Major article

Toward the rational use of standardized infection ratios to benchmark surgical site infections

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Benchmark
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Background: The National Healthcare Safety Network transitioned from surgical site infection (SSI) rates to the standardized infection ratio (SIR) calculated by statistical models that included perioperative factors (surgical approach and surgery duration). Rationally, however, only patient-related variables should be included in the SIR model.

Methods: Logistic regression was performed to predict expected SSI rate in 2 models that included or excluded perioperative factors. Observed and expected SSI rates were used to calculate the SIR for each participating hospital. The difference of SIR in each model was then evaluated.

Results: Surveillance data were collected from a total of 1,530 colon surgery patients and 185 SSIs. C-index in the model with perioperative factors was statistically greater than that in the model including patient-related factors only (0.701 vs 0.621, respectively, \( P < .001 \)). At one particular hospital, for which the percentage of open surgery was lowest (33.2%), SIR estimates changed considerably from 0.92 (95% confidence interval: 0.84-1.00) for the model with perioperative variables to 0.79 (0.75-0.85) for the model without perioperative variables. In another hospital with a high percentage of open surgery (88.6%), the estimate of SIR was decreased by 12.1% in the model without perioperative variables.

Conclusion: Because surgical approach and duration of surgery each serve as a partial proxy of the operative process or the competence of surgical teams, these factors should not be considered predictive variables.

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a composite of endoscopic surgeries. Since 2010, however, the National Healthcare Safety Network (NHSN, formerly NNIS) transitioned from SSI rates based on an index to an SSI standardized infection ratio (SIR)\(^4\) based on logistic regression modeling.

Whereas risk adjustment for SSI rates based on multiple modeling is undoubtedly a better approach, development of an adequate model is still needed for this newer method. For example, risk models developed by NHSN have included surgical approach and duration of surgery,\(^5\) but these factors were also partially determined by patient characteristics and proxies of the perioperative process or the competence of surgical team.\(^6,7\) Multiple modeling for SSI risk adjustment aims to filter out only the noise in SSI rates caused by variation in intrinsic patient characteristics. If that fails, then it is possible that the interpretation of the resulting SIR would be distorted. Therefore, the present study aimed to calculate the SIR based on a model that included all collected variables in the current surveillance system in Japan and on a model that included only patient-related variables. In addition, we aimed to compare the interpretations of the SIRs between the 2 models.

**METHODS**

**Study population**

There are 2 SSI surveillance systems in Japan: the Japanese Healthcare Associated Infections Surveillance (JHAIS) system, established in 1999 and coordinated by the Japanese Society of Environmental Infections; and the Japan Nosocomial Infection Surveillance (JANIS) system, established in 2002 and coordinated by the Ministry of Health, Labor, and Welfare. The systems are run independently because of different coordinators and entry criteria, although both JHAIS and JANIS use Centers for Disease Control and Prevention definitions of SSI\(^8\) and perform surveillance following NHSN protocols. JANIS receives voluntary SSI surveillance data from hospitals with more than 200 beds.

We collected data from 8 participating JANIS hospitals regarding patients who underwent colon surgery through December 2010. The beginning of data collection varied by hospital and ranged from September 2007 to September 2010. Except for one hospital where SSI surveillance was not performed for emergency operations, SSI surveillance was conducted for all colon surgeries. The hospitals had an average of 578 acute care beds (range, 312-592 beds), with 5 classified as tertiary care and the other 3 as secondary care. Ethics approval to collect patient data from the hospitals was obtained from the Institute for Health Economics and Policy.

**Data collection**

Infection control professionals collected the following data for each patient under surveillance: type of SSI, wound class, ASA score, general anesthesia, emergency procedure, trauma association, implant, colostomy, sex, age, laparoscopic use, and duration of surgery. The following dichotomous variables were established from components of the basic risk index\(^2\): wound class (clean or clean-contaminated vs contaminated or dirty) and ASA score (1 or 2 vs 3, 4, or 5). Age and surgery duration were continuous variables.

**Statistical analysis**

We developed 2 multiple logistic regression models for SIR calculation and compared the probabilities of hospital-level expected SSI between these models. The 2 models were (1) a model that included all variables currently collected in the JANIS system and (2) a model that included only patient characteristics and not variables related to the perioperative process or surgical technique. These models can be presented by the following equations:

\[
\text{Logit } P(\text{SSI}) = \alpha + \beta_1 \text{ Wound class} + \beta_2 \text{ASA Score} + \beta_3 \text{Emergency} + \beta_4 \text{Colostomy} + \beta_5 \text{Sex} + \beta_6 \text{Age} + \beta_7 \text{Surgical approach} + \beta_8 \text{Duration of surgery}
\]

Predictive performance of each model was evaluated by calculating the c-index. The difference between the 2 c-indices generated from the above models was tested using the algorithm suggested by DeLong et al.\(^9\) These models were then used to predict the probability of occurrence of an SSI (expected SSI). SIRs were calculated for each model as the ratio of an observed SSI rate in a population divided by the expected SSI rate in that population.\(^4\)

To facilitate the interpretation of SIRs between analysis strategies, we calculated the difference in expected SSI rates. A P value of less than .05 was considered as statistically significant. All analyses were performed with STATA software, version 10.1 (STATA Corp, College Station, TX).

**RESULTS**

Observed SSI rates, patient characteristics, and clinical characteristics are summarized by hospital in Table 1. Hospitals were sorted in increasing order of observed SSI rate. Surveillance data were collected for 1,530 colon surgery patients. Colon surgery patients had a total of 185 SSIs (12.1% infection rate), of which 111 were superficial, 27 were deep, and 47 were space/organ infections. Among the hospitals, hospital 4 had the lowest percentage of patients with open surgery at 33.2%, as well as the longest duration of surgery (272 minutes). Conversely, hospital 2 had the highest percentage of open surgery (95.8%) and the shortest duration of surgery (166 minutes).

Table 2 displays the odds ratios (ORs) for adjusted risk models based on the model that included patient and clinical variables versus the model that included patient-related variables only. Given that almost all surgeries in the study were performed under general anesthesia and did not have trauma or implants, these factors were excluded from the logistic regression covariates. For the full variables model (model 1), wound class (OR, 2.72; 95% confidence interval [CI]: 1.70-4.35), surgical approach (OR, 3.69; [95% CI: 2.21-6.16]), and duration of surgery in 10-minute intervals (OR, 1.05; [95% CI: 1.03-1.07]) were statistically associated with increased risk of SSI. For the other model, which excluded perioperative variables (model 2), wound class (OR, 2.79; [95% CI: 1.75-4.44]) was statistically associated with increased risk of SSI. No statistical associations were observed between the ASA scores and SSI rates in either model. The c-indices for models 1 and 2 were calculated as 0.701 and 0.621, respectively. The 2 models differed statistically in their predictive ability (P < .001).

The expected SSI rates predicted by the 2 models and SIR are shown in Table 3. In model 1, the expected SSI rates for hospital 4 and hospital 5 were predicted as 11.1% and 13.4% and ranked fifth and third in terms of SIR, respectively. However, when perioperative variables were excluded (model 2), expected SSI rates for hospital 4 and hospital 5 were predicted as 12.9% and 11.8% and ranked third and fifth in terms of SIR, respectively. Compared with the expected SSI rate in model 1, the expected SSI rates for model 2 at hospital 4 and hospital 5 were increased to 15.6% and decreased...
ASA the observed SSI was significantly lower than the expected SSI. Because surgical approach and duration of surgery serve as partial proxies of the operative process or the hospitals or surgeons. Because surgical approach and duration of surgery serve as partial proxies of the operative process or the

competence of surgical teams,6,7 these factors should not be considered predictive variables. The present study indicated that these perioperative factors were significant risk factors for SSI; thus, the inclusion of these factors influenced SIR values considerably. Hospitals with better process performances were inappropriately evaluated as institutions with worse performance in SIR models that included perioperative factors.

Our results showed that SIR estimates of hospital 4 and hospital 5 changed dramatically depending on the statistical model. Because the percentage of open surgery at hospital 4 was the lowest (33.2%), the estimated 95% CIs of the SIR in models with and without perioperative factors changed from 0.84 to 1.00 to 0.75 to 0.85. Therefore, hospital 4's performance interpretation changed from "standard hospital" to "statistically high performance hospital." In contrast, hospital 5 had a relatively high percentage (88.6%) of open surgery and a long duration of surgery. The SIR was 0.85 according to the full variables model and 0.96 according to the model that only included patient-related variables, and hospital 5's ranking consequently fell to third.

### DISCUSSION

This multicenter study was conducted at 8 medical institutes in Japan to compare SIR across models with and without perioperative variables such as surgical approach or duration of surgery. We revealed that including perioperative factors can considerably change the interpretation of the SIR. The SIR is the ratio derived from an observed SSI rate divided by an expected SSI rate. An observed SSI rate included factors regarding all patient, surgeon, and hospital characteristics. By predicting an expected SSI rate that accounts for differences in all patient-related factors only, SIR can be used as a quality indicator to compare performance across hospitals or surgeons. Because surgical approach and duration of surgery serve as partial proxies of the operative process or the

To 12.1%, respectively. Whereas the SIR results and 95% CI of hospital 4 in model 1 indicated that the observed SSI was not significantly lower than the expected SSI, model 2 indicated that the observed SSI was significantly lower than the expected SSI.

### Table 1

<table>
<thead>
<tr>
<th>Hospital</th>
<th>SSI incidence, n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hospital 1 (n = 276)</td>
<td>20 (7.2)</td>
</tr>
<tr>
<td>Hospital 2 (n = 142)</td>
<td>13 (9.2)</td>
</tr>
<tr>
<td>Hospital 3 (n = 115)</td>
<td>11 (9.6)</td>
</tr>
<tr>
<td>Hospital 4 (n = 283)</td>
<td>29 (10.2)</td>
</tr>
<tr>
<td>Hospital 5 (n = 35)</td>
<td>4 (11.4)</td>
</tr>
<tr>
<td>Hospital 6 (n = 341)</td>
<td>45 (13.2)</td>
</tr>
<tr>
<td>Hospital 7 (n = 164)</td>
<td>29 (17.7)</td>
</tr>
<tr>
<td>Hospital 8 (n = 174)</td>
<td>34 (19.5)</td>
</tr>
</tbody>
</table>

### Table 2

<table>
<thead>
<tr>
<th>Odds Ratio</th>
<th>95% CI</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>ASA score</td>
<td>3-5</td>
<td>Reference</td>
</tr>
<tr>
<td>1-2</td>
<td>2.72</td>
<td>1.70-4.35</td>
</tr>
<tr>
<td>Emergency</td>
<td>yes</td>
<td>1.13</td>
</tr>
<tr>
<td>Colostomy</td>
<td>yes</td>
<td>1.25</td>
</tr>
<tr>
<td>Wound class: contaminated or dirty</td>
<td>clean or clean-contaminated</td>
<td>Reference</td>
</tr>
<tr>
<td>Contaminated or dirty</td>
<td>2.72</td>
<td>1.70-4.35</td>
</tr>
<tr>
<td>Perioperative variables</td>
<td>Surgical approach: open surgery, n (%)</td>
<td>230 (83.3)</td>
</tr>
<tr>
<td>Endoscopic surgery</td>
<td>Reference</td>
<td></td>
</tr>
<tr>
<td>Duration of surgery (10 min)</td>
<td>1.05</td>
<td>1.03-1.07</td>
</tr>
</tbody>
</table>

ASA, American Society of Anesthesiologists; SSI, surgical site infection.
To develop procedure-specific models for SIR, Mu et al selected models through stepwise variables selection and included perioperative factors and hospital-specific factors. In contrast to explanatory multiple modeling, which aims to explain as much of the data variability as possible, we propose that multiple modeling for SIR calculation should not feature perioperative process or surgical team competence as predictive variables. Because the SIR could be used as a benchmark to compare hospitals or surgeons, we think that model development should be based on sound clinical rationale and not driven solely by statistical objectives.

We chose colon surgery as the target procedure of this study. Because of the relatively high number of operations and high risk of SSI, colon surgery is considered one of the most important targets of infection control. However, this selection may also result in several difficulties with regard to the interpretation of the results. Given that “colon surgery” is an extremely broad category of surgery, including diverse procedures such as colectomy for cancer patients, appendectomy for a ruptured appendix, and colostomy for a ruptured diverticulitis, it stands to reason that there are variations in the proportions of diagnoses and surgical needs at the hospital level. Therefore, especially in colon surgery, it might be appropriate to utilize surgery duration as a proxy to indicate severity of these diagnostic ranges. Institutions that desire better SIR performance might resort to patient skimming that excludes more difficult cases, thereby unfairly distorting SIRs derived from models that do not take into account the duration of surgery. Because we focused on colon surgery and could not eliminate this possibility, the results of SIR must be interpreted with caution. Although SSI surveillance at JANIS does not collect data regarding diagnosis, this study could identify diagnoses of each patient by matching cases with another administrative database. According to the additional database, the average proportion (min-max) of patients undergoing colectomy for colon cancer at the hospital level was 65% (54%-80%). We conducted an additional analysis that adjusted for primary diagnosis in the SIR model without perioperative factors, but there was no significant difference in the SIR results between both models (data not shown).

Two limitations must be considered when interpreting the results of the present study. Our study is based on only 8 hospitals in Japan, which may limit the generalization of the parameter estimates regarding risk factors for SSI (Table 2) and predictive performance of SIR model. However, we do believe that the impact of including perioperative factors in SIR calculation would still have a detrimental effect on its interpretation, regardless of the number of facilities and the country. The second limitation concerns the availability of patient-related factors. Because the JANIS network performed surveillance following NHSN protocols, the collected data were the same as those from NHSN, and thus patient-related variables available for analysis were also limited. Whereas this study suggested that only patient-related factors should be used as covariates to calculate SIR, some patient-related risk factors such as types of diagnoses, types of surgeries, diabetes, smoking, and body mass index (BMI) which have been shown to be important in other studies—were not included. The limited number of available patient-level variables yielded a c-index of 0.621, which might be considered inadequate for predictive ability. However, a new directive to the NHSN surveillance system will include the collection of BMI and diabetes data after January 2013, which is likely to further improve SIR predictive ability. Given the work required for data collection combined with the impact of risk adjustment of patient case, other patient-related variables should be examined to determine whether they should be included in the surveillance system.

In conclusion, this study revealed that adjusting for duration of surgery and surgical approach might detrimentally affect the interpretation of SIR. Although duration of surgery and surgical approach have acted as proxies for patient severity, we believe that these factors should not be included into SIR calculation models because these perioperative variables are potentially surgeon-dependent factors. However, it is likely that the only 2 patient factors considered (wound class and ASA score) would not sufficiently account for the variability in patient presentation and severity of patient. Appropriate estimation of SIR should essentially be adjusted with patient severity, and SSI surveillance should collect patient-dependent factors such as primary diagnosis and comorbidities, as well as BMI and smoking status. The quality of SIR to benchmark SSI remains dependent on being able to account fully for the severity of a patient’s condition, and future SIR estimation should be designed to improve the comprehensive collection of the relevant information.

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References


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