

A Prospective Clinical Study to Evaluate the Role of Prophylactic Antibiotics in Laparoscopic Cholecystectomy Patients: An Experience in Rural Setting

Somendra Pal Singh¹, Shashi Prakash Mishra², Mohit Gupta³

¹Associate Professor ³Junior Resident, Department of Surgery, UP University of Medical Sciences, Saifai, Etawah, Uttar Pradesh 206130, India. ²Associate Professor, Department of Surgery, Institute of Medical Sciences, BHU, Varanasi, Uttar Pradesh 221005, India.

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Abstract

Objectives: Three groups were compared on basis of postoperative symptoms and complications and overall duration of hospital stay to assess the role and rationale of use of antibiotics in patients undergoing Laparoscopic Cholecystectomy. **Setting:** This study was done in a rural tertiary centre of western region of Uttar Pradesh state of India. This area caters a major population of Gall stone diseases. **Participants:** 452 patients were included in the study between the age group of 18-60 yrs. Majority of patients in the study population were females (n=407; 90.04%). Female : Male ratio was 1:0.11. **Interventions:** Patients were divided into 3 groups. In Grp A- No Antibiotics were given, in Grp B- preoperative single shot antibiotics were given at the time of induction, in Grp C- antibiotics were given both pre and post operatively. **Primary and secondary outcome measures:** Surgical site infection, Pain as per VAS and postoperative symptoms were taken as primary outcome measures. **Results:** At stitch removal most common complaint in overall patients was pain abdomen (n=63; 13.94%), followed by port-site infection (n=40; 8.85% each), fever (n=40, 8.85%) and vomiting (n=17; 3.76%). Prevalence of all the above complaints was higher in Group A compared to Group B and Group C, differences were found to be statistically significant only for vomiting, fever and port-site infection for Group A from group B and C while differences were not found to be significant between Group B and C. **Conclusions:** After our study we recommend the use of single dose of pre-operative antibiotics as they are sufficient and

comparable to antibiotics given in both pre-operative and post-operative period in the low-risk elective Laparoscopic Cholecystectomy procedure. This will definitely demoralize the unjudicious use of antibiotics which have a risk of antibiotic resistance and other complications and will increase the cost effectiveness of the procedure.

Keywords: Laparoscopic Cholecystectomy; Antibiotics.

Introduction

Diseases involving the Gall bladder and biliary tract are among the commonest surgical conditions affecting the digestive tract worldwide and within this group, Biliary tract calculus disease constitutes the overwhelming majority. Autopsy reports have shown a prevalence of gallstones from 11 to 36% [1]. Cholelithiasis is one of the commonest problems encountered in Surgery [2]. In Asia, the prevalence of gallstone disease is 5-10 % of population especially among older individuals and females [2]. In Western countries, the prevalence of gall stone disease ranges from approximately 7.9 % in men and 16.6 % in women [2]. Recently there is increase in the incidence of gall stones in rural population also over the past decade, the likely causes being the changes in lifestyle, environmental factors and also easily available as well as cheap imaging facilities [3]. Among the known complications of LC, the surgical site infection (SSI) is one of the most common with its incidence reported to be 0.4 to 1.7% after LC, mostly at umbilical port site [4, 5-7]. The Southern Surgeons Club studied 1518 patients undergoing LC and found the most common complication to be the superficial wound infection at the site of the Umbilical trocar insertion [7]. They found

Corresponding Author: Mohit Gupta, Junior Resident, Department of Surgery, UP University of Medical Sciences, Saifai, Etawah, Uttar Pradesh 206130, India.
E-mail: drmohitguptams@yahoo.com

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that the offending organisms were consistent with the skin flora [7]. Regarding risk of infective complications, gallstone diseases have been classified into low and high risk group. Those falling in the high risk group have one or more of the following; diabetes mellitus, age >60 years, history of biliary colic in past 30 days, presence of jaundice, or history of acute cholecystitis or acute cholangitis [5,8-10]. As the low risk group comprises the main bulk of patients with gallstone disease, there has been a rising interest to evaluate the need of prophylactic antibiotic in this group. As per tradition, we are consistently giving antibiotic prophylaxis in each case of LC, without ever arguing the need of the antibiotics in this safe procedure. Now this protocol of giving routine antibiotic prophylaxis in low risk elective LC is being challenged by Surgeons [5-6, 8-10] around the world.

The aims and objectives of our study was to assess the role of prophylactic antibiotics on post-operative complications and the rationale and cost effectiveness of their use in Laparoscopic Cholecystectomy.

Methods and Materials

Our study was a prospective randomized case control study involving all patients who undergone Laparoscopic Cholecystectomy in the Department of Surgery, UP University of Medical Sciences, Saifai, Etawah, U.P. (India) during January 2015 to July 2016 i.e. 18 months.

Group A: NO Antibiotics pre-operative and post-operative.

Group B: Inj ceftriaxone 1gm iv stat at the time of induction of anaesthesia.

Group C: Inj ceftriaxone 1gm iv stat at the time of induction of anaesthesia followed by Inj ceftriaxone 1 gm iv Bd for 2 days.

These 3 groups were compared on basis of postoperative symptoms and complications and overall duration of hospital stay to assess the role and rationale of use of antibiotics in patients undergoing Laparoscopic Cholecystectomy. The data was further analysed statistically in IBM SPSS software ver. 15.0®. In every Case, statistical significance was accepted when p-value was less than 0.05. (Table 1).

Results and Discussion

Out of 452 patients included in the study, 150 (33.19%) who did not receive any antibiotics either before surgery or after surgery were labelled as Group A, 151 (33.41%) received antibiotics only before surgery were labelled as Group B and rest 151 (33.41%) received antibiotics before surgery and after surgery were labelled as Group C.

At day 2, most common complaint in overall patients was pain abdomen (n=242; 53.54%) followed by abdominal distension (n=22; 4.87%) and vomiting (n=15; 3.32%). No other complaint like fever or port-site infection was reported by any of the patient. Though proportion of patients with pain abdomen were higher in Group C (55.63%) and Group B (54.97%) as compared to Group A (50.00%) but this difference was not found

Table 1:

	Group A	Group B	Group C
Pre-Operative	No antibiotics	Inj ceftriaxone 1gm iv stat at the time of induction of anaesthesia	Inj ceftriaxone 1gm iv stat at the time of induction of anaesthesia
Post-Operative	No antibiotics	No antibiotics	Inj ceftriaxone 1 gm iv Bd for 2 days

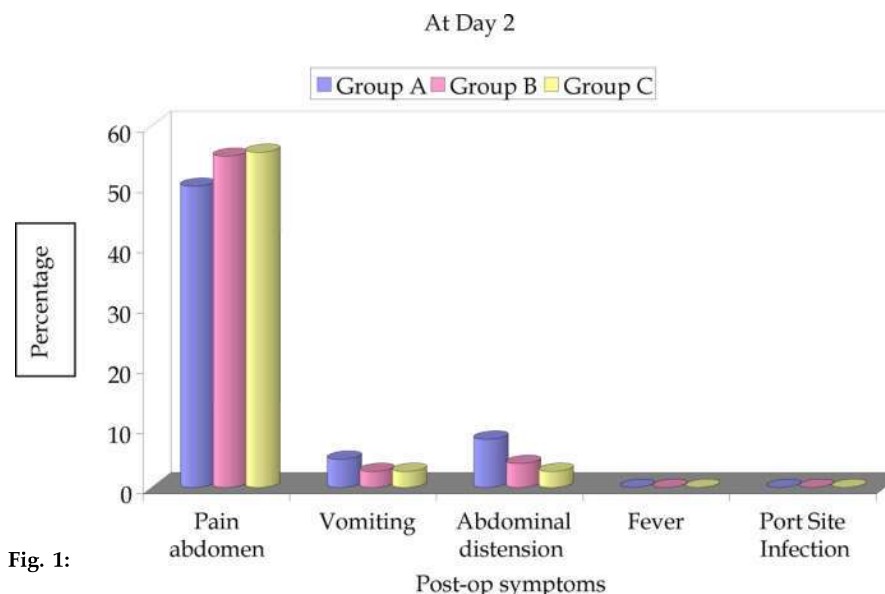


Fig. 1:

At Discharge

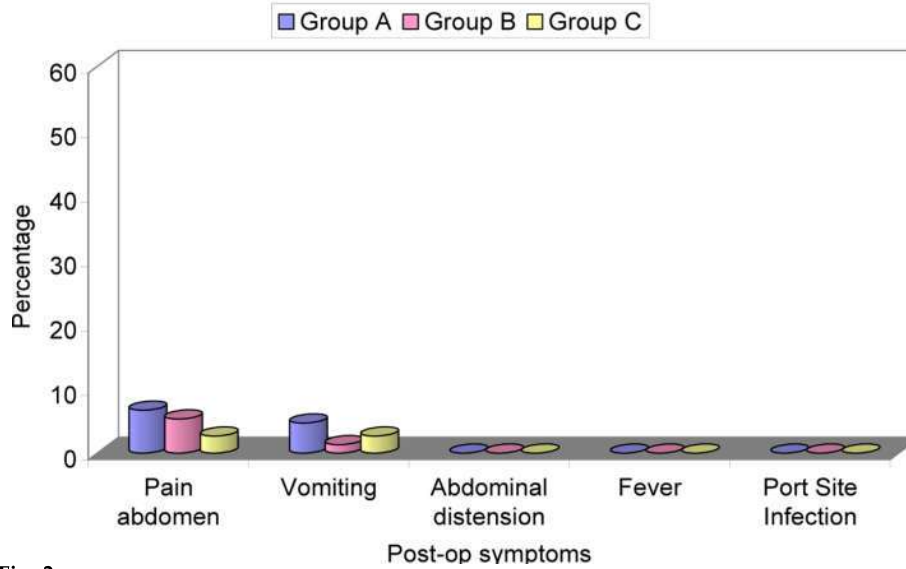


Fig. 2:

At Stitch Removal

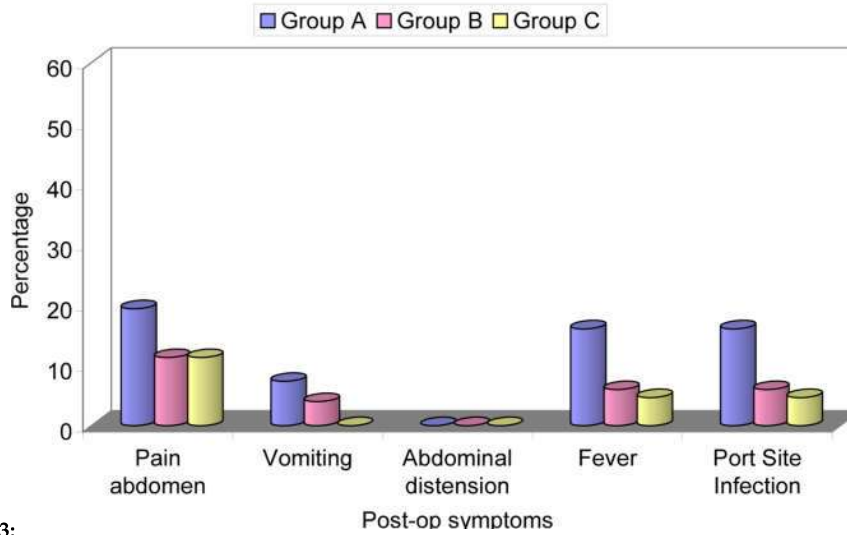


Fig. 3:

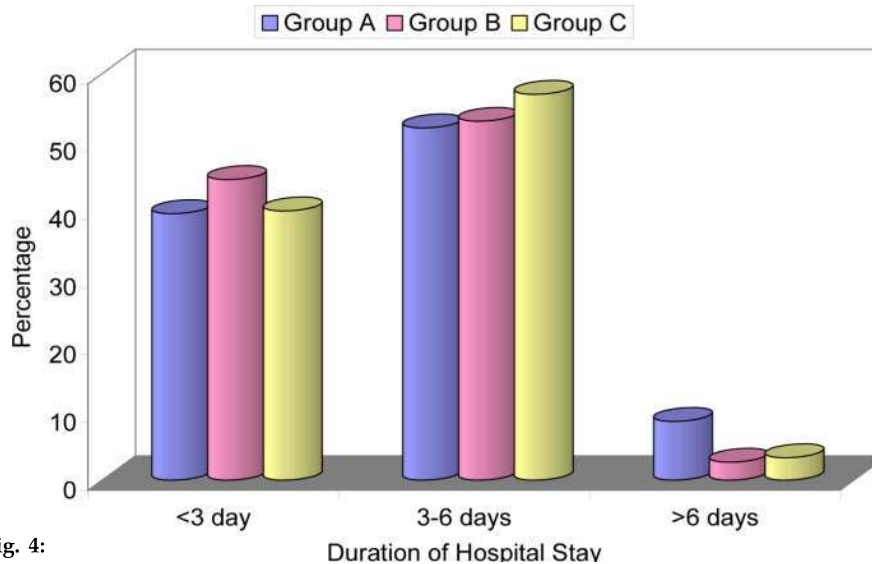


Fig. 4:

to be statistically significant ($p=0.564$). Proportion of patients with complaints of vomiting was higher in Group A (4.65%) as compared to Group B and Group C (2.65% each) but this difference was also not found to be statistically significant ($p=0.530$).

At discharge, most common complaint in overall patients was pain abdomen ($n=22$; 4.87%) and vomiting ($n=13$; 2.88%). No other complaint like abdominal distension, fever or port-site infection was reported by any of the patient. Though proportion of patients presented with pain abdomen was higher in Group A (6.67%) and Group B (5.30%) as compared to Group C (2.65%) but this difference was not found to be statistically significant ($p=0.257$) while proportion of patients with vomiting was higher in Group A (4.67%) as compared to Group B (1.32%) and Group C (2.65%) and this difference too was not found to be statistically significant.

At stitch removal most common complaint in overall patients was pain abdomen ($n=63$; 13.94%), followed by port-site infection ($n=40$; 8.85% each), fever ($n=40$, 8.85%) and vomiting ($n=17$; 3.76%). Prevalence of all the above complaints was higher in Group A compared to Group B and Group C, differences were found to be statistically significant only for vomiting, fever and port-site infection for Group A from group B and C while differences were not found to be significant between Group B and C.

Duration of hospital stay in majority of study population was 3-6 days but longer duration of hospital stay i.e. >6 days was prevalent in higher proportion of patients of Group A which do not receive Prophylactic antibiotics pre-operatively or post-operatively (Figures 1-3).

Conclusions

Our study showed difference in the occurrence of Post-operative symptoms like Pain Abdomen, Fever, Vomiting, Abdominal Distension and Port site infections between the Non Antibiotic (NA) i.e. Group A, Pre-operative Antibiotics i.e Group B and both Pre-operative and Post-operative Antibiotics i.e. Group C study groups. We observed significant association of postoperative Port site infection in Laparoscopic Cholecystectomy with the postoperative hospital stay in the overall study and thus increasing the cost of procedure, as there was statistical significance of the same between three study groups. This conclude that longer post-operative hospital stay is a result of wound infection which can be minimized by antibiotic

prophylaxis and thus reducing the overall cost of the procedure.

After our study we recommend the use of single dose of pre-operative antibiotics as they are sufficient and comparable to antibiotics given in both pre-operative and post-operative period in the low-risk elective Laparoscopic Cholecystectomy procedure. This will definitely demoralize the unjudicious use of antibiotics which have a risk of antibiotic resistance and other complications and will increase the cost effectiveness of the procedure.

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