

Role of Antibiotic Prophylaxis in Laparoscopic Cholecystectomy: A Randomized Prospective Study.

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Abstract: There is ambiguity about the use of antibiotic prophylaxis in laparoscopic cholecystectomy. The present study was undertaken to evaluate the rate of infection in laparoscopic cholecystectomies, and to assess the usefulness and efficacy of antibiotic prophylaxis in laparoscopic cholecystectomy. A total of 240 patients were included, they were randomized in two groups. Group A received an intravenous dose of Ceftriaxone + Sulbactam 1.5g, at induction of anesthesia. Group B received an intravenous dose of Ceftriaxone + Sulbactam 1.5g twice daily for upto 3 days post-operatively. Group B were not given any dose at induction. Results were compared and Data analysed using the Chi-square test. Complications in both the groups were compared. Rate of superficial infection was 0.83% (n = 1) and 0% (n = 0) respectively in group A and B. On statistical analysis these differences were not significant. Rate of deep infection and seroma formation were 0% (n = 0) in both the groups. **Conclusion:** This study document that one single dose of prophylactic antibiotic, administered at induction of anesthesia, is sufficient to prevent post-operative infective complications in patients undergoing elective laparoscopic cholecystectomy. **Keywords:** Laparoscopic cholecystectomy. Prophylactic antibiotics. Wound infection

INTRODUCTION

Antibiotic prophylaxis can prevent infection in contaminated wounds but are clearly not indicated for most patients undergoing straightforward clean surgical operations in which no obvious bacterial contamination or insertion of a foreign body has occurred.¹

The infective complications of open cholecystectomy are well known, and prophylactic antibiotics are a routine practice. However, the wounds created after open cholecystectomy behave differently as compared to laparoscopic cholecystectomy. First, the wounds created are smaller as compared to the open surgery. Secondly, it has been proved that the immune system is better preserved in laparoscopic surgery since the tissue trauma is less.² These results in lesser activation of the inflammatory response following the laparoscopic procedure.² Furthermore, laparoscopic cholecystectomy per se does not violate the mucosal defense barrier of the respiratory, gastro-intestinal or genital epithelium.

Observing the low incidence of infections following laparoscopic cholecystectomy, the need for antibiotics is now frequently questioned. The over-use of antibiotics can result in a rising frequency of adverse effects, emergence of drug resistant organisms, as well as increased cost.^{3,4} It is not clear whether antibiotic prophylaxis in laparoscopic cholecystectomy is of any advantage to the patient in terms of preventing infection. Thus, the present study was undertaken to evaluate the rate of infection in laparoscopic cholecystectomies, and to assess the usefulness and efficacy of antibiotic prophylaxis in laparoscopic cholecystectomy.

MATERIALS AND METHODS

240 consecutive patients suffering from symptomatic gall stones with documented gall stones on ultrasonography and undergoing laparoscopic cholecystectomy were included in the study conducted between 2007 to 2009.

Exclusion criteria: Patients with acute cholecystitis, Antibiotic intake in the last 48 hours prior to surgery, Regular corticosteroid therapy, ERCP treated choledocholithiasis, Patients with cardiac prosthesis, Conversion to open cholecystectomy, Intra-operative gall bladder rupture.

After taking a written informed consent, detailed history and clinical examination, all patients were subjected to routine investigations, Liver function tests and abdominal ultrasonography.

Patients were randomized to one of two groups of equal size (120). Group A received an intravenous dose of Ceftriaxone + Sulbactam 1.5g, at induction of anesthesia. Group B received an intravenous dose of Ceftriaxone + Sulbactam 1.5g twice daily for upto 3 days post-operatively. Group B were not given any dose at induction. The abdominal skin was

prepared with povidone-iodine.

All patients were followed-up daily till discharged, then after 2 weeks and then after 4 weeks following surgery to evaluate the status of the surgical wound, and to look for signs and symptoms suggestive of any deep-seated infection. In the event of any post-operative wound infection, microbiological investigations were performed by taking wound swab for aerobic and anaerobic culture and antibiotic sensitivity.

RESULTS AND ANALYSIS

All the patients were examined and investigated prior to their surgery, and the information needed was recorded. Patients were randomized to one of two groups of equal size (30). 42 patients (70%) were between 30 to 59 years of age. The mean age in our study was 44 years. The majority of patients in our study (50 patients or 83.3 %) were females. Male to female ratio in our study was 1:5. 60 % of patients in our study presented with only pain abdomen and 40 % presented with pain abdomen and vomiting.

Table 1: Wound complications in the two groups

Wound complications	Groups			
	A		B	
	n (total = 120)	%	n (total = 120)	%
Superficial infection	1	0.83%	0	0
Deep infection	0	0	0	0
Seroma formation	0	0	0	0
Other complications	0	0	0	0
Total	1	0.83%	0	0

According to table 1, only 1 patient (0.83%) of group A developed superficial infection at the umbilical port site. This is due to the standard protocol followed by our unit of extracting the gall bladder through the umbilical port. Zero patients of group B developed superficial infection. No patient of either group developed deep infection, seroma formation or other complications.

Table 2: Intervention in wound complications

Intervention in wound complications	Groups			
	A		B	
	n (total = 120)	%	n (total = 120)	%
Wound laid open	1	0.83%%	0	0
Swab taken	1	0.83%%	0	0
Secondary suturing done	1	0.83%%	0	0

According to table 2, 1 patient (0.83%) of group A had her wound laid open, and swab for culture and sensitivity taken and did not reveal any growth of micro-organisms. The same patient underwent daily dressings, and secondary suturing was performed on the 3rd post-operative day.

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Table 3: Distribution of Patients according to associated Co-morbidities in both the groups

Co-morbidity	No. of patients in group A (A)	%	No. of patients in group B (B)	%
Diabetes mellitus	8	6.7	8	6.7
Hypertension	4	3.3	8	6.7
Diabetes mellitus + Hypertension	4	3.3	4	3.3
No co-morbidity	104	86.7	100	83.3

Table 3 indicates the associated co-morbidities in both. In our study, 8 patients each in group A and group B were diabetic, and none of them developed post-operative wound infection. When analyzed statistically, no significant association between the presence of diabetes and wound infection could be obtained.

DISCUSSION

It is well documented that prophylactic antibiotic coverage of most 'clean-contaminated' surgical procedures can significantly prevent infectious complications, including wound infection, thereby affecting the overall rates of morbidity and mortality. However, the benefit of antibiotic prophylaxis in other 'clean' surgical procedures, such as laparoscopic cholecystectomy, has been considered questionable.⁵ The low rate of wound infections and the straight-forward treatment, if they occur at all, are the main arguments against routine antibiotic coverage during laparoscopic cholecystectomy. Laparoscopic cholecystectomy is an elective clean operation, and the post-operative wound infection rate would be very low.⁵ Prophylaxis in clean operations has been shown to be of value in other areas of surgery such as trauma⁶ and vascular surgery^{7,8} but in laparoscopic cholecystectomy, its benefits remain uncertain.⁵ Due to the unknown impact on bacterial resistance, Waldvogel and associates suggested that the routine use of antibiotic prophylaxis should be discouraged.⁹

The aim of our study was to assess the role of prophylactic antibiotics in preventing post-operative complications in laparoscopic cholecystectomy. The mean age in our study was 44 years. The percentage of females in our study was 83.3 %. Symptomatic cholelithiasis most commonly presents in the 5th decade of life, with a significant female preponderance. Pain abdomen was the commonest presenting symptom. In the present study, 16 patients (6.7 %) were diabetic, 12 patients (5 %) were hypertensive and 8 patients (3.3 %) were both diabetic and hypertensive. There are several risk factors that are significantly associated with an increased incidence of infective complications in patients who undergo elective laparoscopic cholecystectomy, one of them is the presence of diabetes mellitus.¹⁰

In our study, 119 out of 120 patients in group A had completely healed wounds post-operatively. 1 patient (0.83%) had wound infection. In group B, all 120 patients (100 %) had completely healed wounds. However, this difference yielded a Yates corrected two tailed P-value of 0.3132, which is statistically insignificant, thereby illustrating that the rates of wound infection in patients given only a single shot of prophylactic antibiotic, and in patients given post-operative antibiotics is statistically insignificant.

In a randomized controlled trial on 417 patients undergoing laparoscopic cholecystectomy, conducted by Gaur and Pujahari¹¹, they reported an overall infection rate of 2.2 %, which is consistent with the results obtained in our study. All the infections healed before the availability of culture and sensitivity report without any specific therapy.

Our findings are also similar to the findings obtained by Pokharel and associates¹², who stated that the use of prophylactic antibiotics is a factor for lower incidence of post-operative infection following laparoscopic cholecystectomy. Good surgical techniques and the judicious use of prophylactic antibiotics are two major factors for decreasing the incidence of septic complications after biliary tract surgery.¹²

In another study conducted by Mahmoud and associates¹³ to assess the role of antibiotic prophylaxis in elective laparoscopic cholecystectomy,

they stated that antibiotic prophylaxis does not prevent wound infection in elective laparoscopic cholecystectomy. This is probably due to the fact that Mahmoud and associates excluded all patients with associated co-morbidities, like diabetes mellitus, hypertension etc. from their study. They also concluded that the use of antibiotic prophylaxis is preferred to be restricted to high-risk patients such as patients with associated co-morbidities like diabetes mellitus.

The rate of post-operative wound infection in our study was low (0.41%) and there was no significant difference between wound infection in patients receiving prophylactic antibiotics and post-operative antibiotics. This can be attributed to the following reasons:

- Good surgical technique
- Better handling of tissues
- Strict adherence to aseptic precautions
- Experienced laparoscopic surgeons

Wound complications and its management - In our study, 1 patient in group A developed superficial wound infection at the umbilical port site. The wound was laid open, and a swab was taken for culture and antibiotic sensitivity. However, the swab revealed no growth of any micro-organisms after 48 hours of culture. Daily dressings were done, and secondary suturing was performed once the wound was clean on the 3rd post-operative day.

In a study conducted by Gaur and Pujahari¹¹, they concluded that the umbilicus is the commonest site for sepsis following laparoscopic cholecystectomy. This may be because the deep umbilical depression is sometimes difficult to clean. Also, it may be due to the routine protocol of our unit to extract the gall bladder through the umbilical port. Colizza and associates¹⁴ also stated that the umbilicus is the commonest site for sepsis in elective laparoscopic cholecystectomy.

In a study conducted by Koc and associates¹⁰, it was stated that the presence of diabetes mellitus is a risk factor for the development of post-operative infective complications in patients undergoing elective laparoscopic cholecystectomy. The presence of diabetes mellitus is a known risk factor for biliary sepsis. The altered motility of the common bile duct muscles, which is secondary to autonomic neuropathy observed in diabetic patients, as well as increased lipid concentration in bile, are the elements that can cause an increased susceptibility to biliary sepsis in patients with diabetes.

In our study, 8 patients each in group A and group B were diabetic, and none of them developed post-operative wound infection. When analyzed statistically, no significant association between the presence of diabetes and wound infection could be obtained. Thus, we could not find out significant association between diabetes mellitus and post-operative infection in our study.

SUMMARY

240 consecutive patients suffering from symptomatic gall stones with documented gall stones on ultrasonography and undergoing laparoscopic cholecystectomy were included in the study. Patients were followed up 1,2,3 and 4 weeks post-operatively for the development of septic complications.

1. Maximum incidence of cholelithiasis was found in the 5th decade of life. Majority of our patients (83.3 %) were females; male to female ratio was 1:5.
2. Pain abdomen was the commonest presentation, with 60 % of our patients presenting with only pain abdomen.
3. 15 % of our patients had one or more co-morbidities (Diabetes mellitus, hypertension).
4. In group A, only 1 patient had duration of hospitalization of > 1 week, while in group B, no patient had duration of hospitalization of > 1 week.
5. One patient in group A (receiving only prophylactic antibiotics) developed superficial wound infection, which was treated by laying the wound open, taking a swab for culture and antibiotic sensitivity, daily dressings and secondary suturing.

- The overall incidence of post-operative wound infection in our study was 0.41%. It was 0.83% in the patients who received only prophylactic antibiotics, and 0 % in the patients who received post-operative antibiotics.
- There was no statistical difference in the incidence of post-operative infection (p = 0.3132) in patients with or without post-operative antibiotics..
- There was no association between any of the co-morbidities and wound complications in the 2 groups.

CONCLUSION

Based on the findings of our study, it may be concluded that post-operative antibiotics do not reduce post-operative infective complications after elective laparoscopic cholecystectomy for cholelithiasis. One single dose of prophylactic antibiotic, administered at induction of anesthesia, is sufficient to prevent post-operative infective complications in patients undergoing elective laparoscopic cholecystectomy.

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