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Review Article

Biomarkers in Clinical Research on Cancer by the Use of Drugs

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Abstract

A biological molecule that may be found in tissues, physiological fluids, or blood and serves as a biomarker for a disease, condition, or healthy process. To determine how effectively the body responds to a disease or condition therapy, a biomarker may be utilised also known as a signature molecule and a molecular marker. Biomarkers, also known as biological markers, are biological indicators of a condition of biology (Lubin et al., 2008). A biomarker is, according to its official definition, "a characteristic that is objectively measured and evaluated as an indicator of normal biological processes, pathogenic processes, or pharmacological responses to a therapeutic intervention". In order to design an effective treatment intervention, biomarkers are the measurements used to conduct a clinical evaluation, such as blood pressure or cholesterol level. Biomarkers are used to monitor and forecast health conditions in individuals or across groups. To evaluate a person's health or illness condition, biomarkers may be utilised singly or in combination (Jakobsson 2008).

Keywords: Biomarkers, Cancer, Blood pressure, Pathogenic, Therapy, Testing drugs

INTRODUCTION

Biomarkers are quantifiable physical traits of the body. Therefore, your blood pressure is a biomarker. In general, biomarkers are crucial to medicine. We're all accustomed to seeing the doctor and receiving the results of all our tests, and even imaging tests like CAT scans and x-rays, which provide quantitative information about the health of the body, serve as biomarkers. Because scientists need to gauge how experimental medications affect volunteers during clinical trials, biomarkers are crucial to drug development. And we do that by examining their impact on biomarkers. Therefore, it's crucial that we have access to a wide variety of biomarkers that can help us determine all we need to know about how the experimental medicine affects people (Johnsen et al., 2016).

The main issue with drug development nowadays is the failure rate, which is one of several challenges. Therefore, even medications that have undergone the whole preclinical procedure, including animal testing, and several other types of assays, may only have a one in ten probability of being approved for sale if they are administered to humans. During such development, nine out of ten people might fail. And if we want to speed up the availability of treatments, cut the cost of drug research and stop it from rising, and genuinely allow many innovators to participate in the process of developing new drugs, we need to do more than that. We need a brand-new generation of biomarkers that are more informative and that can alert developers earlier as to whether or not their drug may have toxicity or it actually may not work at all, as well as to get that early read on what's going to be successful, in order to significantly increase the success rate and efficiency of drug development. Thus, such biomarkers are hypothetical ones that have not yet been created (Lauzon et al., 2000).

The properties of biomarkers may be used to categorise them, such as whether they are molecular or imaging biomarkers (such as those used in positron emission tomography, magnetic resonance imaging, and computed tomography). Non-imaging biomarkers with biophysical properties that enable measurement in biological samples are referred to as molecular biomarkers. These include nucleic acid-based

biomarkers like gene mutations or polymorphisms and quantitative gene expression analysis, as well as peptides, proteins, lipid metabolites, and other small molecules. Additionally, there are many categories of biomarkers dependent on how they are used, including diagnostic biomarkers, disease staging biomarkers, disease prognosis biomarkers (such as cancer biomarkers), and biomarkers for tracking the clinical outcome of an intervention. The biomarkers utilised in early drug development decision-making are a different group of biomarkers. For example, pharmacodynamic biomarkers are indicators of a specific pharmacological reaction and are particularly relevant to investigations of dosage optimisation (Lauzon et al., 1993).

A biomarker is a quantifiable sign of the existence or presence and severity of a disease condition in medicine. A biomarker is, more broadly speaking, anything that may be utilised as a sign of a certain disease condition or another physiological state of an organism. The measurement might be functional, physiological, biochemical, cellular, or molecular, and the indicator can be of a chemical, physical, or biological origin, according to the WHO. A chemical that is injected into an organism as a way to assess organ function or other elements of health might be referred to as a biomarker. Rubidium chloride, for instance, is employed in isotopic labelling to assess the perfusion of cardiac muscle. It may also be a material whose existence signals the presence of a certain disease condition, such as an infection, as in the case of an antibody (James et al., 2003). A biomarker, more particularly, denotes a change in the expression or condition of a protein that is associated with the risk of developing a disease, its development, or its responsiveness to a particular treatment. Biomarkers are distinctive biological traits or substances that may be found and assessed in bodily fluids like blood or tissue. They might be a sign of healthy or unhealthy bodily functions. Specific cells, chemicals, genes, gene products, enzymes, or hormones can serve as biomarkers. Biomarkers can also be complex organ functions or broad-based modifications to biological components. Biomarkers have been employed in pre-clinical research and clinical diagnostics for a long time, despite the fact that the name "biomarker" is rather recent. For instance, a well-known biomarker for fever is body temperature. Stroke risk is assessed using blood pressure. Additionally, it is well established that C-reactive protein (CRP) is a marker for inflammation and that cholesterol levels are biomarkers and risk factors for coronary and vascular disease (Pálka et al., 2015).

Biomarkers are molecules that show whether a process in your body is normal or abnormal and may be an indication of a disease or underlying issue. Since each of these molecules reveals something regarding your health, many sorts of molecules, including DNA (genes), proteins, and hormones, can be used as biomarkers. In reaction to cancer, the body's cells or the cancer tissue itself may release biomarkers. They can be found in many tissues and biological fluids, including the blood, faeces, urine, tumour tissue, and others. It's noteworthy that biomarkers are not just for cancer (Denning et al., 2012). Heart disease, multiple sclerosis, and many other illnesses have biomarkers. Understanding the significance of biomarkers in cancer requires knowledge of several fundamental concepts relating to DNA, RNA, and proteins. Deoxyribonucleic acid, or DNA, is an intracellular molecule that contains genetic information and transmits it from one generation to the next. Information from DNA is copied into RNA, also known as ribonucleic acid. Multiple kinds of RNA molecules are produced by body cells, and these RNA molecules are essential for the creation of protein molecules (Kim et al., 2015). For instance, messenger RNA (mRNA) molecules act as templates for the synthesis of proteins from the building blocks of amino acids, while transfer RNA (tRNA) molecules transport the amino acid residues to the ribosome. Translation occurs when the tRNA "reads" the mRNA template inside the ribosome, an organelle where proteins are synthesised. Proteins are the building blocks of the body's structures like skin and hair and aid in optimal bodily function. They perform a variety of tasks inside the human body. Enzymes speed up chemical reactions; cytokines influence immune system performance; and antibodies set off certain immunological reactions in response to antigens, potentially hazardous substances that the body must occasionally fight against.

For the purpose of cancer detection, screening, diagnosis, therapy, and monitoring, the concepts of biomarkers in illness have been employed. In the past, anti-cancer medications were substances that destroyed both cancer cells and normal cells. More focused treatments, however, may now be designed to destroy specific cancer cells while sparing healthy ones. The evaluation of a typical cancer biomarker aids in the creation of treatments that can target the biomarker. This can cut down on the likelihood of toxicity and lower the price of therapy. Because genetic defects frequently contribute to the development of cancer, genetic studies are important in the field of cancer research. Therefore, some DNA or RNA markers may aid in the early diagnosis and management of particular malignancies (Tsankova 2006).

Using biomarker testing, we can determine the most effective cancer treatment. Certain cancer medications, such as targeted therapies and immunotherapies, could only be effective for patients whose tumours exhibit particular biomarkers. For instance, EGFR inhibitors are medications that are given to patients with cancer that has specific genetic alterations in the EGFR gene. An EGFR gene alteration that can be treated with an EGFR inhibitor in this situation can be discovered by biomarker testing on a patient's tumour. You might be eligible to enrol in a clinical trial for a novel cancer treatment with the assistance of biomarker testing. As opposed to where in the body the cancer first developed, some studies recruit participants depending on the biomarkers in their disease. These are

referred to as basket trials at times. Biomarker testing is an integral component of the research for several other clinical studies. Biomarkers testing, for instance, are being used in trials like NCI-MATCH and NCI-COG Paediatric MATCH to match patients to therapies based on the genetic alterations in their tumours.

One of your cancer's biomarkers may be targeted by a recognised therapy, according to the findings of a biomarker test. Therefore, the therapy may be effective in treating your cancer. The FDA-approved medication, an off-label treatment, or enrolment in a clinical trial may all be options for the matching therapy. The findings can also indicate that your cancer possesses a biomarker that could render a certain medication ineffective. This knowledge could assist you avoid receiving a therapy that won't benefit you. In many circumstances, cancer biomarker testing may reveal alterations that are not useful to your doctor in determining the best course of action. For instance, treatment decisions are not based on genetic variations that are assumed to be innocuous (benign) or whose consequences are uncertain (variant of unknown significance). Your doctor could suggest a treatment that is FDA-approved for the treatment of a different form of cancer that shares your disease's biomarker even if it is not FDA-approved for the type of cancer you have based on the findings of your tests. Since your cancer has the biomarker that the medication is targeting, it would be used outside the rules but could still work for you. Some biomarker tests can detect inherited (perhaps present at birth) genetic abnormalities that raise your chance of developing cancer or other illnesses. Germline mutations are another name for these genetic alterations. If such a change is discovered, you might need to undergo another genetic test to determine whether you actually carry an inherited mutation that raises your chance of developing cancer. Your family may be impacted if you learn that you have a hereditary mutation that raises your chance of developing cancer. In order to assist you understand what the test findings imply for you and your family, your healthcare practitioner could advise that you talk with a genetic healthcare specialist (such as a genetic counsellor, clinical geneticist, or a certified genetic nurse).

CONCLUSION

The improvement of the drug development process as well as the overall biomedical research sector depends heavily on biomarkers. Expanding our toolbox of therapies for all illnesses and improving our comprehension of typical, healthy physiology depend on our ability to relate quantifiable biological processes to clinical outcomes. The need for employing biomarkers as surrogate outcomes in large trials of serious diseases, including as cancer and heart disease, has been hotly debated at least since the 1980s. The FDA continues to support research on possible novel biomarkers that might be used as surrogates in future studies, as well as the use of biomarkers in fundamental and clinical research. Even while they have the potential to be beneficial—speeding up drug development, lowering exposure to unsuccessful experimental therapies, etc.—biomarkers pose serious hazards when trial planners mistake them for clinical objectives. If we fully comprehend the physiology of a biological process in its healthy state, the pathophysiology of that process in the disease state, and the effects of an intervention - pharmacological, device-based, or otherwise - on these processes, only then could biomarkers truly replace clinically relevant endpoints. Biomarkers as surrogate endpoints require continuous re-evaluation since we seldom, if ever have the whole picture of those kinds of processes, and there are always additional elements we don't know or comprehend. Clinical outcomes should always be the primary outcome measure in biomarker studies, at the very least for retrospective examination of biomarker correlation success. We run the danger of once again approving entire classes of medications that either have no added benefit or, worse, actually damage patients without on-going re-evaluation of the link between surrogate endpoints and real clinical endpoints.

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