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Epigenetic detection of early-stage non-small cell lung cancer in blood

Keywords: lung cancer, SCLC vs.NSCLC, adenoma vs. squamous cell carcinoma, specimen variety, lung vs. liquid biopsy, diagnosis, staging

INVENTION NOVELTY

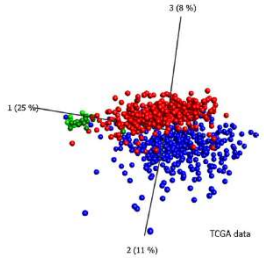
Lung cancer is the leading cause of cancer-related death worldwide, with non-small cell lung cancer (NSCLC) being the predominant morphology and adenocarcinoma (AC) the most common histology. Choosing the appropriate therapy depends on early and definite diagnosis, which is particularly challenging when a specimen's tumor cell content is low. In fact, most diagnostic markers (including DNA methylation profiles) have been determined in a single specimen and based on samples with high tumor cell content, and accordingly struggle to detect lung cancer in real-life samples. The innovative and proprietary epigenetic panel enables the reliable detection of early-stage lung cancer from a wide range of specimens, incl. biopsies with low tumor content.

VALUE PROPOSITION

The innovative epigenetic panel is a versatile tool for lung cancer detection that offers several decisive advantages over existing methods. It expands the toolbox of lung cancer diagnosis and enables the generation of more comprehensive and accurate data sets, including information on the tumor entity (SCLC vs. NSCLC), tumor subtype (AC vs. SQC), tumor stage and prognosis. Most importantly, unlike state-of-the-art methods, the panel enables therapeutically important early-stage detection of lung cancer (stages I and II) from virtually any specimen, including biopsies with low tumor content as well as non-invasive blood samples.

TECHNOLOGY DESCRIPTION

DNA methylation is an epigenetic modification essential for the regulation and adaption of gene activity. Accordingly, epigenetics has been proposed as a diagnostic tool also in oncology. Previous strategies have identified specific epigenetic panels using high-quality cancer samples with high tumor cell content, which is certainly useful for understanding tumor biology, but does not reflect the situation in real biopsy specimens such as collected during bronchoscopy. Beyond that, methylation patterns derived from different specimens (e.g., solid vs. liquid biopsy) have been shown to only partially correlate, which (until now) prevented the exploitation of a certain panel for a sample derived from another specimen.



Principal component anaylsis on lung cancer entities. *Red spheres: AC (n=439), blue: SQC (n=369), green: control (n=26) (from Goldmann, 2021)*

To overcome the limitations and shortcomings of previous approaches, the inventors carefully collected and analyzed samples of diverse origin. The starting point were paired solid biopsy samples of confirmed benign or malignant origin, which yielded a set of methylation markers that was further improved by analyzing cell-free DNA (cfDNA) derived from liquid biopsies, and fine-tuned with data sets from diverse studies, eventually giving rise to a set of tumor-specific and prognostic CpG loci, covering a multitude of genetic regions. This epigenetic panel was validated in a pilot study, clearly demonstrating its accuracy and diagnostic potential. Besides detection of (even early-stage) lung cancer in various specimens (incl. blood), the panel provides further valuable diagnostic and prognostic information on a given sample.

COMMERCIAL OPPORTUNITY

The epigenetic panel is available for co-development and in-licensing.

DEVELOPMENT STATUS

The innovative epigenetic panel was validated in a pilot study, identifying malignant lung tumors already at stage I with 100% accuracy. Beyond that, the panel (as well as certain sub-panels derived thereof) allowed the accurate determination of the tumor entity, subtype, stage, and prognosis. Further clinical validation is in progress within the scope of the DZL's EMoLung study.

PATENT SITUATION

The technology is protected by the international PCT application WO2021/043986 A1.

FURTHER READING

Goldmann et al. (2021) DNA methylation profiles of bronchoscopic biopsies for the diagnosis of lung cancer. Clin. Epigenet. 13:38.

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