Stem Cell Care India

A GUIDE FOR PATIENTS

LITERATURE

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❖ Crohn's Disease

➢ Immune modulation by mesenchymal stem cells

Mesenchymal stem cells (MSCs) can be derived from various adult tissues with multipotent and self-renewal abilities. The characteristics of presenting no major ethical concerns, having low immunogenicity and possessing immune modulation functions make MSCs promising candidates for stem cell therapies. MSCs could promote inflammation when the immune system is underactivated and restrain inflammation when the immune system is overactivated to avoid self-overattack. These cells express many immune suppressors to switch them from a pro-inflammatory phenotype to an anti-inflammatory phenotype, resulting in immune effector cell suppression and immune suppressor cell activation. We would discuss the mechanisms governing the immune modulation function of these cells in this review, especially the immune-suppressive effects of MSCs.

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➢ Shattering barriers toward clinically meaningful MSC therapies

More than 1050 clinical trials are registered at **FDA.gov** that explore multipotent mesenchymal stromal cells (MSCs) for nearly every clinical application imaginable, including neurodegenerative

and cardiac disorders, perianal fistulas, graft-versus-host disease, COVID-19, and cancer. Several companies have or are in the process of commercializing MSC-based therapies. However, most of the clinical-stage MSC therapies have been unable to meet primary efficacy end points. The innate therapeutic functions of MSCs administered to humans are not as robust as demonstrated in preclinical studies, and in general, the translation of cell-based therapy is impaired by a myriad of steps that introduce heterogeneity. In this review, we discuss the major clinical challenges with MSC therapies, the details of these challenges, and the potential bioengineering approaches that leverage the unique biology of MSCs to overcome the challenges and achieve more potent and versatile therapies.

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➢ Mesenchymal Stem Cells for Perianal Crohn's Disease

Perianal fistulizing Crohn's disease (PFCD) is associated with significant morbidity and might negatively impact the quality of life of CD patients. In the last two decades, the management of PFCD has evolved in terms of the multidisciplinary approach involving gastroenterologists and colorectal surgeons. However, the highest fistula healing rates, even combining surgical and anti-TNF agents, reaches 50% of treated patients. More recently, the administration of mesenchymal stem cells (MSCs) have shown notable promising results in the treatment of PFCD. The aim of this review is to describe the rationale and the possible mechanism of action of MSC application for PFCD and the most recent results of randomized clinical trials. Furthermore, the unmet needs of the current administration process and the expected next steps to improve the outcomes will be addressed.

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➢ Umbilical Cord Mesenchymal Stem Cell Treatment for Crohn's Disease: A Randomized Controlled Clinical Trial

Stem cell therapy has been applied to treat a variety of autoimmune diseases, including Crohn's disease (CD), but few studies have examined the use of umbilical cord mesenchymal stem cells (UC-MSCs). This trial sought to investigate the efficacy and safety of UC-MSCs for the treatment of CD.

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➢ Mesenchymal stem/stromal cells as a valuable source for the treatment of immune-mediated disorders

Over recent years, mesenchymal stem/stromal cells (MSCs) and their potential biomedical applications have received much attention from the global scientific community in an increasing manner. Firstly, MSCs were successfully isolated from human bone marrow (BM), but in the next steps, they were also extracted from other sources, mostly from the umbilical cord (UC) and adipose tissue (AT). The International Society for Cellular Therapy (ISCT) has suggested minimum criteria to identify and characterize MSCs as follows

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➢ Mesenchymal stromal cells: clinical challenges and therapeutic opportunities

Mesenchymal Stromal Cells (MSCs) have been the subject of clinical trials for more than a generation and the outcomes of advanced clinical trials have fallen short of expectations raised by encouraging pre-clinical animal data in a wide array of disease models. In this perspective, important biological and pharmacological disparities in pre-clinical research and human translational studies are highlighted, and analysis of clinical trial failures and recent successes provide a rational pathway to MSC regulatory approval and deployment for disorders with unmet medical needs.

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➢ Efficacy of stem cell therapy for Crohn's fistula: A meta-analysis and systematic review

Fistulas have always puzzled us, and stem cell therapy is still in its infancy. We conducted a meta-analysis and systematic review to evaluate the efficacy of stem cells and their potential mechanisms in managing Crohn's fistula.

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➢ Ex vivo immunosuppressive effects of mesenchymal stem cells on Crohn's disease mucosal T cells are largely dependent on indoleamine 2,3-dioxygenase activity and cell-cell contact

Crohn's disease (CD) is a disabling chronic enteropathy sustained by a harmful T-cell response toward antigens of the gut microbiota in genetically susceptible subjects. Growing evidence highlights the safety and possible efficacy of mesenchymal stem cells (MSCs) as a new therapeutic tool for this condition. Therefore, we aimed to investigate the effects of bone marrow-derived MSCs on pathogenic T cells with a view to clinical application.

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➢ Expanded allogeneic adipose-derived mesenchymal stem cells (Cx601) for complex perianal fistulas in Crohn's disease: A phase 3 randomized, double-blind controlled trial

Complex **perianal fistulas** in **Crohn's disease** are challenging to treat. Allogeneic, expanded, adipose-derived stem cells (Cx601) are a promising new therapeutic approach. We aimed to assess the safety and efficacy of Cx601 for treatment-refractory complex **perianal fistulas** in **patients** with **Crohn's disease**.

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