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REVIEW PAPER OPEN ACCESS

Clinical importance of stem cells in T2D treatment: A systematic review

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ABSTRACT

Advanced pharmacological treatments have not been able to effectively manage the course of type 2 diabetes mellitus [T2DM] as a result of these challenges to investigate the possible intervention of regenerative medicine such as stem-cell therapies to restore metabolic functions and improve complications of diabetes. The systematic review was done in accordance with PRISMA 2020, PubMed/MEDLINE [2016-2026] were searched on the topic of stem cell therapies in T2DM. Eight studies [RCTs, Phase I-IV trials, observational and case studies] were counted, and they were based on bone marrow-derived MSCs, adipose-derived stromal cells, and umbilical cord-derived MSCs. MSC based therapy has shown high therapeutic promise in T2DM with a consistent improvement in the HbA1C, glycemic control and 8-cell performance, especially using umbilical cord MSCs and bone marrow MSCs. Metabolic results are further improved as a consequence of combination [e.g., in hyperbaric oxygen]. The long-term outcomes such as long-term glycemic control and 8 years of 15 8cell functioning have been reported. The complications that have been reported to have improved notably include wound healing, limb perfusion, and slowed down kidney disease progression. These processes are mediated by β-cell regeneration in patients with long-term diabetes, which demonstrates the benefit of early intervention. Regenerative therapies through stem cells offer an option to treat T2DM. The approaches have the potential to improve glycemic control and result in improvements in complications associated with diabetes.

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INTRODUCTION

T2DM is a complicated metabolic condition with a combination of insulin resistance, progressive pancreatic 2-cell dysfunction, and chronic hyperglycemia resulting in the severe complications related to diabetes such as foot ulcers, kidney disease, and critical limb ischemia (Zhao *et al.*, 2017). Despite development and advances in pharmacological care, the number of patients with progressive disease and complications remains high, over the last few years, regenerative medicine, such as stem cell-based therapy, has been growing fast and is being as a clinical option for the diabetic treatment (Zhao *et al.*, 2017). There is developing evidence that cell-based regenerative therapies can have a beneficial effect on pancreatic activity and metabolic control. Indicatively, platelet-derived mitochondria have been reported to express embryonic stem cell markers and improve pancreatic islet cell function in humans which suggests a new way of metabolic recovery in diabetes (Zhao *et al.*, 2017). Bone marrow-derived cell therapies have been shown to have a potential beneficial effect in diabetes management, such as tissue regeneration and muscle control. It has been clinically demonstrated that bone marrow mesenchymal stem cell transplantation has proven to be effective in the treatment of diabetic complications, including long-term treatment of severe diabetics such as recurrent cases of lower limb bullosis diabeticorum (Chen *et al.*, 2018). Moreover, there are randomized controlled trials conducted on combination therapies, including autologous bone marrow stem cell transplantation combined with hyperbaric oxygen therapy, which depict therapeutic effectiveness in persons with T2DM (Estrada *et al.*, 2019). Vascular complications in diabetes have also been proven to be treated with the help of stem cell therapies. Long-term outcomes of extracting bone marrow mesenchymal stem cell [BMMSCs] or bone marrow mononuclear cells [BMMNCs] have been shown to have positive results in diabetic critical limb ischemia patients and foot ulcer patients (Lu *et al.*, 2019).

Moreover, adipose-derived stromal cells and stromal vascular fraction cells showed their regenerative potential in reversing chronic diabetic foot ulcers, by enhancing wound-healing process (Carstens *et al.*, 2021; Soria-Juan *et al.*, 2021). An additional mesenchymal stem cell source of the umbilical cord has also undergone clinical trials and reported safety and the possibility of an effective outcome in adults with type 2 diabetes to enhance metabolic parameters (Zang *et al.*, 2022; Zang *et al.*, 2023). These regenerative treatments have facilitated tissue repair through mechanisms such as angiogenesis, immunomodulation, and enhanced microvascular circulation.

Also, recent studies have been investigating the mesenchymal stromal cell therapy with regards to diabetic kidney disease, noting its safety and initial effectiveness in the enhancement of renal outcomes (Habiba *et al.*, 2024). The clinical outcomes of stem cell therapies can differ depending on the disease duration and disease, which was proved to affect the efficacy of the autologous bone marrow-derived mesenchymal stem cell transplantation (Velikova *et al.*, 2024). Experimental and clinical research has been building evidence that stem cell-based therapies and regenerative medicine technologies can provide a prospective tool in enhancing metabolic regulation and intervention of the complications that can be linked to type 2 diabetes mellitus. Nevertheless, there is need to carry out additional research and properly designed clinical trials to determine the safety, long-term efficacy, and clinical applicability of these emerging therapeutic interventions. Thus, the current review aimed to summarize the stem cell-based therapies of type 2 diabetes, and especially highlight recent clinical developments, the current challenges in the field, and the future outlook of regenerative diabetes care.

SEARCH STRATEGY

Subjects and study selections

This review analyzed clinical evidence from 8 published studies investigating regenerative and metabolic therapeutic approaches to manage type 2 diabetes mellitus [T2DM] and its associated complications. The included literature comprised of clinical trials [Phase I,

II, III, IV], Randomized Controlled Trials [RCT], Observational Studies, Clinical studies, and observational analyses published between 2016 and 2026. Data were extracted from included studies evaluated the efficacy and safety of stem cell-based therapies, regenerative cellular interventions, and related metabolic treatments in individuals with type 2 diabetes. These interventions included bone marrow-derived mesenchymal stem cells, bone marrow mononuclear cells, adipose-derived mesenchymal stromal cells, umbilical cord-derived mesenchymal stem cells. Clinical endpoints such as body mass index [BMI], glucose metabolism, continuous glucose monitoring data, circulating regenerative cell markers, and long-term metabolic outcomes were assessed across the studies. Collectively, these studies provide insight into the clinical effectiveness, safety profile, and potential mechanisms of regenerative therapies and metabolic interventions for improving outcomes in patients with type 2 diabetes.

PRISMA search strategy and filters applied

This systematic review was implemented in the form of Preferred Reporting Items of Systematic Reviews and Meta-Analyses [PRISMA] 2020 guidelines. The databases PubMed/MEDLINE and Scopus were searched to find the necessary literature published during the years 2016-2026. The search strategy involved the use of Medical Subject Headings [MeSH] and keywords, such as Type 2 diabetes, stem cell therapy, treatment, management, and tissue regeneration, together with Boolean operators. Only the open-access, full-text articles were reviewed (Fig. 1). The quality and risk of bias of the included studies were carefully assessed with the help of the developed tools, including the Newcastle-Ottawa Scale of observational studies and the Cochrane Risk of Bias tool [RoB 2] of randomized trials, to ensure the strength of the synthesis.

Study populations

The reviewed studies primarily enrolled adults diagnosed with type 2 diabetes mellitus [T2DM], including individuals with long disease history and those with diabetes-related complications.

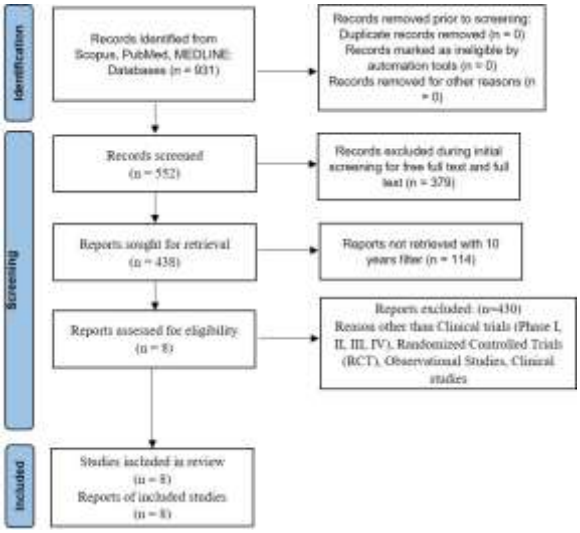

Fig. 1. PRISMA flow diagram for study search and selection of relevant studies for the current research design

Sample sizes varied widely across studies, ranging from 1 to 91 participants. Most clinical trials evaluated regenerative therapies involving mesenchymal stem cells derived from different sources such as bone marrow, adipose tissue, and umbilical cord. Additionally, certain mechanistic investigations examined cellular and molecular processes related to pancreatic β-cell regeneration and metabolic regulation. The study populations were therefore heterogeneous, encompassing adults with varying durations of diabetes, differing levels of disease, and diverse metabolic profiles.

Inclusion criteria

Eligible participants across the studies were generally adults [≥18 years] with a confirmed diagnosis of type 2 diabetes mellitus or diabetes-related complications. Many studies required evidence of poor glycemic control despite conventional treatments such as lifestyle modification, oral antidiabetic drugs, or insulin therapy. Additional eligibility criteria often included stable clinical status, the ability to undergo stem cell transplantation or infusion procedures, and the absence of acute metabolic complications. Some trials included patients with specific diabetes complications, such as diabetic nephropathy or critical limb ischemia, while others required eligibility for bone marrow aspiration or stem cell harvesting.

Overall, the studies included randomized controlled trials, clinical trials, observational studies, and case reports conducted in human populations to evaluate the safety and efficacy of stem cell based regenerative therapies.

Exclusion criteria

Exclusion criteria included such as presence of severe systemic illnesses that could interfere with treatment outcomes or increase procedural risks. These conditions typically involved significant cardiovascular disease, advanced hepatic or renal failure unrelated to diabetes complications under investigation, active infections, malignancies, or immunological disorders. Pregnant or lactating females were excluded due to potential safety concerns linked with stem cell therapies.

Additional exclusion criteria included like any recent major surgery, severe uncontrolled metabolic conditions, or any medication related to which could significantly alter immune responses or stem cell function. Studies were also excluded from the review if they did not meet the predefined eligibility criteria, such as those lacking human participants, appropriate study designs, or clear evaluation of regenerative or stem cell interventions in diabetes.

RESULTS

Regenerative therapies using mesenchymal stem cells [MSCs] have shown promising therapeutic potential for type 2 diabetes mellitus [T2DM] and its related complications. It was observed that the MSC-based interventions involved in improving pancreatic β-cell function, enhanced glycemic control, and facilitated tissue restoration. Clinical outcomes included reductions in glycated hemoglobin [HbA1c], improved insulin secretion, stabilized glucose levels, and beneficial effects on diabetes-related complications such as diabetic skin lesions, critical limb ischemia, and diabetic kidney disease (Chen *et al.*, 2018; Estrada *et al.*, 2019; Zang *et al.*, 2022; Wu *et al.*, 2024). Patient characteristics, such as obesity and longer disease duration, were associated with treatment efficacy. Longer duration of T2DM and higher BMI were associated with reduced responses to MSC therapy, underscoring the potential importance of early intervention (Nguyen *et al.*, 2021). Overall, MSC therapies demonstrated acceptable safety profiles across studies, with minimal adverse events reported, supporting their clinical applicability. These interventions appear to act through multiple mechanisms, including β-cell regeneration; immune modulation, angiogenesis, and tissue repair, leading to both metabolic improvement and management of diabetes-related complications.

Regeneration of pancreatic β-Cells

Clinical studies indicate that MSC therapies can restore pancreatic β-cell function and improve insulin secretion. Autologous bone marrow MSCs enhanced β-cell activity and metabolic control when combined with hyperbaric oxygen therapy (Estrada *et al.*, 2019). Umbilical cord-derived MSC therapy also improved β-cell function and insulin secretion in adults with T2DM (Zang *et al.*, 2022; Zang *et al.*, 2023).

Improvement of glycemic control

Several trials reported improved glycemic parameters following MSC interventions. HbA1c levels decreased significantly after MSC infusion (Zang *et al.*, 2022), while continuous glucose monitoring showed reduced glycemic variability and more stable glucose levels (Zang *et al.*, 2023). Combination therapy with bone marrow MSCs and hyperbaric oxygen further enhanced metabolic outcomes (Estrada *et al.*, 2019).

Effects on diabetes-related complications

MSC therapy was also applied to manage diabetes-related complications such as skin lesions, like bone marrow MSC transplantation, which promoted healing of recurrent bullosis diabeticorum (Chen *et al.*, 2018). Intramuscular adipose MSC injections aimed to improve limb perfusion in patients ineligible for revascularization (Soria-Juan *et al.*, 2021). ORBCEL-M MSC therapy demonstrated renal protection and slowed progression of diabetic kidney disease (Habiba *et al.*, 2024).

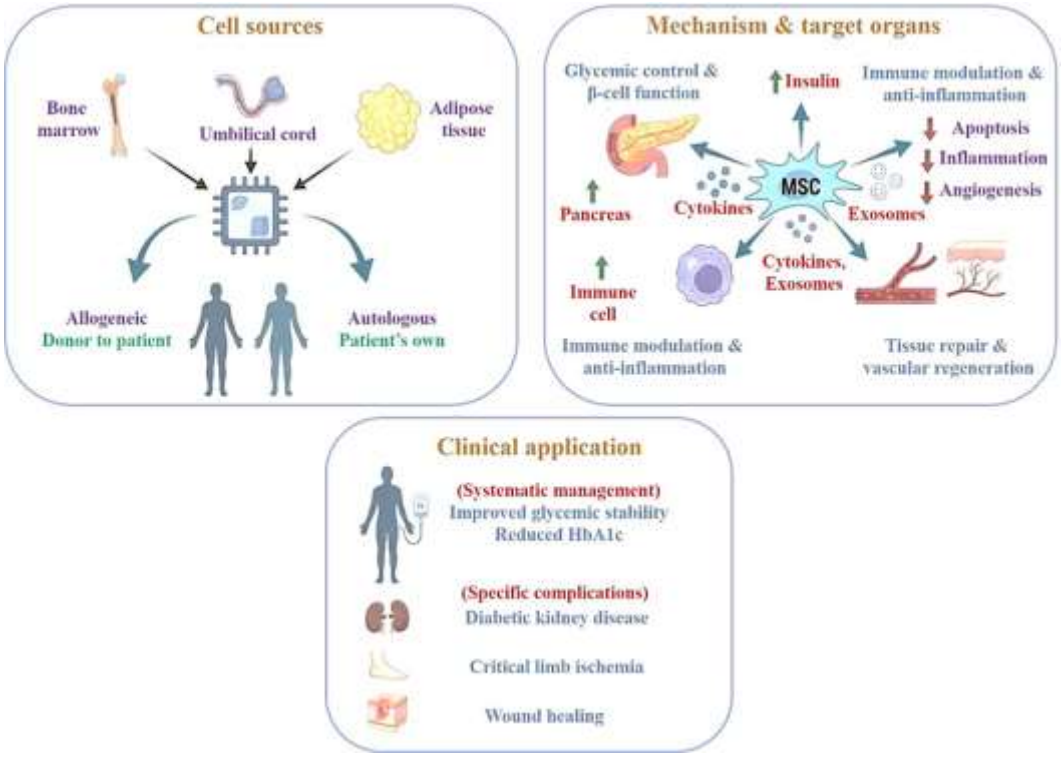

Fig. 2. Demonstration of MSCs sources, mechanism, target organ and clinical impact on cellular regeneration and clinical outcomes

Factors influencing treatment response

Patient-specific factors, particularly obesity and longer T2DM duration, were associated with reduced efficacy of MSC therapy (Velikova *et al.*, 2024). These findings suggest that early intervention and careful patient selection may optimize outcomes.

Long-term efficacy and safety

Longitudinal studies indicate that MSC therapies can sustain metabolic improvements. Long-Term Outcomes like combination therapy with BM-MSCs and mononuclear cells demonstrated sustained β-cell function and glycemic control over an 8-year follow-up period (Wu *et al.*, 2024). Across all studies, MSC and mitochondrial therapies were well-tolerated, with minimal adverse events, indicating suitability for repeated or long-term interventions (Zang *et al.*, 2022; Habiba *et al.*, 2024) (Fig. 2).

DISCUSSION

Mesenchymal stem cell [MSC]-based therapies result in substantial glycemic control, pancreatic β-cell activity, and the complications associated with diabetes in patients with Type 2 Diabetes Mellitus [T2DM]. The results are aligned with the ongoing clinical and scientific evidence of the regenerative and immunomodulatory properties of MSCs in metabolic diseases. As an example, your randomized controlled trial (Estrada *et al.*, 2019) did show better β-cells functioning and metabolism after bone marrow-derived stem cell therapy, which conforms to previous clinical trials, including the work by Kiehl *et al.* (2014), which found that using autologous bone marrow-derived stem cell transplantation had a significant positive effect on insulin secretion and insulin insensitivity in T2DM patients.

The observed reduction in HbA1c and improved glycemic stability in your analysis (Zang *et al.*, 2023; Wu *et al.*, 2024) are also supported by findings from Liu *et al.*, (2014), who reported enhanced glycemic control and β-cell function following Wharton's jelly-derived MSC infusion, further reinforcing the metabolic benefits identified in your dataset. These studies collectively support the concept that MSC therapy not only improves glucose levels but also targets underlying pancreatic dysfunction (Liu *et al.*, 2014). It has been indicated that improved β-cell function is in agreement with preclinical

and clinical evidence showing that MSCs promote β-cell regeneration through paracrine signaling, anti-apoptotic effects, and immunomodulation. Rackham *et al.* (2011) demonstrated that MSC transplantation improved pancreatic islet structure and function in diabetic models, while Gao *et al.* (2022) demonstrated that MSCs can enhance endogenous β-cell recovery and reduce insulin resistance (Gao *et al.*, 2022).

Beyond glycemic control, MSC therapy was beneficial for diabetes-related complications, including diabetic skin lesions and critical limb ischemia. This 8-year study shows that combining mesenchymal stem cells with mononuclear cells improves β-cell function and reduces diabetic complications in patients with type 2 diabetes. Dual therapy increased C-peptide by 50.6% and lowered macrovascular complications [13.8% vs 44.8%] and neuropathy [10.3% vs 48.3%] compared to controls (Wu *et al.*, 2024). Jeyaraman *et al.* (2023) demonstrated improved limb perfusion and neovascularization in patients with critical limb ischemia following stem cell therapy (Jeyaraman *et al.*, 2023). MSC-based therapy [ORBCEL-M] was safe and showed potential in slowing the progression of diabetic kidney disease, aligning with your findings. These studies highlight the systemic regenerative potential of MSCs in addressing both microvascular and macrovascular complications of diabetes (Perico *et al.*, 2023).

Chronic hyperglycemia and prolonged metabolic stress can impair mesenchymal stem cell function and regenerative capacity, potentially reducing the therapeutic efficacy of stem cell-based interventions (Mateen *et al.*, 2024).

Metabolic disorders such as obesity negatively affect stem cell viability and function, which may explain the diminished response observed in patients with advanced T2DM (Nguyen *et al.*, 2021).

A pilot study evaluated placenta-derived mesenchymal stem cells [PD-MSC] in 10 type 2 diabetes patients with prolonged disease, islet dysfunction, and poor glycemic control treated with three intravenous infusions, insulin requirements decreased from 63.7 to 34.7 IU/day [$p<0.01$] and C-peptide increased from 4.1 to 5.6 ng/mL [$p<0.05$], while Four patients achieved >50% insulin reduction and as such no adverse effects were observed, and renal/cardiac function improved suggested PD-MSC therapy appears safe and effective for T2D patients with islet dysfunction (Jiang *et al.*, 2011). A study demonstrated that type 2 diabetes patients treated with MSC therapy experience significantly improved blood sugar control by 1.45% reduction in HbA1c level and insulin use decreased by 2.05U/kg/day suggested with mild or rare adverse event with potential to treat type 2 diabetes (Koishybayeva *et al.*, 2025). It has been said that MSCs exhibit strong regenerative potential in diabetic wound healing, MSC treatment by improving collagen deposit and reduction in matrix metal protein degradation to enhance wound repair (Xu *et al.*, 2017). Another study indicated that MSCs isolated from the bone marrow can assist in wound healing by activating epidermal cell autophagy and assisting in re-epithelialization through the HIF1α/TGFβ1/SMAD signaling pathway (Shi *et al.*, 2022). Additionally, a study indicated that MSCs were able to significantly speed up the closure of the wound, increase angiogenesis, and assist in the regeneration of tissues through activation of the PI3K/AKT pathway (Huang *et al.*, 2025). Clinical trials using umbilical cord derived MSCs in diabetic foot ulcers reported complete wound closure and sustained healing outcomes, highlighting their translational potential in regenerative therapy (Jafar *et al.*, 2025), collectively, these findings confirm that MSC-based therapies not only restore β-cell function and improve glycemic control but also play a critical role in tissue repair and wound regeneration in diabetic conditions and suggested that the MSC therapies are generally well tolerated, with rare adverse events reported (Jafar *et al.*, 2025). It has been said that MSC transplantation in diabetes is safe and does not lead to significant immunological or oncogenic complications, supporting the clinical feasibility of these interventions (Mathur *et al.*, 2023). Despite these promising findings, several limitations remain. As observed, heterogeneity in MSC sources [bone marrow, adipose tissue, umbilical cord], dosing strategies, and administration routes complicates direct comparison across studies. It has been emphasized that there is a

need for standardization in stem cell therapy protocols. Additionally, many studies involve small sample sizes or are early-phase trials, limiting generalizability (Zhang *et al.*, 2024).

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