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Autism and Mesenchymal Stem Cells

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ABSTRACT

Autism Spectrum Disorder (ASD) is a multifactorial neurodevelopmental condition. ASD is characterized by impairments in social communication and repetitive behaviors. Increasing recognition of neurogenetic, immune, and metabolic underpinnings have spurned a plethora of therapeutic strategies. Despite advances in early behavioral interventions and symptomatic pharmacotherapy, no disease-modifying treatments exist. Stem cell therapy has emerged as an experimental approach, targeting the physiological and neurobiological constructs of ASD through mechanisms such as immunomodulation, neuroprotection, and metabolic support. The potent anti-inflammatory and neurotrophic effects of mesenchymal stem cells (MSCs) provide a novel strategy to address the pathophysiological underpinnings. MSCs have demonstrated safety and early efficacy in preclinical models and small clinical studies. Hematopoietic stem cells (HSCs) have also been investigated, particularly in subtypes of ASD associated with immune dysfunction. Preliminary trials suggest that both autologous and allogeneic stem cell infusions may improve core and associated ASD symptoms, though findings remain equivocal due to heterogeneity in patient populations, treatment protocols, and outcome measures. Meta-analyses suggest potential clinical benefit and minimal serious adverse events; however, the evidence base is limited by small sample sizes, short follow-up, and lack of standardized biomarkers or patient stratification strategies. Age, body size, and inflammatory status may also influence response, underscoring the need for personalized approaches. This review synthesizes the current preclinical and clinical literature on stem cell therapies in ASD, with emphasis on mechanistic rationale, treatment heterogeneity, and future directions for research. Larger, controlled trials are needed to clarify optimal stem cell sources, dosing regimens, and responder phenotypes, and to determine whether stem cell-based interventions can achieve durable functional improvements in ASD.

Keywords

Autism, Transplantation, Stem Cell.

Introduction

Autism Spectrum Disorder (ASD) is a complex neurodevelopmental condition characterized by persistent challenges in social

communication and interaction, alongside restricted, repetitive patterns of behavior, interests, or activities [1]. Symptoms typically emerge in early childhood and vary widely in severity and presentation, hence the term "spectrum." ASD affects approximately 1 in 36 children in the U.S., with a higher prevalence in males. The variation in ASD arises in part from its multifactorial origins, which contribute to its classification as a neurogenetic condition with gastrointestinal, immune, and metabolic components that begin developing in utero [2]. Hundreds of genes have been implicated, many involved in brain development, synaptic function, or chromatin remodeling. Environmental risk factors under investigation include prenatal exposures (e.g., infections, certain medications), parental age, and complications during pregnancy or birth [3]. Neurobiologically, ASD is associated with atypical brain connectivity, early brain overgrowth, and alterations in excitatory-inhibitory balance [4]. Functional and structural imaging studies have revealed differences in networks related to social cognition and sensory processing. Behaviorally, individuals with ASD may display sensory sensitivities, communication challenges, and difficulties with theory of mind and executive function [1]. Diagnosis is clinical, based on standardized behavioral assessments (e.g., ADOS-2), typically by age 2–4 [5]. There are no definitive biological markers, although research continues into genetic, metabolic, and neuroimaging-based tools [6]. Early behavioral interventions (e.g., Applied Behavior Analysis) can improve outcomes, particularly when started early. Pharmacologic treatments address co-occurring symptoms such as anxiety, irritability, or ADHD. Ongoing research aims to refine diagnostics, personalize interventions, and better understand the neurobiological underpinnings of the spectrum.

Stem cell therapy is an emerging, experimental approach for treating ASD [7]. Mechanistic targets predominately include modulating neuroinflammation and reducing pro-inflammatory cytokines; enhancing synaptic plasticity and neurogenesis; improving microglial function and blood-brain barrier integrity; and/or supporting mitochondrial function and reducing oxidative stress.

Mesenchymal stem/stromal cells (MSCs), derived from bone marrow, umbilical cord, or adipose tissue; known for their immunomodulatory and anti-inflammatory properties [8] have been the major focus of recent studies. The use of Wharton's Jelly-derived mesenchymal stem cells (WJ-MSCs) in treating ASD marks a significant advancement in therapeutic approaches, introducing a new method aimed at the disorder's core neurobiological issues. Through their ability to reduce neuroinflammation and support neuronal repair and regeneration, WJ-MSCs may help ease ASD symptoms and enhance overall functioning in individuals with the condition [9]. However, hematopoietic stem cells (HSCs), typically used in immune-resetting therapies, have also been investigated. While the therapy appears to be generally well tolerated, its long-term safety and efficacy are not yet established. Importantly, stem cell therapy for ASD is not FDA-approved and remains investigational, with further research needed to validate its clinical utility, identify suitable patient subgroups, and standardize treatment protocols. The objective of this review is to summarize the current knowledge and level of evidence for stem cell therapy as an efficacious treatment for ASD.

Biological Justification. Stem cell therapy in ASD leverages the ability to reprogram somatic cells from patients to model and potentially reshape brain architecture, offering new insights into the disorder's complex neurobiology [10]. At least three key-action mechanisms of stem cells could be useful for ASD therapy: paracrine effect (the secretome tool: cytokines, chemokines, and growth factors released by stem cells and responsible of repair/restoration of injured tissues), immunomodulatory properties affecting the immune response and metabolic dysregulation impacting hormonal feedback mechanisms [11]. By targeting the multifactorial origins of ASD including neurogenetic, immune, and metabolic dysfunctions, stem cell-based approaches aim not only to enhance understanding but also to reverse or mitigate core symptoms by restoring neural connectivity and modulating inflammation at the source.

Neurogenetic: Many forms of ASD involve alterations in genes that regulate synaptic function, neurodevelopment, and neural connectivity [12]. These disruptions can lead to abnormal neural circuit formation, impaired synaptic plasticity, and imbalanced excitatory-inhibitory signaling in the brain. Stem cells, particularly MSCs and induced pluripotent stem cells (iPSCs), have demonstrated the ability to secrete neurotrophic factors, support neuronal differentiation, and modulate immune responses [13]. In preclinical models, stem cell-derived therapies have been shown to restore synaptic integrity and reduce neuroinflammation, both of which are closely tied to genetic abnormalities in ASD. Additionally, patient-derived iPSCs allow for the *in vitro* modeling of neurogenetic defects, enabling personalized therapeutic strategies and drug screening. Collectively, these capabilities position stem cell therapy as a biologically rational approach to addressing the neurogenetic basis of ASD.

Immune: Growing evidence that chronic neuroinflammation and immune dysregulation play a key role in the pathophysiology of ASD [14]. Many individuals with ASD exhibit elevated levels of pro-inflammatory cytokines, activated microglia, and abnormal immune cell profiles, both centrally and peripherally. MSCs, possess immunomodulatory properties that suppress pro-inflammatory cytokine production, promote anti-inflammatory signaling, and regulate the activity of immune cells such as T cells, B cells, and microglia [15]. By restoring immune homeostasis, stem cell therapy may help alleviate the neuroinflammatory environment that contributes to disrupted neural connectivity and behavioral symptoms in ASD. Furthermore, stem cells can enhance blood-brain barrier integrity and reduce oxidative stress, both of which are often compromised in individuals with immune-related ASD phenotypes. This immunoregulatory capacity provides a compelling biological rationale for stem cell-based interventions in ASD subtypes marked by immune dysfunction.

Metabolic: Many individuals with ASD exhibit abnormalities in

mitochondrial function, oxidative stress regulation, and energy metabolism. These metabolic impairments can disrupt neuronal development, synaptic activity, and overall brain function. MSCs have shown the ability to modulate metabolic pathways by enhancing mitochondrial biogenesis [16], reducing reactive oxygen species (ROS), and secreting antioxidant and trophic factors that support cellular energy balance. Additionally, stem cells can restore redox homeostasis and improve the function of metabolically compromised neurons and glia [17]. In preclinical studies, MSCs have been observed to correct metabolic abnormalities and improve cognitive and behavioral outcomes. By targeting these underlying metabolic disturbances, stem cell therapy offers a biologically plausible approach to alleviating symptoms in ASD subtypes characterized by mitochondrial and bioenergetic dysfunction.

ASD is associated with key biological processes that may be modulated by MSC therapy. MSCs can be administered without prior genetic modification, adapt to local tissue environments, and generally present a low risk of tumor formation. Preliminary clinical trials and meta-analyses have demonstrated the safety and potential therapeutic benefits of MSCs in ASD and other immune-related conditions. However, important challenges remain, including understanding their long-term safety, tissue distribution, interaction with other treatments, and the duration of their anti-inflammatory effects. There is also uncertainty about the optimal timing for intervention.

Non-clinical Studies

To identify a link between cellular immune dysregulation and ASD-related behavioral deficits Haiso et al. [19] used a mouse model of autism. They found that offspring of immune-activated mothers display altered immune profiles and function, characterized by a systemic deficit in CD4(+) TCRβ(+) Foxp3(+) CD25(+) T regulatory cells, increased IL-6 and IL-17 production by CD4(+) T cells, and elevated levels of peripheral Gr-1(+) cells. In addition, hematopoietic stem cells from MIA offspring exhibit altered myeloid lineage potential and differentiation. They demonstrated immune abnormalities in MIA offspring can contribute to ASD-related behaviors.

Clinical Studies

Lv et al. [20] conducted a non-randomized open label phase I/II study to investigated the safety and efficacy of combined intrathecal and intravenous injections of human cord blood mononuclear cells (CBMNCs) and umbilical cord-derived mesenchymal stem cells (UCMSCs) in treating children with autism (n=37) divided into three groups: CBMNC group (n=14s, CBMNC transplantation and rehabilitation therapy), combination group (n=9, both CBMNC and UCMSC transplantation and rehabilitation therapy), and control group (n=14, received only rehabilitation therapy). The Childhood Autism Rating Scale (CARS), Clinical Global Impression (CGI) scale and Aberrant Behavior Checklist (ABC) were used to assess the therapeutic efficacy at baseline (pre-treatment) and following treatment. No significant safety issues related to the treatment and no observed severe adverse effects (AEs) were noted and statistically significant differences were shown on CARS, ABC scores and CGI evaluation in the two treatment groups compared to the control at 24 weeks post-treatment.

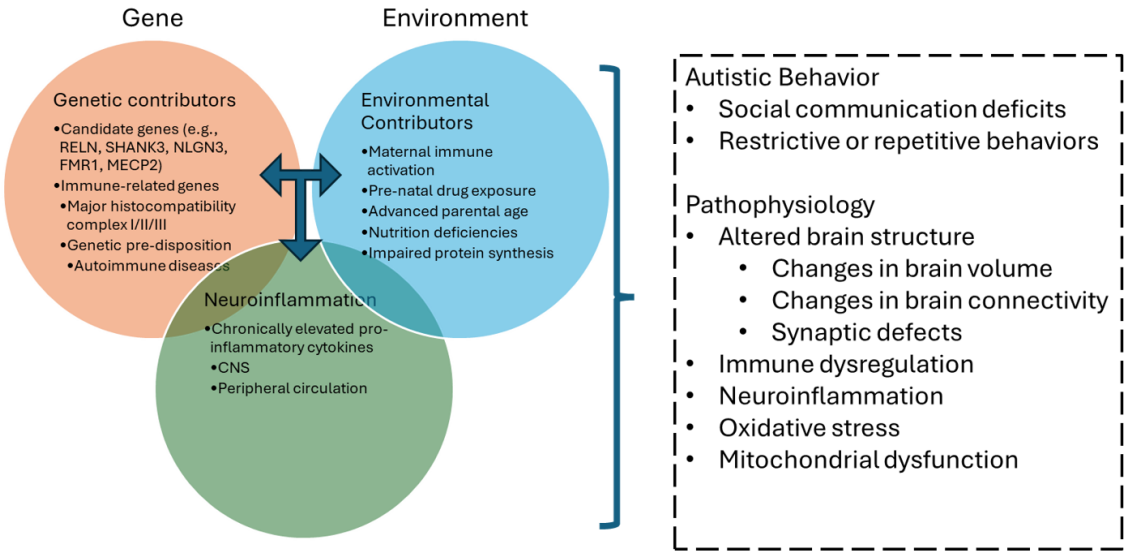

Figure 1: Proposed gene–environment interactions and neuroinflammatory mechanisms contributing to autism spectrum disorder (ASD) pathophysiology. The left panel outlines genetic contributors including candidate genes (e.g., RELN, SHANK3, NLGN3, FMR1, MECP2), epigenetic regulators, and immune-related genes (e.g., MHC class I/II/III), alongside environmental risk factors such as maternal immune activation (MIA), prenatal drug exposure (e.g., SSRIs, VPA), advanced parental age, and abnormal melatonin synthesis. These factors collectively converge on neuroimmune mechanisms involving increased production of pro-inflammatory cytokines (e.g., IL-1β, IL-6, IFN-γ, and TNF-α) both in the central nervous system (CNS) and peripheral circulation. The collective "activation" of these immune and inflammatory alterations link with ASD clinical features, including deficits in social communication and restrictive/repetitive behaviors, as well as brain dysfunctions such as abnormal total brain volume, synaptic defects, immune dysregulation, oxidative stress, and mitochondrial dysfunction. These interrelated biological processes may underlie behavioral phenotypes and physiologic comorbidities in ASD. Modified from [18].

Chez et al. [21] conducted an exploratory study to assess the safety and clinical effects of autologous umbilical cord blood (AUCB) infusion in children ages two to six years (n=29) with ASD. The children were randomized to receive AUCB or placebo. Evaluations were conducted at baseline, 12, and 24 weeks, at which time the children then received the opposite infusion and were re-evaluated at the same time points. While deemed a safe therapy, the authors reported improvement, albeit not significant in socialization, with no differences for any endpoints.

Following treatment with a single infusion of autologous cord blood in a phase I open-label trial Carpenter et al. [22] evaluated structural connectivity using diffusion tensor imaging (DTI) and deterministic tractography in the brains of two to six-year-old children (n=19) with ASD to understand whether these improvements were associated with concurrent changes in brain structural connectivity from baseline to six months. Clinical outcome measures included the Vineland Adaptive Behavior Scales-II Socialization Subscale, Expressive One-Word Picture Vocabulary Test-4, and the Clinical Global Impression-Improvement (CGI) Scale. They reported a direct association between behavioral improvements and white matter connectivity in frontal, temporal, and subcortical regions (hippocampus and basal ganglia). These regions have been previously shown to show anatomical, connectivity, and functional abnormalities in ASD. The results suggest improvements in social communication skills and a reduction in symptoms in children with ASD following treatment with autologous cord blood infusion.

Sharifzadeh et al. [23] conducted a randomized controlled trial, in children ages 5-15 years with ASD (n=32) in which the children were randomly assigned to receive either intrathecally injected autologous bone marrow mesenchymal stem cell (BMMSC) twice in four weeks plus rehabilitation therapy and risperidone (n=14) or rehabilitation therapy and risperidone (control group, n=18). Twenty-seven were male and mean age was 9.50 ± 2.14 years. There were improvements in CARS total score, GARS-II autism index, and CGI global improvement in both groups with no significant differences detected. However, the main effect for time*group interaction for CGI-severity of illness was significantly improved in the intervention group, suggesting limited clinical efficacy.

Dawson and colleagues [24] conducted a randomized, placebo-controlled, double-blind study in children with ASD, aged 2-7 years (n=180), who received a single intravenous autologous (n = 56) or allogeneic (n = 63) cord blood (CB) infusion vs placebo (n = 61). While CB infusion was safe and well tolerated there was no evidence that CB was associated with improvements in social communication (Vineland Adaptive Behavior Scales-3 [VABS-3] Socialization Domain) or symptoms (Pervasive Developmental Disorder Behavior Inventory) and vocabulary (Expressive One-Word Picture Vocabulary Test) when the overall sample was analyzed. However, a sub-analysis of children without intellectual disability (ID), revealed allogeneic, but not autologous, CB was associated with improvement in the GCI, albeit not significant. Children without ID treated with CB showed significant improvements in communication skills (VABS-3 Communication Domain), and exploratory measures including attention to toys and sustained attention (eye-tracking) and increased alpha and beta electroencephalographic power.

Thanh et al. [25] conducted an open label clinical trial to evaluate the safety and efficacy of autologous bone marrow MSC combined with educational intervention for children with ASD (n=30) who had CARS scores >37. After the first transplantation, all patients underwent 8 weeks of educational intervention based on the Early Start Denver Model. Median CARS score significantly decreased and adaptive capacity increased. Social communication, language, and daily skills significantly improved within 18 months after transplantation and repetitive behaviors and hyperactivity decreased.

Qu and colleagues [26] conducted a systematic review and meta-analysis of SCT in children with ASD. Evaluating five studies that met the inclusion criteria rehabilitation therapy was used as the reference standard. Data showed that the Childhood Autism Rating Scale (CARS) score of stem cell group was significantly lower than the control group. The Clinical Global Impression (CGI) score consolidated effect size RR = 1.01, 95%CI [0.87, 1.18], Z = 0.14 (p = 0.89), the effective rate for The Clinical Global Impression was 62% and 60% in the stem cell group and the control group, respectively. There was no significant difference in the occurrence adverse events (AEs) in each group.

The results of this meta-analysis suggested that stem cell therapy for children with autism might be safe and effective. However, the evidence was compromised by the limitations in current study size, lacking standardized injection routes and doses of stem cells, as well as shortages in diagnostic tools and long period follow-up studies. Hence, it calls for more studies to systematically confirm the efficacy and safety of stem cell therapy for children with autism spectrum disorders.

More recently, Saisa and colleagues [27] conducted a systematic review and meta-analysis evaluating the efficacy and safety of HSC therapy for children with ASD. The authors purport this analysis as the first to focus specifically on HSC therapy for ASD in children, excluding MSCs due to their established anti-inflammatory effects. The review included six studies, though meta-analysis was limited to subsets with available data. The primary efficacy measures included the Vineland Adaptive Behavior Scale (VABS), CGI scores, and CARS). VABS was assessed in four studies, with two showing significant improvements post-HSC treatment, particularly in children with nonverbal IQ ≥ 70. However, two RCTs did not show significant benefits compared to placebo. Factors such as study design, dosage inconsistencies, and follow-up duration may have influenced outcomes. Overall, the meta-analysis indicated a pooled increase in all VABS domains, suggesting a positive effect, though further research is needed for qualitative validation. CGI scores were analyzed in four studies,

Stem Cell Type	Source	Mechanism of Action	Limitations	Status in ASD Research
MSCs (Mesenchymal Stem/Stromal Cells)	Bone marrow, adipose tissue, umbilical cord	Immunomodulation, anti-inflammatory, neuroprotection, trophic support	Limited long-term data, variability in source and potency	Multiple early-phase trials show safety and potential efficacy
WJ-MSCs (Wharton's Jelly MSCs)	Wharton's Jelly umbilical cord matrix	Strong anti-inflammatory and neuroprotective properties; low immunogenicity	Still experimental, less standardized	Emerging evidence of safety and potential benefit
HSCs (Hematopoietic Stem Cells)	Bone marrow, peripheral blood, cord blood	Immune system reconstitution	Highly invasive; risks include graft-vs-host disease (GVHD) and conditioning toxicity	Rarely used for ASD due to safety concerns
iPSCs (induced Pluripotent Stem Cells)	Reprogrammed adult somatic cells	Patient-specific modeling; potential for neuron generation	Tumor risk, ethical and technical challenges, not yet safe for transplantation	Mainly used in research to study ASD mechanisms; not yet applied clinically
Autologous Cord Blood (CB-MSCs)	Patient's own stored umbilical cord blood	Immunomodulation, neurotrophic support	Limited cell quantity and variability in potency	Investigated in clinical trials with mixed efficacy outcomes
Allogeneic Cord Blood (CB-MSCs)	Donated cord blood from another individual	Immune modulation, regenerative signaling	Potential immune response, lower compatibility	Used in randomized controlled trials; recent studies show mixed or no significant effects

with two showing significant improvements and two reporting insignificant results. A notable study administering multiple cord blood infusions found significant CGI improvements, suggesting that dosage and infusion frequency may be crucial factors in therapeutic efficacy. CARS scores were analyzed in three studies, with two qualifying for meta-analysis. The pooled mean post-therapy CARS score remained in the mild-to-moderate ASD range, indicating room for improvement in HSC interventions. Longer follow-up durations and repeated infusions were associated with better outcomes. Additional measures included the Expressive One-Word Picture Vocabulary Test (EOWPVT), where only one study showed significant improvement, and electroencephalogram (EEG) findings, which revealed increased alpha and beta power in children with higher IQs but no significant changes in theta or gamma power. Safety assessments across five studies reported primarily non-serious AEs, including mild fever, nausea, and infusion-related reactions. One study reported serious AEs such as viral gastroenteritis and pediatric autoimmune neuropsychiatric disorders, though no cases of death, graft-versus-host disease, or severe infections were observed. The authors conclude that HSC therapy may offer potential benefits, but further studies with better-controlled variables, longer follow-up durations, and standardized protocols are needed to establish its efficacy definitively.

Although equivocal findings raise concern of the efficacy of stem cell treatment for ASD, the landscape continues to evolve. Kabatas et al. [9], recently report a case study in which significant improvement in the child's functional outcomes (CARS, Denver 2 Developmental Screening Test), especially in language and gross motor skills after intrathecal and intravenous Wharton's jelly-derived mesenchymal stem cells (WJ-MSCs) transplantation combined with neurorehabilitation.

The equivocal findings may be attributed to age or body size variability. Stancioiu et al. [28] administered autologous (CB) and a non-placebo, material intervention represented by an individualized combination of supplements (ICS) to children with ASD (n=56) to evaluate markers correlated with the child's progress in order to better predict efficacy. Treatment efficacy was evaluated pre-treatment and post-treatment at 6 months using the Autism Treatment Evaluation Checklist, Quantitative Checklist for Autism in Toddlers and a 16-item comparative table score in addition to biochemical tests including inflammatory, metabolic and oxidative markers, and the neuronal specific enolase. The infusion of CB showed improved score in younger children age 3-7-years (n = 28), but showed limited efficacy was much less effective in children > 8 years. In addition, CB treatment had limited efficacy in larger children 35 kg (n = 28; only 11% of children improved scores). High initial levels of inflammation and ferritin were associated with no improvement.

MSCs and WJ-MSCs are the most promising candidates due to their strong immunomodulatory effects and safety profiles. Autologous cord blood has shown potential, particularly in early trials, but results are inconsistent. Allogeneic cord blood is more accessible but may have limited efficacy and immune compatibility concerns. HSCs and iPSCs are less commonly used in ASD treatment due to safety and feasibility issues, though iPSCs offer powerful tools for research and personalized drug testing.

Stem cell therapy for ASD has been administered through three main routes: intrathecal, intracerebral, and intravenous. The intrathecal route, involving lumbar puncture, is considered minimally invasive and effective, as it delivers cells into the cerebrospinal fluid (CSF), allowing them to reach target brain regions. The intravenous route is the least invasive but less efficient due to the blood-brain barrier, which limits cell delivery to the brain. Intracerebral (intraventricular) injection is the most direct and efficient but is highly invasive and carries greater clinical risk. Clinical trials have explored intrathecal, intravenous, or combined methods, generally reporting safety, though more rigorous evaluation is needed. Another major variable is cell dosage, which varies widely across studies. This variability highlights the need to standardize dosing protocols to optimize treatment outcomes.

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