Heated Abdominal Chemotherapy Not Beneficial in Patients With Advanced Colorectal Cancer

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ASCO Perspective
“This study is an example where less is more. It suggests we can spare many people with colorectal cancer from unnecessary chemotherapy that often comes with harsh side effects,” said ASCO Expert Andrew Epstein, MD.

CHICAGO – A randomized phase III clinical trial shows that people with advanced colorectal cancer may not need a frequently considered component of treatment – heated chemotherapy delivered to the abdomen during surgery. There was no difference in survival between patients with metastases in the abdomen who received heated chemotherapy during surgery and those who received surgery alone. Long-term side effects were more common with chemotherapy.

The study will be featured in a press briefing today and presented at the 2018 American Society of Clinical Oncology (ASCO) Annual Meeting.

Peritoneal carcinomatosis – metastatic tumors on the lining of the abdominal cavity called the peritoneum – occur in about 20% of people with metastatic colorectal cancer. When tumors can be completely removed, a treatment that has been used is surgery with chemotherapy delivered into the abdomen (known as hyperthermic intra-peritoneal chemotherapy, HIPEC). Surgery with HIPEC may prolong survival (compared to systemic therapy alone), and surgery may cure up to 16% of patients with peritoneal carcinomatosis.

“When this approach was introduced more than 15 years ago, it was the first effective treatment for metastatic tumors on a patient’s abdomen, but we didn’t know whether delivering heated chemotherapy during surgery was an important component of the treatment or not,” said lead study author Francois Quenet, MD, head of the hepato-biliary and peritoneal surface malignancy unit at the Regional Cancer Institute in Montpellier, France. “This is the first randomized study assessing the role of this special type of chemotherapy in advanced colorectal cancer, and it shows that it does not provide added benefit over surgery.”

About the Study
The PRODIGE 7 trial enrolled 265 patients in France who had stage IV colorectal cancer with peritoneal carcinomatosis, and no metastases elsewhere in the body. The patients were randomly assigned to receive surgery plus HIPEC (chemotherapy oxaliplatin heated to 43°C in an attempt to increase chemotherapy efficacy) or surgery alone. Most (96%) of the patients also received systemic chemotherapy, before surgery,
after surgery or both. The type of systemic therapy was per physician choice.

Key Findings
At a median follow-up of 64 months, the median overall survival was 41.2 months in the non-HIPEC group vs. 41.7 months in the HIPEC group (the difference between the two groups was not statistically significant). The time until the cancer returned (recurrence-free survival) was also similar between the two groups: median 11.1 months in the non-HIPEC group vs. median 13.1 months in the HIPEC group.

The overall mortality rate at 30 days after surgery was 1.5% in both groups, and there was no difference in the rate of side effects during the first 30 days. At 60 days, however, the rate of complications in the HIPEC group was almost double that in the non-HIPEC group (24.1% vs. 13.6%).

Next Steps
More research is needed to determine if there are patients who would still benefit from receiving HIPEC with surgery. A subgroup analysis from this study suggests that HIPEC might be beneficial for patients with a mid-range peritoneal cancer index (a measure of the amount of cancer in the abdomen), but the numbers were too small to be conclusive. People with a low peritoneal cancer index can likely forgo HIPEC, whereas those with a high index may not benefit from either surgery or HIPEC. Meanwhile, other types of chemotherapy may be more effective than oxaliplatin, the type of chemotherapy used in HIPEC for this study.

This study received funding from R&D UNICANCER.

Study at a Glance

<table>
<thead>
<tr>
<th>Disease</th>
<th>Metastatic Colorectal Cancer</th>
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<tbody>
<tr>
<td>Trial Phase, Type</td>
<td>Phase III, Randomized</td>
</tr>
<tr>
<td>Patients on Trial</td>
<td>265</td>
</tr>
<tr>
<td>Intervention Tested</td>
<td>Surgery plus HIPEC vs. surgery</td>
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<tr>
<td>Primary Finding</td>
<td>mOS 41.7 months with surgery plus HIPEC vs. 41.2 months with surgery alone</td>
</tr>
<tr>
<td>Secondary Finding(s)</td>
<td>mRFS 13.1 months with surgery plus HIPEC vs. 11.1 with surgery alone</td>
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</tbody>
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View the full abstract.

For your readers:

- Guide to Colorectal Cancer
  (Cancer colorrectal)
- Understanding Chemotherapy
  (Qué es la quimioterapia)

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