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Nationwide survey and establishment of a clinical database for gastrointestinal surgery in Japan: Targeting integration of a cancer registration system and improving the outcome of cancer treatment

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As there was no nationwide database for gastrointestinal surgery in Japan at the time, in 2006, a Clinical Database Committee was established in the Japanese Society of Gastrointestinal Surgery (JSGS) to create a clinical database in Japan. The Committee first organized preliminary nationwide Japanese surveys in gastrointestinal surgery in 2006 and 2007. Data from more than 770 000 patients were accumulated from these web-based surveys, including 333 627 patients in 1039 institutions in 2006 and 440 230 patients in 1464 institutions in 2007. The mortality rate was stratified by organ, surgical procedure and hospital volume without using risk-adjustment techniques. The overall mortality rate was 0.95% in the 2006 survey and 0.92% in the 2007 survey. The organ-based analysis found that the mortality rates were almost similar in 2006 and 2007. Hospital volume influenced the mortality rate in six major surgical procedures, namely esophagectomy, gastrectomy, total gastrectomy, low anterior rectal resection, hepatic resection and pancreaticoduodenectomy. A risk reduction of 30–80% was noted in each surgical procedure, at least in our non-risk-adjusted analysis, in hospitals with a high volume of operations. These preliminary surveys indicate that hospital volume might influence the mortality rate after major abdominal surgery. Further analysis using risk-adjustment techniques should be conducted to understand the specific contribution of hospital volume to surgical mortality. A nationwide database of patients who have undergone gastrointestinal surgery and risk-adjustment analysis of the data are currently planned in Japan. (*Cancer Sci* 2011; 102: 226–230)

National clinical databases for patients with cancer or patients who have had surgery have recently been established in the United States, and in several nations in the European Union and East Asia.[1–4] One of the major programs in the field of cancer is the SEER (Surveillance Epidemiology and End Result)–Medicare database in the United States (http://healthservices.cancer.gov/seermedicare/).[4] The SEER–Medicare database, which includes a large number of patients with cancer, is a unique resource that collects information on cancer site, stage and histology in patients newly diagnosed with cancer. In addition, a database of patients who have undergone surgical treatment, the American College of Surgeons National Surgical Quality Improvement Program (ACS-NSQIP), has also been established. The ACS-NSQIP is the first nationally validated database in the United States and it is a risk-adjusted, outcome-based program to measure and improve the quality of surgical care.[5] These databases aimed to establish an understanding of the national standard of clinical care and trends in clinical treatment, and to continuously improve surgical techniques and quality of care. Furthermore, it has allowed easy comparisons between countries.

The Japan Cardiovascular Surgery Database Organization started collecting data on patients who had undergone cardiovascular surgery in 2001.[6] Also, a cancer registration system has been started to collect data relating to individual cancer patients in Japan; however, it does not specify which patients had surgery and does not include short-term surgical outcomes.[7] Thus, in the field of gastrointestinal surgery, there was no large clinical database in Japan that included the short-term surgical outcome (i.e. morbidity and mortality), and there was a great need to establish such a nationwide database. In this context, the Clinical Database Committee was established in the Japanese Society of Gastrointestinal Surgery (JSGS), with the remit of establishing a nationwide clinical database of gastrointestinal surgery in Japan. In 2006 and 2007, preliminary surveys were performed targeting every field of gastrointestinal surgery. In this paper, we report the results of these surveys, and analyze the relationship between mortality rates of major surgical procedures in gastrointestinal surgery and hospital volume.

Methods

Web-based nationwide preliminary surveys were performed in 2377 institutions in 2006 and in 2360 institutions in 2007, including patients who had major gastrointestinal surgery. We examined individual hospital characteristics, number of operations and both the number of 30-day hospital deaths and

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Table 1. Total number of operations and mortality by organ in 2006 and 2007

Organ	No. operations (%)	No. deaths		Total no. deaths (%)
		30-day mortality (%)	In-hospital mortality (%)	
Esophagus				
2006	5027 (1.5)	53 (1.05)	134 (2.67)	187 (3.72)
2007	6476 (1.5)	53 (0.82)	182 (2.81)	235 (3.63)
Gastroduodenum				
2006	48 688 (14.6)	196 (0.40)	440 (0.90)	636 (1.31)
2007	61 103 (13.9)	285 (0.47)	517 (0.85)	802 (1.31)
Small intestine/colon				
2006	80 770 (24.2)	317 (0.39)	575 (0.71)	892 (1.10)
2007	112 041 (25.5)	485 (0.43)	675 (0.60)	1160 (1.04)
Rectum/anus				
2006	47 445 (14.2)	90 (0.19)	140 (0.30)	230 (0.48)
2007	58 281 (13.2)	113 (0.19)	147 (0.25)	260 (0.45)
Liver				
2006	13 863 (4.2)	96 (0.69)	141 (1.02)	237 (1.71)
2007	16 742 (3.8)	101 (0.60)	135 (0.81)	236 (1.41)
Gallbladder				
2006	58 546 (17.5)	45 (0.08)	106 (0.18)	151 (0.26)
2007	74 314 (16.9)	66 (0.09)	119 (0.16)	185 (0.25)
Pancreas				
2006	7183 (2.2)	64 (0.90)	126 (1.75)	190 (2.65)
2007	9354 (2.1)	66 (0.71)	130 (1.39)	196 (2.10)
Others				
2006	72 105 (21.6)	304 (0.42)	345 (0.48)	649 (0.90)
2007	101 919 (23.2)	496 (0.49)	479 (0.47)	975 (0.96)
Total				
2006	333 627 (100)	1165 (0.35)	2007 (0.60)	3172 (0.95)
2007	440 230 (100)	1665 (0.38)	2384 (0.54)	4049 (0.92)

in-hospital deaths after surgery. Organ-specific and procedure-specific mortality rates were calculated and analyzed.

Results

Overview. We received the data reports from 1039 institutions in 2006 and 1464 institutions in 2007, a response rate of 43.7% (1039/2377 institutions) in 2006 and 62.0% (1464/2360 institutions) in 2007. In total, data from 333 627 patients in 2006 and 440 230 patients in 2007 were accumulated and analyzed. The total number of deaths was 3172/333 627 (0.95%) in 2006 and 4049/440 230 (0.92%) in 2007. The 30-day hospital death rate was 1165/333 627 (0.35%) in 2006 and 1665/440 230 (0.38%) in 2007. The in-hospital death rate was 2007/333 627 patients (0.60%) in 2006 and 2384/440 230 patients (0.54%) in 2007.

Organ-based analysis and data comparison between 2006 and 2007. We stratified surgery into eight regions: esophagus, gastroduodenum, small intestine/colon, rectum/anus, liver, gall bladder, pancreas, and other regions. The number of patients and mortality by organ are shown in Table 1. Organ-based proportions of the accumulated data in 2006 and 2007 were comparable. Half of the total gastrointestinal surgeries were gastroduodenal and colorectal surgeries. Approximately 20% were hepatobiliary surgery. The proportion of surgery of the esophagus or pancreas was very low (1.5–2.2%).

Mortality rates were variable and depended on the organ. The best mortality rate was 0.25% for gallbladder surgery in 2007, while the worst was 3.72% for esophageal surgery in 2006. The 30-day mortality rate after surgery was very low (0.09–1.05%). In-hospital mortality was also very low and mostly <1.0%, except for esophageal or pancreatic surgery. The mortality rates of patients by organ in 2006 and 2007 were also very similar and there was a significant correlation between the data of 2006 and 2007 ($R^2 = 0.9287$, $Y = 1.0026X + 0.0009$).

Hospital volume and mortality after major surgical procedures. Subsequent to the organ-based analysis, we examined the correlation between surgical mortality and hospital volume for six major gastrointestinal surgical procedures, namely esophagectomy, gastrectomy (which includes distal gastrectomy, pyrolus-preserving distal gastrectomy and segmental gastrectomy), total gastrectomy, low anterior resection, hepatic resection and pancreaticoduodenectomy. We grouped the institutions into four categories, namely low, medium, high and very high, according to the number of operations per year. The distribution of the number of hospitals, patients and mortality rates are shown in Table 2. Surprisingly, in Japan, 53.6–77.6% of hospitals performed only a small number of operations (only 1–5 or 1–10) annually in these six procedures. Also, a small number (40 hospitals, 5.5% of the total) categorized as high or very high performed a large number of the operations (1813 patients, 42.8% of all operations) in esophagectomy. This trend was not observed in other surgical procedures.

Mortality rates of the six major procedures were 0.44–3.3% (lowest in low anterior resection and highest in esophagectomy) and were acceptable. In terms of the correlation between mortality rate and hospital volume, mortality rates of hospitals categorized as high or very high were always low compared with that of hospitals categorized as low or medium in every procedure except for low anterior resection. In the low anterior resection group, mortality rates were always low and <1.0% in every hospital volume category.

We then calculated the relative risk reduction ratio to determine the effect of hospital volume on mortality (Fig. 1). In the very high volume category, a relative risk reduction of approximately 60–80% was observed in all procedures except for

Table 2. Distribution of number of patients, number of hospitals and mortality rate for six gastrointestinal surgery procedures by hospital volume per year

Procedure	Hospital volume				
	Low	Medium	High	Very high	Total
Esophagectomy					
No. hospitals (%)	565 (77.6)	123 (16.9)	27 (3.7)	13 (1.8)	738
No. patients (%)	1164 (27.5)	1252 (29.6)	831 (19.6)	982 (23.2)	4229
Volume	1–5	6–20	21–50	>51	
Mortality rate %	4.5	4.6	1.7	1.8	3.3
Gastrectomy					
No. hospitals (%)	1065 (60.0)	372 (21.0)	266 (15.0)	72 (4.0)	1775
No. patients (%)	5170 (21.5)	5575 (23.1)	8006 (33.2)	5349 (22.2)	24 100
Volume	1–10	11–20	21–30	>31	
Mortality rate %	1.1	0.8	0.4	0.4	0.56
Total gastrectomy					
No. hospitals (%)	868 (53.6)	369 (22.8)	330 (20.4)	51 (3.2)	1618
No. patients (%)	2309 (17.7)	2854 (21.8)	5661 (43.3)	2240 (17.1)	13 064
Volume	1–5	6–10	11–30	>31	
Mortality rate %	2.5	1.3	1.1	0.5	1.3
Low anterior resection					
No. hospitals (%)	963 (61.9)	331 (21.3)	182 (11.7)	80 (5.1)	1556
No. patients (%)	2481 (24.5)	2517 (24.9)	2585 (25.6)	2530 (25.0)	10 413
Volume	1–5	6–10	11–20	>21	
Mortality rate %	0.9	0.3	0.4	0.2	0.44
Hepatic resection					
No. hospitals (%)	609 (76.0)	89 (11.1)	68 (8.5)	35 (4.4)	801
No. patients (%)	1279 (30.3)	673 (15.9)	991 (23.5)	1280 (30.3)	4223
Volume	1–5	6–10	11–20	>21	
Mortality rate %	3.7	3.1	2.2	2.6	2.9
Pancreaticoduodenectomy					
No. hospitals (%)	751 (76.5)	131 (13.3)	71 (7.2)	29 (3.0)	982
No. patients (%)	1651 (36.6)	1011 (22.4)	1018 (22.6)	830 (18.4)	4510
Volume	1–5	6–10	11–20	>21	
Mortality rate %	3.9	2.8	1.5	1.6	2.7

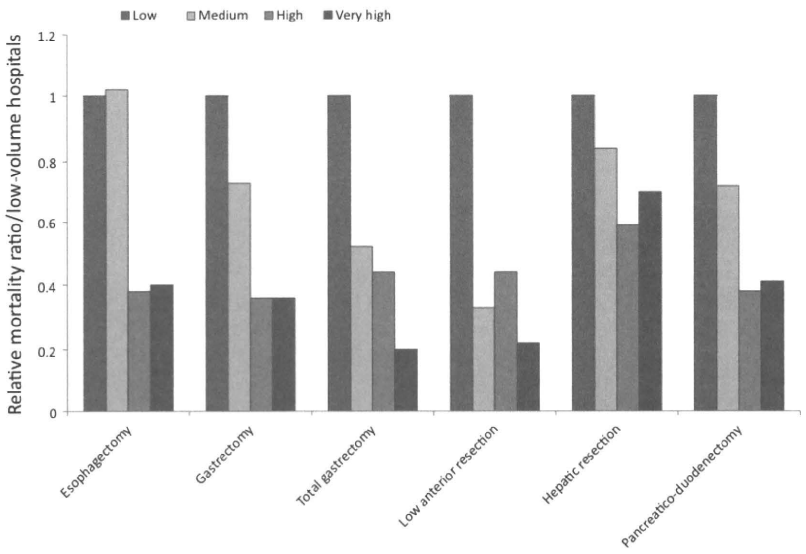

Fig. 1. Relative risk reduction by hospital volume without risk-adjustment procedures. Marked risk reductions by hospital surgical volume were observed for most of the major gastrointestinal procedures (~80% risk reduction was confirmed in very high volume centers compared with low-volume centers), while the risk reduction in hepatic resection was marginal.

hepatic resection. In hepatic resection, only a 30% risk reduction was observed.

Discussion

Establishment of a nationwide clinical database for patients who have had gastrointestinal surgery has just been started in Japan by the JSGS. First, large scale preliminary surveys were carried out, and the survey protocol can now be enhanced to perform a full-scale national survey. In this report, we have presented the preliminary data and we have gained crucial information.

The major aims of this project are continuous improvement of medical techniques and clinical care, and efficient use of medical resources. In addition, this database will allow easy

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international comparison as a secondary achievement. According to the results of our database analysis, mortality rates were satisfactory in every type of surgical procedure. In comparison with data of other nations, the mortality rate of every type of surgical procedure was extremely low. For instance, in esophagectomy, the total mortality rate was 3.3%, while US data have shown a rate of 8.0–21.7%,[8] and Taiwan data have shown a rate of 5.49–7.6%.[2] Also in colectomy, our data showed mortality of 0.44% for low anterior resection, in comparison with 1.81–3.03% in Taiwan, while for pancreatic resection, our data showed a mortality of 2.7%, compared with 3.7–16.3% in the United States and 1.2–6.09% in Taiwan data.[2] In esophagectomy, the mortality was low (3.3%) compared with a worldwide mortality reported as 6.7% in 2004.[9] In addition this analysis has clearly shown that the mortality rate after most major gastrointestinal operations was influenced by the hospital surgical volume, which is consistent with a number of previous reports.[2,10–15] It is one of the major issues that we need to understand, whether there is a certain correlation between both the short- and long-term outcomes of surgery and hospital surgical volume, because several previous studies have shown controversial results of correlations between hospital volume and short- or long-term outcomes in patients who have had surgery for gastrointestinal cancer. For example, Enzinger *et al.* [16] have mentioned that hospital volume had no overall effect on long-term gastric cancer survival, excluding the impact of perioperative mortality. Furthermore, Schmidt *et al.* have shown that the surgeon's experience remained an important determinant of overall morbidity in patients who have had pancreaticoduodenectomy. Experienced surgeons had comparable outcomes irrespective of annual surgical volume.[17] A full-scale nationwide survey, which we are going to start, certainly might solve this question.

Our report clearly showed that short term surgical outcomes in Japan were superior to those of other nations; however, it should be noted that our data have not been subject to a risk-adjustment procedure, unlike most other studies.[2,8,12,13,15,18] It has been considered that the outcomes of surgery are determined by patient preoperative risk, the quality of structures and processes of care at the providing institutions, and other random variations.[19] For these reasons, risk adjustment is thought to be necessary to compare actual differences in mortality between the databases. Indeed, a previous report has clearly shown that obvious changes were observed in the result of risk ranking before and after risk-adjustment treatment.[19] Thus, risk adjustment is essential to obtain convincing results from a clinical database, but it is a very complex procedure to obtain adequate data to perform risk adjustment. A previous report indicated that over 30 clinical or laboratory variables were necessary for creating the necessary risk-adjustment data.[19] In addition, the variables related to short-term post-operative deaths were all similar for the individual surgical procedures, but different in detail. For instance, the serum albumin level is usually an important parameter for predicting post-operative mortality, but in vascular surgery it is not ranked as a high-level predictor.[19] Data used in this report were not based on risk-adjusted clinical data, therefore we should not simply compare with other database results, and we should consider the inclusion of risk-adjustment data to make this database much more valuable. Currently, we are preparing to include data for risk-adjustment analysis.

One of the most important issues in establishing this database is data linkage to other databases, such as databases concerned with long-term clinical outcome. One of the largest databases that aggregates multiple databases is the SEER–Medicare-linked database.[4] This database includes both epidemiological information on cancer and information on insurance-based medical costs by treatment, so, for instance, investigators using this combined dataset have conducted studies on the patterns of care for people with cancer before a cancer diagnosis, over the period of initial diagnosis and treatment, and during long-term follow up (http://healthservices.cancer.gov/seermedicare/overview/). We have two large-scale databases in Japan, which are possible candidates for linkage with our surgical database. One is the Cancer Registration System,[6] supervised by the National Cancer Center in Japan, and is a large scale clinical database of patients with cancer (http://ganjoho.ncc.go.jp/professional/registration/index.html). The Cancer Registration System collects data on cancer incidence, cancer stage, treatment modality and long-term outcome, but it does not include the short-term outcome or risk by treatment procedure. Therefore, aggregation of the Cancer Registration System and our surgical clinical database would definitely produce a novel and important database, not only in the field of clinical medicine but also public health. Another possible candidate for linkage to our database is the medical insurance database including diagnosis procedure combination (DPC) data. Basically, DPC data are a government-driven insurance-based database that includes not only clinical information on the disease but also the medical costs by disease or treatment. Linking DPC data with our surgical clinical database would contribute to the field of medical economics, and quality control of medical treatment based on medical costs. Thus, there is no doubt that the linkage of these databases certainly would provide important and extremely useful clinical information. However, it is not easy to establish a linked database because each database includes a clearly different property dataset. It will be difficult to establish a large-scale aggregated database, but we should consider it in future.

In this report, we described the summarized data of a preliminary national survey of patients having gastrointestinal surgery and the outline of our road map for establishing a large-scale nationwide clinical database in Japan. Preliminary data accumulated in a limited number of institutions have clearly shown that the short-term clinical outcome, as measured by mortality, after major gastrointestinal surgery was satisfactory compared with other clinical databases. Also, the data suggest that hospital volume influenced the short-term surgical outcome of most gastrointestinal procedures except colonic resection. The preliminary study also gave an indication of the problems to be solved in future surveys. An urgent issue in the upgrade is to build up the risk-adjustment analysis to construct a much more meaningful database. Another issue, which is important rather than urgent, is data aggregation with outside datasets to make our database more useful.

We also need to understand the results of endoscopic surgery (characteristics of short-term complications and long-term outcomes), which is recently and widely spreading in this field. In this preliminary study, 23% of patients who have had gastric and colorectal surgery received endoscopic surgery (data not shown).

Currently, we are preparing to initiate a full-scale survey of patients not only in gastrointestinal surgery but also in other fields of surgery (e.g. general thoracic, pediatric, vascular, endocrinology and breast cancer), with the ultimate aim of construction of a positive feedback system to establish optimum patient care.

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Disclosure Statement

The authors have no conflict of interest.

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