Adibkia and Mahmoudi Gharehbaba, ***BioImpacts.*** 2026;16:33099
doi: 10.34172/bi.33099
https://bi.tbzmed.ac.ir/

Exosomes: Redefining intercellular communication and the future of translational medicine

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Article Info

Article Type:
Editorial

Article History:
Received: 2 Nov. 2025
Revised: 15 Nov. 2025
Accepted: 17 Nov. 2025
ePublished: 5 Jan. 2026

Abstract

Exosomes are promising extracellular vesicles for diagnostics, drug delivery, and regenerative medicine. While we have made significant strides in understanding exosomes biogenesis and cargo variability, the translation of exosome-based methods into clinical applications remains limited by challenges in manufacturing, standardization, and regulatory requirements. This editorial attempts to summarize the diverse field of exosome research including advances in isolation technologies and methodologies, omics characterization, and emerging bioengineering strategies that are elevating profile of exosomes as biomaterials for biomedical applications. We propose that exosomes are not just by-products of biological processes, but active information carriers with exceptional therapeutic potential. Therefore, the advancement of exosome methodologies in practice will ultimately alter the ways clinicians will evaluate diagnostic and therapeutic measures. We anticipate that the coming decades will establish a new, integrated framework for exosome science, one that harmonizes innovation, ethics, and cross-disciplinary collaboration to translate the promise of exosomes into tangible clinical reality.

Keywords: Exosomes, Extracellular vesicles, Nanomedicine, Drug delivery, Precision medicine, Translational biotechnology

Exosomes have long been a subject of intense interest in the study of intercellular communication, recognized as exceptional carriers of molecular information. Research in this field is motivated by their extraordinary capacity to serve as natural biological carriers, which fundamentally link basic cellular mechanisms to translational applications. Exosomes represent a unique convergence of molecular biology and nanotechnology, forming a paradigm in which natural systems can inform novel therapeutic and diagnostic strategies. Exosomes reflect the physiological and pathological state of their parent cells, making them valuable as diagnostic biomarkers and delivery vehicles for precision medicine. Studying exosomes provides key insights into cellular communication and disease mechanisms.

Exosomes, a category of Extracellular Vesicles, ranging from 25–200 nm, have witnessed an increasing number of citations, well-known for their ever-expanding importance in governing cell-to-cell communication.[1] Exosomes, produced from multivesicular bodies, contain diverse proteins, lipids, and nucleic acids that reflect the properties of their cells of origin.[2,3] This naturally acquired biomimicry leads them to serve as advantageous instruments for diagnosis and therapy, thereby achieving a paradigm shift in nanomedicines.[4]

Despite such potential, there are several challenges that the field currently faces. The absence of standardized procedures for isolations and characterization affects reproducibility and translation.[4] Further, concerns related to scalability, heterogeneity, and regulatory uncertainties are obstacles for translation from bench to bedside.[5]

The purpose of this editorial is to provide a broad analytical overview of exosome science, examining its current status, emerging innovations, and translational outlook. By integrating insights from cellular biology, nanotechnology, and clinical research, this piece aims to highlight how exosomes could redefine the trajectory of precision medicine.

The exosome research landscape has changed from basic biology to translational innovation, spanning oncology, neurology, immunology, and regenerative medicine.[6,7] As biomarkers, exosomal molecular signatures mirror disease progression in cancer and neurodegenerative disorders.[8] Therapeutically, they can be engineered to deliver RNA or drugs, offering targeted delivery with superior biocompatibility to synthetic nanoparticles.[9]

Significant bottlenecks persist, however. Isolating pure exosome populations is technically demanding, with methods like ultracentrifugation posing trade-offs between

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yield and purity.[10] Reproducibility remains a major barrier, prompting international efforts to establish minimal experimental standards.[11] Large-scale biomanufacturing and regulatory frameworks for exosomes as biologics are also still under development. In addition, large-scale exosome production faces challenges such as limited production speed, instability of cargo during processing and storage, and potential immunological safety concerns. Addressing these limitations is essential for developing reliable and clinically viable exosome-based therapies.

Exosomes can provide variable or incomplete information, as their contents depend on cellular conditions and isolation methods. Recognizing this limitation is essential when interpreting their diagnostic or therapeutic potential.

Recent advances are reshaping the field. AI-assisted analytics and single-vesicle profiling enable more precise characterization of exosome heterogeneity.[12] Bioengineering approaches, including surface modification and the formation of exosome-mimetic nanovesicles, enhance delivery specificity and offer scalable alternatives.[13-15]

In diagnostics, the convergence of microfluidics and exosome analysis is enabling rapid, point-of-care disease monitoring.[16] These breakthroughs suggest a paradigm shift from passive observation to the active manipulation of exosomes for therapeutic gain.[17]

Recent clinical trials highlight the growing therapeutic potential of exosome-based treatments. For instance, trial NCT05228899 is evaluating Amniotic fluid (AF)-derived exosomes (Zofin) for intravenous use in COVID-19 therapy, while NCT04202770 investigates a combined approach using focused ultrasound and AF exosomes for treating refractory depression, anxiety, and neurodegenerative dementia. In regenerative medicine, NCT04134676 demonstrated promising results using Wharton's Jelly mesenchymal stem cell (WJMSC)–derived secretomes and exosomes to promote chronic ulcer healing, and NCT05413148 is currently assessing the efficacy of WJ-derived exosomes in retinitis pigmentosa. These studies collectively emphasize the broad clinical applicability of exosome-based therapeutics across diverse medical conditions.

In the authors' opinion, exosomes are one of the coolest communication systems in biology, tiny messengers that capture the amazing complexity of human physiology and disease. They are a natural link between the fields of cellular biology and nanotechnology and provide inspiration for nature-based engineering. However, in order to successfully translate these new potential applications into practice, key areas of emphasis must first be focused upon.

Most importantly, this field needs standards and quality control assurance. Without defined and reproducible processes, even the greatest findings come into question and lose their clinical significance. The establishment of shared reference materials, standardized testing procedures and clear reporting practices will help us ensure the research findings remain unconflated.

Collaboration across scientific disciplines is essential for advancing exosome-based therapeutics. Exosome research spans cell biology, bioengineering, data science, and clinical medicine, requiring joint efforts to address challenges in regulation, biogenesis, cargo modification, and therapeutic application.

Equally important is the scalability of exosome-based therapies. To reach patients, exosomes must be produced in automated, closed-system bioreactors and purified under GMP conditions. Recent advances, such as the EXODUS T-2800 system for large-scale, GMP-compliant isolation and ExoXpert's certified GMP manufacturing platform in Belgium, demonstrate progress toward industrial-scale production. Early partnerships with pharmaceutical companies will further streamline clinical approval.

The ethical aspects should not be neglected either. As exosome technology begins to cross over into genomics and personalized medicine, the international community must ensure that we have clear and fair expectations regarding consent, data privacy, and overall access to information and resources. The ultimate role of innovation should first and foremost be about the patients.

Exosome science is evolving from exploratory research to a true stage of translational science, poised to transform diagnostics and therapeutics. Maintaining a balance between innovation and accountability will enable the biomedical community to fully harness the potential of these natural nanocarriers.

In the next ten years, we can anticipate exosome science will most likely have advanced into a recognized and commercially sustainable field. Important aspects of progress will be in standardized manufacturing platforms, automated analytical processes, and AI models to forecast how an exosome will behave. Close partnerships between academia, biotechnology, and regulators will be essential to establishing safety and efficacy standards.

Exosome treatment options may potentially become available soon to rival and possibly even replace traditional delivery methods utilized in gene therapy and immune modulation. The intersection of synthetic biology and extracellular vesicle research could enable the creation of "smart exosomes" capable of sensing and responding to their environment, opening new possibilities for precision treatments in cancer, neurological, and metabolic diseases.

In conclusion, exosomes stand at the forefront of biomedical innovation, bridging cellular biology and nanotechnology to advance diagnostics and therapeutics. While challenges in standardization, manufacturing, and regulation remain, sustained collaboration, ethical oversight, and responsible innovation will be essential to

Study Highlights

What is the current knowledge?

- Exosomes are recognized as natural carriers of molecular information between cells, with significant diagnostic and therapeutic potential.
- Major challenges include a lack of standardized isolation methods, manufacturing scalability, and unclear regulatory pathways.
- Their use as biomarkers and unengineered therapeutic agents is well-established in basic research.

What is new here?

- A shift from observation to active bioengineering of exosomes for enhanced drug delivery and specificity.
- Integration of AI analytics, microfluidics, and single-vesicle profiling to overcome heterogeneity and characterization hurdles.
- A proposed framework prioritizing cross-disciplinary collaboration, standardized manufacturing, and ethical oversight for clinical translation.

transforming exosomes from experimental curiosity into clinical reality.

We warmly invite researchers, clinicians, and innovators to share their latest insights, perspectives, and discoveries on exosome biology and translational applications with our journal. Together, through open scientific dialogue, we can accelerate the responsible and impactful advancement of exosome research worldwide.

Authors' Contribution
Conceptualization: Khosro Adibkia.
Supervision: Khosro Adibkia.
Writing–original draft: Adel Mahmoudi Gharehbaba.
Writing–review & editing: Khosro Adibkia.

Competing Interests
Authors have no conflict of interest to declare for this article.

Consent for Publication
Not applicable.

Data Availability Statement
Not applicable.

Ethical Approval
Not applicable.

Funding
The author declares that no funding was received for this work.

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