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Use of Prevena Incision Management System for the Prevention of Surgical Site Infection in Hepatopancreatobiliary Patients

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Abstract

Background: Closed incision negative pressure therapy has been shown to be effective in the prevention of surgical site infection across many surgical disciplines. This study aims to evaluate whether negative pressure wound therapy reduces risks of surgical site infection in hepatopancreatobiliary patients.

Methods: This is a retrospective cohort study of 70 patients who underwent hepatopancreatobiliary surgery at a single tertiary care institution from 1 January 2020 to 13 June 2022. Univariate and multivariable logistic analyses were performed to assess the association between surgical site infection and type of wound dressing (Prevena *vs* standard dressing) with baseline demographics, clinical variables. Statistical significance was set at $p \leq 0.05$.

Results: In our multivariable analysis of 70, patients with Prevena had a lower risk of surgical site infection [odds ratio (OR)=0.03, 95% confidence interval (CI)=0.001-0.57, p=0.020)]. Patients with operation duration greater than 8 hours had a higher risk of surgical site infection [odds ratio (OR)=7.63, 95% confidence interval (CI)=1.62-35.71, p=0.010)] after adjusting for baseline demographics and clinical variables.

Conclusion: The use of Prevena negative pressure dressing was associated with a significant decrease in the risk of surgical site infection in hepatopancreatobiliary patients. This therapy is promising in the prevention of surgical site infection and serves as a tool to mitigate the effects of long surgery in hepatopancreatobiliary patients.

Keywords: Closed incision negative pressure therapy; Prevena; Surgical site infection; Quality improvement; Hepatopancreatobiliary surgery

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Introduction

Surgical site infection (SSI) is a healthcare burden across all surgical disciplines in terms of morbidity, mortality and increased financial cost [1]. In patients who underwent hepatopancreatobiliary surgeries such as hepatectomies, the incidence of SSI can range from 20% to as high as 40% [2]. This may be attributable to the long operative duration, and large surgical incision in majority of hepatopancreatobiliary surgeries [3,4].

A review of literature reveals that up to 60% of SSI, which is an iatrogenic infection, are preventable [2]. Hence, there has been great interest in preventive measures such as Prevena incision management system for the prevention of SSIs. Closed incision negative pressure therapy has been shown to be effective in the prevention of surgical site wound morbidity across many surgical disciplines [5-8]. Prevena is a wound management system that applies continuous negative pressure over a closed surgical incision. It promotes better wound healing by maintaining wound apposition, removing exudates and fluids from the wound, promoting perfusion in the area and preventing external contamination [6,9].

In a randomized controlled trial by O'Leary et al., the use of negative pressure therapy was associated with significant reduction in SSI from 32% to 8.3% [10]. This is similarly echoed in other literature including a meta-analysis [8,11]. Yet, studies involving the use of Prevena incision management system in the prevention of SSI in hepatopancreatobiliary surgery patients have been scarce. This study aims to evaluate whether Prevena incision management system reduces the risk of surgical site infection in hepatopancreatobiliary patients as compared to conventional wound

dressing.

Methods

Study design

This is a retrospective cohort study of patients who underwent hepatopancreatobiliary surgery at Ng Teng Fong General Hospital between 1 January 2020 to 13 June 2022. This study included patients who underwent hepatopancreatobiliary surgery and had either Prevena incisional management system or standard surgical dressings. The decision to employ Prevena incisional management system was at the discretion of the primary surgeon.

The study population consisted of 70 patients. This study conforms to the Strengthening the Reporting and Observational studies in Epidemiology (STROBE) guidelines. The study was approved by the ethics committee, centralized institutional review board (DSRB reference number 2022/00526).

Data collection

Data of the baseline demographics, clinical variables, operative characteristics, and postoperative outcomes were obtained from electronic medical records. Surgical site infection is defined based on the Centre of Disease Control (CDC) classification [12]. SSI is divided into three categories; superficial incisional, deep incisional and organ space SSI. Superficial SSIs involve the skin and subcutaneous tissues while deep SSIs involve deep soft tissues such the fascial and muscle layers. Together they can be grouped as incisional surgical site infections (iSSI). Organ / space SSI involves any part of the body deeper than the fascial/muscle layers that is opened or manipulated during the operative procedure (e.g. anastomotic leak). Operative duration of more than 8 hours has been shown to be associated with an increased risk of surgical site infection and wound morbidity [3]. The primary outcome was the assessment of surgical site infection within 30 days of surgery. The secondary outcomes were wound morbidity (wound dehiscence, seroma and haematoma formation), intercurrent illness and adverse outcomes (mortality, reoperation / procedures, unplanned admissions).

Surgical procedure

All patients received the same preoperative care and same surgical preparation – intraoperative skin shaving, skin antisepsis with hexodane 2%, and intravenous prophylactic antibiotics (1g rocephin and 500mg metronidazole).

Intraoperatively, surgical incisions employed included a reversed L-shaped, roof top, kocher incision, or midline laparotomy. For closure of the abdominal fascia, re-absorbable suture material [i.e. looped PDS (polydioxanone) suture] was used to close the anterior and posterior abdominal sheaths in layers. Skin apposition was achieved using skin staples. Subsequently, either Prevena or standard surgical dressing was used postoperatively. Prevena was applied under a sterile environment to the surgical wound in the operating theater and set at a pressure of 125 mm Hg [13].

Figure 1 illustrates the steps involved in the application of Prevena. Firstly, tension free and good skin apposition was achieved with skin staples. Secondly, the Prevena foam dressing was cut to cover the entire length of the surgical incision. Subsequently, the vacuum assisted closure adhesive sheet was draped across the foam while encompassing the surgical drain and applied onto the surrounding skin. Tegaderm was applied in a circumferential manner at the exit site of the surgical drain as this area was prone to loss of suction. Similarly, the sites with pain busters were covered with tegaderm. Finally, when the system was connected, negative pressure was applied to the wound at 125 mm Hg continuous mode [14].

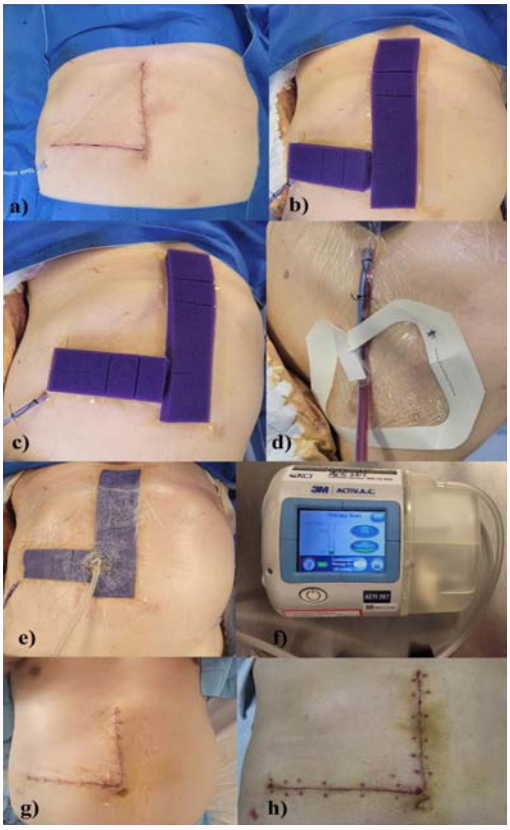

Figure 1: Application of incisional Prevena management system and postoperative outcome.
a. Skin closure with staples. b. Application of Prevena foam dressing on the surgical incision (top-down view). c. Application of Prevena foam dressing on the surgical incision (side view). d. Application of tegaderm circumferentially around the surgical drain to achieve good suction. e. Adhesive sheets are applied to the surrounding skin to fix the device. f. When the system is connected, the negative pressure is applied to the wound at 125 mm Hg. g. Wound of a patient with Prevena at 5 days after surgery. h. Wound of a patient with Prevena at 11 days postoperatively after removal of staples.

Postoperatively, Prevena was removed most commonly at 5 days after surgery to evaluate the status of the surgical wound or earlier if there were any concerns of SSI.

Statistical analysis

Data analyses were performed using IBM SPSS version 21 (SPSS Inc.; Chicago, IL, USA). Baseline demographics, clinical variables, operative characteristics and postoperative outcomes were reported as mean and standard deviation for continuous variables and frequency (percent) for categorical variables. Analysis of variance tests were conducted to investigate the significance of baseline demographics, clinical variables, operative characteristics, and postoperative outcomes based on the type of wound dressing (Prevena *vs* standard dressing). Independent T-test was used for normally distributed continuous measure whereas Chi-square test or Fisher's exact test were used for categorical factors. The associations between the presence of surgical site infection and demographic and clinical variables were tested using univariate and multivariable logistic regression analyses [2-8,10,11]. Statistical significance was set at $p \leq 0.05$.

Results

Table 1 summarizes the preoperative and demographic characteristics of patients. In this study of 70 patients, there were 60% of male gender and an average age of 64±11 years. Majority of the cohort were non-smokers (74%), and healthy weight individuals (91%). In these patients, 44% had diabetes mellitus, 57% had hyperlipidaemia, 60% had hypertension, 14% had chronic kidney disease, 19% had metastatic malignancy, 30% had previous abdominal surgery, and 11% had undergone chemotherapy before. There was no significant difference in the preoperative hemoglobin 11.8±2.1 g/dL (p=0.661), albumin 36±6 g/dL (p=0.749) and HbA1C≥7 (p=0.258). Overall, there was no significant difference in the demographics or clinical variables of the Prevena negative pressure wound therapy group and the standard dressing control study group (p>0.05) except for BMI≥30 (p<0.001) and hyperlipidemia (p=0.023).

Table 2 presents the operative characteristics for the Prevena group and standard dressing control study group. All surgeries were performed under general anesthesia with 90% being elective surgeries. The mean operative duration was 402±156 minutes, and 33% of the surgeries lasted more than 8 hours. The most common operative procedure included 41% with Whipple's procedure, and 29% with hepatectomy. The most common diagnosis was 26% with pancreatic cancer. On average, Prevena negative pressure wound therapy was applied for 5±1 days. Between the Prevena group and the standard dressing control group, there was no significant difference in the operative time (p=0.127) and operative procedure (p=0.314).

Table 3 presents the operative outcomes for the Prevena group and standard dressing control study group. Regardless of the type of dressings used, patients stayed in the intensive care/high dependency unit for post operative monitoring for an average of 3 days. The mean duration of hospitalization was shorter for the Prevena negative pressure wound therapy group as compared to the standard dressing control study group (11 days *vs* 14 days). Notably, patients who received standard surgical dressings developed both deep SSI (2%) and organ space SSI (17%), while patients on prevena did not. In addition, patients who received Prevena negative pressure wound therapy had a lower prevalence of superficial SSI (10%) as compared to patients who received standard dressing (26%). Furthermore, 39% of patients who received standard dressing developed wound dehiscence, which was almost double the prevalence as compared to patients who received Prevena (20%). In addition, patients on Prevena, did not develop any seroma or haematoma. In the Prevena group, there was one unplanned readmission that was unrelated to SSI. Moreover, the patients on Prevena did not have any mortality or reoperations / procedures. On average, adverse wound outcomes were diagnosed after 9 days and 12 days in the Prevena group and standard dressing control study group respectively. The prevalence of intercurrent illness was also similar between the Prevena group and standard dressing control study group (17% *vs* 20%). The use of Prevena negative pressure wound therapy was also associated with a significant reduction in surgical site infection (p=0.036) and in any adverse outcomes (p=0.037).

Figure 1 illustrates the steps for application of Prevena and the postoperative outcome.

Table 4 shows the univariate and multivariate analysis for surgical

Table 1: Preoperative and demographic characteristics of patients.

Variables	All	Prevena	Standard dressing	*P*-value
	***N* = 70**	***N* = 10**	***N* = 60**	
Age (year), mean (SD)	64 (11)	69 (13)	64 (11)	0.201
Male gender, *n* (%)	60	60	60	1
Smoker, *n* (%)	26	20	27	0.655
BMI ≥ 30 kg m^{-2}, *n* (%)	9	40	3	<0.001
Comorbidities, *n* (%)				
Diabetes Mellitus	44	50	43	0.694
Hyperlipidemia	57	90	52	0.023
Hypertension	60	70	58	0.486
Chronic kidney disease	14	20	13	0.577
Metastatic cancer	19	10	20	0.452
Previous abdominal surgery, *n* (%)	30	40	28	0.456
Hemoglobin (g/dL)	11.8	12.1 (2.7)	11.8 (2.0)	0.661
	-2.1			
Albumin (g/dL)	36 (5)	36 (6)	36 (5)	0.794
HbA1c ≥ 7(%)	34	50	32	0.258
Chemotherapy, *n* (%)	11	10	12	0.878
Preoperative sepsis, *n* (%)	13	30	10	0.08
ASA Class, *n* (%)				0.745
1	3	0	3	
2	42	40	42	
3	51	50	52	
4	4	10	3	

Table 2: Operative characteristics.

Variables	All	Prevena	Standard dressing	*P*-value
	N = 70	*N* = 10	*N* = 60	
Elective operation, *n* (%)	90	90	90	1
Operative time >8 hours (%)	33	20	35	0.35
Mean operative duration (min), *n (SD)*	402	329 (183)	415	0.127
	-156		-149	
General anesthesia, *n* (%)	100	100	100	1
Operative procedure, *n* (%)				0.314
Whipple's procedure	41	41	30	43
Hepatectomy	29	29	40	27
Radical cholecystectomy	7	7	20	5
Open cholecystectomy +/- common bile duct exploration	14	14	10	15
Pancreatectomy and splenectomy	9	9	0	10
Diagnosis, *n (%)*				0.536
Acute necrotising pancreatitis with perforation	1	0	2	
Pancreatic Cancer	26	20	26	
Periampullary/ampullary Cancer	6	10	5	
Cholangitis	5	10	3	
Hepatocellular carcinoma	7	20	5	
Gallbladder carcinoma	7	20	5	
Choledocholithiasis	3	10	2	
Hepatic metastasis from colorectal cancer	14	10	15	
Cholangiocarcinoma	1	0	2	
Mirizzi syndrome	1	0	2	
Acute/ Chronic cholecystitis	6	0	7	
Pancreatic cyst	10	0	11	
Trauma related	7	0	8	
Hepatic cyst	5	0	5	
Duodenal cancer	1	0	2	
Duration of Prevena application (days), n(%)		5 (1)		
Intercurrent illness, n(%)	17	20	17	

site infections. In our univariable analysis, patients with Prevena incision management system had a lower risk of surgical site infection [odds ratio (OR)=0.03, 95% confidence interval (CI)=0.001-0.57, *p*=0.020)]. Patients with operation duration greater than 8 hours had a higher risk of surgical site infection [odds ratio (OR)=7.64, 95% confidence interval (CI)=1.62-35.96, *p*=0.010)].

In our multivariable analysis, patients with Prevena incision management system had a lower risk of surgical site infection [odds ratio (OR)=0.03, 95% confidence interval (CI)=0.001-0.57, *p*=0.020)]. Patients with operation duration greater than 8 hours had a higher risk of surgical site infection [odds ratio (OR)=7.63, 95% confidence interval (CI)=1.62-35.71, *p*=0.010)] after adjusting for baseline demographics and clinical variables.

Discussion

In summary, patients who received Prevena incision management system had a lower risk of developing SSI. In particular, patients who received Prevena negative pressure wound therapy did not develop any deep or organ SSI as compared to patients who received standard dressing where 2% developed deep SSI and 17% had organ SSI. In addition, patients who received Prevena negative pressure wound therapy had a lower prevalence of superficial SSI (10%) as compared to patients who received standard dressing (26%). Furthermore, 39% of patients who received standard dressing developed wound dehiscence, which was almost double the prevalence as compared to patients who received Prevena (20%). Furthermore, patients on Prevena negative pressure wound therapy did not develop any seroma or haematoma. In the Prevena group, there was one unplanned readmission that was unrelated to SSI. Moreover, the patients on Prevena negative pressure wound therapy did not have any mortality or reoperations / procedures. In addition, patients with operation duration greater than 8 hours had a higher risk of SSI.

In a study conducted by Yu Liu et al., it is proposed that negative pressure wound therapy enhances wound healing through the regulation of angiogenesis and thus promotes wound granulation [9]. In a randomized controlled trial by Jose et al., it has additionally been proposed that negative pressure wound therapy works through exudative control and improves microvascular perfusion by removing

Table 3: Postoperative outcomes.

Variables	All	Prevena	Standard dressing	*P*-value
	N = 70	*N* = 10	*N* = 60	
Length of ICU/HD stay (days), *n* (SD)	3 (6)	4 (3)	3 (6)	0.926
Length of hospital stay (days), *n* (SD)	14 (13)	11 (6)	14 (13)	0.46
Surgical site infection, *n* (%)				0.036
Superficial	24	10	26	0.655
Deep	1	0	2	0.143
Organ space	14	0	17	0.137
Wound morbidity				0.193
Wound dehiscence, *n* (%)	36	20	39	0.248
Seroma formation, *n* (%)	6	0	7	0.4
Hematoma formation, *n* (%)	3	0	3	0.558
Time to diagnosis of SSI/wound morbidity (days), *n* (SD)	12 (10)	9 (2)	12 (10)	0.074
Intercurrent illness	17	20	17	0.796
Adverse outcome, *n* (%)				0.037
Mortality	23	0	27	0.06
Reoperation / procedures	11	0	13	0.22
Unplanned readmission (related)	11	10	13	0.326

Table 4: Univariate and multivariate analysis for surgical site infection.

Variables	Univariate		Multivariate	*P*-value
	OR (95% CI)	*P*-value	OR (95% CI)	
Age (year)	1	0.957	1.01 (0.94-1.07)	0.957
	(0.93-1.07)			
Male gender	1.44	0.617	0.7	0.617
	(0.35-5.97)		(0.17-2.89)	
Smoker	0.89	0.899	0.90 (0.19-6.51)	1.12
	(0.15-5.18)			
BMI ≥ 30 kg m^{-2}	0.08	0.186	12.52	0.186
	(0.002-3.39)		(0.30-531)	
Previous abdominal surgery	0.26	0.097	3.91	0.097
	(0.05-1.28)		(0.78-19.57)	
Diabetes mellitus	1.01	0.992	0.99	0.992
	(0.25-4.00)		(0.25-3.94)	
Hyperlipidemia	0.63	0.579	1.60 (0.31-8.33)	0.579
	(0.12-3.27)			
Hypertension	0.12	0.027	0.12 (0.02-0.79)	0.027
	(0.04-1.08)			
Chronic kidney disease	0.35	0.296	2.89	0.296
	(0.05-2.53)		(0.40-21.22)	
Metastatic malignancy	2.7	0.464	0.37 (0.03-5.29)	0.464
	(0.19-38.48)			
Chemotherapy	10.1	0.245	0.10 (0.002-4.89)	0.245
	(0.20-499.63)			
Preoperative sepsis	0.48	0.442	2.09	0.442
	(0.07-3.12)		(0.32-13.60)	
Intercurrent illness postoperatively	0.07	0.155	6.46 (0.86-48.47)	0.07
	(0.02-1.16)			

Type of wound dressing (Prevena vs standard dressing)	0.03	0.02	0.03 (0.001-0.57)	0.02
	(0.001-0.57)			
Operation duration > 8hours	7.63	0.01	7.64 (1.62-35.96)	0.01
	(1.62-35.71)			

OR: Odds Ratio; CI: Confidence Interval

fluid across wound edges. This is associated with decreased tension at the surgical wound site, which would in turn reduce the rates of seroma and haematoma formation. As such, this mechanism helps to reduce the rate of infection and dehiscence [6]. This is in good corroboration with a review by Bovill E et al., which suggested that negative pressure wound therapy decreases the accumulation of inflammatory mediates through clearance of exudates [15]. In a prospective study conducted by Cantero et al, it was shown that negative pressure wound therapy may prevent SSI in dirty wounds such as those patients who had ileostomy closure. This works by improved vascularity, augmenting wound granulation and exudative control [16].

The findings of this study that the use of Prevena negative pressure wound therapy reduces the risks of SSI is in good corroboration with published literature. In a meta-analysis of 9 studies by Sahebally et al., the use of negative pressure wound therapy significantly reduced the risks of SSI compared with standard dressing with odds ratio of 0.25. This result is firmly supported in 8 studies which is in good agreement with the findings of our study [11]. Similar to this study, Sahebally et al. also concluded that there was no association between the use of negative pressure wound therapy and the reduction of seroma formation or wound dehiscence [11]. In another meta-analysis of 16 studies by Strugala et al. evaluating the benefit of PICO negative pressure wound therapy, there was a significant decrease in SSI from 12.5% to 5.2.%, (RR 0.43 [95% CI 0.32-0.57] $p<0.0001$), a significant reduction in wound dehiscence (RR 0.71 [95% CI 0.54-0.92] $p<0.01$), and length of hospitalization (-0.47 days [95% CI -0.71 to -0.23] $p<0.0001$) [17]. In a retrospective case control study of patients who underwent laparotomy for colorectal disease by Curran et al., the use of negative pressure wound therapy was shown to be significant in reducing the incidence of SSI from 15% to 7% [7]. In this study, patients received an average of 5±1days of Prevena postoperatively, which was associated with a decreased risk of SSI. This corroborates with a prospective study by Pleger et al. which reported that the duration of Prevena application has been shown to be effective in the first 7 days ($p<0.0005$) in decreasing the risk of SSI [18].

Contrary to conventional belief that Prevena is an expensive wound therapy, based on economic studies, the decreased rates of SSI in patients with Prevena would entail decreased healthcare costs and improved quality of life. Whilst the absolute cost of negative pressure wound therapy is up to 6 times greater than that of standard dressing, the total treatment costs would still be lower for the patients with negative pressure wound therapy. This is attributable to decreased rates of SSI and requirement for dressing change [19,20]. In a randomized controlled trial by Bueno-Lledó et al., it was shown that patients with negative pressure wound therapy had a shorter duration of hospitalization [6,21,22]. This was similarly reported in this study where the mean duration of hospitalization was 11 days for the Prevena group as compared to 14 days for the standard dressing control study group.

The learning curve for negative pressure wound therapy application is minimal so it can be applied easily by anyone with almost minimal training. Patients and family can continue to use negative pressure wound therapy at home or in the outpatient setting. This therapy is also discontinued easily as it will turn off automatically after 7 days, and this thereby minimises the healthcare burden [5].

The strengths of this study include its novelty in being one of the first few to be performed in hepatopancreatobiliary surgery patients. The results of this study corroborate with that of several large cohort studies including randomized controlled trials and meta-analyses. Logistic regression was performed to account for confounding factors. This study can be used as a stepping stone to elucidate the utility of Prevena incision management system as a beneficial preventive tool for surgical site infection in hepatopancreatobiliary patients.

Limitations of this retrospective study are that a temporal relationship is frequently difficult to assess, and the follow-up period could not be strictly controlled unlike in a prospective study. Knowledge of the baseline clinical characteristics was gathered from the Ng Teng Fong General hospital database and electronic medical records.

There was a lack of blinding of participants as this is a retrospective and nonrandomized study. The knowledge of group assignment can potentially result in assessment bias as there is room for unintentional subjective reporting. To minimize the risk of observation bias and subjective appraisal during wound assessment, the data collected was cross referenced between two independent assessors with reference to the CDC definition of SSI before the data was finalized.

The small population size of the study would affect the generalisability of the results as it may lead to higher variability and cognitive bias. There were only 10 patients from the study placed on Prevena negative pressure wound therapy. Of note, 20% of these patients had wound dehiscence. Taking into account the limited empirical evidence, this percentage may be an overstatement of the true numbers of wound dehiscence in the Prevena study group. Furthermore, the small sample of patients who underwent open hepatopancreatobiliary surgery in Ng Teng Fong General Hospital is not representative of the overall population worldwide.

Despite the limitations of this study, this pilot study would provide an initial foray to enhance the understanding of the use of Prevena dressing in the reduction of SSI. Based on this study, Prevena has been proven to be a potentially beneficial preventive tool for SSI in hepatopancreatobiliary patients. This study remains valuable as more prospective studies and randomized controlled trials can potentially build upon our initial study design, and further evaluate the use of Prevena in the prevention of SSI and wound morbidity in both hepatopancreatobiliary patients as well other surgical disciplines.

Conclusion

In conclusion, this study has shown that the use of Prevena incision management system is associated with a decreased risk of SSI in hepatopancreatobiliary surgery patients. This group of patients did not develop any organ or deep SSI, wound site morbidity

such as seroma or hematoma formation. In addition, there was a lower prevalence of wound dehiscence, and no requirement for any reoperations or procedures. The use of Prevena incisional management system serves to be promising in the prevention of SSI, wound morbidity, and to mitigate the effects of long surgery in hepatopancreatobiliary patients. More studies such as randomized controlled trials could be performed prospectively to elucidate the utility of Prevena incision management system as a beneficial preventive tool for surgical site infection.

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TXY, HSY, and TYX conceived the idea of the study and developed the protocol. TXY, HSY, and MDA conducted the research study and synthesized the data. TXY wrote the first draft of the paper. HSY and TYX critically revised successive drafts of the paper and approved the final version. TYX supervised the overall work and is the guarantor of the study.

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