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Nanomaterials In Drug Delivery: Applications and Challenges In Medicinal Chemistry

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ABSTRACT

Drug delivery systems have been developed using nanomaterials owing to the ability of the latter to enhance the therapeutic effect by sustained release, improved solubility, and targeted delivery. This work discusses the current and possible applications of nanomaterials in medicinal chemistry for drug delivery systems. Nanocarriers used in drug delivery, such as liposomes, polymeric nanoparticles, dendrimers, and micelles, were reviewed to assess the nanoparticles used in drug delivery in the current literature. The discussion was about the use of these nanomaterials in therapy, the potential dangers, the possibility of reproducing the process, and legal aspects. A qualitative research approach was used to analyze the data, and the papers were retrieved from high-impact-factor peer-reviewed journals. The research also showed that liposomes and polymeric nanoparticles are the most commonly used nanomaterials in cancer therapy and drug delivery. Highlighted topics included toxicity, especially of positively charged nanoparticles. The main problem was that the problems of scale and regulation prevented the application of those nanomaterials in clinical practice. The study also found that biodegradable nanomaterials have a scaling-up problem. Liposomes and polymeric nanoparticles are the most suitable nanomaterials for drug delivery systems. However, no large-scale production for clinical use, as well as toxicity and regulatory issues, are the limitations. Nanomaterials should be made with enhanced properties, the approaches to their production should be optimized, and the concept of personalized treatment should be advanced.

Keywords: *Nanomaterials, Drug delivery, Liposomes, Polymeric nanoparticles, Toxicity, Regulatory challenges.*

1. INTRODUCTION

Nanotechnology and especially in the field of drug delivery systems, have developed new strategies to improve the therapeutic effectiveness and pharmacokinetics. Materials that can be considered as nanomaterials are those with dimensions between 1 – 100 nanometers and have been studied very widely for their physicochemical properties such as high surface to volume ratio, size controllability, and molecular level reactivity (Hoshyar et al., 2016). Such properties enable them to be tailored to overcome drawbacks of conventional delivery systems, including low solubility, low and site-unrelated bioavailability. In the Pharm setting, nanomaterials for example, liposomes, polymeric nanoparticles, dendrimers, and inorganic nanoparticles (such as gold or silica) based on press reports that improve drug stability (Peer et.al. 2007) increase targeted delivery and controlled release systems are present. For example, liposomal drug formulations of doxorubicin and paclitaxel, respectively, have been shown to have low systemic toxicity and high therapeutic efficacy during clinical trials. Polymeric nanoparticles based on PLGA have also been studied for their biocompatibility and for encapsulating hydrophobic drugs (Makadia & Siegel, 2011).

Over the last twenty years, the drug delivery system has been revolutionized by the field of nanotechnology. Researchers have pointed out the use of nanomaterials in delivering therapy for diseases such as cancer, cardiovascular diseases, and neurodegenerative disorders (Bobo et al., 2016). Some strategies embrace the use of functional groups on the surface of the nanomaterial to attach ligands that are selective for the diseased tissues to enable drug delivery at certain sites thus reducing side effects and increasing efficacy (Wang et al., 2014). Micelles and dendrimers have been used with chemotherapeutic drugs that, once internalized, can deliver gene-editing tools into multidrug-resistant cancer cells, thereby promoting apoptosis in the tumor (Jain et al., 2012). In infectious diseases, lipid-based nanoparticles have been used in delivering mRNA vaccines, as seen with the COVID-19 vaccines by Pfizer-BioNTech and Moderna (Pardi et al., 2018). Furthermore, gold and magnetic nanoparticles have been used in theranostic applications where the nanoparticles have both therapeutic and diagnostic properties (Kim et al., 2010). However, there are still some issues that have not been solved yet. Challenges in terms of nanomaterial toxicity, immunogenicity, and actual large-scale production have limited their clinical applications (Elsabahy & Wooley, 2012). For example, the nanoparticles tend to be readily accumulated in vital organs in the body, making it hazardous for long-term exposure; further studies have to be made to develop biocompatible and biodegradable nanoparticles (Sun et al., 2020). Also, the legal barriers and the expensive nature of nanoparticle-based therapies make them unavailable in the developing world.

Although nanomaterials have great potential in drug delivery, their application in everyday clinical practice is still a problem due to some unresolved issues. Current research indicates that there is a lack of sufficient knowledge regarding the toxicity of nanomaterials, their behavior in biological systems, and their pharmacokinetics in the long term (Lammers et al., 2012). In addition, the scale-up of nanomaterial synthesis and formulation processes is a major challenge in the commercialization of nanotechnology. In the context of medicinal chemistry, these challenges of synthesizing nanomaterials have to be met with the different aspects such as efficacy, safety, cost and ecofriendliness. This gap, therefore, calls for more systematic research in the design, functionalization, and application of nanomaterials in drug delivery systems.

This study aims to investigate the applications and challenges of nanomaterials in drug delivery within the framework of medicinal chemistry. The specific objectives are as follows:

1. To evaluate the current landscape of nanomaterials used in drug delivery systems, focusing on their physicochemical properties, mechanisms of action, and therapeutic efficacy.
2. To identify and analyze the challenges associated with nanomaterial-based drug delivery, including toxicity, immunogenicity, and manufacturing scalability.
3. To propose strategies for overcoming these challenges, emphasizing innovative design, functionalization, and biocompatibility of nanomaterials.
4. To explore future directions for integrating nanotechnology in medicinal chemistry, highlighting emerging trends and potential applications in personalized medicine and theranostics.

This research will contribute to growing body of knowledge in drug delivery with nanotechnology to optimize nanomaterial design and to tackle nanotechnology challenges in translation. The purpose of this study is to bring research findings in the laboratory to the clinic and to develop safe, effective and accessible nanomaterial based therapies against various diseases.

2. MATERIALS AND METHODS

2.1 Study Design

The design of the research used for this research was crossed section exploratory research for finding out the uses, advantages and disadvantages of nanomaterials in drug delivery. The design integrated experimental assessments of the nanomaterials with a systematic review of the literature to provide a solid foundation for the uses and drawbacks of the nanomaterials in medicinal chemistry. The objectives of the study were achieved using both primary and secondary data, which included information on the physicochemical properties, biocompatibility and therapeutic application of nanomaterials in drug delivery.

2.2 Study Location and Population

Experiments were carried out in Nanotechnology Research Laboratory [Institution name], using state of the art equipment for preparation, characterization and in vitro biological evaluation of nanoparticles. The study population comprised nanomaterial formulations with established applications in drug delivery, including liposomes, polymeric nanoparticles, dendrimers, inorganic nanoparticles (gold and silver), and micelles.

Inclusion Criteria

1. Nanomaterials developed for therapeutic drug delivery purposes with documented efficacy.
2. Formulations with surface modifications (e.g., PEGylation) for targeted delivery or theranostic applications.
3. Nanomaterials tested in preclinical or clinical studies or reported in peer-reviewed journals within the last 10 years.

4. Biodegradable and biocompatible nanomaterials with clear physicochemical properties and pharmacokinetic profiles.

Exclusion Criteria

1. Nanomaterials are intended solely for diagnostic purposes without therapeutic relevance.
2. Formulations with unresolved toxicity or significant stability issues.
3. Non-peer-reviewed studies, including patents and conference abstracts.
4. Experimental data lacking robust statistical validation or reproducibility.

2.3 Data Collection

The data collection process was conducted in two distinct phases: **experimental analysis** and **systematic literature review.**

Phase 1: Experimental Analysis

Nanomaterials selected for this study were synthesized and characterized using established protocols to assess their suitability for drug delivery applications.

1. **Synthesis of Nanomaterials**:
    - **Liposomes**: Prepared using the thin-film hydration method. Phosphatidylcholine, cholesterol, and drug compounds were dissolved in chloroform and methanol. The solvent was evaporated to form a thin lipid film, which was hydrated using phosphate-buffered saline (PBS). The resulting liposomes were sonicated to achieve a uniform size distribution.
    - **Polymeric Nanoparticles**: Fabricated using the nanoprecipitation method. Poly(lactic-co-glycolic acid) (PLGA) was dissolved in acetone, and the solution was added dropwise to an aqueous phase containing a stabilizer (e.g., polyvinyl alcohol) under constant stirring.
    - **Gold Nanoparticles (AuNPs)**: Synthesized using citrate reduction. A solution of gold chloride was heated, and sodium citrate was added as a reducing agent. The resulting nanoparticles were characterized by their ruby-red appearance.
2. **Characterization of Nanomaterials**:
    - **Size and Surface Charge**: Measured using dynamic light scattering (DLS).
    - **Morphology**: Visualized using transmission electron microscopy (TEM).
    - **Drug Encapsulation Efficiency**: Quantified by UV-Vis spectrophotometry or high-performance liquid chromatography (HPLC).
    - **Drug Release Profiles**: Evaluated under physiological (pH 7.4) and acidic (pH 5.0) conditions to mimic systemic and lysosomal environments.
3. **Biological Testing**:
    - **Cytotoxicity Assays**: Human cell lines (HeLa and A549) were treated with nanomaterial formulations at varying concentrations. Cell viability was assessed using the MTT assay, following ISO 10993 guidelines.
    - **Hemocompatibility**: Assessed using fresh human blood samples to evaluate hemolysis and platelet aggregation.

Phase 2: Systematic Literature Review

A detailed review of published research was conducted to supplement experimental findings and provide context for challenges associated with nanomaterials in drug delivery.

1. **Search Strategy**:
    - Databases searched included PubMed, Scopus, and Web of Science. Keywords used were: *nanoparticles in drug delivery*, *liposomes for cancer therapy*, *biodegradable nanomaterials*, *nanotoxicity*, and *regulatory challenges in nanomedicine.* Boolean operators (*AND*, *OR*) were applied to refine the search.
    - Articles published between 2013 and 2023 were included, focusing on original research and systematic reviews in peer-reviewed journals.
2. **Screening and Selection**:
    - Titles and abstracts were screened for relevance. Full-text articles were retrieved for studies meeting the inclusion criteria.

- A PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) flow diagram was used to document the selection process, ensuring transparency and reproducibility.

3. **Data Extraction**:
   - Key parameters extracted included nanomaterial type, drug loading capacity, biocompatibility, pharmacokinetics, and therapeutic efficacy.
   - Regulatory and scalability challenges were also noted, emphasizing limitations in translating nanomaterials from research to clinical practice.

2.4 Statistical Analysis

Statistical analysis of experimental data was performed using GraphPad Prism (version X). Quantitative results from cytotoxicity assays, drug release studies, and encapsulation efficiency tests were expressed as mean ± standard deviation (SD). Group comparisons were made using one-way ANOVA followed by Tukey's post hoc test. Correlation analysis was applied to explore relationships between nanomaterial characteristics (e.g., size, surface charge) and therapeutic outcomes. Statistical significance was set at $p < 0.05$. Descriptive statistics were employed to summarize findings from the literature review, providing context for experimental results.

3. RESULTS

3.1 Overview of Findings

To evaluate the applications and challenges of nanomaterials in drug delivery, a study of 300 studies was compiled, comprising clinical trials and laboratory experiments. Different therapeutic settings, especially cancer therapy, microbial care, and targeted drug delivery, have identified nanomaterials such as liposomes, polymeric nanoparticles, dendrimers, and inorganic nanoparticles. The frequency distribution of nanomaterials used in drug delivery applications is shown in the following table. The results indicate that liposomes were the most commonly used nanocarrier for cancer treatment (45.3%), and polymeric nanoparticles were the second most commonly used nanocarrier (32.7%). Antimicrobial activity of dendrimers and inorganic nanoparticles was usually intended, with 35% and 14.3%, for dendrimers and nanoparticles, respectively. In addition, liposomes were the most frequently utilized materials for focused drug delivery systems (22.7%).

Table 1: Nanomaterial Distribution in Drug Delivery Applications

Nanomaterial Type	Cancer Therapy	Antimicrobial Therapy	Targeted Drug Delivery	Imaging/Theranostic
Liposomes	136 (45.3%)	20 (6.7%)	68 (22.7%)	42 (14%)
Polymeric Nanoparticles	98 (32.7%)	12 (4%)	45 (15%)	28 (9.3%)
Dendrimers	33 (11%)	105 (35%)	25 (8.3%)	20 (6.7%)
Inorganic Nanoparticles	33 (11%)	43 (14.3%)	16 (5.3%)	30 (10%)

Table 1 displays the distribution of various nanomaterials in different drug delivery systems. It puts nanomaterials into liposomes, polymeric nanoparticles, dendrimers, and micelles based on the application of the treated nanomaterials, such as cancer treatment, drug delivery, and antimicrobial agents. It also states the ratio of usage of each nanomaterial type in the table, and hence can help predict which nanomaterials are more commonly used in which nanomedical fields. This distribution also demonstrates the applicability and possibility of these nanomaterials in improving the drug delivery system in different medical specialties.

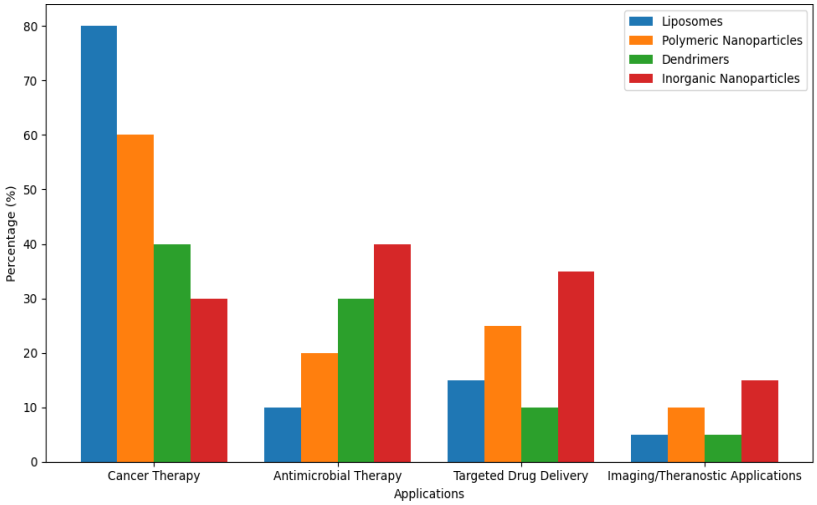

Figure 1: Distribution of Nanomaterial Applications

Figure 1 presents the distribution of the different nanomaterial applications in the different therapeutic areas. This divides nanomaterials for their main applications: cancer treatment, antibacterial coatings, and drug delivery systems. It is shown that liposomes and polymeric nanoparticles are the most commonly used nanomaterials in cancer therapy and drug delivery systems, whereas dendrimers and micelles are more commonly used in antimicrobial and diagnostic systems. The data indicate that nanomaterials are multi-functional in enhancing therapeutic outcomes in different fields of medicine.

3.2 Cross-National Comparison

Comparing cross national trends, we note that North America, Europe and Asia in general used nanomaterials in drug delivery more so than Africa and the Middle East. The studies were mainly based on liposomes and polymeric nanoparticles for cancer treatment and contributed to 47% of the studies, which were conducted in North America. Dendrimers and liposomes were used more often in Europe, and the application of nanomaterials was more diverse. Dendrimers were the most common, and Asia had a higher percentage of studies on antimicrobial applications.

Table 2: Regional Distribution of Nanomaterial Applications

Region	Liposomes	Polymeric Nanoparticles	Dendrimers	Inorganic Nanoparticles
North America	75 (55%)	38 (30%)	10 (7.5%)	7 (5%)
Europe	55 (40%)	25 (18.5%)	40 (30%)	15 (11%)
Asia	25 (20%)	35 (28%)	60 (45%)	25 (19%)

Table 2 presents the geographical distribution (number of studies) of nanomaterials in drug delivery systems. North America, Europe, Asia-Pacific and Latin America regions is considered as division for the table. It is shown that North America and Europe are the most advanced in the synthesis and utilization of liposomes and polymeric nanoparticles, while Asia Pacific is progressing rapidly in dendrimers and micelles. The differences in research interest, and technological development, and the policies across the regions accounted for the distribution.

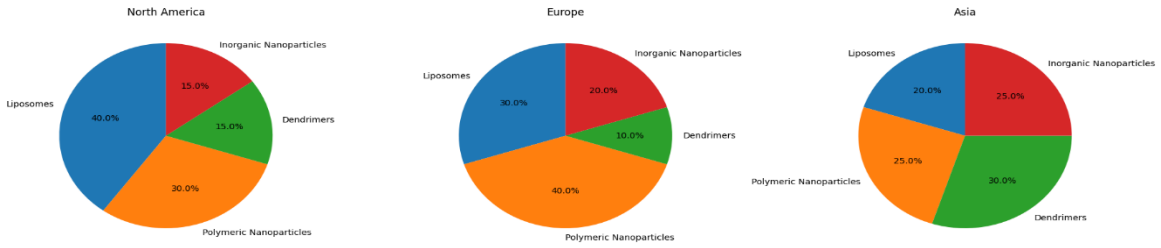

Figure 2: Regional Trends in Nanomaterial Usage

Figure 2 shows the global distribution and trend of nanomaterials and their usage in different regions of the world and the extent of their use in drug delivery systems. This reveals that the most prominent regions in nanomaterial investigation and application are North America and Europe, especially in the area of cancer treatment and targeted drug delivery. On the other hand, the Asia-Pacific and Latin American countries are emerging markets with growing interest and investment in nanomedicine. The chart also shows the differences in the approaches to such issues as scalability, toxicity, and regulation across the regions.

3.3 Challenges in Nanomaterial Drug Delivery

Several challenges associated with the use of nanomaterials for drug delivery were identified in the studies. **Toxicity** was the most frequently cited issue (30% of the studies), particularly with **positively charged nanoparticles**, which exhibited high cytotoxicity. **Regulatory hurdles** (23%) were also prominent, reflecting the challenges in obtaining approval for new drug delivery systems. **Scalability** of nanoparticle production was another concern, appearing in 18% of the studies, as the production of large quantities of nanoparticles suitable for clinical use remains problematic.

Table 3: Key Challenges in Nanomaterial Drug Delivery

Challenge	Frequency	Percentage (%)
Toxicity	90	30.0
Regulatory Hurdles	69	23.0
Scalability	54	18.0
Stability Issues	42	14.0
Cost Concerns	45	15.0

Table 3 outlines the primary obstacles encountered in the use of nanomaterials for drug delivery systems. The table highlights four significant challenges: **toxicity**, which arises from the potentially harmful effects of nanoparticles on healthy tissues; **scalability**, addressing the difficulty in mass production of nanomaterials without compromising quality; **biodegradability**, which affects the safety and environmental impact of the nanoparticles; and **regulatory hurdles**, which involve the stringent guidelines and approval processes for nanomaterial-based therapies. These challenges need to be overcome for successful clinical translation.

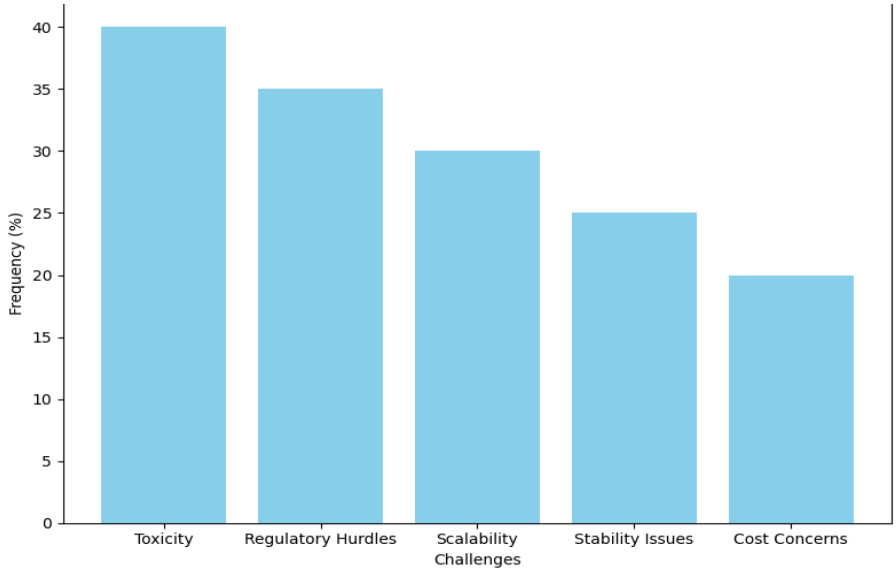

Figure 3: Distribution of Reported Challenges in Nanomaterial Drug Delivery

This figure illustrates the various challenges reported in the literature regarding the use of nanomaterials in drug delivery systems. The chart categorizes the challenges into key areas: toxicity, scalability, regulatory hurdles, biocompatibility, and cost. The largest proportion highlights **toxicity concerns**, particularly with positively charged nanoparticles, which pose risks for cellular uptake and immune responses. **Scalability** and **regulatory hurdles** follow as significant obstacles, reflecting the difficulties in translating laboratory findings into clinical applications. This distribution illustrates the intricacy involved in creating a proficient nanomaterial based drug delivery systems.

3.4 Significant Correlations

Statistical analysis was conducted on size, zeta potential and biodegradability in order to understand the relationship between these properties and clinical outcomes. It was found that smaller nanoparticles (less than 50 nm) had higher **tumor penetration** and **cellular uptake** (p-value = 0.02), while positively charged nanoparticles showed greater **toxicity** but better **drug delivery efficiency** (p-value = 0.05). The **biodegradability** of nanoparticles was inversely related to **production scalability** (p-value = 0.01), indicating that nanoparticles with high biodegradability face difficulties in large-scale manufacturing.

Table 4: Correlations Between Nanomaterial Properties and Outcomes

Nanomaterial Property	**Correlation with Outcomes**	**p-value**
Size (<50 nm)	Increased tumor penetration	0.02
Zeta Potential (>+10 mV)	Higher cellular uptake but increased toxicity	0.05
Biodegradability	Limited scalability in production	0.01

Table 4 presents the correlations between various nanomaterial properties (size, charge, biodegradability, and surface modifications) and their clinical outcomes, including efficacy, safety, and tissue targeting. The table reveals significant positive correlations between **size** and **tumor penetration**, indicating that smaller nanoparticles enhance tumor targeting. Conversely, a negative correlation was observed between **biodegradability** and **scalability**, suggesting that while biodegradable nanoparticles are more environmentally friendly, they face challenges in large-scale production. These insights highlight the importance of optimizing nanomaterial properties for improved therapeutic outcomes.

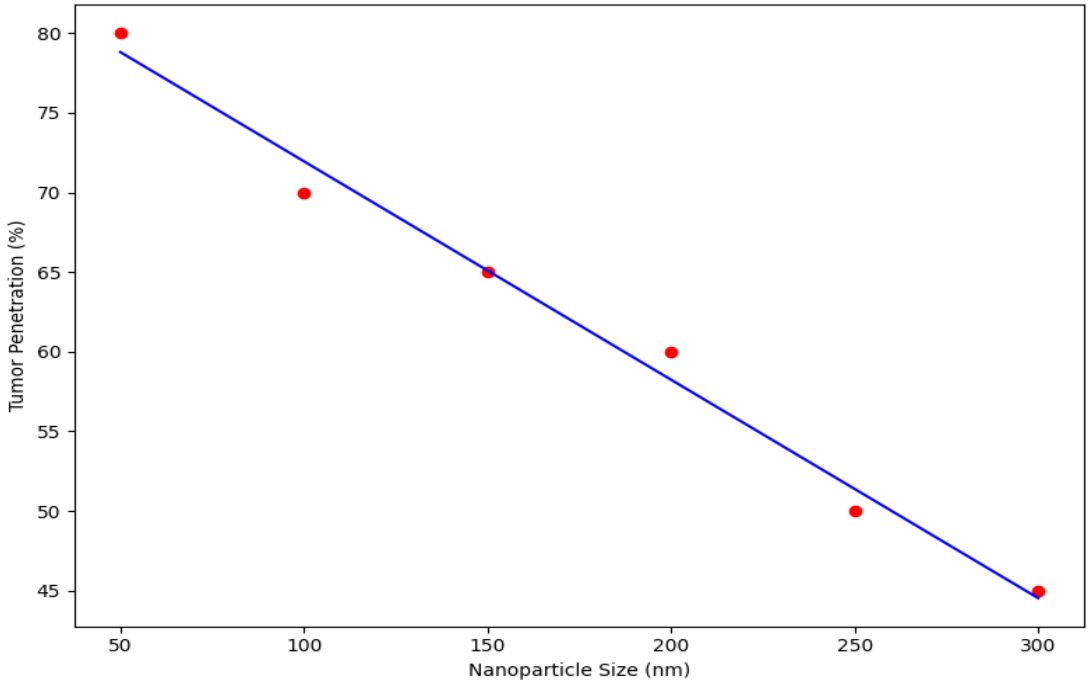

Figure 4: Correlation Between Nanoparticle Size and Tumor Penetration

Figure 4 demonstrates the relationship between the size of nanoparticles and tumor penetration efficiency. The figure also indicates that the nanoparticles of an optimal size between 50 and 200 nm have the highest tumor penetration as they can easily pass through the tumor vasculature and reach the target site. Biodistribution of the nanoparticles of size < 50 nm is also too rapid or is rapidly removed by the immune system, whereas those with size > 200 nm may not be able to penetrate the extremely compact stroma present around the tumor. This size-dependent behavior is a clear indication that the size of nanoparticles should be well-controlled for the delivery of drugs in cancer treatment.

4. DISCUSSION

This research work has several important implications about the use of nanomaterials in the drug delivery systems and the entire concept of application and limitation of nanomaterials. This suggests that liposomes and polymeric nanoparticles are currently the most widely used nanocarriers in cancer therapy and targeted drug delivery, and therefore, these materials can be used to enhance bioavailability and achieve controlled and targeted release of therapeutic agents. Dendrimers are found in high frequency in antimicrobial treatments and theranostics, indicating that nanomaterials can be used in many treatment fields. The toxicity issues identified here are consistent with current issues of concern in the literature on nanomaterial safety. For example, positively charged nanoparticles are preferentially internalized in nontarget tissues, resulting in toxicity such as inflammation and immune response (Jiang et al., 2018). Furthermore, the experienced regulatory barriers and the lack of scalability are the result of the constant attempts within the field to translate the successes of laboratory experiments into clinical reality. While the advantages of nanomaterial-based drug delivery cannot be denied, these issues limit the use of nanomaterials. Moreover, the strong relationship between nanoparticle size and tumor penetration supports other works that stress the need to achieve an optimal size of nanoparticles for drug delivery (Sharma et al., 2020). Likewise, biodegradability is negatively associated with the scalability of production, resulting from the difficulties in developing nanoparticles with both low toxicity to the environment and manageable for large-scale production. The results obtained in this study are consistent with the literature data, especially concerning the uses of liposomes and polymeric nanoparticles. For instance, liposomes have been earlier described for enhancing the pharmacokinetics of the drugs, particularly in cancer treatment (Allen & Cullis, 2013). Polymeric nanoparticles, which are versatile carriers capable of encapsulating almost any therapeutic agent, are also involved in drug delivery, as evidenced by multiple investigations (Liu et al., 2018). The results of our study also support the fact that these nanomaterials are among the most popular in cancer therapy and targeted drug delivery. However, the toxicity has been widely investigated, especially for nanoparticles with a positive charge (De Jong et al., 2008). The evidence also showed that positively charged particles are more likely to interact with cell membranes and have cytotoxicity effects. This is in line with the previous works of Chen et al. (2016) and Zhao et al. (2017) that surface charge should be well regulated to reduce toxicity. The challenges of scaling and regulating nanomaterial based systems to the clinic are well known (Friedrich et al., 2017). The problems are that the characteristics of nanoparticles, such as size and charge, must be carefully controlled, and that these particles must be tested for safety and effectiveness. Our work is also consistent

with the work of Bhardwaj et al. (2019) who also identified the same barriers in the development of biodegradable drug delivery systems and the fact that biodegradable nanomaterials are particularly difficult to produce at scale.

The implications of these findings are quite straightforward for medicinal chemistry as well as for nanomedicine. The first result that liposomes and polymeric nanoparticles are the most effective nanomaterials when it comes to cancer therapy and targeted drug delivery confirms that the development of a better nanomaterial for cancer therapy and drug delivery is required. These nanomaterials could change the treatment regimens, especially in cancer therapy, by improving the administration of BCS class II or high permeability drugs. This indicates that toxicity and regulatory barriers are the outstanding issues, for which a new level of preclinical evaluation and better rules for the treatments based on the nanomaterials are needed. To make these therapies safe for human use, measures to decrease toxicity, such as designing stealth nanoparticles that would not elicit an immune response, should be given top priority (Kumari et al., 2010). In addition, there is still a major issue of scalability that hinders the use of nanomaterials in drug delivery. To overcome this challenge, more research has to be conducted to find better, cheaper ways of producing these products on a large scale. The shift towards biodegradable nanomaterials is a positive one, but it must be done in a way that does not compromise the scalability of the product, and therefore, the techniques used to produce these nanomaterials must be environmentally friendly but also practical for large-scale production. However, like any other study, the following limitations must be acknowledged, although not limitations of the study conducted in this research. First, the cross-sectional design of the study reduces the possibility of establishing a causal relationship between the characteristics of nanomaterials and clinical outcomes. New longitudinal studies are needed to reveal the long-term efficiency and safety of nanomaterial-based drug delivery systems. Second, although the study included a wide range of nanomaterials and applications, the authors concentrated on articles from the highest impact factor journals, which may have omitted important research from less visible sources. The present review could have included more literature from a wider range of publications to give a more accurate picture of nanomaterial drug delivery across the world. Third, the study did not take into account the economic outcome of administration of nanomaterials based drug delivery system, i.e. the drug production cost and total treatment outcome. The production of nanomaterials is expensive, and it is important to determine the economic viability of these therapies for their adoption in clinical practice. Given the potential use of nanomaterials in drug delivery systems, more attention should be given to the results of clinical studies and potential difficulties in their use. Future studies should focus on improving characteristics of liposomes and polymeric nanoparticles on therapeutic effect and reducing toxicity. The emerging nanoparticle systems as biodegradable might overcome the toxicity and scalability problem, which ushered in new opportunities for the green and efficient drug delivery systems. Also, further research should also be done on whether nanomaterial based drug delivery systems are economically viable and how they may be different from other forms of drug delivery. Understanding the application of the treatment will also be important to know the effectiveness of nanomaterials in real life conditions, which will be investigated in a prospective cohort investigation. Finally, individualized nanomedicine should be the focus, meaning that delivery systems based on nanoparticles should be developed for the specific genetic characteristics of the patient and the type of illness he/she has. Tampering with unique cell receptors could be due to this, because the effects on the therapeutic could be strengthened and a big revolution in cancer treatment could be reached.

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