Monitoring tumor-informed circulating tumor DNA after CGP

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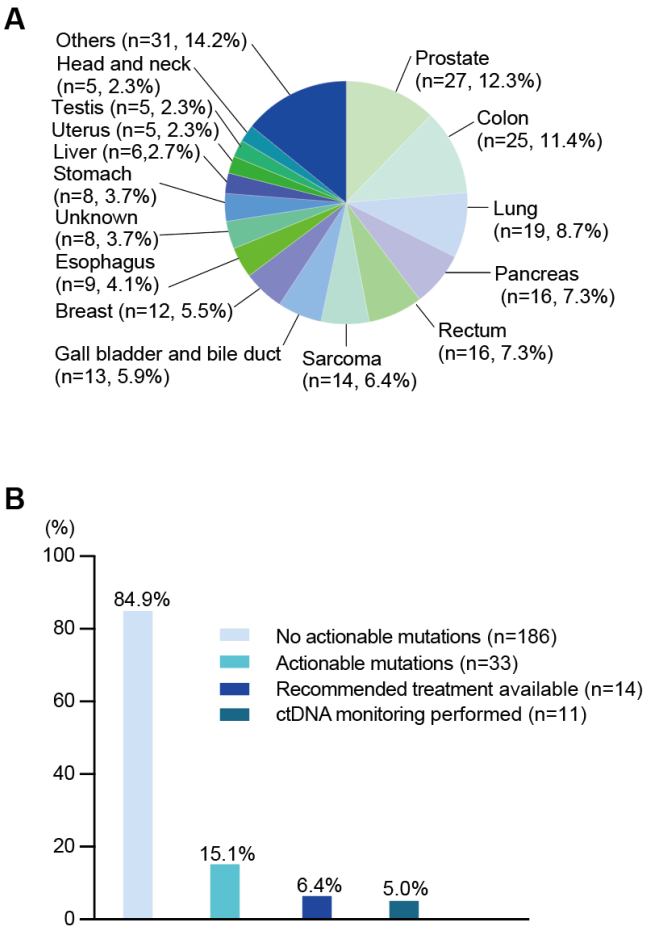
Body: Researchers from Iwate Medical University and Tohoku University have revealed that it is possible to predict cancer relapse and treatment response by measuring circulating tumor DNA (ctDNA), in tandem with data from comprehensive genomic profiling (CGP).

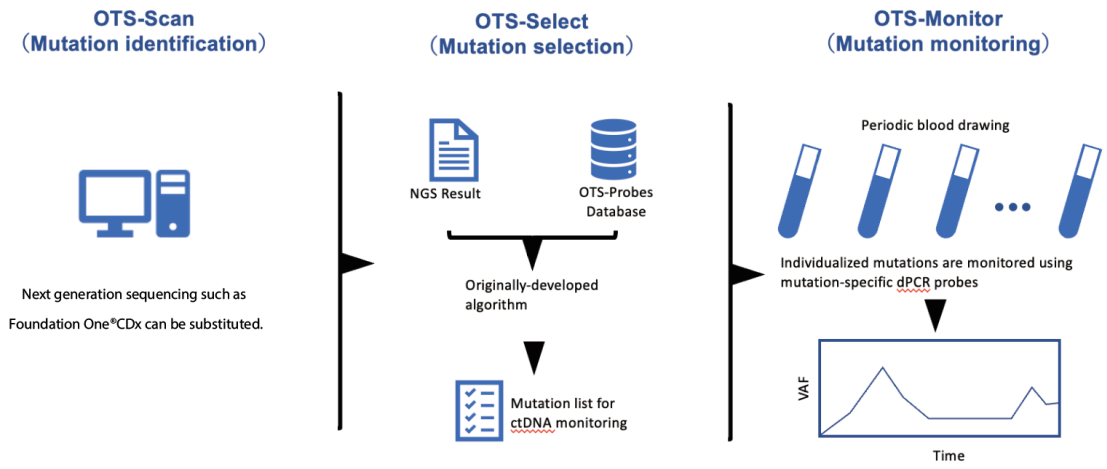
CGP test results can be used to tailor recommendations for advanced cancer treatment, with the goal of matching individual patients with the most effective option to prolong survival. This study retrospectively looked at the CGP and clinical data of 219 patients of Iwate Medical University with advanced cancer registered with the Center for Personalized Medicine at Tohoku University Hospital. Of these patients, only 14 (6.4%) received a tailored treatment based on their CGP results.



<Figure 1>
<Caption:> *(A) Breakdown CGP by organs of origins.*
(B) The percentage of patients with mutations that could not be matched with a relevant drug; The percentage of patients that obtained a subsequent treatment recommendation based on CGP; the percentage of patients who actually received the recommended next treatment; the percentage of patients who also received ctDNA monitoring in the present cohort. ©Sasaki et al.

The research team proposed that patients who underwent CGP could undergo ctDNA monitoring by using digital PCR (dPCR) (Off The Shelf-assay, hereafter OTS-Assay). The OTS-Assay was originally developed at Iwate Medical University, and has been clinically validated for a number of different cancers. Strengthening our knowledge and further testing the validity of this system is crucial, so that it can potentially become more commonplace in clinical practice.

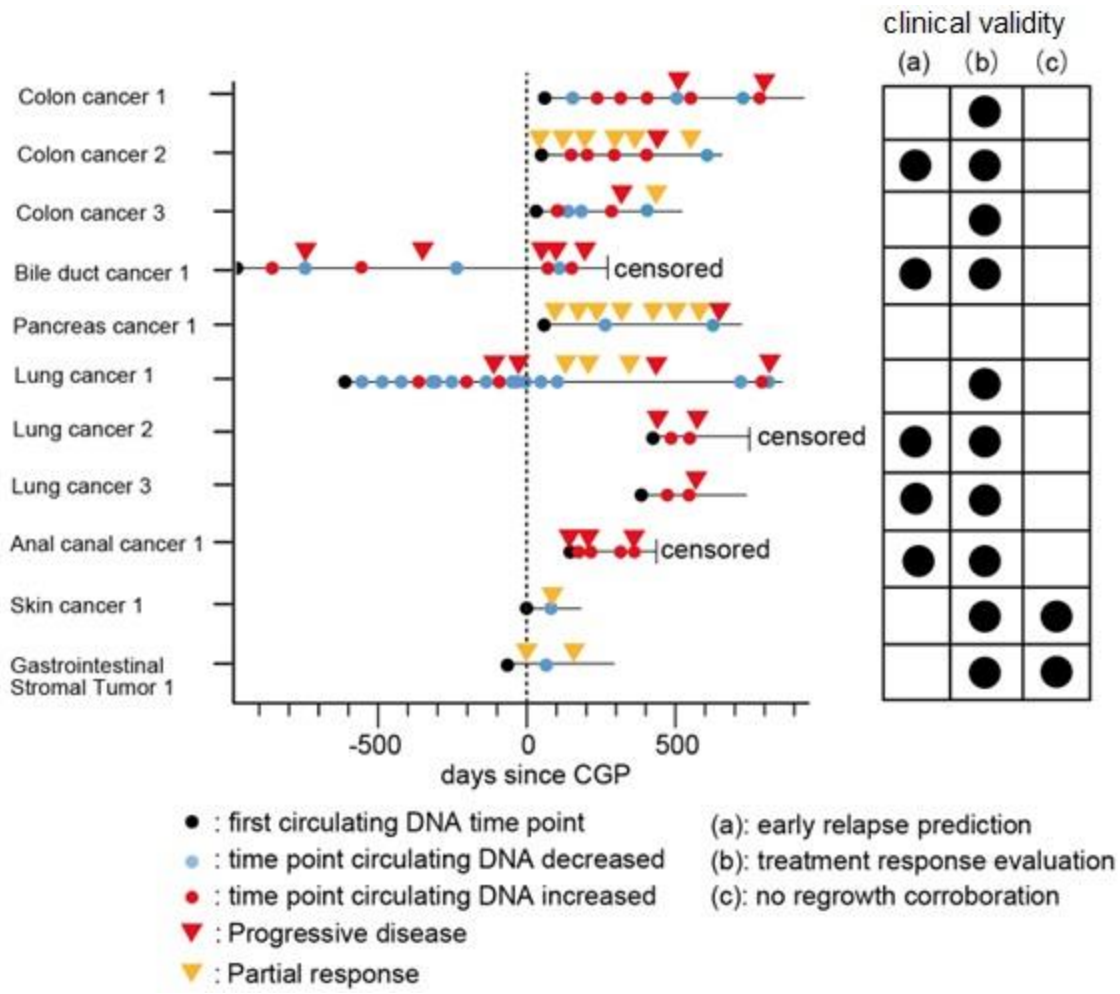
“First, we complete CGP to recommend an ideal treatment. Then, we can further predict and monitor the efficacy of that treatment using a relevant ctDNA – a measure of tumor DNA in the blood that can pick up even minimal hints that the cancer is still persisting,” explains Satoshi Nishizuka (Iwate Medical University).



<Figure 2>
<Caption:> *OTS-Scan analyzes the results of OTS-Scan using a proprietary algorithm to list gene mutations more closely related to cancer. OTS-Monitor quantifies the gene mutations selected by OTS-Select every few months.. ©Sasaki et al.*

The clinical validity of the OTS-Assay was evaluated for “early relapse prediction,” “treatment response evaluation,” and “no relapse/regrowth corroboration”. Monitoring of ctDNA by dPCR was performed in 11 patients. Overall, 10 of 11 patients (90.9%) achieved at least one of the following validated outcomes: “early relapse prediction,” “treatment response evaluation,” and “no relapse/regrowth corroboration”.

This study demonstrated that ctDNA monitoring using the OTS-Assay system can be used effectively in conjunction with CGP data in order to predict patient outcomes for a broad range of cancer types. This finding represents a step forward for personalized precision medicine. Importantly, the majority of patients who receive CGP but do not actually receive a recommended treatment (the remaining 93.6%) can still undertake ctDNA monitoring using the OTS-Assay system to evaluate their disease progression. This type of personalized medical care could improve clinical management techniques, and ultimately help cancer patients around the world.



<Figure 3>

<Caption:> *The righthand columns show that clinical validity was confirmed in 10 out of 11 cases. Cases classified as having a progressive on imaging showed that corresponding variant allele frequencies (VAFs) also increased. For five cases in which early relapse was considered likely to occur, the average lead time was 43 days of the disease progression confirmed by imaging. In two cases who showed VAFs remained below detection limit (BDL, <0.01%), clinical findings of no relapse/regrowth were well supported. One case of pancreatic cancer, the VAFs remained below detection limit, despite disease progression on imaging, possibly due to the DNA of the pancreas being highly fragmented. ©Sasaki et al.*

<Publication Details>

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