
Risk Stratification of 7,732 Hepatectomy Cases in 2011 from the National Clinical Database for Japan

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BACKGROUND: There has been no report on risk stratification for hepatectomy using a nationwide surgical database in Japan. The objective of this study was to evaluate mortality and variables associated with surgical outcomes of hepatectomy at a national level.

STUDY DESIGN: We analyzed records of 7,732 patients who underwent hepatectomy for more than 1 segment (MOS) during 2011 in 987 different hospitals, as identified in the National Clinical Database (NCD) of Japan. The NCD captured 30-day morbidity and mortality as well as 90-day in-hospital mortality outcomes, which were submitted through a web-based data entry system. Based on 80% of the population, independent predictors for 30-day mortality and 90-day in-hospital mortality were calculated using a logistic regression model. The risk factors were validated with the remaining 20% of the cohort.

RESULTS: The median postoperative length of hospitalization was 16.0 days. The overall patient morbidity rate was 32.1%. Thirty-day mortality and 90-day in-hospital mortality rates were 2.0% and 4.0%, respectively. Totals of 14 and 23 risk factors were respectively identified for 30-day mortality and 90-day in-hospital mortality. Factors associated with risk for 90-day in-hospital mortality were preoperative condition and comorbidity, operative indication (emergency surgery, intrahepatic/perihilar cholangiocarcinoma, or gallbladder cancer), preoperative laboratory data, and extent and location of resected segments (segment 1, 7, or 8). As a performance metric, *c*-indices of 30-day mortality and 90-day in-hospital mortality were 0.714 and 0.761, respectively.

CONCLUSIONS: Here we report the first risk stratification analysis of hepatectomy using a Japanese nationwide surgical database. This system would predict surgical outcomes of hepatectomy and be useful to evaluate and benchmark performance. (J Am Coll Surg 2014;218:412–422. © 2014 by the American College of Surgeons)

The safety and efficacy of liver resection have improved dramatically in recent years, allowing broader indications for the procedure in both benign and malignant diseases.¹ Perioperative mortality rates in high volume cancer centers are reportedly 0% to 2%.²⁻⁴ In contrast, population-based

analyses using administrative data from Western countries have reported mortality rates of 5% to 10%,⁴⁻⁷ indicating capacity for further improvement.

In 2006, the Japanese Society of Gastroenterological Surgery (JSGS) formed a committee to devise a database

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National Clinical Database (NCD) and the hospitals participating in NCD are the source of the data used herein and they have not verified and are not responsible for the statistical validity of the data analysis or the conclusions derived by the authors.

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Abbreviations and Acronyms

| | |
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| ADL | = activities of daily living |
| ASA | = American Society of Anesthesiologists |
| JSGS | = Japan Society of Gastroenterological Surgery |
| LOS | = length of stay |
| MOS | = more than 1 segment |
| NCD | = National Clinical Database |
| PT-INR | = prothrombin time-international normalized ratio |
| ROC | = receiver operating characteristic |
| SSI | = surgical site infection |

to track surgical cases performed in Japan over 3 years (2006 to 2008), which reported relatively low mortality rates in major surgical procedures.^{8,9} The JSGS, realizing the importance of risk-adjusted surgical outcomes for accurate comparisons and quality improvement, created the database as a subset of the National Clinical Database (NCD) of Japan, with significant support from the Japan Surgical Society. Submitting cases to the NCD is a prerequisite for all member institutions of both the Japan Surgical Society and JSGS, and only registered cases can be used for board certification.

The NCD collaborates with the American College of Surgeons National Surgical Quality Improvement Program (ACS-NSQIP),¹⁰ which shares a similar goal of developing a standardized surgery database for quality improvement. Traditionally, various governing bodies, including the ACS-NSQIP, have used 30-day patient mortality as a benchmark to assess the quality of both hospital and surgeon performance in virtually all major surgical procedures. However, Mayo and colleagues¹¹ recently reported that mortality based only on known data at 30 days is misleading and greatly underestimates the actual perioperative mortality by up to 50% compared with data at 90 days. The Japanese system of universal health care allows almost all patients who undergo surgery to be cared for in the hospitals performing the operation until the patients can function independently in activities of daily living (ADL).^{12,13} Therefore, the risk for 30- and 90-day in-hospital mortality should be analyzed using parameters similar to those of the ACS-NSQIP for patients undergoing hepatectomy of more than 1 segment (MOS). We evaluated more than 7,000 cases to formulate risk models associated with hepatectomy. This is the first reported hepatectomy risk model of cases derived from a nationwide population recorded through a web-based data entry system.

METHODS

Data collection

The NCD is a nationwide collaborative in association with the Japanese surgical board certification system, in which

more than 1.2 million surgical cases from over 3,500 hospitals were collected throughout 2011. The NCD is continuously in communication with hospital personnel who approve data and those in charge of tracking cases annually, as well as those responsible for data entry through the NCD web-based data management system, assuring data traceability. The NCD also consistently validates submitted data through random site visits. Hepatectomy outcomes include rigorously defined morbidities (categorized as wound, respiratory, urinary tract, central nervous system, and cardiac, among others) as well as mortality. Furthermore, the NCD supports an e-learning system for participants to continuously input data, responds to all inquiries regarding data entry (approximately 80,000 inquiries in 2011), and regularly posts some of the queries received via the website under the heading, "Frequently Asked Questions."

This analysis focused on hepatectomy procedures performed in Japan from January 1, 2011 to December 31, 2011. We collected data on 20,455 hepatectomy cases after excluding patients undergoing simultaneous operations including esophagectomy (n = 21), pancreaticoduodenectomy (n = 97), and operations for acute diffuse peritonitis (n = 3). The 30-day mortality and 90-day in-hospital mortality rates for the 20,455 cases were 1.2% and 2.3%, respectively.

The variables and definitions adopted by the NCD are almost identical to those established by ACS-NSQIP. The detailed input of these items for hepatectomy is limited only to procedures in which MOS were resected, excluding the lateral segment. All variables, definitions, and inclusion criteria maintained by the NCD are accessible to participating institutions on their website at <http://www.ncd.or.jp/>. The numbers of cases of partial hepatectomy, lateral segmentectomy, systemic subsegmentectomy, and S4a/S5 resection were 10,161; 1,489; 1,054; and 225, respectively. Thirty-day and 90-day in-hospital mortality rates for each procedure were 0.7/1.3%; 0.5/1.3%; 0.8/1.4%; and 0.9/1.3%, respectively. These cases were not applicable for this analysis. Although laparoscopic surgery has been widely applied for lateral segmentectomy and partial hepatectomy, laparoscopic surgery for MOS was performed only in a limited number of institutes as clinical trials. These cases were also excluded from this study. The exclusion criteria and the respective number of cases are shown in a flow chart in [Figure 1](#). As a result, 7,732 patients, who underwent MOS hepatectomy in 987 hospitals from January 1 2011 to December 31, 2011, were eligible for inclusion.

Indications for benign and malignant tumors were identified using the Union for International Cancer Control (UICC) classification system. Specific hepatectomy procedures were identified by variables indicating resected

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