

Role of nanoparticles biodegradable polymers in chemotherapy

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ABSTRACT

Cancer afflicts over 10 million individuals yearly, standing as the leading cause of death worldwide. Each year, cancer claims the lives of 6 million people globally, constituting 12% of all fatalities. The United States has witnessed nearly 16 million new cancer diagnoses since 1990, resulting in 553,768 cancer-related deaths. In 2002, there were more than 1.3 million new cancer cases and over half a million cancer-related

deaths, amounting to one in every four deaths. In 1950, the cancer mortality rate in the United States was 193.9 per 100,000, remaining essentially unchanged at 194.0 per 100,000 in 2001. This multifaceted issue necessitates enhanced collaboration between physicians, medical and biological scientists, and biomedical engineers to seek solutions. The emergence of nanotechnology holds the promise of significant advancements in the near future.

Key Words: *Anticancer drugs; Biomaterials; Cancer; Chemotherapeutic engineering*

INTRODUCTION

Chemotherapy, a potent treatment, holds promise in addressing not only cancer but also other perilous conditions like cardiovascular restenosis and AIDS. However, chemotherapy is a complex procedure with numerous variables impacting its outcomes. It carries a heightened risk of drug toxicity, particularly when more potent drugs are used. Despite successful chemotherapy, significant challenges persist. Patients must endure severe side effects and a diminished quality of life. The inefficacy and side effects of chemotherapy primarily stem from factors such as drug formulation, pharmacokinetics, and toxicity of the therapeutic agents. Moreover, cancer cells can develop resistance to these drugs, exemplified by paclitaxel, a commonly used anticancer treatment (known as Taxol, by Bristol-Myers Squibb).

In the past decade, extensive research has been devoted to the development of biodegradable polymer nanoparticles as effective drug delivery vehicles for chemotherapy. Progress in nanoparticle technology, material science, engineering, and cellular and molecular physiology and pathology has fueled the advancement of nanoparticle technology for chemotherapy. The polymers employed, whether synthetic or natural, are both biocompatible and biodegradable, and they have received FDA approval. Medication can either be distributed within the polymeric matrix or conjugated/attached to polymer molecules. Subsequently, the drug can be released from these nanoparticles upon administration.

Beyond drug formulation, biodegradable polymer nanoparticles offer solutions to issues related to pharmacokinetics, drug toxicity, and

drug resistance in chemotherapy. This innovative approach may encompass sustained, controlled, and targeted chemotherapy, personalized chemotherapy, and addressing various physiological drug barriers. For instance, this could include overcoming the gastrointestinal barrier for oral chemotherapy and breaching the Blood-Brain Barrier (BBB) to treat brain tumors and other Central Nervous System (CNS) diseases. Ultimately, it may even facilitate chemotherapy administered in a home-based setting.

FORMULATION OF NANOPARTICLES

Polymeric nanoparticles can be fabricated through two methods: dispersing pre-existing polymers or polymerizing monomers, both necessitating the application of chemical engineering techniques. For this purpose, the FDA has approved biodegradable and biocompatible polymers such as polylactic acid, polylactic-co-glycolic acid, and polyepsilon-caprolactone. During the polymer dispersion process, the polymer is typically dissolved in an organic solvent like dichloromethane, chloroform, or ethyl acetate. However, if the anticancer medication is hydrophilic, minor adjustments to the procedure are needed to create a water-in-oil-in-water emulsion. The resulting particles are gathered through centrifugation or filtration and subsequently freeze-dried to form powders suitable for storage. Numerous variables come into play during the formulation process, including the type of polymer, its molecular weight, the blend ratio of copolymers, the choice of organic solvent, the quantity of medication loaded, the emulsifier/stabilizer/additive employed, the ratio of oil to water phases, the mechanical vigor during mixing, temperature, and pH levels. The type of polymer, molecular weight, and copolymer blend ratio significantly influence the degradation and erosion rates

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of the nanoparticles, making them critical parameters for both in vitro and in vivo drug release assessments.

NANOPARTICLES: CHARACTERIZATION

To characterize drug-loaded nanoparticles made from biodegradable polymers, a range of state-of-the-art methods can be employed. The size and distribution of these nanoparticles play a crucial role in determining their fate and therapeutic effectiveness upon delivery. Nanoparticles possess a notable advantage due to their higher surface area-to-weight or volume ratio compared to larger particles, facilitating drug release. Furthermore, the size and distribution are pivotal in understanding their interactions with cell membranes and their ability to traverse physiological barriers for drug delivery. Techniques such as laser light scattering and other particle analyzers are employed to measure these attributes.

To achieve the desired drug release kinetics in chemotherapy design, a combination of nanoparticles of varying sizes can be utilized. The performance of drug-loaded nanoparticles can be evaluated by comparing the therapeutic effects of the released drug with those of the free drug administered under the same conditions. Additionally, the physicochemical characteristics of the drug within the nanoparticles can determine their suitability for chemotherapy. Most anticancer drugs exhibit physicochemical stability. For example, a Differential Scanning Calorimetry (DSC) analysis revealed that paclitaxel within the PLGA nanoparticles exists in an amorphous state, with no significant change in the thermogram compared to the raw drug. Further scrutiny of other physicochemical attributes of the medication enclosed within the polymer matrix is also warranted.

CHALLENGES

In the realm of chemotherapy, pharmacokinetics holds pivotal significance. It is imperative to ensure that cancer cells are exposed to the medication at a sufficiently high concentration for an extended duration. Presently, chemotherapy is administered on an as-needed basis, typically involving regular injections or infusions. However, these treatment cycles necessitate intervals for patient recovery. Unfortunately, this pause allows tumor blood vessels to proliferate rapidly, which compromises the therapeutic effects. High peak concentrations of medication during treatment lead to severe side effects. It is believed that prolonged exposure to the drug at lower concentrations may be more beneficial than administering high-concentration pulsed doses.

The ultimate objective of chemotherapy is to deliver highly effective drugs precisely when and where needed, ensuring a high concentration while maintaining safety. Another critical concern is drug resistance, which must be addressed at vascular, interstitial, and cellular levels to achieve successful treatment. Drug transport through tumor microvessels can occur via interendothelial junctions and transendothelial channels. Several tumor models have identified pore cutoff sizes in the range of 380 nm to 780 nm. The tumor interstitium, marked by high hydrostatic pressure, induces drug resistance by promoting an outward convective interstitial flow. Cellular processes, such as changes in specific enzyme activity and apoptotic regulation, as well as transport-based systems, contribute to tumor resistance to treatment drugs.

Nanoparticles may offer a potential solution to drug resistance due to their small size and suitable surface coating. In the context of chemotherapy, oral administration of anticancer drugs presents a formidable challenge. However, it offers the promise of enhanced efficacy, reduced adverse effects, and greater patient convenience. Oral delivery facilitates the exposure of cancer cells to a safe yet effective medication concentration over an extended period, potentially yielding superior results with fewer side effects compared to injection or infusion. Regrettably, most anticancer drugs suffer from poor bioavailability. For example, paclitaxel has a bioavailability of less than 1% because it undergoes elimination by cytochrome P450 and the efflux pump P-gp during its first metabolic phase. To enable oral chemotherapy, therapeutic strategies using P450/P-GP inhibitors like cyclosporine A are presently under investigation. Oral anticancer drug delivery empowers patients to manage their own chemotherapy from the comfort of their homes, markedly improving their quality of life.