

# The predictive value of developing surgical site infections in colorectal surgery

A comparison between the OR-cockpit grade, SSI-bundle and best model selection

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**Background:** Since 2016, Medisch Spectrum Twente (MST) uses the NewCompliance® OR-cockpit system, among other things, to evaluate surgeries. Based on a bundle of interventions, including: time-out, sign-out, number of door movements during surgery, preoperative hair removal, perioperative normothermia and antibiotics prophylaxis, the OR-cockpit system grades the surgeries. The main aim of this study was to examine the predictive value of the OR-cockpit grade on developing surgical site infections (SSIs) and to explore whether there is a model with a better predictive value based on other variables.

**Methods:** A retrospective cohort design was performed in patients who underwent a colorectal surgery during the three-year period of 2016-2018 at MST. Patients were followed during a period of 30-days. Data has been collected from medical records according to the PREZIES protocol combined with standardized registered data from the OR-cockpit system. First, the OR-cockpit grade was tested on its predictive value. Thereafter, a new model, based on the bundle of interventions to reduce SSIs, was tested with multiple regression to find out if the OR-cockpit model can be improved. Univariate analysis and best subset selection were used to determine the optimum set of predictors for multiple logistic regression. Multiple regression was used to examine the predictive value of the best models on developing SSIs. The best models were compared with the model of the OR-cockpit system.

**Results:** There were 629 patients included in this study of whom 114 patients (18.1%) developed an SSI. The predictive value of the OR cockpit grade appeared to be poor (AUC = 0.545). The new model based on the interventions did not improve (AUC = 0.570). Best model analysis showed an improved model with an AUC of 0.684.

**Conclusion:** The OR-cockpit grade is not able to give a good prediction for developing SSIs. After best model selection and multiple regression, the model based on wound classification, ASA classification, BMI, surgical approach, surgery duration and perioperative normothermia appears to be the model with the highest predictive value in colorectal surgery.

**Keywords:** Colorectal surgery, OR-cockpit, Predictive value, SSI-bundle, Surgical site infections

## Introduction

Surgical site infections (SSIs) (1) are among the most common complications in patients who have undergone surgery in hospitals. SSIs can lead to reduced surgery results, permanent disability, or even death. SSIs may also result in longer hospitalization, reoperations and higher healthcare-

related costs. The costs of SSIs vary from € 1,000 for a superficial SSI to € 20,000 for a deep SSI. According to the latest figures (2), from the 2012-2015 period, 6,570 (2.4%) SSIs were found in 274,306 surgeries in the Netherlands. The incidence of SSIs is the highest in colorectal surgery (figure 1). 7,731 Colorectal surgeries were performed in the 2012-2015 period. The cumulative incidence of the total SSIs as

a result of a colorectal surgery is 16.8 per 100 patients (CI 95% 16.0-17.6). The main reason for the higher rate of SSIs in colorectal surgery compared to other surgeries is due to the high complexity of the surgery, combined with the presence of a higher concentration of microorganisms in the colon (3).

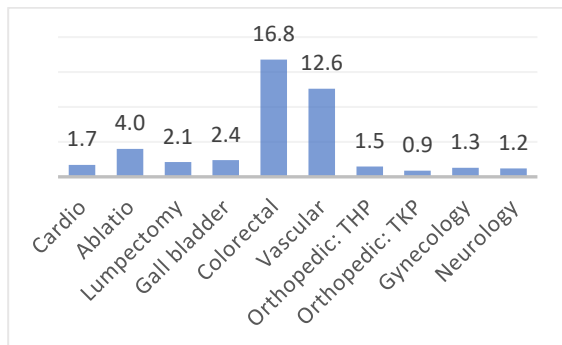


Figure 1: Cumulative incidence (%) per surgical specialism in the Netherlands in the 2012-2015 period (2).

Since SSIs have unpleasant consequences for patients and hospitals, it is important to reduce the number of SSIs as much as possible. SSIs can be reduced by providing care in accordance with the current guidelines by the *Werkgroep Infectie Preventie (WIP)* (4). Based on these guidelines, a bundle of four interventions has been prepared by the *VMS Veiligheidsprogramma* (5): limiting the number of door movements, timely administration of antibiotic prophylaxis, preoperative hair removal procedure and the perioperative normothermia of patients. This bundle is further referred to as the SSI-bundle. However, there is still no consensus about the effectiveness of these interventions on the prevention of SSIs. In 2011, Prakken et al. (1) described that compliance with the four interventions was not significantly related to the occurrence of SSIs. In 2012, a prospective quasi-experimental cohort study by Crolla et al. (6) showed that the use of the four interventions in colorectal surgery does reduce the number of SSIs by 36%. However, they argue that it cannot be excluded that other factors have been responsible for reducing the number of SSIs. Gervaz et al. (7) concluded in 2012 that the variables wound classification, ASA classification, surgical approach and BMI play a major role in the development of SSIs.

Since 2016, *Medisch Spectrum Twente (MST)* measures the compliance with the four interventions with the *NewCompliance® OR-cockpit system* (8). Variables, like for example number of door movements, will be automatically registered by the system. The system also integrates data from

patient files, planning software and large operating equipment. It shows information to the clinical staff that is essential during surgery. The OR-cockpit system uses the four interventions plus the surgery sign-out and time out as indicators to rate the surgery on a scale from 0 to 10. The final grade is calculated based on a specific formula (9). If the OR-cockpit grade is a reliable and accurate measure for the risk of SSIs, the work culture in the operation room can be improved. If so, the OR staff become more aware of the risks that patients are exposed to when the staff does not fully adhere to the surgery and safety guidelines.

The OR-cockpit grade should give a prediction on the chance of the development of SSIs: the higher the grade, the lower the chance of developing an SSI. However, no research had yet been done on the predictive value of this system. This, combined with the controversy in the literature (1, 6), has led to this study with the aim to determine the predictive value of the SSI-bundle on the development of SSIs in colorectal surgery. In addition, based on available data of other relevant variables, we have investigated which model can predict the development of SSIs best.

## Methods

Patients who underwent a colorectal surgery in the period January 2016 – December 2018 at MST, were enrolled in this study to determine the incidence of SSIs. Patients were included (10) if/when:

- Minimum age of one year at time of surgery
- The main surgery indicated a colorectal surgery (multi-surgery like HIPEC or Debulking not allowed)
- The surgery has been the patient's first colorectal surgery (previous appendectomy or hysterectomy allowed)
- Patients had undergone no surgery in the same body area within 90 days before the indicated surgery (laparoscopy, biopsies and placement of stents allowed)
- The patient's surgery was not the result of a perforation of the colon

The follow-up period to assess whether a patient developed an SSI in colorectal surgery was 30 days. Endpoints of the follow-up surveillance were: superficial SSI, deep/organ space SSI, death of a patient or no SSI. It is assumed that patients who are lost-to-follow-up within the 30-days follow-up,

returned to the hospital or general practitioner to undergo treatment if they have developed an SSI. Therefore, lost-to-follow-up patients remained included.

### Data collection

The study data has been registered according to the PREZIES protocol (10). The data was derived from patient files and databases within MST: XCare, DSV and ESV-web. In addition, standardized registered data were derived from the OR-cockpit system. The study database was built in a Microsoft Excel database. To strengthen the validation of the registered data, independent random sampling of 10% has been executed by a physician assistant of the department of surgery. Data analyses have been performed with *IBM SPSS Statistics 25* (11) and *R 3.6.0* (12).

### Potential independent predictive variables

Potential independent predictive variables for developing SSIs that were included in the study are:

- Age (years)
- BMI (kg/m<sup>2</sup>)
- Wound classification (class II vs. class III-IV)
- ASA classification (class I vs. class II vs. class III-IV)
- Presence of malignancy (yes/no)
- Creating a stoma (yes/no)
- Urgency of surgery (elective vs. emergency)
- Surgery duration (minutes)
- Surgical approach (laparoscopic vs. open vs. converted surgery)
- Type of resection (sigmoid-mesorectal vs. ileocecal-transversum vs. (sub)total colectomy)
- Antibiotics gift: pre and post-OR (yes/no)

### OR-cockpit variables

The OR-cockpit system at MST generates a grade at the end of the surgery (9). This grade is based on the SSI-bundle variables, time-out and sign-out (5). The four SSI-bundle variables are:

- Number of door movements during surgery
- Hair removal procedure: the patient is not allowed to shave the body area of surgery within one week before surgery (yes/ no)
- Antibiotic prophylaxis: according to protocol, antibiotics must be given between 60 and 15 minutes before incision (too early, in time or too late)

- Perioperative normothermia: according to protocol, the patient's temperature must be between 35.5 – 37.5 °C at the end of the surgery (yes / no)

### Dependent variable

The primary endpoint of the study surveillance was the development of SSIs (yes or no) (13). There are two types of SSIs: superficial and deep/organ space SSIs. Superficial SSIs concerns skin and subcutaneous tissue. At least one of the following symptoms should be present: pus from incision, signs or symptoms of infection (pain, redness, local swelling, heat) followed by a positive wound culture isolated from wound tissue/fluid or after the surgeon opened the wound. Deep SSIs were diagnosed after anastomotic leakage or infection of deeper tissue combined with one of the following symptoms: pus from deeper incision, abscess, other signs of infection or when the patient experienced pain, local swelling, redness or heat combined with a positive wound culture. Infection at any anatomic structure opened or manipulated during surgery, combined with at least one of the following symptoms: pus from drain, abscess, other signs of infection or positive wound culture, were also diagnosed as deep SSI.

### Statistical analysis

Descriptive statistics are presented as follows: categorical data as absolute numbers (%) and continuous data as means (standard deviation (SD)). Differences between the groups, based on whether an SSIs developed, were analysed with univariate logistic regression. To assess if the OR-cockpit grade has a significant effect in predicting SSIs, it also has been tested with univariate logistic regression. To compare the model with SSI-bundle variables (without time-out and sign-out) with the OR-cockpit grade, the SSI-bundle variables were analysed together with a multiple logistic regression model. To determine whether there was any difference in predicting value on developing SSIs between the OR-cockpit grade and the new model with the SSI-bundle variables, both models were compared to each other with the area under the curve (AUC) of the ROC-curves.

To identify the best model to predict SSIs in colorectal surgery, variables with  $P < 0.100$  were used in multiple logistic regression. Thereafter, the "bestglm" packages in *R* is used for best subset selection to determine which combination of

variables suits best for multiple logistic regression. Best subset selection is based on the Akaike information criterion (AIC): based on likelihood, the lower the AIC, the better the predictive value of the model (14). The discriminative value of the final models has been analysed with the AUC of the ROC-curves. For the statistical analyses,  $p < 0.05$  was used.

## Results

During the three-year period, 802 patients underwent a colorectal surgery at MST. After applying for in- and exclusion criteria, 629 (78.4%) patients met the criteria and were included.

Of the 173 (21.6%) excluded patients, 81 (10.1%) patients underwent a multi-surgery, 24 (3.0%) patients have undergone a surgery in the same body area within 90 days before the indicated surgery, 49 (6.1%) patients had have a previous colorectal surgery and 19 (2.4%) patients have undergone a colorectal surgery as a result of colon perforation. Figure 2 shows a flowchart of the study in- and exclusion.

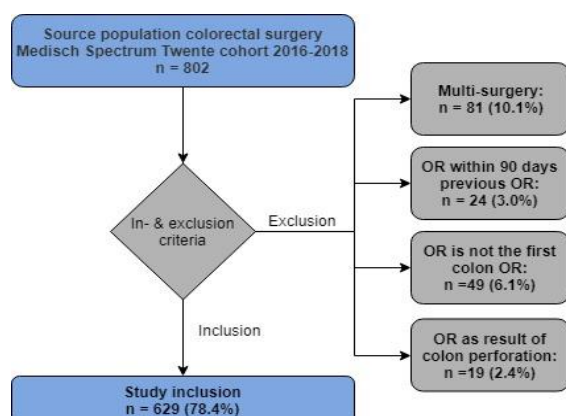


Figure 2: Study in- & exclusion.

There were 346 men and 283 women included in the study, both with a mean age of 66 (SD 10 for men and 12 for women). During the 30-days follow-up, 114 patients (18.1%) developed an SSI. There were 52 patients (8.3%) with a superficial SSI and 62 patients (9.8%) with a deep/ organ space SSI. Fifty-one of the 62 deep SSIs (82.3%) were the result of an anastomotic leakage. Table 1 summarizes the characteristics and clinical features of the study population based on whether SSIs were developed.

### Univariate analysis

Univariate analysis with logistic regression shows that a couple of variables are statistically significant associated with a higher incidence of SSIs: surgical

approach ( $P = 0.005$ ), BMI ( $P = 0.010$ ), ASA classification ( $P = 0.016$ ) and surgery duration ( $P = 0.032$ ). Stated that a  $P$ -value  $> 0.100$  has been set as a cut-off value for variable selection, the variable wound classification ( $P = 0.074$ ) is included in the multiple logistic analysis to decide which models have the highest predictive value to predict SSIs in patients after colorectal surgery. Table 1 shows an overview of the predictive variables and their association with the development of SSIs.

Table 1 – Study characteristics by SSI for colorectal surgery at MST cohort 2016-2018.

All patients (n=629)	SSI absent (n=515)	SSI present (n=114)	P-value
<b>Gender</b>			0.788
Female	233 (45.2%)	50 (43.9%)	
Male	282 (54.8%)	64 (56.1%)	
<b>Age</b>			0.175
1-50	47 (9.1%)	8 (7.0%)	
50-70	281 (54.6%)	54 (47.4%)	
> 70	187 (36.3%)	52 (45.6%)	
<b>BMI*</b>			0.010
< 18.5	10 (2.0%)	2 (1.8%)	
18.5-25	180 (35.7%)	33 (29.5%)	
25-30	205 (40.7%)	43 (38.4%)	
> 30	109 (21.6%)	34 (30.4%)	
<b>Urgency</b>			0.116
Elective	486 (94.4%)	103 (90.4%)	
Emergency	29 (5.6%)	11 (9.6%)	
<b>Surgery duration</b>			0.032
< 90 minutes	247 (48.0%)	42 (36.8%)	
> 90 minutes	268 (52.0%)	72 (63.2%)	
<b>Surgical approach</b>			0.005
Laparoscopic	387 (75.1%)	72 (63.2%)	
Open	81 (15.7%)	33 (28.9%)	
Converted	47 (9.1%)	9 (7.9%)	
<b>Type of colon</b>			0.543
Sigmoid - mesorectal	259 (50.3%)	51 (44.7%)	
Ileocecal - transversum	233 (45.2%)	58 (50.9%)	
(Sub)total colectomy	23 (4.5%)	5 (4.4%)	
<b>Wound classification</b>			0.074
Class II	471 (91.5%)	98 (86.0%)	
Class III-IV	44 (8.5%)	16 (14.0%)	
<b>ASA classification</b>			0.016
Class I	94 (18.3%)	11 (9.6%)	
Class II	347 (67.5%)	77 (67.5%)	
Class III-IV	73 (14.2%)	26 (22.8%)	
<b>Malignancy</b>			0.699
Stoma creation	57 (11.1%)	13 (11.4%)	0.918
Ab pre-OR	489 (95.0%)	106 (93.0%)	0.402
Ab post-OR	99 (19.2%)	26 (22.8%)	0.386

SSI, Surgical site infection; BMI, Body Mass Index (Kg/m<sup>2</sup>); ASA, American Society of Anesthesiologists; Ab, Antibiotics, \*mean (standard deviation).

Univariate logistic regression of the OR-cockpit grade in association with whether an SSI developed, showed a significant difference ( $P = 0.019$ ). When analysing the four SSI-bundle variables univariately, only one of the SSI-bundle variables showed a significant difference in association with SSIs: perioperative normothermia ( $P = 0.045$ ). Table 2 shows the characteristics of the SSI-bundle variables and the OR-cockpit grade and its association with development of SSIs in colorectal surgery.

All patients (n=629)	SSI absent (n=515)	SSI present (n=114)	P-value
<b>Door movements*</b>	7 (6)	8 (6)	0.263
<b>Hair removal procedure</b>			0.196
According to protocol	492 (95.5%)	112 (98.2%)	
Not according to protocol	23 (4.5%)	2 (1.8%)	
<b>Antibiotic prophylaxis</b>			0.550
According to protocol	498 (96.7%)	109 (95.6%)	
> 60 min.	16 (3.1%)	4 (3.5%)	
< 15 min.	1 (0.2%)	1 (0.9%)	
<b>Perioperative normothermia</b>			0.045
According to protocol	484 (94.0%)	101 (88.6%)	
Not according to protocol	31 (6.0%)	13 (11.4%)	
<b>OR-cockpit grade*</b>	7.9 (1.9)	7.4 (2.5)	0.019

SSI, Surgical site infection; \*mean (standard deviation)

When analysing Table 2 on compliance to the SSI-bundle interventions, we can see that these

interventions are generally well respected by the OR-staff.

### Multiple analysis

To decide which model has the best predictive value to predict SSIs in colorectal surgery, the six variables with a  $P$ -value  $< 0.100$ , as described in the results of the univariate analysis, were included for best model selection. Table 3 shows an overview of the five best models to predict SSIs. Based on the AIC value, the best model to predict SSIs in colorectal surgery is a model with the six variables: wound classification, ASA classification, BMI, surgical approach, surgery duration and perioperative normothermia. This model shows a ROC-curve with an AUC of 0.684.

When analysing the best model variables, patients who underwent an open colorectal surgery (vs. laparoscopic approach; OR = 2.28) have the highest odds to develop SSIs. The same applies for patients with wound class III or IV (vs. wound class II; OR = 1.81), patients with an ASA class II (vs. ASA class I; OR = 1.96) or III-IV (vs. ASA class I; OR = 2.98). When BMI increases with one, the odds of developing an SSI increases with 1.06. Surgeries that take longer than 90 minutes have higher odds (1.72) to develop an SSI compared to surgeries that took less than 90 minutes. The odds of patients whose temperature after surgery is not between the 35.5 and 37.5 °C is 1.96 compared to the patients whose temperature is according to protocol.

Model 2, 3, 4 and 5 have a slightly higher AIC compared with best model 1. Looking at the ROC-curves of the best models, model 1 has the highest AUC (0.684). Perioperative normothermia is the only SSI-bundle variable that is integrated in the models.

Model	Variables in candidate model	Df	AIC	Δ AIC	AUC
<b>1</b>	Wound classification + ASA classification + BMI + Surgical approach + Perioperative normothermia + surgery duration	8	565.52	0.00	0.684
<b>2</b>	Wound classification + ASA classification + BMI + Surgical approach + Surgery duration	7	565.76	0.24	0.676
<b>3</b>	ASA classification + BMI + Surgical approach + Perioperative normothermia + Surgical duration	7	566.28	0.76	0.674
<b>4</b>	ASA classification + BMI + Surgical approach + Surgery duration	6	566.97	1.45	0.666
<b>5</b>	BMI + Surgical approach + Perioperative normothermia + Surgery duration	5	568.87	3.35	0.645
<b>OR-cockpit</b>	OR-cockpit grade	1	594.18	28.66	0.545
<b>POWI-Bundle</b>	Perioperative normothermia + Antibiotics prophylaxis + Hair removal procedure + Door movements	5	599.80	34.28	0.570

SSI, Surgical site infection; ASA, American Society of Anesthesiologists; BMI, Body Mass Index.

## Discriminating capacity

The OR-cockpit grade shows a significant difference ( $P = 0.019$ ) in association with SSIs. The discriminating value, based on the AUC of the ROC-curve, shows a poor AUC (0.545) for the OR-cockpit grade (Table 3). Leaving out time-out and sign-out and combining the four SSI-bundle variables in a new multivariable model, the AUC (0.570) did not improve (Table 3).

When comparing the model of the OR-cockpit grade with the models based on best subset selection, shown in Table 3, there is an increased AUC for all of the five best models. The best model, based on the AIC value, has an AUC value of 0.684. The four other best models have a slightly lower value of AUC compared to the best model. Figure 3 shows ROC-curves based on the differences in predictive value for developing SSIs between the OR-cockpit grade (green), the SSI-bundle model (red) and best model 1 (blue).

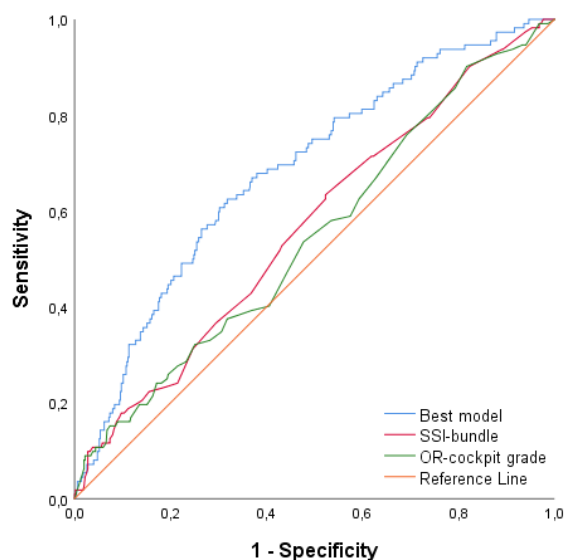


Figure 3: ROC-curves for the best model (based on wound classification, ASA classification, BMI, surgical approach, perioperative normothermia and surgery duration) compared to the ROC-curve for the OR-cockpit grade and the SSI-bundle model for the prediction of SSIs in colorectal surgery.

## Discussion

Compared to the national average in the Netherlands, the incidence of SSIs in colorectal surgery at MST is slightly higher (18.1% vs. 16.8%). The reason of the higher incidence at MST is not clear. A possible explanation could be the composition of the study population. We found a high rate of patient whom are suffering from being overweight. Given the fact that the population in the region of Twente (15) has a higher percentage

of overweight citizens (52.1%) compared to the national average (50.2%), it is not surprising that we found a large group of over weighed patients in our study population. A high BMI value turned out to be a high-risk factor for developing an SSI in colorectal surgery. So, this could be a possible explanation of the higher incidence of SSIs at MST compared to the national average in the Netherlands.

The higher rate of deep SSIs compared to superficial SSIs we found in our study, can be linked to the creation of anastomoses in colorectal surgeries. An anastomosis always gives a risk of anastomotic leakage, which automatically results in a deep SSI.

The compliance to the SSI-bundle appears to be good. But since the SSI-bundle variables are not a good predictor for the development of SSIs, it is not sure whether compliance to this bundle could be linked to reducing SSIs.

The predictive value of the OR-cockpit grade in colorectal surgery, based on the variables: number of door movements during surgery, hair removal procedure, antibiotics prophylaxis, perioperative normothermia, time-out and sign-out, appears to be very low (AUC = 0.545). A new model, based on the SSI-bundle variables without time-out and sign-out, hardly improved compared to the OR-cockpit model (AUC 0.570). The small difference between these two models can be linked to the integration of the time-out and sign-out in the OR-cockpit grade model. Because of the non-adequate registration, these two variables have been omitted in the SSI-bundle model. Given the slight difference between these two models, time-out and sign-out appear to have almost no effect on predictive value. In conclusion, the models based on the OR-cockpit and the SSI-bundle variables do not have predictive value for the development of SSI in colorectal surgery.

To determine if there are better models to predict SSIs, a best model selection based on several predictive variables has been executed. The five models presented (Table 3) appear to have better predictive values compared to the OR-cockpit grade and the SSI-bundle models. The best model, with an AUC of 0.684, is based on six variables: wound classification, ASA classification, BMI, surgical approach, surgery duration and perioperative normothermia. This result partially confirms the 2012 research of Gervaz et al (7). They concluded that a preoperative prediction model, based on the four variables wound classification, ASA classification, BMI and surgical approach has a

discrimination capacity of 0.729. In our study we found two extra variables in the best prediction model: surgery duration and perioperative normothermia. The discrimination capacity of the best model in our study (AUC = 0.684) almost approached the result of the Gervaz et al. study.

Some of the variables found in the best model can be seen as logical. Patients with a higher wound classification (16) and ASA classification (17) automatically have an increased risk of developing an infection. This due to the worse contamination of the wound and the bad conditional status of the patient, which has been proven as high-risk factors for developing SSIs. Given that we found a large group of overweight patients in our study and overweight has a negative effect on the patient's immune system (18, 19), it can be explained that we found BMI as a predictive variable in our best model. The result of finding surgical approach as predictive variables in our best model can be explained by the fact that the reason for an open surgical approach comes with high risk factors, for example high BMI. Due the open approach of the surgery, a bigger surgical wound will be created. An open approach of the surgery automatically takes more time. The longer the surgery duration, the longer the surgical wound will be exposed to bacteria, which can lead to SSIs (20).

### Study limitations

The main limitation of this study is that it includes a retrospective study design. Within a retrospective design, it is not certain that SSIs are registered correctly: the so-called information bias. The information bias affects the validity of the study. With the retrospective study design, the distribution between some of the subgroups is not equal. This resulted that some groups were too small to perform valid analysis.

Another limitation of the study is that patients could be lost-to-follow-up during the 30 days follow-up period. The assumption that patients, who developed an SSI, went to the hospital or general practitioner is not completely reliable. It is possible that there were patients lost-to-follow-up with an SSI. So, the incidence of SSIs could be underdiagnosed.

A limitation of the data analysis is that the analysis where performed over the entire dataset. The data set was not randomly split into a training and test set.

### Future recommendations

Additional research can be considered to create a better prospective model. Therefore, several other variables can be taken into account to explore if there will be a higher predictive value than found in this study. For example, the number of people present in the operating room during surgery (21) or the number of aerial particles in the operating room (22) can possibly play a major role in higher incidence of SSIs.

To strengthen the validation of the main outcome (SSI), it can be recommended that when an SSI evolved, it always will be registered by the medical practitioner on duty in the standard registration format. This could lead to fewer errors because the researcher does not have to determine this from the medical reports.

Another recommendation is to change the study design into a prospective cohort study design. This will increase the validity of the study.

To strengthen de validation of the data analysis it can be recommended that the dataset will be randomly split into a training set and a test set. By training the dataset, the analysis will be more reliable.

### Conclusions

In conclusion, the variables based on the SSI-bundle are not good predictors for the development of SSIs in colorectal surgery. But since the range of the data in this study is limited, due to the good compliance with the SSI-bundle variables, it gives the surgical staff no permission to ignore the procedures of the prevention protocol. Given that, the compliance of the SSI-bundle variables during surgery procedures must always be taken into account. The SSI-bundle variables simply just have a poor predictive value.

Based on the results of the best model analysis, the model with the variables wound classification, ASA classification, BMI, surgical approach, surgery duration and perioperative normothermia is the model with the highest predictive value (AUC = 0.684) for the development of SSIs and can be recommended as useful to take into account when patients underwent colorectal surgery. Patients who cope with one of more of the following conditions can be seen as high-risk patients for developing SSIs:

- Open approach
- Wound class III or IV
- ASA class II, III or IV
- Overweight (BMI > 25)
- Surgery duration > 90 minutes
- Patients temperature not between 35.5 – 37.5 °C at the end of the surgery

Taking precautions and monitoring these higher risk patients can possibly lower the incidence of SSIs after colorectal surgery. This will lead to a positive effect, for both patients and hospital.

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