進行大腸がんに対しては治療が少ない方がよい可能性がある(Abstract LBA3503)

癌性腹膜炎患者において腹腔内温熱化学療法は有益でない

Heated abdominal chemotherapy not beneficial in patients with peritoneal carcinomatosis

2018 ASCO Annual Meetingで取り上げられた第III相ランダム化試験の結果、進行大腸がん患者には腹腔内温熱化学療法(HIPEC)は不要である可能性があることが示された。追跡期間中央値64か月の時点で、全生存期間中央値は2群間で差はなかった(非HIPEC群41.2か月対HIPEC群41.7か月、p=0.995)。無再発生存期間もまた、2群間で同様であった(非HIPEC群11.1か月対HIPEC群13.1か月、p=0.486)。長期の副作用は化学療法の方が多かった。

Full Text

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 was featured at the 2018 American Society of Clinical Oncology (ASCO) Annual Meeting.

Peritoneal carcinomatosis occurs in about 20% of people with metastatic colorectal cancer. When tumors can be completely removed, a treatment that has been used is surgery with 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."

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.

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 (p=0.995). The 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 (p=0.486).

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%).

"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.

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, 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.

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