



## ELECTIVE LAPAROSCOPIC CHOLECYSTECTOMY WITHOUT ANTIBIOTICS: A PROSPECTIVE STUDY

### Surgery

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### ABSTRACT

**INTRODUCTION** - Observing the low incidence of infections following laparoscopic cholecystectomy, the need for antibiotics is frequently being questioned. The overuse of antibiotics can result in rising frequency of adverse effects, emergence of drug resistant organisms.

**METHODS** - In study group, no antibiotic was given at the time of induction of anaesthesia whereas in control group, one dose of injection Ceftriaxone 1 g IV was given at the time of induction of anaesthesia. A sample of bile will be aspirated with the needle from gall bladder and sent to microbiological laboratory for bacterial detection. The postoperative course will be monitored for incidents such as fever, infection at trocar site.

**RESULTS** - The p-values drawn for the difference in the number of patients in either group having positive bile culture, postoperative fever, signs of inflammation and wound discharge came out to be less than 0.05. The p-values drawn for the difference in the number of patients having post op surgical site infection in relation to report of bile culture and intra op bile or stone spillage came out to be less than 0.05.

**CONCLUSION** - Intraoperative bile and gall stone spillage has poor correlation with the postoperative surgical site infections. Statistically insignificant differences are there between the two study groups as far as postoperative surgical site infections are concerned.

### KEYWORDS

#### 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 complication of open cholecystectomy are very well known and prophylactic antibiotics are a routine practice. However the wound created after laparoscopic cholecystectomy behave differently as compared to open cholecystectomy.

- Firstly, the wounds created are smaller as compared to open surgery
- Secondly, it has been proved that immune system is better preserved in laparoscopic surgery since the tissue trauma is less [2].

These two factors result in lesser activation of inflammatory response following the laparoscopic procedure [2]. Furthermore, laparoscopic cholecystectomy per se does not violate the mucosal defence barrier of the respiratory, gastro-intestinal or genital epithelium [3].

Observing the low incidence of infections following laparoscopic cholecystectomy, the need for antibiotics is now frequently being questioned. The overuse of antibiotics can result in rising frequency of adverse effects, emergence of drug resistant organisms, as well as increased costs [4, 5].

#### MATERIALS AND METHODS

##### SOURCE OF DATA

- Cases admitted and operated in surgery department at Dr Sushila Tiwari Government Hospital, Haldwani undergoing elective laparoscopic cholecystectomy were clinically evaluated.

##### METHOD OF COLLECTION OF DATA

- Data was collected from patient admitted between November 2016 to October 2018 suffering from symptomatic gall stones with documented gall stones on ultrasonography and undergoing elective laparoscopic cholecystectomy in each group of study. Randomization was done with the alternate patient being placed in case and control group. Total 105 patients were studied.

##### INCLUSION CRITERIAS

- Diagnosed case of symptomatic cholelithiasis.
- Patients giving consent to be the part of the study.

##### EXCLUSION CRITERIAS

- Antibiotic intake for any indication in last 48 hours prior to

surgery.

- Patients with acute cholecystitis
- Regular corticosteroid therapy.
- Comorbid conditions e.g. TB, DM, HIV, obstructive jaundice.
- Conversion to open cholecystectomy.
- ERCP treated choledocholithiasis.
- Patients with cardiac prosthesis.
- Patients not giving consent to be the part of the study.

#### METHOD OF STUDY

- In study group, no antibiotic was given at the time of induction of anaesthesia; whereas in control group, one dose of injection Ceftriaxone 1 g IV was given at the time of induction of anaesthesia.
- A sample of bile was aspirated with the needle from gall bladder before starting the dissection and was sent to microbiological laboratory for bacterial detection.
- The postoperative course was monitored for incidents such as fever, infection at trocar site.

#### OBSERVATIONS & RESULTS

##### OBSERVATIONS

##### AGE WISE DISTRIBUTION

The major clustering of patients is around 20 – 50 years of age in both the groups (76% of the patients in study group and 65% of the patients in control group); with lesser number of patients on both the extremes of age. Thus both the groups exhibit almost similar age wise distribution of patients. [Table 1]

**Table 1: Age Wise Distribution Of Participants**

Age group	Laparoscopic cholecystectomy without antibiotic cover (53)	Laparoscopic cholecystectomy with antibiotic cover (52)
<20	3 (5.66)	4 (7.69)
21-30	12 (22.64)	13 (25.00)
31-40	21 (39.62)	10 (19.23)
41-50	8 (15.09)	11 (21.15)
51-60	5 (9.43)	9 (17.31)
61-70	3 (5.66)	4 (7.69)
>71	1 (1.89)	1 (1.92)

##### GENDER WISE DISTRIBUTION

Again both the groups have similar gender wise distribution with 8 male patients (15% of the total) being in each group. Thus both the groups are comparable when it comes to gender wise distribution

without any significant discrepancy. [Table 2]

**Table 2: Gender Wise Distribution Of Participants**

	Number of patient	Male	Female
Laparoscopic cholecystectomy with antibiotic cover	52	8 (15.38)	44 (84.62)
Laparoscopic cholecystectomy without antibiotic cover	53	8 (15.09)	45 (84.91)
Total	105	16 (15.24)	89 (84.76)

**RESULTS OF BILE CULTURE AND SENSITIVITY**

Bile was aspirated in the intraoperative period before starting the dissection in hepatocystic triangle and sent for bacteriological culture and sensitivity. The culture was found to be negative in more than 90% of the patients in both the groups. It was found to be positive in 5 patients (9.60%) in control group and 3 patients (5.70%) in study group. [Table 3]

**Table 3: Results Of Bile C/s**

	Number of patient	Bile culture positive	Bile culture negative
Laparoscopic cholecystectomy with antibiotic cover	52	5 (9.60)	47 (90.40)
Laparoscopic cholecystectomy without antibiotic cover	53	3 (5.70)	50 (94.30)
Total	105	8 (7.62)	97 (92.38)

P-value = 0.445 i.e. > 0.05.

**INTRAOBILE OR STONE SPILLAGE**

Patient was observed for any intra op spillage of bile or gall stones keeping in mind possible association with postoperative surgical site infection because of contact of bacteriologically positive bile with the surgical site. In both the groups, more than 90% of the time no spillage occurred. 2 patients (3.85%) in control group and 3 patients (5.66%) in study group had intraop bile and stone spillage. [Table 4]

**Table 4: Incidence Of Intraop Bile Or Stone Spillage**

	Number of patient	Intra op bile or stone spillage	No spillage
Laparoscopic cholecystectomy with antibiotic cover	52	2 (3.85)	50 (96.15)
Laparoscopic cholecystectomy without antibiotic cover	53	3 (5.66)	50 (94.34)
Total	105	5 (4.76)	100 (95.24)

P-value = 0.663 i.e. > 0.05.

**INCIDENCE OF POSTOP FEVER**

Patients were followed up in the post op period for occurrence of fever as one of the features of postoperative surgical site infections. 2 patients (3.85%) in the control group and 3 patients (5.66%) in the study group had fever in the postop period. [Table 5]

**Table 5: Incidence Of Postop Fever**

	Number of patient	Post op fever	No post op fever
Laparoscopic cholecystectomy with antibiotic cover	52	2 (3.85)	50 (96.15)
Laparoscopic cholecystectomy without antibiotic cover	53	3 (5.66)	50 (94.34)
Total	105	5 (4.76)	100 (95.24)

P-value = 0.663 i.e. > 0.05.

**INCIDENCE OF SIGNS OF INFLAMMATION**

As a part of surgical site infection, signs of inflammation were looked out. 2 patients (3.85%) in the control group and 1 patient (1.89%) in the study group had typical signs of inflammation around the port sites. [Table 6]

**Table 6: Incidence Of Signs Of Inflammation**

	Number of patient	Signs of inflammation	No inflammation
Laparoscopic cholecystectomy with antibiotic cover	52	2 (3.85)	50 (96.15)
Laparoscopic cholecystectomy without antibiotic cover	53	1 (1.89)	52 (98.11)
Total	105	3 (2.86)	102 (97.14)

P-value = 0.547 i.e. > 0.05.

**INCIDENCE OF WOUND DISCHARGE**

Both the patients (3.85%) in control group having signs of inflammation had discharge from the wound in the post op period. None of the patients in study group had wound discharge. [Table 7]

**Table 7: Incidence Of Postop Wound Discharge**

	Number of patient	Wound discharge	No wound discharge
Laparoscopic cholecystectomy with antibiotic cover	52	2 (3.85)	50 (96.15)
Laparoscopic cholecystectomy without antibiotic cover	53	0 (0.00)	53 (100.00)
Total	105	2 (1.90)	103 (98.10)

P-value = 0.149 i.e. > 0.05.

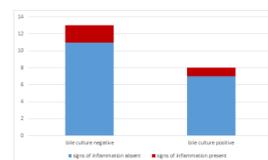
**Relationship Between Results Of Bile C/s And Post Op Signs Of Inflammation**

Total 21 patients had the relation between reports of bile culture and postop signs of inflammation. [Table 8, bar chart 1]

**Table 8: Relationship Between Results Of Bile C/s And Post Op Signs Of Inflammation**

		SIGNS OF INFLAMMATION		Total
		No	Yes	
BILE CULTURE	negative	11	2	13
	positive	7	1	8
Total	18	3	21	

p-value = 0.854 i.e. > 0.05.



**Bar Chart 1**

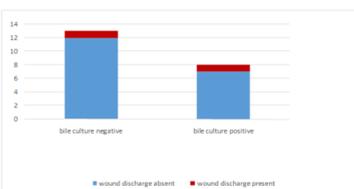
**Relationship Between Results Of Bile C/s And Post Op Wound Discharge**

Total 21 patients had the relation between reports of bile culture and postop wound discharge. [Table 9, bar chart 2]

**Table 9: Relationship Between Results Of Bile C/s And Post Op Wound Discharge**

		WOUND DISCHARGE		Total
		No	Yes	
BILE CULTURE	Negative	12	1	13
	positive	7	1	8
Total		19	2	21

p-value = 0.716 i.e. > 0.05.



**Bar Chart 2**

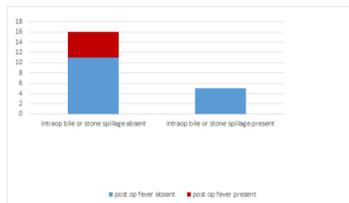
**Relationship Between Incidence Of Intra Op Bile Or Stone Spillage And Post Op Fever**

Total 21 patients had the relation between incidence of intra op bile or stone spillage and post op fever. [Table 10, bar chart 3]

**Table 10: Relationship Between Incidence Of Intra Op Bile Or Stone Spillage And Post Op Fever**

		POSTOP FEVER		Total
		No	Yes	
INTRAOP BILE OR STONE SPILLAGE	no	11	5	16
	yes	5	0	5
Total		16	5	21

p-value = 0.152 i.e. >0.05.



**Bar Chart 3**

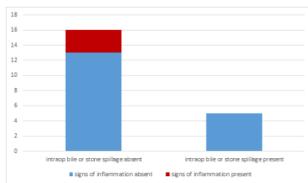
**Relationship Between Incidence Of Intra Op Bile Or Stone Spillage And Post Op Signs Of Inflammation**

Total 21 patients had the relation between incidence of intra op bile or stone spillage and post op signs of inflammation. [Table 11, bar chart 4]

**Table 11: Relationship Between Incidence Of Intra Op Bile Or Stone Spillage And Post Op Signs Of Inflammation**

		SIGNS OF INFLAMMATION		Total
		No	Yes	
INTRAOP BILE OR STONE SPILLAGE	No	13	3	16
	Yes	5	0	5
Total		18	3	21

p-value = 0.296 i.e. >0.05.



**Bar Chart 4**

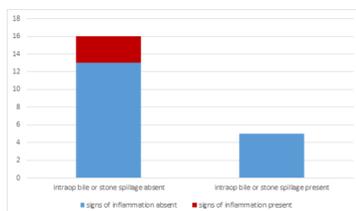
**Relationship Between Incidence Of Intra Op Bile Or Stone Spillage And Post Op Wound Discharge**

Total 21 patients had the relation between incidence of intra op bile or stone spillage and post op wound discharge. [Table 12, bar chart 5]

**Table 12: Relationship Between Incidence Of Intra Op Bile Or Stone Spillage And Post Op Wound Discharge**

		WOUND DISCHARGE		Total
		No	Yes	
INTRAOP BILE OR STONE SPILLAGE	no	14	2	16
	yes	5	0	5
Total		19	2	21

p-value = 0.296 i.e. >0.05.



**Bar Chart 4**

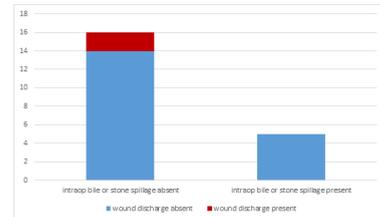
**Relationship Between Incidence Of Intra Op Bile Or Stone Spillage And Post Op Wound Discharge**

Total 21 patients had the relation between incidence of intra op bile or stone spillage and post op wound discharge. [Table 12, bar chart 5]

**Table 12: Relationship Between Incidence Of Intra Op Bile Or Stone Spillage And Post Op Wound Discharge**

		WOUND DISCHARGE		Total
		No	Yes	
INTRAOP BILE OR STONE SPILLAGE	no	14	2	16
	yes	5	0	5
Total		19	2	21

p-value = 0.406 i.e. >0.05.



**RESULTS**

1. Bile was sent for culture and sensitivity in all the patients i.e. in both the groups. Culture and sensitivity reports reveal ESBL producing E. coli and Pseudomonas as the most common organisms grown with Ceftazidime and Amikacin being the predominant antibiotics to which the organisms were sensitive. The purpose of sending the culture was to compare the report of culture and sensitivity taken from postoperative surgical site infection with the preoperative bile culture report. The idea was that in case both of them match, probability of infected bile being the cause of postoperative surgical site infection increases. This happens as the gall bladder brushes off the surgical site during its extraction. None of the patients with positive bile culture had postoperative surgical site infection and none of the patient with postoperative surgical site infection had preoperative positive bile culture. Therefore this relationship between preoperative bile culture and postoperative surgical site swab culture could not be established in this study.
2. The p-values drawn for the difference in the number of patients in either group having positive bile culture, postoperative fever, signs of inflammation and wound discharge came out to be less than 0.05. Therefore, the difference in the number of postoperative complications in study and control group came out to be statistically insignificant.
3. The p-values drawn for the difference in the number of patients having post op surgical site infection in relation to report of bile culture and intra op bile or stone spillage came out to be less than 0.05. Therefore this difference again came out to be statistically insignificant.

**DISCUSSION**

Antibiotic prophylaxis is a standard component of biliary tract surgery and there is about 50 % decrease in postoperative wound infection with the use of prophylactic antibiotics [11]. **However these data cannot be extrapolated to include laparoscopic surgeries.**

Koc M et al [10] observed 2.04% infections in antibiotic prophylaxis group (gr A, n = 49) and 2.32 % of infections in non-antibiotic prophylaxis group (gr B, n=43) in their prospective double blinded randomized study of over 92 patients undergoing elective laparoscopic cholecystectomy.

Kuthe SA et al [9] observed 2.5% of postoperative wound infection in the antibiotic prophylaxis group (gr A, n=40) and 3.80 % of postoperative wound infection in the non- antibiotic prophylaxis group (gr B, n= 53) in their prospective randomized trial of over 93 patients undergoing elective laparoscopic cholecystectomy.

Yildiz B et al [12] observed 4 of 105 patients, that is, 3.80 % of the postoperative wound infection in the antibiotic prophylaxis group, and 3 of 103 patients, which is 2.91 % in the no antibiotic prophylaxis group in their randomized double blind study to evaluate determinants of postoperative infection of over 208 patients undergoing elective

laparoscopic cholecystectomy.

Nilay Mandal et al found the postoperative wound infection rate 2.94 %, in their prospective study for elective laparoscopic cholecystectomy without prophylactic antibiotics in over 102 patients [7].

In a randomized controlled trial on 417 patients undergoing laparoscopic cholecystectomy, conducted by Gaur and Pujahari et al [13], 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 associates [17], 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.**

In another study conducted by Mahmoud and associates [18] to assess the role of antibiotic prophylaxis in elective laparoscopic cholecystectomy, they concluded that the use of antibiotic prophylaxis is preferred to be restricted to high-risk patients such as patients with associated comorbidities like diabetes mellitus.

**The rate of post-operative wound infection in our study was low (1.90%) and there was no significant difference between wound infection in patients receiving prophylactic antibiotics and post-operative antibiotics.**

In the study conducted by Hamad Hadi et al the overall postoperative infective complications was 3.62% (2.7 % in Group A and 4.6 % in Group B) with no significant statistical difference between the two groups [6].

In our study, all infective complications were superficial wound infection and all were treated with pus drainage, wound care. No deep incisional, deep seated or distant infections were reported in the study. The role of positive bile culture, bile and stones spillage due to intraoperative gallbladder perforation on the occurrence of SSI is still controversial. Intraoperative gallbladder perforation has been reported to occur in 11% to 20% of laparoscopic cholecystectomy [23, 24]. The rate of positive bile culture among patients with gallbladder stones has been found to range between 10% and 42.5% [22, 10, 14, 19 and 20]. In our study bile spillage due to gallbladder perforation occurred in 4.76% (n=5) of patients whereas the bile culture was positive for microorganism in 7.62% (n=8). Several studies have stated that both bactibilia and intraoperative gallbladder perforation were strongly associated with occurrence of SSI [14, 20]. However, many other studies did not observe this association, concluding that **both bactibilia and intraoperative gallbladder perforation with bile and stones spillage does not increase the rate of SSI** [21, 22, 10, 15, 24, 8]. **In our study, no such association could be assessed.** Only one patient with positive bile culture developed superficial wound infection, although the wound swab culture was negative. **There was no relationship between the isolated organisms from the bile and the SSI culture results in several studies** [21, 22 and 25].

Higgins et al [16] also performed a similar study in which he compared single dose prophylactic antibiotics with no antibiotics and also had identical results.

Our study also verified that when low risk patients are the part of study, number of postoperative infective complications were similar in both the groups whether antibiotic prophylaxis is used or not. It means that difference in incidence of postoperative surgical site infection is statistically insignificant.

## CONCLUSION

1. Intraoperative bile and gall stone spillage has very poor correlation with the postoperative surgical site infections.
2. Statistically insignificant differences are there between the two study groups as far as postoperative surgical site infections are concerned.

3. Antibiotics can be very well avoided when it comes to clean surgeries.

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