The Effects of Wound Protector to Decrease the Incisional Surgical Site Infection in Open Abdominal Surgery, Double-Blind Prospective Randomized Controlled Trial

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ABSTRACT

Background: Surgical site infection (SSI) is the most common cause of postoperative morbidity after laparotomy. Many independent factors show to increase risk of SSI. Prevention of SSI is very important especially intraoperative period.

Methods: Patients undergoing a standard midline laparotomy were prospectively randomized to use or not use a wound protector between September 2016 and January 2018. The 128 patients were eligible for the study. Preoperative and perioperative data, those can be risk factors for SSI, incidence of the SSI in each group were collected for analysis.

Results: Wound protector was used in 64 patients (WP group) and not used in 64 patients (Non-WP group). All demographic data and surgical variability of the 2 groups are no significantly difference. A patient in non-WP group dead from non-SSI related condition. Three patients (1 patient from non-WP and 2 patients from WP group) undergone re-operation before 30 days without any wound complication. Incisional surgical site infection had significantly higher incidence in Non-WP group than WP group (35.5% vs 12.9%, P-value 0.006). Multivariate analysis revealed that placement of a wound protector could decrease the incidence of I-SSI (odds ratios [OR] 0.269, 95% confidence interval [CI] 0.109-0.667). Many specific conditions that wound protector could prevent the I-SSI were found.

Conclusion: Using wound protector placement is effective for decreasing the incidence of incisional surgical site infection in the major laparotomy operation.

Key word: intra-abdominal operation, laparotomy, surgical site infection, wound protector, wound retractor

INTRODUCTION

Surgical site infection is among leading postoperative morbidity after laparotomy especially one involves colonic resection. Untreated or mismanaged of SSI could lead to serious complications such as sepsis or septic shock. It also increase the length of hospital stay, increase costs as well as decrease patient and family mentality (1,2).

CDC classified SSI into two categories, incisional surgical site infection (I-SSI) and organ/space surgical site infection. The incisional type was further separated by the depth of infection into superficial and deep incisional surgical site

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infection. Superficial incisional surgical site infection does not involve abdominal wall deeper than subcutaneous while the deep incisional counterpart involves anything deeper to that. Organ/space SSI includes intra-abdominal infection (3).

Several previous studies have predicated various independent risk factors that are associated with the I-SSI after the intra-abdominal operation. For instances, gender, history of smoking, the American Society of Anesthesia (ASA) score, body mass index (BMI), wound classification, surgical skin preparation, prophylactic antibiotics, operative time, ostomy creation, drainage placement, blood transfusion (4-9). The relationship between preoperative serum albumin level and I-SSI are still controversy (9,10). A traditional research proposed that the incidence rate of the I-SSI difference depends on the wound classification. The estimated postoperative rates of surgical site infections is 1-5% for clean wound, 3-11% for clean contaminated wound, 10-17% for contaminated wound, and > 27% for dirty wound (11). There are recent researches providing the rate of the I-SSI in each classification of the wound. Incidence of the I-SSI in clean and clean contaminated wound are in the same range with previous studies, but in contaminated and dirty wound are lower (8.61% and 11.80% respectively) (12).

Prevention of the I-SSI is important especially in perioperative period. The objective of this study is to assess the effect of the wound protector to prevent the I-SSI and to find the factors those increase the efficacy of the wound protector.

METHODS

Participants

There were 142 patients at Police General Hospital underwent non-traumatic, major laparotomy operation during September 2016 to January 2018; appendectomy, rectal and liver surgery cases were not included. Subjects eligible for participation were adult (age 18-80 years old) patients who underwent non-traumatic major laparotomy surgery. The exclusion criteria were as follows: pregnancy, autoimmune disease, received chemotherapy or any immunosuppressive agents, HIV infection, any organ transplantation, previous abdominal radiation, American Society of Anesthesiologists physical status classification (ASA) more than 3, and primary closure of the abdomen cannot be done.

This study was a randomized controlled trials to evaluate the effects of Double-O-ring wound protector

to prevent the surgical site infection. Patients were consecutively assigned to each treatment group according to a computer-generated randomization list. The allocation ratio was 1:1 with the block size of 4. The intervention assignments were stored in sealed opaque brown envelopes.

Informed consent was obtained from all participants. This protocol was approved by the ethics committee of Police General Hospital and registered at Thai Clinical Trial Registry (TCTR20180508002).

Intervention

All patients received prophylactic antibiotics as 2 g Ceftriaxone and 500 mg Metronidazole (400 mg Ciprofloxacin was used instead of Ceftriaxone in penicillin allergy), the repeated dose was given if the operation extended more than 4 hours. Two doses of bowel preparation with Sodium picosulfate were given to the patient at 2 and 6 pm on the day before elective colonic surgery. Skin preparation was performed using providone iodine surgical scrub. Envelope randomization was opened after intraperitoneal cavity had approached. In the wound protector group, double-O-ring wound protector was inserted immediately. Size of the wound protector was related to the incision length.

Primary closure of the surgical wound was done in every patients. Polyglactin or polyglyconate absorbable suture was used to approximate the muscular-aponeurotic plane. Subcutaneous fat and skin were irrigated with sterile normal saline solution. The skin incision was approximated by suture or stapler. The decision to insert a drainage was made by the operating surgeon. All operations were performed by the skilled surgeons in each subspecialty.

Postoperative pain control includes narcotic agent (morphine, pethidine and fentanyl) and paracetamol (acetaminophen), which was prescribed after the patients started oral intake. Per oral diet was initiated once the bowel sound was detected on routine post-operative physical exam. Dry dressings were applied daily until stitches or staple were removed.

Surgical wounds were observed daily during admission. Patients were appointed to visit outpatient department on the second and fourth week after the operation. The patients who was diagnosed with I-SSI would be admitted for the further treatment. Patients who did not visit the outpatient department as scheduled would be followed up by telephone interviewing general condition, swelling, redness or wound discharge.

Definition of surgical site infection

The definition of incisional surgical site infection was followed the Centers for Disease Control and Prevention (CDC) criteria. 2A superficial I-SSI occurred within 30 days postoperatively and involved only skin and subcutaneous, including one of the following: 1. purulent drainage from the wound; 2. organism identified from an aseptically obtained culture of fluid or tissue from the wound; 3. any signs or symptoms of infection, including pain/tenderness, localized swelling, redness/heat, and wound opened by surgeon; 4. a diagnosis of superficial I-SSI by a surgeon. A deep I-SSI occurred within 30 days after the surgery, involving deep soft tissue of the incision (fascia and muscle layers).

Surgeon who assessed the surgical wound postoperatively and diagnosed for I-SSI were blinded to the patient's treatment.

Data collections

Preoperative data was recorded on the day of admission including: age, sex, underlying disease, smoking history, BMI, history of previous intra-abdominal operation, history of ostomy creation, and serum albumin. Intraoperative and postoperative data were collected at ward. Intraoperative data including: type of the surgery, wound classification and size, operative time, drain placement, blood loss and blood transfusion. Postoperative data was the wound complication including: superficial and deep incisional surgical site infection, wound dehiscence. Postoperative pain cannot be recorded and analyzed because of additional pain control may added in some patients which are spinal and epidural anesthesia. Patients who got an additional pain control would have a very low pain score of 1-3 and no additional pain reliever needed.

Statistical analysis

Sample size was calculated by using an α of 0.05 and power of 80%. Patient demographic and surgical variability data were summarized as numbers or median, percentage and differentiation using Pearson's χ^2 test. The primary outcome (incidence of surgical site infection) was analyzed with Fisher's exact test. Multivariable logistic regression was used to evaluate the confounding factor that were considered clinically relevant. Other comparisons between the 2 groups were analysed with Pearson's χ^2 test and Fisher's exact test. For the forest plot showing the odds ratios of the

confounding factors were created using Microsoft Excel 2013.

All analyses were two-sided and considered statistically significant at P-value less than 0.05 (at 95% confidence interval). Data analysis was performed using IBM SPSS Statistic v.18 software.

RESULT

Patient characteristics

One hundred twenty eight from the total of 142 patients were included in this study. The excluded subjects included 5 patients with immunocompromised and 9 patients with ASA classification higher than 3 (*fig. 1*). The 128 participants were divided into two equal groups of 64, the wound protector group (WP group) and the non-wound protector group (Non-WP group).

There were 3 patients who required re-operation within 30 days from the first procedure due to post-operative complications, one from the non-WP group and two from the WP group. One patient from the non-WP group expired within 30 days as a consequence of post-operative myocardial infarction. None of the patients had wound complication before each event.

The demographic aspect of 124 participants was analysed. There were 77 male and 47 female patients. The participants were between 61 and 80 years old with within normal range of BMI. The WP group included 4.8% of regular smokers compared to 8.1% of the non-WP group smoked. The comorbidity in the study subjects included diabetes mellitus (DM), hypertension (HT), dyslipidaemia (DLP), cardiovascular disease (CVD) and chronic kidney disease (CKD). Large percentage of the patients had Albumin level above 4 mg/dL. The overall demographic data of the patients from both groups were not significantly different (*table 1*).

There was no significant difference in term of surgical variability between the two groups (*table 2*). HPB surgery (41.1%) included Open cholecystectomy, Common bile duct exploration, Choledochoduodenostomy, Pancreaticoduodenectomy, Distal pancreatectomy and Splenectomy. Colorectal surgery (24.2%) included Left/Right hemicolectomy, Total/Subtotal colectomy, Sigmoidectomy and Anterior resection. Small bowel surgery (21.0%) included Segmental small bowel resection and Lysis adhesion. Peptic ulcer perforation and Gastrojejunostomy were accounted for upper GI surgery (13.7%). The majority of surgical wound classification in this study were clean

Figure 1 - Consort diagram showing the progression of participants **Table 1 - Demographic data**

	Using of Wound protector				P-Value
	WP (n=62)		Non-WP (n=62)		
	n	Percent	n	Percent	
Sex					0.835
Male	39	31.5	38	30.6	
Female	23	18.5	24	19.4	
Age (years)					0.362
≤ 40	7	5.6	12	9.7	
41-60	20	16.1	15	12.1	
≥ 61	35	28.2	35	28.2	
BMI					0.666
Underweight (<18.5)	6	4.8	7	5.6	
Normal (18.5-22.9)	27	21.8	23	18.5	
Overweight (23-24.9)	9	7.3	12	9.7	
Obesity level I (25-29.9)	18	14.5	15	12.1	
Obesity level II (≥ 30)	2	1.6	5	4.0	
Smoking	6	4.8	10	8.1	0.284
Underlying disease					
Diabetes mellitus	14	11.3	16	12.9	0.675
Hypertension	32	25.8	27	21.8	0.369
Dyslipidemia	15	12.1	14	11.3	0.832
Cardiovascular disease	4	3.2	5	4.0	0.729
Chronic kidney disease	4	3.2	1	0.8	0.171
ASA Classification					0.535
Class I	10	8.1	6	4.8	
Class II	22	17.7	22	17.7	
Class III	30	24.2	34	27.4	
Serum albumin (g/dL)					0.393
≤ 3.0	5	4.0	9	7.3	
3.1-3.4	10	8.1	6	4.8	
3.5-3.9	11	8.9	15	12.1	
≥ 4.0	36	29.0	32	25.8	
History of Intra-abdominal Operation	19	15.3	21	16.9	0.701

Table 2 - Surgical variability

	Using of Wound protector				P-Value
	WP (n=62)		Non-WP (n=62)		
	n	Percent	n	Percent	
Type of Surgery					
HBP surgery	28	22.6	23	18.5	0.275
Colorectal surgery	14	11.3	16	12.9	0.675
Small bowel surgery	13	10.5	13	10.5	1.000
Upper GI surgery	6	4.8	11	8.9	0.192
Size of the surgical wound					0.453
≤ 10 cm	4	3.2	6	4.8	
10.1-20 cm	50	40.3	44	35.5	
≥ 20.1 cm	8	6.5	12	9.7	
Wound classification					0.822
Clean wound	1	0.8	1	0.8	
Clean contamination wound	49	39.5	46	37.1	
Contamination wound	8	6.5	8	6.5	
Dirty wound	4	3.2	7	5.6	
Operative time					0.712
≤ 1 Hr	7	5.6	5	4.0	
1-3 Hr	38	30.6	44	35.5	
3-5 Hr	11	8.9	9	7.3	
> 5 Hr	6	4.8	4	3.2	
Drainage					0.857
Yes	35	28.2	34	27.4	
No	28	22.6	27	21.8	
Blood loss (mL)	330 (10-1500)	411 (10-3300)	0.265		
Blood transfusion (mL)	194 (67-1013)	243 (255-2170)	0.457		

contaminated wound (76.6%). Intraoperative drainage was applied in 55.6% of the patients in this study.

Surgical site infection

Table 3 is the 2x2 table showing the primary outcome of the study. Surgical site infection was occurred in 30 patients (24.2%), with the significantly higher incidence of SSI in the non-WP group (22/62 patients, 35.5%) than in the WP group (8/62 patients, 12.9%). Timing of I-SSI onset was varied from post-operative day 2 to 23, the median timing was on post-operative day 6.

In multivariable analysis, using of wound protector significantly decreased surgical site infection (Odds ratios; OR 0.269, 95%CI 0.109-0.667). Gender is not a

risk factor of surgical site infection (OR 0.77, 95%CI 0.324-1.829). Perioperative wound protector placement can significantly reduce the incidence of the I-SSI in non-smoker patients, but not in smoker patients (OR 0.170 vs 2.333). Wound protector also reduced the incidence in the patient with hypertension and the patient without diabetes. Dyslipidaemia, asthma, chronic obstructive pulmonary disease (COPD), chronic kidney disease (CKD), and chronic liver disease do not affected the outcome of the wound protector placement. The patients who experienced intra-abdominal operation will have a benefit from the wound protector (OR 0.17, 95%CI 0.038-0.765). Intra-abdominal operation includes appendectomy, cholecystectomy, colectomy, small bowel resection, closure of the organ perforation, etc. Only ASA class III patients (defined as patients with severe systemic disease) can obtain the benefit from wound protector (P-value = 0.007). Using of the wound protector in the difference types of surgery have no difference in the incidence of I-SSI. (OR 0.366 in HBP, 0.214 in colorectal, 0.133 in small bowel and 0.533 in upper GI surgery, P-value > 0.05). Serum albumin does not affected to the wound protector placement in reducing the incidence of I-SSI. The multivariate analysis revealed that wound protector can significantly prevent the I-SSI in clean

Table 3 - Primary outcome [Incidence of Incisional surgical site infection]

	Using of Wound protector		P-value
	WP	Non-WP	
I-SSI	8 (12.9%)	22 (35.5%)	0.006*
No I-SSI	54 (87.1%)	40 (64.5%)	
Total	62	62	

* Fisher's exact test

contaminated wound only (P-value = 0.014). Operative time of 1-3 hours has the most benefit from the wound protector placement significantly.

For the subgroup analysis, clean wound, serum albumin ≤ 3 and 3.1-3.4, and underweight, the number of the patients in each subgroup are too few to calculate the odds ratios. *Table 4* shows the odds ratios with 95% confidence intervals for the effect of wound protector in each patient condition.

DISCUSSION

Surgical site infection is the most complication after the laparotomy operation, especially for the operation involve gastrointestinal tract. Once SSI occurred, it cause an unsatisfied outcome to the patients. Patients should be admitted for a longer period and increase in hospital cost. Prevention of the SSI is the solution of this problem.

The previous studies demonstrated different factors associated with surgical site infection. These major risk factors included previous intra-abdominal operation, prolong operative time, COPD and hypoalbuminemia (10,13). There had been many attempt to reduce the surgical site infection complication such as the usage of appropriate prophylactic antibiotics (14,15). One study compared the incidence of surgical site infection between laparoscopic surgery and laparotomy (16).

One study in 2009 compared the use of skin preparation agents prior to the procedure. It found that alcohol-based solution was superior to aqueous based solution in term of broader spectrum of bacteria coverage. However the inflammability of the alcohol-based solution offset the preventive property. It also required to be completely dry in order to be safe (17).

Nakayama et al studied the subcutaneous drainage prior to skin closure in liver resection cases. The drainage was believed to reduce the subcutaneous accumulation of effusion hence less subcutaneous collection which could potentially cause the surgical site infection. From 260 subjects included, there was no statistical difference in the outcome of subcutaneous drained group (5).

Several research documented on general surgery, lower gastrointestinal tract, gynecologic and hepato-biliary surgery favored the usage of wound protectors in term of decreasing the risk of superficial surgical site infection (13,18-21). However the application of the instruments was difficult in rectal surgery (anterior resection, low and ultra-low anterior resection, pelvic exenteration) and liver surgery (hepatectomy) due to the bulkiness of the wound

Table 4 - Multivariable analysis for surgical site infection

	Odd ratio	95% CI	P-Value*
Wound protector			
Yes	0.269	0.109-0.667	0.006
No	ref		
Male	0.770	0.324-1.829	0.667
Smoking	2.333	0.287-18.965	0.607
No smoking	0.170	0.058-0.500	0.001
Diabetes	0.278	0.046-1.692	0.226
No Diabetes	0.268	0.094-0.764	0.015
Hypertension	0.097	0.019-0.492	0.003
Dyslipidemia	0.996	0.377-2.631	1.000
Previous Intra-abdominal Operation	0.170	0.038-0.765	0.022
ASA Classification			
Class I	0.857	0.098-7.510	1.000
Class II	0.276	0.062-1.233	0.162
Class III	0.131	0.026-0.647	0.007
Type of Surgery			
HBP	0.366	0.092-1.453	0.182
Colorectal	0.214	0.036-1.288	0.118
Small bowel	0.133	0.013-1.365	0.160
Upper GI Surgery	0.533	0.043-6.655	1.000
Wound classification			
Clean wound	N/A	N/A	N/A
Clean contaminated wound	0.262	0.092-0.746	0.014
Contaminated wound	0.143	0.012-1.762	0.282
Dirty wound	0.833	0.051-13.633	1.000
Serum albumin (g/dL)			
≤ 3.0	N/A	N/A	0.258
3.1-3.4	N/A	N/A	0.008
3.5-3.9	0.194	0.031-1.221	0.109
≥ 4.0	0.714	0.212-2.402	0.759
BMI			
Underweight (<18.5)	N/A	N/A	1.000
Normal (18.5-22.9)	0.493	0.120-2.022	0.480
Overweight (23-24.9)	0.175	0.016-1.881	0.178
Obesity level I (25-29.9)	0.109	0.018-0.652	0.020
Obesity level II (≥ 30)	1.500	0.055-40.633	1.000
Age			
≤ 40	0.333	0.029-3.800	0.603
41-60	0.667	0.152-2.915	0.712
≥ 61	0.103	0.021-0.500	0.003
Operative Time			
1 Hr	N/A	N/A	0.045
1-3 Hr	0.187	0.056-0.621	0.004
3-5 Hr	0.778	0.087-6.983	1.000
> 5 Hr	N/A	N/A	0.467

CI - Confidence Interval; ASA-the American Society of Anesthesiologists; HBP-Hepato-Biliary-Pancreatic Surgery; GI-Gastrointestinal; BMI-Body Mass Index. * Fisher's exact test

protector edge upon the surgical field. Therefore these were not included in the study.

Nonetheless, the antecedent studies in prevention of surgical site infection by wound protectors, specific patient characters were not staged there for it was not concluded which patients could potentially benefit from the usage of wound protectors. This study focused on the patient and operation characteristics in relation to the reduction of surgical site infection. Although

Figure 2 - Odds ratios for the effect of wound protector on the occurrence of surgical site infection according to each risk subgroup. *P-value less than 0.05

many confounding factors could significantly decrease the incidence of complication, wound protectors were significantly effective in the following subgroups: non-smoking, non-diabetes, hypertension, patients with previous intra-abdominal operation, ASA class III, clean contaminated wound, BMI 25-29.9 (obesity level I), age ≥ 61 , and operative time 1-3 hr (*fig. 2*).

We simply that the serum albumin does not affected to the wound protector placement in reducing the incidence of I-SSI, even the serum albumin level 3.1-3.4 has a significant calculation but the number of the patients are too few to evaluate.

At the beginning of the study, we aimed that wound protector will reduce the incidence of I-SSI especially in the contaminated and dirty wound, but the multivariate analysis revealed that wound protector can significantly prevent the I-SSI in clean contaminated wound only (P-value = 0.014). This result may be happen because the surgical wound can be exposed by the contamination before wound protector was inserted.

CONCLUSION

Intraoperative wound protector placement is effective

for decreasing the incidence of incisional surgical site infection in the major laparotomy operation. The factors those can increase the effectiveness of the wound protector includes: non-smoking, non-diabetes, hypertension, previous intra-abdominal surgery, ASA class III, clean contaminating wound, level I obesity, age > 61 and operative time of 1-3 hr.

Conflict of interest

The authors declared no conflicts of interest.

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