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Comparative Study Of Prophylaxis With Cefazolin Versus Ceftriaxone In Cholecystectomy Patients

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Abstract

Introduction: Infection is defined an invasion of tissue by pathogenic microorganisms. Through their history, hospitals have coexisted with nosocomial infection (NI) which has been defined as the infection that was not presented neither was incubated at moment of patient admission at the hospital. Surgical site infections (SSIs) are the most common types of NI. Post-operative infections are the most common health care associated infection in surgical patients. SSI is the second most common hospital associated infections accounting 14-16% of all hospitalized patients and 38% among that of surgical patients. SSIs remain among the main causes of post-operative morbidity, prolonging hospitalization. It is found that patients who develop SSI are five times more likely to be readmitted to hospital and twice as likely to die as compared to patients without an SSI.

Objectives: To assess the efficacy and advantages of Ceftriaxone compared to Cefazolin in prevention of systemic and surgical site infection after laparoscopic cholecystectomy patients receiving Cefazolin versus Ceftriaxone.

Material and Methods: Prospective observational comparative was undertaken after approval by IEC. Study area was CRG hospital attached to RDGMC. This study was conducted for a period of one year from December 2017 to December 2018, where it was carried out in the department of surgery R.D Gardi Medical College, Ujjain, M.P. During this period, 84 cases were selected for our study purpose, all of which were clean or clean contaminated surgeries done under meticulous surgical technique. All the patients clinically diagnosed and radiologically confirmed a case of cholecystitis or cholelithiasis were included for the study and Patients who administered antibiotics 1 week before operation, uncontrolled hypertension and diabeties mellitus, patients on regular corticosteroids, patients with elevated liver enzymes twice the reference level, patients who wee treated with ERCP, patients who declined for being operated, case unfit for surgery, patients staying for less than 24 hours post surgery, patients below 17 years of age, death cases within 3 days post surgery and failed laparoscopy were excluded from the study.

Results: Laparoscopic cholecystectomy is an elective clean operation, and the post-operative wound infection rate would be very low. The benefit of antibiotic prophylaxis in laparoscopic cholecystectomy, a 'clean' surgical procedures, has been considered questionable. 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.

Conclusion: From the findings of our study we can conclude that antibiotic prophylaxis is not necessary in low-risk patients with gallstone or cholecystitis disease undergoing elective laparoscopic cholecystectomy to prevent postoperative infection-related complications. However there are some incidence rate of complications in this operation which were considered statistically insignificant. When comparing two cepahalosporins, cefazolin

(second generation) and ceftriaxone (third generation), the efficacy of ceftriaxone is considered better than cefazolin for antibiotic prophylaxis.

Keywords: SSIs, NI, ceftriaxone, cefazolin, cholecystectomy, antibiotic prophylaxis

Introduction

Infection is defined an invasion of tissue by pathogenic microorganisms. Through their history, hospitals have coexisted with nosocomial infection (NI) which has been defined as the infection that was not presented neither was incubated at moment of patient admission at the hospital. Surgical site infections (SSIs) are the most common types of NI[1]. Post-operative infections are the most common health care associated infection in surgical patients[2]. SSI is the second most common hospital associated infections accounting 14-16% of all hospitalized patients and 38% among that of surgical patients[3]. SSIs remain among the main causes of post-operative morbidity, prolonging hospitalization. It is found that patients who develop SSI are five times more likely to be readmitted to hospital and twice as likely to die as compared to patients without an SSI.[4] A Swiss study showed an incidence rate of SSI of 5.6% in 2002, with 38% of attributable death.[5] Post-surgical sepsis continues to be a significant problem across the globe.[1]

Despite the advances in the operative techniques and a better understanding on the pathogenesis of the surgical wound infections, post-operative wound infections continue to be a major challenge for surgical society.[6] Prevention of SSI is a public health priority.[7] 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.[8] 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. Surgical antibiotic prophylaxis (SAP) is administration of short course of antimicrobial agent prior to surgery to prevent SSI. Routine SAP to prevent postoperative infection has become a well-established practice all over the world. SAP represents approximately one-third of the hospital antimicrobial prescription.[9] In spite of extensive knowledge about the effectiveness of antibiotic prophylaxis, its administration is often inappropriate. The proper use of antibiotic prophylaxis in surgical procedures requires the consideration of several factors. Effectiveness depends on the correct application of the following items: appropriate antibiotic choice, timing of the initial administration, the number of dosages administered during surgery, and post-operative drug use. Incorrect execution of any of these factors can influence the rate at which infections at the surgical site occur. Therefore, it is very important to be aware of what is being done in surgical prophylaxis in order to establish improvement strategies.[10] That's why drug therapy should be scrutinized at international, national, regional and institutional level and efforts are required to evolve a consensus protocol and policy for the same. Thus, the present study/ research was undertaken to evaluate the usefulness and efficacy of first generation Cefazolin in laproscopic cholecystectomy as compared with that of third generation cephalosporin Ceftriaxone.

Objectives: To determine the efficiency of Cefazolin compared to Ceftriaxone in post surgical prophylaxis of cholecystectomy patients.

Material and Methods: A prospective observational comparative study was conducted among cases admitted to Chandrikaben Rupchand Gardi medical hospital (CRGH) under Ruxmaniben Deepchand Gardi Medical College (RDGMC), situated at Surasa, Ujjain, Madhya Pradesh, India after approval by RDC and IEC. This study was conducted for a period of one year from December 2017 to December 2018, where it was carried out in the department of Surgery R.D Gardi Medical College. During this period, 84 cases were selected for our study purpose, all of which were clean or clean contaminated surgeries done under meticulous surgical technique. The study involved only cases which were fit into the inclusion criteria. All adults groups patients clinically

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diagnosed and radiologically confirmed a case of cholecystitis or cholelithiasis were included and Patients who administered antibiotics 1 week before operation, uncontrolled hypertension and diabeties mellitus, patients on regular corticosteroids, patients with elevated liver enzymes twice the reference level, patients who wee treated with ERCP, patients who declined for being operated, case unfit for surgery, patients staying for less than 24 hours post surgery, patients below 17 years of age, death cases within 3 days post surgery and failed laparoscopy were excluded from the study.

Sample Size :

To calculate the sample size based on the prevalence with approximate 95% confidence level, we use the following formula:

n= z2 *P*(100-P)/d2

where,

z= 1.96 at confidence interval

p= 47% (outcome percentage 47% (healing at 01 month ref. no..12….)

d= absolute error 10%

n= (1.96*1.96)*47*(100-47)/10*10=42 patients in each groups.

Study group involved 84 surgical cases. Study group was split into group A and group B each. Ethical clearance was taken from the college ethical committee prior to the study. Group A comprises patients who received a pre-operative single intravenous dose of Cefazolin 1 gram a first generation cephalosporin. Group B patients received a single intravenous 1 gram dose of ceftriaxone a broad spectrum third generation cephalosporin. The groups were split into two taking into consideration the type of surgery, the age of patient, the presence or absence of risk factorsfor development of SSI, and associated medical co-morbidities/ conditions, all of which were represented in both groups almost equal and a comparative clinical study was made.

On admission to the hospital, meticulous preoperative patient preparation was initiated, consent for laparoscopic cholecystectomy (LC) operation and consent for conversion to open approach taken and a detailed proforma was completed which includes:

Age, sex, date of admission, date of operation and date of discharge, Detailed history of present illness, Significant past history particularly relating to infections, injury and any history of previous surgeries, Diagnosis, Medical co-morbidities, General examination findings, Per abdominal examinatioin findings, Pain in abdomen by using visual analogue scale,

Post operative:

1. Significant C- reactive proteins (CRP) levels,
2. Significant total leucocyte counts (TLC),
3. Significant temperature pertaining to fever,
4. SSI, and Post operative hospital stay.

Preoperative investigations include:

1. Complete blood picture with blood grouping,
2. Urine routine and microscopy,
3. HIV, HbSAg and HCV status by microbiology laboratory,
4. An erect chest radiograph,
5. Ultrasound abdomen showing type of gallbladder pathology.

Any co morbidities such as uncontrolled diabetic or hypertensive state, cardiopulmonary conditions were optimized and then posted for operation.

Preoperative skin preparation was done meticulously. Patients were allowed to take a thorough scrub bath after which parts were prepared with povidine iodine and was isolated with surrounding by covering the operative site by sterile gauze. Patients were bought to the waiting room next morning and were given single dose of i.v antibiotic of respective group under aseptic precaution one hour before the surgery. All of the cases were done in the morning hours.patients were anaesthetized under aseptic precautions. Sterile gauze was removed and patient's skin was painted with povidine iodine solution and spirit. Then the surface was allowed to dry. Then it was covered with sterile towel and sheets. Surgery was performed by the senior staff and postgraduates, whenever possible, cautery was minimized. Movements in operating room was restricted. Whenever necessary closed suction drain was preferred and wound was closed with sterile dressings. Patients were isolated in the post operative ward for at least 3 days. Drains were

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removed on 3rd or 4th postoperative day. Wound was inspected on 3rd postoperative day, any signs of inflammation, infection were noted down and findings were entered in the proforma. Fever charts was done 8 hourly for 48 hours in all post operative patients. SSI were monitored by direct observation of wound on days 3 and a wound swabs were sent for culture and sensitivity in the infected cases. All the patients were followed upto 10 days postoperatively.

Observations And Results: Present conducted study maximum number of patients with gall bladder pathology (cholelithiasis and cholecystitis) with or without associated co- morbidities involved maximum cases from age group (in years) 41-50 which was 31 %, followed by 31-40: 28.6%, 21-30: 13.1%,51-60 and more than 60:11.9%. least incidence was among age group less than 20 years : 3.6%

Table:1 Distribution of patients according to age groups

Age Groups (in year)	Frequency	Percent
<= 20	3	3.6
21 – 30	11	13.1
31 – 40	24	28.6
41 – 50	26	31
51 – 60	10	11.9
> 60	10	11.9
Total	84	100

Diagram:1 Distribution of patients according to sex

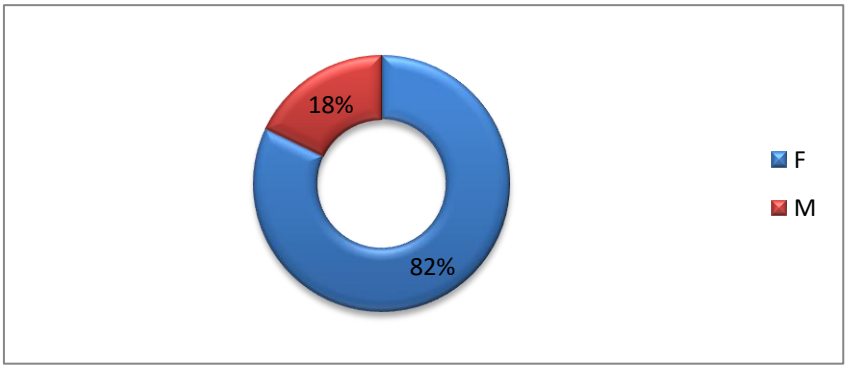

Table:2 Distribution of patients according to post op hospital stay

Post op hospital stay	Frequency	Percent
<= 4 days	74	88.1
> 4 days	10	11.9
Total	84	100

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Diagram:2 Association between treatment groups and post op hospital stay

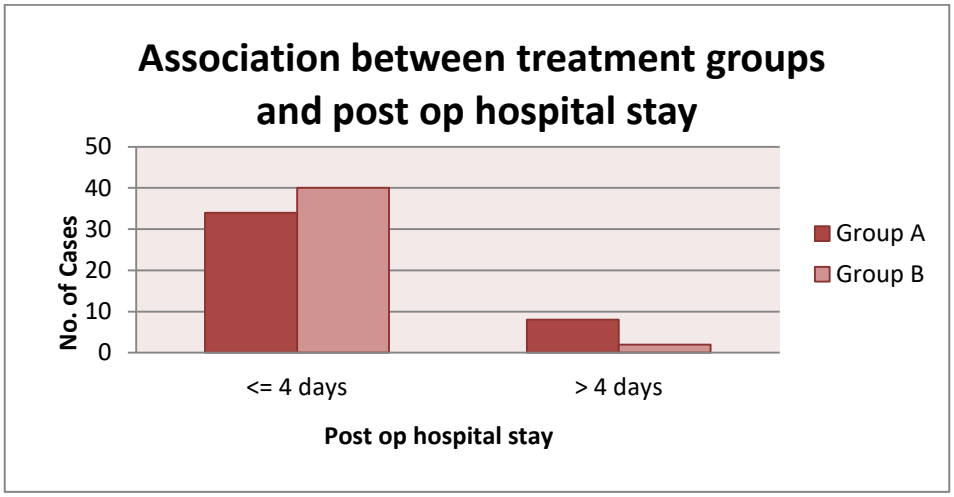

Diagram:3 Distribution of patients according to fever

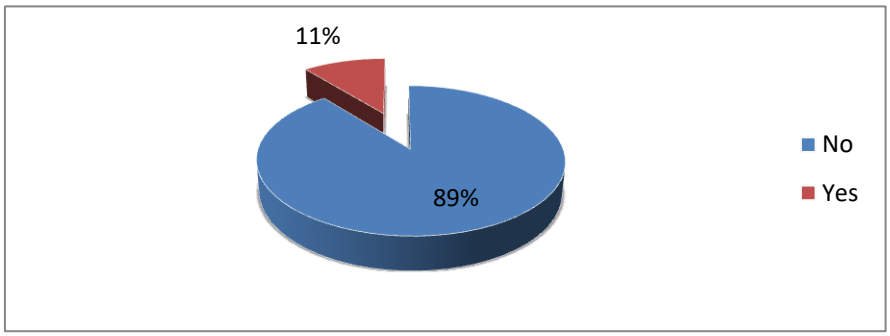

Diagram:4 Distribution of patients according to SSI

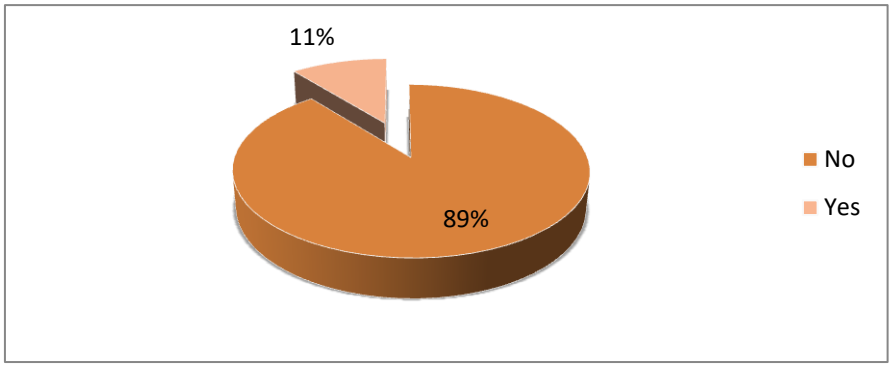

Table:3 Association between treatment groups and fever

fever	Groups		Total
	Group A	Group B	
No	36	39	75
	48.00%	52.00%	100.00%
Yes	6	3	9

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	66.70%	33.30%	100.00%
Total	42	42	84
	50.00%	50.00%	100.00%
Chi-square=1.120, p=0.29			

Table:4 Association between treatment groups and CRP

CRP	Groups		Total
	Group A	Group B	
No	35	36	71
	49.30%	50.70%	100.00%
Yes	7	6	13
	53.80%	46.20%	100.00%
Total	42	42	84
	50.00%	50.00%	100.00%
Chi-square=0.091, p=0.763			

Table:5 Association between treatment groups and total leucocyte count

Total leucocyte count	Groups		Total
	Group A	Group B	
No	30	39	69
	43.50%	56.50%	100.00%
Yes	12	3	15
	80.00%	20.00%	100.00%
Total	42	42	84
	50.00%	50.00%	100.00%
Chi-square=6.574, p=0.01			

Table:6 Association between treatment groups and SSI

SSI	Groups		Total
	Group A	Group B	
No	35	40	75
	46.70%	53.30%	100.00%
Yes	7	2	9

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	77.80%	22.20%	100.00%
Total	42	42	84
	50.00%	50.00%	100.00%
Chi-square=2.68 , p=0.078			

Discussion:

Our present study was conducted in 84 patients divided into two equal groups, the maximum cases belong to age group (in years) was 41-50, 26 patients having 31% incidence. While minimum age group was less than 20. Gender included were mostly females (69) with the frequency of 82.1%. male patients included only 15. Total 65 (77.4%) patients presented with complain of pain in abdomen Incidence of post operative fever (>100 F) in overall patients was 10.7%, 9 out of 84 cases. Group A (cefazolin) 6 (66.70%) patients had fever whereas group B had 3 (33.33%). p value was 0.29 considered insignificant, Chi square value was 1.120.

Total leukocyte counts (TLC) were done on each patient post operatively. Fifteen (17.85%) cases had raised TLC findings, 12 (80%) patients were cases from group A and 3 (20%) were from group B. This finding was considered significant because the p value was 0.01, it was verified by Chi square = 6.574. CRP levels were assessed in blood. Thirteen cases (15.5%) showed elevated CRP. Seven (53.80%) cases from group A and six (46.20%) cases from group B. The overall incidence of Post operative stay in the both antimicrobial prophylactic group was 11.9% (10 patients). Cefazolin prophylactic group patients were eight (80%) and two (20%) patients from Ceftriaxone prophylactic group. They were discharged after 4 days due to multiple reasons, some showed elevated CRP or TLC levels, developed high grade fever or developed infection at the surgical site.

Surgical site infection:

Surgical site infection though has been documented ever since origin of surgery, has not been able to be mastered. It's incidence can be reduced by strict asepsis, meticulous surgical techniques, prophylactic antimicrobials have drastically reduced the incidence of SSI.

The overall incidence of SSI in LC was 10.7%, which was found to be reduced with antibiotic prophylaxis. Antibiotic prophylaxis in the present study is justified with the use of third generation cephalosporins as it is used as a single dose and is having a prolonged half life up to 8 to 12 hours which will take care of wound in its initial crucial phase. It was administered one hour before the incision under aseptic precaution to all the patients in group B and two (4.76%) patients got infected as compared to group A with 7 (16.6%) infected patients. Incidence rate of SSI in group A was high as compared to group B. This means the difference occurrence of surgical site infection between two groups was found to be insignificant (p=0.078).

A randomized placebo controlled recipient blind trial done by Shibaji Basu, Pankaj Kumar et. al[11] compared cefazolin antibiotic with placebo in laparoscopic cholecystectomy overall incidence of SSI was 7.5%, with cefazolin group showed incidence 5% and placebo group 10% results were insignificant. Colliza S et al[12] comparison between two antibiotic group (ceftriaxone and ceftazidime) which patients were distributed equally. Ceftriaxone was considered as gold standard in biliary tract surgery but ceftazidime was equivalent (no statistically difference between two antibiotics group p= 0.59, no significant). Elsadg FE Ahmed et al[13] study showed that total 85 patients underwent cholecystectomy were divided into two group one with injection of cefuroxime dose 1.5 gram (44 cases) and other group (41 cases) received placebo. The analysis of all risk factors in this study showed no significant association with SSI, and this included age (p-value 0.1), morbidity (p-value0.7), SSI in this study was statitically insignificant p=0.79.

A randomized controlled trail by Navneet Sharma et al[14] 100 patients were included in study, 50 patients were present in each group. One group was given ceftriaxone, other one was given placebo. Incidence of SSI in ceftriaxone group was 2% and placebo group had 4%. Result was compared p=0.40 Chi square = 0.71 insignificant by binary logistic

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regression analysis. A case control study by Kazuhisa Uchiyama et al[15] total 397 patients were included divided into two group one antibiotic given with cefaperazone + Sulbactam drug (200 cases) and other one was placebo group (197 cases). Mean WBC count was recorded, antibioitic group showed 9860/cumm and 10520/cumm. Result was compared and it was statistically significant with $p<0.05$.

A Randomized Prospective Study conducted by Ashwani Kumar et al[16] consisted of total 240 patients, divided nto two groups. Group A was given single dose preoperative Ceftriaxone 1.5gm. group B was given same antibiotic twice daily for 3 days without preoperative dose. 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. Pain abdomen was the commonest presentation, with 60 % of our patients presenting with only pain abdomen. 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. The overall incidence of post-operative wound infection in our study was 0.41%. There was no statistical difference in the incidence of post-operative infection ($p = 0.3132$) in patients with or without post-operative antibiotics.

Many prospective studies have suggested that antibiotic prophylaxis is probably not required in elective LC, because the infection rate of LC is already low and the use of prophylactic antibiotics does not decrease the incidence of SSIs and other postoperative infection complications. The rate of post-operative wound infection in our study was low (10.7%) 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.

Conclusion:

Our study conclude that antibiotic prophylaxis is not necessary in low-risk patients with gallstone or cholecystitis disease undergoing elective laparoscopic cholecystectomy to prevent postoperative infection-related complications. However there are some incidence rate of complications in this operation which were considered statistically insignificant. When comparing two cepahalosporins, cefazolin (second generation) and ceftriaxone (third generation), the efficacy of ceftriaxone is considered better than cefazolin for antibiotic prophylaxis. Ceftriaxone was associated reduced post operative hospital stay. Many surgeons still prefer giving antibiotic prophylaxis in laparoscopic cholecystectomy. Therefore keeping above complications in mind it is better to use Ceftriaxone as antibiotic prophylaxis in Laparoscopic cholecystectomy.

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