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Impact of adherence to board-certified surgeon systems and clinical practice guidelines on colon cancer surgical outcomes in Japan: A questionnaire survey of the National Clinical Database

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Abstract

Aim: To investigate the effectiveness of the institutional medical structure and of the implemented clinical practice guidelines for improving colon cancer surgical outcomes.

Methods: We conducted a web-based questionnaire survey among departments registered at the National Clinical Database in Japan from October 2014 to January 2015 to assess the association between quality indicators (QIs), including structure and process indicators (clinical practice guideline adherence), and the risk-adjusted odds ratio for operative mortality (AOR) after right hemicolectomy for colorectal cancer during the study period.

Results: Among the 2064 departments registering at least one colorectal surgery during the study period, we obtained responses from 814 departments (39.4%). Our analysis on data from 22 816 patients with right hemicolectomy demonstrated that three structural QIs (certification of training hospitals by the Japanese Society of Gastroenterological Surgery and the presences of board-certified gastroenterological and colorectal surgeons) were associated with significantly lower AOR ($P < .001$,

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P = .02, and P = .05, respectively). The "performed at the doctor's discretion" answer was associated with poorer short-term outcomes in six process QIs than other answers. **Conclusion:** The board certification system for gastroenterological and colorectal surgeons and the adherence to the clinical guidelines improve the operative mortality after right hemicolectomy. It is desired to clarify the most suitable QIs to reduce the operative mortality after colorectal surgery.

KEYWORDS

board-certified surgeon, colon cancer, quality indicator, questionnaire survey, right hemicolectomy

1 | INTRODUCTION

Colorectal cancer is the second most common cause of cancer death in Japan, and its incidence is increasing rapidly.[1,2] Therefore, improving colorectal cancer treatment is essential.

Surgical techniques and procedures for colorectal cancer have improved.[3-8] In addition, especially during the last two decades, chemotherapy improvements have led to better clinical outcomes.[9-13] Other than surgery and chemotherapy, what other options for clinical outcome improvement in patients exist? A study demonstrated that a certification system for oncological care institutions may contribute to constant oncological care quality improvement.[14] Another study reported that clinical guidelines for the treatment of colorectal cancer contributed to the adherence to the standard treatment, such as lymph node dissection and adjuvant chemotherapy.[15]

Japanese gastroenterological surgeons usually belong to the Japan Surgical Society (JSS) and the Japanese Society of Gastroenterological Surgery (JSGS). Additionally, colorectal surgeons belong to the Japan Society of Coloproctology (JSCP). Each society has a certification system for surgeons and institutions. However, the effectiveness of the certification system to improve the outcomes of patients with colorectal cancer is unknown.

More than 95% of the surgical operations in Japan are registered in the National Clinical Database (NCD).[16] The NCD is a registry of surgical cases established in 2010 by ten academic societies affiliated with the board-certified surgeon system,[17] including the JSS and the JSGS. More than 5000 institutions throughout Japan are joining the NCD, and approximately 1.5 million surgical cases were registered in 2017. In the gastroenterological surgery field, detailed data on eight major surgical procedures have been collected to prepare a risk model for each surgical procedure, which is utilized as a calculator for risk evaluations in clinical settings.[18-25] As for colorectal operations, detailed data on low anterior resection and right hemicolectomy have been collected. In a previous study, the 30-day mortality rates of patients after elective and emergency right hemicolectomy were 0.7% and 6.0%, respectively (P < .001).[20] Our clinical question was whether right hemicolectomy was performed safely at every hospital in Japan.

This web-based questionnaire study was designed to investigate whether the board-certified surgeon systems and adherence to the clinical practice guidelines were effective in improving the short-term surgical treatment outcomes of patients with colon cancer.

2 | METHODS

2.1 | Questionnaire survey

We generated a web questionnaire page on the NCD registration system and requested that a responsible party at the departments responsible for colorectal surgeries in each registered institution provide their answers. The survey period was from 1 October 2014 to 31 January 2015. In all, 814 of the 2064 departments (39.4%) that registered at least one colorectal surgery during this period responded to the questionnaire. In addition, we collected data form 22 816 patients who underwent right hemicolectomy during this period in Japan on quality indicators (QIs) related to the colorectal cancer treatment (see Table 1 for details).

For questions (Qs) 6 to 16, the respondents selected one of three possible responses: performed according to the guideline (group A); performed without following the guideline (group B); and recommended by the institution, but performed at the doctor's discretion (group C).

We created Q6 to Q16 based on discussions among council members of the Japanese Society for Cancer of the Colon and Rectum (JSCCR), considering the higher recommendation grades in the 2014 Guidelines for the treatment of colorectal cancer.[26]

This specific project was approved on April 2016 by the Ethics Committee of Fukushima Medical University (No1057).

For this study, we only investigated the outcomes after right hemicolectomy, one of the most common surgical procedures, to exclude biases as much as possible.

2.2 | Association between QIs and the level of medical care

Of the patients who underwent right hemicolectomy in 2013 or 2014 at the 814 departments that responded to the questionnaire,

TABLE 1 The questionnaire items related to the treatment of colon cancer

Q1	Is your institution accredited by or related to the Japan Surgical Society (JSS)?
Q2	Is your institution certified by the Japanese Society of Gastroenterological Surgery (JSGS)?
Q3	How many surgeries for colorectal cancer were performed at your institution in 2013?
Q4	Is there a board-certified gastroenterological surgeon by JSGS?
Q5	Is there a board-certified colorectal surgeon by the Japan Society of Coloproctology?
Q6	Are all the items below described in the pathological report for pT1 colorectal cancer resected endoscopically: distance of submucosal invasion (actual measured value), histologic type, lymphatic invasion, venous invasion, budding (grade 1-3), horizontal resection margin, and vertical resection margin?
Q7	Do you perform D3 lymph node dissection in patients with cStage II-III colorectal cancer?
Q8	Do you perform lateral pelvic lymph node dissection for T3 or T4 lower rectal cancer?
Q9	Do you ensure a resection margin of 3 cm in rectosigmoid and upper rectal cancer and that of 2 cm in lower rectal cancer in patients with cStageg II or III rectal cancer.
Q10	Does a pathological report for the resected colorectal cancer include all items defined in the Japanese classification?
Q11	Do you administer adjuvant chemotherapy for pStage III colorectal cancer?
Q12	Do you perform chest-abdomen-pelvis CT every six months for postoperative surveillance of pStage III colorectal cancer?
Q13	Do you perform surveillance colonoscopy one year after surgery for pStage I to III colorectal cancer?
Q14	Do you resect primary tumor or perform colostomy/bypass surgery in patients with stenosed Stage IV colorectal cancer?
Q15	Do you choose surgery as an initial treatment for resectable distant metastasis from colorectal cancer?
Q16	Do you check *ras* mutation status before first-line chemotherapy for advanced colorectal cancer?

we only analyzed data of those who did not refuse registration, had no missing data on their gender or outcome, and gave approval to participate in the survey (22 816 patients in total). To evaluate the association between QIs and operative mortality in these patients, we defined the operative mortality as any death within the index hospitalization period regardless of the length of hospital stay (up to 90 days), as well as any deaths after discharge up to 30 days after surgery. In right hemicolectomy, the 90-day mortality is thought to be an appropriate outcome measure because it reflects the true death risk based on particulars of the surgeon and patient.[20]

2.3 | Multivariable regression analysis

To clarify the association between each questionnaire answer and operative mortality, we fitted multivariable logistic regression models with generalized estimating equations, considering patient clusters by hospital levels. To adjust patient-level risk factors, we used the following published risk model variables[24]: age category, activity of daily life within 30 days before surgery (any assistance), presence of ascites, congestive heart failure, history of peripheral vascular disease surgery, preoperative dialysis, disseminated cancer, chronic steroid use, cancer metastasis/relapse, weight loss (>10%), sepsis, American Society of Anesthesiologists (ASA) class 3, ASA classes 4-5, hematocrit (<37% in men and < 32% in women), white blood cells (WBCs; >9000/μL), platelets (<120 000/μL and <80 000/μL), albumin (<3.0 g/dL), total bilirubin (>1.0 mg/dL), aspartate aminotransferase (AST; >40 U/L), blood urea nitrogen (BUN; >60 mg/dL), serum Na (<138 mEq/L and >145 mEq/L), and prothrombin time-international normalized ratio (PT-INR; >1.1). We expressed the results as adjusted odds ratios (AORs) and confidence intervals (95% CI). We did not use Q10 and Q11 for multivariable analyses, because their distributions were extremely low (<1%) (Table 2).

2.4 | Statistical analyses

We performed chi-squared or Fisher's exact tests to compare categorical data and their distributions as appropriate. We considered two-sided probability values lower than 0.05 as statistically significant. All statistical calculations were performed with the STATA 15 software (StataCorp, College Station, TX, USA).

3 | RESULTS

3.1 | Patient characteristics, response distributions, and association between each QI result and the crude operative mortality

Table 3 shows the patient characteristics in this study and their association with crude operative mortality rates. Most risk-model variables showed statistically significant associations with high crude operative mortality rates.

Table 2 shows the response distribution in each QI and the association between each QI result and crude operative mortality rates. We found 587 (86.4%) out of 814 departments were accredited by the JSS, and 550 (76.4%) were certified by the JSGS. Although the JSS accreditation for each department was not associated with the right hemicolectomy crude operative mortality ($P = .216$), the JSGS certification for each department was associated with a low crude operative mortality rate ($P < .001$). The rates of board-certified surgeons

TABLE 2 The response distributions and relationship between each quality Indicator and the crude operative mortality

Questionnaire item	Department No.	Operative death (n = 508) Pt No.	%	Alive (n = 22 308) Pt No.	%	Total No.	%	Mortality rate
Q1 Is your institution accredited by or related to the Japan Surgical Society (JSS)?								*P* = .216*
No	32	7	1.4%	319	1.4%	326	1.4%	2.15%
Accredited	587	439	86.4%	19 789	88.7%	20 228	88.7%	2.17%
Related	195	62	12.2%	2200	9.9%	2262	9.9%	2.74%
Q2 Is your institution certified by the Japanese Society of Gastroenterological Surgery (JSGS)?								*P* < .001
Certified	550	388	76.4%	18 961	85.0%	19 349	84.8%	2.01%
No	264	120	23.6%	3347	15.0%	3467	15.2%	3.46%
Q3 How many surgeries for colorectal cancer were performed at your institution in 2013?								*P* < .001
100 and more	204	198	39.0%	11 139	49.9%	11 337	49.7%	1.75%
50 to 99	284	187	36.8%	7664	34.4%	7851	34.4%	2.38%
Less than 50	326	123	24.2%	3505	15.7%	3628	15.9%	3.39%
Q4 Is there a board-certified gastroenterological surgeon by JSGS?								*P* < .001
No	57	32	6.3%	763	3.4%	795	3.5%	4.03%
Yes	757	476	93.7%	21 545	96.6%	22 021	96.5%	2.16%
Q5 Is there a board-certified colorectal surgeon by the Japan Society of Coloproctology?								*P* = .23
No	511	314	61.8%	12 040	54.0%	12 354	54.1%	2.54%
Yes	303	194	38.2%	10 268	46.0%	10 462	45.9%	1.85%
Q6 Are all the items below described in the pathological report for pT1 colorectal cancer resected endoscopically: distance of submucosal invasion (actual measured value), histologic type, lymphatic invasion, venous invasion, budding (grade 1-3), horizontal resection margin, and vertical resection margin?								*P* < .001
Performed in principle	622	418	82.3%	18 838	84.4%	19 256	84.4%	2.17%
Not performed in principle	43	16	3.1%	484	2.2%	500	2.2%	3.20%
Doctor's discretion	149	74	14.6%	2986	13.4%	3060	13.4%	2.42%
Q7 Do you perform D3 lymph node dissection in patients with cStage II-III colorectal cancer?								*P* = .009
Performed in principle	578	386	76.0%	17 907	80.3%	18 293	80.2%	2.11%
Not performed in principle	28	15	3.0%	347	1.6%	362	1.6%	4.14%
Doctor's discretion	208	107	21.1%	4054	18.2%	4161	18.2%	2.57%
Q8 Do you perform lateral pelvic lymph node dissection for T3 or T4 lower rectal cancer?								*P* = .003
Performed in principle	241	160	31.5%	8599	38.5%	8759	38.4%	1.83%
Not performed in principle	227	136	26.8%	5004	22.4%	5140	22.5%	2.65%
Doctor's discretion	346	212	41.7%	8705	39.0%	8917	39.1%	2.38%
Q9 Do you ensure a resection margin of 3 cm in rectosigmoid and upper rectal cancer and that of 2 cm in lower rectal cancer in patients with cStageg II or III rectal cancer.								*P* = .061*

(Continues)

TABLE 2 (Continued)

Questionnaire item	Department No.	Operative death (n = 508) Pt No.	%	Alive (n = 22 308) Pt No.	%	Total No.	%	Mortality rate
Performed in principle	601	386	76.0%	17 886	80.2%	18 272	80.1%	2.11%
Not performed in principle	22	7	1.4%	258	1.2%	265	1.2%	2.64%
Doctor's discretion	191	115	22.6%	4164	18.7%	4279	18.8%	2.69%
Q10 Does a pathological report for the resected colorectal cancer include all items defined in the Japanese classification?								*P* = .215*
Performed in principle	737	476	93.7%	21 195	95.0%	21 671	95.0%	2.20%
Not performed in principle	17	4	0.8%	99	0.4%	103	0.5%	3.88%
Doctor's discretion	60	28	5.5%	1014	4.5%	1042	4.6%	2.69%
Q11 Do you administer adjuvant chemotherapy for pStage III colorectal cancer?								*P* = .171*
Performed in principle	624	399	78.5%	18 199	81.6%	18 598	81.5%	2.15%
Not performed in principle	10	2	0.4%	78	0.3%	80	0.4%	2.50%
Doctor's discretion	180	107	21.1%	4031	18.1%	4138	18.1%	2.59%
Q12 Do you perform chest-abdomen-pelvis CT every six months for postoperative surveillance of pStage III colorectal cancer?								*P* = .030
Performed in principle	516	320	63.0%	15 282	68.5%	15 602	68.4%	2.05%
Not performed in principle	36	20	3.9%	715	3.2%	735	3.2%	2.72%
Doctor's discretion	262	168	33.1%	6311	28.3%	6479	28.4%	2.59%
Q13 Do you perform surveillance colonoscopy one year after surgery for pStage I to III colorectal cancer?								*P* = .046
Performed in principle	397	243	47.8%	11 907	53.4%	12 150	53.3%	2.00%
Not performed in principle	64	39	7.7%	1579	7.1%	1618	7.1%	2.41%
Doctor's discretion	353	226	44.5%	8822	39.5%	9048	39.7%	2.50%
Q14 Do you resect primary tumor or perform colostomy/bypass surgery in patients with stenosed Stage IV colorectal cancer?								*P* = .100
Performed in principle	532	342	67.3%	15 878	71.2%	16 220	71.1%	2.11%
Not performed in principle	42	20	3.9%	945	4.2%	965	4.2%	2.07%
Doctor's discretion	240	146	28.7%	5485	24.6%	5631	24.7%	2.59%
Q15 Do you choose surgery as an initial treatment for resectable distant metastasis from colorectal cancer?								*P* = .006
Performed in principle	480	315	62.0%	15 209	68.2%	15 524	68.0%	2.03%
Not performed in principle	70	43	8.5%	1346	6.0%	1389	6.1%	3.10%
Doctor's discretion	264	150	29.5%	5753	25.8%	5903	25.9%	2.54%
Q16 Do you check ras mutation status before first-line chemotherapy for advanced colorectal cancer?								*P* = .884
Performed in principle	555	371	73.0%	16 457	73.8%	16 828	73.8%	2.20%
Not performed in principle	51	30	5.9%	1215	5.4%	1245	5.5%	2.41%
Doctor's discretion	208	107	21.1%	4636	20.8%	4743	20.8%	2.26%

*Fisher's exact test.

from the JSGS and JSCP were 93.0% and 38.2%, respectively. The presence of a board-certified surgeon from the JSGS ($P < .001$) and JSCP ($P < .001$) was associated with a low right hemicolectomy crude operative mortality (Table 2). The numbers of right hemicolectomy in each department were also associated with the crude operative mortality rate (Table 2).

TABLE 3 Patients' characteristics and crude operative mortality rates

Variables	Operative death (n = 508) No.	%	Alive (n = 22 308) No.	%	*P* value
Age					
-59	38	7.5%	2930	13.1%	<.001
60-64	29	5.7%	2137	9.6%	
65-69	49	9.6%	3010	13.5%	
70-74	66	13.0%	3979	17.8%	
75-79	98	19.3%	4117	18.5%	
80-	228	44.9%	6135	27.5%	
Emergent surgery	241	47.4%	1930	8.7%	<.001
Preoperative ADL; Any assistance	213	41.9%	2022	9.1%	<.001
Ascites (Any)	107	21.1%	909	4.1%	<.001
Congestive heart failure	28	5.5%	225	1.0%	<.001
Previous PVD surgery	10	2.0%	89	0.4%	<.001
Preoperative dialysis	38	7.5%	212	1.0%	<.001
Disseminated cancer	67	13.2%	814	3.6%	<.001
Chronic steroid use	20	3.9%	267	1.2%	<.001
Weight loss > 10%	52	10.2%	1034	4.6%	<.001
sepsis	107	21.1%	273	1.2%	<.001
ASA Class 3	202	39.8%	3262	14.6%	<.001
ASA Class 4, 5	113	22.2%	196	0.9%	<.001
Cancer metastasis/relapse	25	4.9%	591	2.6%	.002
Hematocrit					
M < 37%,F < 32%	333	65.6%	9357	41.9%	<.001
Platelet < 120 000/μL	95	18.7%	557	2.5%	<.001
Platelet < 80 000/μL	37	7.3%	135	0.6%	<.001
Albumin < 3.0 g/dL	275	54.1%	2854	12.8%	<.001
Total bilirubin > 1.0 mg/dL	83	16.3%	904	4.1%	<.001
AST > 40 U/L	146	28.7%	1396	6.3%	<.001
BUN < 8 mg/dL	28	5.5%	984	4.4%	.233
BUN > 60 mg/dL	32	6.3%	111	0.5%	<.001
Serum Na < 138 mEq/L	217	42.7%	3119	14.0%	<.001
Serum Na > 145 mEq/L	19	3.7%	107	0.5%	<.001
PT-INR > 1.1	210	41.3%	2982	13.4%	<.001
WBC > 9000/μL	181	35.6%	2753	12.3%	<.001

Abbreviations: ADL, activity of daily life; ASA, American Society of Anesthesiologists; AST, aspartate aminotransferase; BUN, blood urea nitrogen; BUN, blood urea nitrogen; COPD, chronic obstructive pulmonary disorder; PT-INR, prothrombin time-international normalized ratio; PVD, peripheral vascular disease; WBC: white blood cell.

3.2 | Association between the board-certified surgeons and the risk-adjusted odds ratio for operative mortality (AOR)

Figure 1 shows the results after risk adjustment using the factors mentioned above. Although we found no difference in the AOR between departments with and without JSS certification (Q1), the AOR of right hemicolectomy in the departments without JSGS certificates was 1.79 (1.39-2.31, $P < .001$) compared with that in the departments with JSGS certifications (Q2). The AORs in the departments with less than 50 colorectal surgeries were higher than those in the departments with more than 100 procedures (1.97, 1.51-2.57, $P < .001$, Q3). The AORs in the departments with the JSGS-certified surgeons (0.6, 0.38-0.93,

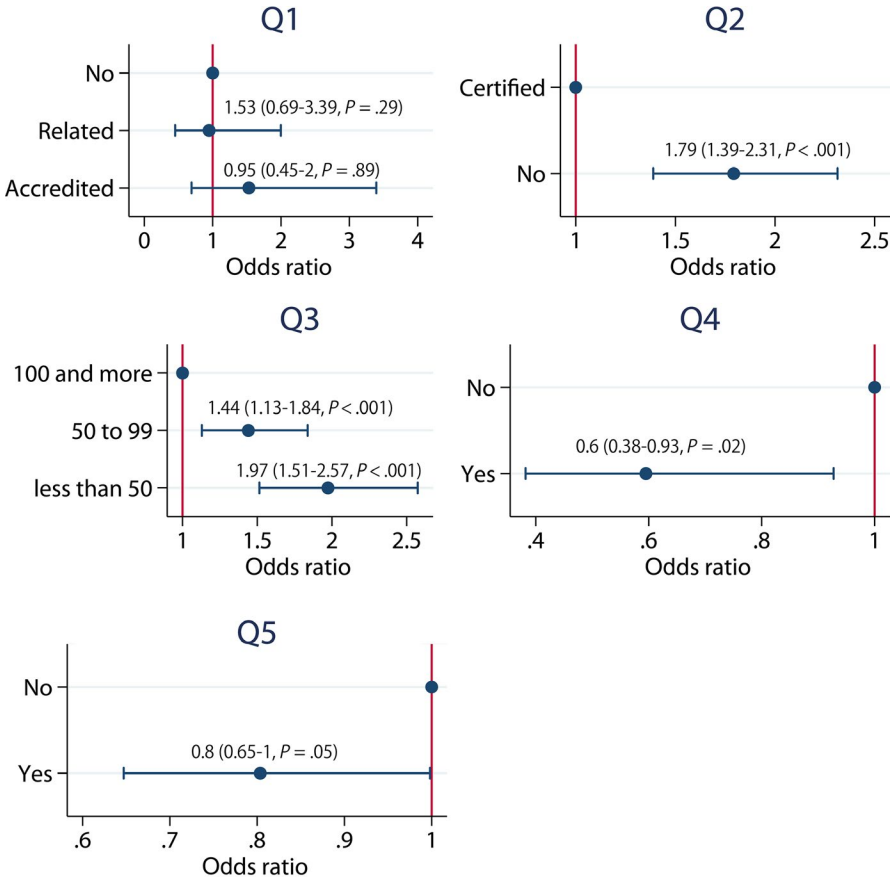

FIGURE 1 Association between board certification systems for surgeons and institutions and AOR in right hemicolectomy for colon cancer in Japan. The results show point estimates of odds ratios and 95% confidence intervals. The content of each questionnaire is as follows: Q1 Is your institution accredited by or related to the Japan Surgical Society (JSS)? Q2 Is your institution certified by the Japanese Society of Gastroenterological Surgery (JSGS)? Q3 How many surgeries for colorectal cancer were performed at your institution in 2013? Q4 Is there a board-certified gastroenterological surgeon by JSGS? Q5 Is there a board-certified colorectal surgeon by the Japan Society of Coloproctology?

P = .02, Q4) and JSCP-certified surgeons (0.8, 0.65-1.0, *P* = .05, Q5) were lower than those in the departments without certified surgeons.

3.3 | Association between the rate of implementation of various QIs and AOR

Figure 2 shows the association between implemented QI rates and AORs.

3.3.1 | Q6: Pathological report for pT1 colorectal cancers resected endoscopically

Groups A, B, and C had 622, 43, and 149 departments, respectively. The AOR of group A was better than that of group B (0.54; 0.31-0.94; *P* = .03).

3.3.2 | Q7: D3 lymph node dissection in patients with cStage II–III colorectal cancers

Groups A, B, and C had 578, 28, and 208 departments, respectively. The majority of the departments in this study performed D3 lymph node dissections for cStage II–III colorectal cancer according to the Japanese guidelines. We found similar AORs among the three groups.

3.3.3 | Q8: Lateral pelvic lymph node dissection for T3 or T4 lower rectal cancers

Groups A, B, and C had 241, 227, and 346 departments, respectively. The AOR of group A was better than those of groups B (0.74; 0.55-0.99; *P* = .04) and C (0.74; 0.57-0.94; *P* = .02).

3.3.4 | Q9: Distal resection margin for rectal cancers

Groups A, B, and C had 601, 22, and 191 departments, respectively, and the majority abided to the recommended distal resection margin during the rectal cancer resections. The AOR of group A was better than that of group C (0.70; 0.54-0.91; *P* = .01).

3.3.5 | Q12: CT for postoperative surveillance of pStage III colorectal cancers

Groups A, B, and C had 516, 36, and 262 departments, respectively. The AOR of group A was better than that of group C (0.70; 0.55-0.88; *P* < .001).

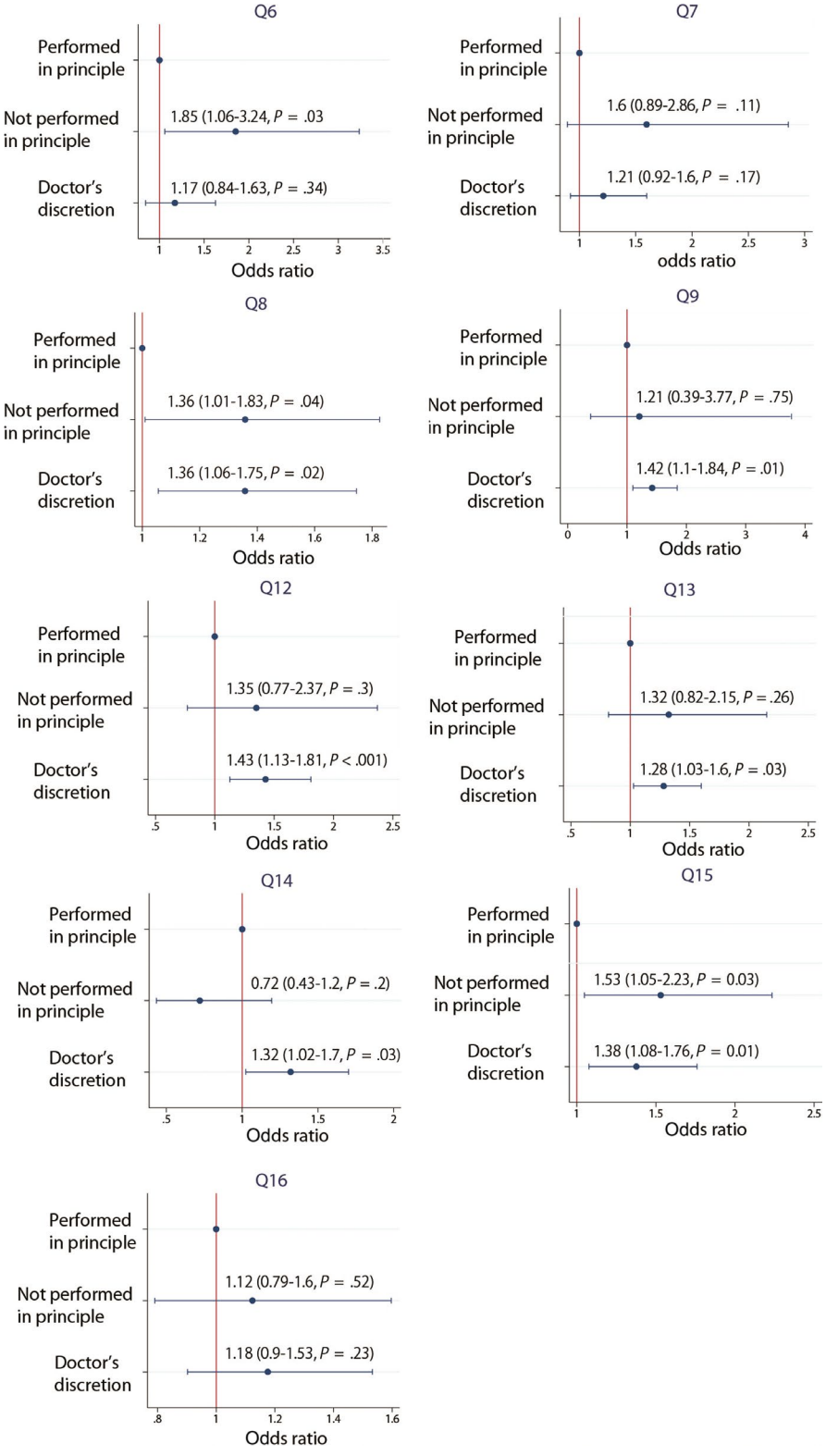

FIGURE 2 Association between process indicators related to right hemicolectomy for colon cancer and AOR in Japan. The results show point estimates of odds ratios and 95% confidence intervals. The expression "Doctor's discretion" indicates "recommended by the institution, but performed at the doctor's discretion." The content of each questionnaire is as follows: Q6 Are all the items below described in the pathological report for pT1 colorectal cancer resected endoscopically: distance of submucosal invasion (actual measured value), histologic type, lymphatic invasion, venous invasion, budding (grades 1-3), horizontal resection margin, and vertical resection margin? Q7 Do you perform D3 lymph node dissection in patients with cStage II–III colorectal cancer? Q8 Do you perform lateral pelvic lymph node dissection for T3 or T4 lower rectal cancer? Q9 Do you ensure a resection margin of 3 cm in rectosigmoid and upper rectal cancer and that of 2 cm in lower rectal cancer in patients with cStage II or III rectal cancer? Q12 Do you perform chest–abdomen–pelvis CT every 6 months for postoperative surveillance of pStage III colorectal cancer? Q13 Do you perform surveillance colonoscopy 1 year after surgery for pStage I to III colorectal cancer? Q14 Do you resect primary tumor or perform colostomy/bypass surgery in patients with obstructive Stage IV colorectal cancer? Q15 Do you choose surgery as an initial treatment for resectable distant metastasis from colorectal cancer? Q16 Do you check ras mutation status before first-line chemotherapy for advanced colorectal cancer?

3.3.6 | Q13: Colonoscopy 1 year after surgery for pStage I to III colorectal cancers

Groups A, B, and C had 397, 64, and 353 departments, respectively. The AOR of group A was better than that of group C (0.78; 0.63-0.97; $P = .03$).

3.3.7 | Q14: Colostomy/bypass surgery for obstructive Stage IV colorectal cancers

Groups A, B, and C had 532, 42, and 240 departments, respectively. The AOR of group A was better than that of group C (0.76; 0.59-0.98; $P = .03$).

3.3.8 | Q15: Surgery as an initial treatment for resectable distant metastasis from colorectal cancer

Groups A, B, and C had 480, 70, and 264 departments, respectively. The AOR of group A was better than those of groups B (0.65; 0.45-0.95; $P = .03$) and C (0.72; 0.57-0.93; $P = .01$).

4 | DISCUSSION

Colorectal cancer treatment has remarkably progressed. However, developing new surgical techniques and anti-cancer drugs is time and energy consuming. Therefore, we investigated other ways to improve the short-term patient outcomes after colon resection operations. We set the operative mortality as a primary endpoint to validate the certification programs of the Japanese surgical societies and the adherence to the Japanese clinical guidelines for colorectal cancer treatment.

We investigated the association between the operative mortality and certification program in this study. The operative mortality rates after right hemicolectomy in the JSGS-certified departments were lower than those in the noncertified departments. However, the operative mortalities between the departments with and without the JSS certification were similar. The JSS certification coverage ratio may explain this. JSS members consist of not only gastroenterological surgeons, but also breast, cardiovascular, thoracic, and other surgeons. Similarly, the departments with JSGS or JSCP board-certified surgeons had lower operative mortalities than those without certified surgeons. The percentage of departments with JSGS or JSCP board-certified surgeons was lower than that of JSS-accredited departments. The specialties of gastroenterological or colorectal surgeons contributed to the lower operative mortality for these departments in standard surgical procedures, such as right hemicolectomy. Another study demonstrated that the medical institutional board-certified training structures for esophageal surgeons and the participation of board-certified esophageal surgeons improved short-term outcomes after esophagectomy.[27] These findings validate the importance of the board certification programs of the Japanese surgical societies.

In order to improve the quality of treatment for cancer patients, the German Cancer Society implemented a certification system for oncological care institutions. Wesselmann et al reported that certified centers performed good-quality colorectal operations as judged by the tumor and lymph node retrieval specimens.[14] Konno et al reported that participation of JSGS board-certified gastroenterological surgeons contributed to improving the operative mortality after eight gastroenterological procedures in Japan, and that the number of board-certified surgeons in the field of gastroenterological surgery per hospital may be used as a surrogate marker of operative mortality.[28] These studies indicate that certification systems in cancer treatment have contributed to the quality control in both Japanese and Western countries.[14,28]

Our study demonstrated an inverse correlation between the operative mortality and hospital volume. The AOR was highest in the departments with less than 50 colorectal surgeries performed. In contrast, the AOR was lowest in the departments with 100 or more right hemicolectomies. Begg et al reported the impact of the hospital volume on the operative mortality for major cancer operations and found a significant difference in 30-day operative mortality rates after pelvic exenteration among the hospitals performing one to five, six to 10, and more than 10 cases.[29] However, right hemicolectomy is one of the most standardized surgical procedures and can be performed in any hospital in Japan. Thus, improving the short-term outcomes after right hemicolectomy in the departments with small numbers of surgeries is essential, and to achieve this, the educational system, including the certification system in the surgical societies, will play an important role.

Moreover, we investigated the association between operative mortality and various QIs other than the medical care system. We included a question about the pathological diagnosis system (Q6). A detailed pathological report along with the recommended treatment according to guidelines contributed to decreased mortality rates after right hemicolectomy. Although the reason for this is unclear, a detailed pathological report may reflect the hospital environment for cancer treatment. Q7, Q8, and Q9 enquired about the surgical techniques and strategies. Q7 asked for the extent of lymph node dissection in patients with cStage II–III colorectal cancer. The Japanese classification of colorectal carcinoma defines the extent of lymph node dissection as D0, D1, D2, and D3,[30] and the Japanese guidelines recommend D3 dissection for cStage II–III colorectal cancers.[26] We found no differences in the operative mortality among the three groups in our study. This may indicate the high quality of the surgical skills of the Japanese surgeons. Although complications after surgery usually occur more frequently after invasive procedures, there was no difference in the AOR between the institutions performing D3 dissection and those not. This means similar short-term outcomes among the three groups with different lymph node dissection extents. On the other hand, studies have demonstrated that the extent of lymph node dissection in colon cancer is associated with better long-term outcomes.[31,32]

Q8 enquired about the lymph node dissection for lower rectal cancer. The Japanese guidelines recommend lateral pelvic lymph node dissection for patients with cT3-4 lower rectal cancer. This may mean that having a colorectal surgery expert contributes to improving operative mortality, because lateral lymph node dissection is performed only in departments with a colorectal surgery expert. In fact, lateral pelvic lymph node dissections for cT3-4 lower rectal cancers were performed in approximately 40% of the departments in this study.

Q12 and Q13 were questions about the postoperative surveillance in colorectal cancer. The operative mortality of group A was better than that of group C in both cases, probably because adherence to the clinical guidelines may be associated with the professionalism of colorectal surgeons (as in the case of Q6).

Q14 enquired about the strategy for obstructive colorectal cancer. We found no difference in the operative mortality rates between groups A and B, probably due to a stent placement for obstructive

colorectal cancer. Tomita et al reported that self-expandable metallic stenting is an option as a bridge to surgery.[33] In their study, primary anastomoses after decompression by self-expandable metallic stents were possible in 91.8% of patients, and the postoperative mortality rate was 0.5%.[33]

Q15 enquired about the initial treatment for resectable distant metastases from colorectal cancer. In other words, therapeutic options, such as chemotherapy, were available for resectable distant metastasis in groups B and C. The operative mortality rate in group A was better than those of groups B and C. Similar therapeutic strategies were probably adopted for primary colon cancer in each department. The departments of groups B and C tended to adopt neoadjuvant therapies for advanced primary colorectal cancer, and the operative mortality rate was higher in such cases.

Q16 was a question for surgeons about the *ras* mutation status before the first-line chemotherapy for advanced colorectal cancer. We found no difference in the operative mortality among the three groups. In Japan, chemotherapy for colorectal cancer is managed by surgeons in many hospitals since the *ras* mutation test is highly prevalent among patients with colorectal cancer.

For this study, we assessed the association between the right hemicolectomy operative mortality and each QI using clinical data from the NCD database and answers to a questionnaire survey through the same database. The registration of surgical cases in the NCD started in 2011; the database has grown to contain the most reliable representation of surgical treatments in Japan.[16,17] The JSGS has actively conducted research in various fields using these data.[18-25,34] But, this is the first study attempting to validate the quality of surgical treatment using the database and a questionnaire survey through the NCD. Thus, our results reflect operative mortality up to 90 days after right hemicolectomy and its association with board certification, hospital volume, and adherence to clinical guidelines.

In turn, we identified various preoperative patients' conditions associated with the crude operative mortality. Approximately half of the patients who died within the first 90 days received emergency surgery. Frail patients requiring special assistance or with ASA scores of three or higher were at risk of operative mortality. At the same time, preoperative blood tests were predictive for the operative mortality in this cohort. In particular, most patients with operative mortality had hypoalbuminemia or anemia. These findings were consistent with those in our previous study[20] and proved the reliability of the NCD database.

We are aware of the limitations in this study. First, since the study was based on a questionnaire survey, the data may not necessarily reflect the entire departmental situations. Second, the response rate of this questionnaire was approximately 40%, and our results may not accurately represent the clinical practice in Japan. Third, the appropriateness of the QIs is unclear in the present study. In the future, more objective methods of QI selection should be adopted.[35]

In conclusion, the Japanese departments with the lowest operative mortality rates after right hemicolectomy had the most board-certified gastroenterological and colorectal surgery systems and adhered to clinical guidelines most frequently. Clarifying the most suitable QIs is important to reduce operative mortality after colorectal surgery.

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