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Niosome-Based Nanotechnology in Breast Cancer Therapy: Advances in Targeted Drug Delivery

Seyede Fatemeh Tabatabaii [*1]

[1] Department of Biological Sciences, Faculty of Biology, East Tehran Branch, Islamic Azad University, Tehran, Iran.

Corresponding Author's E-mail: fatemehtabatabaii.kajbaf@gmail.com.

Abstract

Breast cancer remains a leading health concern among women worldwide, owing to its high incidence and substantial impact on morbidity and healthcare systems. Despite significant advances in diagnostic and therapeutic approaches, tumor molecular heterogeneity, drug resistance, disease recurrence, and treatment-associated systemic adverse effects remain major obstacles to achieving effective and safe therapy. In recent years, nanotechnology has provided promising opportunities for improving cancer treatment. Among various nanocarriers, niosomes have attracted considerable attention because of their favorable stability, surface modification potential, and controlled drug-release properties. This review examines the structure and composition of niosomes, their preparation and optimization methods, and their applications in the delivery of anticancer drugs. Furthermore, the role of modified and targeted niosomes in enhancing drug accumulation and penetration into tumor tissue while reducing systemic toxicity is discussed. In addition to conventional chemotherapeutic agents, the potential of niosomes for delivering novel anticancer therapeutics, including DNA, siRNA, miRNA, and other biological agents, is also addressed. Available evidence suggests that targeted niosomes can improve therapeutic efficacy by enhancing cellular uptake and controlling drug release while reducing drug exposure in healthy tissues. However, challenges including formulation instability, precise control of physicochemical properties, potential toxicity, manufacturing scalability, and limited clinical evidence remain. The development of smart, multifunctional, and personalized niosomal systems may shape the future of this technology in precision breast cancer therapy.

Keywords: Nanobiotechnology, Niosomes, Nanodrug Delivery, Targeted Delivery, Cancer Therapy.

Introduction

Breast malignancies continue to impose a substantial global health burden, with breast cancer accounting for a significant proportion of cancer cases and deaths among women. Although chemotherapy remains an important component of treatment, its clinical utility can be compromised by nonspecific distribution of therapeutic compounds, damage to healthy tissues, inadequate drug accumulation at the tumor site, and the emergence of resistance. In recent years, nanomedicine has attracted increasing attention as a means of overcoming some of these limitations. Among the available nanocarrier systems, niosomes have emerged as versatile vesicular platforms

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for the delivery of anticancer drugs. Their structural properties can facilitate the protection of encapsulated agents, improve drug solubility and stability, provide sustained or controlled drug release, and enhance interaction with cancer cells. By potentially increasing drug deposition within tumor tissue while reducing exposure to normal organs, niosome-mediated delivery may improve therapeutic performance and reduce treatment-associated toxicity, highlighting its potential as a strategy for developing more efficient breast cancer therapies (1, 2).

Breast Cancer: Epidemiology, Molecular Subtypes, and Therapeutic Challenges

Breast cancer represents a substantial global health burden and is currently the leading cancer diagnosis among women. Global epidemiological estimates indicate that nearly 2.4 million women were newly diagnosed with the disease in 2024, while approximately 694,000 deaths were attributed to breast cancer during the same period. However, the burden of disease is not uniformly distributed worldwide, as both incidence and survival differ considerably between populations and geographic regions. These disparities are influenced by a combination of biological, lifestyle, reproductive, and socioeconomic determinants. Established risk factors include increasing age, genetic and familial predisposition, reproductive and hormonal characteristics, excess body weight, alcohol intake, and differences in the availability of early detection and effective cancer treatment. From a biological perspective, breast cancer encompasses a diverse group of tumors rather than representing a single disease entity. Molecular and immunohistochemical characteristics, particularly the status of estrogen receptor (ER), progesterone receptor (PR), and human epidermal growth factor receptor 2 (HER2), together with indicators of cellular proliferation, provide the basis for clinically relevant tumor classification. Major molecular categories include Luminal A, Luminal B, HER2-enriched, and triple-negative breast cancer (TNBC). Identification of these distinct subtypes is essential because they differ in their patterns of tumor growth, prognosis, and sensitivity to treatment. Accordingly, therapeutic decisions are increasingly guided by tumor biology; endocrine-based approaches are commonly used for hormone receptor-positive disease, whereas tumors exhibiting HER2 overexpression or amplification may be candidates for HER2-directed therapies (1,2).

Despite significant advances in early detection, surgery, radiotherapy, chemotherapy, hormonal therapy, and targeted treatments, the management of breast cancer continues to face considerable challenges. Intratumoral and intertumoral heterogeneity, the development of drug resistance, disease recurrence, and metastasis are among the major factors limiting therapeutic success. Therefore, accurate characterization of the molecular features of tumors and the development of personalized medicine and targeted therapeutic approaches represent important future directions for the effective management of breast cancer ((1, 2).

Nanotechnology in Breast Cancer Treatment: Principles, Advantages, and Future Perspectives

In recent years, advances in nanomedicine have opened new possibilities for improving the therapeutic management of breast cancer. The fundamental principle of this technology is the use of nanoscale structures and nanocarriers capable of delivering anticancer drugs while improving their pharmacokinetic properties, bioavailability, and tissue distribution. Nanocarriers can protect drugs from premature degradation, thereby increasing the effective drug concentration at the tumor site. Moreover, surface modification of nanoparticles with ligands, antibodies, or other targeting molecules can facilitate more specific recognition of cancer cells. This approach is particularly important in heterogeneous malignancies such as breast cancer and in where selective targeting may enhance antitumor efficacy while reducing drug exposure to healthy tissues and consequently minimizing systemic adverse effects (3, 4).

Despite promising results, the translation of nanotechnology-based systems from laboratory studies to clinical applications remains challenging because of factors such as manufacturing complexity, precise control of particle size and surface properties, stability, safety, accumulation in non-target organs, and differences between animal models and clinical conditions. In addition to drug delivery, combining nanobiotechnology with gene therapy, RNA-based therapy, immunotherapy, and diagnostic approaches may facilitate the development of theranostic platforms and personalized treatment strategies (3, 4).

Niosomes: Structure, Composition, Properties, and Mechanisms of Action

Niosomes are vesicular nanocarriers formed through the spontaneous organization of nonionic amphiphilic surfactants in an aqueous medium. Their membranes are commonly stabilized with cholesterol or related membrane-modifying substances, while certain formulations may also incorporate agents that alter the surface charge. The resulting architecture is characterized by one or multiple surfactant layers, with the nonpolar segments concentrated within the membrane and the polar groups exposed toward the aqueous phase. This structural organization provides niosomes with the ability to accommodate therapeutic molecules with different physicochemical

properties: water-soluble agents can be entrapped in the internal aqueous compartment, whereas lipophilic compounds can be incorporated into the hydrophobic membrane domain. Depending primarily on vesicle diameter and lamellar organization, these carriers are generally categorized into small unilamellar vesicles, large unilamellar vesicles, and multilamellar vesicles. Such structural differences can influence important formulation characteristics, including drug-loading capacity, stability, release behavior, and interactions with biological tissues. The type and ratio of surfactant, cholesterol content, physicochemical properties of the payload, and hydration conditions are important factors determining the size, morphology, stability, encapsulation efficiency, and drug-release behavior of niosomes (5, 6).

The mechanism of action of niosomes as drug delivery systems is based on the encapsulation, protection, transport, and controlled release of active compounds. Following administration, niosomes can modify pharmacokinetic and biodistribution profiles, potentially prolonging its residence time in the biological environment. Interactions between niosomes and cell membranes, as well as cellular uptake through mechanisms such as endocytosis, can facilitate intracellular delivery of the encapsulated payload. Moreover, surface modification of niosomes can enhance active targeting of specific tissues. Their tunable size and composition, relatively favorable biocompatibility, ability to encapsulate diverse compounds, and surface-engineering potential make niosomes promising carriers for anticancer drugs as well as biological molecules. However, phenomena such as vesicle aggregation, physical instability, and drug leakage or degradation may compromise their performance and therefore need to be carefully considered during formulation and optimization (5, 6).

Methods of Niosome Preparation and Optimization for Drug Delivery Applications

The fabrication of niosomal carriers can be achieved through a range of formulation strategies, with the choice of technique being influenced by factors such as drug characteristics, desired vesicle dimensions, lamellar structure, loading capacity, and the intended therapeutic application. Several approaches have been described, including thin-film hydration, reverse-phase evaporation, solvent or ether injection, sonication, microfluidization, the bubble technique, and proniosome conversion methods. Among these approaches, thin-film hydration is one of the most widely employed procedures. In this technique, the selected nonionic surfactant and cholesterol are first solubilized in a suitable organic solvent. Removal of the solvent under controlled conditions produces a dry surfactant-containing film, which is subsequently exposed to an aqueous hydration medium. Hydration causes the components to reorganize spontaneously and form closed vesicular structures capable of entrapping the desired therapeutic compound. Other techniques, particularly microfluidization and mechanical size-reduction methods such as ball milling, can provide greater control over vesicle dimensions and particle-size uniformity. These approaches may therefore be advantageous when reproducibility, formulation consistency, and potential scale-up for pharmaceutical manufacturing are important considerations (7, 8).

Optimization of niosomal formulations aims to achieve an appropriate particle size, narrow size distribution, high encapsulation efficiency, adequate physical and chemical stability, and a desirable drug-release profile. The surfactant-to-cholesterol ratio, type and concentration of surfactant, drug concentration, hydrophilicity of the active compound, hydration temperature, sonication time and intensity, and other processing conditions are among the major factors influencing the final properties of niosomes. Particle size, polydispersity index (PDI), and zeta potential are commonly evaluated to assess the uniformity and stability of the formulation. Appropriate adjustment of these parameters can improve drug encapsulation, regulate drug release, and enhance overall drug-delivery performance. Therefore, the use of systematic approaches such as Design of Experiments (DoE) and quality-by-design strategies can be valuable for developing reproducible niosomal formulations with improved performance and potential scalability (7, 8).

Niosomal Systems for Anticancer Drug Encapsulation and Targeted Delivery

Niosomes, as nanoscale vesicular systems, have considerable role for loading of anticancer agents with different physicochemical properties. Accordingly, drugs such as doxorubicin, paclitaxel, docetaxel, methotrexate, as well as various natural anticancer compounds, can be incorporated into niosomal formulations. Drug encapsulation within niosomes can protect the therapeutic agent from premature degradation, improve its solubility and stability, and alter its biodistribution, thereby facilitating more effective delivery to tumor tissue. Moreover, the use of niosomes containing more than one therapeutic agent can enable the co-delivery of drugs or the combination of drugs with bioactive compounds and genetic materials, potentially producing synergistic therapeutic effects (9, 10).

Drug delivery by niosomes can occur through enhanced interaction of the carrier with cells, cellular uptake via endocytosis, and subsequent release of the encapsulated cargo within or around the target cells. Physicochemical characteristics including bilayer composition play important roles in the

biological fate of niosomes. Furthermore, surface modification of niosomes with targeting ligands or specific recognition molecules can facilitate more selective delivery of therapeutic agents to cancer cells. Recent reviews have demonstrated that, in addition to conventional chemotherapeutic drugs, niosomes have the potential to co-deliver drugs and nucleic acid molecules such as siRNA, miRNA, shRNA, and DNA, which may contribute to overcoming drug resistance and developing combination therapies for cancer. However, achieving optimal therapeutic performance requires careful optimization of vesicle size and uniformity, formulation stability, encapsulation efficiency, and drug-release profiles (9, 10).

Targeted Niosomal Nanocarriers for Selective Delivery to Breast Cancer Cells

Specific targeting of breast cancer cells is an important strategy in the development of advanced drug delivery systems, as it can increase drug accumulation in tumor tissue while reducing exposure of healthy tissues and, consequently, systemic toxicity. Nanostructured niosomes can be surface-modified to incorporate ligands and recognition molecules that specifically interact with receptors overexpressed on breast cancer cells. Important molecular targets in this approach include HER2, folate receptors, CD44, and EGFR. In active targeting, the ligand present on the niosomal surface interacts with a specific receptor expressed on tumor cells, thereby enhancing cellular binding and endocytosis and facilitating the intracellular delivery of the encapsulated drug. Studies have shown that modification of niosomes with folic acid or hyaluronic acid can enhance cellular uptake and selective cytotoxicity in breast cancer models (11, 12).

One promising approach involves the use of specific antibodies, such as trastuzumab, for targeting HER2-positive breast cancer cells. In one study, pH-sensitive niosomes containing palbociclib and conjugated with trastuzumab demonstrated enhanced cellular uptake and increased induction of apoptosis in HER2-overexpressing cells, while drug release was also achieved in a pH-dependent manner (2). In another study, cetuximab-conjugated niosomes were developed for EGFR targeting and the simultaneous delivery of doxorubicin and vitexin, resulting in increased cellular uptake and enhanced antitumor activity compared with non-targeted formulations. However, further evaluation of targeting specificity, safety, pharmacokinetics, and therapeutic efficacy in animal models and clinical studies remains necessary (11, 12).

Modified and Targeted Niosomes for Enhanced Drug Penetration into Tumors

Modified and targeted niosomes can improve drug delivery to tumor tissues by combining nanoscale properties with active targeting and responsiveness to the tumor microenvironment. Surface Engineering Strategies for Niosomal Nanocarriers with molecules including, hyaluronic acid, folic acid, or other specific ligands enables recognition of overexpressed receptors on tumor cells and enhances cellular uptake. The development of stimuli-responsive niosomes, such as pH-sensitive systems, can promote preferential drug release within the acidic tumor microenvironment or intracellular compartments. Furthermore, studies suggest that combining active targeting with optimized physicochemical properties of niosomes can improve the accumulation, and penetration of therapeutic cargo into tumor tissues (14).

Niosome-Based Strategies for Enhancing Therapeutic Outcomes and Minimizing Treatment-Related Toxicity in Breast Cancer

Niosomes, can improve the bioavailability, and biodistribution of anticancer drugs, thereby enhancing the therapeutic efficacy of breast cancer treatment. Drug encapsulation within niosomal structures also enables controlled release and, in some designs, stimulus-responsive release mechanisms, such as pH-sensitive drug release, which may increase the effective drug concentration at the tumor site. This feature is particularly relevant for drugs such as doxorubicin, whose systemic administration is associated with significant adverse effects. Studies have demonstrated that drug-loaded niosomes can provide improved cellular uptake and antitumor activity compared with free drugs, while targeted niosomal systems may further enhance the delivery of therapeutic agents to tumor cells (15, 16).

Application of Niosomes in the Delivery of Novel Anticancer Compounds: Gene Therapy, RNA, and Biological Agents

Niosomes, owing to their vesicular structure, surface-modification capability, and ability to encapsulate compounds with diverse physicochemical properties, have attracted considerable attention as non-viral carriers for the delivery of genetic materials and biological agents in cancer therapy. In gene therapy, niosomes can be employed to deliver DNA, plasmids, and oligonucleotides to target cells while protecting their cargo from enzymatic degradation and facilitating cellular uptake. Moreover, cationic niosomes can promote the encapsulation and delivery of nucleic acids through electrostatic interactions between the positively charged vesicle surface and negatively charged nucleic acid molecules. In the field of RNA-based therapy, molecules such as siRNA, miRNA, shRNA, and lncRNA have emerged as potential niosomal cargos. These RNA molecules can regulate genes involved in cancer cell

proliferation, survival, invasion, and drug resistance, thereby enabling the targeting of molecular pathways associated with tumor progression (17, 18).

One of the advanced applications of niosomes is the co-delivery of genetic materials with chemotherapeutic drugs or other biological agents, which may provide synergistic therapeutic effects and help overcome drug resistance. For example, cationic and PEGylated niosomes have been investigated for the delivery of miRNA-33a to MCF-7 breast cancer cells, demonstrating the potential of these systems for improving intracellular RNA delivery (2). In addition to RNA, niosomes have the potential to transport proteins and other therapeutic macromolecules, while surface modification can further enhance selective tumor targeting and intracellular delivery. Nevertheless, several challenges remain, including the instability of RNA under physiological conditions, endosomal escape, control of surface charge, potential cytotoxicity, and precise intracellular release of the therapeutic cargo. Therefore, the development of smart, targeted, and multifunctional niosomal systems may provide an important platform for integrating gene therapy, RNA therapy, and conventional chemotherapy, contributing to the development of more precise and personalized approaches to cancer treatment (17, 18).

Challenges, Limitations, and Future Perspectives of Niosomes in Breast Cancer Therapy

Despite the considerable potential of niosomes to improve the efficacy of anticancer drug delivery, their application is associated with several challenges. Physical instability, vesicle aggregation and fusion, leakage of encapsulated drugs, reduced encapsulation efficiency, and limited shelf life are among the major limitations of niosomal formulations. In addition, the type and concentration of surfactants may affect cellular toxicity and biocompatibility, while some conventional preparation methods involve organic solvents, high production costs, long processing times, and difficulties in controlling product characteristics, which may limit their scalability for industrial production. Furthermore, specific tumor targeting under in vivo conditions is more complex than in cellular models because serum proteins, immune responses, biological barriers, and variations in receptor expression can influence the biodistribution and cellular uptake of niosomes. Therefore, standardization of critical parameters, including particle size, surface charge, encapsulation efficiency, and drug-release profile, together with comprehensive evaluation of toxicity and stability, is essential for the successful translation of niosomal systems into clinical applications (19, 20).

The future of niosomes in breast cancer therapy is moving toward the development of smart, targeted, stimuli-responsive, and multifunctional delivery systems. Surface modification of niosomes with specific ligands and antibodies, the design of pH- or enzyme-responsive systems, and the co-delivery of chemotherapeutic drugs with RNA, siRNA, miRNA, or other biological agents may enable more precise treatment and help overcome therapeutic resistance. In addition, advanced manufacturing approaches such as microfluidics and the development of dry or lyophilized formulations may improve particle uniformity, stability, and scalability. However, realizing the full clinical potential of niosomes requires long-term studies addressing safety and pharmacokinetics, standardization of manufacturing processes, determination of the relationship between nanocarrier characteristics and therapeutic outcomes, and well-designed clinical trials. Ultimately, integrating niosomal drug delivery with personalized medicine and multimodal therapeutic strategies may represent an important future direction for targeted breast cancer treatment (21-25).

Conclusion and Future Perspectives

Overall, the available evidence indicates that niosomes, as non-ionic nanocarriers, have considerable potential for improving breast cancer therapy. They can overcome some limitations of conventional treatments by enhancing drug stability and bioavailability, enabling controlled drug release, facilitating targeted delivery to tumor cells, and allowing the co-delivery of chemotherapeutic agents and biological compounds. Preclinical evidence also suggests that niosomal formulations may enhance antitumor efficacy while reducing drug exposure to healthy tissues. However, several challenges—including the instability of some formulations, drug leakage, difficulties in standardization and large-scale production, potential surfactant-related toxicity, and the limited number of extensive clinical studies—remain major barriers to their clinical translation (25-28).

In the future, the development of smart, targeted, and tumor microenvironment-responsive niosomes, together with the incorporation of specific ligands, co-delivery of drugs with siRNA/miRNA and other biological agents, and integration of diagnostic and therapeutic functions, may facilitate the development of more precise and personalized approaches to breast cancer treatment (28-30). Nevertheless, realizing this potential will require well-standardized in vivo studies, comprehensive evaluation of the relationship between nanocarrier characteristics and therapeutic responses, long-term safety assessments, standardization of manufacturing processes, and well-designed clinical trials.

Table 1. Selected preclinical and clinical studies investigating probiotic-based approaches in colorectal cancer.

Study	Study Objective	Main Findings	Significance for Challenges and Future Perspectives
Sahrayi et al., 2021 (21)	Design of letrozole- and cyclophosphamide-loaded niosomes for co-delivery of the drugs and surface modification with folic acid for targeted delivery to breast cancer cells.	Folic acid-decorated niosomes exhibited pH-dependent drug release, enhanced cellular uptake, and greater cytotoxicity compared with non-targeted formulations. Increased expression of apoptosis-related genes and decreased expression of some genes associated with proliferation and invasion were also observed.	Demonstrates the potential of niosomes for combination therapy and active targeting. However, the findings are predominantly preclinical, highlighting the need for further evaluation of safety and efficacy in animal models and clinical studies.
Akbarzadeh et al., 2021 (22)	Preparation and optimization of curcumin-loaded niosomes coated with calcium alginate to improve curcumin delivery for breast cancer treatment.	The optimized formulation improved the drug-delivery properties of curcumin and enhanced its anticancer activity in in vitro studies.	Indicates that formulation optimization and polymeric coatings may help overcome stability and delivery limitations of poorly soluble compounds. However, translation of these findings to in vivo conditions remains challenging.
Saharkhiz et al., 2023 (23)	Development of a pH-sensitive niosomal formulation for separate, co-administered, and co-loaded delivery of doxorubicin and curcumin.	Particles of approximately 200 nm were produced, with encapsulation efficiencies of approximately 77% for doxorubicin and 79% for curcumin. Co-loading of the drugs increased cell death to approximately 79%, and pH-dependent drug release was observed.	Supports the potential of multi-drug co-delivery and smart drug release within the tumor microenvironment. Nevertheless, particle size, formulation stability, and actual in vivo efficacy require further investigation.
Malathi et al., 2023 (24)	Development of cetuximab-targeted niosomes for simultaneous delivery of doxorubicin and vitexin and targeting of EGFR.	Antibody-conjugated niosomes demonstrated greater anticancer activity than non-antibody formulations, with cytotoxicity reaching approximately 63% versus 53%. Effective cellular uptake and antitumor activity were also reported in a murine breast cancer model.	Demonstrates the potential of active targeting and reduction of nonspecific drug distribution. However, the complexity of antibody conjugation and formulation quality control represents a major challenge for industrial and clinical development.
Faddah et al., 2024 (25)	Preparation and optimization of doxorubicin-loaded niosomes coated with hyaluronic acid for targeted delivery to breast cancer cells.	Niosome size increased from approximately 120 to 183 nm following hyaluronic acid coating. Doxorubicin encapsulation efficiency was approximately 94.1%, with sustained and prolonged drug release for up to 48 h. The targeted formulation showed greater activity against MCF-7 cells than against CD44-negative cells.	Demonstrates that targeted coating, improved stability, and controlled drug release can enhance niosomal performance. However, long-term stability, manufacturing scalability, and confirmation of safety in in vivo and clinical studies remain essential.

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Declarations

Competing Interest

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