New Drug Combinations Maintain Quality of Life for Patients With Colorectal and Liver Cancers

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ASCO Perspective

“Patient-reported outcomes, or PROs, are now recognized as important endpoints of cancer clinical trials that provide important insights regarding the impact of treatment on patients’ quality of life. PROs inform us about the tolerability of new therapies, which is just as important as efficacy in gauging their utility and acceptance by patients. There is also evidence that suggests that PROs can have prognostic value for cancer patients. As we get better at including quality of life measures in clinical trials, we will continue to see the importance of patient reports grow,” said Richard L. Schilsky, MD, FACP, FSCT, FASCO, ASCO Chief Medical Officer and Executive Vice President

ALEXANDRIA, Va. – Patient-reported outcomes from two large studies show that quality of life is maintained longer with newer drug combinations compared with standard of care for the treatment of patients with a specific type of colorectal cancer and unresectable hepatocellular carcinoma. The results will be presented at the 2020 Gastrointestinal Cancers Symposium, taking place January 23-25 in San Francisco, California.

Quality of Life Maintained for Patients Treated With Atezolizumab and Bevacizumab for Unresectable Hepatocellular Carcinoma

The combination of atezolizumab and bevacizumab delayed declines in quality of life in a
study comparing the two-drug treatment with sorafenib (the standard of care) for patients with unresectable hepatocellular carcinoma (HCC). Atezolizumab is a programmed cell death ligand 1 (PD-L1) inhibitor; bevacizumab is a vascular endothelial growth factor (VEGF) inhibitor.

“Because it reflects both the effects of disease and the side effects of treatment, sustained or improved quality of life is particularly important for patients,” said lead author Peter R. Galle, MD, PhD, of the University Medical Center in Mainz, Germany. “Patients with liver cancer are typically more fragile and frail than others. Toxicity of the treatments can be much more serious for these patients, and their quality of life can decline quite quickly.”

The results come from the phase-III IMbrave 150 trial, which compared atezolizumab plus bevacizumab with sorafenib alone as a first-line treatment for patients with HCC who had not received prior systemic therapy. The primary endpoint of overall survival was presented at the European Society for Medical Oncology (ESMO) Asia Congress in November 2019. At that time, median overall survival had not yet been reached for atezolizumab plus bevacizumab compared with overall survival of 13.2 months for patients receiving sorafenib alone. The overall response rate was 27% with atezolizumab plus bevacizumab and 12% for sorafenib.

At the Gastrointestinal Cancers Symposium, researchers will present patient-reported outcomes results from the study. Time to deterioration, assessed by two validated patient-reported quality of life tools, was a prespecified secondary endpoint of the study. Time to deterioration was defined as a decrease of 10 points from baseline in key patient-reported outcomes. At baseline, every three weeks during therapy, and every three months after discontinuation of therapy, patients completed two questionnaires (one specific to HCC) to assess quality of life, physical functioning, and role functioning. Questionnaire completion rates were about 92%.

Time to deterioration was a median of 11.2 months for the combination treatment compared with 3.6 months for sorafenib. Declines in physical functioning were also delayed with the combination treatment, with a median delay of 13.1 months with atezolizumab and bevacizumab compared with 4.9 months for sorafenib.

The study was funded by F. Hoffmann-La Roche, Ltd.
Quality of Life Better Than Standard of Care With Treatments Targeting Metastatic Colorectal Cancer with Mutated \textit{BRAF V600E}

Patient-reported outcomes improved with double- and triple-drug treatments compared with current standard of care options for patients with a particular type of colorectal cancer. Patients with colorectal cancer (CRC) that has a \textit{BRAF V600E} mutation, treated with encorafenib and cetuximab with or without binimetinib were able to maintain their quality of life longer than those treated with one of two standard of care regimens, consisting of irinotecan plus cetuximab or FOLFIRI (leucovorin, calcium folinate, fluorouracil, and irinotecan) with cetuximab. The \textit{BRAF V600E} mutation occurs in about 10\% of CRC patients and has a poor prognosis.

“The findings highlight that with these novel targeted therapy regimens, not only was disease controlled longer, but patient-reported quality of life was maintained longer,” said lead author Scott Kopetz, MD, PhD, FACP, who is a professor of Gastrointestinal Medical Oncology at The University of Texas MD Anderson Cancer Center in Houston.

The findings come from the open-label, phase-III BEACON CRC trial (Binimetinib, Encorafenib, and Cetuximab Combined to Treat BRAF-Mutant Colorectal Cancer), which included 655 patients. Binimetinib and encorafenib are inhibitors of proteins involved in cancer cell growth.

Efficacy data was previously published in the \textit{New England Journal of Medicine}. The median overall survival was 9.0 and 8.4 months with the triplet and doublet targeted treatments, compared to 5.4 months in the control group of patients, which received irinotecan plus cetuximab or FOLFIRI plus cetuximab.

At the Gastrointestinal Cancers Symposium, researchers will report on quality of life, which was a secondary endpoint of the study. Quality of life was assessed at baseline and after every treatment cycle using four validated measurement tools: the European Organisation for Research and Treatment of Cancer (EORTC) QOL Questionnaire, Functional Assessment of Cancer Therapy, EuroQol 5D 5L, and the Patient Global Impression of Change.

In particular, the researchers looked at the time to 10\% or greater deterioration between the
study arms, which is considered to represent a clinically meaningful decline in quality of life. Patients treated with the triplet had a roughly 44-45% reduction in the risk of quality of life deterioration compared with patients in the standard of care group, based on two of the measures. Those receiving the doublet had a roughly 46% reduction in risk. Similar results were seen with the EuroQuol 5D 5L and Patient Global Impression of Change. There was no significant difference in quality of life for patients in the triplet and doublet groups.

The study was funded by Pfizer, Inc.

View the full abstract

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ATTRIBUTION TO THE 2020 GASTROINTESTINAL CANCERS SYMPOSIUM IS REQUESTED IN ALL NEWS COVERAGE.

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The American Gastroenterological Association (AGA) is the trusted voice of the GI community. Founded in 1897, the AGA has grown to include more than 16,000 members from around the globe who are involved in all aspects of the science, practice and advancement of gastroenterology. The AGA, a 501(c6) organization, administers all membership and public policy activities, while the AGA Institute, a 501(c3) organization, runs the organization's practice, research and educational programs. On a monthly basis, the AGA Institute publishes three highly respected journals, Gastroenterology and Clinical Gastroenterology and Hepatology, and Cellular and Molecular Gastroenterology and Hepatology. The organization's annual meeting is Digestive Disease Week®, which is held each May and is the largest international gathering of physicians, researchers and academics in the fields of gastroenterology, hepatology, endoscopy, and gastrointestinal surgery. The AGA Research Foundation provides digestive disease research grants on behalf of the AGA Institute.

Learn more information about the American Gastroenterological Association, including how to join.

About the American Society for Radiation Oncology:
The American Society for Radiation Oncology (ASTRO) is the premier radiation oncology society in the world, with more than 10,000 members who are physicians, nurses, biologists, physicists, radiation therapists, dosimetrists and other health care professionals that specialize in treating patients with radiation therapies. As the leading organization in radiation oncology, the Society is dedicated to improving patient care through professional education and training live activities as well as online through the ASTRO Academy, support for clinical practice and health policy standards, advancement of science and research, and advocacy. ASTRO publishes three medical journals, International Journal of Radiation Oncology, Biology, Physics, Practical Radiation Oncology, and Advances in Radiation Oncology, developed and maintains an extensive patient website; and created the Radiation Oncology Institute, a non-profit foundation to support research and education efforts around the world that enhance and confirm the critical role of radiation therapy in improving cancer treatment.
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About the Society of Surgical Oncology:
The Society of Surgical Oncology (SSO) is a dynamic global community of cancer surgeons shaping advancements in the profession to deliver the highest quality surgical care for cancer patients. SSO promotes leading-edge research, quality standards and knowledge exchange connecting cancer surgeons worldwide to continuously improve cancer outcomes. Our highly regarded educational resources, the Society's clinical journal, *Annals of Surgical Oncology* and events, including SSO 2020 - International Conference on Surgical Cancer Care, inspire members and spur each cancer surgeon to grow, improve and thrive. Learn more about the Society of Surgical Oncology.


About ASCO:

Founded in 1964, the American Society of Clinical Oncology, Inc. (ASCO®) is committed to making a world of difference in cancer care. As the world's leading organization of its kind, ASCO represents nearly 45,000 oncology professionals who care for people living with cancer. Through research, education, and promotion of the highest-quality patient care, ASCO works to conquer cancer and create a world where cancer is prevented or cured, and every survivor is healthy. ASCO is supported by its affiliate organization, the Conquer Cancer Foundation. Learn more at [www.ASCO.org](http://www.ASCO.org), explore patient education resources at [www.Cancer.Net](http://www.Cancer.Net), and follow us on Facebook, Twitter, LinkedIn, and YouTube.