Abstract Title

Implemantation of a next-generation sequencing-based gene panel (OncoPrime™) to cancer patients in Japan

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BACKGROUND: Advances of next-generation sequencing (NGS) technology has enabled us to survey multiple cancer-related genes at a time and identify the potentially actionable abnormalities including point mutations, insertions, deletions, rearrangements and copy number alterations in an individual patient. NGS-based gene panel certified by Clnical Laboratory Improvement Amendments (CLIA) has now increasingly avaialble in daily clinical practice in the United States.

METHODS: Since 2015, we have launched a NGS-based gene panel (OncoPrime™) certified by CLIA in Japan. The indication of OncoPrime™ to patients with cancer of unknown primary (CUP), rare tumor types for which no standard treatment exists, or patients for which standard treatment option failed. OncoPrime™ requires 100 ng of tumor DNA (usually obtained from 10 FFPE slides) and includes 223 cancer-related genes. OncoPrime™ can identify point mutations (over 21,000 COSMIC mutations), insertions and deletions. Rearrangements of 17 specific genes are also evaluable using this panel.

RESULTS: From April 2015 to December, 60 patients received OncoPrime™ test. Success rate of sequencing was over 90%, and majority of sequencing failures were attributable to poor DNA quality or DNA fragmentation. Potentially actionable mutation was reported in 84% of patients, which was consistent with previously published reports; however, only 17% of patients received the treatment indicated by OncoPrime™ reports. Reasons for not receiving indicated therapy were: (1) deterioration of general condition before receiving the test results, (2) expensive medical cost for indicated treatment, (3) no clinical trials close to the patients' home. Some patients who received indicated treatment showed good response. Now, we strive to increase clinical utility of OncoPrime™ and to promote precision medicine based on genomic testing in Japan.