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Exosomes as a Next-Generation Therapeutic Platform for Spinal Cord Injury: From Mechanistic Insights to Clinical Translation

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Abstract: ***Spinal cord injury (SCI) leads to devastating neurological deficits, with its complex pathophysiology posing significant challenges for complete functional recovery. In recent years, extracellular vesicles, particularly exosomes, have emerged as a promising "cell-free" therapeutic strategy due to their crucial role in intercellular communication. This review systematically summarizes recent advances in exosome-based therapies for SCI. We first delineate the unique biological characteristics and therapeutic potential of exosomes derived from diverse sources, including mesenchymal stem cells, glial cells, and Schwann cells. We then provide an in-depth analysis of the core evidence demonstrating how exosomes, through the delivery of specific cargoes such as microRNAs, modulate multiple repair mechanisms, including neuroinflammation, apoptosis/pyroptosis, axonal regeneration, angiogenesis, and blood-spinal cord barrier integrity. Furthermore, we critically evaluate engineering strategies developed to overcome the limitations of natural exosomes, encompassing biomaterial-based delivery systems (e.g., hydrogels, scaffolds), cargo pre-modification, and synergistic interactions with traditional therapies (e.g., Chinese medicine, acupuncture). While preclinical findings are encouraging, this review also highlights significant challenges in current research regarding standardized preparation, targeting efficiency, long-term safety, and clinical translation pathways. Finally, we propose future directions involving multi-omics integration, intelligent delivery systems, and well-designed clinical trials to facilitate the transition of exosome therapies from bench to bedside.***

Keywords: Spinal cord injury, Exosomes, Extracellular vesicles, MicroRNA, Neuroregeneration, Delivery system, Cell-free therapy.

1. Introduction

Spinal cord injury (SCI) represents a devastating form of central nervous system trauma, characterized by primary mechanical damage followed by a complex secondary cascade involving neuroinflammation, oxidative stress, apoptosis, glial scar formation, and blood-spinal cord barrier disruption, ultimately leading to neuronal death and permanent functional impairment [8,15]. Current clinical interventions, including surgical decompression, pharmacological management, and physical rehabilitation, primarily aim at symptom alleviation and offer limited potential for neural regeneration and functional recovery [8].

The advent of stem cell therapy initially offered hope for SCI repair; however, its clinical translation faces substantial hurdles such as immune rejection, tumorigenic risks, ethical concerns, and poor cell survival post-transplantation [25,50]. Notably, a growing body of evidence indicates that the therapeutic benefits of stem cell transplantation are largely mediated through paracrine mechanisms rather than direct cell replacement [25,42,43]. Exosomes—lipid bilayer nanovesicles (30–150 nm in diameter) actively secreted by cells—have emerged as key mediators of this paracrine signaling and a focal point in regenerative medicine [3,25]. These vesicles carry a diverse cargo of proteins, lipids, and nucleic acids (including mRNA and miRNA), serving as "molecular messengers" that precisely modulate recipient cell physiology [2,16,20].

Compared with whole-cell therapies, exosomes offer distinct advantages, including low immunogenicity, high stability, an innate ability to cross biological barriers (e.g., the blood-brain/spinal cord barrier), and ease of storage and administration [16,25]. Consequently, exosome-based "cell-free therapy" presents a safer and more controllable paradigm for SCI repair. This review aims to comprehensively synthesize current knowledge on the mechanisms of action of exosomes from various sources in SCI treatment, advanced engineering strategies, intersections with traditional medicine, and a critical appraisal of existing limitations and future translational prospects.

2. Core Themes and Evidence Synthesis

2.1 Diverse Sources of Therapeutic Exosomes and Their Distinct Properties

Exosomes inherit a unique molecular signature from their parent cells, which dictates their therapeutic orientation.

Mesenchymal Stem Cell (MSC)-Derived Exosomes: These are the most extensively studied, sourced from bone marrow, umbilical cord, adipose tissue, and dental pulp, among others [14,25,31]. They function as "versatile modulators" with potent immunomodulatory, anti-apoptotic, and pro-regenerative capacities [25,36,39,43]. For instance, human umbilical cord MSC-derived exosomes (HUC-MSC-Exo) effectively promote microglial polarization toward the anti-inflammatory M2 phenotype, thereby attenuating neuroinflammation [6,11].

Glial Cell-Derived Exosomes: These exosomes offer insights into native neural microenvironment regulation. Microglia/Macrophage-derived exosomes play a direct role in neuroimmune modulation. While activated M1 cells may release pro-inflammatory exosomes, evidence also indicates that they can secrete vesicles with neuroprotective properties, suppressing astrocyte hyperactivation and fostering repair [7,18]. Schwann Cell-derived exosomes exhibit particular efficacy in promoting axonal regeneration, supporting neuronal survival while mitigating excessive angiogenesis and scar formation detrimental to regeneration [34,35].

Other Stem/Progenitor Cell-Derived Exosomes: Endothelial Progenitor Cell-derived small extracellular vesicles (EPCs-sEVs) demonstrate pronounced pro-angiogenic effects, providing vital nutritional support for neural repair [48]. Menstrual Blood-Derived Stem Cell exosomes, an emerging, easily accessible, and ethically non-controversial source, are also under investigation for their therapeutic potential [33].

2.2 Mechanisms of Action: A Multi-Target Repair Network Orchestrated by Exosomal Cargo

The therapeutic efficacy of exosomes is primarily attributed to their cargo, especially microRNAs (miRNAs), which regulate target gene expression, forming an intricate repair network.

Modulation of Neuroinflammation and Immune Microenvironment: This constitutes a central mechanism. Zhang Xixian [2] systematically elucidated that stem cell exosomes deliver miRNAs (e.g., miR-124, miR-146b) to regulate signaling pathways such as Toll-like receptor/nuclear factor-κB, inhibiting pro-inflammatory cytokine release (e.g., TNF-α, IL-1β, IL-6) and promoting anti-inflammatory factors (e.g., IL-10, TGF-β) [9,28,32]. A pivotal action is driving microglia/macrophage polarization from the pro-inflammatory M1 to the reparative M2 phenotype [6,11,17,32].

Inhibition of Cell Death: Exosomes protect neurons via anti-apoptotic and anti-pyroptotic pathways. Adipose MSC exosomes, through miR-29b-3p, upregulate the Bcl-2/Bax ratio to inhibit apoptosis [21]; bone marrow MSC exosomes suppress Caspase-3 activity via miR-210 [38]. Furthermore, Yang Sheng et al. [30] reviewed that MSC exosomes can inhibit NLRP3 inflammasome-mediated pyroptosis, a Gasdermin protein-dependent inflammatory cell death.

Promotion of Neuroregeneration and Remyelination: Exosomes foster axonal regeneration by upregulating growth-associated proteins (e.g., GAP-43, NF) and modulating pathways like PTEN/Akt and CREB via specific miRNAs (e.g., miR-133b, miR-216-5p) [14,31,37]. Concurrently, they enhance oligodendrocyte precursor cell differentiation and myelination, restoring neural conduction [2].

Protection of the Blood-Spinal Cord Barrier (BSCB) and Promotion of Angiogenesis: BSCB disruption exacerbates secondary injury. Studies by Zheng Mingkui and Hu Wei et al. [26,40] demonstrated that MSC exosomes protect tight junction proteins (ZO-1, Occludin) by downregulating endothelin-1 or matrix metalloproteinase-9, thereby reducing BSCB permeability and limiting infiltration of harmful agents. Moreover, exosomal pro-angiogenic factors (e.g., VEGF) and related miRNAs promote local vascularization, improving tissue perfusion [27,48].

Regulation of Cellular Metabolic Stress: Emerging evidence implicates exosomes in novel cell death pathways. Chen Shaochu et al. [4] found that hypoxia-preconditioned MSC exosomes counteract ferroptosis in chondrocytes by upregulating GPX4 and suppressing ACSL4, suggesting potential neuroprotective applications in SCI. Long Zhisheng et al. [23] showed that drug-loaded (tea polyphenol) exosomes synergistically inhibit endoplasmic reticulum stress markers ATF6 and GADD153.

2.3 Engineering Strategies: Evolving from "Natural Carriers" to "Precision Therapeutics"

Inherent limitations of natural exosomes—short half-life, poor targeting, and batch variability—necessitate engineering approaches to enhance efficacy and enable clinical translation [1,3,16,29].

Biomaterial-Based Delivery Systems: Integrating exosomes with biomaterials enables localized sustained release and structural support. Hydrogels (e.g., hyaluronic acid, chitosan-based) are favored for their biocompatibility and tunable properties, effectively prolonging exosome retention and bioactivity [1,12,47]. Three-dimensional scaffolds (polymeric or metal-organic frameworks) provide biomimetic architectures for guided tissue regeneration while serving as exosome reservoirs [3,13].

Cargo Modification and Preconditioning: Genetic engineering of parent cells to overexpress or knockdown specific miRNAs (e.g., miR-210-5p) yields exosomes with augmented functions [37,38]. Hypoxic preconditioning is a physical strategy that alters the exosomal cargo profile, enhancing anti-inflammatory and pro-survival capacities [4,14,29].

Innovative Delivery Modalities: Microneedle-based transdermal systems combine the benefits of exosomes and minimally invasive delivery, offering a promising route for pain-free, patient-compliant administration, particularly for conditions involving skin lesions or requiring chronic treatment [13].

2.4 Intersection with Traditional Medicine: Exosomes as Effector Mediators

A compelling emerging paradigm investigates whether traditional therapies exert their effects via modulation of endogenous exosomes.

Chinese Herbal Medicine Regulation: Work by Geng Jie, Xie Yan et al. [5,9] revealed that Shaoyao Gancao Decoction upregulates plasma exosomal miR-125a-5p and miR-125b-5p in SCI rats, subsequently inhibiting neuronal apoptosis (via Bax suppression) and inflammation (via IL-6/IL-16 downregulation), respectively. Wu Chengjie et al. [45] demonstrated that Jisuikang modulates the serum exosomal miR-21/126/133b cluster, inhibiting the RhoA/ROCK pathway to promote recovery.

Acupuncture Regulation: Research by Zhao Lihua [10] and Zhuo Yue, Liang Xuesong et al. [24,28] introduced the concept of "acupuncture-exosomes (Acu-exos)," providing evidence that electroacupuncture alters serum exosomal miRNA profiles. These changes correlate with exosome-mediated anti-inflammatory and neuroprotective effects, offering a novel mechanistic framework for acupuncture's systemic actions.

3. Discussion

The current body of research compellingly positions exosomes as a multifaceted therapeutic platform for SCI. However, the path to clinical application is fraught with challenges that must be rigorously addressed:

(1) Mechanistic Depth and Systems-Level Understanding: Most studies focus on single miRNA-pathway axes, overlooking the synergistic interplay among proteins, lipids, and various RNA species within exosomes. A systems biology approach utilizing proteomics, lipidomics, and multi-omics integration is essential to unravel the complex functional networks.

(2) Standardization and Manufacturing Hurdles: The lack of consensus on isolation methods (ultracentrifugation, size-exclusion chromatography, etc.), characterization standards (NTA, western blot, TEM), and quantification poses a major barrier to reproducibility and comparability across studies [14,31]. Development of scalable, reproducible, and Good Manufacturing Practice (GMP)-compliant production processes is paramount for clinical translation [14].

(3) Pharmacokinetics and Targeted Delivery: While engineering improves targeting, the in vivo biodistribution, pharmacokinetics, and long-term fate of administered exosomes remain poorly understood. Comprehensive preclinical studies are needed to define optimal dosing regimens, administration routes (intravenous, local, intrathecal), and treatment windows [36].

(4) The Clinical Translation Chasm: To date, no exosome-based therapy for SCI has progressed to pivotal clinical trials [1,12,14]. Bridging this gap requires close collaboration among researchers, industry, and regulatory agencies (e.g., FDA, EMA, NMPA) to establish appropriate safety and efficacy evaluation frameworks for these complex biological products.

Future directions should prioritize: (1) Fostering interdisciplinary convergence among biologists, materials scientists, and clinicians to develop next-generation smart exosome delivery platforms; (2) Leveraging artificial intelligence and computational tools to decipher cargo-function relationships and enable rational exosome design; and (3) Initiating carefully designed early-phase clinical trials to establish safety profiles and identify predictive biomarkers, paving the way for definitive efficacy studies.

4. Conclusion

Exosomes, harnessing innate intercellular communication pathways and offering extensive engineerability, represent a transformative platform technology for SCI treatment. Robust preclinical evidence confirms their ability to simultaneously engage multiple pathological cascades of SCI through the delivery of sophisticated molecular cargo, presenting a therapeutic advantage over single-target agents. Notwithstanding the significant obstacles in standardization, scalable manufacturing, and clinical translation, continued mechanistic elucidation coupled with technological innovation holds great promise. Within the next decade, concerted efforts may successfully translate exosome-based therapies from preclinical promise to clinical reality, ultimately offering new hope for patients suffering from spinal cord injury.

5. Glossary

Exosomes: A subtype of extracellular vesicles (30-150 nm in diameter) of endosomal origin, characterized by a lipid bilayer membrane and carrying proteins, nucleic acids, and lipids. They function as key mediators of intercellular communication.

microRNA (miRNA): Small non-coding RNA molecules (~22 nucleotides) that post-transcriptionally regulate gene expression by binding to target messenger RNAs (mRNAs), leading to translational repression or mRNA degradation. They are pivotal functional components of exosomal cargo.

Blood-Spinal Cord Barrier (BSCB): A highly selective diffusion barrier, analogous to the blood-brain barrier, that separates the circulating blood from the spinal cord parenchyma. It is essential for maintaining neural homeostasis.

Microglial Polarization: The process by which microglia, the resident immune cells of the CNS, adopt distinct functional phenotypes (e.g., pro-inflammatory M1 or anti-inflammatory/ reparative M2) in response to microenvironmental cues.

Engineered Exosomes: Exosomes that have been intentionally modified through genetic, chemical, or physical methods (e.g., parental cell transfection, membrane modification, drug loading) to enhance their targeting specificity, cargo loading, stability, or therapeutic potency.

Cell-free Therapy: A therapeutic strategy that utilizes biological agents secreted by or derived from cells (such as exosomes, cytokines, or conditioned medium) instead of administering whole live cells, thereby avoiding risks associated with cell transplantation.

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