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A prospective observational study examining quality of life in patients with malignant gastric outlet obstruction

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Abstract

BACKGROUND: Gastric outlet obstruction (GOO) often complicates advanced malignancy. Palliative options include surgical bypass, endoscopic stent, percutaneous gastrostomy (PEG), or percutaneous jejunostomy (PEJ).

METHODS: We enrolled 50 patients with GOO secondary to unresectable primary or metastatic cancer in a study examining palliative interventions. Validated instruments assessed quality of life (QOL) at baseline, 1 month, and 3 months following intervention.

RESULTS: Median overall survival was 64 days. A shorter hospital stay and trend to lower mortality were observed after stent placement; solid food intake and rates of secondary intervention were comparable. Both stent and surgical bypass were associated with acceptable QOL outcomes. Fifteen patients refused participation at 1 month and 28 died of disease before 3 months, so 10 patients completed all surveys.

CONCLUSIONS: Although malignant GOO is associated with poor survival, there are reasonable alternatives for palliation. QOL studies are difficult to complete in this population due to severity of illness and short life expectancy.

Gastric outlet obstruction (GOO) secondary to unresectable primary or metastatic malignancy is a challenging aspect of patient care. This condition complicates 20% to 30% of periampullary malignancies[1] but may also result from invasion and growth of upper abdominal carcinomatosis or metastases from advanced extra-abdominal cancer. Patients suffer from a variety of symptoms, including eating restrictions, dysphagia, nausea, vomiting, reflux, and abdominal pain. Treatment of malignant GOO is individualized and depends upon disease prognosis, patient/physician preferences, and the skill set of available proceduralists. Options include endoscopic stent or surgical bypass, and patients with short life expectancy are often managed with medical therapy, percutaneous gastrostomy (PEG), or percutaneous jejunostomy (PEJ).

The factors that determine ideal treatment for an individual patient are not well defined and prospective studies examining quality of life (QOL) in this patient population are few. We describe the results of a prospective observational trial assessing changes in QOL for patients undergoing palliative treatment of malignant GOO. We compare QOL outcomes in patients who underwent endoscopic stent placement, surgical bypass or palliation with PEG or PEJ alone. The secondary objective of our study was to characterize factors most influential to patients in their decision about which type of palliative intervention to receive.

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Materials and Methods

Approval for the study was provided by the Institutional Review Board of Memorial Sloan-Kettering Cancer Center (MSKCC). Patients over age 18 with metastatic or unresectable cancer who presented with acute or chronic GOO were recruited from the Surgical or Gastroenterology and Nutrition services at MSKCC over a 2-year period. The diagnosis of GOO was based on a combination of clinical, endoscopic and radiographic studies. We excluded patients with multiple levels of intestinal obstruction, those who could not speak or read English without an appropriate translator, and those unable or unwilling to give informed consent. The original goal for accrual was 100 patients; however, due to slower than anticipated enrollment in the surgical arm, the study was closed at 50 patients.

At the time of enrollment, demographic and other clinical data were collected and patients completed baseline QOL surveys and a questionnaire regarding important factors influencing choice of palliative intervention. Patients ranked these factors influencing their decision-making using a scale from 0 (not important) to 5 (most important), and data were available from 46 patients. Values are reported as mean score with 95% confidence intervals. All patients were evaluated for endoscopic stent insertion or surgical bypass, and the decision to undergo either palliative intervention was not dependent upon participation in the study. Treating physicians were not required to deviate from their standard practice for patients enrolled in the study.

Patients were followed prospectively after enrollment and overall survival was defined as time from palliative intervention to either death or last follow-up. Survival curves were estimated using the Kaplan–Meier method and significant differences between groups determined by the log-rank test. Periprocedural mortality was defined as death within 30 days of intervention. Length of hospital stay (LOS) was defined as number of days after palliative intervention until hospital discharge; of note, some patients were hospitalized before the palliative procedure and these days were not included in the LOS comparison. Failure of initial treatment was defined as any secondary procedure performed for palliation of recurrent GOO symptoms. Comparison between the treatment groups was performed using the Kruskall–Wallis test for continuous variables and Fisher exact test for categorical variables.

Follow-up QOL surveys were administered to all patients alive at 1 month and 3 months after stent, surgical bypass or PEG/PEJ. A research assistant (E.Z.) trained by the study investigators administered questionnaires personally to inpatients or conducted interviews by telephone for outpatients. Patients were also asked to describe current diet at baseline, 1 month, and 3 months after intervention from the following options: regular, soft foods, liquids, enteral nutrition, none, or other.

Surgical bypass was typically performed using gastroenterostomy, specifically anastomosis of the stomach proximal to the obstruction to a loop of small bowel distal to the obstruction. Palliative resection of the obstructing tumor was not performed in any patient. Two patients underwent a laparoscopic approach and the remaining cases were performed using open laparotomy. Two patients underwent concomitant biliary bypass for obstructive jaundice.

All endoscopic stents were placed by or under direct supervision of the attending gastroenterologist, and choice of stent was left to the discretion of the physician performing the procedure. Flexible endoscopy was used to visualize the obstructed area, and the metal stent and delivery system were inserted through the endoscope into the luminal narrowing under both endoscopic and fluoroscopic guidance. Once deployed, the stent was expanded to open the pylorus or duodenal lumen where obstructed.

QOL was assessed by questionnaire using the European Organization for Research and Treatment of Cancer (EORTC) QLQ-C30 and QLQ-STO22 instruments.[2,3] These surveys have been validated for assessment specifically in the oncology patient population.[4,5] The QLQ-C30 survey evaluates a variety of functional, physical, social and emotional domains and also measures symptoms related to QOL in cancer patients including fatigue, nausea/vomiting, pain, dyspnea, insomnia, appetite loss, constipation and diarrhea. The QLQ-STO22 is specifically designed to measure symptoms and QOL issues related to gastric cancer including dysphagia, pain, reflux, eating restrictions, anxiety, dry mouth, taste, body image, and hair loss. Although most patients in our study do not have gastric cancer, they have similar disease-specific symptoms captured in this validated instrument.

Both EORTC QOL instruments are composed of measures represented by single or multiple questions. These measures assess function, symptoms, and global health status/overall QOL. All single-item questions and multi-question scales range from 0 to 100 for the total score for each particular measure. A high score for any functional scale represents a high/healthy level of functioning and a high score in global health status represents a high QOL. A high score for any symptom scale represents a more severe or worse level of that symptom. A summary score for all measures was calculated by creating a raw score as the estimated average of the items (questions) contributing to that measure. Next, a linear transformation was used to standardize the raw scores such that each score ranged from 0 to 100.

The QOL data were summarized at each time and median values between groups and time points within groups compared using the Wilcoxon rank-sum test. Missing data were a significant problem in the study due to patient mortality and refusal of patients to complete follow-up questionnaires near the end of life. Because this is not a randomized trial comparing stent to surgical bypass and we were interested primarily in QOL after either procedure when successful, we did not perform an intention-to-treat analysis in regards to patients who underwent surgical bypass after failed stent placement.