超高齢者における内視鏡的粘膜下層剥離術は早期胃癌に適した治療である　：　非高齢者との短期成績と長期成績の比較による検討

Komori, Keishi
Department of Medicine and Bioregulatory Science, Graduate School of Medical Sciences, Kyushu University

Nakamura, Kazuhiko
Department of Medicine and Bioregulatory Science, Graduate School of Medical Sciences, Kyushu University

Ihara, Eikichi
Department of Medicine and Bioregulatory Science, Graduate School of Medical Sciences, Kyushu University

Iwasa, Tsutomu
Department of Medicine and Bioregulatory Science, Graduate School of Medical Sciences, Kyushu University

他

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Original Article

Endoscopic Submucosal Dissection is Feasible for Very Elderly Patients with Early Gastric Cancer : Comparison of Short-Term and Long-Term Outcomes in Very Elderly and Non-Elderly Patients

Keishi Komori[1)], Kazuhiko Nakamura[1)], Eikichi Ihara[1)], Tsutomu Iwasa[1)], Minako Hirahashi[2)], Yoshinao Oda[2)] and Ryoichi Takayanagi[1)]

[1)]*Department of Medicine and Bioregulatory Science, Graduate School of Medical Sciences, Kyushu University, Fukuoka, Japan*

[2)]*Department of Anatomic Pathology, Pathological Sciences, Graduate School of Medical Sciences, Kyushu University, Fukuoka, Japan*

Abstract

Background/Aims : Endoscopic submucosal dissection (ESD) has become a standard procedure for the resection of early gastric cancer (EGC). However, the feasibility of ESD for very elderly patients, aged ≥ 80 years, has not been determined.

Methodology : The study population included 67 non-elderly (NE) patients aged ≤ 65 years (80 lesions) and 22 very elderly (VE) patients ≥ 80 years (26 lesions) with EGC who underwent ESD and met the criteria for absolute or expanded indications. Eighteen patients (18 lesions) who underwent ESD but did not meet the criteria for absolute and expanded indications were defined as the outside the indications (OI) group.

Results : En bloc and complete resection rates were excellent in both the VE and NE groups, without differing significantly. Although the rates of ischemic heart disease and antithrombotic agent use were higher in the VE than in the NE group, procedure-related complication rates did not differ significantly. Of the seven very elderly patients in the OI group, two underwent additional gastrectomy, and the other five were followed-up without surgery. No patient in any group experienced local recurrence, metastasis or disease-specific death.

Conclusions : Short- and long-term outcomes of ESD for VE patients with EGC were favorable and did not differ significantly from outcomes in NE patients. ESD may therefore be a good therapeutic option for both VE and NE patients with EGC.

Key Words : Gastric cancer・Endoscopic submucosal dissection・Outcome・Aged・Very elderly patients

Introduction

As Japanese society ages, the need to treat very elderly patients has increased. The Japanese Ministry of Health, Labour and Welfare estimated that in 2013 the mean life expectancy in Japan for men and women was 80.2 and 86.6 years, respectively, and the mean life expectancy at age 80 years was 8.6 and 11.5 years, respectively[1)]. Thus, the numbers of very elderly patients requiring endoscopic treatment for early gastric cancer (EGC) are expected to increase, creating a need to determine optimal treatment strategies for these patients.

Correspondence : Kazuhiko Nakamura, M.D., Ph.D.
Department of Medicine and Bioregulatory Science, Graduate School of Medical Sciences, Kyushu University, 3-1-1, Maidashi, Higashi-ku, Fukuoka 812-8582, Japan
Fax : + 81-92-642-5287 ; Tel : + 81-92-642-5286
E-mail : knakamur@intmed3.med.kyushu-u.ac.jp

EGC without lymph node or distant metastasis is curable by endoscopic treatment[2]. Endoscopic mucosal resection (EMR), the first developed method of endoscopic resection, has been used to treat EGC for a substantial period of time. To improve outcomes, several modified EMR techniques have been developed, including strip biopsy using a two-channel fiberscope[4], EMR with a cap-fitted panendoscope[5] and EMR with a ligation device[6]. Nevertheless, EMR still has limitations, including the low en bloc resection rates of lesions larger than 2 cm in size and those with ulcerative characteristics. Endoscopic submucosal dissection (ESD) was developed to overcome these limitations and has been shown to have markedly higher en bloc and complete resection rates than EMR[7)8)]. Additionally, ESD is considered to have an advantage over surgery, because it is both less invasive and organ-conserving, thereby enhancing postoperative quality of life[9]. ESD has become the current standard endoscopic treatment for EGC[7)8)]. Despite ESD having a higher cure rate for EGC than EMR, ESD has several drawbacks, including its greater technical difficulties ; its higher rates of procedure-related complications, such as perforation and delayed bleeding ; and its significantly longer procedure time[8]. In addition, the ESD resection of larger lesions results in the need to treat larger post-operative artificial gastric ulcers[10]. Compared with younger patients, elderly patients have a greater frequency of comorbidities, including hypertension, cardiovascular disease, diabetes, respiratory disease, and liver disease, and these comorbidities may affect recovery from surgery[11)12)]. Thus, it is unclear whether ESD is as safe for elderly as for non-elderly patients.

Although previous studies have shown the feasibility of ESD for EGC patients aged ≥ 65 years and ≥ 75 years[13)~16)], fewer studies have investigated its feasibility in very elderly patients aged ≥ 80 years. One multicenter retrospective study analyzed the long-term outcomes of ESD for EGC patients aged ≥ 80 years[17], but that study was a single arm analysis and did not include comparisons between very elderly and non-elderly patients. In addition, a meta-analysis of nine studies assessed ESD for elderly patients with EGC. Of the included studies, one defined elderly as ≥ 65 years and seven as ≥ 75 years[3]. Although the ninth study evaluated patients aged ≥ 80 years, that study analyzed only the financial costs of ESD for EGC, not treatment outcomes or safety[18]. Thus, it has not yet been determined whether ESD is suitable for the treatment of EGC in very elderly patients aged ≥ 80 years. The aging of society has increased the need to determine the feasibility of ESD for patients aged ≥ 80 years. This study was therefore designed to determine the feasibility of ESD in very elderly patients aged ≥ 80 years with EGC, by comparing short- and long-term outcomes in groups of very elderly and non-elderly patients.

Material and Methods

Patients

Fig. 1 shows the flowchart for patient inclusion. Between December 2002 and March 2012, 271 EGC lesions were removed from 251 patients by ESD in the Department of Medicine and Bioregulatory Science of Kyushu University Hospital. The indications for endoscopic resection of EGC followed Japanese Gastric Cancer Treatment Guidelines[19]; these consist of an absolute indication (AI), defined as differentiated mucosal cancer ≤ 20 mm in size without ulcer findings, and expanded indications (EI), including : (1) differentiated mucosal cancer > 20 mm in size without ulcer findings ; (2) differentiated mucosal cancer ≤ 30 mm in size with ulcer findings ; (3) differentiated cancer with minute submucosal invasion (< 500 μm from the muscularis mucosa) and ≤ 30 mm in size ; and (4) undifferentiated mucosal cancer ≤ 20 mm in size without ulcer findings. All other lesions were defined as outside the indications (OI).

The very elderly (VE) group consisted of 22 patients (26 lesions) aged ≥ 80 years and the

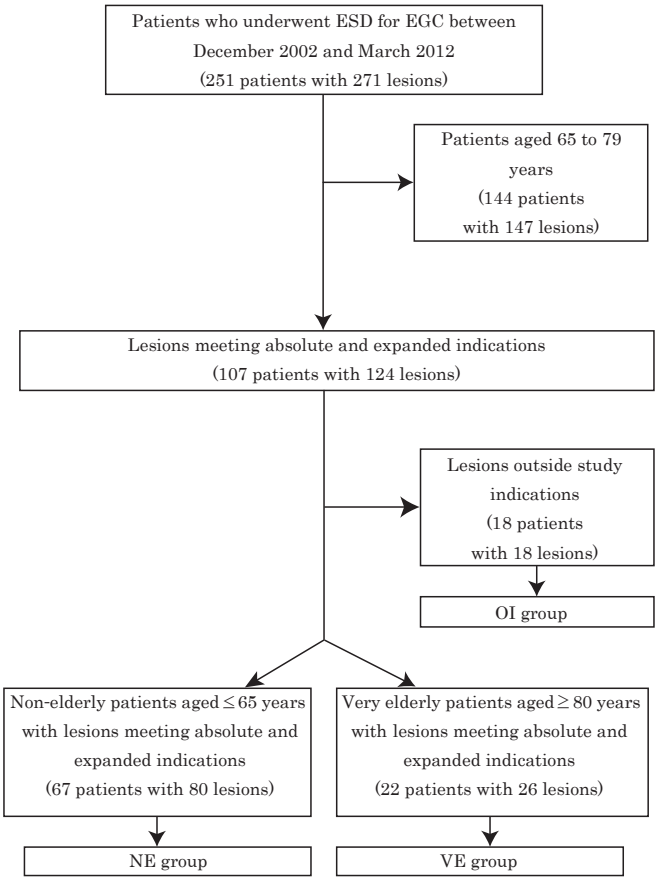

Fig. 1 Patient flowchart.

non-elderly (NE) group consisted of 67 patients (80 lesions) aged ≤ 65 years ; the 147 lesions in the 144 patients aged 66-79 years were excluded. Histopathological analyses of the resected tissue specimens showed that 18 lesions in 18 patients were OI. Therefore, 106 lesions in 89 patients fulfilled the criteria for AI and EI and were enrolled in this study. Demographic and clinical parameters were compared in these groups, including sex, follow-up period, comorbidities, medications, lesion characteristics (size, location and type), duration of hospitalization, en bloc resection rate, complete resection rate, procedure time, procedure-related complications, recurrence rate and death rate. The patients were followed up by annual esophagogastroduodenoscopy and, at the discretion of the attending physician, by computed tomography or abdominal ultrasonography Mean follow-up period was 1202 ± 97.1 days. This retrospective study was approved by the Ethics Committee of Kyushu University Hospital. Information regarding this study has been posted on the website of the Department of Medicine and Bioregulatory Science of Kyushu University at (http : //www.intmed3.med.kyushu-u.ac.jp).

ESD procedure

ESD was performed using standard methods[7)8)20)21)]. Electrosurgical knife devices including an insulation-tipped knife (Olympus, Tokyo, Japan), a flush knife (Fuji Film, Tokyo, Japan) and a clutch cutter (Fuji Film). In our department, ESD was indicated in patients with a performance status (PS) of 0, 1, or 2, but was allowed in patients with a PS of 3 if they desired after discussion with their families and the endoscopists. Postoperative bleeding was defined

Table 1 Baseline demographic and clinical characteristics of patients in the NE and VE groups

	NE group (N=67)	VE group (N=22)	*p* value
Mean age (range)	60 (44-65)	81.5 (80-86)	< 0.0001*
Gender ratio (M : F)	54 : 13	14 : 8	0.1467
Mean follow-up period (days)	915	926	0.3828
Comorbidities			
Cerebrovascular disease	2 (2.99%)	1 (4.55%)	1
Ischemic heart disease	1 (1.49%)	5 (22.72%)	0.0032*
Diabetes mellitus	15 (22.4%)	5 (22.72%)	1
Dyslipidemia	6 (8.96%)	2 (9.09%)	1
Hypertension	18 (26.87%)	11 (50%)	0.0656
Chronic kidney disease with hemodialysis	0	2 (9.09%)	0.059
Usage of antithrombotic agents	2 (2.99%)	4 (18.18%)	0.031*

Abbreviations : NE, non-elderly ; VE, very elderly
*$P < 0.05$

as hematemesis or melena or a decrease in Hb > 2 g/dL ≥ 6 hours after the end of ESD, with confirmation of evident bleeding sites on resected lesions and a requirement for emergency endoscopic hemostasis.

Statistical analyses

Factors in the VE and NE groups were compared using the Mann-Whitney U-test, Chi-square test or Fisher's exact test, as appropriate. Survival rates were determined using the Kaplan-Meier method and compared by log-rank tests and generalized Wilcoxon tests. $P < 0.05$ was considered statistically significant.

Results

Clinical characteristics of patients in the VE and NE groups

The clinical characteristics of the patients in the VE and NE groups are summarized in Table 1. The two groups had similar gender distribution, mean follow-up periods and rates of certain comorbidities, including cerebrovascular disease, diabetes mellitus, dyslipidemia, hypertension and chronic kidney disease treated with hemodialysis. In contrast, the incidence of ischemic heart disease and the percentage of patients taking antithrombotic agents were significantly higher in the VE than in the NE group.

Outcomes of ESD in the VE and NE groups

The characteristics of EGC and early outcomes of ESD are summarized in Table 2. There were no significant between group differences in tumor location, macroscopic type, histological type, lesion size, procedure time, length of hospitalization and rate of procedure-related complications. The en bloc resection rate was 100% in both groups, while the complete resection rates in the NE and VE groups were 95.0% and 100%, respectively, with the difference not statistically significant. All patients with incomplete resection refused additional surgery due to their general health conditions and were carefully followed-up.

The median follow-up periods were 1256 days (interquartile range [IQR], 7-3332 days) in the NE group and 1017 days (IQR, 13-3324 days) in the VE group. No patient in either group

Table 2 Short-term outcomes of ESD for patients in the NE and VE groups.

	NE group (N=80)	VE group (N=26)	*p* value
Tumor location			0.5372
Upper third	15 (18.8%)	4 (15.4%)	
Middle third	35 (43.8%)	8 (30.8%)	
Lower third	30 (37.5%)	12 (46.2%)	
Macroscopic type			0.29
Elevated	22 (27.5%)	11 (42.3%)	
Depressed	56 (70%)	15 (57.7%)	
Flat	2 (2.5%)	0	
Histological type			1
Differentiated type	79 (98.75%)	26 (100%)	
Undifferentiated type	1 (1.25%)	0	
Indication			0.2051
Absolute indication	57 (71.3%)	22 (84.6%)	
Expanded indication	23 (28.8%)	4 (15.4%)	
Mean size of lesion (mm)	14.36	15.23	0.7076
ESD procedure time (min)	115.5	81.85	0.1191
Post ESD hospital stay, days(range)	8 (4-42)	8 (6-20)	0.9962
Complications related to procedure			
Delayed bleeding	5 (6.25%)	2 (7.7%)	1
Perforation	1 (1.25%)	0	1
Pneumonia	1 (1.25%)	0	1
En bloc resection rate	80 (100%)	26 (100%)	1
En bloc plus R0 resection rate	76 (95%)	26 (100%)	0.57

experienced local or metastatic recurrence. Three patients in the NE group and one in the VE group died during the follow-up period, but none of these deaths was disease-related. Kaplan-Meier analysis showed that the 3-year overall survival (OS) rates in the NE and VE groups were 100% and 92.8%, respectively, and the 5-year OS rates were 96.1% and 85.7%, respectively, with no significant between group differences by either the log-rank test (p=0.7941) or the Wilcoxon test (p=0.9820) (Fig. 2).

Outside the indications group

The clinical characteristics and short-term outcome of patients in the OI group are summarized in Table 3. Gender distribution, mean follow-up period, comorbidities, and rates of use of antithrombotic agents were similar in very elderly and non-elderly patients in this group. In addition, lesion size, histological type, ulcerative change, vessel infiltration, depth of invasion, ESD procedure time, length of hospitalization, rate of procedure-related complications and en-bloc resection rate did not differ significantly between very elderly and non-elderly OI patients. Because

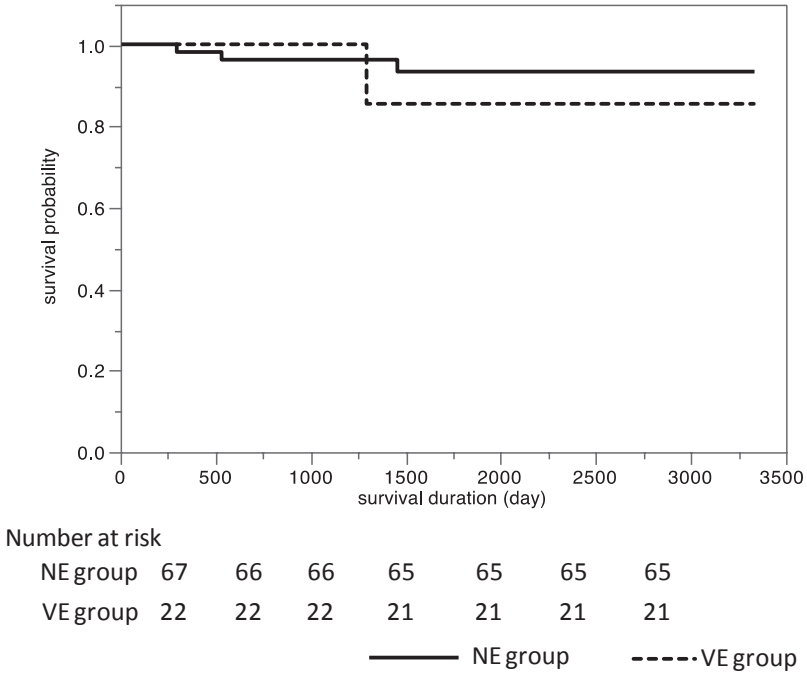

Fig. 2 Kaplan-Meier analysis of survival rates of patients in the VE and NE groups who underwent ESD for EGC. There was no significant between group differences by either the log rank test ($P = 0.7941$) or the Wilcoxon test ($P = 0.9820$).

of the risks of residual lesions and lymph node metastases, nine patients underwent additional gastrectomy with lymph node dissection. The rate of additional gastrectomy tended to be higher in non-elderly than in very elderly OI patients, but the difference did not reach significant difference. Of the nine patients who underwent additional gastrectomy, five had massive submucosal invasive cancer plus angiolymphatic invasion, and one each had M cancer $>$ 3 cm in diameter plus an ulcer, SM1 cancer plus an ulcer, SM1 cancer plus angiolymphatic invasion, and undifferentiated cancer $>$ 3 cm in diameter. Additional gastrectomy revealed a residual lesion in only one non-elderly patient. The remaining nine patients refused surgery because of their age and general health conditions ; these patients were carefully followed-up. One very elderly patient died of pneumonia 18 months after ESD. There were no gastric cancer-related deaths during the observation period.

Discussion

The need to treat very elderly patients with EGC is increasing. ESD has become the treatment of choice for endoscopic resection of EGC because of its higher en bloc and complete resection rates when compared with EMR[8]. However, ESD is more invasive than EMR, with a higher procedure-related complication rate and a longer procedure time. Thus, the feasibility of ESD in non-elderly patients does not guarantee its safety in very elderly patients. ESD was shown safe and feasible for patients aged $\geq$ 75 years with EGC[13~16], but its safety and feasibility in patients aged $\geq$ 80 years remained unclear. Although one previous study found that ESD had favorable short- and long-term outcomes in VE patients aged $\geq$ 80 years, there were no comparisons of outcomes with NE patients[17]. Therefore, this study compared short- and long-term outcomes of ESD in VE patients aged $\geq$ 80 years and NE patients aged $\leq$ 65 years.

Table 3 Histological findings and short term outcome of resected specimens of outside the indications group.

	non-elderly OI group (N=11)	very elderly OI group (N=7)	*p* value
Mean (SD) tumor size	24.4 ± 14.2	30.0 ± 11.0	0.8203
Histological type			0.3260
Well differentiated	9 (81.8%)	4 (57.1%)	
Poorly differentiated	2 (18.1%)	3 (42.9%)	
Ulcerative change UL(+)	2 (18.1%)	1 (14.3%)	1
Vessel infiltration Ly (+) or v(+)	3 (27.2%)	4 (57.1%)	0.3322
Depth of invasion			0.9385
Intramucosal carcinoma	4 (36.3%)	2 (28.5%)	
SM1 (invasion depth ≤ 500μm)	3 (27.2%)	2 (28.5%)	
Massive submucosal invasive carcinoma	4 (36.3%)	3 (42.9%)	
Duration of Hospitalization (day)	11.4	10.9	0.8794
ESD Procedure time	185.6	143.8	0.4568
Complications related procedure			
Later Bleeding	1 (9.1%)	0	1
Perforation	1 (9.1%)	1 (14.3%)	1
pneumoniae	0	1 (14.3%)	0.3889
En-block resection	11 (100%)	7 (100%)	1
Additional gastrectomy	7 (63.64%)	2 (28.57%)	0.1448
Residual lesion	1 (9.09%)	0	1

Compared with younger patients, elderly patients have a greater frequency of comorbidities, including hypertension, cardiovascular disease, diabetes, respiratory disease, liver disease, and dementia. As these comorbidities may affect recovery from ESD, not all elderly patients with EGC can safely undergo ESD. In our department, the indication for ESD was performance status (PS) 0, 1, or 2, but the procedure was allowed in patients with a PS of 3 if they desired it after discussion with their families and the attending endoscopists. This study found no significant differences in early outcomes between the VE and NE groups. En bloc and complete resection rates and post-ESD hospital stay were excellent in both groups, with no significant differences between them. Most importantly, the incidence of procedure-related complications, such as delayed bleeding, perforation and pneumonia, did not differ significantly in the two groups. As expected, the rates of ischemic heart disease and use of antithrombotic agents were significantly higher in the VE than in the NE group, but the rates of myocardial infarction and bleeding requiring transfusion were similar. More importantly, there were no procedure-related deaths in either group. Rates of delayed bleeding and perforation at the time of complication-related procedures were similar, in agreement with previous findings[14]. Complications, once they occur, can be more serious in elderly than in younger patients. After inclusion of the OI group, we found that, of VE patients, two experienced late bleeding and one each experienced perforation and pneumonia. The

patients with late bleeding and perforation were cured easily by endoscopic treatment, and their hospital stays were not prolonged. However, the patient who developed pneumonia experienced a more severe condition. A previous study reported pneumonia rates of 0 % and 0 .5% in patients aged < 65 and ≥ 65 years, respectively[16]. In comparison, this study found that one NE patient (1 .25%) and no VE patients (0 %) developed pneumonia ; when the OI group was included, one NE (1 .09%) and one VE (3 .03%) patient had developed pneumonia. As both patients who developed pneumonia had underlying respiratory disease, pneumonia was likely caused by patient inability to expectorate after ESD[16]. The NE patient who developed pneumonia had a PS of 0 and was cured easily by administration of intravenous antibiotics, without prolongation of hospital stay. In contrast, the VE patient who developed pneumonia had a PS of 2, required a long period of recovery and was not discharged until 24 days after ESD. Regardless of age and PS, care should be taken in performing ESD in patients with respiratory disease, especially in VE patients.

Long-term outcomes were similar in the NE and VE groups, with no patient experiencing local recurrence or metastasis during the follow up period. Three patients in the NE group and one in the VE group died of other diseases, but there were no gastric cancer-related deaths in either group. Thus, long-term outcomes of ESD are as favorable for VE as for NE patients. None of the patients in the OI group showed evidence of local recurrence or metastasis during additional gastrectomy after noncurative ESD. Careful follow up after noncurative ESD may be an option in very elderly OI patients who have difficulties undergoing surgery or are at high risk of death from diseases other than gastric cancer[17]. Similarly, we found no evidence of local recurrence or metastasis in very elderly OI patients who did not undergo additional gastrectomy after noncurative ESD.

This study had several limitations, including its small sample size and retrospective design. In addition, there were differences in operators' level of technical skill in performing ESD.

In conclusion, these findings suggest that ESD is as safe, feasible and effective for the treatment of EGC in VE patients aged ≥ 80 years as in NE patients. ESD is therefore the endoscopic treatment of choice for EGC in VE patients. Large-scale prospective studies are needed, however, to confirm the feasibility of ESD for EGC in VE patients.

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None.

Author Contributions

Study concept and design : Keishi Komori, Kazuhiko Nakamura and Ryoichi Takayanagi.

Acquisition of subjects and/or data : Keishi Komori, Kazuhiko Nakamura, Eikichi Ihara, Tsutomu Iwasa, Minako Hirahashi and Yoshinao Oda.

Analysis and interpretation of data : Keishi Komori, Kazuhiko Nakamura, Eikichi Ihara, Tsutomu Iwasa, Minako Hirahashi, Yoshinao Oda and Ryoichi Takayanagi.

Preparation of manuscript : Keishi Komori

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（和文抄録）

超高齢者における内視鏡的粘膜下層剥離術は早期胃癌に適した治療である：非高齢者との短期成績と長期成績の比較による検討

[1)]九州大学大学院医学研究院 病態制御内科学
[2)]九州大学大学院医学研究院 形態機能病理学

小森圭司[1)]，中村和彦[1)]，伊原栄吉[1)]，岩佐　勉[1)]，
平橋美奈子[2)]，小田義直[2)]，髙柳涼一[1)]

【背景】内視鏡的粘膜下層剥離術は早期胃癌治療のスタンダードとなっている．しかしながら，80歳以上の超高齢者に適した治療であるかはいまだ明らかではない．
【方法】ガイドライン絶対適応内病変と適応拡大病変と診断した89名の患者106症例を65歳以下のNE群，80歳以上のVE群とし両群の比較検討を行った．ガイドラインを満たさない18症例は適応外病変と定義した．
【結果】一括完全切除率はVEとNE両群で良好であり，統計学的有意差は認めなかった．NE群と比較してVE群に虚血性心疾患の併存症と抗血栓薬の使用が多かったが，内視鏡的粘膜下層剥離術における合併症に有意差は認めなかった．
適応外病変の患者18症例のうち7症例が超高齢者であり，うち2名が追加外科切除をうけ，残る5名は経過観察とした．すべての群で局所再発，遠隔転移，胃癌関連死は認めなかった．
【結論】早期胃癌に対する内視鏡的粘膜下層剥離術の短期及び長期成績は超高齢者において非高齢者と同様に良好であった．