



A Comprehensive Review On Milk Vesicle-And Microbe-Inspired Platforms For Next-Generation Drug Delivery

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Abstract: There is a lot of interest in nature-inspired nanocarriers because of the increasing need for effective and biocompatible medication delivery systems. Milk-derived extracellular vesicles (mEVs) and microbe-inspired platforms are two new bioinspired approaches that have shown great promise for therapeutic delivery. Because of their intrinsic stability, biocompatibility, and capacity to encapsulate a wide variety of bioactive compounds, mEVs are desirable options for transdermal, intravenous, and oral delivery. Their low immunogenicity and natural origin make them even more suitable for clinical translation. In parallel, biological processes like adhesion, motility, and molecular recognition are used by microbe-inspired microneedle arrays and nanosystems to enhance tissue targeting and regulated drug release. By imitating microbial efficiency, these technologies can get beyond physiological barriers and provide minimally invasive site-specific delivery. The basic characteristics, design ideas, and most recent developments of delivery systems based on milk vesicles and microbes are thoroughly examined in this paper. Their manufacturing processes, modes of action, therapeutic uses in cardiovascular disorders, cancer, and regenerative medicine, as well as the difficulties with scalability, safety, and regulatory approval, are highlighted. Combining these bioinspired strategies is a possible first step towards patient-specific, next-generation treatments. Future advancements are anticipated to concentrate on intelligent delivery systems and hybrid micro-nano architectures that integrate manufactured and natural elements for improved clinical efficacy.

Index terms- Milk-derived extracellular vesicles, microneedles, microbial-inspired nanocarriers, nanotherapeutics, bioinspired drug delivery.

1. INTRODUCTION

One of the ongoing challenges in contemporary therapeutics is the creation of focused, safe, and efficient drug delivery methods [1]. Traditional drug delivery methods frequently have serious drawbacks, such as low bioavailability, quick systemic clearance, poor solubility, and restricted site-specific targeting ability [2]. These flaws usually lead to more adverse effects and less than ideal treatment results [3]. Furthermore, biological hurdles including immunological recognition, enzymatic breakdown, and ineffective tissue penetration make it difficult for many therapeutic agents—especially proteins, nucleic acids, and hydrophobic medications—to be delivered effectively [4]. As a result, more attention is being paid to creating novel carrier systems that may overcome these physiological obstacles while preserving stability and safety during transportation [5].

Bioengineered and nature-inspired nanocarriers have become a potential area of study in medicine delivery in recent years [6]. In order to provide enhanced biocompatibility, targeted delivery, and controlled drug release, these carriers leverage the inherent mechanisms of natural components, drawing inspiration from biological systems [7]. Exosomes, liposomes, extracellular vesicles, and cell membrane-coated nanoparticles are examples of bioinspired nanocarriers that have shown improved stability and decreased

immunogenicity when compared to synthetic nanoparticles [8]. Among these, microbe-inspired platforms and milk-derived extracellular vesicles (mEVs) have drawn more interest because of their distinct biological traits, structural variety, and translational potential.

Mammary epithelial cells spontaneously generate milk-derived extracellular vesicles, which are vital for biomolecule transport and intercellular communication [9]. They are naturally made to safely carry bioactive compounds throughout biological systems and contain a complex mixture of proteins, lipids, and nucleic acids [10]. Because of their non-toxic nature, oral stability, and biocompatibility, mEVs are excellent choices for creating patient-friendly and sustainable medication delivery systems [11]. Their therapeutic potential is further increased by their capacity to penetrate cellular barriers and shield encapsulated compounds from deterioration [12]. Recent studies have shown that mEVs are a versatile natural nanocarrier system that can be effectively used to carry anti-inflammatory, anticancer, and small interfering RNA (siRNA) drugs [13].

Innovative medication delivery platforms have been developed in tandem with advancements in mEV-based systems, motivated by the structures and mechanisms of microorganisms [14]. In order to improve the effectiveness of medication administration, designed nanocarriers can imitate the complex host cell recognition, intracellular transport and penetration methods of microorganisms like bacteria and viruses [15]. To mimic microbial adhesion, movement, and communication, microbial membrane-coated nanoparticles and microneedle arrays modelled after microorganisms have been created [16]. By achieving site-specific and stimuli-responsive drug release, these devices minimise off-target effects and allow for accurate dosage management [17]. Furthermore, by fusing mechanical accuracy with biological activity, microbe-inspired microneedle systems offer a minimally intrusive method of transdermal and localised distribution.

A promising paradigm for next-generation therapies is the combination of drug delivery methods inspired by microbes and milk vesicles [18]. These bioinspired systems combine the accuracy and adaptability of nanotechnology with the safety and adaptability of natural materials. However, issues with stability, purity, large-scale production, and regulatory approval still need to be resolved [19].

The goal of this analysis is to give a thorough summary of the most recent advancements in drug delivery systems inspired by microbes and milk vesicles [20]. It talks about their history, physicochemical characteristics, design approaches, modes of action, and many medical uses [21]. This study also discusses current obstacles and potential solutions for bringing these cutting-edge technologies from lab research to clinical settings, which will ultimately help to develop precision and personalised medicine [22].

2. MECHANISTIC INSIGHTS

Cellular uptake and intracellular trafficking

Microbe-inspired nanocarriers and milk-derived extracellular vesicles (mEVs) mainly enter cells by endocytosis routes such as macropinocytosis, caveolin-dependent, or clathrin-mediated processes. They improve intracellular medication bioavailability and targeted action by releasing therapeutic cargo into the cytoplasm or nucleus after being internalised and passing through early and late endosomes [23].

Interaction with biological membranes

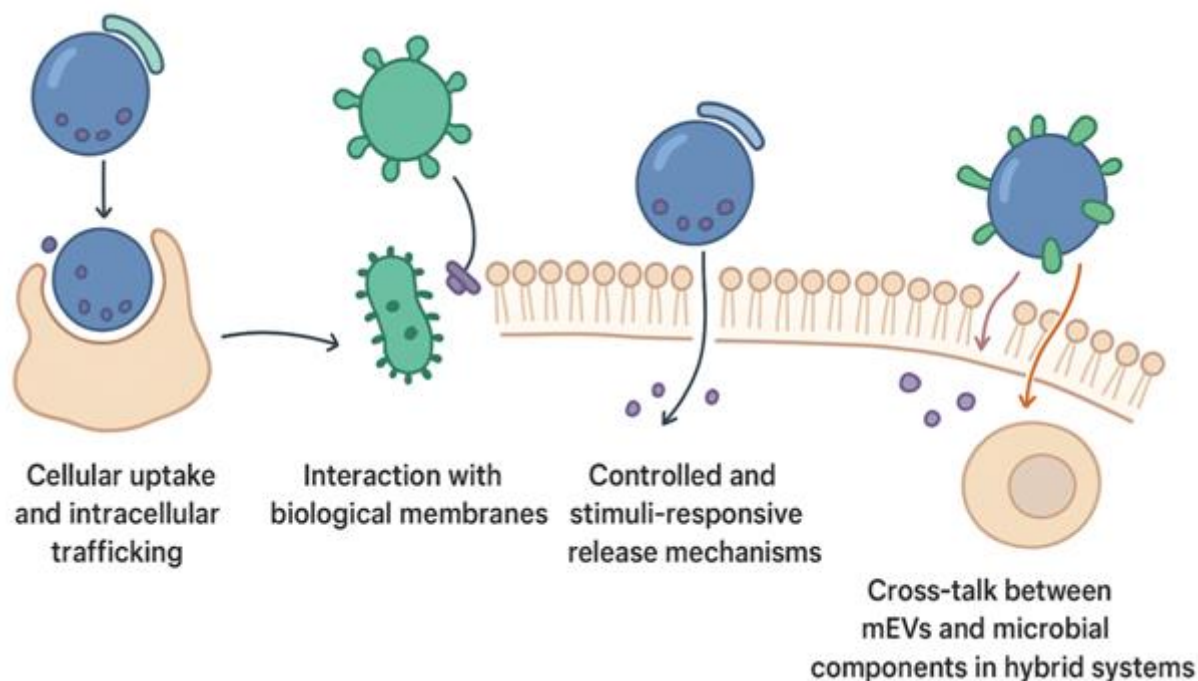
By means of lipids, surface proteins, and adhesion molecules, mEVs and microbial nanocarriers engage in dynamic interactions with cell membranes [24]. These biomimetic interactions promote internalisation or fusion and enhance receptor-mediated recognition. While lipid content affects fusion efficiency and membrane fluidity during drug transport, the presence of membrane-bound ligands guarantees specificity [25].

Controlled and stimuli-responsive release mechanisms

Enzyme-, pH-, or temperature-responsive mechanisms that allow for site-specific and regulated medication release are frequently incorporated into bioinspired systems [26]. While microbe-derived systems use external triggers to initiate therapeutic release, lowering systemic toxicity and improving the spatiotemporal accuracy of drug action, mEVs' inherent lipid and protein composition offers environmental sensitivity [27].

Cross-talk between mEVs and microbial components in hybrid systems

Dual-targeting and enhanced stability are made possible by the synergistic behaviour of hybrid platforms that combine mEVs with microbial nanostructures [28]. To improve tissue specificity, mEVs can mimic microbial adhesion characteristics or encapsulate microbial peptides. For sophisticated, multipurpose treatment approaches, this interaction facilitates effective cell communication, immunological regulation, and co-delivery of therapeutic biomolecules [29].



Mechanistic view of milk vesicle- and microbe-inspired nanocarriers in drug delivery [11]

3. THERAPEUTIC APPLICATIONS AND CASE STUDIES

Application in Cardiovascular Diseases (e.g., Atherosclerosis)

Atherosclerosis and other cardiovascular disorders may be treated with bioinspired nanocarriers, including microbial-based platforms and milk-derived extracellular vesicles (mEVs). By directly delivering antioxidant or anti-inflammatory chemicals to endothelial cells, mEVs can improve vascular healing and lessen the production of plaque [30]. By using ligand-receptor interactions unique to inflammatory tissues, microbe-mimetic nanoparticles improve targeting even more. Research indicates that these carriers enhance endothelium regeneration, inhibit macrophage activation, and improve lipid metabolism. They are excellent candidates for focused and prolonged cardiovascular therapy because of their inherent biocompatibility and capacity to penetrate biological barriers, which may lessen systemic side effects and enhance long-term patient results [31].

Cancer Nanotherapy

Drug delivery systems inspired by milk vesicles and microbes provide innovative methods for cancer treatment by releasing drugs in a targeted and regulated manner [32]. To ensure selective accumulation within tumour microenvironments, mEVs can enclose immunomodulators, chemotherapeutic drugs, or small interfering RNA (siRNA). Their inherent lipid makeup reduces immunological clearance while increasing cellular absorption. Deep tumour infiltration is made possible by microbe-inspired nanoparticles, which imitate microbial adherence and penetration. Drug stability and tumour selectivity are improved by hybrid systems that include mEVs and microbial components. Their potential in precision oncology is highlighted by preclinical studies that show notable improvements in tumour regression, less toxicity, and increased immune activation [33].

Vaccination and Immune Modulation

Bioinspired nanocarriers are becoming more and more popular as platforms for immunotherapy and vaccines [34]. Strong humoral and cellular immune responses can be elicited by mEVs presenting antigens and immune-stimulating chemicals. They are appropriate for oral or mucosal vaccine administration due to their intrinsic stability and low immunogenicity. In order to improve immune recognition and memory, microbe-inspired nanoparticles that incorporate bacterial or viral surface motifs can imitate pathogen-associated molecular patterns (PAMPs). Long-lasting immune protection is made possible by these systems, which enable regulated antigen release and adjuvant co-delivery. These platforms offer safe, adaptable, and incredibly effective substitutes for conventional vaccination techniques, representing a next-generation approach to vaccine development [35].

Regenerative Medicine and Wound Healing

Microbial-inspired systems and mEVs speed up tissue repair and reduce inflammation in regenerative medicine. Growth factors, lipids, and nucleic acids found in mEVs made from human or bovine milk promote angiogenesis, collagen synthesis, and fibroblast proliferation [36]. In order to promote quicker healing and less scarring, microbe-based microneedle systems improve the local delivery of these vesicles

or bioactive compounds to wound sites. Additionally, extracellular matrix components can be mimicked by microbially inspired nanostructures, enhancing cell adhesion and differentiation. By coordinating immune regulation and tissue rebuilding, their combined use improves regeneration results and offers a potent bioinspired approach for tissue engineering applications and chronic wound treatment [37].

4. CHALLENGES AND LIMITATIONS

Standardization and Large-Scale Production

One significant challenge is increasing the production of natural vesicles, such as extracellular vesicles or exosomes[38]. Inconsistent yields and characteristics result from variations in cell sources, culture conditions, and isolation methods. For large-scale production, standardising procedures is essential to guaranteeing consistency in vesicle size, content, and functionality. Furthermore, existing techniques like as size-exclusion chromatography and ultracentrifugation are labour-intensive and difficult to modify for industrial manufacturing. Translating vesicle-based treatments into clinical and commercial applications requires the development of reliable, repeatable, and economical production techniques [39].

Purity and Reproducibility of Natural Vesicles

Because proteins, lipoproteins, and other cellular detritus can co-isolate, it can be difficult to achieve high purity in natural vesicle preparations [40]. The content and bioactivity of vesicles can be greatly impacted by slight changes in isolation procedures. Reproducibility is complicated by this heterogeneity, which makes it challenging to duplicate therapeutic benefits or compare results from different trials. Furthermore, the efficacy and safety of vesicles made from various cell types or batches may be impacted by the diverse molecular cargo they contain. To guarantee constant quality, isolation, characterisation, and storage procedures must be optimised. For clinical and regulatory approval, repeatability must also be confirmed using analytical methods for accurate vesicle profiling[41].

Immunogenicity and Biosafety

Depending on their biological origin and surface indicators, vesicles can elicit immunological responses even though they are natural carriers [42]. Tumor-derived or allogeneic vesicles may cause off-target effects, inflammation, or unexpected immunogenicity. Furthermore, biosafety issues arise from possible contamination with pathogens or leftover biological components. Because of the incomplete understanding of the long-term effects of repeated treatment, a thorough preclinical evaluation is necessary. Techniques to lessen immunogenicity are being researched, including vesicle engineering and the use of autologous sources. Clinical translation depends on ensuring biosafety, which calls for strict quality control, sterility testing, and a careful evaluation of any potential negative effects [43].

Regulatory and Translational Barriers

Complex regulatory obstacles stand in the way of vesicle-based medicines' clinical translation [44]. Prior to approval, regulatory bodies want precise characterisation, safety, and efficacy data; yet, standardisation is made more difficult by the variability of natural vesicles. Guidelines for vesicle therapies are still developing, and manufacturing under Good Manufacturing Practices (GMP) is challenging. Commercialisation is made more difficult by factors including cost-effectiveness, scalability, and intellectual property. Strong proof of safety, bioactivity, and reproducibility is required to move preclinical results into human trials. To provide clear standards and hasten the safe, effective transition of vesicle-based technologies into clinical practice, cooperation between researchers, industry, and regulatory agencies is crucial [45].

5. FUTURE PERSPECTIVES

Integration of mEVs with Synthetic and Microbial Nanocarriers

In order to improve transport effectiveness and functional variety, future techniques are probably going to combine natural microvesicles (mEVs) with synthetic nanoparticles or microbial-derived carriers [46]. Hybrid systems can combine controllable qualities from synthetic materials, including controlled release or improved stability, with the targeting capability and biocompatibility of mEVs. Microbial carriers could offer scalable production or new bioactive functions. Current restrictions in tissue specificity, biodistribution, and cargo loading may be resolved by such integration. To fully utilise these combinatorial systems' potential in therapeutic and diagnostic applications, safety, immunogenicity, and efficacy must be carefully balanced throughout optimization [47].

Smart Hybrid Bioinspired Systems

The goal of current research is to create intelligent hybrid bioinspired systems that react to particular physiological stimuli, such as temperature, pH, or enzymes [48]. The precise spatiotemporal delivery of medicines can be achieved by these systems by simulating normal cellular communication and transport pathways. Enhanced therapeutic results, better targeting, and programmable release are made possible by combining mEVs with responsive polymers, lipids, or peptides. Real-time illness condition monitoring may be made possible by the integration of sensing and diagnostic capabilities in such systems. These developments hold promise for bridging the gap between designed nanotechnology and natural vesicle function, providing sophisticated therapeutic interventions and personalised medicine solutions [49].

AI-Driven Design and Optimization of Bio-Nanoplatfoms

Machine learning and artificial intelligence (AI) have the potential to completely transform bio-nanoplatfom design and optimization [50]. AI can forecast the best designs for certain therapeutic objectives by examining vast datasets on vesicle composition, cargo interactions, and delivery results. It can reduce experimental trial-and-error by streamlining the selection of cell sources, surface changes, and loading tactics. Additionally, AI-driven modelling may predict biodistribution and immunogenicity, speeding up preclinical development. In the end, this computational method speeds up clinical translation by improving reproducibility, efficiency, and scalability while offering a potent tool for developing next-generation nanocarriers with accurate targeting, enhanced bioavailability, and few off-target effects [51].

Potential for Clinical Translation and Commercialization

The resolution of present manufacturing, regulatory, and scaling issues is essential for the clinical translation of mEV-based systems in the future [52]. Reliability and safety will increase with developments in large-scale production, purification, and standardisation. AI-driven optimisation and integration with hybrid systems improve effectiveness and shorten development time. A new class of treatments for cancer, neurological illnesses, and regenerative medicine may result from successful translation. Cost-effective manufacturing, regulatory approval, and the proof of a definite clinical benefit are all necessary for commercial viability. mEVs have the potential to become commercially available bio-nanoplatfoms that can revolutionise personalised medicine and provide creative answers to unmet clinical requirements with sustained interdisciplinary cooperation.

SUMMARY OF KEY INSIGHTS

A new area in bioinspired drug delivery is represented by milk-derived extracellular vesicles (mEVs) and microbe-inspired nanocarriers, which combine superior therapeutic effectiveness with inherent biocompatibility. Therapeutic cargo is stabilised and protected by mEVs, which are released by mammary epithelial cells and naturally encapsulate lipids, proteins, and nucleic acids. They are very appealing for clinical translation because of their low immunogenicity, capacity to pass through biological barriers, and suitability for oral, intravenous, and transdermal delivery. These vesicles have shown targeted administration, improved bioavailability, and decreased systemic toxicity in cancer treatment, cardiovascular disease management, immunological modulation, and regenerative medicine [53].

In order to get past physiological barriers and enable precise tissue targeting, microbe-inspired platforms imitate bacterial or viral tactics including adhesion, motility, and molecular recognition. This strategy is demonstrated by microneedle arrays and microbial membrane-coated nanoparticles, which offer site-specific, regulated, and less invasive drug release. By combining mEVs with synthetic or microbial components, hybrid systems allow for programmed release, enhanced stability, and dual-targeting, further expanding therapeutic possibilities. The potential of these bio-nanoplatfoms for precision medicine is further supported by mechanistic investigations that show effective cellular absorption via endocytosis, dynamic interactions with membranes, and stimuli-responsive cargo release [54].

Large-scale production, batch-to-batch reproducibility, purity, immunogenicity, and regulatory obstacles are some of the issues that still exist despite their potential [55]. To guarantee clinical viability, standardised production procedures, strong characterisation methods, and exacting biosafety assessments are necessary. Future directions emphasise the creation of modular micro-nano architectures that can be customised for each patient, AI-driven design and optimisation, and intelligent hybrid bioinspired systems. All of these observations highlight the revolutionary potential of mEVs and microbe-inspired nanocarriers as next-generation drug delivery systems, providing secure, effective, and clinically applicable solutions that combine state-of-the-art nanotechnology and natural biomimicry [56].

CONCLUSION

Microbe-inspired nanocarriers and milk-derived extracellular vesicles (mEVs) are revolutionary approaches to next-generation medication delivery. Their intrinsic biocompatibility, stability, and low immunogenicity are attributed to their natural origin, and their ability to encapsulate a variety of bioactive compounds makes oral, intravenous, and transdermal administration possible. Microbe-inspired platforms use motility, biomimetic adhesion, and molecular recognition to further improve tissue targeting and controlled release. The promise of hybrid systems that combine mEVs with synthetic or microbial components is highlighted by mechanistic insights that demonstrate effective cellular uptake, membrane contacts, and stimuli-responsive cargo release. With their accuracy, effectiveness, and decreased systemic toxicity, these approaches have shown therapeutic promise in immunomodulation, cardiovascular disease, cancer, and regenerative medicine. Large-scale production, reproducibility, purity, biosafety, and regulatory approval continue to be obstacles despite their benefits. For clinical translation, standardisation and reliable characterisation techniques are essential. In the future, it is anticipated that AI-driven design, smart bioinspired systems, and hybrid micro-nano architectures will maximise patient-specific customisation, targeting, and delivery efficiency. Platforms inspired by milk vesicles and microbes have a great deal of promise to develop into clinically feasible, commercially scalable, and influential instruments in customised nanotherapeutics, pushing the boundaries of secure and efficient drug delivery through interdisciplinary cooperation and technological innovation.

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