

Original Research Article

Role of Antibiotic Prophylaxis in Laparoscopic Cholecystectomy-A Randomized Prospective Study

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Abstract: Surgical site infection is a rare complication during laparoscopic cholecystectomy, so role of prophylactic antibiotic is questionable. This was a hospital based prospective, randomized study comparing the prophylactic use of antibiotic ceftriaxone (Group A) vs placebo (Group B) in patients undergoing laparoscopic cholecystectomy. This study was conducted in department of general surgery, S. P. Medical College, Bikaner, and Rajasthan for a total duration of more than 1 year (Nov. 2015- Feb. 2017). During this study period, 200 patients were randomly divided in two groups. Overall, 2.07 % (4/193) cases were observed to have post laparoscopic cholecystectomy wound infection. Wound infection was observed in 1.04% (1/96) cases in group A and 3.09% (3/97) cases in group B ($P > 0.05$). In group A, 39.58% (38/96) cases and in group B 45.46 % (44/97) cases had fever post-operatively ($p > 0.05$). Based on our study we concluded that for post laparoscopic cholecystectomy surgical site infection rate is very low (2.07%) and use of prophylactic antibiotics does not decreases the incidence of surgical site infection.

Keywords: Laparoscopic cholecystectomy, antibiotic prophylaxis, surgical site infection, fever, bile culture, bile spillage

INTRODUCTION

Laparoscopic cholecystectomy (LC) has been adapted by surgeons at an unprecedented rate. LC can be performed with much ease and safety because of better magnification. It has shown clear benefits in terms of shortened hospital stay, less morbidity, mortality, a quicker return to work and with cosmetic advantage. One of the several advantages offered by LC is significant reduction in surgical site infections (SSIs). So, use of antibiotic prophylaxis during LC has been questioned. Nonetheless, antibiotic prophylaxis continues to be administered routinely in elective LC.

At present, there are six meta-analyses that included a total of 20 randomized controlled trials that evaluated the role of prophylactic antibiotics for low-risk laparoscopic cholecystectomy [1-5]. All of these randomized studies and their meta-analyses showed no significant differences in the occurrence of postoperative infectious complications between the prophylactic antibiotics group and no prophylaxis group.

A recent comment has highlighted a problem with meta-analyses that reviewed randomized trials with a small sample size in that the true occurrence of postoperative infections might be underestimated [6]. Indeed, several trials included in these meta-analyses also pointed out that a larger sample size would be necessary to detect significant differences because of the rarity of complications [7-10].

Till now, our practice is to give three doses of i.v. antibiotic (first at the time of induction followed by two post-operative doses 12 hours apart) in elective laparoscopic cholecystectomy. The purpose of study is to look for infectious complications after elective LC in two groups, and whether antibiotics are useful in preventing these complications.

MATERIAL AND METHOD

This was a hospital based prospective, randomized study comparing the prophylactic use of ceftriaxone (Group A) vs placebo (Group B) in patients undergoing laparoscopic cholecystectomy. This study was conducted in department of general surgery, S. P. Medical College, Bikaner, Rajasthan for a total duration

of more than 1 year. 100 cases were taken in each group. Seven patients were excluded from study 4 in antibiotic group and 3 in non-antibiotic group due to conversion of LC to open cholecystectomy. So, the results are observed in 193 patients only.

Patients of all age groups who are having documented gall stones on ultrasonography were included in study. Patients with diabetes mellitus, immunosuppression, and acute cholecystitis or endoscopic retrograde cholangiopancreatography treated choledocholithiasis were excluded from study. Antibiotic intake in preceding week and patient requiring conversion to open cholecystectomy were also excluded.

The study protocol was approved by the local ethical committee of hospital. Elective LC was done after overnight fasting. All surgeries were done under general anesthesia (GA) by same surgical team. Patients in the Antibiotics prophylaxis group (Group A) were given a total of three 1-g doses of intravenous ceftriaxone: the first, just before skin incision, second & third at 12 h and 24 h, respectively. Patients in Group B received no antibiotics. Careful note was made of operating difficulties, bile spillage & drainage tube insertion. Postoperative course was monitored, and any incident such as fever, CBC count, infection of trocar site, or intra-abdominal collection of pus recorded. After discharge from hospital, the patients underwent weekly clinical post-operative monitoring for SSI's for 30 day period.

Statistical analysis was performed with the Microsoft excel. The categorical data were presented as numbers (percent) and were compared among groups using Chi square test. Probability P value < 0.05 was considered statistically significant.

RESULT & DISCUSSION

Both the groups were similar at baseline. No significant differences existed between the 2 groups regarding sex & age. All the procedures were performed under same surgical unit. 4 patients in Group A and 3 patients from Group B were excluded from study as LC was converted in open cholecystectomy. So, 96 cases in group A and 97 cases in group B were taken for final assessment.

The rate of post-operative wound infection in our study was 4/193 (2.07%). Wound infection was observed in 1.04% cases in prophylactic antibiotic group and 3.09% cases in non-antibiotic group (P value=0.62108). While incidence of wound infection in study by Naqvi *et al.*; [11], Uludag *et al.*; [9], and Darzi *et al.*; [12], were 8/176 (4.5%), 3/68 (4.41%) and 3/182 (1.7%) cases in antibiotic prophylaxis and 7/173 (4.0%), 2/76 (2.63%) and 5/247 (2%) in non-prophylactic antibiotic group respectively. Similar to our study they concluded that antibiotic prophylaxis does not seem to affect the incidence of SSIs and is not necessary for elective LC in low-risk patients (p-value> 0.05).

Table 1: Characteristics of patients and complications

Characteristics	Group A (N=96)	Group B (N=97)
Male/Female ratio	13/83	16/81
Mean age	39.2±13.9	41.1±14.5
Bile spillage	5 (5.21%)	7 (7.22%)
Post-operative fever (>37.22 ⁰ C)	38 (39.58%)	44 (45.36%)
SSIs	1(1.04%)	3 (3.09%)
Raised TLC (>11,000)	5(5.21%)	4 (4.12%)
Positive bile culture	26(27.08%)	21(21.65%)

In our study epigastric port site was most common site of wound infection which was contrary to results obtained in previous studies conducted by Gaur and Pujahari [13], Colizza and associates [14], and Naqvi *et al.*; [11], in which they concluded that the umbilicus is the commonest site for sepsis following laparoscopic cholecystectomy. This may be because of routine protocol of extracting the gall bladder through the umbilical port by them, which was epigastric port in

our study. From these studies it may be concluded that mechanical trauma and seeding of wound during extraction of gall bladder might be the cause of increased SSI at port site. Also it has been found that incidence of infection is further reduced if a bag is used during extraction of gall bladder.

Post-operative fever (37.22 Celsius/Harrison) was noted in 42.48% of our cases. However only 7/193

(3.62%) patients had spike over 38.5 Celsius. In antibiotic group, 38/96 (39.58%) cases and in non-antibiotic group 44/97 (45.46 %) cases had fever post-operatively. Most cases were observed to have fever within 24 hours after surgery which subsided on next day. This finding may be due to the inflammation caused by surgical trauma and probably not an infection related complication. While in study by Gaur and Pujahari they strictly monitored fever (> 38.5 Celsius) [13]. They have reported almost similar number of postoperative fever cases in both the groups.

In our study, overall 47/193 (24.35 %) cases were shown to have positive bile culture. In antibiotic group 26/96 (27.08%) and in non-antibiotic group 21/97 (21.65%) cases were having positive bile culture. Wound infection was present in 2/47 (4.25%) cases of positive bile culture and 2/146 (1.36%) cases of negative bile culture (P= 0.24). The results were comparable to study by Gaur *et al.*; [13], and Mehmet Uludag *et al.*; [9], in which they concluded that overall rate of SSI did not correlate with the presence of bacteria in the bile or gallbladder rupture.

Table 2: Organisms grown on bile culture

Organism	Group A (Total 96)	Group B (Total 97)	Total
E. coli	7	11	18
Klebsiella	5	3	8
Staphylococcus	6	8	14
Proteus	0	1	1
Pseudomonas	2	1	3
Mixed	1	2	3
TOTAL	21	26	47

CONCLUSION

Based on our study we concluded that for post LC SSI rate is very low and use of prophylactic antibiotics does not decrease the incidence of SSI. So, we strongly recommend that there is no role of prophylactic antibiotics for uncomplicated gall stone disease undergoing LC.

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