



## Research Article

# Outcomes of R0 Distal Gastrectomy with Limited (D1) Lymph Node Dissection for Advanced Gastric Cancer in Elderly Patients $\geq 80$ Years

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### Abstract

**Background:** In Asian countries, the standard operation for Advanced Gastric Cancer (AGC) is gastrectomy with extended Lymph Node (LN) Dissection (D1+/D2). However, there is no evidence regarding optimal LN dissection for AGC in elderly patients ( $\geq 80$  years). The present study examined the technical and oncological outcomes of R0 Distal Gastrectomy (DG) with limited LN (D1) dissection and extended LN dissection (D1+/D2) for AGC in elderly patients.

**Methods:** Thirty patients aged  $\geq 80$  years old with AGC ( $\geq pT2$ ) who underwent R0 resection by DG from 1998-2015 were enrolled. Patients were classified into two groups by extent of LN dissection: D1 group, D1 LN dissection (n = 13), and D1+/D2 group, D1+ or D2 LN dissection (n = 17), and short- and long-term outcomes were examined and compared.

**Results:** No significant differences were observed in patient characteristics between the two groups. Operative and pathological findings and incidences of mortality and morbidity were not different between the D1 and D1+/D2 groups. No significant differences were observed between the two groups in 3-year relapse-free survival (RFS) (log-rank test, P = 0.678) or 3-year overall survival (log-rank test, P = 0.964). Sub analysis showed no patients with recurrence among those without LN metastasis. Furthermore, no significant differences were observed in 3-year RFS between the two groups of patients with LN metastasis within the D1 area (log-rank test, P = 0.228).

**Conclusion:** DG with limited LN Dissection (D1) for AGC may be technically and oncological accepted in elderly patients, when R0 resection is achieved.

**Keywords:** Advanced Gastric Cancer; Elderly Patients; LN Dissection; Prognoses

### Introduction

Gastric cancer is one of the most common malignant diseases with high mortality in the world [1]. The incidence of gastric cancer in elderly patients has been increasing in Asian countries. Recently in Japan, about 60–70% of gastric cancers have been diagnosable in the early stage with the expansion of medical

checkups by barium or gastroscopic examination. However, the incidence of Advanced Gastric Cancer (AGC) still remains high in elderly patients because of the low numbers of elderly patients with symptomatic AGC and those who undergo an annual medical checkup [2].

There is little evidence regarding standard surgical treatment for elderly patients with AGC. Recently, as society has continued to age, studies to clarify optimal surgical management for AGC in elderly patients have begun to be reported from the viewpoints

of the pathological characterization of AGC, patients' physical tolerance of surgical stress, and surgical invasiveness depending on the type of gastrectomy, especially Lymph Node (LN) dissection. Several reports revealed pathological characteristics of AGC in elderly patients, such as i) tumors are mostly located on the lower stomach; ii) macroscopically, most are of the localized type; iii) histologically, they are primarily differentiated-type adenocarcinoma; and iv) the incidence of LN metastasis is not different from that in younger patients [3-7]. However, elderly patients showed the following physical characteristics: i) intolerance for surgical stress with multiple comorbidities, ii) high incidence of multiple primary cancer, and iii) poor health and short life expectancy. Accordingly, elderly patients are considered to be at risk for operative complications after gastrectomy. Therefore, several physical evaluation systems, such as the Prognostic Nutrition Index (PNI) and the Physiological and Operative Severity Score for the Enumeration of Mortality and Morbidity (POSSUM), were developed [8,9].

Standard LN dissection in gastrectomy for cancer is still controversial even in younger patients because of the lack of evidence showing survival benefits with extended LN dissection (D1+/D2) [8,10-14]. Therefore, D1 LN dissection is popular in Western countries, but D1+/D2 LN dissection is common in Asian countries [15]. Several reports also compared the technical safety between D1 vs. D2 LN dissection in gastrectomy and showed a lower incidence of morbidity in D1 LN dissection along with less surgical invasiveness. In the clinical setting, D1 LN dissection was often performed in elderly patients with gastric cancer due to its decreased surgical invasiveness [12,13]. More evidence on the technical and oncological outcomes of limited LN Dissection (D1) for AGC in elderly patients is required. In this study, to evaluate the technical and oncological outcomes of R0 Distal Gastrectomy (DG) with limited LN Dissection (D1) for AGC in elderly patients of 80 years or older, the short- and long-term outcomes after R0 resection by DG with D1 vs. D1+/D2 LN dissection in these patients were compared.

## Patients and Methods

### Patients

In this retrospective study, we enrolled 30 patients aged 80 years or older with Primary AGC (pT2 or deeper) who underwent R0 resection by DG in our department between January 1998 and December 2015. The Ethical Committee of Oita University Faculty of Medicine approved this study, and all patients included in the study gave their written informed consent. The TNM stage was classified according to the UICC, 7th edition. The LN station numbers (No.) and macroscopic type of tumor were based on the Japanese Classification of Gastric Cancers, 14th edition [16], and the extent of LN dissection was classified as D0, D1, D1+, or D2 according to the Japanese Gastric Cancer Treatment Guidelines

2010 (ver. 3) [17]. D1, D1+, and D2 areas are defined as D1: No. 1, 3, 4sb, 4d, 5, 6, and 7; D1+: D1 + No. 8a and 9; and D2: D1 + No. 8a, 9, 11p, and 12a [16,17]. The presence or absence of residual tumor after surgery is described as the R status; R0 is a curative resection with negative resection margins [16].

Histologic types were classified into two groups: differentiated type, including tubular and papillary adenocarcinoma, and undifferentiated type, including poorly differentiated adenocarcinoma, signet ring cell carcinoma, and mucinous adenocarcinoma. The clinical and pathological findings including the extent of LN dissection and the R status for all patients were obtained from the patients' medical, surgical, and pathology records.

### Evaluations

The extent of LN dissection was determined according to the inference of the patients' surgeons. Most of the patients who were diagnosed preoperatively as having clinically negative LN metastasis or who had a low level of physical performance with multiple co-morbidities were treated with DG with D1 LN dissection. To evaluate the technical and oncological outcomes of limited (D1) LN dissection in R0 DG for AGC in elderly patients, the patients were classified into two groups according to the extent of LN dissection: D1 group, D1 LN dissection (n = 13), and D1+/D2 group, D1+ or D2 LN dissection (n = 17).

The two groups were examined and compared in terms of patient characteristics and clinical findings such as age, sex, Body Mass Index (BMI), American Society of Anesthesiologists Physical Status (ASA-PS) classification, serum levels of Albumin (Alb), Hemoglobin (Hb), and Carcinoembryonic Antigen (CEA), comorbidity, and past surgical history. Operative findings were compared in terms of the approach method (laparoscopic or open), reconstruction method (Billroth-I, Billroth-II, or Roux-en-Y), operation time, blood transfusion, and intra-operative complications. Short-term outcomes were evaluated in terms of postoperative complications, hospital mortality, meal start, and hospital stay. Pathological findings were evaluated in terms of tumor location, macroscopic type, maximum tumor diameter, histologic type, pTNM factors, number of retrieved LNs, and lymphovascular invasion. Long-term outcomes were evaluated by 3-year rates of Relapse-Free Survival (RFS) and Overall Survival (OS).

### Statistical Analysis

Quantitative data are given as the median and range. Differences between the two groups were assessed by chi-square test, Fisher's exact test, or Mann-Whitney U test as appropriate. Survival rates were calculated by the Kaplan-Meier method, and the statistical significance of survival differences was analyzed by the log-rank test. RFS and OS were defined as the time from the

beginning of the operative day to first event. These analyses were carried out using EZR (Saitama Medical Center, Jichi Medical University, Saitama, Japan version 1.33) [18], which is a graphical user interface for R (version 3.3.1; The R Foundation for Statistical Computing, Vienna, Austria). More precisely, EZR is a modified version of R commander (version 2.3-0) designed to add statistical functions frequently used in biostatistics. A *P*-value of less than 0.05 was considered statistically significant.

## Results

### Elderly Patients and Surgeries

Patient characteristics are presented in (Table 1). No significant differences between the two groups were observed in age, sex, BMI, ASA-PS classification, serum levels of Alb, Hb, and CEA, comorbidity, and past surgical history. The incidence of comorbidity was 67% (20 patients), of which cardiovascular diseases accounted for a large part (70%) of the comorbidities. The patients in the D1 group often had more than two kinds of comorbidities compared with those in the D1+/D2 group. However, there was no significant difference in the incidence of comorbidities between the D1 group (61.5%) and D1+/D2 group (70.6%).

Characteristics	D1	D1+/D2	P-value
	(n = 13)	(n = 17)	
Age <sup>a</sup> , (years)	84 (80-89)	83 (80-92)	0.933
Sex			0.462
Male	5	10	
Female	8	7	
BMI <sup>a</sup> (kg/m <sup>2</sup> )	22.4 (15.0-30.0)	21.9 (18.1-26.5)	0.3
ASA-PS <sup>a</sup>	2 (1-2)	2 (1-2)	0.424
Alb <sup>a</sup> (g/dL)	3.7 (3.0-4.5)	3.5 (2.8-4.2)	0.315
Hb <sup>a</sup> (g/dL)	10.8 (7.6-14.2)	11.4 (9.0-13.8)	0.706
CEA <sup>a</sup> (ng/mL)	2.2 (0.7-7.1)	3.0 (1.2-14.1)	0.082
Comorbidity			0.705
Absence	5	5	
Presence	8	12	
Number of comorbidities <sup>a,*</sup>	2 (0-4)	1 (0-3)	0.965
Details			
Cardiovascular	9	12	1
Diabetes	2	3	1

Pulmonary	0	3	0.238
Renal	0	0	-
Brain infarction	1	2	1
Past surgical history			0.965
Absence	7	12	
Presence	6	5	
Upper abdomen	2	1	
Lower abdomen	4	4	
BMI, body mass index; ASA-PS, American Society of Anesthesiologists physical status; Alb, serum level of albumin; Hb, serum level of hemoglobin; CEA, carcinoembryonic antigen. a-Median (range). * There is some overlapping.			

**Table 1:** Characteristics of the elderly patients (n = 30).

### Operative Findings of gastrectomy in Elderly Patients

Operative findings are summarized in (Table 2). No significant differences were observed in approach method, reconstruction method, operation time, blood transfusion, and intra-operative complications. Estimates of the amount of blood loss were larger (but not significantly so) in the D1 group than in the D1+/D2 group. One patient in the D1 group had an estimated blood loss of 720 mL because of vessel injury.

Findings	D1	D1+/D2	P-value
	(n = 13)	(n = 17)	
Approach			0.264
Open	6 (46%)	12 (71%)	
Laparoscopic	7 (54%)	5 (29%)	
Reconstruction			0.113
Billroth-I	4	0	
Billroth-II	3	5	
Roux-en-Y	6	12	
Operation time <sup>a</sup> (min)	241 (165-380)	257 (145-443)	0.503
Blood loss <sup>a</sup> (mL)	190 (20-720)	120 (5-320)	0.285
Blood transfusion			0.628
Not performed	10	15	
Performed	3	2	

Intra-operative complications			0.138
Absence	9	16	
Presence	4	1	
Bleeding	1	1	
Injury	2	0	
Others	1	0	
<sup>a</sup> Median (range)			

**Table 2:** Operative findings (n = 30).

### Short-term Outcomes of gastrectomy in Elderly Patients

Short-term outcomes are presented in (Table 3). No significant differences were observed in hospital mortality, meal start, and hospital stay. With regard to postoperative complication, the incident rates were not significantly different between the D1 group (46.2%) and the D1+/D2 group (52.9%). The incidence of general complications was also not significantly different: 15.4% in the D1 group and 17.6% in the D1+/D2 group. Anastomotic leakage was observed in one patient in the D1 group, which resulted in a postoperative hospital stay 60 days.

Outcomes	D1 (n = 13)	D1+/D2 (n = 17)	P-value
Postoperative complication			1
Absence	7	8	
Presence	6	9	1
Local	4	6	
Anastomotic leakage	1	0	
Stasis	2	5	
Surgical site infection	1	1	1
General*	2	3	
Respiratory	1	3	
Cardiovascular	0	0	
Renal	0	0	
Colitis	1	1	-
Hospital mortality	0	0	
Meal start <sup>a</sup> (days)	4 (4-11)	4 (4-12)	0.283
Hospital stay <sup>a</sup> (days)	20 (10-60)	19 (11-27)	0.615

<sup>a</sup> Median (range).
* There is some overlapping.

**Table 3:** Short-term outcomes (n = 30).

### Pathological Findings of AGC in Elderly Patients

The pathological findings of the resected specimens are summarized in (Table 4). The numbers of patients with tumors located on the lower stomach were significantly greater in the D1+/D2 group than in the D1 group (D1 group: upper = 1, middle = 8, lower = 4; D1+/D2 group: upper = 0, middle = 3, lower = 14; P = 0.0109). The median numbers of retrieved LN were also significantly greater in the D1+/D2 group than in the D1 group (D1 group = 21, D1+/D2 group = 28, P = 0.01). However, there was no significant difference in the median numbers of metastatic LNs between the two groups (D1 group = 2, D1+/D2 group = 2, P = 0.558). No significant differences were observed in other pathological findings including macroscopic type, tumor size, histologic type, pTMN factors, and lymphovascular invasion.

Findings	D1 (n = 13)	D1+/D2 (n = 17)	P-value
	Tumor location		
Middle	9	3	
Lower	4	14	
Macroscopic type			0.109
0	3	2	
1	0	0	
2	4	12	
3	4	3	
4	2	0	0.516
Maximum diameter (mm) <sup>a</sup>	52 (24-85)	52 (18-100)	
$\leq 70$	10	9	
$> 70$	3	8	
Histologic type			1
Differentiated	6	8	
Undifferentiated	7	9	
Invasion depth			0.284
pT2	4	8	
pT3	6	6	

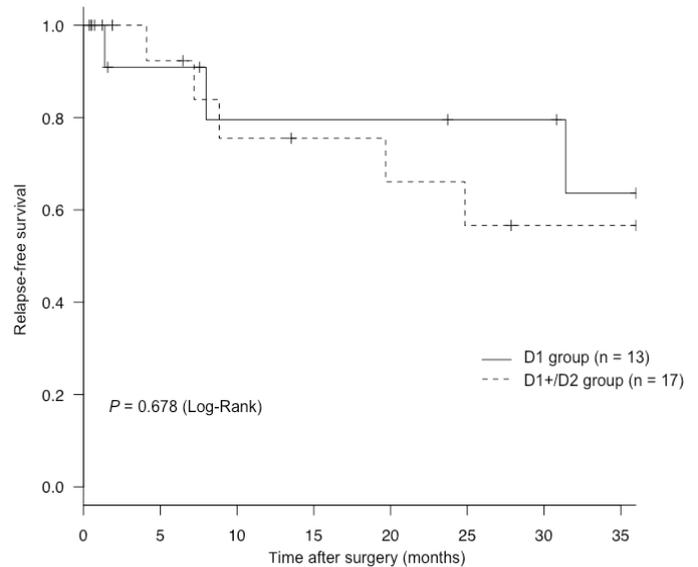
pT4a	3	3	
pN			0.264
Negative	7	5	
Positive	6	12	
Number of metastatic LN <sup>a</sup>	2 (0-14)	2 (0-12)	0.558
Number of retrieved LN <sup>a</sup>	21 (10-31)	28 (4-43)	0.021
pStage			0.528
IB	6	5	
IIA, IIB	2	6	
IIIA, IIIB, IIIC	5	6	
Ly			1
Negative	3	3	
Positive	10	14	
v			0.462
Negative	8	7	
Positive	5	10	
LN, lymph nodes.			
<sup>a</sup> Median (range).			

**Table 4:** Pathological findings of advanced gastric cancer in the elderly patients (n = 30).

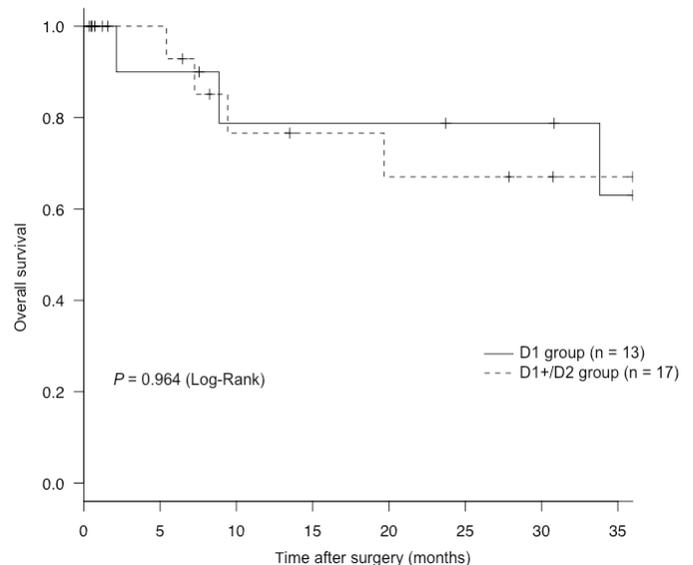
### Long-term Outcomes of Gastrectomy in Elderly Patients

Rates of 3-year RFS and OS are plotted in (Figures 1,2), respectively. The median follow-up periods of the D1 group and D1+/D2 group were 25 months (range, 0-60 months) and 14 months (range, 0-60 months), respectively. No significant differences were observed in the rates of 3-year of RFS between the two groups. The D1 group had a median RFS that was not available (NA) (95% Confidence Interval [CI], 7.98-NA months), as did the D1+/D2 group (95% CI, 7.19-NA months). Three patients in each group suffered recurrence. Patterns of recurrence are summarized in (Table 5). There were no significant differences in the patterns of recurrence between the two groups. As well, no significant differences were observed in the rates of 3-year OS between the two groups. Both the D1 group and D1+/D2 group had a median OS of NA (D1 group: 95% CI, 2.13-NA months; D1+/D2 group: 95% CI, 9.42-NA months). Four patients died in each group. Three and two cases of cancer-specific death were observed in the D1

group and D1+/D2 group, respectively. In addition, a sub analysis of RFS was performed in the patients without LN metastasis and in those with LN metastasis within the D1 area that showed no significant differences between the D1 group and the D1+/D2 group (data not shown).



**Figure 1:** Three-year relapse-free survival of all patients. There was no significant difference in 3-year RFS between the two groups (log-rank test,  $P = 0.678$ ).



**Figure 2:** Three-year overall survival of all patients. There was no significant difference in 3-year OS between the two groups (log-rank test,  $P = 0.964$ ).

Recurrence patterns	D1	D1+/D2	P-value
	(n = 13)	(n = 17)	
Recurrence			1.000
Absence	10 (77%)	14 (82%)	
Presence	3 (23%)	3 (18%)	
Recurrence type*			-
Local	1	0	
Lymph node	1	2	
Peritoneal dissemination	2	1	
Distant organ	1	2	
Liver	1	1	
Brain	0	1	
* There is some overlapping.			

**Table 5.** Recurrence patterns of advanced gastric cancer in the elderly patients (n = 30).

## Discussion

In this retrospective study, to evaluate the technical and oncological outcomes of DG with limited (D1) LN dissection for AGC in elderly patients aged 80 years or older, we compared the short- and long-term outcomes of the elderly patients who underwent R0 DG between the D1 and D1+/D2 groups. As a result, no significant differences were observed in patient characteristics including the incidence of comorbidities, in operative and pathological findings, and in the incident rates of postoperative complications between the two groups. Furthermore, long-term outcomes in terms of the rates of 3-year RFS and OS were also not significantly different between the two groups. These results indicate that extended LN dissection (D1+/D2) was a safe procedure, but it provided no additional survival benefits to elderly patients, suggesting that DG with limited LN Dissection (D1) for AGC may be accepted in these elder patients, when R0 resection is achieved.

This was a single-institution retrospective cohort study of elderly patients spanning 17 years. Therefore, the sample size of this study was not large, and nine patients failed to follow their postoperative course after leaving our hospital. There were several selection biases in this study. The patients enrolled in this study were limited to those aged 80 years or older, and their physical status was considered to be tolerable for surgical invasiveness by preoperative examination. Moreover, there were some confounding factors to affect the postoperative course, such as several kinds of surgical teams, extent of LN dissection, and reconstruction methods

after DG. However, no significant differences were observed in the patients' characteristics and surgical findings between the D1 and D1+/D2 groups. The extent of LN dissection depended on clinical decisions determined during preoperative case conferences with the members of the surgical teams in our department. Most of the patients who underwent D1 LN dissection were preoperatively diagnosed as having AGC with negative LN metastasis or they were evaluated as having a low level of physical performance status. Furthermore, only those patients with pathologically R0 resection were enrolled in this study.

Most previous Randomized Clinical Trials (RCTs) have enrolled patients less than 70 to 75 years old and excluded super-elderly patients (aged 80 years or older) [19]. Several studies reported that the length of operation, the amount of blood loss, and the incidence of postoperative complications in the D2 group were significantly greater than those in the D1 group [20-23]. These data suggested that surgical invasiveness by D2 LN dissection might be greater for the patients than D1 LN dissection. Several reports also investigated the risk factors for postoperative complications in gastrectomy. It was reported that extended LN dissection, total gastrectomy, and age of 60 years or older were found to be significant independent risk factors for overall postoperative complications of gastrectomy [24]. Furthermore, an ASA-PS of 3 or 4 and moderate or severe malnutrition plus these three factors were risk factors for general complications. Jiang et al. reported that age of more than 60 years was one of the risk factors for postoperative complications [25]. Accordingly, "elderly" is considered to be a risk factor for postoperative complications in gastrectomy for gastric cancer.

There are few studies on the relationship between the extent of LN dissection and the incidence of postoperative complications after gastrectomy in elder patients. Biondi et al. reported that D1 LN dissection decreased the incidence of postoperative complications [10]. In our present study, there were no significant differences in the incidence of postoperative complications between the D1 and D1+/D2 groups. Some retrospective studies reported that both of the extent of LN dissection and the number of retrieved LNs were smaller in elderly patients than in young patients [8,10]. These reports suggest that D1 LN dissection with its lower surgical invasiveness is popularly used for the surgical treatment of AGC in elderly patients aged 80 years or older when the local clearance of cancer cells can be completely performed by gastrectomy with limited LN dissection.

The survival benefits of extended LN Dissection (D2) in gastrectomy were discussed in previous reports of multicenter RCTs. Although survival benefits of D2 LN dissection were shown in a RCT in Taiwan [26], an Italian trial [19], the MRC ST01 trial [27], and a Dutch trial [28] failed to show survival benefits from D2 LN dissection. There are few studies on the survival benefits of D2 LN dissection for AGC in elderly patients. Yoshikawa K.

et al. reported that no significant differences were observed in prognosis between D1 LN dissection and D2 LN dissection under R0 gastrectomy in elderly patients [13]. Also, in our present study, no survival benefit from D1+/D2 LN dissection was observed in the elderly patients. It may be the reason that all patients enrolled in our present study underwent R0 DG regardless of the extent of LN dissection.

Several reports have identified the prognostic factors of AGC after gastrectomy [9,25,29]. According to these previous reports, the absence of LN metastasis, early stage by TNM stage classification, the absence of comorbidities, a high serum level of Alb, the absence of sarcopenia, and the lack of postoperative complications were reported as prognostic factors of AGC after gastrectomy. Interestingly, extended LN Dissection (D2) was not included as a prognostic factor. Most elderly patients with AGC have several factors indicative of a poor prognosis including the presence of comorbidity and sarcopenia and a low serum level of Alb. The survival benefits of extended LN Dissection (D2) may be lower in elderly patients than in younger patients.

In conclusion, DG with limited LN Dissection (D1) may be technically and oncological accepted for AGC in elderly patients aged 80 years old or older, when R0 resection is achieved. To confirm our results, matched case controlled studies and multicenter RCTs with a larger sample size would be required in the future. Furthermore, to determine optimal LN dissection for complete local clearance of AGC in elderly patients, the developments of better methods of preoperative or/and intra-operative diagnosis of LN metastasis are greatly needed.

## Conflict of Interest

All authors disclose no conflicts of interest relevant to this study. This study did not receive any funding from any sources.

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