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EFFICACY OF TOPICAL ANTIBIOTICS FOR PREVENTING PORT SITE INFECTION FOLLOWING DAYCARE LAPAROSCOPIC CHOLECYSTECTOMY

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ABSTRACT

Background: Wound-related complications and infections are seen rarely following daycare laparoscopic cholecystectomy (LC). These complications and infections can have a significant effect on the postoperative course following an uneventful elective laparoscopic cholecystectomy. The use of topical antibiotics over the port site can prevent these complications.

Aim: The present study aimed to assess the efficacy of topical antibiotics for preventing port site infection following daycare laparoscopic cholecystectomy.

Methods: The present study assessed 500 subjects who met the inclusion criteria and underwent laparoscopic cholecystectomy at the Institute within the defined study period. These subjects were randomly divided into topical antibiotic group (n=250) and control group (n=250) subjects. All subjects underwent four-port laparoscopic cholecystectomy. Mupirocin 25 topical antibiotic ointment was applied at all four-port sites in Group I and no topical antibiotic was applied in control group subjects. One dose of prophylactic systemic antibiotic was given to all the subjects from both groups.

Results: The mean of the study subjects was 43.20 ± 12.5 and 43.42 ± 12.3 years in Groups I and II. Among the two groups, the comorbidities and other variables were comparable. The PSI (port site infection) was seen in 2 subjects from Group I and in 6 subjects from Group II that depicted statistically non-significant results with $p=0.624$. The mean time for detection of infection was 4.73 ± 1.5 days. All the infections seen were superficial surgical site infections. The microbiological swab culture of the infected wounds depicted no bacterial growth.

Conclusions: The present study concludes that the incidence of port site infection (PSI) following laparoscopic cholecystectomy was very low. The use of topical antibiotics to prevent port site infections following laparoscopic cholecystectomy could not be established in these subjects.

Keywords: antibiotics, Laparoscopic cholecystectomy, mupirocin, port-site infection, topical antibiotics

INTRODUCTION

LC or laparoscopic cholecystectomy in elective procedures is a clean and contaminated surgery. The incidence rates of PSI (port site infection) following laparoscopic cholecystectomy have been reported to be in the range of 1.4-6.8. PSI

poses a significant adverse effect on the overall outcomes of laparoscopic cholecystectomy as it can lead to increased cost, disfigurement, delayed wound healing, and pain which might decrease the benefit of a minimally invasive approach in that subject. This is considered significant keeping in mind the large number of cholecystectomies done globally including in India.¹

Port-site infections following elective laparoscopic cholecystectomies are not done frequently, however, various complications decrease the benefits associated with laparoscopic cholecystectomies. Port site infections are still prevalent despite various advancements in surgical techniques, prophylactic antibiotics, and fields of sterilization. Port-site infections pose an additional financial burden on both subjects and healthcare sectors affecting cosmetic outcomes and postoperative quality of life in affected subjects.²

Antibiotic prophylaxis plays a vital role in preventing wound infections. The prevention of port-site infection is a better approach compared to its management after the infection has developed which can be proved as frustrating to both the operating surgeon and the subjects. Surgeons advocate routine intravenous antibiotics use in elective laparoscopic cholecystectomy for the prevention of postoperative infections. These antibiotics are given at general anesthesia induction. Topical antibiotics are applied postoperatively as they can prevent surgical site infection.³

Various benefits of using topical antibiotics rather than systemic antibiotics have been reported including ease of administration, reduced cost, low interaction with the intestinal flora, higher local antibiotic concentration with small drug quantity, and low risk of systemic adverse events. Few studies in the literature have assessed the efficacy of using topical antibiotics postoperatively in preventing PSI in subjects undergoing elective laparoscopic cholecystectomy and the results shown were inconsistent.⁴ The present study aimed to assess the efficacy of topical antibiotics for preventing port site infection following daycare laparoscopic cholecystectomy.

MATERIALS AND METHODS

The present prospective randomized controlled clinical study was aimed to assess the efficacy of topical antibiotics for preventing port site infection following daycare laparoscopic cholecystectomy. The study subjects were from the Outpatient Department of Pharmacology of the Institute. Verbal and written informed consent were taken from all the subjects before participation.

The study assessed all the subjects from both genders who underwent laparoscopic cholecystectomy at the Institute within the defined study period and aged 18-80 years. The study includes subjects with ASA (American Society of Anesthesiologists) status I-III. The exclusion criteria for the study were subjects who were not willing to participate in the present study, unwilling to comply with the protocol, subjects on systemic antibiotics for other indications, subjects with empyema and/or acute cholecystitis, bile spillage during gall bladder extraction, gallbladder perforation, intraoperative bile and stone spillage, and subjects on immunosuppressants.

Baseline assessment in all the subjects was done before inclusion and in all the included subjects, age, medical history as comorbidities, recent antibiotic use history, and basic blood investigation as recommended based on ASA grade were recorded. This was followed by an abdominal ultrasonogram in all the subjects to confirm the diagnosis of gallstone disease. LFT (liver function test), particularly, alkaline phosphatase and bilirubin were assessed in all the subjects to rule out any suspicion of bile duct stones.

500 subjects were randomly divided into 2 groups where Group I subjects were given topical antibiotics application at all four port sites and Group II (control) group subjects. In both groups, subjects underwent a standard four-port laparoscopic cholecystectomy with a single prophylactic cefuroxime dose 30 minutes to 1 hour before the incision. Povidone iodine was used for skin preparation in both groups.

All the subjects from Group I were given a single 3ml topical application of 2% mupirocin antibacterial ointment at all four port sites after completion of the procedure and just before the primary dressing. Subjects from Group II were not given any topical antibiotic and primary dressing was applied after surgery completion. Application of 3ml of 2% mupirocin ointment was done to all four port sites on 24, 48, and 72 hours postoperative.

All the included subjects were recalled and assessed postoperatively on days 1, 3, 7, 14, and 28, and wound infections were defined following the criteria of CDC (Centers for Disease Control and Prevention).⁵ Subjects were also advised to report if they noticed signs of infections which were told to them during their discharge. The wound was opened and thorough lavage was done for wound infection. Secondary suturing was then done following standard clinical practice.

Statistical analysis of gathered data was using SPSS (Statistical Package for the Social Sciences) software version 24.0 (IBM Corp., Armonk. NY, USA) for assessment of descriptive measures, Student t-test, ANOVA (analysis of variance),

Fisher's exact test, Mann-Whitney U test, and Chi-square test. The results were expressed as mean and standard deviation and frequency and percentages. The p-value of <0.05 was considered.

RESULTS

The present prospective randomized controlled clinical study was aimed to assess the efficacy of topical antibiotics for preventing port site infection following daycare laparoscopic cholecystectomy. The present study assessed 500 subjects who met the inclusion criteria and underwent laparoscopic cholecystectomy at the Institute within the defined study period. These subjects were randomly divided into topical antibiotic group (n=250) and control group (n=250) subjects.

For demographic and disease characteristics in the study subjects, mean age was statistically comparable in Group I and II with $p=0.871$. Gender distribution in the two groups was comparable statistically with $p=0.552$. The prevalence of various comorbidities such as hypothyroidism, diabetes, cardiac, and no comorbidity was statistically comparable in Group I and control group subjects with $p=0.709$. The distribution of smokers and non-smokers was comparable statistically in Group I and II with $p=0.211$. Gall bladder extraction port was where umbilical and epigastric showed non-significant difference with $p=0.496$ (Table 1).

The study results showed that for comparison of the day of identification and port-site infection in two groups of study subjects, the mean day of identification was 3.0 ± 0 and 5.31 ± 1.51 days in Group I and II which was statistically comparable with $p=0.315$, and port site infection was seen in 0.8% (n=2) subjects from Group I and 2.4% (n=6) subjects from Group II which was statistically comparable in two groups with $p=0.624$ (Table 2).

It was seen that entire port site infections seen in two groups were superficial and were seen at the same port from where the gallbladder was extracted. On examination of the wound swab from the infected area, no microbial growth was seen. In the present study, no subject developed any side effects including contact dermatitis, redness, and itching at the site of application of topical antibiotic.

DISCUSSION

The present study assessed 500 subjects who met the inclusion criteria and underwent laparoscopic cholecystectomy at the Institute within the defined study period. These subjects were randomly divided into topical antibiotic group (n=250) and control group (n=250) subjects. The design of the present study was comparable to the design from the studies of Votik AJ et al⁶ in 2001 and Hamzaoglu et al⁷ in 2004 where the study design adopted by the authors in their studies was comparable to the results of the present study.

Concerning the demographic and disease characteristics of the study subjects, mean age was statistically comparable in Group I and II with $p=0.871$. Gender distribution in the two groups was comparable statistically with $p=0.552$. The prevalence of various comorbidities such as hypothyroidism, diabetes, cardiac, and no comorbidity was statistically comparable in Group I and control group subjects with $p=0.709$. The distribution of smokers and non-smokers was comparable statistically in Group I and II with $p=0.211$. Gall bladder extraction port was where umbilical and epigastric showed non-significant difference with $p=0.496$. These results were consistent with the findings of Neri V et al⁸ in 2008 and Macano C et al⁹ in 2017 where authors assessed subjects with demographic and disease data comparable to the present study in their respective studies.

It was seen that for comparison of the day of identification and port-site infection in two groups of study subjects, the mean day of identification was 3.0 ± 0 and 5.31 ± 1.51 days in Group I and II which was statistically comparable with $p=0.315$, and port site infection was seen in 0.8% (n=2) subjects from Group I and 2.4% (n=6) subjects from Group II which was statistically comparable in two groups with $p=0.624$. These findings were in agreement with the results of Liang B et al¹⁰ in 2016 and Shindholimath VV et al¹¹ in 2003 where the comparison of the day of identification and port-site infection reported by the authors in their studies were comparable to the results of the present study.

The study results showed that entire port site infections seen in two groups were superficial and were seen at the same port from where the gallbladder was extracted. On examination of the wound swab from the infected area, no microbial growth was seen. In the present study, no subject developed any side effects including contact dermatitis, redness, and itching at the site of application of topical antibiotic. These results were in line with the findings of Siddiqui NA et al¹² in 2012 and Colizza S et al¹³ in 2004 where port site infection results similar to the present study were also reported by the authors in their respective studies.

CONCLUSIONS

Considering its limitations, the present study concludes that the incidence of port site infection (PSI) following laparoscopic cholecystectomy was much less. The use of topical antibiotics to prevent port site infections following laparoscopic cholecystectomy could not be established in these subjects.

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S. No	Characteristics	Group I		Group II		p-value
		n	%	n	%	
1.	Mean age (years)	43.20±12.75		43.42±12.53		0.871
2.	Gender					
a)	Males	64	25.6	56	22.4	0.552
b)	Females	186	74.4	194	77.6	
3.	Comorbidities					
a)	Hypothyroidism	2	0.8	4	1.6	0.709
b)	Diabetes	20	8	12	5	
c)	Cardiac	2	0.8	4	1.6	
d)	None	246	98.4	242	96.8	
4.	Smoking					
a)	Smoker	10	4	2	0.8	0.211
b)	Non-smoker	240	96	248	99.2	
5.	Gall bladder extraction port					
a)	Umbilical	0	0	4	1.6	0.496
b)	Epigastric	250	100	246	98.4	

Table 1: Demographic and disease characteristics of study subjects

S. No	Characteristics	Group I		Group II		p-value
		n	%	n	%	
1.	The mean day of identification	3.0±0		5.31±1.51		0.315
2.	PSI n (%)	2	0.8	6	2.4	0.624

Table 2: Comparison of day of identification and port-site infection in two groups of study subjects