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ORIGINAL ARTICLE – PERITONEAL SURFACE MALIGNANCY

The Chicago Consensus on Peritoneal Surface Malignancies: Management of Gastric Metastases

Chicago Consensus Working Group

Chicago, IL

ABSTRACT The Chicago Consensus Working Group provides multidisciplinary recommendations for the management of gastric cancer specifically as it relates to the management of peritoneal surface malignancy. These guidelines are developed with input from leading experts including surgical oncologists, medical oncologists, pathologists, radiologists, palliative care physicians, and pharmacists. These guidelines recognize and address the emerging need for increased awareness of the appropriate management of peritoneal surface disease. They are not intended to replace the quest for higher levels of evidence.

GASTRIC CANCER WITH PERITONEAL METASTASES

This article provides multidisciplinary recommendations for the management of peritoneal surface malignancies of gastric origin and constitutes 1 article in a series composed by the Chicago Consensus Working Group for the Management of Peritoneal Surface Malignancies.[1–10] Information regarding formation of the Chicago Consensus Group and explanation of the working group's consensus methodology is discussed elsewhere.[1,2]

The collaborators for the Chicago Consensus Working Group are listed in the acknowledgments.

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INTRODUCTION

Gastric cancer (GC) is the second leading cause of cancer-related death and sixth most common malignancy worldwide.[11] In a Western population of patients with gastric cancer, up to 30% may have occult peritoneal disease that was found at laparoscopy but was otherwise undetectable on computed tomography.[12–14] The peritoneum is the most common site of metastasis, potentially leading to significant symptoms, particularly bowel obstruction. Despite administration of systemic chemotherapy, survival remains dismal, typically within the range of 6 to 15 months.[15]

The role of cytoreductive surgery (CRS) and perioperative chemotherapy in the management of GC with peritoneal metastases (PM) is evolving. Cytoreductive surgery and hyperthermic intraperitoneal chemotherapy (HIPEC) have demonstrated a significant survival benefit in a variety of cancers. Only 1 phase 3 randomized clinical trial comparing CRS/HIPEC with CRS alone has been completed. In this trial, which was performed in China, CRS/HIPEC was associated with a median survival of 11.0 months, as compared with 6.5 months in the CRS-alone group.[16] However, no phase 3 trials have been completed in a Western population of patients with GC and PM, and biologic differences in GC between Eastern and Western populations of patients are known.[17,18] The consensus panel recognizes the need for multi-institutional and randomized trials within the United States. While we await randomized controlled trials outside the United States, patients should be considered for current nonrandomized trials and currently available prospective registries. One such study, the CYTO-CHIP study, used prospective databases from 19 French cancer treatment centers to analyze the effect of CRS alone versus that of CRS/HIPEC in patients with GC and PM. This study included only patients undergoing curative-intent surgery who had complete cytoreduction, with no tumor deposits larger than 2.5

mm remaining. The CRS/HIPEC group had significantly improved overall survival (18.8 vs 12.1 months) and 5-year recurrence-free survival (17.05% vs 3.76%) compared with the group receiving CRS alone.[19]

Here we describe current treatment strategies for the management of GC with PM on the basis of best available evidence.

PRINCIPLES OF SYNCHRONOUS METASTASES VERSUS METACHRONOUS METASTASES

In patients with proven GC, PM can be difficult to determine with standard cross-sectional imaging. Diagnostic laparoscopy before the initiation of systemic chemotherapy should be strongly considered. If synchronous PM are present, initial standard-of-care treatment is systemic chemotherapy. This is followed by restaging imaging and consideration of laparoscopy. In patients with stable disease or improvement, no extraperitoneal disease, no distant nodal disease, and good functional status, surgical intervention can be considered. (See *Gastric Cancer with Synchronous Peritoneal Metastasis Management Pathway*, Fig 1). In patients with GC who develop metachronous PM, we recommend standard systemic therapy. We recommend restaging in patients with a low metastatic burden or a long disease-free interval after administration of systemic therapy. In patients with stable or responsive disease that has undergone restaging, surgical intervention can be considered.

Although prognostic factors for localized GC have been described, less is known about GC with PM. Most completed studies and ongoing trials have predominantly included patients with synchronous PM. Because of the limited trials of CRS and HIPEC in patients with GC with PM and the introductory nature of these guidelines, the focus of the current algorithm is on synchronous PM. However, evidence supports continued study of CRS and HIPEC in patients with metachronous disease. In a single institutional series of 255 patients with GC and PM, no significant difference in median overall survival was seen between the synchronous (4.8 months) and metachronous (4.7 months) cohorts. Synchronous distant metastatic disease in patients with PM was overall a major independent negative prognostic factor.

In a multi-institutional study of 159 patients with GC/PM treated with CRS and perioperative intraperitoneal chemotherapy, median survival was not significantly different between patients with synchronous carcinomatosis (8 months) and those with metachronous carcinomatosis (9 months). Completeness of cytoreduction was the principal

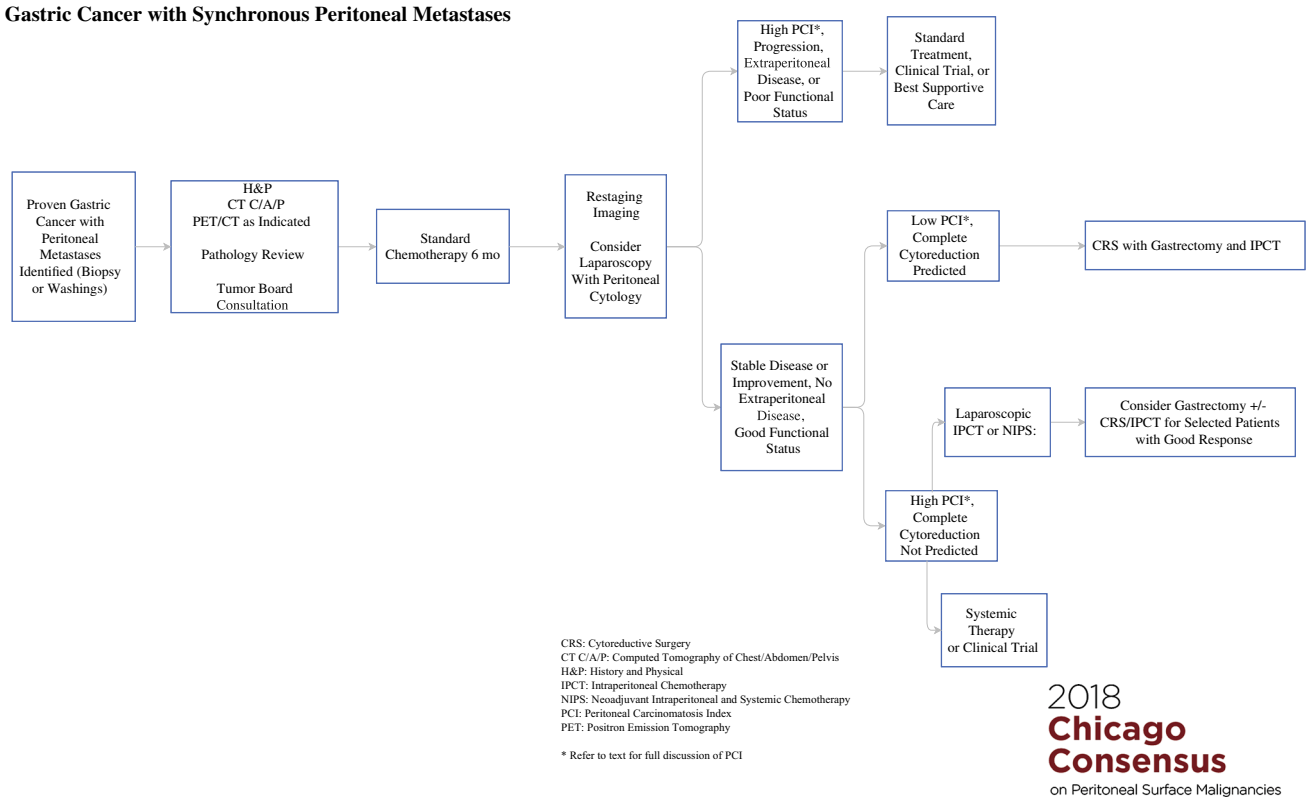

FIG. 1 Gastric cancer with synchronous peritoneal metastases management pathway

independent prognostic factor on multivariate analysis. In patients with CC0 cytoreductions, the only prognostic factor was the peritoneal cancer index (PCI).[20]

PRINCIPLES OF SURGERY

Given the differences in biologic and epidemiologic characteristics of GCs in Eastern and Western populations, as well as heterogeneity in screening and clinical practices, there is no standardized approach to cytoreductive surgery in patients with GC/PM. Independent prognostic factors for overall survival, however, have been described. As previously mentioned, in a recent meta-analysis CC0 cytoreduction was shown to be an independent predictor for overall survival in patients undergoing CRS/HIPEC for GC/PM.[21] Compared with CC1 cytoreduction, CC0 cytoreduction was associated with greater 1- and 3-year survival. The PCI has also been independently associated with overall survival, with both French and Japanese studies reporting a PCI of 6 or less to be associated with improved survival.[21] The completeness of cytoreduction and PCI are related. Yonemura et al reported that complete cytoreduction could be obtained in 91% of patients with a PCI of 6 or less but was possible in only 42% of patients with a PCI of 7 or more.[22] Signet ring cell gastric cancer, which in itself is typically associated with a poorer prognosis, is likewise associated with poor outcomes in patients with GC/PM who are undergoing CRS/HIPEC. A study of 1 series of such patients found 72% complete cytoreductions, a 46% complication rate, and significantly lower median survival in patients who did not have a complete cytoreduction.[23]

The extent of gastrectomy (total versus subtotal) has also been heterogeneous among major studies. In a series of 107 patients studied by Yonemura et al, 68% of patients who underwent gastrectomy had a total gastrectomy, whereas the other 32% underwent partial gastrectomy.[24] In a randomized trial by Yang et al, 8 of 34 patients in the CRS/HIPEC arm (24%) underwent total gastrectomy and 25 (76%) underwent subtotal gastrectomy.[16] The extent of gastrectomy was not an independent predictor of survival in either study.[16,24] Although practice differences between Eastern and Western populations regarding the extent of regional lymphadenectomy (D1/D2/D3) in resectable gastric cancer are well described, data in patients with GC/PM who are undergoing CRS/HIPEC are lacking. Therefore, we recommend cytoreduction with the goal of CC0 and also considering extent of gastrectomy and regional lymphadenectomy along with factors such as ability to obtain complete cytoreduction, PCI score, disease biology, location, and risk of morbidity. Gastrectomy only (for palliation in patients with PM) should not be performed, according to the results of the REGATTA trial.[25]

PRINCIPLES OF SYSTEMIC CHEMOTHERAPY, INTRAPERITONEAL CHEMOTHERAPY, AND DOSING REGIMENS

In patients with known GC/PM, first-line therapy includes platinum- and fluoropyrimidine-containing systemic chemotherapeutic regimens, most often for a minimum of 6 months. Commonly used regimens include FOLFOX, XELOX, FLOT, ECF, and S-1/cisplatin (where available). An assessment of HER2 status, microsatellite instability, and PD-L1status should also be made, given the availability of targeted and immune therapies (Fig 1). The role of HER2-targeted therapy was established by the ToGA trial, which demonstrated improved overall survival in patients receiving trastuzumab in addition to standard-of-care systemic chemotherapy (13.8 months) versus systemic chemotherapy alone (11.1 months).[26] While genetic sequencing of a tumor provides useful information and can impact systemic therapy options, the impact of molecular differentiation in GC on the choice of CRS/HIPEC is currently being investigated. It is important to note that PM have been predictive of poorer responses to systemic chemotherapy, and the subset of patients with advanced/metastatic GC were not analyzed separately in the vast majority of studies. One study of 237 patients with GC/PM randomized patients to receive only 5-FU or to receive methotrexate and 5-FU and did not find a difference in overall survival between groups.[27]

Given the poor response of PM to systemic chemotherapy, intraperitoneal chemotherapy has been explored and used in a variety in settings with patients with GC/PM. Yonemura et al pioneered a neoadjuvant intraperitoneal and systemic chemotherapy protocol (NIPS) in which patients with known GC/PM received S-1 orally, with docetaxel and cisplatin administered intraperitoneally via port (bidirectional chemotherapy). Free peritoneal cancer cells were found in 82% of patients before NIPS, and cytology revealed no cancer cells in 63% of patients after NIPS. Complete cytoreduction occurred in 78% of patients.[28] Hyperthermic intraperitoneal chemotherapy and early postoperative intraperitoneal chemotherapy (EPIC) have been used in conjunction with CRS in patients with GC/PM. Badgwell et al described serial laparoscopic HIPEC procedures after completion of systemic chemotherapy, with disease in 5 of 19 patients downstaged to resectability.[29] Representative dosing regimens from published studies are as follows:

- Shen et al[30]
  - Mitomycin 30 mg + additional 10 mg at 60 minutes, for a total of 120 minutes at 41°C to 42°C inflow, 40°C outflow
- Glehen et al[20]
  - Mitomycin 30 to 50 mg/m^2 ± cisplatin 50 to 100 mg/m^2 for 60 to 120 minutes at 41°C to 42.5°C
  - Oxaliplatin 360 to 460 mg/m^2 ± irinotecan 100 to 200 mg/m^2 ± intravenous 5-FU and leucovorin for 30 minutes at 43°C
  - EPIC: abdominal cavity filled with 1 L/m^2 of lactated Ringer solution at end of surgical procedure, drains clamped at 23 to 24 hours. Day 1: mitomycin C 10 mg/m^2. Days 2 to 5: 5-FU 600 mg/m^2.
- Yonemura et al[31]
  - Mitomycin 30 mg + cisplatin 300 mg + etoposide 150 mg at 42°C to 43°C
- Yang et al[16]
  - Mitomycin 30 mg + cisplatin 120 mg for 60 to 90 minutes at 43.0°C ± 0.5°C
- Badgwell et al[29]
  - Mitomycin 30 mg + cisplatin 200 mg for 60 minutes, target inflow 41°C to 42°C, target outflow 39°C to 40°C; loading dose of 7.5 g/m^2 sodium thiosulfate infused prior to addition of cisplatin, with maintenance infusion of sodium thiosulfate 25.56 g/m^2 continuously over 12 hours

SYNOPTIC PATHOLOGY REPORT

Macroscopic

Specimen type:

- Biopsy
- Small excision
- Major resection

Tumor site:

- Peritoneum
- Omentum
- Organ site

Microscopic

- Histologic type:
- Margin status:
- Nuclear grade/differentiation:
- Mitotic count:
- Signet ring: Y/N
- Lymph nodes:
- PD-L1 expression:
- HER2 expression:

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