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Original Research Paper

General Surgery

TO STUDY THE OUTCOME OF PATIENT UNDERGOING ELECTIVE LAPAROSCOPIC CHOLECYSTECTOMY WITH SINGLE DOSE OF ANTIMICROBIAL PROPHYLAXIS.

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ABSTRACT

INTRODUCTION :- Laparoscopic cholecystectomy is very commonly performed surgery for symptomatic cholelithiasis. There is very low risk of infective complications in elective Laparoscopic cholecystectomy and hence standard guideline doesn't recommend prophylactic antibiotic usage for low risk cases. However it is very commonly practicised in dosage and duration inconsistent among various surgeons. This study is being done to assess the efficacy of single dose antibiotic prophylaxis over multiple dose in the prevention of surgical site infection in patients undergoing elective laparoscopic cholecystectomy to avoid antibiotic resistance and overuse of it .

METHODS: The study included 60 patients admitted for elective Laparoscopic cholecystectomy. First 30 patients received injectable ceftriaxone 1 gram intravenous peri-operatively, first dose twelve hour before surgery and second dose half hour before surgical incision and then followed by injection (conventional dose) ceftriaxone 1 gram/day iv twice daily for the first 5-7 days post-operatively. Next 30 was defined as the single dose (post-operative) antibiotic patients , this group were given only single dosage of injectable ceftriaxone 1 gram intravenous post-operatively.operation-room anesthetic assistant administered prophylactic antibiotics at induction of anaesthesia to all the patients. On the third, fifth, tenth and fifteenth days post operatively, based on Southampton scoring system the wound was seen and grading of the infection was done

RESULT: The post-operative surgical site infection rate in group receiving single dose was 7.76 % and that in multiple dose group was found to be 6.67% . Chi- square test was used to analyse the data and the difference in the rate of SSI in both the groups was found to be statistically insignificant.

CONCLUSION: There is no significant difference in the outcome of elective laparoscopic cholecystectomy in terms of post operative surgical site infection in single dose and multiple dose group. Also single dose of antibiotics are more patient compliant, cost effective, have less adverse effects and reduce the incidence of antibiotic resistance

KEYWORDS : Single dose vs. multiple dose, Antibiotic prophylaxis, Laparoscopic cholecystectomy

INTRODUCTION

Cholelithiasis is one of the most common health problems worldwide. About 10-15% of adult population of world and 10-22% of Indian population are affected by it. Today, laparoscopic cholecystectomy (LC) is the gold standard procedure for cholelithiasis as it is minimally invasive less and associated with less pain after surgery ,decreased hospital stay duration and reduction of hospital cost when compared to open cholecystectomy[1-4]

Surgical site infection (SSI) is a major complication associated with any surgery which can lead to increased hospital duration, cost and add to patient's morbidity and mortality. Not only antimicrobial prophylaxis but various others like the procedure duration, hospital environments, preoperative preparation like skin antisepsis, hair removal technique, glycemic control and other medical comorbidities of the patient may influence SSI rates. More often, there is worldwide irrational use of antibiotics to reduce the SSI, which not only increases the hospital cost but also paves path for emergence of drug resistance. So a standardized protocol is needed for its prevention .

LC has low rate of postoperative infections which is supported by a study analysis of 1702 patients who underwent laparoscopic cholecystectomy and had an overall infections rate of 2.3% and surgical site infection rate 0.4%.[5] Due to this, the necessity for antibiotic prpophylaxis is now a matter of debate .

Chang WT et al and many others are of the view that there is no role of prophylactic antibiotics in elective LC as they do not decrease the already low rate of postoperative infectious complications (6-9) . However , Lippert H et al, believed that neither laparoscopic nor conventional open cholecystectomy be performed without the adequate perioperative antimicrobial prophylaxis .(10-13) Some on the other hand believe prophylactic antibiotics reduce the incidence of wound infection in laparoscopic cholecystectomy[14]

Society of American Gastrointestinal and Endoscopic Surgeons (SAGES) has laid down the following guidelines for antibiotic prophylaxis:

1. Low-risk patients undergoing laparoscopic cholecystectomy donot require antibiotic prophylaxis
2. Antibiotics may reduce the incidence of wound infection in high-risk patients (age >60 years, the presence of diabetes, acute colic within 30 days of operation, jaundice, acute cholecystitis, or cholangitis)
3. If given, they should be limited to a single pre-operative dose given within 1 hour of skin incision.

The aim of this study was to compare the efficacy of single dose of antibiotic prophylaxis prophylaxis with regard to incidence of surgical site infections in elective laparoscopic cholecystectomies performed in the Department of General Surgery at Dr B R A M Hospital, Raipur .

MATERIALS AND METHODS

This is prospective analytical type study conducted from jan 2020 to dec 2020 in the Surgery department of Dr. Bhim Rao Ambedkar Memorial Hospital (Dr. BRAMH) And Associated Pt. Jawaharlal Nehru Memorial Medical College, Raipur (C.G) . The study was approved by the institutional ethics committee of the college.

All patients of age above 18 years suffering from symptomatic documented gallstones on ultrasonography and undergoing elective LC were included in the study.

Patients with acute cholecystitis ,associated choledocholithiasis or intraoperative biliary leak, unwilling for the study, Open conversion , emergency operation, history of cephalosporin group hypersensitivity, treatment with steroids and those drug classified to cause immune deficiency were excluded.

The study population were randomly assigned into group 1 and group 2.

All surgical interventions were carried out in similar operative backgrounds, and with identical preoperative methods of safety, and care given post-operatively is followed for all patients.

Group-1 received Injectable Ceftriaxone 1 gram intravenous peri-operatively, First dose twelve hour before surgery and second dose half hour before surgical incision and then followed by injection (conventional dose) ceftriaxone 1 gram/day IV twice daily for the first 5-7 days post-operatively.

Group-2 received Single dosage of Injectable Ceftriaxone 1 gram intravenous pre-operatively.

At any time, patient shows wound gap, wound infection, redness, induration treatment could be changed.

Patients were admitted 1 day before surgical procedure and routine tests were carried out. Operative area was shaved the night before and patients were advised to take a bath in morning on the day of the operation.

On the third, fifth, tenth and fifteenth days post operatively, based on Southampton scoring system the wound was seen and grading of the infection was done.

Southampton scoring system grading:

0 – Wound healing normally
1 - Mild erythema with Bruising
2 – Inflammatory signs and Erythema
3 - Serous (or) clear discharge
4 – Formation of pus
5 – Deep seated and severe wound infections.

RESULTS

TABLE 1:Distribution of age in Group 1 and Group 2

Age group	Group 1		Group 2	
	N	%	N	%
< 20 years	0	0	2	7.69
21-30 years	9	30	5	19.23
31-40 years	8	26.67	8	30.77
41-50 years	9	30	6	23.08
51-60 years	3	10	2	7.69
61-70 years	1	3.33	3	11.54
Total	30	100	26	100

Chi square value=4.68 P=0.45 NS

It was found that in this study the sample were distributed widely across all age groups, in group one maximum patients (9) were present in two age group 21-30 yrs and 41-50 yrs and minimum patients (0) in age group <20yrs, with mean age of 38.83 and SD of ±10.81 .

In group two maximum patients were present in age group 31-40 yrs and minimum patients (2) in two age groups of <20yrs and 51-60yrs with mean age of 41.46 and SD of ±12.96 .

The p-value was 0.55 which is not significant.

Table 2: Sex Distribution in Group 1 and Group 2

Sex distribution	Group 1		Group 2	
	N	%	N	%
Male	9	30	6	23.08
Female	21	70	20	76.92
Total	30	100	26	100

Chi square value=0.34 P=0.56 NS

In this study, in group one 30% patients were male and 70 % were female. In group two 23.08% patients were male and 76.92% patients were female. The p-value is 0.56 which is not significant.

Table 3 : Incidence of Grade 2 Infections in Group 1 and Group 2

Grade 2 Infection	Group 1	Group 2	P value
Post-Operative Day 3	2(6.67%)	2(7.69%)	0.88
Post-Operative Day 5	2(6.67%)	2(7.69%)	0.88
Post-Operative Day 10	0	0	1.00
Post-Operative Day 15	0	0	1.00

In group 1, 2 patients (6.67%) developed grade 2 infection on post op day 3 and on post op day 5 In group 2, there were 26 patients of whom 2 developed grade 2 infection (7.6%). All these patients were managed conservatively and no intervention or change in antibiotic regimen was needed. The p value came out to be 0.88 which was statistically insignificant.

Table 4: Association between Grade 2 infection and Diabetes in Group 1

		Diabetes (Group 1)		
		Yes (N=2)	No (N=28)	P value
Incidence of grade 2 infection	After 3 days	1(50%)	1(3.6%)	0.011
	After 5 days	1(50%)	1(3.6%)	0.011

In group 1, 2 patients were diabetic of which 1 developed grade 2 infection.However among the rest non diabetics(28) there was a single case of grade 2 infection. The p value was 0.011 which was statistically significant.

Table 5: Association between Grade 2 infection and Diabetics in Group 2

		Diabetes (Group 2)		
		Yes (N=7)	No (N=19)	P value
Incidence of grade 2 infection	After 3 days	1(14.29%)	1(5.26%)	0.51
	After 5 days	1(14.29%)	1(5.26%)	0.51

In group 2, among the 26 cases, 7 were diabetic and 19 non diabetic. Among the diabetics, one developed SSI (14.29%).Among the non diabetics, the incidence of SSI was 5.26% i.e. one case developed SSI among the rest 19 .The p value was 0.51 which was not significant.

DISCUSSION

Gall stone disease or cholelithiasis is one of the most common disease prevalant in many parts of world. The gold standard treatment of the disease is laparoscopic cholecystectomy which is one of the most frequently performed surgeries. Due to the benefits of minimal invasive nature of the surgery, laparoscopic cholecystectomy has widely replaced open cholecystectomy although open cholecystectomy is still practiced in some parts of the world.

In this study 60 patients who met the inclusion criteria were taken which were randomly divided into two groups , Group 1 was defined as the conventional(multiple) dose antibiotic group. Group 2 was defined as the single dose (post-operative) antibiotic .However, 4 cases of group 2 got converted to open cholecystectomy and so were excluded. Hence 30 cases in group 1 and 26 cases in group 2 finally participated in the study.

Age Distribution:-

Gall stone disease usually affects 4th decade of life. The study sample was widely distributed across all age groups with the

mean age of presentation being 40.14 years ,which is similar when compared to various studies [15,16,17]

FEMALE PREPONDERANCE Gall stone disease is much more prevalent in female population [18,19] In this study also, about 73.92 % of the cases were female and male patients occupied the remaining 26.08 % .

Cholecystectomy wounds come under clean and contaminated wound with incidence of surgical site infection upto 20% without chemoprophylaxis [20,21,22,23] . To reduce the incidence of Surgical Site Infection , antibiotic prophylaxis has a definitive role in clean and contaminated wound [22,24,25]

However, laparoscopic cholecystectomy has less chance of SSI as there is minimal tissue handling ,less contamination and smaller incisions.[26,27]

Hence the present study was conducted to analyse the outcome of single dose of antimicrobial prophylaxis and compare the results with the multiple dosage in terms of incidence of SSI in elective laparoscopic cholecystectomy

In this study,out of 30 cases in group 1 (multiple dosage), 2 patients developed SSI .The incidence was calculated to be 6.67% .In Group 2 (single dose), SSI was found to be present in 2 patients , with an incidence of 7.69 % . Though group 2 recorded increased incidence of SSI, it was not statistically significant when compared to that of group 1.(p value was 0.88) The result was similar to the report published in **NATIONAL NOSOCOMIAL INFECTIONS SURVEILLANCE (NNIS)** in January 2004[28]

Shah YD et al conducted a study in which a total of 120 cases were included. Out of 120 patients by random selection, 72 patients were given single dose of antibiotic and 48 patients were given multiple dose of antibiotic.Based on followup and surgical site infection they concluded that Single dose of antibiotics are more patient compliant, cost effective, less adverse effects, prevents emergence of antibiotic resistance and more rational than multiple dosages of antibiotics; as in laparoscopic surgery chances of gross contamination is less. Hence the use of single dosage of antibiotics in laparoscopic surgery was advocated.(29)

Meijer et al conducted a metaanalysis in which all available clinical trials of antibiotic prophylaxis in biliary tract surgery, published from 1965 to 1988, were examined. Results of 42 randomized, controlled trials (4129 patients), in which a group of patients treated with antibiotics was compared with a group of patients not treated with antibiotics, were pooled. Comparison of wound infection rates in patients treated with single-dose versus multiple-dose regimens (15 trials, 1226 patients) did not reveal any significant effect (P greater than 0.05) in each trial separately as well as in the overall (30)

CONCLUSION

There is no significant difference in the outcome of elective laparoscopic cholecystectomy in terms of post operative surgical site infection in single dose and multiple dose group. Also single dose of antibiotics are more patient compliant, cost effective, have less adverse effects and reduce the incidence of antibiotic resistance. So, we advocate the use of single dose of antibioticds in laparoscopic cholecystectomy. However, it would have been more informative if the study was larger and was conducted on patients from multiple centers.

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