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A REVIEW ON NANOTECHNOLOGY BASED DRUG DELIVERY SYSTEM

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ABSTRACT

Nanotechnology based drug delivery systems are a breakthrough in the pharmaceutical sector as it provides an opportunity for precise, controlled and sustained release of the drugs. Several nanocarriers including liposomes, niosomes, polymeric nanoparticles, solid lipid nanoparticles, dendrimers, nanoemulsions and biological nanocarriers are being developed which are capable of improving the solubility, stability, bioavailability and therapeutic efficiency of drugs. Nanocarriers can protect the drug from degradation, improve its cellular uptake and deliver it to a specific target which leads to reduction in the systemic toxicity and side effects. There are various ways for preparing and characterizing the nanoparticles for optimal performance and safety. Drug delivery mechanisms with nanoparticles like passive targeting, active targeting and stimuli-responsive release helps in gaining better results. Various applications of nanotechnology based drug delivery systems such as cancer, infectious diseases, cardiovascular disease, neurological disorders, diabetes, ophthalmic applications, and gene therapy etc are being explored. Though safety, large scale production, stability and regulatory approval remain challenges, but advanced research is exploring more opportunities for nano medicine in the healthcare sector.

KEYWORDS: Nanotechnology; Drug Delivery Systems; Nanoparticles; Nanomedicine; Liposomes; Polymeric Nanoparticles; Targeted Drug Delivery; Controlled Drug Release; Nanocarriers; Therapeutic Applications; Precision Medicine; Drug Targeting.

INTRODUCTION

Drug delivery is one of the most important aspects of modern healthcare since the efficacy of a medicine depends not only on the drug itself but also on the way it reaches the target site in the body. Tablets, capsules, injections and creams have been the conventional dosage forms for decades. But, many drugs suffer from poor solubility, low bioavailability, rapid degradation and unwanted side effects. Consequently, only a small fraction of the administered drug can reach the desired site of action. These limitations may reduce therapeutic efficacy and increase the cost of treatment. Therefore, researchers have focused on the development of advanced drug delivery systems that can enhance drug absorption, improve therapeutic outcomes, minimize adverse effects, and improve patient compliance and safety.[1]

Nanotechnology has been one of the most promising innovations in pharmaceutical sciences and medicine. It involves the design and application of materials and devices at the nanometer scale, usually between 1 and

100 nanometers. At this very small size, materials possess special physical, chemical and biological properties which are different from those of larger size. Scientists have exploited these features to create nanoparticles that deliver drugs directly to specific tissues, organs or cells. A targeted approach can increase the efficacy of the drug and reduce the exposure of normal tissues to potentially harmful drugs. Hence, nanotechnology has opened up new frontiers in the treatment of complicated diseases that were difficult to treat with the conventional drug delivery systems.[2]

Nanotechnology based drug delivery systems comprise a wide range of carriers including liposomes, polymeric nanoparticles, dendrimers, solid lipid nanoparticles, nanostructured lipid carriers, nanoemulsions and metallic nanoparticles . These systems can entrap drugs, protect them from degradation and deliver them in a controlled manner over a defined period of time. Such capabilities are especially useful for drugs that have poor stability or a short biological half-life. Moreover, nanocarriers can be designed to respond to specific biological signals like pH, temperature or enzymes, enabling site-specific drug release. These advanced systems have demonstrated great promise in the treatment of cancer, infectious diseases, neurological disorders, cardiovascular diseases, diabetes and a variety of inflammatory conditions, thus revolutionizing the field of modern therapeutics.[3]

The increasing emphasis on the applications of nanomedicine in drug delivery has initiated numerous research efforts and clinical trials and several nanomedicines have already been marketed. However, major drawbacks such as manufacturing on a large scale, regulatory issues, long-term toxicity and cost-effectiveness require solutions in order for nanodrugs to be widely used in clinic. Future developments in the areas of materials science, biotechnology and pharmaceutical engineering will continuously tackle these issues and improve nanocarriers. Nanotechnology will play a pivotal role in targeted therapy and individualized medicine.

FUNDAMENTALS OF NANOTECHNOLOGY IN DRUG DELIVERY

Nanotechnology drug delivery is based on the idea of encapsulating drug into nanocarriers to deliver drugs into a specific region in vivo. The nanocarrier may be made of lipids, polymers, metals, proteins, or any other biocompetitive materials. Nanoparticles could overcome biological barriers by reason of their tiny size; the efficiency of penetrating tissues and uptake by cell could also be improved. They could also prevent drugs from being degraded, increase the solubility of drugs, increase circulation time and control the release of drugs. Drug delivery targeted to a certain region could also be accomplished by modifying the surface properties of nanoparticles, which could increase drug efficacy and reduce systemic toxicity. Therefore, nanotechnology is a significant development area of drug delivery systems.[4]

HISTORICAL DEVELOPMENT OF NANOMEDICINE

1959–1980: The basis of nanomedicine can be dated back to 1959 when Richard Feynman was to introduce the concept of nanoscale manipulation of atoms and molecules through his famous lecture "There's Plenty of Room at the Bottom." Though at the time there were no technologies available to fulfill his concepts, they laid inspiration for future scientists. The further decades saw further advancement of materials science and molecular biology providing the foundations for nanotechnology for use in medicine.

1981–1990: The Scanning Tunneling Microscope (STM) was introduced in 1981, then followed by the Atomic Force Microscope (AFM) in 1986. These enabled researchers to view and manipulate structures at the nanoscale and the term nanotechnology came into prominence with Eric Drexler in 1986, thus introducing a high interest to nanoscale applications in medicine and pharmacy.[5]

1991–2000: Developments in nanomaterial research escalated in the 1990's. 1991 saw the emergence of carbon nanotubes with novel mechanical and electrical characteristics making them appropriate for biomedical applications. The exploration of nanoparticles, liposomes and polymer-based drug delivery systems was also undertaken during this era. Perhaps the most notable event in nanotechnology occurred in 1995 with the first nanomedicine being FDA-approved, liposomal doxorubicin (Doxil) was launched as a treatment for cancer, proving the viability of nanomedicine as a form of treatment.[6]

2001–2015: The growth and expansion of nanomedicine during this period was largely due to advances in the fields of biotechnology, materials science and molecular targeting. Developments in nanomedicine during these years include dendrimers, solid lipid nanoparticles, nanoemulsions, and polymeric nanoparticles for controlled and targeted drug delivery. Furthermore a number of nanoformulations were also given approval during these years for their use in cancer and infectious diseases, as well as diagnostic imaging, biosensors, gene delivery and regenerative medicine.[7]

2016–Present: The era of nanomedicine beginning in 2016 is characterized by the development of smart drug delivery systems and the move towards precision medicine. During these years stimuli-responsive nanoparticles, exosome based carriers and multi-functional nanoplatforms are being developed in order to provide better treatment outcomes. The outbreak of the COVID-19 pandemic demonstrated the potential of nanomedicine as mRNA vaccines using lipid based nanoparticles are successfully being developed. Future research is set to involve personalized nanomedicine, gene editing, theranostics and an approach towards the

development of nanocarriers through the use of artificial intelligence.[8]

CLASSIFICATION OF NANOTECHNOLOGY-BASED DRUG DELIVERY SYSTEMS

Organic Nanocarriers

Liposomes: Liposomes are spherical vesicles, consisting of one or more phospholipid bilayers, with an aqueous compartment. They have the ability to carry both hydrophilic and lipophilic drugs and provide protection against degradation. Liposomes are useful for targeted delivery of the drug to the desired tissue or organ. They enhance drug bioavailability and also offer reduced toxicity, and provide controlled drug release. Applications include use in the cancer therapy, vaccine delivery, gene delivery and other such systems.

Niosomes: Niosomes are vesicles prepared from non-ionic surfactants that are useful in drug delivery applications. They share structural similarities with liposomes, but are found to be cheaper and more stable than liposomes. They carry a wide variety of therapeutic agents and improve drug penetration, bioavailability and controlled release. They are actively being researched for use as transdermal, oral, ocular, targeted drug delivery systems

Solid Lipid Nanoparticles (SLNs): Solid lipid nanoparticles are sub-micron colloidal carrier systems consisting of physiologically compatible solid lipid particles, stabilized by surfactants. They are essentially a combination of the advantages of polymeric nanoparticles and lipid emulsions, while at the same time keeping the system safe from toxicity. SLNs provide good drug stability and control drug release and enhance bioavailability. They can be employed as drug carriers because they are biodegradable and can protect sensitive drugs.[9]

Nanostructured Lipid Carriers (NLCs): Nanostructured lipid carriers are advanced lipid-based systems developed to overcome the limitations of solid lipid nanoparticles. They consist of a mixture of solid and liquid lipids that create an imperfect lipid matrix, allowing higher drug loading and reduced drug leakage. NLCs provide enhanced stability, prolonged drug release, improved bioavailability, and better therapeutic performance.

Polymeric Nanoparticles: Polymeric nanoparticles are nanocarriers constructed from natural or synthetic biodegradable polymers. The drugs can be entrapped into the polymeric matrix or adsorbed onto the nanoparticle surface. These nanoparticles provide control and sustained release of drugs, and good stability and targetability. They are widely used in cancer therapy, vaccine delivery and gene based therapy.

Polymeric Micelles: Polymeric micelles are self-assembled nanocarriers formed from amphiphilic block copolymers in aqueous solutions. They have a hydrophobic core and hydrophilic shell that are appropriate for delivery of water insoluble drugs. The drug solubility and circulation time can be increased by using these nanocarriers. They also exhibit tumor targeted distribution of drugs. Polymeric micelles are particularly useful in delivery of anticancer drugs.[10]

Dendrimers: Dendrimers are highly branched, tree-like macromolecules with a well-defined architecture. It possesses a large number of surface functional groups that provides efficient drug loading, target ligands and release of drugs at the targeted sites in controlled fashion. Dendrimers exhibit excellent biocompatibility and predictable structures. They hold a promising prospect in gene delivery, cancer therapy, imaging and other therapeutic applications.

Nanoemulsions: Nanoemulsions are thermodynamically or kinetically stable emulsions which comprise oil, water and surfactant and whose droplet sizes are less than 200 nm. They are used for the solubility and absorption of water-insoluble drugs. The nanoemulsion leads to enhanced bioavailability, faster absorption and enhanced formulation stability. It finds use in oral, topical and parenteral delivery.

Nanogels: Nanogels are water-swellable polymer matrixes of nanometer size that can encapsulate a large amount of water. They are biocompatible and biodegradable as well as sensitive to changes in pH and temperature. Nanogels allows for a sustained and targeted drug delivery and could find use in cancer, gene therapy and protein delivery.[11]

Inorganic Nanocarriers

Gold Nanoparticles: The unique optical, electronic and surface properties of gold nanoparticles are useful in drug delivery and bioimaging. The surface of gold nanoparticles can be modified easily with drugs, antibodies and targeting ligands. Gold nanoparticles are highly biocompatible and stable. They have been widely studied for their role in cancer therapy, photothermal therapy, bioimaging and targeted drug delivery.

Silver Nanoparticles: Silver nanoparticles are known for their effective antimicrobial, antiviral and antifungal activity. Large surface area and the capability of serving as carriers for therapeutic drugs enhance their effectiveness. The drug efficacy is enhanced with silver nanoparticles and antimicrobial resistance is decreased. They are utilized in wound healing, antimicrobial coatings, disease prevention and targeted drug delivery studies.[12]

Magnetic Nanoparticles: Magnetic nanoparticles are generally iron oxide based nanomaterials which respond to an external magnetic field. These nanoparticles can be used for site-specific drug delivery using magnetically guided targeting to avoid harmful off-target effects.

Their use in magnetic resonance imaging (MRI), hyperthermia treatment and theranostic approaches also demonstrates their potential. Multifunctional properties are very useful in nanomedicine.

Silica Nanoparticles: Silica nanoparticles, particularly mesoporous silica nanoparticles have a very high porosity and surface area and the pore sizes can be controlled. These properties facilitate drug loading and release in a sustained and controlled manner. Silica nanoparticles are very stable, biocompatible and can be surface-modified and are studied widely for applications like drug targeting and delivery, imaging, biosensing and cancer therapy.

Quantum Dots: Quantum dots are semiconductor nanocrystals with interesting optical and fluorescence properties. Their emission depends on their size and they are extremely useful for biomedical imaging and diagnostics. They can be coupled with drugs and targeting agents for combined imaging and therapeutic applications. There is huge potential for cancer imaging, tracking of cells and theranostics.[13]

Carbon Nanotubes: Carbon nanotubes are cylindrical nanostructures formed by rolling graphene sheets which have very high strength and conductivity. They can be functionalized for drug loading and are known for good cell penetration. They can deliver therapeutic agents, genes, biomolecules etc. To the tumor and are studied for cancer therapy, biosensing and tissue engineering.

Graphene-Based Nanomaterials: Single or multiple layers of carbon atoms organized in a two-dimensional honeycomb structure constitute the graphene-based nanomaterials, showing excellent mechanical, thermal and electrical properties. Graphene derivatives possess high drug-loading capacity and great surface functionalization ability, and they have been widely investigated for applications in drug delivery, bioimaging, tissue regeneration and cancer therapy.[14]

Biological Nanocarriers

Exosomes: Exosomes are naturally occurring extracellular vesicles with a size of about 30–150 nm and secreted by various types of cells. Exosomes transport proteins, lipids, RNA, and signaling molecules between cells to realize intercellular communication. The excellent biocompatibility, low immunogenicity and ability to cross biological barriers render exosomes suitable candidates for the targeted delivery of drugs and gene, cancer treatment, regenerative medicine.

Cell Membrane-Coated Nanoparticles: Cell membrane-coated nanoparticles are biomimetic systems generated by coating artificial nanoparticles with natural cell membranes (e.g., red blood cells, platelets or immune cells). The coating with cell membranes provides effective immune evasion, sustained circulation and great targeting ability. Combining biological function with nanotechnological advantages, cell membrane-coated nanoparticles have been applied in cancer therapy, infectious diseases, vaccine delivery and inflammation treatment.

Virus-Like Nanoparticles: The virus-like nanoparticles (VLPs) are virus-sized nano-particles composed of virus structural proteins assembled into spherical structures, without carrying any infectious genetic material. Their uniformity of size, high stability and effective cellular targeting provide to them as a carrier for vaccines and drugs. VLPs can induce strong immunological response and are widely applied for vaccine development, gene delivery, cancer therapy and target therapies.[15]

METHODS OF NANOPARTICLE PREPARATION

Top-Down Approaches: In this approach, bulk materials are fragmented into nanoscale dimensions with the help of some physical, chemical or mechanical process. Milling, grinding, lithography, high pressure homogenization are some examples of this method. These processes are used for the synthesis of nanoparticles from bulk materials, they consume lot of energy, and are prone to particle aggregation. This method is used for the synthesis of solid lipid nanoparticles, solid lipid nanocrystals.

Bottom-Up Approaches: In this method, atoms, molecules or molecular cluster assemble to form nanostructure with size at nanometer scale. These methods make use of some physical, chemical reaction or self-assembly process or precipitation to synthesize nanoparticles. The bottom-up methods provide good control on particle size, morphology and composition in compared to the top-down methods. This technique is extensively used in the synthesis of polymer nanoparticles, liposomes, dendrimers, and metal nanoparticles.

Solvent Evaporation Method: This is one of the most popular method for the formulation of polymeric nanoparticles. The drug and polymer is dissolved in the organic solvent and then an emulsion is formed in the aqueous phase containing stabilizer. This organic solvent is removed by evaporation technique and the nanoparticles are formed. This method possesses good encapsulation efficiency and good control over the particle size and it is very useful for delivery of hydrophobic drug.[16]

Nanoprecipitation Technique: The nanoprecipitation, the solvent displacement method is a simple technique which consists on dissolving the drug and polymer in a water-miscible organic solvent and then pouring rapidly into the aqueous phase. The solvent instantaneously diffuses to the continuous phase resulting in precipitation of the polymer and formation of nano-particles. This method is reproducible and does not require any high energy, this method is beneficial for the polymeric nanoparticle with a narrow size distribution.

Emulsification Method: The emulsification technique works on the principle of creating the oil-in-water (O/W) or water-in-oil (W/O) emulsions, where oil phase would be where drug and carrier material are dispersed. To stabilize these oil droplets an emulsifier is incorporated in water phase (continuous phase). These emulsions were then subjected to different methods such as subsequent extraction of solvent or by solidification leading to nano-particle formation. This technique is a common method for preparing lipid nanoparticle, nanoemulsions, and polymeric drug delivery system.[17]

Spray Drying: Spray drying is a fast technique which allows the conversion of liquid formulation to nanoparticle powder form. It has been used to produce nanoparticles of various drugs. Drug solution or suspension is atomized into the hot air stream. This leads to rapid evaporation of solvent and particle formation. The technique produces particles of well-controlled morphology and suitable for the manufacturing of nanoparticle powder, having an advantage of fast production rate and also it is safe to process with the sensitive materials.

Supercritical Fluid Technology: In this technology the fluids are kept above their critical temperature and pressure-typically carbon dioxide is used. Supercritical fluid technology is often employed in the synthesis of nanoparticles, where the fluid acts as either a solvent, antisolvent, or extraction medium. The technique gives precise control over both the size and morphology of the nanoparticles formed, and it also uses very little organic solvent. The technology is an 'eco friendly' way of synthesizing nanoparticles.

Microfluidics-Based Nanoparticle Fabrication: Microfluidic technology takes advantage of microscale channels to obtain excellent control over fluid flow and mixing when preparing nanoparticles. A consistent outcome of this controlled process is the uniformity and reproducibility of the nanoparticles formed, with a narrow size distribution. Continuous fabrication is also possible and optimum conditions can be calculated more easily. It has been increasingly utilized for the fabrication of liposomes, polymeric nanoparticles, and lipid-based nanocarriers for application in targeted drug delivery.[18]

Green Synthesis of Nanoparticles: Green synthesis approach is environment friendly approach which uses biological sources such as extracts from plants, microorganisms, enzymes, natural biomolecules to prepare nanoparticles, thus reduces the usage of toxic chemical and also effect on environmental impact. The nature of green synthesized nanoparticles has higher biocompatibility and lower toxicity. The approach has developed considerable interests in the synthesis of metal nanoparticles such as gold nanoparticles, silver nanoparticles for the biomedical applications.

Characterization of Nanoparticles: Nanoparticle characterization is an essential part in the development of nanotech based drug delivery system. Because physiochemical properties of nanoparticle significantly influence the stability, biodistribution, uptake by cells, drug release and activity. A good characteristic profile helps assure the consistency, quality and safety as well as effectiveness of the nanoformulation.[19]

CHARACTERIZATION OF NANOPARTICLES

Particle Size Analysis: Size distribution analysis of particle size and shape determination of nanoparticles. Size determination of nanoparticle can be carried out using dynamic light scattering (DLS), Nanoparticle Tracking Analysis (NTA) and electron microscopy. Size of the particle is important due to effect on drug loading, circulation time and cellular uptake as well as tissue permeation. Size has an effect on cellular internalization and biodistribution (smaller particle tends to have more cellular uptake) but the tissue permeability of larger particles would not be great and it may be quickly cleared from the system.

Morphological Characterization: Shape, size and texture and structural state of the nanoparticle can be characterized. Scanning Electron Microscopy (SEM), Transmission Electron Microscopy (TEM) and Atomic Force Microscopy (AFM) have widely used for this purpose. These analyses will produce a direct image of nanoparticles which reveal details about particles shape, aggregation, surface rough or smooth, and interior structure. Morphology of nanoparticles has a major effect on the drug release pattern, stability and cell interaction.[20]

Surface Charge Measurement: Surface charge measurement has typically been studied by using zeta potential analysis. The zeta potential provides an indication of the charge present on the particle surface and indicates colloidal stability, Particles with significantly high negative or positive zeta potential value tend to repel each other resulting in reduced aggregation and a stable colloidal system. The surface charge of the nanoparticle would influence their interaction with cell membrane and physiological medium.

Drug Entrapment Efficiency: The DEE describes how much drug has been incorporated into the nanoparticles with respect to the quantity used during the formulation. Usually, the entrapment efficiency is determined by calculating the amount of free drug dispersed with and within the nanoparticles after separating from the nanocarriers. The entrapped drug can be measured by spectrophotometric assay or using HPLC. High entrapped efficiency proves successful formulation.

Drug Loading Capacity: DLC refers to the mass of drug incorporated in unit mass of nanoparticle. It determines the dosage and therapeutic potential of

nanoformulation. It is usually calculated using analytical methods like HPLC and UV-Visible spectrophotometry. High DLC is beneficial because the carriers would be minimized, hence could be more efficient.[21]

In-vitro Drug Release Studies: The in-vitro drug release studies of encapsulating nanocarriers are commonly performed to explore the rate and extent of drug release in simulated physiological conditions. Dialysis bag, diffusion study and dissolution testing are typically employed to investigate drug release mechanism and kinetics. These experiments help in obtaining information about instant release, sustained or controlled drug release profile.

Stability Studies: Physical and chemical stability studies are carried out on the nanoparticles during their storage over time, with variation of parameters like particle size, zeta potential, drug contents, and aggregation under the different temperature and humidity condition to find the shelf-life of the formulation, quality of products as well as maintain its effectiveness in therapy until the delivery and distribution of the product.

Crystallinity and Thermal Analysis: The study of crystallinity and thermal properties of the drug and the carriers are essential as it describes about the physical state of the drug and carriers. X-ray Diffraction (XRD) is often used for determination of whether the drug is crystalline or amorphous form. However, differential Scanning Calorimetry (DSC) and Thermogravimetric Analysis (TGA) are used for determining thermal property such as melting point, thermal transitions and thermal stability, which also gives the idea about drug-polymer interaction and formulation compatibility.

Surface Chemistry Analysis: Surface chemistry analysis is to identify the chemical groups and chemical constitution at the surface of nanoparticle. Common techniques are Fourier Transform Infrared Spectroscopy (FTIR), Raman Spectroscopy and X-ray Photoelectron Spectroscopy (XPS), which can determine drug encapsulation, modification of surface, attachment of ligands as well as interaction between the constituent molecules and helps to know the formulation compatible to cell surface and target organs.[22]

MECHANISMS OF NANOPARTICLE-MEDIATED DRUG DELIVERY

Passive Targeting Through the Enhanced Permeability and Retention (EPR) Effect: Passive targeting is one of the most commonly exploited mechanisms in nanoparticle based drug delivery. Pathological conditions and tumors may have defective blood vasculature with large gaps on the endothelial cells with slow lymphatic draining and consequently there are increased permeations of nanoparticles from the blood circulation to the specific tissue, which is known as EPR effect. Due to the EPR effect nanoparticles can accumulate in the tumor sites and target diseased tissues more efficiently to increase drug concentration and reduced system toxicity in the treatment of cancer and inflammatory diseases.

Active Targeting via Ligand-Receptor Interactions: Active targeting based on the interaction of ligands with receptors The nanoparticle surface is modified with some ligands, such as antibodies, peptides, aptamers, carbohydrate or small molecules that selectively bind to the receptors, overexpressed on the surface of targeted cell. Binding of nanoparticles with receptor can activate receptor mediated endocytosis and deliver drug to the intracellular compartment of the target cells efficiently with enhanced targeted delivery, efficient cell internalization and reduces the off targeted accumulation in tumor targeting cancer therapy, gene therapy and target organ treatment.[23]

Cellular Uptake Through Endocytosis: The cellular uptake of nanoparticles is largely achieved through different endocytic pathways. Endocytosis is a biological mechanism whereby particles are surrounded by the cell membrane and internalised in intracellular vesicles. The main endocytic pathways that are utilized for nanoparticles are; clathrin-mediated endocytosis, caveolae-mediated endocytosis, macropinocytosis, and phagocytosis, although size, shape, surface charge and composition of nanoparticles play crucial roles in defining the appropriate uptake mechanism. Within intracellular components, the nanoparticles release therapeutic drugs allowing disease treatment at the cellular level.

Controlled and Sustained Drug Release: Nanoparticles can be designed to deliver therapeutic drugs in a controlled & sustained fashion over time. Drugs can be entrapped, adsorbed onto the nanoparticle or covalently conjugated within the nanoparticle matrix, allowing their eventual release via gradual breakdown of the carrier matrix or by diffusion out of the nanoparticle. This offers an extended time for the drug's effects and subsequently reduces the need for administration of multiple doses. Controlled systems may result in optimal drug concentration being maintained within the therapeutic window, avoiding fluctuations that may lead to toxic effects or loss of efficacy.[24]

Stimuli-Responsive Drug Release: Stimuli-responsive nanoparticles are engineered to release drugs when specific internal or external stimuli are present. Internal stimuli can be variations in pH, enzyme concentration, redox potential and temperature within the target diseased tissues. External stimuli can be light, magnetic fields, ultrasonic signals and electrical stimuli. After treatment, structural changes of nanoparticles occur due to stimuli, and drugs are released to the targeted tissues. Smart nanoparticles overcome the limitation of poor targeting efficiency and damage of healthy tissues during therapy.

Transcytosis Across Biological Barriers: Some nanoparticles may also utilize transcytosis mechanism to transport through biological barriers. The transcytosis mechanism involves endocytosis, movement within cells and exocytosis from the other end of the cells. The mechanism is critical to deliver drugs to challenging barriers such as blood brain barrier (BBB), intestinal epithelia and lung mucosa. Targeted ligand decoration on the nanoparticle surface will increase the efficiency of transcytosis across barriers

Intracellular Drug Delivery and Endosomal Escape: In most cases, drugs loaded in nanoparticles are taken up into cells through endocytosis and entrapped within endosomes and lysosomes, which prevent drug reaching its target before degradation. In many nanoparticles, materials with pH-sensitivity and membrane-disruption were used in order to escape from endosomes. After escaped from endosomes into the cytoplasm, therapies agents such as anticancer drugs, proteins and nucleic acids will exert biological actions. This mechanism plays an essential role in gene therapy and RNA therapy.

Gene and Nucleic Acid Delivery: Nanoparticles are a great choice of vehicle for delivery of nucleic acids including DNA, mRNA, siRNA and CRISPR components. The nanoparticle offers protection from nucleases and a means to reach the target cells. Once released into the cells, these genetic materials are able to alter the expression of specific genes and silence genes responsible for disease, or to correct genetic defects. Gene delivery with nanoparticles is a popular method to develop therapeutic drugs for diseases such as cancer, genetic disorders and infectious diseases.[25]

Mucoadhesion and Enhanced Absorption: With use in oral, nasal, pulmonary and ocular routes, nanoparticles can adhere to mucosal membranes and provide increased drug absorption. Nanoparticles with mucoadhesive properties increase the retention time of the particles at the site of administration and increase permeability through the epithelial membrane. This enhances bioavailability, especially in the case of drugs with poor solubility and poor absorption.

Targeted Accumulation Through Surface Modification: Targeted accumulation by surface modification: nanoparticles surfaces functionalized with biological molecules such as antibodies, peptides, polyethylene glycol (PEG) and other biomolecules could significantly increase circulation time, targeting capability. PEGylation reduces immune responses and increases circulation time in the body, increasing accumulations in the diseased areas and facilitates target cell and tissues targeting, in turn leading to increased effectiveness while minimizing detrimental side effects.[26]

APPLICATIONS OF NANOTECHNOLOGY-BASED DRUG DELIVERY SYSTEMS

Cancer Therapy: Nanotechnology-based drug delivery system has dramatically enhanced cancer therapy through the ability to deliver chemotherapeutics specifically toward tumor cells. Nanocarriers including liposomes, polymeric nanoparticles and dendrimers can increase drug accumulation in tumor site, reduce systemic toxicity and multidrug resistance and increase therapeutic efficacy while minimize injury on normal cells.

Infectious Diseases: Nanoparticles increase the efficacy of antimicrobial therapy by improving the stability, bioavailability and the penetration of drugs into specific tissues, allowing targeted delivery of anti-bacterial, anti-viral and anti-fungal agents while at the same time minimizing the development of drug resistance. The innate ability of metallic nanoparticles and particularly of silver nanoparticles to kill microorganisms is well explored and their use is widely investigated in various infectious diseases.

Cardiovascular Disorders: Nanotechnology based drug delivery systems enhance the treatment of various cardiovascular disorders by delivering drugs directly into the affected blood vessels and heart tissues. Nanocarriers enhance bioavailability and reducing the systemic side effects and thereby increasing the efficiency and outcome of therapy in various cardiovascular diseases such as hypertension, atherosclerosis, myocardial infarction and thrombosis and are useful in diagnostic imaging.[27]

Neurological Disorders: The blood-brain barrier can be successfully crossed by nanoparticles and thus these carriers help in delivering therapeutic drugs to the brain, enhancing the treatment of various neurological disorders such as Alzheimer's disease, Parkinson's disease, epilepsy and brain tumors, improving distribution and reducing peripheral toxicity.

Diabetes Management: Nanotechnology based treatment of diabetes involves effective delivery of insulin and oral anti-diabetic drugs to the cells. The presence of nanocarriers improves the absorption of insulin as it protects it from degradation and allows its controlled delivery to target sites, while smart glucose responsive nanoparticles could control the delivery of insulin in the body based on blood glucose levels and hence optimize and enhance therapeutic outcomes of treatment with increase in patient compliance.

Inflammatory and Autoimmune Diseases: **N**anocarriers are effective for target-specific delivery of anti-inflammatory and immunosuppressive drugs to inflamed tissues. These can minimize systemic exposure and potential side-effects, thereby enhance efficacy. nanotechnology is found to be useful in treating rheumatoid arthritis, psoriasis, IBD and others

autoimmune diseases by controlling the release rate at specific sites.

Pulmonary Disorders: The nanotechnology based inhalation delivery systems allow drugs to deliver directly into the lungs which helps for better treatment of diseases like asthma, COPD, cystic fibrosis, lung infection, lung cancer. They increase the local concentration and the residence time and also enhance the absorption and minimize the side effects associated with conventional therapy.[28]

Ophthalmic Diseases: Nanoparticles enhance delivery to the eyes, which include the better corneal penetration, retention in the eyes and elimination of barriers in the eye. They are used for treatment of glaucoma, cataract, retinal diseases and ocular infections using various liposomes, nanoemulsions and nanogels. The therapy becomes more effective.

Dermatological Disorders: The nanocarriers effectively increase penetration through skin barrier and provide site-specific and controlled release for dermatological disorders like psoriasis, eczema, acne, fungal infection, and skin cancer. They increase the drug stability, local bioavailability and minimize irritation.

Gene and Nucleic Acid Delivery: Nanocarriers are widely used to achieve safe and effective delivery of genetic material including DNA, RNA, siRNA, mRNA and CRISPR-related factors, to protect the nucleic acid from degradation and to promote efficient cellular uptake for enhanced gene expression, making them the important tools for the future of gene therapy, personalized medicine and vaccines development.[29]

Vaccine Delivery Systems: Nanoparticle-based vaccine delivery systems effectively increase the stability of antigen, facilitate the generation of immune response and realize targeted delivery to immune cells. Nanocarriers have the dual functions of carriers and adjuvants, so as to optimize the immune response generated by vaccines, which is evident in modern vaccine designs as a successful approach to prevent the infectious diseases and develop rapid vaccines.

Regenerative Medicine and Tissue Engineering: Tissue engineering requires specific signals including growth factors, stem cells and bioactive molecules delivered to sites of damaged tissue to stimulate regeneration. Nanomaterials, in analogy to the natural extracellular matrix, could serve as nanocarriers to promote cell growth and repair in the process of tissue engineering. Current applications are mainly focused on skin wound healing, bone and cartilage regeneration and cardiovascular tissue engineering.

Theranostics and Personalized Medicine: Nanoparticles that simultaneously incorporate therapeutic and imaging properties called theranostics have recently attracted the attention of the scientific community. Theranostic systems are capable of delivering therapeutics while also providing real-time tracking of drug delivery and therapy monitoring within the body, offering real-time feedback for evaluation of therapeutic effect and contributing to the personalization of medicine.[30]

SAFETY PROFILE OF NANOTECHNOLOGY-BASED DRUG DELIVERY SYSTEMS

In general, the nanotechnology based drug delivery systems seem safer than conventional drug formulations, as they deliver drugs at targeted sites in a controlled manner. Drug carriers with therapeutic agent are targeted to the tissues that are diseased. This minimizes the contact of organs with toxic drug leading to less side effects. Safe materials are used to formulate nanoparticles like lipids, biodegradable polymers, and naturally derived biomolecules. Few nanomedicines are approved by regulatory bodies, and their successful clinical evaluation shows safety and tolerability with good efficacy. But safety of nanoparticles depends on the size, surface charge, components, dose, and the route of administration.

Although some promising results can be obtained using nanoparticles, the safety of long-term exposure to nanomaterials is a significant issue which still needs extensive research. Long-term exposure of some nanoparticles could potentially causetoxicity since some could accumulate in organs such as spleen, lung, kidney and liver. Surface characteristics and chemistry of nanoparticles affect immunity, oxidative stress, inflammation and cellular damage. Certain inorganic nanoparticles have very poor biodegradability which could increase the possibility of bioaccumulation. Consequently, thorough toxicological study, Pharmacokinetic study and regulatory assessments need to be completed before clinical translation. Studies are further aiming to achieve an excellent biocompatible, biodegradable, safety nanomaterials for clinical application.[31]

ADVANTAGES OF NANOTECHNOLOGY-BASED DRUG DELIVERY SYSTEMS

Improved Bioavailability: Drug bioavailability can also be improved using nanotechnology. This is especially the case with drugs with low water solubility and poorly absorbed. Increasing the surface area of the drug, in the form of nanocarriers, allows greater dissolution and greater contact with the biological membrane, improving absorption and consequently allowing higher drug concentration within systemic circulation. With greater drug bioavailability lower concentrations of the drug are able to elicit therapeutic action which translates into greater affordability and reduced potential for side effects of drugs. The enhanced bioavailability gained is of particular benefit for oral, transdermal and targeted delivery approaches.

Targeted Drug Delivery: Another of the most desirable attributes of nanotechnology-based drug delivery systems is targeted drug delivery. Nanoparticles can be manufactured so that they recognize specific receptors or markers in tissues and cells, so accumulation is concentrated to that target site. As a result there is greater drug concentration where needed and less drug in normal tissues, increasing drug efficacy and also decreasing side effects seen in typical drug therapies.[32]

Controlled and Sustained Drug Release: Nanocarriers could be developed to control and release the drugs in a controlled and sustained way for long periods. This system increases and maintain the desired concentration of drugs in the body and minimize fluctuations in drugs concentration in case of the conventional dosage form. The controlled release increases the effectiveness and decrease the dose frequency as well as improves the patient compliance. It also reduces peak mediated toxicity and ensures sustained activity of the drugs over long periods and hence nanotechnology is ideal for chronic disease treatment.

Protection of Drugs from Degradation: Numerous drug agents including proteins, peptides and nucleic acids have a short half life because of their sensitivity to enzyme and other factors. These drugs are prone to degradation. Nanocarriers have been utilized to encapsulate these sensitive drugs within a protective layer preventing their premature degradation during storage as well as after administration, hence delivering higher concentration of active drugs at the target sites. Drug stability as well as their effectiveness increase.[33]

Enhanced Cellular Uptake: Due to their extremely small size nanocarriers efficiently interact with cell membranes and cellular uptake is also improved through many possible ways. Higher intracellular concentration of drugs achieved through effective cellular uptake is vital for treatment of cancers and infectious diseases and for gene therapy. Increased intracellular uptake and penetration at cell level is important in the effective treatment for diseases that cannot be easily accessed by conventional routes.

Reduced Systemic Toxicity: Nanobased drug delivery systems minimize systemic toxicity, by keeping drugs in the diseased site and out of healthy tissue (system). By keeping drug confined, side effects are minimized and the risk to the patient is reduced. The decrease in systemic toxicity is particularly useful with very high-powered drugs like anticancer therapies, which cause life-threatening side effects when given in the conventional ways.

Ability to Cross Biological Barriers: Nanoparticles can cross the biological barriers that exclude conventional drug delivery, crossing through the blood-brain barrier, GI epithelium, pulmonary epithelium and skin. Through this trait, therapies can be directed to target neurological, pulmonary and many other diseases in which traditional therapy is unavailable or hindered. Access across biological barriers in general improves the delivery and effectiveness of therapies and expands what may be treated.

Improved Patient Compliance: The simplified dosage and targeting achieved with controlled-release and site-directed systems reduce the number of drug administrations and treatment complexity for the patient. Benefits to the patient include decreased dose number, reduced side effects, and increased treatment success. This simplification will make it easier for patients to comply with treatments.

Versatility in Drug Delivery: Nanoparticulate Drug Delivery System can load a diversity of therapeutic agents like small molecules, proteins, peptides, vaccines, and nucleic acid. The types of nanocarriers can be modified with relation to drug characters and therapeutic application. Thus it allows versatile application and innovation of novel therapies and strategies for diverse health problem.

Support for Personalized Medicine: The nanomedicine is also used to develop personalized medicine in the terms of customized drug delivery and response tracking of treatment. In accordance with individual biological marker and diseases characteristic the nanocarrier can be engineered and customized in relation to disease or patient which increase the treatment effectiveness, decrease useless exposure of drug and developed the concept of precision medicine.[34]

LIMITATIONS AND CHALLENGES OF NANOTECHNOLOGY-BASED DRUG DELIVERY SYSTEMS

High Production Cost : Nanoparticle-based delivery systems are usually developed using sophisticated equipment, expensive materials and advanced technology. This consequently results in high production costs for nanoparticle based drugs compared to conventional formulation. The high cost of R&D and bulk production may hinder the implementation of nanomedicines, especially in resource-limited regions.

Scale-Up and Manufacturing Difficulties: Although many nanoparticle formulations have proven effective in laboratory tests, scale-up into industrial level has proven problematic. Many challenges include the difficulty in controlling particle size, loading capacity, stability and quality during scale-up. The performance of nano-formulated drugs can be affected during industrial scale production due to deviation from established process parameters making industrial-scale manufacturing challenging.

Toxicity and Safety Concerns: Despite the benefits in therapeutic delivery, some nanoparticles exhibit unexpected biological interactions due to their small size

and physiochemical properties. It has been documented that some nanoparticles are able to accumulate within the liver, spleen, lung and kidney, causing toxicity. Limited long-term data has been established on many nanomaterials, and further extensive research into toxicity profile is mandatory for the future use of these materials in patients.[35]

Stability Issues: Nanoparticle formulation could be compromised due to physical and chemical instability in storage and transport. Physical instability could arise due to aggregation, drug release, growth of the particles or degradation of carriers which consequently impact the quality and therapeutic efficiency of formulation. It is important to guarantee long-term stability with acceptable nanoparticles character for marketing and clinical use.

Regulatory and Approval Challenges : Nanomedicines need to be evaluated by regulatory authorities more strictly than traditional drugs. Due to unique features of nanoparticles, currently established regulatory standards can be found lacking, leading to complicated assessment of safety and efficacy. Manufacturers are required to present extensive characterization, toxicology and clinical data, which lead to longer development times and higher costs.

Limited Clinical Translation and Reproducibility: Many nanoparticle-based systems have showed positive preclinical results but few reached clinical stage. Variations between laboratory condition and in vivo system are frequently observed, which may compromise performance. Irreproducible biological responses, unpredictable in vivo behaviors etc are always significant obstacles to achieve clinical translation of nanomedicine.[36]

FUTURE PERSPECTIVES

The future prospects for drug delivery systems using nanotechnology appear to be vast as researchers are actively working towards better targeting, accuracy, safety and clinical application of these systems. Newer techniques and tools focus on developing smart nanoparticles that can be activated upon specific physiological stimuli including pH, temperature, enzymes, magnetic fields etc. Such smart systems deliver drugs only at target disease site, reduce tissue toxicity and increase therapeutic outcome. Apart from this, development of better targeting methods, gene therapy, mRNA therapeutics and biomimetic nanocarriers are all expected to enhance treatment options for cancer, neurodegenerative diseases, infectious and genetic disorders. The application of AI and machine learning tools may also speed up the design of more efficient and personalized nanomedicine systems.

Despite great advancements, in the future challenges of scale production, safety over long term, regulatory approval and cost efficiency will need to be conquered. More attention will be paid to biodegradable and green nanomaterials that will also show minimal toxicity and biocompatibility. Moreover, breakthroughs in nanotheranostics (dual function of imaging and therapy) will further advance the real-time disease monitoring and tailor-made treatment options. Partnership of the pharmaceutical scientists, clinicians, regulatory authorities and industry would also be vital to translate promising nanotechnology from benchtop to bed. With these challenges being successfully addressed, nanodrug delivery systems will find their prominent place in the future of personalized and sophisticated healthcare.[37]

CONCLUSION

The application of nanotechnology based drug delivery systems have revolutionized in pharmaceutical sciences as it provides new strategies to solve various drawbacks faced by traditional drug delivery systems. With the use of nanocarriers, these systems exhibit better solubility, stability, bioavailability and therapeutic activity as well as control the delivery and targeted administration of drugs. A range of nanocarriers, like liposomes, polymeric nanoparticles, solid lipid nanoparticles, dendrimers and biological nanocarriers have showed promising results in improving treatment of numerous diseases. It has been proved that nanoparticles can facilitate delivery across biological barriers, shield the therapeutic molecule from degradation, and also ensure site specific delivery leading to significant advancement in the field of modern therapeutics and patient focused medicine.

Despite this progress, the difficulties in large scale manufacturing, long term safety, stability, reproducibility and regulatory approval, still affect their clinical translation. Research are actively ongoing to engineer nanocarriers that are safer, degradable, more efficient and target specific. Various cutting-edge nanomedicine technologies are being developed such as stimuli responsive nanoparticles, theranostic platforms, gene therapy, artificial intelligence in nanomedicine design. All these technological advancement are likely to broaden the application of nanotechnology in medicine. As our scientific knowledge and technology are ever advancing, nanomedicine is considered as a promising strategy that will serve as a core pillar in precise medicine, personalized therapy and future pharmaceuticals development.

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