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EMERGING BIOMARKERS FOR CARDIOMETABOLIC DISORDERS

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ABSTRACT: Cardiometabolic disorders, encompassing cardiovascular diseases, diabetes mellitus, metabolic syndrome, and obesity, represent a significant global health burden. This comprehensive review explores emerging biomarkers that offer promising avenues for improving diagnosis, risk stratification, and management of these complex conditions. We focus on twelve novel biomarkers: growth hormone-15 (GH-15), CD40, ST2, interleukin-6 (IL-6), heart-type fatty acid-binding protein (H-FABP), matrix metalloproteinases (MMPs), neuregulin-1 (NRG-1), copeptin, adropin, preptin, irisin, and galectin-3 (Gal-3). Each biomarker is examined in terms of its biological role, potential clinical applications, and evaluation methods. These biomarkers reflect various pathophysiological processes, including inflammation, fibrosis, metabolic dysregulation, and cardiac remodeling, providing insights into the complex mechanisms underlying cardiometabolic disorders. Clinical applications range from early diagnosis and risk stratification to monitoring disease progression and treatment response. Some biomarkers, such as NRG-1 and irisin, also represent potential therapeutic targets. Despite their promise, challenges remain in translating these biomarkers into clinical practice. These include the need for standardization of assay methods, integration with existing risk assessment tools, and validation through longitudinal studies. Future directions in this field involve developing multimarker panels, point-of-care testing, and personalized medicine approaches. As research progresses, these emerging biomarkers are expected to play an increasingly important role in the personalized management of cardiometabolic disorders, potentially improving patient outcomes and reducing the global burden of these diseases.

INTRODUCTION: Cardiometabolic disorders encompass a spectrum of interconnected conditions that significantly contribute to global morbidity and mortality [1]. These disorders include cardiovascular diseases, diabetes mellitus, metabolic syndrome, and obesity [2]. As our understanding of the complex pathophysiology underlying these conditions evolves, there is growing interest in identifying novel biomarkers to aid in early diagnosis, risk stratification, and therapeutic monitoring [3]. This narrative review provides a comprehensive overview of emerging biomarkers for cardio-metabolic disorders, focusing on growth hormone-15 (GH-15), CD40, ST2, interleukin-6 (IL-6), heart-type fatty acid-binding protein (H-FABP), matrix metalloproteinases (MMPs), neuregulin-1 (NRG-1), copeptin, adropin, preptin, irisin, and galectin-3 (Gal-3).

An illustration depicting the involved biomarkers is shown in **Fig. 1.** We explore their biological roles, potential clinical applications, and evaluation methods, as well as discuss future directions and challenges in this rapidly advancing field.

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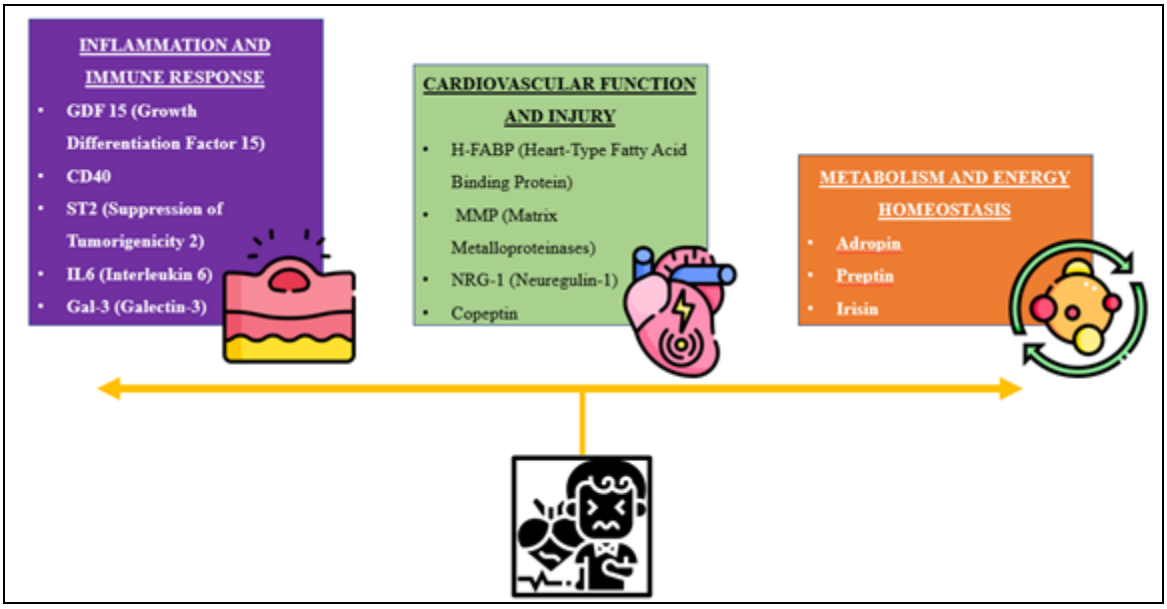

FIG. 1: BIOMARKERS INVOLVED IN CARDIOMETABOLIC DISORDERS

Overview of Cardiometabolic Disorders:

Cardiovascular Diseases: Cardiovascular diseases (CVDs) remain the leading cause of death globally, encompassing conditions such as coronary artery disease, heart failure, and stroke [4]. The complex interplay between genetic predisposition, lifestyle factors, and environmental influences underscores the need for improved diagnostic and prognostic tools in CVD management [5].

Diabetes Mellitus: Diabetes mellitus, particularly type 2 diabetes, is characterized by chronic hyperglycemia and insulin resistance [6]. Its rising prevalence worldwide has led to increased focus on early detection and prevention strategies [7].

Metabolic Syndrome: Metabolic syndrome is a cluster of conditions including abdominal obesity, hypertension, dyslipidemia, and impaired glucose tolerance [8]. It significantly increases the risk of developing cardiovascular diseases and type 2 diabetes [9].

Obesity: Obesity, defined as excessive fat accumulation, is a major risk factor for various cardiometabolic disorders [10]. Its complex interplay with inflammation, insulin resistance, and cardiovascular dysfunction underscores the need for biomarkers that can capture its multifaceted impact on health [11].

Emerging Biomarkers:

Growth Hormone-15 (GH-15): GH-15, a novel member of the growth hormone family, has gained attention for its potential role in glucose homeostasis and lipid metabolism [12].

Evaluation Method: GH-15 levels are typically measured in serum or plasma using enzyme-linked immunosorbent assay (ELISA) techniques. Efforts are ongoing to standardize assays and establish reference ranges in different populations. Some research groups are exploring multiplex assays that can simultaneously measure GH-15 along with other related hormones. Genetic studies examining polymorphisms in the GH-15 gene may provide insights into its role in cardiometabolic disorders. Longitudinal studies are needed to assess the predictive value of GH-15 levels for disease progression and treatment response. The development of high-sensitivity assays and the exploration of GH-15 isoforms may further enhance its utility as a biomarker.

CD40: CD40, a member of the tumor necrosis factor receptor super family, plays a crucial role in immune responses and inflammation. Emerging evidence suggests its involvement in the pathogenesis of atherosclerosis and other cardiometabolic disorders [13].

Evaluation Method: CD40 can be evaluated through various methods, including flow cytometry to measure cell surface expression on immune cells and ELISA to quantify soluble CD40 in serum or plasma. Immunohistochemistry techniques are used to assess CD40 expression in tissue samples,

particularly in atherosclerotic plaques. Genetic studies examining CD40 polymorphisms provide additional insights into its role in disease susceptibility. Functional assays measuring CD40-induced cellular responses, such as cytokine production or cell proliferation, can offer information on the biological activity of this pathway in cardiometabolic disorders. The development of standardized assays and the establishment of clinically relevant cutoff values are ongoing areas of research.

Soluble Suppressor of Tumorigenicity-2 (sST2): sST2, a member of the interleukin-1 receptor family, exists in two forms: a transmembrane receptor (ST2L) and a soluble form (sST2). Elevated levels of sST2 have been associated with adverse outcomes in heart failure and other cardiovascular conditions [14].

Evaluation Method: Soluble ST2 (sST2) is typically measured in serum or plasma samples using ELISA or automated immunoassay platforms. The FDA-approved Presage® ST2 Assay is widely used in clinical settings. Point-of-care testing devices for rapid sST2 measurement are under development. Serial measurements of sST2 can provide valuable information on disease progression and treatment response in heart failure patients. Cutoff values for risk stratification have been proposed, but may vary depending on the specific clinical context and assay used. Integration of ST2 measurements with other established biomarkers and clinical parameters is recommended for optimal risk assessment. Ongoing research focuses on improving assay sensitivity and specificity, as well as exploring the role of ST2 in various cardiometabolic disorders beyond heart failure.

Interleukin-6 (IL-6): IL-6 is a pleiotropic cytokine with pro-inflammatory properties. It has been implicated in the pathogenesis of various cardiometabolic disorders, including atherosclerosis, insulin resistance and obesity [15].

Evaluation Method: IL-6 levels are commonly measured in serum or plasma using ELISA or multiplex immunoassay platforms. High-sensitivity assays have been developed to detect low concentrations of IL-6, which is particularly relevant in assessing cardiovascular risk. Standardization efforts are ongoing to improve comparability between different assays and establish clinically relevant cutoff values. Some researchers are exploring the use of IL-6 measurements in other biological fluids, such as saliva or urine, as less invasive alternatives. Genetic studies examining IL-6 and IL-6 receptor polymorphisms provide additional insights into the role of this pathway in cardiometabolic disorders. Functional assays assessing IL-6 signaling in cell cultures or ex vivo samples can offer information on the biological activity of this cytokine in different disease states.

Heart-type Fatty Acid-Binding Protein (H-FABP): H-FABP is a small cytoplasmic protein involved in fatty acid metabolism. It has shown promise as an early marker of myocardial injury and may have applications in diagnosing acute coronary syndromes [16].

Evaluation Method: H-FABP can be measured in serum or plasma using ELISA or point-of-care testing devices. Rapid tests have been developed for emergency settings, allowing for quick assessment of potential myocardial injury. Serial measurements of H-FABP can provide information on the extent and progression of cardiac damage. Some studies have explored the use of H-FABP in combination with other cardiac biomarkers, such as troponins, to improve diagnostic accuracy. Urine H-FABP measurements have also been investigated as a non-invasive alternative. Standardization of H-FABP assays and establishment of universal cutoff values for different clinical scenarios are ongoing areas of research. The development of high-sensitivity assays and the exploration of H-FABP isoforms may further enhance its utility as a biomarker for cardiometabolic disorders.

Matrix Metalloproteinases (MMPs): MMPs are a family of enzymes involved in extracellular matrix remodeling. Various MMPs, particularly MMP-2 and MMP-9, have been implicated in the pathogenesis of atherosclerosis, cardiac remodeling, and diabetic complications [17].

Evaluation Method: MMPs can be evaluated through several methods, including ELISA for measuring protein levels in biological fluids and

zymography for assessing enzymatic activity. Multiplexed assays allow for simultaneous measurement of multiple MMPs and their tissue inhibitors (TIMPs). Immunohistochemistry and in situ zymography techniques are used to localize MMP expression and activity in tissue samples. Some researchers are exploring the use of fluorescent or radiolabeled MMP substrates for *in-vivo* imaging of MMP activity.

Genetic studies examining MMP polymorphisms provide insights into their role in disease susceptibility. Given the complex regulation of MMPs, integrating measurements of both MMPs and their inhibitors is often recommended for a more comprehensive assessment.

Neuregulin-1 (NRG-1): NRG-1 is a growth factor that plays crucial roles in cardiac development and adult heart function. Emerging evidence suggests its potential as a biomarker and therapeutic target in heart failure and other cardiovascular conditions [18].

Evaluation Method: NRG-1 levels can be measured in serum or plasma using ELISA techniques. Some researchers are developing assays to detect specific NRG-1 isoforms, as their biological activities may differ. Genetic studies examining NRG-1 polymorphisms provide insights into its role in cardiovascular disease susceptibility. Functional assays assessing NRG-1 signaling in cardiomyocytes or endothelial cells can offer information on its biological activity in different pathological states.

Imaging techniques, such as PET scans with radiolabeled NRG-1, are being explored for *in-vivo* assessment of NRG-1 receptor activity. Integration of NRG-1 measurements with other biomarkers of cardiac function and remodeling may provide a more comprehensive assessment of cardiovascular health. Ongoing research focuses on developing standardized assays and establishing clinically relevant cutoff values for NRG-1 in various cardiometabolic disorders.

Copeptin: Copeptin, the C-terminal part of the vasopressin prohormone, has emerged as a stable and easily measurable surrogate marker for vasopressin. It has shown potential in risk stratification for various cardiovascular conditions and metabolic disorders [19].

Evaluation Method: Copeptin is typically measured in serum or plasma using automated immunoassay platforms. These assays offer high sensitivity and specificity, allowing for accurate quantification of copeptin levels. Point-of-care testing devices for rapid copeptin measurement in emergency settings are under development. Serial measurements of copeptin can provide valuable information on disease progression and treatment response in various cardiometabolic disorders. Cutoff values for risk stratification have been proposed for different clinical scenarios, such as ruling out myocardial infarction or predicting outcomes in heart failure. Integration of copeptin measurements with other established biomarkers and clinical parameters is recommended for optimal risk assessment. Ongoing research focuses on refining assay techniques, establishing population-specific reference ranges, and exploring the utility of copeptin in various cardiometabolic disorders beyond acute coronary syndromes and heart failure.

Adropin: Adropin is a peptide hormone involved in energy homeostasis and metabolic regulation. Recent studies have suggested its potential role as a biomarker for various cardiometabolic disorders, including obesity, diabetes, and cardiovascular diseases [20].

Evaluation Method: Adropin levels are typically measured in serum or plasma using ELISA techniques. Efforts are ongoing to develop more sensitive and automated assays for high-throughput screening. Some researchers are exploring the use of adropin measurements in other biological fluids, such as saliva, as less invasive alternatives. Genetic studies examining adropin (ENHO) gene polymorphisms provide insights into its role in metabolic regulation and disease susceptibility. Animal studies using adropin knockout or overexpression models offer valuable information on its physiological functions. Integration of adropin measurements with other metabolic parameters and adipokines may provide a more comprehensive assessment of metabolic health. Ongoing research focuses on standardizing assay methods, establishing reference ranges in different populations, and investigating the relationship between adropin levels and various cardiometabolic risk factors.

Preptin: Preptin is a peptide hormone derived from proinsulin-like growth factor II (pro-IGF-II). It has been implicated in glucose metabolism and bone homeostasis, with potential relevance to diabetes and metabolic bone disorders [21].

Evaluation Method: Preptin levels can be measured in serum or plasma using ELISA techniques. Standardization of assays and establishment of reference ranges in different populations are ongoing areas of research. Some studies are exploring the use of preptin measurements in combination with other pancreatic hormones to assess beta-cell function. Genetic studies examining preptin-related gene polymorphisms provide insights into its role in metabolic regulation. Functional assays assessing preptin's effects on insulin secretion and bone metabolism in cell culture models offer information on its biological activity. Longitudinal studies are needed to assess the predictive value of preptin levels for the development and progression of metabolic disorders. Ongoing research focuses on developing more sensitive and specific assays, investigating the relationship between preptin and other metabolic biomarkers, and exploring its potential as a therapeutic target in cardiometabolic disorders.

Irisin: Irisin, a myokine released during exercise, has gained attention for its potential role in energy metabolism and glucose homeostasis. It has been studied as a potential biomarker and therapeutic target for obesity, diabetes, and cardiovascular diseases [22].

Evaluation Method: Irisin levels are typically measured in serum or plasma using ELISA techniques. However, there has been controversy regarding the specificity of some commercially available assays, highlighting the need for standardization and validation. Mass spectrometry-based methods have been developed for more accurate quantification of irisin. Some researchers are exploring the use of irisin measurements in other biological fluids, such as saliva or urine. Genetic studies examining FNDC5 (the precursor of irisin) polymorphisms provide insights into its role in metabolic regulation. Functional assays assessing irisin's effects on adipocyte browning and glucose uptake in cell culture models offer information on its biological activity. Integration of irisin measurements with other exercise-related biomarkers and metabolic parameters may provide a more comprehensive assessment of metabolic health. Ongoing research focuses on developing more specific and sensitive assays, investigating the relationship between irisin levels and various cardiometabolic risk factors, and exploring its potential as a therapeutic target.

Galectin-3 (Gal-3): Galectin-3 is a β-galactoside-binding lectin involved in various biological processes, including inflammation and fibrosis. It has emerged as a promising biomarker for heart failure, renal dysfunction, and other fibrotic conditions associated with cardiometabolic disorders [23].

Evaluation Method: Galectin-3 levels are typically measured in serum or plasma using ELISA or automated immunoassay platforms. The FDA-approved VIDAS® Galectin-3 assay is widely used in clinical settings. Point-of-care testing devices for rapid galectin-3 measurement are under development. Immunohistochemistry techniques are used to assess galectin-3 expression in tissue samples, particularly in fibrotic lesions. Genetic studies examining galectin-3 (LGALS3) polymorphisms provide insights into its role in disease susceptibility. Functional assays measuring galectin-3-induced cellular responses, such as fibroblast activation or macrophage polarization, can offer information on its biological activity in different pathological states. Integration of galectin-3 measurements with other biomarkers of fibrosis and inflammation is recommended for a more comprehensive assessment of organ damage in cardiometabolic disorders. Ongoing research focuses on refining assay techniques, establishing population-specific reference ranges, and exploring the utility of galectin-3 in various cardiometabolic disorders beyond heart failure.

Clinical Applications:

Diagnosis and Screening: The emerging biomarkers discussed in this review offer potential for improving the diagnosis and screening of cardiometabolic disorders. For instance, H-FABP has shown promise as an early marker of myocardial injury, potentially allowing for more rapid diagnosis of acute coronary syndromes [24].

Similarly, the combination of multiple biomarkers, such as ST2, galectin-3, and established markers like natriuretic peptides, may enhance the accuracy of heart failure diagnosis and prognosis [25].

Risk Stratification: Several of the biomarkers discussed have demonstrated value in risk stratification for various cardiometabolic disorders. For example, elevated levels of sST2 and galectin-3 have been associated with poor outcomes in heart failure patients, potentially allowing for more targeted interventions in high-risk individuals [26, 27]. Similarly, copeptin has shown promise in risk stratification for both cardiovascular and metabolic disorders [28].

Monitoring Disease Progression and Treatment Response: The dynamic nature of many of these biomarkers makes them potentially useful for monitoring disease progression and treatment response.

For instance, changes in MMP levels may reflect ongoing cardiac remodeling processes, while fluctuations in irisin or adropin concentrations could provide insights into metabolic adaptations to lifestyle interventions or pharmacological treatments [29, 30]. **Fig. 2** shows the various factors to be considered diagnosing and monitoring.

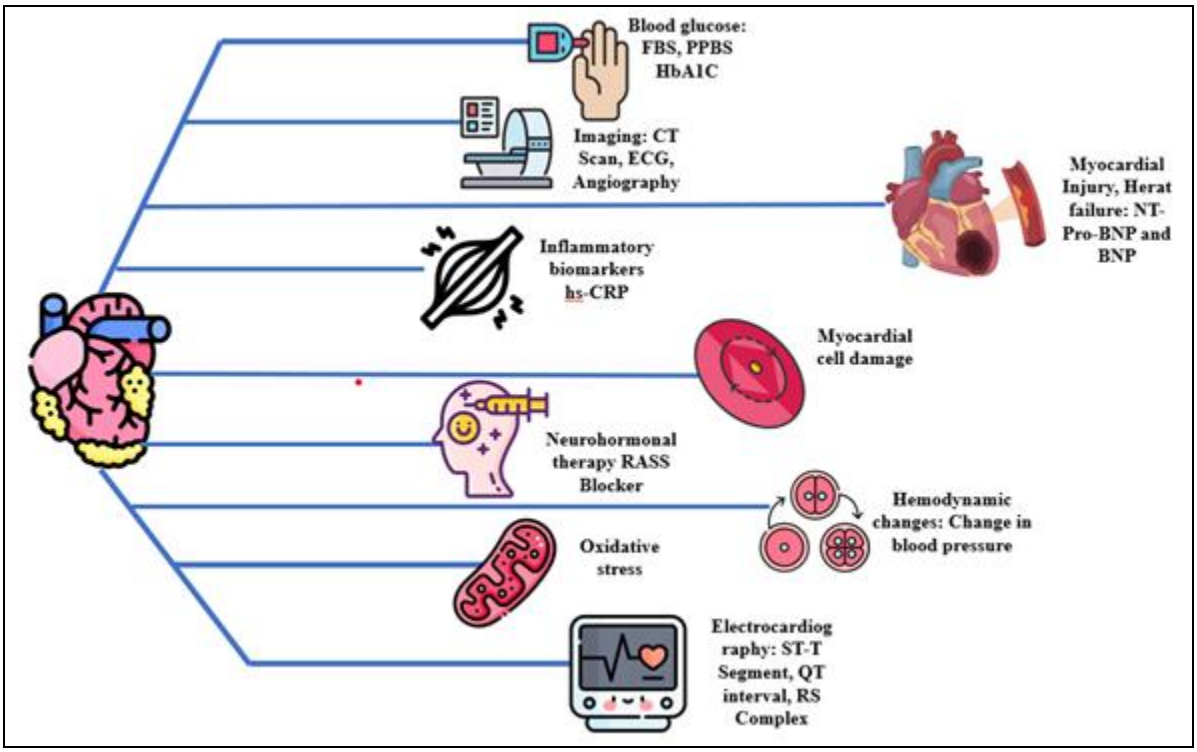

FIG. 2: VARIOUS FACTORS INVOLVED AND THEIR DIAGNOSTIC APPROACHES

Therapeutic Targets: Some of the biomarkers discussed not only serve as indicators of disease but also represent potential therapeutic targets. NRG-1, for example, has shown cardioprotective effects in preclinical studies, suggesting its potential as a novel treatment for heart failure [31]. Similarly, the manipulation of irisin levels through exercise or pharmacological means is being explored as a potential strategy for managing obesity and metabolic disorders [32].

Future Directions and Challenges: The field of biomarkers for cardiometabolic disorders is rapidly evolving, offering exciting opportunities for improving patient care. However, several challenges and areas for future research remain:

Standardization and Validation: One of the primary challenges in biomarker research is the need for standardization of assay methods and establishment of universally accepted reference ranges. This is particularly important for newer biomarkers like GH-15, adropin, and preptin, where variations in measurement techniques can lead to inconsistent results across studies. Large-scale, multicenter studies are needed to validate

these biomarkers in diverse populations and clinical settings [33].

Integration with Existing Risk Assessment Tools: While individual biomarkers offer valuable insights, their true potential may lie in their integration with existing risk assessment tools and clinical parameters. Future research should focus on developing and validating multimarker panels or risk scores that incorporate these emerging biomarkers alongside established risk factors. This integrated approach may provide a more comprehensive and personalized assessment of cardiometabolic risk [34].

Longitudinal Studies: Many of the biomarkers discussed in this review have been primarily studied in cross-sectional or short-term studies. Longitudinal investigations are crucial to fully understand the temporal relationships between biomarker levels and disease progression, as well as to establish their predictive value for long-term outcomes [35].

Mechanistic Studies: While associations between these biomarkers and cardiometabolic disorders have been established, the underlying mechanisms are not always fully understood. Further research into the biological roles of these molecules in health and disease may uncover new therapeutic targets and improve our understanding of disease pathophysiology [36].

Point-of-Care Testing: The development of rapid, reliable, and cost-effective point-of-care testing methods for these emerging biomarkers could significantly enhance their clinical utility. This is particularly relevant for biomarkers like H-FABP and copeptin, where rapid assessment could impact acute patient management [37].

Personalized Medicine Approaches: As our understanding of these biomarkers grows, there is potential for their use in tailoring preventive strategies and treatments to individual patients. Research into how genetic variations, environmental factors, and lifestyle choices influence biomarker levels and their predictive value will be crucial for realizing this potential [38].

CONCLUSION: The emerging biomarkers discussed in this review offer promising avenues for improving the diagnosis, risk stratification, and management of cardiometabolic disorders. From GH-15's potential role in metabolic regulation to galectin-3's implications in fibrosis and heart failure, these biomarkers reflect the complex pathophysiology underlying cardiometabolic health. While significant progress has been made in identifying and characterizing these biomarkers, challenges remain in translating this knowledge into clinical practice. Standardization of assay methods, integration with existing risk assessment tools, and conducting longitudinal studies are crucial steps in realizing the full potential of these biomarkers.

As research in this field continues to evolve, we anticipate that these emerging biomarkers will play an increasingly important role in personalized medicine approaches to cardiometabolic disorders. By providing more accurate risk assessment, early diagnosis, and targeted treatment strategies, these biomarkers have the potential to significantly improve patient outcomes and reduce the global burden of cardiometabolic diseases. The journey from bench to bedside is complex, but the promise held by these emerging biomarkers makes this an exciting time in cardiometabolic research. Continued collaboration between basic scientists, clinical researchers, and healthcare providers will be essential in translating these scientific discoveries into meaningful improvements in patient care.

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