



## Complete Summary

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### **GUIDELINE TITLE**

Surgical treatment of gastric cancer.

### **BIBLIOGRAPHIC SOURCE(S)**

Society for Surgery of the Alimentary Tract (SSAT). Surgical treatment of gastric cancer. Manchester (MA): Society for Surgery of the Alimentary Tract (SSAT); 2004 May 15. 4 p. [8 references]

### **GUIDELINE STATUS**

This is the current release of the guideline.

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## SCOPE

### **DISEASE/CONDITION(S)**

Gastric cancer

### **GUIDELINE CATEGORY**

Diagnosis  
Evaluation  
Treatment

### **CLINICAL SPECIALTY**

Family Practice  
Gastroenterology  
Internal Medicine

Oncology  
Surgery

## **INTENDED USERS**

Physicians

## **GUIDELINE OBJECTIVE(S)**

To guide primary care physicians to the appropriate utilization of surgical procedures on the alimentary tract or related organs

## **TARGET POPULATION**

Patients with gastric cancer

## **INTERVENTIONS AND PRACTICES CONSIDERED**

### **Diagnosis and Evaluation**

1. Computed tomography (CT) scans or upper gastrointestinal barium studies
2. Esophagogastroduodenoscopy (EGD) with biopsy
3. Patient history and physical examination
4. Basic laboratory tests including liver function tests and a complete blood count
5. Chest radiography
6. Endoscopic ultrasound

### **Treatment**

1. Staging laparoscopy
2. Surgery (total gastrectomy, proximal gastrectomy, distal gastrectomy, or esophagogastric resection)
3. Lymph node dissection
4. Chemotherapy (5-fluoruracil and leucovorin)
5. Radiotherapy
6. Chemoradiotherapy

## **MAJOR OUTCOMES CONSIDERED**

- Survival rate
- Risk of death from gastrectomy or from postoperative chemoradiotherapy

## **METHODOLOGY**

### **METHODS USED TO COLLECT/SELECT EVIDENCE**

Searches of Electronic Databases

### **DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE**

Not stated

**NUMBER OF SOURCE DOCUMENTS**

Not stated

**METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE**

Not stated

**RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE**

Not applicable

**METHODS USED TO ANALYZE THE EVIDENCE**

Review

**DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE**

Not stated

**METHODS USED TO FORMULATE THE RECOMMENDATIONS**

Expert Consensus

**DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS**

The Society for Surgery of the Alimentary Tract (SSAT) guidelines are based on statements and recommendations that were overwhelmingly supported by clinical evidence. Each represents a consensus of opinion and is considered a reasonable plan for a specific clinical condition.

(See companion document: Gadacz TR, Traverso LW, Fried GM, Stabile B, Levine BA. Practice guidelines for patients with gastrointestinal surgical diseases. J Gastrointest Surg 1998;2:483-484.)

**RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS**

Not applicable

**COST ANALYSIS**

A formal cost analysis was not performed and published cost analyses were not reviewed.

**METHOD OF GUIDELINE VALIDATION**

## DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

The guidelines were reviewed by several committee members and then by the entire committee on several occasions. Each guideline was then sent back to the original author for final comment and reviewed again by the committee. Each guideline was approved by the Board of Trustees of the Society for Surgery of the Alimentary Tract and final comments were reviewed by the committee.

(See companion document Gadacz TR, Traverso LW, Fried GM, Stabile B, Levine BA. Practice guidelines for patients with gastrointestinal surgical diseases. *J Gastrointest Surg* 1998;2:483-484.)

## RECOMMENDATIONS

### MAJOR RECOMMENDATIONS

#### Symptoms and Diagnosis

Patients with gastric cancer typically present with upper gastrointestinal complaints such as pain, heartburn, dysphagia, and bloating. Unfortunately, by the time these symptoms are evaluated, about one third of gastric cancer patients will have metastatic disease with an associated 2% 5-year relative survival rate. In the vast majority of cases, diagnosis is made by flexible esophagogastroduodenoscopy (EGD) with biopsy. Heartburn is a very frequent complaint that generally is managed by a trial of an H2 blocker or a proton-pump inhibitor. However, if a patient presents with both heartburn and anemia, EGD should be performed to exclude cancer. Some patients with gastric cancer present with bleeding from a gastric ulcer. The initial bleed may be sufficiently severe to preclude endoscopic biopsy at the time of the initial bleed, but follow-up EGD in several days with biopsy is mandatory, as 10 to 15% of malignant ulcers can heal with H2 blocker or proton pump inhibitor treatment. Proximal gastric cancers can present with heartburn and/or dysphagia. A complaint of dysphagia mandates EGD to exclude malignancy. Some patients present with nausea, vomiting, or weight loss. Usually they are evaluated with computed tomography (CT) scans or upper gastrointestinal barium studies. Unless these studies unequivocally diagnose a non-malignant etiology for the symptoms, an EGD should be performed.

#### Staging

The recent tumor, node, metastasis (TNM) staging system for gastric cancer changed to incorporate the fact that the prognosis of gastric cancer is dependent upon the number of nodes that are positive. Further, the T2 stage has been divided into T2a (invasion into the muscularis propria) and T2b (invasion into the subserosa) to reflect the impression that node negative tumors should have postoperative chemoradiotherapy if the T stage is greater than or equal to T2b.

Patients with a diagnosis of gastric cancer should be evaluated with a history and physical examination; basic laboratory tests including liver function tests and a

complete blood count; a chest radiograph; and a CT scan of the abdomen and pelvis. If a patient without evidence of metastatic disease does not require a palliative gastrectomy for persistent bleeding, then staging laparoscopy should be considered to exclude incurable disease on the basis of peritoneal carcinomatosis. In this setting, staging laparoscopy typically is done at the time of a planned curative resection. If laparoscopy documents metastatic disease, then the planned resection is abandoned and the patient is referred for possible palliative chemotherapy. If a particular treatment protocol depends upon specific knowledge of the T and N stages, then endoscopic ultrasound should be considered although the accuracy of this test is far from ideal.

## **Treatment**

Treatment depends upon the clinical stage at presentation and the comorbid disease of the patient. For patients who are medically fit and who have potentially resectable disease, surgery should be performed with an effort to achieve an R0 resection that is defined as a curative en bloc resection with negative proximal, distal, and radial margins (i.e., no obvious residual tumor). The surgeon should attempt to achieve >5-cm proximal and distal margins. For distal tumors, this usually requires a distal gastrectomy. For proximal tumors, a total gastrectomy or proximal gastrectomy is acceptable. For gastric cancers that approach the gastroesophageal junction, the proximal margin should be at least 6 cm; this requirement usually mandates a formal esophagogastric resection with thoracotomy. An extended (D2) lymph node dissection (removing an average of 25 to 30 lymph nodes) can provide more complete staging than a limited (D1) lymph node dissection (removing an average of 15 lymph nodes), but there are no randomized Western trials that demonstrate a survival advantage associated with a D2 dissection yet. A large multi-center, randomized Dutch trial demonstrated that a D2 dissection was associated with increased morbidity and mortality but not with increased survival. A smaller, controlled British trial confirmed the findings of the Dutch study. Splenectomy should be avoided unless the spleen is involved by tumor and at least 15 lymph nodes should be assessed to properly stage the lymph nodes. To ensure that 15 lymph nodes are removed usually requires removal of the lesser omentum, greater omentum, common hepatic arterial lymph nodes, and the left gastric lymph nodes to the celiac axis. In most cases, this lymph node dissection approximates a D2 dissection with the important exception that the splenic hilar lymph nodes are not removed (which is an important component of most D2 dissections) to avoid removal of the spleen.

After curative resection, adjuvant combination chemotherapy and radiotherapy should be offered patients with node positive disease or tumors that penetrate the full thickness of the muscularis propria (T2b). This standard was set with the results from a randomized, controlled clinical trial published in 2001. This multi-center trial (INT-0116) treated patients with Stages Ib through IV M0 with one cycle of 5-fluorouracil (5-FU) and leucovorin, followed by 4.5 Gy external beam radiotherapy with 5-FU and leucovorin, followed by two cycles of 5-FU and leucovorin at monthly intervals. Between 1991 and 1998, 603 patients entered the study. Nodal metastases were noted in 85%. Improved survival was noted in the treatment arm, and will be discussed below.

For patients who are medically fit, with locally advanced unresectable disease, combination chemotherapy and radiotherapy can be used. For patients who have

comorbid disease that makes the risk of resection greater than the benefit, combination chemotherapy and radiation, chemotherapy alone, or no treatment (best supportive care) are options. For patients with metastatic disease, chemotherapy should be considered. For patients who present with bleeding and are not candidates for resection from the standpoint of either medical condition or metastases, radiation therapy can be helpful for palliation.

### **Expected Outcomes**

Most Americans with gastric cancer present with tumor penetrating the full thickness of the stomach (T3) and positive lymph nodes. Unfortunately, surgery alone for this stage results in a 5-year survival rate of only 15 to 20%. As noted above, the randomized trial INT-0116 included predominantly patients with positive nodes (85%) and T3 tumors. INT-0116 showed that the 3-year overall survival time with surgery alone was only 41%; with adjuvant chemoradiotherapy, it rose to 52%. This study included T2bN0, Stage Ib, tumors and suggests that this subset will benefit by adjuvant postoperative chemoradiotherapy. However, only 36 patients had Stage Ib in INT-0116, and a recent study shows that T2a or T2b N0 gastric cancer resected with at least 15 lymph nodes in the specimen will be associated with a >85% 5-year survival rate without adjuvant postoperative chemoradiotherapy. Thus, it is not clear that Stage Ib gastric cancer benefits from adjuvant chemoradiotherapy.

For stage IV (M1) gastric cancer, combination chemotherapy is associated with about a 10-month median survival time, while "best supportive care" is associated with only a 3 to 4 month median survival time.

### **Qualifications**

At a minimum, surgeons who are certified or eligible for certification by the American Board of Surgery, the Royal College of Physicians and Surgeons of Canada, or their equivalent should perform operations for gastric cancer. These surgeons have successfully completed at least 5 years of surgical training after medical school graduation and are qualified to perform operations for gastric cancer. The level of training in advanced laparoscopic techniques necessary to conduct minimally invasive surgery of the stomach is important to assess. The qualifications of a surgeon performing any operative procedure should be based on training (education), experience, and outcomes.

### **CLINICAL ALGORITHM(S)**

None provided

## **EVIDENCE SUPPORTING THE RECOMMENDATIONS**

### **TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS**

The type of supporting evidence is not specifically stated for each recommendation.

## BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

### POTENTIAL BENEFITS

- Appropriate use of surgical resection and adjuvant chemotherapy or chemoradiotherapy for the treatment of gastric cancer
- Surgical resection is necessary to cure local or regional disease, but recently postoperative chemoradiotherapy was shown to improve survival rates.

### POTENTIAL HARMS

The risk of death from a gastrectomy should be <5%. Complications include impaired transit of food—either too slow or too fast, bleeding, and infection. The risk of death from adjuvant postoperative chemoradiotherapy was 1% in one multicenter trial (INT-0116).

## QUALIFYING STATEMENTS

### QUALIFYING STATEMENTS

These patient care guidelines were written for the primary care physicians on a variety of digestive diseases to assist on when to refer the patient for surgical consultation. Their goal is to guide primary care physicians to the appropriate utilization of surgical procedures on the alimentary tract or related organs and they are based on critical review of the literature and expert opinion. Both of the latter sources of information result in a consensus that is recorded in the form of these Guidelines. The consensus addresses the range of acceptable clinical practice and should not be construed as a standard of care. These Guidelines require periodic revision to ensure that clinicians utilize procedures appropriately but the reader must realize that clinical judgment may justify a course of action outside of the recommendations contained herein.

## IMPLEMENTATION OF THE GUIDELINE

### DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

## INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

### IOM CARE NEED

Living with Illness

### IOM DOMAIN

Effectiveness

## IDENTIFYING INFORMATION AND AVAILABILITY

### **BIBLIOGRAPHIC SOURCE(S)**

Society for Surgery of the Alimentary Tract (SSAT). Surgical treatment of gastric cancer. Manchester (MA): Society for Surgery of the Alimentary Tract (SSAT); 2004 May 15. 4 p. [8 references]

### **ADAPTATION**

Not applicable: The guideline was not adapted from another source.

### **DATE RELEASED**

2004 May 15

### **GUIDELINE DEVELOPER(S)**

Society for Surgery of the Alimentary Tract, Inc - Medical Specialty Society

### **SOURCE(S) OF FUNDING**

Society for Surgery of the Alimentary Tract, Inc

### **GUIDELINE COMMITTEE**

Patient Care Committee

### **COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE**

Not stated

### **FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST**

Not stated

### **GUIDELINE STATUS**

This is the current release of the guideline.

### **GUIDELINE AVAILABILITY**

Electronic copies: Available from the [Society for Surgery of the Alimentary Tract, Inc. Web site](#).

Print copies: Available from the Society for Surgery of the Alimentary Tract, Inc., 900 Cummings Center, Suite 221-U, Beverly, MA 01915; Telephone: (978) 927-8330; Fax: (978) 524-0461.

## AVAILABILITY OF COMPANION DOCUMENTS

The following is available:

- Gadacz TR, Traverso LW, Fried GM, Stabile B, Levine BA. Practice guidelines for patients with gastrointestinal surgical diseases. J Gastrointest Surg 1998;2:483-484.

Print copies: Available from the Society for Surgery of the Alimentary Tract, Inc., 900 Cummings Center, Suite 221-0, Beverly, MA 01915; Telephone: (978) 927-8330; Fax: (978) 524-8890.

## PATIENT RESOURCES

None available

## NGC STATUS

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