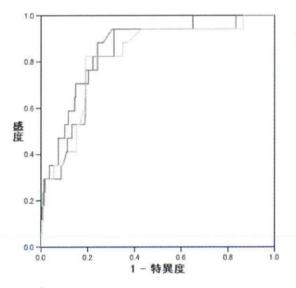
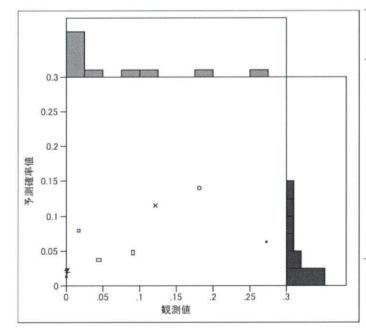
表 1.2 推定結果

	Eq. (1)		Eq. (2)		Eq. (3)	
	Exp	有 意	Exp	有 意	Exp	有 意
	(B)	確率	(B)	確率	(B)	確率
70 歳未満						
70 歳以上	3.169	0.056	2.882	0.064	3.882	0.014
出血量(対数)	1.066	0.890				
尿導カテーテル挿入日数(対数)	5.790	0.031	8.703	0.002	6.558	0.003
Stage1	2.036	0.351	2.025	0.282	1.899	0.309
Stage2						
Stage3	0.000	0.998	0.000	0.998	0.000	0.998
Stage4	0.000	0.999	0.000	0.999	0.000	0.999
Stage 分類不詳	7.132	0.046	7.768	0.013	6.827	0.013
術前ホルモン療法 有						
術前ホルモン療法 無	5.129	0.148	4.857	0.149		
術前ホルモン療法 不詳	9.468	0.210	12.774	0.140		
高血圧既往 有						
高血圧既往 無	0.883	0.836				
高血圧既往 不詳	0.000	0.999				
脳血管障害 有						
脳血管障害 無	0.000	0.999				
肺疾患 有						
肺疾患 無	1.100	0.935				
腎疾患 有				0.135		
腎疾患 無	9.250	0.092	6.225	0.135		
抗菌薬使用期間 1日						
抗菌薬使用期間 2日	0.736	0.791				
抗菌薬使用期間 3日	0.213	0.225				
抗菌薬使用期間 4日	0.764	0.801				
抗菌薬使用期間 不詳	0.000	1.000				
定数	0.000	0.998	0.000	0.997	0.000	0.997
AIC	133.0		119.4		118.6	



モデル式	ROC 下面積	
Eq. (1)		0.857
Eq. (2)		0.834
Eq. (3)		0.820

図 1.2.1 ROC 曲線



	SSI	予測
施設	発生率	確率値
	(観測値)	(期待値)
Α	0.000	0.012
В	0.000	0.020
C	0.120	0.114
D	0.017	0.079
E	0.273	0.063
F	0.000	0.023
G	0.000	0.023
Н	0.000	0.022
1	0.182	0.141
J	0.043	0.037
K	0.091	0.046

図 1.2.2 OE 比

研究成果の刊行に関する一覧表

書籍

著者氏名	論文タイトル名	書籍全体の 編集者名	書籍	名	出版社名	出版地	出版年	ページ

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Activities of Daily Living and Quality of Life of Elderly Patients After Elective Surgery for Gastric and Colorectal Cancers

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Objective: To establish reliable standards for surgical application to elderly patients 75 years old or older with gastric or colorectal cancer with special reference to the postoperative recovery of activities of daily living (ADL) and quality of life (QOL).

Summary Background Data: ADL and QOL are important outcomes of surgery for the elderly. However, there has been only limited evidence on the natural course of recovery of functional independence.

Methods: Two hundred twenty-three patients 75 years old or older with gastric or colorectal cancer were prospectively examined. Physical conditions, ADL, and QOL were evaluated preoperatively and at the first, third, and sixth postoperative month.

Results: The mortality and morbidity rates were 0.4% and 28%, respectively. Twenty-four percent of patients showed a decrease in ADL at 1 month postoperatively, but most patients recovered from this transient reduction, with only 3% showing a decline at the sixth postoperative month (6POM). ADL of these patients was likely to decrease after discharge from the hospital. QOL of the patients showed a recovery to an extent equal to or better than their average preoperative scores.

Conclusions: Of the patients 75 years old or older who underwent elective surgery for gastric or colorectal cancer, only a few showed a protracted decline in ADL and most exhibited better QOL after surgery. This indicates that surgical treatment should be considered, whenever needed, for elderly patients 75 years old or older with gastric or colorectal cancer. Estimation of Physical Ability and

Surgical Stress is useful for predicting postoperative declines in ADL and protracted disability; this could aid in establishing a directed rehabilitation program for preventing protracted disability in elderly patients.

(Ann Surg 2007;246: 222-228)

n 2004 Japanese citizens 75 to 80 years old were expected on average to live for an additional 8 to 11 years, respectively. Even 85-year-olds were likely to live for additional years, 8 for women and 6 for men. With such rapid growth in the elderly population, numbers of surgical procedures at this age have been increasing.2 Major surgery, such as aortic aneurysm repair, gastrointestinal resection, and joint replacement can be performed in elderly patients with considerable safety due to recent advances in anesthesia, metabolic and critical care, and surgical techniques.2 The surgical treatment of elderly patients, however, remains controversial. Generally, the overall outcome of surgery represents a balance between beneficial effects on a patient and risk of mortality or morbidity. Accordingly, surgical treatment of a disease is attempted for a particular patient only if expected mortality and morbidity are acceptably low. In elderly patients, especially those with comorbidities, surgical procedures considered standard when performed in younger individuals for a particular disease sometimes are inappropriate; that is, patients treated by surgical operation may recover from the disease, but become so disabled that they are bedridden for the remainder of their lives. According to previous reports, more than 10% of elderly patients older than 80 years may have protracted postoperative disability.3 Postoperative functions of patients, assessed by activities of daily living (ADL) and quality of life (QOL), have become an especially important measure of outcomes of surgical treatment for the elderly.4-10 When one considers elderly patients with malignancies, the problem is more serious because there has been an increase in the number of aged patients who develop cancers as a result of the rapid expansion of the elderly population. It seems that surgical treatment decisions for elderly cancer patients, especially those with comorbidities, are based mostly on the subjective

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TABLE 1.	Activities Exhibiting a Decline After Surgery							
Katz Index	Patients Showing Decline at 6POM (%)	Additional Functions	Patients Showing Decline at 6POM (%)					
Transferring	10/193 (5.2)	Sitting in a bed	5/193 (2.6)					
Feeding	5/193 (2.6)	Sitting down on a chair or stool	6/193 (3.1)					
Toileting	7/193 (3.6)	Maintaining a standing posture	5/193 (2.6)					
Grooming	8/193 (4.1)	Moving in a wheelchair	9/193 (4.7)					
Dressing	6/193 (3.1)	Walking on a level surface	7/193 (3.6)					
Bathing	5/193 (2.6)							

judgment of surgeons from their individual experiences. Furthermore, "ageism," a negative attitude toward elderly individuals, does exist so that elderly patients with sufficient function are sometimes not treated using the same standard surgical procedures used for younger patients and receive less aggressive surgery based on their age alone.2,11 Yet, only a radical operation that removes the primary tumors and regional lymph nodes can cure patients with advanced stages of cancer. Thus, reliable standards for surgery on elderly cancer patients supported by scientific data that include information on postoperative functions of patients are urgently needed. Toward this goal, we systematically examined postoperative recovery of physical conditions, ADL and QOL, and identified predictors for the functional recovery of patients 75 years old or older who underwent elective surgery for gastric or colorectal cancer. Gastric and colorectal cancers were chosen because these are the most common gastroenterological malignant tumors occurring in the elderly worldwide. We designed and performed this prospective study with special reference to the postoperative functions of elderly patients to establish criteria that might help surgeons decide whether standard surgical treatment should or should not be applied to elderly patients with gastric or colorectal cancer.

PATIENTS AND METHODS

A total of 232 eligible patients 75 years old or older with gastric or colorectal cancer who were referred to the surgical department in 29 affiliated hospitals between June 2003 and June 2004 were enrolled consecutively in this study. All 232 patients underwent surgical resection of gastric or colorectal cancer at those hospitals.

Physical Status, Operative Severity, Morbidity, and Mortality

The parameters examined were physical status, operative severity, and morbidity. They were measured by the Physiological and Operative Severity Scoring system for enUmeration of Mortality and morbidity (POSSUM), ¹² the Estimation of Physical Ability and Surgical Stress (E-PASS), ¹³ and the Acute Physiology And Chronic Health Evaluation (APACHE II). ¹⁴ The severity of each comorbidity and postoperative complication was categorized from grade 1 to grade 4 using the National Cancer Institute - Common Toxicity Criteria (NCI-CTC) v 2.0. ¹⁵ Postoperative complications of grades 3 and 4 were defined as major complications. Outcomes in all patients as of April 1, 2005, which was 6 months after entry of the last patient

into the study, were examined, and a mortality rate for the entire patient population was calculated.

Activities of Daily Living

Functional dependence in basic ADL was evaluated using the Katz Index. 16 Necessity of supervision, direction, personal assistance, or total care for any dependent function of the Katz Index also were recorded as parameters to assess minute declines or increments of patients' ADL. 17 In addition to the Katz Index, the following functions important for elderly postoperative patients also were evaluated; (Table 1) maintaining a sitting position in the bed (impossible, sitting with Gatch up, sitting without Gatch up), sitting down on a chair or stool from a standing position (bedridden, unable to sit down on a chair from a standing position, sitting down in a chair, sitting upright on a chair or stool); maintaining a standing posture (impossible, possible with both hands held, possible with 1 hand held, possible unassisted); and walking on a level surface or, if unable to walk, moving in a wheelchair (impossible, using a wheel chair with help, propelling a wheel chair independently, walking with help, walking independently). 16

Quality of Life

QOL was evaluated using the SF-12 and EuroQoL 5-D (EQ5D). The SF-12 is a set of generic, coherent, and easily administered QOL measures that produce 2 summary measures of physical and mental aspects of health, based on 12 questions. ¹⁸ The EQ5D is a short, 5-item self-completion measure of health status in terms of mobility, self care, usual activities, pain or discomfort, and anxiety or depression, which are used to produce a combined single index score that ranges from -0.111 (worse than death) to 1.000 (best health). ¹⁹

Additional Measures

Additional measures included the Folstein Mini-Mental State Examination (MMSE).^{20,21}

Data Collection

The attending physician made physical assessments of participants and recorded operative severity using their operative records. Physical conditions and QOL were assessed at the time of admission to the surgical department and at 1, 3, and 6 months postoperatively. ADL were evaluated at the time of admission and 4 times postoperatively (at 7 to 10

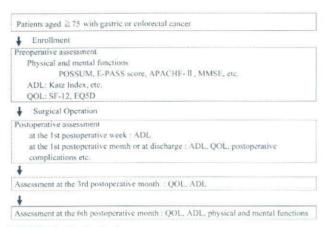


FIGURE 1. Study design.

days, and 1, 3 and 6 months) by a researcher in each institute who had taken a training course for this prospective study beforehand. In some cases, data collection at 1 month was replaced by that at the time of discharge (Fig. 1). When patients were referred to other hospitals postoperatively, the attending physicians of the hospital where the patients stayed were interviewed by telephone. At the end of the study, we assessed the patients for interim health events that would modify the course of recovery such as fractures, other significant operations, and cerebrovascular accidents.

Statistical Analysis

To identify the risk factors for a decline in ADL after surgery, the odds ratio for the postoperative decline was calculated using a Generalized Estimating Equations (GEE) model.²² To make a direct comparison between the odds ratios of surgical scores (POSSUM, E-PASS, and APACHE II), these scores were transformed linearly to range from 0 (best score) to 10 (worst score) before inclusion into the model. Besides the surgical scores, age, gender, cancer site (stomach or colorectum), pathologic stage, and MMSE were included in the GEE model. We then examined whether these variables correlated significantly with postoperative ADL declines. A -2 log likelihood value for fitting a model with all the explanatory variables was calculated for each GEE model, which included POSSUM or E-PASS or APACHE II, and was used to compare the performance of these 3 models. The adjusted means of QOL scores were calculated preoperatively, and 1, 3 and 6 months after surgery using a MIXED procedure with the repeated statement. All statistical analyses were performed by SAS Version 9 software (SAS Institute, Cary, NC).

Ethical and Human Considerations

This study was approved by the institutional Review Board of National Center for Geriatrics and Gerontology and all participating hospitals, and all participants gave their written informed consent.

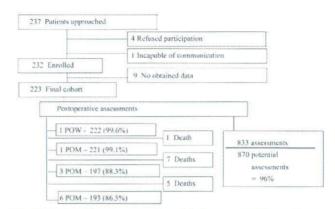


FIGURE 2. Study recruitment and follow-up. POW, postoperative week; POM, postoperative month.

RESULTS

Patient Recruitment and Follow-Up

The outline of patient recruitment and follow-up is shown in Figure 2. Of 232 patients enrolled 9 (4%) declined data collection and 223 patients were followed and evaluated. The rates of data collection were 99.6% at 1 week, 99.1% at 1 month, 88.3% at 3 months, and 86.5% at 6 months. Patient data were available for 833 (96%) of the 870 total potential postoperative assessments.

Baseline Characteristics

The study population consisted of 132 men and 91 women. Ages ranged from 75 to 92 years with a mean of 80.1 ± 4.3 : 37, 71, and 115 patients were aged 85 years or older, 80 to 84 years, and 75 to 79 years, respectively. Ninety-six patients had gastric cancer and 127 patients had colorectal cancer. Their pathologic cancer stages and operative procedures were summarized in Table 2.

TABLE 2. Stage and Operation for Studied Patients

Stage*	Gastric Cancer	Colorectal Cancer
0		3
I	51	18
II	15	44
Ш	26	53
IV	4	9
Lymphadenectomy ^{32,33}		
D0	2	2
D1	48	22
D2	44	58
D3	2	45
Residual tumor34		
R0, R1	92	119
R2	4	8
Operation time (min)	178 ± 4.9	
Blood loss (g)	310 ± 28.8	

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Mortality and Morbidity

The 1-year survival rate for the 232 patients was 92.1%. There were 13 deaths by 6 months after surgery, including 1 operative death. Of the 13 patients, 3 died of advanced stages of cancer (gastric cancer, n = 1; colorectal cancer, n = 2). Ten patients died of other diseases; pneumonia (n = 3), unknown cause (n = 2), sudden cardiac arrest, cardiac failure, leukemia, brain stem hemorrhage and sepsis (each n = 1). Four patients died of postoperative complications in the hospital (sudden cardiac arrest, sepsis, cardiac failure, and pneumonia, each n = 1). Sepsis was a postoperative complication of a laparotomy for small bowel obstruction. There was 1 operative death (0.4%) due to sudden cardiac arrest. If those 13 deaths were included, 92.4% of the patients completed their final 6-month follow-up. Sixty-three patients (28.3%) had major postoperative complications; delirium (10%) was the most frequent complication, followed by respiratory failure (8%), anastomotic leakage (4%), surgical site infection (4%), and pneumonia (4%) (Table 3).

ADL

Twenty-four percent of the patients had a lower Katz index during the first postoperative month than preoperatively. However, most patients recovered from this transient reduction in ADL measured by the Katz Index. The percentage of patients showing a decline at 6POM by the Katz Index alone was 3% (Fig. 3). The number of patients, however, who showed declines in any function evaluated at 6POM (a change from independent to dependent in any function or an increase in care needs for any dependent function) was as high as 21 (11%) (Table 1). Of these 21 patients, 18 did not have any complications or accidental events, although 3 patients had adverse events such as cerebral hemorrhage, small bowel obstruction, or hip joint fracture (each n = 1) during the 6 postoperative months. Those 3 patients were not included in those patients (3%) who showed a decline of function at 6POM by the Katz Index alone.

TABLE 3.	Morbidity (≥Grade 3)
Postop. Con	plications	

Postop. Complications	No. Patients (%)
Delirium	23 (10)
Respiratory failure	18 (8)
Anastomotic leakage	9 (4)
Surgical site infection	8 (4)
Pneumonia	8 (4)
Hypertension	7 (3)
Atelectasis	5 (2)
Arrhythmia/hypotension	4/4 (2)
DIC/ileus	3/3 (1)
Dysuria/sepsis/fungal infection/wound dehiscence/anastomotic stenosis	2 per complication (1)
Heart failure/jaundice/renal dysfunction/renal failure/urinary tract infection/pancreatitis/peritoneal hemorrhage/peritoneal abscess/neuropathy	1 per complication (0.5)
Total	63/223 (28)

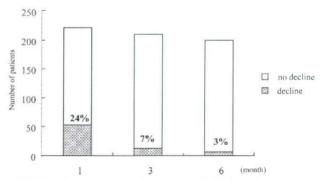


FIGURE 3. Postoperative change in ADL (Katz Index).

There were 3 representative declining patterns in the postoperative course of ADL. In pattern A the ADL deteriorated immediately after surgery and remained low (or had some recovery but did not reach the preoperative level); in pattern B the ADL fell immediately after surgery, but recovered completely or almost completely to the preoperative level briefly, followed by a second decline after discharge from the hospital; and in pattern C the ADL did not decrease until discharge from the hospital. The proportions of patients showing patterns A, B, and C were 11%, 40%, and 49%, respectively. Overall, the ADL of elderly patients was likely to decrease after discharge from the hospital, regardless of whether they had a brief recovery from their initial drop or no decline at all during their hospital stay.

Of the 3 surgical scores, the E-PASS scores showed the strongest correlation with postoperative declines in Katz index (Table 4). The -2 log likelihood values with all the explanatory variables were 408.4, 406.4, and 416.1 for the GEE models of POSSUM, E-PASS, and APACHE II, respectively. Since the degrees of freedom were the same in all 3 models, these results indicate that the GEE model of E-PASS best fitted the observed ADL data. Among the other variables, age correlated significantly with postoperative ADL declines in every model. The pathologic stage was also significant except for the POSSUM model where the disease stages were integrated. Males tended to have a greater risk of postoperative ADL declines in every model. The cancer site and MMSE were not significant in any model. The odds ratios for protracted ADL declines, analyzed by the GEE model, were 2.31 (95% confidence interval 1.14-4.70) for patients with E-PASS scores of 0.5 or more, 2.19 (95% confidence interval 1.15-4.18) for patients aged 85 years or older, and 2.30 (95% confidence interval 1.16-4.57) for patients with pathologic stages of II or more advanced.

QOL

The mean scores of the Physical Components Score (PCS) and Mental Components Score (MCS) in SF-12 fell immediately after surgery, but recovered from a temporary decline to the preoperative level, or became even higher, in 3 to 6POM (Fig. 4).

The average QOL scores of EQ5D measured before, immediately after, 3 months after, and 6 months after operation were 0.769, 0.764, 0.790, and 0.806, respectively. The

TABLE 4. Predictive Value of Clinical Factors for Postoperative Declines in Katz ADL Index: Results of GEE Analyses

	POSS	UM Model		E-PA	SS Model		APACE	HE II Model	
Variables	Odds Ratio	95% CI	P	Odds Ratio	95% CI	P	Odds Ratio	95% CI	P
Surgical score*	1.19	1.05-1.34	0.005	1.26	1.08-1.47	0.003	1.08	0.97-1.20	0.171
Age	1.10	1.03-1.17	0.003	1.08	1.01-1.14	0.014	1.08	1.02-1.15	0.014
Male	1.72	0.95-3.12	0.071	1.71	0.94-3.14	0.081	1.79	0.99-3.20	0.051
Colon cancer†	0.89	0.52-1.51	0.656	0.86	0.52-1.43	0.563	0.79	0.47-1.32	0.364
MMSE	0.95	0.87-1.03	0.213	0.97	0.87-1.08	0.572	0.94	0.86-1.03	0.179
Pathologic cancer stage	1.27	0.93-1.74	0.137	1.39	1.04-1.87	0.026	1.42	1.05-1.92	0.021
-2 log likelihood	2.4	408.4			406.4			416.1	

^{*}POSSUM score, E-PASS CRS score, and APACHE II score were included separately in the GEE model.

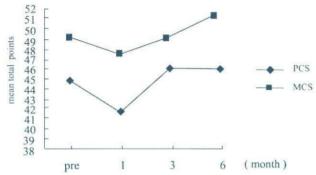


FIGURE 4. Change in mean scores of Physical Components Score (PCS) and Mental Components Score (MCS) (SF-12).

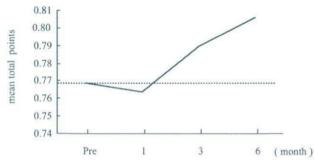


FIGURE 5. Postoperative change in QOL (EQ5D).

average EQ5D score was significantly higher at 6POM than preoperatively (P < 0.005) (Fig. 5).

DISCUSSION

As medical and surgical problems affecting elderly patients cover multiple fields and require a coordinated approach among medical and surgical professionals, elderly patients often have multiple additional needs: social, psychologic, economic, rehabilitative, and nursing when they become disabled after surgery. From medical, social, and functional points of view, it is important to anticipate the expected postoperative function and care needs prior to surgery, and to

inform patients and their families. Although the postoperative functions of patients such as ADL and QOL are important among the outcomes of surgical treatment for the elderly, there has been only a limited number of reports on the natural course of recovery of functional independence. 4,23 We have conducted a prospective study with special reference to the postoperative functions of patients 75 years or older who underwent elective surgical resection of gastric or colorectal cancer. Standard tools were used for the preoperative, intraoperative, and postoperative evaluation of physical conditions, psychologic conditions, postoperative complications, ADL, and QOL, so that the results obtained from this study can be widely applied to gastric and colorectal cancer patients. The systematic study on the postoperative recovery of ADL showed that elderly patients frequently showed a transient decrease in ADL immediately after surgery. However, patients displaying a decrease at 1 week or at 1 month after surgery recovered, and there was no difference in the postoperative mid- to long-term ADL between the patients with and without temporary postoperative disability. Moreover, the number of patients showing declines in any ADL parameter at 6 POM did not exceed 21 (11%). These findings indicate that most patients are unlikely to develop a mid- to long-term decrease in ADL after they survive the perioperative period.

One interesting finding was that most late-developing disabilities occurred after a transient recovery of certain aspects of function, sometimes during the period of follow-up after discharge from the hospital. Ferrucci et al24 reported similar findings. Either some complications or accidental events that occur after a transient recovery or less effective physical rehabilitation at home and in outpatient clinics may be responsible for the protracted disability. Since only 3 patients showing protracted disability in our series had any complications or accidental events after discharge, their lifestyle after discharge and/or less effective physical rehabilitation at home may be responsible. Traditionally, senior citizens are highly respected in Japan whose culture has been greatly influenced by Confucianism. Too much care by their family members that leads to lack of exercise by elderly patients at home might accelerate the decrease in ADL. Timonen et al²⁵ reported that a multicomponent training program that included strength training after an illness was an

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effective form of rehabilitation for frail woman older than 75 years old, and that its beneficial effects lasted for at least 9 months after training. Frail and aged patients may need more active and intensive rehabilitation that includes exercise at home, at outpatient clinics, or in nursing homes to restore and stimulate their function after discharge. 26,27

We were able to identify several risk factors for the transient and protracted decline in ADL. The patients who developed postoperative complications were more likely to show a transient drop in ADL than those who did not, and older patients tended to develop a temporary decrease. Age, gender, and cancer stages were risk factors for the protracted decline in ADL. Analysis of these risk factors using the GEE model allowed us to construct such criteria that might help select a population at very high risk for long-term postoperative declines in ADL. Such criteria will be more valuable when more practical and useful scoring systems are established that predict the functional recovery of elderly patients from major elective gastroenterological surgeries.

We also found that POSSUM and E-PASS were useful for predicting protracted disability of patients. The efficacy of E-PASS was the best of all the scoring systems examined. Our study may be the first to directly compare the efficacy of these surgical scores for the prediction of postoperative recovery in ADL.

Our present study clearly shows that surgical treatment does improve the QOL of elderly patients 75 years old or older with gastric and colorectal cancers. Patients in our series displayed a recovery in their SF-12 scores to an extent equal to or better than their average preoperative scores. Our preliminary results, however, show that QOL scores in several items of some patients decreased after surgery and remained low on more detailed examination of individual cases (unpublished data). Additional studies, on which items are more likely to decrease and on what causes the decrease in these items, will not only further improve the QOL changes of elderly patients but also enable us to inform patients and their families of expected moderate- to long-term postoperative QOL during the preoperative period.

Patients with advanced gastric or colorectal cancers can only be cured by radical surgery, and an improvement in the survival rate by radical surgery has been reported in recent years. 28,29 Resection of primary gastric or colorectal cancer with extended lymphadenectomy is the standard procedure in Japan. 30,31 In the present study, radical surgery was performed for 92 (96%) gastric and 119 (94%) colorectal cancer patients. Our result showing as low as a 0.4% mortality rate confirms that radical surgery for gastric or colorectal cancers rarely results in death, even for elderly patients 75 years old or older. In addition, our data also show that radical surgery is unlikely to decrease the ADL and QOL in most of the patients 75 years old or older with gastric or colorectal cancer at 6POM. This then indicates that elderly patients who are medically fit before surgery have little more risk than do younger ones and implies that major gastroenterological surgeries accompanying similar surgical stress with radical surgeries for gastric or colorectal cancers can also be applied to the elderly. A systematic evaluation of the postoperative

complications using a standard tool (NCI-CTC), however, suggested that the incidence of major complications (categorized as ≥ grade 3) in elderly patients was as high as 28%. To reduce morbidity, therefore, it is necessary to establish an effective method for selecting frail subpopulations with post-operative complications requiring special intensive care and to improve our current intensive care system for them during the perioperative period. Randomized trials may be needed to test the hypothesis that preoperative and postoperative physical rehabilitation programs can prevent the protracted disability observed in 10% of the elderly patients examined.²⁷

CONCLUSIONS

Of the patients 75 years old or older who underwent elective surgery for gastric or colorectal cancer, only a few showed a protracted decline in ADL and most exhibited better QOL after surgery. This indicates that surgical treatment can be offered to elderly patients 75 years old or older with gastric or colorectal cancer. E-PASS is more useful compared with POSSUM and APACHE II for predicting postoperative declines in ADL. E-PASS is able to predict the protracted disability, and may be helpful for establishing an effective rehabilitation program for restoring their function and thereby preventing the protracted disability observed in some elderly patients.

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