World J Surg (2019) 43:571–579
https://doi.org/10.1007/s00268-018-4816-2

ORIGINAL SCIENTIFIC REPORT (INCLUDING PAPERS PRESENTED AT SURGICAL CONFERENCES)

Role of Palliative Resection in Patients with Incurable Advanced Gastric Cancer Who are Unfit for Chemotherapy

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Published online: 8 October 2018

Abstract

Background The REGATTA trial showed that gastrectomy followed by chemotherapy for advanced gastric cancer with a single non-curable factor did not improve survival outcomes in comparison with chemotherapy alone. Chemotherapy is therefore the mainstay treatment for incurable gastric cancer. However, for patients who are unfit for chemotherapy, the role of palliative gastrectomy remains controversial.

Methods We retrospectively identified 207 patients with in curable gastric cancer who underwent palliative gastrectomy or bypass surgery because of urgent symptoms who were treated from 2002 to 2014. Fifty-nine of these patients who did not receive chemotherapy following surgery were enrolled in the present study. The patients were divided into the palliative gastrectomy group (n = 40) and the bypass surgery group (n = 19). The survival outcomes of the two groups were compared. Independent prognostic factors were identified using multivariate analysis.

Results The rate of patients who underwent gastrectomy was significantly higher among patients whose tumors were located in the upper third (n = 19/20, 95%) than in patients whose tumors were located in the lower or middle third (n = 21/39, 54%, p = 0.001). The median survival time (MST) in the gastrectomy group (145 days) was significantly longer than that in the bypass group (86 days) (p = 0.008). Bypass surgery was identified as an independent prognostic factor in the multivariate analysis (HR = 2.3; 95%CI = 1.3–4.2 p = 0.007).

Conclusions Palliative gastrectomy may improve survival in patients with incurable gastric cancer who show emergent symptoms and who are unfit for chemotherapy.

Background

The prognosis of patients with incurable advanced gastric cancer is poor. Chemotherapy is the standard treatment for these patients, and the median overall survival of patients who receive chemotherapy alone is 10.8–13.8 months [1–3].

Patients with incurable advanced gastric cancer often suffer from urgent symptoms such as bleeding or obstruction. Palliative gastrectomy or bypass surgery is generally indicated for such patients.

In the past decade, a number of previous studies demonstrated that palliative resection improved the survival of patients with incurable gastric cancer in comparison with non-resection [4–6]. It is remarkable that the presence of chemotherapy following palliative gastrectomy is a powerful indicator of prolonged survival [7–10]. However, because these studies were retrospective single institutional case series and were confounded by selection bias, the effect of palliative gastrectomy had been considered unclear. The REGATTA trial clarified that

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gastrectomy followed by chemotherapy did not demonstrate a survival benefit in comparison with chemotherapy alone in advanced gastric cancer patients with a single non-curable factor [11].

The number of elderly patients with gastric cancer is increasing. These patients are frequently unfit for chemotherapy due to a poor performance status (PS) or severe comorbidities, such as renal dysfunction or chronic heart disease. The effect of palliative gastrectomy in patients with incurable advanced gastric cancer who cannot receive chemotherapy remains unclear.

The aim of the present study is to determine the role of palliative resection in the treatment of patients with incurable advanced gastric cancer who are unfit for chemotherapy.

Patients and methods

Between November 2002 and December 2014, 207 patients underwent palliative gastrectomy or gastrojejunostomy for incurable advanced gastric cancer with urgent symptoms such as bleeding or obstruction at Shizuoka Cancer Center, Shizuoka, Japan. Fifty-nine of these patients who did not receive chemotherapy were included in this study. In all patients, the pathological examination of biopsy specimens from the stomach revealed adenocarcinoma. Patients who had previously undergone gastrectomy or received chemotherapy for gastric cancer were not included in this study, and patients with only positive peritoneal lavage cytology were not included in this study. The patients' clinicopathological data were collected retrospectively from our database and from the individual patients' records. The reason why the patients did not receive chemotherapy was also investigated from the individual patients' records.

The patients were divided according to the surgical procedure into the palliative gastrectomy group (n = 40) and the bypass surgery group (n = 19).

The clinicopathological data, including age, sex, Eastern Cooperative Oncology Group (ECOG) performance status, body mass index (BMI), urgent symptom, preoperative body weight loss, tumor location, tumor size, macroscopic type, histology, incurable factors (invasion to adjacent organ, peritoneal metastasis, distant lymph node metastasis, and hematogenous metastasis), operative time, estimated blood loss, surgical complication, change of albumin and hemoglobin level, oral intake, and period of oral intake, postoperative blood transfusion and survival outcome were compared between the two groups. Postoperative complications were graded according to the Clavien–Dindo classification [12].

This study followed the ethical guidelines for human subjects and was approved by the institutional review board of the Shizuoka Cancer Center (29-J126-29-1-3).

Pretreatment examination

Patients were diagnosed as having incurable gastric cancer based on contrast enhanced computed tomography findings, and peritoneal metastasis and invasion of the adjacent organs were determined during laparotomy. The clinicopathological features was described according to the Japanese Classification of Gastric Carcinoma 3rd English edition [13].

The diagnosis of bleeding and obstruction

Tumor bleeding was diagnosed according to the presence of symptoms such as hematemesis, tarry stool, and the need for preoperative blood transfusion. All patients with gastric outlet obstruction (GOO) were diagnosed based on the findings of gastrointestinal endoscopy, such as residual food and stenosis.

Indications for gastrectomy or bypass surgery

Patients who underwent palliative gastrectomy or bypass surgery from 2002 to 2014 were enrolled in the present study. During this period, the treatment policy for incurable gastric cancer patients with emergent symptom had not been established. The decision to proceed with resection was made at the discretion of each physician. The extent of gastric resection was defined according to the location of the primary lesion. Reconstruction methods such as Billroth I, Billroth II, or Roux-en-Y reconstruction were selected at the physician's discretion.

Follow-up

Patients underwent follow-up, mainly on an outpatient basis. If patients were transferred to other hospitals, their condition was confirmed by telephone interview. As of January 2015, the overall follow-up rate was 100% (59/59) and the median follow-up period was 130 (17–1089) days.

Assessment of oral intake

The oral intake was assessed by the standardized Gastric Outlet Obstruction Scoring System (GOOSS) (0 = no oral intake, 1 = liquids only, 2 = soft solids, and 3 = almost complete or full diet) [14]. GOOSS was evaluated before the operation, at two weeks after the operation and at three months after operation. When assessing the period of oral intake, the oral intake was defined as eating any kind of

food, including liquid food, regardless of whether the patient received a transfusion. The period of oral intake was defined as the time from the operation to the cessation of oral intake.

Statistical analysis

Continuous data were compared using the Mann–Whitey *U* test. Categorical data were compared using Fisher's exact test. The probability of survival and the period of oral intake were estimated with the Kaplan–Meier method, and the log-rank test was used to compare the two groups. Independent prognostic factors were identified using a Cox proportional hazards model. P values of <0.05 (two-sided) were considered to indicate statistical significance. The Bonferroni method was used to correct p values in multiple evaluations. The statistical analyses were performed using the JMP software program (version 11.2, SAS Institute Inc., Cary, NC, USA).

Results

The major reasons for being unfit for chemotherapy included old age (n = 31; 53%), comorbidities (n = 20; 34%), a poor performance status (n = 14; 24%), the patient's refusal (n = 10; 17%), disease progression (n = 15, 25%), and surgical complications (n = 10, 17%).

The patient characteristics are shown in Table 1. The gastrectomy and bypass groups included 40 patients and 19 patients, respectively.

There were no significant differences between the two groups with respect to age, sex, ECOG PS, BMI, preoperative body weight loss, tumor size, macroscopic type, and histology. The incidence of tumor bleeding was significantly higher in the gastrectomy group (n = 20/40, 50%) than the bypass group (n = 3/18, 16%, p = 0.021), while the incidence of gastric outlet obstruction was significantly higher in the bypass group (n = 19/19, 100%) than the gastrectomy group (n = 31/40, 78%, p = 0.047). Therefore, the incidence of GOOSS 0–1 was higher in the bypass group (n = 14/19, 74%) than in the gastrectomy group (n = 18/40, 45%, p = 0.031). The rate of patients who underwent gastrectomy was significantly higher among patients whose tumors were located in the upper third (n = 19/20, 95%) than in patients whose tumors were located in the lower or middle third (n = 21/39, 54%, p = 0.001). More than half of the patients had ≥2 incurable factors, and there were no significant differences in the number of incurable factors between the groups. Among the 40 patients in the gastrectomy group, 24 (60%) patients underwent TG and 16 (40%) patients underwent DG. All patients underwent gastrectomy by an open approach and combined resection of other organs was performed in 10 (25%) of the patients; pancreatic body and spleen (n = 2, 5%), spleen (n = 2, 5%), small intestine (n = 1, 3%), gallbladder (n = 2, 5%). In the gastrectomy group, the operative time was significantly longer and the amount of blood loss was significantly greater. Surgical complications classified as Clavien–Dindo Grade ≥III were observed in 10 patients (10/40, 25%), all of whom were in the gastrectomy group. Three cases of anastomotic leakage (TG: 2, DG: 1), 3 cases of ileus (TG: 2, DG: 1), 2 cases of intraabdominal bleeding (TG: 1, DG: 1), and 4 cases of intraabdominal abscess (TG: 4) occurred. One patient who underwent DG died due to intraabdominal bleeding on postoperative day 17. The 30-day mortality rate was 2.5% (1/40). There were no statistically significant differences in the postoperative complication rates of the DG and TG groups (TG: 29%, 7/24, DG: 19%, 3/16; p = 0.71).

The median survival time (MST) in all the patients was 130 days, and the one-year survival rate was 5.1%. Figure 1 shows the overall survival curves in the gastrectomy and bypass groups. The MST in the gastrectomy group (145 days) was significantly longer than that in the bypass group (86 days) (p = 0.008).

The numbers of patients who died due to early tumor progression within 30 days after surgery were 4/40 (10%) in gastrectomy group and 1/19 (5.3%, p = 1.0) in the bypass group. Although the gastrectomy group showed better survival in comparison with the bypass surgery group, the incidence of early tumor death in the two groups did not differ to a statistically significant extent.

Figure 2 shows the overall survival curves of the patients who underwent TG, DG and bypass surgery. The MSTs of the patients who underwent TG, DG and bypass surgery were 168, 132, and 86 days, respectively. The survival of the patients who underwent TG and DG did not differ to a statistically significant extent (p = 0.86). The MST of patients who underwent TG or DG tended to be longer in comparison with those who underwent bypass surgery (p = 0.019, p = 0.048, respectively).

The survival outcomes of patients who underwent bypass surgery and the patients who suffered postoperative complications (C–D grade ≥III) were compared. The MSTs of the patients who underwent bypass surgery and the patients who suffered postoperative complications after gastrectomy were 86 and 122 days, respectively (p = 0.54). The survival of the patients who underwent bypass surgery and the patients who suffered complications after gastrectomy did not differ to a statistically significant extent.

Table 2 shows the results of the univariate and multivariate analyses. Bypass surgery was identified as an independent prognostic factor in the multivariate analysis

Table 1 Clinicopathological characteristics of patients

	Gastrectomy (n = 40)		Bypass (n = 19)		p value
Age	77	(48–86)	78	52–90	0.23
Sex					
Male	33	(83%)	13	(68%)	0.31
Female	7	(17%)	6	(32%)	
ECOG PS					
0	19	(48%)	12	(63%)	0.47
1	16	(40%)	6	(32%)	
2	5	(12%)	1	(5%)	
BMI	21.2	(14.7–29.8)	21.5	(12.5–27.2)	0.53
Tumor bleeding					
Yes	20	(50%)	3	(16%)	0.021
No	20	(50%)	16	(84%)	
Gastric outlet obstruction					
Yes	31	(78%)	19	(100%)	0.047
No	9	(22%)	0	(0%)	
GOOSS					
0	5	(13%)	7	(37%)	0.031
1	13	(32%)	7	(37%)	
2	15	(37%)	1	(5%)	
3	7	(18%)	4	(21%)	
Body weight loss $\geq$10%					
Yes	8	(20%)	2	(11%)	0.48
No	32	(80%)	17	(89%)	
Tumor location					
U	19	(47%)	1	(5%)	0.001
M/L	21	(53%)	18	(95%)	
Tumor size	98	(30–140)	100	(20–120)	0.52
Macroscopic type					
Non Type 4	30	(75%)	13	(68%)	0.76
Type 4	10	(25%)	6	(32%)	
Histology					
Differentiated type	15	(37%)	8	(47%)	0.56
Undifferentiated type	25	(63%)	9	(53%)	
Number of incurable factors					
1	17	(42%)	7	(37%)	0.78
$\geq$2	23	(58%)	12	(63%)	
Invasion to adjacent organ					
Yes	28	(70%)	13	(68%)	1.0
No	12	(30%)	6	(32%)	
Peritoneal metastasis					
Yes	26	(65%)	14	(32%)	0.56
No	14	(35%)	5	(26%)	
Distant lymph node metastasis					
Yes	12	(30%)	2	(11%)	0.19
No	28	(70%)	17	(89%)	
Hematogenous metastasis					
Yes	6	(15%)	2	(11%)	1.0
No	34	(85%)	17	(89%)	

Table 1 continued

	Gastrectomy (n = 40)		Bypass (n = 19)		p value
Operative procedure					
Total gastrectomy	24	(60%)	–	–	–
Distal gastrectomy	16	(40%)	–	–	
Lymph node dissection					
D0	4	(10%)	–	–	–
D1	29	(73%)	–	–	
D1+	6	(15%)	–	–	
D2	1	(2%)	–	–	
Combined resection (total)	10	(25%)	–	–	
Pancreatic body and spleen	2	(5%)	–	–	
Spleen	2	(5%)	–	–	
Colon	2	(5%)	–	–	
Small intestine	1	(3%)	–	–	
Gallbladder	2	(5%)	–	–	
Operative time (min)	190	(97–366)	87	(40–186)	<0.001
Estimated blood loss (g)	457	(66–5883)	16	(0–83)	<0.001
Surgical complication (total)	10	(25%)	0	(0%)	0.022
Leakage	3	(8%)	0	(0%)	
Pancreatic fistula	1	(3%)	0	(0%)	
Abdominal abscess	4	(10%)	0	(0%)	
Ileus	3	(8%)	0	(0%)	
Intraabdominal bleeding	2	(5%)	0	(0%)	

ECOG PS Eastern cooperative oncology group performance status, *BMI* body mass index

Surgical complication: Clavien–Dindo classification III or more, GOOSS, Gastric Outlet Obstruction Scoring System (0 = no oral intake, 1 = liquids only, 2 = soft solids, and 3 = almost complete or full diet)

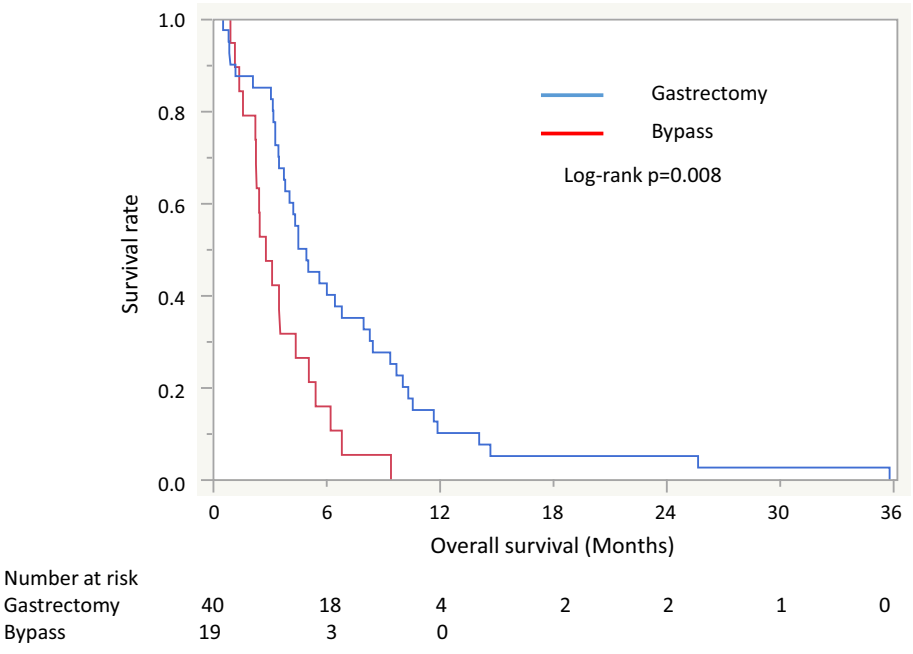

Fig. 1 The survival curves of the patients with and without gastrectomy

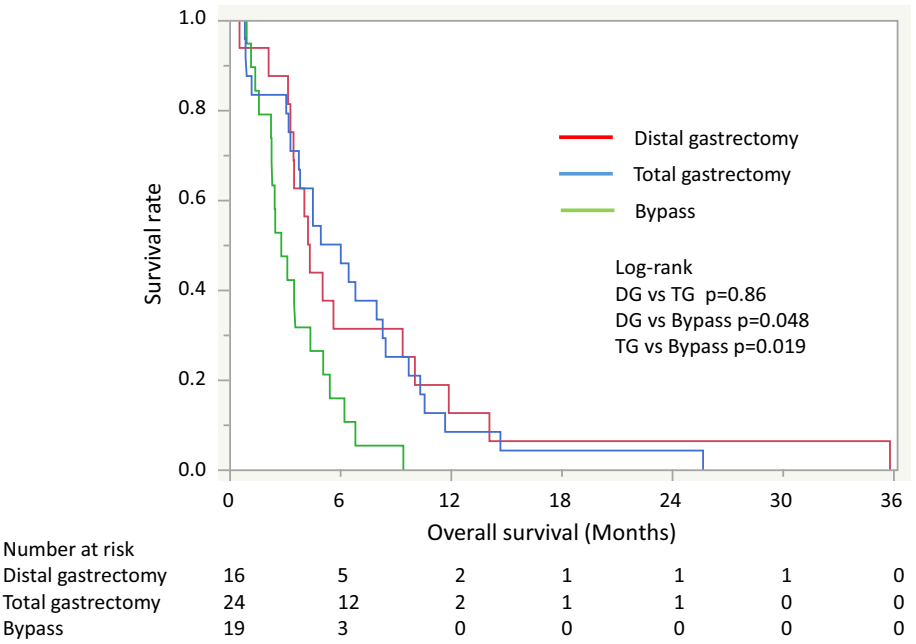

Fig. 2 The survival curves of the patients with total gastrectomy, distal gastrectomy and bypass surgery

Table 2 Prognostic factors on the univariate and multivariable analysis

Variables	Univariate analysis			Multivariable analysis		
	HR	95%CI	*p* value	HR	95%CI	*p* value
Age (<80 vs. ≥80)	0.70	0.40–1.2	0.18			
Sex (Male vs. Female)	1.0	0.50–1.9	0.97			
BMI (<18.5 vs. ≥18.5)	0.83	0.43–1.5	0.56			
Tumor bleeding (absent vs. present)	0.74	0.43–1.3	0.28			
Stenosis (absent vs. present)	0.77	0.38–1.8	0.52			
Body weight loss ≥10% (absent vs. present)	0.93	0.44–1.8	0.84			
Number of incurable factors (1 vs. ≥2)	2.1	1.2–3.8	0.007	2.1	1.2–3.7	0.009
Tumor size (<80 vs. ≥80 mm)	1.0	0.60–1.8	0.95			
Macroscopic type (type 0–3 vs. 4)	1.5	0.80–2.7	0.20			
Tumor location (L/M vs. U)	0.67	0.38–1.1	0.14			
Blood transfusion (no vs. yes)	0.69	0.38–1.2	0.19			
Histology (differentiated vs. undifferentiated)	1.3	0.74–2.2	0.38			
Operation type (Gastrectomy vs. Bypass)	2.4	1.3–4.3	0.005	2.3	1.3–4.2	0.007
Complication CD grade (0/I vs. ≥II)	0.73	0.42–1.2	0.25			

BMI body mass index, *CD grade* Clavien–Dindo grade

(HR = 2.3; 95%CI = 1.3–4.2 $p = 0.007$). Although prognostic factors were explored in variables that contained postoperative complications and body weight loss, these factors were not selected as individual prognostic factors in the present study.

Figure 3 shows the period of oral intake in the gastrectomy and bypass groups. The period of oral intake after surgery in the gastrectomy group (140 days) was significantly longer than that in the bypass group (67 days, $p = 0.023$).

Concerning the postoperative GOOSS values of the gastrectomy and bypass groups, at two weeks after the operation, the GOOSS recovered to 2 or 3 in almost all of the patients in both groups (80% vs. 84%, $p = 1.0$). At three months after the operation, the percentage of patients with GOOSS 2 or 3 in the gastrectomy group (83%) tended

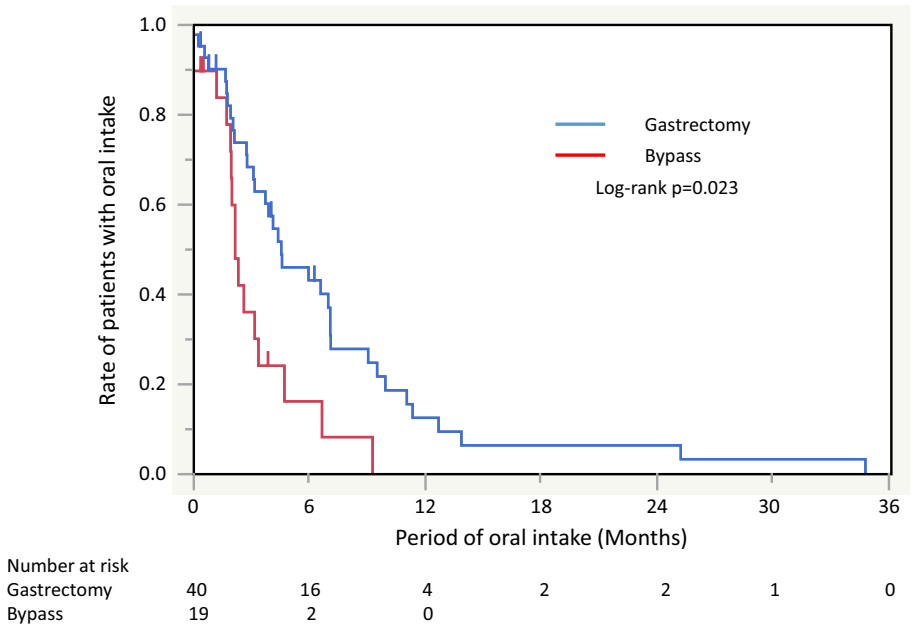

Fig. 3 The period of oral intake in the gastrectomy and bypass groups, as compared using the Kaplan–Meier method

to be higher than the percentage in the bypass group (50%, $p = 0.071$).

The postoperative serum albumin levels of the two groups did not differ to a statistically significant extent. However, at two months after surgery, the hemoglobin level of the gastrectomy group was significantly higher than that of the bypass group (10.8 vs. 9.8 g/dl, $p = 0.049$). The incidence of blood transfusion in the gastrectomy and bypass groups did not differ to a statistically significant extent (13% vs. 26%, $p = 0.27$).

Discussion

This study investigated the availability of palliative resection as a treatment for patients with incurable gastric cancer who were unfit for chemotherapy using retrospective data from a single institution. Our results demonstrated that the survival of the patients who underwent palliative gastrectomy was longer in comparison with those who underwent bypass surgery. The multivariate analysis revealed that bypass surgery was independently associated with poor survival.

The eligibility criteria of previous retrospective studies that showed the efficacy of palliative resection were uncertain with regard to emergency symptoms. Furthermore, the REGATTA trial did not include patients with urgent symptoms, and protocol defined patients who randomized into both arm had received chemotherapy following palliative gastrectomy or not. Thus, the effectiveness of palliative gastrectomy for incurable gastric cancer patients with urgent symptoms and who are unfit for chemotherapy is unknown. The present study is the first report to demonstrate the role of palliative resection in patients with incurable advanced gastric cancer who have an urgent symptom and who are unfit for chemotherapy.

The median overall survival of patients with incurable advanced gastric cancer who undergo chemotherapy alone is 10.8–13.8 months [1–3]. The median survival time of all patients in the present study was approximately 5 months. The survival time in the present study was less than half that of previously reported trials. Because all patients did not received chemotherapy and suffered urgent symptom in the present study. This study showed survival in patients who received the best supportive care and who underwent surgical intervention to relieve urgent symptoms.

In our study, the decision to perform resection or bypass surgery was made according to each physician's preference. The policy of treatment for incurable gastric cancer patients with urgent symptoms had not been established. Even if the tumor was found to have invaded adjacent organs, palliative gastrectomy was sometimes preferentially selected by the physician. The backgrounds of the patients in the gastrectomy and bypass groups differed in several points. The incidence of tumor bleeding and U-lesion tumors was significantly higher in the gastrectomy group. If the tumor was located in the upper third of the stomach, physicians tended to select palliative gastrectomy because at this location, surgeons could not find unaffected gastric wall suited anastomosis site due to tumor invasion. Physicians tended to select palliative gastrectomy for patients who suffered from tumor bleeding because physicians thought that bypass surgery was not sufficient for completely preventing tumor re-bleeding.

In our study, the decision as to whether or not to perform lymphadenectomy in the gastrectomy group was made according to each physician's preference. The impact of lymphadenectomy on survival was investigated in patients who underwent palliative gastrectomy. The MSTs of the patients who underwent D2 or D1+ and D1 or D0 were 258 and 136 days, respectively. The survival of the patients who underwent D2 or D1+ and D1 or D0 did not differ to a statistically significant extent ($p = 0.092$). The extent of lymphadenectomy may not influence the reduction in the tumor burden.

In the present study, incidence of postoperative complication (Clavien–Dindo grade ≥II: 37.5%, ≥III: 25.0%) is slightly higher than in the patients who received curative gastrectomy. It has been reported to be 20.9% of patients receive D2 lymph node dissection [15], while 16.1% of patients receive total gastrectomy without splenectomy [16]. On the other hand, the rate of morbidity in patients undergoing palliative gastrectomy was reported to be approximately 35% [7, 17]. We compared the incidence of complications and early tumor death between patients with upper gastric cancer and those with middle or lower gastric. Among 19 patients whose tumors were located in the upper third of the stomach, 18 patients underwent TG and 1 patient underwent DG. Among these patients, surgical complications of Clavien–Dindo Grade ≥III were observed in 5 patients (26%). This did not differ from the rate in patients with middle or lower gastric cancer (5/21, 24%) to a statistically significant extent ($p = 1.00$). In addition, the number of the patients who died due to early tumor progression within 30 days after surgery was 2/19 (11%) among patients whose tumor was located in the upper third of the stomach and 2/21 (10%) in patients with tumors in other locations; the difference was not statistically significant ($p = 1.0$). Thus, even though total gastrectomy is considered to be an invasive procedure, the postoperative complications and short-term survival was not worse in patients who underwent palliative gastrectomy for upper gastric cancer.

This study showed that palliative TG had a survival benefit in unresectable gastric cancer patients who were unfit for chemotherapy. In contrast, the REGATTA trial showed that gastrectomy plus chemotherapy was associated with significantly worse survival in patients with tumors located in the upper third. In patients with tumors located in the upper third, the number of chemotherapy cycles after gastrectomy was reduced in comparison with patients who received chemotherapy alone. It was presumed that impaired compliance with chemotherapy after TG worsened their survival [11]. The present study did not include patients who received chemotherapy. Thus, impaired compliance to chemotherapy had no influence in either group. The results suggested that palliative gastrectomy including TG reduced the tumor burden, and thus prolonged the survival of patients with incurable gastric cancer who had urgent symptoms.

Although our study showed that palliative resection had a favorable survival benefit, it was associated with several limitations. First, it was a retrospective study that was performed in a single institution with a relatively small study population. Secondly, the decision to perform resection or bypass surgery was made according to the preference of each physician. A selection bias might have existed due to the retrospective nature of the study.

In conclusion, the results of the present study show that palliative gastrectomy may improve survival in patients with incurable advanced gastric cancer who show urgent symptoms and who are unfit for chemotherapy.

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