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ORIGINAL ARTICLE

Surgical outcomes after gastrectomy in very elderly patients with gastric cancer

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Abstract

Purpose Whether or not gastrectomy is feasible for very elderly gastric cancer patients is unclear. This study aimed to clarify the feasibility and safety of surgical treatment for patients in this age group.

Method The study included 55 very elderly patients with resectable gastric cancer who underwent gastrectomy (≥85 years of age; very-E group). The surgical outcomes were compared with those of 611 elderly patients (75–84 years old; E group).

Results Female sex, a poor physical and performance status, and a low serum albumin level patients were more frequent in the very-E group than in the E group. Lymphadenectomy was less aggressive in the very-E group than in the E group ($P < 0.001$). The overall postoperative complication rate was not significantly different between the groups (46 vs 33%; $P = 0.073$). A multivariate analysis to predict the overall survival identified male sex (hazard ratio 1.75, 95% confidence interval 1.30–2.36), low body mass index (2.19, 1.52–3.16), poor performance status (2.14, 1.60–2.86), low serum albumin level (1.84, 1.37–2.48), and advanced tumor stage (1.71, 1.29–2.27) but not age (1.31, 0.84–2.03) as independent prognostic factors.

Conclusion Chronological age alone is not a contraindicative factor for gastrectomy in very elderly patients.

Keywords Elderly · Gastrectomy · Gastric Cancer · Prognostic Factors · Survival

Introduction

The proportion of people ≥75 years of age is growing rapidly, increasing from 1.9% of the world population in 1980 to over 3.3% in 2015 [1]. This phenomenon is especially pronounced in Japan, a country with one of the longest life expectancies in the world. Japanese women now are expected to live for 87 years and Japanese men for 80 years [2]. At present, people ≥75 years of age comprise 13.5% of the total population of Japan [3], and the same age group also accounts for 52.6% of male gastric cancer patients and 41.4% of females [4].

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Many studies regarding the feasibility and safety of surgical treatment for patients ≥75 years of age have been conducted [5–8], and gastrectomy seems to be tolerable if patients are appropriately selected [9]; however, the physical status can differ greatly among elderly patients. In general, the physiological reserve capacity decreases with advancing age, resulting in an increased incidence of postoperative complications [10]. In addition, the expected 5-year survival rate of 85 years in the general population of 70.1% is markedly worse than that of 75 years, at 91.6% [11]. These factors of higher postoperative morbidity rates and shorter life expectancy can make surgeons reluctant to perform standard gastrectomy for patients ≥85 years of age [12–14].

Nevertheless, the mainstay of treatment for resectable gastric cancer is gastrectomy [15], making it a pressing task to ensure the validity of gastrectomy for the growing group of very elderly patients. Recent progress in perioperative management and team medicine has increased the overall safety of surgery for the elderly cohort [12, 13, 16]. In addition, recent studies have suggested that gastrectomy in very elderly patients might be feasible as long as the surgical

indications are considered carefully [17–20], although the number of cases in each study was small and the overall feasibility remains unclear.

The aim of the present study was, therefore, to clarify the feasibility and safety of gastrectomy for very elderly gastric cancer patients (≥ 85 years of age) in comparison with the surgical outcomes of elderly patients (75–84 years of age).

Methods

This study included 854 patients ≥ 75 years of age who received gastrectomy for primary gastric cancer at the Shizuoka Cancer Center from September 2002 to August 2015. The patients were classified into an elderly group (75–84 years of age; E group; $n = 786$) and a very elderly group (≥ 85 years of age; very-E group; $n = 68$) according to the age at the time of surgery. We excluded 188 patients as follows: 15 patients with clinical stage IV cancer, 7 patients who received preoperative chemotherapy, 18 patients with special-type cancer, 70 patients with co-existing active primary cancer, 4 patients who received thoracotomy, 5 patients who received local gastrectomy, 67 patients who received palliative gastrectomy defined as R1 or R2 resection [21], and 2 patients with pathological stage IV cancer. Accordingly, we compared the surgical outcomes of 611 patients in the E group with those of 55 patients in the very-E group (Fig. 1). The Institutional Review Board of the Shizuoka Cancer Center approved the present study.

Surgical procedure

The surgical indications for every patient were discussed at multi-disciplinary team meetings. In brief, elderly patients in our institute were indicated for surgery if they satisfied the following criteria: Eastern Cooperative Oncology Group performance status (EGOG-PS) of 0–2, an adequate organ function, no severe cognitive disorder, and no severe comorbidities. In addition, we inquired about the patients' housing environments, including the possibility of caregiver support, before a final decision was made to proceed with the operation. We used an incentive spirometer (Coach2; Smiths Medical, St. Paul, MN, USA) for perioperative respiratory rehabilitation, and for high-risk patients, such as those with an Eastern Cooperative Oncology Group Performance Status (ECOG-PS) of ≥ 2 or an impaired pulmonary function, a multi-disciplinary team effort including perioperative respiratory rehabilitation, preoperative oral care and early postoperative mobilization program was made to prevent early complications such as pneumonia [22, 23]. Written informed consent was obtained from all patients prior to the surgery. We normally determined the extent of gastrectomy and lymphadenectomy using the Japanese Gastric Cancer Treatment Guidelines 2014. Limited surgery with a reduced degree of lymphadenectomy was performed in patients predicted to have a high postoperative morbidity rate under full agreement of the multi-disciplinary team.

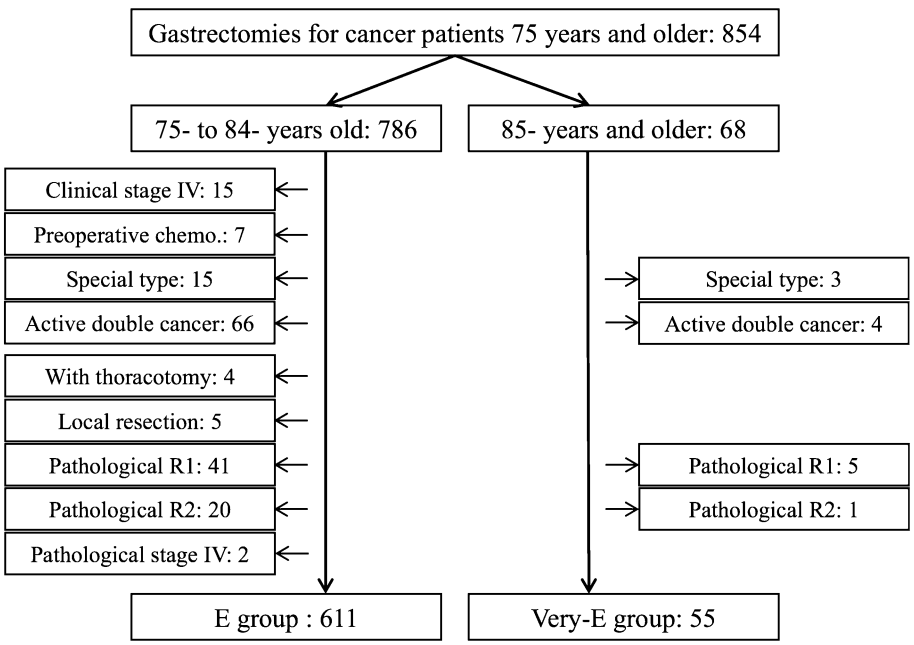

Fig. 1 Flow diagram of the study selection process. R1: microscopic residual tumor, e.g., positive resection margin or peritoneal cytology for carcinoma cells, R2: macroscopic residual tumor

Table 1 Patient characteristics

	E group ($n=611$)	very-E group ($n=55$)	P
Age (years)			<0.001**
Median	78	86	
Range	75–84	85–95	
Gender			0.035*
Male	414 (67.8)	29 (52.7)	
Female	197 (32.2)	26 (47.3)	
BMI (kg/m^2)			0.143**
Median	22.5	21.7	
Range	13.4–36.7	13.9–27.8	
ASA-PS score			0.009*
1	32 (5.2)	0	
2	473 (77.4)	37 (67.3)	
≥3	106 (17.3)	18 (32.7)	
ECOG-PS score			<0.001*
0	484 (79.2)	34 (61.8)	
1	110 (18.0)	14 (25.5)	
≥2	17 (2.8)	7 (12.7)	
Respiratory impairment			0.252*
Yes	239 (39.1)	26 (47.3)	
No	372 (60.9)	29 (52.7)	
Serum albumin level (g/dl)			<0.001**
Median	4.1	3.8	
Range	1.8–5.0	2.7–4.9	
Serum creatinine level (mg/dl)			0.973**
Median	0.76	0.75	
Range	0.32–10.1	0.45–1.29	
Comorbidity			0.600*
Yes	488 (79.9)	42 (76.4)	
No	123 (20.1)	13 (23.6)	
Metachronous other cancer			1.000*
Yes	87 (14.2)	7 (12.7)	
No	524 (85.8)	48 (87.3)	
Main tumor location			0.984*
U	170 (27.8)	15 (27.3)	
M	225 (36.8)	21 (38.2)	
L	216 (35.4)	19 (34.5)	
Clinical T classification			0.051*
1	332 (54.3)	20 (36.4)	
2	83 (13.6)	10 (18.2)	
3	54 (8.8)	5 (9.1)	
4	142 (23.2)	20 (36.4)	
Clinical N classification			0.520*
0	487 (79.7)	40 (72.7)	
1	69 (11.3)	9 (16.4)	
2	36 (5.9)	4 (7.3)	
3	19 (3.1)	2 (3.6)	
Clinical stage			0.130*
I	409 (66.9)	30 (54.5)	
II	108 (17.6)	12 (21.8)	
III	94 (15.4)	13(23.6)	

Values in parentheses are percentages

BMI body mass index, *ASA-PS* the American Society of Anesthesiologists Physical Status, *ECOG-PS* the Eastern Cooperative Oncology Group Performance Status

*P value for two groups compared using Fisher's exact test

**P value for two groups compared using the Mann–Whitney test

Definition of outcomes

The clinicopathological, surgical, and pathological findings were collected from a prospectively maintained database, as well as from individual patient medical records when necessary. Complications were graded according to the Clavien–Dindo (CD) system. Postoperative complications in this study were defined as any adverse event corresponding to CD classification grade II or greater, occurring within 30 days of gastrectomy. If a patient had more than one type of complication, the complication with the highest grade was used for the analysis. Postoperative mortality was defined as death from any cause during hospitalization. Stage classification was determined according to the 7th American Joint Committee on Cancer/Union for International Cancer Control staging system.

Follow-up was scheduled according to our protocol. In brief, in cases with advanced gastric cancer, patients were required to attend an outpatient clinic every 3 months for 3 years and every 6 months thereafter for up to 5 years. In

Table 2 Surgical outcomes

	E group (n = 611)	very-E group (n = 55)	*P*
Approach			0.170*
Open	513 (84.0)	46 (83.6)	
Laparoscopy-assisted	69 (11.3)	9 (16.4)	
Robot-assisted	29 (4.7)	0	
Extent of resection			0.324*
Total	166 (27.2)	13 (23.6)	
Distal	378 (61.9)	40 (72.7)	
Proximal	36 (5.9)	2 (3.6)	
Pylorus preserving	30 (4.9)	0	
Pancreatico-duodenectomy	1 (0.2)	0	
Lymphadenectomy			0.007*
D0	5 (0.8)	2 (3.6)	
D1	32 (5.2)	9 (16.4)	
D1+	294 (48.1)	26 (47.3)	
D2	262 (42.9)	17 (30.9)	
D2+	18 (2.9)	1 (1.8)	
Degree of dissection			< 0.001*
Standard	556 (91.0)	36 (65.5)	
Reduced	55 (9.0)	19 (34.5)	
Operative time (minutes)			< 0.001**
Median	217	186	
Range	85–562	73–427	
Estimated blood loss (ml)			0.073**
Median	224	154	
Range	0–1872	0-1051	
Retrieved lymph nodes (number)			0.170**
Median	35	34	
Range	2–113	3–79	
Reoperation	11 (1.8)	2(3.6)	0.292*
Postoperative hospital stay (days)			0.329**
Median	10	11	
Range	7–110	7–89	
Adjuvant chemotherapy			< 0.001*
Indication	194 (31.8)	23 (41.8)	
Administration	65	0	

Values in parentheses are percentages

**P* value for two groups compared using Fisher's exact test

***P* value for two groups compared using the Mann–Whitney test

Table 3 Postoperative complications

	E group ($n=611$)	very-E group (n=55)	*P*
(a) Summary			
All complications (Grade II or higher; patients)			0.073
Yes	200 (32.7)	25 (45.5)	
No	411	30	
Surgical complication (Grade II or higher; patients)			0.231
Yes	136 (22.3)	8 (14.5)	
No	475	47	
Non-surgical complication (Grade II or higher; patients)			< 0.001
Yes	100 (16.4)	20(36.4)	
No	511	35	
Mortality	3 (0.5)	0 (0)	1.000
(b) Details			
Surgical complications (Grade II or higher)			
Anastomotic leakage	11 (1.8)	0 (0)	0.613
Stump leakage	11 (1.8)	0 (0)	0.613
Pancreas-related infection	40 (6.5)	0 (0)	0.067
Intra-abdominal abscess	22 (3.6)	3 (5.5)	0.452
Anastomotic stenosis	12 (2.0)	2 (3.6)	0.324
Bleeding	13 (2.1)	1 (1.8)	1.000
Ileus	20 (3.3)	4 (7.3)	0.128
Wound infection	21 (3.4)	0 (0)	0.246
Stasis	18 (2.9)	0 (0)	0.387
Reflux esophagitis	2 (0.3)	0 (0)	1.000
Others	2[†]	0	–
Non-surgical complications (Grade II or higher)			
Pneumonia	36 (5.9)	6 (10.9)	0.146
Heart failure	2 (0.3)	1 (1.8)	0.228
Thrombosis	6 (1.0)	1 (1.8)	0.455
Pleural effusion	12 (2.0)	0 (0)	0.612
Cholecystitis	6 (1.0)	1 (1.8)	0.455
Liver failure	2 (0.3)	1 (1.8)	0.228
Phlebitis	3 (0.5)	0 (0)	1.000
Urinary tract infection	9 (1.5)	1 (1.8)	0.580
Enterocolitis	4 (0.7)	0 (0)	1.000
Delirium	29 (4.7)	9 (16.4)	0.002
Others	2[‡]	2[§]	–

(a) A comparison of the postoperative complications between the E group and the very-E group

(b) Details of the postoperative complications in the E group and the very-E group. Values in parentheses are percentages. Grade: complication grading using the Clavien–Dindo classification

P value for two groups compared using Fisher's exact test

[†]Two patients; incarcerated inguinal hernia (Grade IIIb), chylous ascites (Grade IIIa)

[‡]Two patients; pneumothorax (Grade III), subarachnoid hemorrhaging (Grade II)

[§]Two patients; urethral injury (Grade IIIa), arrhythmia (Grade II)

cases with early gastric cancer, patients were required to attend the clinic every 6 months for 3 years and every year thereafter for up to 5 years. The follow-up data were updated in February 2017.

Statistical analyses

All continuous variables are presented as the median (range). Statistical analyses were performed using Fisher's exact test and the Mann–Whitney test, as appropriate. Survival curves

were estimated by the Kaplan–Meier method, and the log-rank test was used to assess differences. The overall survival was recorded from the time of surgery until death from any cause. The disease-specific survival was measured as the time from surgery to gastric cancer-related death. Univariate and multivariate analyses of prognostic factors related to the survival were performed using the Cox proportional hazards model.

All P values < 0.05 were considered statistically significant. All statistical analyses were conducted using the R version 3.2.0 statistical software package.

Results

The patient characteristics are summarized in Table 1. The very-E group included a significantly larger proportion of female patients, those with a poor physical and performance status, and those with a lower albumin level than the E group. There were no significant differences in the preoperative oncological data between the groups.

Table 2 details the surgical outcomes. There were no marked differences between the groups in the surgical approach or the extent of resection. Reduced lymphadenectomy was more common in the very-E group (34.5%) than in the E group (9.0%; $P < 0.001$), resulting in a significant difference in the degree of lymphadenectomy ($P = 0.007$) and operation time ($P < 0.001$). The number of retrieved lymph nodes and the estimated amount of blood loss did not differ markedly between the groups. The median duration of postoperative hospital stay was 11 and 10 days in the very-E and E groups, respectively. No patients received adjuvant chemotherapy in the very-E group.

Postoperative complication data are shown in Table 3. Although the overall postoperative complication rate was not significantly different between the groups, it tended to be higher in the very-E group (46%) than in the E group (33%, $P = 0.073$). When we classified complications into surgical and non-surgical ones, non-surgical ones were significantly more common in the very-E group ($P < 0.001$). Specifically, postoperative delirium was more common in the very-E group than the E group ($P = 0.002$), as was the incidence of postoperative pneumonia, although this difference was not statistically significant ($P = 0.146$). The mortality rate was 0% in the very-E group, although three patients died in the E group after multiple organ failure due to bleeding, pneumonia and pulmonary embolism (one each).

The pathological findings are summarized in Table 4. The very-E group contained fewer T1 cases ($P = 0.022$) than the E group, but no marked differences in the number of metastatic lymph nodes or the pathological stage were observed between the groups.

Table 4 Pathological findings

	E group ($n = 611$)	very-E group ($n = 55$)	P
T classification			0.022*
1	352 (57.6)	22 (40.0)	
2	62 (10.1)	12 (21.8)	
3	114 (18.7)	11 (20.0)	
4	83 (13.6)	10 (18.2)	
N classification			0.746*
0	375 (61.4)	32 (58.2)	
1	101 (16.5)	12 (21.8)	
2	69 (11.3)	5 (9.1)	
3	66 (10.8)	6 (10.9)	
Tumor size (mm)			0.209**
Median	42	46	
Range	4–210	20–120	
Proximal margin (mm)			0.310**
Median	35	28	
Range	1–160	1–90	
Distal margin (mm)			0.681**
Median	60	52	
Range	1–250	3–260	
Histological type			0.573*
Differentiated	271 (44.4)	22 (40.0)	
Mixed	215 (35.2)	28 (50.9)	
Undifferentiated	125 (20.5)	5 (9.1)	
Lymphovascular involvement			0.176*
Yes	409 (66.9)	42 (76.4)	
No	(33.1)	13 (23.6)	
Pathological stage			0.373**
I	360 (58.9)	28 (50.9)	
II	(21.4)	16 (29.1)	
III	(19.6)	11 (20.0)	

Values in parentheses are percentages

*P value for two groups compared using Fisher's exact test

**P value for two groups compared using the Mann–Whitney test

The overall survival after surgery was significantly lower in the very-E group than in the E group (Fig. 2a, $P = 0.010$). The causes of death within 5 years after surgery are summarized in Table 5. In both groups, approximately 10% of patients died due to gastric cancer. In contrast, the proportion of patients who died due to causes other than gastric cancer was much higher in the very-E group (23.6%) than in the E group (13.7%). Accordingly, the difference in the overall survival disappeared when we drew survival curves with the disease-specific survival (Fig. 2b, $P = 0.380$). The site of recurrence was also reviewed, and only one patient showed suprapancreatic

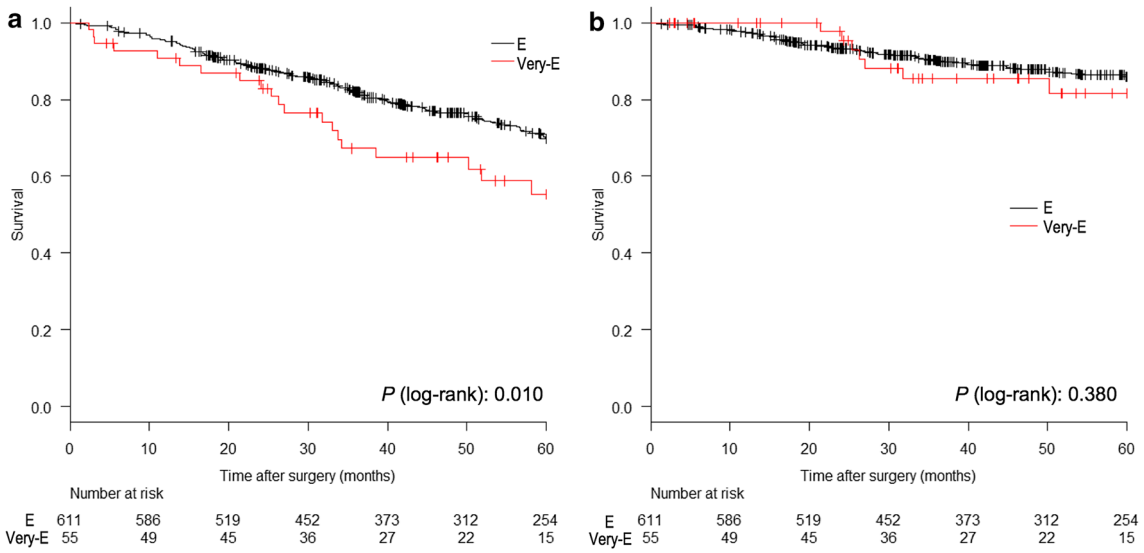

Fig. 2 Survival curves in both groups derived using the Kaplan–Meier method. **a** Overall survival and **b** disease-specific survival curves. The *P* values for the two groups were compared using the log-rank test

Table 5 Cause of death within 5 years after surgery

	E group ($n=611$)	very-E group ($n=55$)
Total	154 (25.2)	20 (36.4)
Surgery-related death	3 (0.5)	0
Gastric cancer	67 (11.0)	7 (12.7)
Others	84 (13.7)	13 (23.6)
Other malignancies	16 (2.6)	0
Pneumonia	22 (3.6)	3 (5.5)
Cardiac failure	9 (1.5)	1 (1.8)
Cerebrovascular disease	5 (0.8)	1 (1.8)
Digestive disorder	4 (0.7)	2 (3.6)
Renal failure	4 (0.7)	0
Trauma	3 (0.5)	0
Natural	9 (1.5)	4 (7.3)
Unknown	12 (2.0)	2 (3.6)

Values in parentheses are percentages

lymph node recurrence in the very-E group, despite undergoing limited lymphadenectomy. According to a multivariate analysis, male sex [hazard ratio (HR) 1.75, 95% confidence interval (CI) 1.30–2.36, $P<0.001$], preoperative low body mass index (BMI; HR 2.19, 95% CI 1.52–3.16, $P<0.001$), poor ECOG-PS (HR 2.14, 95% CI 1.60–2.86, $P<0.001$), low serum albumin level (HR 1.84, 95% CI 1.37–2.48, $P<0.001$) and advanced tumor stage (HR 1.71, 95% CI 1.29–2.27, $P<0.001$) but not age (HR 1.31, 95% CI 0.84–2.03, $P=0.230$) were identified as independent prognostic factors for the overall survival (Table 6).

Discussion

Gastrectomy was shown to be a feasible and safe option for very elderly patients in this study. Interestingly, the multivariate analysis did not identify age as an independent prognostic factor in the high-aged group. Instead, reflections of the physical condition, such as the BMI, ECOG-PS, and serum albumin level, more strongly affected the survival. To our knowledge, this is the first study providing evidence that high chronological age alone is not a contraindicative factor for gastrectomy in elderly gastric cancer patients. With careful selection, gastrectomy can be safely performed, achieving an acceptable long-term survival even in patients ≥ 85 years of age.

In our institute, all surgical candidates are reviewed in a multi-disciplinary team meeting [24], at which both the tumor stage and surgical tolerability are assessed. In accordance with the decision made at this meeting, surgeons recommended a rehabilitation program before surgery if the patient's general condition is bad but can be improved [25]. If surgeons believe the patient will never be able to tolerate surgery, they do not recommend gastrectomy and instead offer palliative care. Accordingly, the present study included highly select patients, which might have contributed to the comparative surgical outcomes between the groups. Nevertheless, the present study provided the important finding that chronological age itself might not be a contraindicative

Table 6 Univariate and multivariate analyses for the overall survival by a Cox proportional hazards model

Variable	Univariate analysis			Multivariate analysis		
	HR	(95% CI)	*P*	HR	(95% CI)	*P*
Age (years)						
< 85						
≥ 85	1.721	(1.135–2.611)	0.011	1.310	(0.843–2.034)	0.230
Gender						
Female						
Male	1.397	(1.045–1.867)	0.024	1.750	(1.297–2.362)	< 0.001
BMI (kg/m^2)						
≥ 18.5						
< 18.5	1.927	(1.342–2.767)	< 0.001	2.189	(1.515–3.162)	< 0.001
ASA-PS score						
1–2						
≥ 3	1.827	(1.359–2.456)	< 0.001	1.144	(0.827–1.582)	0.416
ECOG-PS score						
0						
≥ 1	2.259	(1.709–2.987)	< 0.001	2.140	(1.602–2.858)	< 0.001
Respiratory impairment						
No						
Yes	1.325	(1.018–1.725)	0.037	1.158	(0.882–1.520)	0.292
Comorbidity						
No						
Yes	1.277	(0.907–1.798)	0.161			
Serum albumin (g/dl)						
≥ 3.8						
< 3.8	2.528	(1.915–3.337)	< 0.001	1.840	(1.366–2.477)	< 0.001
Serum creatinine (mg/dl)						
< 1.05						
≥ 1.05	1.358	(0.938–1.966)	0.105			
Clinical stage						
I						
II–III	2.084	(1.602–2.711)	< 0.001	1.712	(1.293–2.267)	< 0.001
Extent of resection						
Non total						
Total	1.434	(1.082–1.901)	0.012	1.229	(0.915–1.650)	0.171
Degree of dissection						
Standard						
Reduced	1.924	(1.407–2.633)	< 0.001	1.307	(0.940–1.816)	0.111

HR hazard ratio, *95% CI* 95% confidence interval, *BMI* body mass index, *ASA-PS* the American Society of Anesthesiologists Physical Status, *ECOG-PS* the Eastern Cooperative Oncology Group Performance Status

factor, and if we select patients appropriately, gastrectomy can be performed safely.

The incidence of postoperative complications on the whole was not markedly different between the groups in this study; however, interestingly, the incidence of surgical complications was lower while that of non-surgical complications was higher in the very-E group than in the E group. The difference in the degree of lymphadenectomy might have been associated with the lower incidence of surgical complication in the very-E group, and although Kiyokawa et al. reported that gastrectomy with standard lymphadenectomy was able to be safely completed in 54.5% of patients ≥ 85 years of age [17], surgeons now generally consider that standard D2 lymphadenectomy is not suitable for very elderly patients [7, 16, 18–20]. Actually, in the present study, standard dissection was less frequently performed in the very-E group (65.5%) than in the E group (91.0%).

Non-surgical complications were, by contrast, more frequently observed in the very-E group than in the E group, including delirium and pneumonia. Pneumonia is the more hazardous of these complications, because elderly patients with this condition often enter a critical state [26]. Perioperative interventions, including respiratory rehabilitation, oral care, and early mobilization programs, are reported to be effective for preventing postoperative pneumonia [22, 23], especially in elderly patients [27]. The enhancement of our perioperative management program may, therefore, be a plausible option for reducing the incidence of non-surgical complications.

In the multivariate analysis, we included only factors that could be obtained prior to surgery as covariates, based on the aim to avoid unnecessary surgery and offer other treatment options if we could identify high-risk patients prior to surgery. Our multivariate analyses of the overall survival revealed male sex, low BMI, poor ECOG-PS, low serum albumin level, and advanced tumor stage but not age as independent risk factors. These findings, therefore, suggest that, in elderly populations, chronological age does not affect the survival as strongly as in the general population, because the physical status cannot be determined based on the chronological age alone. In contrast, other factors reflecting the general condition, such as the body weight, ECOG-PS, and serum albumin, were strong predictors of the survival in elderly patients. Perioperative nutritional intervention is considered a plausible way of improving the nutritional status, but the effectiveness of preoperative nutrition for very elderly patients is in doubt, as their weak metabolic function may not allow them to fully process the nutrients [28]. Therefore, we should consider the indications of gastrectomy more seriously in very elderly patients with poor nutrition and performance status than in very elderly patients without a poor nutrition and performance status.

Several limitations associated with the present study warrant mention. First, this is a retrospective study in a single institute. Second, our study excluded patients with unresectable gastric cancer due to absolutely poor outcomes [17, 29]. Third, our study failed to evaluate the perioperative life quality due to the difficulty of establishing a fixed methodology.

In conclusion, the feasibility and safety of gastric surgery for very elderly patients were shown to be equivalent to that of elderly patients, as long as the surgical indications were considered carefully. Chronological age alone does not seem to be a valid reason for avoiding gastrectomy, and a comprehensive assessment is necessary to determine the optimum treatment strategy for elderly patients with gastric cancer.

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Compliance with ethical standards

Conflict of interest Hikage, Tokunaga, Makuuchi, Irino, Tanizawa, Bando, Kawamura, and Terashima have no conflicts of interest or financial ties to disclose.

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