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Review Article

REVOLUTIONIZING DRUG DISCOVERY: UTILIZING BIOMARKERS FOR PRECISION MEDICINE AND TARGETED THERAPIES

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ABSTRACT

Drug discovery remains a complex and time-consuming process, often hindered by inefficiencies and high failure rates. Biomarkers, measurable indicators of biological processes, have emerged as powerful tools to revolutionize this landscape. This article explores the multifaceted role of biomarkers throughout drug discovery, from target identification and drug development to clinical trials and patient stratification. We highlight how biomarkers enhance our understanding of disease mechanisms; facilitate the selection of promising drug candidates, and enable objective assessment of drug efficacy and safety. Furthermore, the integration of biomarkers with companion diagnostics allows for personalized medicine approaches, tailoring treatment options to individual patient needs. We discuss the various types of biomarkers employed in drug discovery, including genomic, proteomic, and imaging biomarkers, while acknowledging the challenges associated with their validation and regulatory approval. In conclusion, the strategic utilization of biomarkers holds immense potential to streamline drug discovery, accelerate development timelines, and ultimately bring safer and more effective therapies to patients.

Keywords: Drug discovery, Biomarkers, Cancer, COVID 19, Applications, Types.

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INTRODUCTION

Biological markers also referred to as biomarkers are certain measures or tests that serve as an early indicator for any disease present within our body or analyze an individual's overall health [1]. It functions by analyzing and examining the organ or cell function to check for any disorders. They provide information about a disease which makes it easier for the doctor to understand and create a personalized treatment plan for keeping it under control or rapid recovery. Biomarker testing aids in understanding and finding out certain attributes and features of a disease and can evaluate the complex activity of the proteins and hormones present in the human body. Some common biomarkers are blood pressure (BP), pulse, body mass index, etc. [2]. Blood glucose levels, complete blood count, and cholesterol are some examples of biomarkers that can be found in our blood, stool, and urine samples.

The most common fecal biomarker present is calprotectin [3]. Diseases such as colorectal cancer and inflammatory bowel disease can be detected if high levels of calprotectin are present in stool samples. Such biomarkers are less invasive compared to other endoscopic procedures which may lead to an infection or intestinal perforation, causing harm to the patient [4]. In the case of a urinary tract infection (UTI), leukocyte esterase is a common biomarker that indicates the presence of white blood cells in urine samples [5]. Liquid biopsies are a type of biomarker test that can detect and identify specific cancers such as breast and prostate cancers by examining a patient's fluid sample for the presence of tumor cells. Hemoglobin A1c is a biomarker used to detect the presence of diabetes [6]. The HbA1c test checks the average blood glucose levels over the past 3 months [7].

Type 0 biomarkers or natural history biomarkers indicate the progression of an illness or disease and to what extent it can affect an individual if the appropriate treatment is not provided on time [8]. An example of this can be checking the levels of serum creatinine to monitor for any injury to the kidneys or evaluate kidney function. Type 1 biomarkers or drug activity biomarkers confirm the presence or absence of a condition or disease in a patient [9]. They also help to understand the side effects of consuming certain medicines to keep the disease under control. An example of this can be circulating tumor DNA, which is a less invasive biomarker that can indicate how effective chemotherapy is for a patient [10]. Type 2 biomarkers or surrogate biomarkers are linked with the development of a disease. They also aid in predicting and analyzing the effects of the medical remedy provided [11]. This is necessary as different drugs affect individuals differently as they are influenced by various factors such as metabolism, genetics, diet, and age. An example of a type 2 biomarker can be high levels of BP [12]. High BP can be associated with the presence of heart disease or other health issues such as diabetes or hypertension.

Biomarkers play a role in grouping patients into subgroups based on their genetic makeup, gender, age, medical history, presence or absence of a disease, and so on. This process is also known as stratified medicine and is particularly important during clinical trials as it helps doctors to treat and focus on different groups of patients differently with a more personalized treatment plan and they can be closely studied to confirm whether one drug can work for many individuals of the same age or gender [13]. This is generally carried out before a transplant to confirm whether the recipient's body will accept or reject the organ. For example, human leukocyte antigen typing can serve as a biomarker during the process of organ transplantation and tissue typing helps to confirm if the donor organ is a good match or not. This helps to increase the probability of a successful transplant and reduce the risk of rejection [14].

DISCOVERY AND DEVELOPMENT OF BIOMARKERS

Drug development is the process of introducing a new and effective remedy or drug to cure a disease once a primary compound has been established along the course of drug discovery. This process is generally time and resource consuming [15]. During the planning of clinical trials, researchers need to define whether their goal is to identify a biomarker associated with disease evaluation, prognosis, or treatment effectiveness [16] (Fig 1). Based on this, specific patients will be selected for the trials if they fulfill all the medical criteria required.

During the clinical trial phase, a sample group of people affected by the associated or target disease are bought together and their vital signs and health are closely monitored throughout this process. This is the stage where biomarker discovery begins. This also involves the process of assay development, which means the assessment and measurement of the activity of a specific drug in a biological sample derived from the patient [17].

There are several methods and techniques involved in the discovery of biomarkers.

i. Genomic approach involves the analysis of one's genetic information to observe for any trends or variations with respect to the target disease. This helps to discover and identify any promising or potential biomarkers. Some methods for genomic evaluation may include northern blot and DNA microarray assessment [18].
ii. Proteomic approach involves the analysis and assessment of various proteins within a biological sample to check whether any of them can be a potential biomarker. These samples such as urine and blood are prepared and subjected to specific separation techniques such as gel electrophoresis or liquid chromatography. This helps to separate proteins based on their molecular size and net charge. In the case of electrophoresis, these fluorescent bands consisting of proteins are drawn out and subjected to reduction, alkylation, and digestion [19]. This allows for certain peptides to be released which is then prepared for mass spectrometry and to identify undetermined substances as specific proteins as it has the ability to quantify each protein's mass-to-charge ratio. Finally, this leads to protein profiling which helps to identify biomarkers [20].
iii. There are several other approaches such as the glycomic approach which involves the identification and analysis of any glycan-based biomarker present in a biological sample [21]. For example, high levels of alpha-fetoprotein (AFP) can serve as a biomarker for certain liver diseases such as chronic hepatitis. Another approach may be the lipidomic approach for biomarker discovery which involves the inspection of the presence of lipid molecules in biological samples which can serve as potential biomarkers for disease diagnosis and prognosis [22]. For example, increased levels of serum triglycerides can be indicative of atherosclerosis which is a condition characterized by the blocking or thickening of arteries.

Identifying and developing biomarkers are a time-consuming and lengthy process which generally involves the following steps-

i. Forming a hypothesis which involves coming up with an educated guess based on previous existing knowledge that can be tested and worked on to understand a particular occurrence or phenomenon. It can aid in refining your focus of research, directing the collection of data, analyzing and examining results, and deducing a conclusion.
ii. Sample procurement and examination involves collecting biological specimens such as blood and urine from individuals involved in a study or clinical trial [23]. These are then sent to the laboratory for a thorough analysis to help identify and measure the presence of any relevant biomarkers. If present, this process will serve as an important step in the early detection of certain diseases and in exploring various therapeutic options.
iii. Assay development and validation involves the process by which researchers and scientists create and establish a reliable method to detect and examine specific biomarkers present within a biological sample [24]. Researchers create and refine this assay, ensuring its accuracy and particularity. Assay validation refers to the verification that the biomarker detection method that has been developed is precise and suitable. The effective assay is vital for the appropriate application of biomarkers in disease diagnosis, prognosis, research, treatment, etc.
iv. Administrative approval of drugs includes obtaining and securing an official clearance from relevant higher authorities for the application of a specific biomarker in a clinical setting [25].

TYPES OF BIOMARKERS

Molecular biomarkers

These are certain molecules or fragments found in a sample derived from the body that indicates the presence of a disease or any other genetic condition [27]. These make it easier to collect samples and are less expensive compared to others (Fig. 2).

Histologic biomarkers

Histologic biomarkers, also known as histopathological biomarkers, help in detecting various conditions including cancer by examining and analyzing different characteristics of tissues and cells present in our body. One example of this can include the stage and grade of a cancer [29]. Cancer staging provides information on the tumor growth and how far it has spread from its point of origin. Stage 1 is the early stage where tumor is small has not spread and can be easily excisable in stage 2, the tumor has begun to grow and might have spread to the lymph nodes near the mass; in stage 3, the cancer is larger and spreads to the nearby tissue; and in stage 4, the cancer has metastasized and may be difficult to completely remove. Cancer grading refers to the appearance of cancer cells under a microscope, that is, whether they look normal or abnormal. In low grade, the sample contains normal cells with similar shape and size and no cell death. In high grade, the cells appear to be abnormally shaped and they divide more rapidly and aggressively and cell death occurs (Fig. 3).

Examples of histological biomarkers-

1. Ki-67: Ki-67 is a nuclear protein [30] that was discovered in the year 1967. It has various applications in immunohistochemistry and serves as an indicator of cellular proliferation rates. Immunohistochemistry allows for specific antibodies to bind to antigens present in our body. This allows for the analysis and visualization of the antigen location and helps in the diagnosis of cancers and other related diseases. Neuroendocrine neoplasm is a form of cancer found in the neuroendocrine cells. They can occur in any part of the body, commonly in the gastrointestinal tract and the lungs [31]. Ki-67 proliferation index can help in the grading of neuroendocrine tumors. By retrieving a tissue sample from the patient and incubating it with specific antibodies such as MIB-1 and NCL-Ki-67p, Ki-67 levels can be studied using a light microscope [32]. According to the Ki index, grade 1 means that only 2% of the cells are rapidly dividing (2 in 100) which means that the tumor growth is slow and unaggressive, grade 2 means that the rate of cell division is between 3% and 20% which indicates that the cells are poorly differentiated, and grade 3 means >20% of cell division, suggesting the presence of a highly aggressive tumor. Based on the results obtained, treatment options can be discussed. Researchers can interpret high Ki-67 indices as the presence of an aggressive tumor with a high risk of metastasis. This protein can also help in the detection and distinction of luminal A and luminal B breast cancer [33]. According to a study, the Ki-67 protein levels were found to be <14% in luminal A breast cancer patients, indicating that the tumor is less aggressive and slowly growing whereas in luminal B breast cancer patients, the Ki-67 protein level is found to be more than 14%, indicating that the cancer is rapidly growing and more aggressive [34].
2. Gleason score: A Gleason score is a biomarker that is specific to prostate cancer. It can indicate the extent of abnormality of prostate cancer cells, whether they are invasive or not, how rapidly they are dividing, etc., and the rate of metastasis [35]. To assess the Gleason score of an individual, the tissue samples are collected either through a biopsy or during a routine prostate surgery, which is then studied by a pathologist or researcher under a microscope. According to a Gleason grading system, grade 1 means that the patient is at a very low risk and has almost normal prostate cells, grade 2–3 means that the outcomes could be favorable or unfavorable, and grades 4–5 means that the patient is at a very high risk and has abnormal and poorly differentiated prostate cells. This score is assigned by

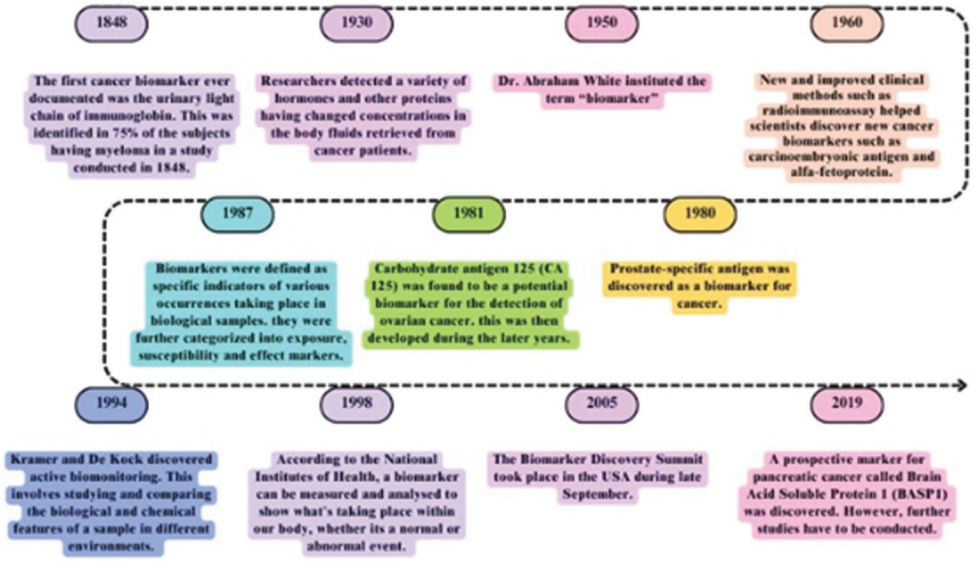

Fig. 1: Discovery and development of biomarkers [26]

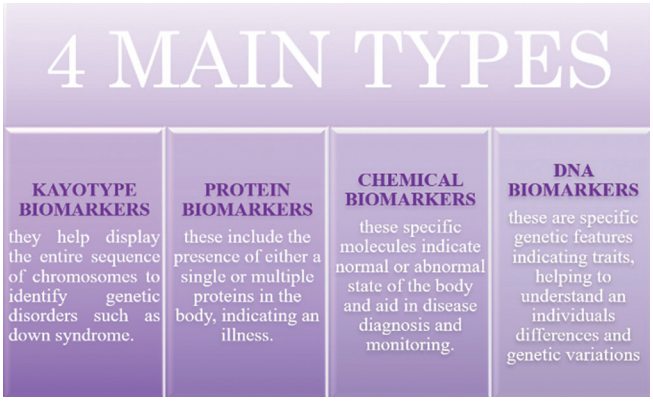

Fig. 2: Types of biomarkers [28]

analyzing two areas in the prostate where most of the cancer exists and then obtaining the sum of the two grades [36]. For example, if the Gleason score is given as 2+4=6, this means that the majority of the tumor is grade 2 and the rest is grade 4. A score of 6 indicates properly differentiated prostate cells with normal growth whereas a score of 8–10 may indicate poorly differentiated cells with rapid and abnormal growth. Gleason's score can be a reliable indicator of an individual's overall well-being and health, the stage of cancer, and further treatment options and help provide the results of other blood tests.

Radiographic biomarkers

Radiographic biomarkers or imaging biomarkers help to identify any abnormalities or disorders present in the body through medical images produced by clinical imaging methods [37]. Some examples are as follows: X-rays are a form of electromagnetic radiation which are so strong that it can pass through the human body and provide black and white images in different shades. This is because different tissues take up different amounts of radiation. They help to give quick results and produce detailed images of our bones and organs [38]; magnetic resonance imaging uses a strong magnetic field and radio waves to produce 3D images of any part of the body from any angle. It is a non-invasive technique, produces more accurate and detailed images compared to other diagnostic imaging tools, and helps to diagnose any cancer [39], however, they are more expensive than an X-ray or computed tomography (CT) scan; medical ultrasounds or ultrasonography uses sound waves to produce images of internal organs and other structures. It is commonly used by doctors to monitor the growing fetus inside the womb and keep track of the baby's health; CT scan uses a series of X-ray scans and a computer to create 2D cross-sectional images of your organs, bones, and tissues [40].

Physiological biomarkers

These biomarkers indicate whether all the physiological functions and processes in our body such as metabolism, digestion, and reproduction are taking place normally or not. These help doctors to assess and analyze blood reports and provide customized treatment plans to patients. Some examples are as follows: Body temperature indicates how well our body is at maintaining its internal and external body heat and provides information on our metabolic activity [41], it is important to keep our hormone levels in check because they control our sleep-wake cycle, metabolism, growth, and development, etc. They can help to indicate the presence of some conditions such as PCOD, PCOS, infertility, and so on; keeping track of our heart rate can help us understand how healthy our heart is. The normal resting heart rate of the human body is 60–100 beats/min, anything slightly below this may also indicate a healthy heart and a good lifestyle; an electrocardiogram records the heart's electrical activity and uses it to determine whether any heart conditions are present [42]. It is a straightforward and non-invasive test.

CHARACTERISTICS OF BIOMARKERS

Based on the roles, they play in the medical field and clinical trials, all of the above-mentioned biomarkers can be categorized into either predictive, prognostic, or diagnostic [43].

Predictive biomarkers

Predictive biomarkers also known as imaging or cellular biomarkers are used when the patient is affected by a particular disease but has not started treatment yet. It indicates how an individual will respond to a particular type of therapy and helps the doctor to make the best decision [44]. Not all patients respond in the same way to a particular treatment plan because certain factors such as lack of sleep, poor metabolism, and other hormonal issues can alter the effects of a medication. For example, human epidermal growth factor receptor 2 (HER2) protein helps cancer cells to multiply rapidly in certain types of breast cancers [45]. HER-2-positive breast cancers tend to be more deadly making them harder to treat. However, HER-2 serves as a predictive biomarker as it responds to certain monoclonal antibody treatments [46]. Perjeta is a medicine that binds to HER-2 protein and prevents it from receiving growth and chemical signals, thus lowering the rate at which cancerous

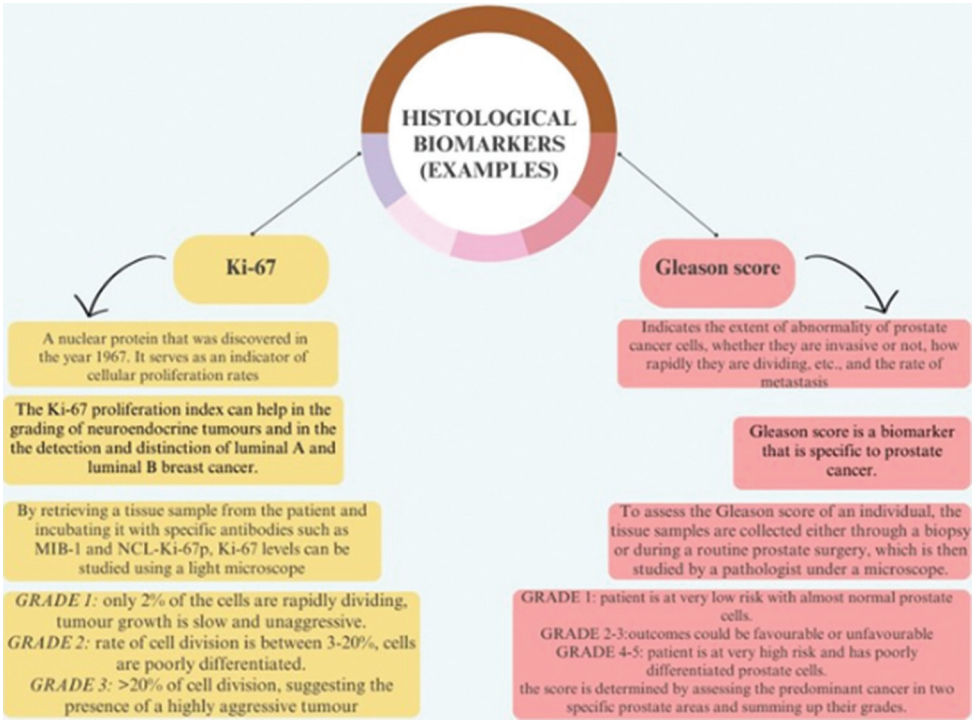

Fig. 3: Examples of histologic biomarkers

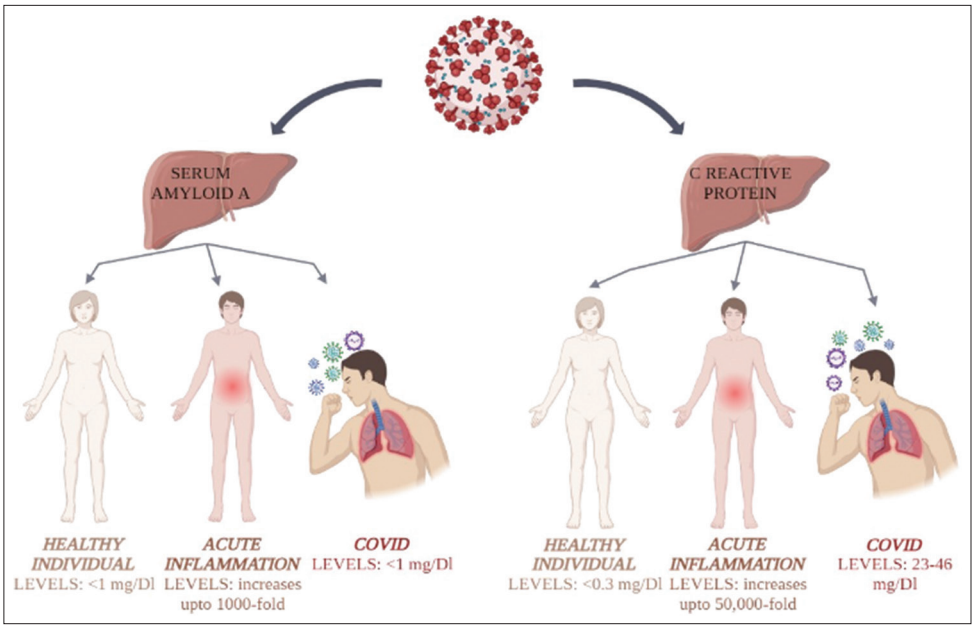

Fig. 4: Role of biomarkers in cancer (drawn using BioRender)

cells divide and grow [47], and another drug, Margenza, serves as a HER-2 inhibitor and prevents cells from metastasizing [48]; mutation in the BRAF gene (v-RAF murine sarcoma viral oncogene homolog B1) is linked with a type of skin cancer known as melanoma. In melanoma, the pigment-producing cells present in our skin become cancerous. The BRAF gene acts as a predictive biomarker [49]. by responding to certain medications such as Zelboraf and Tafinlar.

Prognostic biomarkers

These are synonymous with type 0 biomarkers. These biomarkers indicate or inform us on how the disease will affect the patient irrespective of the treatment provided and the probability of it recurring later in the future [50]. Some examples may be prostate-specific antigen (PSA) which can help us keep track of the advancement of prostate cancer in patients [51]. Prostate cancer can be the primary cause for elevated PSA levels [52]; however, this may not always be a firm indication of cancer, it can also be related to increasing age and a person's race and other prostate conditions such as UTIs and benign prostatic hyperplasia; for a healthy person, the glomerular filtration rate 90 mL/min or higher, however, if a person has a kidney disease, it may drop to <60 mL/min/1.7 m^2, this will remain for 3 or more months persistently [53]. One's glomerular filtration rate can be measured by a blood test which quantifies creatinine levels. An individual's urine sample can also help in assessing whether chronic kidney disease is

present by measuring the urine albumin-to-creatinine ratio.

Diagnostic biomarkers

These can be correlated with type 1 biomarkers as they have the same functions. They help to analyze a diseased individual and what steps can be taken to cure the condition [54]. Some examples include that CA 125 (cancer antigen 125) is linked with ovarian cancer [55]. Levels of CA 125 can be measured by taking a sample of the blood and if levels are above 35 U/mL, ovarian cancer is present. This protein can help to detect how large the tumor is and guide the doctor in opting for the right treatment plan, the accuracy of CA 125 levels for diagnosing ovarian cancer is around 78% [56]; for diagnosing Down syndrome in a fetus, the gynecologist conducts a triple antigen test at around 15–18 weeks. This test calculates the levels of alpha-fetoprotein, human chorionic gonadotropin (hCG), and unconjugated estriol (uE3). If Down syndrome is present, AFP and uE3 levels decrease and hCG levels increase [57]. This test is accurate in the diagnosis of this condition almost 60% of the time. Edward's syndrome can also be diagnosed using this test; in this case, the levels of all three components are low.

APPLICATIONS OF BIOMARKERS

Biomarkers generally play an important role in drug discovery and its development. They help to provide information on how the drug interacts with a particular individual, how efficiently the drug is working, what dosage will be appropriate, and what can be done to improve the drug and help it reach its maximum potential [58]. It helps to fasten the process of developing a drug which may otherwise take 10–15 years to develop [59]. Since every human being has a different genetic makeup and rate of metabolism, biomarkers are necessary to indicate how differently a treatment is working in different people. With the help of biomarkers, researchers can execute their clinical trials and other studies with more precision and accuracy [60]. Biomarkers play a role in target validation and identification [61]. Biomarkers help to assess whether the particular treatment is interacting with the right disease pathway or not. Since biomarkers help to study many fundamental biological processes in the human body, they can serve as a clear indicator of interactions that take place between the drug and its receptor in the body. There are several other advantages of using biomarkers for target identification and validation such as faster detection, easier monitoring, faster development of the vaccine or drug, better understanding of the disease pathway and progression, and more cost-efficient [62]. Biomarkers play a role in clinical trials [63]. One of the main objectives of pharmaceutical researchers while conducting these clinical tests is to understand how beneficial a drug can be and what steps can be taken to minimize their side effects. Instead of waiting till the trial is over to check for the outcomes, biomarkers can allow for an in-depth understanding of the drug metabolism [64]. This helps to save a lot of time and can help prevent the clinical trial subjects from facing any harmful side effects by providing them with an appropriate dosage of medication. Small molecule biomarkers are formed through the various interactions between a body's proteins and genes, and they can also be produced through some external factors such as an individual's diet and physical activity. Some examples include carbohydrates, glucose, amino acids, etc. Since these are small in size and already present in our body [65], they are relatively cost-efficient and non-invasive options, they allow for accurate and early diagnosis of any disease, indicate how a person is responding to a specific drug and what dosage is most suitable, and also help the doctor to create a personalized treatment plan for the patient. For example, in the case of diabetes, measuring glucose levels is crucial in any clinical trial, to check how one's glucose metabolism is getting affected [66]. Biomarkers play a role in the toxicological aspect of treatments. In general, biomarkers help to measure and analyze the biological response to a particular drug or toxin. During the process of drug development, the usage of biomarkers can help to predict the harmful and toxic effects of a drug by measuring the fluctuating levels of biological processes in the human body. Researchers can study the following changes occurring in the body and then finalize an appropriate dose that can be taken and discuss steps on how to cut down or control the long-term toxic side effects of treatment. In drug discovery and development, accurate toxicology reports can be obtained using certain mechanistic biomarkers [67]. These biomarkers are present in the pathogenesis of a disease, and hence, they help to provide a more accurate understanding of a diseased state. In cancer research, mechanistic biomarkers provide information on the disease progression and how an affected individual responds to a certain treatment [68]. They help to understand and evaluate the underlying mechanisms of tumor growth and metabolism, gene alterations, and therapeutic resistance [69]. Biomarkers play a role in pharmacokinetics [70]. Pharmacokinetics is defined as the movement of drugs through the body, which also refers to what the body is doing to the drug. It includes many different aspects such as drug absorption, metabolism, distribution, and excretion [71]. For example, genetic biomarkers present in our body such as proteins and hormones can help to determine the rate at which our body will metabolize a particular drug, allowing the doctors to create an appropriate dosage. Biomarkers play a role in pharmacodynamics [72]. Pharmacodynamics is defined as the body's biological response to a drug, which also refers to what the drug does to the body [73]. For example, certain biomarkers can help predict the outcome of a treatment during a clinical trial. This can help doctors monitor how the patient is responding to a drug and what necessary improvements and changes need to be made.

CLINICAL APPLICATIONS

Biomarkers are involved in various aspects of the clinical field [74]. They are essential as they serve to detect several chronic diseases and disorders and gauge the probability of illness progression. Chronic illnesses such as dementia, arthritis, osteoporosis, and cancer [75] are increasingly present with the increasing age of individuals. This calls for a desperate need for a long-term solution and appropriate treatment. Hence, biomarkers are essential to the medical and pharmaceutical world as they help to speed up the process of developing drugs by providing accurate readings and diagnoses. In addition, they also assist in evaluating the effectiveness of the prescribed medications and identify particular groups of patients who could benefit greatly from a particular treatment [76]. They also contribute to enhancing drug safety by predicting potential side effects at an early stage of clinical trials [77]. Furthermore, they aid researchers by providing a better and more informed understanding of certain cellular activities and changes taking place within the body and how each organ reacts with a particular drug [78]. Overall, the use of biomarkers is a necessity for the medical realm to advance to a better and healthier future.

Role of biomarker in COVID-19

Biomarkers have played a vital role in various aspects of COVID-19 ranging from the early identification of the respiratory disease to assessing an appropriate treatment plan for the affected individual for their speedy recovery and discharge from the hospital [79]. Some important indicators of COVID-19 are serum amyloid A (SAA) [80] and C-reactive protein (CRP) [81]. SAA is an acute-phase protein that is mainly synthesized in the liver. They are associated with high-density lipoproteins, in case of conditions such as inflammation [82]. When the body faces injuries such as infections and cancer, the SAA level in the body may increase up to 1000-fold. The levels of SAA in a healthy individual are generally <10 mg/L, whereas in the case of COVID-19, as the disease progressively becomes worse, the levels of SAA significantly rise [83]. C reactive proteins are similar to SAA; however, they can rise up to 50,000-fold in case of acute inflammation. Normal levels of CRP in healthy individuals are usually <0.3 mg/Dl, however, in patients affected by COVID-19 mildly, it was found to be 23 mg/dL and in the more severe cases, it was found to be 46 mg/dL [84]. CT scans can help to detect lung lacerations in patients affected by COVID-19 [85]. A study in China found that doctors were unable to distinguish between mild and severe cases. However, when these were compared with an erythrocyte sedimentation rate test, it was revealed that CRP levels were much higher during the initial stages of severe cases, making it the more suitable biomarker for COVID-19 detection [86].

Role of biomarker in cancer

Cancer biomarkers are certain biological matter released by an individual's body or tumor present within them [87] (Fig. 4). The thorough analysis of these biomarkers can help to identify specific changes within to tumor to determine how rapidly or slowly a tumor is growing [88]. They can be used in multiple aspects such as estimating the risk of cancer occurrence or reoccurrence in an individual [89], predicting whether the chosen therapy will be effective or not and if effective then to what extent and monitoring the disease progression and severity. The BRAF gene present in our body serves as a mechanistic biomarker for several types of cancer [90]. A mutation in the BRAF gene (v-RAF murine sarcoma viral oncogene homolog B1) can instruct the cells to divide rapidly and uncontrollably [91], leading to the formation of a tumor and resulting in cancers of ovaries, colon, brain, etc.

There are various types of cancer biomarkers and they are generally categorized based on their varying functions [92]:

i. Biomarkers that activate cells, allowing them to grow and spread abnormally – one example of this can by cyclin D1. In a healthy individual, cyclin D1 serves as an important regulator of cell cycle advancement. However, in some cases, the overexpression of this cyclin due to gene amplification or gene reorganization can lead to uncontrolled cell division causing cancer [93]. This is generally involved in the breast, liver, bladder cancer, etc. [94]. Other biomarkers such as HER2 protein and epidermal growth factor receptor (EGFR) are also present and are associated with uncontrolled cell proliferation rates [95].
ii. Biomarkers that assist the treatment's fundamental action – an example of this may be excision repair cross-complementation group 1 (ERCC1) which is a protein endonuclease carrying out several important functions associated with DNA restoration [96] which can help enhance and maintain genomic stability, homologous DNA repair, etc. It is involved in repairing DNA alterations caused by ultraviolet radiation, genotoxic agents, and some cancer chemotherapeutic complexes [97]. In the case of cancers, it helps to repair the tumor DNA present in the individual's body. ERCC1 is associated with laryngeal cancer, lung, and colon adenocarcinoma [98].
iii. Biomarkers that interfere with the treatment's fundamental action – an example of this is the EGFR which plays a major role in regulating cell division and growth [99]. During the course of cancer treatment, certain EGFR inhibitors are given such as afatinib [100] and gefitinib [101] which are given to delay or set back cell growth. However, if there is a mutation or change present in the EGFR gene which can lead to its overexpression causing cell proliferation, then these inhibitors may be less effective in the treatment of cancer as the mutated cells may not respond as expected.

To identify whether specific biomarkers are present within an affected individual, the doctor may take a sample of the tumor or bodily fluid such as urine and blood. These are then sent to the laboratory to conduct complex tests which can help determine the pathology and molecular composition of the submitted sample. If anything unusual is found, the doctor creates a personalized treatment plan for the patient to ensure speedy recovery.

CONCLUSION

Biomarkers are measurable indicators of biological processes taking place in the body, aiding in disease diagnosis, prognosis, etc. Various applications of biomarkers can range from monitoring blood glucose levels in a diabetic patient to cancer detection and treatment assessment. They have several advantages which may include early disease identification, personalized therapy, effective clinical trials, and positive patient outcomes.

AUTHORS CONTRIBUTION

All authors listed have made a substantial, direct, and intellectual contribution to the work and approved it for publication.

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