Cost-effectiveness analysis of cell-free DNA-based molecular tumor profiling platforms for the detection of EGFR mutations in lung cancer

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Background & objectives

Molecular analyses of liquid biopsies are becoming routine diagnostic tests. The detection of mutations in circulating tumor-derived DNA (ctDNA) in blood plasma of lung cancer patients can be used to monitor the response of the tumor to therapy, and for the early detection of resistance mechanisms. In 2017, the Roche Cobas® EGFR Mutation Test v2 for the detection of the *EGFR* c.2369C>T p.(T790M) mutation in plasma-derived ctDNA was approved as a companion diagnostic test to identify patients eligible for osimertinib treatment who progressed on targeted therapy with a first or second generation EGFR inhibitor. Today, different platforms are available for *EGFR* mutation testing in ctDNA. The objective of this study was to compare the clinical utility of five platforms for the detection of *EGFR* mutations in plasma-derived ctDNA to gain insight in their operational costs, target coverage, hands-on-time and turn-around-time.

Methods

Four PCR-based platforms (Bio-Rad QX200 droplet digital PCR (ddPCR), BioCartis Idylla™ ctEGFR Mutation Assay, Agena MassARRAY® UltraSEEK® Lung Panel, Roche Cobas® EGFR Mutation Test v2) and one NGS-based approach (Roche AVENIO ctDNA Expanded kit) for the detection of *EGFR* mutations were compared. Operational, maintenance, material and personnel costs were calculated for each platform and used as input variables for our recently developed ctDNA micro-costing framework (doi.org/10.1016/j.jmoldx.2022.10.004). This was compared to target coverage and turn-around-time of each platform.

Results

The BioCartis Idylla™ platform was the least expensive and had the shortest turn-around-time when only one sample needed to be analysed. However, when multiple samples can be analysed in a run, the per sample costs decreased. These savings were platform dependent.

Differences between these five platforms with respect to costs, hands-on and turn-around time and target coverage will be presented.

Conclusion

Costs for *EGFR* ctDNA mutation analysis can be reduced when the number of samples per analysis increases. This implies that centralization of testing can improve cost-efficiency but may increase turn-around time. The current study was focused on the detection of *EGFR* mutations in the setting of therapy resistance. With the advent of ctDNA analysis beyond *EGFR* in the context of targeted therapies for lung cancer, multigene detection assays will become more cost-effective.