Hypothesis: For distant metastatic (M1) gastric adenocarcinoma, a policy to maximally avoid resection of the primary tumor is safe and efficacious.

Design: Cohort study.

Setting: Academic tertiary care center.

Patients: Sixty-seven (32%) of 211 consecutive patients with adenocarcinoma of the stomach or gastroesophageal junction had synchronous M1 disease on computed tomography or laparoscopy. Sixty-three patients with M1 disease were treated nonoperatively, and complete data sets were available for 40 men and 15 women (median age, 73 years). Pretreatment functional performance status was good in 67%. The primary tumor was at the gastroesophageal junction in 20% and was poorly differentiated in 60%. The M1 disease involved the peritoneum in 80% or was exclusively nonperitoneal in 20%. Systemic chemotherapy was administered to 67%.

Main Outcome Measures: Incidence of subsequent invasive intervention for primary tumor–related complications and survival in 55 nonoperatively managed patients with M1 disease.

Results: Fourteen patients (25%) had intervention a median of 5 months after diagnosis. Eight patients had more than 1 intervention. Intervention was for gastric obstruction (20%), bleeding (7%), or perforation (2%). No patient underwent gastrectomy. Laparotomy was performed in 9%; the remainder had endoscopic or radiologic procedures or radiotherapy. There was no intervention-related mortality. Median survival was 7 months (95% confidence interval, 4-10 months). In Cox regression univariate analysis, good functional performance status, exclusively nonperitoneal metastasis, nonpoor differentiation, and chemotherapy predicted significantly longer survival; chemotherapy was the only independently significant predictive factor.

Conclusions: Palliative interventions were performed in 25% of patients, with no mortality. Survival characteristics were similar to those of previous series of noncurative gastrectomy for M1 disease.

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vasive procedure for worsening or new-onset symptoms is unquantified.

For patients with newly diagnosed gastric adenocarcinoma and synchronous M1 disease, we adopted a strategy to maximally avoid surgery and to consider early systemic chemotherapy. Subsequent palliative intervention was reserved for specific symptoms and was not undertaken on a preemptive or anticipatory basis. For such a cohort of patients, this study examined (1) the incidence and type of palliative procedures for primary tumor–related complications and (2) survival characteristics.

**METHODS**

A database of all the patients who had been referred to the Upper Gastrointestinal Surgery Unit at The General Infirmary at Leeds, Leeds, England, with newly diagnosed adenocarcinoma of the gastroesophageal junction (GEJ) or stomach between October 1, 2001, and October 31, 2004, was prospectively maintained. The primary tumor location was identified at endoscopy, and a diagnosis of adenocarcinoma was confirmed by means of histopathologic examination of endoscopic biopsy specimens. Radiologic staging was conducted using spiral computed tomography (CT) of the thorax and abdomen. Computed tomographic scanning and interpretation was conducted using a modification of the technique that has been previously described at The General Infirmary at Leeds. Based on the accuracy of CT staging in this previous study, laparoscopy was conducted selectively, mainly for patients with suspected peritoneal disease on CT. Laparoscopic staging was conducted using a standardized 3-port technique with sequential, thorough examination of the supracolic and infracolic compartments. Magnetic resonance imaging of the liver was liberally used for further characterization of abnormalities identified on CT. Positron emission tomography was not routinely available during this study. Functional performance status (FPS) was assessed according to the system of the Eastern Cooperative Oncology Group.

As per the directives of the UK National Health Service Cancer Plan, each case was discussed and a clinical management plan was formulated at a weekly multidisciplinary meeting of surgeons, medical oncologists, radiation oncologists, gastroenterologists, radiologists, pathologists, palliative care physicians, and specialist nurses. Patients with M1 disease were closely monitored by local community–based members of the palliative care team, with regular follow-up at surgical, radiation, or medical oncology clinics. Decisions regarding palliative interventions were tailored according to the requirements and goals of individual patients.

For this study, all patients with newly diagnosed gastric adenocarcinoma and synchronous M1 disease were identified. The volume of peritoneal metastasis in individual patients was categorized as limited (perigastric or upper abdominal disease) or extensive (widely disseminated) according to radiology or laparoscopy reports. Similarly, liver disease was classified as limited (single or multiple metastasis in 1 lobe) or extensive (bilocar metastasis). Follow-up medical records were reviewed in detail to determine (1) the incidence of any subsequent invasive procedure for palliation and (2) survival. Patients who did not undergo gastrectomy because of locoregionally advanced (but M0) disease, high-risk perioperative status, or personal preference and those who underwent palliative procedures for locoregionally advanced (M0) disease were specifically excluded from this study.

This work was classified as a clinical audit. A software program (SPSS version 10.0 for Windows; SPSS Inc, Chicago, Ill) was used for statistical analysis. Summary data are given as median (range). The association between the incidence of intervention and clinical characteristics was examined using the χ² test. Survival was estimated using the method of Kaplan-Meier, and comparisons were made by use of a log-rank test. The Kaplan-Meier method was also used to compute the cumulative hazard of stomach-related palliative intervention. For this analysis, a stomach-related intervention was taken as the event of interest, and patients with no intervention were treated as censored observations. For patients who had more than 1 intervention, only the first intervention was counted as an event. Prognostic variables were investigated using forward and backward Cox regression analysis. P ≤ .05 was considered statistically significant.

**RESULTS**

A total of 211 new patients were seen during the study period. Three patients were terminally ill at diagnosis, and staging CT was deemed unnecessary. Radiologic staging was performed for the remaining 208 patients. After multidisciplinary discussion, 87 patients did not undergo any surgical intervention (Figure 1). Of these 87 patients, 45 had radiology–determined M1 disease and were included in the present study. The remaining 42 patients had radiologic M0 disease but were treated nonsurgically because of extraordinarily high perioperative risk factors, locoregionally advanced tumor, or patient preference and were not included in this study. A second group of 57 patients had staging laparoscopy, and M1 disease was laparoscopically detected in 16. These 16 patients did not have any further surgical intervention and were included in the present study. Of the 41 patients with laparoscopic M0 disease, 3 were false-negative cases. One patient had an “open-close” procedure after detection of M1 disease at laparotomy and was retained in this study because of the intention to treat nonoperatively. The remaining 2 patients with false-negative laparoscopic findings had a noncurative gastrectomy after detection of M1 disease at laparotomy. A third group of 62 patients proceeded to laparotomy after radiologic staging. Of these 62 patients, 2 had M1 disease on CT and it was decided to perform palliative gastrectomy. The M1 disease was unexpectedly detected at laparotomy in a third patient, who was radiologically staged M0; no further procedure was performed, and this patient was included in the present study on an intention-to-treat basis. Thus, M1 disease was detected in 67 patients with newly diagnosed stomach or GEJ adenocarcinoma. Four patients with M1 disease had a noncurative gastrectomy: 1 patient required repeated laparotomy for postoperative hemorrhage, another patient developed a deep wound infection, and a third patient had abdominal wound dehiscence. The range of postoperative survival of these 4 patients was 1 to 14 months. The remaining 63 patients were treated with intent to avoid surgery. Of the 63 patients with a plan for nonoperative management, 8 had follow-up care outside The General Infirmary at Leeds. Because complete follow-up data were not available for these 8 patients, the present study focused on the remaining 55 patients, for whom compre-
had a "Open-Close" procedure.

311 Patients With a New Diagnosis of Gastric Adenocarcinoma

208 Underwent Radiologic Staging

87 Patients Had No Surgery

57 Patients Had Laparoscopy

62 Patients Had Laparotomy

2 Patients Had EMR

45 Had Radiologic M1 Disease

30 Had Radiologic M0 Disease and Were Unfit/Unwilling for Operation

12 Had Radiologic M0 Disease and Were Locoregionally Advanced

16 Had Laparoscopic M1 Disease

41 Had Laparoscopic M0 Disease

3 Had False-Negative M0 Disease (M1 at Laparotomy)

2 Had Gastrectomy

1 Had an "Open-Close" Procedure

2 Had Radiologic M1 Disease and Palliative Gastrectomy

1 Had Radiologic M0 Disease But M1 Disease at Laparotomy and an "Open-Close" Procedure

response to chemotherapy was monitored by means of CT. Thirteen patients proceeded to receive second-line chemotherapy.

**INTERVENTION**

Of the 55 patients with M1 disease and no resection, 28 (51%) were admitted to the hospital on a median of 2 occasions (range, 1-7 occasions) subsequent to diagnosis. The median duration of total hospital stay was 15 days (range, 1-53 days). The median interval between diagnosis and the first hospital admission was 5 months. Fourteen patients (25%) underwent a primary tumor–related invasive procedure (Figure 2). Eight patients (15%) had more than 1 intervention, with a maximum of 3 interventions for any one patient. The need for palliative intervention because of any stomach-related symptom (ie, obstruction, bleeding, or perforation) was not significantly associated with a pattern of exclusively nonperitoneal metastasis vs peritoneal metastasis (18% vs 27%; P = .7); poor histologic differentiation vs nonpoor differentiation (23% vs 27%; P = .8); chemotherapy vs no chemotherapy (30% vs 17%; P = .3); FPS 0 to 1 vs FPS 2 to 3 (27% vs 22%; P = 1.0); or men vs women (28% vs 20%; P = .7).

Eleven patients (20%) underwent a total of 15 procedures for gastric luminal obstruction (Figure 2). Two of these 11 patients also had a separate intervention for bleeding. Three patients underwent laparotomy for insertion of feeding jejunostomy tubes (tumor location in the GEJ, proximal stomach, or whole stomach). Other interventional procedures included GEJ stenting (4 events), radiation to the GEJ (4 events), endoscopic photodynamic therapy to the GEJ (2 events), endoscopic pyloroduodenal stenting (1 event, antral tumor), and placement of a nasojejunal feeding tube (1 event, whole-stomach tumor). Thus, 7 (64%) of 11 patients with GEJ tumors had intervention for obstruction compared with 4 (9%) of 44 patients with strictly gastric tumors (P < .01).

Blood was transfused in 18 patients (33%). A median of 4 U (range, 2-20 U) of packed red blood cells was trans-
fused. Four patients (7%) underwent a total of 6 interventional procedures for gastric bleeding; there was 1 laparotomy, with intent to perform gastrectomy, for problematic bleeding (Figure 2). The tumor was judged to be unresectable at laparotomy, and a feeding jejunostomy tube was inserted for anticipated nutritional support. Of the remaining interventional procedures, endoscopic argon plasma coagulation was used on 4 separate occasions. Finally, in 1 case, an endoscopic band was applied to a discrete bleeding point.

One patient was admitted to the hospital with perforation of the gastric tumor (Figure 2). This was a 46-year-old man with a middle body tumor and extensive peritoneum-only disease at laparoscopy. The perforation occurred 5 weeks after diagnosis, soon after commencing epirubicin, cisplatin, and fluorouracil chemotherapy. He underwent a laparotomy with suture repair of the perforation and spent 20 days in the hospital, without any major perioperative complication.

Apart from the 14 patients who underwent a stomach-related intervention, an entirely different group of 8 patients (14%) underwent intervention for complications due to distant metastasis. Nine separate interventions were performed: abdominal paracentesis (6 events), biliary stenting (1 event), inferior vena cava stenting (1 event), and bilateral ureteric stenting (1 event). Thus, 22 patients (40%) underwent any intervention, either stomach related or distant. The incidence of any intervention (stomach related or distant) seemed higher in patients with peritoneal metastasis compared with those with exclusively nonperitoneal disease (8 vs 4 months; \(P = .3\)). In multivariate analysis, only chemotherapy retained independently significant predictive value (Table). For the subgroup of patients who received chemotherapy, survival was significantly longer for those with exclusively nonperitoneal disease (median survival, not reached; 1-year survival, 78%) compared with those with peritoneal disease (median survival, 8 months; 1-year survival, 43%; \(P = .02\)).

**SURVIVAL CHARACTERISTICS**

Of the 55 patients with M1 disease and no gastrectomy, 13 were alive at last analysis. Median follow-up for the living patients was 13 months (range, 6-33 months). Actuarial survival after diagnosis was 35% at 1 year and 16% at 2 years (Figure 3). Median survival was 7 months (95% confidence interval, 4-10 months). Eight patients were alive for more than 1 year, and 2 patients survived for more than 2 years. It was estimated that 48% of patients who survive up to 1 year after diagnosis require a stomach-related palliative intervention (Figure 4). In univariate Cox regression analysis, FPC 0 to 1, exclusively nonperitoneal metastasis, histologic grade other than poor, and chemotherapy predicted significantly longer survival (Table). Age and incidence of stomach-related palliative intervention were not statistically significantly associated with survival. For patients with peritoneal metastasis, median survival seemed to be longer in patients with limited-volume disease compared with extensive disease, but the difference was not significant (8 vs 4 months; \(P = .3\)). In multivariate analysis, only chemotherapy retained independently significant predictive value (Table). For the subgroup of patients who received chemotherapy, survival was significantly longer for those with exclusively nonperitoneal disease (median survival, not reached; 1-year survival, 78%) compared with those with peritoneal disease (median survival, 8 months; 1-year survival, 43%; \(P = .02\)).

**COMMENT**

This study explored the role of surgery for patients with newly diagnosed gastric adenocarcinoma and synchronous distant metastasis. It was our philosophy that such patients had incurable disease and that surgery should be performed only to palliate specific symptoms that could not be addressed by nonsurgical modalities. The concept of nonsurgical management of metastatic gastric carcinoma is not novel. In the setting of M1 disease, several investigators\(^{9-12}\) compared patients who had gastrectomy with those who did not have resection and proposed that gastrectomy may prevent future complications and prolong survival. Such earlier studies do not state a previously decided treatment policy, and selection bias in favor of operating on patients with good performance status and low disease burden is likely. Similar arguments have been previously applied to the management of the primary tumor in patients with incurable stage IV rectal carcinoma.\(^{13}\) Systematic investi-
gation has shown that, in fact, only a small proportion of patients with unresected primary colorectal tumors require intervention and that such patients do not experience any survival disadvantage.14,15

For patients with incurable gastric carcinoma, appropriate treatment goals center around optimization of quality of life, symptom relief, and survival, with minimum treatment-related complications.16 Decision making about palliative intervention is complex and is based on the interplay of several factors, such as the symptom constellation, availability of expertise in different treatment modalities, anticipated efficacy of various procedures, and estimated risks of intervention. A critical triangle, between the patient, family members, and surgeon, that clarifies and defines the goals of each patient’s individual treatment has been described.17 In the present study, only 6% of patients with M1 disease underwent a palliative gastrectomy, and the remainder were treated with the intent to avoid an operation. Because serial data on symptom severity and quality of life were not prospectively recorded, interventional procedures for complications related to the primary tumor were used as a surrogate for the efficacy of the present strategy of nonoperative management. Previous studies of surgical palliation have adopted a similar approach to measure clinically significant events.14,15

In the present study, 25% of nonoperatively treated patients required a subsequent intervention for a primary tumor–related complication. It may be argued that such a subsequent intervention could have been prevented by “preemptive” gastrectomy. However, even in large-volume centers, noncurative gastrectomy is associated with substantial morbidity (>50%) and mortality (6%). Another large, contemporary series12 reports perioperative mortality of 12%. In contrast, there was no intervention-related mortality in the present study. Length of hospital stay in the present study compares favorably with a mean perioperative hospital stay of 18 days in a previously reported large series of noncurative gastrectomy.18 The efficacy of the various nonsurgical palliative interventions was not evaluated in the present study, and it is difficult to make meaningful comparisons with the palliative efficacy of gastrectomy. A large, prospective study19 of surgical palliation reports no difference in the frequency of symptom resolution with endoscopic procedures or operation. Also, up to 10% of patients who undergo a noncurative gastrectomy subsequently require further palliative intervention.18

In the present study, 20% of nonoperatively treated patients required intervention for gastric obstruction. The spectrum of interventional procedures was dictated by locally available expertise. For example, percutaneous en-

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Abbreviations: CI, confidence interval; ECOG FPS, Eastern Cooperative Oncology Group functional performance status; HR, hazard ratio; NA, not applicable.

Figure 3. Kaplan-Meier analysis of survival for 55 patients with synchronously metastatic adenocarcinoma of the stomach or gastroesophageal junction and an unresected primary tumor (median survival, 7 months; 1-year actuarial survival, 35%).

Figure 4. Kaplan-Meier analysis of the cumulative hazard of need for a palliative intervention for symptoms related to an unresected primary tumor in patients with M1 gastric adenocarcinoma (estimated cumulative hazard of 48% at 1 year).
dososcopic jejunostomy was not available at The General Infirmary at Leeds; hence, laparotomy was used for the placement of jejunostomy feeding tubes. Advances in endoscopic therapy, such as the relatively recent popularization of self-expanding gastroduodenal stents,²⁰ may further diminish the need for surgical palliation in gastric cancer.

One third of the nonoperatively treated patients received a blood transfusion during follow-up. In addition to tumor bleeding, anemia may have been caused by chemotherapy-related toxic effects, nutritional deficiencies, hemolysis, or suppressed hematopoiesis.²¹ Apart from endoscopic therapy, tumor bleeding can be satisfactorily controlled by a short course of high-dose-per-fraction radiotherapy, although this may not be effective if a large vessel has eroded.²² One patient required an operation for gastric tumor perforation during chemotherapy. Perforation is a potentially lethal event, but it is rare and, in a large series of gastric cancer at any stage, no more than 2% of patients had this complication.²³ Use of new biological agents, such as bevacizumab, which has a toxicity profile of perforation, may require particularly careful reconsideration of a nonoperative strategy.²⁴

The presently reported median survival of 7 months compares favorably with median survival of 8 to 10 months in previous series of gastrectomy for selected patients with metastatic disease.⁹,¹² The present study was not designed to examine the role of chemotherapy, which was administered only to a selected group, but the data highlight the survival benefit of commencing systemic treatment soon after diagnosis. The particularly adverse prognostic implications of peritoneal metastasis are consistent with similar data about colorectal cancer.²⁵ The volume of metastatic disease did not affect prognosis, and this may be partly due to the recognized difficulty with radiologic quantification of peritoneal disease.²⁶ Functional performance status is an important prognostic factor in advanced malignancy¹⁹, in the present study, the prognostic effect of FPS seemed to be related to selection for chemotherapy. Low serum albumin levels, weight loss, and anemia are also likely to be important prognostic factors.¹⁹ Anticipated survival characteristics define a period during which symptoms must be controlled and add a useful perspective in consideration of the risk-benefit ratio of intervention, particularly to help patients decide their own treatment preferences.²⁶

There is limited evidence that highly selected patients with M1 gastric carcinoma may benefit from curative intent strategies that incorporate systemic and local chemotherapy and radical surgery.²⁷,²⁸ Young patients with low-volume metastatic disease are particularly likely to have a small survival benefit from resection.¹² In our opinion, such curative intent approaches should be undertaken only in specialist centers. For most of the remaining patients, the treatment paradigm is one of noncurative intent. A clinical trial that randomizes patients with newly diagnosed M1 gastric adenocarcinoma to gastrectomy vs no gastrectomy is unlikely to be successful, and surgical strategy must be guided by series such as the present one. The relatively low incidence (25%) and safety (0% mortality) of palliative interventions provide compelling reasons to reserve noncurative resection for preemption of anticipated symptoms for only exceptional circumstances. Truly palliative gastrectomy is likely to remain necessary for selected patients but should be undertaken only after careful risk-benefit analysis and detailed discussion.

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Invited Critique

Dr Sarela and colleagues present a nice, timely study on nonoperative management of M1 gastric cancer. Surgeons are in a unique position to care for such patients and should guide appropriate selection of palliative measures. Increasing survival time is a secondary goal in this group; symptom control usually is the patient’s and the family’s primary concern. Ideally, palliative therapy should be directed to maximizing the patient’s quality of life with minimal morbidity while anticipating brief periods of survival (median survival, 7 months). The paradigm shift for us is that surgery is now not usually needed. Although we were trained to consider gastrectomy to prevent subsequent bleeding and obstruction, advances in noninvasive techniques have made it necessary in very few patients.

Noncurative gastrectomy is associated with substantial morbidity (>50%) and mortality (6%).1 Furthermore, the benefit (<50% of patients) and durability of such an approach remains controversial.2,3 Even after surgery, many patients will require additional interventions (more for distant disease), which have inherent risks.2 In the present study, the authors report no intervention-related mortality with reduced morbidity (25%) among 22 patients treated. Although not specifically addressed, strictly directing interventions for specific symptom control avoided potential intervention-related morbidity, allowing suitable patients the opportunity for early systemic therapy. The demonstrated efficacy of various nonsurgical palliative approaches warrants further investigation.

This study highlights the paradigm of avoiding anticipatory palliative procedures for TXNXM1 disease. Seventy-five percent of patients did not require palliative intervention. Also, early commencement of systemic treatment seems to offer selected patients (37 of 55) a distinct survival advantage.

The intention not to treat, or nonsurgical palliative approaches to, metastatic gastric cancer has a favorable risk-benefit ratio, and this compelling evidence should push us to reserve noncurative gastrectomy strictly for those who need it.

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