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Review Article

Autologous vs. Allogeneic Stem Cell Therapy: Balancing Benefits, Safety, and Efficacy in Regenerative Medicine

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Abstract

Mesenchymal stem cells (MSCs), both autologous and allogeneic, have been explored in clinical applications for treating various diseases. Autologous MSCs are easily obtainable and do not pose a risk of immune rejection after infusion. However, their preparation requires several weeks for isolation, expansion, quality control, and patient-derived MSCs may be influenced by underlying systemic conditions to exhibit altered proliferation, differentiation potential, immunomodulatory properties, and secretory profiles. In contrast, allogeneic MSCs provide advantages such as donor selection, diverse sources, low immunogenicity and, most importantly, immediate availability. Although the potential triggered immune responses under certain conditions of allogenic continues to be addressed by advancements in testing and technology, the use of allogeneic MSCs in translational medicine is increasing, with evidence supporting their safety and efficacy. On the other hand, the dynamic interaction between autologous MSCs could affect their therapeutic efficacy and regenerative capacity (e.g., chronic inflammation may prime MSCs towards a pro-inflammatory phenotype, altering their ability to modulate immune responses; increased oxidative stress in systemic diseases may reduce MSC viability, self-renewal capacity, and differentiation potential). This paper addresses some of the current regarding optimized beneficial effects of allogenic compared to autologous MSC transplantation. To optimize MSC-based therapies, disease-specific genetic and environmental factors should be considered, particularly in cases where the microenvironment may impact MSC function and therapeutic efficacy.

Keywords: Stem Cells, Allogenic, Autogenic, Regenerative Medicine

Introduction

The concept of tailoring treatments to the individual patient has revolutionized therapeutics strategies across domains and is gaining momentum in regenerative medicine and cellular therapy. Historically, regenerative medicine has lagged in the concept of individualized medicine, largely unstudied within the context of improving outcomes challenges by individual response to therapeu-

tics. The complexity of understanding donor-to-donor variability of any autologous regenerative product has challenged the critically important first step in tailoring a therapeutic to a given disease.

The existence of mesenchymal stem cells (MSCs) was first suggested by the German pathologist Cohnheim 150 years ago, as cells that contributed to the homeostasis of musculoskeletal tissue as well as support for the growth and differentiation of primitive hemopoietic cells. It is now understood that MSCs are multipotent cells present in most fully developed organs, including bone marrow, adipose tissue, placenta, umbilical cord, heart, and peripheral blood. Originating from various embryonic lineages, MSCs possess the ability to self-renew and differentiate into multiple cell types, including those from mesodermal and neuroectodermal origins [1,2]. Beyond differentiation, MSCs secrete bioactive molecules that promote angiogenesis, modulate inflammation, and enhance tissue regeneration through paracrine signaling [3]. Their immunomodulatory properties also make them an attractive option for allogeneic transplantation, reducing the risk of rejection and improving graft survival. Given their self-renewal and differentiation properties, immunomodulatory capabilities, lacking major histocompatibility complex (MHC) class II molecules, migration and tissue remodeling potential, MSCs play a pivotal role in harnessing the body's natural ability to heal and restore damaged tissues. Recent advancements in tissue engineering and regenerative medicine have highlighted MSCs as a potential source of cells which not only may differentiate to a variety of tissue tailored to individual needs but also, and perhaps more importantly, exert beneficial effects via involvement of paracrine effects. The paracrine effects of cells employed in stem cell therapy are emerging as important mechanisms in stimulating regeneration [4].

MSCs are widely studied for applications in orthopedic injuries, cardiovascular diseases, neurodegenerative disorders, and autoimmune conditions, offering promising therapeutic potential. Advances in biomaterials, 3D bioprinting, and exosome-based therapies are further enhancing MSC-based regenerative strategies, paving the way for innovative treatments that restore function and improve patient outcomes.

Historical Context

The use of grafting techniques in medical procedures has evolved significantly over time, progressing from traditional tissue transplantation to cutting-edge regenerative therapies. Historically, autografts, where a patient's own tissue is used for repair, were the gold standard due to their superior biocompatibility, though they were limited by donor site availability. Autografts play a crucial role in regenerative medicine by providing a natural and highly effective means of tissue repair and regeneration. Since autografts utilize the patient's own cells and extracellular matrix, they offer superior biocompatibility, eliminating the risk of immune rejection and the need for immunosuppressive therapy [5]. This advantage enhances tissue integration, promotes faster healing, and supports the regeneration of functional tissues. In fields such as orthopedic surgery, wound healing, and organ regeneration, autografts serve as a gold standard for bone, skin, and cartilage repair, ensuring long-term stability and biological activity. Additionally, they contain essential growth factors that facilitate the natural regenerative process, making them particularly valuable for complex tissue engineering applications. However, their use is often limited by tissue availability and donor site morbidity, which has driven research into advanced techniques such as tissue expansion, bioprinting, and stem cell therapies to maximize their potential in regenerative medicine. As surgical techniques advanced, allografts, tissue transplants from genetically different individuals of the same species, became widely used, particularly in bone grafting, skin replacement, and organ transplantation, though they required immunosuppressive strategies. On the other hand, allografts, derived from a donor (often cadaveric), eliminate the need for a second surgical site, reducing patient discomfort and recovery time [6]. They are widely used in orthopedic reconstruction, wound healing, and soft tissue repair, offering an effective alternative when autografts are not feasible due to limited tissue availability. Processed allografts can retain essential extracellular matrix components that support cell adhesion, migration, and tissue remodeling, promoting regenerative outcomes. However, their use comes with challenges such as potential immune rejection, slower integration, and a small risk of disease transmission. Furthermore, allografts may take longer to integrate with the patient's body and, in some cases, may not achieve the same strength and functionality as autografts. The evolution from traditional grafting techniques, such as allografts and autografts, has paved the way for advanced regenerative therapies, including allogenic and autologous stem cell treatments. These challenges have driven the development of allogenic stem cell therapies, where donor-derived stem cells are expanded and engineered for broader clinical applications, offering off-the-shelf solutions for regenerative medicine. Simultaneously, autologous stem cell therapies, using a patient's own cells, reduce immune rejection risks and are increasingly utilized in personalized medicine approaches, such as in tissue engineering and gene therapies. Together, these advancements represent a shift from conventional grafting toward biologically tailored regenerative strategies that enhance healing and reduce complications [4] (Figure 1).

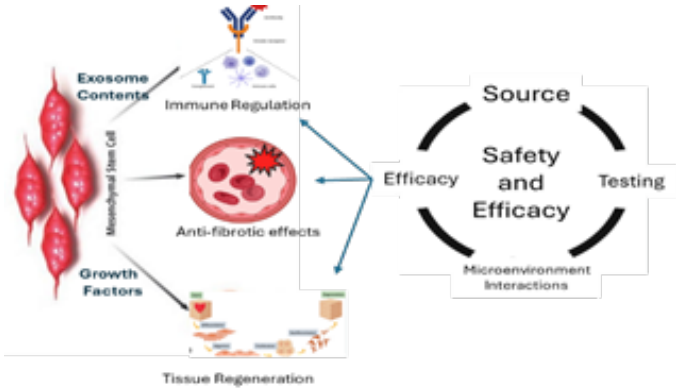

Figure 1: The mechanisms through which MSCs contribute to therapeutic effects, leading to safety and efficacy in medical treatments.

Safety Concerns

These multipotent stromal cells play a role in tissue repair and immune modulation, interacting with their microenvironment through various mechanisms including directly interact with other cells via gap junctions and receptor-ligand signaling, influencing cellular responses in damaged tissues. MSCs release extracellular vesicles that contain bioactive molecules such as proteins, lipids, and RNA, which mediate intercellular communication and influence target cells. MSCs secrete cytokines and growth factors that promote cell survival, proliferation, and differentiation, facilitating tissue repair. MSCs modulate immune responses by interacting with immune cells, reducing inflammation and promoting immune tolerance. In addition, MSCs help prevent excessive fibrosis by inhibiting fibroblast proliferation and extracellular matrix deposition, which is critical for preventing tissue scarring and support tissue repair and regeneration by promoting the replacement of damaged cells and restoring tissue function. The combination of these mechanisms ensures the therapeutic potential of MSCs while maintaining treatment safety and efficacy, making them a valuable tool in regenerative medicine and disease treatment.

Because allogenic and autologous stem cells differ in their origin, safety and quality control assessment differs as well. Allogenic stem cells undergo extensive screening to ensure safety (mainly related to immune consideration) and efficacy. This includes donor eligibility assessments for infectious diseases, genetic abnormalities, and immune compatibility (such as HLA matching in hematopoietic stem cell transplants) [7]. Once harvested, the cells are typically expanded, cryopreserved, and tested for sterility, viability, and potency before clinical use. Additionally, regulatory guidelines require rigorous batch testing to maintain consistency in large-scale manufacturing. Conversely, autologous stem cells require individualized processing and quality control. The testing process begins with cell collection, followed by viability and purity assessments to confirm the cells' regenerative potential. Since immune rejection is not a concern, HLA matching is unnecessary, but patient-specific factors such as prior treatments or age-related decline in stem cell function may require additional characterization. As a result, while they still undergo viability, purity, and functional assessments, they typically face fewer regulatory hurdles related to donor screening and batch standardization. However, patient-specific factors like age, disease state, and prior treatments can impact cell quality and quantity, requiring case-by-case evaluations [8].

Since its inception less than twenty years ago, stem cell platforms have revolutionized both scientific research and therapeutic advancements. Investigations into somatic cell reprogramming have revealed the intricate cellular transformations that occur during the transition to a pluripotent state, highlighting the interplay between physiological predictable and idiopathic processes. These insights have underscored the pivotal role of transcription factors in gene regulation, the significance of epigenetic modifications in determining cell fate, and the collaborative nature of reprogramming effectors. As knowledge of reprogramming mechanisms deepens, novel approaches to enhance the efficiency and scalability of MSC generation continue to emerge, including chemically induced reprogramming techniques that offer a more controlled and reproducible process [5].

Clinical Evidence and Efficacy

Most research has focused on bone marrow (BM-MSCs) and adipose tissue (AT-MSCs), as they can be easily obtained in large quantities while maintaining their immunomodulatory properties and ability to produce extracellular matrix components, besides being from adult origin.

Cardiac

Administration of MSCs to diseased hearts improves cardiac function and reduces scar size. While MSCs from different sources share a substantial degree of similarity, there are variations in safety, survival, and clinical outcomes [9,10]. The POSEIDON-DCM (The PercutaneOus StEm Cell Injection Delivery effects On Neomyogenesis) study was a randomized comparison of allo-hMSCs vs. auto-hMSCs in patients with NIDCM10. Allogenic MSCs produced multiple clinically meaningful effects, which were concluded to be of greater magnitude than autologous MSCs. These outcomes in-

cluded significant improvement in ejection fraction (EF), 6-minute walk test, and quality of life score. Endothelial function was improved only in those receiving allogenic MSCs. Elevated levels of TNF-α, a crucial pro-inflammatory cytokine tied to progression of heart disease, are implicated in modulating both cardiac contractility and peripheral resistance and TNF-α suppression was greater with allogenic. Several additional findings showed evidence of clinical efficacy including improved NYHA class, lower MACE and hospitalization rates at one year in allogenic compared to autologous. The authors reasoned that the age of the donors, possible adverse impact the pro-inflammatory phenotype, and preferential response to allogenic, which undergo more rigorous testing may reflect enhanced capacity to harvest immune cells towards a less inflammatory/exhausted phenotype.

Metabolic

In diabetes treatment, both allogeneic and autologous stem cell therapies are being actively explored to restore insulin production and achieve long-term glycemic control. Autologous approaches aim to enhance pancreatic regeneration while minimizing immune rejection, with MSCs playing key roles [11]. Regenerative aspects may reside both in differentiation potential and the paracrine effects on immunomodulation, reducing β-cell destruction, and improving metabolic function. However, challenges include limited scalability and variability in patient-derived cells [12]. Allogeneic therapies offer a more standardized and scalable solution, particularly with pluripotent and embryonic stem cell-derived pancreatic progenitors. Advances in immune-evasive strategies, such as gene editing and encapsulation technologies, are helping to protect transplanted cells from autoimmune attack, reducing the need for lifelong immunosuppression. Clinical trials are increasingly evaluating combination approaches, integrating bioengineered scaffolds, metabolic interventions, and immune tolerance induction to enhance engraftment and function.

The therapeutic potential of MSCs may also be affected by the type of diabetes presented by the patient. Savio-Silva and colleagues [13] reported that autologous MSCs from individuals with type 1 diabetes exhibited preserved morphology, growth kinetics, multipotency, and proliferative, immunomodulatory, immunosuppressive, and migratory capacities, while those from individuals with type 2 diabetes exhibited greater senescence, lower viability, increased apoptosis, less proliferative potential associated with increased doubling time, and a reduction in angiogenic potential. As such, testing of autologous transplantation including the type of diabetes, time elapsed since the diagnosis due to cellular metabolic memory, and cell source, which may impair MSC functional properties may be essential. Packman and colleagues also demonstrated allogeneic BM-derived MSCs were safe and improved diabetic nephropathy complication after administration in a randomized and placebo-controlled clinical study [14].

Autoimmune Diseases

MSCs possess several advantageous characteristics that make them promising for the treatment of autoimmune diseases. They can be easily isolated and expanded, simplifying their clinical application. MSCs can migrate to injured tissues, promoting repair and regeneration. Their low immunogenicity, due to the lack of MHC-II and co-stimulatory molecules (B7-1, B7-2, CD40), prevents recognition by T cells, allowing for successful allogeneic transplantation without rejection. Additionally, MSCs exert immunomodulatory effects by suppressing the proliferation of CD3+ T cells and regulating cytokine secretion. They also inhibit CD19+ B cell proliferation and reduce autoantibody production, further contributing to immune regulation. Moreover, MSCs interfere with the maturation of dendritic cells (CD45+, MHC-II+, CD1+/CD3-, CD19-, CD14-, CD56-, CD66b-) and suppress the cytotoxic activity of CD56+ natural killer (NK) cells, making them effective in modulating the immune response in autoimmune conditions [15].

Autoimmune diseases can significantly impact the therapeutic potential of autologous MSCs by altering their immunomodulatory properties, differentiation capacity, and regenerative potential [16]. Chronic exposure to inflammatory cytokines, such as IFN-γ and TNF-α, can epigenetically reprogram MSCs, reducing their ability to suppress pro-inflammatory immune responses and compromising their effectiveness in tissue repair [17]. Additionally, MSCs from autoimmune patients often exhibit premature senescence, reduced proliferation, and telomere shortening, which may limit their longevity and functional capacity. In some cases, aberrant differentiation may contribute to fibrosis rather than regeneration, further complicating their therapeutic use [17]. Another major concern is that patient-derived MSCs, already primed by systemic inflammation, may lose their immune privilege and potentially exacerbate autoimmunity instead of suppressing it. To overcome these challenges, strategies such as preconditioning MSCs with anti-inflammatory cytokines, genetic modifications to enhance their immunoregulatory function, or the use of allogeneic MSCs from healthy donors are being explored. These approaches aim to restore MSC efficacy while minimizing the risk of worsening the underlying autoimmune condition.

Systemic lupus erythematosus (SLE) is a chronic autoimmune disease characterized by the loss of T and B cell tolerance to nuclear antigens, leading to the production of cytokines and autoantibodies that form immune complexes. These complexes activate the complement system, triggering inflammation and tissue damage in various organs, including the kidneys, gastrointestinal tract, lungs, cardiovascular system, and skin, with clinical manifestations varying based on the severity and extent of immune complex deposition. Allogeneic MSCs have shown therapeutic potential for SLE patients, with clinical studies reporting significant disease remission in some patients. Genetic factors in SLE contribute to MSC dysfunction, affecting their immunosuppressive properties. On the other hand, autologous MSCs may not be suitable for SLE treatment due to impaired immune-regulatory capacity. Carrion and colleagues transplanted autologous BM-derived MSCs in two SLE patients. Although there were no adverse events, the therapy was also not clinically efficacious in response to 14 weeks of treatment. A pilot trial demon-

strated clinical improvement in 12 of 13 SLE patients, with reduced disease activity and lower autoantibody levels post-transplantation [18]. Further, Wang et al conducted a multicenter study that confirmed the safety and efficacy of allogeneic umbilical cord-derived MSCs in severe SLE [19].

Skin and Orthopedics

Both allogeneic and autologous stem cell therapies are being explored to enhance tissue regeneration in orthopedic and skin pathologies and-or injuries. MSC have shown to accelerate healing, and improve outcomes in conditions such as osteoarthritis, fractures, and tendon injuries. Autologous therapies are widely used to promote cartilage repair, bone healing, and inflammation reduction, with applications in procedures such as microfracture augmentation and platelet-rich plasma (PRP) therapies. However, variability in cell quality and patient age-related decline in regenerative capacity pose challenges. In this sense, allogeneic stem cell therapies offer standardized cell quality and higher proliferative capacity.

King et al [20] conducted a non-randomized, parallel-assignment, open-label safety and feasibility study in patients undergoing semi-elective below-knee amputation due to untreatable Rutherford 4 to 5 ischemia. Patients (n=34) were assigned to receive allogeneic bone marrow- MSC therapy obtained from healthy female donors (n=13), autologous concentrated BMC obtained via bone marrow aspiration at the iliac crest (n=6), and untreated controls (n=15). Patients were followed for 24 weeks postamputation. Similar results were obtained for allo- and auto groups with a revision-free survival was 79.4% at 24 weeks. Death, conversion to above knee amputation, and use of prosthetic did not differ between groups, though the study wasn't powered to detect differences.

Arango-Rodriguez and colleagues [21] performed a randomized, prospective, double-blind and controlled pilot study in Twenty-four diabetic patients in the advanced stage of chronic limb-threatening ischemia (4 or 5 in Rutherford's classification). Patients with CLTI who received auto-MSCs and allo-MSCs presented an improvement in Rutherford's classification, a significant increase in TcPO2 values, a reduction in the lesion size in a shorter time, a decrease in the pain score and an increase in the pain-free walking distance, in comparison with the placebo group. Both groups also conserved 100% of their limb during 12 months of the follow-up compared to the placebo group. However, a faster improvement in the allo- MSC group was reported.

Vega et al conducted a randomized controlled multicenter for treatment of knee osteoarthritis demonstrating that allogeneic BM-derived MSC transplantation was safe and effective for cartilage repair, as evidenced by the quantitative magnetic resonance imaging that indicates the healing of partial articular cartilage and no major adverse events.

Innovations in biomaterial-based delivery systems, including hydrogel scaffolds and exosome-based therapies, are enhancing cell survival and integration into wound sites with allogenic MSCs. Immunomodulatory strategies, including gene editing and biomaterial encapsulation, are addressing potential immune rejection risks. As research progresses, combination therapies integrating biological scaffolds, 3D bioprinting, and bioengineered tissues are emerging as promising approaches for orthopedic regenerative medicine. Current research is also exploring combination approaches, integrating stem cells with bioengineered skin substitutes, platelet-rich plasma (PRP), and growth factor-enhanced matrices to improve chronic wound healing, particularly in diabetic ulcers and burn injuries.

Cancer

The use of autologous or allogeneic MSC for cancer treatment, frequently depends on many factors such as the type of malignancy, age of the recipient, availability of a suitable donor, the ability to collect a tumor-free autograft, as well as the stage of disease, and chemosensitivity to conventional chemotherapy are relevant considerations.

Although the lower risks of using allogenic MSC is well described, Notwithstanding, there are challenges with autologous transplants in cancer patients [22]. In particular, integration of malignant cells in the blood and bone marrow, affords the potential for contamination of autologous transplant with tumor cells increasing risk of relapse [23]. Relapse rates tend to be higher after autologous transplants than after allogeneic transplantation. Further, other cell types may also be as well evaluated, such as the extent to which a patient has undergone other therapies has been shown to increase adverse outcomes after autologous hematopoietic transplantation. While this represents a different cell type, this study demonstrates the potential consideration for evaluation of autologous compared to allogenic MSC in cancer therapy. The rigorous testing prior to allogeneic transplantation ensures the graft is free of contaminating tumor cells. While there is generally a lower risk for disease recurrence after allogeneic transplants compared to autologous transplantation, allogeneic transplants may be associated with regimen-related organ toxicity, graft failure, and graft-versus-host disease. Given the benefit-risk considerations, historically, allogeneic hematopoietic transplantation has often been restricted to younger patients in good general condition. However, most malignancies that are effectively treated by allogeneic transplantation are more common in older patients. Current trends focus on improving outcomes with novel conditioning regimens, immune modulation strategies (such as CAR-T and NK cell therapies), and gene editing to reduce complications. Advances in haploidentical transplants and reduced-intensity conditioning are expanding allogeneic options for older and high-risk patients, while autologous approaches are integrating immunotherapies to enhance efficacy and durability.

A meta-analysis and systematic review conducted by Du et al (2021) [24] including data extracted from the 30 studies including 880 patients who underwent allogeneic HSCT and 885 who underwent autologous HSCT for T-Cell Lymphoma, concluded that

overall survival (OS), progression-free survival (PFS) was similar in the allogeneic HSCT and autologous HSCT groups; however, allogeneic HSCT was associated with specific survival benefits among patients. In a meta-analysis conducted by Wang et al25 in patients with B-Cell Non-Hodgekin Lymphoma, the authors reported that relapsed or refractory in patients who received auto-SCT had improved OS than those treated with allo-SCT but lower PFS. However, the study is limited by a lack of randomized trials, patients' heterogeneity, and possible selection bias.

Summary and Conclusion

The greatest limitation of autologous therapies extends beyond age-related decline in stem cell quality, lengthy processing times, and the need for invasive harvesting procedures, to uncertainty related to potential related to lack of rigorous testing. While there are also limitations, allogenic MSC sources can provide scalable solutions with consistent quality and high proliferative capacity, making them suitable for applications in cancer, diabetes, and wound healing, the extensive testing helps ensure strong immunomodulatory effects. Moreover, the limitations are being circumvented by advances in gene editing, immune-evasive technologies, and biomaterial scaffolds, improving the safety and efficacy of allogeneic therapies. We highlight the therapeutic potential of MSC-based therapy to the rescue of damaged organ or tissue leveraging differentiation and paracrine effects. The remarkable properties of cellular therapeutics have an increasingly expanding impact in the development of new strategies in regenerative medicine. While these bold new strategies could be developed to improve current clinical trial outcomes the safety and efficacy remain the highest priority. It is essential to determine the safety and efficacy of cell therapy for optimal clinical translation, given the important influences on the distribution, retention, and survival of the administered cells. While both types have demonstrated safety in clinical studies, the more rigorous testing promoting a higher likelihood of a more favorable safety profile for allogeneic therapies, suggest allogenic for first line of therapy as autologous cells continue to undergo safety profile testing as a second-tier approach.

The field continues to progress, with advancements gaining traction, with ongoing preclinical and clinical trials exploring their use in immune cell therapies for cancer, genetic disorders requiring cell replacement, and age-related diseases affecting tissue integrity. Despite challenges in MSC-based therapies, technological innovations, such as multi-omics, gene editing, epigenetic engineering, and machine learning, continue to refine our understanding of MSC biology, optimize differentiation protocols, and enhance drug discovery platforms. Increased collaboration, the establishment of diverse MSC biobanks, and automation in differentiation processes will further improve reproducibility and scalability, facilitating high-throughput applications. Ultimately, advancements in MSC technology are poised to drive fundamental discoveries and innovative treatments, paving the way for future breakthroughs in regenerative medicine and disease modeling.

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