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Proniosomes Used in Cancer Therapy

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ABSTRACT

Millions of people die from cancer every year, making it one of the world's most serious health issues. Its aggressive behavior and resistance to treatment are influenced by its complex genesis, genetic variability, and capacity to elude immune monitoring. Conventional cancer treatments like chemotherapy, radiation, and surgery frequently fail because of non-specific drug distribution, systemic toxicity, and restricted therapeutic indices, even with improvements in diagnostic and therapeutic techniques. Although they are good at killing quickly dividing cells, chemotherapy drugs can also harm healthy tissues, which can have negative consequences on a patient's quality of life and treatment compliance. Through the creation of specialized drug delivery systems that increase therapeutic efficacy while reducing collateral damage to healthy cells, the area of nanomedicine has recently given rise to fresh optimism. Proniosomes have become one of these new and adaptable drug delivery systems. Proniosomes are free-flowing, dry formulations that transform into niosomes, which are non-ionic surfactant-based vesicles that can hold both lipophilic and hydrophilic medications. Compared to conventional formulations, they have a number of benefits, including as decreased toxicity, regulated drug release, increased chemical stability, and improved bioavailability. Proniosomes use processes like the increased permeability and retention (EPR) effect to enable the targeted administration of chemotherapeutic drugs directly to tumor locations in the context of cancer therapy. This focused strategy reduces exposure to healthy cells, which lessens side effects while simultaneously enhancing medication accumulation in tumor tissues. This paper highlights the revolutionary potential of proniosomes in oncology by examining their structural characteristics, preparation methods, characterisation techniques, and therapeutic uses.

1. INTRODUCTION

One of the most dangerous diseases in the world today is cancer, which is defined by the unchecked growth of cancerous cells that have the ability to spread to other organs and infiltrate neighboring tissues[(1)]. The clinical management of cancer still presents many difficulties, even with notable improvements in early identification and treatment approaches. Even if they work well in many situations, traditional treatment techniques including radiation, chemotherapy, and surgery frequently have significant drawbacks. For example, chemotherapy has severe systemic adverse effects like immunosuppression, gastrointestinal disorders, alopecia, and organ damage because it lacks specificity and targets both malignant and quickly proliferating normal cells[(1)]. These side effects affect treatment outcomes by lowering patient quality of life and limiting the acceptable dosage and length of therapy.

Furthermore, chemotherapy drugs usually have low bioavailability and poor water solubility, which leads to less than ideal drug concentrations at the tumor location. The emergence of multidrug resistance (MDR), in which cancer cells lose their sensitivity to a variety of medications due to mechanisms such accelerated DNA repair, increased drug efflux, and changed drug targets, is a major challenge in the long-term therapy of cancer[(2)]. All of these restrictions call for the creation of cancer treatment strategies that are more effective, focused, and less harmful.

As a result of these difficulties, nanotechnology has become a ground-breaking area in oncology, providing novel drug delivery methods intended to raise the therapeutic index of anticancer drugs. The ability of nanocarriers, including liposomes, niosomes, dendrimers, solid lipid nanoparticles, and polymeric micelles, to encapsulate medications, shield them from deterioration, and deliver them straight to tumor tissues through processes like the Enhanced Permeability and Retention (EPR) effect has been extensively researched[(2,3)]. This tailored administration minimizes systemic distribution and related toxicities while dramatically increasing medication accumulation in tumors.

Many of these nanocarrier systems, however, have real-world issues like chemical and physical instability, high production costs, limited shelf lives, and limitations with large-scale manufacturing, despite their potential[(1)]. Despite their effectiveness,

liposomes frequently need complicated storage conditions and are prone to leaking. Concerns about toxicity may arise from dendrimers, and certain lipid-based nanoparticles may have a restricted ability to load drugs.

Proniosomes have shown promise in addressing a number of these problems. These are dry, free-flowing granular formulations that can be moistened as needed to create niosomes, which are vesicles based on non-ionic surfactants that can hold both lipophilic and hydrophilic medications. Proniosomes are superior to traditional methods in a number of ways, including as better bioavailability, high entrapment efficiency, improved physical and chemical stability, and ease of handling and storage[2]. Because they are solid, there is less chance of drug deterioration and leakage, and they can be used in a variety of ways, such as intravenous, transdermal, and oral, because they can change into vesicles when hydrated[1].

Proniosomes are a major breakthrough in cancer treatment because they allow for the regulated and targeted distribution of chemotherapeutic drugs, which lowers systemic toxicity.

and improves therapeutic results. Proniosomal systems have enormous potential to fill the gaps in contemporary cancer treatment as research into them develops[1,3].

2. METHODOLOGY

A thorough and methodical analysis of the body of research on proniosome use in cancer treatment led to the development of the current paper. To find pertinent publications, a thorough search was carried out across several scientific databases, including PubMed, ScienceDirect, Google Scholar, and Web of Science. To guarantee a comprehensive yet targeted data collection, the search method used specific terms like "proniosomes," "niosomes," "cancer drug delivery," "nanocarriers in oncology," "proniosomal formulations," and the names of different malignancies (e.g., breast cancer, lung cancer, colon cancer). The most recent developments and innovations in the discipline were mainly thought to be captured by publications published in the past ten years.

Research publications, review papers, and clinical trial reports that included proniosome formulation methods, physicochemical characterization, drug encapsulation effectiveness, in vitro and in vivo anticancer activity, and safety profiles were all included in the inclusion criteria. To put proniosomes' benefits and drawbacks into perspective, studies contrasting them with other nanocarriers like liposomes, niosomes, and solid lipid nanoparticles were also examined. Proniosomal composition, preparation techniques (such as coacervation and spray coating), vesicle characterisation characteristics (such as size, zeta potential, and morphology), and their therapeutic results in various cancer models were all carefully evaluated during the data extraction process.

The essay seeks to give readers a thorough grasp of the present state, difficulties, and prospects of proniosomes as a novel nanocarrier system for efficient and targeted cancer treatment by combining and critically evaluating this varied collection of knowledge. This approach guarantees that the review is comprehensive, current, and pertinent to researchers and clinicians who are interested in cutting-edge drug delivery techniques.

3. UNDERSTANDING PRONIOSOMES

3.1 Definition and Structure

Proniosomes are free-flowing, dry formulations that, when hydrated, transform into niosomes. Like liposomes, niosomes are non-ionic surfactant vesicles with a bilayer membrane composed of cholesterol and non-ionic surfactants. Proniosomes can be reconstituted to create multilamellar or unilamellar vesicles using water or biological fluids[1].

3.2 Components of Proniosomes

Non-ionic surfactants: These are the main components of proniosomes' vesicular bilayer. Non-ionic surfactants such as Tween 80 (polysorbate 80) and Span 60 (sorbitan monostearate) are frequently employed. Tween 80 improves flexibility and biocompatibility, while span 60 is preferred for its high phase transition temperature and capacity to create stable bilayers[4]. Vesicle size, drug entrapment effectiveness, and release properties are all strongly impacted by the selection and ratio of surfactants. These surfactants are appropriate for use in pharmaceutical applications because they are less irritating and biocompatible than ionic surfactants.

Cholesterol: Cholesterol is used into the formulation to stabilize the bilayer structure and control the fluidity and rigidity of the membrane. It reduces permeability and stops the encapsulated medicine from leaking too soon by intercalating between the surfactant molecules in the bilayer[4,5]. Additionally, cholesterol helps keep the vesicles physically stable both while they are being stored and when they are being hydrated.

Solvent: When making proniosomes, organic solvents like ethanol or isopropanol are utilized to dissolve the cholesterol and surfactants. When using the slurry or coacervation phase separation process, these solvents aid in uniformly coating the carrier material[2,3]. The solubility of the constituents and the caliber of the resulting proniosomal film are influenced by the solvent selection.

Carrier material: The dry proniosomal formulation is supported by solid carriers such as sorbitol, mannitol, or maltodextrin.

The liquid phase is converted by these hydrophilic carriers into a dry, freely-flowing powder that is convenient to handle, transport, and store[6]. The carrier plays a crucial role in preserving the stability and functionality of proniosomes because the drug-loaded surfactants rearrange into vesicular structures (niosomes) during hydration.

3.3 Advantages of Proniosomes

Enhanced chemical and physical stability

Long shelf life

Ease of storage and transportation

Better entrapment efficiency

Controlled and targeted drug release

Reduction in dose frequency and side effects

4. METHODS OF PREPARATION

4.1 Coacervation Phase Separation Method

Because of its ease of use and repeatability, the coacervation phase separation process is one of the most popular methods for creating proniosomes. This approach involves dissolving a mixture of cholesterol, non-ionic surfactant, and the required medication in a tiny amount of an appropriate organic solvent, like ethanol or isopropanol[1,2]. To guarantee a consistent coating, this organic solution is then added to a pre-weighed quantity of a carrier substance, usually maltodextrin, and carefully mixed. To aid in the solvent's evaporation, the mixture is thereafter heated gradually, typically to between 50 and 60°C. A dry, free-flowing proniosomal powder is produced when the solvent evaporates and the cholesterol and surfactant surround the carrier particles in a thin layer[5]. Niosomes can be created by subsequently hydrating this powder with an aqueous phase. The process is scalable for industrial production and works especially well for medications that are sensitive to temperature changes.

4.2 Slurry Method

Making a semi-solid or slurry-like mixture of formulation ingredients is the first step in the slurry process. First, a suitable alcohol, like ethanol, is used to dissolve the cholesterol and surfactant. Under constant stirring, this solution is progressively added to a predetermined volume of the drug-containing aqueous phase[7]. A slurry of dissolved medication and hydrated surfactant vesicles is created when the alcohol permeates the aqueous media. The solvent and water are subsequently removed from this slurry by drying it under low pressure or by gently heating it, leaving behind a dry proniosomal formulation. The technique can be especially helpful for hydrophilic medications and is beneficial for formulations that gain from initial partial hydration.

4.3 Spray-Coating Method

The surfactant, cholesterol, and medication are dissolved using a volatile organic solvent (such as acetone, ethanol, or chloroform) in the spray-coating approach. A spray-drying or spray-coating device is then used to evenly spray this solution over a solid carrier material, such as sorbitol, mannitol, or maltodextrin[8]. The drug-loaded surfactant is uniformly coated on the carrier particles after the volatile solvent quickly evaporates during spraying or right after owing to heating. A dry, stable proniosomal powder that is readily reconstitutable into niosomes is the end product[2]. Because it provides exceptional control over coating thickness and homogeneity and permits continuous processing, this approach is especially well-suited for large-scale industrial applications.

5. CHARACTERIZATION OF PRONIOSOMES

5.1 Vesicle Size and Distribution

One important factor affecting the pharmacokinetics, biodistribution, and cellular absorption of proniosomal formulations is vesicle size. Usually, methods like laser diffraction or Dynamic Light Scattering (DLS) are used to determine the size and size distribution[1-3]. Vesicle diameters between 100 and 200 nanometers (nm) are thought to be ideal for cancer treatment because they allow passive targeting to tumor tissues through the Enhanced Permeability and Retention (EPR) effect. While the mononuclear phagocyte system (MPS) may quickly clear larger vesicles, a narrow size distribution also guarantees uniformity in drug administration.

5.2 Zeta Potential

Zeta potential is a crucial sign of colloidal stability that quantifies the surface charge of vesicles. Strong electrostatic repulsion between vesicles is indicated by a high absolute zeta potential value (usually above ±30 mV), which inhibits aggregation and improves suspension stability. Drug integrity, shelf life, and reliable treatment efficacy all depend on stable vesicles[9]. Surface charge can also affect how vesicles interact with cell membranes and how cancer cells absorb them.

5.3 Entrapment Efficiency

The percentage of the medicine that is successfully encapsulated within the vesicles as compared to the total amount employed during formulation is known as entrapment efficiency (EE%). It is frequently assessed by separating the free drug from the encapsulated medication using centrifugation, dialysis, or ultrafiltration procedures[2]. Minimizing systemic side effects, lowering dosage frequency, and guaranteeing therapeutic efficacy all depend on high entrapment efficiency. EE% is influenced by variables like preparation technique, cholesterol content, and surfactant type.

5.4 Morphology

Transmission Electron Microscopy (TEM) and Scanning Electron Microscopy (SEM) are used to evaluate the vesicles' form, lamellarity (number of bilayers), and physical appearance[1]. While SEM provides information on surface shape, TEM provides in-depth understanding of the underlying structure and validates the vesicles' spherical and multilamellar nature. Validating the vesicle formation process and maximizing formulation parameters for homogeneous and stable proniosomal systems are two benefits of morphological analysis[10].

5.5 In Vitro Drug Release

In vitro drug release investigations are carried out employing configurations such as dialysis bags, Franz diffusion cells, or modified USP apparatus to assess the controlled release behavior of proniosomes[3]. These tests aid in simulating the drug's gradual release under biological circumstances. In cancer treatment, a sustained release profile is ideal because it keeps therapeutic drug levels at the tumor site for long stretches of time, minimizing systemic exposure and requiring fewer doses.

6. MECHANISM OF DRUG DELIVERY

Proniosomes can encapsulate hydrophilic medications in the aqueous core and hydrophobic drugs in the bilayer membrane after they have been hydrated to niosomes. These vesicles have the ability to endocytose, which releases the medication straight into the cytoplasm, or fuse with the membranes of cancer cells[11]. Furthermore, proniosomes are appropriate for passive targeting because of the preferential accumulation of nanoparticles made possible by the Enhanced Permeability and Retention (EPR) effect in tumor tissues.

7. APPLICATIONS IN SPECIFIC CANCER TYPES

7.1 Breast Cancer

Doxorubicin-loaded proniosomes have demonstrated great potential in the treatment of breast cancer, especially when used against the human breast cancer cell line MCF-7. Although doxorubicin is a powerful chemotherapeutic drug, dose-dependent cardiotoxicity frequently restricts its clinical use[3,12]. Due to better intracellular transport and retention, the medication exhibits increased cytotoxicity toward cancer cells when encapsulated in proniosomes. The gradual and targeted release improves medication accumulation at the tumor location, while the proniosomal formulation minimizes systemic distribution to protect healthy cardiac tissue[5,6]. In addition to increasing therapeutic efficacy, this focused strategy lessens the side effects that are frequently connected to traditional doxorubicin therapy.

7.2 Lung Cancer

A common treatment for non-small cell lung cancer (NSCLC), paclitaxel has a significant systemic toxicity and poor water solubility. It has been discovered that encapsulation in proniosomes greatly increases its stability and solubility, enabling more control over the drug release profile[13]. By encouraging continuous drug release, the proniosomal system reduces the need for frequent dosing and sustains therapeutic concentrations over time. Additionally, research has shown that lung cancer cells accumulate more paclitaxel intracellularly, which improves cytotoxic effects and decreases pulmonary toxicity—a significant drawback of free paclitaxel treatment[3].

7.3 Colon Cancer

Localized administration is frequently chosen for colon cancer in order to reduce systemic exposure and enhance drug concentration in the afflicted area. Proniosomal gel formulations for topical or rectal administration have effectively included 5-fluorouracil (5-FU), a frequently used antimetabolite medication[14]. This method reduces undesirable side effects like mucositis and gastrointestinal toxicity by allowing the drug to remain in the colon for a longer period of time, guaranteeing a higher local drug concentration and a lower systemic absorption. Better patient compliance and increased treatment efficacy are two benefits of the proniosomal gel's controlled release.

7.4 Skin Cancer

Since topical drug administration enables direct application to the tumor site, it is perfect for treating skin cancer. Due to its low skin permeability and poor solubility, curcumin, a naturally occurring polyphenolic molecule with strong anticancer effects, has little practical application[15]. The chemical exhibits improved skin penetration, extended retention, and higher cytotoxic effects on malignant skin cells when it is synthesized in curcumin-loaded proniosomes. Proniosomal curcumin

applied topically provides a non-invasive, patient-friendly option for treating skin malignancies like melanoma or basal cell carcinoma while avoiding systemic side effects[2].

7.5 Prostate Cancer

One of the main chemotherapy drugs used to treat advanced prostate cancer is docetaxel; nevertheless, its systemic toxicity and low absorption frequently limit its therapeutic efficacy. Proniosomes loaded with docetaxel provide a way around these restrictions by enabling controlled medication release and targeted distribution[1,7]. By increasing medication accumulation in prostate tumor tissues and improving oral bioavailability, the nanosized vesicles promote anticancer activity and reduce side effects like neuropathy or neutropenia. The patient's quality of life during therapy may be enhanced by this distribution method, which may also lower the amount needed[6].

8. COMBINATION THERAPY

The capacity of proniosomes to concurrently encapsulate several therapeutic substances, including both hydrophilic and hydrophobic medications, within a single vesicle is one of their amazing benefits[1-4]. This characteristic is very helpful in the treatment of cancer, as combination therapy is frequently used to target several tumor development pathways, get beyond medication resistance, and produce synergistic therapeutic benefits.

The co-administration of curcumin and doxorubicin in a proniosomal formulation is a noteworthy example. Doxorubicin is a powerful anthracycline antibiotic that is frequently employed because of its capacity to intercalate DNA and inhibit topoisomerase II, which causes cancer cells to undergo apoptosis[16]. However, significant cardiotoxicity and the emergence of multidrug resistance (MDR) often impede its clinical use.

However, curcumin, a naturally occurring substance that comes from turmeric, has potent anti-inflammatory and anti-cancer qualities. By altering signaling pathways and inhibiting drug resistance mechanisms such P-glycoprotein overexpression, it can make tumor cells more sensitive to chemotherapy[9].

Both medications are administered directly to the tumor site when they are co-encapsulated in proniosomes[1]. Because curcumin reduces the dosage of doxorubicin while simultaneously enhancing its efficacy, this co-delivery results in a synergistic cytotoxic impact that minimizes adverse effects. Additionally, the delayed and regulated release from proniosomes contributes to the long-term maintenance of ideal medication concentrations at the tumor site.

Table 1. Advantages Over Conventional Systems

Feature	Conventional Chemotherapy	Proniosomal System
Targeting	Non-specific	Tumor-specific (via EPR)
Stability	Poor	Excellent
Side effects	High	Reduced
Drug loading	Limited	High
Cost	High	Moderate
Storage	Short shelf life	Long shelf life

9. LIMITATIONS AND CHALLENGES

Difficulty in scaling up production

Variability in vesicle size

Batch-to-batch reproducibility

Stability concerns for some formulations under high humidity

Lack of comprehensive clinical trials

10. DISCUSSION

Proniosomes have shown great promise in resolving a number of important drawbacks of traditional cancer treatments, such as systemic toxicity, inadequate bioavailability, and poor drug solubility. Their capacity to increase the therapeutic index of anticancer drugs while reducing side effects is the primary benefit supported by the evaluated literature (Ansari et al., 2022)[2]. Compared to conventional liposomal systems, which frequently have limited shelf life and leakage problems, their dry, free-

flowing character enhances handling and storage stability.

Each formulation technique, including coacervation, slurry, and spray coating, adds to the distinct vesicle features. For instance, it has been demonstrated that the slurry and spray-drying methods improve homogeneity and drug encapsulation efficiency, two important aspects of drug delivery system efficacy (Mulla & Nemade, 2024)[1]. These methods also make it possible to encapsulate a wide variety of therapeutic substances, such as proteins, hydrophilic and hydrophobic medications, and even genetic elements, which increases their suitability for treating different kinds of cancer.

In the context of cancer treatment, the Enhanced Permeability and Retention (EPR) effect is particularly pertinent. Due to leaky vasculature, niosomes that have been converted from pronesomes after injection can passively aggregate in tumor tissues. This phenomenon is well-documented and used for targeted drug delivery (Ansari et al., 2022; Nima et al., 2025)[2,4]. In addition to raising the drug's local concentration at the tumor site, passive targeting lowers systemic exposure, which lessens the severity of side effects.

Additionally, the proniosomal system facilitates combination therapy, which is essential for successful cancer treatment. According to Reddy et al. (2017)[8], encapsulating drugs like doxorubicin and curcumin together has demonstrated synergistic anticancer effects while reducing toxicity. By using curcumin's capacity to alter drug resistance pathways, this dual-drug approach makes cancer cells more susceptible to chemotherapeutics.

Even with these benefits, there are still difficulties. Commercialization of proniosomal formulations is still hampered by problems like batch-to-batch repeatability, vesicle size variability, and production scale challenges. Furthermore, situations with high humidity levels may compromise their long-term stability, requiring better formulation and packaging techniques (Tiwari et al., 2020)[14]. There are still regulatory obstacles, particularly for intricate drug delivery systems that need solid clinical evidence to prove their efficacy and safety.

Ongoing research, however, indicates that these difficulties are solvable. The performance of proniosomal drug delivery platforms is anticipated to be greatly improved by developments in nanotechnology, such as the incorporation of biomimetic materials and responsive drug release systems. Deeper insights into maximizing vesicle behavior in physiological conditions are also provided by advancements in characterization techniques, such as dynamic light scattering, differential scanning calorimetry, and zeta potential analysis (Mulla & Nemade, 2024)[1].

11. CONCLUSION

Proniosomes are a potent and adaptable platform in the field of cancer nanomedicine that has quickly drawn interest. Their stability and convenience of handling as dry powders, along with their unique structure that enables the encapsulation of both hydrophilic and hydrophobic medicines, overcome many of the drawbacks of traditional drug delivery methods. Proniosomes guarantee that a greater percentage of the supplied medication reaches the tumor site in its active state by enhancing the stability and bioavailability of chemotherapeutic drugs. In addition to improving therapeutic efficacy, this also makes it possible to utilize smaller dosages of the drug, which may lessen the harmful side effects that sometimes accompany cancer chemotherapy.

Additionally, proniosomes are naturally capable of targeting, especially through passive targeting mechanisms like as the Enhanced Permeability and Retention (EPR) effect, which permits drug-loaded vesicles to accumulate preferentially in tumor tissues. By avoiding the damaging effects of chemotherapy on healthy tissues and organs, this targeted administration helps to lower systemic toxicity. Patients have less negative reactions as a result, which can greatly enhance therapy results and patient compliance. Proniosomal formulations' adaptability also makes combination therapy and site-specific drug administration possible, which increases their usefulness in individualized cancer treatment plans.

Notwithstanding these encouraging characteristics, more investigation and thorough clinical validation are needed to get proniosome-based formulations from the lab to clinical use. To prove their effectiveness and dependability in humans, thorough research on pharmacokinetics, toxicology, and long-term safety is necessary. For these systems to become economically viable, developments in formulation methods and scale-up procedures will also be essential. Proniosomes have the potential to transform cancer therapy by providing safer, more effective, and more patient-friendly treatment choices once these issues are resolved.

In the end, proniosome technology's incorporation into conventional oncology may improve the lives of cancer patients everywhere. Proniosomal drug delivery systems provide a future in which cancer treatments are not only more effective in eliminating tumors but also more tolerated by patients, allowing for longer and healthier lives. This is because they combine increased therapeutic efficiency with decreased systemic toxicity.

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