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ORIGINAL ARTICLE

Is Postoperative Albumin Level Related with Surgical Site Infection?

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Purpose: Surgical site infection (SSI) is a hospital-acquired infection (HAI) associated with increased mortality, length of hospital stay, and cost of hospitalization. The aim of this study was to identify the value of albumin as an indicator of the nutritional status, postoperative C-reactive protein (CRP), and white blood cell (WBC) levels in predicting an outbreak of SSI and SSI-related epidemiology after colorectal surgery and identifying the risk factors for SSI.
Materials and Methods: A total of 198 patients, who underwent colorectal surgery from September 1, 2015 to December 31, 2016, were included in the study. The patient identity, operation characteristics, and SSI data were analyzed retrospectively by a chart review and national SSI reporting sheet. The relationship of the SSI and clinical data was analyzed statistically, and the SSI detection time and post-operative inflammatory laboratory findings were analyzed individually using cumulative incidence analysis and cause-specific hazard model.
Results: The incidence of SSI post colorectal surgery was 15.7% (31 out of 198 cases). Chronic renal failure (CRF), open surgery, long operation time, and stoma were identified as significant risk factors for SSI using univariate analysis. The CRF, long operation time, and stoma were significant risk factors according to multivariate analysis. The decrease in albumin on post-operative day (POD)#3 and CRP elevation on POD#4 were related to the early detection of SSI.
Conclusion: The actual incidence of SSI might be higher than expected, particularly in cases where patients have several clinical and operative factors. In addition, the albumin level and multiple postoperative inflammation tests can be employed as an early predictors of SSI. **(Surg Metab Nutr 2018;9:59-67)**

Key Words: Surgical site infection, Colorectal surgery, Risk factors

INTRODUCTION

Hospital-acquired infection (HAI) is one of the biggest problems in recent medicine and surgical site infection (SSI) is the most common course of HAI. SSI occurs in 2∼5% operations in the United States.[1] SSI is associated with increase in mortality, length of hospital stay and medical cost.[2-4] It is well known that SSI incidence is high after colorectal surgery, however its frequency of occurrence may not be accurate.[5]

In Korea, SSI has been reported intermittently and indirectly during the process of investigating HAI, and accuracy of these reports was considered doubtful as the reported incidence rate ranged from 2.0 to 9.7%.[6] In 2006, the Korean Nosocomial Infections Surveillance System (KONIS) was established to survey incidences of SSI across the nation. Many hospitals voluntarily participated in this surveillance system. This system employed KONIS Web-based Report and Analysis Program.[7-9] For a more effective surveillance of SSI, Korean Surgical Site Infection Surveillance (KOSSIS) program was developed in 2014. This system focused on SSI among nosocomial infections. One prospective multicenter study employed the KOSSIS program to evaluate SSI rates and identify risk

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factors for SSI. A total of 197 colon surgeries were included in the study. The incidence of SSI after colon surgery was reported as 10.15%.[10]

The main purpose of this study is to confirm the effect of postoperative albumin levels which is commonly used as an indicator of the nutritional status of patient on development of SSI. Furthermore, this study aims to identify the value of postoperative c-reactive protein (CRP) and WBC levels in predicting outbreak of SSI after colorectal surgery in patients, who were rigorously examined and reported as per the standard survey process of KOSSIS. The study also aims to identify other clinical factors related to SSI after colorectal surgery.

MATERIALS AND METHODS

1. Patient characteristics

A total of 198 patients who underwent colorectal surgery between Sep. 1. 2015 and Dec. 31. 2016 were included in the study. Patient characteristics are reported in Table 1. There was no difference in sex ratio. The proportion of overweight patients with body mass index (BMI) ≥25 was 29%. Approximately 14% of patients were in American society of anesthesiologists (ASA) score 3 to 4. Compared with patients with hypertension or diabetes, the number of patients with CRF and chronic respiratory disease was relatively small (10 and 5, respectively).

2. Study design

The primary end-point of the study was to identify epidemiology of clinical variables associated with SSI and the secondary end-point was to identify postoperative albumin, CRP and WBC levels as predictors of SSI after colorectal surgery.

Patient and operation characteristics were identified by review of patient charts. Patient characteristics included age, sex, BMI, ASA score, and medical conditions including hypertension, diabetes, chronic renal failure, and pulmonary respiratory disease. Operation characteristics included type and method of operation, operation time, elective or non-elective operation and formation of stoma (Table 2). Postoperative albumin, WBC and CRP levels were recorded every day starting on Postoperative day 1 (POD#1) till day 5 (POD#5). Laboratory test was not performed daily for some patients as some surgeons do not prefer daily testing.

SSI was confirmed by the operating surgeons as per definition of SSI and its classification by KOSSIS. Data from each patient with SSI was recorded in a clinical reporting sheet and included in the KOSSIS reporting system. In order to diagnose SSI post patient discharge, all patients who underwent colorectal surgery were evaluated for SSI during their clinic visit by surgeons. If SSI was found during these office visit, clinicians recorded the findings in patient charts.

First, the correlation between SSI and various clinical factors was statistically analyzed.

On the other hand, patients with SSI were divided into two groups, 'early SSI (ESSI; less than 7 days)' and 'late SSI (LSSI; 7 and more than 7 days)' based on the time the medical staff detected the infection. Correlation between ESSI/LSSI and clinical findings was analyzed.

Table 1. Patient characteristics

Variable	Number (%)
Sex	
Male	100 (50.51)
Female	98 (49.49)
Age (yr)	
<65	97 (48.99)
≥65	101 (51.01)
Body mass index (BMI; kg/m^2)	
<25	135 (68.18)
≥25	59 (29.80)
American Society of Anesthesiologists (ASA) physical status score (1~5)	
1 or 2	170 (85.86)
3 or 4	28 (14.14)
Hypertension	
None	111 (56.06)
Yes	86 (43.43)
Diabetes mellitus	
None	158 (79.80)
Yes	39 (19.70)
Chronic renal failure	
None	187 (94.44)
Yes	10 (05.05)
Chronic respiratory disease	
None	192 (96.97)
Yes	5 (02.53)

This study was approved by Institutional Review Board of Soonchunhyang University Seoul Hospital (IRB No.2018-06-002). Because this was a retrospective study with minimal risk to patients, the Internal Review Board, Soonchunhyang University Seoul Hospital, exempted it from obtaining informed consent from the patients whose records were included in the study.

Table 2. Operative characteristics

Variable	Numbers (%)
Laparoscopic/open surgery	
Lapa	126 (63.6)
Open	72 (36.4)
Elective/emergent	
Elec	136 (68.7)
Emer	61 (30.8)
Operative time (minutes)	
<240	100 (50.5)
≥240	98 (49.5)
Stoma creation	
None	173 (87.4)
Yes	25 (12.6)
Operation types	
(Extended) Right hemicolectomy	36 (18.2)
Transverse colectomy	5 (2.5)
Left hemicolectomy	6 (3.0)
Anterior resection	37 (18.7)
Low anterior resection	22 (11.1)
Mile's operation	5 (2.5)
Hartmann's operation	13 (6.6)
Ileostomy reversal	9 (4.2)
Hartmann's reversal	3 (1.5)
Ileocecectomy	27 (13.6)
etc.	36 (18.2)

3. Study analysis

In this study, we first tried to analyze the correlation between infection and various clinical features using the Chi-square test and then an in-depth analyzing was performed for the correlation between epidemiologic data and laboratory findings of two groups with a competing risk regression model. We employed two statistical analysis methodologies to identify the risk factors. Cut off points for continuous variables including postoperative serum albumin, CRP and WBC levels were calculated using Youden index (Table 3) and all blood lab levels were coded into binary variables based on it being higher or lower than the pre-determined reference point. First, cumulative incidence analysis was performed by using cause-specific cumulative incidence function. Cumulative incidence was estimated for different causes of failure in each groups (Albumin, WBC or CRP events) and P-value was calculated by comparison for each factor across groups. Cumulative incidences of ESSI and LSSI were calculated individually. A Second, cause specific hazard model employed was based upon an inverse probability censoring weighting (IPCW) method. In the univariate

Table 3. Cut off table of Albumin, C-reactive protein (CRP) and White blood cell count (WBC) by Youden index

	Criteria	Sensitivity	95% CI*	Specificity	95% CI	PPV†	95% CI	NPV‡	95% CI	AUC§	95% CI
Albumin (g/dL)											
POD 1	≤3.050	0.516	0.334~0.694	0.629	0.550~0.701	0.205	0.125~0.315	0.875	0.800~0.926	0.549	0.429~0.669
POD 2	≤3.35	0.678	0.485~0.827	0.467	0.390~0.546	0.190	0.125~0.280	0.886	0.797~0.941	0.496	0.387~0.606
POD 3	≤3.95	0.968	0.815~0.998	0.178	0.126~0.248	0.180	0.127~0.248	0.968	0.815~0.998	0.493	0.379~0.608
POD 4	≤2.85	0.194	0.081~0.380	0.886	0.826~0.928	0.24	0.102~0.455	0.855	0.792~0.903	0.555	0.404~0.707
POD 5	≤3.05	0.419	0.251~0.607	0.743	0.668~0.806	0.232	0.134~0.367	0.873	0.805~0.921	0.607	0.490~0.725
CRP (mg/L)											
POD 1	≥3.075	0.774	0.585~0.897	0.497	0.419~0.575	0.222	0.15~0.314	0.922	0.841~0.966	0.643	0.551~0.735
POD 2	≥10.79	0.419	0.251~0.607	0.755	0.681~0.816	0.241	0.139~0.379	0.875	0.807~0.922	0.610	0.490~0.730
POD 3	≥6.87	0.645	0.454~0.802	0.653	0.575~0.724	0.256	0.167~0.37	0.908	0.838~0.951	0.659	0.551~0.767
POD 4	≥11.535	0.29	0.149~0.482	0.91	0.854~0.947	0.375	0.196~0.592	0.874	0.813~0.917	0.659	0.514~0.804
POD 5	≥4.6	0.452	0.278~0.637	0.719	0.643~0.784	0.23	0.135~0.358	0.876	0.806~0.924	0.637	0.520~0.754
WBC (/μL)											
POD 1	≥12,750	0.419	0.251~0.607	0.623	0.544~0.696	0.171	0.977~0.278	0.853	0.774~0.908	0.544	0.425~0.663
POD 2	≥9,650	0.387	0.224~0.577	0.713	0.637~0.779	0.2	0.112~0.327	0.862	0.791~0.913	0.563	0.428~0.697
POD 3	≥9,050	0.419	0.251~0.607	0.749	0.674~0.811	0.237	0.137~0.373	0.874	0.806~0.922	0.561	0.440~0.682
POD 4	≥8,500	0.355	0.198~0.546	0.832	0.765~0.884	0.282	0.156~0.451	0.874	0.810~0.92	0.601	0.455~0.746
POD 5	≥7,350	0.484	0.306~0.666	0.713	0.637~0.779	0.238	0.144~0.365	0.881	0.812~0.929	0.595	0.485~0.706

*CI = Cumulative Index; †PPV = Positive Predictive Value; ‡NPV = Negative Predictive Value; §AUC = Area under the ROC curve.

analysis, a candidate risk factor with P-value of less than 0.2 was employed, and backward variable selection was performed using a P-value of 0.05 in multiple analysis. R version 3.1.2 was employed for all statistical analysis (using 'cmprsk' and 'crrstep' packages). All statistical analyses were performed using SPSS, version 14.0.

RESULTS

The incidence of SSI after colorectal surgery in the current study was 15.7% (31 of 198 cases).

Based on univariate analysis, CRF (OR 4.0, 95% CI, 1.046～14.926), open surgery (OR 2.5, 95% CI, 1.136～5.381), operation time exceeding 240 minutes (OR 3.4, 95% CI, 1.492～8.337) and stoma formation (OR 4.8, 95% CI, 1.921～12.122) are potential risk factors for occurrence of SSI post colorectal surgery (Table 4).

And then multivariate analysis was performed with these significant related factors in univariate analysis. Chronic renal failure (OR 4.0, 95% CI, 1.046～14.926), longer operation time (OR 3.8, 95% CI, 1.534～9.167) and stoma formation (OR 5.2, 95% CI, 1.977～13.735) were determined to be statistically significant risk factors.

In-depth analysis of statistical relationship between epidemiologic factors and inflammatory lab tests for the ESSI/LSSI, from POD #3, there is a tendency for cumu-

Table 4. Univariate analysis of risk factors for surgical site infection

Variable	SSI (%)		OR	95% CI		P-value
	Yes	None		Upper	Lower	
Sex						
Male	16 (51.6)	84 (50.3)	Ref.			
Female	15 (48.4)	83 (49.7)	1.054	0.489	2.269	0.893
Age (yr)						
<65	15 (48.4)	82 (49.1)	Ref.			
≥65	16 (51.6)	85 (50.9)	1.029	0.478	2.216	0.942
BMI (kg/m^2)						
<25	22 (73.3)	113 (68.9)	Ref.			
≥25	8 (26.7)	51 (31.1)	0.806	0.336	1.931	0.628
ASA score (1～5)						
1 or 2	26 (83.9)	144 (86.2)	Ref.			
3 or 4	5 (16.1)	23 (13.8)	1.204	0.420	3.453	0.730
Lapascopic/Open surgery						
Lapa	14 (45.2)	112 (67.1)	Ref.			
Open	17 (54.8)	55 (32.9)	2.473	1.136	5.381	0.022
Elective/Emergency operation						
Elect	21 (67.7)	115 (69.3)	Ref.			
Emer	10 (32.3)	51 (30.7)	1.074	0.472	2.433	0.865
Operative time (min)						
<240	8 (25.8)	92 (55.1)	Ref.			
≥240	23 (74.2)	75 (44.9)	3.527	1.492	8.337	0.004
Stoma creation						
No	21 (67.7)	152 (91)	Ref.			
Yes	10 (32.3)	15 (9)	4.825	1.921	12.122	0.001
Hypertension						
No	14 (45.2)	97 (58.4)	Ref.			
Yes	17 (54.8)	69 (41.6)	1.707	0.789	3.693	0.174
Diabetes mellitus						
No	26 (83.9)	132 (79.5)	Ref.			
Yes	5 (16.1)	34 (20.5)	0.747	0.267	2.088	0.578
Chronic renal failure						
No	27 (87.1)	160 (96.4)	Ref.			
Yes	4 (12.9)	6 (3.6)	3.951	1.046	14.926	0.043
Chronic Respiratory disease						
No	30 (96.8)	162 (97.6)	Ref.			
Yes	1 (3.2)	4 (2.4)	1.350	0.146	12.501	0.792

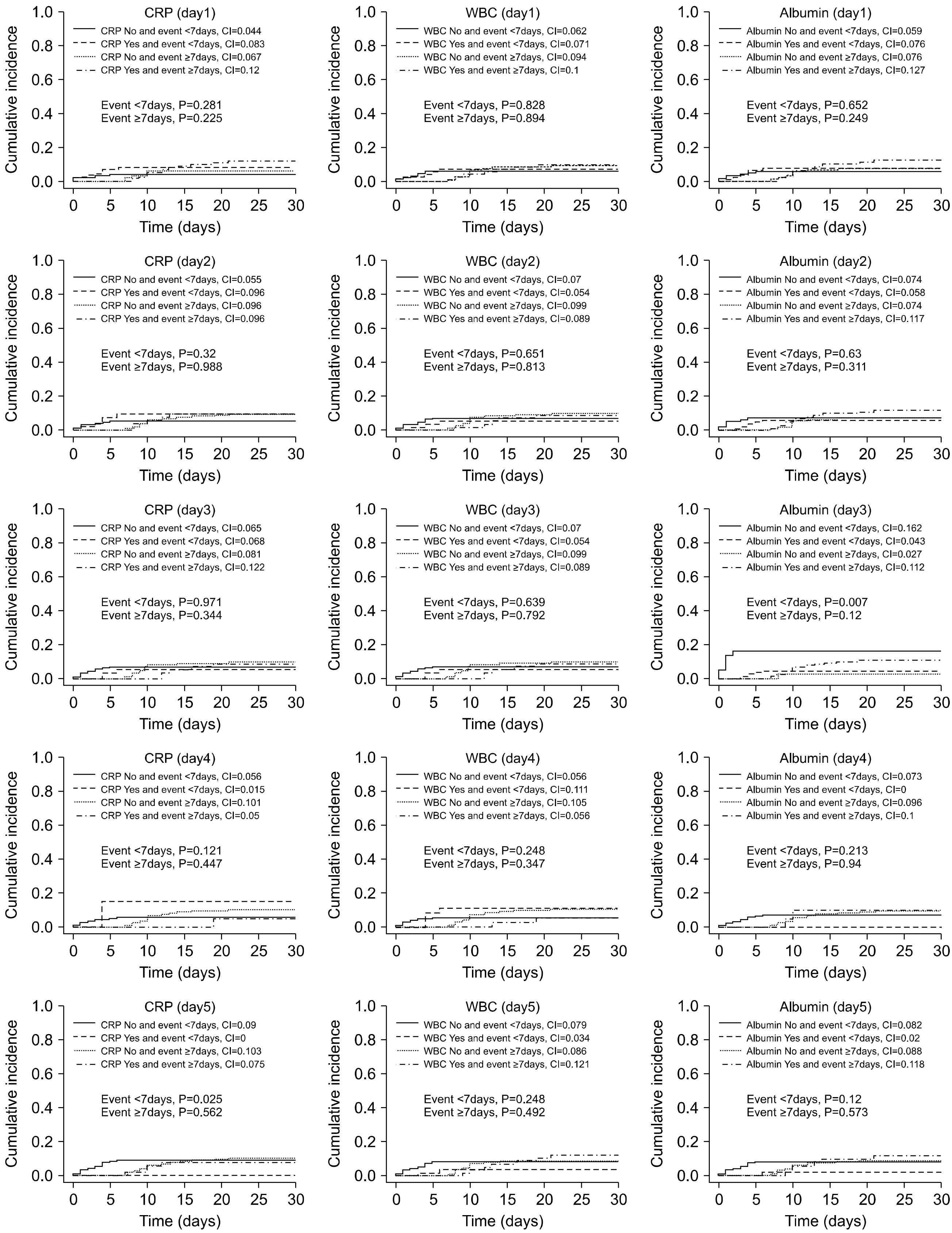

Fig. 1. Cumulative incidence curves using the stage of Albumin, CRP and WBC in the ESSI or LSSI as a competing risk.

lative incidence to differ between albumin declining group and non-declining groups. On POD#3, the cumulative incidences of ESSI for albumin level ([Albumin Yes and Event <7 days] and [Albumin NO and Event <7 days]) were 0.043 and 0.162, respectively. Cumulative incidence in the CRP group also tends to show a difference after POD #4. On POD #5, the cumulative incidences of ESSI for CRP level ([CRP Yes and Event <7 days] and [CRP NO and Event <7 days]) were 0 and 0.09, respectively (Fig. 1). In the cause specific hazard model for occurrence of ESSI, variables with P-values lower than 0.2 (univariate analysis) were stomy formation, open surgery, operation time longer than 240 minutes, POD#3 and #5 low albumin levels and POD#4 high CRP levels and stomy formation, long operation time, hypertension, chronic renal failure and POD #3 low albumin show lower P-values with LSSI (univariate analysis) (Table 5). These variables were considered as potentially independent and employed for multivariate analysis. The risk factors associated with ESSI and LSSI after colorectal surgery by multiple regression analysis are shown in Table 6. Statistically significant risk factors for ESSI as determined by multivariate model were operation time longer than 240 minutes (CHR=9.794 [95% CI, 1.804~53.171], P<0.008), and decrease in albumin levels on POD#3 (Value ≤3.95 g/dL, CHR=0.096 [95% CI, 0.025~0.369], P<0.001) and elevation in CRP level on POD#4 (Value ≥11.535 mg/L CHR=12.634 [95% CI, 4.195~38.050], P=0.000). For LSSI, there were no statistically significant variables.

DISCUSSION

Surgical site infection is with a significance concern in colorectal surgery. Multiple studies show that the in-

Table 5. Univariate analysis of relative risk for surgical site infection to early SSI (ESSI) vs late SSI (LSSI)

		<7 days (ESSI)				≥7 days (LSSI)			
		CHR*	95% CI Lower	95% CI Upper	P-value‡	CHR*	95% CI Lower	95% CI Upper	P-value‡
Female		1.139	0.878	1.139	0.810	1.104	0.906	1.104	0.830
Year ≥65		1.132	0.884	1.132	0.820	0.711	0.711	1.407	0.460
BMI ≥25 kg/m^2		0.672	0.672	1.489	0.540	1.154	0.867	1.154	0.770
Stomy formation§		3.218	0.311	3.218	0.048	2.535	0.394	2.535	0.065
Emergency operation		0.652	1.534	0.652	0.520	1.258	0.795	1.258	0.620
Open surgery		2.939	0.340	2.939	0.055	1.299	0.770	1.299	0.570
Operaitive time ≥240 min		5.943	0.168	5.943	0.020	2.342	0.427	2.342	0.082
Hyptertension		1.542	0.649	1.542	0.430	1.851	0.540	1.851	0.180
Diabetes mellitus		0.706	0.706	1.416	0.650	1.068	0.937	1.068	0.910
Chronic renal failure		1.605	0.623	1.605	0.650	3.897	0.257	3.897	0.026
Chronic respiratory diseases		3.215	0.311	3.215	0.230	N/A†			
POD#1	CRP (mg/L)	1.887	0.584	6.094	0.290	1.799	0.682	4.748	0.240
	WBC (/μL)	1.131	0.375	3.414	0.830	1.065	0.424	2.679	0.890
	Albumin (g/dL)	1.283	0.435	3.781	0.650	1.684	0.689	4.117	0.250
POD#2	CRP	1.747	0.582	5.246	0.320	1.008	0.366	2.778	0.990
	WBC	0.745	0.209	2.654	0.650	0.885	0.325	2.411	0.810
	Albumin	0.766	0.261	2.253	0.630	1.609	0.638	4.060	0.310
POD#3	CRP	1.021	0.340	3.061	0.970	1.538	0.630	3.753	0.340
	WBC	0.737	0.208	2.608	0.640	0.873	0.323	2.359	0.790
	Albumin	0.240	0.082	0.704	0.009	4.254	0.560	32.298	0.160
POD#4	CRP	2.659	0.781	9.057	0.120	0.473	0.066	3.370	0.450
	WBC	1.965	0.629	6.136	0.250	0.507	0.121	2.122	0.350
	Albumin	N/A†				1.058	0.245	4.565	0.940
POD#5	CRP	N/A†				0.724	0.241	2.171	0.560
	WBC	0.426	0.096	1.884	0.260	1.381	0.554	3.445	0.490
	Albumin	0.231	0.031	1.732	0.150	1.317	0.510	3.403	0.570

*CHR = Cause specific hazard model; †N/A = not available; ‡P-value by Inverse probability censoring weighting (IPCW); §Both Ileostomy and Colostomy are included.

Table 6. Multivariate analysis of relative risk for surgical site infection to early SSI (ESSI) vs late SSI (LSSI)

	<7 days (ESSI)				≥7 days (LSSI)			
	CHR*	95% CI		P-value†	CHR*	95% CI		P-value†
		Lower	Upper			lower	upper	
Operaitive time ≥240 min	9.794	1.804	53.171	0.008				
POD#3 of Albumin	0.096	0.025	0.369	0.001				
POD#4 of CRP	12.634	4.195	38.050	0.000				

*CHR = Cause specific hazard model; †P-value by Inverse probability censoring weighting (IPCW).

cidence rate of SSI after colorectal surgery is higher than other surgery types.[11,12] According to the American College of Surgeons' National Surgical Quality Improvement Program data (ACS NSQIP) widely used in United States, the SSI rates of colorectal surgery range from 9% to 14%.[13-15] According to the Japan Nosocomial Infections Surveillance (JANIS), the incidences of SSI after colon and rectal surgery from 2008 to 2010 were 15.0% and 17.8%, respectively.[16] Higher rate of SSI post colorectal surgery may be due to the inherent possibility of microbial contamination at the operation wound site.[17]

SSI rate in our study (15.7%) is minimally higher than that of previous studies. We believe this may be due to two reasons. Firstly, the reported SSI incidence may have been underestimated in previous studies. Secondly, the actual SSI rate at our hospital may be higher than that at the others. In accordance with the first reason, 9～15% SSI rate was reported in recent US surveys,[18,19] 10.15% in Korean,[10] and 15.0～17.8% in Japanese reports.[9] In accordance with the second reason, authors in this study focused on high rate of emergency operation. Compared to elective surgery, peritonitis due to perforation and stoma formation are relatively more frequent in emergency surgery, and the rate of SSI incidence is also expected to be higher. However, detailed analysis and risk-adjustment for these factors was not performed. For a more meaningful comparisons of SSI rates across each hospital setting, calibration is required for each hospital's patient population as is performed by the National Healthcare Safety Network (NHSN) risk-adjusted measurement system in the United States.

In accordance with the antibiotic guideline for SSI prevention, our institute has a standard principle of administering second-generation cephalosporin IV antibiotics twice, at 30 minutes pre-operation and at post operation. However, in cases requiring emergency surgery, antibiotics are used for treatment of peritonitis or sepsis before operation, and antibiotic treatment should be continued for a longer period after surgery. Compared to previous studies, this institute conducts relatively more emergency operations, and this may have affected the outcome of this study; however, this study did not control for these differences.

In this study, we classified SSI into two groups; before POD#7 (Early SSI) and after and POD#7 (Late SSI). 'POD#7' was based on the average post-operative admission of a target patient population (6.2 days). This may be slightly higher than other hospitals (also when compared to our recent data), considering that the emergency operation rate is slightly higher in our hospital, however no detailed analysis focused on this factor has been performed.

We examined the possibility of employing albumin, WBC and CRP as tools to predict the occurrence of SSI by analyzing the correlation between postoperative albumin, WBC and CRP levels after surgery with occurrence of SSI using multiple statistical analysis methodologies. According to statistical results, ESSI could be reliably predicted when albumin level decreased on POD#3 (≤3.95) and CRP level was elevated on POD 4 (≥11.535 mg/L).

Malnutrition has an adverse effect on outcomes in surgical patients.[20] Albumin is most commonly used as an indicator of the nutritional status of a patient and is a negative acute-phase protein that is downregulated in response to acute illness or stress.[21] A recent study shows that hypoalbuminemia is an independent risk factor for the development of SSI following gastro-intestinal surgery. It shows that albumin <30 mg/dL was associated with an increased rate of SSI.[22]

C-reactive protein (CRP) and white blood cells (WBC) are known as biologic markers of postoperative infection.[23-25] They have limited sensitivity and are good predictors of SSI. In a recent study, postoperative CRP level at 48 hours was useful in predicting organ-space surgical site infection after colorectal surgery.[26] In a similar study, elevated CRP levels at 2^{nd} and 4^{th} post-operative day (POD) were considered as predictors of anastomotic leak and postoperative complication after colorectal surgery. Multivariate analysis suggested that CRP level >125 mg/L at 4th POD was a significant predictor for anastomotic leak (Odd ratio [OR] 18.15) and septic complication (OR 14.27).[27]

We carefully recommend that clinicians measure albumin level as an indicator of nutritional status and CRP level as an inflammation marker more frequently for earlier detection of SSI. Although studies should be conducted on cohorts with more homogeneous and large numbers of patient, this study is meaningful in that it raised the necessity of monitoring nutritional status including serum albumin level.

In addition to albumin and CRP levels, univariate and multivariate analysis showed that longer operation time, CRF and stoma formation were other significant risk factors of SSI.

Limitations of this study include its small sample size, which was not adequate to analyze all of the risk factors of SSI. Additionally, all of the operations were conducted in a single hospital and by a single colorectal team, thereby limiting any variation that may occur in different facilities. Most importantly, a selection bias may exist as the study data was collected retrospectively. This may limit the study to identify all of the risk factors associated with SSI.

And we did not investigate the degree of infection according to SSI classification. Although we assessed wound infection through thorough surveillance, this would be another limitation. Therefore, further research is needed in the future.

The biggest limitation is that because this study was based entirely on the national SSI survey report and chart records, we could not investigate other factors that could assess nutritional status of patients except for the albumin levels and overweight. We plan to increase the number of patients participating in the study, and to study other nutritional indicators.

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