A COMPARATIVE STUDY TO ASSESS THE ROLE OF PROPHYLACTIC ANTIBIOTICS IN ELECTIVE LAPAROSCOPIC CHOLECYSTECTOMY

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ABSTRACT

Benign biliary tract diseases are one of the most common surgical problems in the world. Cholelithiasis is rare in the first two decades of life. Incidence gradually increases after 21 years and reaches peak in 5th and 6th decade women are more commonly affected than men in the ratio of 4:1.¹ The advent of laparoscopic surgery ushered in a new era in general surgery in the management of symptomatic gall stones. Open cholecystectomy is associated with a higher wound infection rate ranging from 1-21%. The use of prophylactic antibiotics reduced this rate to 3%-7% and so has become common practice. Laparoscopic cholecystectomy is associated with smaller wounds and minimal tissue damage and therefore presumably a lower risk of wound infection.

METHODOLOGY

A prospective randomized control study involving a sample size of 52 patients (26 in the study group + 26 in the control group) was conducted over a period of 2 years. Chi square test of significance was used to test the difference in the proportion between the groups. To test whether there is significant difference in the means of 2 groups; Independent t-test/Mann Whitney test will be used. Statistical analysis was done using IBM SPSS 20 statistical software.

RESULTS

The mean age in the study group was 43 years and the mean age in the control group was 44.42. Samples are age matched with P=0.421, Student 't' test. Incidence of Gallbladder disease was more in females in both the study group and the control group. Samples are gender matched with P=0.768. No SSI noted in the control group. 1 patient [3.8%] had SSI in the study group=1.000, Not significant, Fisher Exact test. E. coli was the organism isolated in the patient with SSI.P=1.000, Not significant, Fisher Exact test. Incidence of bile spillage was 7.7% in both the control group and the study group=1.000, Not significant, Fisher Exact test.

DISCUSSION

The use of prophylactic antibiotics in open cholecystectomy to reduce the rate of postoperative infective complications is considered to be the standard of practice. However, its use in laparoscopic cholecystectomy has been an area of conflicting opinion.

CONCLUSION

In conclusion, the results of this study have shown that avoiding prophylactic antibiotics in patients undergoing elective laparoscopic cholecystectomy increases the incidence of postoperative infective complication but not to a statistically significant degree.

KEYWORDS

Cholecystectomy, Antibiotic Prophylaxis.

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INTRODUCTION

Benign biliary tract diseases are one of the most common surgical problems in the world. Gallstones especially affect millions of people worldwide. Cholelithiasis is rare in the first two decades of life. Incidence gradually increases after 21 years and reaches peak in 5th and 6th decade women are more commonly affected than men in the ratio of 4:1.¹

Female sex, obesity, pregnancy, fatty foods, Crohn's disease, terminal ileal resection, gastric surgery, hereditary spherocytosis, sickle cell disease and thalassemia are associated with an increased risk for developing gall stones. Classic presenting symptoms of the majority of patients include stabbing (Colicky) pain in the right upper quadrant radiating to the back and to the shoulder. Frequently the pain is associated with nausea and vomiting, but is rarely accompanied by jaundice, fever or chills, unless acute cholecystitis.¹ or cholangitis is present. Once symptomatic, patients tend to have recurring symptoms, usually repeated episodes of biliary colic.

Ultrasound of the abdomen is an extremely useful and accurate method for identifying gallstones and pathologic changes in the gallbladder consistent with acute cholecystitis. Ultrasound of abdomen has a high specificity of >98% and sensitivity of >95% in diagnosing cholelithiasis. In addition to identifying gallstones, ultrasound can also detail signs of cholecystitis such as thickening of the gallbladder wall, pericholecystic fluid and impacted stone in the neck of the gallbladder.² Dilatation of the extra hepatic (>10mm) or

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intrahepatic (>4mm) bile ducts suggests biliary obstruction. Surgery plays an important part in the treatment and over half a million cholecystectomies are performed worldwide. During the last 100 years, open cholecystectomy has remained the gold standard for the definitive management of patients with gallstones. The advent of laparoscopic surgery ushered in a new era in general surgery.

One of the main benefits of minimally invasive surgery is the reduced rates of surgical site infection. The advantages of laparoscopic cholecystectomy over open cholecystectomy were earlier return of bowel functions, less postoperative pain, better cosmesis, shorter length of hospital stay, earlier return to full activity and decreased overall cost. Laparoscopic cholecystectomy is now considered the first option and has become the "gold standard" in treating benign gallbladder disease.

The risk of intraoperative injury during laparoscopic cholecystectomy is higher than in open cholecystectomy. It has been anticipated that this will diminish with increasing surgeon experience in the use of laparoscopic procedures. Although both open cholecystectomy and laparoscopic cholecystectomy are well tolerated wound infection remains the most common complication which not only increases the duration of hospital stay, cost of treatment, complications like septicaemia and lastly incisional hernia. Laparoscopic cholecystectomy has the potential to decrease the frequency of infections and also modify their characteristics. The basis of these claims were studies that compared historical controls with patients who underwent laparoscopic cholecystectomies, but these studies were unsatisfactory as they did not take into account advances in improvements in intraoperative and perioperative care of patients.

In the first published study by Barkun et al. they compared mini cholecystectomy with laparoscopic cholecystectomy and showed that patients who underwent laparoscopic cholecystectomy had significantly shorter convalescence and return to normal activities. In the second published study by McMahon et al. they compared open cholecystectomy with laparoscopic cholecystectomy and showed that patients who underwent laparoscopic cholecystectomy had significantly shorter convalescence and return to normal activities.³

Open cholecystectomy was associated with a wound infection rate ranging from 1%-21%. The use of prophylactic antibiotics reduced this rate to 3%-7% and so has become common practice. Laparoscopic cholecystectomy is associated with smaller wounds and minimal tissue damage and therefore presumably a lower risk of wound infection. Post-operative infection and the need for antibiotic prophylaxis are well documented in open biliary surgery. The use of antibiotic prophylaxis, however, for laparoscopic procedures is unfounded.⁴

AIM OF THE STUDY

- To assess surgical site infection in patients undergoing elective laparoscopic cholecystectomy.
- To compare surgical site infection between the two groups.

METHODOLOGY

Study Design

Prospective randomized control study.

Size of the Study Population

Fifty two (26 in the study group + 26 in the control group). Based on a study conducted by Mehmet Uludag et al. on the role of prophylactic antibiotic in elective laparoscopic cholecystectomy, it was observed that mean and standard deviation of length of hospital stay, among the control group

was 1.17+/- 0.324 and among the treated group it was found to be 1.5118+/- 0.325 with an alpha error of 5%. Keeping the power of study as 80%, sample size was estimated to be 26 in each arm. The duration of the study was 2 years. Chi square test of significance was used to test the difference in the proportion between the groups. To test whether there is significant difference in the means of 2 groups; independent t-test/Mann Whitney test will be used. Statistical analysis was done using IBM SPSS 20 statistical software.

Inclusion Criteria

- Diagnosed case of symptomatic cholelithiasis.
- Patients younger than 60 years.

Exclusion Criteria

- Antibiotic intake in the 7 days prior to surgery.
- Acute cholecystitis in the 6 months prior to surgery.
- Evidence of cholangitis and/or obstructive jaundice and biliary pancreatitis.
- Evidence of diabetes mellitus.
- ASA higher than score 2.
- Conversion to open cholecystectomy.

Patients undergoing elective laparoscopic cholecystectomy were selected as suitable for the study protocol. Informed written consent was taken from all the patients participating in the study. Patients were randomly divided into the study group and the control group; 2nd and 3rd generation cephalosporin was administered intravenously during induction of anaesthesia for the patients in the study group. No antibiotic was administered to the control group of patients.

After induction of anaesthesia, skin was disinfected with povidone iodine. Laparoscopic cholecystectomy was performed in all patients. The postoperative course was monitored for and any incidents such as fever, infection of the trocar site or intraabdominal collection of pus, superficial or deep incisional soft tissue surgical site infection. If local signs of inflammation or a pus collection present, bacteriological swabs were taken from the wound site to confirm surgical site infections.

RESULTS

Age in Years	Study Group		Control Group	
	No	%	No	%
31-40	9	34.6	8	30.8
41-50	14	53.8	12	46.2
51-60	3	11.5	6	23.1
Total	26	100.0	26	100.0
Mean ± SD	43.00±5.36		44.42±7.15	

Table 1: Age distribution of patients studied

The mean age in the study group was 43 years and the mean age in the control group was 44.42. Samples are age matched with P=0.421, Student 't' test.

Graph 1: Age distribution of patients studied

Gender	Study Group		Control Group	
	No	%	No	%
Female	18	69.2	17	65.4
Male	8	30.8	9	34.6
Total	26	100.0	26	100.0

Table 2: Gender distribution of patients studied

Incidence of gallbladder disease was more in females in both the study group and the control group. Samples are gender matched with $P=0.768$.

Graph 2: Gender distribution of patients studied

Antibiotic Prophylaxis	Study Group		Control Group	
	No	%	No	%
No	26	100.0	0	0.0
Yes	0	0.0	26	100.0
Total	26	100.0	26	100.0

Table 3: Antibiotic prophylaxis in two groups of patients studied

Antibiotic prophylaxis [Injection Cefazolin 1g, IV] was given to all the patients in the control group. No antibiotic prophylaxis were given to the patients in study group.

Graph 3: Antibiotic prophylaxis in two groups of patients studied

SSI	Study Group		Control Group	
	No	%	No	%
No	25	96.2	26	100.0
Yes	1	3.8	0	0.0
Total	26	100.0	26	100.0

Table 4: SSI in two groups of patients studied

No SSI noted in the control group. One patient [3.8%] had SSI in the study group=1.000, Not significant, Fisher Exact test.

Graph 4: SSI in two groups of patients studied

Organism	Study Group		Control Group	
	No	%	No	%
Nil	25	96.2	26	100.0
E.coli	1	3.8	0	0.0
Total	26	100.0	26	100.0

Table 5: Organism isolated in two groups of patients studied

E.coli was the organism isolated in the patient with SSI. P=1.000, Not significant, Fisher Exact test.

Graph 5: Organism isolated in two groups of patients studied

Bile Spillage	Study Group		Control Group	
	No	%	No	%
No	24	92.3	24	92.3
Yes	2	7.7	2	7.7
Total	26	100.0	26	100.0

Table 6: Bile Spillage in two groups of patients studied

Incidence of bile spillage was 7.7% in both the control group and the study group=1.000, Not significant, Fisher Exact test.

Graph 6: Bile Spillage in two groups of patients studied

DISCUSSION

The use of prophylactic antibiotics in open cholecystectomy to reduce the rate of postoperative infective complications is considered to be the standard of practice. However, its use in laparoscopic cholecystectomy has been evaluated by many studies with controversial results. Several studies have recommended the use of prophylactic antibiotics stating that it significantly reduces the incidence of postoperative infective complications. On the contrary, several prospective studies have concluded that the use of prophylactic antibiotics in low-risk patients undergoing laparoscopic cholecystectomy is unnecessary, because the rate of postoperative infective complications is already low in such patients and therefore the use of prophylactic antibiotics will not reduce the rate of postoperative infective complications significantly.

It has been reported in the literature that the average rate of SSI after Laparoscopic Cholecystectomy to be 0.4%–6.3%, although a higher rate of SSI has been reported after open cholecystectomy.⁵ In this study, the overall postoperative infective complications was 1.9% (3.8% in study group and 0.0% in control group) with no significant statistical difference between the two groups. All infective complications were superficial wound infection and all were treated with pus drainage, wound care and antibiotics. No deep incisional, deep seated or distant infections were reported in this study.

The role of positive bile culture, bile and stones spillage due to intraoperative gallbladder perforation with bile spillage on the occurrence of SSI is still controversial. Intraoperative gallbladder perforation with bile spillage has been reported to occur in 11% to 20% laparoscopic cholecystectomies.⁶ In this study bile spillage due to gallbladder perforation occurred in 7.6% (n=4) of patients. Several studies have stated that intraoperative bile spillage was strongly associated with occurrence of surgical site infections.^{7,8} However, many other studies did not observe this association, concluding that intraoperative gallbladder perforation with bile spillage does not increase the rate of surgical site infections.⁹ In our study as well, no such association was observed.

CONCLUSION

In conclusion, the results of this study have shown that avoiding prophylactic antibiotics in patients undergoing elective laparoscopic cholecystectomy increases the incidence of postoperative infective complication, but not to a statistically significant degree.

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