

## Original Research Article

# Is there a need for antibiotic cover in clean surgery like laparoscopic cholecystectomy: a prospective study

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## ABSTRACT

**Background:** Even with a low post-operative infection complication rate in elective laparoscopic cholecystectomy (LC), most surgeons use prophylactic antibiotics out of habit. This prospective study was done to analyze the need for such prophylaxis in cases of elective LC.

**Methods:** 135 successive patients undergoing elective LC were included in the study. Patients were randomized into 3 groups. Group A (n=45) cases received 3 doses of injection ceftriaxone in the post op period, group B (n=48) cases received a single dose of injection ceftriaxone at the time of induction of anesthesia, and group C (n=42) cases did not receive any antibiotic pre or post operatively. Post-operative infectious complications between three groups were compared.

**Results:** There was no significant difference in surgical site infection rates between the groups for variables such as age, sex, body mass index, duration of symptoms, duration of surgery and hospital stay. Intraoperative spillage of bile [6.7% (A): 4.6% (B): 5.2% (C)] did not increase infectious complications.

**Conclusions:** Routine use of prophylactic antibiotic in a clean, uncomplicated cases of laparoscopic cholecystectomy is not required. One dose of ceftriaxone at the time of induction or 3 doses of injection ceftriaxone post operatively following elective LC even in the urban Indian setting should be abandoned as it neither reduces the rate of surgical site infection but also contributes to adverse reactions, drug resistance, and unnecessary financial burden.

**Keywords:** Elective laparoscopic cholecystectomy, Prophylactic antibiotic, Surgical site infection

## INTRODUCTION

Laparoscopic cholecystectomy (LC) has been universally accepted as the method to manage symptomatic uncomplicated cholelithiasis and other benign gallbladder diseases, because it can cure the disease and has low morbidity and mortality.

The role antibiotic prophylaxis is to prevent infection in contaminated wounds, but its indication in straight forward clean surgical operations like LC, in which no obvious bacterial contamination or insertion of a foreign

body has occurred is not clear.<sup>1</sup> The small size of wound in LC and also due to lower tissue trauma in LC, the immune system is better preserved in laparoscopic surgery, hence the over-use of antibiotics is a cause for rising frequency of adverse effects, emergence of drug resistant organisms, as well as increased cost.

While the most frequent complication in patients undergoing cholecystectomy is surgical site infection, it is not clear whether antibiotic prophylaxis in laparoscopic cholecystectomy is of any advantage to the patient in terms of preventing infection.<sup>7</sup> Thus, the present study

was undertaken to evaluate the need for such prophylaxis in cases of elective LC in a semi-urban setting.

## METHODS

This prospective randomized study was conducted in the department of General Surgery, Saveetha Medical College, Chennai, during the period from February 2019 to December 2019. All patients undergoing elective cholecystectomy were entered into the trial unless they refused consent or were already being treated with antibiotics. The 135 studied patients undergoing elective laparoscopic cholecystectomy were randomized into three groups. Randomization took place by computer generated allocation of group, thereby deciding if the patient would receive three doses of antibiotics, single dose of antibiotics or no antibiotics at all. Post-operative infectious complications between the three groups were compared for variables such as age, sex, body mass index and bile spillage. Post operatively Repeat total leucocyte count and post op ultrasound was done for all patients.

All surgeries were done under general anesthesia (GA). Group A (n=45) cases who received 3 doses of injection ceftriaxone in the post op period, group B (n=48) cases who received a single dose of injection ceftriaxone only at the time of induction of anesthesia, and group C (n=42) cases those who did not receive any antibiotic pre or post operatively. LC was performed in both gatherings utilizing the standard four ports. Gall bladder was taken out from the umbilical port and a specimen for bile culture was taken at the time of gall bladder recovery. Any blood or bile in the Calot's triangle and subhepatic space was wiped utilizing suction and water system cannula. When there is leak due to cystic duct or gallbladder perforation during dissection, it is noted as bile spillage. Wounds were sutured with 3-0 non-absorbable monofilament suture. Age, sex, intra-operative observations, ASA scoring, spillage of bile in operative field, were documented in every patient. Any occurrence of fever was recorded post operatively. Asymptomatic patients were released on first or second postoperative day when taking and enduring food orally.

### Inclusion criteria

All cases of uncomplicated chronic cholecystitis, cholelithiasis and benign gall bladder pathology like GB polyp who underwent LC in the Department of General Surgery from February 2019 to December 2019. Normal gall bladder wall thickness on pre-op USG and afebrile patients with total leucocyte counts within normal limits were included.

### Exclusion criteria

Patients who underwent lap cholecystectomy along with another procedure like hernia repair etc. were excluded from the study. Cases of complicated and acutely inflamed GB like empyema, mucocoele, gangrenous gall

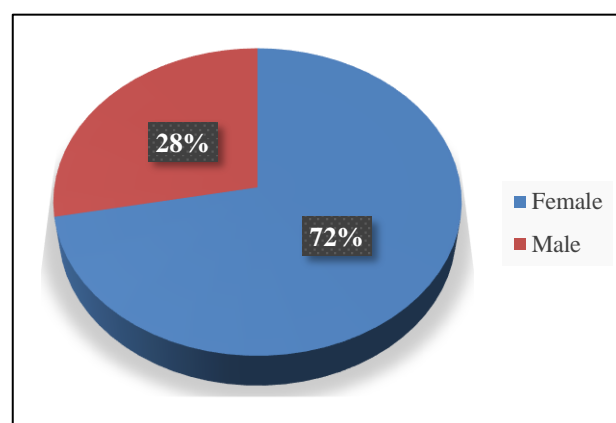
bladder, GB perforation etc. and immuno-compromised patients were also excluded.

### Statistical analysis

First descriptive statistics, including count and percentage were used to describe the demographic characteristics of the patients observed in this study. Analysis for association between use of antibiotics and their potential to reduce post op infections was performed using Chi Square test. P value <0.05 was considered statistically significant.

## RESULTS

A total of 135 patients underwent LC in the study period; Group A (3ABG) (n=45) cases who received 3 doses of injection ceftriaxone in the post op period, Group B (1ABG) (n=48) cases who received a single dose of injection ceftriaxone only at the time of induction of anesthesia, and Group C (NABG) (n=42) cases those who did not receive any antibiotic pre or post operatively. There were 97 (72%) females and 38 (28%) males as shown in Figure 1.



**Figure 1: Male to female ratio.**

Mean age of the patients was similar in all three groups (45.4 years in 3ABG, 44.8 years in 1ABG and 45.1 years in NABG). All groups were homogeneous for sex and age and ASA score. Mean duration of surgery in 3ABG was 43.5, 1ABG was 43.9 minutes and in NABG was 42.9 minutes. Mean length of hospital stay in 3ABG was  $1.56 \pm 0.6$  days, 1ABG was  $1.51 \pm 0.5$  days where as NABG in  $1.69 \pm 0.8$  days.

Spillage of bile occurred in 26 cases. There were no cases of sub-hepatic abscess/deep seated infection seen in any of the three groups. 2 cases of superficial surgical, i.e. trocar site infection was noted in 3ABG, 3 cases in were noted in 1ABG and 2 cases in NABG. The most common site of infection was umbilical trocar site in both the group. Fever was recorded in 3 cases of 3ABG, 2 cases of 1ABG and 4 cases of NABG. In 7 cases fever subsided on the next day.

No statistical difference (p-value=0.915656) was observed among the groups in deep and superficial infections.

**Table 1: Comparing the occurrence of infection with the use of antibiotics.**

	Infection present	Infection absent	Marginal row totals
<b>Antibiotic group (3ABG)</b>	2 (2.33) [0.05]	43 (42.67) [0.00]	45
<b>Antibiotic group (1ABG)</b>	3 (2.49) [0.10]	45 (45.51) [0.01]	48
<b>Non antibiotic group (nABG)</b>	2 (2.18) [0.01]	40 (39.82) [0.00]	42
<b>Marginal column total</b>	7	128	135

## DISCUSSION

From the first laparoscopic cholecystectomy performed by Mouret in the year 19881, LC has come a long way becoming the procedure of choice in numerous pathologies of the gall bladder like cholelithiasis, calculous cholecystitis, acute acalculous cholecystitis, gallstone pancreatitis, biliary colic, biliary dyskinesia, GB polyps, cholesterosis and adenomyomatosis. Approximately 115 patients undergo a cholecystectomy for every 100,000 of the world's population for benign gallbladder disease annually.<sup>18</sup> Laparoscopic cholecystectomy, has evolved in technique, instrumentation and postoperative management yet there is a wide variation in the management, especially in antibiotic prophylaxis during cholecystectomy. Studies have failed to demonstrate any clinical benefit, such as reduction in surgical site infections in patients administered antibiotic prophylaxis during an elective cholecystectomy.<sup>19</sup>

With increased surgeon experience, LC has slowly migrated from a major procedure to one that is now widely done in an outpatient setting. The delicate anatomy of the gall bladder, bile duct, cystic triangle and anatomical variations in this region provide ample challenges to even experienced surgeons at times. Hence even though LC is a common procedure, LC carries substantial risk of complications. A study by Alli et al shows a shifting distribution of operative indications and increasing rates of digestive, infectious, respiratory, and renal complications complications, with overall cholecystectomy complication rates of 9.29%.<sup>2</sup> The average rate of SSIs for LC has been reported in the literature to be between 0.4% and 6.3%.<sup>8-10</sup> The need for antibiotics is now frequently questioned as laparoscopic procedure results in lesser activation of the inflammatory response.<sup>2</sup> Furthermore, laparoscopic cholecystectomy per se, does not violate the mucosal defense barrier of the respiratory, gastro-intestinal or genital epithelium. Surgical site infections with elective laparoscopic cholecystectomy are less frequent and less severe, leading

to suggest that prophylactic antibiotics (PA) are no longer indicated.<sup>6</sup>

In present study, overall rate of infection was 5.18% that compares favorably to rates of 0.4%-6.3% from similar studies. The infection rate was similar in a persistent antibiotic group versus single dose group (4.4% vs. 6.2%), which is not statistically significant, and similar to the other studies. None of the patients in all 3 groups developed any deep intra-abdominal or systemic infections. Earlier studies by Lippert et al, Uchiyama et al advocated that both laparoscopic and conventional open cholecystectomy are performed with adequate perioperative antimicrobial prophylaxis because patients receiving prophylaxis fared significantly better than those with no prophylaxis in terms of the rate of post-operative infections, other complications, reoperation and mortality.<sup>11-15</sup> However, as in present study, most of the other studies have concluded the opposite that prophylactic antibiotics neither affect the development nor the course of infectious complications following LC as the infection rate is very low.<sup>16</sup> Present study demonstrated the same with no significant complications in Group C. While some studies suggest that single dose of antibiotic prophylaxis was sufficient for clean and clean contaminated surgeries because hospital stay of the patients was reduced by using single dose antibiotic prophylaxis, our study shows that the mean duration of hospital stay in all three groups is similar and hence prophylactic antibiotics do not influence the duration of hospital stay.<sup>20</sup>

Bile leak occurs during LC due to traction, dissection and manipulation during extraction of gall bladder and is seen in 11%-30% cases.<sup>12,15</sup> Shindholimath et al concurred that positive bile culture was the most important predictor of wound infection in low-risk patients undergoing elective LC and recommended prophylactic antibiotic coverage for such cases.<sup>13</sup> Dervisoglou et al concluded that both positive bile culture and intraoperative gallbladder rupture were strongly associated with the development of SSI.<sup>14</sup> They also found in their study that SSI was caused by exactly the same pathogens found in intraoperative cultures. However, in present study, it was observed that positive bile culture and perforation of gallbladder and bile leak did not lead to increased infectious complications. None of the 30 (15.87%) cases with spillage of bile developed SSI. Other newer studies have also concluded the same that SSIs are not related to bile culture, rupture of the gallbladder, or spillage of gallbladder stones or bile. We believe thorough peritoneal toilet and suction of irritant fluid prevents the development of SSI even in spillage of bile.

Stratification of accepted independent risk factors for complications in LC, like increased age, male sex, number of ports, BMI, did not show increased complications in our study between the three groups. As in our study, others have also reported umbilicus as the commonest site for sepsis.<sup>14</sup> There was a significant

association of infectious complications with increased operative time ( $p < 0.05$ ) in present study which is similar to accepted findings by other authors.<sup>17</sup> Present study shows that risk of SSI in LC is low and does not seem to be reduced by the routine use of prolonged post-operative antibiotic prophylaxis in uncomplicated cases, still most clinicians continue to use it out of tradition, habit or medico legal reasons. There is a risk of adverse reactions to antibiotic use that may lead to significant morbidity and financial burden. In view of the above, we suggest that there is no need for antibiotic prophylaxis and despite most studies concluding no role of antibiotics in elective LC, they still recommend larger studies.<sup>15</sup>

## CONCLUSION

Routine use of prophylactic antibiotic in a clean and uncomplicated cases of laparoscopic cholecystectomy is not required. A single dose of injection ceftriaxone at the time of induction or 3 doses of injection ceftriaxone post operatively following elective LC, even in the rural/semi-urban Indian setting and routine continued administration of antibiotic should be abandoned as it neither reduces the rate of SSI but also contributes to adverse reactions, drug resistance. Avoiding unnecessary use of antibiotics reduces financial burden and hence is also cost effective for the patient. Hence a clean case of cholelithiasis does not require prophylactic antibiotic cover.

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