

Laparoscopic Cytoreductive Surgery and Hyperthermic Intraperitoneal Chemotherapy (HIPEC) in patients with limited Peritoneal Surface Malignancies

Research Protocol

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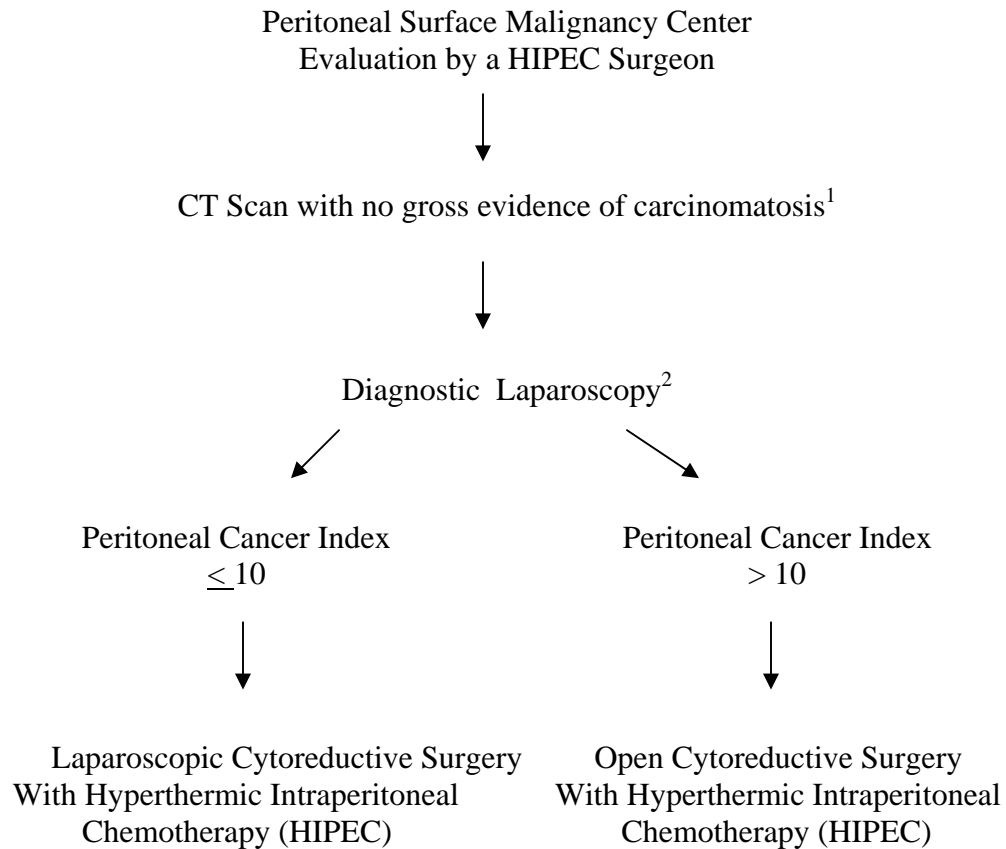
RATIONALE:

Cytoreductive Surgery and HIPEC have become standard practice in the treatment of patients with Peritoneal Surface Malignancies. The open procedure has been associated with a high Grade III and Grade IV Morbidity and a prolonged hospitalization. The proposed study will evaluate the feasibility of performing this procedure via a laparoscopic approach and will also document the Grade III and IV complication rate as measured by the National Cancer Institute Common Toxicity Criteria (CTCAE, version 3.0) using this minimally invasive approach.

METHODS:

Patients with the diagnosis of a Peritoneal Surface Malignancy of Appendiceal, Colonic or well differentiated peritoneal mesothelioma origin will be evaluated by the Peritoneal Surface Malignancy Center at St. Agnes Hospital. If there is no gross evidence of carcinomatosis on the CT scan of the abdomen and pelvis, the patients will go to the operating room for a diagnostic laparoscopy. If indeed there is limited carcinomatosis (defined as a PCI < 10) that can be removed completely via the laparoscopic approach, then the procedure will continue laparoscopically. If at the time of the diagnostic laparoscopy, more than limited carcinomatosis (defined as a PCI > 10) is found, then the procedure will be converted to the standard open approach. See Figure 1 and foot notes.

Clinical Pathway for the Laparoscopic Management of Peritoneal Surface Malignancies



1. CT Scan with no gross evidence of carcinomatosis:

Complete Cytoreduction means that no macroscopic residual disease was left after the operative procedure. The following are radiographic variables that are usually associated with increase chances of achieving a complete removal of all tumors greater than 2.5mm.

No evidence of extra-abdominal disease

No evidence of parenchymal hepatic metastases

No evidence of biliary obstruction

No evidence of ureteral obstruction

No evidence of intestinal obstruction at more than one site

No evidence of gross disease in the mesentery of the small bowel and no evidence of several segmental sites of partial obstruction.

No evidence of bulky disease in the gastro-hepatic ligament

2. Diagnostic Laparoscopy

If none of the above mentioned parameters are identified in the CT scan of the abdomen and pelvis, the patients will be taken to the operating room for a diagnostic laparoscopy. During the laparoscopy, the intraoperative Peritoneal Cancer Index (PCI) will be determined as previously described by Sugarbaker (see attachment #1). In summary, the PCI can range from 0 to 39. PCI values from 1 to 10 are considered low volume carcinomatosis and are associated with the highest chances of having a complete cytoreduction. PCI values from 11 to 20 are considered medium volume carcinomatosis and values > 20 are considered extensive carcinomatosis.

If the intraoperative Peritoneal Cancer Index determination is 10 or less, the case will continue as a laparoscopic procedure. If the PCI is greater than 10, then the case will be converted to an open procedure. Additional reasons for converting from a laparoscopic to an open procedure include intraoperative complications like bleeding or injuries to any intrabdominal organs.