Table III. Prescription rate of discharge cardiac medications according to the indications for PCI in the United States and Japan

	United States				Japan			
	Overall (n = 732,345)	Elective (stable/no angina; n = 232,111)	UA/NSTEMI (n = 394,612)	STEMI (n = 105,622)	Overall (n = 9941)	Elective (stable/no angina; n = 5030)	UA/NSTEMI (n = 2631)	STEMI (n = 2288)
Antiplatelet agents								
Aspirin (%)	95.9	96.1	96.1	94.8	96.3	97.2	96.5	94.1
Clopidogrel (%)	88.7	90.2	89.2	83.6	88.3	88.3	88.7	87.9
Prasugrel (%)*	7.3	6.1	7.2	10.2	–	–	–	–
Ticlopidine (%)	0.4	0.4	0.4	0.3	3.8	5.0	3.8	1.2
Cilostazol (%)	–	–	–	–	2.1	2.7	1.5	1.5
β-Blockers (%)	82.5	76.2	83.9	91.6	67.5	64.3	63.8	78.9
Calcium blockers (%)	–	–	–	–	31.6	37.9	34.5	14.2
Statins (%)	87.2	85.3	87.5	90.3	82.2	81.1	82.0	84.7

Abbreviations: *UA*, Unstable angina; *NSTEMI*, non–ST-elevation myocardial infarction.
*Prasugrel was not available in Japan during the study period.

Table IV. In-hospital mortality and complication rates according to the indications for PCI in the United States and Japan

	United States				Japan			
	Overall (n = 732,345)	Elective (stable/no angina; n = 232,111)	UA/NSTEMI (n = 394,612)	STEMI (n = 105,622)	Overall (n = 9941)	Elective (stable/no angina; n = 5030)	UA/NSTEMI (n = 2631)	STEMI (n = 2288)
Cardiogenic shock (%)	0.8	0.2	0.5	3.1	1.8	0.8	1.3	3.9
Heart failure (%)	0.8	0.3	0.6	2.8	1.8	0.4	1.5	5.2
Stroke (%)	0.2	0.1	0.2	0.5	0.4	0.2	0.5	0.7
Tamponade (%)	0.1	0.1	0.1	0.1	0.3	0.1	0.1	0.7
Blood transfusion (%)	2.5	1.3	2.4	5.2	2.2	1.3	2.7	3.7
Bleeding event rate (%)	1.8	1.1	1.7	3.8	2.9	2.1	3.3	4.4
Bleeding from the access site	0.5	0.4	0.5	0.9	1.0	0.8	1.1	1.1
Bleeding from the nonaccess site	1.3	0.7	1.2	2.9	1.9	1.3	2.2	3.3
In-hospital mortality rate (%)	0.9	0.3	0.7	3.3	1.6	0.4	1.7	4.3

Abbreviations: *UA*, Unstable angina; *NSTEMI*, non–ST-elevation myocardial infarction.

duration in Japan compared with in the United States (29.7 ± 21.5 vs 14.4 ± 11.5 minutes, $P < .001$).

As shown in Table III, most of the enrolled patients were discharged with aspirin and secondary antiplatelet agents (eg, clopidogrel) in both countries. Overall, 80% to 90% of the patients in the United States received β-blockers, as compared with only 60% to 70% of Japanese patients. The prescription rate for statins was high in both countries, ranging from 80% to 90%.

On average, Japanese patients had more periprocedural complications compared with the US patients. In particular, they had higher bleeding complication rates within 72 hours of PCI (2.9% vs 1.8%, $P < .001$). Moreover, Japanese patients had a significantly higher in-hospital mortality rate (1.6% vs 0.9%, $P < .001$), as shown in Table IV.

When the observed event rates were compared with the expected event rates based on the established NCDR risk models, the O/E ratios for in-hospital mortality were constant at around 1.0 (1.002 and 0.921, respectively, for US and Japanese patients) (Table V). When the patients were subcategorized according to the PCI status (elective, acute coronary syndrome, and STEMI), the outcomes for elective and STEMI patients were better and worse, respectively, in the United States, whereas an opposite pattern was observed in Japan. Furthermore, the NCDR in-hospital model showed excellent applicability, with a *c* index value of 0.919 (95% CI 0.899-0.939), and the *c* index for in-hospital mortality was consistent across all PCI indications (Table VI). In contrast, the NCDR bleeding model showed only modest applicability for prediction of bleeding complications, with a *c* index score of 0.662 (95% CI 0.639-0.685). Figures 1 and 2 show the calibrations of the risk models for mortality and bleeding complications, respectively.

Table V. Comparison of the observed in-hospital mortality in the Japanese registry and the corresponding values calculated from the US NCDR model

	O/E ratio for mortality rate calculated from 2013 NCDR mortality model		O/E ratio for bleeding rate calculated from 2013 NCDR bleeding model	
	NCDR registered US patients	Japanese patients	NCDR registered US patients	Japanese patients
Overall	1.002	0.921	0.981	0.467
Elective	0.801	1.000	0.868	0.700
UA/NSTEMI	1.065	0.939	1.024	0.549
STEMI	0.998	0.860	0.989	0.318

Abbreviations: *UA*, Unstable angina; *NSTEMI*, non–ST-elevation myocardial infarction.

Table VI. Performances of the NCDR in-hospital mortality and bleeding models in the Japanese registry

	c Index of 2013 NCDR mortality model for Japanese patients	95% CI
A.		
Overall (n = 9941)	0.919	0.899-0.939
Elective (n = 5030)	0.915	0.821-1.000
UA/NSTEMI (n = 2631)	0.895	0.864-0.926
STEMI (n = 2288)	0.789	0.741-0.838
B.		
Overall (n = 9941)	0.662	0.639-0.685
Elective (n = 5030)	0.664	0.616-0.692
UA/NSTEMI (n = 2631)	0.645	0.600-0.691
STEMI (n = 2288)	0.636	0.589-0.693

Abbreviations: *UA*, Unstable angina; *NSTEMI*, non–ST-elevation myocardial infarction.

Discussion

This study was a direct comparison of patients undergoing PCI in Japan and the United States. Few international comparisons have been performed, with the exceptions of trials, and this study represents a unique effort in using standardized variable definitions among 2 registries to facilitate such comparisons. In the present study, the characteristics of patients undergoing PCI in clinical practice in Japan and the US differed substantially; the Japanese cohort was significantly older, with higher proportions of men, diabetes, and smoking. Moreover, a higher proportion of STEMI patients and, angiographically, higher rate of bifurcation and CTO lesions, as well as a longer procedure time, were observed. Moreover, when the in-hospital outcomes were compared, the Japanese patients had higher mortality and bleeding complication rates; the updated statistical model from the NCDR data applied well for the prediction of mortality but not for bleeding complications, with the model constantly underestimating the bleeding risk.

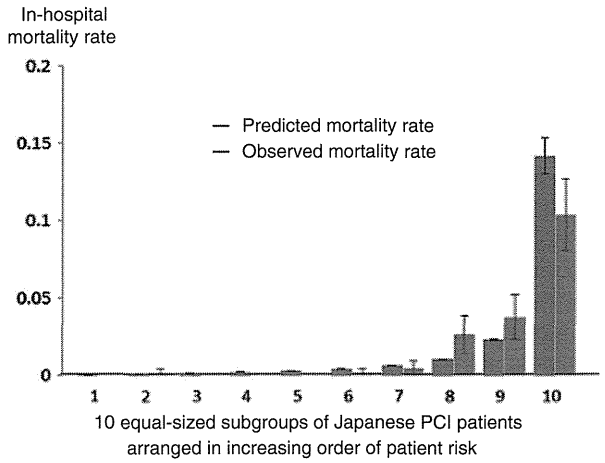
General points about international comparisons

It is important to determine the clinical characteristics and profiles of patients who undergo PCI in different regions, because such data are necessary to evaluate whether patients are being managed appropriately and in line with the available clinical guidelines and evidence-based medicine.The current findings from 2 large-scale registries underscore the importance of establishing clinical registry programs using common data elements/standards in individual regions or countries, because their procedural "culture" may differ substantially. Common data elements within clinical, but not administrative, data would enable specific differences in the patient characteristics and outcomes with adequate risk adjustment. The JCD registry is the first international registry designed prospectively with similar data definitions as those used in the US NCDR (under version 4.0 of the CathPCI Data Collection Form and Data Specifications). As such, it was ideally designed to compare the clinical characteristics of patients undergoing PCI in Japan and the United States. Comparative studies such as the present study can further help evaluate the appropriateness of the procedures and may assist in individual or institutional quality improvements.

Comparisons of the patient background characteristics

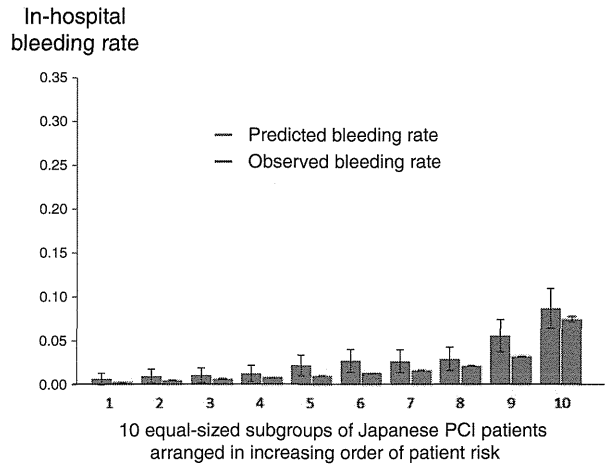
A high number of PCI procedures are performed in Japan every years (>200,000 procedures annually in 2012), but little is currently known about the characteristics of the Japanese patients and how they compare to their counterparts in the United States.[7] In addition, the Asian subgroup in the US registries is relatively small. In our study, most of baseline patient characteristics were comparable between the 2 countries, although the Japanese patients were generally older than the US patients and had a lower burden of predisposing cardiac risk factors. Indirect comparisons of large-scale clinical studies and databases have been performed in the past, and the data from the current study are consistent with these results.[8-11] Lesion complexity, as demonstrated by a higher prevalence of type C, bifurcation, and CTO lesions, was observed more frequently in the PCIs performed in Japan compared with in the United States. Although cardiothoracic surgeons in Japan have comparable surgical skills to their counterparts in the United States,[12] Japanese patients prefer to undergo less invasive procedures. In addition, Japanese patients also have a significantly lower rate of thromboembolic complications, such as stent thrombosis.[13] Of note, the use of dual antiplatelet therapy was applied in 88.3% of our patients in the Japanese data set. This is in concordance with the recent multicenter acute myocardial infarction registry in Japan (J-AMI) study, which demonstrated that clopidogrel loading was used in 79.2% of 2,030 consecutive STEMI patients from 213 Japanese institutions.[14] These numbers are comparable to the use of clopidogrel in the US PCI patients (88.7%).

Figure 1



Calibration of the US mortality model for Japanese PCI patients.

Figure 2



Calibration of the US bleeding model for Japanese PCI patients.

It is of interest that, despite differences in the patient characteristics, the mortality model performed well in this study. Some of the variables seemed to favor US patients (eg, age [64.6 vs 67.9 years] and DM [35.7% vs 42.7%], for the US and Japanese patients, respectively), whereas others favored the Japanese patients (eg, BMI [30.0 vs 24.2 kg/m^2] and other comorbid conditions such as chronic lung disease, peripheral vascular disease, and cerebrovascular disease). It is indeed possible that some of these parameters may have had opposite effects on the observed outcomes. The greater prevalence of diabetes in Japanese patients is in accordance with the rates of diabetes recorded by other coronary artery disease registries in Japan.[13] Moreover, we have previously shown a higher prevalence of DM in Japanese patients compared with in US patients undergoing revascularization procedures during a similar period (prior to the drug-eluting stent era).[9] Interestingly, despite the higher prevalence of DM in Japanese patients, these patients had a better prognosis compared with DM patients in the United States, even after adjustment for known confounding factors. Furthermore, in another previous study by our group, investigating the impact of BMI on procedure-related outcomes,[15] we found that, interestingly, lean patients, rather than obese patients, were at greater risk for in-hospital complications after PCI in Japan. As for the other comorbid conditions, the prevalence of these variables was significantly lower in the Japanese data set compared with in the NCDR data set in the present study (chronic lung disease [14.9% vs 3.1%], peripheral vascular disease [12.4% vs 7.2%], and cerebrovascular disease [12.1% vs 8.1%]) and may have contributed partly, although likely in a very limited amount, to the outcomes of the patients in the Japanese data set.

Comparisons of the outcome information

Comparing clinical outcomes of 2 completely different patient populations remains a challenge, and the evaluation of the applicability of the NCDR risk models in this study was an original approach to circumvent this limitation. The NCDR mortality model performed well when applied to the Japanese cohort. This excellent discrimination appears to be unaffected by the indication of PCI and was evident in all patient subgroups. Our results validate the NCDR in-hospital model as a useful tool in the risk stratification of Japanese patients who undergo PCI under a preformatted clinical registration system and demonstrate that its discrimination is not affected by the international differences of the PCI practice or by its indications.

Interestingly, better outcomes were observed in elective patients in the United States, whereas an opposite pattern was observed in Japanese patients, with a better outcome for STEMI patients rather than elective patients. It has been previously reported that the risk profile is worse for Japanese patients in both the STEMI and elective groups, largely owing to the higher age, higher prevalence of multivessel disease, and higher proportion of patients presenting with cardiogenic shock.[16,17] Of note, there may be some overlap in the risk distributions of the individuals with and without the events. Furthermore, based on the premise that ethnical difference and specific therapeutic measures would reduce the morbidity and mortality, the favorable outcome in Japanese cardiovascular patients together with the use of the radial approach might have contributed to the observed overestimation to some extent. Given the current performance of the NCDR prediction model, minor adjustments in the lowest and/or highest risk category patients may thus be needed.

On the other hand, the discriminatory performance for bleeding complication was suboptimal, and there are several plausible explanations for the limited model discrimination. Asian patients, in general, experience a higher incidence of bleeding complications when treated for cardiovascular conditions in US hospitals,[18,19] and this is also reflected in the constantly higher rate of observed bleeding compared with the predicted bleeding rate in our calibration analysis (Figure 2). Moreover, differences in the sensitivity or availability of antiplatelet or anticoagulation treatments may have led to these differences. For example, glycoprotein IIb/IIIa receptor antagonists and bivalirudin are not available of use in coronary patients in Japan. A previous phase III trial of IIb/IIIa receptors antagonists in Japan showed no improvement in the major cardiac event rates, with increased incidence of bleeding in a dose-dependent manner, whereas bivalirudin has not yet been introduced to the Japanese market.[20] Another possible reason may be related to the fact that the US bleeding model was derived almost exclusively from femoral access patients, whereas about one-third of Japanese patients were treated via the radial access. In addition, the previously stated overreliance on PCI may have affected the predictability of the bleeding model. Increased use of PCI in high-risk, salvage-category patients would naturally reduce the accuracy of the statistical models.

Strengths and limitations

The main strengths of our analysis include the large numbers of participating centers with trained coordinators and patients registered under common variables. The limitations of our analysis are as follows: although the NCDR is a nationwide registry from the United States, the JCD-KiCS is currently only a regional registry, with the recruiting sites mostly based in the Kanto (Tokyo) area of Japan. However, when compared with the national PCI registration data of 2011 (J-PCI; http://www.cvit.jp/registry/progress.html), the patient backgrounds were similar (Supplementary Table II), and our results, hence, seem to carry certain generalizability. At present, the J-PCI only comprises a limited number of variables (14 common variables with the JCD-KiCS) and runs without verification of the registered data; therefore, it cannot be used for international comparisons. Nevertheless, it is under development to incorporate an individual feedback system and auditing in order to further the quality of care among PCI patients in Japan. Second, the reasons for the differences between the 2 populations remain unclear: is it the presentation/progression of coronary artery disease or rather the management and the revascularization strategy of coronary artery disease that are responsible for the observed differences between the 2 countries? Lastly, although our analyses considered several key variables identified from contemporary models developed and validated within national registries, residual confounding is still possible, given the observational nature of the study. For example, the JCD-KiCS does not include the annual operator volume as a variable. Moreover, no procedure-volume analysis has been performed from a Japanese catheter or PCI data set, and it is unclear whether the average annual operator volumes are higher than the international average. This point warrants further investigation, and nationwide registries such as the J-PCI may serve as ideal databases in the future.

Conclusions

In conclusion, data from the JCD registry demonstrated the clinical characteristics of patients who undergo PCI in Japan. Although patients undergoing PCI in Japan differ significantly from those treated in the US, the NCDR mortality model offered useful predictive capacity in Japanese PCI patients as well. On the other hand, the applicability was limited in the bleeding model. This ongoing study will continue to provide valuable information regarding the pathophysiologic, therapeutic, and prognostic issues related to PCI, and this information is expected to aid in conducting safer and more effective PCI treatments.

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Appendix. Supplementary data

Supplementary data to this article can be found online at http://dx.doi.org/10.1016/j.ahj.2015.09.017.

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OBSERVATIONAL STUDY

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Comparison of National Operative Mortality in Gastroenterological Surgery Using Web-based Prospective Data Entry Systems

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Abstract: International collaboration is important in healthcare quality evaluation; however, few international comparisons of general surgery outcomes have been accomplished. Furthermore, predictive model application for risk stratification has not been internationally evaluated. The National Clinical Database (NCD) in Japan was developed in collaboration with the American College of Surgeons National Surgical Quality Improvement Program (ACS-NSQIP), with a goal of creating a standardized surgery database for quality improvement. The study aimed to compare the consistency and impact of risk factors of 3 major gastroenterological surgical procedures in Japan and the United States (US) using web-based prospective data entry systems: right hemicolectomy (RH), low anterior resection (LAR), and pancreaticoduodenectomy (PD).

Data from NCD and ACS-NSQIP, collected over 2 years, were examined. Logistic regression models were used for predicting 30-day mortality for both countries. Models were exchanged and evaluated to determine whether the models built for one population were accurate for the other population.

We obtained data for 113,980 patients; 50,501 (Japan: 34,638; US: 15,863), 42,770 (Japan: 35,445; US: 7325), and 20,709 (Japan: 15,527; US: 5182) underwent RH, LAR, and, PD, respectively. Thirty-day mortality rates for RH were 0.76% (Japan) and 1.88% (US); rates for LAR were 0.43% versus 1.08%; and rates for PD were 1.35% versus 2.57%. Patient background, comorbidities, and practice style were different between Japan and the US. In the models, the odds ratio for each variable was similar between NCD and ACS-NSQIP. Local risk models could predict mortality using local data, but could not accurately predict mortality using data from other countries.

We demonstrated the feasibility and efficacy of the international collaborative research between Japan and the US, but found that local risk models remain essential for quality improvement.

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Abbreviations: ACS-NSQIP = American College of Surgeons National Surgical Quality Improvement Program, ASA = American Society of Anesthesiologists, AST = Aspartate aminotransferase, BMI = body mass index, CKD = chronic kidney disease, COPD = chronic obstructive pulmonary disease, LAR = low anterior resection, NCD = National Clinical Database, PD = pancreaticoduodenectomy, PT-INR = prothrombin time–international normalized ratio, RH = right hemicolectomy, SIRS = systemic inflammatory response syndrome, US = United States.

INTRODUCTION

Improving the quality of surgical procedures is dependent on the collection of accurate data. The National Clinical Database (NCD) in Japan was developed in collaboration with the American College of Surgeons National Surgical Quality Improvement Program (ACS-NSQIP), with a shared goal of creating a standardized surgery database for quality improvement. NCD and ACS-NSQIP have developed systems using standardized variable definitions to collect data on risk factors and outcomes after surgery. These databases collect prospective rather than retrospective data. Both use web-based data collection software, contributing to effective quality improvement, via benchmarking and risk-adjusted feedback reports to hospitals; this enables the identification of specific problems and works towards their improvement. The ACS initiated ACS-NSQIP in 2006 and demonstrated improved surgical outcomes among participating private sector hospitals.[1] More than 500 hospitals participated in ACS-NSQIP. NCD in Japan, which was launched in 2010, is a nationwide prospective registry linked to the surgical board certification system. NCD systematically collects accurate data on structures, processes, and outcomes, to develop a standardized surgery database for quality improvement and healthcare quality evaluation.[2] NCD contains the records of >1,200,000 surgical cases collected in 2011, with approximately 4000 institutions participating in 2013.

One of the important advantages of NCD and ACS-NSQIP is the ability to benchmark and compare risk-adjusted outcomes. This ability allows fair comparisons to be made along with collaborative learning. International collaboration is

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important in healthcare quality evaluation and produces meaningful results; however, few international comparisons of general surgery outcomes using clinical registry data have been accomplished. There is a lack of data regarding outcomes of Japanese patients undergoing gastroenterological surgery and comparison with the United States (US). Furthermore, predictive model application for clinical risk stratification has not been internationally evaluated. Differences in the prevalence of patient comorbidities and their association with outcomes remain unknown. The purpose of this study was to compare patient characteristics; procedure details; operative outcomes; the consistency and impact of risk factors for 3 major gastroenterological surgery procedures: right hemicolectomy (RH), low anterior resection (LAR), and pancreaticoduodenectomy (PD) in Japan and US; and to examine whether risk prediction models built for one population were accurate for the other population. To the best of our knowledge, this is the first study to use large, high-quality data from different patient populations.

METHODS

Study Design and Outcomes

Patient cohorts and risk subcategories for RH, LAR, and PD were selected from both NCD/Japan and ACS-NSQIP/US data. Univariate analysis of each selected predictors for the 3 procedures was conducted for both datasets. Subsequent multivariate models were separately constructed using data from NCD and ACS-NSQIP. Finally, risk models were exchanged and evaluated to determine whether risk prediction models built for one population were accurate for the other population.

Data from NCD and ACS-NSQIP collected over 2 years (2011–2012) were examined. The primary outcome measure of this study was 30-day mortality. Thirty-day mortality was defined as death within 30 days after the operation date regardless of whether the patient had been discharged from initial admission.

Data Acquisition and Patient Selection

The NCD project was approved on November 2010 by the Japan Surgical Society Ethics Committee. The developmental history and current status of the NCD, including sampling strategy, data abstraction procedures, variables collected, outcomes, and structure, are described elsewhere.[2,3] NCD recruits individuals to approve the inputted data from members of various departments in charge of annual cases, as well as data entry officers through a web-based data management system to assure the traceability of the data. NCD conducted onsite audits using source data randomly for mortality, and the results were found to be accurate. Currently, NCD is planning to perform onsite and remote audit for verifying the accuracy of existing data for morbidities. The ACS-NSQIP program and dataset have been described elsewhere.[4,5] Data are abstracted by trained Surgical Clinical Reviewers using standardized definitions, including patient demographics, comorbidities, laboratory values, operative variables, and complications.

Patients who underwent RH, LAR, and PD were identified using Current Procedural Terminology (CPT) (US) and NCD codes (Japan). Both NCD and ACS-NSQIP contain patient cohorts limited to malignant tumor patients only. Any records with entry denied by patients were excluded from this analysis. Records with missing information regarding age, sex, or status at 30 days postoperation were also excluded. For the PD procedure, we excluded cases with simultaneous major hepatectomy.

All variables, definitions, and inclusion criteria in NCD/Japan are accessible on the NCD website (http://www.ncd.or.jp/). Descriptions of the qualifications, auditing of data collection personnel, case inclusion criteria, sampling data collection strategy, and variable and outcome definitions in ACS-NSQIP/US are available online in ACS-NSQIP user guide.[6]

Variables

Two sets of predictive variables were constructed from the NCD/Japan and ACS NSQIP/US data fields. Patient demographic variables considered were age and sex. General factors considered were as follows: preoperative functional status (independent, partially dependent, or totally dependent); American Society of Anesthesiologists (ASA) class; dyspnea (none, moderate exertion, or at rest); emergency cases; and body mass index (BMI: normal, underweight, overweight, and 3 categories of obesity). ASA class was not considered in further multivariate analysis because the criterion to determine class was inconsistent between countries. Comorbidities included were diabetes (oral medication or insulin-dependent); a history of chronic obstructive pulmonary disease (COPD); hypertension requiring medication; congestive heart failure; bleeding disorders; sepsis (systemic inflammatory response syndrome, sepsis, and septic shock); disseminated cancer; chronic kidney disease (CKD) stage; and weight loss (>10% in previous 6 mo). Length of hospital stay was also compared.

Preoperative laboratory variables examined included albumin, white blood count, prothrombin time-international normalized ratio (PT-INR), total bilirubin, and aspartate aminotransferase (AST). Missing laboratory data continued as separate categories. It should be noted that missing values are virtually nonexistent for predictors, except for laboratory variables, where clinical issues have a substantial impact on the ordering of tests.

Statistical Analysis

Raw frequencies and chi-square tests were used to assess differences in the distribution of general factors, comorbidities, and laboratory values, as well as their association with 30-day mortality. Because of the low number of deaths, the risk models were developed with a limited number of variables.[7] To identify these variables, we first used a logistic regression technique with forward selection to identify the most significant predictor variables. Sharing the same SAS code, we generated 3 models (1 for each surgical group) in each country, with lists of the top predictors (data not shown). We used these lists to select a common set of predictors to be used in the final risk models. For the final risk models, logistic regression techniques with forced selection were used to develop models that predict 30-day mortality using a set of relevant comparably defined risk factor variables in both countries. Model fit was assessed using Hosmer–Lemeshow goodness-of-fit statistic for calibration and c-statistic for discrimination.[8,9] The c-statistic allows model discrimination to be measured, with 1.0 indicating perfect discrimination and 0.5 being no better than chance. These models were then used to predict mortality using data from the other dataset (ie, the NCD model was used to predict mortality using the ACS-NSQIP data and vice versa). Observed and expected mortality rates were compared. All data manipulation and analysis were performed with SAS version 9.3 (SAS Institute Inc.).

RESULTS

Risk Profiles and Outcomes

During the study period, a total of 50,501 patients underwent RH (Japan, 34,638; US, 15,863), 42,770 patients underwent LAR (Japan, 35,445; US, 7325), and 20,709 patients underwent PD (Japan, 15,527; US, 5182). Thirty-day unadjusted mortality rates for RH were 0.76% in Japan and 1.88% in US; mortality rates for LAR were 0.43% in Japan and 1.08% in US; and mortality rates for PD were 1.35% in Japan and 2.57% in US. The risk profiles and outcomes of each procedure from both databases are described in Table 1 (RH), Table 2 (LAR), and Table 3 (PD). The ACS-NSQIP population for each procedure tended to be younger. When we looked at the 30-day mortality associated with age, we observed that in both countries, mortality increases as age increases; however, the effect was more pronounced in the ACS-NSQIP data. Laparoscopy was conducted in 36.6% of the Japanese and 56.9% of the US RHs, and 42.9% of the Japanese and 44.2% of the US LARs. Notably, the percentage of patients with a high BMI substantially differed between cohorts. The ACS-NSQIP cohort had a significantly shorter length of hospital stay. The prevalence of patients with CKD differed between Japan and US. Univariate analysis revealed the patient risk factors that were significant predictors of mortality after RH, LAR, and PD (Tables 1–3).

The Risk Models for Mortalities

The final logistic model for 30-day mortalities of each procedure, along with odds ratios (ORs) and 95% confidence intervals (CIs), is presented in Table 4. For RH, 14 significant risk factors for 30-day mortality were identified in Japan, and, in contrast, 17 significant risk factors were identified in US. The c-statistic was calculated to evaluate model performance. The c-statistic was 0.857 for the Japan model and 0.840 for the US model, indicating adequate discrimination. The Hosmer–Lemeshow statistic was 11.243 ($P = 0.19$) for the Japan model and 5.8660 ($P = 0.66$) for the US model, indicating both models adequately assigned risk. For LAR, 12 significant risk factors for 30-day mortality were identified in Japan; in contrast, 10 significant risk factors were identified in US. The c-statistic was 0.782 for the Japan model and 0.822 for the US model, indicating adequate discrimination. The Hosmer–Lemeshow statistic was 5.2355 ($P = 0.63$) for the Japan model and 10.9464 ($P = 0.20$) for the US model, indicating both models adequately assigned risk. For PD, 9 significant risk factors for 30-day mortality were identified in Japan; in contrast, 11 significant risk factors were identified in US. The c-statistic was 0.684 for the Japan model and 0.719 for the US model, indicating good discrimination. The Hosmer–Lemeshow statistic was 9.908 ($P = 0.27$) for the Japan model and 8.6192 ($P = 0.38$) for the US model, indicating both models adequately assigned risk. ORs for each variable were similar between countries.

Exchange Each Risk Model

Models were exchanged between countries and were used to create new models with forced selection to evaluate model transferability (Table 5). For RH, the c-statistic was 0.789 based on US data using the Japan model formula and 0.828 based on Japanese data using the US model formula, indicating adequate but decreased discrimination. The Hosmer–Lemeshow statistic was 171.01 ($P < 0.001$) based on US data using the Japan model formula and 955.23 ($P < 0.001$) based on Japanese data using the US model, indicating neither model adequately assigned risk. For LAR, the c-statistic was 0.786 based on US data using the Japan model formula and 0.778 based on Japanese data using the US model formula, indicating good but decreased discrimination. The Hosmer–Lemeshow statistic was 49.54 ($P < 0.001$) based on US data using the Japan model formula and 145.37 ($P < 0.001$) based on Japanese data using the US model, indicating neither model adequately assigned risk. For PD, the c-statistic was 0.674 based on US data using the Japan model formula and 0.540 based on Japanese data using the US model formula, indicating inadequate discrimination. The Hosmer–Lemeshow statistic was 8.8173 ($P = 0.36$) based on US data using the Japan model formula and 366.22 ($P < 0.001$) based on Japanese data using the US model. In all three procedures, we ran each risk model using the other country's data to assess the discrimination of each model.

Observed and Expected Mortality

Both NCD and ACS-NSQIP models were able to predict the number of deaths in the Japan dataset accurately. However, we decreased accuracy when using models from one country's dataset to predict the number of deaths in the other; we sound the ACS-NSQIP model overpredicted deaths in the NCD dataset, whereas the NCD model underpredicted deaths in the ACS-NSQIP dataset (Table 5). Figures 1 and 2 show the 30-day mortality model calibrations and observed event rates versus predicted rates. In measures of calibration (Hosmer–Lemeshow plots), the y axis gives the predicted number of deaths, and the x axis gives the actual number of deaths observed, that is, a perfect straight line would be a perfect model. Risk models based on local data accurately predicted mortality rates; however, risk models based on the other country's data could not accurately predict mortality rates.

DISCUSSION

Our study is the first international comparison of nationwide operative mortality in gastroenterological surgery using similar web-based prospective data entry systems, with collaboration between the NCD/Japan and the ACS-NSQIP/US. Although some international comparative studies provided variations in mortality rate between countries,[10,11] these studies were under the restriction of the inherent differences in the data collection methods between the datasets. Also, these studies did not examine whether risk prediction models built for one population were accurate for the other population. ACS-NSQIP participation have not offered a clear mechanism for quality improvement[12,13]; however, these are undeniably considered the highest clinical quality standards for evaluating risk-adjusted surgical outcomes. Both use rigorous, standardized data collection methods. Preoperative variables are clearly defined with the same definitions used in both databases and the same defined data collection methodology, including a strict follow-up period for outcomes.[2,14] By comparing the 2 datasets, we found differences in the following: descriptive data including preoperative patient variables; definitions and interpretation of ASA classifications; missing data from preoperative blood tests; duration of hospital stay after surgery; and 30-day mortality. We then created risk models based on local data for each country to predict mortality after each procedure. We found that although the exchanged models had adequate discrimination for mortality after each procedure, the models failed to yield adequate calibration between countries. This finding clearly indicated that risk models based on local data remain essential for quality assessment and improvement.

TABLE 1. Univariate Analysis for 30-Day Mortality of Right Hemicolectomy

	US/NSQIP (N = 15,863) (Died = 299, Died [%] = 1.88%)			Japan/NCD (N = 34,638) (Died = 264, Died [%] = 0.76%)		
	Total (N [%])	Died (n [%])	*P*	Total (N [%])	Died (n [%])	*P*
Age			<0.001			<0.001
<60	3903 (24.6)	14 (0.4)		3756 (10.8)	13 (0.3)	
60–70	4242 (26.7)	50 (1.2)		8453 (24.4)	33 (0.4)	
70–80	4408 (27.8)	86 (2.0)		12825 (37.0)	73 (0.6)	
80–90	2851(18.0)	114 (4.0)		8616 (24.9)	110 (1.3)	
≥90	459 (2.9)	35 (7.6)		988 (2.9)	35 (3.5)	
Sex			0.113			0.108
Men	7398 (46.6)	153 (2.1)		17596 (50.8)	121 (0.7)	
Women	8465 (53.4)	146 (1.7)		17042 (49.2)	143 (0.8)	
Diabetes			0.015			0.73
Insulin	999 (6.3)	29 (2.9)		1171 (3.4)	10 (0.9)	
Noninsulin	14864 (93.7)	270 (1.8)		33467 (96.6)	254 (0.8)	
COPD			<0.001			<0.001
No	14823 (93.4)	258 (1.7)		33618 (97.1)	244 (0.7)	
Yes	1040 (6.6)	41 (3.9)		1020 (2.9)	20 (2.0)	
Hypertension			<0.001			0.041
No	6371 (40.2)	85 (1.3)		21706 (62.7)	149 (0.7)	
Yes	9492 (59.8)	214 (2.3)		12932 (37.3)	115 (0.9)	
Congestive heart failure			<0.001			<0.001
No	15676 (98.8)	281 (1.8)		34147 (98.6)	241 (0.7)	
Yes	187 (1.2)	18 (9.6)		491 (1.4)	23 (4.7)	
Bleeding disorder			<0.001			<0.001
No	15207 (95.9)	260 (1.7)		33282 (96.1)	228 (0.7)	
Yes	656 (4.1)	39 (6.0)		1356 (3.9)	36 (2.7)	
Emergency status			<0.001			<0.001
No	15153 (95.5)	247 (1.6)		33027 (95.3)	201 (0.6)	
Yes	710 (4.5)	52 (7.3)		1611 (4.7)	63 (3.9)	
Functional status			<0.001			<0.001
Independent	15299 (96.4)	247 (1.6)		31345 (90.5)	138 (0.4)	
Partially dependent	489 (3.1)	41 (8.4)		2536 (7.3)	78 (3.1)	
Totally dependent	75 (0.5)	11 (14.7)		757 (2.2)	48 (6.3)	
ASA class			<0.001			<0.001
1-No disturb	333 (2.1)	0 (0.0)		10660 (30.8)	24 (0.2)	
2-Mild disturb	6205 (39.1)	26 (0.4)		19454 (56.2)	104 (0.5)	
3-Severe disturb	8349 (52.6)	191 (2.3)		4278 (12.4)	107 (2.5)	
4-Life threat	965 (6.1)	78 (8.1)		189 (0.5)	21 (11.1)	
5-Moribund	11 (0.1)	4 (36.4)		57 (0.2)	8 (14.0)	
Dyspnea			<0.001			<0.001
None	14030 (88.4)	231 (1.7)		33707 (97.3)	225 (0.7)	
Moderate	1691 (10.7)	55 (3.3)		789 (2.3)	25 (3.2)	
At rest	142 (0.9)	13 (9.2)		142 (0.4)	14 (9.9)	
Sepsis			<0.001			<0.001
None	15371 (96.9)	251 (1.6)		34323 (99.1)	222 (0.6)	
SIRS/sepsis/septic shock	492 (3.1)	48 (9.8)		315 (0.9)	42 (13.3)	
Weight loss			<0.001			<0.001
No	15129 (95.4)	259 (1.7)		32654 (94.3)	219 (0.7)	
Yes	734 (4.6)	40 (5.5)		1984 (5.7)	45 (2.3)	
Disseminated cancer			<0.001			<0.001
No	14770 (93.1)	235 (1.6)		32539 (93.9)	200 (0.6)	
Yes	1093 (6.9)	64 (5.9)		2099 (6.1)	64 (3.0)	
BMI			<0.001			<0.001
Underweight	390 (2.5)	20 (5.1)		5294 (15.3)	69 (1.3)	
Normal	4718 (29.7)	115 (2.4)		22845 (66.0)	156 (0.7)	
Overweight	5465 (34.5)	85 (1.6)		5640 (16.3)	32 (0.6)	
Obese 1	3077 (19.4)	49 (1.6)		688 (2.0)	5 (0.7)	
Obese 2/3	2213 (13.9)	30 (1.4)		170 (0.5)	2 (1.2)	

	US/NSQIP (N = 15,863) (Died = 299, Died [%] = 1.88%)			Japan/NCD (N = 34,638) (Died = 264, Died [%] = 0.76%)		
	Total (N [%])	Died (n [%])	*P*	Total (N [%])	Died (n [%])	*P*
Steroid			<0.001			0.006
No	15432 (97.3)	281 (1.8)		34276 (99.0)	256 (0.7)	
Yes	431 (2.7)	18 (4.2)		362 (1.0)	8 (2.2)	
Surgical approach			<0.001			<0.001
Lap	9031 (56.9)	82 (0.9)		12664 (36.6)	39 (0.3)	
Open	6832 (43.1)	217 (4.0)		21974 (63.4)	225 (1.0)	
Albumin (g/dL)			<0.001			<0.001
≥3.5	7994 (50.4)	80 (1.0)		23102 (66.7)	69 (0.3)	
2.8–3.5	2095 (13.2)	89 (4.3)		6831 (19.7)	78 (1.1)	
≤2.8	769 (4.9)	76 (9.9)		2824 (8.2)	103 (3.6)	
Missing	5005 (31.5)	54 (1.1)		1881 (5.4)	14 (0.7)	
PT-INR			<0.001			<0.001
≤1.25	7520 (47.4)	163 (2.2)		30576 (88.3)	169 (0.6)	
>1.25	804 (5.1)	52 (6.5)		1474 (4.3)	61 (4.1)	
Missing	7539 (47.5)	84 (1.1)		2588 (7.5)	34 (1.3)	
Chronic kidney stage			<0.001			<0.001
Stage 1 (GFR ≥90)	3928 (24.8)	77 (2.0)		3100 (8.9)	27 (0.9)	
Stage 2 (GFR 60–89)	7598 (47.9)	104 (1.4)		13287 (38.4)	64 (0.5)	
Stage 3 (GFR 30–59)	3017 (19.0)	85 (2.8)		15661 (45.2)	120 (0.8)	
Stage 4 (GFR 15–29)	244 (1.5)	16 (6.6)		1229 (3.5)	29 (2.4)	
Stage 5 (GFR ≤15 or dialysis)	145 (0.9)	12 (8.3)		499 (1.4)	14 (2.8)	
Missing	931 (5.9)	5 (0.5)		862 (2.5)	10 (1.2)	
Platelets (×1000/μL)			<0.001			<0.001
>120	14743 (92.9)	269 (1.8)		30332 (87.6)	165 (0.5)	
≤120	361 (2.3)	25 (6.9)		3843 (11.1)	95 (2.5)	
Missing	759 (4.8)	5 (0.7)		463 (1.3)	4 (0.9)	
Total bilirubin (mg/dL)			<0.001			<0.001
≤2.0	10847(68.4)	241 (2.2)		33607 (97.0)	248 (0.7)	
>2.0	107 (0.7)	6 (5.6)		281 (0.8)	11 (3.9)	
Missing	4909 (30.9)	52 (1.1)		750 (2.2)	5 (0.7)	
AST (U/L)			<0.001			<0.001
≤100	10762(67.9)	242 (2.3)		33914 (97.9)	236 (0.7)	
>100	82 (0.5)	4 (4.9)		212 (0.6)	24 (11.3)	
Missing	5019 (31.6)	53 (1.1)		512 (1.5)	4 (0.8)	
WBC (×1000/μL)			<0.001			<0.001
≥3.5 to ≤9.0	11818 (74.5)	171 (1.5)		28358 (81.8)	144 (0.5)	
<3.5 or >9.0	3289 (20.7)	121 (3.7)		5530 (16.0)	115 (2.1)	
Missing	756 (4.8)	7 (0.9)		750 (2.2)	5 (0.7)	
		Median (IQR)			Median (IQR)	
Length of stay (d)						
Total		5 (4–7)			14 (10–20)	
Survived		5 (4–7)			14 (10–20)	
Died		8 (5–13)			15 (6.25–22)	

Data are expressed as mean ± standard deviation or frequency(%).

T test/Wilcoxon Mann–Whitney test applied for continuous variables and chi-square/Fisher exact test applied for categorical variables.

ASA = American Society of Anesthesiologists, AST = aspartate aminotransferase, BMI = body mass index, COPD = chronic obstructive pulmonary disease, GFR = glomerular filtration rate, IQR = interquartile range, NCD = National Clinical Database, NSQIP = National Surgical Quality Improvement Program, PT-INR = prothrombin time–international normalized ratio, SIRS = systemic inflammatory response syndrome, WBC = white blood cell.

More than 2000 hospitals performing gastrointestinal (GI) tract surgery joined NCD, and 95% of surgical cases (949,824 cases in 2011 and 2012) were collected in this database, making NCD a nationally representative sample.[15] Meanwhile, data submitted to ACS-NSQIP from participating hospitals include a considerable proportion of cases (442,149 cases from 315 sites in 2011) sufficient to provide benchmark support to individual hospitals. We identified a number of differences in risk factor prevalence between datasets. Mortality rates reported in this study differed slightly, with lower unadjusted mortality rates for all 3 procedures in Japan than in US. The duration of hospital stay also differed, being longer in Japan compared to the US for all 3 procedures. The Japanese patients were older and had a higher prevalence of CKD. In contrast, US patients were younger and substantially more obese.

TABLE 2. Univariate Analysis for 30-Day Mortality of Low Anterior Resection

	US/NSQIP (N = 7325) (Died = 79, Died [%] = 1.08%)			Japan/NCD (N = 35,445) (Died = 154, Died [%] = 0.43%)		
	Total (N [%])	Died (n [%])	*P*	Total (N [%])	Died (n [%])	*P*
Age			<0.001			<0.001
<60	3172 (43.3)	10 (0.3)		8329 (23.5)	9 (0.1)	
60–70	1944 (26.6)	19 (1.0)		12300 (34.7)	38 (0.3)	
70–80	1409 (19.2)	25 (1.8)		10541 (29.8)	59 (0.6)	
80–90	720 (9.8)	22 (3.1)		4010 (11.3)	40 (1.0)	
≥90	80 (1.1)	3 (3.8)		265 (0.7)	8 (3.0)	
Sex			0.030			0.015
Men	4126 (56.3)	54 (1.3)		23140 (65.3)	115 (0.5)	
Women	3199 (43.7)	25 (0.8)		12305 (34.7)	39 (0.3)	
Diabetes			0.395			0.109
Insulin	321 (4.4)	5 (1.6)		1194 (3.4)	9 (0.8)	
Noninsulin	7004 (95.6)	74 (1.1)		34251 (96.6)	145 (0.4)	
COPD			<0.001			0.008
No	6994 (95.5)	66 (0.9)		34512 (97.4)	144 (0.4)	
Yes	331 (4.5)	13 (3.9)		933 (2.6)	10 (1.1)	
Hypertension			<0.001			<0.001
No	3775 (51.5)	24 (0.6)		24061 (67.9)	78 (0.3)	
Yes	3550 (48.5)	55 (1.6)		11384 (32.1)	76 (0.7)	
Congestive heart failure			<0.001			0.001
No	7282 (99.4)	75 (1.0)		35190 (99.3)	148 (0.4)	
Yes	43 (0.6)	4 (9.3)		255 (0.7)	6 (2.4)	
Bleeding disorder			<0.001			<0.001
No	7123 (97.2)	70 (1.0)		34441 (97.2)	139 (0.4)	
Yes	202 (2.8)	9 (4.5)		1004 (2.8)	15 (1.5)	
Emergency status			<0.001			0.006
No	7216 (98.5)	72 (1.0)		35077 (99.0)	148 (0.4)	
Yes	109 (1.5)	7 (6.4)		368 (1.0)	6 (1.6)	
Functional status			<0.001			<0.001
Independent	7200 (98.3)	69 (1.0)		33982 (95.9)	124 (0.4)	
Partially dependent	111 (1.5)	9 (8.1)		1242 (3.5)	20 (1.6)	
Totally dependent	14 (0.2)	1 (7.1)		221 (0.6)	10 (4.5)	
ASA class			<0.001			<0.001
1-No disturb	201 (2.7)	0 (0.0)		14205 (40.1)	21 (0.1)	
2-Mild disturb	3402 (46.4)	15 (0.4)		18307 (51.6)	86 (0.5)	
3-Severe disturb	3471 (47.4)	50 (1.4)		2848 (8.0)	42 (1.5)	
4-Life threat	250 (3.4)	14 (5.6)		58 (0.2)	5 (8.6)	
5-Moribund	1 (0.1)	0 (0.0)		27 (0.1)	0 (0.0)	
Dyspnea			<0.001			<0.001
None	6799 (92.8)	62 (0.9)		34909 (98.5)	145 (0.4)	
Moderate	487 (6.7)	11 (2.3)		464 (1.3)	7 (1.5)	
At rest	39 (0.5)	6 (15.4)		72 (0.2)	2 (2.8)	
Sepsis			<0.001			<0.001
None	7232 (98.7)	71 (1.0)		35356 (99.7)	149 (0.4)	
SIRS/sepsis/septic shock	93 (1.3)	8 (8.6)		89 (0.3)	5 (5.6)	
Weight loss			<0.001			<0.001
No	6996 (95.5)	65 (0.9)		34254 (96.6)	137 (0.4)	
Yes	329 (4.5)	14 (4.3)		1191 (3.4)	17 (1.4)	
Disseminated cancer			<0.001			<0.001
No	6690 (91.3)	61 (0.9)		33895 (95.6)	131 (0.4)	
Yes	635 (8.7)	18 (2.8)		1550 (4.4)	23 (1.5)	
BMI			0.849			0.005
Underweight	161 (2.2)	2 (1.2)		4223 (11.9)	29 (0.7)	
Normal	2266 (31.0)	28 (1.2)		23889 (67.4)	94 (0.4)	
Overweight	2520 (34.4)	26 (1.0)		6433 (18.2)	22 (0.3)	
Obese 1	1479 (20.2)	16 (1.1)		755 (2.1)	9 (1.2)	
Obese 2/3	899 (12.2)	7 (0.8)		145 (0.4)	0 (0.0)	

	US/NSQIP (N = 7325) (Died = 79, Died [%] = 1.08%)			Japan/NCD (N = 35,445) (Died = 154, Died [%] = 0.43%)		
	Total (N [%])	**Died (n [%])**	***P***	**Total (N [%])**	**Died (n [%])**	***P***
Steroid			0.231			0.019
No	7171 (97.9)	76 (1.1)		35214 (99.3)	150 (0.4)	
Yes	154 (2.1)	3 (2.0)		231 (0.7)	4 (1.7)	
Surgical approach			0.007			<0.001
Lap	3238 (44.2)	23 (0.7)		15208 (42.9)	42 (0.3)	
Open	4087 (55.8)	56 (1.4)		20237 (57.1)	112 (0.6)	
Albumin			<0.001			<0.001
≥3.5	4437 (60.6)	28 (0.6)		28807 (81.3)	91 (0.3)	
2.8–3.5	631 (8.6)	15 (2.4)		3804 (10.7)	45 (1.2)	
≤2.8	190 (2.6)	16 (8.4)		946 (2.7)	13 (1.4)	
Missing	2067 (28.2)	20 (1.0)		1888 (5.3)	5 (0.3)	
INR			<0.001			<0.001
≤1.25	3704 (50.6)	42 (1.1)		32069 (90.5)	122 (0.4)	
>1.25	167 (2.3)	10 (6.0)		872 (2.5)	18 (2.1)	
Missing	3454 (47.1)	27 (0.8)		2504 (7.0)	14 (0.6)	
Chronic kidney stage			0.002			<0.001
Stage 1 (GFR ≥90)	2441 (33.3)	26 (1.1)		2808 (7.9)	11 (0.4)	
Stage 2 (GFR 60–89)	3575 (48.8)	31 (0.9)		13958 (39.4)	35 (0.3)	
Stage 3 (GFR 30–59)	893 (12.2)	20 (2.2)		16678 (47.1)	87 (0.5)	
Stage 4 (GFR 15–29)	49 (0.7)	2 (4.1)		815 (2.3)	16 (2.0)	
Stage 5 (GFR <15 or dialysis)	36 (0.5)	0 (0.0)		334 (0.9)	4 (1.2)	
Missing	331 (4.5)	0 (0.0)		852 (2.4)	1 (0.1)	
Platelets (× 1000/μL)			0.160			<0.001
>120	6879 (93.9)	77 (1.1)		31408 (88.6)	112 (0.4)	
≤120	172 (2.4)	2 (1.2)		3599 (10.2)	41 (1.1)	
Missing	274 (3.7)	0 (0.0)		438 (1.2)	1 (0.2)	
Total bilirubin (mg/dL)			0.776			0.603
≤2.0	5290 (72.2)	58 (1.1)		34445 (97.2)	150 (0.4)	
>2.0	50 (0.7)	1 (2.0)		271 (0.8)	2 (0.7)	
Missing	1985 (27.1)	20 (1.0)		729 (2.0)	2 (0.3)	
AST (U/L)			0.463			0.188
≤100	5193 (70.9)	59 (1.1)		34811 (98.2)	151 (0.4)	
>100	39 (0.5)	1 (2.7)		151 (0.4)	2 (1.3)	
Missing	2093 (28.6)	19 (0.9)		483 (1.4)	1 (0.2)	
WBC (× 1000/μL)			0.004			0.003
≥3.5 to ≤9.0	5890 (80.4)	55 (0.9)		30481 (86.0)	120 (0.4)	
<3.5 or >9.0	1167 (15.9)	23 (2.0)		4235 (11.9)	32 (0.8)	
Missing	268 (3.7)	1 (0.4)		729 (2.1)	2 (0.3)	
		Median (IQR)				**Median (IQR)**
Length of stay						
Total		6 (4–8)				16 (12–25)
Survived		6 (4–8)				16 (12–25)
Died		6 (4–10)				10 (6–20)

Data are expressed as mean ± standard deviation or frequency (%).

T test/Wilcoxon Mann–Whitney test applied for continuous variables and chi-square/Fisher exact test applied for categorical variables.

ASA = American Society of Anesthesiologists, AST = aspartate aminotransferase, BMI = body mass index, COPD = chronic obstructive pulmonary disease, GFR = glomerular filtration rate, IQR = interquartile range, NCD = National Clinical Database, NSQIP = National Surgical Quality Improvement Program, PT-INR = prothrombin time–international normalized ratio, SIRS = systemic inflammatory response syndrome, WBC = white blood cell.

The NCD and ACS-NSQIP data have been used in prediction tools to facilitate risk stratification before surgery in a procedure-targeted manner.[16–24] More specifically, the ACS-NSQIP risk calculator works by utilizing information regarding the patient's risk factors related to the planned surgical procedure. The calculator then provides a predicted risk of complications after surgery.[25] However, the ability of risk models created using nationwide databases to predict the surgical risk for patients undergoing the same procedure in other countries has yet to be evaluated. In this study, we used the NCD and NSQIP databases to develop independent 30-day mortality risk models, and identified significant variables

TABLE 3. Univariate Analysis for 30-Day Mortality of Pancreaticoduodenectomy

	US/NSQIP (N = 5182) (Died = 133, Died [%] = 2.57%)			Japan/NCD (N = 15,527) (Died = 210, Died [%] = 1.35%)		
	Total (N [%])	Died (n [%])	*P*	Total (N [%])	Died (n [%])	*P*
Age			<0.001			<0.001
<60	1466 (28.3)	17 (1.2)		2186 (14.0)	14 (0.6)	
60–70	1732 (33.4)	44 (2.5)		5181 (33.4)	62 (1.2)	
70–80	1456 (28.1)	50 (3.4)		6394 (41.2)	99 (1.6)	
80–90	508 (9.8)	19 (3.7)		1755 (11.3)	35 (2.0)	
≥90	20 (0.4)	3 (15.0)		11 (0.1)	0 (0.0)	
Sex			0.029			0.004
Male	2749 (53.1)	83 (3.0)		9604 (61.8)	150 (1.6)	
Female	2433 (46.5)	50 (2.1)		5923 (38.2)	60 (1.0)	
Diabetes			0.842			0.425
Insulin	613 (11.8)	15 (2.5)		1637 (10.5)	18 (1.1)	
Noninsulin	4569 (88.2)	118 (2.6)		13890 (89.5)	192 (1.4)	
COPD			<0.001			0.028
No	4935 (95.2)	117 (2.4)		15115 (97.3)	199 (1.3)	
Yes	247 (4.8)	16 (6.5)		412 (2.7)	11 (2.7)	
Hypertension			<0.001			0.028
No	2314 (44.6)	34 (1.5)		10009 (64.5)	199 (2.0)	
Yes	2868 (55.4)	99 (3.5)		5518 (35.5)	11 (0.2)	
Congestive heart failure			1.000			0.058
No	5174 (99.8)	133 (2.6)		15462 (99.6)	207 (1.3)	
Yes	8 (0.2)	0 (0.0)		65 (0.4)	3 (4.6)	
Bleeding disorder			0.415			0.001
No	5040 (97.3)	128 (2.5)		15044 (96.9)	194 (1.3)	
Yes	142 (2.7)	5 (3.5)		483 (3.1)	16 (3.3)	
Emergency status			0.577			0.002
No	5149 (99.4)	132 (2.6)		15429 (99.4)	204 (1.3)	
Yes	33 (0.6)	1 (3.0)		98 (0.6)	6 (6.1)	
Functional status			0.304			<0.001
Independent	5118 (98.8)	130 (2.5)		15007 (96.7)	189 (1.3)	
Partially dependent	58 (1.1)	3 (5.2)		472 (3.0)	18 (3.8)	
Totally dependent	6 (0.1)	0 (0.0)		48 (0.3)	3 (6.3)	
ASA class			<0.001			<0.001
1-No disturb	37 (0.7)	0 (0.0)		4696 (30.2)	35 (0.8)	
2-Mild disturb	1341 (25.9)	15 (1.1)		9368 (60.3)	136 (1.5)	
3-Severe disturb	3502 (67.5)	100 (2.9)		1421 (9.2)	35 (2.5)	
4-Life threat	300 (5.8)	18 (6.0)		28 (0.2)	3 (10.7)	
5-Moribund	2 (0.1)	0 (0.0)		14 (0.1)	1 (7.1)	
Dyspnea			<0.001			<0.001
None	4794 (92.5)	110 (2.3)		15349 (98.8)	202 (1.3)	
Moderate	377 (7.3)	20 (5.3)		165 (1.1)	8 (4.9)	
At rest	11 (0.2)	3 (27.3)		13 (0.1)	0 (0.0)	
Sepsis			0.297			0.043
None	5091 (98.2)	129 (2.5)		15452 (99.5)	208 (1.4)	
SIRS/sepsis/septic shock	91 (1.8)	4 (4.4)		75 (0.5)	2 (2.7)	
Weight loss			0.960			0.105
No	4333 (83.6)	111 (2.6)		14422 (92.9)	189 (1.3)	
Yes	849 (16.4)	22 (2.6)		1105 (7.1)	21 (1.9)	
Disseminated cancer			0.014			0.294
No	5021 (96.9)	124 (2.5)		15455 (99.5)	208 (1.4)	
Yes	161 (3.1)	9 (5.6)		72 (0.5)	2 (2.8)	
BMI			0.016			<0.001
Underweight	140 (2.7)	5 (3.6)		2293 (14.8)	21 (0.9)	
Normal	1864 (36.0)	39 (2.1)		10938 (70.4)	137 (1.3)	
Overweight	1842 (35.5)	39 (2.1)		2068 (13.3)	47 (2.3)	
Obese 1	850 (16.4)	29 (3.4)		187 (1.2)	3 (1.6)	
Obese 2/3	486 (9.4)	21 (4.3)		41 (0.3)	3 (7.3)	

	US/NSQIP (N = 5182) (Died = 133, Died [%] = 2.57%)			Japan/NCD (N = 15,527) (Died = 210, Died [%] = 1.35%)		
	Total (N [%])	**Died (n [%])**	***P***	**Total (N [%])**	**Died (n [%])**	***P***
Steroid			0.237			0.323
No	5062 (97.7)	128 (2.5)		15350 (98.9)	208 (1.4)	
Yes	120 (2.3)	5 (4.2)		177 (1.1)	2 (1.1)	
Surgical complexity			0.009			0.020
PD alone	4444 (85.8)	104 (2.3)		12975 (83.6)	161 (1.2)	
With adjacent organ	240 (4.6)	13 (5.4)		623 (4.0)	14 (2.3)	
Vascular ± other organ	498 (9.6)	16 (3.2)		1929 (12.4)	35 (1.8)	
Albumin			0.003			0.012
≥3.5	3303 (63.7)	69 (2.1)		10963 (70.6)	129 (1.2)	
2.8–3.5	1030 (19.9)	34 (3.3)		3391 (21.8)	55 (1.6)	
≤2.8	414 (8.0)	20 (4.8)		706 (4.6)	16 (2.3)	
Missing	435 (8.4)	10 (2.3)		467 (3.0)	10 (2.1)	
INR			0.004			<0.001
≤1.25	4277 (82.5)	99 (2.3)		14086 (90.7)	175 (1.2)	
>1.25	272 (5.3)	15 (5.5)		627 (4.0)	21 (3.4)	
Missing	633 (12.2)	19 (3.0)		814 (5.3)	14 (1.7)	
Chronic kidney stage			0.002			<0.001
Stage 1 (GFR ≥90)	2139 (41.3)	39 (1.8)		1627 (10.5)	13 (0.8)	
Stage 2 (GFR 60–89)	2255 (43.5)	62 (2.8)		6857 (44.1)	69 (1.0)	
Stage 3 (GFR 30–59)	641 (12.4)	24 (3.7)		6382 (41.1)	110 (1.7)	
Stage 4 (GFR 15–29)	30 (0.6)	2 (6.7)		281 (1.8)	6 (2.1)	
Stage 5 (GFR <15 or dialysis)	25 (0.5)	3 (12.0)		149 (1.0)	7 (4.7)	
Missing	92 (1.8)	3 (3.3)		231 (1.5)	5 (2.2)	
Platelets (× 1000/μL)			0.045			<0.001
>120	4982 (96.1)	123 (2.5)		9602 (61.8)	73 (0.8)	
≤120	104 (2.0)	6 (5.8)		5795 (37.3)	134 (2.3)	
Missing	96 (1.9)	4 (4.2)		130 (0.9)	3 (2.3)	
Total bilirubin (mg/dL)			0.576			0.156
≤2.0	3482 (67.2)	86 (2.5)		11578 (74.5)	147 (1.3)	
>2.0	1211 (23.4)	31 (2.6)		3800 (24.5)	59 (1.6)	
Missing	489 (9.4)	16 (3.3)		149 (1.0)	4 (2.7)	
AST (U/L)			0.260			0.612
≤100	3993 (77.1)	97 (2.4)		13510 (87.0)	183 (1.4)	
>100	757 (14.6)	26 (3.4)		1887 (12.2)	24 (1.3)	
Missing	432 (8.3)	10 (2.3)		130 (0.8)	3 (2.3)	
WBC (× 1000/μL)			0.169			0.303
≥3.5 to ≤9.0	3966 (76.5)	96 (2.4)		13434 (86.5)	177 (1.3)	
<3.5 or >9.0	1122 (21.7)	32 (2.9)		1944 (12.5)	29 (1.5)	
Missing	94 (1.8)	5 (5.3)		149 (1.0)	4 (2.7)	
		Median (IQR)			**Median (IQR)**	
Length of stay						
Total		9 (7–14)			31 (22–43)	
Survived		9 (7–14)			31 (22–43)	
Died		11 (6–17)			15 (7–24)	

Data are expressed as mean ± standard deviation or frequency (%).

T test/Wilcoxon Mann–Whitney test applied for continuous variables and chi-square/Fisher exact test applied for categorical variables.

ASA = American Society of Anesthesiologists, AST = aspartate aminotransferase, BMI = body mass index, COPD = chronic obstructive pulmonary disease, GFR = glomerular filtration rate, INR = international normalized ratio, IQR = interquartile range, NCD = National Clinical Database, NSQIP = National Surgical Quality Improvement Program, PD = pancreaticoduodenectomy, SIRS = systemic inflammatory response syndrome, WBC = white blood cell.

from both datasets to create NCD/ACS-NSQIP risk models using a common set of variables. For the purpose of estimating risk, the 2 models based on the 2 country's own dataset were able to adequately predict mortality with a good c-index and similar ORs observed for each variable (Table 4).

We found that discrimination decreased when we ran each risk model using the other country's data. When we focused on a measure of calibration (the Hosmer–Lemeshow plot), we found that both NCD and ACS-NSQIP models accurately predicted the number of deaths in their respective datasets. However, calibration diminished when data from the other country were

TABLE 4. Risk Models of Preoperative Factors for 30-Day Mortality Rates After RH, LAR, and PD

	US/NSQIP			Japan/NCD		
		95% CI			95% CI	
RH Variables	**Odds Ratio**	**Lower CI**	**Upper CI**	**Odds Ratio**	**Lower CI**	**Upper CI**
Age 60–70	3.641	1.984	6.682	1.068	0.563	2.147
Age 70–80	5.427	3.028	9.726	1.426	0.796	2.761
Age ≥80	10.473	5.890	18.623	2.23	1.249	4.309
Sex (male)	1.615	1.267	2.059	1.332	1.006	1.766
Bleeding disorder (yes)	1.826	1.249	2.668	1.721	1.134	2.534
Emergency status (yes)	1.653	1.146	2.384	1.873	1.304	2.644
Functional status (partially dependent)	1.923	1.317	2.810	2.767	1.994	3.815
Functional status (totally dependent)	3.429	1.644	7.153	4.241	2.83	6.263
Dyspnea at rest	2.697	1.414	5.144	2.519	1.22	4.844
Dyspnea moderate exertion	1.404	1.026	1.923	1.485	0.909	2.327
Sepsis (yes)	2.113	1.424	3.135	2.899	1.829	4.524
Weight loss (yes)	1.678	1.149	2.451	1.244	0.854	1.774
Disseminated cancer (yes)	3.045	2.233	4.151	3.385	2.452	4.616
Albumin (g/dL) 2.8–3.5	2.315	1.674	3.200	2.022	1.432	2.856
Albumin (g/dL) ≤2.8	3.991	2.777	5.736	3.447	2.385	4.989
Albumin (g/dL) missing	1.162	0.808	1.670	1.571	0.767	2.943
CKD missing	0.617	0.225	1.691	4.115	1.69	8.835
CKD stage 3	1.242	0.940	1.642	1.352	0.994	1.845
CKD stage 4/5	2.699	1.730	4.211	2.123	1.383	3.21
WBC (×1000/μL) <3.5 or >9.0	1.572	1.210	2.043	1.885	1.423	2.487
WBC (×1000/μL) missing	1.490	0.628	3.534	0.475	0.133	1.422
C-statistic	0.840			0.857		
Hosmer–Lemeshow chi-square	5.866 ($P=0.662$)			11.243 ($P=0.188$)		

	US/NSQIP			Japan/NCD		
		95% CI			95% CI	
LAR Variables	**Odds Ratio**	**Lower CI**	**Upper CI**	**Odds Ratio**	**Lower CI**	**Upper CI**
Age 60–70	2.833	1.299	6.180	2.725	1.372	6.033
Age 70–80	4.976	2.332	10.619	4.584	2.372	9.984
Age ≥80	7.220	3.265	15.967	7.988	4.009	17.757
Sex (male)	1.880	1.140	3.100	1.742	1.212	2.558
Bleeding disorder (yes)	2.250	1.028	4.925	1.987	1.091	3.366
Emergency status (yes)	2.433	0.924	6.403	1.768	0.608	4.227
Functional status (partially dependent)	1.931	0.810	4.603	1.91	1.111	3.132
Functional status (totally dependent)	5.118	0.608	43.110	3.798	1.734	7.534
Dyspnea at rest	5.606	1.816	17.307	2.21	0.346	7.743
Dyspnea moderate exertion	1.370	0.688	2.728	1.1	0.446	2.313
Sepsis (yes)	2.020	0.765	5.333	3.79	1.132	10.471
Weight loss (yes)	2.585	1.315	5.082	1.798	1.003	3.036
Disseminated cancer (yes)	2.736	1.520	4.925	3.087	1.887	4.835
BMI class (obese)	1.118	0.662	1.888	3.723	1.728	7.069
BMI class (underweight)	0.721	0.162	3.199	1.16	0.74	1.761
Steroid use (yes)	0.934	0.273	3.190	3.102	0.936	7.584
Albumin (g/dL) 2.8–3.5	2.190	1.127	4.254	2.091	1.406	3.066
Albumin (g/dL) ≤2.8	5.425	2.547	11.557	1.887	0.952	3.464
Albumin (g/dl) missing	1.533	0.854	2.752	0.775	0.272	1.729
C-statistic	0.822			0.782		
Hosmer–Lemeshow chi-square	10.946 ($P=0.205$)			5.236 ($P=0.631$)		

PD Variables	US/NSQIP			Japan/NCD		
		95% CI			95% CI	
	Odds Ratio	Lower CI	Upper CI	Odds Ratio	Lower CI	Upper CI
Age 60–70	1.933	1.085	3.442	1.706	0.977	3.193
Age 70–80	2.591	1.447	4.638	1.989	1.157	3.688
Age ≥80	3.280	1.656	6.498	2.462	1.317	4.844
Sex (male)	1.519	1.059	2.181	1.325	0.949	1.866
Bleeding disorder (yes)	1.013	0.401	2.556	1.829	1.033	3.025
Emergency status (yes)	0.651	0.084	5.056	4.389	1.666	9.566
Functional status (dependent)	1.378	0.415	4.572	2.394	1.44	3.789
Disseminated cancer (yes)	2.161	1.044	4.471	1.854	0.3	6.113
Hypertension (yes)	1.738	1.145	2.639	1.393	1.048	1.85
Albumin (g/dL) 2.8–3.5	1.520	0.994	2.324	1.233	0.885	1.696
Albumin (g/dL) ≤2.8	1.985	1.174	3.357	1.515	0.846	2.54
Albumin (g/dL) missing	1.030	0.486	2.182	1.643	0.747	3.209
CKD missing	1.665	0.448	6.192	2.148	0.69	5.471
CKD stage 3	1.183	0.736	1.903	1.421	1.031	1.969
CKD stage 4/5	3.020	1.133	8.044	2.054	1.057	3.704
Surgical complexity (adjacent organ)	2.281	1.234	4.214	1.796	0.986	3.018
Surgical complexity (vascular)	1.524	0.881	2.633	1.701	1.154	2.44
COPD (yes)	2.382	1.371	4.137	1.541	0.775	2.758
BMI class (obese)	1.905	1.306	2.779	1.53	0.535	3.434
BMI class (underweight)	1.823	0.712	4.668	0.659	0.404	1.023
C-statistic	0.719			0.782		
Hosmer–Lemeshow chi-square	8.619 ($P=0.375$)			9.908 ($P=0.272$)		

BMI = body mass index, CI = confidence interval, CKD = chronic kidney disease, COPD = chronic obstructive pulmonary disease, LAR = low anterior resection, NCD = National Clinical Database, NSQIP = National Surgical Quality Improvement Program, PD = pancreaticoduodenectomy, RH = right hemicolectomy, US = United States, WBC = white blood cell.

TABLE 5. Observed and Expected Mortality after RH, LAR, and PD

Mortality	US/NSQIP Model	Japan/NCD Model	Difference in Mortality Rate (%)
RH			
US/NSQIP mortality	(Observed)	(Expected)	
%	1.88	0.60	−68
C-statistic	0.840	0.789	
Hosmer–Lemeshow chi-square	5.866 ($P=0.662$)	171.01 ($P<0.001$)	
Japan/NCD mortality	(Expected)	(Observed)	
%	3.83	0.76	404
C-statistic	0.828	0.857	
Hosmer–Lemeshow chi-square	955.233($P<0.001$)	11.243 ($P=0.188$)	
LAR			
US/NSQIP mortality	(Observed)	(Expected)	
%	1.08	0.60	−44
C-statistic	0.822	0.786	
Hosmer–Lemeshow chi-square	10.946 ($P=0.205$)	49.54 ($P<0.001$)	
Japan/NCD mortality	(Expected)	(Observed)	
%	1.08	0.43	151
C-statistic	0.778	0.782	
Hosmer–Lemeshow chi-square	145.375 ($P<0.001$)	5.236 ($P=0.631$)	
PD			
US/NSQIP mortality	(Observed)	(Expected)	
%	2.57	2.41	−6
C-statistic	0.719	0.674	
Hosmer–Lemeshow chi-square	8.619 ($P=0.375$)	8.817 ($P=0.358$)	
Japan/NCD mortality	(Expected)	(Observed)	
%	4.23	1.35	213
C-statistic	0.540	0.782	
Hosmer–Lemeshow chi-square	366.217 ($P<0.001$)	9.908 ($P=0.272$)	

LAR = low anterior resection, NCD = National Clinical Database, NSQIP = National Surgical Quality Improvement Program, PD = pancreaticoduodenectomy, RH = right hemicolectomy, US = United States.

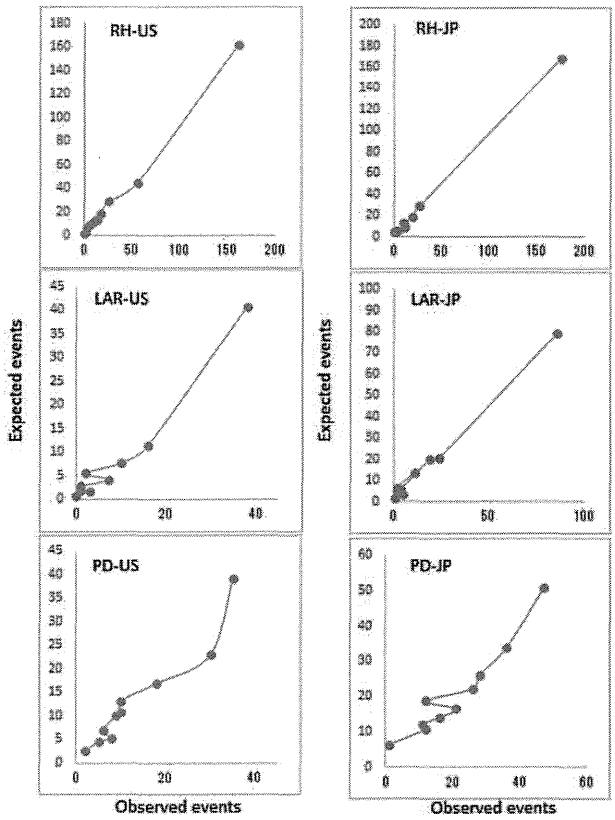

FIGURE 1. Calibration for 30-day mortality models for RH, LAR, and PD based on the US data using the US/ACS-NSQIP model (US) and the Japanese data using the Japan/NCD model (JP). ACS-NSQIP = American College of Surgeons National Surgical Quality Improvement Program, JP = Japan, LAR = low anterior resection, PD = pancreaticoduodenectomy, RH = right hemicolectomy, US = United States.

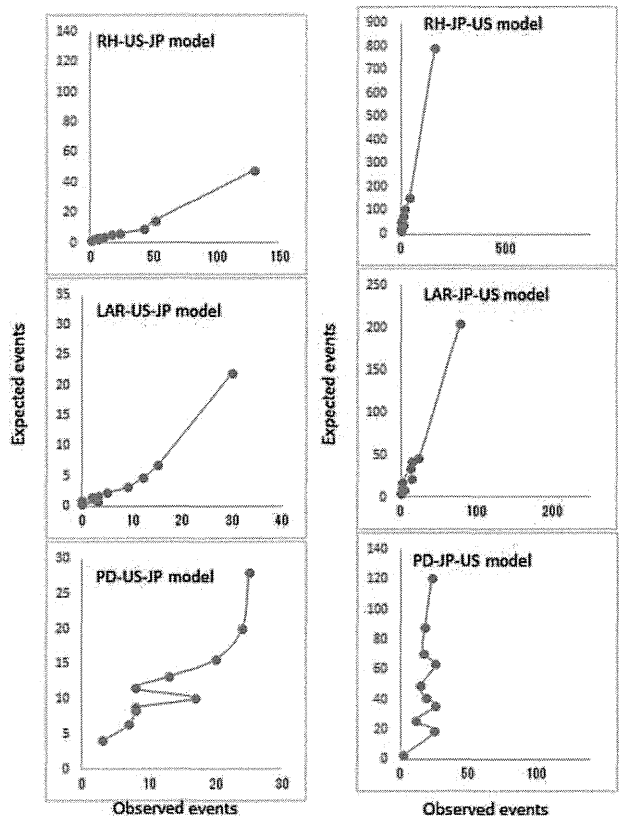

FIGURE 2. Calibration for 30-day mortality models for RH, LAR, and PD based on the US data using the Japan/NCD model (US-JP model) and the Japanese data using the US/ACS-NSQIP model (JP-US model). ACS-NSQIP = American College of Surgeons National Surgical Quality Improvement Program, JP = Japan, LAR = low anterior resection, PD = pancreaticoduodenectomy, RH = right hemicolectomy, US = United States.

used. These results indicate that risk models based on local data accurately predict mortality rate; however, risk models based on data from other countries are unable to accurately predict mortality rate. When evaluating the performance of a prediction model in adherence to the transparent reporting of a multivariable prediction model for individual prognosis or diagnosis guideline,[26] investigators should pay attention to the discrepancy, involving the use of participant data collected by another country for external validation.

We considered reasons for this discrepancy. Differences in the prevalence of risk factors are unlikely to have a significant impact on model performance since we conducted a risk-adjusted analysis. However, there may be several risk factors not included in our model. These are likely to be ethnicity; operative information (operation time, amount of bleeding, and transfusion amount); and incidence and management of postoperative complications. Cytokine response has been shown to differ between races[27,28]; it is reasonably assumed that this difference may lead to different outcomes. Because the incidence of severe morbidity affects mortality, successful prophylactic management as a team may reduce the incidence of morbidity and decrease mortality rates.[10,29] Relatively longer hospital stays after surgery due to the insurance system in Japan[30] may protect patients with high morbidity after surgery, but this assumption needs to be fully assessed in future comparative studies.

This study should be interpreted with the appreciation of several limitations. We were unable to combine data from the 2 datasets due to the prohibition by NCD for security reasons. The backgrounds of the databases may be different. Although the NCD/Japan contains nearly 95% of surgical cases from all hospitals in Japan, ACS-NSQIP contains samples from selected hospitals in US only. This may be a source of bias if there was a difference in surgical practice or hospital procedural volume. Other differences in patient factors, including social, economic, and racial differences, have not been considered. Secondly, 30-day mortality was the only outcome studied. The 30-day mortality likely underestimates treatment-associated mortality by not including mortality occurring 30 days after operations. Thirdly, the impact of perioperative and postoperative complications that potentially affects surgical mortality are unknown due to a lack of data regarding these variables.

In conclusion, we found significantly different mortality rates, comorbidity prevalences, and procedural practices between Japan and the US. Risk-prediction models that can be reasonably used for both patient groups should be developed while recognizing that some risk predictors may be population-specific. This study demonstrates the feasibility and utility of

international collaborative research between Japan and the US, but risk models based on local data remain essential for quality assessment and improvement.

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This problem is well illustrated in the study by Mangurian et al[1] in this issue of *JAMA Internal Medicine*. The authors used California Medicaid data to identify patients who were prescribed an antipsychotic medication. They then assessed what percentage of the patients had some form of glucose screening, a recommendation by the American Diabetes Association[2] for persons taking antipsychotic medications, in a yearlong period. Overall, 30.1% of individuals were screened. It would be fair to point out that the efficacy of screening for diabetes has not been well established. However, that less than one-third had such screening for a known adverse effect of antipsychotic medication use suggests opportunities for improvement in integrated health care. Among those who had at least 1 primary care visit during the year, the proportion screened was significantly higher at 35.6% vs 19.8% for those who had no primary care visit.

To improve care for persons with serious mental illness, it will be necessary to break down the silos that separate the mental health and physical health care systems. Integrated care (care provided by a team of physical and mental health clinicians)—or at least colocated care (care provided by physical and mental health clinicians in the same place)—offers the promise of improving the physical health of individuals with mental illness, as well as the mental health of those seeking physical health services.

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LESS IS MORE

Use of Intra-aortic Balloon Pump in a Japanese Multicenter Percutaneous Coronary Intervention Registry

We read with interest the recent meta-analysis by Ahmad et al,[1] demonstrating a negative association between intra-aortic balloon pump (IABP) therapy and mortality among patients experiencing acute myocardial infarction. We agree that efforts are needed to clarify the role of IABP therapy and to examine its effect on care in other regions and countries. In Japan, IABP therapy is frequently used in patients with guideline-based indications and in patients with less established indications, and the judicious use of invasive procedures has been highlighted.[2,3] Our objective herein was to investigate the prognostic effect of IABP use in patients undergoing percutaneous coronary intervention (PCI) for nonacute and acute indications registered in a contemporary multicenter Japanese PCI registry (Japan Cardiovascular Database-Keio Interhospital Cardiovascular Studies[4]).

Invited Commentary
page 1982

Methods | We analyzed data from 14 378 consecutive patients treated between September 2, 2008, and May 19, 2014. Of those, 1124 patients were excluded because of missing baseline information (n = 192), registration for staged PCI during the same hospitalization (n = 801), or PCI performed under percutaneous cardiopulmonary support (n = 132). The remaining 13 253 patients were included herein, and logistic regression models for in-hospital mortality were used to correct for differences in variables. We included in the logistic regression model all variables exhibiting a significant ($P < .10$) bivariate association with IABP use. Baseline inequality between patients with and without IABPs was evaluated with the baseline inequality index, the same method used by Ahmad et al.[1] Because our study focused on the effect of IABP on in-hospital mortality for all PCIs, we redefined a list of baseline characteristics recognized as markers of mortality risk based on a previous study.[5] Data analyses were performed using statistical software (SPSS, version 22.0; SPSS Inc). This study was approved by each participating hospital's ethics review board (Keio University School of Medicine, Saiseikai Utsunomiya Hospital, Ashikaga Red Cross Hospital, Saitama City Hospital, Saitama National Hospital, Hino Municipal Hospital, Tokyo Dental College Ichikawa General Hospital, Tokyo Saiseikai Central Hospital, Tokyo Medical Center, St Luke's International Hospital, Kawasaki Municipal Hospital, and Yokohama Municipal Citizen's Hospital), and written informed consent was obtained from each patient.

Results | Baseline demographics in patients with and without IABPs are summarized in the **Table**. Overall, PCIs after ST-segment elevation myocardial infarctions and PCIs after non-ST-segment elevation myocardial infarctions or unstable angina accounted for 23.9% and 24.2% of the procedures, respectively. Before PCI, 486 patients (3.7%) and 900 patients (6.8%) manifested complications of cardiogenic shock and serious heart failure (New York Heart Association functional classification ≥3), respectively. The proportions of interventions for left main trunk and 3-vessel disease were 3.7% and 0.9%, respectively. Intra-aortic balloon pumps were inserted in 885 patients (6.7%). There were 134 in-hospital deaths (15.1%) among the patients receiving an IABP and 111 in-hospital deaths (0.9%) among the patients not receiving an IABP. In the crude analysis, the use of IABP was associated with an increased risk of in-hospital mortality (**Figure**, A).

Intra-aortic balloon pump use remained an independent predictor of in-hospital mortality after adjusting for baseline differences (odds ratio, 3.87; 95% CI, 2.71-5.52; $P < .001$). Among several subgroups thought to potentially have indications for IABP use, the use of IABPs was consistently associated with risk of in-hospital death (Figure, B), and IABP recipients had a worse baseline risk profile than nonrecipients (Figure, C). Notably, the risk of death appeared to be higher (with higher odds ratios) as the indications for IABP use became less established.

Discussion | Among a cohort of Japanese patients undergoing PCI in whom IABP use was frequent, we found that the use of IABP was associated with a higher risk of in-hospital death. This

Table. Baseline Characteristics of Patients With and Without Intra-aortic Balloon Pump Use in the Entire Cohort[a]

Variable	Patients Without IABP (n = 12 368)	Patients With IABP (n = 885)	P Value
Age, mean (SD), y	67.9 (10.9)	69.0 (11.7)	.004
Male sex, No. (%)	9807 (79.3)	695 (78.5)	.59
History of heart failure, No. (%)	1050 (8.5)	121 (13.7)	<.001
NYHA functional classification ≥3, No. (%)[b]	645 (5.2)	255 (28.8)	<.001
Diabetes mellitus, No. (%)	5201 (42.1)	388 (43.8)	.28
Previous myocardial infarction, No. (%)	3050 (24.7)	183 (20.7)	.008
Previous PCI, No. (%)	4723 (38.2)	183 (20.7)	<.001
Previous coronary artery bypass graft, No. (%)	680 (5.5)	49 (5.5)	.96
Cerebrovascular disease, No. (%)	1078 (8.7)	114 (12.9)	<.001
Peripheral vascular disease, No. (%)	1059 (8.6)	58 (6.6)	.04
Chronic lung disease, No. (%)	376 (3.0)	30 (3.4)	.55
Hypertension, No./total No. (%)	9330/12 363 (75.5)	624/883 (70.7)	.001
Current or recent smoker, No./total No. (%)	4150/12 347 (33.6)	332/880 (37.7)	.01
Dyslipidemia, No./total No. (%)	8298/12 359 (67.1)	500/883 (56.6)	<.001
Renal dysfunction, No./total No. (%)[c]	4772/11 368 (42.0)	475/863 (55.0)	<.001
Urgent or emergent PCI, No. (%)	5130 (41.5)	773 (87.3)	<.001
Presentation, No. (%)	(n = 12 369)		
STEMI	2612 (21.1)	551 (62.3)	<.001
NSTEMI	941 (7.6)	113 (12.8)	
Unstable angina	2068 (16.7)	102 (11.5)	
Stable angina or silent ischemia	6663 (53.9)	95 (10.7)	
Other indication	84 (0.7)	24 (2.7)	
No. of target vessels, No. (%)	(n = 12 358)	(n = 884)	
1	11 226 (90.8)	715 (80.8)	<.001
2	1036 (8.4)	145 (16.4)	
3	96 (0.8)	24 (2.7)	
Unknown	10 (0.1)	1 (0.1)	
LMT lesion, No. (%)	1006 (8.1)	203 (22.9)	<.001
Proximal left anterior descending intervention, No. (%)	2886 (23.3)	298 (33.7)	<.001
Cardiogenic shock, No. (%)	206 (1.7)	280 (31.6)	<.001

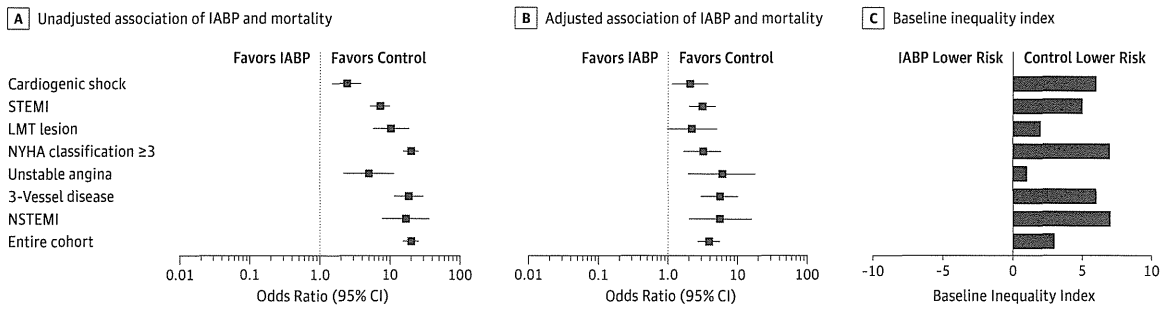
Abbreviations: IABP, intra-aortic balloon pump; LMT, left main trunk; NSTEMI, non-ST-segment elevation myocardial infarction; NYHA, New York Heart Association; PCI, percutaneous coronary intervention; STEMI, ST-segment elevation myocardial infarction.

[a] Differences in each variable between the patients with and without IABP use were evaluated using the χ^2 test for categorical variables and the unpaired *t* test for continuous variables.

[b] At the time of the procedure.

[c] Defined as an estimated glomerular filtration rate exceeding 60 mL/min/1.73 m^2.

Figure. Unadjusted and Adjusted Effects of Intra-aortic Balloon Pump (IABP) Use on In-Hospital Mortality in Various Situations



A and B, Intra-aortic balloon pump use was adversely associated with patient outcome, regardless of situation, in crude (A) and multivariable (B) analyses. In the logistic regression model, adjustments were made using all variables exhibiting a bivariate association with the use of IABP with $P < .001$ in the Table, which included all variables except the following: diabetes mellitus, previous coronary artery bypass graft, chronic lung disease, stable angina or silent ischemia, and 1-vessel disease. C, For evaluating the baseline inequality index, we redefined a list of the following baseline characteristics that are recognized markers of mortality risk: age, cardiogenic shock, prior heart failure, peripheral vascular disease, chronic lung disease, renal dysfunction, NYHA functional classification of at least 3 at the time of percutaneous coronary intervention, and clinical presentation (STEMI or NSTEMI). LMT indicates left main trunk; NSTEMI, non-ST-segment elevation myocardial infarction; NYHA, New York Heart Association; and STEMI, ST-segment elevation myocardial infarction.