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To the Press

Clinical Utility of Circulating Tumor DNA After Surgery for Colorectal Cancer Demonstrated in a Large-Scale Prospective Study

A Step toward Personalized Postoperative Adjuvant Chemotherapy

January 24, 2023 National Cancer Center Kyushu University

Highlights

- One of the world's largest prospective studies measuring circulating tumor DNA (ctDNA) in colorectal cancer patients undergoing curative surgery demonstrate its utility
- Strong correlation between ctDNA status at 4 weeks after surgery and the risk of postoperative recurrence
- Reductions anticipated in the risk of recurrence with adjuvant chemotherapy even in patients who were ctDNA-positive at 4 weeks after surgery

Summary

The research group, led by Takayuki Yoshino, Deputy Director of National Cancer Center (President, Hitoshi Nakagama; Chuo-ku, Tokyo) Hospital East (Director, Atsushi Ohtsu; Kashiwa-shi, Chiba) and Eiji Oki, Associate Professor of Department of Surgery and Science, Kyushu University Hospital (Director, Masafumi Nakamura; Fukuoka-shi, Fukuoka), has reported interim analysis results for their registry study investigating the correlation between ctDNA, measured over time before and after surgery, and the clinical course in patients diagnosed with colorectal cancer who underwent curative surgery (GALAXY study). This clinical research was conducted as part of "CIRCULATE-Japan," at approximately 150 participating institutions in Japan and overseas, on the platform of the industry-academia collaborative nationwide genome screening project "SCRUM-Japan".

An analysis of 1,039 colorectal cancer patients showed that patients who were ctDNA-positive at 4 weeks after surgery had a higher risk of recurrence than ctDNA-negative patients. In addition, among the patients with stage 2/3 disease who were ctDNA-positive at 4 weeks after surgery, those receiving postoperative adjuvant chemotherapy had a lower risk of recurrence than those not receiving such therapy.

The study demonstrated the clinical utility of ctDNA after surgery for colorectal cancer, which could be a step toward personalized medicine for colorectal cancer patients undergoing curative surgery based on appropriate postoperative adjuvant chemotherapy according to their risk of recurrence. This study was published in the scientific journal "Nature Medicine" (January 17, 2023, Japan time).

Prospects

This study is one of the world's largest prospective studies demonstrating the clinical utility of ctDNA in colorectal cancer patients undergoing curative surgery. Measurement of ctDNA levels would lead to personalized postoperative adjuvant chemotherapy for patients undergoing curative surgery according to their risk of recurrence. To test the results of this study, a randomized phase 3 trial in ctDNA-positive patients (ALTAIR study, JapicCTI-205363) and a randomized phase 3 trial in patients who were ctDNA-negative at 4 weeks after surgery (VEGA study, jRCT1031200006) have been ongoing and results are awaited.

Publication

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"An investigator-initiated basket trial of TAS-120 for refractory, advanced/recurrent solid tumors not amenable to curative resection harboring FGFR gene alterations based on circulating tumor DNA screening with the use of the platform of SCRUM-Japan (19ck0106447h0002)" (Principal Investigator: Takayuki Yoshino)

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