>Introduction:</b> To treat gallbladder disorders, including symptomatic cholelithiasis, laparoscopic cholecystectomy is a common surgical treatment. Antibiotic prophylaxis should be considered since, despite the procedure's less invasive nature, worries about postoperative infections continue. <b>Aims:</b> The goals of this study are (1) to determine whether or not antibiotic prophylaxis is necessary for elective laparoscopic cholecystectomy and (2) to compare the rates of surgical site infections across patient groups. <b>Materials and method:</b> An institute-based prospective observational comparative research was the nature of the current investigation. From June 2022 to June 2023, in a medical college and teaching hospital in Kolkata carried out the study. This research comprised a total of 200 patients.



**Result:** Only 8(4%) patients out of 200 had stone leakage, while 10(5%) patients had bile spillages. A p-value of 0.470, obtained from a Chi-square test, indicated that the two groups were similar and were, therefore, not statistically significant. **Conclusion:** To sum up, this observational research sheds light on the function of antibiotics in avoiding postoperative infections by comparing the use of antibiotics with no antibiotics in patients having laparoscopic cholecystectomy in a tertiary care hospital in West Bengal. Antibiotics may lower infection risk in certain situations, but the results imply that they may not be required for all patients, especially those without risk factors, to take them regularly. As a result, antibiotic stewardship is crucial for lowering healthcare costs and preventing antibiotic resistance. To validate these findings and inform therapeutic practice, more randomized controlled studies are suggested.

## [1] INTRODUCTION

Laparoscopic cholecystectomy is a common surgical treatment for gallbladder disorders, including symptomatic cholelithiasis. Even if it's minimally intrusive, people are nonetheless worried about getting infections after the surgery, in clear contaminated surgery so antibiotic prophylaxis is something to consider. While some research has shown no differences in the use of antibiotic prophylaxis to reduce postoperative complications, other investigations have found different results.

Among the many healthcare-associated infections that cause illness and mortality, surgical site infection (SSI) ranks third [1]. Antibiotic prophylaxis is warranted to reduce post-op. morbidity & complications related to SSI. Gold Stn it for cholelithiasis being Lap. cholecystectomy has shown infections at surgical site of about 3–4% in US population & hence routine antibiotic is not avoided.

The laparoscope is a commonly used tool for abdominal operations these days. However, there is a minor risk of little damage occurring during disinfection, and these tiny parts might harbor germs that could cause infection [4]. “Indications for laparoscopic cholecystectomy include acute cholecystitis, acalculous cholecystitis, chronic cholecystitis, cholecystectomy with common bile duct exploration, and operations such as gastric bypass surgery.” This kind of surgery is done frequently across the globe. Bacteria, both aerobic and anaerobic, may be found in the gall bladder's bile. The improved aseptic procedures have not eliminated the issue of SSI.[5,6,7]

“For postoperative prophylaxis, second-generation cephalosporins and fluoroquinolones are the medications of choice.” Newer recommendations no longer support the use of prophylactic antibiotics during routine laparoscopic cholecystectomy. Although prophylaxis has been helpful in studies involving open cholecystectomy, its efficacy in laparoscopic procedures is less certain. Therefore, it is still unclear if antibiotic prophylaxis is helpful or not in laparoscopic surgery patients. Data about antibiotic prophylaxis have all been collected from international studies. However, a large sample from Indian subcontinent was lacking. [8] The goals of this study are to determine whether or not antibiotic prophylaxis is necessary for elective laparoscopic cholecystectomy and to compare the rates of surgical site infections in patients hospitalized for this procedure with and without this precaution.

## [2] MATERIALS AND METHODS



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**Study area:** Department of General Surgery in a Medical College and a tertiary care training hospital in Kolkata.

**Study Population:** The study included two hundred (200) individuals who were having elective laparoscopic cholecystectomy due to symptomatic gallstone disease.

**Study Duration:** June 2022 to June 2023.

**Study Design:** Institute Prospective, Observational, and Comparative Study.

**Sample Size:** 200

**Randomization:** Simple computer-generated randomization.

#### INCLUSION CRITERIA:

- Cases of asymptomatic gallstone disease undergoing laparoscopic cholecystectomy.
- Cases of symptomatic gallstone disease (Grade 1 as per Tokyo Classification)
- BMI  $\leq 30$  kg/m<sup>2</sup>.
- Age 10- 60 years.

#### EXCLUSION CRITERIA:

- Presence of acute cholecystitis (Grade 2 & Grade 3 as per Tokyo Classification) or choledocholithiasis or pancreatitis, previous biliary tract surgery, conversion to open intraoperatively
- Use of antibiotics within 48 hours prior to surgery.
- Patients with renal or hepatic impairment
- Presence of immune-suppressing conditions or taking medications compromising immunity (Patients on steroids & diabetes, hypothyroidism, pregnancy, prosthetic heart valves patients) & smoking.
- Not giving consent

#### Protocol

- The patients were randomized as per computer generated random numbers into 2 groups.
- One group who received antibiotics and the other group that did not receive antibiotics.
- The post operative incidence of SSI was compared between the two groups using the ASEPSIS scoring system and the data presented
- The groups were compared for other possible confounding factors such as age, sex, comorbidities like DM, HTN, connective tissue disorders, history of smoking and BMI.

#### Statistical Analysis:

The data was first input into an Excel spreadsheet for statistical analysis. SPSS (version 27.0; SPSS Inc., Chicago, IL, USA) and GraphPad Prism (version 5) were then used for further analysis. "Means and standard deviations were used to summarise numerical data, whereas counts and percentages were used to characterise categorical variables." To evaluate differences between groups, two-sample t-tests were used. These tests compare the means of independent or unpaired samples. The power of paired t-tests is higher than that of unpaired tests because they take into consideration the correlation between the two sets of data. "In order to test hypotheses when the test statistic's sample distribution is a chi-squared distribution under the null hypothesis,  $\chi^2$  tests, also known as Pearson's chi-squared test or just the chi-squared test, were used." The chi-square test or Fisher's exact test was used for comparisons of unpaired proportions, as appropriate for the given scenario. With the appropriate degrees of freedom specified for each test, t-tests were conducted using the appropriate test statistic formulas that either nearly resemble

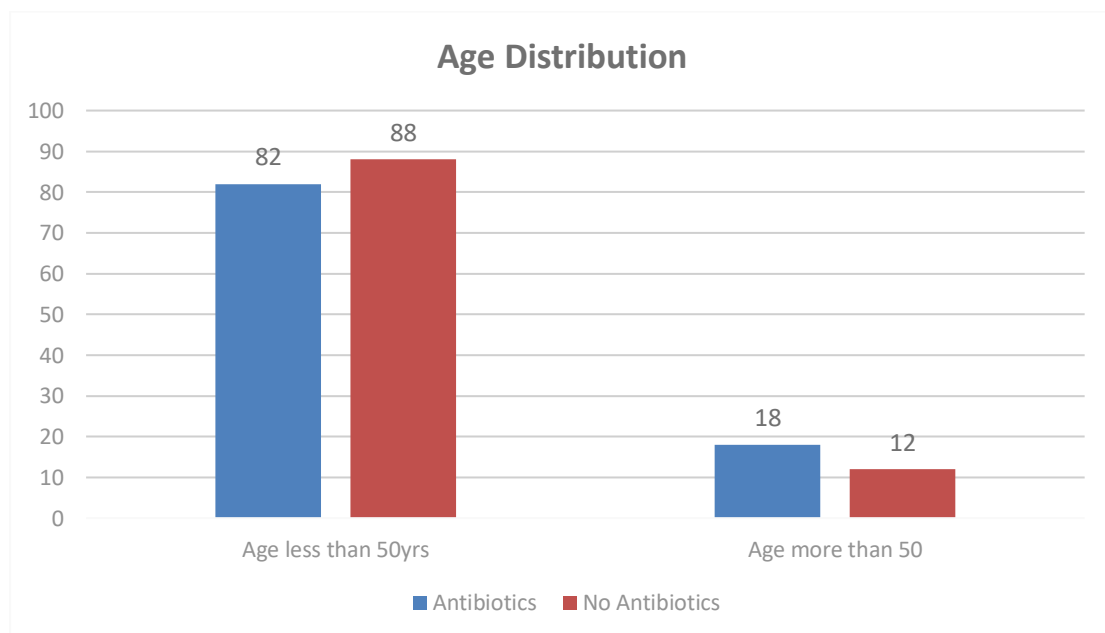


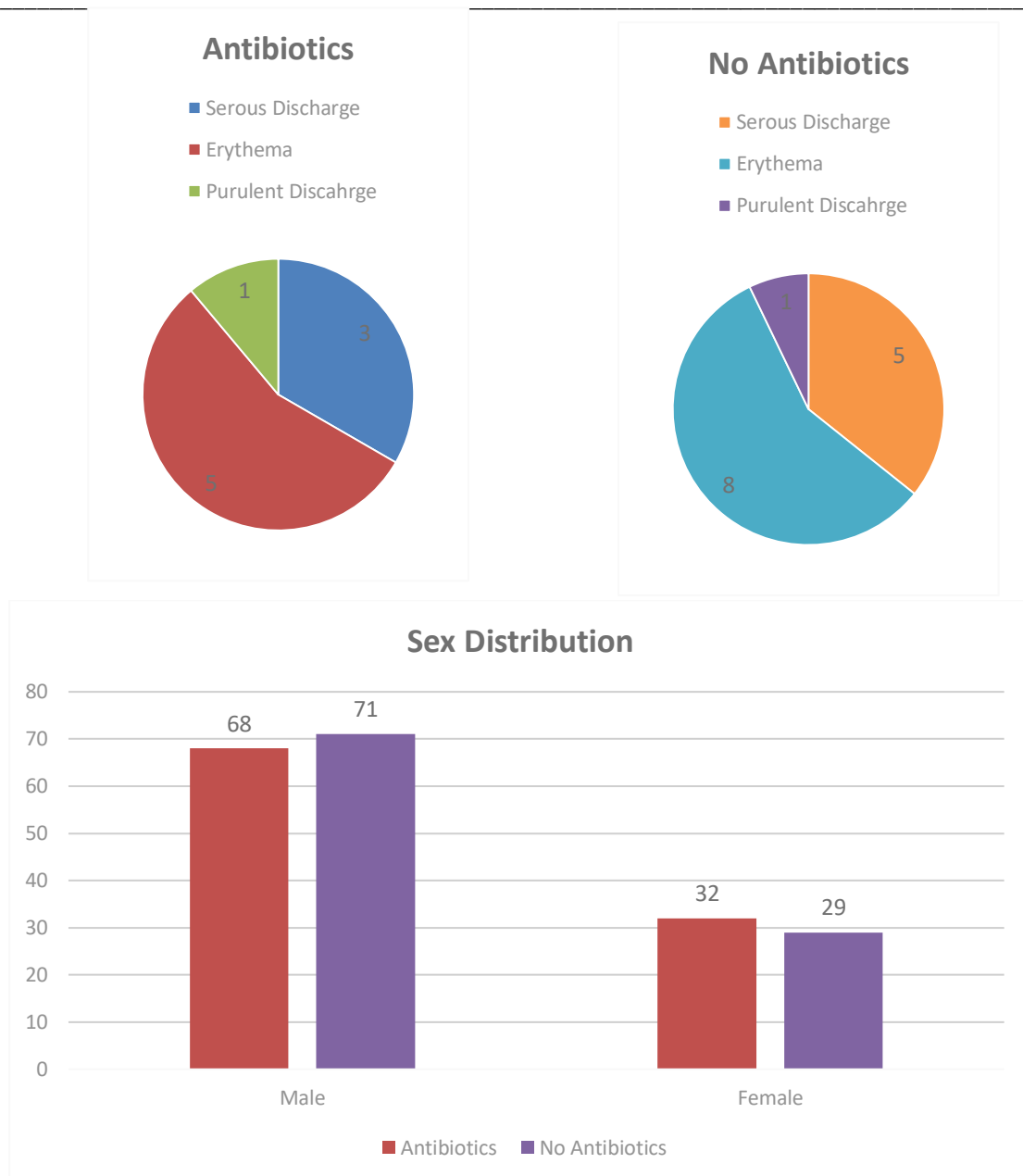
or precisely follow a t-distribution under the null hypothesis. Our p-values were calculated using the tables provided by Student's t-distribution. The alternative hypothesis was accepted instead of the null hypothesis because a p-value less than or equal to 0.05 was deemed statistically significant.

## Results

	Antibiotics	No Antibiotics	P value
Age Distribution(<50 yrs)	82	88	0.309
Age distribution (>50 yrs)	18	12	0.235
Sex Distribution	68:32	71:29	0.759
Average BMI	23	25	0.740

	Antibiotics	No Antibiotics	P Value
Serous Discharge	3	5	0.470
Erythema	5	8	0.389
Purulent Discharge	1	1	0.50
Wound Dehiscence	0	0	0
Any Incidence of prolonged stay ( More than 14 days due to infection)	0	0	0
Additional treatment received ( Drainage of pus, debridement of wound)	0	0	0





The two groups were statistically equivalent in terms of age, sex and BMI distribution.

Only 8 patients out of 200 had a serous discharge, while 13 patients developed an erythema and 2 out of 200 had a purulent discharge from the wound. The results of the Chi-square test indicated that the two groups were similar; Only 8 patients out of 200 had stone leakage, 10 patients of 200 had an incidence of intra operative accidental bile spillage. Although bile spillage is considered to be associated with increased incidence of SSI, we did not find any significant increase of SSI in our study population due to bile spill.

### [3] DISCUSSION

After all potential confounding variables were investigated and eliminated, both groups were matched and equivalent with regard to age, sex, length of surgery, intra-operative leakage, and postoperative infections.

When it comes to surgical site infections (SSIs) in clean contaminated surgery, antibiotic prophylaxis is pointless. Providing antibiotics for extended periods will not help avoid infections & in this chances of antibiotic resistance [9] According to one study, antibiotic prophylaxis may not help prevent or manage surgical site infections, regardless of the procedure's risk level. [10] Antibiotic prophylaxis does not significantly reduce risk, according to research by Yan C.[11]

Statistical analysis revealed no difference between the groups in terms of the risk of surgical site infections (SSIs) during routine postoperative follow-up (i.e., on POD-0, POD-28).

1. 8 pts developed a serous discharge, 13 pts developed an erythema around wound & 2 patients had purulent discharge. However, despite a purulent discharge in 1 patient of No antibiotic group, the post op outcome & SSI incidence remained same.
2. There was no incidence of long hospital stay & no additional treatment was necessitated.

### [4] CONCLUSION

A tertiary care hospital in West Bengal conducted observational research comparing antibiotic usage to no antibiotic use in patients having laparoscopic cholecystectomy. The results shed light on the importance of antibiotics in avoiding infections after the operation. Antibiotics may lower infection risk in certain situations, but the results imply that they may not be required for all patients, especially those without risk factors, to take them regularly. As a result, antibiotic stewardship is crucial for lowering healthcare costs and preventing antibiotic resistance. To validate these findings and inform therapeutic practice, more randomized controlled studies are suggested.

### [5] AUTHOR(S) CONTRIBUTION

Dr. Zealous Mary comprehended and conducted the study, as well as evaluated and interpreted the results. Dr. Vathana wrote and updated the main manuscript. All authors read and approved the final version of the manuscript.

### [6] LIMITATIONS

The size of the sample was very small.

The study was completely conducted on senior citizens.

### [7] RECOMMENDATIONS

Needs to conduct in Tai-chi exercise to assess the physical problems in old age people. Comparison research may be done to discover changes in adults and old age Recommend to do this study as qualitative research.

### [8] ACKNOWLEDGEMENT

Individuals / resources participated in the work are acknowledged properly.

### [9] SOURCES OF FUNDING

The authors received no financial aid to support the study.



#### [10] PLAGIARISM POLICY

The author(s) declare that any kind of violation of plagiarism, copyright, and ethical matters will be handled by all authors. Journalists and editors are not liable for the aforesaid matters.

#### [11] CONFLICTS OF INTEREST

The authors declared that no potential conflicts of interest concerning the research, authorship, and/or publication of this article.

#### [12] PROTECTION OF RESEARCH PARTICIPANTS

This study do not involve any such criteria or condition.

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