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Cytoreduction with hyperthermic intraperitoneal chemotherapy: an appraisal of outcomes and cost at a newly established peritoneal malignancy program

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Abstract

BACKGROUND: Outcome measures after cytoreductive surgery with hyperthermic intraperitoneal chemotherapy (CRS/HIPEC) for peritoneal carcinomatosis in established centers are well defined. However, results from newly emerging US centers have not been reported.

METHODS: This is a retrospective review of a prospectively maintained database of patients with peritoneal malignancies undergoing CRS/HIPEC.

RESULTS: Fifty-six patients underwent exploratory laparotomy with 36 receiving CRS/HIPEC over 36 months. The median peritoneal cancer index score was 18, and the cytoreduction 0/1 rate was 92%. Postoperative major morbidity was 16.7% with one perioperative death. The median length of hospital stay and intensive care unit days were 9 and 3 days, respectively. Disease-free survival in high-grade vs low-grade tumors was 12.6 and 31.0 months (*P*, .03), respectively. Average direct cost for patients undergoing CRS/HIPEC was $25,917.

CONCLUSIONS: Our emerging center's short-term results are comparable with established programs with a trend toward more selective intraoperative judgment on who undergoes CRS/HIPEC.
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Cytoreduction (CC) with intraperitoneal chemotherapy has been shown to be an effective strategy in the management of peritoneal-based malignancies that improves outcomes in what was previously considered a terminal condition. Cytoreductive surgery (CRS) involves resection of all visible tumor, organs involved, and peritoneum. Resection is followed by intraperitoneal infusion of chemotherapy, which delivers a regional dose escalation with minimal systemic cytotoxicity. These methods have proven

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themselves effective in the management of a variety of histologic subtypes including colorectal cancer, ovarian cancer, appendiceal cancer, and mesothelioma.[1–13]

With the growth of this treatment modality, numerous peritoneal malignancy centers have emerged, but most published reports emanate from well-established high-volume centers. As such, it is unclear whether short- and long-term outcomes reported at these high-volume centers are being replicated in new programs. Numerous studies on the surgical management of malignancies have demonstrated disparate outcomes based on the volume and experience of the institutions.[14–17]

Not only is it important to document complex, patient-based end points including perioperative morbidity and mortality and oncologic outcomes at these new centers but also surrogate outcome measures like cost. To date, there have been 2 studies in the United States that analyzed the direct hospital cost associated with this complex procedure.[18,19]

Acceptance of the role of CRS with hyperthermic intraperitoneal chemotherapy (CRS/HIPEC) among the oncology community is low because of the lack of large prospective clinical trials and the perception that CRS/HIPEC is associated with high morbidity and cost that outweighs its potential benefits. Therefore, part of developing a new peritoneal malignancy program involves appraisal and analysis of institution-specific outcomes as well as dissemination of information to the medical community as to the survival benefits associated with CRS/HIPEC in appropriately selected patients as to change perceptions that may already exist. Our aim was to prospectively determine the perioperative and oncologic outcomes of patients undergoing CC with HIPEC at a new peritoneal malignancy center and longitudinally evaluate changes in perioperative outcomes and cost.

Methods

This was a retrospective review of patients who were referred with peritoneal malignancies for CRS/HIPEC at a new peritoneal malignancy program established at an academic tertiary care hospital in 2011. Patients were considered to be candidates for CRS after a multidisciplinary discussion between surgical, medical and gynecologic oncologists, and radiologists. Patients considered for CC had an Eastern Cooperative Oncology Group performance status less than or equal to1; absence of extraperitoneal disease and lack of extensive intra-abdominal disease seen on computer tomography scan, ie, disease in the retroperitoneum, porta hepatis, or small bowel mesentery. The preoperative workup included computer tomography scans and endoscopic evaluation. Patient demographics, clinicopathologic data, and outcomes were collected in a prospectively maintained database. Postoperative morbidity was defined as complication or death within 30 days of surgery. Perioperative complications were graded according to the Dindo–Clavien system, and major morbidity was defined as an event of grade 3 or greater.[20] For purposes of longitudinal comparison, patients were divided into 2 time periods: patients who had surgery in the first 18 months of the program (early), and those who underwent CRS/HIPEC in the last 18 months of the program (late).

Surgeries were performed by 1 of 2 fellowship trained surgical oncologists. Surgical techniques for CRS have been previously described.[21,22] Extensive CC was defined as greater than 3 organ resections or greater than 2 enteric anastomoses. The peritoneal cancer index (PCI), a measure of disease evaluated in 13 different locations within the abdominopelvic cavity, as defined by Sugarbaker was obtained, and the completeness of CC score was generated before HIPEC; CC-0 score indicates no visible and/or macroscopic disease; CC-1 score indicates tumor nodules less than 2.5 mm in diameter; CC-2 score indicates nodules greater than 2.5 mm but less than 2.5 cm in diameter; CC-3 score indicates nodules greater than 2.5 cm in diameter.[23,24] The chemotherapeutic agents selection was based on the histopathology of the underlying malignancy and in a closed system as follows: mitomycin C 40 mg at 42°C for 90 minutes, oxaliplatin 200 mg at 42°C for 60 minutes, cisplatin mg at 42°C for 60 minutes, and melphalan 50 mg/m^2 for 60 minutes. The decision to abort the operation was at the discretion of the operating surgeon after consultation with a second fellowship trained surgical oncologist.

After discharge, ongoing follow-up care was provided in the surgical oncology clinic. At each visit, disease status was assessed and entered into the prospective database. Overall survival (OS) was defined as the duration from the date of CRS/HIPEC to the date of death. Progression-free survival (PFS) was defined as the duration between the date of CRS/HIPEC and the date of clinically documented tumor recurrence. In cases of incomplete CC, progression was defined as the date of clinically documented tumor progression relative to baseline postoperative radiologic findings and tumor marker levels. For all outcomes, patients were censored at the time of most recent follow-up.

Direct cost was obtained from the hospital finance department. Statistical analysis was performed with SAS. Statistical analysis was performed using Student's *t*-test for continuous variables and chi-square or Fisher's exact test where appropriate for categorical variables. A Kaplan–Meier analysis was performed to compare recurrence-free survival between patients with high-grade tumors and those with low-grade tumors. A P value less than .05 was considered significant.

Results

Patient demographics

A total of 56 patients underwent exploratory laparotomy with the intention of CRS with HIPEC. Thirty-six patients underwent CRS/HIPEC, whereas in 20 patients the operative plan was aborted after finding extensive disease not amenable to complete CC (Table 1). Of patients who underwent CRS/

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