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Injectable Liposomal Formulations for Sustained Release of Anticancer Drugs

Deepesh Lall[1*], Amit vaishnav[2], Prakash Kumar Ratre[3]

[1*]LCIT School of Pharmacy, Bilaspur (C.G.) India, Pin: - 495001

***Corresponding Email: deepesh.officework@gmail.com**

Abstract

Liposomal formulations have been a lot of interest as an improved drug delivery system to overcome the key drawbacks of traditional chemotherapy namely low solubility, premature metabolism, nonspecific biodistribution, and overwhelming systemic toxicity. Liposomes increase the stability of anticancer drugs like doxorubicin and topotecan, extend plasma circulatory time and offer targeted and steady drug delivery by entrapping these drugs within lipid bi-layers. These formulations take advantage of passive targeting using the increased permeability and retention (EPR) effect of tumor vasculature and can be further refined using active methods that include PEGylation or ligand conjugation to allow selective tumor accumulation. Preclinical experiments show that liposomal encapsulation enhances intratumoral drug concentrations, therapeutic efficacy, and off-target toxicity and permits increased effective dose. Besides, the safety assessment in animals showed reduced cardiotoxicity, nephrotoxicity, and hematological toxicity, which points to their good safety profile. Regardless of the issues surrounding batch-to-batch variability, premature release, or burst release of drugs and the lack of consistency in large-scale production, recent studies on lipid composition optimization, multifunctional surface modification, and standardized production protocols highlight how liposomal formulations can be translated to clinical use. Altogether, injectable liposomal systems offer a flexible, convenient, and efficient system of advanced cancer therapy with better pharmacokinetics, greater tumor targeting, lower systemic toxicity, and combination therapy, which can be used to achieve optimal anticancer effects.

Key Words:

Injectable liposomes, Anticancer drugs, Sustained release, Tumor targeting, Pharmacokinetics, EPR effect, PEGylation, Therapeutic efficacy

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1. INTRODUCTION

Cancer is one of the major causes of morbidity and mortality in the global society, making it a major challenge in healthcare systems[1]. Although conventional chemotherapy is effective in attacking fast multiplying cancerous cells, it is usually constrained by systemic toxicity, low solubility of anticancer agents and lack of specificity during body distribution. These not only decrease the effectiveness of the therapeutic process of drug use, but also cause serious side effects, reducing the dose and frequency of intake. In order to address such challenges, there has been the emergence of developed drug delivery systems as promising measures to enhance safety and

effectiveness of chemotherapeutic agents[2]. The liposomal formulations are one of them and have received great interest because of their capacity to entrap hydrophilic and hydrophobic drugs, increase circulation time, and actively and passively target the tumor tissues.

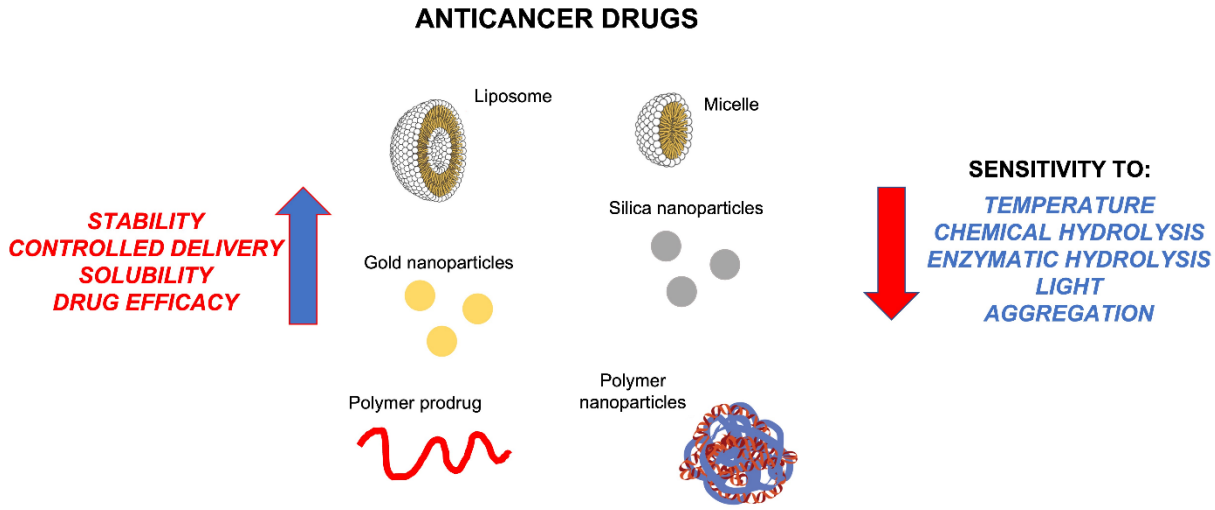

Figure 1: Anticancer Drugs[3]

Injectable liposomal formulations, in particular, are a practical platform for modified/reduced release drugs, resulting in extended distribution and prolonged exposure at the systemic level and improvement of drug concentration at the tumor site. Such optimization can occur by altering the lipid matrix composition, vesicle size, and surface composition, that each play a role in pharmacokinetics, potential off-target toxicity, and therapeutic improvement. A myriad of preclinial and clinical studies of liposomal drugs over the past several decades supports the training data of doxorubicin and topotecan for potential improvement of efficacy with less toxicities. This review intends to provide an overview of injectable liposomal formulations used for anticancer therapeutic use with a focus related to design strategy and pharmacokinetics, tumor targeting, therapeutic efficacy, and future developments focusing on anticancer clinical use[4].

1.1 Background Information and Context:

The use of liposomes as drug delivery vectors has made major breakthroughs in therapy of cancer as it has addressed various drawbacks of traditional chemotherapy. Liposomes also increase the circulation time of the anticancer drugs in the bloodstream by protecting the active agents in lipid bilayers against enzymatic degradation and early clearance[5]. This prolonged systemic effect is the ability to maintain a continuous exposure to drugs and enhance therapeutic effects. Furthermore, liposomes take advantage of the increased permeability and retention (EPR) effect, which is one of the tumor vasculature characteristics, with leaky blood vessels, and poor lymphatic drainage resulting in favorable localization of the drug to the tumor site. Not only does this targeted delivery maximize intratumoral levels of different drugs, but also decreases off-target toxicity leading to improved safety and efficacy of cancer treatment[6].

1.2 Objectives of the Review:

This review aims to:

- To evaluate the design strategies of injectable liposomal formulations for enhancing drug stability, circulation time, and controlled release of anticancer agents.
- To analyze the pharmacokinetic properties and drug release profiles of liposomal anticancer drugs, including plasma half-life, bioavailability, and tumor-specific accumulation.
- To assess tumor targeting mechanisms and therapeutic efficacy of liposomal formulations through passive (EPR effect) and active (PEGylation, ligand conjugation) strategies.
- To investigate the safety and toxicological profile of liposomal anticancer drugs in preclinical animal models, including systemic toxicity, immunogenicity, and organ-specific effects.
- To identify current challenges, gaps, and future research directions for optimizing injectable liposomal therapies and their clinical translation in cancer treatment.

1.3 Importance of the Topic:

It is necessary to know the design, development and performance of liposomal drug delivery systems in regard to the advancement of cancer therapy and better patient outcomes[7]. Liposomes present the possibility to improve drug stability, increase circulation period, and direct delivery to tumor tissues, and thereby, increase therapeutic efficacy and reduce systemic toxicity. Researchers can maximize the clinical utility of these nanocarriers by studying the factors that affect their pharmacokinetics, accumulate in the tumor, and release in a controlled manner. The information gained through such studies also assists in the formation of more effective and safer chemotherapeutic methods, as well as aid in the formulation of treatment methods that are easy to administer to a patient, which ultimately leads to better management and treatment of a patient[8].

2. PRECLINICAL EVALUATION AND THERAPEUTIC POTENTIAL OF LIPOSOMAL ANTICANCER DRUG FORMULATIONS

Anticancer drugs in liposomal formulations including doxorubicin and topotecan have demonstrated considerable promise in preclinical trials by extending drug retention, targeting tumors more effectively by using the enhanced permeability and retention (EPR) effect and by eliminating long-term drug release[9]. Deoxyribonucleic liposomes of doxorubicin lead to reduced cardiotoxicity and enhanced intratumor drug delivery, and topotecan liposomes lead to time-controlled 24-hour drug release, which is associated with better therapeutic index and reduced systemic toxicity. In animal models, preclinical studies normally determine pharmacokinetics, biodistribution, and tumor specific-accumulation by the use of imaging and histological studies. All in all, liposomal encapsulation can enhance drug stability, blood circulation time, and tumor selectivity; although, issues like early or premature rupture, variations in lipid composition, vesicle size, and the preparation procedures can interfere with reproducibility and treatment uniformity.

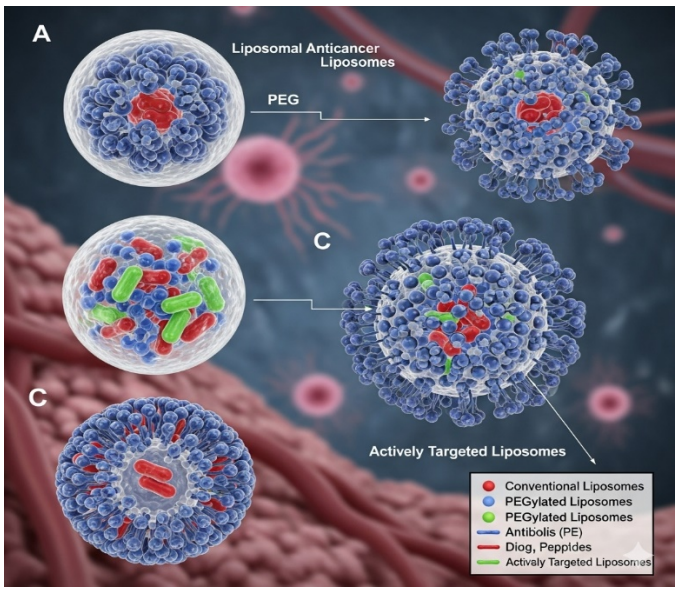

Figure 2: Liposomal Anticancer Drug Formulations[10]

2.1 Key Research Studies

Doxorubicin- and topotecan-loading liposomes amplify the anticancer therapy by increasing the lifetime of the drug circulation, tumor targeting by the EPR effect, and prolonging the drug release. These formulations minimize system toxicity, enhance intratumoral drug concentration and retain therapeutic activity in preclinical models[11].

- **Liposomes -doxorubicin:** In a number of preclinical trials in the murine model, the encapsulation of doxorubicin in liposomes has shown a much longer blood circulation time than the free drug. This encapsulation can increase passive accumulation in tumor tissues through the enhanced permeability and retention (EPR) effect, and hence the therapeutic index. Cardiotoxicity, a frequent adverse effect of conventional doxorubicin preparations has also been said to be decreased with liposomal doxorubicin with no or increased effects on antitumor activity[12]. The results provide evidence of the potential of liposomal delivery systems to decrease the systemic toxicity and increase the drug concentration in the tumor site (PMC).
- **Topotecan-Loaded Liposomes:** It has been demonstrated that liposomal formulations of topotecan can be applied successfully in animal models because of the ability of the liposomes to release the drug over a period of about 24 hours. This is a controlled release profile that enables extended exposure to tumor tissues of the cytotoxic agent resulting in increased therapeutic efficacy. Research shows that the liposomes enhance the delivery of drugs to tumor areas, reduce off-target effects and a longer therapeutic concentration is maintained, thus maximizing anticancer effects and may result in minimum systemic toxicity (AACR Journals)[13].

2.2 Methodologies and Findings

Preclinical testing of liposomal anticancer drugs is normally done intravenously in the animal model (mice and rats). Pharmacokinetic parameters, such as plasma half-life, area under a curve (AUC), and tumor-to-blood ratios, are attentively determined to ascertain the period of circulation

of the drug and distribution[14]. Tissue-specific drug accumulation, tumor targeting, and biodistribution are assessed using imaging methods, e.g., fluorescence or radiolabeling, and histological methods. These methodologies offer a holistic awareness of the effect of liposomal formulations on drug delivery, efficacy and safety profile.

2.3 Strengths and Weaknesses

The anticancer drug delivery is more enhanced through liposomal encapsulation that enhances a longer circulation time, preservation of drugs, and targeting of tumors using the EPR effect. The weaknesses however are early release of drugs and variability in formulations that may diminish treatment effects and adherence[15].

- **Strengths:** Liposomal encapsulation has a number of strengths in the delivery of anticancer drugs. It increases the length of circulation by preventing renal clearance and enzymatic breakdown of the drug to guarantee prolongate levels of the drug in the blood. Also, liposomes increase tumor targeting by the enhanced permeability and retention (EPR) effect, which permits passive accumulation in tumor tissues which result in increased intratumoral drug levels and better treatment.
- **Weaknesses:** These advantages notwithstanding, the liposomal formulations have some limitations. There are those that can have premature rupture or bursting drug release, soon after the administration, which may lead to systemic toxicity, and diminish the overall effectiveness of the treatment[16]. Moreover, lipid composition, size of vesicles and preparation methodology can produce a different profile of drug release which leads to inconsistencies in reproducibility and therapeutic performance across batches.

3. LIPOSOMAL ANTICANCER DRUG DELIVERY: PHARMACOKINETICS AND EFFICACY

Anticancer drugs in liposomal formulations have demonstrated a better therapeutic effect due to improved pharmacokinetics, targeting of the tumor and release of the drug[17]. These formulations substantially reduce clearance rates and extend plasma half-lives to allow sustained systemic exposure, and predictable drug delivery is ensured by controlled release using optimized lipid composition and vesicle size and PEGylation. The increased permeability and retention (EPR) effect aids tumor accumulation which can be enhanced by surface modification or ligand conjugation and optimizes selective uptake and reduces off-target effects. Liposomal delivery is demonstrated to be effective in inhibiting the growth and spreading of tumors, slowing down their progression, and prolonging the life of a person, as well as is synergistically applicable in combination with other treatment methods. The decreased systemic toxicity enables patient to have increased effective doses and liposomal formulations can be used as an advanced platform of cancer therapy[18].

3.1 Pharmacokinetics and Drug Release Profiles

The liposomal preparations have a significant effect on the pharmacokinetics of the encapsulated anticancer drug and lead to significant enhancements compared to their free-drug counterparts. These formulations result in prolonged systemic exposure to drugs, which increases therapeutic

efficacy but may reduce dosing frequency, due to reduced clearance rates and increased plasma half-lives[19]. The increased pharmacokinetic properties have been shown to be useful especially in cancer applications where the consistent drug concentrations at the tumor site are imperative in achieving the optimum cytotoxic effects on the cancerous cells and minimum systemic toxicity. It has continually been demonstrated through preclinical studies that liposomal encapsulation enhances the penetration of drugs into the target tissues through the increasing effect of permeability and retention (EPR) effect, which can further enhance treatment outcomes.

The use of lipids composition, vesicle size, and surface properties is carefully optimized in order to undergo controlled drug release in liposomes. Introduction of cholesterol into the lipid bilayer increases the rigidity of the membrane and minimizes premature leakage of drugs, and PEGylation of the liposome surface gives a stealth effect, which avoids opsonization and clearance by the mononuclear phagocyte system[20]. All these alterations prolong the circulation time, permit more predictable release of a drug and selective delivery to tumor tissue. These design approaches will see to it that the release of anticancer drugs is done in a sustained fashion at the target site thereby enhancing the therapeutic effectiveness and minimizing the chances of systemic side effects.

3.2 Tumor Targeting and Accumulation

The passive targeting of the tumor with the liposomal drug formulations is central to the enhanced permeability and retention (EPR) effect. The tumor blood vessels tend to be abnormal, the endothelial junctions are leaky and lymphatic drainage is poor, thus providing a favorable environment in which nanoparticles such as liposomes can selectively accumulate[21]. Such selective accumulation allows the encapsulated drug to accumulate in the tumor tissues more than the normal tissues, therefore, increasing the therapeutic index with minimal systemic exposure. In preclinical research, it has been demonstrated that liposomes are able to have prolonged retention in tumors which results in increased antitumor and decreased adverse effects.

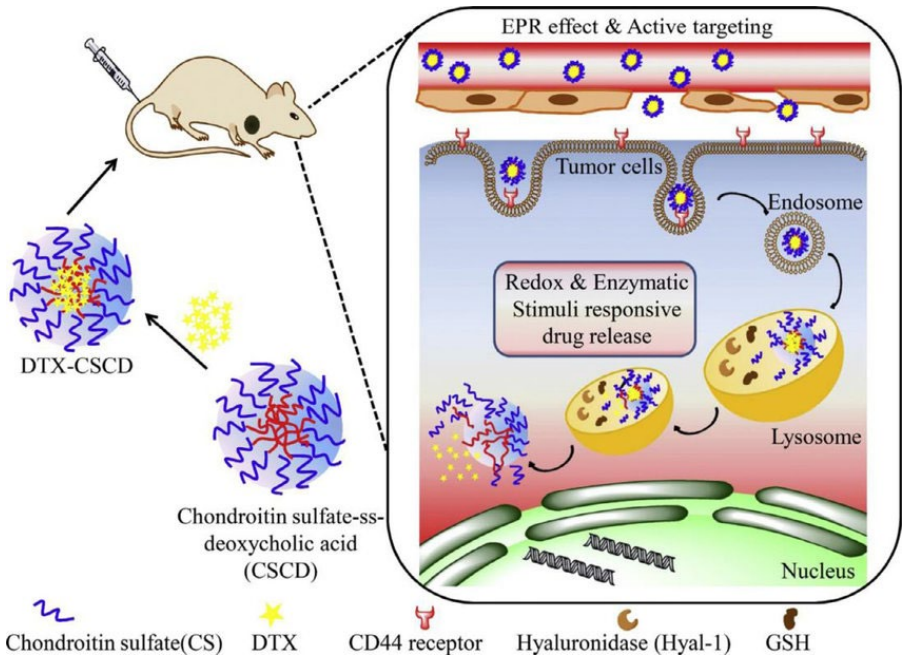

Figure 3: Tumor Targeting and Accumulation[22]

Along with the passive mode of targeting with the EPR effect, active methods, including surface modifications, enhance tumor accumulation to an even greater extent. PEGylation, e.g., is used to enhance liposome stability in plasma circulation by forming a steric barrier which makes the liposome less recognized and less cleared by the reticuloendothelial system (RES). Liposomes can also be targeted further by ligand conjugation, as in the case of antibodies or small molecules, which can be targeted to tumor-associated receptors and increase selective uptake by cancer cells[23]. The combination of these strategies increases the time interval of circulation, decreases off-target distribution of the therapeutic agent, and concentrates the therapeutic agent in the tumor microenvironment, resulting in maximum anticancer efficacy and reduced systemic toxicity.

3.3 Therapeutic Efficacy

Preclinical animal trials have always indicated that liposomal drug delivery enhances therapeutic effect on cancer treatment. Liposomal formulations are effective in inhibiting tumor growth and delaying tumor progression and improving survival in different animal models by improving drug accumulation at the tumor sites and facilitating sustained release of drugs[24]. The enhanced pharmacokinetic properties and targeted tumor therapy (less systemic exposure) increase the safety and effectiveness of the treatment by reducing the adverse effects that patients typically experience due to regular chemotherapy.

Besides monotherapy, liposomal formulations are also combined to achieve the combination approaches which may improve further the antitumor effects. Synergistic effects can be achieved through co-delivery of liposomal drugs with immunotherapeutic agents, other chemotherapeutics or radiosensitizers, and maximize tumor cell destruction and minimize toxicity to normal tissues[25]. Lower systemic toxicity of liposomal encapsulation allows successively increasing the effective doses with minimal risk, which contributes to a better therapeutic index and their potential as a flexible platform of advanced cancer treatment in preclinical models.

4. SAFETY AND TOXICOLOGICAL EVALUATION IN ANIMAL MODELS

Safety and toxicology testing of liposomal drug preparations on animal models is an important procedure in preclinical development that is done to ensure the effectiveness and safety of these delivery systems before humans can take them. The liposomal encapsulation is normally meant to minimize the systemic toxicity of anticancer drugs through the regulation of drug release and increased tumor-selective accumulation[26]. Nevertheless, animal models should be properly evaluated through detailed examination to determine possible negative impact on the key organs, immune system and overall physiological performance. The acute and chronic toxicity are usually studied and the parameter of body weight, hematological indices, liver and kidney functioning, and histopathological alterations of body organs used to reveal the toxic effects of liposomal administration[27].

Simulated human response to liposomal therapies are conducted on animal models such as mice, rats and in some instances larger mammals. IV delivery is the most commonly used to recreate clinical delivery, and repetitive dosing schedules are used in order to see cumulative effects. The hematology and blood biochemistry studies are conducted to monitor systemic toxicity whereas organ histology is conducted to provide information about tissue-specific effects[28].

Immunogenicity tests are also done to identify whether the liposomes invoke undesirable immune reactions, especially when the liposomes are modified on their surface e.g. PEGylation or ligand conjugation. The safety of liposomal formulations has been generally demonstrated at preclinical studies that lower the cardiotoxicity, nephrotoxicity and the hematological toxicity of conventional chemotherapy[29].

Biodistribution and clearance studies which are supplementary to the conventional toxicity studies are used to monitor the fate of the liposomes in vivo. The studies assist in determining the possible build-up in non-target organs and estimating the possibility of toxicity in the long run. In general, animal models have shown to be vital in regard to overall safety and toxicological assessment of liposomal formulation, dose choice, and clinical trial design and maximize therapeutic utility with minimum side effects[30].

Table 1: Summary of Key Studies on Liposomal Formulations for Targeted and Sustained Anticancer Drug Delivery[31]

Author(s) & Year	Study	Focus Area	Methodology	Key Findings
Sarfraz et al., (2018)[32]	Development of dual drug-loaded nanosized liposomal formulation	Optimizing encapsulation efficiency and particle size for combinatorial anticancer therapy	Reengineered ethanolic injection method; preclinical pharmacokinetic studies	Liposomal formulation improved bioavailability and circulation time compared to free drugs, suggesting a promising dual-drug delivery strategy
Sheoran et al., (2019)[33]	Review on liposomes: patents, formulation techniques, classification, and characterization	Advances in liposomal design, targeting, and controlled release systems	Literature review of recent patents and studies	Liposomes were highlighted as versatile nanocarriers improving drug solubility, stability, and targeted delivery, reducing systemic toxicity
Shukla, Singh, & Singh, (2024)[34]	Vincristine-based nanoformulations: preclinical and clinical overview	Nanoformulations for safer and effective vincristine delivery	Analysis of preclinical and clinical studies	Nanoformulations enhanced solubility, reduced systemic toxicity, improved antitumor activity, and facilitated safer clinical translation
Song et al., (2020)[35]	Combinatorial liposomal formulation of genistein and plumbagin	Targeted anticancer therapy in prostate tumor models	Liposomal encapsulation; targeting Glut1 and Akt3 in mice	Dual-drug liposomes enhanced cellular uptake, reduced tumor growth, and exhibited synergistic anticancer effects

Takayama et al., (2021)[36]	Mesenchymal stem cells (MSCs) as carriers for liposomal anticancer drugs	Targeted drug delivery using MSCs	Preclinical studies with MSC-mediated liposomal delivery	MSCs selectively delivered liposomal drugs to tumors, improving efficacy and reducing off-target toxicity

5. DISCUSSION

The use of injectable liposomal formulations is a major breakthrough in drug delivery of anticancer drugs, which have overcome most of the shortcomings of traditional chemotherapy. Liposomal encapsulation constitutes preclinical studies consistently show an increase in drug stability and prolongs the circulation time, increases tumor accumulation through the enhanced permeability and retention (EPR) effect, and enables sustained release of cytotoxic agents[37]. Liposomulated drugs like doxorubicin and topotecan have better pharmacokinetic characteristics, less systemic toxicity and better therapeutic effects in animal models. The results have highlighted the possibility of liposomal systems to enhance chemotherapy through the maximization of therapeutic index and reduction of off-target effects.

5.1 Interpretation and Analysis of Findings

The analysed articles demonstrate that liposomal preparations have considerable pharmacodynamics and pharmacokinetic benefits in comparison with free-drug analogues. The long plasma half-life and the release profile provides constant exposure of the drug to cancer cells, increasing cytotoxic efficacy and decreasing effects of peaks and the toxicities associated with them. Passive (EPR effect) and active (PEGylation and ligand conjugation) targeting of the tumor serve as effective methods of tumor targeting and enhance selective drug delivery[38]. Translational possibilities of liposomal carriers as a safer and effective therapeutic agent are shown by preclinical results, such as delayed tumor growth, minimized systemic toxicity and enhanced survival.

5.2 Implications and Significance

The results show the clinical utility of liposomal anticancer therapies, which has an enhanced capacity to increase patient safety, optimization of dosing schedules, and higher effective doses of such therapies with the same adverse effects. These formulations may also be used as the platforms of combination therapies, such as co-delivery with Immunotherapeutics or radiosensitizers, which may enhance the antitumor effects[39]. Liposomes enhance the bioavailability of drugs whose solid solubility and stability cause limitations in clinical use; this increases the number of chemotherapeutics to which clinical use may be applied.

5.3 Gaps and Future Research Directions

Although the promising outcomes are present, there are still a few challenges. The lipid composition, size and methods of preparation of vesicles can vary and therefore could lead to lack of reproducibility and consistency of drug release that limits clinical translation. There is still the

issue of premature or burst release of encapsulated drugs, which should be optimized. Future studies ought to seek to unify the manufacturing guidelines, new lipid designs, and multifunctional surfaces to be added in targeting. Also, long-term toxicity, immunogenicity, and biodistribution are required in big animal models and clinical trials to ensure safety and therapeutic efficacy. The opportunity to discover personalized liposomal therapies which are different in tumor-type and patient-specific pharmacokinetics is a promising future possibility[40].

6. CONCLUSION

Injectable liposomal formulations are a major breakthrough in anticancer therapy, which have overcome the major limitations of the traditional chemotherapy such as low solubility, high levels of clearance and systemic toxicity. The preclinical evidence of drug liposomal encapsulation has shown to improve the pharmacokinetic characteristics, increase the circulation time, release drugs in a sustained and controlled manner, and can increase tumor-specific accumulation using both passive (EPR effect) and active targeting approaches. These advancements result in increased therapeutic effect, decreased off-target toxicity and a possible increase in effective dose as well as facilitating combination therapy resulting in synergistic anticancer effects. Liposomal carriers have a favorable safety profile as safety and toxicological analyses in animal models suggest that their toxicity is less than cardiotoxicity, nephrotoxicity, and hematological toxicity. Although there are issues when it comes to variability of formulations, premature release of drugs, and cross tram translational consistency, current studies are in the process of developing improved lipid profiles, surface alterations, and standardized manufacturing guidelines with a view of clinical transference. In general, injectable liposomal preparations provide a flexible patient-friendly and effective system of advanced cancer therapy, which has a potential to impact the treatment outcomes and quality of life of a patient.

CONFLICT OF INTEREST

The authors have no conflicts of interest regarding this investigation**.**

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