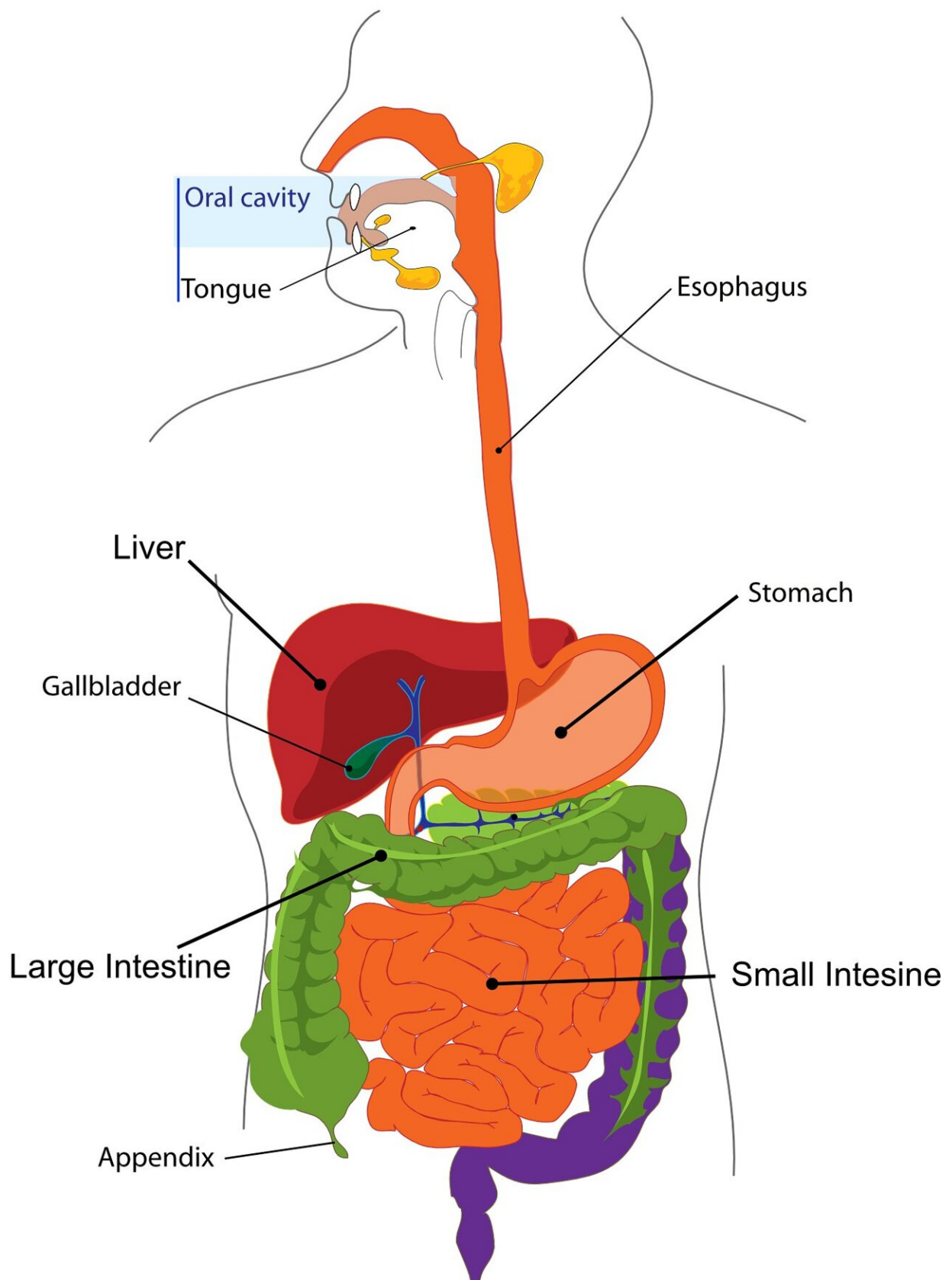


Nab-paclitaxel does not extend biliary tract cancer survival, but may benefit some

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Adding nab-paclitaxel to a standard treatment of gemcitabine plus cisplatin does not significantly extend median overall survival (OS) time for patients with advanced biliary tract cancers, although it may provide a benefit for subsets of patients with locally advanced disease or gallbladder adenocarcinoma.

These results are from the phase 3 S1815 trial conducted by the SWOG Cancer Research Network. The findings will be delivered in an oral presentation at the [2023 Gastrointestinal Cancers Symposium](#) of the American Society of Clinical Oncology (ASCO GI) on January 20 (abstract LBA490).

The S1815 trial was led by Rachna Shroff, MD, a SWOG investigator who is associate professor of medicine at the University of Arizona Cancer Center. Dr. Shroff will present the results at the ASCO GI meeting.

"This was the first randomized phase 3 trial to be conducted in the United States in biliary tract cancers," Dr. Shroff said. "It was a pivotal trial that demonstrates the ability to swiftly complete these studies in what are thought to be rare malignancies. The study did not meet its primary goal of improving overall survival with the addition of nab-paclitaxel to gemcitabine/cisplatin, though the overall survival, median progression-free survival, and overall response rate were numerically better."

Biliary tract cancers (BTCs)—a group of rare cancers that include

cholangiocarcinoma and gallbladder [cancer](#), among others—typically are diagnosed at an advanced stage, with a poor prognosis. Gemcitabine-based regimens are [standard treatment](#) in advanced disease, but median OS with these regimens is only about 12 months.

An earlier phase 2 trial led by Dr. Shroff found that adding nab-paclitaxel to a standard regimen of gemcitabine plus cisplatin extended median OS in these patients to about 19 months. Given those promising results, SWOG S1815 was designed as a randomized phase 3 trial to compare this nab-paclitaxel combination to the standard gemcitabine–cisplatin regimen to determine whether it would extend survival times in a larger group of patients newly diagnosed with advanced BTCs.

Of the 441 eligible patients randomized on the trial, about two-thirds had intrahepatic cholangiocarcinoma. The remaining third were almost evenly split between gallbladder adenocarcinoma and extrahepatic cholangiocarcinoma. The 441 patients were randomized 2:1 to a combination of nab-paclitaxel, gemcitabine, and cisplatin or to a standard regimen of gemcitabine and cisplatin.

The researchers found that median OS among patients on the nab-paclitaxel arm was 14 months, while median OS among patients on the standard gemcitabine–cisplatin arm was 12.7 months, a difference in OS that was not statistically significant (HR=0.93; 95% CI=0.74-1.19; $p=0.58$).

The objective response rate among patients overall on the investigative arm was 34% versus 25% on the control arm, and the [median progression-free survival](#) times were 8.2 months and 6.4 months, respectively.

The proportion of patients with Grade 3 or greater hematologic adverse

events (side effects) was significantly higher on the nab-paclitaxel combination than the standard gemcitabine–cisplatin regimen: 60% versus 45% ($p=0.003$). The rate of treatment discontinuation due to toxicity was also slightly higher on the nab-paclitaxel arm—24% versus 19%—although this difference did not reach the level of statistical significance.

In exploratory subset analyses, the researchers found that median OS was significantly longer on the nab-paclitaxel combination than on the standard [gemcitabine–cisplatin](#) regimen for those patients who had locally advanced disease (19.2 months versus 13.7 months) or gallbladder adenocarcinoma (17.0 months versus 9.3 months).

"While the addition of nab-paclitaxel did not improve survival, the triplet may merit further investigation in locally advanced biliary cancers as a potential neoadjuvant approach," Shroff said. "Additional ongoing genomic analyses from S1815 may also help elucidate potential molecular subsets of [patients](#) who could benefit from this combination."

"S1815 really shows the reach and importance of the NCTN in conducting trials in rare tumors such as biliary tract cancers," said Philip A. Philip, MD, Ph.D., professor of oncology at Henry Ford Cancer Institute at Wayne State University, chair of the SWOG gastrointestinal cancers committee, and senior author on the ASCO GI abstract. "This phase 3 trial was quickly opened at sites across the U.S. and, with more than 150 sites enrolling at least one patient to the study, it completed enrollment in just over two years."

Provided by SWOG Cancer Research Network

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