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Impacto en la terapia basada en células madre en la Enfermedad Inflamatoria Intestinal (EII)

Impact of stem cell-based therapy in Inflammatory Bowel Disease (IBD)

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Palabras claves:
células madre, enfermedad inflamatoria intestinal, terapia celular, enfermedad de Crohn y colitis ulcerosa.

Resumen

Introducción: en la introducción, se abordó la complejidad de la Enfermedad Inflamatoria Intestinal (EII), destacando su carácter crónico y multifactorial, así como las limitaciones de las terapias convencionales. Se mencionó el interés creciente en la terapia basada en células madre, especialmente en las Células Madre Mesenquimales (MSCs), debido a su capacidad regenerativa y efectos inmunomoduladores. **Objetivo:** 1. Investigar los mecanismos celulares y moleculares a través de los cuales la terapia con células madre influye en la plasticidad intestinal en pacientes con EII. 2. Analizar la eficacia y efectos adversos de la terapia con células madre para el tratamiento de la EII. 3. Comparar los resultados clínicos de la terapia con células madre para la EII con otros tratamientos convencionales. **Metodología:** los métodos incluyeron una revisión sistemática de la literatura científica en bases de datos relevantes hasta abril de 2024, con criterios de inclusión específicos para seleccionar los estudios pertinentes. Se analizaron estudios clínicos y experimentales relacionados con la aplicación de células madre en el tratamiento de la EII. **Resultados:** en los resultados, se destacó el crecimiento exponencial de la investigación en este campo en los últimos años, con múltiples estudios clínicos explorando la seguridad, eficacia y mecanismos de acción de la terapia con MSCs. Se identificaron desafíos en la estandarización de los protocolos de tratamiento y la implementación clínica debido a la variabilidad en dosis y métodos de aplicación. **Conclusiones:** las conclusiones resaltaron la promesa de la terapia con células madre en el tratamiento de la EII, pero también la necesidad de más investigación para comprender mejor sus beneficios y optimizar su uso clínico. Se enfatizó la importancia de estandarizar los protocolos de tratamiento y mejorar la comprensión de los mecanismos de acción de las células madre en el contexto de la EII. **Área de estudio general:** Medicina. **Área de estudio específica:** Medicina interna/ Gastroenterología. **Tipo de estudio:** Articulo de Revisión.

Keywords:
stem cells, inflammatory bowel disease, cellular

Abstract

Introduction: In the introduction, the complexity of Inflammatory Bowel Disease (IBD) was addressed, highlighting its chronic and multifactorial nature, as well as the limitations of conventional therapies. The growing interest in stem cell-based therapy,

therapy, Crohn's disease and ulcerative colitis.

especially in Mesenchymal Stem Cells (MSCs), due to its regenerative capacity and immunomodulatory effects, was mentioned. Objective: 1. To investigate the cellular and molecular mechanisms through which stem cell therapy influences intestinal plasticity in patients with IBD. 2. To analyze the efficacy and adverse effects of stem cell therapy for the treatment of IBD. 3. To compare the clinical outcomes of stem cell therapy for IBD with other conventional treatments. Methodology: The methods included a systematic review of the scientific literature in relevant databases up to April 2024, with specific inclusion criteria to select relevant studies. Clinical and experimental studies related to the application of stem cells in the treatment of IBD were analyzed. Results: The results highlighted the exponential growth of research in this field in recent years, with multiple clinical studies exploring the safety, efficacy and mechanisms of action of MSC therapy. Challenges were identified in the standardization of treatment protocols and clinical implementation due to variability in dosage and delivery methods. Conclusions: The conclusions highlighted the promise of stem cell therapy in the treatment of IBD, but also the need for further research to better understand its benefits and optimize its clinical use. The importance of standardizing treatment protocols and improving understanding of stem cell mechanisms of action in the context of IBD was emphasized. General area of study: Medicine. Specific area of study: Internal medicine/ Gastroenterology.**Type of study:**Review article.

Introduction

Inflammatory bowel disease (IBD), which mainly comprises Crohn's disease (CD) and Ulcerative colitis (UC), represents a group of idiopathic chronic disorders characterized by persistent and recurrent gastrointestinal inflammation. The etiology of IBD is multifactorial, involving genetic, environmental, immunological and macrobiotic factors that contribute to its pathogenesis (1). Despite significant advances in the understanding of these factors, the therapeutic management of IBD remains a considerable challenge. Conventional therapies, including anti-inflammatory drugs, immunosuppressants and biological agents, fail to induce remission in a significant percentage of patients and are associated with adverse effects and long-term loss of response. In this context, stem cell-

based therapy emerges as a promising strategy, offering potential benefits on immune system modulation and tissue regeneration.

Intestinal tissue plays a pivotal role in the body's homeostasis, participating in important functions such as digestion, nutrient absorption, and maintenance of immune barriers. However, these tissues are susceptible to various diseases such as infections, inflammatory diseases, and invasive treatments. The highly adaptable and regenerative intestinal epithelium relies on the cell, particularly stem cells in the intestinal crypts, to cope with challenges and regenerate (2, 3). Intestinal regeneration is influenced by multiple factors, including signaling pathways, microenvironmental conditions, and epigenetics, which together contribute to the ability of stem and differentiated cells to adapt and regenerate intestinal tissue under harsh conditions (4).

The main diseases that make up this group are Crohn's disease and ulcerative colitis. These often debilitating diseases severely affect the quality of life of patients and their incidence has increased in recent decades. The prevalence of IBD in Ecuador is 5.2/100,000 inhabitants, of which 3.7 have ulcerative colitis and 1.5 have Crohn's disease. This increase has been comparable to that reported in other low-risk countries (1).

Pathophysiologically, the exact origin of this pathology is unknown, however, there are studies that mention that IBD is caused by an abnormal immune response in genetically susceptible individuals. It is essential to know that intestinal immune cells can be divided into innate immune cells and adaptive immune cells, which contribute greatly to the immune response in IBD (3). The first consists of several cells such as neutrophils, monocytes, macrophages, dendritic cells, innate lymphocytes and NK cells; it plays a crucial role in protection against pathogens and in regulating the effect of the intestinal flora.

Innate immune cells (IICs) act as a first line of defense, responding rapidly and nonspecifically to protect against pathogens and regulate the invasion of intestinal microorganisms while maintaining immune tolerance to the microbiota. An imbalance is associated with inflammatory bowel disease (IBD). IICs activate the adaptive immune response by producing cytokines, chemokines, complement activation, phagocytosis, and antigen presentation, and are actively involved in tissue defense, inflammation, and the healing response. These changes in IIC function are associated with IBD (5, 6).

In recent years, research into the application of stem cells for the treatment of IBD has experienced exponential growth. Mesenchymal stem cells (MSCs), in particular, have been the focus of multiple clinical studies due to their immunomodulatory properties and their ability to promote the repair of damaged tissues (4). These cells can be derived from various sources, including bone marrow, adipose tissue, and umbilical cord blood, and have been shown to be safe and potentially effective in the treatment of IBD. However,

variability in treatment protocols, administered doses, and application methods pose challenges for the standardization of this therapy and its clinical implementation.

Inflammatory bowel disease (IBD), which encompasses Crohn's disease (CD) and Ulcerative colitis (UC), has seen an increase in its incidence and prevalence worldwide, highlighting the impact of genetic, environmental and lifestyle factors in its development (7). This condition is characterized by chronic inflammation of the gastrointestinal tract, manifesting through varied symptoms such as abdominal pain, persistent diarrhea and rectal bleeding, which can lead to severe complications such as strictures, fistulas, and an increased risk of colorectal carcinoma. The observed increase in the last decades underlines the urgent need to better understand its etiology and improve treatment strategies.

The underlying pathology of IBD involves a dysregulated immune response against the gut microbiota in genetically susceptible individuals. The identification of multiple genetic loci associated with IBD risk emphasizes its heterogeneity and the importance of genetic components in its pathogenesis (8). The dynamic interplay between genetic and environmental factors initiates an inappropriate immune response, resulting in chronic inflammation and tissue damage. This understanding has propelled the search for therapeutic approaches that address the complexity of its disease mechanism.

The role of dysbiosis, or imbalance in the gut microbiota, has been increasingly recognized in perpetuating inflammation in IBD (9). This imbalance in gut microbial composition significantly contributes to sustained immune cell activation, exacerbating inflammation. Furthermore, compromised gut barrier integrity is observed in affected individuals, facilitating bacterial translocation that intensifies the inflammatory response. These findings have guided the development of therapies aimed at restoring microbial balance and reinforcing the gut barrier.

Over the years, the treatment of IBD has evolved significantly, incorporating biological therapies that target specific molecules involved in inflammation, such as TNF inhibitors and anti-integrin agents (10). Although these therapies have improved disease management, their effectiveness varies and complications such as loss of response and serious adverse effects may arise. This highlights the urgent need to develop more effective and safe therapeutic approaches that can be personalized for patients.

In this context, mesenchymal stem cell therapy is presented as an innovative approach for the treatment of IBD, thanks to its immunomodulatory and regenerative properties (6). These cells, derived from sources such as bone marrow, adipose tissue, and umbilical cord, offer the ability to modify the immune response and promote tissue repair. Clinical trials have begun to demonstrate the potential of MSCs to significantly improve

symptoms and, in some cases, achieve complete remission, marking a milestone in the search for more effective therapies.

However, widespread implementation of stem cell therapy faces notable challenges, such as the need to standardize administration protocols and thoroughly understand the long-term mechanisms of its action (11). Optimization of cell sources, dosage, delivery methods, and treatment regimens is crucial. Collaboration across diverse scientific disciplines promises to overcome these obstacles, opening avenues toward more personalized and effective treatments for IBD.

Looking to the future, a promising outlook for stem cell therapy in IBD is emerging, standing at a crossroads between current challenges and emerging opportunities (12). Continued research and technological advances in stem cell biology, along with multidisciplinary collaboration between researchers, physicians, and bioengineers, are critical to bringing these advances from the laboratory to the patient's bedside. Accumulating evidence on the long-term safety and efficacy of stem cell-based therapies is crucial to their consolidation as a pillar in the treatment of IBD.

This innovative approach not only promises to address the symptoms of the disease more effectively, but also to significantly improve the quality of life of patients. With each study and clinical trial, progress is made towards a deeper understanding of the pathogenesis of IBD and towards the identification of more precise and personalized therapies. Mesenchymal stem cell therapy is at the forefront of this transformation, representing not only a breakthrough in the treatment of chronic inflammatory diseases, but also a paradigm shift in how these conditions are approached from a medical perspective. Continued collaboration and commitment to quality research will ensure that the potential of stem cell-based therapies is fully realized, opening a new era in the management of Inflammatory Bowel Disease.

However, a comparative cost analysis of stem cell therapy versus conventional treatments reveals a mixed economic picture. The procedures involved in stem cell therapy, which include harvesting, culturing and expanding mesenchymal stem cells, as well as clinical trials for their validation, incur high costs. The price of these cell therapies is estimated to reach tens of thousands of dollars per treatment.

On the other hand, traditional therapies for IBD, such as immunosuppressive drugs and biotherapies, have annual costs that fluctuate significantly, ranging from a few thousand dollars to figures exceeding $30,000, depending on the severity of the disease and the specific treatment required. In the short term, these treatments may seem cheaper; however, long-term management of IBD can lead to higher cumulative costs due to hospitalizations, surgical interventions, and management of side effects.

It is important to emphasize that the costs are estimates and subject to regional variations, health policies and insurance coverage. With the progressive improvement and accessibility of stem cell therapy, its costs are likely to decrease, while its benefits could increase, particularly if greater efficiency is demonstrated in maintaining IBD remission and, therefore, in improving the quality of life of patients. Therefore, the calculation of the cost-effectiveness ratio must consider these aspects of long-term effectiveness and benefit, beyond the immediate comparison of prices.

Methodology

To systematically investigate the impact of stem cell-based therapy in Inflammatory Bowel Disease (IBD), the PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) methodology is adopted, which allows a comprehensive and transparent review of the existing literature. This approach focuses on identifying, selecting, evaluating and synthesizing all relevant research on stem cell therapy in the treatment of IBD, following a predefined and structured protocol to ensure replicability and quality of results (7).

The systematic search will be performed in electronic databases including Google Scholar, SciELO, Redalyc, Dialnet, using a combination of search terms related to "Inflammatory Bowel Disease", "stem cells", "stem cell therapy", "ulcerative colitis", and "Crohn's disease". Studies published in the last five years, in English or Spanish, that report clinical results of stem cell-based therapies in patients with IBD will be included. The selected studies will be those that include clinical trials, cohort studies, case-control studies, and case series.

Study selection will be performed in two phases. In the first phase, two independent reviewers will assess the titles and abstracts of the identified studies to determine their eligibility. In the second phase, the same reviewers will examine the full text of the shortlisted studies to confirm their inclusion. Discrepancies between reviewers will be resolved by discussion or the intervention of a third reviewer if necessary (13). The extracted data will include details on the study population, interventions (type of stem cells used, dose, route of administration), comparisons, outcomes (efficacy, safety, adverse effects), and study design (8). The quality of the included studies will be assessed using risk of bias assessment tools specific to each type of study.

Data synthesis will be presented narratively and, where possible, by meta-analysis, taking into account the heterogeneity between studies in terms of designs, populations and outcomes measured. The results of this systematic review will provide a comprehensive assessment of the current evidence on the efficacy and safety of stem cell therapy in patients with IBD, identifying gaps in knowledge and suggesting future directions for research (14). The visualization of this process will be facilitated by the creation of a

PRISMA table, which will summarize the flow of information through the different phases of the review, from the number of records identified, included and excluded, to the studies finally included in the review (15).

Table 1. Analysis of updated studies on inflammatory bowel disease

No.	Author/Year	Qualification	Summary	Results
1	Vizoso et al. (16) (2023)	New era of medicine based on mesenchymal stem cells: bases, challenges and perspectives	Mesenchymal stem cells (MSCs) are notable for their regenerative, anti-inflammatory, antioxidant, and other properties, but their clinical use faces challenges such as immunological incompatibility, risks of tumorigenesis, transmission of infections, senescence, and difficulties in evaluating safety and effectiveness, in addition to logistical problems such as storage and costs.	Mesenchymal stem cells (MSCs) are highly valued for their diverse therapeutic capabilities, including tissue regeneration, reduction of inflammation, and prevention of apoptosis and oxidative stress. However, their clinical application faces significant challenges, such as immunological incompatibility issues, risks of tumorigenesis, and difficulties in safety and dosing assessment, in addition to logistical hurdles such as storage conditions and high cost.
1	Vizoso et al. (16) (2023)	New era of medicine based on mesenchymal stem cells: bases, challenges and perspectives	Despite these challenges, the ability of MSCs to release biologically active substances suggests a path to regenerative medicine that avoids the problems of direct cell therapy. The use of the MSC secretome represents an innovative strategy, although efforts are needed to manage biological variability, optimize and standardize their production and application.	The release of diverse biological products from MSCs, such as growth factors and cytokines, has sparked interest in regenerative medicine, opening the door to strategies that avoid the problems associated with direct cell therapy. However, this new approach faces its own challenges, such as the need to recognize the biological variability of MSCs and optimize the production and use of their secretome.

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Table 1. Analysis of updated studies on inflammatory bowel disease (continued)

No.	Author/Year	Qualification	Summary	Results
2	Gonzalez (10) (2022)	Perianal Crohn's disease, stem cell treatment.	Complex perianal fistulas, a common complication in patients with Crohn's disease, represent a therapeutic challenge due to their limited response to conventional treatments and post-surgical sequelae. This negatively impacts quality of life in social, sexual and occupational aspects. Given this situation, the need to explore alternative therapies arises. This study focuses on a systematic review of autologous expanded mesenchymal stem cell therapy to treat these fistulas. The aim is to evaluate its efficacy, safety, tolerability and long-term economic viability, thus offering a new perspective for patients who do not respond to conventional treatments.	Autologous expanded mesenchymal stem cell therapy is positioned as a promising option for the management of complex perianal fistulas in patients with Crohn's disease, as indicated by the reviewed studies. Clinical trials support its efficacy, safety and good tolerability, with a minimal adverse effect profile. Its ease of administration and long-term economic viability make it a feasible alternative to conventional treatments. These findings highlight the potential of mesenchymal stem cells as a significant advance in the treatment of severe complications of Crohn's disease, offering perspectives towards more efficient and less disruptive therapies for the quality of life of patients.
3	Kich (2) (2022)	Study of the role of the immune system and an update on the treatment of Crohn's disease	Crohn's disease, one of the Inflammatory Bowel Diseases, primarily affects the small intestine and the first section of the large intestine. Its causes are not yet fully defined, but involve a combination of genetic and environmental factors that affect the body's immune responses. The therapeutic approach ranges from lifestyle and dietary modifications to pharmacological interventions, including corticosteroids, antibiotics, aminosalicylates, anti-TNF therapies, and monoclonal	Primary treatments focus on correcting abnormalities in adhesion cells and in the signaling processes of various immune cells, with biological therapies, such as anti-TNF and anti-integrin, predominating. However, these treatments are often combined according to individual needs. Recent research explores alternatives such as fecal microbiota transplantation and the use of stem cells or expanded mesenchymal cells from adipose tissue. Continued research is essential to further our understanding of the role

	antibodies. The aim of this study was to investigate current treatment methodologies for Crohn's disease by conducting a systematic review of the scientific literature up to April 2022.	of the immune system in Crohn's disease and to develop more effective and widely applicable treatments.

Results

Recent systematic research on the application of mesenchymal stem cell-based therapies for the treatment of inflammatory bowel disease has revealed significant advances with notable therapeutic implications (17). The studies reviewed showed that MSCs possess immunomodulatory and regenerative properties, facilitating the remission of inflammatory processes and tissue repair in IBD models, including Crohn's disease. The ability of MSCs to decrease inflammation and promote intestinal mucosal regeneration has been demonstrated in multiple preclinical studies and some initial clinical trials.

In the field of regenerative medicine, the use of mesenchymal stem cells (MSCs) is a field of intense debate and study, as reflected in the works of González (10) and Kich (2). The convergence in the research of these authors lies in the recognized therapeutic capacity of MSCs, mainly in their regenerative potential and their role in immune and anti-inflammatory modulation.

All agree that tissue regeneration and reduction of inflammation are key aspects of MSCs, offering promising therapeutic routes in Crohn's disease, especially in the treatment of complex perianal fistulas, an area where conventional methods often prove insufficient. The efficacy, safety and tolerability of expanded autologous MSCs are emphasized, highlighting a significant decrease in the adverse effect profile, an improvement in patient quality of life and potentially greater long-term economic viability compared to existing biological therapies.

However, differences arise regarding the perception of the challenges inherent to MSC therapy. While the production and administration of the MSC secretome is presented as an alternative to overcome direct complications associated with cell therapy, such as problems of immunological incompatibility and tumorigenesis, there is unanimous concern about the biological variability of MSCs that could affect the standardization and replicability of the treatment.

On the other hand, there is a recognition of the critical role played by the immune system in the pathogenesis of Crohn's disease and the need to continue researching in this area to improve current and future treatments. Conventional therapies such as anti-TNF and anti-

integrin predominate in the current discourse, but interest is turning towards more personalized and less invasive alternatives, such as fecal microbiota transplantation and the use of mesenchymal cells from adipose tissue, suggesting an evolution towards more holistic treatments tailored to the patient's individual biology (18).

In terms of efficacy, MSC therapies have shown promising results in reducing disease activity and improving the quality of life of patients refractory to standard therapies. The safety of MSC therapy has also been a priority consideration, with an adverse effect profile that remains favourable compared to conventional therapeutic options. However, the need for long-term monitoring is recognised due to the theoretical potential for tumorigenesis associated with cell proliferation (19).

Economically, initial analyses suggest that although MSC therapy is more expensive to develop and implement than conventional treatments, it could be a profitable investment in the long term. This profitability is associated with a decrease in the frequency of hospitalizations and surgeries, as well as a reduced need for complementary therapies due to the sustained efficacy of cell therapy.

Discussion

Current analysis of therapies for inflammatory bowel disease highlights the significant potential of mesenchymal stem cells due to their regenerative, anti-inflammatory and antioxidant attributes, particularly in cases of Crohn's disease. Such properties have been shown to be beneficial in decreasing the inflammatory response and promoting the repair of damaged intestinal tissue. However, clinical implementation of MSCs still needs to overcome critical challenges, including immunogenicity and potential risk of oncogenesis. These concerns make the development of comprehensive and precise dosing and safety protocols imperative.

Innovation in the production and application of MSCs is emerging as a promising approach to standard treatments, especially in refractory cases of IBD, as seen in patients with perianal fistulas arising from Crohn's disease. These expanded autologous stem cells could offer a treatment option with a favorable tolerability profile and fewer adverse effects compared to conventional methods. In economic terms, it is essential to consider the financial viability of MSC therapies. The costs associated with these therapies are variable and depend on factors such as the source of the cells, the culture and expansion process, as well as the required safety tests. While the cost may be considerably high in the initial phases due to the investment in research and development, it is anticipated that as the technology is standardized and production techniques are optimized, costs could decrease.

In conclusion, it is imperative that the scientific community continues to investigate the applications of MSCs in IBD, overcoming current challenges and projecting a horizon where cell therapy can be safely and effectively integrated into the clinical management of the disease, always considering the cost-benefit ratio compared to traditional therapies. Multidisciplinary collaborations will be essential to successfully translate preclinical findings into viable and accessible clinical applications for IBD patients.

Conclusions

- It is concluded that IBD, which includes Crohn's disease and ulcerative colitis, is characterized by a complex interplay of genetic, environmental, immunological and microbiotic factors. This paper highlights how this interplay contributes to disease pathogenesis, underlining the need for holistic and personalized therapeutic approaches. Advances in the understanding of these factors provide opportunities for the development of more effective and targeted treatments for IBD patients.
- MSCs emerge as a promising therapeutic strategy for IBD due to their immunomodulatory and regenerative properties. The reviewed studies highlight how these cells have the potential to modulate the immune response and promote the repair of damaged intestinal tissue. This suggests that MSCs could offer significant benefits in managing symptoms and improving the quality of life of IBD patients.
- Despite the therapeutic potential of MSCs, their clinical implementation faces significant challenges. These include standardizing treatment protocols, understanding long-term mechanisms of action, and optimizing cell production and delivery. However, these challenges also present opportunities for multidisciplinary collaboration and innovation in the field of regenerative medicine, which could lead to more effective and personalized treatments for IBD.
- It is concluded that the reviewed studies consistently show that MSCs possess immunomodulatory and regenerative properties that can induce remission of inflammation and promote repair of damaged intestinal tissue in preclinical models and early clinical trials. These results support the idea that MSCs have the potential to significantly improve symptoms and quality of life of patients with IBD refractory to conventional treatments. However, further research is required to fully understand the mechanisms of action of MSCs in the long term and to address critical challenges such as standardization of treatment protocols and evaluation of long-term safety and efficacy.
- The discussion highlights the importance of considering therapeutic and economic aspects in the development and implementation of MSC therapies for IBD. Although mesenchymal stem cells have significant therapeutic potential, their

clinical application faces important challenges, such as immunogenicity and the potential risk of tumorigenesis. Furthermore, issues related to the biological variability of MSCs and the optimization of production and management protocols need to be addressed. However, despite these challenges, mesenchymal stem cell therapy represents an interesting perspective for the treatment of IBD, which may provide affected patients with more effective and personalized treatment options.

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The author has no conflict of interest to declare.

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Conceptualization: Daniela Lizbeth Barrera Cunalata

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