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Role of Drain in the Wound for Prevention of Superficial Surgical Site Infection Following Open Choledocholithotomy

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Abstract **Original Research Article**

Background*:** Surgical site infections (SSIs) are still a major problem in surgical practice. Despite the preventive strategies such as antibiotic prophylaxis and anti-septic skin cleansing, the SSI rate remains above 15 % after general abdominal surgery. This complication is also common after open choledocholithotomy. Several studies have shown that wound drainage is beneficial for reducing infection; however, there is a paucity of data regarding its benefit in open choledocholithotomy. ***Objective*:** To assess the effectiveness of placing a drain in the subcutaneous plane in order to reduce superficial SSI after open choledocholithotomy. ***Methods*:** Following convenience sampling, a total of 44 patients who underwent open choledocholithotomy from March 2019 to July 2021 were included in the study. Patients were divided into two groups. A subcutaneous closed suction drain was inserted in 19 patients (group I) and no subcutaneous drain was placed in 25 patients (group II). Daily drain collection was recorded in the case group. All the patients were examined and evaluated postoperatively for detection of wound seromas, superficial SSIs, and wound dehiscence. Data analysis and presentation made by statistical software SPSS 22 windows version 10. ***Results*:** It was observed that 10.5% of patients had SSI in group I and 60.0% in group II. The difference was statistically significant (p=0.001) between the two groups. The mean postoperative hospital stay was 11.58±2.91 days in group I and 15.04±5.78 days in group II. The difference in length of postoperative hospital stay was statistically significant between the two groups. Organisms isolated from bile culture and wound swab culture both are dominated by Escherichia coli. ***Conclusion: The placement of a drain in the wound in open choledocholithotomyshowed a positive impact on the prevention of superficial surgical site infection. It also significantly reduces the length of hospital stay and SSSI rate.

Keywords: Surgical site infection, Open choledocholithotomy, Length of hospital stay.

INTRODUCTION

The incidence of common bile duct stones (CBDS) in patients with symptomatic cholelithiasis varies between 5% and 33%. CBDs are of primary origin within the CBD or of secondary origin in the gallbladder and enter the CBD [1]. Approximately 15% of people with cholelithiasis develop CBDS, smaller stones can be removed by endoscopic retrograde cholangiopancreatography (ERCP) and larger stones require surgery - either open or laparoscopic [2]. A recent article [3] stated that surgical site infection (SSI) is one of the most common complications of abdominal surgery and is associated with significant discomfort, morbidity, and cost. Patients who underwent open surgery were 6.5 times more likely to develop SSI than those who underwent laparoscopic surgery. With the development of technique and skill, laparoscopic common bile duct exploration (LCBDE) has shown great benefits and is being accepted more and more for CBDS treatment. Patients requiring open CBDE had significantly greater complications such as operative blood loss, longer operating time, and longer hospital stay after surgery, and higher infection at a surgical site than those who underwent LCBDE [4]. Surgical site infections (SSIs), including wound infections, are defined as wound infections following surgical procedures. These remain a major problem for patients undergoing procedures despite advances in surgical techniques and medical care. SSIs have been shown to contribute up to 20% of nosocomial infections with an overall incidence of approximately 5% across all invasive surgical procedures [5]. Laparotomy has a higher risk of wound infection and a combined rate of 15% has been reported in upper and lower gastrointestinal surgery, more than three times the average risk [6]. Risk factors significantly associated with SSIs included diabetes, wound classification, pre-operative ASA scores, pre-procedure white blood cell count (WBC), type of surgery, the extent of blood loss, transfusion, duration of operation, risk index, gastrointestinal or urinary catheter use, and postoperative drainage [7, 8] have proposed that the use of closed subcutaneous suction vacuum drainage will result in a statistically significant reduction of wound infection in emergency surgery for perforated peritonitis. The role of drainage in preventing wound infection has been widely debated. Recently, retrospective studies have revealed that multi-channel drains with side slits prevent wound infection in colorectal and liver surgery [9]. There is also a benefit to using drains in high-risk patients, including patients with a contaminated wound. The efficacy of wound drainage in preventing SSSI after open choledocholithotomy has never been studied. This study is designed to evaluate the role of the drain in the wound in preventing SSSI after open choledocholithotomy.

OBJECTIVES

General Objective

- To assess the effectiveness of placing a subcutaneous drain in the wound in order to reduce SSSI after open choledocholithotomy.

Specific Objectives

- To see the incidence of SSSIs in two groups.
- To assess the microbiological profile of Bile and wound swab and its relationship with SSSIs.
- To see the duration of the postoperative hospital, stay in two groups.
- Compare the two groups on the basis of all three outcomes.

MATERIALS & METHODS

This was an observational study was carried out in the Department of General Surgery, Bangabandhu Sheikh Mujib Medical University and Dhaka Medical College and Hospital, Dhaka. The study was conducted from March 2019 to July 2021. Fulfilling the inclusion and exclusion criteria a total of 44 patients of both genders who underwent open choledocholithotomy surgery during the study period in the Department of Surgery, BSMMU, and DMCH were considered as the study population. Among 44 participants 19 were recruited as control group I and 25 as case group II. A convenience sampling technique was followed for sample selection.

Inclusion criteria

- All adult patients who underwent open choledocholithotomy.

Exclusion criteria

- Immunocompromised patients including patients on steroid therapy
- History of recent failed ERCP.
- History of recent cholangitis.
- Hepatic or renal insufficiency

Data were processed and analyzed using computer software SPSS version 23.0. The outcome variable was presented in frequencies and percentages. A hypothesis test was conducted using the chi-squared test.

RESULTS

Total 44 patients who underwent open choledocholithotomy were included in this study, they were divided into two groups. Group I was with subcutaneous closed suction drain included 19 patients and group II was without placement of subcutaneous drain included 25 patients. Our aim is to see the role of the placement of a drain in the prevention of superficial surgical site infection after open choledocholithotomy.

Table-1: Distribution of the study patients by demographic profile (N=44)

Demographic profile	Group I (n=19)		Group II (n=25)		*p-value*
	n	%	n	%	
Age (in years)					
≤30	3	15.8	3	12.0	0.223^{ns}
31-40	6	31.6	4	16.0	
41-50	5	26.3	7	28.0	
>50	5	26.3	11	44.0	
Mean ±SD	43.74±12.78		48.4±12.08		
Range (min-max)	20-70		25-65		

Table 1 showed the distribution of the study patients by age group. It was observed that the highest 31.6% patients belonged to age 31-40 years in group I and the highest 44% patients belonged to >50 years in group II. The mean age was 43.74±12.78 years in group I and 48.4±12.08 years in group II. The difference was statistically not significant (p>0.05 between the two groups.

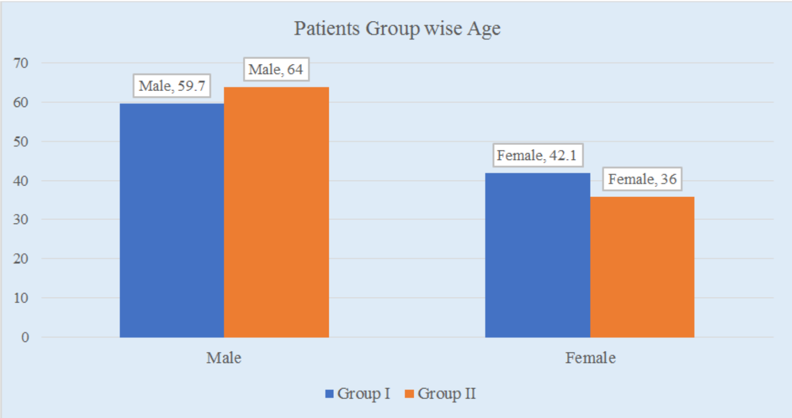


Fig-I: Bar-diagram showing the distribution of the study patients by gender

Among a total of 44 patients, 27 patients were male and 17 patients were female. Figure 1 Bar-diagram showing the distribution of the study patients by gender. It was observed that more than half (57.9%) patients were male and 42.1% of patients were female in group I and more than half (64.0%) patients were male and 36.0% of patients were female in group II. The difference was statistically not significant (p-value is 0.680) between the two groups.

Table-2: Distribution of the study patients by clinical information (N=44)

Clinical information	**Group I (n=19)**		**Group II (n=25)**		***p-value***
	n	**%**	**n**	**%**	
BMI (kg/m2)					
<18.5	0	0.0	1	4.0	$^{a}0.295^{ns}$
18.5-30	15	78.9	20	80.0	
>30	4	21.1	4	16.0	
Mean ±SD	25.24±4.49		26.6±4		
Range (min-max)	18.5-32.5		17.2-33.6		

Table 2 showed the distribution of the study patients by clinical information. It was observed that majority of the patients 78.9% in group I and 80.0% in group II belonged to a BMI of 18.5-30 kg/m^2 which means the nonobese group. Only 21.1% in group I and 16.0% in group II belonged to an obese group of BMI>30. The mean BMI was 25.24±4.49 kg/m^2 in group I and 26.6±4 kg/m^2 in group II. The difference was statistically not significant (p>0.05) between the two groups.

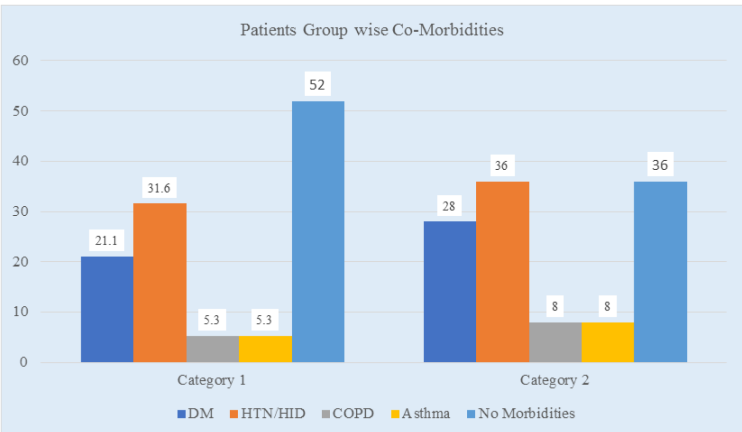


Fig-II: Bar-diagram showing the distribution of the study patients by co-morbidity

Figure II Bar-diagram showing the distribution of the study patients by Co-morbidity. It was observed that 52.6% of patients in group I and 36.0% in group II had no co-morbidity. It was observed that 31.6% of patients had HTN/IHD in group I and 36.0% in group II. 21.1% of patients had DM in group I and 28.0% in group II. The difference was statistically not significant (p-value is 0.894) between the two groups.

Table-3: Distribution of the study patients by investigation findings (N=44)

Investigation findings	**Group I (n=19)**	**Group II (n=25)**	***p-value***
	Mean ±SD	**Mean ±SD**	
TC of WBC(×109/L) Range (min-max)	10.2±4.7 6-26	10.2±3.1 5-16	0.973^{ns}
S. Bilirubin (mg/dl) Range (min-max)	4.3±2.2 0.2-8.1	4.4±2.5 0.6-8.2	0.846^{ns}
SGPT (U/L) Range (min-max)	83.0±50.9 25-211	71.9±34.1 15-135	0.394^{ns}
ALP (U/L) Range (min-max)	334.8±218.5 68-857	305.3±221.2 54-821	0.662^{ns}
S. albumin (gm/dl) Range (min-max)	3.5±0.6 2.5-4.6	3.4±0.5 1.9-4.6	0.549^{ns}
PT (sec) Range (min-max)	13.6±2.3 10-20	14.2±3.3 11.4-27.4	0.502^{ns}
INR (sec) Range (min-max)	1.1±0.2 0.88-1.6	1.2±0.3 0.88-2.28	0.217^{ns}

Table 3 showed the distribution of the study population by their hematological and biochemical investigation findings. The mean total count of WBC was 10.2±4.7 in group I and 10.2±3.1 in group II. The mean S. bilirubin was 4.3±2.2 (mg/dl) in group I and 4.4±2.5 (mg/dl) in group II. The mean SGPT was 83.0±50.9 (U/L) in group I and 71.9±34.1 (U/L) in group II. The mean alkaline phosphatase was 334.8±218.5 (U/L) in group I and 305.3±221.2 (U/L) in group II. The mean S. albumin was 3.5±0.6 (gm/dl) in group I and 3.4±0.5 (gm/dl) in group II. The mean PT was 13.6±2.3 (sec) in group I and 14.2±3.3 (sec) in group II. The mean INR was 1.1±0.2 (sec) in group I and 1.2±0.3 (sec) in group II. The difference was statistically not significant (p>0.05) between the two groups.

Table-4: Distribution of the study patients by per-operative variables (N=44)

Per-operative variables	**Group I (n=19)**		**Group II (n=25)**		***p-value***
	n	**%**	**n**	**%**	
Number of stone					
Single stone	5	26.3	5	20.0	0.621^{ns}
Multiple stones	14	73.7	20	80.0	
Length of operation					
<120 minutes	5	26.3	5	20.0	0.336^{ns}
120-180 minutes	9	47.4	17	68.0	
>180 minutes	5	26.3	3	12.0	
Blood transfusion					
Yes	3	15.8	5	20.0	0.719^{ns}
No	16	84.2	20	80.0	
Condition of liver					
Normal	8	42.1	12	48.0	0.697^{ns}
Congested	11	57.9	13	52.0	

Table 4 showed the distribution of the study patients by per-operative variables. It was observed that almost 73.7% of patients had multiple stones in group I and 80.0% in group II. Almost half (47.4%) patients belonged to the length of operation 120-180 minutes in group I and more than a half (68.0%) in group II. Three (15.8%) patients in group I and five (20.0%) in group II had a per-operative blood transfusion. 57.9% of patients in group I and 52.0% in group II had congested liver. The difference was statistically not significant (p>0.05) between the two groups.

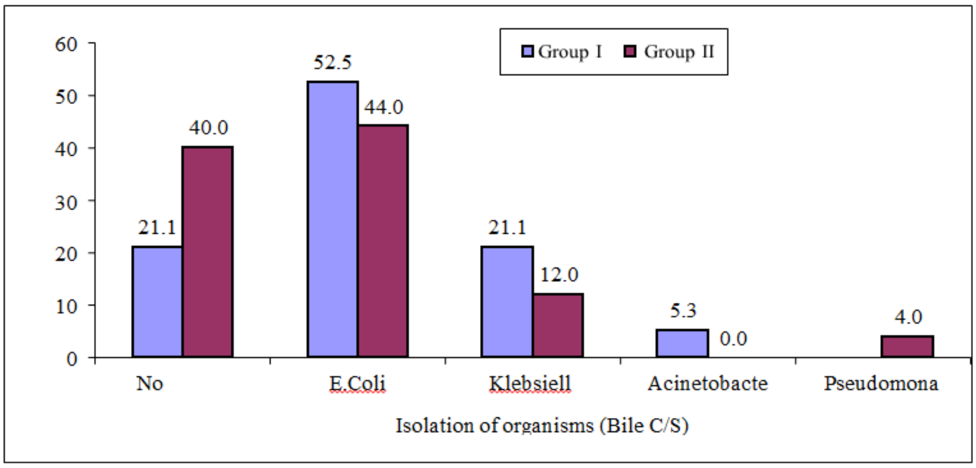


Fig-III: Bar diagram showing the distribution of the study patients by Isolation of organisms from Bile C/S

Figure III Bar-diagram is showing the distribution of the study patients by Isolation of organisms from Bile C/S. In group I, 21.1% of patients did not show any growth of an organism from bile culture, and 78.9% of patients showed growth of organisms. It was observed that in 52.5% cases E. Coli, and in 21.1% cases klebsiella spp. was isolated from bile culture. In group II, 40.0% of patients did not show any growth organism from bile culture and 60.0% patients showed growth of organisms. It was observed that in 44.0% cases E. Coli, and in 12.0% cases klebsiella spp. was isolated from bile culture. The difference was statistically not significant (p-value is 0.404) between the two groups. P-value reached from Chi-square test.

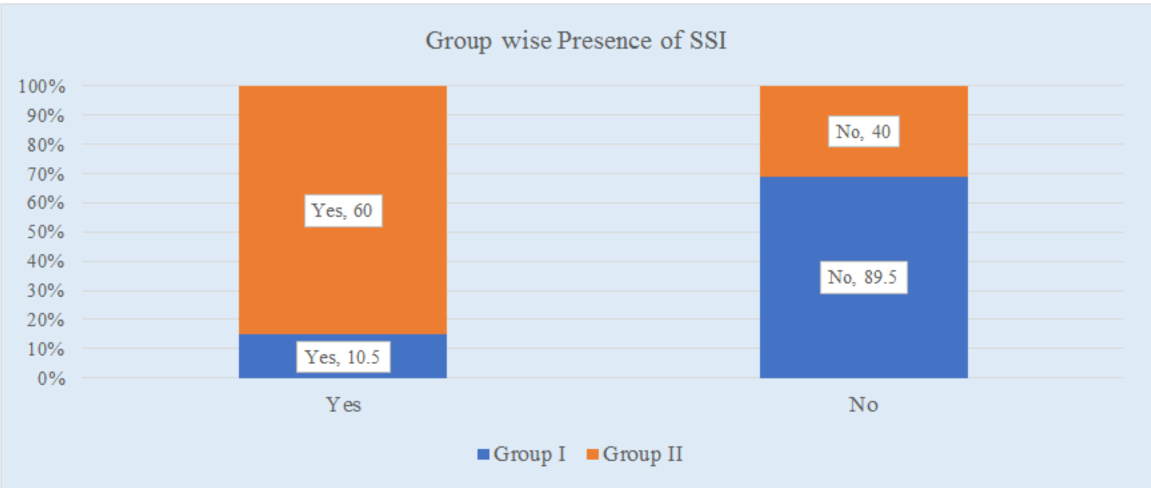


Fig-IV: Bar-diagram showing distribution of the study patients by the presence of SSI

Figure IV Bar-diagram showing the distribution of the study patients by the presence of SSI. It was observed that 2(10.2%) patients had SSI in group I and 15(60.0%) in group II. The difference was statistically significant (p-value is 0.001) between the two groups.

Table-5: Distribution of the study patients by postoperative hospital stay (N=44)

	Group I (n=19)	**Group II (n=25)**	***p-value***
	Mean ±SD	**Mean ±SD**	
Post-operative hospital stays (days)	11.58±2.91	15.04±5.78	0.022^{s}
Range (min-max)	7-17	7-30	

Table 5 showed the mean postoperative hospital stay was 11.58±2.91 days in group I and 15.04±5.78 days in group II which is shown in Table V. The difference in length of postoperative hospital stay was statistically significant (p<0.05) between the two groups.

Table-6: Distribution of the study patients with SSIs, by post-Operative variable (n=17)

	Group I (n=2)		Group II (n=15)		*p-value*
	n	%	n	%	
Isolation of organisms (from wound swab)					
Not done	0	0.0	1	6.7	0.811^{ns}
No growth	0	0.0	1	6.7	
E. Coli	2	100.0	8	53.3	
Klebsiella spp.	0	0.0	4	26.6	
Staphylococcus	0	0.0	1	6.7	

Table 6 showed the distribution of the study patients by post-operative variable. In group II, 6.7% of patients did not show any growth of the organism and in 6.7% of cases wound swab C/S was not done. Two (100.0%) patients had isolation of E. coli from wound swab C/S in group I and 8(53.3%) in group II. It was observed that in 26.7 % of cases klebsiella was isolated from wound swab culture in group II. The difference was statistically not significant (p>0.5) between the two groups.

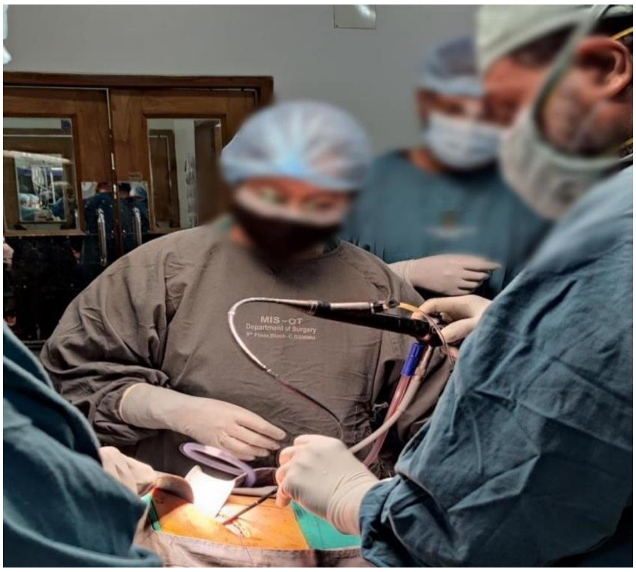
Table-7: Distribution of the study patients by drain collection and drain removal (n=19)

Drain collection (POD-ml)	Mean ±SD	Range (min-max)
1st(ml)	10.2±5.9	3-20
2nd(ml)	7.1±5.1	2-17
3rd(ml)	4.9±3.1	2-12
4th(ml)	4.6±3.0	2-10
5th(ml)	2.7±1.5	2-6
6th(ml)	2.0±0.0	2-2
Total	24.21±18.08	5-67
Drain removal (POD)	5.5±1.3	4-8

Picture-I: Right subcostal incision

Table 8 showed the distribution of the study patients by drain collection. The mean total drain collection was 24.21±18.08 (ml) with a range from 5 to 67 (ml). The mean day of drain removal was 5.5±1.3th post-operative day

Picture-II: Aspiration of Bile from CBD



Picture-III: Evaluation of CBD by choledochoscope

Picture-IV: Negative suction subcutaneous drainage system

DISCUSSION

In our study, a total of 44 patients was included who underwent open choledocholithotomy. 19 patients with subcutaneous closed suction drains were included in group I and 25 patients without any subcutaneous drain were included in group II. The distribution of the study patients by demographic profile showed 31.6% patients belonged to age 31-40 years in group I and 44% patients belonged to >50 years in group II. The mean age was 43.74±12.78 years in group I and 48.4±12.08 years in group II. In a study [10], reported that the mean patient age for disease presentation was 39 years ±11 years which is comparable to our study. In our study, the mean age was 43.74±12.78 years in group I and 48.4±12.08 years in group II. 57.9% of patients were male and 42% of patients were female in group I and 64.0% of patients were male and 36% of patients were female in group II. These two parameters are comparable to our study. [10] identified obesity, thick subcutaneous adipose tissue, long operation time, and being>70 years of age as risk factors for incisional SSI [6,11] also showed that the SSI-positive group had a significantly higher average BMI than the SSI-negative group (P=0.046). In contrast, these parameters are not significantly associated with a higher rate of SSIs in our study. 26.3% in group I and 44.0% in group II are>50 years of age. Only 21% in group I and 16% in group II belonged to the obese group of BMI>30. In our study, 26.3% in group I and 12% in group II required a long operation time (>180 minutes) [8,12] stated in their study that length of surgery, transfusion, diabetes mellitus, smoking history, body mass index, pre-and postoperative albumin level were not significantly associated with the development of SSIs. In our study, the results were also similar. 21.1% of patients had DM in group I and 28.0% in group II. 15.8% of patients in group I and 20.0% in group II had a per-operative blood transfusion. The pre-operative mean S. albumin was 3.5±0.6 (gm/dl) in group I and 3.4±0.5 (gm/dl) in group II. All these parameters were not statistically significant [7]. Found that the elevated level of WBC was an independent risk factor for the development of SSI in patients undergoing a surgical procedure. In our study, the mean total count of WBC was 10.2±4.7 in group I and 10.2±3.1 in group II, which was not statistically significant. In our study, 73.7% of patients in group I and 80.0% in group II had multiple stones, which were not significantly associated with postoperative wound infection. In a prospective cohort study cited by [3], SSIs are associated with higher hospital stay lengths and costs. Our study noted that 2(10.2%) patients in group I and 15 (60.0%) in group II had SSI. The mean postoperative hospital stay was 11.58±2.91 days in the subcutaneous drain group and 15.04±5.78 days in the no subcutaneous drain group. It means that no subcutaneous drain group has a high incidence of SSI and therefore has a long hospital stay. The rate of SSIs was much higher with abdominal surgery than with other types of surgery, with several prospective studies indicating an incidence of 15%-25% depending on the level of contamination. In their prospective cohort study, the overall incidence of SSI was 16.3% (55/337). In our study, the overall incidence of SSI was 36.6% (17/44). which is much higher than the [3] study. In this study, regarding the distribution of the study patients by the presence of SSI, it was observed that 2(10.2%) patients had SSI in group I and 15(60.0%) in group II. The difference was statistically significant between the two groups [8, 12]. Reported that 24% of patients in the drain group develop surgical site infections. 50% of patients in the non-drain group develop the infection. The incidence of infection in the drain group was lower than the no-drain group and was statistically significant. They highlighted the important role of subcutaneous drainage in emergency laparotomy in reducing the incidence of surgical site infection [13]. Conducted a prospective, open and comparative cohort study. The total sample size was 300 patients with 150 in each group. SSI was present in 15.3% of cases and 30% of controls and the difference was statistically significant (p value=0.002). The results show that the use of negative suction drain in the subcutaneous plane during laparotomy for class III wounds reduces the incidence of postoperative surgical site infection, seroma formation, and wound dehiscence [11]. Performed an RCT to evaluate the clinical benefits of using a subcutaneous closed suction Blake drain in patients undergoing colorectal surgery. The incidence of incisional SSIs rate was 12.8 % in the control arm and 4.5 % in the subcutaneous drainage arm. A meta-analysis conducted by [14] compared drained with undrained surgeries featuring gastrointestinal (GI) tract opening. A total of 8 studies, including 2833 patients, were considered eligible to collect the data necessary. The use of subcutaneous suction drains did not exhibit any significant differences between drained and undrained patients in developing SSI (odds ratio 0.76, 95% CI 0.56-1.02; p=0.07). In this study, they did not encourage the use of subcutaneous drains on a routine basis. It was not possible to meta-analyze data about SSI for the type of surgical procedures because of a lack of detailed parting within the individual studies. In our study, we only included the patients who underwent open choledocholithotomy and we have found subcutaneous drain useful in preventing SSIs. A review article by [5] showed, in three trials there is a significant reduction in surgical site infections in the drainage group. They draw a conclusion that using subcutaneous wound drainage after laparotomy in all patients is unnecessary as it does not reduce SSI risk. There may be benefits in using drains in patients who are at high risk, including patients who are obese and/or have contaminated wound types [8]. Have conducted a randomized controlled study to determine the role of a subcutaneous closed vacuum drain in the prevention of surgical site infection in emergency surgery for perforated peritonitis. They found that the use of a subcutaneous closed suction vacuum drain results in a statistically significant reduction in wound infection (58% vs. 16%; p <0.001). The most common organism causing SSI was found to be Escherichia Coli accounting for 62.5% of cases in the drain group and 62.7% of cases in the control group, followed by Klebsiella 24.14% of cases in the control group. In our study, 100.0% of patients had isolation of E. coli from wound swab in the drain group and 53.3% in the ND group. 26.7 % of cases klebsiella was isolated from wound swabs in the control group. These findings are comparable to the study by [8]. In our study, regarding the distribution of the study patients by isolation of organisms (Bile C/S), it was observed that more than half (52.5%) patients had isolation of (Bile C/S) E. coli in group I and 11(44.0%) in group II. The difference was statistically not significant (p>0.05) between the two groups [15]. Reported that the most common pathogens in biliary infection are Gram-negative anaerobes, dominated by Escherichia coli, Klebsiella spp, Acinetobacter, baumannii complex, and Enterobacter spp. The average total drain collection in group I was 24.21 ± 18.08 (ml) with a range from 5 to 67 (ml). This amount of fluid must accumulate in the subcutaneous plane in group II. [13] showed that inserting subcutaneous suction drainage at the end of the operation could effectively drain the wound collections and wound seroma, thereby preventing SSSIs and wound dehiscence.

Limitations of the study

The sample size was small. The sampling method was not random. Operations were performed by different surgeon groups at different institutions.

CONCLUSION & RECOMMENDATION

The placement of a drain in the wound in open choledocholithotomy showed a positive impact in the prevention of superficial surgical site infection. It also significantly reduces the length of hospital stay and SSSI rate. Subcutaneous drain is useful in the prevention of SSIs after open choledocholithotomy. But before recommending it for routine use further studies of a larger scale and more rigorous design are warranted.

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