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Customizing Cancer Treatments: Engineering Patient-Specific Therapies

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ABSTRACT

The advancement of personalized cancer treatment marks a pivotal transformation in oncology, offering hope for more effective, patient-specific therapeutic strategies. Traditional cancer research, often reliant on animal models or generic cell lines, fails to address the vast heterogeneity present in human tumors. Recent breakthroughs in genomic sequencing, bioengineering, and nanomedicine have enabled the design of targeted treatments tailored to individual tumor profiles. By leveraging technologies such as tumor-on-chip models, microfluidic systems, pharmacogenomics, and immunotherapy innovations like CAR-T cells, clinicians are now better equipped to match therapies with patient-specific genetic, molecular, and microenvironmental contexts. The integration of artificial intelligence, digital twins, and advanced biomarkers further enhances patient selection and monitoring, optimizing therapeutic outcomes while minimizing off-target effects. Despite the promise, personalized cancer treatment faces challenges including high development costs, limited standardization, and regulatory complexities. Nonetheless, interdisciplinary collaborations and evolving clinical trial models are setting the stage for a new era in precision oncology, transforming cancer from a terminal illness into a manageable chronic condition.

Keywords: Personalized medicine, precision oncology, cancer genomics, CAR-T therapy, pharmacogenomics, tumor microenvironment, targeted therapy.

INTRODUCTION

As two recent reviews have pointed out, the majority of cancer research efforts focus on the study of tumors in mice or cell lines, hoping to translate results into improved clinical outcomes. The evolution of personalized medicine (PM) relies critically on developing better tumor models that more accurately recapitulate human tumors in vivo, as they are required to understand the biology of rare and recurring aberrations in cancer and also screen for new drugs with the hope of developing companion diagnostics. While these models were originally too simplistic, recent dramatic developments in microfabrication techniques, stem cell biology, biochemistry, and materials science have allowed bioengineers to develop a new generation of tumor models that reflect key features of human tumors in 3D, ex vivo. As such, there has been work developing micro- and nanoscale platforms to screen for mAbs that target aberrant tumor antigens, tumor exosomes that modulate the immune response, and drug-nanomaterials that specifically treat tumors. The bottleneck to personalized precision medicine (PPM) is the cost and practical issues of producing patient-specific drugs. PPM therapies could leverage conventional pharmaceuticals, i.e., broadly used drugs whose use is expanded through the development of companion diagnostics. Recent advances have made it possible to engineer mAbs, mRNA, and a complex of the two using yeast, with synthetic computer-designed proteins that target previously undruggable epitopes, improving specificity to the tumor. Recent results indicate these therapies can be delivered in combination with existing

monoclonal absorbents (mAbs), RNA vaccines, and nanomedicines. However, additional developments are required to ensure efficacy and safety [1, 2].

Understanding Cancer Biology

Each year, millions of cases of cancer are diagnosed worldwide, making it one of the top causes of mortality. With each malignant cell exhibiting a unique constellation of genetic deficiencies, malignancies are as varied and individualized as the patients themselves. Conventional treatment methods are ineffective due to this heterogeneity, which makes personalized cancer treatment—prescribing tailored drugs and dosages to individual patients' tumors—the next advance in "precision" medicine. The development of personalized therapeutic agents is in several pre-clinical and clinical research phases. The entire body of knowledge of cancer biology, or the molecular mechanisms behind the aberrant cell growth property, is based on the careful and patient observation of the outcome of a variety of treatments performed on malignant cells. The interconnected knowledge generated by cancer biologists has aided in the precise design of combinatorial treatments, attested against the cellular system-on-chip tumor micro-fluidic device (TMD) containing patient isolates. Some treatments designed against cellular and biochemical targets and their combinations are effective in inhibiting the growth of co-cultured aggressive malignant colon cancer cells. The TMD and devices connecting the TMD with the micro-thermocyclers have been demonstrated to initiate and monitor the TEPP-PCR with dual-channel exposure camera acquisition. The generation of tailored oligonucleotides that simultaneously probe nucleobase mutations in several oncogenes is realized. This method effectively differentiates homozygous mutant cells from wild-type control ones among co-cultured cancer cells. The TMD is capable of measuring the cellular concentration of each subtype of cancer in an initial pool containing ten cancer cells of different species and concentrations per subtype. The capability of the TMD to measure the efficacy and IC50 concentrations of combinatorial treatments against patient-derived cancer cells is demonstrated. Patients' insensitivity or developed resistance to targeted drugs and the off-target cytotoxic effects, toxicity, and unclear mechanism of action of traditional chemotherapies have prompted in-depth and extensive investigations into the causes of drug resistance and novel cancer therapies. The aberration of biological circuitry and signaling pathways, as well as the cell microenvironment, are the most formidable challenges for patient-derived tumor therapy [3, 4].

Genetic Profiling in Cancer Treatment

Over the past decade, cancer treatment has advanced significantly towards precision medicine, leveraging individual genomic information. Next-generation sequencing (NGS) technologies provide a comprehensive view of cancer genomes, including genetic alterations and gene expression. A personalized approach using this genomic data can identify actionable targets and aid in selecting appropriate therapies for individual patients. Genomic diagnostics are becoming standard, with several NGS-based tests approved by the FDA, serving as companion diagnostics for targeted drugs and facilitating patient enrollment in clinical trials. Immunotherapy, which encompasses checkpoint blockade therapy, personalized vaccines, and T-cell therapies, is a novel treatment approach. Analyzing genomes and epigenomes improves diagnostic precision and enhances risk stratification, while uncovering new therapeutic targets like small-molecule inhibitors and monoclonal antibodies. Structural precision-diagnostic designs have shown success across various cancer types in clinical settings. To enhance cancer treatment, it's essential to combine molecular profiling of patients and tumors with treatments tailored to unique mutational profiles. Understanding the mechanisms of action of targeted therapies can lead to synergistic effects and reduce resistance to single agents. New inhibitors reveal novel DNA damage response mechanisms, and promising results from laboratory drug development are being validated in preclinical and clinical trials, expanding therapeutic options. The integration of targeted treatments and molecular profiling aims to achieve personalized medicine, ultimately improving patient outcomes and transforming many cancers into manageable, chronic conditions [5, 6].

Biomarkers In Cancer Therapy

The treatment of cancer at the right time and place with appropriate agents is central to precision medicine, where biomarkers are vital for therapeutic customization. DNA alterations, including driver mutations and fusions, serve as relevant biomarkers for drug selection, leading to improved therapy outcomes. Additionally, biomarkers derived from cellular RNA are intricate yet potentially comprehensive indicators of cancers, revealing deviations from normal expression that affect cancerous tissue properties such as growth, invasion, and metastasis. These properties influence the clinical behavior

of cancers and responses to treatments, including inhibition, resistance, side effects, and metastasis. Extensive research on biomarkers has led to some successful clinical translations over the decades, with RNA-based strategies proving particularly valuable. However, the diversity of biomarker strategies and the shift from tissue to blood complicate the evaluation of trade-offs between various candidates. Highlighting best-practice examples in patient studies can shed light on challenges faced and classes of biomarkers with limited clinical traction, signaling a need for further research. A more systematic examination of newly introduced liquid BERAs is expected to enhance project success in the future. Additionally, the integration of artificial intelligence tools presents opportunities for developing robust, cost-effective clinical assays to monitor therapy outcomes [7, 8].

Targeted Therapy Approaches

In recent decades, significant advancements in surgical resection, chemotherapy, and radiotherapy have led to reduced cancer mortality rates. Despite this progress, challenges remain, particularly regarding tumor recurrence and patient mortality. This has prompted the exploration of novel treatments targeting the undruggable aspects of cancer. Research indicates that somatic mutations play a vital role in tumor initiation and recurrence, leading to a focus on mutation-targeted therapies. Cancer cells possess mutated genes that create dysfunctional proteins absent in normal cells, allowing for specific therapeutic targeting, which enhances the sensitivity of malignant cells compared to nonmalignant ones. Targeted therapies can lead to rapid tumor regression and tend to have fewer side effects than traditional chemotherapy. The new paradigm of targeted anti-cancer therapy relies on detailed molecular and genetic profiling of tumors. Progress in drug discovery for mutation-targeted therapies has provided significant benefits, particularly with drugs that target activated oncogenes and inactivating tumor suppressors. However, a substantial number of patients still face limited treatment options. A major hurdle in developing new targeted therapies lies in understanding the distinct molecular mechanisms of various clinical tumor forms. Although some drugs targeting receptor tyrosine kinases and signaling pathways have been clinically tested, very few mutation-targeted therapies have received approval. Moreover, targeted treatments may not apply uniformly across different mutations in the same protein, necessitating new drug discovery efforts for each unique mutation type. This requires substantial resources, and alternative approaches, like non-mutant-targeting combination therapies, may need to be considered for effective cancer treatment [9, 10].

Immunotherapy Innovations

The use of T cells engineered to express chimeric-antigen receptors (CARs) to treat hematologic malignancies has been called one of the biggest breakthroughs in cancer research in decades. CAR-T therapies can yield complete remission in more than two-thirds of subjects treated with therapies targeting CD19 in diffuse large B-cell lymphoma (DLBCL) and acute lymphoblastic leukemia (ALL). The mechanistic basis of CAR-T efficacy centers on the ability of CAR-T cells to kill target cells via T cell receptor (TCR)-independent binding of target antigens and on the ability of these cells to proliferate, survive, and persist long-term in the host. Knowledge of the biology and engineering of CARs is now well developed, and as first-generation CAR-T therapies are extended to target other cancers or to increase efficacy in lymphomas shown to be less responsive to CD19-targeted CARs, novel second-generation and multivalent approaches are being developed to enhance efficacy 11. On the other hand, Cancer-associated fibroblasts (CAFs) constitute a major cell type in the TME of solid tumors and are a relevant therapeutic target. Targeting CAFs has been shown to amplify CD8+ T cell activity, inhibit tumor cell proliferation, and enhance the efficacy of immune checkpoint blockade therapy. However, currently available strategies targeting CAFs lack tumor specificity, raise safety concerns, and may cause irreversible damage to healthy tissues. To design a CAF-targeted imaging and therapeutic platform that does not affect healthy tissues, it is highly important to establish a biomarker that distinguishes CAFs in TME from those in normal tissues. Many tumors have a high mutational burden due to intrinsic factors and/or extrinsic factors that cause the emergence of tumor-specific mutations. Novel mutated proteins can be expressed in tumor cells. These mutated proteins are recognized as "non-self" epitopes by T leukocytes, allowing for the precise targeting of tumor cells. It is thus important to identify the corresponding mutated genes and peptide sequences of mutant proteins to develop personalized immunotherapy against various types of cancers, particularly the newly emerging targetable tumor-associated mutational forms such as RNA-binding protein fused with serine-rich domain and DOCK4 [12, 13].

Engineering Patient-Specific Therapies

"Personalized medicine" refers to the prognosis, diagnosis, or pharmacotherapy selected based on a patient's characteristics. A field in personalized medicine called pharmacogenomics focuses on the study of how a person's genes can influence the effect of drug therapy. The use of pharmacogenomics could potentially increase the efficacy of cancer therapies and reduce toxicity. Personalized cancer therapy would ideally consist of selecting chemotherapeutic agents that would kill the greatest number of tumor cells while sparing normal cells. Current pharmacogenomic approaches aim to discover and characterize genomic signatures capable of predicting a patient's sensitivity to a specific anticancer drug in tumor or blood samples. For example, several studies have shown that the absence of EGFR mutation and/or amplification predicts a lack of sensitivity to erlotinib. Neoadjuvant treatment with bevacizumab selects patients with a high probability of treatment response, and patients whose tumors presented pontin overexpression retained a significant benefit. Another approach is to study the number of "adaptive" bioinformatics pharmacogenomic methods that can be applied to a given cell line data and pharmacologic profiling set. Interpretation of the classifier-dependent, expert-curated features led to new hypotheses about the association of certain protein expressions with resistance to multikinase inhibitors. However, the application of those methods requires a considerable amount of patient tissue or blood samples. Additionally, many helpful pharmacogenomic associations discovered this way have remained out of clinical use. Therefore, there is a compelling need to develop a "test-tube" device capable of testing the efficacy of multiple anticancer drugs on tumor tissue obtained from a patient during neurooncology drug screening or re-resection surgery. To be clinically useful, such an assay would also need to stimulate the patients' tumor cells so that parallel drug treatment can be tried on cytogenetically stable populations of tumor cells. A parallel assay of this type would not be a trivial task. Each extra tumor type would need to be validated rigorously concerning cell isolation and stimulation, growth factors, specific adhesion assay, how quickly after tissue receipt the medicine application should start, and other critical parameters [14, 15].

Clinical Trials and Patient Selection

Remarkable advances have been made in discovering new anticancer agents, but accompanying drug development methods have not significantly evolved in terms of scale. A recent survey of recent innovations for cancer treatment showed that a majority of the innovations do not have a commonly used drug approval pathway. In contrast to decades of transformative innovations in the biological understanding of cancer, new developments in drug development are mostly limited to ad-hoc changes to the proposals made decades before, rather than systemic reform of how anticancer drugs could be proposed and analyzed, as seen in other areas of medical research. With the existence of a large toolset of sophisticated statistical methods to analyze the merits of a treatment, pressing needs for new analytical methods that are relevant to address the questions of anticancer treatments are presented. The future of drug development in oncology is perceived as a missed opportunity. Further thought is anticipated to be dedicated to the development of accurate methods to analyze the gains from existing combinations of agents for prespecified patients with the prespecified likelihood of developing each toxicity before obtaining access to the full dataset. With the availability of potentially few patients, different designs are considered. The need to individually consider patients introduces a new need for statistics. The only way to optimize an intervention for an individual patient is to reframe their treatment as their personalized trial. A computational framework for performing personalized trials is formulated that relies on four mathematical techniques: mathematical models calibrated with patient-specific data, digital twins built on these models, optimal control theory applied to the digital twins, and data assimilation to update predictions in response to therapeutic interventions. A framework for planning and monitoring patient-specific combination therapy trials is also presented [16, 17].

Challenges in Personalized Cancer Treatment

Despite the promise of improved treatments and patient outcomes, implementing personalized approaches is often more challenging than conventional therapies. The complexity of various systems has outstripped the standardization of biomarker detection and drug development. To help, regulatory guidelines are being created to ensure personalized drugs operate effectively and capture the patient's tumor characteristics. Some guidelines, such as recommendations for animal model stasis and exclusion criteria for clinical trials based on tumor or biomarker issues, are already in place. However, due to the diverse national tumor lines and treatment histories, predicting outcomes remains difficult. Protecting against

bias from patient characteristics may require rapid assay development, necessitating extensive collaboration, which can be challenging for individual professionals but achievable for larger organizations. Creating procedures for patient-specific PPM therapy design is possible, though ensuring compliance with inter-institutional protocols is more complex. Early work has primarily focused on refining patient data outputs for drug candidates, with several evolving programs available. Standardizing these outputs could enhance compatibility across various models and patients. To address known batch effects, data outputs could be standardized. Any standardization efforts in cancer treatments should remain alert to biases from overuse of certain tumors or treatments and avoid competitive collusion that may centralize cancer research. Regulatory approval for PPM models in early-stage trials will likely emphasize two bioengineering concerns. First, patient-specific devices, produced at points of care, will require a unified bioengineering framework to define GMP compliance and operating standards for devices and treatments. This will help avoid bias against researchers in less-developed regions, preventing misuse of technology and drugs. Second, the bioengineering field should focus on quantitative methods to assess drug and device efficacy, which would enhance cohort selection, patient outcomes, and reduce regulatory setbacks, hopefully leading to widespread benefits from personalized cancer treatments [18, 19].

Future Directions in Cancer Therapy

The most widely applied cancer treatments today remain genomic instability-inducing agents that target all dividing cells through various means. Antimetabolites and alkylating agents inhibit nucleotide metabolism and DNA molecule integrity, respectively. Biologically based cancer treatments, such as selective anti-hormones and monoclonal antibodies, have perceived limitations concerning efficacy and side effects and thus have not been widely utilized in monotherapy on the solid cancers that account for over 90% of deaths. While major advances in molecular biology, genomics, and biotechnology have produced a plethora of potential cancer therapeutic approaches, most are poorly developed for practical use. Popular targets such as receptors and signal transducing protein kinases can be inhibited by many compounds, but only a few have progressed to clinical use with modest results. Potentially useful cytotoxic agents, especially those targeting the downstream signal transducing proteins and components of the effector machinery, such as immediate early gene activations, protein phosphatases, cleavage activators, and nucleases, have not been sufficiently explored. Much attention on the prevention of angiogenesis has been prompted, inspired by RTK inhibitors. Anti-angiogenic treatments have encountered problems of limited efficacy, tumor rebound, and functional switch to more aggressive cancer phenotypes. More research focusing on the tumor-inducing side of the dysregulation of the angiogenic–thrombotic system is now being sought. Unlike avascular tumors, where safety allowing total treatment is feasible, it is hoped that chemotherapy may induce a chronic non-lethal disease state in well-vascularized advanced tumors. In consideration of the use of extensive preclinical approaches in diverse tumors, chances are that remote drug combinations at preclinical stages may all progress in parallel along with extensive biomarker workup. Thus, it is suggested that comprehensive biomarker designation be considered of crucial importance [20, 21].

Patient-Centric Care Models

The notion of customizability in the health care sector relates to the ability of health care systems to adapt their care delivery processes to the specific needs of a patient. Customization comes in degrees, usually measured by three typical dimensions: breadth, height, and contours of the customization solution. While it is commonly understood and appreciated that the social and political construction of the field of health care systems and care delivery is difficult, complex, and long, it is argued that numerous incremental developments have occurred over the last few decades that might lessen fragmentation, improve the fluidity of the health care system and make a patient's care pathway more patient-centric. Care customization seeks to develop a patient-centric model of care that manages the entire pathway of care that is necessary to treat a specific disease or episode of care, such as a cancer. The first main axis consists of searching for or developing evidence- or knowledge-based protocols that explain all the medical steps that need to be taken, in what sequence, by whom, by when, and using what resources in a patient-centric manner to treat the specific disease, such as the treatment of breast cancer, of diabetes and stroke. The second axis tries to ensure that all components of the protocols are easily accessible, available, and usable promptly. Compliance with appropriate treatment guidelines and protocols is more of an issue for common chronic diseases, such as diabetes and stroke. On the other hand,

elder patients with schizophrenia or complex and multiple diseases and disorders need more flexible or adapted protocols regarding the major interventions that specifically fit with this customized patient profile and situation. The desirability, feasibility, and acceptability of the care customization process rely on a wide variety of factors. Ultimately, success and profitability depend upon the value of care customization construction policy. Several interrelated factors are particularly highlighted and discussed in terms of these key issues and their scientific, technical, and practical aspects [22, 23].

Case Studies of Successful Personalized Treatments

A young patient with refractory acute lymphoblastic leukemia (ALL) faced a grim prognosis, expected to live less than two months without intervention. Although allogeneic hematopoietic stem cell transplant (HSCT) is a potential cure, it generally requires remission first. Given the resistance many ALL patients develop against chemotherapy, personalized T-cell immunotherapy was utilized, engineered from the patient's haplo-identical T cells for affordability and rapid application. This "one-time therapy" showcased minimal side effects and a quick T-cell expansion manufacturing process through DNA electroporation of CD19, CD20, and TCR constructs. Post-infusion, the patient initially suffered a fever and hypotensive reaction, but a subsequent PET/CT scan revealed targeted activity against CD19 and CD20 in the bone marrow and leukemia lesions. Remarkably, within three days, symptoms resolved, and normal activity resumed. By day five, scans confirmed remission and recovery. The patient then received two booster doses of T-cells, prompting a rapid and effective in vivo response. Advanced CAR-T cell re-engineering aimed to tackle acquired resistance, creating a second-generation therapy tailored for antibody escape variants of the CD19 antigen. These CAR-T cells were designed to navigate toward high-CD19 targets, sparing healthy tissue in low-expression areas. An overview of personalized treatment indications is also provided, detailing diagnostic methods and outcomes. Challenges remain, such as the absence of identified mechanisms for resistance to PI3K inhibitors despite PI3K mutations being present in over 10% of tumors, prompting the exploration of combinatorial strategies to combat such resistance and enhance patient outcomes [24, 25].

Collaboration In Cancer Research

Implementing personalized therapy faces a significant challenge in developing robust clinical bioinformatics tools to integrate complex patient genomic information. Analyzing DNA, RNA, proteins, and tumor phenotypes at various scales requires advanced algorithms for real-time bioinformatics data analysis in clinical settings. While bioinformatics has addressed specific patient questions, a comprehensive, integrated approach for diverse observations is lacking, which is vital for personalized cancer programs. Tools must be simple enough for general biologists with computing training to evaluate cases. A relational database design is necessary for integrated multi-modal genomic analysis, enabling easy updates with current knowledge about the druggable genome, variants related to drug response and toxicity, and relevant drug-gene interactions. Challenges compound in clinical environments with varied analysis platforms. A push for precision medicine to target cancer biology has emerged from recommendations by academic institutions and industry consortia, advocating for large-scale tumor sequencing and integration of genomic data with patient information. Yet, human genome sequencing is not standard practice, requiring additional basic research. Near-term approaches must phenotype tumor samples using multi-scale data for robustness beyond just genomic targeting. Proposals exist for integrating genomic, transcriptomic, proteomic, and metabolomic data to achieve this goal. Ultimately, protein expression and activation data complement genomic analyses and can yield a more comprehensive understanding of tumor biology than relying solely on transcriptomics or proteomics [26, 27, 28].

CONCLUSION

Personalized cancer treatment represents a revolutionary shift from one-size-fits-all approaches to therapies engineered with the individual patient's genetic and biological makeup in mind. By combining the insights of cancer biology with cutting-edge innovations in genomics, immunotherapy, and bioengineering, we are witnessing a paradigm shift toward therapies that are more effective and less toxic. Technologies such as tumor microfluidic devices, RNA-based diagnostics, and digital twin modeling are enabling a granular understanding of tumor heterogeneity and drug response, thus paving the way for customized treatment regimens. However, realizing the full potential of these personalized therapies requires overcoming challenges in cost, standardization, clinical integration, and regulatory oversight. Future success will depend on global collaboration, interdisciplinary innovation, and robust

clinical validation. As these hurdles are addressed, engineered, patient-specific therapies are poised to redefine the landscape of cancer care, offering renewed hope to millions of patients worldwide.

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