# **Original Research Paper**



# **Hepatobiliary Surgery**

# SINGLE DOSE AND MULTIDOSE ANTIBIOTIC PROPHYLAXIS IN ELECTIVE LAPAROSCOPIC CHOLECYSTECTOMY-A COMPARATIVE STUDY

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ABSTRACT Laparoscopic Cholecystectomy (LC) is the gold standard for treatment of cholelithiasis. The incidence of surgical site infections after Laparoscopic Cholecystectomy is significantly lower when compared with infections in Open

Cholecystectomy. Numerous complications are observed during and after this procedure, one post-operative complication that can lead to significant morbidity is Surgical Site Infection (SSI), which can be reduced by administration of prophylactic antibiotics. The role of prophylactic antibiotic in various clean or clean contaminated surgeries reduces the risk of postoperative infective complication thereby reducing morbidity and mortality. Appropriate antibiotic prophylaxis in surgery is directed towards the most likely pathogens encountered during the surgical procedure. 62 patients were included in the study and were divided into 2 groups. One group was given Single Dose and the other was given Multiple Doses of Antibiotics. Intraoperative bile contamination, leakage and operative time were noted. Port site was inspected on day 3, 7, 15 and 30, for evidence of surgical site infection. Out of undue fear of surgical site infections the prophylactic antibiotics are being misused and continued for many days in postoperative period in many places adding to the cost burden to the patients as well as drug resistance to the microbes. Keeping this in mind this study is being conducted to assess the incidence of SSI in Elective laparoscopic cholecystectomy done in our hospital and the effectiveness of single v/s multiple dose antibiotic prophylaxis in preventing surgical site infection as well as the economic burden of the same on the patient.

## **KEYWORDS:**

#### INTRODUCTION

Gallstones are a major health problem in developed countries with around 10%-15% of adult population affected[1] and is one of the most common cause of emergency hospital admission for people with abdominal pain worldwide.[2]

At present, Laparoscopic Cholecystectomy (LC) is the gold standard for treatment of symptomatic gallstones. The incidence of surgical site infections after Laparoscopic Cholecystectomy is significantly lower when compared with infections in Open Cholecystectomy.[5] One of the post-operative complications that can lead to significant morbidity is Surgical Site Infection(SSI) which can be reduced by administration of prophylactic antibiotics.

Prophylactic use of antibiotics in various clean and clean contaminated surgeries reduce the risk of postoperative infective complication thereby reducing morbidity and mortality.

Appropriate antibiotic prophylaxis in surgery is directed towards the most likely pathogens encountered during the surgical procedure. The appropriate antibiotic is chosen before surgery and administered before the skin incision is made. The use of prophylactic antibiotics as a means of preventing surgical site infections is still controversial in elective Laparoscopic Cholecystectomy. [11-13]. A school of thought is that antibiotic prophylaxis may not be necessary at all in clean, elective, and low risk cases, but the current practice still prescribes use of antibiotic prophylaxis preoperatively.

Out of undue fear of surgical site infections the prophylactic antibiotics are being misused and continued for many days in postoperative period in many places adding to the cost burden to the patients as well as drug resistance to the microbes.

This study is being conducted at our institute to assess the incidence of SSI in Elective laparoscopic cholecystectomy done in our hospital and the effectiveness of single vs. multiple dose antibiotic prophylaxis in preventing surgical site infection.

## AIMS AND OBJECTIVES

of wound.

1. To evaluate and compare the incidence of Surgical Site Infections and efficacy of perioperative single vs. multiple doses of antimicrobial therapy in patients undergoing elective laparoscopic cholecystectomy. 2. To establish relation between SSI and bile spillage or contamination

#### MATERIALS AND METHODS

This is a prospective, comparative, randomized study, conducted on the patients who were diagnosed with symptomatic cholelithiasis and planned for laparoscopic cholecystectomy. A total of 62 cases were included in our study. Patients who were admitted through Outpatient Department of MGM Medical College and Hospital, Navi Mumbai from December 2018 to November 2020, were included in the study after taking ethical clearance from Institutional Ethics Committee. Complete clinical history and necessary pre-operative investigations were recorded in case proforma. Patients were advised to have a full body shower with soap, no earlier than the night before the day of surgery.

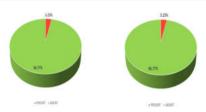
A total of 62 patients were included in the study. They were divided into 2 groups of 31 patients each and the patient selection was done by a Lottery System. One group was given Single Dose and the other was given Multiple Doses of Antibiotics.

Patients in single dose group were given Inj Ceftriaxone + Sulbactam 1.5gm at the time of induction. Patients in multi dose group were given Inj Ceftriaxone + Sulbactam 1.5g first at the time of induction and second dose of Inj Ceftriaxone + Sulbactam 1.5 gm 12 hours postoperatively. The surgical site was prepared inside the operation theatre by painting and draping with betadine scrub, chlorhexidine, and betadine solution, respectively.

Intraoperative bile contamination, leakage and operative time were noted. Port site was inspected on day 3 and day 7 for evidence of surgical site infection. Patients were called up for follow up on day 15 and day 30. Once the diagnosis of surgical site infection was made, patients were started on broad spectrum antibiotics after collecting fluid/pus for culture and regular dressing till wound is healed.

### OBSERVATIONS AND RESULTS

PARAMETER	Y/N	SINGLE DOSE	MULTI DOSE	TOTAL	P VALU E
POST-OP FEVER	Y	1 (1.61%)	1 (1.61%)	2 (3.23%)	0,999
	N	30 (48.39%)	30 (48.39%)	60 (96.77%)	
ERYTHEMA	Y	1 (1.61%)	0 (0%)	1 (1.61%)	0.500
	N	30 (48.39%)	31 (50%)	61 (98.39%)	
DISCHARGE FROM WOUND SITE	Y	1 (1.61%)	1 (1.61%)	2 (3.23%)	0.999
	N	30 (48.39%)	30 (48.39%)	60 (96.77%)	
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**Figure 1:** Distribution of the study population according to the presence of post-operative fever

Figure 2: Distribution of the study population according to the presence of surgical site infection



Figure 4: Distribution of the study population according to the the antibiotic dose and presence of discharge from wound site

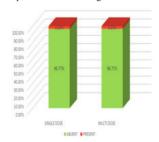


Figure 3: Distribution of the study population according to the presence of erythema

#### RESULTS

The conclusion frpm the current study is

- 1. Cholelithiasis shows a female preponderance. Out of 62 patients, 43 cases were females (69.34%).
- 2. Cholelithiasis affects population aged 18 to 76 years with a mean age of  $44.85\pm15.12$  years.
- 3. Comorbidities were present in a minority of cases of cholelithiasis (14 out of 62) which accounts to 22.58%. Diabetes is more common comorbidity than hypertension.
- 4. Intra-operative spillage of bile occured in 6 out of the 62 cases (9.68%), with the difference between the two groups being statistically insignificant (P value: 0.433).
- 5. Post-operative surgical site infection was seen in only 2 patients out of the 62 cases after elective laparoscopic cholecystectomy. One from single dose group and one from multidose group. Both the patients had spillage of bile on the umbilical port site while removing the specimen. Both patients had serous discharge from the wound in the postoperative period which was treated with broad spectrum antibiotics and regular dressing till the wound is healed. The port site infection can be related to the wound contamination rather than the antibiotic prophylaxis. The difference in the incidence of infection in the two groups is statistically insignificant.
- 6. The mean operative time was  $64.92 \pm 17.78$  minutes and the difference between the two groups is statistically insignificant (P value: 0.596).

Comparing all the above results, the incidence of wound infection in patients who were given Single Dose and Multiple Dose antibiotic prophylaxis was found to be statistically insignificant.

#### DISCUSSION

It was observed in our study that majority of the patients affected with cholelithiasis were females (69.34%). There was no statistically

significant difference in the mean age of females  $(43.81\pm14.98\ \text{years})$  and males  $(47.21\pm15.59\ \text{years})$ . Comorbidities were present in 22.58% of the cases. Amongst the cases where comorbidity was present, diabetes was the most prevalent comorbidity (64.29%), followed by hypertension (28.57%). It was observed that 7.14% of the population was affected by both diabetes and hypertension. Other comorbidities were respiratory disease (2.64%), heart disease (1.68%), jaundice (1.2%) and immunosuppression (0.2%).

Intra-operative bile spillage happened in 6 cases out of the 62 cases accounting to 9.68%. Out of these 6, 2 patients had minor post-operative wound infection which was treated with dressings and antibiotics.

In the present study, it was observed that post-operative fever, discharge from wound site and surgical site infection were present in 3.23% (2 out of 62) of the cases each while erythema was present in only 1.61% (1 out of 62) of the cases. Presence of infection was assessed by the presence of fever, port side erythema, tenderness, discharge from wound, wound gape and wound abscess. Wound Infection was present in only 2 patients who had bile spillage while removing the specimen.

In the present study, the mean operative time was  $64.92 \pm 17.78$  minutes (range: 45 to 120 minutes). It was also found that there was no statistically significant difference in the operative time between the two groups (P value: 0.596).

Koirala A. et al conducted a prospective study to compare single dose versus multiple dose antibiotics in laparoscopic cholecystectomy where they found that the incidence of infection in the single dose group was 4% and in the multi dose group was 3%. There was no significant difference in the incidence of infection between the two groups (P value: 0.500).

In the study by Thapa S. et al, they found that the incidence of wound infection in the Single dose group was 4.24% and, in the Muliple dose, group was 3.28%. The incidence was comparable in both the groups (P value: 0.75).

Zahid M. et al also conducted a similar study where they found the overall incidence of post-operative wound infection was 4.6%. When assessed in terms of the two groups, the incidence was 4% with single dose antibiotic therapy and 5.3% with multi dose antibiotic therapy. The difference between the two groups was statistically insignificant (Pvalue: more than 0.05).

In a study by Meijer W. and Schimtz P, it was found that the infection rates were: 6.6% versus 6.2% for minor wound infection (P=0.78) and 4.6% versus 3.8% for major wound infection (P=0.52).

Thus, it can be effectively concluded from the present study and other studies, that single dose antibiotic prophylaxis at induction of the surgery and Multiple Dose Antibiotics which include one more dose 12 hours after the first dose doesn't make much difference in the incidence of Surgical Site Infection in patients undergoing elective laparoscopic cholecystectomy. So single dose antibiotic prophylaxis can be effectively used to prevent Surgical Site Infection in elective Laparoscopic Cholecystectomy.

Among the wounds which got infected, the isolated organism was E. Coli and can be correlated with bile contamination and statistically, no significance in wound infection can be related to single or multiple dose antibiotic prophylaxis.

Limitations of study: The present study was a single centre study done by a single surgical unit over a period of 2 years, on patients undergoing laparoscopic cholecystectomy. Therefore, the results cannot be generalised and it needs a multicentre trial with a big sample size for reaching a better conclusion.

#### CONCLUSION

It can be concluded after evaluating the results that the rate of wound infection in elective laparoscopic cholecystectomy is negligible and there is no significant difference in outcome in terms of wound infection with the use of single and multiple dose antibiotic prophylaxis . So the practice of single dose prophylaxis can be continued without significant increase in rate of wound infection.

- Koirala A, Thakur D, Agrawal S, Chaudhary BL. Single dose versus multiple dose antibiotics in laparoscopic cholecystectomy: A prospective comparative single blind study. Journal of Society of Anaesthesiologists of Nepal (JSAN) 2018;5(1):11-15.
- study, Journal of Society of Anaesthesiologists of Nepa (ISAN) 2018;(17:11-15). Thapa S, Kher Y, Tambay Y. Single dose Intraoperative Antibiotics versus Postoperative Antibiotics for Patient Undergoing Laparoscopic Cholecystectomy for Symptomatic Cholelithiasis. Journal of Lumbini Medical College. 2017;5(1):13-20. Zahid M, Bakhsh R, Dar F, Akhter N, Malik Z. Comparison of single dose and three dose antibiotic prophylaxis with cefotaxime sodium in cholecystectomy. J Ayub Med Coll
- Abbottabad. 2003;15(1):1-10.
  Meijer W, Schimtz P. Prophylactic use of cefuroxime in biliary tract surgery:
- randomized controlled trial of single versus multiple dose in high-risk patients. Br J Surg. 1993; 80:917-921.
- Gaur A, Pujahari A. Role of Prophylactic Antibiotics in Laparoscopic Cholecystectomy.

  Medical Journal Armed Forces India. 2010;66(3):228-230
- Aziz R. Practical Manual of Operative Laparoscopy, New York: Springer- Verlag 1992 pp 1-8. Horan TC, Gaynes RP, Martone WJ, et al. CDC definitions of nosocomial surgical site
- infections, 1992: a modification of CDC definitions of surgical wound infections. Infect Control Hosp Epidemiol 1992; 13:606–608.
- Chiu CC, Lee WJ, Wang W, Wei PL, Huang MT. Prevention of trocar-wound hernia in laparoscopic bariatric operations. Obes Surg. 2006; 16:913-8.
- Mc Gurgan P, P Donovan P. Optical versus as an entry technique. Endose, 1999, 8:379-
- Mettler J,Schmidt EH, Frank V, Semm K. Laparoscopic entry and its complications, GynaecolEndose, 1999;8:383-385 Mangram AJ, Horan TC, Pearson ML, Silver LC, Jarvis WR. The Hospital Infection 10.
- 11. Control Practices Advisory Committee. Guideline for the prevention of surgical site infection, 1999. Infect Control Hosp Epidemiol 1999; 20:247-280.

  Kalloo AN, Kantsevoy SV. Gallstones and biliary disease. Prim Care. 2001; 28:591-606.
- 1. Mills JC, Stappenbeck TS, Bunnett NW. Gastrointestinal disease. In: McPhee SJ, Hammer GD, eds. Pathophysiology of Disease: An Introduction to Clinical Medicine. 6th ed. New York, NY: McGraw-Hill Medical; 2010.