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MINI REVIEW

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Emerging molecular biomarkers for early diagnosis of human diseases

Shrabani Pattanaik[1], Asutosh Panigrahi[2]

[1]Department of Biotechnology, MITS School of Biotechnology, Bhubaneswar, Odisha, India
[2]Department of Biotechnology, Utkal University, Bhubaneswar, Odisha, India

ABSTRACT

The initial detection of human diseases remains a critical cause of therapeutic ability and patient survival, therefore involving the development of sensitive and specific molecular biomarkers. Additional diagnostic approaches are limited by low sensitivity, delayed detection, and invasive procedures, underscoring the need for innovative molecular strategies. This mini review aims to evaluate emerging molecular biomarkers and their potential use in the initial diagnosis of major human diseases, including cancer, cardiovascular disorders, and neurodegenerative conditions.

Current advances in high-throughput omics technologies encompassing genomics, transcriptomics, proteomics, and metabolomics have facilitated the recognition of diverse biomarker. Circulating biomarkers such as cell-free DNA (cfDNA), microRNAs (miRNAs), extracellular vesicles, and disease-specific protein signatures have reveal significant promise due to their minimally invasive nature and high diagnostic accuracy. Additionally, integrative multi-omics approaches combined with artificial intelligence-driven analytical models have increased biomarker discovery, validation, and predictive performance.

Despite these advancements, several limitations force their clinical translation. These involves the lack of standardized protocols for sample collection and analysis, variability across populations, limited large-scale validation studies, and challenges related to cost-effectiveness and regulatory approval. Additionally, the heterogeneity of diseases and biomarker expression profiles complicates their universal applicability.

The emerging molecular biomarkers represent a transformative approach for initial disease detection and precision medicine. However, addressing existing methodological and translational challenges through rigorous validation and standardization is essential to facilitate their integration into routine clinical practice and better healthcare outcomes.

KEY WORDS

Molecular biomarkers; Liquid biopsy; Multi-omics; Early diagnosis; Precision medicine; Circulating tumor DNA; Proteomics

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Introduction

The molecular biomarkers have appeared as powerful tools for initial disease diagnosis and prognosis. Molecular biomarkers indicate to measurable biological molecules that involve normal or pathological processes or responses to therapeutic interventions [1]. Current advances in high-throughput technologies, such as next-generation sequencing (NGS), mass spectrometry, and microarray platforms, have improved the identification of a wide spectrum of biomarkers, including circulating cell-free DNA (cfDNA), microRNAs (miRNAs), long non-coding RNAs (lncRNAs), proteins, and metabolites [2]. Of particular interest are liquid biopsy-based biomarkers, which can be detected in easily accessible body fluids such as blood, saliva, and urine, offering a non-invasive alternative to conventional diagnostic methods [3]. These arising biomarkers provide insights into disease pathogenesis and hold considerable promise for improving initial detection, risk stratification, and personalized therapeutic interventions.

An increasing body of literature underlines the clinical connection of molecular biomarkers in initial disease detection. These studies have demonstrated that cfDNA, particularly circulating tumor DNA (ctDNA), can serve as a sensitive indicator of early-stage cancers, allowing the detection of tumor-specific mutations important to clinical manifestation [4]. The microRNAs have been highly examined due to their stability in circulation and their regulatory roles in gene expression; altered miRNA expression profiles have been linked with various cancers, cardiovascular diseases, and neurological disorders [5]. Proteomic analyses have also identified disease-specific protein signatures with potential diagnostic value, while metabolomic profiling has revealed distinct metabolic alterations associated with disease onset and progression. The integrative multi-omics approaches have gained traction, allowing for the comprehensive characterization of complex biological systems and increasing biomarker discovery. Current studies have also highlighted the role of artificial intelligence and machine learning in analyzing large-scale omics data, thereby increasing the accuracy and predictive power of biomarker-based diagnostics [6].

Through these promising developments, several challenges hinder the clinical translation of emerging molecular biomarkers. One of the main limitations is the lack of standardization in sample collection, processing, and analytical methodologies, which contributes to variability and limits reproducibility across studies. Many biomarker studies are conducted on relatively small and heterogeneous cohorts, thereby restricting their generalizability. The high cost and technical complexity associated with advanced omics technologies further limit their widespread adoption, particularly in resource-constrained settings. The regulatory and ethical considerations, including data privacy and clinical validation requirements, pose additional barriers to implementation. The heterogeneity of diseases, particularly cancers, further complicates the identification of universally applicable biomarkers, necessitating disease-specific and population-specific validation strategies [7].

***Correspondence:** Ms. Shrabani Pattanaik, Department of Biotechnology, MITS School of Biotechnology, Bhubaneswar, Odisha, India. email: shrabanipattanaik02@gmail.com

The present mini review aims to unfavourably examine the emerging molecular biomarkers and their potential role in the initial diagnosis of human diseases. The review seeks to categorize and describe key classes of molecular biomarkers, examine current technological advancements facilitating biomarker discovery, assess their clinical applicability across major disease conditions, and identify existing challenges and future directions for their effective translation into clinical practice. By synthesizing recent evidence, this review plans to provide a comprehensive understanding of the evolving landscape of molecular diagnostics and its implications for precision medicine.

Classification of Molecular Biomarkers

Molecular biomarkers encompass a heterogeneous spectrum of measurable biological entities classified across genomic, epigenetic, transcriptomic, proteomic, metabolomic, and liquid biopsy categories [8,9]. Genomic biomarkers, including single nucleotide polymorphisms, copy number variations, and somatic mutations, provide fundamental disease susceptibility and oncogenic driver information, with polygenic risk scores demonstrating prospective prediction of incident coronary artery disease and breast cancer with performance exceeding established clinical risk algorithms [10]. Epigenetic biomarkers, particularly DNA methylation signatures detectable in circulating cell-free DNA, have demonstrated multi-cancer early detection capability, with the Galleri assay achieving 51.5% sensitivity across fifty cancer types at 99.3% specificity in the CCGA prospective study [11]. Transcriptomic biomarkers encompassing messenger RNA expression profiles, long non-coding RNAs, and circulating microRNAs provide dynamic regulatory state information, with disease-specific miRNA signatures, including miR-208a for myocardial injury and miR-21 for colorectal cancer, demonstrating diagnostic potential in multiple independent cohort studies [12,13]. Proteomic biomarkers, including circulating proteins, post-translational modification profiles, and autoantibody panels, constitute the most clinically established biomarker category, while metabolomic profiling has identified branched-chain amino acid signatures predicting incident type 2 diabetes up to twelve years before clinical diagnosis [14]. Liquid biopsy-based biomarkers, encompassing circulating tumor DNA, cell-free DNA, circulating tumor cells, and extracellular vesicles, represent a minimally invasive diagnostic frontier enabling real-time tumor molecular profiling from peripheral blood with transformative implications for cancer early detection and treatment response monitoring [15,16].

Genomic biomarkers

Genomic biomarkers majorly involve changes in the DNA-level, including single nucleotide polymorphisms (SNPs), copy number variations (CNVs), and epigenetic modifications such as DNA methylation. Circulating tumor DNA (ctDNA), a fraction of cell-free DNA (cfDNA), has gained considerable attention due to its ability to capture tumor-specific genetic alterations. Studies have revealed that ctDNA can detect oncogenic mutations in early-stage cancers, often preceding radiological detection. The aberrant DNA methylation patterns have been identified as initial indicators in colorectal and lung cancers [17].

Transcriptomic biomarkers

Transcriptomic biomarkers involve the coding and non-coding RNA molecules. Among these, microRNAs (miRNAs) and long non-coding RNAs (lncRNAs) are highly studied due to their regulatory roles in gene expression. Circulating miRNAs exhibit remarkable stability in body fluids and have been linked with initial disease onset. The specific miRNA signatures have been involved in initial detection of pancreatic and breast cancers. Similarly, lncRNAs such as HOTAIR and MALAT1 have shown diagnostic potential across multiple disease conditions [18].

Proteomic biomarkers

Proteomic biomarkers include the changes in protein expression, structure, and post-translational modifications. Modern in mass spectrometry-based proteomics have enabled high-throughput identification of disease-specific protein signatures [19]. The protein biomarkers, such as cardiac troponins, are widely used in clinical practice; but the emerging protein panels offer improved accuracy for initial diagnosis. Proteomic profiling has also facilitated the discovery of novel biomarkers for neurodegenerative diseases, including amyloid-beta and tau proteins [20].

Metabolomic biomarkers

Metabolomics focuses on small-molecule metabolites that represent downstream products of cellular processes. Disease-specific metabolic alterations can provide initial diagnostic clues. For example, altered lipid metabolism has been linked with cardiovascular diseases, while changes in amino acid profiles have been linked to cancer progression [21]. The addition of metabolomic data with other omics layers enhances biomarker robustness and diagnostic accuracy.

Emerging Biomarker Modalities

Recent research has shifted toward minimally invasive biomarkers detectable in body fluids, commonly referred to as liquid biopsy-based biomarkers [22].

Circulating cell-free DNA (cfDNA)

cfDNA originates from apoptotic and necrotic cells and can be detected in plasma and other body fluids [23]. Tumor-derived cfDNA (ctDNA) carries genetic and epigenetic alterations reflective of the tumor genome. Advanced sequencing technologies have enabled highly sensitive detection of ctDNA, facilitating initial cancer diagnosis and monitoring.

Extracellular vesicles and exosomes

Extracellular vehicles (EVs), including exosomes, are lipid bilayer-bound vesicles released by cells into the extracellular environment [24]. They carry proteins, lipids, and nucleic acids, thereby serving as carriers of disease-specific molecular information. Exosomal miRNAs have shown potential as non-invasive biomarkers for early detection of cancers and neurodegenerative diseases.

Circulating microRNAs

Circulating miRNAs are among the most promising biomarkers due to their stability, tissue specificity, and ease of detection. Differential expression profiles of miRNAs have been reported in various diseases, including cardiovascular disorders and diabetes [25]. Their combinantion into diagnostic panels increase the sensitivity and specificity.

Multi-omics biomarker panels

The complexity of human diseases necessitates the use of integrated biomarker panels. Multi-omics approaches combine genomic, transcriptomic, proteomic, and metabolomic data to generate comprehensive disease signatures [26]. These integrative models have demonstrated superior diagnostic performance compared to single biomarker approaches.

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Technological Advances in Biomarker Discovery

The rapid evolution of analytical technologies has significantly accelerated biomarker discovery and validation.

Next-generation sequencing (NGS)

NGS technologies have transform genomic and transcriptomic examined by allowing high-throughput, cost-effective sequencing. NGS facilitates the detection of rare mutations, gene expression changes, and epigenetic modifications, making it indispensable for biomarker discovery [27].

Mass spectrometry-based proteomics

Mass spectrometry (MS) provides high sensitivity and specificity for protein identification and quantification. Advances in MS-based workflows have enabled large-scale proteomic studies, leading to the identification of novel disease-associated proteins.

CRISPR-based diagnostics

Clustered Regularly Interspaced Short Palindromic Repeats (CRISPR)-based systems have emerged as innovative tools for molecular diagnostics. Platforms such as SHERLOCK and DETECTR enable rapid and precise detection of nucleic acid targets, offering potential for point-of-care diagnostics [28].

Artificial intelligence and machine learning

Artificial intelligence (AI) and machine learning (ML) algorithms play a critical role in analyzing complex, high-dimensional omics datasets. These tools facilitate pattern recognition, biomarker selection, and predictive modeling, thereby enhancing diagnostic accuracy and clinical decision-making.

Clinical Applications

Cancer

Molecular biomarkers have transformed cancer diagnostics by enabling early detection, prognosis, and treatment monitoring. Liquid biopsy approaches, including ctDNA and circulating tumor cells (CTCs), provide real-time insights into tumor dynamics. Multi-gene panels and epigenetic markers are increasingly used for initial cancer screening.

Cardiovascular diseases

Biomarkers such as high-sensitivity troponins and natriuretic peptides are well-established in cardiovascular diagnostics. Emerging biomarkers, including miRNAs and metabolomic signatures, offer potential for initial detection of atherosclerosis and heart failure.

Neurodegenerative disorders

Initial diagnosis of neurodegenerative diseases remains challenging due to the lack of reliable biomarkers. Current studies have identified cerebrospinal fluid (CSF) and blood-based biomarkers, including amyloid-beta, tau proteins, and neurofilament light chain (NfL), as promising candidates.

Infectious diseases

Molecular biomarkers have played a important role in the diagnosis of infectious diseases, mainly during the COVID-19 pandemic. Nucleic acid-based diagnostics, including RT-PCR and CRISPR-based assays, have demonstrated high sensitivity and rapid detection capabilities.

Challenges and Limitations

Notwithstanding substantial upgrades in molecular biomarker research, several barriers continue to block their seamless integration into routine clinical practice. A principal concern related to the absence of harmonized pre-analytical and analytical protocols, which introduces considerable inter-laboratory variability and compromises the reproducibility of biomarker measurements across independent cohorts [29]. Inconsistent standardization protocols and data heterogeneity remain among the most barriers to clinical translation, limiting the generalizability of findings across diverse patient populations.

A substantial proportion of biomarker discovery studies are constrained by limited sample sizes and an insufficient representation of longitudinal validation data, increasing the statistical strength and external validity of reported associations. Analytical validation must ensure that a responsible measure the biomarker across different sample types, instruments, and laboratories, where the clinical validation is a necessary demonstration that the biomarker predicts a meaningful clinical outcome [30].

The implementation of advanced omics research in low- and middle-income countries is blocked by significant structural, technological, and institutional hurdles, keeping access to precision diagnostic tools a persistent global health challenge. The severe underrepresentation of non-European genetic origins in omics datasets further blocks the generalizability of findings and complicates the pre-existing health differences.

The intrinsic disease of heterogeneity and pronounced inter-individual biological differences continue to block the identification of universally applicable molecular signatures. Systematic misalignment between analytical measurement, biological interpretation, and clinical decision-making requirements represents a recurrent but unnoticed source of translational failure that demands urgent methodological resolution through fast designed, multicentric, longitudinal investigations [31].

Future Perspectives

The trajectory of molecular diagnostics is secure for transformative progress, driven by the combination of multi-omics technologies, AI-enabled analytics, and next-generation point-of-care platforms. The addition of multi-omics data, spanning genomics, transcriptomics, proteomics, metabolomics, and radiomics holds considerable promise for increasing diagnostic and prognostic rate, with current integrated classifiers showing area under the curve values of 0.81–0.87 for diagnostically challenging malignancies [32]. AI-augmented multi-omics approaches further facilitate real-time biomarker monitoring, enabling immediate assessment of treatment effectiveness and disease recurrence.

The paradigm of precision medicine is rapidly embedded in individual molecular profiling. The generation and addition of multi-omics data allows more precise and tailored therapeutic strategies, increasing the treatment efficacy and reducing adverse effects, thereby signaling a fundamental shift from population-based to individualized disease management.

From a technological standpoint, nanotechnology-driven biosensor platforms show a particularly compelling frontier. Nanosensors, engineered at the nanometer scale, have also appeared as transformative tools in healthcare due to their ability to detect biochemical, physiological, and molecular changes with exceptional specificity and sensitivity, and their integration into point-of-care diagnostic devices offers significant advantages in initial disease detection [33]. The platforms integrate AI-based tools for increased analytical accuracy and wireless readout technologies to further position point-of-care biosensors as the future decentralized diagnostics. These interdisciplinary advancements are predicted

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to redefine the clinical landscape of molecular diagnostics, enabling initial detection, more precise risk stratification, and optimized therapeutic outcomes across diverse disease contexts.

Conclusion

In conclusion, emerging molecular biomarkers constitute a paradigmatic increment in the initial diagnosis and clinical management of human diseases. The combination of next-generation sequencing, multi-omics integration, artificial intelligence, and single-cell omics technologies has considerably accelerated the pace of biomarker discovery, enabling the exploration of complex diseases across multiple biological layers. Liquid biopsy and multi-omic biomarker integration have transformed precision oncology by providing real-time, minimally invasive insights into tumor biology, allowing clinicians to monitor clonal evolution, therapeutic response, and recurrence risk.

The emergence of omics technology, thousands of possible biomarkers have been identified, dramatically increasing the opportunities for developing more effective therapeutics with profound benefits for patients and for the economics of healthcare. Nonetheless, careful regulation, rigorous validation, and the tightening of quality controls in routine laboratories remain essential for the successful implementation of biomarkers in clinical practice, necessitating greater global collaboration among regulatory authorities, academia, industry stakeholders, and bioanalytical laboratories.

Future research should prioritize the confirmation of novel biomarkers, optimization of delivery and detection platforms, and ensuring wider access to precision diagnostics to improve patient lifespan and quality of life. The judicious and evidence-based translation of validated molecular biomarkers into routine clinical workflows will not only refine initial disease detection but will fundamentally advance the precision medicine paradigm, culminating in substantially improved patient outcomes at both individual and population levels.

Disclosure Statement

No potential conflict of interest was reported by the authors.

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