

## 胆管がん患者の生存期間延長(Abstract 4006)

**BILCAP: 経口抗がん剤が胆管がん患者の生存期間を1年以上延長する**

**BILCAP: Oral chemotherapy extends survival by more than a year in biliary tract cancer**

胆管がん患者447人を対象とした第III相ランダム化比較試験の結果、術後にカペシタビン投与することにより、手術単独の場合と比較し、生存期間中央値が15か月延長することが示された。と2017年American Society of Clinical Oncology年次集会で発表された。がん再発までの期間中央値は、カペシタビン投与群で25か月であり、コントロール群では18か月であった。最も顕著な副作用は、カペシタビンによく見られる手足の発疹であった。これらの所見は、本疾患に新たな標準治療の基盤を提供する可能性がある。

### Full Text

A phase III randomized clinical trial of 447 patients with biliary tract cancers (BTCs) showed that giving capecitabine after surgery extends survival by a median of 15 months compared to surgery alone. The finding could provide the basis for a new standard of care in the disease.

This trial, called BILCAP, is one of the first randomized studies of adequate size to look at the use of adjuvant therapy in this rare and hard-to-treat cancer. The study is being presented at the 2017 ASCO Annual Meeting in Chicago.

"Biliary tract cancer is a disease of decidedly unmet need as until recently there has been little research on treating the disease," said lead study author John N. Primrose, MD, Professor of Surgery at the University of Southampton, United Kingdom. "Our trial is the first to enroll a sufficient number of patients to show that chemotherapy after surgery can have a significant improvement in survival, with modest side effects."

Patients with BTCs face considerable odds in that only about 20% of such cancers can be surgically removed, and for those that have a successful surgery, fewer than 10% survive five years.

At the time the trial was designed in the U.K. there was no standard of care for adjuvant therapy in BTC. Capecitabine was chosen out of several commonly used systemic therapies because it could be given as a tablet and had shown efficacy in pancreatic cancer, a disease with similarly poor outcomes. Subsequent to the start of the trial, two chemotherapy agents in combination, gemcitabine and cisplatin, have evolved to be the current standards of care in the setting of advanced BTC on the basis of results from other studies done in the U.K.

In the trial, 447 patients were randomly assigned to either treatment with capecitabine for 6 months or observation for recurrence of cancer. More than 80% of the patients were followed for at least three years with regular clinical exams, CT imaging, and a variety of blood tests that could be useful later in determining biomarkers for tumors.

While patients in the observation group lived a median of 36 months after surgery, those who received capecitabine lived a median of 51 months. Capecitabine was associated with a 20% lower chance of death than observation, but the difference was not statistically significant for the overall population of 447 patients in this study, which includes patients that stopped capecitabine early. However, in the subgroup of 430 patients that received treatment per study protocol, capecitabine was associated with a 25% lower chance of death than observation, and this difference was statistically significant.

The median time to cancer recurrence was 25 months for patients who received capecitabine and 18 months for patients in the control group. The most notable side effect related to treatment was a rash on the hands and feet, which is common with capecitabine. There were no deaths due to the use of capecitabine.

"One of the major benefits of our trial is the fact that we now have a tumor tissue collection associated with very robust clinical data which will be used for genomic exploration," said Dr. Primrose. "Since we started planning this trial at the start of this century, a number of new agents have become available, including several that treat cancer based on its genetic profile. This is where our tumor tissue repository will play an important role."

"This study helps resolve long-standing questions about adjuvant treatment for biliary tract cancer, for which there has been no standard of care," said ASCO President Daniel F. Hayes, MD, FACP, FASCO. "This oral chemotherapy is widely available and can offer patients the chance to live more than a year longer."

Dr. Primrose emphasized, however, that new approaches are urgently needed to develop and recruit patients for clinical trials in biliary cancer, as this trial's ten-year timeline is much too long to conduct a trial in a rapidly evolving era of treatments and approaches. International cooperation is desperately needed, he noted.

The authors are currently working on a subgroup analysis as there are four distinct types of BTC – three of which involve the liver and its ducts and one of which involves the gallbladder. This analysis may help define more precisely which patients could benefit the most from adjuvant chemotherapy.

This study received funding from Cancer Research UK.

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