

Nanomedicine-Overview

Dr. S. Sreeremya

Faculty of Pharmacology

Department of Pharmacology

Crescent College of Nursing, Palakkad, Kerala, India

Corresponding Author Email: *sreeremyasasi@gmail.com*

Abstract

There is an arena of application for nanotechnology in the field of medicine and in clinical trials. The aim of the 'Nanomedicine' may be broadly defined as the comprehensive monitoring, control, construction, repair, defence and the improvement of all human biological systems, working from the molecular level availing engineered devices and nanostructures, ultimately to achieve medical benefit. In this context, the nanoscale should be taken to include active components or objects in the size ranges from one nanometre to hundreds of nanometres. They may be included in a micro-device (that might have a macro-interface) or in the biological environment.

Keywords: *Nanomedicine, nanoscale, nanotechnology, biological environment, clinical trials.*

INTRODUCTION

The nanointeractions within a framework of the larger device or biologically, within a sub-cellular (or cellular) system. Forward Look on Nanomedicine Miniaturisation of the devices, chip-based technologies and, on the other hand, ever more sophisticated the novel nanosized materials and chemical assemblies are already providing novel tools that are mainly contributing to improved healthcare in the 21st century(Feynman,1961). Opportunities include superior diagnostics and the biosensors, improved imaging techniques – from molecules to man – and not least, the innovative therapeutics and technologies to enable tissue regeneration and repair. However, to realise the Nanomedicine's full potential, important challenges must be addressed. The New regulatory authority guidelines must be developed quickly to ensure

the safe and reliable transfer of new advances in Nanomedicine from lab to bedside (Masciangioli et al., 2003).

The Nanomaterials and Nanodevices Advances should begin with the optimisation of existing technologies towards the specific Nanomedicine challenges. The development of new multifunctional, spatially ordered, architecturally differing systems for targeted drug delivery was seen as a priority. There is a pressing need to enhance and copious the expertise in scale-up manufacture and the material characterisation, and to ensure material reproducibility, effective quality control and the cost-effectiveness. These issues should be addressed urgently to enable rapid realisation of the clinical benefit (within five years). For realisation to application within the next decade new materials are needed for sensing multiple, the complicated analytes in vitro, for applications in tissue engineering, regenerative medicine and the 3D display of multiple biomolecular signals. Telemetrically controlled, functional, mobile in vivo sensors and the devices are required, encompassing construction of multifunctional, spatially ordered, architecturally varied systems for diagnosis and combined the drug delivery (theranostics). The advancement of bioanalytical methods for the single-molecule analysis was seen as a priority (Moghimi et al., 2005).

Novel Therapeutics and Drug Delivery Systems

The Nanosized drug delivery systems have already entered routine bioclinical use and Europe has been pioneering in this field. The most pressing challenge is application of the nanotechnology to design of multifunctional, structured materials able to target specific diseases or containing the specific functionalities to allow transport across biological barriers. In addition, the nanostructured scaffolds are urgently needed for tissue engineering, stimuli-sensitive devices for the drug delivery and tissue engineering, and physically targeted treatments for the local administration of therapeutics (e.g. via the lung, eye or skin). To realise the desired clinical benefits rapidly, the significance of focusing the design of technologies on specific target diseases was stressed: cancer, the neurodegenerative and cardiovascular diseases were identified as the first priority areas (Boeskey, 2001). Longer term priorities encompass the design of synthetic, bioresponsive systems for intracellular delivery of the macromolecular therapeutics (synthetic vectors for gene therapy), and bio responsive or the self regulated delivery systems including smart nanostructures such as the biosensors that are coupled to the therapeutic delivery systems. Toxicology There is an urgent

need to specifically improve the understanding of toxicological implications of Nanomedicines in relation to the specific nanoscale properties currently being studied, in particular in relation to their proposed clinical use by the susceptible patients. In addition, due consideration should be given to the biopotential environmental impact and there should be a safety assessment of all the manufacturing processes and procedures. Risk-benefit assessment is needed in respect of both acute and chronic effects of nanomedicines in biopotentially pre-disposed patients – especially in relation to target disease. A shift from the risk-assessment to proactive risk-management is considered essential at the earliest stages of the discovery, and then the development of new nanomedicines. The Clinical Applications and Regulatory Issues As the technologies are designed based on a clear understanding of a particular disease, the disease specific oriented focus is mainly required for the development of novel pharmaceuticals. In addition, it will be important to establish a case-by-case approach to the clinical and regulatory evaluation of each nanopharmaceuticals (Harisinghani et al., 2003).

Nanomedicines Applications- Advanced Drug Delivery and Carrier Systems

Advanced drug delivery systems aim to mainly improve bioavailability and pharmacokinetics⁶ of pharmaceuticals and to replace invasive by non-invasive routes of the administration. Examples for advanced drug delivery systems or carrier systems are controlled release formulations or pulmonary dosage forms of proteins, such as insulin. Nano drug delivery systems (NDDS) are a sub-class or a sub category of advanced drug delivery systems that consists of drug carriers with a size of less than one micrometer and mostly less than around 200 nm (Freitas RA Jr, 2005). Examples for NDDS are liposomes, nanosuspensions, polymeric nanoparticles, dendrimers, the fullerenes, carbon nanotubes, and inorganic nanoparticles. Furthermore, so-called the "polymer therapeutics" such as polymer-protein conjugates, polymer-drug conjugates, polymeric micelles and the polymeric drugs are frequently classified as NDDS. Research and development on some of these systems, e.g. The liposomes, has started as early as the 1960s. The Dendrimers, fullerenes or carbon nanotubes have entered the drug delivery arena more recently.

The systems with currently the highest biopharmaceutical and commercial biopotential are described in the following:

Liposomes: Liposome drug delivery systems or carrier systems are nanoscale spheres composed of a lipid layer surrounding the drugs (Bharali et al., 2009). First liposomal formulations of the anti-cancer drug doxorubicin were launched beginning of the 1990s, such as Doxil®/Caelyx® or Myocet®. By availing a liposomal formulation the cardiac safety of the drug doxorubicin could be much improved. There are currently 11 liposome-enhanced drugs on the market and about 30 in bioclinical trials.

Nanosuspensions: Nanosuspensions are dispersions of the pure nanosized drug particles, which are stabilized by surfactants. By reducing the sizes of drug particles to about 10 to 100 nm (nanonisation) the solubility of the drug can be significantly elevated. This technology is of interest for about 40% of drugs in the development pipe lines which are much poorly water soluble and therefore cannot be specifically administered. There are five drugs on the market and more than ten drugs in clinical trials that are formulated with nanosuspension technology (Park, 2002).

Polymeric Nanoparticles: The Polymeric nanoparticles are either nanosized solid particles or capsules which consist of natural or biosynthetic polymers and to which the drug is attached. They are investigated as drug delivery systems for the site-specific targeting of tumours and for the transport of drugs across biological barriers, particularly the blood-brain barriers. At present the number of companies that work on the polymeric nanoparticle drug delivery systems is quite small; only six companies were mainly identified in this study. The anticancer drug Abraxane™, the substance paclitaxel stabilised by the albumine is the only drug on the market that uses a (bio) polymeric nanoparticle drug delivery system. The One additional product was identified being currently in clinical trials (Thorek et al., 2006).

THE USES OF NANOMEDICINE

The possible uses of the nano technology in medicine are based on three basics as: 1. The Nanomaterials and the nano instruments which can be used as biosensors, as aids in treatment and as transporters of active substances. 2. The knowledge of the molecular medicine in the fields of genetics, proteomics and synthetically produced or the modified microorganisms. 3. The nanotechnologies which can be used for the rapid biodiagnosis and for therapy, for repair of genetic materials and for the cell surgery, as well as for the improving of the natural physiological functions.

The Applications of Nano Medicine: Contrast agents for cancer cell imaging-The Nanoparticles of the cadmium selenide (quantumdots) glow when exposed to ultraviolet lights (280-300nm). These When injected, as they seep into cancer tumors. The surgeon can see the glowing tumors, and use it as a guide for more accurate tumor removal procedures according to the protocol (Partha et al., 2009).

Therapeutics for Treating the Cancer Diseases: The Gold nano shells can be mainly targeted to bond to the cancerous cells. By causing irradiating the area of the tumors with infrared lasers, as which passes through the flesh without heating it and the gold is heated sufficiently to mainly cause death or lysis to the cancer cells.

The Medical Applications of the Nanomaterials: This could solve the difficulties and blood leaks caused when the surgeon tries to re stitch the arteries that have been nicked during a kidney or heart transplantation (Stya Kumar et al., 2006).

The Nano Electronic Biosensors Diagnostic Devices: The Nanotechnology is bio advancement in the use of arthroscopes that are availed in surgeries with lights and cameras, so surgeons can do the surgeries with smaller incisions.

The Physical Therapy Applications: It is availed in photodynamic therapy; a small particle is placed within the body and is identified with the light from the outside. The light gets absorbed by the particle and if the particle is metal, the energy from the light will heat the particle and surrounding tissues.

The Application of Neuro-Electronic Interfaces: The applications of the Neuro-electronic interfacing is a visionary goal dealing with the construction of the nanodevices that will permit computers to be joined and linked to the nervous system (Hirsch et al., 2006).

The Applications in Tissue Repair: The Nanotechnology may be able to help reproduce or repair damaged tissue. The "Tissue engineering" makes use of the artificially stimulated cell proliferation by using suitable nano material-based on the scaffolds and growth factors. For example, bones could be regrown on carbon nano tube scaffolds. The Tissue engineering

might mainly replace today's conventional treatments like organ transplants or artificial implants (Chris et al., 2003)

Nanoparticles in Cancer therapy- Nanoparticles are being designed to mainly treat various kinds of diseases, an important breakthrough in their application remains to be the main focus on detection and treatment of cancer. The drug delivery process in the cancer treatment consists of five steps, known as 'CAPIR' wherein circulation of the nanoparticle in the blood takes place followed by accumulation and penetration into the cancer tumor. This is followed by the internalization into the cell and drug release through the use of nanoparticles (Phoenix, 2003). The nanometals mainly enhance drug dissolution and adhesion to targeted tumor surfaces, resulting in the rapid onset of effective therapeutic action.¹⁰ Drug-loaded delivery vehicles or nanoparticles are the attractive because they can be passively or actively targeted to cancer tissues to mainly improve anticancer drug delivery and thereby reduce severe side effects. Another approach being mainly explored is the application of nanoparticles by combining various drugs into one carrier in order to mainly address the concern of poor drug delivery achieved by the use of the present-day medicine and the need for enhancement. This would also enable the multiple tumors targeting for better diagnosis and treatment of cancer (Freitas RA Jr, 2002a).

Nanodevices for Diagnosis -The nanomaterial offers enormous scope to be mainly developed as an advanced diagnostic tool. A nanoscale device or the nanomaterials could affect direct interaction with the biological system at the sub cellular and the bio molecular level and thus can be developed as a more sensitive and accurate molecular probe and the biosensor which enables diagnosis. For example, some companies are attempting to develop the microchips that use electrodes to identify the dielectric properties of cancerous cells, viruses, and the bacteria in body fluids.

Pulmonary Drug Delivery: The treatment of respiratory infections is mainly challenging because the infections may possess multidrug-resistance, and the microbes may mainly reside deep inside the airways. Delivery of drugs to such deeper parts of the airway systems remains to be a major milestone to be accomplished in the future for nanomedicine by the use of such characteristic bionanoparticles and their ability to cross biological barriers in the human body with ease (Freitas RA Jr, 2000).

Controlled Response systems Nanoparticles: may be bioengineered to enables sustained release systems within the body which may be able to address the concerns pertaining to the lethal toxicity and drug release raised by the numerous researchers in the use of nanoparticles in drug delivery in human body.

The nanoparticles are developed in a way to allow the release of the drug upon receiving certain stimuli and as a response this approach is currently being researched and assessed further for application in medicine.

For Blood: Related Diseases Many diseases, from heart attacks and strokes to bacterial sepsis and metastasizing cancer, involve the blood in some way. The researcher has proposed an aggressive nanomedical device, a “Vasculoid” that would specifically replace the blood volume and take over its functions by lining the entire vascular system with a multi-segmented robot (Freitas RA Jr, 1998). In addition to mainly preventing many diseases, and limiting the scope of others (such as poisoning), such a system would provide detailed control of the body’s chemical environments around each individual capillary, allowing heterostasis to be availed extensively. The vasculoid is a single, complex, multi-segmented nano technological medical robotic system capable of mainly duplicating all essential thermal and biochemical transport functions of the blood, encompassing circulation of respiratory gases, glucose, hormones, cytokines, waste products, and the cellular components. This nanorobotic system, a very aggressive and physiologically intrusive macroscales and nanomedical device comprised of around 500 trillion stored or active individual nanorobots, weighs around 2 kg and consumes from 30-200 watts of power in the basic human model, depending on activity level. The vasculoid system conforms to the shape of existing blood vessels and serves as a complete replacement for natural blood (Malsch et al., 2004). The Vasculoid is extremely complicated and would require much research to build and use successfully. This particular device may never be used, but it can provide a hint of the possibilities inherent in advanced nanomedicine. A second application would be to provide metabolic support in the event of impaired circulation. Poor blood flow, caused by a variety of conditions, can result in serious tissue damage. A major cause of tissue damage is inadequate oxygen. A simple method of improving the levels of available oxygen despite reduced blood flow would be to provide an “artificial red blood cell.” We will consider a simple design here: a sphere with an internal diameter of 0.1 microns (100 nanometers) filled with high pressure oxygen at ~1,000

atmospheres (about 108 pascals). The oxygen would be allowed to trickle out from the sphere at a constant rate (without feedback). Diamond has a Young's modulus of about 10^{12} pascals. An atomically precise diamondoid structure should be able to tolerate a stress of greater than 5×10^{10} pascals (5% of the modulus). Thus, a 0.1 micron sphere of oxygen at a pressure of 108 pascals could be contained by a hollow diamondoid sphere with an internal diameter of 0.1 microns and a thickness of less than one nanometer. While providing oxygen to healthy tissue should maintain metabolism, tissues already suffering from ischemic injury (tissue injury caused by loss of blood flow) may no longer be able to properly metabolize oxygen. In particular, the mitochondria will, at some point, fail. Increased oxygen levels in the presence of nonfunctional or partially functional mitochondria will be ineffective in restoring the tissue. However, more direct metabolic support could be provided. The direct release of ATP, coupled with selective release or absorption of critical metabolites (using the kind of selective transport system mentioned earlier), should be effective in restoring cellular function even when mitochondrial function had been compromised (Freitas RA Jr, 2002b).

CLASSIFYING NANOMEDICINES IN INDIA

Currently, majority of commercial applications of nanomedicine is geared towards drug delivery and targeting of diseases in the human body.¹⁴ Given the nature of application of nanomedicine these would traditionally fall within the ambit of the definition of a drug under DCA. Further, the Guidelines for Evaluation of Nanopharmaceuticals in India, 2019 ("Nanopharmaceuticals Guidelines") defines nanopharmaceuticals to mean a pharmaceutical preparation containing nanomaterials intended for internal use or external application on human body for the purpose of therapeutics, diagnostics and health benefits.¹⁵ Similarly, a direct approach is adopted in categorizing nanodevices. All nanotechnology applications which are akin to devices or implants and assist with functions such as diagnosis, mitigation and treatment will be a medical device for the purposes of application of MDR. However, due consideration must be given in assigning a legal character to combination nanomedicine products (Mastrobattista et al., 2006). As per the definition prescribed under MDR, a device, instrument or apparatus which "assists" in functions as opposed to having a direct pharmacological, immunological or metabolic effect will be a medical device. This creates an uncertainty as to whether a combination product such as a smart pill, which performs functions similar to a medical device in assisting with diagnosis and recognition of a target area and may subsequently also act as a drug with pharmacological efficacy will fall under

this definition of a medical device in MDR. In such instances, the classification will be based upon an assessment of the likeness of the product in terms of its functions to a drug or a device(Freitas RA Jr,2002c).Ayurveda is one among the medicine practices(S.Sreeremya,2022) which can be integrated with other modern medicines and also can integrate chiropractic technique(Dr. S. Sreeremya,2024a).Modern day pharmacology(Dr. S. Sreeremya,2024) and categories like paediatric pharmacology and geriatric pharmacology has to be deeply assessed(Dr. S. Sreeremya,2019b).Even the molecular level assessment using RNA nanodesign is a forward step in nanomedicine (Dr. S. Sreeremya,2019a).The gene level assessment of the human body paves new possibilities in the field of diagnosis(Dr. S. Sreeremya,2025). Usage of new nanomaterials and its updation makes this field ignited scientifically (S.Sreeremya, 2018c).The history of biotechnology (Dr. S. Sreeremya, 2024b) and history of pharmacology paves the way for the new innovations (Dr. S. Sreeremya, 2024c). Nanotechnology can be used in various aspects (S.Sreeremya2017), apart from medicinal filed like waste water treatment (S. Sreeremya, 2018a) and it can be used for sustainable approaches (S. Sreeremya, 2018b).

CONCLUSION

There are several aspects of nanotechnology in medical field. The usage of nanomedicine to cure diseases is one major aspect. For drug delivery nanomaterials such as dendrimers, liposomes are used. To cure cancer doxorubicin is used, the drug is delivered to the target site using nanotechnology.

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