

Development and Validation of Liquid Biopsy for Cancer Diagnosis

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Abstract

A minimally invasive technique called liquid biopsy (LB) seeks to identify circulating tumor-derived elements in bodily fluids. It provides an alternative to current cancer screening methods that use tissue biopsies for the confirmation of diagnosis. This essay looks at the degree to which the governance, legislative, and regulatory frameworks enable the integration of LB into healthcare systems and offers suggestions for how to make things better.

Keywords: Liquid biopsy • Molecular diagnostics • Genomic variations • Phenotypes • Drug effectiveness

Introduction

It is now commonly acknowledged that molecular diagnostics can revolutionise accuracy in healthcare and significantly enhance oncology screening and treatment. However, a number of logistical and technical issues impede progress. Currently, fine-needle aspirates, needle biopsies, and resection tissue samples are the foundation of molecular diagnostics. However, needle biopsies still account for the majority of molecular diagnoses in malignancies, including those of the lung. Since individual tumours comprise of various subpopulations, the tiny amount of tissue acquired by needle biopsies might not capture the most aggressive subclones available. Additionally, because some tumour forms, like lung cancer, are found in remote locations, a needle biopsy can be extremely challenging and dangerous for the patient.

Literature review

The features of metastases, the major target for systemic anticancer therapy, may be inferred incorrectly from the study of the primary tumour alone after it has been removed. There are medical risks particularly in children from repeated anesthesia to obtain sufficient diagnostic and prognostic information. The biopsy of metastases is also an intrusive and occasionally risky technique. The promise of precision medicine as a model to tailor medical care to each individual patient, utilising cutting-edge genomic techniques to categorise and describe diseases and their hosts, has so not lived up to its full potential. With obvious detrimental effects on resources and patient comfort, achieving its goals would require a vast increase in invasive procedures in order to collect enough data to accurately capture and describe genomic variations and their phenotypes [1]. This would be the case even if traditional tumour sampling methods such as needle and surgical biopsy were used. More importantly, LB can be repeated throughout cancer treatment to track minimal residual disease or check drug effectiveness. The resolution of these issues, the adoption of LB techniques and next-generation sequencing technology for routine clinical use,

and other developments should all help to advance and personalise anticancer therapy. Adjuvant therapy after curative treatment; cancer treatment selection and monitoring, i.e., using LB to choose targeted treatment and track the progression of disease and treatment response [2].

The goal was to figure out the best way to encourage LB use in ordinary patient practice and to address the difficulties this presents. While the supply of exams is a function of the related infrastructure, arrangements for having paid for procedures and materials, and the extent to which underlying evidence generates calls for testing, the demand for LB tests is inexorably influenced by the organizational issues relating to standardisation, guidelines, and awareness between many physicians and in the patient community. An LB is a straightforward, non-invasive technique that became popular a decade ago as an appealing alternative. It now stands for one of the cancer research fields with the highest level of activity. The ability to real-time study the genome, transcriptome, proteome, and recent genetic studies of circulating tumour cells is crucial for determining the functionality of the most aggressive and propagating clones [3,4]. Circulating tumour DNA has quickly grown popular because it makes it possible to analyse the tumour mutational profile in real-time. Drs. Alix-Panabières and Pantel first introduced and defined the term "LB" in 2010 and used it to characterise circulating tumour cells in the peripheral blood at the time. Nowadays, the definition has been expanded to include all circulating tumor-derived biomarkers as well as immune cells in all body fluids. These biomarkers provide supplementary data at various levels. To demonstrate their clinical significance in cancer patients, numerous LB-based investigations and clinical trials for a wide range of cancer types have been started.

Epidermal growth factor receptor mutations in patients as well as KRAS proto-oncogene, GTPase mutations in patients with metastatic CRC have both been identified using the clinical utility of LB. Similar findings have been found when comparing patients' consequences on therapeutic strategies based on LB and tissue for those with NSCLC. Companion diagnostic tests are increasingly recommended as an alternative in national and international guidelines when tissue-based biopsies are not accessible, of poor quality, or entail a major risk to obtain. The clinical value of LB for companion diagnostics for several cancer types has been demonstrated. In addition, four other diagnostic tests have so far been authorised. It would be simpler to demonstrate the therapeutic efficacy of LB and its value for research if there were straightforward, reliable, and repeatable procedures [5]. There are no integrated processes for the clinical setting that have been tested across several sites as of yet. Such workflows should have Standard Operating Procedures for each of the aforementioned stages of laboratory testing, from the collection of the test material to the interpretation of the results, for example, through bioinformatics analysis. Organizations and foundations that understand the significance of working toward the global application of LB in oncology practise in order to support clinical decision-making and regulatory concerns are required to form an international LB standardised alliance. Awareness of profiling opportunities,

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Date of Submission: 11 June, 2022, Manuscript No. jhbe-22-74159; **Editor Assigned:** 15 June, 2022, PreQC No. P-74159; **Reviewed:** 23 June, 2022, QC No. Q-74159; **Revised:** 26 June, 2022, Manuscript No. R-74159; **Published:** 30 June, 2022, DOI:10.37421/2380-5439.2022.10.100028

comprehension of the methodologies and results, conversion of the results into actionable insight, reimbursement strategies, and expert guidance for the interpretation and application of cfDNA analyses are all necessary for LB to increase access to testing in advanced cancer.

In order to choose which patients to test, which panels to order and for which indication and issue with which technology, and which labs to use—whether outsourced or in-house—as well as how to standardise value-based precision medicine hospital-wide, as well as what the results mean—precision oncology necessitates polymath proficiency across various knowledge domains. It necessitates the capacity to respond to queries from patients regarding the rationale behind their specific course of treatment and whether a certain test will enhance their outcome. It is necessary to define which tests should be compensated and for which treatment at the level of health systems in order to increase volume and improve reimbursement. Because technology, evidence, and approvals are always changing, precision oncology and information overload are concerns. Designing and conducting adaptive clinical trials based on LB/MRD detection in the adjuvant setting, as well as enhancing the sensitivity and reproducibility of ctDNA assays, are urgently required to demonstrate their clinical benefit. The necessity for additional clinical trials to evaluate what would be the clinical significance of tumour heterogeneity detection using ctDNA testing is one of the existing limitations. There is insufficient information to make sound recommendations with regard to additional applications of ctDNA, such as screening, MRD assessment, etc. For the adoption of ctDNA assays, new technologies that are under development may offer the data needed to make decisions in clinical settings.

Discussion

Communication breakdowns between HCPs: When pathologists and clinicians receive a report, they are unsure of what to do with it because they are not yet familiar with NGS data and with LB outside of a clinical trial or a research study. There are too many differences in information, advice, and suggestions across Europe. In reaction to the same outcomes, clinicians frequently use different techniques. Some parts of Europe lack molecular tumour boards, insufficient patient awareness and insufficient patient contact when participants in research projects come in for a blood sample, they typically get little to no feedback. There are still restrictions on how LB is being used to treat people when there are no treatments available. It would be simpler to demonstrate the therapeutic efficacy of LB and its value for research if there had been straightforward, reliable, and repeatable procedures. There are no integrated processes for the clinical setting that have been tested across several sites as of yet. Such workflows should have Standard Operating Procedures for each of the aforementioned stages of laboratory testing, from the collection of the test

material to the interpretation of the results, for example, through bioinformatics analysis. Organizations and foundations that understand the significance of working toward the global adoption of LB in cancer practise to assist clinical decision-making and regulatory considerations and aim to promote it in their communities could form an international LB standardised alliance.

Conclusion

The current screening and diagnostic methods' well-documented shortcomings prevent a greater use of molecular diagnostics and obstruct the development of personalised treatment. Perversely, the obvious benefits of LB are still not fully appreciated. There has been enough information about its potential to warrant additional investigation, although the evidence of its predictive value in therapeutic utility still is developing. Experience is proving to be valuable in gauging therapy efficacy and prognosis, as well as in terms of cost. Incorporating more contemporary technology, such as digital breast tomosynthesis for breast cancer and HPV testing for cervical cancer, is called for in the plan. Although LB is not mentioned, updating guidelines should take full advantage of screening technology's capabilities, which has advanced significantly since 2000. By specifically including it in its new suggestion, the EU should promote the development of LB alongside other cutting-edge techniques. Along with ongoing scientific and technological advancements that improve the precision and predictability of LB, policy can help create an environment that fosters further progress.

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How to cite this article: Jimba, Joseph. "Development and Validation of Liquid Biopsy for Cancer Diagnosis." *J Health Edu Res Dev* 10 (2022):100028.