Prediction model for complications after low anterior resection based on data from 33,411 Japanese patients included in the National Clinical Database

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Background. *Low anterior resection is associated with a relatively high incidence of postoperative morbidities, including anastomotic leakage and other operative site infections, which sometimes result in postoperative mortality. Therefore, recognition of the incidence and risk factors of postoperative complications following low anterior resection is essential.*
Methods. *Data from the National Clinical Database on patients who had undergone low anterior resection in 2011 and 2012 were retrospectively analyzed. Multiple logistic regression analyses were performed to generate predictive models of postoperative complications. Receiver-operator characteristic curves were generated, and the concordance index was used to assess the model's discriminatory ability.*
Results. *The number of patients who had undergone low anterior resection was 33,411. Seven complications, namely, overall operative site infections except for leakage, anastomotic leakage, urinary tract infection, pneumonia, renal failure, systemic sepsis, and cardiac events, were selected to construct statistical risk models. The concordance indices for the first 2 complications, which were dependent on the operative procedure, were relatively low (0.593–0.625), and the other 5, unrelated to operative procedures, showed high concordance indices (0.643–0.799).*
Conclusion. *This study created the world's second risk calculator to predict the complications of low anterior resection as a model based on mass nationwide data. In particular, this model is the first to predict anastomotic leakage. (Surgery 2016;■:■-■.)*

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COLORECTAL CANCER is the third most common malignant disease worldwide.[1] In Japan, colorectal cancer is rapidly increasing, and it is the second commonly diagnosed cancer and the third and first leading causes of cancer death in men and women, respectively.[2] In spite of recent advances of chemotherapy and radiotherapy for colorectal cancer, operative resection remains the prevailing

treatment. Among the various operative procedures for colorectal cancer, low anterior resection (LAR) for rectal cancer is one of the most demanding procedures because it requires resection of cancer with surrounding mesorectal tissue and reconstruction with anastomosis in the narrow pelvis while preserving the autonomic nerves of the urogenital organs.

Thus, LAR is associated with a relatively high incidence of postoperative morbidities, including anastomotic leakage and other surgical site infections (SSI), which sometimes result in postoperative mortality.[3,4] Therefore, recognition of the incidence and risk factors of postoperative complications after LAR is essential for both the informed consent provided to the patients and the safe performance of this procedure.

LAR is now an established procedure for rectal cancer treatment, and it is performed widely not only in specialized centers but also in general hospitals in Japan. Therefore, information on postoperative complications using a large, nationwide, prospective database is necessary. In the United States, the American College of Surgeons National Surgical Quality Improvement Program (ACS-NSQIP) collects nationwide data from many institutions and uses them to predict postoperative morbidity and mortality.[5,6] In Japan, the National Clinical Database (NCD), a nationwide project that is linked to the surgical board certification, started patient registration in January 2011.

Risk models using the NCD have been published for various gastrointestinal malignancies, such as esophageal,[7] gastric,[8,9] pancreatic,[10] and colonic cancers.[11] Recently, a report on risk factors and mortality rates after LAR using data from the NCD has been published.[12] In this study, we aimed to construct a risk model to predict the postoperative complications of LAR using this large, nationwide database.

METHODS

Data collection. The NCD is a nationwide project that was created in cooperation with the board certification system of surgery in Japan in which data are collected from >1,200,000 operative patients each year at >3,500 hospitals where >95% of the operative procedures in Japan are performed. The NCD started in 2011 and includes all cases registered since then. A few institutions missed the registration date in 2011 and registered later, but currently >98% of operative procedures are included in the NCD.

The NCD continuously identifies individuals via a Web-based data management system and can thus ensure data traceability. It also consecutively validates data consistency by randomly inspecting institutions. In the present study, we focused on the NCD section for gastrointestinal operation. The variables and definitions were almost identical to those of the ACS-NSQIP.

The acquired variables included demographic variables (including age, sex, smoking status, and alcohol drinking status) and physical status (including activities of daily living [ADL] and the American Society of Anesthesiologists physical status classification system; pre-existing co-morbidities, including cardiovascular, respiratory, renal, hematologic, and oncologic statuses; and whether a preoperative blood transfusion was performed).

The patients' laboratory parameters (white blood cell count, hemoglobin level, platelet count, and serum levels of albumin, total bilirubin, aspartate aminotransferase, alanine aminotransferase, alkaline phosphatase, urea nitrogen, creatinine, sodium, hemoglobin A1c, and C-reactive protein) also were included in the analysis. Finally, the postoperative outcomes were acquired, including morbidities and 30-day and operative mortality rates.

All variables and definitions of inclusion criteria regarding the NCD are accessible to participating institutions on the website (http://www.ncd.or.jp/). The website supports e-learning, so participants can upload consistent data. In the present study, we focused on the patients who had undergone LAR, which was defined as a partial or complete proctectomy with anastomosis below the peritoneal reflection, including intersphincteric resection with hand-sewn coloanal anastomosis.

NCD data entry privileges allow people other than physicians to enter the data. As published previously,[13] the department chair entered information in 58% of the departments, a medical information manager entered information in 10.2% of the departments, and a medical administrative assistant did so in 35.1% of the departments. Importantly, to secure data accuracy, either the department chair or a physician designated by the department chair must approve each case for data entry when somebody other than a physician enters the data. The accuracy of the data in the NCD is guaranteed by means of these audit trails.

End point. This study focused on LAR operations performed in Japan between January 1, 2011, and December 31, 2012. Any NCD records that were not included by patients were excluded from this analysis. Records with missing age or sex information were also excluded. The study focused on postoperative complications, including superficial incisional SSI, deep incisional SSI, organ space SSI, anastomotic leakage, pancreatic fistula, urinary tract infection, pneumonia, renal failure, systemic sepsis, central nervous system events, cardiac events, and pulmonary embolism.

SSI was defined according to the Centers for Disease Control guideline (http://www.cdc.gov/HAI/ssi/ssi.html). Anastomotic leakage was defined as "Cases with bowel content from drainage tube, cases which required drainage of extra-bowel bowel content, or cases in which apparent anastomotic leakage was identified by imaging modalities." All other definitions of