

A Prospective Study on Role of Antibiotic Prophylaxis in Laparoscopic Cholecystectomy in South India: A Tertiary Care Centre Experience

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ABSTRACT

Introduction: In the medical literature for the first time is widespread and described in March 1987 by Mouret in Lyon, France, and later improved by Dubois. Nowadays Laparoscopic cholecystectomy (LC) is the "gold standard" surgical procedure for cholecystectomy. Clinicians do not give up the traditional practice easily despite the fact that recent meta-analysis and reviews have concluded that a prophylactic antibiotics for elective LCs in low-risk patients is not useful, but there were no results in high-risk patients. The role of prophylactic antibiotic in various clean or clean contaminated surgery reduce the risk of postoperative infective complication thereby reducing morbidity and mortality.

Materials and Methods: This prospective study was conducted in a tertiary Care Hospital of SRMC and Research Centre in Thiruvananthapuram, South India; on 200 patients suffering from symptomatic gall stones with documented gall stones on ultrasonography and undergoing laparoscopic cholecystectomy. All the patients were distributed into two different equal size Groups (100). At induction of anesthesia, Group A received an intravenous dose of Ceftriaxone + Sulbactam 1.5g. At induction of anesthesia Group B were not given any dose. Group B received an intravenous dose of Ceftriaxone + Sulbactam 1.5g twice daily for upto 3 days post-operatively. The abdominal skin was prepared with povidone iodine.

Results: A total 200 patients suffering from symptomatic gall stones with documented gall stones on ultrasonography and undergoing laparoscopic cholecystectomy were included. Patients were categorized randomly in two groups of equal size with a total of 100 patients in each group. Among 200 patients the majority were females with 65% of the total number which counted to 130; and the rest 35% were males with a total

number of 70. 64% of the total patients aged between 28-60 years which gives the mean age of 44 in our study. 132 (66%) of the patients were admitted with the issue of only abdominal pain whereas the rest 68 (34%) were having both pain in abdomen and vomiting.

Conclusion: Our study concludes that the gold standard in the management of symptomatic cholelithiasis is laparoscopic cholecystectomy. To prevent postoperative infection related complications in low-risk patients with symptomatic gallstone disease undergoing elective laparoscopic cholecystectomy one single dose of prophylactic antibiotic injected at induction of anaesthesia antibiotic prophylaxis is sufficient. Post-operative infective complications after elective laparoscopic cholecystectomy for cholelithiasis do not reduced by post-operative antibiotics.


Keywords: Laparoscopic Cholecystectomy, High-Risk, Prophylactic Antibiotic.

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INTRODUCTION

In the medical literature for the first time is widespread and described in March 1987 by Mouret¹ in Lyon, France, and later improved by Dubois.² Nowadays Laparoscopic cholecystectomy (LC) is the "gold standard" surgical procedure for cholecystectomy.^{3,4} Surgical site infection (SSI), length of hospital

stay, healthcare costs, and postoperative pain are reduced by development of minimally invasive laparoscopic cholecystectomy. Electively it has very low risk for infectious complications, having average infection rate between 0.4-1.1%^{3,5-10} and when compared to laparotomy has a lower incidence of infectious

complications^{4,9,10}; however, many surgeons still use it routinely.¹¹⁻¹⁴ The role of prophylactic antibiotic in various clean or clean contaminated surgery reduce the risk of postoperative infective complication thereby reducing morbidity and mortality.

Regarding the use of antibiotic prophylaxis (AP) in LC, despite the controversies, there is a growing consensus in support of not using AP in uncomplicated cases.¹⁵⁻¹⁸ However, clinicians do not give up the traditional practice easily despite the fact that recent meta-analysis and reviews have concluded that a prophylactic antibiotics for elective LCs in low-risk patients is not useful, but there were no results in high-risk patients.¹⁹ Moreover, controversy still exists regarding the effectiveness of antibiotic prophylaxis for elective laparoscopic cholecystectomy.

Because of its broad-spectrum antimicrobial effect, low toxicity, and low cost, the single-dose use of cefazolin and cephalothin has been recommended for patients undergoing open cholecystectomy and other biliary surgery,^{20,21} and it was recommended by the United States Centers for Disease Control and Prevention as the general principle for prevention of postoperative surgical site infection (SSI) in open cholecystectomy.^{22,23}

The more adverse effects results by over-use of antibiotics, in terms of emergence drug resistant organisms, as well as cost increased in treatment.²⁴ It is not clear whether postoperative use of antibiotic prophylaxis in laparoscopic cholecystectomy is of any advantage to the patient in terms of preventing infection.

MATERIALS AND METHODS

This prospective study was conducted in a tertiary Care Hospital of SRMC and Research Centre in Thiruvananthapuram, South India; on 200 patients suffering from symptomatic gall stones with documented gall stones on ultrasonography and undergoing laparoscopic cholecystectomy. Ethical committee of institution approved the study and from all the patients' informed written consent were taken. Out of 200 patients 130 (65%) were females and 70 (35%) were males. Acute cholecystitis, intake of antibiotics

in last 48 hours prior to surgery, corticosteroid therapy, choledocholithiasis treated by ERCP, cardiac prosthesis patients, Conversion to open cholecystectomy, gall bladder rupture by intra-operation were excluded from the present study.

All the patients' detailed history and clinical examination were done and subjected to regular routine investigations, Liver Function Test (LFT) and abdominal ultrasonography (USG). All the patients were distributed into two different equal size Groups (100). At induction of anesthesia, Group A received an intravenous dose of Ceftriaxone + Sulbactam 1.5g. At induction of anesthesia Group B were not given any dose. Group B received an intravenous dose of Ceftriaxone + Sulbactam 1.5g twice daily for upto 3 days post-operatively. 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

The subjects were examined and inspected before the surgery, and their informed consent was recorded in written as per the requirement of our study. A total 200 patients suffering from symptomatic gall stones with documented gall stones on ultrasonography and undergoing laparoscopic cholecystectomy were included. Patients were categorized randomly in two groups of equal size with a total of 100 patients in each group. Among 200 patients the majority were females with 65% of the total number which counted to 130; and the rest 35% were males with a total number of 70. 64% of the total patients aged between 28-60 years which gives the mean age of 44 in our study. 132 (66%) of the patients were admitted with the issue of only abdominal pain whereas the rest 68 (34%) were having both pain in abdomen and vomiting.

Fig 1: Distribution of patients by gender

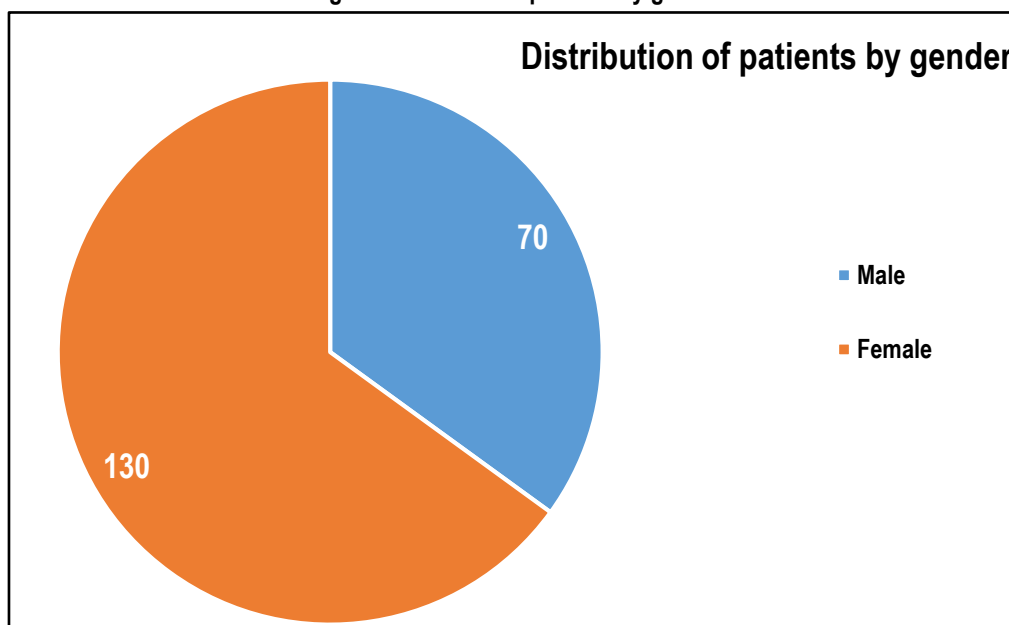


Table 1: Wound complications in the two groups

Wound complications	Groups			
	A		B	
	n=100	Percentage (%)	n=100	Percentage (%)
Superficial infection	1	1	0	0
Deep infection	1	1	0	0
Seroma formation	0	0	0	0
Other complications	0	0	0	0
Total	2	2	0	0

Table 2: Intervention in wound complications

Intervention in wound complications	Groups			
	A		B	
	n=100	Percentage (%)	n=100	Percentage (%)
Wound laid open	1	1	0	0
Swab taken	1	1	0	0
Secondary suturing done	1	1	0	0

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

Co-morbidity	Group A		Group B	
	No. of patients	% patients	No. of patients	% patients
Diabetes mellitus	10	10	10	10
Hypertension	5	5	7	7
Diabetes mellitus+ Hypertension	5	5	5	5
No co-morbidity	80	80	78	78

Fig 2: Distribution of Patients according to associated Co-morbidities in both the groups

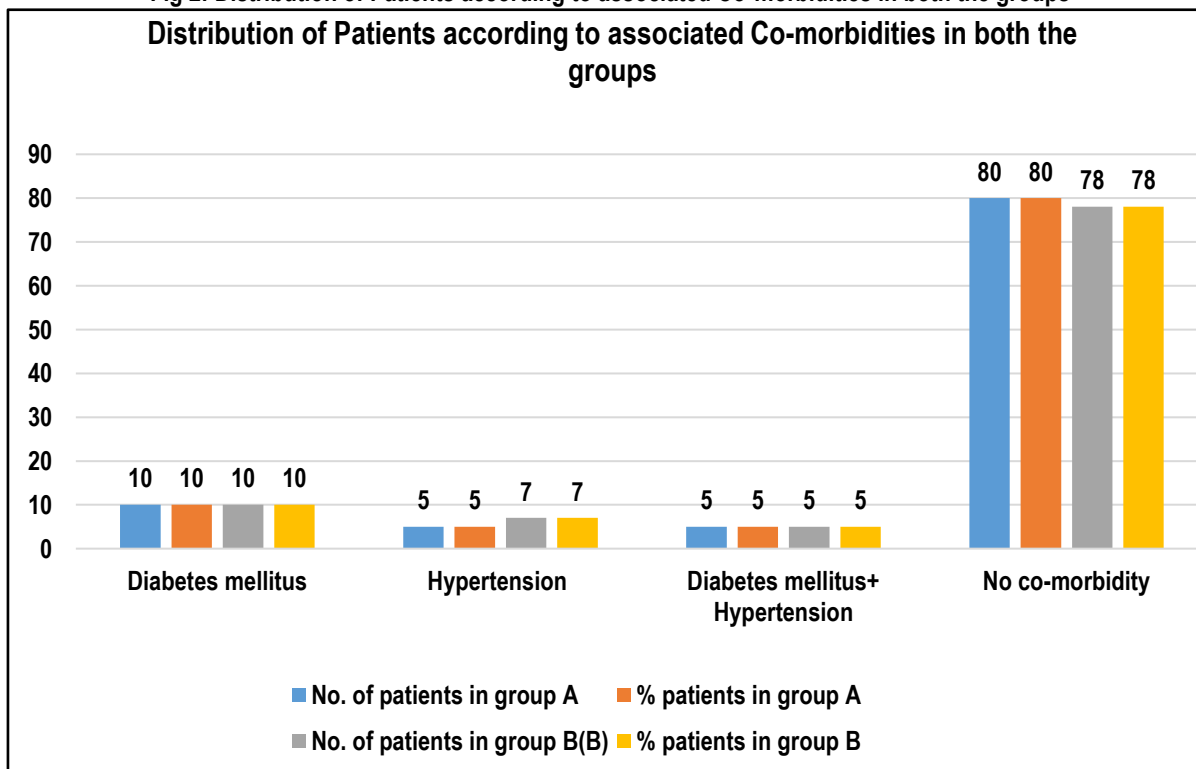
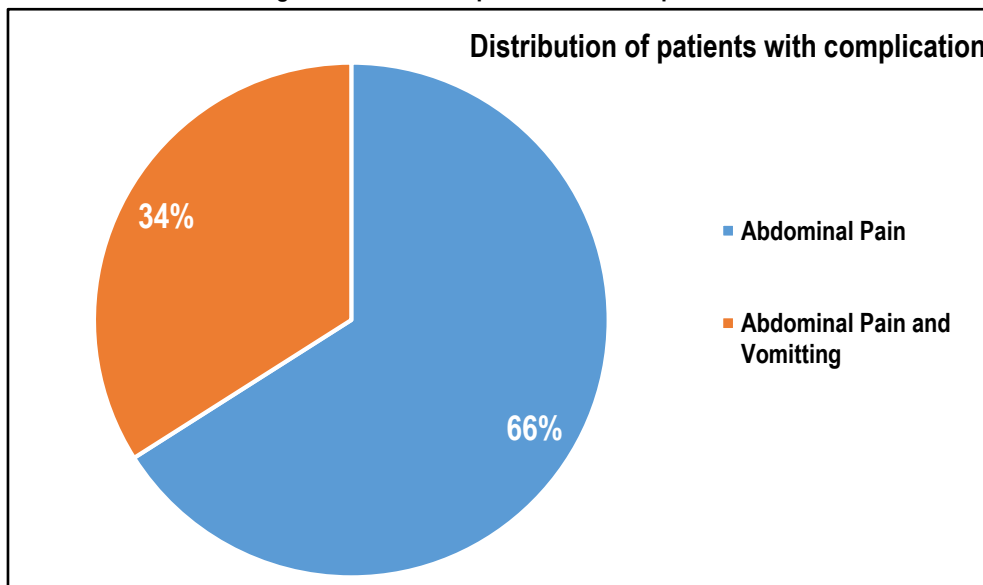


Fig 3: Distribution of patients with complication



As shown in table 1, the superficial infection at the umbilical port site was developed in only 1 patient (1%) of group A. The reason is the standard protocol followed by our unit of extracting the gall bladder through the umbilical port. Superficial infection was developed in 1% of patients of group A. Similarly 1% of patients of Group A also developed deep infection. Neither of the patients of any group developed seroma formation or other complications.

1 patient (1%) of group A had her wound laid open, and swab for culture and sensitivity was taken. After the examination, no growth of micro-organisms in the wound was revealed as shown in table 2. The same patient underwent daily dressings, and secondary suturing was performed on the 3rd day after the surgery.

The associated co-morbidities in both groups is shown in table 3. 10 patients in each group of our study were diabetic and none of them developed post-operative wound infection. No significant association between the presence of diabetes and wound infection could be obtained after the statistical analysis.

DISCUSSION

Among surgeons the use of prophylactic antibiotics in surgery still causes controversy. One should take into account that their misuse increases the rate of infection and involves unnecessary cost. To reduce the incidences of complications in open cholecystectomy antibiotic prophylaxis is considered standard protocol, its use is still debated in LC. Lippert and Gastinger²⁵ performed a prospective population-based multicenter study to evaluate antimicrobial prophylaxis in laparoscopic and conventional cholecystectomy.

Infectious complications, including wound infection which affects the overall rates of fatality and deaths is significantly prevented by the prophylactic antibiotic coverage of most 'clean contaminated' surgical procedures. However, the question of the benefit of antibiotic prophylaxis in other 'clean' surgical procedures, such as laparoscopic cholecystectomy still remains unsolved.²⁶ The main arguments against routine antibiotic coverage during laparoscopic cholecystectomy is if the low rate of wound infections and the straight-forward treatment occurs or not. It is an elective clean operation, and the wound infection after the surgery is very rarely seen.²⁶ Prophylaxis in clean operations has been shown to be of

value trauma²⁷ and vascular surgery.^{28, 29} Waldvogel and associates suggested that the routine use of antibiotic prophylaxis should be discouraged because of the unknown impact on bacterial resistance.³⁰ Our study aims to assess the role of prophylactic antibiotics in avoiding any kind of complications after the surgery in laparoscopic cholecystectomy. The mean age in our study was 44 years. The percentage of females in our study was 65%. Abdominal pain was the commonest presenting symptom in our study with the total of 66% of the patients.

In the present study, 20 patients (10%) were diabetic, 12 patients (6%) were hypertensive and 10 patients (5%) were both diabetic and hypertensive. Several risk factors significantly increases the incidence of infective difficulties and complications in patients who undergo elective laparoscopic cholecystectomy; the presence of diabetes mellitus is one of them.³¹ In our study, 98 out of 100 patients in group A had completely healed wounds after the surgery. Among the rest 2 patients, 1 patient (1%) had superficial wound infection and 1 had deep infection. In group B, all 100 patients (100 %) had completely healed wounds. In a randomized controlled trial conducted on 417 patients undergoing laparoscopic cholecystectomy by Gaur and Pujahari³², the overall infection rate was reported to be 2.2% which is consistent with the results obtained in our study.

No specific therapy was needed to heal the wounds or infections. All the infections healed before the availability of culture and sensitivity report. Pokharel and associates³³, stated that one of the factors for lower incidence of post-operative infection following laparoscopic cholecystectomy is the use of prophylactic antibiotics. Hence, this findings also matches with our findings in the study. The two major factors for decreasing the incidence of septic complications after biliary tract surgery are good surgical techniques and the judicious use of prophylactic antibiotics.³³ The rate of post-operative wound infection in our study was low and there was no significant difference between wound infection in patients receiving prophylactic antibiotics and post-operative antibiotics. The reasons may be good surgical technique, better handling of tissues, strict adherence to aseptic precautions, experienced laparoscopic surgeons, wound complications and its management etc.³⁴

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, no growth of any micro-organisms in the wound was revealed after 48 hours of culture. Daily dressings were done, and secondary suturing was performed on the 3rd day after the surgery. According to the study of Gaur and Pujahari³², the umbilicus is the commonest site for sepsis following laparoscopic cholecystectomy. The reason may be 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.

CONCLUSION

Our study concludes that the gold standard in the management of symptomatic cholelithiasis is laparoscopic cholecystectomy. To prevent postoperative infection related complications in low-risk patients with symptomatic gallstone disease undergoing elective laparoscopic cholecystectomy one single dose of prophylactic antibiotic injected at induction of anesthesia antibiotic prophylaxis is sufficient. Post-operative infective complications after elective laparoscopic cholecystectomy for cholelithiasis do not reduced by post-operative antibiotics.

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