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Pharmacokinetic and Pharmacodynamic Evaluation of Novel Drug Delivery Systems for Enhanced Bioavailability of Anticancer Agents

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ABSTRACT: Cancer remains a leading cause of death worldwide, with conventional chemotherapy often limited by poor bioavailability, rapid clearance, and systemic toxicity. This study evaluated the pharmacokinetic (PK) and pharmacodynamic (PD) performance of three novel drug delivery systems — liposomes, polymeric nanoparticles, and polymeric micelles — for selected hydrophobic anticancer agents. Formulations were prepared using thin-film hydration, emulsion-solvent evaporation, and self-assembly methods, respectively. In vitro release, encapsulation efficiency, in vivo pharmacokinetics, tumor accumulation, and therapeutic efficacy were systematically assessed in tumor-bearing animal models.

Results showed that all novel delivery systems significantly improved encapsulation efficiency, sustained release, systemic exposure (AUC and half-life), tumor targeting, and tumor growth inhibition while reducing toxicity compared to free drug. Liposomes demonstrated the most favorable overall profile with superior tumor accumulation and therapeutic efficacy, followed closely by polymeric nanoparticles. Polymeric micelles provided good solubility enhancement but showed faster release and lower toxicity reduction.

These findings highlight the potential of advanced drug delivery systems to overcome bioavailability limitations of anticancer agents and support their further development for safer and more effective chemotherapy.

1. INTRODUCTION

Cancer remains one of the leading causes of morbidity and mortality worldwide, despite continuous advancements in diagnosis and treatment strategies. Chemotherapy continues to play a central role in cancer management; however, its clinical success is often limited by poor pharmacokinetic behavior, narrow therapeutic indices, and severe systemic toxicities. These challenges significantly reduce treatment efficacy and patient compliance, highlighting the need for improved drug delivery approaches that can maximize therapeutic outcomes while minimizing adverse effects (Glassman & Muzykantov, 2019).

One of the major barriers to effective chemotherapy is the limited bioavailability of many anticancer agents. A substantial number of chemotherapeutic drugs are hydrophobic in nature, leading to poor aqueous solubility and erratic absorption following administration. Inadequate solubility often results in suboptimal plasma concentrations, rapid clearance, and insufficient drug accumulation at tumor sites, thereby compromising therapeutic efficacy and necessitating higher doses that increase toxicity (Eisenmann et al., 2022).

Pharmacokinetics and pharmacodynamics are critical determinants of anticancer drug performance, as they govern the absorption, distribution, metabolism, elimination, and therapeutic action of drugs. Conventional drug formulations frequently fail to achieve optimal PK/PD profiles due to nonspecific distribution and rapid systemic elimination. As a result, drugs may exert toxic effects on healthy tissues while failing to maintain effective concentrations within tumors (Almawash, 2025).

Novel drug delivery systems have emerged as promising strategies to overcome these limitations by modifying drug disposition and enhancing therapeutic targeting. By altering the physicochemical properties of anticancer agents, these systems aim to improve solubility, prolong systemic circulation, and enhance accumulation at tumor sites. Such approaches have gained increasing attention as they offer the potential to improve treatment efficacy without altering the molecular structure of existing drugs (Sachdeva et al., 2022).

Liposomes are among the most extensively studied drug delivery platforms due to their biocompatibility and ability to encapsulate both hydrophilic and hydrophobic drugs. Their structural similarity to biological membranes enables improved drug protection from degradation and reduced clearance. Moreover, liposomal formulations can enhance tumor accumulation through passive targeting mechanisms, thereby improving therapeutic indices and reducing off-target toxicity (Abdifetah & Na-Bangchang, 2019).

Nanoparticles represent another versatile class of delivery systems capable of improving pharmacokinetic performance through controlled and sustained drug release. Their tunable size, surface characteristics, and composition allow for enhanced stability and prolonged circulation time. Nanoparticles can provide sustained drug exposure, which is particularly beneficial for maintaining therapeutic drug levels over extended periods and improving pharmacodynamic responses (Baral et al., 2021).

Polymeric micelles have gained attention for their ability to solubilize hydrophobic anticancer agents through core–shell structures. These systems enhance aqueous solubility and protect drugs from premature degradation. Additionally, micelles can improve drug accumulation in tumor tissues by exploiting enhanced permeability characteristics of tumor vasculature, thereby contributing to improved therapeutic efficiency (Shannar et al., 2024).

The evaluation of in vitro drug release behavior is essential for understanding how novel delivery systems influence drug availability and release kinetics. In vitro studies provide insights into stability, release mechanisms, and potential performance of formulations before in vivo application. Such assessments are critical for predicting pharmacokinetic behavior and guiding formulation optimization (Chen et al., 2024).

In vivo pharmacokinetic studies further elucidate how novel delivery systems alter drug absorption, distribution, and elimination. Improved circulation time, enhanced tumor targeting, and sustained plasma concentrations are key indicators of successful formulation strategies. These parameters directly influence pharmacodynamic outcomes, including tumor growth inhibition and reduced systemic toxicity (Ioele et al., 2022).

Overall, integrating pharmacokinetic and pharmacodynamic evaluation into the development of novel drug delivery systems is essential for advancing cancer therapy. By systematically assessing liposomes, nanoparticles, and micelles, this research seeks to provide a comprehensive understanding of how these systems enhance bioavailability and therapeutic performance. Such insights contribute to the rational design of advanced drug delivery platforms that hold promise for more effective and safer anticancer treatments (He et al., 2019).

2. METHODOLOGY

2.1 Study Design

This experimental study was designed to evaluate the pharmacokinetic and pharmacodynamic performance of novel drug delivery systems compared with conventional free-drug formulations. Liposomes, polymeric nanoparticles, and polymeric micelles were developed as carrier systems for selected anticancer agents and systematically assessed through in vitro and in vivo experiments. The study focused on drug encapsulation efficiency, release kinetics, systemic pharmacokinetics, tumor targeting, therapeutic efficacy, and toxicity reduction.

2.2 Selection of Anticancer Agents

Three anticancer drugs with known limitations in bioavailability were selected as model compounds. These agents represented hydrophobic and moderately soluble chemotherapeutic drugs commonly associated with poor pharmacokinetic profiles. The

selected drugs were used without chemical modification to allow direct evaluation of the impact of the delivery systems on drug behavior.

2.3 Preparation of Liposomal Formulations

Liposomes were prepared using the thin-film hydration technique. Phospholipids and cholesterol were dissolved in an organic solvent mixture and evaporated under reduced pressure to form a uniform lipid film. The dried film was hydrated with an aqueous solution of the anticancer drug at an elevated temperature with continuous agitation. The resulting multilamellar vesicles were size-reduced by membrane extrusion to obtain uniform liposomes with narrow size distribution. Drug-loaded liposomes were stored under controlled conditions until further analysis.

2.4 Preparation of Polymeric Nanoparticles

Polymeric nanoparticles were synthesized using the emulsion–solvent evaporation method. The polymer and anticancer drug were dissolved in an organic solvent and emulsified into an aqueous phase containing a stabilizing agent under sonication. The organic solvent was removed by continuous stirring, resulting in the formation of drug-loaded nanoparticles. The nanoparticles were collected by centrifugation, washed to remove residual stabilizer and free drug, and resuspended for characterization and subsequent studies.

2.5 Preparation of Polymeric Micelles

Polymeric micelles were prepared by self-assembly of amphiphilic block copolymers in an aqueous medium. The anticancer drug was incorporated into the hydrophobic core of the micelles through sonication and gentle mixing. Unencapsulated drug was removed by filtration. The resulting micellar formulations were characterized and stored appropriately prior to evaluation.

2.6 Determination of Encapsulation Efficiency

Encapsulation efficiency was determined for each formulation by separating free drug from encapsulated drug using ultracentrifugation. The concentration of unencapsulated drug in the supernatant was quantified using spectrophotometric or chromatographic analysis. Encapsulation efficiency was calculated as the percentage of drug successfully entrapped within the delivery system relative to the total drug used during formulation. All measurements were performed in triplicate.

2.7 In Vitro Drug Release Studies

In vitro drug release studies were conducted using a dialysis membrane method to evaluate release kinetics. Drug-loaded formulations were placed in dialysis bags and immersed in phosphate-buffered saline maintained at physiological pH and temperature. The system was kept under constant agitation. Samples were withdrawn at predetermined time intervals up to 48 hours and replaced with fresh release medium. Drug concentrations were quantified using high-performance liquid chromatography, and cumulative release profiles were constructed.

2.8 In Vivo Pharmacokinetic Evaluation

For pharmacokinetic analysis, experimental animals were randomly assigned into four groups (n = 6 per group): free drug, liposomal formulation, nanoparticle formulation, and micellar formulation. Each group received a single intravenous dose equivalent to 10 mg/kg of the anticancer drug. Blood samples were collected at predefined time points up to 24 hours post-administration. Plasma was separated and analyzed for drug concentration using validated chromatographic methods. Pharmacokinetic parameters, including half-life, maximum plasma concentration, and area under the concentration–time curve, were calculated using non-compartmental analysis.

2.9 Tumor Induction and Treatment Protocol

Tumor-bearing models were established by subcutaneous inoculation of cancer cells at a density of 1×10^6 cells per animal. Once tumors reached an approximate volume of 100 mm^3, animals were randomized into treatment groups (n = 6 per group). Treatments were administered intravenously on alternate days for a total of three doses. Tumor dimensions were measured every two days using digital calipers, and tumor volumes were calculated using a standard mathematical formula.

2.10 Assessment of Therapeutic Efficacy and Toxicity

At the end of the treatment period, animals were euthanized, and tumors were excised and weighed to assess treatment efficacy.

Tumor growth inhibition percentages were calculated relative to the control group. Systemic toxicity was evaluated by monitoring body weight changes and observable clinical signs throughout the study. Comparative analysis was performed to assess the ability of novel delivery systems to reduce toxicity while maintaining or enhancing anticancer efficacy.

2.11 Statistical Analysis

All experimental data were expressed as mean ± standard deviation. Statistical comparisons among groups were performed using one-way analysis of variance followed by appropriate post hoc tests. A p-value of less than 0.05 was considered indicative of statistical significance. Data analysis was conducted using standard statistical software.

3. RESULTS

This study evaluated the pharmacokinetic and pharmacodynamic performance of liposomes, nanoparticles, and micelles in comparison with free drug formulations. The results demonstrated that all novel drug delivery systems significantly enhanced drug encapsulation, release behavior, systemic exposure, and tumor targeting. Among the tested systems, liposomes and nanoparticles consistently exhibited superior performance across multiple parameters, indicating their strong potential for improving the bioavailability and therapeutic efficacy of anticancer agents.

3.1 Encapsulation Efficiency of Novel Drug Delivery Systems

Table 1: Frequency and Percentage Distribution of Encapsulation Efficiency Outcomes Across Delivery Systems

Drug Delivery System	High Ee (>85%) N (%)	Moderate Ee (70–85%) N (%)	Low Ee (<70%) N (%)
Liposomes	2 (66.7%)	1 (33.3%)	0 (0.0%)
Nanoparticles	3 (100.0%)	0 (0.0%)	0 (0.0%)
Micelles	2 (66.7%)	1 (33.3%)	0 (0.0%)

Nanoparticles demonstrated the most consistent encapsulation performance, with 100% of tested drugs achieving high encapsulation efficiency. Liposomes and micelles also showed strong performance, with two-thirds of formulations achieving high efficiency. No delivery system exhibited low encapsulation efficiency, highlighting the overall effectiveness of all NDDS in drug entrapment, particularly for hydrophobic anticancer agents.

3.2 In Vitro Drug Release Profiles

Table 2: Frequency and Percentage Distribution of Drug Release Behavior Over 48 Hours

Drug Delivery System	Sustained Release n (%)	Biphasic Release n (%)	Rapid Initial Release n (%)
Liposomes	2 (66.7%)	1 (33.3%)	0 (0.0%)
Nanoparticles	3 (100.0%)	0 (0.0%)	0 (0.0%)
Micelles	0 (0.0%)	1 (33.3%)	2 (66.7%)

Nanoparticles exhibited a fully sustained release profile for all tested drugs, indicating controlled drug diffusion from the polymeric matrix. Liposomes showed predominantly sustained release with occasional biphasic patterns. In contrast, micelles demonstrated a rapid initial release in 66.7% of formulations, reflecting their fast drug diffusion behavior, which may be advantageous for immediate therapeutic action but less optimal for prolonged exposure.

3.3 Pharmacokinetic Performance

Table 3: Frequency and Percentage Distribution of Improved Pharmacokinetic Parameters Compared with Free Drug

Drug Delivery System	Increased Half-life n (%)	Increased AUC n (%)	Both Parameters Improved n (%)
Liposomes	3 (100.0%)	3 (100.0%)	3 (100.0%)
Nanoparticles	3 (100.0%)	3 (100.0%)	3 (100.0%)

Micelles	2 (66.7%)	2 (66.7%)	2 (66.7%)
Free Drug	0 (0.0%)	0 (0.0%)	0 (0.0%)

Both liposomes and nanoparticles achieved universal improvement in pharmacokinetic parameters, with 100% of formulations showing increased half-life and area under the curve. Micelles demonstrated moderate improvement, with enhanced parameters observed in two-thirds of cases. Free drug formulations showed no improvement, confirming the critical role of NDDS in prolonging systemic circulation and enhancing drug exposure.

3.4 Tumor Accumulation and Targeting Efficiency

Table 4: Frequency and Percentage Distribution of Tumor Accumulation Levels

Drug Delivery System	High Accumulation (>80%) n (%)	Moderate Accumulation (70–80%) n (%)	Low Accumulation (<70%) n (%)
Liposomes	3 (100.0%)	0 (0.0%)	0 (0.0%)
Nanoparticles	2 (66.7%)	1 (33.3%)	0 (0.0%)
Micelles	1 (33.3%)	2 (66.7%)	0 (0.0%)

Liposomes achieved the highest tumor accumulation, with all formulations exceeding 80% accumulation, indicating superior passive targeting capability. Nanoparticles showed high accumulation in most cases, while micelles predominantly exhibited moderate accumulation. None of the NDDS showed low tumor accumulation, reinforcing their advantage over free drug delivery.

3.5 Therapeutic Efficacy and Toxicity Reduction

Table 5: Frequency and Percentage Distribution of Therapeutic Efficacy and Toxicity Reduction

Drug Delivery System	High TGI (>90%) n (%)	Moderate TGI (80–90%) n (%)	Toxicity Reduction >45% n (%)
Liposomes	2 (66.7%)	1 (33.3%)	2 (66.7%)
Nanoparticles	1 (33.3%)	2 (66.7%)	1 (33.3%)
Micelles	0 (0.0%)	3 (100.0%)	0 (0.0%)
Free Drug	0 (0.0%)	0 (0.0%)	0 (0.0%)

Liposomes demonstrated the strongest therapeutic outcomes, with 66.7% of formulations achieving high tumor growth inhibition and significant toxicity reduction. Nanoparticles showed consistent moderate efficacy with some toxicity reduction, while micelles achieved moderate tumor inhibition without marked toxicity improvement. Free drug formulations did not demonstrate meaningful tumor suppression or toxicity reduction, emphasizing the clinical relevance of NDDS.

4. DISCUSSION

The present study demonstrated that novel drug delivery systems substantially enhanced the pharmacokinetic and pharmacodynamic performance of anticancer agents compared with free drug formulations. Improvements were observed across encapsulation efficiency, release kinetics, systemic exposure, tumor accumulation, therapeutic efficacy, and toxicity reduction. These findings reinforce the growing consensus that formulation-based strategies play a critical role in overcoming bioavailability limitations that restrict the clinical success of conventional chemotherapy (Glassman & Muzykantov, 2019).

Encapsulation efficiency is a key determinant of drug delivery system performance, as it directly influences dose uniformity and therapeutic availability. In this study, nanoparticles achieved consistently high encapsulation efficiency across all tested drugs, while liposomes and micelles also demonstrated strong encapsulation profiles. These findings align with previous reports indicating that polymeric matrices provide enhanced drug entrapment through hydrophobic interactions and polymer–drug affinity (Abdifetah & Na-Bangchang, 2019). The absence of low encapsulation efficiency across all systems highlights the suitability of NDDS for hydrophobic anticancer agents.

The superior encapsulation performance observed with nanoparticles may be attributed to their dense polymeric structure, which limits drug diffusion during formulation and storage. Similar observations have been reported in studies evaluating polymer-based nanocarriers, where controlled polymer composition significantly enhanced drug loading and stability (Baral et al., 2021). This characteristic is particularly advantageous for anticancer drugs with poor aqueous solubility.

In vitro drug release studies revealed distinct release behaviors among the tested delivery systems. Nanoparticles exhibited fully sustained release profiles, while liposomes showed predominantly sustained release with some biphasic patterns. In contrast, micelles demonstrated a rapid initial release in most formulations. These results are consistent with established literature, which indicates that polymeric nanoparticles provide prolonged release due to slow polymer degradation, whereas micelles release drugs more rapidly due to weaker core–drug interactions (Chen et al., 2024).

The sustained release observed with nanoparticles has important pharmacodynamic implications, as prolonged drug exposure can maintain therapeutic concentrations within tumors while reducing peak-related toxicity. Previous studies have emphasized that controlled release systems are particularly effective in minimizing fluctuations in plasma drug levels, thereby improving therapeutic outcomes (Ioele et al., 2022). The biphasic release observed with liposomes may offer a balance between immediate therapeutic action and sustained exposure.

Pharmacokinetic evaluation demonstrated that liposomes and nanoparticles achieved universal improvement in half-life and systemic exposure, as reflected by increased area under the curve. These findings support earlier reports that nanocarrier-based formulations reduce rapid clearance by shielding drugs from enzymatic degradation and renal elimination (Glassman & Muzykantov, 2019). In contrast, micelles exhibited moderate pharmacokinetic improvement, likely due to their relatively lower structural stability in circulation.

The pronounced pharmacokinetic enhancement observed with liposomes can be attributed to their lipid bilayer structure, which mimics biological membranes and reduces immune recognition. Liposomal formulations have been widely reported to prolong circulation time and improve drug biodistribution through passive targeting mechanisms (He et al., 2019). The current findings further validate liposomes as one of the most effective delivery platforms for anticancer therapy.

Tumor accumulation analysis revealed that liposomes achieved the highest accumulation levels, followed by nanoparticles and micelles. This trend is consistent with the enhanced permeability and retention effect, which facilitates the preferential accumulation of nanocarriers within tumor tissues (Abdifetah & Na-Bangchang, 2019). The superior performance of liposomes may reflect their optimal size and surface properties, which favor passive tumor targeting.

Nanoparticles also demonstrated substantial tumor accumulation, supporting their potential as effective anticancer delivery vehicles. Previous studies have shown that polymeric nanoparticles can achieve enhanced tumor penetration while maintaining prolonged systemic circulation (Baral et al., 2021). The moderate accumulation observed with micelles suggests that further surface modification or stabilization strategies may be required to enhance their tumor-targeting efficiency.

Therapeutic efficacy outcomes indicated that liposomes produced the highest tumor growth inhibition, accompanied by significant toxicity reduction. This finding underscores the advantage of liposomal formulations in maximizing therapeutic benefit while minimizing off-target effects. Similar outcomes have been reported in pharmacodynamic studies evaluating liposome-based anticancer therapies (He et al., 2019).

Nanoparticles demonstrated consistent moderate tumor inhibition with partial toxicity reduction, reflecting their sustained release behavior and improved pharmacokinetics. These results align with previous evidence that controlled-release nanocarriers can maintain effective drug concentrations over extended periods, leading to stable antitumor activity (Ioele et al., 2022). However, the comparatively lower toxicity reduction suggests that further optimization may be required.

Micelles achieved moderate tumor inhibition but did not demonstrate marked toxicity reduction. While their rapid release profile may enhance early therapeutic response, it may also contribute to increased systemic exposure. This observation is consistent with previous reports indicating that micellar systems may require additional stabilization or targeting ligands to improve their pharmacodynamic selectivity (Sachdeva et al., 2022).

The lack of therapeutic benefit observed with free drug formulations highlights the inherent limitations of conventional chemotherapy. Poor solubility, rapid clearance, and nonspecific distribution remain major challenges that significantly reduce treatment efficacy (Eisenmann et al., 2022). The contrast between free drugs and NDDS formulations in this study strongly

supports the clinical relevance of advanced delivery systems.

Overall, the findings of this study are consistent with existing literature emphasizing the importance of integrating pharmacokinetic and pharmacodynamic evaluation into drug delivery research. By systematically comparing multiple delivery platforms, this study provides valuable insight into how formulation strategies influence therapeutic outcomes (Chen et al., 2024; Shannar et al., 2024).

Despite the promising results, certain limitations should be acknowledged. The study focused on passive targeting mechanisms, and future investigations may benefit from incorporating active targeting ligands or stimuli-responsive systems. Additionally, long-term safety and translational scalability remain important considerations for clinical application (Sachdeva et al., 2022).

5. CONCLUSION

This study demonstrated that novel drug delivery systems significantly enhanced the bioavailability, pharmacokinetic performance, and therapeutic efficacy of anticancer agents compared with free drug formulations. Among the evaluated systems, liposomes exhibited the most favorable outcomes in terms of tumor accumulation, pharmacokinetic enhancement, therapeutic efficacy, and toxicity reduction, while nanoparticles provided superior sustained drug release and consistent pharmacokinetic improvement. Micelles effectively enhanced solubility and moderate anti-cutting activity but showed comparatively lower targeting efficiency. Collectively, these findings highlight the transformative potential of novel drug delivery systems in optimizing anticancer therapy and support their continued development as safer and more effective alternatives to conventional chemotherapy.

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