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Original article

A multicenter retrospective study of endoscopic resection for early gastric cancer

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Abstract

Background. **The reported outcomes of endoscopic resection (ER) for early gastric cancer (EGC) remain limited to several single-institution studies.**

Methods. **A multicenter retrospective study was conducted at 11 Japanese institutions concerning their results for ER, including conventional endoscopic mucosal resection (EMR) and endoscopic submucosal dissection (ESD).**

Results. **A total of 714 EGCs (EMR, 411; ESD, 303) in 655 consecutive patients were treated from January to December 2001. Technically, 511 of the 714 (71.6%) lesions were resected in one piece. The rate of one-piece resection with ESD (92.7%; 281/303) was significantly higher compared with that for EMR (56.0%; 230/411). Histologically, curative resection was found in 474 (66.3%) lesions. The rate of curative resection with ESD (73.6%; 223/303) was significantly higher compared with that for EMR (61.1%; 251/411). Blood transfusion because of bleeding was required in only 1 patient (0.1%) with EMR of 714 lesions. Perforation was found in 16 (2.2%). The incidence of perforation with ESD (3.6%; 11/303) was significantly higher than that with EMR (1.2%; 5/411). All complications were managed endoscopically, and there was no procedure-related mortality. The median follow-up period was 3.2 years (range, 0.5–5.0 years). In total, the 3-year cumulative residual-free/recurrence-free rate and the 3-year overall survival rate were 94.4% and 99.2%, respectively. The 3-year cumulative residual-free/recurrence-free rate in the ESD group (97.6%) was significantly higher than that in the EMR group (92.5%).**

Conclusion. **ER leads to an excellent 3-year survival in clinical practice and could be a possible standard treatment for EGC. ESD has the advantage of achieving one-piece resection and reducing local residual or recurrent tumor.**

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Key words Early gastric cancer · Endoscopic mucosal resection · Endoscopic submucosal dissection · Multicenter study

Introduction

Early gastric cancer (EGC) is defined as invasion confined to the mucosa or submucosa, regardless of the presence of regional lymph node metastasis [1]. The incidence of EGC has reached 40%–60% of all gastric cancer cases, and gastrectomy with lymph node dissection has provided an excellent prognosis in patients with EGC in Japan [2,3]. On the other hand, endoscopic resection (ER) has been accepted as a less invasive local resection for EGC, with a negligible risk of lymph node metastasis [4,5].

The method of ER varies from conventional endoscopic mucosal resection (EMR) to endoscopic submucosal dissection (ESD), which was developed recently. EMR procedures include strip biopsy, EMR with a cap-fitted panendoscope (EMRC), endoscopic aspiration mucosectomy (EAM), and EMR with a ligating device (EMRL) [6–9]. ESD is a new method of ER developed for achieving one-piece resection even in patients with large and ulcerative lesions [10–14].

The use of ER varies between institutions. The general indications proposed by the Japanese Gastric Cancer Association (JGCA) comprise; (1) differentiated adenocarcinoma, (2) intramucosal cancer, (3) lesion size 20 mm or less, and (4) without ulcer finding (UL) [15]. Lesions that meet all of the above criteria have negligible risk of lymph node metastasis and allow

Table 1. Expanded histological criteria for ER

1. Differentiated adenocarcinama
and
2. No lymphatic or venous invasion
and
3a. Intramucosal cancer without UL regardless of size
or
3b. Intramucosal cancer ≤30 mm in size with UL
or
3c. Minute submucosal cancer (sm 1) ≤30 mm in size

ER, endoscopic resection; UL, ulcer finding

one-piece resection by EMR. Recently, based on the risk of lymph node metastasis in EGC obtained from a large number of surgical cases, expanded histological criteria for ER in EGC have been reported (Table 1) [16]. These include lesions of more than 20 mm in size and ulcerative lesions which can be resected by ESD.

Although there are several single-institution studies reporting the outcome of ER for EGC [6–10, 12–14], there is only one multicenter report of the outcome of EMR in Japan [17]. Under the ER committee of the JGCA, this study aimed to determine the current nationwide results of ER, including EMR and ESD.

Patients and methods

Eleven Japanese institutions participating in this study were selected from major centers with accumulated experience in ER for EGC (Table 2). Consecutive patients with EGC who underwent ER at the 11 institutions from January to December 2001 were analyzed. This study was carried out with the approval of each institutional review board.

Inclusion criteria

EGC that met all the following criteria before ER were included.

1. Histological type: differentiated adenocarcinoma (well- and moderately differentiated tubular adenocarcinoma and papillary adenocarcinoma) confirmed histologically by biopsy
2. Depth of invasion: limited to the mucosa or sm1 (≤500-μm penetration into the submucosa) basically estimated by endoscopic prediction and also by endoscopic ultrasound (EUS) if needed
3. Size and ulcer finding (UL): lesions without UL regardless of size, or 30 mm or less in size with UL.

Exclusion criteria

1. Patients suffering from other cancers
2. EGC previously treated by an endoscopic procedure

Table 2. Participating institutions and numbers of patients

Institution	Number of patients (lesions)	EMR	ESD
1. Endoscopy Division, National Cancer Center Hospital, Tokyo	196 (223)	10	213
2. Division of Gastroenterology, Saitama Cancer Center, Ina, Saitama	85 (86)	86	0
3. Department of Gastrointestinal Oncology, Osaka Medical Center for Cancer and Cardiovascular Diseases, Osaka	83 (94)	94	0
4. Department of Gastroenterology, Kitasato University School of Medicine, Sagamihara	49 (55)	50	5
5. Gastroenterology, Saku Central Hospital, Saku	49 (52)	0	52
6. Division of Endoscopy and Gastrointestinal Oncology, National Cancer Center Hospital East, Kashiwa	48 (53)	35	18
7. Department of Surgery, Keio University, School of Medicine, Tokyo	42 (44)	36	8
8. Endoscopy Division, Cancer Institute Hospital, Tokyo	35 (36)	31	5
9. Division of Molecular and Diagnostic Pathology, Graduate School of Medical and Dental Sciences, Niigata University, Niigata	32 (34)	34	0
10. Department of Internal Medicine, Social Health Insurance Medical Center, Tokyo	21 (21)	19	2
11. Digestive Disease Center, Showa University Northern Yokohama Hospital, Yokohama	15 (16)	16	0

3. EGC diagnosed in a remnant stomach after gastrectomy
4. EGC diagnosed in a gastric tube reconstruction after esophagectomy

The following factors were analyzed from the medical records: clinicopathological characteristics (age, sex, tumor location, macroscopic type, endoscopic indication for ER), ER method, and short-term (one-piece resection rate, curability, and complications) and long-term outcomes after ER.

Clinicopathological characteristics

The location of the tumor was classified, based on the *Japanese classification of gastric carcinoma* [1], into upper, middle, and lower thirds of the stomach. Macroscopic type was divided into elevated type and depressed type.

Endoscopic indications for ER were divided into general indications (lesions ≤20 mm in size without UL) and expanded indications (lesions >20 mm in size without UL, or ≤30 mm in size with UL).

ER methods

ER methods were divided into EMR (strip biopsy, EMRC, EAM, and EMRL) and ESD.

Short-term outcome

The one-piece resection rate, histological curability, and complications were evaluated. Curability was assessed histologically, based on the expanded criteria (Table 1) and the tumor margin status, as curative, noncurative, and nonevaluable. When a lesion was within the expanded criteria, with tumor-free margins, the curability was defined as curative. Piecemeal-resected specimens were first of all reconstructed using endoscopic pictures obtained before ER and clue markings previously located around the lesion, and then evaluated histologically. When histological evaluation revealed that a lesion was outside the expanded criteria or that it had a positive margin, the curability was defined as noncurative. When histological assessment was difficult, the lesion was defined as nonevaluable.

In relation to complications, the incidence of bleeding that needed blood transfusion and the incidence of perforation were evaluated.

Long-term outcome

The follow-up period and clinical course after ER were investigated. We defined a cancer diagnosed histologically at the resected site after ER as a residual or recurrent tumor according to differences in the period of detection. Residual tumor was defined as a cancer diagnosed histologically at the resected site within 6 months after the ER. Recurrent tumor was defined as a cancer diagnosed histologically at the resected site more than 6 months after the ER.

The cumulative residual-free/recurrent-free curve was evaluated from the date of ER to the date of histological confirmation of the residual or recurrent tumor, or the last follow-up. The cumulative residual-free/recurrence-free survival curve was evaluated from the date of ER to the date of confirmation of the residual or recurrent tumor, death, or the last follow-up. The overall survival curve was evaluated starting from the date of ER to the date of death or the last follow-up. Patients followed for 6 months or less were excluded from analysis.

Data from the 11 institutions were collected and analyzed in April 2005, according to the ethical guidelines for epidemiological research proposed by the Ministry of Education, Culture, Sports, Science and Technology and the Ministry of Health, Labour and Welfare.

Statistical analysis

Clinicopathological characteristics and short-term outcome were analyzed using the χ^2 test and Fisher's exact test, as appropriate (Statview; Abacus Concepts, Berkeley, CA, USA), and $P < 0.05$ was considered significant.

Data for long-term outcome were calculated by the Kaplan-Meier method and analyzed using the log-rank test (Statview; Abacus Concepts), and $P < 0.05$ was considered significant.

Results

During the 1-year study period, a total of 714 EGCs were treated in 655 consecutive patients.

Clinicopathological characteristics and ER methods

Clinicopathological characteristics and ER methods are shown in Table 3. The median age was 68 years (mean, 67; range, 28–93 years) and the male/female ratio was 3.4. Of the 714 lesions, 568 (80%) were diagnosed using the general indications of ER before treatment and 146 (20%) were diagnosed using the expanded indications. The latter group included 69 lesions that were more than 20 mm in size without UL and 77 lesions that were 30 mm or less in size with UL.

Four hundred and eleven lesions (58%) were resected by EMR (strip biopsy, 330; EAM, 48; EMRC,

Table 3. Clinicopathological characteristics and ER methods

	EMR	ESD	*P* value	Total
Median age (years)	68	67		68
Male/female ratio	3.5	3.4		3.4
Location				
U	75 (18%)	48 (16%)		123 (17%)
M	126 (31%)	122 (40%)		248 (35%)
L	206 (50%)	133 (44%)	NS	339 (47%)
Unknown	4 (1%)	0 (0%)		4 (1%)
Macroscopic type				
Elevated	217 (53%)	103 (34%)	<0.01	320 (45%)
Depressed	186 (45%)	199 (66%)		385 (54%)
Unknown	8 (2%)	1 (0.3%)		9 (1%)
Diagnosis before ER				
General indication	367 (89%)	201 (66%)	<0.01	568 (80%)
Expanded indication	44 (11%)	102 (34%)		146 (20%)
>20 mm without UL	25	44		69
≤30 mm with UL	19	58		77
Total	411 (58%)	303 (42%)		714 (100%)

ER, endoscopic resection; U, upper third; M, middle third; L, lower third; UL, ulcer finding

Table 4. Assessment of histological curability

	EMR	ESD	*P* value	Total
One-piece resection	56.0% (230)	92.7% (281)	<0.01	71.6% (511)
Curative resection	41.8% (172/411)	71.9% (218/303)	<0.01	54.6% (390/714)
Noncurative resection	10.0% (41/411)	17.2% (52/303)	<0.01	13.0% (93/714)
Nonevaluable resection	4.1% (17/411)	3.6% (11/303)	NS	3.9% (28/714)
Piecemeal resection	44.0% (181)	7.3% (22)		28.4% (203)
Curative resection	19.2% (79/411)	1.7% (5/303)	<0.01	11.8% (84/714)
Noncurative resection	10.5% (43/411)	1.0% (3/303)	<0.01	6.4% (46/714)
Nonevaluable resection	14.4% (59/411)	4.6% (14/303)	<0.01	10.2% (73/714)
Total	100% (411)	100% (303)		100% (714)
Curative resection	61.1% (251)	73.6% (223)	<0.01	66.3% (474)
Noncurative resection	20.4% (84)	18.2% (55)	NS	19.5% (139)
Nonevaluable resection	18.5% (76)	8.3% (25)	<0.01	14.1% (101)

27; and others, 6). The remaining 303 (42%) were resected by ESD. Macroscopically, there were 217 (53%) and 103 (34%) elevated lesions in the EMR and ESD groups, respectively ($P < 0.01$). Before ER, 34% (102/303) of the lesions in the ESD group were diagnosed using the expanded indications, compared with 11% (44/411) in the EMR group ($P < 0.01$).

Short-term outcome of ER

One-piece resection was performed in 511 of the 714 (71.6%) lesions. The rate of one-piece resection using ESD (92.7%; 281/303) was significantly higher compared with that using EMR (56.0%; 230/411; $P < 0.01$; Table 4).

Assessment of histological curability is summarized in Table 4. Histologically, curative resection was found in 474 (66.3%) lesions. The rate of curative resection in the ESD group (73.6%; 223/303) was significantly higher compared to that in the EMR group (61.1%; 251/411; $P < 0.01$).

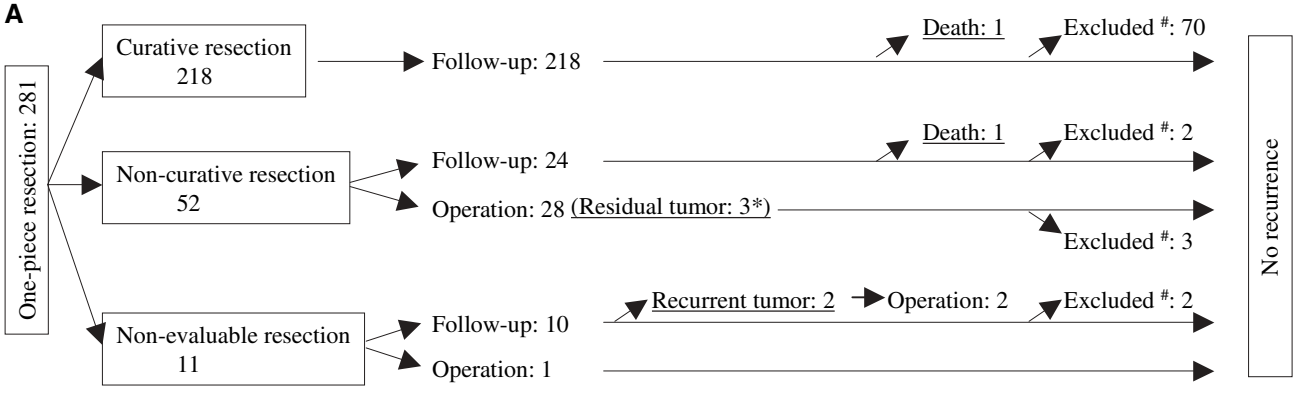
The relationships between clinicopathological characteristics and the one-piece resection rate, and curative resection rate are shown in Table 5. Even for lesions diagnosed using the expanded indications, the one-piece resection rate and curative resection rate in the ESD group were significantly higher than those in the EMR group.

Noncurative resection was observed in 139 lesions (19.5%); 55 in the ESD group and 84 in the EMR group. In the ESD group, 7 of the 55 lesions (13%) were within the expanded histological criteria with a positive resection margin, and 48 of the 55 lesions (87%) were outside the expanded histological criteria regardless of the resection margin. In contrast, in the EMR group, 54 of the

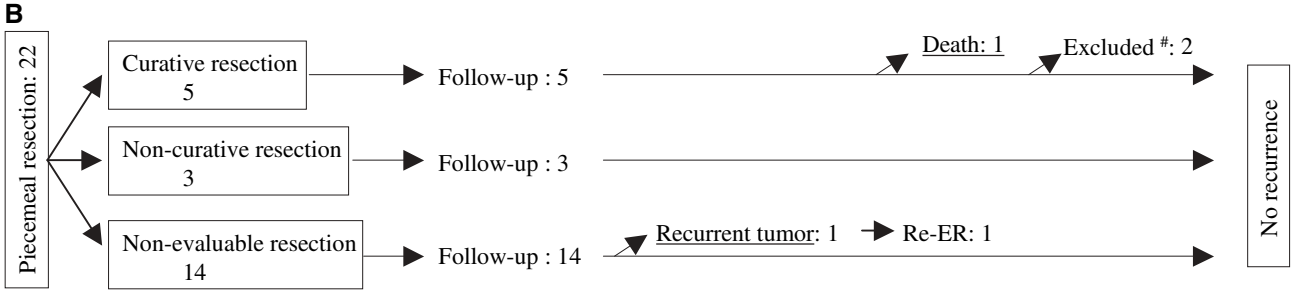
Table 5. Relationships between clinicopathological characteristics and the one-piece resection and curative resection rates

	One-piece resection rate			Curative resection rate		
	EMR	ESD	*P* value	EMR	ESD	*P* value
Location						
U	50.7% (38/75)	97.9% (47/48)	<0.01	62.7% (47/75)	68.8% (33/48)	NS
M	50.8% (64/126)	91.8% (112/122)	<0.01	42.9% (54/126)	70.5% (86/122)	<0.01
L	61.2% (126/206)	91.7% (122/133)	<0.01	71.4% (147/206)	78.2% (104/133)	NS
Unknown	50.0% (2/4)	—		75.0% (3/4)	—	
Macroscopic type						
Elevated	56.7% (123/217)	92.2% (95/103)	<0.01	63.6% (138/217)	79.6% (82/103)	<0.01
Depressed	54.8% (102/186)	93.0% (185/199)	<0.01	56.5% (105/186)	70.9% (141/199)	<0.01
Unknown	62.5% (5/8)	100% (1/1)		100% (8/8)	0% (0/1)	
Diagnosis before ER						
General indication	59.1% (217/367)	94.5% (190/201)	<0.01	65.7% (241/367)	81.1% (163/201)	<0.01
Expanded indication	29.6% (13/44)	89.2% (91/102)	<0.01	22.7% (10/44)	58.8% (60/102)	<0.01
>20 mm without UL	28.0% (7/25)	95.5% (42/44)	<0.01	24.0% (6/25)	61.4% (27/44)	<0.01
≤30 mm with UL	31.6% (6/19)	84.5% (49/58)	<0.01	21.1% (4/19)	56.9% (33/58)	<0.01
Total	56.0% (230/411)	92.7% (281/303)	<0.01	61.1% (251/411)	73.6% (223/303)	<0.01

U, upper third; M, middle third; L, lower third; UL, ulcer finding



*; Two of 3 cases showed lymph node metastases in resected specimens.
#; patients were excluded from analysis due to short follow-up periods (≤6 months)



ER; endoscopic resection
#; patients were excluded from analysis due to short follow-up periods (≤6 months)

Fig. 1A,B. Clinical outcome in the endoscopic submucosal dissection (ESD) group. **A** One-piece resection; **B** piecemeal resection

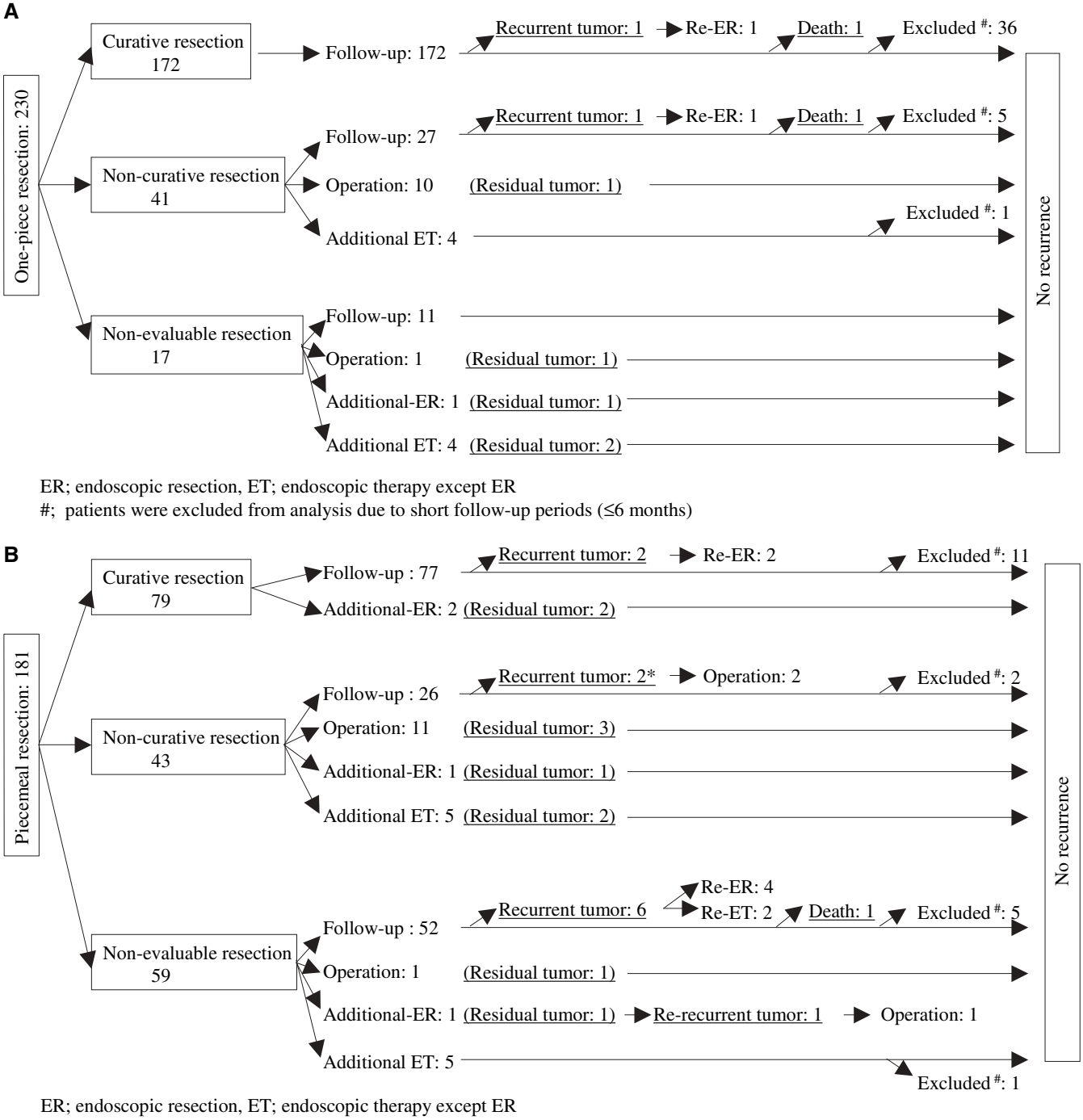


Fig. 2A,B. Clinical outcome in the endoscopic mucosal resection (EMR) group. **A** One-piece resection; **B** piecemeal resection

84 lesions (64%) were within the expanded histological criteria with a positive resection margin and 30 of the 84 (36%) were outside the expanded histological criteria regardless of the resection margin. Moreover, the percentage of lesions outside the expanded histological criteria among all lesions was significantly higher (16%; 48/303) in the ESD group than in the EMR group (7%; 30/411; $P < 0.01$).

Blood transfusion because of bleeding was required in only 1 patient (0.1%) with the EMR method of 714 lesions. Gastric wall perforation occurred in 16/714 lesions (2.2%). The incidence of perforation with the ESD

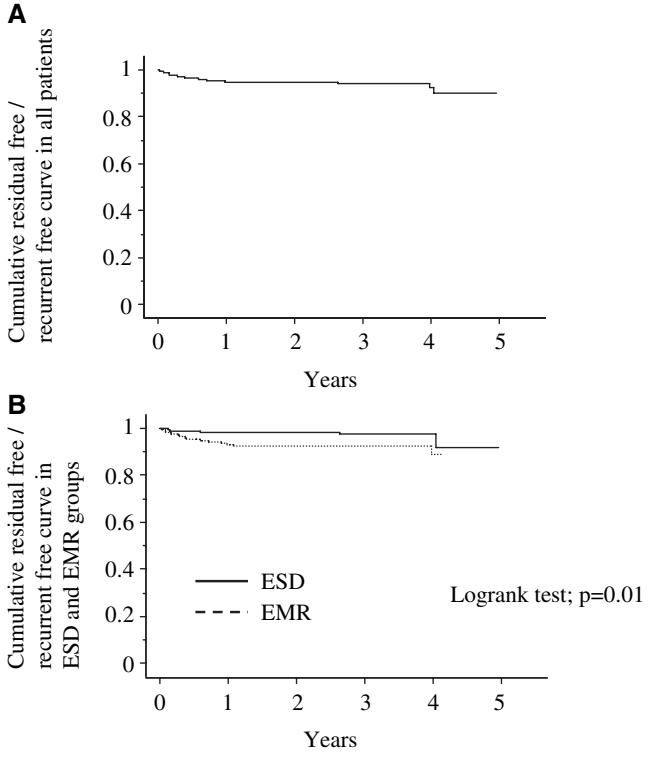


Fig. 3. Cumulative residual-free/recurrence-free curves; **A** in all patients; **B** in ESD and EMR groups

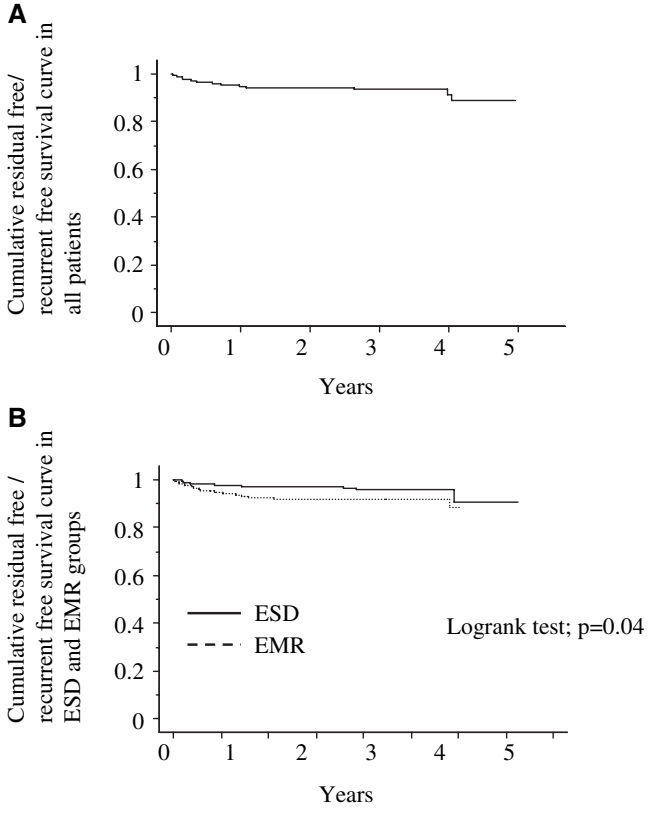


Fig. 4. Cumulative residual-free/recurrence-free survival curves; **A** in all patients; **B** in ESD and EMR groups

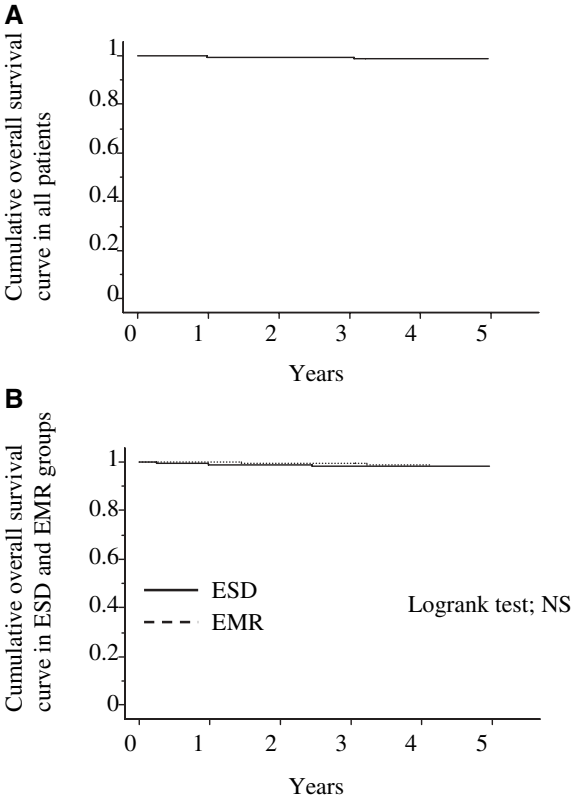


Fig. 5. Overall survival curves; **A** in all patients; **B** in ESD and EMR groups. *NS*, not significant

method (3.6%; 11/303) was significantly higher than that with the EMR method (1.2%; 5/411; $P < 0.05$). All endoscopic-related complications were managed endoscopically, and there was no procedure-related mortality.

Long-term outcome after ER

The overall clinical outcomes in the ESD and EMR groups are shown in Figs. 1 and 2. Residual or recurrent tumor was found in 33 lesions (4.6%); 6 (2.0%) in the ESD group and 27 (6.6%) in the EMR group. We found one re-recurrence tumor after an additional ER in the EMR group. There was neither residual nor recurrent tumor in patients with curative resection in the ESD group. Six patients died of other causes; there was no gastric cancer-related death.

The cumulative residual-free/recurrence-free curves, cumulative residual-free/recurrent-free survival curves, and overall survival curves are shown in Figs. 3, 4, and 5. The median follow-up period was 3.2 years (range, 0.5–5.0 years). The 3-year residual-free/recurrence-free rate, residual-free/recurrence-free survival, and overall survival were 94.4%, 93.7%, and 99.2%, respectively. The 3-year residual-free/recurrence-free rate in the ESD group (97.6%) was significantly higher than that in the EMR group (92.5%; $P = 0.01$). The 3-year residual-

free/recurrence-free survival in the ESD group (96.1%) was significantly higher than that in the EMR group (92.2%; $P = 0.04$). There was no difference in the 3-year overall survival between the ESD group (98.5%) and the EMR group (99.7%).

Discussion

This is the first multicenter Japanese study to report the outcome of endoscopic treatment for EGC, including the newly developed ESD technique.

Of the 714 consecutive eligible lesions at 11 institutions during the study period, 568 lesions (80%) were treated based on the general indication for ER before treatment and 146 (20%) were considered for ER based on the expanded indication, including 69 lesions more than 20 mm in size without UL and 77 lesions 30 mm or less in size with UL. In the year 2000 the expanded criteria for ER in EGC were proposed [16]. These expanded criteria included lesions more than 20 mm in size and ulcerative lesions that were originally resected by surgery. However, it was still difficult to resect large and ulcerative lesions by EMR techniques, so a new technique, ESD, was developed [10–14]. In fact, in this study, the cases diagnosed using the expanded indication in the ESD group outnumbered those in the EMR group.

Technically, the one-piece resection rate was higher with ESD compared to that with EMR. However, the incidence of perforation with ESD (3.6%) was significantly higher than that with EMR (1.2%). We should beware of perforation, especially in ESD. In addition, blood transfusion because of bleeding was required in only one patient (0.1%) with the EMR method of 714 lesions. All complications were managed endoscopically and no surgical intervention was required.

The rate of curative resection using ESD (73.6%) was significantly higher compared with that for EMR (61.1%; $P < 0.01$). Because curability is assessed histologically based on the expanded criteria and tumor margins, it is influenced by technical and diagnostic aspects. From the aspect of diagnosis, the percentage of lesions outside the expanded histological criteria among all lesions was significantly higher (16%) in the ESD group than in the EMR group (7%; $P < 0.01$). The reason for this finding is thought to reflect that, in the ESD group, cases diagnosed using the expanded indications outnumbered those in the EMR group and the percentage of lesions outside the expanded histological criteria was highs in these cases. In fact, of 102 lesions diagnosed using the expanded indications in the ESD group, 28 (27%) lesions were outside the expanded histological criteria, compared with 5 of 44 (11%) lesions in the EMR group (data not shown). Although the ESD group had an unfavorable diagnostic result with the higher percentage of lesions outside the expanded histological criteria, the rate of curative resection using ESD was significantly higher compared with that for EMR. Therefore, ESD has a technical advantage in achieving a negative tumor margin.

Concerning residual or recurrent tumor, the 3-year cumulative residual-free/recurrence-free rate in the ESD group (97.6%) was significantly higher than that in the EMR group (92.5%). In addition, there was neither residual nor recurrent tumor in curative resection cases in the ESD group. We speculate that the technical advantage of ESD in achieving a one-piece resection with negative tumor margins reduces the probability of residual or recurrent tumor. During the follow-up of patients treated with EMR, we should monitor for residual or recurrent tumor and carry out additional appropriate treatment if required.

Although 140 (19.6%) lesions were excluded from the analysis of long-term outcome due to short follow-up periods (≤6 months), this study showed that all patients with EGC treated by both ESD and EMR had an excellent 3-year survival rate, considering the previously reported results in surgical cases [18–20]; thus, ER appears to be a feasible method of treating EGC.

In conclusion, this retrospective study has shown that ER leads to excellent 3-year survival in clinical practice and could be a possible standard treatment for EGC. ESD offers the greatest advantage of achieving one-piece resection and reducing local residual or recurrent tumor, even in large and ulcerative lesions. ESD has helped us to expand the indications for ER and thus, to reduce the need for surgery in EGC.

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